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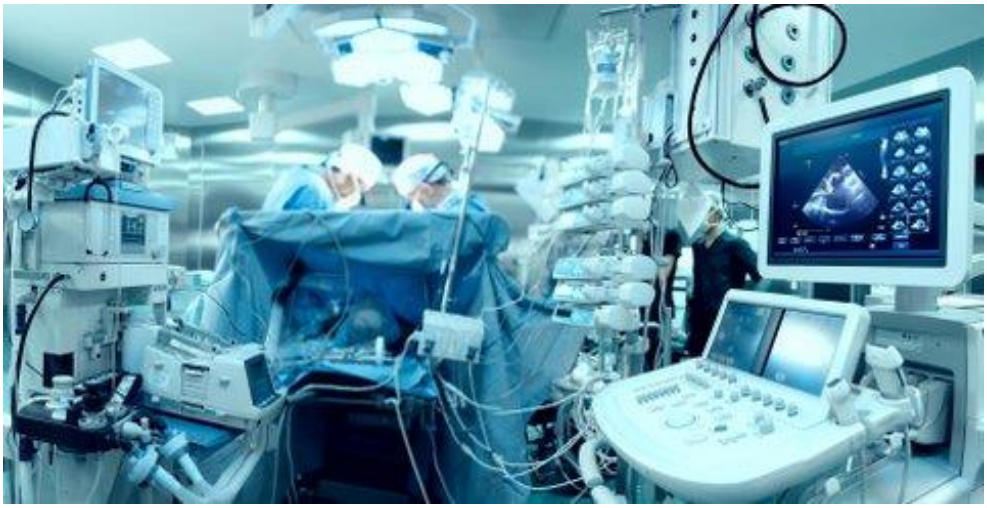
Robot-assisted surgery in thoracic and visceral indications – Update 2023



A systematic review

Final report

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Robot-assisted surgery in thoracic and visceral indications – Update 2023

A systematic review

Vienna, August 2023

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List of abbreviations

ASA	American Society of Anesthesiologists
BMI	Body Mass Index
CG	control group
DD	Drainage Dauer
DFS	disease-free survival/krankheitsfreies Überleben
DKH	Dauer des Krankenhausaufenthaltes
ESMO	European Society for Medical Oncology
FDA	Food and Drug Administration
FU	follow-up
GERD	gastroesophageal reflux disease/gastroösophageale Refluxkrankheit
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HCC	hepatocellular carcinoma
HTA	Health Technology Assessment
ICU	intensive-care unit
IG	intervention group/Interventionsgruppe
IO	intraoperativ
KG	Kontrollgruppe
KP	Komparatoren
NCCN	National Comprehensive Cancer Network
NE	nicht erhoben
NICE	National Institute for Health and Care Excellence
NSCLC	non-small-cell-lung cancer/nicht-kleinzelliger Lungenkrebs
OS	overall survival/Gesamtüberleben
PO	postoperativ
PPI	proton pump inhibitor
QoL	Quality of Life/Lebensqualität
RAS	Robot-assisted surgery/roboterassistierte Chirurgie
RCT(s)	randomised controlled trial(s)/randomisierte kontrollierte Studie(n)
RoB	Risk of Bias
SCLC	small-cell lung cancer
SD	standard deviation
ss	statistisch signifikant
VATS	video-assisted thoracoscopic surgeries/videoassistierte thorakoskopische Operationen

Executive Summary

Introduction

Description of technology and comparators

Robot-assisted surgery (RAS) is a technically advanced form of minimally invasive surgery whereby the instruments of the robotic system are controlled by a direct telemanipulator. This remote manipulator allows the surgeon to perform the normal movements associated with surgery in a more precise way compared to the laparoscopic approach, due to a higher degree of dexterity.

robot-assisted surgery: a form of minimally invasive surgery

high degree of dexterity

Currently, there are 19 known manufacturers of robotic systems to aid in surgical procedures (identified via hand search), of which ten companies offer a total of 14 CE-marked products in the area of thoracic and visceral surgery. The robotic procedure used in most of the studies included in this HTA involved the da Vinci® Surgical System.

19 manufacturers of robotic systems → 14 CE-marked products for thoracic & visceral surgery

The currently available robotic systems aim to provide technology only to assist surgeons, they do not replace them. These devices are a tool that surgeons can choose to use to provide their patients with a further minimally invasive surgical option. Comparators used in the clinical studies were conventional laparoscopic techniques or open surgery.

comparators: laparoscopic techniques & open surgery

Health Problem

This assessment is an update of a report that investigated the use of RAS in the area of thoracic and visceral surgery, conducted in 2019. Thoracic surgery is concerned with conditions of the lungs, chest wall and diaphragm and is generally dominated by the treatment of malignant disease. Three thoracic procedures were included in the review: lung lobectomy, lung segmentectomy and mediastinal surgery. Visceral surgery deals with all aspects of the surgical treatment of benign and malignant diseases of abdominal organs, the entire gastrointestinal tract, endocrine organs, the abdominal wall, and the peritoneum. The eleven visceral procedures that were included in the review were anti-reflux surgery/fundoplication, oesophagectomy or oesophageal repair, heller myotomy, gastrectomy, bariatric surgery, small bowel resection, colectomy, rectal resection, ventral mesh rectopexy, cholecystectomy, liver resection/hepatectomy and hernia repair.

14 surgical procedures:

thoracic (lungs, chest wall & diaphragm)

& visceral (abdominal organs gastrointestinal tract, endocrine organs, abdominal wall, peritoneum)

Methods

Primary studies were included, when the pre-defined inclusion criteria that are outlined in the scope of the assessment, were fulfilled. Moreover, a systematic literature search in the following databases was performed:

systematic literature search in 2 databases

- The Cochrane CENTRAL Register of Controlled Trials
- Ovid Medline

The Cochrane Risk of Bias (RoB) tool was used for the quality assessment of RCTs, and for grading the body of evidence GRADE (Grading of Recommendations Assessment, Development and Evaluation) was used.

Cochrane RoB tool & GRADE

inclusion of RCTs > 20 patients

Randomised controlled trials (RCTs) enrolling >20 patients were used for assessing the evidence in the effectiveness and safety domains. Comparators were laparoscopic surgery or open surgery.

Results

20 RCTs + 5 follow-up (FU) publications

differences compared with previously published report

A total of 20 RCTs and an additional five follow-up publications were identified, addressing nine out of the 14 investigated surgical procedures. The present update is in line with patient-relevant outcomes presented in the formerly published HTA. Nevertheless, one statistically significant improvement considering recurrence that was associated with robot-assisted hernia repair could be observed. Apart from this, this update report differs from the previously published assessment (see Table 0-1).

clinical effectiveness & safety related outcomes → results contradicting, not statistically significant or not reported

robot-assisted surgery higher mean cost per procedure

Considering clinical effectiveness and safety-related outcomes, results were either contradicting, not statistically significant, or not reported. RAS claims to reduce readmissions and shortened hospital stays, however, statistically significant differences compared to the laparoscopic or open procedure were not detected. In addition, contradicting evidence was identified considering operation time. Moreover, evidence suggests that RAS methods result in a higher mean cost per procedure than conventional surgical methods. However, for some indications and outcomes, RAS might be useful. For instance, blood loss was decreased in lung lobectomy, oesophagectomy, rectal resection, liver resection, and gastrectomy. Furthermore, postoperative complications occurred less often in patients who underwent robot-assisted gastrectomy, rectal and liver resection. Nonetheless, only a few of the asserted benefits of RAS may be fulfilled.

Discussion

overall quality of included studies was low

Altogether, the included studies showed an overall low quality of evidence, consequently studies with larger sample sizes (n>100) and longer follow-up times are needed. Another aspect is the scarcity of evidence concerning patient-relevant outcomes like quality of life, time resume to work as well as patient satisfaction.

overall statement on RAS not possible → heterogeneity of results & lack of evidence

In conclusion due to the heterogeneity of results as well as the lack of evidence for several outcomes and procedures an overall statement regarding the superiority of RAS is not possible. While it may present potential advantages for certain indications and outcomes (e.g., blood loss, postoperative complications), most of the claimed benefits of RAS could not be materialized. Moreover, financial and environmental implications must be taken into account in purchasing decisions.

Zusammenfassung

Einleitung

Beschreibung der Technologie und der Komparatoren

In der roboterassistierten Chirurgie (RAS), welche dem Bereich der minimalinvasiven Chirurgie zuzuordnen ist, werden Instrumente nicht unmittelbar durch Chirurg*innen, sondern mithilfe eines Telemanipulators gesteuert. Ein Telemanipulator befähigt den Chirurgen/die Chirurgin über Fernsteuerung Hand- und Fingerbewegungen an einen Roboter zu übermitteln. Im Vergleich zur Laparoskopie wird ein höheres Maß an Geschicklichkeit in der Manipulation erreicht, welche Operationen auf sehr engem Raum im Körper ermöglicht. Ziel ist es, klinische Ergebnisse und den Ressourcenverbrauch zu verbessern.

roboterassistierte Chirurgie → minimalinvasive Chirurgie

OP in sehr engen Körperbereichen möglich

Momentan gibt es 19 bekannte Hersteller für Robotersysteme, welche in der Chirurgie eingesetzt werden (Identifizierung über Handsuche). Von diesen bieten zehn Hersteller insgesamt 14 Produkte mit CE-Kennzeichnung für thorakale und viszerale Chirurgie an. In den inkludierten Studien wurden primär Produkte von Intuitive (da Vinci® Surgical System) verwendet.

19 Hersteller → 14 Produkte eine CE-Kennzeichnung für den thorakalen & viszeralen Bereich

Gesundheitsproblem

In diesem Bericht stehen Indikationen für Operationen im Bereich des Thorax- und Bauchraumes im Zentrum.

- Indikationen im Bereich des Thorax sind Erkrankungen der Lunge, der Brustwand und des Zwerchfells. In dem Bericht wurden (i) Lobektomie und (ii) Mediastinal Chirurgie untersucht.
- Indikationen im Bereich des Bauchraumes stellen gutartige und bösartige Erkrankungen der Bauchorgane, des gesamten Magen-Darmtraktes, der endokrinen Organe, der Bauchwand und des Peritoneums dar. In diesem Bericht wurden (i) Anti-Reflux Chirurgie/Fundoplikatio, (ii) Ösophagektomie/ Ösophagus-Chirurgie, Heller Myotomie, Gastrektomie, Bariatrische Chirurgie, Dünndarmresektion, Kolektomie, Rektumresektion, Cholezystektomie, Leberresektion/ Hepatektomie und Hernienreparatur untersucht.

inkludierte Studien verwenden hauptsächlich Produkte von Intuitive

Indikationen des

Thorax

&

Bauchraumes

Ziele

Ziel ist es, die Wirksamkeit und Sicherheit roboterassistierter Chirurgie bei 14 Indikationen im Thorax und Bauchraum, im Vergleich zu laparoskopischer oder offener Chirurgie, zu untersuchen. Der Bericht stellt ein Update eines systematischen Reports aus dem Jahr 2019 dar.

Update zur Wirksamkeit & Sicherheit roboterassistierter Chirurgie

Methoden

Für die Wirksamkeits- und Sicherheitsbewertung wurde eine systematische Literatursuche in zwei Datenbanken (Cochrane CENTRAL Register of Controlled Trials und Ovid Medline), ergänzt um eine Hand- und Scopus-Suche, durchgeführt. Es fand keine systematische Suche nach laufenden Studien statt.

systematische Literatursuche in 2 Datenbanken

RoB Tool & GRADE

Das Cochrane Risk of Bias (RoB) Tool wurde für die Qualitätsbewertung von randomisierten kontrollierten Studien (RCTs) und zur Beurteilung des Vertrauens in die Evidenz wurde GRADE (Grading of Recommendations Assessment, Development and Evaluation) verwendet.

RCTs > 20 Patient*innen

Es wurden lediglich RCTs, welche mehr als 20 Patient*innen eingeschlossen haben, für die Bewertung der Wirksamkeit und Sicherheit inkludiert. Folgende Indikationen im Bereich des Thorax- oder des Brauchraumes standen im Fokus des Berichtes:

Indikationen Thoraxchirurgie

Patient*innen mit Operationsindikationen im Thoraxbereich:

- Pulmonale (Manschetten-) Lobektomie (nicht-kleinzelliges Lungenkarzinom)
- Mediastinal Chirurgie (Mediastinal Tumor, mediastinale bronchogene Zyste)

Indikationen Viszeralchirurgie

Patient*innen mit Operationsindikationen im Bauchraumbereich:

- Anti-Reflux Chirurgie (Gastroösophageale Refluxkrankheit (z.B. Nissenfundoplikatio)
- Ösophagektomie (Speiseröhrenkrebs)
- Gastrektomie (subtotal für Magenkrebs <Stadium IB, radikal für IB-III)
- Bariatrische Chirurgie (Adipositas z.B. ROUC-en Y- Magenbypass, Magenbypass und Schlauchmagen-Magenverkleinerung)
- Dünndarmresektion (Blutung, Infektion, Ulcera, Verstopfungen, Morbus Crohn, Colitis Ulcerosa, Divertikulitis, Krebsprävention (z.B. totale Kolektomie, partiale Kolektomie, Hemikolektomie und Proktokolektomie)).
- Rektumresektion (Rektumkarzinom (z.B. Polypektomie und lokale Exzision))
- Hepatektomie (Leberresektion)
- Hernien Chirurgie (Hernien)
- Myotomie (Achalasie)
- Cholezystektomie (Gallenkolik, akute Cholezystitis, Cholangitis (z.B. verursacht durch symptomatische Gallensteine), Gallenblasenkrebs)

Ergebnisse

insgesamt: 20 RCTs + 5 Follow-up (FU) Publikationen

Verfügbare Evidenz

Insgesamt wurden 20 RCTs und weitere fünf Follow-up Publikationen identifiziert.

Thoraxchirurgie

Die systematische Literatursuche ergab vier RCTs und eine Follow-up Publikation zur Lobektomie, keine RCTs konnten zur Mediastinal Chirurgie identifiziert werden.

Lungenlobektomie 4 RCTs + 1 FU Publikation n=677; IG: 338 vs KG: 339

& keine RCTs zur Mediastinal Chirurgie

Thorax (insgesamt 338 Patient*innen mit roboterassistierter Intervention)

- 4 RCTs & 1 Follow-up Publikation (677 Patient*innen; Interventionsgruppe (IG): 338 vs Kontrollgruppe (KG): 339) verglichen roboterassistierte Lobektomie oder roboterassistiere Thorakoskopie mit videoassistierter Lobektomie, videoassistierter Thorakoskopie oder Thorakotomie (VATS).

Die systematische Literatursuche identifizierte 16 RCTs und vier Follow-up Publikationen für Indikationen im Bauchraum, keine RCTs konnten zur Heller-Myotomie, Bariatrischen Chirurgie, Dünndarmresektion und Cholezystektomie identifiziert werden.

Viszeralchirurgie
16 RCTs
+ 4 FU Publikationen

Ösophagus (insgesamt 259 Patient*innen mit roboterassistierter Intervention)

Ösophagus

- 1 RCT (40 Patient*innen; IG:20 vs KG: 20) verglich roboterassistierte laparoskopische Fundoplikatio mit konventioneller laparoskopischer Fundoplikatio.

Fundoplikatio: 1 RCT
n=40; IG:20 vs KG: 20

- 2 RCTs (474 Patient*innen; IG: 239 vs KG: 235) verglichen roboterassistierte minimal invasive Ösophagektomie mit konventioneller minimal invasiver Ösophagektomie oder offener transthorakaler Ösophagektomie.

Ösophagektomie:
2 RCTs
n=474;
IG: 239 vs KG: 235

Magen (insgesamt 302 Patient*innen mit roboterassistierter Intervention)

Magen

- 3 RCTs (606 Patient*innen; IG: 302 vs KG: 304) verglichen robotische (distale) Gastrektomie mit offener Gastrektomie oder laparoskopischer (distalen) Gastrektomie.

Gastrektomie: 3 RCTs
n=606;
IG: 302 vs KG: 304

Darm (insgesamt 888 Patient*innen mit roboterassistierter Intervention)

Darm

- 2 RCTs (198 Patient*innen; IG: 78 vs KG: 120) verglichen robotische Kolektomie oder roboterassistierte rechtsseitige Kolektomie mit laparoskopischer Kolektomie oder laparoskopisch-assistierter rechtsseitiger Kolektomie.

Kolektomie: 2 RCTs
n=198;
IG: 78 vs KG: 120

- 2 RCTs (1,589 Patient*innen; IG: 794 vs KG: 793) verglichen robotische Rektumresektion mit laparoskopischer, oder robotische Operation für Rektumtumore mit konventioneller laparoskopischer Operation.

Rektumresektion: 2 RCTs
n=1.589;
IG: 794 vs KG: 793

- 2 Follow-ups eines RCTs (30 Patientinnen; IG: 16 vs KG: 14) verglichen roboterassistiere ventrale Netzrektopexie mit laparoskopischer Netzrektopexie.

Netzrektopexie: 2 FU Publikationen
n=30; IG: 16 vs KG 14

Gallenblase/Leber/Milz (insgesamt 298 Patient*innen mit roboterassistierter Intervention)

Gallenblase/Leber/Milz
Hernienreparatur:
5 RCTs + 2 FU Publikationen, n=471;
IG: 237 vs KG: 231[1]
Hepatektomie: 1 RCT
n=122; IG:61 vs KG: 61

- 1 RCT (122 Patient*innen; IG:61 vs KG: 61) verglich roboterassistierte laparoskopische Hepatektomie mit laparoskopischer Hepatektomie.

Klinische Wirksamkeit und Sicherheit

klinische Wirksamkeit und Sicherheit:

Durch die Vielfalt an unterschiedlichen Eingriffen und Indikationen, und den Mangel an zuverlässiger Evidenz in fast allen Indikationen, ist eine Analyse und Berichterstattung der Ergebnisse schwierig. Folgende Endpunkte wurden – auch basierend auf Erwartungen an die roboterassistierte Chirurgie - analysiert:

patient*innen- & sicherheits-bezogenen Endpunkte & Perioperative Events/Ressourcennutzung

- Patient*innenenbezogene Endpunkte:
  - Überleben/ krankheitsfreies Überleben
  - Wiederauftreten
  - Lebensqualität (QoL)
  - Zeit bis zur Wiederaufnahme täglicher Aktivitäten und Beruf
  - Patient*innenenzufriedenheit
- Sicherheitsbezogene Endpunkte:
  - Intraoperative (IO) Komplikationen
  - Postoperative (PO) Komplikationen
  - Re-Operationen/ zusätzliche Operationen
  - Konversion
- Perioperative Events/Ressourcennutzung
  - Blutverlust
  - Operationszeit
  - Transfusion
  - Drainagedauer (DD)
  - Dauer des Krankenhausaufenthalts (DKH)

Die relevanten Endpunkte wurden in den meisten Studien entweder nicht berichtet, nicht gemessen oder zeigten keine statistische Signifikanz. Ebenso weist der Großteil der Studien eine niedrige Evidenzqualität auf.

9/14 Endpunkte kein ss Unterschied. PO Komplikationen ↓, Blutverlust ↑

Lungenlobektomie: Von 14 Endpunkten zeigten neun keine statistisch signifikanten Unterschiede zum Komparator (laparoskopischer oder offener Eingriff). Ein sicherheitsbezogener Endpunkt (PO Komplikationen) war in der RAS Gruppe schlechter, ein anderer Endpunkt (Blutverlust) war besser im Vergleich zum Komparator. Bezüglich der DD gab es widersprüchliche Ergebnisse. Das RoB wurde größtenteils mit „hoch“ bewertet.

3/14 Endpunkte kein Unterschied zum KP; Operationszeit ↑

Fundoplikatio: Bei drei von 14 Endpunkten konnten keine statistisch signifikanten Unterschiede festgestellt werden. Ein Endpunkt (Operationszeit) war im Vergleich zum laparoskopischen Eingriff besser. Die Studie wurde mit einem hohen RoB bewertet.

8/14 Endpunkte kein Unterschied zum KP; OP-Dauer ↑

Ösophagektomie: Acht von 14 Endpunkten zeigten keine statistisch signifikanten Ergebnisse verglichen mit der Laparoskopie oder dem offenen Eingriff. Ein Endpunkt (Operationszeit) war in der Interventionsgruppe besser. Beide Studien wurden das RoB betreffend mit „hoch“ bewertet.

7/14 Endpunkte kein Unterschied zum KP; OP-Dauer ↓, Blutverlust & PO Komplikationen ↑

Gastrektomie: Bei sieben von 14 Endpunkten konnten keine statistisch signifikanten Ergebnisse erreicht werden. Zwei Endpunkte (PO Komplikationen und Blutverlust) waren in der RAS Gruppe besser, die Operationszeit hingegen länger. Das RoB wurde mit „einige Bedenken“ oder „hoch“ bewertet.

9/14 Endpunkte kein Unterschied zum KP; OP-Dauer ↑

Kolektomie: Neun von 14 Endpunkten zeigten keine statistisch signifikanten Ergebnisse. Ein Endpunkt (Operationszeit) war in der Kontrollgruppe besser. Das RoB wurde mit „einige Bedenken“ oder „hoch“ bewertet.

Rektumresektion: Bei fünf von 14 Endpunkten wurden keine statistisch signifikanten Ergebnisse festgestellt. Drei Sicherheitsbezogene Endpunkte (IO Komplikationen, PO Komplikationen und Konversion) und die Dauer des Krankenhausaufenthaltes waren dem Komparator überlegen. Ein Endpunkt (Operationszeit) war in der RAS Gruppe schlechter. In einer Studie wurde das RoB mit „hoch" bewertet, in der anderen mit „niedrig".

5/14 Endpunkte kein Unterschied zum KP; IO & PO Komplikationen, Konversionen und DKH ↑, OP-Dauer ↓

Ventrale Netzrektopexie: Sechs von 14 Endpunkten zeigten keine statistisch signifikanten Ergebnisse. Keine Endpunkte waren schlechter oder besser im Vergleich zum Komparator. Das RoB wurde mit „hoch" bewertet.

6/14 Endpunkte kein Unterschied zum KP

Hernienreparatur: Bei sieben von 14 Endpunkten konnten keine signifikanten Ergebnisse zwischen den Gruppen festgestellt werden. Zwei Endpunkte (Wiederauftreten und Re-Operation) waren vergleichen mit der Laparoskopie oder einem offenen Eingriff besser. Die Operationszeit war jedoch länger. RoB wurde mit Ausnahme einer Studie mit „einige Bedenken" oder „hoch" bewertet.

7/14 Endpunkte kein Unterschied zum KP; Rezidive & Reoperationen ↑, OP-Dauer ↓

Hepatektomie: Zwei von 14 Endpunkten zeigten keine statistisch signifikanten Ergebnisse. Ein sicherheitsbezogener Endpunkt (PO Komplikationen), sowie drei Endpunkte zu perioperativen Events und Ressourcennutzung (Blutverlust, Operationszeit und Transfusionen) waren dem Komparator überlegen. RoB wurde mit „hoch" bewertet.

2/14 Endpunkte kein Unterschied zum KP; PO Komplikationen, Blutverlust, OP-Dauer & Transfusionen ↑

Table 0-1 gibt einen Überblick über die Ergebnisse zu den wichtigsten Wirksamkeits- und Sicherheitsendpunkten der einzelnen Verfahren.

Diskussion

In der systematischen Literatursuche konnten Studien für neun medizinische Verfahren (Lobektomie, Anti-Reflux/Fundoplikatio, Ösophagektomie, Gastrektomie, Kolektomie, Rektumresektion, ventrale Rektopexie, Hernienreparatur und Hepatektomie) mit >20 Patient*innen identifiziert werden. Für fünf Verfahren (Heller Myotomie, bariatrische Operation, Dünndarmresektion und Cholecystektomie) konnten keine RCTs identifiziert werden.

Evidenz zu 9 von 14 chirurgischen Verfahren

Potentielle Vorteile der RAS sollen verkürzte Krankenhausaufenthalte und verringerte Wiederaufnahmen sein, diese Endpunkte wiesen jedoch keine statistische Signifikanz in den Ergebnissen des vorliegenden Berichtes auf. Ebenso war die Evidenz in Bezug auf die Operationszeiten widersprüchlich. Nichtsdestotrotz könnte die roboterassistierte Chirurgie für manche Indikationen hinsichtlich einiger Endpunkte vorteilhaft sein. Beispielsweise war der Blutverlust bei Lungenlobektomien, Ösophagektomien, Rektumresektionen, Hepatektomien und Gastrektomien geringer als in den Kontrollgruppen. Ebenso traten postoperative Komplikationen nach roboterassistierten Gastrektomien, Rektumresektionen und Hepatektomien seltener auf.

Unterschiede DKH und Wiederaufnahmen nicht ss

widersprüchl. Evidenz OP-Dauer

Blutverlust & PO Komplikationen verbessert in manchen Indikationen

Zu den Limitationen des vorliegenden Berichtes zählen die Heterogenität der Indikationen und Outcomes, sowie die Einschränkung auf RCTs. Weiters gibt es nur wenig Evidenz in Bezug auf patient*innenrelevante Endpunkte, wie QoL, die Zeit bis zur Wiederaufnahme von Beruf und Alltagsaktivitäten, sowie Patient*innenzufriedenheit. Ebenso sollten chirurg*innenbezogene Endpunkte, wie Ergonomie, und Ermüdung auch erwogen werden.

Limitationen → hohe Heterogenität & wenig Evidenz zu patient*innen_ relevanten Endpunkten

mit hohen Kosten verbunden

Im Allgemeinen geht RAS mit höheren Kosten aufgrund von Erwerb und Erhaltung einher, allerdings kann es in Zukunft durch Nachfrage und steigender Konkurrenz zu Preisreduktionen kommen. Jedoch weist die roboterassistierte Chirurgie erhöhte Umweltauswirkungen im Vergleich zu konventionellen laparoskopischen Verfahren auf. Gründe hierfür sind vor allem höhere Treibhausgasemissionen und Abfallerzeugnisse.

erhöhte Umweltauswirkungen

keine allgemeine Aussage zur Wirksamkeit & Sicherheit von roboterassistierter Chirurgie möglich

In Anbetracht der Heterogenität der Ergebnisse und des Mangels an Evidenz für einige Studienendpunkte ist eine allgemeine Aussage zur Wirksamkeit und Sicherheit der RAS nicht möglich. Obwohl für bestimmte Indikationen potenzielle Vorteile bestehen könnten, müssen bei Kaufentscheidungen sowohl die begrenzte Qualität der Evidenz sowie die finanziellen und ökologischen Auswirkungen der RAS berücksichtigt werden.

Table 0-1: Summary of Conclusions

	Survival	Quality of Life	Complications
Thoracic surgery			
Lobectomy	Results not statistically significant*	Results not statistically significant	Results not statistically significant
Mediastinal surgery	No further studies concerning mediastinal surgery could be identified.		
Visceral surgery: Oesophagus			
Anti-reflux/ fundoplication	No studies were found that considered this outcome	Effect not statistically significant & Effect uncertain** (evidence quality: low)	No studies were found that considered this outcome
Heller myotomy	No further studies concerning heller myotomy could be identified.		
Oesophagectomy	Results not statistically significant & Effect uncertain (evidence quality: low)	No studies were found that considered this outcome	Results not statistically significant
Visceral surgery: stomach			
Gastrectomy	Results not statistically significant & Effect uncertain (evidence quality: low - moderate)	No studies were found that considered this outcome	Robot-assisted surgery may reduce postoperative complications vs conventional laparoscopy (evidence quality: very low); no statistically significant effect was reported in open surgery comparison
Bariatric surgery	No further studies concerning bariatric surgery could be identified.		
Visceral surgery: bowel			
Small Bowel resection	No studies concerning heller myotomy could be identified		
Colectomy	Results not statistically significant	No studies were found that considered this outcome	Results not statistically significant & Effect uncertain (evidence quality: very low)
Rectal resection	Results not statistically significant	No studies were found that considered this outcome	Results not statistically significant & Effect uncertain (evidence quality: very low)
Rectopexy	No studies were found that considered this outcome	Effect not statistically significant & Effect uncertain (evidence quality: low)	No studies were found that considered this outcome
Visceral surgery: gallbladder/liver/spleen			
Cholecystectomy	No further studies concerning cholecystectomy could be identified.		
Liver resection	Results not statistically significant & Effect uncertain (evidence quality: very low)	No studies were found that considered this outcome	Results not statistically significant & Effect uncertain (evidence quality: very low)
Hernia repair	Results not statistically significant & Effect uncertain (evidence quality: low)	Results not statistically significant & Effect uncertain (evidence quality: low)	Results not statistically significant & Effect uncertain (evidence quality: low)

*Note: *statistically significant differences to the comparator (laparoscopic or open procedure); **Effect uncertain: in the case of very low-quality evidence, we are uncertain whether robot-assisted surgery improves or reduces the outcome as the quality/certainty of the evidence has been assessed as very low*

1 Introduction

1.1. Robot-assisted surgery

Roboterchirurgie: Weiterentwicklung von minimalinvasiver Chirurgie

Robot-assisted surgery (RAS) is a technically advanced form of minimally invasive or laparoscopic surgery that can be divided into single-port and multi-port surgery. The instruments of the robotic system are controlled by a direct telemanipulator [1], which is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery, using the robotic arms [2].

Erwartung: höheres Maß an Geschicklichkeit & OP in kleinsten Körperbereichen möglich

The aim of developing robotic surgery was to overcome the limitations associated with pre-existing minimally invasive surgery. Thus, the robot has a higher degree of dexterity compared to the laparoscopic approach, allowing surgeons to operate in very tight spaces in the body that would otherwise only be accessible through open surgery [3, 4]. In general, minimally invasive surgery is considered superior to open surgery, assuming surgeons are equally skilled in both procedures, the minimally invasive technique is associated with a lower risk of infection, shorter recovery times and equally successful outcomes. [5, 6].

Annahmen: Verbesserungen der Lebensqualität (QoL) & klinischer Ergebnisse

geringere Inanspruchnahme von Gesundheitsressourcen

Additional benefits of robotic surgery are claimed to relate to improved quality of life (QoL), reduction in healthcare resource utilization, and enhanced perioperative as well as clinical outcomes. It is also thought to allow surgeons to work more ergonomically, resulting in less strain. The claimed benefits of RAS compared to open surgery and/or laparoscopic surgery are as follows [2, 7]:

Healthcare Utilization:

- Reduced length of stay
- Fewer Readmissions
- Reduced intensive-care unit (ICU) Time
- Fewer post-surgery diagnostic tests
- Reduction in need for catheters and other accessories
- Hospital bed utilization
- Shift to outpatient surgery

Clinical Outcomes:

- Reduced blood loss volume
- Fewer transfusions
- Lower overall complication rate
- Fewer conversions to open or laparoscopic surgery
- Lower Positive Surgical Margins
- Reduced surgical trauma to tissue

Improved QoL:

- Improvement in patient-reported outcomes
- Faster return to work for patients
- Reduced burden on caregivers
- Reduced operative pain and discomfort

- Less caring and improved cosmesis.

spezielle Schulungen für das chirurgische Personal notwendig

derzeit kein Standard Trainingsrogramm verfügbar

Generally, no extra personnel requirements are needed according to the manufacturers. However, additional training and learning of the surgical staff is required [7, 8]. Besides, an adequate volume of cases is necessary for the surgical teams to maintain proficiency. Moreover, no consensus or recognized standards exist regarding optimal training programs for RAS. Therefore, some professional organizations (e.g., American Association of Gynecologic Laparoscopist), have begun to develop guidance to help healthcare facilities address the need for adequate training in RAS [9].

19 Hersteller → 13 für die Verwendung in der Thorax- & Viszeralchirurgie

Currently, there are 19 known manufacturers of robotic systems to aid in surgical procedures (identified via hand search), of which ten companies offer a total of 14 CE-marked products in the area of thoracic and visceral surgery (Table 1-1). The robotic procedure used in most of the studies included in this Health Technology Assessment (HTA) involved the da Vinci® Surgical System.

Table 1-1: Features of the intervention and development status [7-27]

Manufacturer[1]	Product name	Development status	Principal characteristics/ Intended Use
Applied Dexterity	RAVEN™ (I, II and III)	Commercialized as an open research platform and distributed to university clinics and research labs	• Developed with a military vision (aim: compactness, remote control) • Multi-arms & generic intended use/
Asensus (former Transenterix)	Senhance™ Surgical System	FDA approval (2017) CE mark (2017) Eye-tracking system, haptic feedback	• Multiarm • Indicated for adult use and laparoscopic surgery (different indications approved by the FDA and CE certificated)
	SurgiBot	In development	• Mobile, Single-port access
Avatera	Avatera	CE Mark (2019)	• Four arms • Generic intended use
AVRA Medical Robotics	AVRA Surgical Robotic System (ASRS)	In development (prototype available)	• Semi/autonomous systems, incorporate • artificial intelligence for enhanced diagnostic and therapeutic capabilities • Generic intended use
Cambridge Medical Robotics	Versius	CE Mark (2019)	• Multiarm • Generic intended use
CAST	MIVR (Miniature in vivo robot)	In development (latest publication 2014)	• Two Arms • Miniaturization of robotic arms and motors
Distal-motion	Dexter	CE Mark (2020) FDA approval planned	• Multiarm • Generic intended use
DLR Robotics	MiroSurge	In development Latest publication 2011	• Multiarm • Multipurpose (laparoscopic) • Haptic feedback
Freehand	Vista Panorama	FDA approval (2009) CE Mark (2009	• Robotic video arm → controlled by a footswitch and a headset
Intuitive Surgical	1st generation of products: da Vinci®	FDA approval (2003) CE Mark (2003)	• da Vinci (IS1200) → no longer supported as a CE-marked product
	2nd generation: da Vinci® S	FDA approval (2009) CE Mark (2007)	• da Vinci S (IS2000) → no longer supported as a CE-marked product
	3rd generation: da Vinci® Si or Si-e Surgical System	FDA approval (2009/10) CE mark (2009/10)	• Four robotics arms (Vinci® Si) • Three robotic arms (da Vinci® Si-e) • Multi-intended use
	4th generation: Vinci® Xi; da Vinci® X; da Vinci® SP	Xi: FDA approval (2014); CE mark (2014) X: FDA approval (2017); CE mark (2017) SP: FDA approval (2018); no CE mark	• Thinner arms and longer instruments than da Vinci® Si • Xi's four arms include a new "patient clearance joint" to facilitate intraoperative arm adjustments and to provide a wider range of motion • X is like the da Vinci Xi but at a lower cost • Multi-intended use
Medical Robotic Technologies	SOFIE (Surgeon's Operating Force-feedback Interface Eindhoven)	In development	• Compact, Haptic feedback, • Multi-arms • Generic intended use
Medrobotics	Flex® Robotic System[2]	FDA clearances (2018) CE mark (2014)	• Highly articulated, serpentine • Intended for transanal or transoral surgery
Medtronic	Hugo	CE Mark 2021	• Multiarm • Multipurpose

[1] Identified via hand search

[2] Robotic system marketed for transoral and transanal surgery.
Manufacturer is not commercially active in thoracic and visceral surgery.

Manufacturer[1]	Product name	Development status	Principal characteristics/ Intended Use
Nanyang Tech. Univ. and National Univ. Health System	MASTER	In development (latest publication 2010)	• Transluminal endoscopic robot • Two arms
Revo Surgical System	REVO-I	CE mark (planned)[3]	• Multiarm • General endoscopic surgery, including cholecystectomy and prostatectomy
Surgica Robotica[4]	Surgenius Beta	CE mark (2012)	• Multiarm • Generic intended use
	Surgenius Gamma	In development	• Confidential
Titan Medical[5]	Single Sport Orifice Robotic Technology (SPORT™) Surgical System	FDA approval planned	• Single-port access • Multiarm • Generic intended use (including general abdominal, gynaecologic, and urologic indications)
Verb Surgical[6]	-	In development (launch planned for 2020)	• Cooperation of Google parent Alphabet Inc.'s Verily Life Sciences and Johnson & Johnson
Virtual Incision	MIRA	Request submitted to FDA 2023	• Single port • Intended use bowel reception procedures
TransEnterix	Senhance™ Surgical System (Former Telelap ALF-X ®)	FDA approval (2017) CE mark (2017)	• Eye-tracking system, haptic feedback • Multiarm • Indicated for adult use and laparoscopic surgery (different indications approved by the FDA and CE certificated)
	SurgiBot	In development	• Mobile, Single-port access
Verb Surgical	-	In development (launch planned for 2020)	• Cooperation of Google parent Alphabet Inc.'s Verily Life Sciences and Johnson & Johnson
Virtual Incision	-	In development	• Single port • Intended use abdominal surgery

Abbreviations: FDA = Food and Drug Administration.

1.2. Thoracic and visceral surgery

Update von Bericht 2019 zu Einsatz von roboterassistierter Chirurgie in Thorax- und Viszeralchirurgie

This report is an update of an assessment on RAS in thoracic and visceral surgery, conducted in 2019 [28]. Thoracic surgery is concerned with conditions of the lungs, chest wall and diaphragm and is generally dominated by the treatment of malignant disease [29]. Visceral surgery deals with all aspects of the surgical treatment of benign and malignant diseases of abdominal organs, the entire gastrointestinal tract, endocrine organs, the abdominal wall, and the peritoneum.

[3] REVO-I has Korean FDA-approval so far (2017)

[4] Manufacturer was contacted via e-mail on the 16th May and 12th June 2018. However, no answer was received; homepage not available

[5] Manufacturer was first contacted on the 16th May 2018. After several e-mails and phone calls with representatives of the manufacturer the contact was discontinued without any additional information from the manufacturer.

[6] Bought by Johnson & Johnson, no further information.

Within this HTA the following surgical procedures performed with the assistance of robots were included:

untersuchte Anwendungsbereiche

Surgical procedures for ***thoracic surgery***:

- pulmonary lobectomy,
- lung segmentectomy and
- mediastinal surgery.

Thoraxchirurgie: Lunge & Mediastinalbereich

Surgical procedures for ***visceral (abdominal) surgery***:

- anti-reflux surgery/fundoplication,
- oesophagectomy or oesophageal repair,
- heller myotomy,
- gastrectomy,
- bariatric surgery,
- small bowel resection,
- colectomy,
- rectal resection,
- cholecystectomy,
- liver resection/hepatectomy and
- hernia repair.

Viszeralchirurgie: Ösophagus, Magen, Darm, Gallenblase/ Leber/Milz, Hernien Etc.

Details on the indications can be found in the 2019 report [28].

2 Objective and Scope

2.1. Project aims and research questions

RAS was developed during the past 25 years to support surgeons performing minimally invasive operations. The use of robots is intended to increase the precision of the intervention and reduce complications, resulting in shorter hospital stays combined with better treatment effects. However, the costs of RAS – for acquisition and maintenance – are far more expensive in comparison to laparoscopic or open surgery [30]. That is why payer-institutions ask for evidence on the added benefit of RAS.

roboterassistierte Chirurgie → hohe Erwartungen an erhöhte Präzision & Reduzierung von Komplikationen

hohe Anschaffungs- & Wartungskosten

Therefore, the report from 2019 [28] aimed to provide a systematic analysis of the literature on the effectiveness and safety of RAS in thoracic and visceral indications. The report concluded that in nine out of 14 investigated indications insufficient evidence was presented. In the case of four indications evidence was provided for some patient-relevant outcomes, but in several instances only a single randomised controlled trial (RCT) was available. Hence, the present assessment aims to update the later-mentioned report by identifying recently published evidence (2018-2023) on the effectiveness and safety of RAS in thoracic and visceral indications.

Ergebnis des Berichts 2019: in 9/14 Indikationen insuffiziente Evidenz

Ziel dieses Berichts 2023: Update

For that purpose, the following research question is answered:

- Is RAS for treating patients with an indication for operations in the thorax and abdomen effective and safe concerning defined outcomes (see PICO scheme, Table 2-1) compared to laparoscopic or open surgery?

Forschungsfrage: vergleichende Wirksamkeit und Sicherheit von RAS in der Thorax- & Viszeralchirurgie

2.2. Inclusion criteria

The inclusion criteria for relevant studies are summarised in Table 2-1.

Einschlusskriterien für klinische Studien

Table 2-1: Inclusion criteria according to PICOS questions

Population	Patients with indication for **thoracic surgery**: Pulmonary (sleeve) lobectomy (non-small cell lung cancer) Lung segmentectomy/wedge resection (non-small cell lung cancer) Pneumonectomy (non-small cell lung cancer) Mediastinal surgery (mediastinal tumour, mediastinal bronchogenic cyst) Pleurectomy (malignant/recurrent pleural effusions; mesothelioma; recurrent pneumothorax) Thymectomy (*Myasthenia gravis* (pseudoparalytica); thymoma) Pleural/pulmonary decortication (pleural empyema) Patients with indication for **visceral (abdominal) surgery**: Anti-reflux surgery (gastroesophageal reflux disease [e.g., Nissen fundoplication]) Oesophagectomy (oesophageal cancer) Oesophageal repair (oesophageal perforation) Gastrectomy (subtotal for gastric cancer <stage IB, radical for IB-III) Bariatric surgery (obesity [e.g., ROUX-en-Y gastric bypass, gastric bypass, and sleeve gastrectomy]) Small bowel resection (bleeding, infection, ulcers, blockage, benign tumours, precancerous polyps, cancer, injuries, Meckel's diverticulum) Colectomy (bleeding, bowel obstruction, cancer, Crohn's disease, ulcerative colitis, diverticulitis, cancer prevention [e.g., total colectomy, partial colectomy, hemicolectomy, and proctocolectomy]) Rectal resection (rectal cancer [e.g., polypectomy, and local excision]) Appendectomy (appendicitis) Pancreatectomy (inflammation, trauma, neoplasms) Hernia Repair (hernia) Myotomy (achalasia) Cholecystectomy (biliary colic, acute cholecystitis, cholangitis [e.g., caused by symptomatic gallstones], gallbladder cancer)
Intervention, Setting	Robot-assisted surgery (several products)
Control	Laparoscopic surgery Open surgery
Outcomes	Effectiveness: Mortality (disease-specific) Rate of reoperations Other disease-specific effectiveness-related outcomes Quality of life Duration of hospital stay Time to resume work/daily activities Patient satisfaction Safety: Intraoperative complications (bleeding, mortality, etc.) Postoperative complications (pain, infections, etc.)
Types of studies	Randomised controlled studies (RCTs) with >20 patients (for effectiveness and safety)
Publication period	26.06.2018 – 04.2023
Language	German, English
Type of publication	published journal articles and research reports

3 Methods

3.1. Systematic literature search

systematische Literatursuche in 2 Datenbanken

The systematic literature search was conducted between the 17th and 19th of April in the following two databases:

- Medline via Ovid
- The Cochrane Library

systematische Suche + Handsuche: 393 Treffer (nach Deduplizierung)

The systematic search was limited to the years 2018 to 2023 and RCTs as well as articles published in English or German. After deduplication, overall, 392 citations were included. By hand-search, one additional article was found, resulting in overall 393 hits. No systematic literature search considering ongoing studies was conducted. The specific search strategy employed can be found in the Appendix.

3.2. Flow chart of study selection

Literaturauswahl

After deduplication, overall, 393 hits were identified through the systematic search and hand search. The references were screened by two independent researchers (LG, CW) and in case of disagreement a third researcher was involved to solve the differences. The selection process is displayed in Figure 2-1.

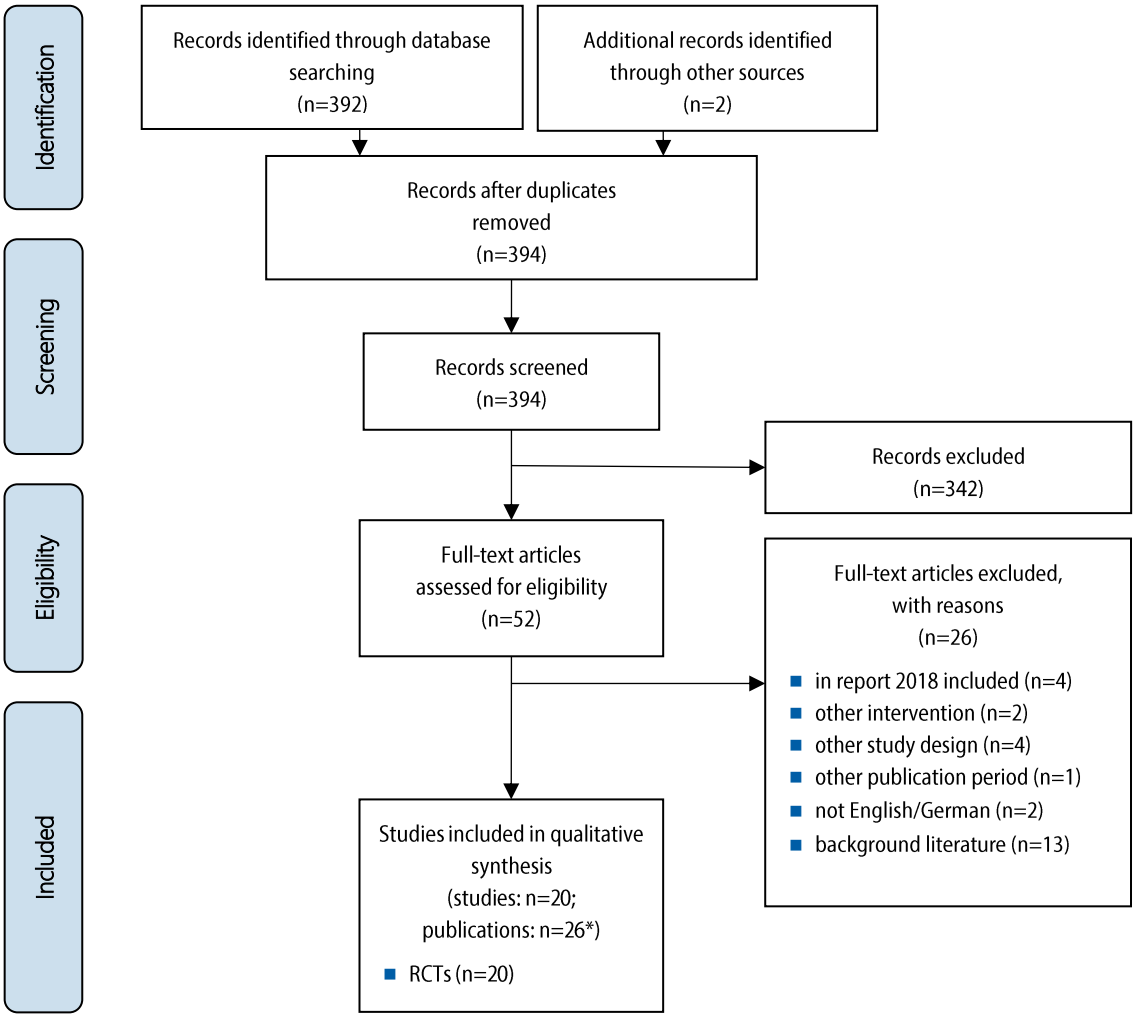

Figure 2-1: Flow chart of study selection (PRISMA Flow Diagram)

** In the case of four studies additional publications (n=5) with different follow-up times were available.*

20 RCTs & 5 Follow-up (FU) Publikationen, 2 Studien überlappend → nachfolgend zusammgefasst

In total, 20 studies, five follow-up publications and one double reporting of a study in two publications [31, 32] were included in the qualitative synthesis. The following list gives an overview of the number of articles in terms of different indications:

Thoracic surgery

- 1. Lung lobectomy (n=4; follow-up publications: n=1)
- 2. Mediastinal surgery (incl. thymectomy) (n=0)

Visceral surgery

- 3. Oesophagus (n=3)
- 4. Stomach (n=3)

- 5. Bowel (n=4; follow-up publications: n=2)[7]
- 6. Gallbladder/Liver/Spleen (n=6; follow-up publications: n=2)

3.3. Quality appraisal

Bewertung von Studienqualität und Verzerrungsrisiko

Two independent researchers (LG, MR) critically appraised all studies (n=20, 5 follow-up publications) in a blinded manner at the study level. The 'Cochrane Collaboration's tool' version 1 [34, 35] was used to systematically assess internal validity and Risk of Bias (RoB), as presented in the Appendix (Table A - 1). Disagreements were solved through consensus. The results of the appraisal have informed data synthesis.

3.4. Data extraction and analysis

systematische Datenextraktion und Kontrolle nach dem 4-Augen Prinzip

The data from the selected studies were first clustered and then extracted into data extraction tables (see Appendix: Table A - 1 & Table A - 2). The single-data extraction with verification by another researcher was conducted: One researcher (LG or MR) extracted the data, and one further researcher (MR or LG) controlled the extracted data.

3.5. Data synthesis

Evidenzsynthese mittels GRADE

Based on data extraction tables (see Appendix Table A - 16 - Table A - 20), data on each selected critical outcome category were synthesised across studies according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE-)scheme [36]. The research questions were answered in plain text format with reference to GRADE evidence tables included in Appendix Table A - 3 - Table A - 10; results were summarised in Table 5 - 1.

[7] Two follow publications refer to the same RCT [33], which was already included in the previous report [28].

3.6. Quality assurance

Begutachtung durch
1 interne/n &
1 externe/n
Reviewer*in

This report was reviewed by one internal and one external reviewer. The external reviewer was primarily asked to assess the report according to the following quality criteria:

- *Technical correctness:* Is the report technically correct (evidence and information used)?
- Does the report *consider the latest findings* in the research area?
- *Adequacy and transparency of method:* Is the method chosen adequate for addressing the research question, and are the methods applied in a transparent manner?
- *Logical structure and consistency of the report:* Is the structure of the report consistent and comprehensible?
- *Formal features:* Does the report fulfil formal criteria of scientific writing (e.g., correct citations)?

The AIHTA considers the external peer review by scientific experts from different disciplines as a method of quality assurance of the scientific work. However, the responsibility for the report content lies with the AIHTA.

4 Results: Evidence of efficacy and safety of robot-assisted surgery (RAS)

Effektivität & Sicherheit von Roboterchirurgie

This chapter describes, first, the study and patient characteristics of

- thoracic and
- visceral surgery

of the included publications (studies n=20, follow-up publications n=5). Finally, the effectiveness and safety of RAS are described in terms of

20 RCTs & 5 FU Publikationen

- patient-relevant efficacy outcomes,
- safety-related outcomes, and
- perioperative events and resource use.

To allow better readability, results are reported as *mean ± SD* (standard deviation), and other statistical values are highlighted. Confidence intervals are only reported if mentioned in the studies. In addition, thoracic and visceral indications for which no RCTs could be identified are listed only once in chapter 4.1 on the study characteristics of included studies.

Indikationen ohne verfügbare Evidenz werden nur im Kapitel 4.1 aufgelistet

4.1. Study characteristics of included studies

4.1.1. Thoracic surgery

Lung lobectomy

Four RCTs (677 patients; intervention group (IG): 338 vs control group (CG): 339) [32, 37-40] and one follow-up publication [40] investigated differences in overall survival (OS) [32, 37], postoperative [37, 39] or perioperative [38] complications, as well as duration of surgery [32, 37, 38] and length of hospital stay [37-39] between study groups.

Lungenlobektomie: 4 RCTs & 1 FU Publikation (n=677; Interventions-gruppe (IG): 338 vs Kontrollgruppe (KG): 339)

Countries, in which the studies were conducted included, China [32, 37], Italy and USA [38] and Brazil [39]. Robotic-assisted lobectomy [37, 38] or robotic-assisted thoracoscopic surgery [32, 39] was compared to either video-assisted lobectomy [37], video-assisted thoracic surgery [38, 39] or thoracotomy [32] in patients with NSCLC [32, 37, 38] or lung lesions [39]. Patients were included when clinical evaluation results showed that the patients were able to undergo the procedure [32, 38, 39]. Follow-up length was either 90 days [39], 48 weeks [40], or two years [32]. Studies were sponsored by industry [37, 38], by the National Natural Science Foundation of China and the Shanghai-Hospital Development Center [32], and by the Brazilian Ministry of Health [39].

Komparatoren (KP): videoassistierte Lobektomie, video-assistierte thorako-skopischen Chirurgie, Thorakotomie
Indikationen: nicht-kleinzelliger Lungen-krebs (NSCLC), Lungenläsionen

mediastinale Chirurgie: keine weiteren RCTs identifiziert

Mediastinal surgery (incl. thymectomy): No further studies concerning mediastinal surgery could be identified.

4.1.2. Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Fundoplikatio
1 RCT
(n=40;
IG: 20 vs KG: 20)

One German RCT (40 patients; IG:20 vs CG: 20) [41] investigated the effects of robotic-assisted laparoscopic fundoplication using the da Vinci Surgical Systems in comparison to conventional laparoscopic fundoplication on QoL and reflux-specific symptoms in adult patients with gastroesophageal reflux disease with a follow-up of twelve years. The study was sponsored by "Projekt DEAL".

Oesophagectomy

Ösophagektomie
2 RCTs (n=474;
IG: 239 vs KG: 235)

KP:
offene transthorakale, konventionelle minimalinvasive Ösophagektomie

Two RCTs (474 patients; IG: 239 vs CG: 235) [42, 43], which were a single-centre RCT of patients with intrathoracic oesophageal cancer conducted in the Netherlands [43], and a Chinese multicentre RCT of patients with oesophageal squamous cell carcinoma [42], investigated overall disease-free survival (DFS) [43], or OS as well as perioperative outcomes[42]. The intervention group underwent a robot-assisted minimally invasive oesophagectomy [42], whilst the control group underwent either an open transthoracic [43] or a conventional minimally invasive oesophagectomy [42]. The follow-up length was either three [42] or five years [43]. One study [43] did not report the sponsors, the other study was sponsored by the Shanghai Hospital Development Center [42].

Heller-Myotomie: keine weiteren RCTs identifiziert

Heller myotomy (Oesophageal repair): No further studies concerning Heller myotomy could be identified.

Stomach

Gastrectomy

Gastrektomie bei Magenkarzinom Patient*innen

3 RCTs
(n=606;
IG: 302 vs KG: 304)

In three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] robotic gastrectomy [45, 46] or robotic distal gastrectomy [44] was either compared to open gastrectomy [46] or laparoscopic (distal [44]) gastrectomy [45] in patients with gastric cancer. The studies were conducted in Brazil [46], China [44] and Japan [45]. Follow-up length varied between 30 days [44], 90 days [46] and 12 months [45]. Assessed endpoints included three-year DFS as well as short-term clinical outcomes [44], surgical outcomes and postoperative outcomes [46]. One study [44] did not report sponsors, one study was sponsored by various foundations [45] and the other study was sponsored by the University of São Paulo [46].

keine weiteren RCTs identifiziert

Bariatric surgery/gastric bypass: No further RCTs concerning bariatric surgery or gastric bypass could be identified.

Bowel

Small Bowel resection: No RCT concerning small bowel resection could be identified.

keine Evidenz verfügbar

Colectomy

Two RCTs were identified (198 patients; IG: 78 vs CG: 120) [47, 48]. One out of two studies is a post hoc analysis of a phase III RCT of patients with cancer or benign colonic pathologies and was conducted in France [48], whilst the other study is a prospective RCT of patients with right-sided colon cancer conducted in South Korea [47]. The studies compared robotic colectomy [48] or robot-assisted right colectomy [47] with laparoscopic colectomy [48] or laparoscopic-assisted right colectomy [47]. The follow-up length was either not reported [48] or five years [47]. Included studies investigated the length of hospital stay and morbidity [47, 48], as well as operation time and DFS [47]. One study [48] was conducted independently, consequently, no funds were received, the other study was sponsored by the Ministry of Health & Welfare [47].

Kolektomie
2 RCTs
(n=198;
IG: 78 vs KG: 120)

KP:
laparoskopische & laparoskopisch-assistierte rechte Kolektomie

Rectal resection

Two RCTs (1,589 patients; IG: 794 vs CG: 793) [49, 50] which were conducted in China, compared either robotic abdominoperineal resection to laparoscopic abdominoperineal resection [49], or robotic surgery for rectal cancer to conventional laparoscopic surgery [50], using the da Vinci S System with a follow-up of three years. Patients aged between 18-75 years with low rectal cancer [49], or between 18-80 years with middle and low rectal cancer [50] were included. Other inclusion criteria were American Society of Anesthesiologists (ASA) Class I-III and histologically proven rectal adenocarcinoma. Included endpoints were either postoperative complications or pathological outcomes [49, 50] as well as recurrence [50]. One study was sponsored by the Zhongshan Hospital Fudan University [49], and the other study was sponsored by various Chinese institutions [50].

Rektumresektion
2 RCTs
(n=1.589;
IG: 794 vs KG: 793)

Ventral mesh rectopexy

Two follow-ups of one RCT (30 patients; IG: 16 vs CG: 14) [51, 52], which was already included in the previously published assessment, reported on the comparison of robot-assisted ventral mesh rectopexy using the da Vinci Si and the laparoscopic ventral mesh rectopexy. The study was conducted in Finland including women aged from 18 to 85 years with external rectal prolapse or internal rectal prolapse with or without the descent of the middle pelvic compartment. Endpoints were defined as maintenance of the repaired pelvic anatomy five years after surgery [51] and QoL [52]. Follow-up lengths were either 24 months [52] or five years [51]. The study was sponsored by the University of Oulu [33].

ventrale Netzrektopexie
2 FU Publikationen → Original-RCT bereits im Bericht 2019 inkludiert
(n=30;
IG: 16 vs KG: 14)

Gallbladder/Liver/Spleen

keine weiteren RCTs zu Cholezystektomie

Cholecystectomy: No further RCTs on cholecystectomy could be identified.

Hernia repair

Hernienreparatur 5 RCTs & 2 FU Publikationen (n=471; IG: 237 vs KG: 231[8])

Five RCTs (471 patients; IG: 237 vs CG: 231[8]) [53-57] of which two [53, 56] published results in two articles on different follow-up lengths (30 days [53] and 12 months [58]; one month [56] and 24 months [59]) included the following procedures in the intervention group: robotic ventral hernia repair [53, 55, 57], robotic-assisted incisional hernia repair [54], or robotic transabdominal preperitoneal repair [56]. Procedures in the control group included laparoscopic (ventral [55, 56]) hernia repair [57], laparoscopic incisional hernia repair [54] or standard laparoscopic transabdominal preperitoneal repair [56]. Studies were conducted either in the USA [53, 55-57] or Brazil [54]. Follow-up length varied between seven days [56] and two years [54]. Patients, with an indication of either ventral hernia [53, 55, 57], abdominal or pelvic incisional hernia [54], or inguinal hernia [56]were included. Endpoints were postoperative complications [54, 55, 57], recurrence [53-55, 57], pain [53, 55, 57] and QoL [53, 54, 57]. Four studies were sponsored by industry [53, 55-57], and one study was conducted independently [54].

Liver resection (hepatectomy)

Hepatektomie 1 RCT (n=122; IG: 61 vs KG: 61)

In one RCT (122 patients; IG:61 vs CG: 61) [60] patients with synchronous colorectal liver metastases underwent either robot-assisted laparoscopic hepatectomy using the da Vinci system, or laparoscopic hepatectomy in China. Endpoints, which were measured in a three-year follow-up, were clinical manifestations, like operation time and blood loss, as well as survival and complications. The study did not report sponsors.

4.2. Patient characteristics of included studies

4.2.1. Thoracic surgery*Lung lobectomy*

Lungenlobektomie Ø Alter: 60.9-68.0 medianes Alter: 61.0-68.4

keine statistisch signifikanten (ss) Unterschiede hinsichtlich BMI und klinischen Stadium

Four RCTs [32, 37-40] included patients with a mean age of 60.9-68.0 [32, 38] or a median age of 61.0-68.4 years [37, 39]. In the intervention group, 32.9-54.0% were female, whereas 29.2- 56.4% female patients were enrolled in the control group. There were no statistically significant differences concerning body mass index (BMI) between study groups. Clinical classification was assessed using either the TNM Classification of Malignant Tumors [32, 37], or the Clinical Stage [38], without statistically significant differences between study groups. In one study [37] most patients were in TNM Stage Ia, in the other study the majority of patients were in TNM Stage III [32], and in the other study, the Clinical Stage Ia was reported in the majority of patients [38]. One RCT [39] did not report on clinical classification.

[8] There is an error in the CONSORT flow diagram in one RCT [53] as 39+39=78

4.2.2. Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

One RCT [41] included patients with a mean age of 49.6 ± 12.0 vs 50.5 ± 12.4 years and a BMI of 29.2 ± 5.83 vs 26.2 ± 3.4. The proportion of women was 50% in the intervention vs 60% in the control group. Concerning clinical classification, the Los Angeles stages (Los Angeles A: IG:9; CG:11; Los Angeles B: IG: 10; CG: 7; Los Angeles C: IG: 1; CG: 2; Los Angeles D: IG: 0; CG: 0) and the gastrointestinal symptom rating scale (4.0 ± 1.7 vs 4.4 ± 1.5) were used. There were no statistically significant differences in baseline characteristics between study groups.

Fundoplikatio
Ø Alter: 49.6 ± 12.0 vs 50.5 ± 12.4

BMI: 29.2 ± 5.83 vs 26.2 ± 3.4

Oesophagectomy

Two RCTs [42, 43] included adult patients under 80 [43] or 75 [42] years, with a mean age of 64 ± 8.9 vs 65 ± 8.2 [43], or a median of 65 (43-75) vs 63 (42-75) years [42]. In the intervention group, 13.8-15.0% were female in comparison to 15.3-24.0% in the control group. The mean BMI was between 23.1-26.1 in the intervention group vs. 23.0-25.5 in the control group. One RCT assessed clinical classification [43] using the ASA Score, whereof the majority of patients were categorised as stage II (38 (70%) vs 34 (62%)), whilst the other RCT [42] reported the Clinical Stage, whereof 94 (51.9) vs 93 (52.5) patients had stage II disease. No statistically significant differences concerning the baseline characteristics described above were found.

Ösophagektomie
Ø Alter: 64 ± 8.9 vs 65 ± 8.2
medianes Alter: 65 (43-75) vs 63 (42-75)

BMI: 23.1-26.1 vs 23.0-25.5

Stomach

Gastrectomy

Three RCTs [44-46] included adult patients, with a mean age of 59.3-59.4 vs 58.1-59.3 years [44, 46] or with a median age of 71 vs 72 years [45]. The proportion of women was 33.3-51.7% in the intervention group, compared with 35.3-36.6% in the control group. Information on BMI was reported either as a mean of 23.2 vs 22.7 [44] or a median of 21.9 vs 22.4 [45]. In addition, one RCT [46] reported that 20 intervention group patients vs 21 control group patients had a BMI under 25. All studies used the ASA Score for clinical classification. The most frequent stage was II, with a mean of 63.2-82.8% vs 60.5-80.6% of included participants. Statistically significant differences between study groups were either not reported [45] or not significant [44, 46].

Gastrektomie
Ø Alter: 59.3-59.4 vs 58.1-59.3
medianes Alter: 71 vs 72

klinische Klassifizierung mittels ASA Score

Bowel

Colectomy

In two RCTs [47, 48] patients had either a mean age of 62.8 vs 66.5 [47] or a median age of 67 vs 65 years [48]. The proportion of women varied from 53.0% to 60.0% in the intervention group, and from 49.0% to 54.3% in the control group. One study reported a mean BMI of 24.4 vs 23.8 [47], whilst the other study reported 37 (86%) vs 73 (87%) cases, where patients had a BMI under or equal to 30, and 6 (14%) vs 11 (13%) cases of a BMI over 30 [48]. The clinical classification was reported using the ASA Score. Stage II was present in 16-23 intervention group vs 12-50 control group patients and stage III

Kolektomie
Ø Alter: 62.8 vs 66.5
medianes Alter: 67 vs 65

klinische Klassifizierung mittels ASA Score

in 4-8 vs 2-7 patients. Differences between baseline characteristics were not statistically significant.

Rectal resection

Rektumresektion
Ø Alter: 58.2-59.1 vs 59.5-60.7

klinische Klassifizierung mittels ASA Score & TNM

Two RCTs [49, 50] reported a mean age of 58.2-59.1 years in the intervention group in comparison to 59.5-60.7 years in the control group. A normal BMI ranges from 18.5 to 23.9 and was present in 109-296 patients in the intervention group and 106-299 patients in the control group. The TNM and ASA Classification were used for clinical classification in both studies, without statistically significant differences between study groups. The majority of patients were categorized in ASA-Stage I in both RCTs. One RCT [50], also reported T-Stage and N-Stage, but no information was given on statistical differences between study groups.

Ventral mesh rectopexy

ventrale Netzrektopexie
Ø Alter: 62.5
100% weiblich

In the two follow-ups of one RCT [51, 52] only women with a mean age of 62.5 years were included. There was no information given on the BMI or the clinical classification.

Gallbladder/Liver/Spleen

Hernia repair

Hernienreparatur
Ø Alter: 50.1-65.2 vs 48.0-59.7

medianes Alter: 56 vs 55

klinische Klassifizierung mittels ASA Score

In five RCTs [53-59] patients had a mean age of 50.1-65.2 years in the intervention group compared to 48.0-59.7 years in the control group [54-57]. One RCT reported age with a median of 56 vs 55 years [53]. Four RCTs [53-55, 57] reported a higher proportion of women (41.0-74.0% vs 58.0-68.4%), whereas, in one RCT [56], only 8.5% vs 11.1% of patients were female. Information on the BMI was either given as a mean ranging from 30.5-32.4 in the intervention groups vs 31.8-32.6 in the control groups or a median (35 vs 31) [53], whereby one RCT reported statistically significant differences (p=0.014; 24.9 vs 26.9) [56]. The clinical classification was either not reported [54, 56] or not statistically significant between study groups. As reported, most patients were either in the ASA stage I-II [57], II [55] or III [53].

Liver resection (hepatectomy)

Hepatektomie
Ø Alter: 57.13 ± 5.86 vs 57.51 ± 6.27

One RCT [60] included patients with a mean age of 57.13 ± 5.86 vs 57.51 ± 6.27 years, whereof 27.9% vs 37.7% were female. BMI was comparable between study groups with a mean of 23.45 ± 2.32 vs 23.59 ± 2.22. The clinical classification using the ASA categorisation yielded 49 (80.33%) vs 44 (72.13%) patients in the ASA I-II, and 12 (19.67%) vs 17 (27.87%) patients in ASA III.

4.3. Efficacy: patient-relevant outcomes

4.3.1. Survival (overall and disease-specific or disease-free)

Thoracic surgery

Lung lobectomy

Three RCTs (600 patients; IG: 300 vs CG: 300) [32, 37, 39, 40] reported survival without detecting statistically significant differences between study groups. One RCT [32], assessed DFS in 90.4% vs 86.0% of patients after one year, and in 76.4% vs 74.2% of patients after two years and 57.5% vs 49.9% after three years [32]. In addition, another RCT [39] reported a similar death rate in both study groups (1 (2.7%) vs 1 (2.5%)) within 90 days after surgery. The third RCT [37] and a follow-up of two years [40] reported more deaths 48 weeks postoperatively in the control group in comparison to the intervention group (7 (4.5%[9]) vs 14 (8.6%[9])).

Lungenlobektomie: keine ss Unterschiede (3 RCTs) → Gesamtüberleben (OS) & krankheitsfreies Überleben (DFS)

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery): The included RCT did not assess survival [41].

Fundoplikatio: Endpunkt nicht erhoben (NE)

Oesophagectomy

Two RCTs (474 patients: IG: 239 vs CG: 235) [42, 43] measured survival. In one RCT [42] mortality was reported within 30 and 90 days after surgery (30-day mortality: 0 (0%) vs 1 (0.6%), 90-day mortality: 1 (0.6%) vs 1 (0.6%)), whereas the other RCT [43] investigated OS and DFS during five years of follow-up (*median in months; rate % (95% CI):* OS: 35; 41% (27–55) vs 41; 40% (26–53), DFS: 28; 42% (28–55) vs 37; 43% (29–57)). Both RCTs did not report statistically significant differences between study groups.

Ösophagektomie: keine ss Unterschiede (2 RCTs)→ OS & DFS

Stomach

Gastrectomy

Three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] considered survival or mortality outcomes. All included patients survived, whereas the statistical differences between study groups were either not applicable [44], not significant [45] or were not reported [46].

Gastrektomie: kein Todesfall berichtet (3 RCTs)

Bowel

Colectomy

One RCT out of two (71 patients; IG: 35 vs CG: 36) [47] investigated DFS and OS in patients with colon cancer three years after surgery (*mean in % (95% CI)*: DFS: 88.1 (77.1–99.1) vs 91.1 (81.4–99.9); OS: 96.8 (90.6–99.9) vs 94.0 (86.0-99.9)) and five years after surgery (*mean in % (95% CI):* DFS: 77.4

Kolektomie: keine ss Unterschiede (1 RCT) → OS & DFS

[9] Self-calculated, based on analysed patients.

(60.6–92.1) vs 83.6 (72.1–97.0); OS: 91.1 (78.8–99.9) vs 91.0 (81.3–99.9)) without any statistically significant differences between study groups.

Rectal resection

Rektumresektion: keine ss Unterschiede (1 RCT) → OS & DFS

In one out of two RCTs (347 patients; IG: 174 vs CG:173) [49] three years after surgery 85.3% of patients in the intervention group and 84.6% of patients in the control group survived without any signs of disease (*95% CI*: 0.555-1.517). OS was 91.1% vs 90.4% (*95% CI:* 0.490-1.697). The RCT failed to detect statistically significant differences between study groups, concerning both, DFS and OS.

ventrale Netzrektopexie: OS NE

Ventral mesh rectopexy: The identified studies did not assess survival [51, 52].

Gallbladder/Liver/Spleen

Hernia repair

Hernienreparatur: kein Todesfall 7 Tage nach der OP (1 RCT)

Short-term mortality within seven days was measured in one out of five RCTs (40 patients; IG: 20 vs CG: 20) [54], resulting in no death in the intervention group and one death (5%) in the control group, without a statistically significant difference.

Liver resection (hepatectomy)

Hepatektomie: Unterschied in OS nicht ss (1 RCT)

One included RCT (122 patients; IG: 61 vs CG: 61) [60] did not find a statistically significant difference between study groups at the one-year follow-up (52 (85.25%) vs 48 (78.69%)), at the two years follow-up (43 (70.49%) vs 40 (65.57%)) and at the three years follow-up (31 (50.82%) vs 26 (42.62%)) concerning survival.

4.3.2. Recurrence (local, regional or distant)

Thoracic surgery

Lung lobectomy

Lungenlobektomie: Unterschied in Rezidiven nicht ss (1 FU Publikation)

The follow-up of one RCT (363 patients; IG: 181 vs CG: 182) [40] reported 48 weeks postoperatively six recurrences (3.3%[10]) in the robotic-assisted group in comparison to five (2.8%[10]) in the control group; however, the difference was not statistically significant.

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Fundoplikatio: Behandlungsmisserfolg kein ss Unterschied (1 RCT)

One RCT (40 patients; IG: 20 vs CG: 20) [41] assessed recurrence as "failure of treatment"; however, no statistically significant result was found (Oesophagitis ≥ Los Angeles-B: 1 (8%) vs 1 (8%), Gastrointestinal Symptom Rating

[10] Self-calculated, based on analysed patients.

Scale-Reflux-Score ≥ 3: 3 (25%) vs 2 (17%), daily PPI for reflux: 4 (31%) vs 4 (33%), dysphagia combined with reflux score ≥ 2: 1 (8%) vs 1 (8%)).

Oesophagectomy

One RCT (112 patients; IG: 56 vs CG: 20) [43] out of two measured overall recurrence-disease without any statistical significance (28 (56%) vs 29 (54%)) between study groups.

Ösophagektomie: Unterschied in Rezidiven nicht ss (1 RCT)

Stomach

Gastrectomy: None of the included studies assessed disease recurrence [44-46].

Gastrektomie: Rezidive NE

Bowel

Colectomy

One (71 patients; IG: 35 vs CG: 36) [47] out of two RCTs reported that no port site recurrence had been noted with a median follow-up of 49 months.

Kolektomie: Unterschied in Rezidiven nicht ss (1 RCT)

Rectal resection

One RCT (347 patients; IG: 174 vs CG: 173) [49] out of two did not find statistically significant differences concerning disease recurrence. However, in five (2.9%) cases in the intervention group and nine (5.2%) cases in the control group locoregional recurrence of rectal cancer was assessed (*mean difference (95% CI):* -2.3 (-7.0 to 2.1). Distant metastases recurred in both groups without statistically significant differences (21 (12.1) vs 23 (13.3); *mean difference (95% CI):* -1.2 (-8.3 to 6.0)).

Rektumresektion: Rezidive in 2.9% IG vs 5.2% KG → Unterschied nicht ss (1 RCT)

Ventral mesh rectopexy

One follow-up (30 patients; IG: 16; CG: 14) [52] out of two, reported one recurrence in the control group (8%) after a follow-up time of 24 months.

ventrale Netzrektopexie: 1 Rezidiv in der KG (1 FU Publikation)

Gallbladder/Liver/Spleen

Hernia repair

Five RCTs (471 patients; IG: 237 vs CG: 231[8]) [53-59]were identified. One RCT [58] reported statistically significantly more recurrences after one year of surgery in the intervention group than in the control group (clinical recurrence: 5 (25%) vs 0 (0%); **p=0.03;** composite recurrence: 9 (24%) vs 2 (6%); **p=0.04**). In addition, two RCTs [54, 55] detected more recurrences in the control group (2 (11.1%) vs 3 (15.75%), 24 months after surgery [54]); 4 (7%) vs 5 (9%) [55]). One RCT [59] reported one case of recurrence in each group after two years of surgery without statistical significance. The fifth RCT [57] did not detect any recurrences.

Hernienreparatur: Rezidive
1 RCT → ss Unterschied: p=0,03
3 RCTs → kein ss Unterschied
1 RCT → Rezidiv NE

Liver resection (hepatectomy): The identified RCT [60] did not assess recurrence.

Hepatektomie: Rezidive NE

4.3.3. Quality of life (QoL)

Thoracic surgery

Lung lobectomy

Lungenlobektomie: Lebensqualität (QoL) → kein ss Unterschied (1 RCT)

QoL was assessed after four weeks (*mean difference (95% CI):* 0.002 (–0.008-0.012)), 24 weeks (0.003 (–0.004-0.010)) and 48 weeks (0.004 (–0.002-0.011)) of surgery in a follow-up report of one RCT (363 patients; IG: 181 vs CG: 182) [40], there was no information given about the statistical significance of the results.

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Fundoplikatio: QoL → kein ss Unterschied (1 RCT)

One RCT (40 patients; IG: 20 vs CG: 20) [41] reported no statistically significant differences between study groups considering QoL measured by the quality of life in reflux and dyspepsia questionnaire (emotional distress: 6.4 ± 1.4 vs 6.5 ± 1.6, food/drink problems: 6.5 ± 0.9 vs 6.3 ± 1.6, physical/social functioning: 6.6 ± 1.0 vs 6.4 ± 1.6, sleep disturbance: 6.4 ± 1.3 vs 6.5 ± 1.5, vitality: 6.3 ± 1.4 vs 6.3 ± 1.6).

Ösophagektomie: QoL NE

Oesophagectomy: QoL was not assessed in the identified RCTs [42, 43].

Stomach

Gastrektomie: QoL NE

Gastrectomy: None of the identified studies assessed QoL measures [44-46].

Bowel

Kolektomie & Rektumresektion: QoL NE

Colectomy: None of the identified studies assessed QoL [47, 48].

Rectal resection: None of the identified studies assessed QoL [49, 50].

Ventral mesh rectopexy

ventrale Netzrektopexie: verbesserte QoL in der IG jedoch kein ss Unterschied (1 FU Publikation)

One follow-up (30 patients; IG: 16 vs CG: 14) [51] out of two assessed QoL five years after surgery, resulting in improved results in the intervention group compared to the control group (CRAIQ-7: 24.3 ±32.0 vs 43.8 ±27.1; POPIQ-7: 9.5 ±26.4 vs 26.0 ±27.9; UIQ-7: 25.7 ±32.7 vs 33.0 ±31.4; PFIQ-7: 58.8 ±82.1 vs 102.7 ±69.9). They failed to detect statistically significant differences between the study groups.

Gallbladder/Liver/Spleen

Hernia repair

Four RCTs out of five (347 patients; IG: 172 vs CG: 172[8]) [53, 54, 56-59] including one follow-up study [59] failed to detect statistically significant differences between study groups concerning QoL. However, one follow-up report found statistically significant differences between study groups one year after surgery (measured by the hernia-specific QoL survey *n (95% CI)*:IG: 92 (82-100); CG: 77 (49-93); **p=0.04**)[58]. In addition, two articles [53, 57] reported QoL improvements after the conventional procedure compared to the control group (*median (IQR):* 30 days postoperative: 67 (45-79) vs 75 (41 to 81) [53]; *median (IQR); difference in median (95% CI):* 52 (37-68) vs 65 (36-86); 8.25 (–1.75 to 20.00) [57]). Similar results between study groups were reported by one RCT [59] after two years of follow-up (physical component summary: 53.1 ± 8.1 vs 54.2 ± 6.1; mental component summary: 53.9 ± 6.8 vs 53.4 ±5.6; general health: 77.8 ± 13.7 vs 77.8 ± 15.5). Another RCT [54] detected improvements in global health (72.07 ± 22.67 vs 67.69 ± 26.32) and in the functional component (77.27 ± 19.85) vs 67.19 ± 21.40) in the intervention group two years after surgery. Whereas the results concerning QoL in the symptoms component were better in the control group (22.13 ± 14.72 vs 30 ± 19.15).

Hernienreparatur:

Unterschiede in QoL nicht ss (4 RCTs, 1 FU)
Verbesserungen hinsichtlich QoL in den IG → Unterschied ss: p= 0.04
(1 FU Publikation)

Liver resection (hepatectomy): The identified RCT [60] did not report on QoL.

Hepatektomie: QoL NE

4.3.4. Time to resume work/daily activities

None of the included RCTs assessed the time to resume work or daily activities for none of the included indications.

Dauer bis zur Wiederaufnahme der Arbeit wurde von keiner RCT erhoben

4.3.5. Patient satisfaction

RCTs considering patient satisfaction measurements were solely available for two indications in visceral surgery.

2 Indikationen erhoben den Endpunkt Patient*innen-Zufriedenheit

Visceral surgery

Bowel

Ventral mesh rectopexy

In one follow-up (30 patients; IG: 16 vs CG: 14) [52] out of two the patient's satisfaction rate was 87% in the intervention group and 69% in the control group; however, no statistically significant differences were found between study groups.

ventrale Netzrektopexie:
IG 87% vs KG 69%
(1 FU Publikation), aber nicht ss

Gallbladder/Liver/Spleen

Hernia repair

Hernienreparatur: Patient*innen-Zufriedenheit Unterschied nicht ss (1 RCT)

One (124 patients; IG: 65 vs CG: 59) [55] out of five RCTs, evaluated patient satisfaction by using the visual analogue scale (satisfaction: (*median (IQR):* 10.0 (8.0-10.0) vs 10.0 (7.5-10.0); cosmetic satisfaction: (10.0 (5.0-10.0) vs 10.0 (6.5-10.0)) after one year of surgery. However, no statistically significant differences were found between study groups.

4.4. Safety-related outcomes

4.4.1. Intraoperative complications (e.g. air leakage)

Thoracic surgery

Lung lobectomy

Lungenlobektomie: intraoperative (IO) Komplikationen → kein ss Unterschied (1 RCT)

Intraoperative complications occurred as arterial lacerations (2 (5.1%[11])) and venous injury (1 (2.6%[11])) in the control group in one RCT (80 patients; IG: 40 vs CG: 40) [39]. There were no statistically significant differences between study groups.

Visceral surgery

Oesophagus

Fundoplikatio: IO Komplikationen NE

Fundoplication (anti-reflux surgery): There was no identified study assessing intraoperative complications [41].

Oesophagectomy

Ösophagektomie: keine Gruppenunterschiede berichtet (1 RCT)

One (362 patients; IG: 183 vs CG: 179) [42] out of two RCTs mentioned intraoperative complications leading to a conversion; however, there were no study group differences reported.

Stomach

Gastrectomy

Gastrektomie: keine Gruppenunterschiede berichtet (1 RCT)

One (65 patients; IG: 33 vs CG: 32) [46] out of three RCTs assessed intraoperative complications. No complication occurred in the intervention group. Complications concerning the control group as well as study group differences were not reported.

[11] Self-calculated, based on analysed patients

Bowel

Colectomy

No statistically significant differences in intraoperative complications between study groups (3 (7%) vs 4 (5%)) occurred in one (127 patients; IG: 43 vs CG: 84) [48] out of two RCTs.

Kolektomie:
IO Komplikationen → kein ss Unterschied (1 RCT)

Rectal resection

The two identified RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] investigated intraoperative complications. There were ten (5.7%) vs 16 (9.2%) cases of intraoperative complications reported in one RCT [49]; however, the study group difference was not statistically significant. In contrast, the other RCT [50] reported statistically significant differences between the robotic-assisted group and the laparoscopic group concerning intraoperative complications favouring the robotic procedure (32 (5.5%) vs 51 (8.7%); *mean difference (95% CI):*–3·3 (–6·3 to –0·3); **p=0.030**). The other assessed complications, like significant bleeding, iatrogenic perforation, damage to organ structure, as well as equipment failure, only occurred in the robotic-assisted groups but did not show any statistically significant study group differences in either of the two included studies. One RCT [49] also assessed damage to the ureter, vagina, prostate, and to seminal vesicle gland, without any statistically significant group differences

Rektumresektion:
IO Komplikationen

1 RCT:
kein ss Unterschied

1 RCT: mehr IO Komplikationen in der KG: 32 vs 52 (IG) → Unterschied ss: p=0,030

Ventral mesh rectopexy: The identified studies did not report intraoperative complications [51, 52].

ventrale Netzrektopexie:
IO Komplikationen NE

Gallbladder/Liver/Spleen

Hernia repair

Intraoperative complications were observed in one RCT (81 patients; IG: 39 vs CG: 39[8]) [53], though no statistically significant difference was found considering overall complications (2 (6%) vs 2 (6%)), bowel serosal injury (1 (3%) vs 2 (6%)) and liver injury (1 (3%) vs 0 (0%)).

Hernienreparatur:
kein ss Unterschied in IO Komplikationen (1 RCT)

Liver resection (hepatectomy): The identified study [60] did not assess intraoperative complications.

Hepatektomie:
IO Komplikationen NE

4.4.3. Postoperative complications (e.g. infections)

Thoracic surgery

Lung lobectomy

Lungenlobektomie:
postoperative (PO) Komplikation
keine ss Unterschiede in 4 RCTs
Krankenhauswiederaufnahme → ss Unterschied (1 RCT)
nicht ss Unterschied (2 RCTs)

Four RCTs (677 patients; IG: 338 vs CG: 339) [32, 37-40] investigated postoperative complications without any statistically significant difference between study groups. Whilst three RCTs [32, 37, 39] reported more overall postoperative complications (23 (14.6%) vs 30 (18.4%)) [37] as well as Clavien Dindo complications (grade I-II: 18 (11.5%) vs 24 (14.7%); grade III-IV: 5 (3.2%) vs 6 (3.7%) [37]), Pneumonia [32], and overall complications [39] in the control group 90 days after surgery, another RCT [38] assessed early complications (13 (37%) vs 9 (24%)) and later complications (5 (23%) vs 2 (11%)) in the intervention group. Concerning readmissions, one RCT [39] yielded statistically significant results that favoured the intervention group (1 (2.7%) vs 8 (20.5%); **p=0.029**), whereas one RCT [37] yielded no difference in readmission (3 (1.9%) vs 3 (1.8%)) between study groups. Another RCT [38] had more readmissions in the intervention group without a statistically significant difference (4 (16%) vs 0 (0%)).

Visceral surgery

Oesophagus

Fundoplikatio:
PO Komplikationen NE

Fundoplication (anti-reflux surgery): Postoperative complications were not assessed in the identified RCT [41].

Oesophagectomy

Ösophagektomie:
PO Komplikationen
kein ss Unterschied (1 RCT)

One RCT (362 patients; IG: 183 vs CG: 179) [42] out of two assessed postoperative complications. The control group showed fewer (88 (48.6%) vs 74 (41.8%)), albeit not statistically significant total complications in comparison to the intervention group. Other reported complications included anastomotic leakage (22 (12.2%) vs 20 (11.3%)) and pulmonary complications (25 (13.8%) vs 26 (14.7%)) of which pneumonia was the most frequent (18 (9.9%) vs 21 (11.9%)), whereas no statistically significant study group difference was found.

Stomach

Gastrektomie:
PO Komplikationen
2 RCTs → ss Unterschied:
Gesamtmorbidität p=0,039;
medizinische Morbidität p=0,02;
Gesamtkomplikationen p=0,01
1 RCT → kein ss Unterschied

Gastrectomy

Postoperative complications were considered in all three identified RCTs (606 patients; IG: 302 vs CG: 304) [44-46]. Two RCTs [44, 45] yielded statistically significant differences in overall morbidity (13 (9.2%) vs 25 (17.6%); **p=0.039**), medical morbidity (9 (6.4%) vs 20 (14.1%); **p=0.033**) [44], and in overall complications (≥grade IIb: 10 (8.8%) vs 23 (19.7%); **p=0.02**; ≥grade IIIa: 6 (5.3%) vs 19 (16.2%); **p=0.01**) favouring the intervention group [45]. However, other reported complications, like anastomotic leakage and pneumonia, for example, showed no statistically significant differences between study groups (anastomotic leakage ≥grade II: 4 (3.5%) vs 5 (4.3%), ≥grade IIIa: 3 (2.7%) vs 5 (4.3%) [45]; pneumonia: 8 (5.7%) vs 16 (11.3%) [44]; ≥grade II: 1 (0.9%) vs 5 (4.3%); ≥grade IIa: 0 (0%) vs 2 (1.7%) [45]. The third RCT [46] reported no statistically significant differences between study

groups considering postoperative complications within as well as after 30 days of surgery (postoperative complications: 1 (3.4%) vs 6 (19.4%)).

Bowel

Colectomy

Both identified RCTs (198 patients; IG: 78 vs CG: 120) [47, 48] reported no statistically significant differences between study groups, considering postoperative surgical complications (7 (16%) vs 10 (12%)), medical complications (4 (9%) vs 8 (10%)) [48], as well as perioperative morbidity (6 (17.1%) vs 7 (20.0%)) [47].

Kolektomie:
PO Komplikationen → kein ss Unterschied (2 RCTs)

Rectal resection

In two RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] statistically significantly fewer postoperative complications of Clavien-Dindo grade II or higher were reported in the robotic-assisted group in comparison to the laparoscopic group (23 (13.2%) vs 41 (23.7%); *mean difference (95% CI)*: -10.5 (-18.6 to -2.3); **p=0.013** [49]]; 95 (16.2%) vs 135 (23.1%); *mean difference (95% CI)*:-6.9 (-11.4 to -2.3); **p=0.003** [50]). One RCT [49] reported statistically significant differences in readmission within 30 days in favour of the intervention group (4 (2.3%) vs 12 (6.9%); *mean difference (95% CI):* −4.6 (−9.6 to −0.1); **p=0.044**). Other complications showed no statistically significant differences between study groups.

Rektumresektion:
ss weniger PO Komplikationen (2 RCTs: p=0,013 & p=0,003) & Krankenhauswiederaufnahmen (1 RCT: p=0,044)

Ventral mesh rectopexy: The identified studies did not assess postoperative complications [51, 52].

ventrale Netzrektopexie:
PO Komplikationen NE

Gallbladder/Liver/Spleen

Hernia repair

Postoperative complications were assessed in five RCTs (471 patients; IG: 237; CG: 231[8]) [53-59], which did not find any statistically significant differences between study groups. However, slightly more complications were measured in the robotic-assisted group in one RCT [56] (8 (16.7%) vs 5 (9.3%)), whereby the most frequent complication was seroma (6 (12.5%) vs 3 (5.6%)). Another RCT [57] yielded more wound complications, especially seroma in the robotic-assisted group (13 (20%) vs 8 (14%)) as well as Clavien-Dindo complications (14 (22%) vs 11 (19%); *relative rate (95% CI):* 1.10 (0.54 to 2.24)). In addition, three RCTs [53-55] reported no statistically significant differences between study groups considering wound complications (9 (15%) vs 8 (15%); *relative risk (95% CI):* 0.93 (0.32 to 2.74) [55]) and complications within seven days (3 (16.7%) vs 2 (10.5%) [54]), as well as in overall complications within 30 days after surgery (2 (6%) vs 3 (8%) [53]).

Hernienreparatur:
kein ss Unterschied in PO Komplikationen (5 RCTs), Wundkomplikationen & Gesamtkomplikationen (3 RCTs)

Liver resection (hepatectomy)

One RCT (122 patients; IG: 61 vs CG: 61) [60] detected a statistically significant difference between the robotic-assisted and the laparoscopic hepatectomy in total complications (2 (3.3%) vs 8 (13.1%) **p=0.048**). Further complications, like intestinal obstruction, bile leakage, pleural effusion, abdominal haemorrhage, and incision infection were reported in the laparoscopic group.

Hepatektomie:
ss Unterschied Gesamtkomplikationen (1 RCT)→ IG: 3.3% vs KG: 13.1%, p=0.048

4.4.4. Reoperations/additional surgeries

Thoracic surgery

Lung lobectomy

Lungenlobektomie: Re-Operationen kein ss Unterschied (1 RCT)

One RCT (80 patients; IG: 40 vs CG: 40) [39] out of four investigated the necessity of reoperations, resulting in no statistically significant differences between study groups (1 (2.7%) vs 2 (5.1%) [39]).

Visceral surgery

Oesophagus

Fundoplikatio & Ösophagektomie: Re-Operationen NE

Fundoplication (anti-reflux surgery): The identified RCT [41] did not assess any reoperations or additional surgeries in both study groups.

Oesophagectomy: None of the included RCTs assessed reoperations [42, 43].

Stomach

Gastrectomy

Gastrektomie: Re-Operationen kein ss Unterschied (3 RCTs)

Three included RCTs (606 patients; IG: 302 vs CG: 304) [44-46] reported on additional surgeries. In two studies [44, 45], reoperations were more often necessary in the control group compared to the intervention group; however, there were no statistically significant differences between study groups (0 (0.0%) vs 1 (0.7%) [44]; 1 (0.9%) vs 3 (2.6%) [45]). Re-do surgeries were not needed in the third RCT [46], but in the intervention group, two patients had a surgical revision. Surgical revisions in the control group, as well as the statistical significance, were not reported.

Bowel

Colectomy

Kolektomie: Re-Operationen kein ss Unterschied (2 RCTs)

In two RCTs (198 patients; IG: 78 vs CG: 120) [47, 48] no statistically significant differences between the groups were identified considering reoperation events (2 (5) vs 4 (5) [48]; 1 (2.8) vs 1 (2.8) [47]).

Rectal resection

Rektumresektion: Re-Operationen kein ss Unterschied (2 RCTs)

The two identified RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] reported additional surgeries within 30 days after surgery in either five (2.9) vs ten (5.8) cases (*mean difference (95% CI):* −2.9 (−7.7 to 1.6)) [49] or in 14 (2.4) vs 24 (4.1) cases (*mean difference (95% CI):* –1.7 (–3.9 to 0.3)) [50], without statistically significant differences.

Ventral mesh rectopexy

ventrale Netzrektopexie: 1 Re-Operation in der KG (1 FU Publikation)

One follow-up (30 patients; IG: 16 vs CG: 14) [52] out of two reported 24 months after surgery, that one additional surgery was necessary in the control group (8%).

Hepatektomie: Re-Operationen NE *Gallbladder/Liver/Spleen*

Hernia repair

Four RCTs (369 patients; IG: 189 vs CG: 177[8]) [53-55, 57, 58] out of five investigated reoperations. There were more reoperations reported in the control groups in comparison to the intervention groups in three RCTs [53, 55, 57], whilst one of them reported a statistically significant difference in favour of the intervention group (0 (0%) vs 5 (9%); **p=0.020** [55]; 30 days follow-up: 0 (0%) vs 1 (3%), 12 months follow-up: 3 (7.7%[12]) vs 4 (11.1%[12]) [53, 58]; 0 (0%) vs 1 (2%) [57]). One RCT [54] reported that there were no re-operations necessary in either group.

Hernienreparatur: Re-Operationen
1 RCT →
ss Unterschied: p=0,020
3 RCTs →
kein ss Unterschied

Liver resection (hepatectomy): Reoperations or additional surgeries were not assessed in the identified study [60].

Hepatektomie: Re-Operationen NE

4.4.5. Conversion

Thoracic surgery

Lung lobectomy

Four RCTs (677 patients; IG: 338 vs CG: 339) [32, 37-40] did not detect statistically significant differences between study groups in conversion. However, conversion to open surgery was more frequently needed in the robot-assisted groups as reported in two RCTs (3 (9%) vs 1 (3%) [38]; (1 (1.3%) vs 0 (0%) [32]). In addition, two RCTs assessed that more procedures had to be converted to open surgery in the control groups (7 (4.5%) vs 9 (5.5%) [37]; 0 (0%) vs 2 (5:1%[13]) [39]).

Lungenlobektomie: Konversionen
kein ss Unterschied
(4 RCTs)

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery): Conversions were not assessed in the identified RCT [41].

Fundoplikatio: Konversionen NE

Oesophagectomy

One RCT (362 patients; IG: 183 vs CG: 179) [42] out of two reported conversions without statistically significant differences 7 (3.9%) vs 6 (3.4%).

Ösophagektomie: Konversionen →
kein ss Unterschied
(1 RCT)

[12] Self-calculated, based on analysed patients

[13] Self-calculated, based on analysed patients

Stomach

Gastrectomy

Gastrektomie: Konversionen

1 RCT → kein ss Unterschied
1 RCT → keine KG Ergebnisse & ss angegeben

Conversions to other surgical techniques were reported in two (306 patients; IG: 152 vs CG: 154) [45, 46] out of three RCTs. In one RCT [45] the difference in overall conversion was not statistically significant between the intervention and the control group (4 (3.4%) vs 2 (1.7%)). In the other RCT [46] two cases (6.7%) were reported where an abdominal incision was needed instead of RAS. Information concerning the control group as well as the statistical significance was not mentioned in the study.

Bowel

Colectomy

Kolektomie: Konversionen
1 RCT → keine Konversionen notwendig
1 RCT→ 1 Konversion je Gruppe

In two RCTs (198 patients; IG: 78 vs CG: 120) [47, 48] conversion from RAS to laparotomy was reported, whereby no events occurred in one of the identified RCTs [47]. In the other RCT [48] in two cases the planned procedure was converted to laparotomy in both, the intervention and the control group. There was no information given on the statistical significance [48].

Rectal resection

Rektumresektion: Konversionen häufiger notwendig in der KG → Unterschied ss (2 RCTs: p=0,030 & p=0,021)

Two RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] yielded statistically significant differences concerning conversion to open surgery. Both studies declared that the laparoscopic procedure needed to convert to open surgery statistically significantly more often than patients from the robotic-assisted group (0 (0%) vs 5 (2.9%); **p=0.030** [49]; 10 (1.7%) vs 23 (3.9%); *mean difference (95% CI):* –2.2 (–4.3 to –0.4); **p=0.021** [50].

ventrale Netzrektopexie: Konversionen NE

Ventral mesh rectopexy: The identified studies did not assess conversions [51, 52].

Gallbladder/Liver/Spleen

Hernia repair

Hernienreparatur: Konversionen keine ss Unterschied (4 RCTs)

No statistically significant differences concerning conversion events were detected in four RCTs (347 patients; IG: 172 vs CG: 172[8]) [53-59] out of five. Two RCTs [53, 56] reported, that one patient had to be converted to the laparoscopic procedure, without stating any statistically significant differences. In addition, one RCT [54] reported that no conversions were registered, and another study [57] yielded similar numbers of patients that needed conversions to open surgery (1 (2%) vs 1 (2%); relative rate (95% CI): 0.76 (0.05 to 11.47)).

Hepatektomie: Konervsionen NE

Liver resection (hepatectomy): The identified study [60] did not report on conversions.

4.5. Perioperative events and resource use

4.5.1. Blood loss (millilitres)

Thoracic surgery

Lung lobectomy

Blood loss was measured in two (520 patients; IG:260; CG:260) [32, 37] out of four RCTs. Both RCTs detected statistically significantly fewer cases of blood loss in the robot-assisted group compared to the control group (*median (IQR):* 100 (50–100) vs 100 (50–150); **p=0.04** [37]; <100ml: 65 (85.5%) vs 16 (22.2%); **p<0.001**, ≥100ml: 11 (14.5%) vs 56 (77.8%); **p<0.001** [32]).

Lungenlobektomie:
ss weniger Blutverlust in den IG (2 RCTs)

Visceral surgery

Oesophagus

Fundoplication (antireflux surgery): Blood loss was not assessed in the identified study [41].

Fundoplikatio:
Blutverlust NE

Oesophagectomy

One (362 patients; IG: 183 vs CG: 179) [42] out of two RCTs reported no statistically significant difference between study groups concerning blood loss.

Ösophagektomie:
Blutverlust kein ss Unterschied
(1 RCT)

Stomach

Gastrectomy

All three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] reported events of blood loss, which occurred statistically significantly less in the intervention group of two studies [44, 46]. One RCT [44] assessed intraoperative blood loss (41.2 ± 45.7 vs 55.7 ± 70.5; **p=0.045**), whilst the other study [46] presented blood loss in general (123.7 ± 89.3 vs 276.3 ± 152.1; **p<0.001**). The third study [45] did not report any statistically significant differences between both groups (*median (range)*: 25 (5-475) vs 25 (5-1,405)).

Gastrektomie:
ss weniger Blutverlust in IG (2 RCTs: p=0,045 & p<0,001)

1 RCT
kein ss Unterschied

Bowel

Colectomy

Blood loss was assessed in one (71 patients; IG: 35 vs CG: 36) [47] out of two RCTs without statistically significant differences between the robotic-assisted and the laparoscopic-assisted group.

Kolektomie:
Blutverlust
kein ss Unterschied
(1 RCT)

Rectal resection

RAS was associated with statistically significantly minor blood loss compared with the laparoscopic procedure in both included RCTs (1,587 patients; IG: 794 vs CG: 793; *median (IQR) mean difference (95% CI):* 100 (90−110) vs 130 (100−150); **p<0.001** [49]; *median (IQR); mean difference (95% CI):* 40.0 (30.0 - 100.0) vs 50.0 (40.0 -100.0); −10·0 (−20.0 to −10.0); **p<0.0001** [50]).

Rektumresektion:
ss weniger Blutverlust in IG (2 RCTs: p<0,001 & p<0,0001)

ventrale Netzrektopexie: Blutverlust NE

Ventral mesh rectopexy: The included studies did not report on blood loss [51, 52].

Gallbladder/Liver/Spleen

Hernienreparatur: Blutverlust NE

Hernia repair: The identified studies did not assess blood loss [53-59].

Liver resection (hepatectomy)

Hepatektomie: mehr Blutverlust in der KG → Unterschied ss (1 RCT: p<0.001)

The laparoscopic hepatectomy was associated with statistically significantly major blood loss than the robotic-assisted alternative (203.11 ± 10.98 vs 356.00 ± 32.00; **p<0.001**) in the included study (122 patients; IG: 61 vs CG: 61) [60].

4.5.2. Operation time (minutes)

Thoracic surgery

Lung lobectomy

Lungenlobektomie: widersprüchliche Ergebnisse bezgl. der OP-Dauer jedoch kein ss Unterschied (4 RCTs)

Operation time was measured in four RCTs (679 patients; IG: 338 vs CG: 339) [32, 37-40]. Operation time took longer in the robot-assisted group in two RCTs (104.2 ± 41.0 vs 102.3 ± 29.2 [32]; *median (95% CI)*: 241.7 (218.3-265.1) vs 214.4 (200.3-228.5) [39], whilst in the remaining two RCTs the conventional procedure took more time (*median (IQR):* 110 (95–140) vs 120 (97.5–150.0) [37]; 179 ± 54.2 vs 183 ± 40.9 [38]). None of the studies showed a statistically significant difference between study groups concerning the outcome operation time.

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Fundoplikatio: ss Unterschied OP-Dauer IG: 88 vs 102 (p=0,033)

One RCT (40 patients; IG: 20 vs CG: 20) [41] reported a statistically significantly longer operation time in the control group in comparison to the intervention group (88 ± 18 vs 102 ± 19, **p=0.033**).

Oesophagectomy

Ösophagektomie: ss Unterschied OP-Dauer, IG: 203.8 vs KG: 244.9 (p<0.001)

In one (362 patients; IG: 183 vs CG: 179) [42] out of two RCTs, surgeons operated statistically significantly shorter in the intervention group than in the control group (203.8 ± 59.4 vs 244.9 ± 61.0; **p<0.001).**

Stomach

Gastrectomy

All three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] measured operation time. Whilst one RCT [44] reported marginal differences between study groups, the other two RCTs showed a statistically significantly longer operation time in the intervention group compared to the control group (*median (range):* 297 (179-654) vs 245 (131-534); **p=0.001** [45]; *mean (SD):* 353.8 ± 96.4 vs 214.6 ± 41.6; **p<0.001** [46]).

Gastrektomie: 1 RCT kein Unterschied in OP-Dauer

2 RCTs ss längere OP-Dauer in IG (p=0,001 & p<0,001)

Bowel

Colectomy

In both RCTs (198 patients; IG: 78 vs CG: 120) [47, 48] the RAS took statistically significantly more operation time than in the control group ((195 ± 41.0 vs 129.7 ± 43.2); **p<0.001** [47]; *median (range)*: 172 (107-353) vs 145 (69-380); **p=0.005** [48]).

Kolektomie: 2 RCTs ss längere OP-Dauer in IG (p<0,001 & p=0,005)

Rectal resection

Two RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] reported on operation time. Whilst one RCT failed to detect a statistically significant difference between the study groups (*median (IQR); mean difference (95% CI):* 173.0 (140.0 - 225.0) vs 170.0 (140.0 – 209.0); 2.0 (–4.0 - 10.0) [50]. The other RCT showed that the robotic-assisted procedure had taken statistically significantly longer than the conventional laparoscopic procedure (*median (IQR):* 205 (195−220) vs 195 (160−238); **p=0.004** [49]).

Rektumresektion:
1 RCT kein Unterschied in OP-Dauer

1 RCT ss längere OP-Dauer in IG (p=0,004)

Ventral mesh rectopexy

One follow-up (30 patients; IG: 16 vs CG: 14) [52] out of two detected no statistically significant difference in operation time between the study groups (125 vs 130, p-value not reported).

ventrale Netzrektopexie:
kein ss Unterschied in OP-Dauer
(1 FU Publikation)

Gallbladder/Liver/Spleen

Hernia repair

Four (347 patients; IG: 172 vs CG: 172[8]) [54-57] out of five RCTs detected a longer time of surgery in the robotic-assisted study arm compared to the control arm. One RCT [53] reported a median of 146 (IQR: 123-192) vs 94 (IQR: 69-116) minutes (**p<0.001)**. In another RCT the robot-assisted procedure took longer [54] (355.6 ± 89 vs 293.5 ± 89; **p=0.04**). Another RCT [56] assessed time from skin incision to closure (*median (IQR):* 75.5 (59.0-93.8) vs 40.5 (29.2-63.8) minutes; **p<0.001**), time for dissection of the hernia (18.0 (12.0-27.0) vs 13.0 (7.0-23.0); **p=0.012**), time for mesh fixation (6.88 (5.00-9.00) vs 1.00 (NR); **p<0.001**) and time for peritoneal closure (7.00(5.00-9.00) vs 2.00 (1.00-3.00) minutes; **p<0.001**). The fourth RCT [57] reported similar numbers as [53] (141 ± 56 vs 77 ± 37; *relative rate (95 % CI):* 62.89 (45.75 to 80.01); **p<0.001**).

Hernienreparatur:
4 RCTs ss längere OP-Dauer in IG vs KG:

146 vs 94 (p<0,001)

355,6 vs 293,5 (p=0,04)

75.5 vs 40.5 (p<0,001)

141 vs 77 (p<0,001)

Liver resection (hepatectomy)

Hepatektomie: ss längere OP-Dauer in KG → IG: 156,34 vs 184,18 (p<0,001)

The laparoscopic surgery took statistically significantly longer than the robotic-assisted laparoscopy (156.34 ± 15.97 vs 184.18 ± 18.03; **p<0.001**), as reported in the single identified RCT (122 patients; IG: 61 vs CG: 61) [60].

4.5.3. Transfusions

Thoracic surgery

Lung lobectomy

Lungenlobektomie: kein ss Unterschied bei Bluttransfusionen (1 RCT)

In one (363 patients; IG: 181 vs CG: 182) [37] out of four RCTs, three (1.9%) intraoperative blood transfusions were necessary for the robotic-assisted group in comparison to the control group, in which two (1.2%) transfusions were used. The difference was not statistically significant.

Visceral surgery

Oesophagus

Fundoplikatio & Ösophagektomie: Bluttransfusionen NE

Fundoplication (anti-reflux surgery): No events of transfusions were reported [41].

Oesophagectomy: No events of transfusions were reported [42, 43].

Stomach

Gastrectomy

Gastrektomie: Bluttransfusionen → kein ss Unterschied (2 RCTs)

In two (541 patients; IG: 269 vs CG: 272) [44, 45] out of three RCTs no statistically significant differences between both groups about either postoperative transfusions (8 (5.7) vs 16 (11.3)) [44] or intraoperative transfusions (1 (0.9) vs 3 (2.6)) [45] were reported.

Bowel

Kolektomie: Bluttransfusionen NE

Colectomy: No information was given on transfusions in the identified studies [47, 48].

Rectal resection

Rektumresektion: Bluttransfusionen → kein ss Unterschied (2 RCTs)

Two RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] did not detect statistically significant differences between study groups concerning transfusions. One study [49] showed transfusions in one patient in the control group (0 (0) vs 1 (0.6)), and the other study [50] reported a total of nine transfusions (2 (0.3) vs 7 (1.2); *mean difference (95% CI):*-0.9 (-2.2 to 0.2)).

ventrale Netzrektopexie: Bluttransfusionen NE

Ventral mesh rectopexy: The identified studies did not assess the outcome of transfusions [51, 52].

Gallbladder/Liver/Spleen

Hernia repair: The identified studies did not assess transfusions [53-59].

Hernienreparatur: Bluttransfusionen NE

Liver resection (hepatectomy)

The included RCT (122 patients; IG: 61 vs CG: 61) [60] yielded a statistically significant difference between study groups in favour of the RAS group compared to the control group (608.31 ± 117.08 vs 656.21 ± 103.75; **p=0.018**).

Hepatektomie: mehr Bluttransfusionen in KG → Unterschied ss: p=0,018

4.5.4. Drain duration (days)

Thoracic surgery

Lung lobectomy

Three (600 patients; IG: 300 vs CG: 300) [32, 37, 39] out of four RCTs reported drain duration or total drainage volume. Whilst one RCT [39] assessed similar results in both groups (*median (IQR)*: 2 (1-2) vs 2 (1-4), not statistically significant), one RCT [32] reported a statistically significantly longer drain duration in the control group (*median (IQR)*: 4.0 (3.3–5.0) vs 5.0 (4.0–7.0); **p=0.002**). There were differences in drainage volume (855.0 (602.5–1,167.5) vs 920.0 (592.5–1,646.3) [32]) without statistical significance. In addition, another RCT [37] reported statistically significantly more drainage volume in the intervention arm compared to the control arm (*median (IQR)*: 830 (550–1,130) vs 685 (367.5–1,160) **p=0.007**).

Lungenlobektomie: Drainage Dauer (DD) → widersprüchliche Ergebnisse in 3 RCTs:

1 RCT kein ss Unterschied;
1 RCT längere DD in KG (p=0,002);
1 RCT längere DD in IG (p=0,007)

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Drain duration was not assessed in the identified study [41].

Fundopliaktio: DD NE

Oesophagectomy

One (362 patients; IG: 183 vs CG: 179) [42] out of two RCTs assessed that a thoracic drainage tube had generally been removed on postoperative day three or four; however, no statistically significant group difference was mentioned.

Ösophagektomie: DD kein ss Unterschied (1 RCT)

Stomach

Gastrectomy

Three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] reported on the study outcome drain duration. In one study [46] drainage was required once in the intervention group, as well as one time in the control group. One study [45] stated that a single abdominal drain had been inserted after reconstruction in both groups. The third study [44] removed the drainage after 6.5 ±1.8 days in the intervention group compared to 7.0 ±2.5 days in the control group, the difference was not statistically significant.

Gastrektomie: kein ss Unterschied in DD (3 RCTs)

Bowel

Colectomy

Kolektomie: kein ss Unterschied in DD (2 RCTs)

Two RCTs (198 patients; IG: 78 vs CG: 120) [47, 48] gave information on drainages. One RCT [47] mentioned that ileus had required nasogastric drainage before discharge, which had occurred in each group in one (2.8%) case. The other RCT [48] assessed the number of patients requiring a drain, which did not show any statistically significant differences (2 (5%) vs 6 (7%)).

Rectal resection

Rektumresektion: kein ss Unterschied in DD (2 RCTs)

Both RCTs (1587 patients; IG: 794 vs CG: 793) [49, 50] reported on drainage tube placements. Whilst one study [50] stated that patients with grade II anastomotic leakage had a drainage tube placed during primary tumour surgery, the other study [49] mentioned that in some cases no drainage tube had been placed in the abdominal cavity (164 (94.3%) vs 158 (91.3%)) and every patient had one drainage tube placed in the pelvic cavity through the perineum (174 (100%) vs 173 (100%)). None of these differences were statistically significant.

ventrale Netzrektopexie: DD NE

Ventral mesh rectopexy: The identified studies did not report drain duration [51, 52].

Gallbladder/Liver/Spleen

Hernienreparatur & Hepatektomie: DD NE

Hernia repair: The identified studies did not assess drain duration [53-59].

Liver resection (hepatectomy): The identified RCT [60] did not assess drain duration.

4.5.5. Length of hospital stay (days)

Thoracic surgery

Lung lobectomy

Lungenlobektomie: kein ss Unterschied bei Dauer des Krankenhausaufenthaltes (DKH) in 4 RCTs

Four RCTs (677 patients; IG: 338 vs CG: 339) [32, 37-39] assessed the length of hospital stay. One RCT [32] reported a median of 10.0 *(IQR:* 8.0-13.0) vs 11 *(IQR:* 9.0-14.8*)* days. Another RCT [38] reported that patients stayed one day longer in the hospital in the intervention group (*median (IQR):* 5 (4-8) vs 4 (3-6), whilst two RCTs [37, 39] reported a longer hospital stay in the control group (*median (IQR):* 3 (2-4) vs 4 (2-5) [39]; 4 (4–5) vs 5 (4–5) [37]). None of the differences were statistically significant.

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

Fundoplikatio: DKH NE

One RCT (40 patients; IG: 20 vs CG: 20) [41] presented no statistically significant difference in the length of hospital stay.

Oesophagectomy

One RCT (362 patients; IG: 183 vs CG: 179) [42] out of two reported no statistically significant difference between study groups considering postoperative hospital stay (*median (range)*: 9 (6–49) vs 9 (6–82)).

Ösophagektomie: kein ss Unterschied in DKH (1 RCT)

Stomach

Gastrectomy

Three RCTs (606 patients; IG: 302 vs CG: 304) [44-46] assessed the length of hospital stay without statistically significant differences between the study groups (7.9 ± 3.4 vs 8.2 ± 2.5 [44]; *median (range):* 12 (7-43) vs 13 (6-45) [45]; 9.1 ± 5.5 vs 8.9 ± 5.6) [46].

Gastrektomie: kein ss Unterschied in DKH (3 RCTs)

Bowel

Colectomy

The length of hospital stay was investigated in both included RCTs (198 patients; IG: 78 vs CG: 120) [47, 48], which yielded no statistically significant differences between the groups (7.9 ± 4.1 vs 8.3 ± 4.2 [47]; *median (range)*: 3 (2–43) vs 4 (2–15); p=0.05 [48]).

Kolektomie: kein ss Unterschied in DKH (2 RCTs)

Rectal resection

Two RCTs (1,587 patients; IG: 794 vs CG: 793) [49, 50] yielded a statistically significant shorter hospital stay in patients who underwent the RAS (*median (IQR):* 5.0 (5.0−6.0) vs 7.0 (6.0−9.0); **p<0.001** [49]; 7.0 (7.0-11.0) vs 8.0 (7.0-12.0); –1.0 (–1.0 to 0.0); **p=0.0001** [50]).

Rektumresektion: ss kürzere DKH in der IG (2 RCTs: p<0,001 & p=0,0001)

Ventral mesh rectopexy

One follow-up (30 patients; IG:16 vs CG: 14) [52] out of two reported a length of hospital stay of 2.2 vs 2.5 days (no information about the statistical value (median or mean)), without a statistically significant group difference.

ventrale Netzrektopexie: DKH kein ss Unterschied (1 FU Publikation)

Gallbladder/Liver/Spleen

Hernia repair

Four (347 patients; IG: 172 vs CG: 172[8]) [53, 54, 56-59] out of five RCTs were not able to detect statistically significant differences in the length of hospital stay. Two RCTs [54, 56] reported similar results in both groups in days (3.67 ± 1.78 vs 3.95 ± 2.66 [54]) and hours (*median (IQR):* 5.75 (5.00- 7.00) vs 5.11 (4.00- 7.00) [56]) of hospital stay. In another RCT [53] patients of the intervention group had to stay 15 days longer in the hospital compared to control group patients (*median (IQR)*: 25 (10- 30) vs 10 (8- 31). The remaining RCT [57] reported the length of hospital stay at 90 days after surgery, most patients stayed in the hospital for one day (9 (14%) vs 4 (7%)) instead of more than three days (2 (3%) vs 4 (7%)).

Hernienreparatur: keine ss Unterschiede in DKH (4 RCTs)

Liver resection (hepatectomy): In the included study [60] the length of hospital was not assessed.

Hepatektomie: DKH NE

5 Certainty of evidence

The RoB was assessed by the Cochrane Collaboration tool version 1 [34, 35]. Thirteen of 20 RCTs were graded with a high RoB, six RCTs with some concerns and two with a low RoB.

RoB → Cochrane Collaboration Tool

The main reasons for a higher RoB included the lack of blinding of patients, selective outcome reporting, a lack of information about power calculations and surgeon experience, as well as inadequate allocation concealment (see Appendix Table A - 1 & Table A - 2).

keine Verblindung, selektives Reporting, keine Infos zu Powerkalkulationen

The overall strength of evidence for RAS was rated for each endpoint individually according to the GRADE scheme. Each critical outcome was rated by two researchers (LG, MR). A more detailed list of criteria applied can be found in the recommendations of the GRADE Working Group.

Qualität der Evidenz für jeden kritischen Studienendpunkt

GRADE uses four categories to rank the strength of evidence:

Qualität der Evidenz nach GRADE

- **High** = We are very confident that the true effect lies close to that of the estimate of the effect;
- **Moderate** = We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- **Low** = Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- **Very low** = Evidence either is unavailable or does not permit a conclusion.

The ranking according to the GRADE scheme for the research question can be found in the summary of findings table below (Table 5 - 1) and the evidence profiles in Appendix Table A - 3 - Table A - 10.

GRADE Tabelle nächste Seite & Anhang

Separate GRADE assessments were performed in all instances where different comparators (open surgery or laparoscopic surgery) were done in the studies. According to the GRADE scheme, only the outcomes defined as crucial to derive a recommendation were considered for the overall strength of evidence. In addition, the overall strength of evidence is generally based on a high level of evidence and downgraded if necessary. Therefore, the overall strength of evidence for the clinical effectiveness and safety of RAS in comparison to open surgery and laparoscopic surgery is low.

separate Bewertung bei unterschiedlichen Komparatoren

insgesamt sehr niedrige Evidenzstärke für Wirksamkeits- & Sicherheitsendpunkte

Table 5 - 1: Summary of Findings of robot-assisted surgery in thoracic and visceral indications

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
Effectiveness- Patient-relevant outcomes					
Survival	Lung	Video-assisted lobectomy/ video-assisted thoracic surgery	1 RCT: **Deaths 48-wks postoperatively:** IG: 7; CG: 14 (2023) 1 RCT: **Mortality within 90 days after surgery:** IG: 1 (2.7); CG: 1 (2.5); p=NS	2 RCTs [37, 39] 221 vs 222)	Very low ⊕◯◯◯
		Open-surgery	1 RCT: *IG vs CG; %; p-value* **Disease-free survival:** 1 yr: 90.4 vs 86.0; NS 2 yrs: 76.4 vs 74.2; NS	1 RCT [32] (137 vs 133)	Low ⊕⊕◯◯
	Oesophagus	Conventional laparoscopic fundoplication/ conventional minimally invasive oesophagectomy	1 RCT: *IG vs CG; n (%);* p=NS **In-hospital mortality:** 0 (0) vs 0 (0) 30-d mortality: 0 (0) vs 1 (0.6) 90-d mortality: 1 (0.6) vs 1 (0.6)	1 RCT [42] (183 vs 179)	Low ⊕⊕◯◯
		Open-surgery	1 RCT: *IG vs CG; median in months (range); rate (95% CI); p=NS* **Overall survival:** 35 (1–60); 41% (95% CI 27–55) vs 41 (2–60); 40% (95% CI 26–53) **Disease-free survival:** 28 (0–56); 42% (95% CI 28–55) vs 37 months (3–56); 43% (95% CI 29–57)	1 RCT [43] (56 vs 56)	Low ⊕⊕◯◯
	Stomach	Laparoscopic (distal) gastrectomy	1 RCT: *IG vs CG; n (%); p-value* **In-hospital mortality within 30 days postoperative:** 0 (0) vs 0 (0); NA 1 RCT: *IG vs CG; n (%); p-value* (per-protocol analysis) **Mortality:** IG: 0; CG: 0; p=NS	2 RCTs [44, 45] (269 vs 272)	Low ⊕⊕◯◯
		Open-surgery	1 RCT: **Mortality14:** IG: 0; CG: 0; p=NR	1 RCT [46] (33 vs 32)	Moderate ⊕⊕⊕◯
	Bowel	Laparoscopic surgery/ laparoscopic ventral mesh rectopexy	1 RCT: *IG vs CG; mean (%) (95% CI); p-value* **Disease-free survival:** 3 yrs after surgery: 88.1 (77.1–99.1) vs 91.1 (81.4–99.9); NS 5 yrs after surgery: 77.4 (60.6–92.1) vs 83.6 (72.1–97.0); NS	2 RCTs [47, 49] (209 vs 209)	Moderate ⊕⊕⊕◯

[14] Death until 90 days after the procedure or during postoperative hospital stay

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
			Overall survival: 3 yrs after surgery: 96.8 (90.6–99.9) vs 94.0 (86.0-99.9); NS 5 yrs after surgery: 91.1 (78.8–99.9) vs 91.0 (81.3–99.9); NS 1 RCT: **Disease-free survival** (3-yrs rate of stage I–III pts): 85.3% vs 84.6% (log-rank NS; HR=0.918; 95% CI = 0.555–1.517); NS **Overall survival** (3-yrs rate of all pts): 91.1% vs 90.4% (log-rank NS; HR=0.912; 95% CI = 0.490–1.697); NS		
	Gallbladder/Liver/Spleen	Laparoscopic ventral/incisional hernia repair/ laparoscopic transabdominal preperitoneal repair/ laparoscopic repair/ laparoscopic hepatectomy	1 RCT: *IG vs CG; n (%); p-value* **Mortality** (short-term, within 7 days): 0 vs 1 (5); NS 1 RCT: *IG vs CG; n (%); p-value* **At 1-yr follow-up:** 52 (85.25) vs 48 (78.69); NS **At 2-yrs follow-up:** 43 (70.49) vs 40 (65.57); NS **At 3-yrs follow-up:** 31 (50.82) vs 26 (42.62); NS	2 RCTs [54, 60] (81 vs 81)	Very Low ⊕◯◯◯
Recurrence	Lung	Video-assisted lobectomy/ video-assisted thoracic surgery	1 RCT: **Recurrence 48-wks postoperatively:** IG: 6; CG:5 (2023)	1 RCT [37] (181 vs 182)	Low ⊕⊕◯◯
		Open-surgery	NR		
	Oesophagus	Conventional laparoscopic fundoplication/ conventional minimally invasive oesophagectomy	1 RCT: *IG vs CG; n (%); p=NR* **Failure of treatment:** Oesophagitis ≥ LA-B: 1 (8) vs 1 (8) GSRS reflux score ≥ 3: 3 (25) vs 2 (17) Daily PPI for reflux: 4 (31) vs 4 (33) Dysphagia combined with reflux score ≥ 2: 1 (8) vs 1 (8)	1 RCT [41] (20 vs 20)	Low ⊕⊕◯◯
		Open-surgery	1 RCT: *IG vs CG; n (%); p=NS* **Overall recurrence disease:** 28 (56) vs 29 (54)	1 RCT [43] (56 vs 56)	Moderate ⊕⊕⊕◯
	Stomach	Laparoscopic (distal) gastrectomy	NR		
		Open-surgery	NR		
	Bowel	Laparoscopic surgery/ laparoscopic ventral mesh rectopexy	1 RCT: No port site recurrence was noted with a median follow-up of 49 months	3 RCTs [47, 49, 52] (225 vs 223)	Very low ⊕◯◯◯

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
			1 RCT: **Recurrence at 3 yrs after surgery** (IG (n=173) vs CG (n=173); difference (95% CI); p-value): **Locoregional recurrence:** 5 (2.9) vs 9 (5.2); -2.3 (-7.0 to 2.1); NS **Distant metastases:** 21 (12.1) vs 23 (13.3); -1.2 (-8.3 to 6.0); NS 1 RCT: At 24-month follow-up (2019): IG: 0 vs CG: 1 (8%); p=NR		
	Gallbladder/Liver/Spleen	Laparoscopic ventral/incisional hernia repair/ laparoscopic transabdominal preperitoneal repair/ laparoscopic repair/ laparoscopic hepatectomy	1 RCT: Hernia recurrence: 4 (7%) vs 5 (9%); NS; relative risk (95% CI): 0.68 (0.17 to 2.68) 1 RCT: *IG vs CG; data captured; n/N (%); p-value* 12-months postoperative: **Hernia recurrence at 1 y:** 13/38 (34) vs 6/33 (18); 71/75 (95); NS **Clinical recurrence at 1 y:** 5/20 (25) vs 0/17 (NR); 37/75 (49); **p=0.03** **Composite recurrence at 1 y**: 9/38 (24) vs 2/33 (6); 71/75 (95); **p=0.04** (2022) 1 RCT: IG: 2 (11.1); CG: 3 (15.75) (in 24-month-follow-up) 1 RCT: *IG vs CG; n;* p=NS NR (2020) Inguinal hernia recurrence: 2 yrs after surgery: 1 vs 1 (2023) 1 RCT: IG: 0 (0%); CG: 0 (0%); p=NS	5 RCTs [54-59] (237 vs 231)	Very Low ⊕◯◯◯
Quality of Life	Lung	Video-assisted lobectomy/ video-assisted thoracic surgery	1 RCT: **QoL:** *Mean difference (95% CI)* 4 wks 0.002 (–0.008~0.012) 24 wks 0.003 (–0.004~0.010) 48 wks 0.004 (–0.002~0.011)	1 RCT [37, 40] (181 vs 182)	Moderate ⊕⊕⊕◯
		Open-surgery	NR		
	Oesophagus	Conventional laparoscopic fundoplication/ conventional minimally invasive oesophagectomy	1 RCT: *IG vs CG; mean ± SD (range);* p=NS **Quality of life in reflux and dyspepsia:** Emotional distress: 6.4 ± 1.4 (1.2–7.0) vs 6.5 ± 1.6 (1.0–7.0) Food/drink problems: 6.5 ± 0.9 (3.5–7.0) vs 6.3 ± 1.6 (1.0–7.0) Physical/social functioning: 6.6 ± 1.0 (2.8–7.0) vs 6.4 ± 1.6 (1.0–7.0) Sleep disturbance: 6.4 ± 1.3 (2.2–7.0) vs 6.5 ± 1.5 (1.0–7.0) Vitality: 6.3 ± 1.4 (1.3–7.0) vs 6.3 ± 1.6 (1.0–7.0)	1 RCT [41] (20 vs 20)	Low ⊕⊕◯◯

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
		Open-surgery	NR		
	Stomach	Laparoscopic (distal) gastrectomy	NR		
		Open-surgery	NR		
	Bowel	Laparoscopic surgery/ laparoscopic ventral mesh rectopexy	1 RCT: *IG vs CG; n; mean (SD); difference between means (95% CI); p-value* **QoL measurements 5 yrs postoperative (2020):** **CRAIQ-7:** 14; 24.3 (32.0) vs 10; 43.8 (27.1); -20.4 (-43.2 to 2.5); NS **POPIQ-7:** 13; 9.5 (26.4) vs 10; 26.0 (27.9); -16.1 (-39.7 to 7.5); NS **UIQ-7:** 14; 25.7 (32.7) vs 10; 33.0 (31.4); -9.4 (-32.3 to 13.6); NS **PFIQ-7:** 14; 58.8 (82.1) vs 10; 102.7 (69.9); -47.8 (-103.7 to 8.0); NS	1 RCT [52] (16 vs 14)	Low ⊕⊕◯◯
	Gallbladder/Liver/Spleen	Laparoscopic ventral/incisional hernia repair/ laparoscopic transabdominal preperitoneal repair/ laparoscopic repair/ laparoscopic hepatectomy	1 RCT: *n (95%CI); p-value* **Measured by Hernia-specific quality of life Survey** 1-y postoperative: IG: 92 (82-100); CG: 77 (49-93); **p=0.04** (2022) 1 RCT: *IG vs CG; mean (SD); p-value* Evaluated with the EORTC QLQ-C30 **2-yrs after surgery:** Global health: 72.07 (22.67) vs 67.69 (26.32); NS Functional: 77.27 (19.85) vs 67.19 (21.40); NS Symptoms: 22.13 (14.72) vs 30 (19.15); NS 1 RCT: *IG vs CG; mean (SD); p-value* Measured with the SF-36 **30 days after surgery:** Physical component summary: -1.98 (8.90) vs -0.59 (8.91); NS Mental component summary: 0.71 (5.84) vs 0.65 (8.29); NS General Health: 1.55 (8.43) vs -2.31 (12.4); NS 1 RCT: *IG vs CG; mean (SD); p-value* **2-yrs after surgery:** Physical component summary: 53.1 (8.1) vs 54.2 (6.1); NS Mental component summary: 53.9 (6.8) vs 53.4 (5.6); NS	4 RCTs [53, 54, 56-59] (172 vs 172)	Very Low ⊕◯◯◯
Safety- Safety-related outcomes					
Intraoperative Complications	Lung	Video-assisted lobectomy/ video-assisted thoracic surgery	1 RCT: IG: 0; CG: 3; p=NS (2 arterial lacerations and 1 venous injury)	1 RCT [39] (40 vs 40)	Low ⊕⊕◯◯
		Open-surgery	NR		

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
	Oesophagus	Conventional laparoscopic fundoplication/ conventional minimally invasive oesophagectomy	1 RCT: Conversion to open surgery: **IG:** 7 (3.9%) vs **CG:** 6 (3.4%)	1 RCT [42] (183 vs 179)	Moderate ⊕⊕⊕◯
		Open-surgery	NR		
	Stomach	Laparoscopic (distal) gastrectomy	NR		
		Open-surgery	1 RCT: IG: 0; CG: NR; p=NR	1 RCT [46] (33 vs 32)	Moderate ⊕⊕⊕◯
	Bowel	Laparoscopic surgery/ laparoscopic ventral mesh rectopexy	1 RCT: *IG vs CG; n (%); p-value* 3 (7) vs 4 (5); NS 1 RCT: *IG vs CG; n (%); p-value* **Pts with any intraoperative complications:** 10 (5.7) vs 16 (9.2); NS 1 RCT: *IG vs CG; n (%); difference (95% CI); p-value* **Intraoperative complications**: 32 (5.5%) vs 51 (8.7%); –3·3 (–6·3 to –0·3); **p=0.030** **Significant bleeding:** 16 (2.7%) vs 26 (4.4%); –1·7 (–4·0 to 0·4); NS	3 RCTs [48-50] (837 vs 877)	Very low ⊕◯◯◯
	Gallbladder/Liver/Spleen	Laparoscopic ventral/incisional hernia repair/ laparoscopic transabdominal preperitoneal repair/ laparoscopic repair/ laparoscopic hepatectomy	1 RCT: *IG vs CG; n (%); p-value* **Intraoperative complications (2021):** 2 (6) vs 2 (6); NR Bowel serosal injury: 1 (3) vs 2 (6); NS Liver injury: 1 (3) vs 0; NS	1 RCT [53] (39 vs 39)	Moderate ⊕⊕⊕◯
Postoperative Complications	Lung	Video-assisted lobectomy/ video-assisted thoracic surgery	1 RCT: *IG vs CG; n (%); p-value* **Postoperative complications:** 23 (14.6) vs 30 (18.4); NS **Clavien Dindo I-II:** 18 (11.5) vs 24 (14.7); NS **Clavien Dindo III-IV:** 5 (3.2) vs 6 (3.7); NS **Readmission:** 3 (1.9) vs 3 (1.8); NS 1 RCT: *IG vs CG; n (%); p-value* **Early postoperative complications15:** 13 (37) vs 9 (24); NS **Readmissions:** 4 (16) vs 0 (0); NS **Later Complication:** 5(23) vs 2 (11); NS 1 RCT: *IG vs CG; n (%); p-value*	3 RCTs [37-39] (259 vs 261)	Very low ⊕◯◯◯

[15] Discrepancies in postoperative complications between Table 1 in the publication and Table S1 in the Supplements could be observed. Data extracted from Supplements.

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
			Complications within 90 days: 7 (18.9) vs 14 (35.9); NS **≥ 3 complications within 90 days:** 7 (18.9) vs 10 (25.6); NS **Readmissions within 90 days:** 1 (2.7) vs 8 (20.5); **p=0.029**		
		Open-surgery	1 RCT: *IG vs CG; n (%); p-value* Prolonged air leak: 6 (7.9) vs 6 (8.3); NS Bronchopleural fistula: 4 (5.3) vs 1 (1.4); NS Pneumonia: 3 (3.9) vs 6 (8.3); NS Hyperpyrexia: 2 (2.6) vs 6 (8.3); NS Haemorrhage: 2 (2.6) vs 1 (1.4); NS Recurrent laryngeal nerve injury: 1 (1.3) vs 4 (5.6); NS Pulmonary embolism: 1 (1.3) vs 0; NS	1 RCT [32] (137 vs 133)	Low ⊕⊕◯◯
	Oesophagus	Conventional laparoscopic fundoplication/ conventional minimally invasive oesophagectomy	1 RCT: *IG vs CG; n (%);* p=NS **Total complications:** 88 (48.6) vs 74 (41.8) C-D classification ≥ III: 22 (12.2) vs 18 (10.2) **Pulmonary complications:** 25 (13.8) vs 26 (14.7) **Severe cardiac complications:** 2 (1.1) vs 1 (0.6) **Anastomotic leakage:** 22 (12.2) vs 20 (11.3) **Vocal cord paralysis:** 59 (32.6) vs 48 (27.1)	1 RCT [42] (183 vs 179)	Moderate ⊕⊕⊕◯
		Open-surgery	NR		
	Stomach	Laparoscopic (distal) gastrectomy	1 RCT: *IG vs CG; n (%); p-value* **Overall morbidity:** 13 (9.2) vs 25 (17.6); **p=0.039** **Surgical morbidity:** 5 (3.5) vs 9 (6.3); NS **Medical morbidity:** 9 (6.4) vs 20 (14.1); **p=0.033** **Clavien-Dindo classification:** I: 0 (0.0) vs 0 (0.0); NS; II: 11 (7.8) vs 22 (15.5); NS; IIIa: 0 (0.0) vs 1 (0.7); NS; IIIb: 1 (0.7) vs 1 (0.7); NS; IV: 1 (0.7) vs 1 (0.7); NS; V: 0 (0.0) vs 0 (0.0); NS 1 RCT: *IG vs CG; n (%); p-value* (per-protocol analysis) **Overall complications, ≥grade IIb:** 10 (8.8) vs 23 (19.7); **p=0.02** **Overall complications, ≥grade IIIa:** 6 (5.3) vs 19 (16.2); **p=0.01** **Surgical complications:** Anastomotic leakage, ≥grade II: 4 (3.5) vs 5 (4.3); NS Anastomotic leakage, ≥grade IIIa: 3 (2.7) vs 5 (4.3); NS Intra-abdominal abscess, ≥grade II: 3 (2.7) 3 (2.6); NS	2 RCTs [44, 45] (269 vs 272)	Low ⊕⊕◯◯

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
			Intra-abdominal abscess, ≥grade IIIa: 2 (1.8) vs 3 (2.6); NS **Medical complications:** Pneumonia, ≥grade II: 1 (0.9) vs 5 (4.3); NS		
		Open-surgery	1 RCT: *IG vs CG; n (%); p-value* **Postoperative complications (0- 30 days postoperative):** Minor: 4 (13.8) vs 6 (19.4); NS Major: 4 (13.8) vs 3 (3.2); NS **Late complications (>30 days postoperative):** 1 (3.4) vs 6 (19.4); NS **Readmission** (<90 days): IG: 1 (3.4); CG: 4 (12.9); NS	1 RCT [46] (33 vs 32)	Moderate ⊕⊕⊕◯
	Bowel	Laparoscopic surgery/ laparoscopic ventral mesh rectopexy	1 RCT: *IG vs CG; n (%); p-value* **Postoperative surgical complication:** 7 (16) vs 10 (12); NS **Anastomotic leak:** 2 (5) vs 3 (4); NS **Medical complication:** 4 (9) vs 8 (10); NS **Clavien Dindo:** 0: 35 (81) vs 68 (81); NS; I: 3 (7) vs 3 (4); NS; II: 3 (7) vs 7 (8); NS; III: 2 (5) vs 4 (5); NS; IV: 0 (0) vs 2 (2); NS 1 RCT: *IG vs CG;n (%); p-value* **Wound infection:** 2 (5.6) vs 2 (5.6); NR **Anastomosis leakage:** 1 (2.8) vs 0 (0); NR **Intraabdominal abscess:** 0 (0) vs 1 (2.8); NR 1 RCT: *IG vs CG: n (%); unadjusted difference (95% CI); p-value (within 30 days after surgery)* **Total 30-day postoperative complication rate (Clavien–Dindo grade II or higher):** 23 1 RCT: *IG vs CG: n (%); difference (95% CI); p-value (within 30 days after surgery)* **Complications of Clavien–Dindo grade II or higher grade within 30 days after operation:** 95 (16.2) vs 135 (23.1); -6.9 (-11.4 to -2.3); p=0.003 **Readmissions within 30 days after operation:** 17 (2.9) vs 20 (3.4); –0.5 (–2.6 to 1.6); NS	4 RCTs [47-50, 57] (872 vs 913)	Very low ⊕◯◯◯
	Gallbladder/Liver/Spleen	Laparoscopic ventral/incisional hernia repair/ laparoscopic trans-	1 RCT: *IG vs CG; n (%); p-value; relative risk (95% CI)* **Wound complication:** 9 (15%) vs 8 (15%); NS; 0.93 (0.32 to 2.74) 1 RCT: *IG vs CG; n (%); p-value*	6 RCTs [53-60] (298 vs 292)	Very Low ⊕◯◯◯

Outcomes	Indication	Comparison	Impact	N studies (Pts IG vs CG)	Certainty of Evidence
		abdominal preperitoneal repair/ laparoscopic repair/ laparoscopic hepatectomy	**Postoperative complications (2021):** 2 (6) vs 3 (8); NS 1 RCT: *IG vs CG; n (%); p-value* Complications (short-term, within 7 days): 3 (16.7) vs 2 (10.5); NS 1 RCT: *IG vs CG; n (%); p-value* 30-days after surgery: **Adverse Events:** 8 (16.7) vs 5 (9.3); NS 1 RCT: *IG vs CG; n (%); relative rate (95% CI); p-value* **Readmission:** 1 (2) vs 3 (5); 0.27 (0.03 to 2.43); p=NS **Emergency room visits:** 7 (11) vs 5 (9); 1.28 (0.43 to 3.75); p=NS **Wound complication:** 13 (20) vs 11 (19); 1.02 (0.51 to 2.08); p=NS **Clavien-Dindo complication:** 14 (22) vs 11 (19); 1.10 (0.54 to 2.24); NS 1-2: 14 (22) vs 10 (17); NR; NR 3-5: 0 (0) vs 1 (2); NR; NR 1 RCT: *IG vs CG; n (%); p-value* **Total complications**: 2 (3.3) vs 8 (13.1); **p=0.048**		

Abbreviations: CG = control group, CI = confidence interval, IG = intervention group, n/N = number of patients, NR = not reported, NS = not significant, pts = patients, QoL = Quality of Life, RCT(s) = randomized controlled trial(s), SD = standard deviation, SF-36 = 36-Item Short Form Health Survey, vs = versus, yr = year, yrs = years.

6 Discussion

RAS is a minimally invasive surgical technique that is assisted by a telemanipulator. This remote manipulator allows the surgeon to perform the normal movements associated with surgery in a more precise manner compared to the laparoscopic approach, due to a higher degree of dexterity. Currently, there are 19 known manufacturers of robotic systems supporting surgical procedures, of which ten companies provide a total of 14 CE-marked products. These companies encompass Intuitive Surgical, Asensus, Avatera, CMR, Distal Motion, Medrobotics, Medtronic, and Freehand 2010 Ltd. The robotic procedure used in most of the clinical trials included in this report is the da Vinci® Surgical System.

Roboterchirurgie
minimalinvasive Chriurgie
derzeit 19 Hersteller → 14 Systeme mit CE-Mark identifizierte Studien untersuchten hauptsächlich daVinci® Surgical System

This assessment aimed to assess the effectiveness and safety of robotic procedures applied in multiple indications in the areas of thoracic and visceral surgery. The report is an update to a previously published HTA assessment in 2019 [28].

Wirksamkeit & Sicherheit roboterassistierte Chirurgie im Bereich der Thorax- & Viszeralchirurgie

6.1. Summary of Findings

In total 14 indications were analysed; however, in the case of five indications no further evidence from RCTs was identified (mediastinal surgery, heller myotomy, bariatric surgery, cholecystectomy, small bowel resection). The detailed findings on four efficacy endpoints (OS/DFS, recurrence, QoL, patient satisfaction)[16], four safety endpoints (intraoperative complications, postoperative complications, re-operations and conversion) and five endpoints on perioperative events and resource use (blood loss, operation time, transfusions, drain duration and length of hospital stay) (Table 6-1) are described below.

14 chirurgische Verfahren eingeschlossen
RCTs für 9 chirurgische Verfahren identifiziert
keine Studien für 5 Eingriffe

A total of 20 studies and five additional follow-up publications, met the predefined inclusion criteria. All RCTs identified in the systematic literature search reported on effectiveness. Most studies compared RAS to laparoscopic surgery. Fourteen studies included patients undergoing surgical cancer treatment. In the subsequent sections, only those nine thoracic and visceral indications with available evidence will be outlined.

20 RCTs
+ 5 FU Publikationen

Thoracic surgery

- **Lung lobectomy:** Out of 14 endpoints, nine endpoints showed no difference to the comparator (laparoscopic or open surgery), one safety endpoint (postoperative complications) was worse in the RAS-group [32, 37-40], another safety endpoint (blood loss) was superior to the comparison [32, 37]. Contradicting results were present considering drain duration [32, 37].

9/14 Outcomes
kein Unterschied zum KP;
PO Komplikationen ↓,
Blutverlust ↑,
DD widersprüchl. Evidenz

[16] None of the included studies assessed time to resume work, which is why it is not listed here.

Visceral surgery

3/14 Outcomes kein Unterschied zum KP; Operationszeit ↑

- **Fundoplication:** Three endpoints out of 14 did not show any differences between study groups. One endpoint related to perioperative events and resource use (operation time) was superior to the laparoscopic procedure [41].

8/14 Outcomes kein Unterschied zum KP; OP-Dauer ↑

- **Oesophagectomy:** Eight out of 14 endpoints did not show statistically significant differences between study groups. One endpoint (operation time) showed superior results in the RAS-group [42].

7/14 Outcomes kein Unterschied zum KP; OP-Dauer ↓, Blutverlust & PO Komplikationen ↑

- **Gastrectomy:** Out of 14 endpoints, seven showed no statistically significant difference to the comparator. One safety-related endpoint (postoperative complications) [44, 45] and one endpoint related to perioperative events and resource use (blood loss) [44, 46] was superior to the comparator, whilst operation time was deteriorated [45, 46].

9/14 Outcomes kein Unterschied zum KP; OP-Dauer ↑

- **Colectomy:** Nine out of 14 endpoints showed no difference between study groups. One endpoint, concerning perioperative events and resource use (operation time), showed significantly better results in the control group [47, 48].

5/14 Outcomes kein Unterschied zum KP; IO & PO Komplikationen, Konversionen und DKH ↑, OP-Dauer ↓

- **Rectal resection:** Out of 14 endpoints, five showed no difference between the study groups. Three safety-related endpoints (intraoperative complications, postoperative complications, and conversion) and one endpoint related to perioperative events and resource use (length of hospital stay) were superior to the comparator. In contrast, the study endpoint operation time was deteriorated [49, 50].

6/14 Outcomes kein Unterschied zum KP

- **Ventral mesh rectopexy:** Six out of 14 endpoints were not statistically significant. No endpoints were either worse or superior to the RAS-group [52].

7/14 Outcomes kein Unterschied zum KP; Rezidive & Reoperationen ↑, OP-Dauer ↓

- **Hernia repair:** Seven out of 14 endpoints showed no statistically significant differences between study groups. One patient-relevant outcome (recurrence) [58], as well as one safety-related outcome (reoperation) [53, 58] were superior to the comparator, whilst one endpoint (operation time) was inferior [54-57].

2/14 Outcomes kein Unterschied zum KP; PO Komplikationen, Blutverlust, OP-Dauer & Transfusionen ↑

- **Liver resection:** Out of 14 endpoints, two showed no statistically significant study group differences. One safety-related outcome (postoperative complications), as well as three endpoints related to perioperative events and resource use (blood loss, operation time, and transfusions), were superior to the comparator [60].

Thoracic surgery

Lung lobectomy

The results of the identified RCTs were contradicting concerning postoperative complications, operation time and transfusions; however, differences were not statistically significant [32, 37-40]. In addition, drain duration showed statistically significant differences between study groups, but the results were contradicting since one study [32] reported statistically significantly longer drain duration in the control group, and another study [37] reported significantly more drainage volume in the intervention group. The outcome of blood loss was reported in statistically significantly fewer cases in the robot-assisted group in two studies [32, 37]. Other outcomes did not show statistically significant differences. The identified studies had mostly a high risk of bias. Compared to the earlier report, results were similar, except for one study [61], which reported significantly longer operation time in the intervention group.

Lungenlobektomie:
widersprüchliche Ergebnisse bezgl. PO Komplikationen, OP-Dauer, Bluttransfusionen, DD Dauer (Unterschiede ss)

ss weniger Blutverlust in Patient*innen der IG (2 RCTs)

hohes Biasrisiko

Visceral surgery

Oesophagus

Fundoplication (anti-reflux surgery)

One study [41], which had a high risk of bias, did not show any statistically significant differences between study groups, except in operation time, which was considered statistically significantly longer in the control arm in comparison to the intervention arm. Results concerning QoL were similar between groups. Fewer RCTs could be included in this report in comparison to the earlier report; however, differences in the former assessment were either not statistically significant or not reported.

Fundoplikatio:
ss längere OP-Dauer in der KG (1 RCT), andere Studienendpunkte → keine ss Unterschiede

(hohes Biasrisiko)

Oesophagectomy

The outcome operation time was statistically significantly longer in the control group in comparison to the intervention group in one RCT [42]. Other results were not statistically significant; however, studies were contradicting in the case of postoperative complications. Both studies were associated with a high risk of bias [42, 43]. The earlier report identified a statistically significantly longer operation time in the intervention group. Other outcomes that yielded statistically significant differences between study groups were QoL, postoperative complications and blood loss favouring the intervention group.

Ösophagektomie:
widersprüchliche Resultate bezgl. PO Komplikationen,
ss längere OP-Dauer in der KG (1 RCT)

hohes Biasrisiko

Stomach

Gastrectomy

Postoperative complications [44, 45] as well as events of blood loss [44, 46] occurred statistically significantly less in the intervention groups of two RCTs. Other statistically significant results yielded two studies [45, 46] in operation time favouring the control group. Other results were not statistically significant; however, the RAS reported fewer events of transfusions. Studies were assessed with a high risk of bias or some concerns about the risk of bias. The earlier report also presented statistically significantly less blood loss as well as a shorter hospital stay in the intervention group in comparison to the control group.

Gastrektomie:
ss weniger PO Komplikationen & Blutverlust (2 RCTs)

Studien verbunden mit hohem Biasrisiko oder mit einigen Bedenken bezgl. des Bias

Bowel

Colectomy

Kolektomie
ss kürzere OP-Dauer in der KG (2 RCTs)

Studien verbunden mit hohen Biasrisiko oder mit einigen Bedenken bezgl. des Bias

Statistically significant differences only occurred in operation time favouring the control groups of two RCTs [47, 48]. Conversions were similar in both groups, whereas drain duration was shorter in the intervention group. Moreover, postoperative complications occurred less often in the intervention group in comparison to the control group. No recurrences were reported in both groups. Both included studies had either a high risk of bias or some concerns about the risk of bias. In contrast to the present assessment, the earlier report presented a statistically significantly longer operation time in the control group.

Rectal resection

Rektumresektion:
ss Vebesserungen in der IG vs KG → 1 RCT: IO Komplikationen &
2 RCTs:
PO Komplikationen, Konversionen, Blutverlust, DKH

ss längere OP-Dauer in der IG (1 RCT)

Statistically significant differences were detected in intra- and postoperative complications, conversions, blood loss, operation time, as well as in the length of hospital stay [49, 50]. All outcomes favoured the intervention group, except operation time, which was statistically significantly longer in the robotic-assisted group. Reoperations, as well as transfusions, were needed in fewer instances in the intervention group, albeit not statistically significant. The risk of bias was assumed high in one RCT [50] and low in the other study [49]. The earlier report also detected a statistically significantly longer operation time in the robotic-assisted group and fewer events of conversions.

Ventral mesh rectopexy

ventrale Netzrektopexie:
kein ss Unterschied in den untersuchten Endpunkten

hohes Biasrisiko

Results concerning recurrence, QoL, as well as drain duration were similar between groups [52]. The operation time took slightly longer in the intervention group in comparison to the control group, without statistically significant differences. The risk of bias was assumed high for the included studies. The earlier publication also did not detect statistically significant differences concerning the investigated study outcomes.

Gallbladder/Liver/Spleen

Hernia repair

Hernienreparatur:
ss mehr Rezidive in der IG (1 RCT) & ss längere OP-Dauer in der IG (4 RCTs)

ss mehr Re-Operationen in der KG (1 RCT) & ss bessere QoL (1 RCT)

niedriges bis hohes Biasrisiko

Recurrences occurred statistically significantly more often in the intervention group than in the control group in one [58] out of five RCTs. The operation time was considered statistically significantly longer in the intervention group in four RCTs [54-57]. However, reoperations were needed statistically significantly more often in the control group of one RCT [53, 58]. Postoperative complications occurred more commonly after the robot-assisted procedure. One follow-up report showed statistically significantly improved QoL one year after surgery [58]. Similar results between groups were measured in drain duration and conversions. One [57] out of five studies was assumed to have a low risk of bias, whilst the risk of bias of the other RCTs was either under some concerns or high. No RCTs could be identified in the earlier report.

Liver resection (hepatectomy)

RAS yielded statistically significant improved results concerning blood loss, operation time and transfusion, as well as postoperative complications [60]. Survival was similar in both groups; other outcomes were not reported. However, the risk of bias was considered high. In the earlier report, no RCTs could be identified.

Hepatektomie:
IG ss Verbesserungen bezgl. Blutverlust, OP-Dauer, Transfusionen & PO Komplikationen

Table 6-1: Comparison of study results from the original [28] and update assessment

Indication/procedure		Patient-relevant outcomes**				Safety-related outcomes				Perioperative events & resource use				
		Survival	Recurrence	QoL	Patient sat.	IO compl.	PO compl.	Re-operations	Conversion	Blood loss	OP time	Transfusions	Drain duration	Length of HS
Thoracic surgery														
Lung lobectomy		OR→	OR^{NR}	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR^{NR}	OR↑	OR^{C}	OR↓	OR→	OR→	OR→
		U→	U→	U→	U^{NR}	U→	U↓	U→	U→	U↑	U→	U→	U^{C}	U→
Mediastinal surgery		OR→	OR→	OR→	OR^{NR}	OR→	OR→	OR→	OR→	OR^{NR}	OR→	OR^{NR}	OR^{NR}	OR→
		-	-	-	-	-	-	-	-	-	-	-	-	-
Visceral surgery														
Oesophagus	Fundoplication	OR^{NR}	OR→	OR→	OR→	OR→	OR→	OR^{NR}	OR→	OR→	OR^{C}	OR^{NR}	OR^{NR}	OR→
		U^{NR}	U→	U→	U^{NR}	U^{NR}	U^{NR}	U^{NR}	U^{NR}	U^{NR}	U↑	U^{NR}	U^{NR}	U→
	Oesophagectomy	OR→	OR^{NR}	OR↑	OR^{NR}	OR→	OR↑	OR→	OR→	OR↑	OR↓	OR^{NR}	OR^{NR}	OR→
		U→	U→	U^{NR}	U^{NR}	U→	U→	U^{NR}	U→	U→	U↓	U^{NR}	U→	U→
	Heller myotomy	OR^{NR}	OR^{NR}	OR→	OR^{NR}	OR→	OR^{NR}	OR^{NR}	OR→	OR→	OR→	OR^{NR}	OR^{NR}	OR→
		-	-	-	-	-	-	-	-	-	-	-	-	-
Stomach	Gastrectomy	OR→	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR→	OR→	OR^{NR}	OR↑	OR↓	OR→	OR^{NR}	OR↑
		U→	U^{NR}	U^{NR}	U^{NR}	U→	U↑	U→	U→	U↑	U↓	U→	U→	U→
	Bariatric surgery/ Gastric bypass	OR^{NR}	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR→	OR^{NR}	OR→	OR^{NR}	OR↑	OR^{NR}	OR^{NR}	OR→
		-	-	-	-	-	-	-	-	-	-	-	-	-
*Bowel**	Colectomy	OR→	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR→	OR^{NR}	OR→	OR→	OR↑	OR^{NR}	OR^{NR}	OR→
		U→	U→	U^{NR}	U^{NR}	U→	U→	U→	U→	U→	U↓	U^{NR}	U→	U→
	Rectal resection	OR→	OR^{NR}	OR→	OR^{NR}	OR→	OR→	OR^{NR}	OR↑[3]	OR^{C}	OR↓	OR^{NR}	OR^{NR}	OR→
		U→	U→	U^{NR}	U^{NR}	U↑	U↑	U→	U↑	U↑	U↓	U→	U→	U↑
	Ventral mesh rectopexy	OR^{NR}	OR^{NR}	OR→	OR^{NR}	OR→	OR→	OR^{NR}	OR→	OR^{NR}	OR→	OR^{NR}	OR^{NR}	OR→
		U^{NR}	U→	U→	U→	U^{NR}	U^{NR}	U→	U^{NR}	U^{NR}	U→	U^{NR}	U^{NR}	U→
G./Liver/Spleen	Cholecystectomy	OR^{NR}	OR^{NR}	OR→	OR↑	OR→	OR→	OR^{NR}	OR→	OR→	OR^{C}	OR^{NR}	OR^{NR}	OR↑
		-	-	-	-	-	-	-	-	-	-	-	-	-
	Hernia repair	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR^{NR}	OR^{NR}	OR^{NR}	OR^{NR}	OR^{NR}	OR→	OR^{NR}	OR^{NR}	OR^{NR}
		U→	U↑	U→	U→	U→	U→	U↑	U→	U^{NR}	U↓	U^{NR}	U^{NR}	U→
	Liver resection	OR→	OR→	OR^{NR}	OR^{NR}	OR→	OR→	OR→	OR→	OR→	OR^{C}	OR^{NR}	OR^{NR}	OR^{NR}
		U→	U→	U^{NR}	U^{NR}	U^{NR}	U↑	U^{NR}	U^{NR}	U↑	U↑	U↑	U^{NR}	U^{NR}

*Abbreviations: C and orange colour = conflicting evidence, compl. = complications, G. = Gallbladder, HS = hospital stay, IO = intraoperative, NR = the study outcome was not reported, OR = original report, PO = postoperative, sat. = satisfaction, U = update report, ↑ and green color= at least one study reported statistically significant results favouring the intervention group, ↓ and red color= at least one study reported statistically significant results favouring the control group, → = no study reported statistically significant results, - = no study was identified, * = the indication of small bowel resection was not included in the table since no RCT was identified either in the present or in the original report. ** = the outcome time resume to work and daily activities was investigated in none of the included studies.*

6.2. Interpretation of findings

The results of this HTA are in line with existing knowledge of RAS [2]. For instance, reduced blood loss associated with robot-assisted procedures has been reported in previous HTAs [62, 63] as well as in the previously published assessment from 2019 [28]. However, the effects of the learning curve were not addressed in these assessments [64].

vergleichbare Ergebnisse in Bezug auf bereits publizierte HTAs

In the present assessment, there is a serious lack of high-quality evidence from RCTs on the performance of RAS compared to open or laparoscopic surgery. Statements on the effects are only possible for some outcomes, but not on patient satisfaction, and time to resume work or daily activities; however, the quality of evidence on the reported outcomes was generally low. For all outcomes and procedures, evidence gaps could be identified. Considering the RoB assessment, most of the studies were highly biased mainly due to missing information on power calculations, selective outcome reporting and inadequate allocation concealment.

mehrheitlich geringe Qualität der Evidenz
Biasrisiko großteils hoch → fehlenden Infos zu Powerkalkulationen, selektives Reporting & unzureichendes Allocation Concealment

In some of the included RCTs, patients undergoing RAS had shortened hospital stays as well as fewer readmissions, though these differences were not large enough to be statistically significant. Nevertheless, evidence suggests that robot-assisted surgical methods result in a higher mean cost per procedure than conventional surgical methods [65, 66]. Moreover, higher acquisition costs are necessary considering robotic surgery as well as increased costs due to the single use of instruments [30]. However, according to the manufacturer, instruments can be reused in the future. Additionally, due to increased competition in the robotic surgery market, a price reduction of 20% is expected.

Roboterchirurgie:

kleine ns Effekte bei Krankenhausaufenthalt und -wiederaufnahmen

höhere Kosten pro Eingriff

In addition to increased costs associated with RAS factors concerning environmental sustainability should be taken into account. A systematic review from 2022 [67] concludes that the increased environmental impact of RAS in contrast to conventional laparoscopic procedures may not sufficiently compensate for the potential clinical benefit. Factors enhancing the environmental impact included higher greenhouse gas emissions (43.5%) and waste productions (24%) as well as fewer disability-adjusted life years averted per ton of carbon dioxide and waste. This is in line with another study by Woods et al. [68], who also showed an increased total carbon footprint of 38% in robot-assisted laparoscopy compared to conventional laparoscopy procedures.

ökologische Nachhaltigkeit
erhöhte Umweltauswirkungen durch roboterassistierte Chirurgie → höhere Treibhausgasemissionen & Abfallerzeugung

6.3. Limitations

The present report is associated with several limitations. This HTA includes various indications and outcomes, consequently, this heterogeneity makes analysing and comparing results difficult. Based on the former report we solely included RCTs. Thus, potentially good quality prospective non-randomised trials could be missed. Furthermore, since no systematic literature search was conducted to identify ongoing studies, it is not possible to provide a solid outlook on upcoming evidence.

Limitationen
Vergleichbarkeit schwierig aufgrund hoher Heterogenität
Fokus auf RCTs

fehlende Evidenz zu Patient*innen relevanten Endpunkten

kaum Infos zu chirurgischen Erfahrungen

Another limitation is the scarcity of evidence concerning patient-relevant outcomes like QoL, time to resume work or daily activities and patient satisfaction. Moreover, surgeon-related outcomes, like surgeon fatigue and ergonomics were rarely mentioned. Another aspect is the lack of stratification according to surgical experience. This information was often not available in a way that would enable a structured classification. Furthermore, differences between study groups were often not statistically significant, which could relate to the small sample sizes in the majority of included RCTs.

7 Conclusion

keine Gruppenunterschiede bezgl. DKH

widersprüchliche Ergebnisse zur OP-Dauer

Verringerung des Blutverlustes & PO Komplikationen

Overall, for several indications and outcomes, no evidence could be identified. Moreover, the included **RCTs did not show statistically significant differences in some outcomes such as the length of hospital stays and readmissions, which is claimed to be superior in RAS**. Additionally, contradicting evidence was identified considering operation time. However, for some indications and outcomes, RAS might be beneficial. For instance, blood loss was decreased in lung lobectomy, oesophagectomy, rectal resection, liver resection, and gastrectomy. Furthermore, postoperative complications occurred less often in patients who underwent robot-assisted gastrectomy, and rectal and liver resection. Moreover, in hernia repair, QoL could be improved. Nevertheless, these results were only shown by a small number of RCTs with a low quality of evidence.

Update vs Bericht 2019:

ss weniger Rezidive → Hernienreparatur

Verbesserungen Sicherheit → Hepa- & Gastrektomie, Hernienreparatur; Verschlechterungen → Lobektomie

widersprüchl. Ergebnisse bezgl. OP-Dauer bei Hernienreparatur

The present update is in line with patient-relevant outcomes presented in the formerly published HTA (https://www.eunethta.eu/wp-content/uploads/2019/05/Robot-assisted-surgery-in-thoracic-and-visceral-indications_v1.4_final.pdf) [28]. Nevertheless, one statistically significant improvement considering recurrence that was associated with robot-assisted hernia repair could be observed. Apart from this, this update report differs from the previously published assessment in finding improvements in safety-related outcomes favouring RAS in the area of gastrectomy, hernia repair as well as liver resection. In contrast, a deterioration in postoperative complications related to robot-assisted lung lobectomy could be observed. Some outcomes (e.g. blood loss) associated with perioperative events and resource use were improved in robot-assisted fundoplication, lung lobectomy and liver as well as rectal resection in this report compared to the formerly published HTA. However, results concerning the operation time were contradicting in the case of robot-assisted colectomy and deteriorated in robot-assisted hernia repairs.

In any case, only a few of the claimed benefits of RAS (see introduction), could be materialized.

hohe Kosten → Anschaffung & Erhaltung

höherer Umweltbelastung

Considering financial matters, RAS is combined with higher costs, since the purchase and maintenance of the robotic system is necessary, albeit the fact, that there might be a price reduction due to higher competition. However, RAS exhibits increased environmental impacts compared to conventional laparoscopic procedures, due to higher greenhouse gas emissions and waste generation.

geringe Evidenzqualität der RCTs → kleine Studienpopulation & kurze FU Zeit

In addition, the included studies showed an overall low quality of evidence. Thus, RCTs with a higher quality of evidence, including larger sample sizes (n>100) and longer follow-up times are needed. Another aspect concerns the scarcity of data considering QoL and patient satisfaction, as well as surgeon-related outcomes, like ergonomics and surgeon fatigue.

keine allgemeine Aussage zur Überlegenheit von roboterassistierter Chirurgie möglich

In conclusion due to the heterogeneity of results as well as the lack of evidence for several outcomes and procedures an overall statement regarding the superiority of RAS is not possible. While it may present potential advantages for certain indications, the limited quality of evidence and the financial and environmental implications must be taken into account in purchasing decisions.

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9 Appendix

9.1. Quality appraisal of the randomised controlled trials using the 'Cochrane Collaboration Tool 1'

Table A - 1: Risk of bias – study level (RCTs)

Trial	Adequate generation of randomization sequence	Adequate allocation concealment	Blinding		Selective outcome reporting unlikely	No other aspects increasing risk of bias	Risk of bias – study level
			Patient	Treating person[1]			
Lobectomy							
Jin 2022 [37]	Y[2]	Y[3]	U[4]	U[4]	U[5]	Y	SC
Huang 2021 [32]	Y[6]	N[7]	N[8]	N[8]	U[5]	N[9]	H
Terra 2022 [39]	Y[10]	N[11]	N[12]	N[12]	N[13]	N[14]	H
Veronesi 2021 [38]	Y[15]	U[4]	U[4]	U[4]	N[16]	N[17]	H
Mediastinal surgery							
Oesophagus							

[1] Since it is impractical for the surgeon to be blinded, we refer here to other healthcare professionals involved in patient care

[2] "Randomization was conducted with a computer-generated random numbers table."

[3] "Assignments were sealed in opaque envelopes, which were opened by the surgeons at the time of the operation."

[4] No information given.

[5] No protocol available.

[6] "Following a list of randomization number generated in the trial statistician's computer with stratification for the participating center, the subjects enrolled in present study were randomly and equally assigned."

[7] „The allocation was done by telephone by the trial coordinator."

[8] "Neither subjects nor any investigators were masked to treatment allocation."

[9] No information on power calculation and experience of surgeons given.

[10] "The research center defined the allocation of the patients using a website software … and used block randomization."

[11] „Randomization was not blinded." Patients were randomised only after having their surgery scheduled, ensuring allocation concealment

[12] „Randomization was not blinded."

[13] Not all predefined outcomes reported, e.g. quality of life.

[14] No information of experience of surgeons. Sample size might have impacted statistical power.

[15] "Randomization was performed through a dedicated Internet based system with a balance software for center stratification."

[16] Secondary outcome data on QoL and recurrence were not reported.

[17] „The analysis did show adequate statistical power with regard to secondary (not primary) outcomes." According to the power calculation, "a sample size of 300 subjects was initially calculated."

Trial	Adequate generation of randomization sequence	Adequate allocation concealment	Blinding		Selective outcome reporting unlikely	No other aspects increasing risk of bias	Risk of bias – study level
			Patient	Treating person[1]			
Lang 2022 [41]	U[4]	U[4]	U[4]	U[4]	Y[18]	N[19]	H
de Groot 2020 [43]	U[4]	U[4]	U[4]	U[4]	Y[20]	N[21]	H
Yang 2022 [42]	N[22]	Y[23]	N[24]	N[24]	N[25]	Y	H
Stomach							
Lu 2021 [44]	Y[26]	U[4]	N[27]	N[28]	Y[18]	Y	SC[29]
Ojima 2021 [45]	Y[30]	U[4]	U[4]	N[31]	Y[18]	N[32]	H
Ribeiro 2022 [46]	Y[33]	U[4]	U[4]	U[4]	Y	Y	SC
Bowel							
Fleming 2022 [48]	Y[34]	U[4]	Y[35]	Y[36]	U[5]	N[37]	H

[18] Study protocol available.

[19] „No power calculation was performed."

[20] Protocol available. Short-time results published.

[21] "The number of patients was powered for short-term postoperative outcomes and not specifically for long-term results."

[22] "Eligible patients were randomized by the central study coordinator."

[23] „Concealment of allocation was performed using computer generated random numbers and further stratified."

[24] "There was no blinding for the patient and operator due to practical difficulties."

[25] Protocol available. However, mortality is stated but not the overall survival like mentioned in the methods.

[26] "The SAS 9.2 program was used to generate serial numbers."

[27] „The study was not blinded after randomization."

[28] „The study was not blinded after randomization."

[29] Some concerns as domain blinding not fulfilled and no information given regarding allocation concealment.

[30] „The minimization method with a random component was used."

[31] "Blinding was not applied regarding postoperative management of the patients."

[32] No information on experience of surgeons.

[33] "Participants were assigned by computer-generated simple randomization … using the block randomization method."

[34] As stated in a previously published study: "Patients were randomized using a computer-generated randomization code.[69]

[35] "The study was carried out under double-blind conditions." [69]

[36] "The study was carried out under double-blind conditions." [69]

[37] No information on the experience of surgeons given. No power calculation.

Trial	Adequate generation of randomization sequence	Adequate allocation concealment	Blinding		Selective outcome reporting unlikely	No other aspects increasing risk of bias	Risk of bias – study level
			Patient	Treating person[1]			
Park 2019 [47]	Y[38]	Y[38]	N[39]	Y[40]	Y[18]	N[41]	SC[42]
Feng 2022a [49]	Y[43]	Y[44]	N[45]	Y[46]	Y[18]	Y	L
Feng 2022b [50]	Y[47]	N[48]	N[49]	U[50]	N[51]	Y	H
Mäkelä-Kaikkonen 2019 [52]	Y[52]	U[4]	Y[53]	N[54]	Y[18]	N[55]	H[56]

[38] "Consenting patients were randomly allocated […] according to a computer-generated random sequence kept concealed by an independent clinical trial coordinator."

[39] "Patients […] could not be masked to treatment assignments."

[40] "Clinicians could not be masked to treatment assignments. However, during the follow-up period, radiologists and pathologists were masked to the procedural allocation."

[41] "The sample size calculation of our trial was based on short-term outcomes such as hospital stay, so our long-term oncological data were inconclusive. Admittedly, the sample size of this study was not adequate."

[42] Some concerns as no patient blinding was done and only short-term outcomes were conclusive.

[43] „A simple randomization method was used with a computer-generated random number sequence in this trial."

[44] „An independent statistician made and kept the envelopes containing group numbers to conceal the sequence. After eligibility and informed consent, one envelope was opened by the principal investigator of this trial to decide the allocation for each patient."

[45] „No blinding to treatment allocation was incorporated in this trial."

[46] „The outcomes were evaluated and recorded by two blinded assessors according to medical documents without information on the grouping allocation."

[47] „An online central randomization system was used for allocation. Randomisation was stratified according to [defined] factors."

[48] „The principal investigator of each participating centre logged onto the system website, obtained the random allocation, and informed the patient."

[49] „The investigators and patients were not blinded to the treatment allocation."

[50] „The investigators and patients were not blinded to the treatment allocation. However, the senior pathologists of each participating centre were masked to the assessment of pathological outcomes."

[51] Protocol available. However, outcomes on survival and quality of life (follow-up) are not reported.

[52] „The patients were randomised to the treatment groups by using a computer randomisation list in a 1:1 ratio." [33]

[53] „The patients were blinded to the operative technique."

[54] Only „the radiologist was also blinded to the technique used."

[55] „Because of the small number of patients this study is underpowered to detect true differences between the robot-assisted and laparoscopic techniques." No information on the experience of surgeons.

[56] High risk of bias as only radiologist was blinded and underpowered study.

Gallbladder/Liver/Spleen							
Dhanani 2021 [55]	Y[57]	Y[58]	Y[59]	Y[59]	U[5]	N[60]	SC[61]
Costa 2023 [54]	Y[62]	Y[63]	Y	N[64]	Y[18]	N[65]	H[66]
Olavarria 2020 [57]	Y[67]	Y[68]	Y[69]	Y[70]	Y[18]	Y	L
Petro 2021 [53]	Y[71]	Y[71]	Y[72]	N[73]	Y[74]	Y	SC[75]
Prabhu 2020 [56]	Y[76]	U[4]	Y[77]	N[78]	N[79]	N[80]	H
Li 2022 [60]	Y[81]	U[4]	N[82]	U[4]	Y	N[83]	H

Note: Y= yes, N= no, U= unclear, H= high SC= some concerns, L= low

[57] „Patients were randomized by computer-generated, variable block in a 1:1 ratio, stratified by surgeon."

[58] „Treatment allocation was determined through opening of sequentially numbered, opaque, sealed envelopes."

[59] „The operating surgeons and research coordinators who determined treatment allocation could not be blinded given the nature of the intervention. However, the patients and post-operative outcome assessors were blinded to the patients' allocation group."

[60] „Given our results and assuming true effect size is 50% lower (4.5% vs 0.5% reoperation rate), 476 patients would be needed for an appropriately powered study to detect a true difference."

[61] Some concerns as only 124 patients were included in the trial (not 476 patients).

[62] "An independent coordinator nurse using the Microsoft Excel random number generation function performed a randomization

[63] "The number generated was kept blinded to the patient in a sequentially numbered opaque sealed envelope."

[64] Single-blinded trial.

[65] There was a "lack of reasonable sample size estimation, and each outcome followed a per-protocol analysis."

[66] High risk of bias as domain "blinding of treating person" not fulfilled, lack of reasonable sample size estimation, and each outcome followed a per-protocol analysis.

[67] „Randomisation… by using a computer generated variable block randomization schema stratified by surgeon."

[68] „Surgeons contacted the research assistant, who determined the treatment allocation through opening of sequentially numbered opaque sealed envelopes."

[69] „The patient and the rest of the research team, including postoperative outcome assessors, were all blinded to the patients' allocation group."

[70] "Operating surgeons and the research coordinator who determined the randomization allocation could not be blinded." „The patient and the rest of the research team, including postoperative outcome assessors, were all blinded to the patients' allocation group."

[71] „A concealed randomization scheme was performed by using a random number of blocks with a 1:1 ratio of assigning patients to each arm."

[72] „Patients were blinded to the operative approach throughout the study."

[73] Single-blinded study.

[74] Protocol available.

[75] Some concerns as only domain "blinding of treating person" is not fulfilled.

[76] „The randomization was performed using a random number of blocks with 1:1 ratio of assigning patients to each group."

[77] „Patients were blinded to their interventions."

[78] Single-blinded study.

[79] Protocol available. However, not all outcomes reported (i.e. hernia recurrence rates, cosmetic results).

[80] "There was essentially no precedent on which to perform a power calculation as robotic adoption was in its infancy for repair of inguinal hernia. Thus, this study was designed as a pilot study."

[81] Patients were selected "according to random number table method".

[82] Patients were fully informed.

[83] No power calculation. No information on experience of surgeons.

Table A - 2: Risk of bias – study levels (RCTs) [28]

Trial	Adequate generation of randomization sequence	Adequate allocation concealment	Blinding		Selective outcome reporting unlikely	No other aspects increasing risk of bias	Risk of bias – study level
			Patient	Treating person[84]			
Gallbladder/Liver Spleen							
Kudi 2017 [70]	Y	Y	U[85]	U[85]	N[86]	N[87]	H
Pietrabissa 2016 [71]	Y	Y	Y	Y	Y	N[88]	L
Grochola 2019 [72]	Y	Y	Y	Y	Y	N[89]	L
Ruurda 2003 [73]	N	U[90]	U[90]	U[90]	Y	N[91]	H
Bowel							
Jayne 2017 [65]	Y	Y	N[92]	N[93]	Y	Y	L
Wang 2017 [74]	U[94]	U[4]	U[4]	U[4]	N[95]	N[96]	H
Kim 2018 [75]	Y	Y	N[92]	N[93]	Y	Y	L
Mäkelä-Kaikkonen 2016 x2 [33, 76]	Y	Y	Y	N[93]	N[97]	N[37]	L
Park 2012 [66]	U[90]	Y	U[4]	U[4]	Y	Y	H
Tolstrup 2018 [77]	U	U	N[92]	N[93]	N[98]	Y	H
Debakey 2018 [78]	U[90]	U[90]	U[90]	U[90]	N[99]	N[9]	H

[84] Since it impractical for the surgeon to be blinded, we refer here to other healthcare professionals involved in patient care

[85] Inconsistently reported

[86] Outcomes regarding quality of life just reported "for female patients with non-missing data: controlled for age, BMI, and prior abdominal surgery"

[87] Single-site (IG) vs multiport (CG) Experience of surgeons (8/10 new to single-site technique) Probably inadequate sample size

[88] Comparison was not made with a standard single-incision technique. No detailed information about patient characteristics was provided

[89] Several surgeons involved, experience not detailed; study not powered for our endpoints of interest

[90] Insufficient information for a judgement

[91] No power calculations, residents in training performed control procedure

[92] Patients were not blinded

[93] Healthcare professionals were not blinded

[94] Only reported that rndomisation was performed using opaque sealed envelopes

[95] Patients that died or did not provide follow-up data were excluded

[96] No details on experience of surgeons

[97] Not all outcomes were reported

[98] Results data unclear

[99] Intraoperative complications analysed but not reported

Oesophagus							
Draaisma 2009 [79]	U[90]	U[90]	U[90]	U[90]	Y	U[100]	
Mueller-Stich 2007, 2009 [80, 81]	U[4]	U[4]	Y	U[90]	Y	N[101]	H
Morino 2006 [82]	Y	Y	U[90]	U[90]	Y	Y	L
Nakadi 2006 [83]	U[102]	U[102]	N[92]	U[90]	N[103]	N[101]	H
van der Sluis 2018 [84]	Y	Y	U[90]	U[90]	Y	N[9]	L
Stomach							
Pan 2017 [85]	U[90]	U[90]	U[4]	U[4]	Y	N	H
Sanchez 2005 [86]	U[4]	U[4]	U[4]	U[4]	Y	N[101]	H
Wang 2016 [87]	U[90]	Y	U[4]	U[4]	Y	N[101]	H

Note: Y= yes, N= no, U= unclear, H= high SC= some concerns, L= low

[100] Unclear how many patients refer to results

[101] Lack of sample size calculation

[102] "Randomised by envelopes"

[103] No outcomes regarding satisfaction score, although predefined

GRADE

Thoracic surgery

Lung lobectomy (n=6 articles; 4 studies)

*Table A - 3: Robot-assisted surgery vs **laparoscopic surgery:** Evidence profile for efficacy and safety for lung lobectomy*

L Video-assisted lobectomy
L Video-assisted thoracic surgery

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients ROB-ASS	N of randomised patients LAP	Effect	Certainty
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs laparoscopic surgery										
Survival (overall and disease-specific or disease-free)										
2 [37, 39]	RCT	Serious[1]	Not serious	Serious[2]	Serious[3]	Serious[4]	221	222	1 RCT: **Deaths 48-wks postoperatively:** IG: 7; CG: 14 (2023); p=NS 1 RCT: **Mortality within 90 days after surgery:** IG: 1 (2.7); CG: 1 (2.5); p=NS	Very low ⊕◯◯◯
Recurrence (local, regional or distant)										
1 [37]	RCT	Not Serious	Not serious	Not serious	Serious[5]	Serious[6]	181	182	1 RCT: **Recurrence 48-wks postoperatively:** IG: 6; CG:5 (2023)	Low ⊕⊕◯◯

[1] High risk of bias due to selective outcome reporting and no power calculation in [39].

[2] Differences in indication (cancer vs lesions).

[3] No confidence interval reported.

[4] Sponsored by the industry (Intuitive)

[5] No confidence interval reported.

[6] Sponsored by the industry (Intuitive).

Quality of life										
1 [37, 40]	RCT	Not serious	Not serious	Not serious	Not serious	Serious[7]	181	182	1 RCT: *Mean difference (95% CI)* 4 wks 0.002 (–0.008~0.012) 24 wks 0.003 (–0.004~0.010) 48 wks 0.004 (–0.002~0.011)	Moderate ⊕⊕⊕◯
Safety – Safety-related outcomes: Robot-assisted surgery vs laparoscopic surgery										
Intraoperative complications										
1 [39]	RCT	Serious[8]	Not serious	Not serious	Serious[9]	None	40	40	1 RCT: IG: 0; CG: 3; p=NS (2 arterial lacerations and 1 venous injury)	Low ⊕⊕◯◯
Postoperative complications										
3 [37-39]	RCT	Serious[10]	Not serious	Serious[11]	Serious[12]	Serious[13]	259	261	1 RCT: *IG vs CG; n (%); p-value* **Postoperative complications:** 23 (14.6) vs 30 (18.4); NS **Clavien Dindo I-II:** 18 (11.5) vs 24 (14.7); NS Pleural effusion: 8 (5.1) vs 12 (7.4); NS Pneumoni: 4 (2.5) vs 1 (0.6); NS Prolonged air leak: 9 (5.7) vs 7 (4.3); NS **Clavien Dindo III-IV:** 5 (3.2) vs 6 (3.7); NS Pleural effusion: 2 (1.3) vs 2 (1.2); NS Pneumonia: 0 vs 1 (0.6), NS Prolonged air leak: 0 vs 3 (1.8); NS **Readmission:** 3 (1.9) vs 3 (1.8); NS 1 RCT: *IG vs CG; n (%); p-value* **Early postoperative complications[14]:** 13 (37) vs 9 (24); NS Air leak: 6 (17) vs 4 (11); NS Atrial Fibrillation: 4 (11) vs 3 (9); NS Atelectasis: 3 (9) vs 1 (3); NS Other Complication: 3 (9) vs 2 (5); NS **Readmissions:** 4 (16) vs 0 (0); NS **Later Complication:** 5(23) vs 2 (11); NS 1 RCT: *IG vs CG; n (%); p-value* **Complications within 90 days:** 7 (18.9) vs 14 (35.9); NS **≥ 3 complications within 90 days:** 7 (18.9) vs 10 (25.6); NS **Readmissions within 90 days:** 1 (2.7) vs 8 (20.5); **p=0.029**	Very low ⊕◯◯◯

Abbreviations: CG = control group, CI = confidence interval, IG = intervention group, LAP = laparoscopic surgery, N = number of patients, NS = not significant, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, vs = versus, wk = week, wks = weeks.
Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

*Table A - 4: Robot-assisted surgery vs **open surgery:** Evidence profile for efficacy and safety for lung lobectomy*

O Thoracotomy

8							**Summary of findings**			
N of studies	**Study design**	**Risk of bias**	**Incon-sistency**	**Indirectness**	**Imprecision**	**Other considerations**	**N of randomised patients**		**Effect**	**Certainty**
							ROB-ASS	**OPEN**		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs open surgery										
Survival (overall and disease-specific or disease-free)										
1 [32]	RCT	Serious[15]	Not serious	Not serious	Serious[16]	None	137	133	1 RCT: *IG vs CG; %; p-value* **Disease-free survival:** 1 yr: 90.4 vs 86.0; NS 2 yrs: 76.4 vs 74.2; NS	Low ⊕⊕◯◯
Recurrence (local, regional or distant)										
NR										

[7] Sponsored by the industry (Intuitive).

[8] High risk of bias due to no blinding, selective outcome reporting and no power calculation.

[9] <100 pts included.

[10] High risk of bias mainly due to selective outcome reporting and no power calculation.

[11] Different sub-outcomes reported.

[12] No confidence interval reported.

[13] Sponsored by the industry (Intuitive).

[14] Discrepancies in postoperative complications between Table 1 in the publication and Table S1 in the Supplements could be observed. Data extracted from Supplements.

[15] High risk of bias due to neither blinding nor power calculation.

[16] No confidence interval reported.

8							Summary of findings			
N of studies	Study design	Risk of bias	Incon-sistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	OPEN		
Quality of life										
NR										
Safety – Safety-related outcomes: Robot-assisted surgery vs open surgery										
Intraoperative complications										
NR										
Postoperative complications										
1 [32]	RCT	Serious[17]	Not serious	Not serious	Serious[18]	None	137	133	1 RCT: **Complications within 2 years after surgery** *IG vs CG; n (%); p-value* Prolonged air leak: 6 (7.9) vs 6 (8.3); NS Bronchopleural fistula: 4 (5.3) vs 1 (1.4); NS Pneumonia: 3 (3.9) vs 6 (8.3); NS Hyperpyrexia: 2 (2.6) vs 6 (8.3); NS Haemorrhage: 2 (2.6) vs 1 (1.4); NS Recurrent laryngeal nerve injury: 1 (1.3) vs 4 (5.6); NS Pulmonary embolism: 1 (1.3) vs 0; NS	Low ⊕⊕◯◯

Abbreviations: CG = control group, IG = intervention group, N = number of patients, NR = not reported, NS = not significant, OPEN = open surgery, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, vs = versus, yr = year, yrs = years.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

[17] High risk of bias due to neither blinding nor power calculation.

[18] No confidence interval reported.

Visceral surgery

Oesophagus (n=3)

Table A - 5: Robot-assisted surgery vs ***laparoscopic surgery:*** *Evidence profile for efficacy and safety for oesophagus*

L Conventional laparoscopic fundoplication
L Conventional minimally invasive oesophagectomy

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Incon-sistency	Indirect-ness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs laparoscopic-surgery										
Survival (overall and disease-specific or disease-free)										
1 [42]	RCT	Serious[19]	Not serious	Not serious	Serious[20]	None	183	179	1 RCT: *IG vs CG; n (%);* p=NS **In-hospital mortality:** 0 (0) vs 0 (0) 30-d mortality: 0 (0) vs 1 (0.6) 90-d mortality: 1 (0.6) vs 1 (0.6)	Low ⊕⊕◯◯
Recurrence (local, regional or distant)										
1 [41]	RCT	Serious[21]	Not serious	Not serious	Very serious[22]	None	20	3	1 RCT: *IG vs CG; n (%); p=NR* **Failure of treatment:** Oesophagitis ≥ LA-B: 1 (8) vs 1 (8) GSRS reflux score ≥ 3: 3 (25) vs 2 (17) Daily PPI for reflux: 4 (31) vs 4 (33) Dysphagia combined with reflux score ≥ 2: 1 (8) vs 1 (8) 1 RCT: *IG vs CG; n (%);* p=NS **Overall recurrence disease:** 28 (56) vs 29 (54) **Anastomoses/gastric conduit:** 3 (6) vs 1 (2) **LN:** 14 (28) vs 15 (28)	Low ⊕⊕◯◯

[19] High risk of bias due to inadequate generation of randomisation sequence, blinding, and selective outcome reporting.

[20] No confidence interval reported in Yang et al. 2022.

[21] High risk of bias due to uncertainty of blinding and no power calculation.

[22] No confidence interval reported, and <100 pts.

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Incon-sistency	Indirect-ness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
									Distant: 26 (52) vs 27 (50)	
Quality of life										
1 [41]	RCT	Serious[23]	Not Serious	Not Serious	Very serious[24]	None	20	20	1 RCT: *IG vs CG; mean ± SD (range);* p=NS **Quality of life in reflux and dyspepsia:** Emotional distress: 6.4 ± 1.4 (1.2–7.0) vs 6.5 ± 1.6 (1.0–7.0) Food/drink problems: 6.5 ± 0.9 (3.5–7.0) vs 6.3 ± 1.6 (1.0–7.0) Physical/social functioning: 6.6 ± 1.0 (2.8–7.0) vs 6.4 ± 1.6 (1.0–7.0) Sleep disturbance: 6.4 ± 1.3 (2.2–7.0) vs 6.5 ± 1.5 (1.0–7.0) Vitality: 6.3 ± 1.4 (1.3–7.0) vs 6.3 ± 1.6 (1.0–7.0)	Low ⊕⊕◯◯
Safety – Safety-related outcomes: Robot-assisted surgery vs laparoscopic surgery										
Intraoperative complications										
1 [42]	RCT	Serious[25]	Not serious	Not serious	Not serious	None	183	179	1 RCT: Conversion to open surgery: **IG:** 7 (3.9%) vs **CG:** 6 (3.4%)	Moderate ⊕⊕⊕◯
Postoperative complications										
1 [42]	RCT	Serious[26]	Not serious	Not serious	Not serious	None	183	179	1 RCT: *IG vs CG; n (%);* p=NS **Total complications:** 88 (48.6) vs 74 (41.8) C-D classification ≥ III: 22 (12.2) vs 18 (10.2) **Pulmonary complications:** 25 (13.8) vs 26 (14.7) **Severe cardiac complications:** 2 (1.1) vs 1 (0.6) **Anastomotic leakage:** 22 (12.2) vs 20 (11.3) **Vocal cord paralysis:** 59 (32.6) vs 48 (27.1)	Moderate ⊕⊕⊕◯

Abbreviations: CG = control group, CI = confidence interval, IG = intervention group, LAP = laparoscopic surgery, LN = lymph nodes, N = number of patients, NR = not reported, NS = not significant, PPI = Proton pump inhibitors, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, SD = standard deviation, vs = versus.

[23] High risk of bias due to uncertainty concerning blinding, randomisation and power calculation for long-term effects.

[24] Population <100, no confidence interval reported.

[25] High risk of bias due to inadequate generation of randomisation sequence, blinding, and selective outcome reporting.

[26] High risk of bias due to inadequate generation of randomisation sequence, blinding, and selective outcome reporting.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

*Table A - 6: Robot-assisted surgery vs **open surgery:** Evidence profile for efficacy and safety for oesophagus*

O Open transthoracic oesophagectomy

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Incon-sistency	Indirectness	Impreci-sion	Other considera-tions	N of randomised patients		Effect	Certainty
							ROB-ASS	OPEN		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs open surgery										
Survival (overall and disease-specific or disease-free)										
1 [43]	RCT	Serious[27]	Not serious	Not serious	Serious[28]	None	56	56	1 RCT: *IG vs CG; median in months (range); rate (95% CI); p=NS* **Overall survival:** 35 (1–60); 41% (95% CI 27–55) vs 41 (2–60); 40% (95% CI 26–53) **Disease-free survival:** 28 (0–56); 42% (95% CI 28–55) vs 37 months (3–56); 43% (95% CI 29–57)	Low ⊕⊕◯◯
Recurrence (local, regional or distant)										
1 [43]	RCT	Serious[29]	Not serious	Not serious	Not serious	None	56	56	1 RCT: *IG vs CG; n (%); p=NS* **Overall recurrence disease:** 28 (56) vs 29 (54)	Moderate ⊕⊕⊕◯
Quality of life										
NR										
Safety – Safety-related outcomes: Robot-assisted surgery vs open surgery										
Intraoperative complications										
NR										
Postoperative complications										
NR										

Abbreviations: CG = control group, CI – confidence interval, IG = intervention group, N = number of patients, NR = not reported, NS = not significant, OPEN = open surgery, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, vs = versus.

[27] High risk of bias due to uncertain blinding and no power calculation for long-term effects.

[28] Wide confidence interval in both groups

[29] High risk of bias, mainly due to other aspects increasing risk of bias.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

Stomach (n=3)

Table A - 7: Robot-assisted surgery vs ***laparoscopic surgery:*** *Evidence profile for efficacy and safety for stomach*

L Laparoscopic distal gastrectomy
L Laparoscopic gastrectomy

Certainty assessment							**Summary of findings**			
N of studies	**Study design**	**Risk of bias**	**Incon-sistency**	**Indirectness**	**Imprecision**	**Other considera-tions**	**N of randomised pa-tients**		**Effect**	**Certainty**
							ROB-ASS	**LAP**		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs laparoscopic surgery										
Survival (overall and disease-specific or disease-free)										
2 [44, 45]	RCT	Serious[30]	Not serious	Not serious	Serious[31]	None	269	272	1 RCT: *IG vs CG; n (%); p-value* **In-hospital mortality within 30 days postoperative:** 0 (0) vs 0 (0); NA 1 RCT: *IG vs CG; n (%); p-value* (per-protocol analysis) **Mortality:** IG: 0; CG: 0; p=NS	Low ⊕⊕◯◯
Recurrence (local, regional or distant)										
NR										
Quality of life										
NR										
Safety – Safety-related outcomes: Robot-assisted surgery vs laparoscopic surgery										
Intraoperative complications										
NR										
Postoperative complications										
2 [44, 45]	RCT	Serious[32]	Not serious	Not serious	Serious[33]	None	269	272	1 RCT: *IG vs CG; n (%); p-value* **Overall morbidity:** 13 (9.2) vs 25 (17.6); **p=0.039**	Low ⊕⊕◯◯

[30] High risk of bias due to uncertainty of adequate allocations concealment and no reported experience of surgeons Ojima et al. 2021

[31] No confidence interval reported.

[32] High risk of bias due to uncertainty of adequate allocations concealment and no reported experience of surgeons Ojima et al. 2021

[33] No confidence interval reported.

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Incon-sistency	Indirectness	Imprecision	Other considera-tions	N of randomised pa-tients		Effect	Certainty
							ROB-ASS	LAP		
									Surgical morbidity: 5 (3.5) vs 9 (6.3); NS **Medical morbidity:** 9 (6.4) vs 20 (14.1); **p=0.033** **Clavien-Dindo classification:** I: 0 (0.0) vs 0 (0.0); NS II: 11 (7.8) vs 22 (15.5); NS IIIa: 0 (0.0) vs 1 (0.7); NS IIIb: 1 (0.7) vs 1 (0.7); NS IV: 1 (0.7) vs 1 (0.7); NS V: 0 (0.0) vs 0 (0.0); NS **Unplanned readmission:** 2 (1.4) vs 2 (1.4); NS 1 RCT: *IG vs CG; n (%); p-value* (per-protocol analysis) **Overall complications, ≥grade IIb:** 10 (8.8) vs 23 (19.7); **p=0.02** **Overall complications, ≥grade IIIa:** 6 (5.3) vs 19 (16.2); **p=0.01** **Surgical complications:** Anastomotic leakage, ≥grade II: 4 (3.5) vs 5 (4.3); NS Anastomotic leakage, ≥grade IIIa: 3 (2.7) vs 5 (4.3); NS Intra-abdominal abscess, ≥grade II: 3 (2.7) 3 (2.6); NS Intra-abdominal abscess, ≥grade IIIa: 2 (1.8) vs 3 (2.6); NS **Medical complications:** Pneumonia, ≥grade II: 1 (0.9) vs 5 (4.3); NS	

Abbreviations: CG = control group, IG = intervention group, LAP = laparoscopic surgery, N = number of patients, NA = not applicable, NR = not reported, NS = not significant, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, vs = versus.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

*Table A - 8: Robot-assisted surgery vs **open surgery:** Evidence profile for efficacy and safety for stomach*

O Open gastrectomy

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	OPEN		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs open surgery										
Survival (overall and disease-specific or disease-free)										
1 [46]	RCT	Not serious	Not serious	Not serious	Serious[34]	None	33	32	1 RCT: **Mortality[35]:** IG: 0; CG: 0; p=NR	Moderate ⊕⊕⊕◯
Recurrence (local, regional or distant)										
NR										
Quality of life										
NR										
Safety – Safety-related outcomes: Robot-assisted surgery vs open surgery										
Intraoperative complications										
1 [46]	RCT	Not serious	Not serious	Not serious	Serious[36]	None	33	32	1 RCT: IG: 0; CG: NR; p=NR	Moderate ⊕⊕⊕◯
Postoperative complications										
1 [46]	RCT	Not serious	Not serious	Not serious	Serious[37]	None	33	32	1 RCT: *IG vs CG; n (%); p-value* **Postoperative complications (0- 30 days postoperative):** Minor: 4 (13.8) vs 6 (19.4); NS Major: 4 (13.8) vs 3 (3.2); NS **Late complications (>30 days postoperative):** 1 (3.4) vs 6 (19.4); NS **Readmission** (<90 days): IG: 1 (3.4); CG: 4 (12.9); NS	Moderate ⊕⊕⊕◯

Abbreviations: CG = control group, IG = intervention group, N = number of patients, NR = not reported, NS = not significant, OPEN = open surgery, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, vs = versus.

[34] No confidence interval reported and <100 pts included.

[35] Death until 90 days after the procedure or during postoperative hospital stay

[36] No confidence interval reported and <100 pts included.

[37] No confidence interval reported and <100 pts included.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

Bowel (n=6 articles; 5 studies)

*Table A - 9: Robot-assisted surgery vs **laparoscopic surgery:** Evidence profile for efficacy and safety for bowel*

L Laparoscopic colectomy
L Laparoscopic-assisted right colectomy
L Laparoscopic abdominoperineal resection
L Conventional laparoscopic surgery
L Laparoscopic ventral mesh rectopexy

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs laparoscopic surgery										
Survival (overall and disease-specific or disease-free)										
2 [47, 49]	RCT	Not Serious	Not serious	Serious[38]	Not Serious	None	209	209	1 RCT: *IG vs CG; mean (%) (95% CI); p-value* **Disease-free survival:** 3 yrs after surgery: 88.1 (77.1–99.1) vs 91.1 (81.4–99.9); NS 5 yrs after surgery: 77.4 (60.6–92.1) vs 83.6 (72.1–97.0); NS **Overall survival:** 3 yrs after surgery: 96.8 (90.6–99.9) vs 94.0 (86.0-99.9); NS 5 yrs after surgery: 91.1 (78.8–99.9) vs 91.0 (81.3–99.9); NS 1 RCT: **Disease-free survival** (3-yrs rate of stage I–III pts): 85.3% vs 84.6% (log-rank NS; HR=0.918; 95% CI = 0.555–1.517); NS **Overall survival** (3-yrs rate of all pts): 91.1% vs 90.4% (log-rank NS; HR=0.912; 95% CI = 0.490–1.697); NS	Moderate ⊕⊕⊕◯
Recurrence (local, regional or distant)										

[38] Different statistical value reported.

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
3 [47, 49, 52]	RCT	Serious[39]	Not serious	Very serious[40]	Serious[41]	None	225	223	1 RCT: No port site recurrence was noted with a median follow-up of 49 months 1 RCT: **Recurrence at 3 yrs after surgery** (IG (n=173) vs CG (n=173); difference (95% CI); p-value): **Locoregional recurrence:** 5 (2.9) vs 9 (5.2); -2.3 (-7.0 to 2.1); NS **Distant metastases:** 21 (12.1) vs 23 (13.3); -1.2 (-8.3 to 6.0); NS 1 RCT: At 24-month follow-up (2019): IG: 0 vs CG: 1 (8%); p=NR	Very low ⊕◯◯◯
Quality of life										
1 [52]	RCT	Serious[42]	Not serious	Not serious	Serious[43]	None	16	14	1 RCT: *IG vs CG; n; mean (SD); difference between means (95% CI); p-value* **QoL measurements 5 yrs postoperative (2020):** **CRAIQ-7:** 14; 24.3 (32.0) vs 10; 43.8 (27.1); -20.4 (-43.2 to 2.5); NS **POPIQ-7:** 13; 9.5 (26.4) vs 10; 26.0 (27.9); -16.1 (-39.7 to 7.5); NS **UIQ-7:** 14; 25.7 (32.7) vs 10; 33.0 (31.4); -9.4 (-32.3 to 13.6); NS **PFIQ-7:** 14; 58.8 (82.1) vs 10; 102.7 (69.9); -47.8 (-103.7 to 8.0); NS	Low ⊕⊕◯◯
Safety – Safety-related outcomes: Robot-assisted surgery vs laparoscopic surgery										
Intraoperative complications										

[39] High risk of bias due to uncertain adequacy of allocation concealment and underpowered study in Mäkelä-Kaikkonen et al. 2019.

[40] Different statistical values reported and different indications.

[41] Confidence interval not reported in Park et al. 2019 and in Mäkelä-Kaikkonen et al. 2019.

[42] High risk of bias due to uncertain adequacy of allocation concealment and underpowered study.

[43] Population <100.

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
3 [48-50]	RCT	Serious[44]	Not serious	Very serious[45]	Serious[46]	None	837	877	1 RCT: *IG vs CG; n (%); p-value* 3 (7) vs 4 (5); NS 1 RCT: *IG vs CG; n (%); p-value* **Pts with any intraoperative complications:** 10 (5.7) vs 16 (9.2); NS 1 RCT: *IG vs CG; n (%); difference (95% CI); p-value* **Intraoperative complications**: 32 (5.5%) vs 51 (8.7%); –3·3 (–6·3 to –0·3); **p=0.030** **Significant bleeding:** 16 (2.7%) vs 26 (4.4%); –1·7 (–4·0 to 0·4); NS	Very low ⊕◯◯◯
Postoperative complications										
4 [47-50]	RCT	Serious[47]	Not serious	Very serious[48]	Serious[49]	None	872	913	1 RCT: *IG vs CG; n (%); p-value* **Postoperative surgical complication:** 7 (16) vs 10 (12); NS **Anastomotic leak:** 2 (5) vs 3 (4); NS **Medical complication:** 4 (9) vs 8 (10); NS **Clavien Dindo:** 0: 35 (81) vs 68 (81); NS I: 3 (7) vs 3 (4); NS II: 3 (7) vs 7 (8); NS III: 2 (5) vs 4 (5); NS IV: 0 (0) vs 2 (2); NS 1 RCT: *IG vs CG;n (%); p-value*	Very low ⊕◯◯◯

[44] High risk of bias due to no power calculation in Fleming et al. 2022 and selective outcome reporting in Feng et al. 2022b.

[45] Different indications and sub-outcomes reported.

[46] Confidence interval not reported in Feng et al. 2022a and Fleming et al. 2022.

[47] High risk of bias mainly due to no power calculation in Fleming et al. 2022 and selective outcome reporting in Feng et al. 2022b.

[48] Different indications and sub-outcomes reported.

[49] No confidence interval reported in Fleming et al. 2022 and Park et al. 2019.

Certainty assessment							Summary of findings			
N of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N of randomised patients		Effect	Certainty
							ROB-ASS	LAP		
									Perioperative morbidity: 6 (17.1) vs 7 (20.0); NS **Wound infection:** 2 (5.6) vs 2 (5.6); NR **Anastomosis leakage:** 1 (2.8) vs 0 (0); NR **Intraabdominal abscess:** 0 (0) vs 1 (2.8); NR **Bleeding:** 1 (2.8) vs 3 (8.5); NR **Ileus:** 1 (2.8) vs 1 (2.8); NR **Readmission** (>30 days after discharge): 1 (2.8) vs 2 (5.6); NS 1 RCT: *IG vs CG: n (%); unadjusted difference (95% CI); p-value (within 30 days after surgery)* **Total 30-day postoperative complication rate (Clavien–Dindo grade II or higher):** 23 1 RCT: *IG vs CG: n (%); difference (95% CI); p-value (within 30 days after surgery)* **Mortality within 30 days postoperatively:** 1 (0.2) vs 1 (0.2); 0.0 (-0.8 to 0.8); NS **Complications of Clavien–Dindo grade II or higher grade within 30 days after operation:** 95 (16.2) vs 135 (23.1); -6.9 (-11.4 to -2.3); p=0.003 **Anastomotic leakage**: 25/486 (5.1) vs 37/449 (8.2); -3.1 (–6.5 to 0.1); NS **Abdominal or anastomotic bleeding:** 8 (1.4) vs 12 (2.1); –0.7 (–2.3 to 09); NS **Wound-related:** 18 (3.1) vs 22 (3.8); –0.7 (–2.9 to 1.5); NS **Urinary retention or infection:** 10 (1.7) vs 17 (2.9); –1.2 (–3.1 to 0.6); NS **Arrhythmia and hypertension:** 12 (2.0) vs 9 (1.5); 0.5 (–1.1 to 2.2); NS **Readmissions within 30 days after operation:** 17 (2.9) vs 20 (3.4); –0.5 (–2.6 to 1.6); NS	

Abbreviations: CG = control group, CI = confidence interval, IG = intervention group, LAP = laparoscopic surgery, N = number of patients, NR = not reported, NS = not significant, pts = patients, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, SD = standard deviation, vs = versus, yrs = years.

Nomenclature for GRADE table:

Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

*Gallbladder/**Liver/Spleen (n=8 articles; 6 studies)***

Table A - 10: Robot-assisted surgery vs laparoscopic surgery: Evidence profile for efficacy and safety for gallbladder/liver/spleen

Certainty assessment							**Summary of findings**			
N of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**N of randomised patients**		**Effect**	**Certainty**
							ROB-ASS	**LAP**		
Effectiveness – Patient-relevant outcomes: Robot-assisted surgery vs laparoscopic surgery										
Survival (overall and disease-specific or disease-free)										
2 [54, 60]	RCT	Serious[50]	Not serious	Very serious[51]	Serious	None	81	81	1 RCT: *IG vs CG; n (%); p-value* **Mortality** (short-term, within 7 days): 0 vs 1 (5); NS 1 RCT: *IG vs CG; n (%); p-value* **At 1-yr follow-up:** 52 (85.25) vs 48 (78.69); NS **At 2-yrs follow-up:** 43 (70.49) vs 40 (65.57); NS **At 3-yrs follow-up:** 31 (50.82) vs 26 (42.62); NS	Very Low ⊕◯◯◯

[50] High risk of bias mainly due to no power calculation.

[51] Different indications and differences in follow-up length

Recurrence (local, regional or distant)										
5 [53-59]	RCT	Serious[52]	Not serious	Not serious	Serious[53]	Serious[54]	237	231	1 RCT: Hernia recurrence: 4 (7%) vs 5 (9%); NS; relative risk (95% CI): 0.68 (0.17 to 2.68) 1 RCT: *IG vs CG; data captured; n/N (%); p-value* 12-months postoperative: **Hernia recurrence at 1 y:** 13/38 (34) vs 6/33 (18); 71/75 (95); NS **Clinical recurrence at 1 y:** 5/20 (25) vs 0/17 (NR); 37/75 (49); **p=0.03** **Composite recurrence at 1 y**: 9/38 (24) vs 2/33 (6); 71/75 (95); **p=0.04** (2022) 1 RCT: IG: 2 (11.1); CG: 3 (15.75) (in 24-month-follow-up) 1 RCT: *IG vs CG; n;* p=NS NR (2020) Inguinal hernia recurrence: 2 yrs after surgery: 1 vs 1 (2023) 1 RCT: IG: 0 (0%); CG: 0 (0%); p=NS	Very Low ⊕◯◯◯
Quality of life										
4 [53, 54, 56-59]	RCT	Serious[55]	Not serious	Serious[56]	Serious[57]	Serious[58]	172	172	1 RCT: *median (IQR); p-value* **Measured by Hernia-specific quality of life Survey** 30-days postoperative: IG: 67 (45-79); CG: 75 (41 to 81); NS (2021) *n (95%CI); p-value* 1-y postoperative: IG: 92 (82-100); CG: 77 (49-93); **p=0.04** (2022) 1 RCT: *IG vs CG; mean (SD); p-value* Evaluated with the EORTC QLQ-C30 **30 days after surgery:** Global health: 77.36 (24.06) vs 71.00 (26.15); NS Functional: 78.93 (23.61) vs 73.36 (21.51); NS Symptoms: 23.13 (18.55) vs 29.07 (19.26); NS **2-yrs after surgery:** Global health: 72.07 (22.67) vs 67.69 (26.32); NS Functional: 77.27 (19.85) vs 67.19 (21.40); NS Symptoms: 22.13 (14.72) vs 30 (19.15); NS	Very Low ⊕◯◯◯

									1 RCT: *IG vs CG; mean (SD); p-value* Measured with the SF-36 **1 wk after surgery:** Physical component summary: -6.95 (8.64) vs -6.52 (8.50); NS Mental component summary: 0.00 (7.38) vs 0.80 (7.91); NS General Health: -1.72 (9.57) vs -1.98 (13.4); NS **30 days after surgery:** Physical component summary: -1.98 (8.90) vs -0.59 (8.91); NS Mental component summary: 0.71 (5.84) vs 0.65 (8.29); NS General Health: 1.55 (8.43) vs -2.31 (12.4); NS 1 RCT: *IG vs CG; mean (SD); p-value* **1-yr after surgery:** Physical component summary: 54.9 (7.3) vs 53.7 (8.2); NS Mental component summary: 55.9 (4.6) vs 54.8 (6.0); NS General Health: 82.6 (13.1) vs 76.8 (17.7); NS **2-yrs after surgery:** Physical component summary: 53.1 (8.1) vs 54.2 (6.1); NS Mental component summary: 53.9 (6.8) vs 53.4 (5.6); NS 1 RCT: *IG vs CG; median (IQR); difference in median (95% CI);* p-value Abdominal wall QoL measured by the modified Activity Assessment Scale: 52 (37-68) vs 65 (36-86); 8.25 (–1.75 to 20.00); NS	
Safety – Safety-related outcomes: Robot-assisted surgery vs laparoscopic surgery										
Intraoperative complications										

[52] High risk of bias due to other selective outcome reporting in Prabhu et al. 2020, missing sample size calculation in Costa et al. 2023 and an underpowered study of Dhanani et al. 2021.

[53] No confidence interval reported.

[54] Sponsored by industry (Intuitive).

[55] High risk of bias due to missing sample size calculation in Costa et al. 2023 and selective outcome reporting Prabhu et al. 2020.

[56] Different outcome measures were used.

[57] No confidence interval reported.

[58] Sponsored by industry (intuitive).

1 [53]	RCT	Not Serious	Not Serious	Not Serious	Serious[59]	None	39	39	1 RCT: *IG vs CG; n (%); p-value* **Intraoperative complications (2021):** 2 (6) vs 2 (6); NR Bowel serosal injury: 1 (3) vs 2 (6); NS Liver injury: 1 (3) vs 0; NS	Moderate ⊕⊕⊕◯
Postoperative complications										
6 [53-60]	RCT	Serious[60]	Not serious	Serious[61]	Serious[62]	Serious[63]	298	292	1 RCT: *IG vs CG; n (%); p-value; relative risk (95% CI)* **Wound complication:** 9 (15%) vs 8 (15%); NS; 0.93 (0.32 to 2.74) 1 RCT: *IG vs CG; n (%); p-value* **Postoperative complications (2021):** 2 (6) vs 3 (8); NS Pulmonary embolism 1 (3) vs 0; NS SSO: 0 vs 1 (3); NS Readmission: 1 (3) vs 1 (3); NS 1 RCT: *IG vs CG; n (%); p-value* Complications (short-term, within 7 days): 3 (16.7) vs 2 (10.5); NS 1 RCT: *IG vs CG; n (%); p-value* 30-days after surgery: **Adverse Events:** 8 (16.7) vs 5 (9.3); NS Superficial surgical site infections: 0 (0.00) vs 1 (1.85); NS Purulent drainage from wound: 0 (0.00) vs 1 (1.85); NS Seroma: 6 (12.5) vs 3 (5.6); NS Hematoma: 1 (2.08) vs 0 (0.00); NS Required Intervention: 0 (0.00) vs 1 (1.85); NS Oral Antibiotics: 0 (0.00) vs 1 (1.85); NS Urinary retention: 1 (2.08) vs 1 (1.85); NS	Very Low ⊕◯◯◯

[59] Population <100, no confidence interval reported.

[60] High risk of bias due to missing sample size calculation in Costa et al. 2023, an underpowered study of Dhanani et al. 2021, and selective outcome reporting in Prabhu et al. 2020.

[61] Different indications within studies.

[62] No confidence interval reported.

[63] Sponsored by industry (Intuitive).

									1 RCT: *IG vs CG; n (%); relative rate (95% CI); p-value* **Readmission:** 1 (2) vs 3 (5); 0.27 (0.03 to 2.43); p=NS **Emergency room visits:** 7 (11) vs 5 (9); 1.28 (0.43 to 3.75); p=NS **Wound complication:** 13 (20) vs 11 (19); 1.02 (0.51 to 2.08); p=NS Surgical site infection: 0 (0) vs 1 (2); NR; p=NS Seroma: 13 (20) vs 8 (14); NR; NS Hematoma: 0 (0) vs 2 (3); NR; NS **Clavien-Dindo complication:** 14 (22) vs 11 (19); 1.10 (0.54 to 2.24); NS 1-2: 14 (22) vs 10 (17); NR; NR 3-5: 0 (0) vs 1 (2); NR; NR 1 RCT: *IG vs CG; n (%); p-value* **Total complications**: 2 (3.3) vs 8 (13.1); **p=0.048** Intestinal obstruction: 1 (1.6) vs 2 (3.3); NR Bile leakage: 0 (0.0) vs 2 (3.3); NR Pleural effusion: 1 (1.6) vs 2 (3.3); NR Abdominal haemorrhage: 0 (0.0) vs 1 (1.6); NR Incision infection: 0 (0.0) vs 1 (1.6; NR)	

L Laparoscopic ventral hernia repair
L Laparoscopic ventral hernia repair
L Laparoscopic incisional hernia repair
L Standard laparoscopic transabdominal preperitoneal repair
L Laparoscopic repair
L Laparoscopic hepatectomy

Abbreviations: CG = control group, CI = confidence interval, EORTC QLQ-C30 = European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire, GSRS = Gastrointestinal Symptom Rating Scale, IG = intervention group, IQR = interquartile range, LAP = laparoscopic surgery, N = number of patients, NR = not reported, NS = not significant, QoL = Quality of Life, RCT = randomized controlled trial, ROB-ASS = robotic-assisted surgery, SD = standard deviation, SF-36 = 36-Item Short Form Health Survey, vs = versus, wk = week, yr = year, yrs = years.

Nomenclature for GRADE table:
Limitations: 0: no limitations or no serious limitations; -1: serious limitations
Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency
Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty
Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

9.2. Applicability tables

Table A - 11: Thoracic surgery: lobectomy and mediastinal surgery

Domain	Description of applicability of evidence
Population	**(i) Lung Lobectomy:** All thoracic surgery procedures included in this HTA were performed due to NSCLC or lung lesions. Four RCTs were identified: (n= 677; IG: 338 vs CG: 339). **(il) Mediastinal surgery:** No further studies concerning mediastinal surgery could be identified.
Intervention	(i) Studies used robot-assisted lobectomy or robotic-assisted thoracic surgery if reported, with the da Vinci system.
Comparators	(i) Video-assisted thoracic surgery, video-assisted lobectomy, as well as thoracotomy, were the control procedures for the lobectomy studies.
Outcomes	(i) Studies investigated differences in overall survival, postoperative or perioperative complications, as well as duration of surgery and length of hospital stay between study groups.
Setting	(i) The studies were conducted in China, Italy, the USA, or Brazil. Studies were published from 2019 to 2023. Surgeon experience varied from >30 major lung resections to >100 robotic-assisted procedures before the intervention.

Abbreviations: CG = control group, HTA = Health Technology Assessment, IG = intervention group, n = number of patients, RCT = randomised controlled trial.

Table A - 12: Visceral surgery: Oesophagus

Domain	Description of applicability of evidence
Population	**(i) Antireflux/fundoplication**: patients had gastro-oesophageal reflux disease in one RCT (n=40; IG:20 vs CG: 20). **(ii) Oesophagectomy**: patients (n=40; IG:20 vs CG: 20) had carcinoma in two RCTs. **(iii) Heller myotomy:** No further studies concerning heller myotomy could be identified.
Intervention	(i) Robotic-assisted laparoscopic fundoplication was used in the anti-reflux/fundoplication studies with da Vinci Surgical System. (ii) Robotic-assisted minimally invasive oesophagectomy was applied in the RCTs, using, if reported, the da Vinci Surgical System.
Comparators	(i) Conventional laparoscopic fundoplication was the control procedure in fundoplication. (ii) Open transthoracic oesophagectomy or conventional minimally invasive oesophagectomy were the comparators.
Outcomes	(i) The study assessed the quality of life and reflux-specific symptoms. (ii) The studies investigated overall disease-free survival or overall survival as well as perioperative outcomes
Setting	(i) The study, which was conducted in Germany, was published in 2022. A surgeon had performed >30 surgeries before the intervention. (ii) The studies were carried out in China and the Netherlands and published in 2020 and 2022. Surgeons performed either ≥50 procedures before or >40 procedures annually.

Abbreviations: CG = control group, IG = intervention group, n = number of patients, RCT = randomised controlled trial.

Table A - 13: Visceral surgery: Stomach

Domain	Description of applicability of evidence
Population	**(i) Gastrectomy:** Gastric cancer patients (n=606; IG: 302 vs CG: 304) were included in three gastrectomy studies. **(ii) Bariatric Surgery/ gastric bypass:** No further RCTs concerning bariatric surgery or gastric bypass could be identified.
Intervention	(i) All robotic-assisted procedures (robotic (distal) gastrectomy) were done using the da Vinci Surgical Systems.
Comparators	(i) For the gastrectomy studies, one used laparoscopic gastrectomy whilst the other used open gastrectomy as a comparator.
Outcomes	(i) Endpoints were defined as three-years disease-free survival as well as short-term clinical outcomes, surgical outcomes, and postoperative outcomes.
Setting	(i) The studies were performed in China, Japan, and Brazil with a publication date from 2021 to 2022. If reported, surgeons had >50 robotic-assisted procedures before the intervention or were certified as console surgeons in the da Vinci platform.

Abbreviations: CG = control group, IG = intervention group, n = number of patients, RCTs = randomised controlled trials.

Table A - 14: Visceral surgery: Bowel

Domain	Description of applicability of evidence
Population	**(i) Small bowel resection:** No RCT concerning small bowel resection could be identified. **(ii) Colectomy**: Patients (n=198; IG: 78 vs CG: 120) with cancer or benign colonic pathologies or right-sided colon cancer were included in two RCTs. **(iii) Rectal resection**: In two studies, patients with (low) rectal cancer (n=1,589; IG: 794 vs CG: 793) were included. **(iv) Ventral mesh rectopexy**: In patients (n=30; IG: 16 vs CG: 14) with external rectal prolapse or internal rectal prolapse with or without the descent of middle pelvic compartment ventral mesh rectopexy was done.
Intervention	(ii) Robotic colectomy was the procedure in the intervention group. (iii) Robot-assisted laparoscopic rectal cancer resection was used with the da Vinci system in the studies. (iv) Robot-assisted ventral mesh rectopexy was used with the da Vinci system in the study.
Comparators	(ii) Laparoscopically assisted colectomy was the comparator for colectomy procedures. (iii) Laparoscopic rectal resection was the control procedure in rectal resection. (iv) Laparoscopic ventral mesh rectopexy was compared with the robotic procedure.
Outcomes	(ii) The studies investigated the length of hospital stay and morbidity, as well as operation time and disease-free survival. (iii) Endpoints were defined as either postoperative complications or pathological outcomes as well as recurrence. (iv) Endpoints were defined as maintenance of the repaired pelvic anatomy five years after surgery and quality of life.
Setting	(ii) Two studies, which were published in 2019 and 2022, were performed in France and South Korea. If reported, surgeons had performed at least 30 robotic procedures before the intervention. (iii) The studies were published in 2022 and conducted in China. The surgeon experience was either >50 procedures before the intervention or >100. (iv) The follow-ups of the study, which was conducted in Finland, were published in 2019 and 2020. There was no information concerning surgeon experience.

Abbreviations: CG = control group, IG = intervention group, n = number of patients, RCT(s) = randomised controlled trial(s).

Table A - 15: Visceral surgery: Gallbladder/Liver/Spleen

Domain	Description of applicability of evidence
Population	**(i) Cholecystectomy:** No further RCTs concerning cholecystectomy could be identified. **(ii) Hernia repair**: patients (n=471; IG: 237 vs CG: 231[1]) recommended for hernia repair **(iii) Liver resection**: patients (n=122; IG:61 vs CG: 61) with synchronous colorectal liver metastases
Intervention	(ii) Robotic ventral hernia repair/ robotic-assisted incisional hernia repair/ robotic transabdominal preperitoneal repair (using the da Vinci Surgical System if reported) was the intervention procedure. (iii) Robot-assisted laparoscopic hepatectomy/liver resection was used with the da Vinci Surgical System in the study.
Comparators	(ii) Laparoscopic (incisional/ventral hernia) repair/ standard laparoscopic transabdominal preperitoneal repair were the comparators. (iii) Laparoscopic hepatectomy was the control procedure.
Outcomes	(ii) Reported outcomes were complications, hernia recurrence, as well as pain and quality of life. (iii) Endpoints were clinical manifestations, like operation time and blood loss, as well as survival and complications.
Setting	(ii) The study, which was published in 2020 took place in China, and there was no information given about surgeon experience. (iii) Studies were conducted in the USA and Brazil, and surgeon experience varied from >25 to <50 procedures before the study, if reported. Studies were published between 2020 and 2023.

Abbreviations: CG = control group, IG = intervention group, n = number of patients, RCTs = randomised controlled trials.

[1] There is an error in the CONSORT flow diagram in one RCT [53] as 39+39=78

9.3. Extraction tables

Table A - 16: Extraction tables Lung Lobectomy

Lung Lobectomy		
	Lung Lobectomy	**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**	**Veronesi et al. 2021 [38]**
Study characteristics		
Study design, indication	Single-centre, open-labelled, parallel-arm, noninferiority RCT of patients with NSCLC	Prospective, randomised, multi-centre study of patients with NSCLC
Country	China	Italy, USA
Funding/Sponsor	National Natural Science Foundation of China (81871882, 82072557), Robotic Research Grant from Intuitive Surgical, Inc, Shanghai Municipal Education Commission-Gaofeng Clinical Medicine Grant Support (20172005), and Outstanding Academic Leader of Shanghai (20XD1402300).	Umberto Veronesi Foundation (Milan, Italy) and Intuitive Surgical Inc. (Sunnyvale, CA, USA)
Intervention (IG) | Product	Robotic-assisted lobectomy | da Vinci S/Si	Robotic-assisted lobectomy | da Vinci Robotic System
Comparator (CG)	Video-assisted lobectomy	Video-assisted thoracic surgery
Experience of surgeon(s); time period	Surgeries were performed by the same surgical group headed by 1 experienced surgeon (>100 procedures by each approach before initiation of this study); May 2017- May 2020 (randomisation)	>30 major lung resections performed using one or each of the two techniques; April 2017 to November 2018 (eligibility screening)
Number of randomised patients	363; IG: 181; CG: 182 (2022)	77; IG: 38; CG: 39
Inclusion criteria	• 18-80 yrs • Satisfactory preoperative laboratory testing • Adequate pulmonary function • ASA Score of I to III	• >18 yrs • Known or suspected NSCLC (In case of suspected lung cancer with no preoperative diagnosis, frozen section was indicated during surgery to confirm the disease. If a benign lesion was diagnosed, the patient was considered a dropout of the study.) • pts in clinical stage T1–T2–T3, N0–N1, candidate for lobectomy, anatomical segmentectomy, or bilobectomy • pts with multiple lung tumours could be included if they could be resected with a lobectomy, lobectomy plus segmentectomy, or bilobectomy and each tumour should be staged separately

Lung Lobectomy		
	Lung Lobectomy	**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**	**Veronesi et al. 2021 [38]**
		• ASA Score 1-3
Primary/secondary endpoints	• Primary: 3-yrs overall survival rate, extent of LN dissection • Secondary: 3-y disease-free survival, R0 resection rate, duration of surgery, intraoperative blood loss, the conversion rate, postoperative hospital stay, the incidence of postoperative adverse events, and medical costs	• Primary: rate of conversions, bleeding, and perioperative complications (assessed by modified Clavien-Dindo scale) • Secondary: duration of surgery, number of resected LNs, number of dissected LN stations, postoperative hospital stay, postoperative pain with daily evaluation, quality of life by EORTC QoL-C30, postoperative respiratory function, and rate of local or distant recurrence at 2 yrs
Follow-up (months)	Every 6 months until the patient death or the completion of the study	2 yrs
Dropouts (n (%))	43 before or during surgery IG: 24 (13.3); CG: 19 (10.4) (2022) IG: 50 (27.6); CG: 48 (26.4)[1] at 48-wk follow-up (2023)	After the intention-to-treat analysis IG: 3; CG: 2
Patient characteristics		
Age of patients (yrs., mean)	*median (IQR);* p=NS IG: 61 (54-66); CG: 62 (53-68)	*mean±SD; p-value*; p=NS IG: 69±8.7; CG: 68±7.4[2]
Sex (% female)	IG: 48.4; CG: 53.4; NS	IG: 43; CG: 41; NS
BMI (kg/m^2, mean)	*median (IQR)*; **p=0.05** IG: 23.4 (21.7-25.6); CG: 22.9 (21.4-24.4)	*mean±SD; p-value* IG: 27±4.1; CG: 26±4.2; NS
Clinical classification	T Stage (IG vs CG; n (%); p=NS I: 137 (87.3) vs 141 (86.5) II: 17 (10.8) vs 20 (12.3) III: 1 (0.6) vs 1 (6.1) IV: 2 (1.3) vs 1 (6.1) N Stage (IG vs CG; n (%); p=NS 0: 138 (87.9) vs 146 (89.6) I: 8 (5.1) vs 6 (3.7) II: 11 (7.0) vs 11 (6.7) TNM Stage (IG vs CG; n (%); p=NS Ia: 123 (78.3) vs 127 (77.9)	ASA Score (IG vs CG; n (%); p=NS I-II: 18 (56) vs 24 (65) III: 14 (44) vs 13 (35) Clinical Stage (IG vs CG; n (%); p=NS Ia: 27 (77) vs 25 (71) Ib: 6 (17) vs 7 (20) IIa: 2 (6) vs 1 (3) IIb: 0 (0) vs 2 (6)

[1] Discrepancies could be observed in Jin 2022 and Jin 2023 [37, 40] regarding the randomised patients of the control group.

[2] Discrepancies in patient characteristics between Table 1 in the publication and Table S1 in the Supplements could be observed. Data extracted from Supplements.

Lung Lobectomy		
	Lung Lobectomy	**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**	**Veronesi et al. 2021 [38]**
	Ib: 11 (7.0) vs 12 (7.4) IIa: 1 (0.6) vs 5 (3.1) IIb: 9 (5.7) vs 7 (4.3) IIIa: 13 (8.3) vs 12 (7.4)	
Patient-relevant outcomes		
Survival (overall and disease-specific or disease-free)	NR (2022) Deaths 48-wks postoperatively: IG: 7; CG: 14 (2023)	NR
Recurrence (local, regional or distant)	NR (2022) 48-wks postoperatively: IG:6; CG:5 (2023)	NR (study authors state that longer follow-up is required)
Quality of life (e.g. measured by EQ-5D or SF-36)	NR (2022) Mean difference (95% CI) (2023) 4 wk 0.002 (–0.008~0.012) 24 wk 0.003 (–0.004~0.010) 48 wk 0.004 (–0.002~0.011)	NR (study authors state that longer follow-up is required)
Time to resume work/daily activities	NR	NR
Patient satisfaction	NR	NR
Safety-related outcomes		
Intraoperative complications (e.g. air-leakage)	NR	NR
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* **Postoperative complications:** 23 (14.6) vs 30 (18.4); NS **Clavien Dindo I-II:** 18 (11.5) vs 24 (14.7); NS Pleural effusion: 8 (5.1) vs 12 (7.4); NS Pneumoni: 4 (2.5) vs 1 (0.6); NS Prolonged air leak: 9 (5.7) vs 7 (4.3); NS Recurrent air leak: 0 vs 1 (0.6); NS	*IG vs CG; n (%); p-value* **Early postoperative complications[3]:** 13 (37) vs 9 (24); NS Air leak: 6 (17) vs 4 (11); NS Atrial Fibrillation: 4 (11) vs 3 (9); NS Serious drainage: 1 (3) vs 1 (3); NS Pneumonia: 4 (11) vs 1 (3); NS Pneumothorax: 0 (0) vs 1 (3); NS Atelectasis: 3 (9) vs 1 (3); NS

[3] Discrepancies in postoperative complications between Table 1 in the publication and Table S1 in the Supplements could be observed. Data extracted from Supplements.

Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
	Haemorrhage: 1 (0.6) vs 1 (0.6); NS Atrial fibrillation: 0 vs 1 (0.6); NS Ischemic stroke: 0 vs 1 (0.6); NS Hypoxemia: 0 vs 1 (0.6); NS **Clavien Dindo III-IV:** 5 (3.2) vs 6 (3.7); NS Pleural effusion: 2 (1.3) vs 2 (1.2); NS Pneumonia: 0 vs 1 (0.6), NS Prolonged air leak: 0 vs 3 (1.8); NS Recurrent air leak: 1 (0.6) vs 1 (0.6); NS Haemorrhage: 1 (0.6) vs 1 (0.6); NS Ischemic stroke: 2 (1.3) vs 0; NS **Readmission:** 3 (1.9) vs 3 (1.8); NS		Urinary tract infection: 1 (3) vs 0 (0); NS Other Complication: 3 (9) vs 2 (5); NS **Readmissions:** 4 (16) vs 0 (0); NS **Later Complication:** 5(23) vs 2 (11); NS
Reoperations/additional surgeries	NR		NR
Conversion	*IG vs CG; n (%); p-value* Conversion to thoracotomy: 7 (4.5) 9 (5.5); NS		*IG vs CG; n (%); p-value* Conversion to open surgery: 3 (9) vs 1 (3); NS
Perioperative events & resource use			
Blood loss (in ml)	*IG vs CG, median (IQR); p-value* 100 (50–100) vs 100 (50–150); **p= 0.04**		NR
Operation time in min.	*IG vs CG, median (IQR), p-value* 110 (95–140) vs 120 (97.5–150); NS		*IG vs CG, mean±SD, p-value* 179±54.2 vs 183±40.9; NS
Transfusions	*IG vs CG, no. (%), p-value* Intraoperative blood transfusion: 3 (1.9) vs 2 (1.2); NS		NR
Drain duration (days)	*IG vs CG [mL], median (IQR); p-value* Chest tube drainage: 830 (550–1,130) vs 685 (367.5–1,160) **p=0.007**		NR
Length of hospital stay (days)	*IG vs CG, median (IQR); p-value* 4 (4–5) vs 5 (4–5); NS		IG vs CG, median (IQR); p-value 5 (4-8) vs 4 (3-6); NS
Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Huang et al. 2019 [31]**	**Huang et al. 2021 [32]**	**Terra et al. 2022 [39]**

Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
Study characteristics			
Study design, indication	Noninferiority, phase 3, multi-centre RCT of patients with single cN2 stage NSCLC		Two-arm randomised clinical trial of patients with lung lesions
Country	China		Brazil
Funding/Sponsor	Shanghai Hospital Development Center, National Natural Science Foundation of China		The Brazilian Ministry of Health
Intervention (IG) | Product	Robot-assisted thoracoscopic surgery | da Vinci Surgical System		Robotic-assisted thoracic surgery| da Vinci Si
Comparator (CG)	Thoracotomy		Video-assisted thoracic surgery
Experience of surgeon(s); time period	NR; January 2016 to December 2018 (trial performance)	NR; January 2016 to July 2020 (enrollment)	NR; April 2015 to June 2017 (trial length)
Number of randomised patients	113; IG: 58; CG:55	159; IG: 79; CG: 78	80; IG: 40; CG: 40
Inclusion criteria	• 18-75 yrs • Clinically diagnosed cN2 NSCLC according to American Joint Committee on Cancer Tumor-Node-Metastasis classification exhibited as a suspicious pulmonary lesion with enlarged mediastinal LN • Adequate organ function to tolerate pulmonary resection		• Eligibility or the treatment of lung cancer or lung metastasis by pulmonary lobectomy • presence of a tumour of less than 5 cm in diameter • absence of tumour invasion into the chest wall, diaphragm, mediastinum, or another lung lobe • clinical and anaesthetic evaluation results showing that the patient was able to undergo the proposed procedure
Primary/secondary endpoints	• operative time, intraoperative blood loss, chest tube duration, drainage at postoperative day one and total drainage, length of hospital day, death (within 28 days), complications, visual analogue score at postoperative day one to five, overall cost, pathological variables	• primary: disease-free survival, overall survival • secondary: operative duration, blood loss volume, drainage duration, total drainage volume, length of stay, overall cost, pain visual analogue scale score (postoperative days 1-5), postoperative complications	• primary: complication rate within 90 days, postoperative complications • secondary: intraoperative complications, drainage time, length of hospital stay, postoperative pain, postoperative QoL and readmissions within 90 days
Follow-up (months)	Only 28 days of follow-up reported	2 yrs after surgery (3-month intervals) Thereafter 6 months intervals	90 days after surgery

Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
	2 yrs after surgery (3-month intervals) (NR) 5 yrs after surgery (6-month intervals) (NR)		
Dropouts (n (%))	None	After randomisation: IG: 3 (3.8%); CG: 6 (7.7%)	After randomisation: IG: 3 (7.5%); CG: 1 (2.5%) At 90-day follow-up: IG: 1 (2.5%); CG: 1 (2.5%)
Patient characteristics			
Age of patients (yrs., mean)	*IG vs CG; mean (±SD); p-value*		*IG vs CG; median (95% CI);* p=NS
	61.9 (±9.0) vs 60.6 (±7.4); NS	60.9 (±9.4) vs 61.0 (±7.6); NS	68.4 (65.2-71.5) vs 65.7 (61.8-69.5)
Sex (% female)	*IG vs CG; %; p-value*		IG: 54%; CG: 56.4%; NS
	29.3% vs 29.1%; NS	32.9% vs 29.2%; NS	
BMI (kg/m^2, mean)	NR		IG vs CG; median (95% CI); p=NS 27.5 (26.2-28.8) vs 26.5 (24.9-28.1)
Clinical classification	*IG vs CG; n (%) ; p-value*		NR
	Pathologic stage: IA: 10 (17.3) vs 10 (18.2); NS IB: 8 (13.8) vs 5 (9.0); NS IIA: 4 (7.0) vs 2 (3.7); NS IIB: 14 (24.1) vs 10 (18.2); NS IIIA: 14 (24.1) vs 19 (34.6); NS IIIB: 6 (10.3) vs 7 (12.8); NS IV: 2 (3.4) vs 2 (3.5); NS	Pathological TNM stage: I: 24 (31.6) 21 vs (29.2); NS II: 24 (31.6) vs 17 (23.6); NS III: 27 (35.5) vs 33 (45.8); NS IV: 1 (1.3) vs 1 (1.4); NS	
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	Mortality within 28 days after surgery: IG: 1 (1.7); CG: 0 (0); NS	*IG vs CG; %; p-value* Disease-free survival: 1 yr: 90.4 vs 86.0; NS 2 yrs: 76.4 vs 74.2; NS 3 yrs: 57.5 vs 49.9; NS Overall survival:	Mortality within 90 days after surgery: IG 1 (2.7); CG: 1 (2.5); NS

Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
		1 yr: 97.2 vs 97.0; NS 2 yrs: 94.2 vs 93.2; NS 3 yrs: 84.6 vs 74.9; NS	
Recurrence (local, regional or distant)	NR		NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR		NR
Time to resume work/daily activities	NR		NR
Patient satisfaction	NR		NR
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR		Intraoperative complications: IG: 0; CG: 3; p=NS (2 arterial lacerations and 1 venous injury)
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value*		*IG vs CG; n (%); p-value*
	Complications within 28 days after surgery: Any complications: 16 (27.6) vs 21 (38.2); NS Pulmonary embolism: 1 (1.7) vs 0 (0); NS Bronchopleural fistula: 3 (5.2) vs 1 (1.8); NS Oesophagus fistula: 0 (0) vs 1 (1.8); NS Acute respiratory distress syndrome: 0 (0) vs 1 (1.8); NS Pneumonia: 3 (5.2) vs 6 (10.9); NS Prolonged air leak: 4 (6.9) vs 6 (10.9); NS Atrial arrhythmia: 2 (3.4) vs 3 (5.5); NS	Prolonged air leak: 6 (7.9) vs 6 (8.3); NS Bronchopleural fistula: 4 (5.3) vs 1 (1.4); NS Pneumonia: 3 (3.9) vs 6 (8.3); NS Atrial fibrillation: 3 (3.9) vs 4 (5.6); NS Atrial arrhythmia: 3 (3.9) vs 4 (5.6); NS Chest tube reinsertion: 3 (3.9) vs 4 (5.6); NS Subcutaneous emphysema: 3 (3.9) vs 2 (2.8); NS Chylothorax: 3 (3.9) vs 2 (2.8); NS Hyperpyrexia: 2 (2.6) vs 6 (8.3); NS Haemorrhage: 2 (2.6) vs 1 (1.4); NS	**Complications within 90 days:** 7 (18.9) vs 14 (35.9); NS **≥3 complications within 90 days:** 7 (18.9) vs 10 (25.6); NS **Readmissions within 90 days:** 1 (2.7) vs 8 (20.5); **p=0.029**

Lung Lobectomy			
	Lung Lobectomy		**Lung Lobectomy**
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
	Chest tube reinsertion: 2 (3.4) vs 3 (5.5); NS Chylothorax: 3 (5.2) vs 0 (0); NS Recurrent nerve injury: 1 (1.7) vs 4 (7.3); NS Others: 1 (1.7) vs 2 (3.6); NS	Recurrent laryngeal nerve injury: 1 (1.3) vs 4 (5.6); NS Pulmonary embolism: 1 (1.3) vs 0; NS Pyothorax: 0 vs 1 (1.4); NS Acute respiratory distress symptom: 0 vs 1 (1.4); NS	
Reoperations/additional surgeries	*IG vs CG; n (%);* p-value Haemorrhage required reoperation (within 28 days): 1 (1.7) vs 1 (1.8); NS		*IG vs CG; n (%); p-value* 1 (2.7) vs 2 (5.1); NS
Conversion	Conversion to open surgery: IG: 5 (8.6%); CG: 0	Conversion to video-assisted thoracic surgery: IG: 1 (1.3%); CG:0	Conversion to open surgery: IG: 0; CG: 2; NS
Perioperative events & resource use			
Blood loss (in ml)	*IG vs CG; mean (±SD); p-value* 86.3 (±41.1) vs 165.7 (±46.4); **p<0.001**	*IG vs CG; n (%); p-value* <100ml: 65 (85.5) vs 16 (22.2); **p<0.001** ≥100ml: 11 (14.5) vs 56 (77.8); **p<0.001**	NR
Operation time in min.	*IG vs CG; mean (±SD); p-value*		*IG vs CG; median (95% CI); p-value* 241.7 (218.3-265.1) vs 214.4 (200.3-228.5); NS
	108 (±39) vs 103 (±30); NS	104.2 (±41.0) vs 102.3 (±29.2); NS	
Transfusions	NR		IG: 0; CG: 0; p=NR
Drain duration (days)	*IG vs CG; mean in mL (range); p-value* 1 day postoperative: 300 (95–840) vs 320 (50–970); NS Total drainage: 820 (220–2,460) vs 960 (320–4,630); p=0.05	*IG vs CG; median (IQR); p-value* Drainage duration (days): 4.0 (3.3–5.0) vs 5.0 (4.0–7.0); **p=0.002** Total drainage volume: (ml) 855.0 (602.5–1,167.5) vs 920.0 (592.5–1,646.3); NS	*IG vs CG; median (IQR); p-value* Chest tube : 2 (1-2) vs 2 (1-4); NS
Length of hospital stay (days)	*IG vs CG; mean (range); p-value*	*IG vs CG; median (IQR); p-value*	*IG vs CG; median (IQR); p-value*

Lung Lobectomy			
	Lung Lobectomy		Lung Lobectomy
Author, year [reference number]	**Jin et al. 2022 & 2023 [37, 40]**		**Veronesi et al. 2021 [38]**
	10 (7-31) vs 11 (6-44); NS	10.0 (8.0–13.0) vs 11.0 (9.0–14.8); p=0.054	3 (2-4) vs 4 (2-5); NS

Table A - 17: Extraction tables Oesophagus

Oesophagus			
	Antireflux/Fundoplication	**Antireflux/Fundoplication**	**Antireflux/Fundoplication**
Author, year [reference number]	**Lang et al. 2022 [41]**	**Draaisma et al. 2006 [79]**	**Morino et al. 2006 [82]**
Study characteristics			
Study design, indication	Randomised controlled trial of patients with gastroesophageal reflux disease	Single-centre RCT of patients with GORD	Single-centre RCT of patients with GORD
Country	Germany	The Netherlands	Italy
Funding/Sponsor	Projekt DEAL	NR	NR
Intervention (IG) | Product	Robotic-assisted laparoscopic fundoplication | da Vinci Surgical System	robot-assisted laparoscopic Nissen fundoplication | da Vinci Robotic System	Robot-assisted fundoplication | da Vinci system
Comparator (CG)	Conventional laparoscopic fundoplication	Laparoscopic-assisted laparoscopic Nissen fundoplication	Traditional laparoscopic fundoplication
Experience of surgeon(s); time period	Robotic-assisted / Conventional laparoscopy: >30 surgeries before;-August 2004 to December 2005 (randomisation)	Surgeons had performed more than 30 laparoscopic Nissen fundoplications and more than 20 robot-assisted laparoscopic procedures. Operations were performed from January 2003-October 2005	3 surgeons all proficient in laparoscopic procedures Operations were performed in February 2002-February 2004
Number of randomised patients	40; IG: 20; CG: 20	IG: 25 CG: 25	IG:25 CG:25
Inclusion criteria	• >18 yrs • History of gastroesophageal reflux disease requiring an acid suppressive therapy within proton pump inhibitor for at least 3 months during the preceding year • Disease was initially diagnosed by the presence of endoscopic oesophagitis or by severe	Inclusion: • Age >18 • Diagnosed with GORD via upper endoscopy, barium oesophagram series, oesophageal manometry, 24-hr pH monitoring Exclusion:	Inclusion: • Clinical GORD that necessitated surgery according to the criteria of Hinder et al. • ASA score I-II Exclusion: • Giant hiatal hernia (larger than 6 cm on preoperative barium meal)

Oesophagus			
	Antireflux/Fundoplication	**Antireflux/Fundoplication**	**Antireflux/Fundoplication**
Author, year [reference number]	**Lang et al. 2022 [41]**	**Draaisma et al. 2006 [79]**	**Morino et al. 2006 [82]**
	clinical symptoms, which resolved with PPI therapy (positive PPI test) and was confirmed by gastrointestinal endoscopy, barium swallow and 24-h pH monitoring	• General contraindications for laparoscopy, psychiatric illness, previous abdominal surgery • 12 patients were excluded before randomisation	• ASA score III–IV • Previous upper abdominal surgery • Contraindications to pneumoperitoneum
Primary/secondary endpoints	• QoL and reflux-specific symptoms	• Primary endpoints: (nadir) end-expiratory LOS pressure, total oesophageal acid exposure time, symptom index, symptom association probability • Secondary endpoints: general health state (10-point VAS 0-100); QoL (Visick scale); self-rated reflux symptoms (instrument NR); satisfaction with the outcome (instrument NR);	• Primary endpoint: In-hospital cost of the procedure • Secondary endpoints were skin-to-skin and total operating time
Follow-up (months)	12 yrs	3-6	Ø 22.3 (R 6-32)
Drop-outs (n (%))	IG: 5 (25%); CG: 5 (25%)	IG: 2/25 (8%) CG: 0	none
Patient characteristics[4]			
Age of patients (yrs., mean)	*IG vs CG; mean ± SD (range);* p=NS 49.6 ± 12.0 (23–71) vs 50.5 ± 12.4 (25–75)	IG: M 48 (R 20-74) CG: M 52 (R 27-71), p=NS	IG: Ø 43.0 ±12.8 CG: Ø 46.3 ±11.3, p=NS
Sex (% female)	IG: 50%; CG: 60%; p=NS	IG: 36% CG: 32%, p=NR	IG: 24% CG: 28%, p=ns
BMI (kg/m^2, mean)	*IG vs CG; mean ± SD (range);* p=NS 29.2 ± 5.83 (21–40) vs 26.2 ± 3.4 (19–31)	IG: M 25.6 (R 19.1-37.2) CG: M 28.7 (R 19.5-46.6), p=ns	IG: Ø 25.5 ±2.9 CG: Ø 26.1 ±2.3, p=ns
Clinical classification	Oesophagitis; p=NS Los Angeles A: IG:9; CG:11 Los Angeles B: IG: 10; CG: 7 Los Angeles C: IG: 1; CG: 2 Los Angeles D: IG: 0; CG: 0 Gastrointestinal symptom rating scale; p=NS	Los Angeles classification of oesophagitis (IG vs.CG) Grade A: 24% vs. 20% Grade B: 28% vs. 24% Grade C: 12% vs. 0 Grade D: 8% vs. 4% No oesophagitis: 24% vs. 32% Unknown: 4% vs. 20%	NR

[4] Patient characteristics taken from preciously published study (Müller-Stich 2007 [80]).

Oesophagus			
	Antireflux/Fundoplication	**Antireflux/Fundoplication**	**Antireflux/Fundoplication**
Author, year [reference number]	**Lang et al. 2022 [41]**	**Draaisma et al. 2006 [79]**	**Morino et al. 2006 [82]**
	IG: 4.0 ± 1.7 (2–7); CG: 4.4 ± 1.5 (2–7)		
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	NR	NR	NR
Recurrence (local, regional or distant)	IG vs CG; n (%); p=NR **Failure of treatment:** Oesophagitis ≥LA-B: 1 (8) vs 1 (8) GSRS reflux score ≥3: 3 (25) vs 2 (17) Daily PPI for reflux: 4 (31) vs 4 (33) Dysphagia combined with reflux score ≥2: 1 (8) vs 1 (8)	IG: 1/25 (4%) hiatal hernia CG: 3/25 (12%) hiatal hernia, p=NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	*IG vs CG; mean ± SD (range);* p=NS Quality of life in reflux and dyspepsia: Emotional distress: 6.4 ± 1.4 (1.2–7.0) vs 6.5 ± 1.6 (1.0–7.0) Food/drink problems: 6.5 ± 0.9 (3.5–7.0) vs 6.3 ± 1.6 (1.0–7.0) Physical/social functioning: 6.6 ± 1.0 (2.8–7.0) vs 6.4 ± 1.6 (1.0–7.0) Sleep disturbance: 6.4 ± 1.3 (2.2–7.0) vs 6.5 ± 1.5 (1.0–7.0) Vitality: 6.3 ± 1.4 (1.3–7.0) vs 6.3 ± 1.6 (1.0–7.0)	General quality of life IG vs CG @ 6 months after surgery, NR $CI_{95\%}$ [-18.1;9.2], p=NS[5] : IG: M 22.5 (R 12-99) vs. M 72.0 (R21-98) CG: M 32.5 (R 0-96) vs. M 76.0 (R 26-100) Self-rated change in reflux symptoms compared with the preoperative state (IG vs CG): Resolved: 14/25 (56%) vs. 15 (60%), p=NS Improved: 9/25 (36%) vs. 9/26 (36%), p=NS Unchanged: 1/25 (4%) vs. 0, p=NS Worsened: 1/25 (4%) vs 1/25 (4%), p=NS Self-rated change in general quality of life compared with the preoperative state (IG vs. CG): Improved: 22/25 (88%) vs. 20/25 (80%), p=NS Unchanged: 0 vs. 3/25 (12%), p=NS Worsened: 3/25 (12%) vs. 2/25 (8%), p=NS	Symptoms at 1 month (IG vs. CG), p=NR Mild transient dysphagia: 3/25 (12%) vs. 3/25 (12%), at 6 months, p=NR Oesophagitis: 0 vs. 0 Authors report that no clinical differences between the two groups were found using the GORD-HRQOL at 3, 6 and 12 months.
Time to resume work/daily activities	NR	NR	NR
Patient satisfaction	NR	IG: 23/25 (92%) CG: 22/25 (88%)	NR

[5] No summary statistic reported, only that the CI relates to CG vs. IG 6 months after surgery

Oesophagus			
	Antireflux/Fundoplication	**Antireflux/Fundoplication**	**Antireflux/Fundoplication**
Author, year [reference number]	**Lang et al. 2022 [41]**	**Draaisma et al. 2006 [79]**	**Morino et al. 2006 [82]**
		p=NS, $CI_{95\%}$ [-0.13.0.21][1]	
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR	Minor complications (IG vs. CG) p=NR: • Liver capsule tear: 2/25 (8%) vs. 4/25 (16%) • Spleen capsule tear: 0 vs. 2/25 (8%) • Pneumothorax: 0 vs. 1/25 (4%) Minor bleeding: 2/25 (8%) vs. 0	IG: 0 CG: 0
Postoperative complications (e.g. infections)	NR	IG vs. CG, p=NR: Pneumonia: 0 vs. 1/25 (4%) Urinary tract infection: 0 vs. 1/25 (4%)	IG: 0 CG: 0
Reoperations/additional surgeries	*IG vs CG; n (%);* n=NR Reoperation for reflux 0 (0) vs 0 (0)	at 6 months FU, p=NR: IG: 2/25 (8%), because of dysphagia and an incisional hernia CG: 2/25 (8%), because of dysphagia	NR
Conversion	NR	IG: 0 CG: 2/25 (8%), p=NR	IG: 1/25 (4%) because of difficulty in pursuing the dissection by robotic techniques with a prolonged operating time. CG: 0, p=NR
Perioperative events & resource use			
Blood loss (in ml)	NR	IG: M 20 (R 0-200) CG: M 45 (R 0-200) Mean Difference 25; $CI_{95\%}$[-58.2;8.9], p=NS	NR
Operation time in min.	*IG vs CG; mean ± standard deviation (range); p-value* ***Total operative time[6]:*** 88 ± 18 (60–150) vs 102 ± 19 (75–152) **p=0.033**	IG: M 120 (R 80-180) CG: M 95 (R 60-210) Mean Difference 25, CI95%[-6.0;32.0]	IG: Ø 131.3 ±18.3 CG: Ø 91.1 ± 10.6, p<0.001
Transfusions	NR	NR	NR
Drain duration (days)	NR	NR	NR

[6] Taken from Müller-Stich 2007 [80].

Oesophagus			
	Antireflux/Fundoplication	**Antireflux/Fundoplication**	**Antireflux/Fundoplication**
Author, year [reference number]	**Lang et al. 2022 [41]**	**Draaisma et al. 2006 [79]**	**Morino et al. 2006 [82]**
Length of hospital stay (days)	*IG vs CG; mean ± standard deviation (range); p-value* 1,710 ± 488 (600–2,400) vs 1,980 ± 481 (1,200–3,000); NS	IG: M 3 (R 2-6) CG: M 3 (R 1-13), p=NR	IG: Ø 2.9 (R 2-6) CG: Ø 3.0 (R 2-7), p=NS

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
Study characteristics			
Study design, indication	Single-centre randomised controlled trial of patients with intrathoracic oesophagal cancer	Prospective, multicentre, randomised, controlled clinical trial of patients with oesophagal squamous cell carcinoma	Single centre RCT
Country	The Netherlands	China	Netherlands
Funding/Sponsor	NR	Shanghai Hospital Development Center	None (but affiliations to Intuitive Surgical Inc.)
Intervention (IG) | Product	Robot-assisted minimally invasive oesophagectomy | NR	Robot-assisted minimally invasive oesophagectomy | da Vinci	Robot-assisted minimally invasive thoracolaparoscopic oesophagectomy | da Vinci Robotic System
Comparator (CG)	Open transthoracic oesophagectomy	Conventional minimally invasive oesophagectomy	Open transthoracic oesophagectomy
Experience of surgeon(s); time period	≥50 robotic-assisted and ≥conventional procedures before; January 2012 and August 2016 (randomisation)	>40 procedures of robotic-assisted or conventional procedures annually; August 2017 to December 2019 (eligibility assessment and randomisation)	All surgical procedures were performed by 2 surgeons, who performed at least 50 of both procedures each. January 2012 to August 2016
Number of randomised patients	112; IG: 56; CG: 56	362; IG: 183; CG: 179	IG: 54 CG: 55
Inclusion criteria	• Age between 18 and 80 • Histologically proven, surgically resectable oesophageal cancer (cT1-4a, N0–3, M0)	• 18-75 yrs	Inclusion Criteria[7]: • Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated

[7] Inclusion and exclusion information extracted from the clinical trials website

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
		• European Clinical Oncology Group performance status of 0, 1, or 2, with primarily resectable oesophageal squamous cell carcinoma of the intrathoracic oesophagus	carcinoma of the intrathoracic oesophagus (including Siewert I and II). • Surgical resectable (T1-4a, N0-3, M0) • Age ≥18 and ≤80 years. • European Clinical Oncology Group (ECOG) performance status 0,1 or 2 • Written informed consent Exclusion Criteria: • Carcinoma of the cervical oesophagus • Carcinoma of the gastro-oesophagal junction (GEJ) with a major tumour in the gastric cardia (Siewert III) • Prior thoracic surgery at the right hemithorax or thorax trauma (rationale: these patients will undergo open resection)
Primary/secondary endpoints	• primary: overall and disease-free survival rates during a follow-up period of 5 years after surgery • secondary: location of disease recurrences	• primary: overall survival • secondary: perioperative outcomes, long-term survival	• Primary: Surgery-related postoperative complications. Secondary: mortality (in-hospital and within 30 days), pulmonary complications, cardiac complications, perioperative outcomes, quality of life, functioning, pain
Follow-up (months)	5 yrs	Every 3 months within the first yr	M: 40 Months
Drop-outs (n (%))	After 5 yrs follow-up: IG: 2 (3.6%); CG: 3 (5.4%)	Until 90 days after surgery: IG: 2 (1.1); CG: 2 (1.1)	41% for quality of life data
Patient characteristics			
Age of patients (yrs., mean)	*IG vs CG; mean (±SD);* p=NS 64 (±8.9) vs 65 (±8.2)	*IG vs CG; median (range);* p=NS 65 (43–75) vs 63 (42–75)	Ø 64 (±8.9) CG: Ø 65 (±8.2) p=NR
Sex (% female)	IG: 15%; CG: 24%; p=NS	IG: 13.8%; CG: 15.3%; p=NS	IG: 15% CG: 24% p=NR
BMI (kg/m^2, mean)	*IG vs CG; mean (±SD);* p=NS 26.1 (±4.4) vs 25.5 (±4.7)	*IG vs CG; mean (±SD);* p=NS 23.1 (± 2.8) vs 23.0 (± 3.1)	IG: Ø 26.1 (±4.4) CG: Ø 25.5 (±4.7) p=NR
Clinical classification	*IG vs CG; n (%);*p=NS Clinical Stadium	*IG vs CG; n (%);* p=NS Clinical Stage	Clinical stage, p=NR IA: IG 7%; CG 7%

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
	I-II: 20 (37) vs 25 (45) III-IV: 34 (63) vs 30 (55) ASA score 1: 13 (24) vs 11 (20) 2: 38 (70) vs 34 (62) 3: 3 (6) vs 10 (18)	I: 28 (15.5) vs 22 (12.4) II: 94 (51.9) vs 93 (52.5) III: 57 (31.4) vs 62 (35.0) Iva: 2 (1.1) vs 0 (0)	IIA: IG 9%; CG 6% IIB: IG 20%; CG 33% IIIA: IG 24% CG 38%; IIIB: IG 24%; CG 11% IIIC: IG 15%; CG 6% Clinical stadium, p=NR cT1N0: IG 7%; CG 7% cT1N1: IG 2%; CG 4% cT2N0: IG 9%; CG 6% cT2N1: IG 7%; CG 7% cT2N2: IG 2%; CG 0 cT2N3: IG 2%; CG 0 cT3N0: IG 11%; CG 22% cT3N1: IG 22%; CG 38% cT3N2: IG 24%; CG 11% cT3N3: IG 11%; CG 4% cT4aN2: IG 2%; CG 0 cT4aN3: IG 0; CG 2%
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	*IG vs CG; median in months (range); rate (95% CI);* p=NS Overall survival: 35 (1–60); 41% (95% CI 27–55) vs 41 (2–60); 40% (95% CI 26–53) Disease-free survival: 28 (0–56); 42% (95% CI 28–55) vs 37 months (3–56); 43% (95% CI 29–57)	*IG vs CG; n (%);* p=NS **In-hospital mortality:** 0 (0) vs 0 (0) 30-d mortality: 0 (0) vs 1 (0.6) 90-d mortality: 1 (0.6) vs 1 (0.6)	In-hospital mortality: IG: 2/54 (4%); CG: 1/55 (2%), p=NS 30-day mortality: IG: 1/54 (1%); CG 0, p=NS 60-day mortality: IG: 3/54 (6%); CG: 1/55 (2%), p=NS 90-day mortality IG: 5/54 (9%); CG: 1/55 (2%), p=NS Disease-free survival: IG: M 26 months; CG M 28 months, p=NS[8]

[8] Overall survival (Kaplan-Meier) plots are shown but data is unclear

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
Recurrence (local, regional or distant)	*IG vs CG; n (%);* p=NS **Overall recurrence disease:** 28 (56) vs 29 (54) **Anastomoses/gastric conduit:** 3 (6) vs 1 (2) **LN:** 14 (28) vs 15 (28) Only inside resection area: 4 (8) vs 3 (6) Only outside resection area: 3 (6) vs 5 (9) Both: 7 (14) vs 7 (13) **Distant:** 26 (52) vs 27 (50) Liver: 6 (12) vs 12 (22) Lung: 5 (10) vs 4 (7) Bone: 5 (10) vs 5 (9) Pleural: 7 (14) vs 5 (9) Soft tissue: 4 (8) vs 4 (7) Peritoneal: 3 (6) vs 3 (6) Adrenal: 3 (6) vs 5 (9) Cerebral: 3 (6) vs 2 (4)	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR	QLQ-C30: Health-related quality of life @ discharge: IG: Ø 57.9 $CI_{95\%}$ [49.9;66.1] vs. Ø CG: 44.6 $CI_{95\%}$ [36.7;52.5], p=<0.05 Health-related quality of life @ 6 wk: IG: Ø 68.7 $CI_{95\%}$ [61.5;75.9] vs.CG: Ø 57.6 $CI_{95\%}$ [50.6;64.6], p<0.05 Physical functioning @ discharge: IG: Ø 54.5 $CI_{95\%}$ [45.8;63.3] vs.CG: Ø 41.0 $CI_{95\%}$ [32.4;49.6], p< 0.05 Physical functioning @ 6 wk: IG: Ø 69.3 $CI_{95\%}$ [61.6;76.9] vs.CG: Ø 58.6 $CI_{95\%}$ [51.1;66.0], p=0.05 Postoperative pain @ 14 days (VAS): IG: Ø 1.86 vs. CG: 2.62, p<0.001

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
Time to resume work/daily activities	NR	NR	Functional recovery within 2 weeks[9]: IG: 38/54 (70%); CG 28/55 (51%), p<0.05
Patient satisfaction	NR	NR	NR
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR	*n (%); conversion reasons* Conversion to open surgery: **IG:** 7 (3.9) Adhesions: 4 Intraoperative bleeding: 2 Unstable circulation: 1 **CG:** 6 (3.4) Tissue adhesions: 3 Injury of right gastroepiploic artery: 2 Torsional conduit: 1	IG: 7/54 (13%) vs. CG: 9/55 (16%) p=NS
Postoperative complications (e.g. infections)	NR	*IG vs CG; n (%);* p=NS **Total complications:** 88 (48.6) vs 74 (41.8) C-D classification ≥III: 22 (12.2) vs 18 (10.2) **Pulmonary complications:** 25 (13.8) vs 26 (14.7) Pneumonia: 18 (9.9) vs 21 (11.9) Respiratory failure: 8 (4.4) vs 9 (5.1) Pleural effusion: 10 (5.5) vs 6 (3.4) Pneumothorax: 3 (1.7) vs 5 (2.8) **Severe cardiac complications:** 2 (1.1) vs 1 (0.6) **Anastomotic leakage:** 22 (12.2) vs 20 (11.3) Type I (conservative): 8 (4.4) vs 5 (2.8); NR Type II (nonsurgical intervention): 13 (7.2) vs 14 (7.9); NR Type III (surgical intervention): 1 (0.6) vs 1 (0.6); NR	Overall surgery-related postoperative complications (Clavien-Dindo ≥2): IG: 32/54 (59%) vs. CG: 44/55 (80%), RR 0.74 $CI_{95\%}$ [0.57;0.96], p<0.05 Overall postoperative complications (MCDC grade≥2) IG: 34/54 (63%) vs CG: 44/55 (80%), RR 0.79 $CI_{95\%}$ [0.62;1.00], p=0.05 Pulmonary complications: IG 17/54 (32%) vs. CG 32/55 (58%), RR 0.54 $CI_{95\%}$, [0.34;0.85], p = 0.005 • Pneumonia: IG 15 vs. CG 30, p<0.01 • Pneumothorax: IG 0 vs. CG 3, p=NS • Pulmonary embolism: IG 3 vs. CG 1, p=NS

[9] Defined as: removal of thoracic tubes; no requirement of intravenous fluid resuscitation; tolerance for solid oral intake; ability to mobilize independently; adequate pain control with analgesics

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
		Vocal cord paralysis: 59 (32.6) vs 48 (27.1) Type I (transient injury requiring no therapy): 55 (30.4) vs 45 (25.4); NR Type II (requiring elective surgical procedure): 1 (0.6) vs 1 (0.6); NR Type III (requiring acute surgical intervention): 3 (1.7) vs 2 (1.1); NR Location (Left/right/bilateral): 49 (27.1)/6 (3.3)/4 (2.2) vs 41 (23.2)/4 (2.3)/3 (1.7) **Chylothoraxy:** 5 (2.8) vs 2 (1.1) Type I (enteric dietary modifications): 4 (2.2) vs 1 (0.6); NR Type II (total parenteral nutrition): 1 (0.6) vs 1 (0.6); NR Type III (interventional or surgical therapy): 0 (0) vs 0 (0); NR **Wound infections:** 3 (1.7) vs 1 (0.6) **Readmission intensive care unit:** 3 (1.7) vs 3 (1.7)	• ARDS: IG 0 vs. CG 1, p=NS Cardiac complications: IG 17/45 (22%) vs. CG 26/55/47%) 0.47 $CI_{95\%}$, [0.27;0.83], p <0.01 • Atrial fibrillation: IG 12; CG 25, p=0,01 • Cardia asthma: IG 1; CG 1, p=NS Wound infections: IG 2/54 (4%) vs. CG 8/55 (15%), p=NS • Cervical: IG 2 vs. CG 1, p=NS • Thoracic: IG 0 vs. CG 5, p=NS • Abdominal: IG 0 vs. CG 2, p=NS Anastomotic leakage • Type I (conservative): IG 0 vs. CG 0 • Type II (non-surgical intervention): IG 1 vs. CG 0 • Type III (surgical intervention): IG 12 vs. CG 11 Mediastinitis: IG 12 vs. CG 11, p=NS Thoracic empyema: IG 2 vs. CG 3, p=NS Gastric conduit necrosis Type III (conduit necrosis extensive, treated with resection and diversion): IG 1 vs. CG 2, p=NR Chylothorax, p=NR • Type I (dietary, low-fat elemental formula ga-vage): IG 9 vs. CG 6 • Type II (total parenteral nutrition): IG 6 vs. CG 5 • Type III (operative): IG 2 vs. CG 1 Recurrent laryngeal nerve injury • Type I (no therapy): IG 5 vs. CG 6, p=NR Postoperative bleeding: IG 2 vs. CG 2, p=NS Dehiscence of abdominal fascia: IG 0 vs. CG 1, p=NS
Reoperations/additional surgeries	NR	NR	IG: 13/54 (24%) vs. CG:18/55 (33%), p=NS

Oesophagus			
	Oesophagectomy	**Oesophagectomy**	**Oesophagectomy**
Author, year [reference number]	**De Groot et al. 2020 [43]**	**Yang et al. 2022 [42]**	**Van der Sluis et al. 2018 [84]**
Conversion	NR	*IG vs CG; n (%)*; p=NS 7 (3.9) vs 6 (3.4)	IG: 3/54 (5%) vs. CG: NA
Perioperative events & resource use			
Blood loss (in ml)	NR	*IG vs CG; median (IQR)*; p=NS 200 (100–400) vs 200 (100–500)	IG M 400 (IQR 258–581) vs. CG: M 568 (IQR 428–800), p<0.001
Operation time in min.	NR	*IG vs CG; mean ± SD* 203.8 ± 59.4 vs 244.9 ± 61.0; **p<0.001**	IG: Ø 349 (±56.9) vs. CG: Ø 296 (±33.9) p<0.001
Transfusions	NR	NR	NR
Drain duration (days)	NR	Thoracic drainage tube was generally removed on postoperative day 3 or 4.	NR
Length of hospital stay (days)	NR	*IG vs CG; median (range);* p=NS Postoperative hospital stay: 9 (6–49) vs 9 (6–82)	IG: M 14 (IQR 11–25) CG: M 16 (IQR 11–27), p=NS

Oesophagus		
	Antireflux/Fundoplication	**Antireflux/Fundoplication**
Author, year [reference number]	**Nakadi et al. 2006 [83]**	**Mueller-Stich et al. 2007 [80]& Mueller-Stich et al. 2009 [81]**
Study design	Single-centre RCT of patients with GERD	Single-centre RCT of patients with symptomatic GERD
Country	Belgium	Germany
Funding/Sponsor	NR	German Research Foundation.
Intervention (IG) | Product	Robot-assisted Nissen fundoplication | da Vinci system	Robot-assisted laparoscopic fundoplication | da Vinci Surgical System
Comparator (CG)	Laparoscopic Nissen fundoplication	Conventional laparoscopic fundoplication
Experience of surgeon(s), time period	All the procedures were performed by 2 surgeons: 1 digestive surgeon experienced in Nissen fundoplication and 1 general surgeon who used laparoscopic techniques. Operations were performed between: NR	All surgeons were reported to be highly experienced in laparoscopy, with at least 30 conventional laparoscopic fundoplications Operations were performed from August 2004-December 2005 by 1 surgeon (IG) and 3 surgeons (CG)
Number of patients	IG: 9 CG: 11	IG: 20 CG:20
Inclusion/exclusion criteria	Inclusion: • Symptoms of pathologic GERD	Inclusion: • Age >18

Oesophagus		
	Antireflux/Fundoplication	**Antireflux/Fundoplication**
Author, year [reference number]	**Nakadi et al. 2006 [83]**	**Mueller-Stich et al. 2007 [80]& Mueller-Stich et al. 2009 [81]**
	• Age >16 • proven complications of GERD like esophagitis, strictures, Barrett without dysplasia and extra digestive symptoms • Recurrence of symptoms or failure following 3 months of proton pump inhibitor (PPI) treatment Exclusion: • Achalasia and diffuse esophageal spasms • Brachyesophagus • Recurrence following previous surgery • History of previous gastric surgery	• History of more than 6 months of symptomatic GERD requiring acid suppressive therapy of a minimal standard dosage of the applied proton pump inhibitor (PPI) for at least 3 months in the preceding year • GERD had to be proven endoscopically or by severe clinical symptoms which resolved with PPI therapy (positive PPI test) Exclusion: • Previous major upper abdominal surgery, hiatal hernias with para oesophagal involvement • Obesity with a BMI of over 40 kg/m2 • Evidence of primary oesophageal disorders such as achalasia, scleroderma or malignant diseases 12 patients were excluded before randomisation
Primary/secondary endpoints	• Aims stated as: Feasibility, benefits and costs (specifically postoperative complaints, satisfaction score, duration of surgical procedure, LOS, and operative costs)	• Primary: Quality of Life in Reflux and Dyspepsia (QOLRAD); Gastrointestinal Symptom Rating Scale (GSRS); patient satisfaction; 4-step Likert scale for specific symptoms • Secondary: Perioperative outcomes regarding operative time, perioperative complications, length of stay and costs
Follow-up (months)	1-12	12 (also 1, 3, 6 months)
Drop-outs (n (%))	None	none
Patient characteristics		
Age of patients (yrs.)	IG: Ø 44 ±4 CG: 48 ±4, p=NS	IG: Ø 49.6 ±12.0 (R 23-71) CG: Ø 50.5 ±12.4 (R 25-75), p=NS
Sex (% female)	IG: 27% CG: 33%, p=NR	IG: 50% CG: 60%, p=NR
BMI (kg/m^2)	IG: Ø 24.8 ±0.7 CG: Ø 25.3 ±1.2, p=NR	IG: Ø 29.2 ±5.8 (R 21-40) CG: Ø 26.2 ±3.4 (R 19-31), p=NS
Clinical classification	NR	Los Angeles classification of oesophagitis (IG vs.CG), p=NS Grade A: 45% vs. 55% Grade B: 50% vs. 35% Grade C: 5% vs. 10% Grade D: 0 vs. 0

Oesophagus		
	Antireflux/Fundoplication	**Antireflux/Fundoplication**
Author, year [reference number]	**Nakadi et al. 2006 [83]**	**Mueller-Stich et al. 2007 [80]& Mueller-Stich et al. 2009 [81]**
Patient-relevant outcomes		
Survival (overall and disease-specific or disease-free)	NR	NR
Recurrence (local, regional or distant)	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	IG vs. CG, p=NR *1 month after surgery:* • Dysphagia for solids: 1/9 (11%) vs. 2/11 (18%) • Epigastric pain: 1/9 (11%) vs. 0 • Flatulence: 1/9 (11%) vs. 2/11 (18%) *3 months after surgery* • Dysphagia for solids: 1/9 (11%) vs. 0 • Epigastric pain: 2/9 (22%) vs. 0 • Flatulence: 1/9 (11%) vs. 0 *12 months after surgery* • Dysphagia for solids: 0 vs. 0 • Epigastric pain: 0 vs. 0 • Flatulence: 0 vs. 2/11 (18%) Soft stools: 1/9 (11%) vs. 0	QOLRAD (min. 1-max. 7) before vs. 12 months after surgery: IG: Ø 3.7 ±1.3 vs. Ø 1.3 (R 1.0-4.6), p=NS CG: Ø 3.7 ±1.2 vs Ø 1.1 (R1.0-2.2), p=NS GSRS (reflux syndrome, min. 1-max. 7) before vs. 12 months after surgery: IG: Ø 4.0 ±1.7 vs. Ø 1.3 (R 1.0-3.5) CG: Ø 4.4 ±1.5, vs. Ø 1.3 (R 1.0-4.0), p=NS
Time to resume work/daily activities	NR	NR
Patient satisfaction	NR	Change of condition (IG vs. CG): Normalised: 11/20 (55%) vs. 5/20 (25%), p=NS Improved: 7/20 (35%) vs. 14/20 (70%), p=NS Unchanged: 2/20 (10%) vs. 1/20 (5%), p=NS Worsened: 0 vs. 0, p=NS Operative result (IG vs. CG): Excellent: 6/20 (5%) vs. 2/20 (10%), p=NS Very good: 7/20 (35%) vs. 9/20 (45%), p=NS Good: 6/20 (30%) vs. 8/20 (40%), p=NS Sufficient: 0 vs. 1/20 (5%), p=NS **Would you decide in favour of an operation again**? (ratio Yes: No) IG: 19:1 CG: 20:0

Oesophagus		
	Antireflux/Fundoplication	**Antireflux/Fundoplication**
Author, year [reference number]	**Nakadi et al. 2006 [83]**	**Mueller-Stich et al. 2007 [80]& Mueller-Stich et al. 2009 [81]**
Safety-related outcomes		
Intraoperative complications (e.g. air-leakage)	NR	IG: 1/20 (5%), 1 pneumothorax CG: 2/20 (10%), 2 bleedings p=NR
Postoperative complications (e.g. infections)	NR	Minor complications (IG vs. CG): • Mild dysphagia at discharge: 16/20 (80%) vs. 18/20 (90%), p=NS • Dysphagia 30 days postoperatively: 5/20 (25%) vs. 4/20 (20%), p=NS • Mild reflux symptoms 30 days postoperatively: 2/20 (10%) vs. 3/20 (15%), p=NS • Reflux score: Ø 1.3 ±0.7 vs. Ø1.6 ±1.3, p=NS Major complications (IG vs. CG): 0 vs. 0 Complications @ 12 months FU (IG vs. CG): • Mild reflux symptoms: 0 vs. 2/20 (10%), p=NR • Gastritis: 0 vs. 1/20 (5%), p=NR • Dysphagia: 0 vs. 0 • Gas bloat: 3/20 (15%) vs. 2/20 (10%), p=NS • Diarrhoea 1/20 (5%) vs. 0, p=NS • Impeded vomiting: 0 vs. 1/20 (5%), p=NS Regurgitation: 0 vs. 1/20 (5%), p=NS
Re-operations/additional surgeries	IG: 1/9 (11%), because of gastric torsion CG: 0, p=NR	at 12 months FU, p=NR IG: 1/20 (5%), because of dysphagia CG: 0
Conversion	IG: 1/9 (11%) CG: 0, p=NR	IG: 0 CG:0
Perioperative events & resource use		
Blood loss (in ml)	NR	NR
Operation time in min.	IG: Ø 137 ±12 CG: Ø 94 ±5, p<0.01	IG: Ø 88 ±18 CG: Ø 102 ±19, p<0.05
Transfusions	NR	NR
Drain duration (days)	NR	NR
Length of hospital stay (days)	IG: Ø 4.4 ±0.2	IG: Ø 2.9 ±0.8

Oesophagus		
	Antireflux/Fundoplication	**Antireflux/Fundoplication**
Author, year [reference number]	**Nakadi et al. 2006 [83]**	**Mueller-Stich et al. 2007 [80]& Mueller-Stich et al. 2009 [81]**
	CG: Ø 4.1 ±0.3, p=NS	CG: Ø 3.3 ±0.8, p=NS

Table A - 18: Extraction table Stomach

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
Study characteristics				
Study design, indication	Open-label, non-inferiority RCT of patients with gastric cancer	Phase 3, prospective superiority RCT of patients with gastric cancer	Single centre RCT of patients with gastric cancer	Single-centre RCT of patients with gastric cancer
Country	China	Japan	China	China
Funding/Sponsor	Joint funds for the innovation of science and technology, Fujian province; the second batch of special support funds for Fujian Province innovation and entrepreneurship talents; Construction Project of Fujian Province Minimally Invasive Medical Center; Natural Science Foundation of Fujian Province; Fujian provincial science and technology innovation joint fund project plan; Fujian provincial health technology project	NR	Supported by the Social Development Fund of Jiangsu Province	National Natural Science Foundation of China
Intervention (IG) | Product	Robotic distal gastrectomy | da Vinci robotic system	Robotic gastrectomy | da Vinci Si and da Vinci Xi	Robotic gastrectomy | NR	Robotic gastrectomy | NR
Comparator (CG)	Laparoscopic distal gastrectomy	Laparoscopic gastrectomy	Laparoscopic gastrectomy	Open gastrectomy

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
Experience of surgeon(s); time period	>300 laparoscopic and >50 robotic procedures before; September 2017 to January 2020 (study conducted)	NR; April 2018 to October 2020 (enrollment)	The surgical team had experience with >550 cases of robotic gastrectomy. Operations were performed from January 2015-August 2016	NR Patients were recruited from May 2012-December 2014
Number of randomised patients	300; IG: 150; CG: 150	241; IG: 119; CG: 122	IG: 102 CG: 61	IG: 153 CG: 158
Inclusion criteria	• 18-75 yrs • Histologically proven gastric cancer, with clinical stage cT1–4aN0/þM0 by preoperative evaluation	• 20-90 yrs • Histologically proven gastric carcinoma • resectable gastric cancer according to the eighth edition of the TNM classification • not applicable for endoscopic submucosal dissection according to the Japanese classification • Eastern Cooperative Oncology Group performance status of 0 or 1 • BMI of less than 35 • no history of gastrointestinal surgery that may affect protocol surgery • no history of chemotherapy or radiotherapy • normal function of major organs	Inclusion: • Endoscopy-considered and biopsy-proven gastric cancer; clinical stage of I, II, or III based on the 7th version of the pathologic classification of the International Union Against Cancer • ASA score of ≤2 Exclusion • Serious cardiovascular or respiratory disorders; hepatic or renal failure; other tumors or metastases; surgical failure (conversion to open surgery); D1/D3/D4 lymphadenectomy	Inclusion: • Patients with gastric cancer, pathologically confirmed via gastroscopy Exclusion: • Patients who had remote metastasis • Preoperative chemotherapy • A history of abdominal surgery • ASA scores above Grade III • Patients with detected abdominal cavity metastases during surgery or who were transferred to open gastrectomy • Patients with factors known to influence fast-track recovery, such as pregnancy, cardiopulmonary dysfunction, chronic kidney or liver disease, complicated diabetes, or anticholinergic drug administration,
Primary/secondary endpoints	• primary: 3-yr disease-free survival rate • secondary: short-term clinical outcomes including intraoperative outcomes, postoperative recovery course, morbidity,	• primary: incidence of postoperative intra-abdominal infectious complications • secondary: surgical results (operation time, blood loss, transition	• Assessed perioperative outcomes and postoperative complications	• Primary: duration of hospitalization, number of nodes retrieved in lymph node dissection, resection type, reconstruction type, surgery duration, proximal and distal resection mar-

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
	quality of lymphadenectomy, adjuvant chemotherapy completion status, cost difference	rate to open or laparoscopic surgery, and the number of retrieval lymph nodes), postoperative courses (times to resumption of drinking and eating, postoperative hospital stay), and oncologic outcomes (overall survival and disease-free survival), rate of conversion		gins, estimated blood loss, and morbidity and mortality during the first 30 days after the procedure
Follow-up (months)	30 days Only disease-free survival rate: 3 yrs	12 months (adjuvant chemotherapy) for patients with pathologic stage II or III	11	NR
Drop-outs (n (%))	After randomisation: IG: 9 (6%); CG: 8 (5.3%)	IG: 6 (5); CG: 5 (4.1)	None	IG: 7/158 (4.43%) CG: 8/153 (5.23%)
Patient characteristics				
Age of patients (yrs., mean)	*IG vs CG; mean (±SD); p-value* 59.4 (±10.2) vs 59.3 (±11.3); NS	*IG vs CG; median (range); p-value* 71 (34-90) vs 72 (40-90); NR	IG: Ø 65.1 ±11.8 CG: Ø 65.7 ±13.6, p=NS	IG: Ø 57.5 ±12.7 CG: Ø 55.9 ±13.1, p=NS
Sex (% female)	IG: 33.3%; CG: 36.6%; p=NS	IG: 37.6%; CG:35.3%; p=NR	IG: 36% CG: 26%, p=NS	IG: 27.82% CG: 38.62%, p=NS
BMI (kg/m^2, mean)	*IG vs CG; mean (±SD); p-value* 23.2 (±3.0) vs 22.7 (±3.3); NS	*IG vs CG; median (range); p-value* 21.9 (14.0-32.1) vs 22.4 (14.0-31.9); NR	IG: Ø 24.1 ±1.7 CG: Ø 23.9 ±1.6, p=NS	IG: Ø 22.1 ±2.9 CG: Ø 21.3 ±2.5, p=NS
Clinical classification	*IG vs CG; n (%); p-value* ASA I: 19 (13.5) vs 20 (14.1); NS II: 112 (79.4) vs 110 (77.5); NS III: 10 (7.1) vs 12 (8.5); NS	*IG vs CG; n (%); p-value* ASA I: 39 (33.3) vs 44 (37.0); NR II: 74 (63.2) vs 72 (60.5); NR III: 4 (3.4) vs 3 (2.5); NR pT stage T1a: 25 (21.4) vs 23 (19.3); NR T1b: 43 (36.8) vs 40 (33.6); NR T2: 10 (8.5) vs 14 (11.8); NR	ASA (IG vs. CG), p=NS I: 77% vs 77% II: 23 vs. 23% TNM (IG vs. CG), p=NS I: 22% vs. 11% II: 46% vs. 64% III: 32% vs. 25%	ASA (IG vs. CG), p=NS I: 39% vs. 35% II: 54% vs. 53% III: 7% vs. 7% TNM (IG vs. CG), p=NS Ia: 11% vs. 9% Ib: 5% vs. 6% IIa: 11% vs. 15% IIb: 22% vs. 26%

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
		T3: 25 (21.4) vs 26 (21.8); NR T4a: 11 (9.4) vs 15 (12.6); NR T4b: 3 (2.6) vs 1 (0.8); NR pN stage N0: 76 (65.0) vs 70 (58.8) N1: 19 (16.2) vs 24 (20.2) N2: 15 (12.8) vs 12 (10.1) N3: 7 (6.0) vs 13 (10.9)		IIIa: 17% vs. 16% IIIb: 27% vs. 25% IIIc: 7% vs. 5%
Patient-relevant outcomes				
Survival (overall and disease-specific or disease-free)	*IG vs CG; n (%); p-value* **In-hospital mortality within 30 days postoperative:** 0 (0) vs 0 (0); NA	*IG vs CG; n (%); p-value* (per-protocol analysis) **Mortality:** IG: 0; CG: 0; p=NS	IG: 102/102 (100%) CG: 61/61 (100%)	Intraoperative IG: 151/151 (100%) CG: 145/145 (100%)
Recurrence (local, regional or distant)	NR	NR	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR	VAS for pain (IG vs. CG) 1st postoperative day: Ø 2.6 ±0.7 vs Ø 7.5 ±1.2, p<0.00 2nd postoperative day: Ø 0.8 ±0,8 vs Ø 3.5 ±1.3, p<0.00 3rd postoperative day: Ø 0.1 ±0.3 vs. Ø 1.0 ±1.0, p<0.00	NR
Time to resume work/daily activities	NR	NR	NR	NR
Patient satisfaction	NR	NR	NR	NR
Safety-related outcomes				
Intraoperative complications (e.g. air-leakage)	NR	NR	NR	IG: 0 CG: 0
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* **Overall morbidity:** 13 (9.2) vs 25 (17.6); **p=0.039** **Surgical morbidity:** 5 (3.5) vs 9 (6.3); NS	*IG vs CG; n (%); p-value* (per-protocol analysis) **Overall complications, ≥grade IIb:** 10 (8.8) vs 23 (19.7); **p=0.02**	IG vs. CG during 11-months FU, p=NS • Ileus: 0 vs. 1/61 (1.6%) • Wound infection: 2/102 (2.0%) vs. 4/61 (6.6%)	At 30 days (p=NS): IG: 14/151 (9.3%) CG: 15/145 (10.3%) Clavien Dindo classification (IG vs. CG), p=NS

Stomach				
	Gastrectomy	Gastrectomy	Gastrectomy	Gastrectomy
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
	Abdominal bleeding: 1 (0.7) vs 3 (2.1); NS Anastomotic leakage: 0 (0.0) vs 1 (0.7); NS Ileus: 1 (0.7) vs 1 (0.7); NS Gastroplegia: 0 (0.0) vs 1 (0.7); NS Wound infection: 1 (0.7) vs 1 (0.7); NS Peritoneal infection: 3 (2.1) vs 2 (1.4); NS **Medical morbidity:** 9 (6.4) vs 20 (14.1); **p=0.033** Pneumonia: 8 (5.7) vs 16 (11.3); NS Cardiovascluar system: 1 (0.7) vs 1 (0.7); NS Livery system: 2 (1.4) vs 1 (0.7); NS Urinary system: 1 (0.7) vs 2 (1.4); NS Deep vein thrombosis: 0 (0.0) vs 1 (0.7); NS **Clavien-Dindo classification:** I: 0 (0.0) vs 0 (0.0); NS II: 11 (7.8) vs 22 (15.5); NS IIIa: 0 (0.0) vs 1 (0.7); NS IIIb: 1 (0.7) vs 1 (0.7); NS IV: 1 (0.7) vs 1 (0.7); NS V: 0 (0.0) vs 0 (0.0); NS **Unplanned readmission:** 2 (1.4) vs 2 (1.4); NS Peritoneal infection: 1 (0.7) vs 1 (0.7); NS Pneumonia: 0 (0.0) vs 1 (0.7); NS	**Overall complications, ≥grade IIIa:** 6 (5.3) vs 19 (16.2); **p=0.01** **Surgical complications:** Anastomotic leakage, ≥grade II: 4 (3.5) vs 5 (4.3); NS Anastomotic leakage, ≥grade IIIa: 3 (2.7) vs 5 (4.3); NS Pancreatic fistula, ≥grade II: 0 vs 2 (1.7); NS Pancreatic fistula, ≥grade IIIa: 0 vs 1 (0.9); NS Intra-abdominal abscess, ≥grade II: 3 (2.7) 3 (2.6); NS Intra-abdominal abscess, ≥grade IIIa: 2 (1.8) vs 3 (2.6); NS Intra-abdominal bleeding, ≥grade II: 0 vs 0; NS Intra-luminal bleeding, ≥grade II: 0 vs 0; NS Ileus, ≥grade IIIa: 1 (0.9) vs 2 (1.7); NS Cholecystitis, ≥grade II: 0 vs 3 (2.6); NS Cholecystitis, ≥grade IIIa: 0 vs 2 (1.7); NS Hepatic portal venous gas, ≥grade IIIa: 0 vs 1 (0.9); NS Stenosis, ≥grade IIIa: 0 vs 3 (2.6); NS Wound infection, ≥grade II: 1 (0.9) vs 1 (0.9); NS Wound infection, ≥grade IIIa: 1 (0.9) vs 0; NS **Medical complications:**	• Pneumonia: 2/102 (1.96%) vs. 4/61 (6.6%) • Oesphago-jejunal anastomosis leak: 0 vs. 2/61 (3.3%) • Duodenal stump leak: 1/102 (1.0%) vs. 1/61 (1.6%) • None: 97/102 (95.1%) vs. 49/61 (80.3%)	I: 7/14 (50.0%) vs. 6/15 (40.0%), of these: • Surgical site infection: 3/14 (21.4%) vs. 4/15 (26.7%) • Fever: 3/14 (21.4%) vs. 2/15 (13.3%) • Fluid collection/abscess: 1/14 (7.1%) vs. 0 II: 3/14 (21.4%) vs. 4/15 (26.7%) of these: • Pneumonia: 2/14 (14.3%) vs. 3/15 (20.0%) • Intra-abdominal bleeding: 1/14 (7.1%) vs. 1/15 (6.7%) III: 4/14 (28.6%) vs. 4/15 (26.7%), of these: • Fluid collection: 0 vs. 1/15 (6.7%) • Anastomotic leakage: 4/14 (28.6%) vs. 3/15 (20.0%) IV: 0 vs 1/15 (6.7%), of these: Acute renal failure: 0 vs. 1/15 (6.7%)

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
	Gastroplegia: 1 (0.7) vs 0 (0.0); NS	Pneumonia, ≥grade II: 1 (0.9) vs 5 (4.3); NS Pneumonia, ≥grade IIIa: 0 vs 2 (1.7); NS Pneumothorax, ≥grade IIIa: 0 vs 1 (0.9); NS Cardiovascular system, ≥grade II: 0 vs 0; NS Liver system, ≥grade II: 0 vs 0; NS Urinary system, ≥grade II: 0 vs 1 (0.9); NS Thrombosis, ≥grade II: 0 vs 0; NS		
Reoperations/additional surgeries	*IG vs CG; n (%); p-value* **Reoperation within 30 days:** 0 (0.0) vs 1 (0.7); NS	*IG vs CG; n (%); p-value* (per-protocol analysis) **Reoperation, grade IIIb:** 1 (0.9) vs 3 (2.6); NS	1 patient in the CG group required Braun anastomosis on postoperative day 10 because of jejunal afferent loop obstruction.	IG: 4/14 (28.6%) CG: 3/15 (20.0%), p=NR (all due to anastomotic leakages).
Conversion	NR	*Conversion type; IG vs CG; n (%); p-value* (per-protocol analysis) **Overall Conversion:** 4 (3.4) vs 2 (1.7); NS **Conversion to open:** 2 (NR) vs 2 (NR); NR **Conversion to laparoscopy:** 2 (NR) vs 0; NR	Conversion as an exclusion criterion	NR
Perioperative events & resource use				
Blood loss (in ml)	*IG vs CG; mean (±SD); p-value* **Intraoperative blood loss:** 41.2 (±45.7) vs 55.7 (±70.5); **p= 0.045**	*IG vs CG; median (range); p-value* (per-protocol analysis) 25 (5-475) vs 25 (5-1,405); NS	IG: Ø 41.3 ±20.2 CG: Ø 83.7 ±32.8, p<0.01	IG: Ø 94.2 ±51.5 CG: Ø 152.8 ±76.9, p<0.001
Operation time in min.	*IG vs CG; mean (±SD); p-value* 187.0 (±32.4) vs 181.6 (±44.4); NS	*IG vs CG; median (range); p-value* (per-protocol analysis)	IG: Ø 153.1 ±16.4 CG: Ø 152.0 ±23.6, p=NS	IG: Ø 242.7 ±43.8 CG: Ø 192.4 ±31.5, p<0.01

Stomach				
	Gastrectomy	**Gastrectomy**	**Gastrectomy**	**Gastrectomy**
Author, year [reference number]	**Lu et al. 2021 [44]**	**Ojima et al. 2021 [45]**	**Pan et al. 2017 [85]**	**Wang et al. 2016 [87]**
		297 (179-654) vs 245 (131-534); **p=0.001**		
Transfusions	*IG vs CG; n (%); p-value* **Postoperative transfusion:** 8 (5.7) vs 16 (11.3); NS	*IG vs CG; n (%); p-value* (per-protocol analysis) **Intraoperative tranfusions:** 1 (0.9) vs 3 (2.6); NS	NR	IG: 1/14 (7.1%) CG: 1/15 (6.7%), p=NR
Drain duration (days)	*IG vs CG; mean (±SD); p-value* **Drainage tube removed time:** 6.5 (±1.8) vs 7.0 (±2.5); NS	A single abdominal drain was inserted into the left subphrenic cavity after reconstruction in both groups. The amylase level in the drainage fluid was checked on postoperative days 1 and 3 (PODs 1 and 3)	NR	NR
Length of hospital stay (days)	*IG vs CG; mean (±SD); p-value* **Postoperative hospital stay:** 7.9 (±3.4) vs 8.2 (±2.5); NS	*IG vs CG; median (range); p-value* (per-protocol analysis) **Postoperative hospital stay:** 12 (7-43) vs 13 (6-45); NS	IG: Ø 3.8 ±0.7 CG: Ø 5.4 ± 1.2, p<0.001	IG: Ø 5.7 ±2.3 CG: Ø 6.4 ±2.5, p<0.05

Stomach		
	Gastrectomy	**Bariatric Surgery**
Author, year [reference number]	**Ribeiro et al. 2022 [46]**	**Sanchez et al. 2005 [86]**
Study characteristics		
Study design, indication	Prospective, single-institution, open-label, non-inferiority RCT of patients with gastric cancer	Single-centre RCT
Country	Brazil	USA
Funding/Sponsor	By the Institution (Department of Gastroenterology, Instituto do Cancer do Estado de São Paulo, Hospital das Clinicas, Faculdade de Medicina, Universidade de São Paulo)	NR
Intervention (IG) | Product	Robotic gastrectomy | da Vinci Si	Totally robotic laparoscopic Roux-en-Y gastric bypass | da Vinci Surgical System
Comparator (CG)	Open gastrectomy	Laparoscopic Roux-en-Y gastric bypass

Stomach		
	Gastrectomy	**Bariatric Surgery**
Author, year [reference number]	**Ribeiro et al. 2022 [46]**	**Sanchez et al. 2005 [86]**
Experience of surgeon(s); time period	Surgeons certified as console surgeons in the da Vinci platform by Intuitive; February 2015 to December 2020 (study inclusion)	Standard FDA mandated training on the da Vinci system Operations were performed from July 2004-April 2005
Number of randomised patients	65; IG: 33; CG: 32	IG: 25 CG: 25
Inclusion criteria	• 18-80 yrs • Histologically confirmed gastric adenocarcinoma • Tumour stage cT1-4a and cN0-1, cM0 (preoperative staged by upper digestive endoscopy, abdominal computed tomography scan + / – endoscopic ultrasound); potentially curative intent gastrectomy; performance status by the Eastern Cooperative Oncology Group of 0 or 1; and (ASA) score up to III.	Inclusion: NR • Exclusion: NR All patients met the minimal criteria for bariatric surgery proposed by the National Institute of Health Consensus Development Panel report of 1991
Primary/secondary endpoints	• primary: short-term surgical outcome; incidence of postoperative intra-abdominal infectious complications (surgical duration, blood loss, number of harvested lymph nodes, R0 resection) • secondary: postoperative complications, hospital length of stay, 90-day readmissions, oncologic outcomes, and surgical mortality (death until 90 days after the procedure or during postoperative hospital stay)	• Not stated as such but included, learning curve analysis, safety, operative times and length of stay
Follow-up (months)	90 days, longer follow-up is planned	NR
Drop-outs (n (%))	After randomisation: IG: 4 (12.1%); CG: 1 (3.1%)	None
Patient characteristics		
Age of patients (yrs., mean)	*IG vs CG; mean (SD); p-value* 59.3 (11.3) vs 58.1 (11.3); NS	IG: M 43.3 (R 27-58) CG: M 44.4 (R 20-59), p=NS
Sex (% female)	IG: 51.7%; CG: 35.5%; p=NS	IG: 92% CG: 88%, p=NS
BMI (kg/m^2, mean)	*IG vs CG; mean (SD); p-value* 23.8 (3.6) vs 23.5 (2.9); NS *IG vs CG;n (%); p-value*	IG: M 45.5 (R 35-62) CG: M 43.4 (R 37-55), p=NS

Stomach		
	Gastrectomy	**Bariatric Surgery**
Author, year [reference number]	**Ribeiro et al. 2022 [46]**	**Sanchez et al. 2005 [86]**
	<25: 20 (69) vs 21 (67.7); NS 25-30: 8 (27.6) vs 9 (29); NS >30: 1 (3.4) vs 1 (3.2); NS	
Clinical classification	*IG vs CG; n (%); p-value* ASA I: 1 (3.4) vs 1 (3.2); NS II: 24 (82.8) vs 25 (80.6); NS III: 4 (13.8) vs 5 (16.1); NS cT T1: 8 (27.6) vs 6 (19.4); NS T2: 6 (20.7) vs 11 (35.5); NS T3: 14 (48.3) vs 11 (35.5); NS T4: 1 (3.4) vs 3 (9.7); NS cN cN0: 21 (72.4) vs 25 (80.6); NS cN+: 8 (27.6) vs 6 (19.4); NS cTNM I: 14 (48.3) vs 14 (45.2); NS II: 15 (51.7) vs 16 (51.6); NS III: 0 (0) vs 1 (3.2); NS	NR
Patient-relevant outcomes		
Survival (overall and disease-specific or disease-free)	**Mortality[10]:** IG: 0; CG: 0; p=NR	NR
Recurrence (local, regional or distant)	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR
Time to resume work/daily activities	NR	NR
Patient satisfaction	NR	NR
Safety-related outcomes		

[10] Death until 90 days after the procedure or during postoperative hospital stay

Stomach		
	Gastrectomy	**Bariatric Surgery**
Author, year [reference number]	**Ribeiro et al. 2022 [46]**	**Sanchez et al. 2005 [86]**
Intraoperative complications (e.g. air-leakage)	IG: 0; CG: NR; p=NR	Complication rate IG vs CG, p=NS Minor complications (IG vs. CG): Oversewed gastrojejunostomy leak after positive bubble test: 1/25 (4%) vs. 0. Major complications (IG vs. CG): 0 vs. 0
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* **Postoperative complications (0-30 days postoperative):** Minor: 4 (13.8) vs 6 (19.4); NS Major: 4 (13.8) vs 3 (3.2); NS **Late complications (>30 days postoperative):** 1 (3.4) vs 6 (19.4); NS **Readmission** (<90 days): 1 (3.4) vs 4 (12.9); NS	IG: 0 CG: 0
Reoperations/additional surgeries	**Re-do surgery:** IG: 0; CG:0; p=NR **Surgical revision:** IG: 2; CG: NR; p=NR	NR
Conversion	**Conversion (abdominal incision):** IG: 2 (6.7%); CG: NR; p=NR	IG: 1/25 (4%) required conversion to traditional LRYGB because of exterior anatomy, p=NR CG: 0
Perioperative events & resource use		
Blood loss (in ml)	*IG vs CG; mean (SD); ,median (IQR); range; p-value* 123.7 (89.3); 111.5 (51.3–153.3); 10–340 vs 276.3 (152.1); 300 (120–400); 40–500; **p<0.001**	NR
Operation time in min.	*IG vs CG; mean (SD); ,median (IQR); range; p-value* 353.8 (96.4); 358 (282–430.5); 185–509 vs 214.6 (41.6); 200 (185–240); 163–320; **p<0.001**	IG: Ø 130.8 CG: Ø 149.4, p<0.02
Transfusions	NR	NR
Drain duration (days)	**Drainage required:** IG: 1; CG: 1; NR	NR
Length of hospital stay (days)	*IG vs CG; mean (SD); ,median (IQR); range; p-value* 9.1 (5.5); 7 (6–11); 5.0–30 vs 8.9 (5.6); 7 (5–10); 5.0–27; NS	IG: Ø 2.7 (R 2-4) CG: Ø 2.7 (R 2-3), p=NS

Table A - 19: Extraction table Bowel

Bowel			
	Colectomy	**Colectomy**	**Colectomy**
Author, year [reference number]	**Fleming et al. 2022 [48]**	**Park et al. 2019 [47]**	**Park et al. 2012 [66]**
Study characteristics			
Study design, indication	Post hoc analysis of a phase III RCT of patients with cancer or benign colonic pathologies	Prospective randomised study of patients with right-sided colon cancer	Single-centre RCT of patients with newly diagnosed right-sided colonic carcinoma
Country	France	South Korea	Korea
Funding/Sponsor	No funds, grants, or other support were received during the preparation of this manuscript.	Ministry of Health & Welfare, Republic of Korea	Supported by the Basic Science Research Programme through the National Research Foundation of Korea funded by the Ministry of Education, Science and Technology
Intervention (IG) | Product	Robotic colectomy | NR	Robot-assisted right colectomy| da Vinci Si HD	Robot-assisted colectomy | da Vinci Surgical System
Comparator (CG)	Laparoscopic colectomy	Laparoscopic-assisted right colectomy	Laparoscopically assisted colectomy
Experience of surgeon(s); time period	NR; NR	Min. 14 yrs operative experience in practice, >400 laparoscopic procedures (including 40 cases of benign disease), ~30 robotic procedures in colon cancer; September 2009 to July 2011 (eligibility assessment and randomisation)	Single surgeon The operating team had undertaken 30 robotic surgery procedures (including five robotic right colectomies) before starting this clinical trial. Operations were performed from September 2009-July 2011
Number of randomised patients	127; IG: 43; CG: 84	71; IG: 35; CG: 36	IG: 35 CG: 36
Inclusion criteria	• ≥18 • Pts undergoing a right or left colectomy for a malignant or benign pathology • Planned minimally invasive surgery	• ≥18 • Medically cleared for radical right colectomy • Diagnosis confirmed by a colonoscopic biopsy	Inclusion: • Age (≥18 years) with newly diagnosed right-sided colonic carcinoma were potential candidates Exclusion: • Patients who were unfit for operative treatment • Patients who presented with an acute surgical emergency, including intestinal obstruction or perforation; • Patients with distant metastasis on preoperative evaluation

Bowel			
	Colectomy	**Colectomy**	**Colectomy**
Author, year [reference number]	**Fleming et al. 2022 [48]**	**Park et al. 2019 [47]**	**Park et al. 2012 [66]**
			• Patients with an advanced tumour with adjacent organ invasion requiring en bloc multiple organ resection.
Primary/secondary endpoints	• Adequacy of exposure to the operative field and overall visibility • Surgical morbidity • Anastomotic leak • Resolution of symptoms • Return to bowel function • Pain • Hospital length of stay • Cost-analysis	• primary: length of hospital stay • secondary: morbidity, operation time, 3-yrs disease-free survival	• Length of hospital stay • Secondary endpoints: duration of operation, complications, pathological completeness of tumour excision and postoperative pain
Follow-up (months)	NR	3-month intervals (first 2 yrs) 6-month interval (third to fifth yr)	24-120 hours
Drop-outs (n (%))	IG: 0 (0%); CG:0 (0%)	Before Surgery: IG: 0 (0%); CG: 1 (2.8%) Lost to follow-up: IG: 0 (0%); CG: 0 (0%)	IG: 0 CG: 1/36 (2.78%) did not receive intervention due to intraperitoneal chemotherapy
Patient characteristics			
Age of patients (yrs., mean)	*IG vs CG; median (range); p-value* 67 (20–93) vs 65 (22–90); NS	*IG vs CG; mean (SD); p-value* 62.8 (10.5) vs 66.5 (11.4); NS	IG: Ø 62.8 ±10.5 CG: Ø 66.5 ±11.4, p=NS
Sex (% female)	IG: 53%; CG: 49%; p=NS	IG: 60.0%; CG: 54.3%; p=NS	IG: 60% CG: 54%, p=NS
BMI (kg/m², mean)	*IG vs CG; n (%); p-value* BMI ≤30: 37 (86) vs 73 (87); NS BMI >30**:** 6 (14) 11 (13); NS	*IG vs CG; mean (SD); p-value* 24.4 (2.5) vs 23.8 (2.7); NS	IG: Ø 24.4 ±2.5 CG: Ø 23.8 ±2.7, p=NS
Clinical classification	*IG vs CG; n (%); p-value* ASA: I: 12 (28) vs 27 (32); NS II: 23 (54) vs 50 (60); NS	*IG vs CG; n (%); p-value* ASA: I: 15 (42.9) vs 21 (60.0); NS II: 16 (45.7) vs 12 (34.3); NS	TNM (IG vs. CG) p=NS I: 26% vs. 29% II: 46% vs. 46% III: 29% vs. 26%

Bowel			
	Colectomy	**Colectomy**	**Colectomy**
Author, year [reference number]	**Fleming et al. 2022 [48]**	**Park et al. 2019 [47]**	**Park et al. 2012 [66]**
	III: 8 (19) vs 7 (8); NS	III: 4 (11.4) vs 2 (5.7); NS	ASA (IG vs. CG) p=NS I: 43% vs. 60% II: 46% vs. 34% III: 11% vs. 6%
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	NR	*IG vs CG; mean (%) (95% CI); p-value* **Disease-free survival:** 3 yrs after surgery: 88.1 (77.1–99.1) vs 91.1 (81.4–99.9); NS 5 yrs after surgery: 77.4 (60.6–92.1) vs 83.6 (72.1–97.0); NS **Overall survival:** 3 yrs after surgery: 96.8 (90.6–99.9) vs 94.0 (86.0-99.9); NS 5 yrs after surgery: 91.1 (78.8–99.9) vs 91.0 (81.3–99.9); NS	At 30-day: IG: 35/35 (100%) CG: 35/35 (100%), p=NS
Recurrence (local, regional or distant)	NR	No port site recurrence was noted with a median follow-up of 49 months	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR	VAS (IG vs. CG) 24 hours: Ø 6.1 ±2.2 vs. Ø 6.1 ±2.2, p=NS 120 hours: Ø 2.0 ±1.8 vs. Ø 2.2 ±1.9, p=NS
Time to resume work/daily activities	NR	NR	NR
Patient satisfaction	NR	NR	At 30-day: IG: 35/35 (100%) CG: 35/35 (100%), p=NS
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	*IG vs CG; n (%); p-value* 3 (7) vs 4 (5); NS	NR	IG: 0 CG: 0

Bowel			
	Colectomy	**Colectomy**	**Colectomy**
Author, year [reference number]	**Fleming et al. 2022 [48]**	**Park et al. 2019 [47]**	**Park et al. 2012 [66]**
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* **Postoperative surgical complication:** 7 (16) vs 10 (12); NS **Anastomotic leak:** 2 (5) vs 3 (4); NS **Medical complication:** 4 (9) vs 8 (10); NS **Clavien Dindo:** 0: 35 (81) vs 68 (81); NS I: 3 (7) vs 3 (4); NS II: 3 (7) vs 7 (8); NS III: 2 (5) vs 4 (5); NS IV: 0 (0) vs 2 (2); NS	*IG vs CG;n (%); p-value* **Perioperative morbidity:** 6 (17.1) vs 7 (20.0); NS **Wound infection:** 2 (5.6) vs 2 (5.6); NR **Anastomosis leakage:** 1 (2.8) vs 0 (0); NR **Intraabdominal abscess:** 0 (0) vs 1 (2.8); NR **Bleeding:** 1 (2.8) vs 3 (8.5); NR **Ileus:** 1 (2.8) vs 1 (2.8); NR **Readmission** (>30 days after discharge): 1 (2.8) vs 2 (5.6); NS	IG vs. CG Total morbidity 6/35 vs 7/35 p=NS • Wound infection: 2/35 (5.71%) vs. 2/35 (5.71%) • Anastomosis leakage: 1/35 (2.86%) vs. 0 • Intra-abdominal abscess: 0 vs. 1/35 (2.86%) • Bleeding: 1/35 (2.86%) vs. 3/35 (8.57%) • Ileus: 1/35 (2.86%) vs. 1/35 (2.86%) Grade of morbidity (Clavien-Dindo (IG vs. CG)) p=NS • I-II: 5/35 (14.29%) vs. 6/35 (17.14%) III-IV: 1/35 (2.86%) vs. 1/35 (2.86%)
Reoperations/additional surgeries	*IG vs CG; n (%); p-value* 2 (5) vs 4 (5); NS	*IG vs CG; n (%); p-value* **Reoperation (>30 days after discharge):** 1 (2.8) vs 1 (2.8); NS	NR
Conversion	*IG vs CG; n (%); p-value* **Surgeon-reported conversion:** 3 (7) vs 10 (12); NS Conversion to laparotomy: 2 (4.7) vs 2 (2.5); NR Conversion to standard pressure: 1 (2.3) vs 8 (9.5); NR **Extraction site:** Conversion to laparotomy: 2 (5) vs 2 (2); NR	*IG vs CG; N (%); p-value* **Conversion to laparotomy:** 0 (0) vs 0 (0); NS	IG: 0 CG:0, p=NS
Perioperative events & resource use			
Blood loss (in ml)	NR	*IG vs CG; mean (SD); p-value* 35.8 (36.3) vs 46.8 (31.3); NS	IG: Ø 35.8 ±26.3 CG: Ø 56.8 ±31.3, p=NS
Operation time in min.	*IG vs (CG; median (range); p-value* 172 (107-353) vs 145 (69-380); **p=0.005**	*IG vs CG; mean (SD); p-value* Skin-to-skin time: 195 (41.0) vs 129.7 (43.2); **p<0.001**	IG: Ø 195 ±41 CG: Ø 130 ±43, p<0.001
Transfusions	NR	NR	IG: 0 CG: 0, p=NS

Bowel			
	Colectomy	**Colectomy**	**Colectomy**
Author, year [reference number]	**Fleming et al. 2022 [48]**	**Park et al. 2019 [47]**	**Park et al. 2012 [66]**
Drain duration (days)	*IG vs CG; n (%); p-value* Number of patients requiring drain: 2 (5) vs 6 (7); NS	*IG vs CG; N (%); p-value* Ileus required a nasogastric drainage before discharge: 1 (2.8) vs 1 (2.8); NR	NR
Length of hospital stay (days)	*IG vs CG; median (range); p-value* 3 (2–43) vs 4 (2–15); p=0.05	*IG vs CG; mean (SD); p-value* 7.9 (4.1) vs 8.3 (4.2); NS	IG: Ø 7.9 ±4.1 CG: Ø 8.3 ±4.2, p=NS

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
Study characteristics				
Study design, indication	Single-centre unblinded, parallel-group, superiority RCT of patients with low rectal cancer	Multicentre, randomised, controlled, unblinded, parallel-group, superiority trial of patients with middle and low rectal cancer	International multicentre RCT of patients with rectal adenocarcinoma (ROLARR clinical trial)	Single-centre RCT of patients with mid to low-lying rectal cancer.
Country	China	China	29 sites across 10 countries (UK, Italy, Denmark, US, Finland, South Korea, Germany, France, Australia, Singapore)	South Korea
Funding/Sponsor	Initiated by the investigators; sponsored by Zhongshan Hospital Fudan University	Shenkang Hospital Development Center, Shanghai Municipal Health Commission (Shanghai), and Zhongshan Hospital Fudan University (Shanghai)	Medical Research Council and NIH	National Cancer Center
Intervention (IG) | Product	Robotic abdominoperineal resection | da Vinci S system	Robotic surgery for rectal cancer (e.g. total and mesorectal excision) | da Vinci Si System	Robot-assisted laparoscopic rectal cancer resection | da Vinci Surgical System	Robot-assisted laparoscopic rectal cancer resection | da Vinci Surgical System
Comparator (CG)	Laparoscopic abdominoperineal resection	Conventional laparoscopic surgery	Laparoscopic rectal cancer resection	Laparoscopic surgery
Experience of surgeon(s); time period	Surgeons had performed >50 robotic and >50 laparoscopic resections before; December 2013 – 2016 (randomisation)	Surgeons had performed >100 robotic and >100 laparoscopic surgeries per	40 surgeons with a minimum of 30 previous minimally invasive rectal cancer	2 surgeons; each had performed laparoscopic rectal cancer in over 500 patients

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
		year; >50 robotic and >50 laparoscopic resections before; July 2016 – December 2020 (randomisation)	resections, of which 10 were conventional and 10 robot-assisted. Patients were assessed for eligibility from January 2011-September 2014.	and robot-assisted surgeries in over 30 patients. Randomisation occurred from February 2012-March 2015
Number of randomised patients	347; IG: 174; CG: 173	1,240; IG: 620; CG: 620	IG: 237 randomised; 1 withdrew before surgery CG: 234 randomised; 4 had no surgery after randomisation	IG: 81 randomised, 66 available for analysis (rest excluded after randomisation) CG: 81, 73 available for analysis (rest excluded after randomisation)
Inclusion criteria	• 18-75 yrs • ASA class I–III • histologically confirmed low rectal adenocarcinoma (inferior tumour edge ≤5 cm from the anal verge) • assessed as clinical T1-T3 (mesorectal fascia not involved), N0-1 or ycT1-T3, Nx after preoperative neoadjuvant chemoradiotherapy by pelvic MRI • suitable for both robotic and laparoscopic surgery • no evidence of distant metastases • no other malignancies in the medical history except adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri	• 18-80 yrs • ASA class I-III • histologically proven rectal adenocarcinoma • assessed as cT1–T3 (the mesorectal fascia not involved) N0–N1 or ycT1–T3 Nx after preoperative radiotherapy or chemoradiotherapy • single middle or low rectal cancer (inferior tumour edge ≤10 cm from the anal verge, as measured by rigid rectoscopy) • the location of the tumour was categorised as middle (>5 to 10 cm from the anal verge) or low (≤5 cm from the anal verge) • no evidence of distant metastasis • no other malignancies in the medical history • suitable for both robotic and laparoscopic surgery	Inclusion: • Diagnosis of adenocarcinoma of the rectum Exclusion: • Patients with benign lesions of the rectum, cancers of the anal canal, locally advanced cancers not amenable to curative surgery or synchronous colorectal tumours requiring multisegment surgical resection	Inclusion: • Patients with mid or low-lying rectal cancer without distant metastases • All patients had rectal adenocarcinoma located within 9 cm of the anal verge Exclusion: • Cancer invading adjacent organs, distant metastases, severe concomitant disease • any other malignancy, • pregnant or breastfeeding females, • hereditary colorectal cancer, • emergency operation. • Patients with c3NO-2 tumours received preoperative chemoradiotherapy
Primary/secondary endpoints	• primary: 30-day postoperative complication rate (Clavien–Dindo grade	• primary: 3-yrs locoregional recurrence (any cancer recurrence in the	• Primary endpoint: Rate of conversion to open surgery	• Primary endpoint: Completeness of total mesorectal excision

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	II or higher) of the intent-to-treat population • secondary: compliance, surgical quality, pathological outcomes, postoperative short-term recovery, urinary and sexual function, and long-term oncological outcomes	pelvic or perineal area at 3 yrs after surgery • secondary: CRM positivity, 30-day postoperative complications, intraoperative outcomes, pathological outcomes, postoperative recovery	• Secondary endpoints: 30-day operative mortality, duration of operation, complications, pathological completeness of tumour excision, patient-reported bladder (International Prostate Symptom Score, I-PSS) and sexual function (International Index of Erectile Function, IIEF, and Female Sexual Function Index, FSFI)	• Secondary outcomes: circumferential and distal resection margin; Global Operative Assessment of Laparoscopic Skills; bowel function; morbidity (postoperative complications using Clavien-Dindo); postoperative pain (Present Pain Intensity Index and VAS); QoL (via Korean version of EORTC QLQ-C30 and the colorectal cancer module QLQ-CR38).
Follow-up (months)	1 month (primary outcome); 3 yrs (36 months) after surgery	1 month; ongoing	30 days and 6 months (latter for QoL)	QoL: postoperative; 3 weeks; 3 months; 12 months
Drop-outs (n (%))	By 30 days after surgery for primary outcome: IG: 0; CG: 0 By 3 yrs after surgery: 17 (4.9%) pts were lost to follow-up, 40 (11.5%) died	Before surgery: IG: 34; CG 35 Change in groups: IG: 6; CG: 7	IG: 1/236 (0.4%) CG: 4/230 (1.7%) PROP bladder data available on 351/466 (75%) PROP sexual function data available on 181/230 men (57%) and 54/15 (36%) women	NR
Patient characteristics				
Age of patients (yrs., mean (SD))	IG: 58.2 (9.6); CG: 59.5 (10.9)	IG: 59.1 (11.0); CG: 60.7 (9.8)	IG: Ø 64.4 ±10.98 CG: Ø 65.5 ±11.93, p=NR	IG: Ø 60.4±9.7 CG: Ø 59.7±11.7, p=NS
Sex (% female)	IG: 37.9; CG: 34.7	IG: 39.2; CG: 39.5	IG: 32% CG: 32%, p=NR	IG: 23% CG: 29%, p=NS
BMI (kg/m^2, n (%))	• Underweight <18.5: 4 (2.3) vs 10 (5.8) • Normal 18.5–23.9: 107 (61.5) vs 106 (61.3) • Overweight 24–27.9: 56 (32.2) vs 52 (30.1)	• Underweight <18.5: 31 (5.3) vs 32 (5.5) • Normal 18.5–23.9: 296 (50.5) vs 299 (51·1)	IG vs. CG, p=NR Underweight/normal (BMI 0-24.9): 39% vs 37% Overweight (BMI 25.0-29.9): 38% vs. 39%	IG: Ø 24.1 ± 3.3 CG: Ø 23.6 ± 3.0, p=NS

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	• Obese ≥28: 7 (4.0) vs 5 (2.9)	• Overweight 24–27.9: 213 (36.3) vs 210 (35.9) • Obese ≥28: 46 (7.8) vs 44 (7.5)	• Obese (BMI ≥ 30.0): 23% vs 24%	
Clinical classification	TNM (IG vs CG) p=NS I: 33.3% vs 38.2% II: 32.2% vs 32.9% III: 34.5% vs 28.9% ASA (IG vs CG) p=NS I: 71.3% vs 67.1% II: 26.4% vs 28.9% III: 2.3% vs 4.0%	TNM Stage (IG vs CG) p=NR I: 35.0% vs 34.7% II: 32.8% vs 34.2% III: 32.3% vs 31.1% ASA (IG vs CG) p=NR I: 55.3% vs 54.4% II: 39.2% vs 41.0% III: 5.5% vs 4.6% T Stage (IG vs CG) p=NR I-II: 42.5% vs 42.6% III: 57.5% vs 57.4% N Stage (IG vs CG) p=NR 0: 67.7% vs 68.9% I: 24.9% vs 24.8% II: 7.3% vs 6.3%	T stage (IG vs. CG), p=NR 0: 9% vs. 10% 1: 10% vs. 9% 2: 27% vs. 27% 3: 50% vs. 50% 4: 4% vs. 2% Tx or missing: 2% vs. 1% N stage: 0: 62% vs. 65% 1:27% vs. 25% 2:11% vs. 9% ASA (IG vs. CG) I: 17% vs. 22% II: 63% vs. 53% III: 19% vs. 22% IV: 0% vs. 0.4% Missing: 1% vs 2%	ASA (IG vs. CG), p=NS I: 30% vs. 41% II: 70% vs. 59% p/ypT classification, p=NS T0: 8% vs. 8% Tis: 3% vs. 6% T1: 12% vs 10% T2: 26% vs. 25% T3: 46% vs. 49% T4a: 3% vs. 1% T4b: 3% vs. 1% p/ypN classification, p=NS N0: 70% vs. 77% N1a: 14% vs. 7% N1b: 11% vs. 8% N1c: 3% vs. 3% N2a: 3% vs. 4% N2b: 0% vs. 1%
Patient-relevant outcomes				
Survival (overall and disease-specific or disease-free)	**Disease-free survival** (3-yrs rate of stage I–III pts): 85.3% vs 84.6% (log-rank NS; HR=0.918; 95% CI = 0.555–1.517); NS **Overall survival** (3-yrs rate of all pts): 91.1% vs 90.4% (log-rank NS; HR=0.912; 95% CI = 0.490–1.697); NS	NR	Mortality within 30 days: IG: 2/236 (0.8%) CG: 2/230 (0.9%), p=NS	NR
Recurrence (local, regional or distant)	*IG vs CG (n(%); difference (95% CI); p-value*	NR	NR	NR

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	Recurrence at 3 yrs after surgery (Locoregional recurrence: 5 (2.9) vs 9 (5.2); -2.3 (-7.0 to 2.1); NS • **Distant metastases:** 21 (12.1) vs 23 (13.3); -1.2 (-8.3 to 6.0); NS			
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR	IPSS score difference of 0.74 $CI_{95\%}$[-0.59;2.07], p=NS IIEF score difference of 0.80 $CI_{95\%}$[-4.10;5.70], p=NS FSFI score difference of 1.23 $CI_{95\%}$[-3.54;6.00], p=NS	PPI pain score postoperative day: IG M 1 (R 0-4) vs. CG M 1 (R 0-4), p=NS VAS score postoperative day: IG M 3(R 1-9) vs. CG M 2 (R 0-8), p=NS Authors report no difference in scores on QLQ-C30 after 3 weeks, 3 months and 12 months except for insomnia scores, where IG showed more sleep disturbances: IG Ø 28.3 $CI_{95\%}$[19.6;37] vs. CG Ø 15.7 $CI_{95\%}$[8.1;23.3], p<0.05 Reported that there were no significant differences in QLQ-CR38 scores except for sexual function after 12 months, where IG showed better functioning: Ø 35.2 $CI_{95\%}$[26.9;43.5] vs. Ø 23.0 $CI_{95\%}$[15.7;30.2], p<0.05
Time to resume work/daily activities	NR	NR	NR	NR
Patient satisfaction	NR	NR	NR	NR
Safety-related outcomes				
Intraoperative complications (e.g. air-leakage)	*IG vs CG; n (%); p-value* **Pts with any intraoperative complications:** 10 (5.7) vs 16 (9.2); NS	*IG vs CG; n (%); difference (95% CI); p-value*	IG: 36/236 (15.3%) CG: 34/230 (14.8%), p=NS	Intraoperative (p=NS) IG: 5/66 (7.6%) CG: 3/73 (4.1%) Perioperative complications (p=NS)

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	Damage to organ or structure: 4 (2.3) vs 7 (4.0); NR Equipment failure: 2 (1.1) vs 0 (0); NR Iatrogenic tumour perforation: 1 (0.6) vs 3 (1.7); NR Significant haemorrhage[11]: 3 (1.7) vs 7 (4.0); NR	**Intraoperative complications**: 32 (5.5%) vs 51 (8.7%);–3·3 (–6·3 to –0·3); **p=0.030** **Significant bleeding:** 16 (2.7%) vs 26 (4.4%); –1·7 (–4·0 to 0·4); NS **Damage to organs or structures:** 8 (1.4%) vs 14 (2.4%); –1·0 (–2·8 to 0·6); NS **Damage to seminal vesicle gland:** 3 (0.5%) 8 (1.4%); –0·9 (–2·2 to 0·3); NR **Damage to prostate:** 2 (0.3%) vs 3 (0.5%); –0·2 (–1·2 to 0·8); NR **Damage to ureter:** 1 (0.2%) vs 2 (0.3%); –0·2 (–1·1 to 0·7); NR **Damage to the vagina:** 2 (0.3%) vs 1 (0.2%); 0·2 (–0·7 to 1·1); NR **Anastomotic complications:** 4/486 (0.8%) vs 9/449 (2.0%); –1·2 (–3·0 to 0·4); NS **Iatrogenic perforation:** 4 (0.7%) vs 5 (0.9%); –0·2 (–1·4 to 1·0); NS **Equipment failure:** 2 (0.3%) vs 0; 0·3 (–0·3 to 1·2); NS		IG: 23/66 (34.8) CG: 17/73 (23.3%) Clavien-Dindo classification (IG vs. CG), p=NS I: 6/66 (9.1%) vs. 3/73 (4.1%) II: 11/66 (16.7) vs. 10/73 (13.7%) IIIa: 4/66 (6.4%) vs. 2/73 (2.7%) IIIb: 2/66 (3.0%) vs. 2/73 (2.7%)
Postoperative complications (e.g. infections)	*IG vs CG: n (%); unadjusted difference (95% CI); p-value (within 30 days after surgery)*	*IG vs CG: n (%); difference (95% CI); p-value (within 30 days after surgery)* **Mortality within 30 days postoperatively**: 1 (0.2) vs 1 (0.2); 0.0 (-0.8 to 0.8); NS	Within 30 days: IG: 78/236 (33.1%) CG: 73/230 (31.7%), p=NS >30days and ≤6months: IG: 34/236 (14.4%)	NR

[11] Intraoperative hemorrhage more than 100 ml at one time.

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	Total 30-day postoperative complication rate (Clavien–Dindo grade II or higher): 23 (13.2) vs 41 (23.7); -10.5 (-18.6 to -2.3); **p=0.013** **Postoperative mortality:** 0 vs 0; NE; NE **Clavien–Dindo classification grade II:** 16 (9.2) vs 28 (16.2); –7.0 (–14.1 to 0.1); NS **Clavien–Dindo classification grade III:** 7 (4.0) vs 12 (6.9); –2.9 (–8.1 to 2.1); NS **Wound infection:** 4 (2.3) vs 4 (2.3); 0 (–3.8 to 3.8); NS **Ileus:** 1 (0.6) vs 3 (1.7); –1.2 (–4.5 to 1.6); NS **Abdominal/pelvic infection/abscess:** 0 (0) vs 2 (1.2); –1.2 (–4.1 to 1.0); NS **Pulmonary infection/pleural effusion:** 1 (0.6) vs 1 (0.6); 0 (–2.7 to 2.7); NS **Stomal complications:** 1 (0.6) vs 1 (0.6); 0 (–2.7 to 2.7); NS **Anastomotic leakage:** 0/6 vs 1/3; –33.3 (–80.7 to 18.5); NS **Clavien–Dindo classification grade IV:** 0 (0) vs 1 (0.6); –0.6 (–3.2 to 1.6); NS **Readmission within 30 days:** 4 (2.3) vs 12 (6.9); –4.6 (–9.6 to –0.1); **p=0.044** In the subgroup analysis, more advantages were observed in the IG for	**Complications of Clavien–Dindo grade II or higher grade within 30 days after operation:** 95 (16.2) vs 135 (23.1); -6.9 (-11.4 to -2.3); **p=0.003** **Anastomotic leakage:** 25/486 (5.1) vs 37/449 (8.2); -3.1 (–6.5 to 0.1); NS **Abdominal or anastomotic bleeding:** 8 (1.4) vs 12 (2.1); –0.7 (–2.3 to 09); NS **Wound-related:** 18 (3.1) vs 22 (3.8); –0.7 (–2.9 to 1.5); NS **Ileus:** 5 (0.9) vs 11 (1.9); –1.0 (–2.6 to 0.3); NS **Urinary retention or infection:** 10 (1.7) vs 17 (2.9); –1.2 (–3.1 to 0.6); NS **Stoma-related:** 3/229 (1.3) vs 4/253 (1.6 ;–0.3 (–2.9 to 2.4); NS **Deep vein thrombosis:** 6 (1.0) vs 9 (1.5); –0.5 (–2.0 to 0.9); NS **Central venous catheter infection**: 7 (1.2) vs 6 (1.0); 0.2 (–1.2 to 1.5); NS **Pulmonary infection:** 4 (0.7) vs 7 (1.2); –0.5 (–1.9 to 0.7); NS **Arrhythmia and hypertension:** 12 (2.0) vs 9 (1.5); 0.5 (–1.1 to 2.2); NS **Others**: 7 (1.2) vs 9 (1.5); –0·3 (–1.9 to 1.1); NS **Readmissions within 30 days after operation:** 17 (2.9) vs 20 (3.4); –0.5 (–2.6 to 1.6); NS	CG: 38/230 (16.5%), p=NS	

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	male patients, age ≥60 yrs, BMI ≥24 kg/m^2, tumour size ≥4 cm, and pathological N stage positivity (no statistical significance in the interaction analysis)			
Reoperations/additional surgeries	*IG vs CG: n (%); unadjusted difference (95% CI); p-value* **Reoperation within 30 days:** 5 (2.9) vs 10 (5.8); –2.9 (–7.7 to 1.6); NS	*IG vs CG: n (%); difference (95% CI); p-value (within 30 days after surgery)* **Reoperation within 30 days:** 14 (2.4) vs 24 (4.1); –1.7 (–3.9 to 0.3); NS	NR	NR
Conversion	*IG vs CG; n (%); p-value* **Open conversion:** 0 (0) vs 5 (2.9); **p=0.030**	*IG vs CG; n (%); difference (95% CI); p-value* Conversion to open surgery: 10 (1.7) vs 23 (3.9); –2.2 (–4.3 to –0.4); **p=0.021**	IG: 19/236 (8.1%) CG:28/230 (12.2%) Unadjusted risk difference 4.1% $CI_{95\%}$[-1.4%;9.6%]	IG: 1/66 (1.5%) CG: 0, p=NS
Perioperative events & resource use				
Blood loss (in ml)	*IG vs CG; median (IQR); p-value* **Intraoperative haemorrhage:** 100 (90–110) vs 130 (100–150); **p<0.001**	*IG vs CG; median (IQR); difference (95% CI); p-value* Estimated blood loss: 40.0 (30.0 - 100.0) vs 50.0 (40.0 -100.0); –10·0 (–20.0 to –10.0); **p<0.0001**		IG: M 100 (R 0-1000) CG: M 50 (R 0-300), p<0.0001
Operation time in min.	*IG vs CG; median (IQR); p-value* 205 (195–220) vs 195 (160–238); **p=0.004**	*IG vs CG; median (IQR); difference (95% CI); p-value* 173.0 (140.0 - 225.0) vs 170.0 (140.0 – 209.0); 2.0 (–4.0 to 10.0); NS	IG: Ø 298.5 ±88.71 CG: Ø 261.0 ±83.24, p=NR Difference in use of operating theatre (IG minus CG): Ø 50.88 minutes $CI_{95\%}$[-20.26;81.56], p=0.001	IG: Ø 339.2 ±80.1 CG: Ø 227.8 ±65.6, p<0.0001
Transfusions	*IG vs CG; n (%); p-value* **Patients with perioperative transfusion:** 0 (0) vs 1 (0.6); NS	*IG vs CG; n(%);difference (95% CI); p-value* **Blood transfusions:** 2 (0.3) vs 7 (1.2); -0.9 (-2.2 to 0.2); NS	NR	NR
Drain duration (days)	*n (%); p-value* **Drainage:**	NR (pts with grade II anastomotic leakage recovered after fasting, anti-infection measures, nutritional support,	NR	NR

Bowel				
	Rectal resection	**Rectal resection**	**Rectal resection**	**Rectal resection**
Author, year [reference number]	**Feng et al. 2022a [49]**	**Feng et al. 2022b [50]**	**Jayne et al. 2017 [65]**	**Kim et al. 2018 [75]**
	No drainage tube placed in the abdominal cavity: 164 (94.3) vs 158 (91.3); NS **One drainage tube placed in the pelvic cavity through the perineum:** 174 (100) vs 173 (100); NE **<u>Urinary drainage:</u>** **Using urinary catheterisation:** 174 (100) vs 173 (100); NE **Since postoperative day 2, clipping the urinary catheter to exercise bladder function. If patients felt bladder filling, remove the catheter:** 165 (94.8) vs 166 (96.0); NS	and drainage (placed during primary tumour surgery))		
Length of hospital stay (days)	*IG vs CG; median (IQR); p-value* **Hospital stay after surgery:** 5.0 (5.0–6.0) vs 7.0 (6.0–9.0); **p<0.001**	*IG vs CG; median (IQR); difference (95% CI); p-value* **Postoperative hospital stay**: 7.0 (7.0-11.0) vs 8.0 (7.0-12.0); –1.0 (–1.0 to 0.0); **p=0.0001**	IG: Ø 8.0 ±5.85 CG: Ø 8.2 ±6.03, p=NR	IG: Ø 10.3 ±3.4 CG: Ø 10.8 ±7.4, p=NS

Bowel			
	Rectal Resection	**Rectal Resection**	**Rectal Resection**
Author, year [reference number]	**Tolstrup et al. 2018[12] [77]**	**Debakey et al. 2018 [78]**	**Wang et al. 2017 [74]**
Study characteristics			

[12] This study reports on a subset of patients from the ROLARR trial pertaining to the Denmark centre. To avoid double-counting, only those results which are not reported in the main trial publication by Jayne et al are reported here.

Bowel			
	Rectal Resection	**Rectal Resection**	**Rectal Resection**
Author, year [reference number]	**Tolstrup et al. 2018[12] [77]**	**Debakey et al. 2018 [78]**	**Wang et al. 2017 [74]**
Study design, indication	Single-centre RCT of patients with rectal adenocarcinoma (ROLARR clinical trial): Denmark centre	Single centre RCT	Single centre RCT
Country	Denmark	Egypt	China
Funding/Sponsor	NR	Funded by the National Cancer Institute, Cairo University, Egypt.	National Natural Science Foundation of China (Grant no. 81500417)
Intervention (IG) | Product	Robot-assisted laparoscopic rectal cancer resection | da Vinci Surgical System	Robot-assisted rectal cancer resection | Da Vinci robotic system Intuitive Surgical Inc, (Sunnyvale, CA)	Robot-assisted total mesorectal excision | device unspecified
Comparator (CG)	Laparoscopic rectal cancer resection	Conventional laparoscopic rectal resection	Conventional laparoscopic total mesorectal excision
Experience of surgeon(s); time period	30 previous minimally invasive rectal cancer resections, 10 conventional and 10 robot-assisted. Study was conducted from November 2012 to April 2014.	Procedures were performed by the same surgeon team but no information on the experience. Randomisation performed from April 2015 to February 2017	No information on the experience of surgeons Randomisation performed from November 2010 to September 2013
Number of randomised patients	IG : 25	IG: 21 CG: 24	IG: 71 CG: 66
Inclusion criteria	NR	Inclusion criteria: • Histological diagnosis of adenocarcinoma of rectum located within 15 cm from the anal verge. • No anesthesiological contraindications to minimally invasive surgery • age ≤ 75 years • ASA ≤ 2 Exclusion Criteria: • Metastatic disease • Malignant bowel obstruction (MBO) • Unresectable tumour	Inclusion criteria • Male patients with medium (7-12 cm from the anal verge) to low (≤ 7 cm from the anal verge) rectal cancer Exclusion criteria: • Pre-operative sexual dysfunction (n=61) • History of: prior rectum or urinary tract surgery, abdominal perineal resection, partial mesorectal resection, local or distant recurrence (n=102) • Death within 12 months (n=25) • Incomplete follow-up data (n=11)
Primary/secondary endpoints	• The aim was to assess perioperative pain via a numeric rating scale (NRS). Length of surgery and complications were also assessed.	Short-term operative outcomes and complications, oncological outcomes	Urinary function (via International Prostate Symptom Score where higher scores indicate more severe symptoms) and

Bowel			
	Rectal Resection	**Rectal Resection**	**Rectal Resection**
Author, year [reference number]	**Tolstrup et al. 2018[12] [77]**	**Debakey et al. 2018 [78]**	**Wang et al. 2017 [74]**
			sexual function (via International Index of Erectile Function where a higher score indicates better functioning) Complete erectile dysfunction defined as domain score < 10; partial erectile dysfunction defined as domain score <17 but ≥19)
Follow-up (months)	Discharge from the recovery ward	1 Month	12 months
Drop-outs (n (%))	NR	NR	Only patients with follow-up data were included in the analysis
Patient characteristics			
Age of patients (yrs., mean)	IG: Ø 63 ±10.9 CG: Ø 68 ±9.9, p=NS	IG: M 53.4 (R 32-67) vs.CG: M 50.3 (R 36-64) p=NS	IG: Ø 60.3 (R 36-68) vs. CG Ø 58.7 (R 36-71), p=NS
Sex (% female)	IG: 72% CG 77%; p=NS	IG: 48% vs. CG:46%, p=NR	IG: 0% vs CG 0%
BMI (kg/m², mean)	IG: Ø 27 ±4.5 CG: Ø 28 ±4.3, p=NS	MBI (kg/m2), p=NS MBI< 30 IG: 48% vs. CG: 33% MBI >/= 30 IG: 11 (52%) vs. CG16 (67%)	IG: Ø 22.9 (R 19.1-30.1) vs. CG: Ø 22.4 (R 18.3-30.6), p=NS
Clinical classification	ASA (% IG vs % CG), p=NS 1: 44% vs. 38% 2: 28% vs. 31% 3: 0 vs. 4% 4: 0 (y)pT-stage (% IG vs. % CG), p=NS 0: 12% vs. 12% 1: 12% vs. 4% 2: 16% vs. 12% 3: 52% vs. 58% 4: 0 vs. 15%	Clinical stage, p=NS I: IG: 1/21 (5%) vs. CG: 4/24 (17%) II: IG:15/21(71%) vs 17/24 (71%) III: IG: 5/21(24%) vs. 3/24 (13%)	TNM (tumour, node, metastasis system) 0/1: IG: 9/71 (13%); CG: 8/66 (12%) II: IG: 22/71 (31%); CG 24/66 (36%) III: IG 40/71 (56%); CG: 34/66 (52%)
Patient-relevant outcomes			

Bowel			
	Rectal Resection	**Rectal Resection**	**Rectal Resection**
Author, year [reference number]	**Tolstrup et al. 2018[12] [77]**	**Debakey et al. 2018 [78]**	**Wang et al. 2017 [74]**
Survival (overall and disease-specific or disease-free)	NR	30-day mortality: IG: 0/21 (0%) vs. CG: 1/24 (4%) p=NR	30-day mortality: IG: 0/71 (0%); CG: 0/66 (0%)
Recurrence (local, regional or distant)	NR	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NRS mean (recovery): IG: 1.800 (0-5) CG: 2.000 (0-5), p=NS NRS max (recovery): IG: 4 (0-10) CG: 5 (0-9), p=NS	NR	<u>Urinary function</u> IG post-op vs pre-op IPSS: 6.79 vs. 4.04, p=NS CG post-op vs. pre-op IPSS: 9.66 vs. 4.12, p<0.05 Total IPSS scores postoperatively: IG 6.79 vs CG 9.66, p<0.05 <u>Sexual function</u> IG post-op vs. pre-op IIEF: 46.2 vs 56.4, p<0.05 CG post-op vs. pre-op IIEF: 40.1 vs. 57.9, p<0.05 Total IIEF scores postoperatively: IG 46.2 vs CG 40.1, p<0.05 Incidence of partial and complete erectile dysfunction: IG 19/71 (27%); CG 32/66 (48%), p<0.05
Time to resume work/daily activities	NR	NR	Return of gastrointestinal function: IG: 37 h vs CG: 51 h, p<0.05
Patient satisfaction	NR	NR	NR
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR	NR	NR
Postoperative complications (e.g. infections)	Not clearly stated but likely to be period until discharge: Total IG 10/25, CG 10/26 p=NS. Clavien-Dindo classification: 1: IG 1; CG 4 2: IG 6; CG 1 3: IG 2; CG 4 4: IG 0; CG 1 5: IG 1; CG 0	Total number, p=NS IG: 6/21 (29%) vs.CG: 7/24 (29%) • Anastomotic leakage: IG 1; CG 1 • Ileus (median days): IG: 2; CG 3 • Wound problems: IG 2; CG 2 • Others: IG 1 (DVT); CG 1 (erectile dysfunction) Severity: • No complications: IG 15/21 (71%) vs. 18/24 (75%), p=NS • Grade I: IG 4/21 (19%) vs. CG 5/24 (21%)	IG: 8/71 (11%): 2 anastomotic leakages, 2 lung infections, 1 urinary tract infection, 1 intraabdominal abscess, 1 abdominal cavity bleeding, 1 incisional wound infection CG: 10/66 (15%): 3 anastomotic leakages, 3 lung infections, 1 urinary tract infection, 3 incisional wound infections.

Bowel			
	Rectal Resection	**Rectal Resection**	**Rectal Resection**
Author, year [reference number]	**Tolstrup et al. 2018[12] [77]**	**Debakey et al. 2018 [78]**	**Wang et al. 2017 [74]**
		• Grade II: IG 1/21 (5%) vs. CG 1/24 (4%) • Grade III: IG 1/21 (5%) vs. 0 • Grade IV: IG 0 vs.CG 0 Grade v: IG 0 vs. CG 1/24 (4%)	
Reoperations/additional surgeries	NR	IG: 0 vs. CG: 1/24 (4%), p=NR	NR
Conversion	IG: 1/25 CG: 10/26, p<0.01	IG 1/21 (5%) vs. CG: 2/24 (8%), p=NR	NR
Perioperative events & resource use			
Blood loss (in ml)	NR	IG: M 200 (R 50-650) vs. CG: M 325 (R 100-800), p=0.05	NR per treatment group
Operation time in min.	IG: 152±43 CG: 170±57, p=NS	IG: M 201 (R 140-280) vs. CG: M 134.5 (R 110-190), p<0.001	IG: Ø 246.9 (R 210-330) vs CG: 207.3 (R 170-230), p<0.01
Transfusions	NR	NR	NR
Drain duration (days)	NR	NR	NR
Length of hospital stay (days)	NR	IG: M 3 (R 2-14) vs. CG: M 2 (R 2-11), p=NS	NR

Bowel		
	Ventral mesh rectopexy	**Ventral mesh rectopexy**
Author, year [reference number]	**Laitakari et al. 2020 [51] & Mäkelä-Kaikkonen et al. 2019 [52]**	**Mäkelä-Kaikonen et al. 2016 [33, 76]**
Study design	Follow-up single-centre randomised controlled trials of patients with external or internal rectal prolapse	Single-centre RCT of patients with rectal prolapse and intussusception
Country	Finland	Finland
Funding/Sponsor	University of Oulu including Oulu University Hospital	State funding of the Medical Research Center Oulu University and the Finnish Menopause Society
Intervention (IG) | Product	Robot-assisted ventral mesh rectopexy | da Vinci Si	Robot-assisted ventral mesh rectopexy | da Vinci Surgical System
Comparator (CG)	Laparoscopic ventral mesh rectopexy	Laparoscopic ventral mesh rectopexy

Bowel		
	Ventral mesh rectopexy	**Ventral mesh rectopexy**
Author, year [reference number]	**Laitakari et al. 2020 [51] & Mäkelä-Kaikkonen et al. 2019 [52]**	**Mäkelä-Kaikonen et al. 2016 [33, 76]**
Experience of surgeon(s), time period	NR; February 2012 and May 2012 (recruitment) (2019, 2020)	3 experienced surgeons performed IG; 4 (these + 1 additional surgeon) performed CG. NR: No of prior operations. Operations performed from February to May 2012
Number of patients	30; IG. 16; CG:14	IG: 16 (total relapse 4, intrassusception 12) CG: 14 (total relapse 2, intussusception 11, 1 excluded)
Inclusion/exclusion criteria	• 18-85 yrs • Female • External rectal prolapse or recto-anal internal rectal prolapse, with or without the descent of the middle pelvic compartment, combined with symptoms of faecal incontinence and/ or obstructive defaecation (Details reported in the previous publication)	Inclusion: • females; • age 18-85; • ASA 1-3; • symptomatic, uncomplicated, isolated, rectal prolapse; symptomatic intussusception and enterocele Exclusion: • male; • ASA 4-5; • previous surgery; pregnancy now or future; suspicion of frozen pelvis
Primary/secondary endpoints	• primary: maintenance of the repaired pelvic anatomy 5 yrs after surgery (2020) • secondary: persistence of the effect of ventral mesh rectopexy on pelvic anatomy and functional results (2020) • primary: health care costs and HRQoL (2019) secondary: anatomical outcome and functional outcome (2019)	Perioperative parameters, complications and restoration of anatomy, postoperative pain via VAS
Follow-up (months)	5 yrs (2020); 24 months (2019)	Pain assessment 2 weeks after surgery Quality of life (Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, Prolapse/Incontinence Sexual Questionnaire) also condition-specific symptom and quality of life questionnaires (unspecified) at 3 months
Drop-outs (n (%)	Until follow-up at 5 yrs postoperative IG: 2 (12.5%); CG: 2 (14.3%)	QoL data on a total of between 19 and 26 patients; drop-out 35% to 52%
Age of patients (yrs.)	Overall; mean (SD); p-value 62.5 (11.2); p=NR (2019) NR (2020);	IG: Ø 60.8 ±11.5 CG: Ø 66.0 ±10.1, p=NR
Sex (% female)	IG: 100%; CG: 100%	IG and CG: 100%, p=NR
BMI (kg/m^2)	NR	IG: Ø 25.6 ±4.5

Bowel		
	Ventral mesh rectopexy	**Ventral mesh rectopexy**
Author, year [reference number]	**Laitakari et al. 2020 [51] & Mäkelä-Kaikkonen et al. 2019 [52]**	**Mäkelä-Kaikonen et al. 2016 [33, 76]**
		CG: Ø 24.3 ±3.0, p=NR
Clinical classification	NR	ASA (% IG vs. % CG), p=NR 1: 19% vs. 21% 2: 63% vs. 36% 3: 19% vs. 36%
Survival (overall and disease-specific or disease-free)	NR	NR
Recurrence (local, regional or distant)	At 24-month follow-up (2019): IG: 0 vs CG: 1 (8%); p=NR	NR
Quality of life or symptoms (e.g. measured by EQ-5D or SF-36)	*IG vs CG; n; mean (SD); difference between means (95% CI); p-value* QoL measurements 5 yrs postoperative (2020): CRAIQ-7: 14; 24.3 (32.0) vs 10; 43.8 (27.1); -20.4 (-43.2 to 2.5); NS POPIQ-7: 13; 9.5 (26.4) vs 10; 26.0 (27.9); -16.1 (-39.7 to 7.5); NS UIQ-7: 14; 25.7 (32.7) vs 10; 33.0 (31.4); -9.4 (-32.3 to 13.6); NS PFIQ-7: 14; 58.8 (82.1) vs 10; 102.7 (69.9); -47.8 (-103.7 to 8.0); NS	VAS @ 2 weeks: IG: Ø 2.9 ±1.8 CG: Ø 2.6 ±1.4, p=NS QoL at 3 months, mean difference (95% CI): PFDI-20: -61.9 $CI_{95\%}$[40.9 ;82.8%], p<0.01 PFIQ-7: -57.0 $CI_{95\%}$[29.3;84.5%], p<0.01 PISQ-12: 3.4 $CI_{95\%}$ [-6.2;-7.6%], p<0.05 No significant differences were found in symptom and condition-specific QoL scores in the between-group comparison as reported for the PFDI and 2 subscales (CRADI and POPDI). No between-group results were reported for PFIQ or PISQ.
Time to resume work/daily activities	NR	NR
Patient satisfaction	Satisfaction rate: (2019) IG: 87% vs 69%; NS	NR
Intraoperative complications (e.g. air-leakage)	NR	Perioperative bleeding: IG 2/16; CG 0/14, p=NS
Postoperative complications (e.g. infections)	NR	Vascular complication: IG 1; CG 0, p=NS Minor complications, p=NS Haemotoma: IG 1/16; CG 0 Perineal pain: IG 1/16; CG 0 Fever: IG 0; CG 1/14
Re-operations/ additional surgeries	At 24-month follow-up (2019):	NR

Bowel		
	Ventral mesh rectopexy	**Ventral mesh rectopexy**
Author, year [reference number]	**Laitakari et al. 2020 [51] & Mäkelä-Kaikkonen et al. 2019 [52]**	**Mäkelä-Kaikonen et al. 2016 [33, 76]**
Conversion	IG: 0 vs CG: 1 (8%); p=NR	IG 0 CG 0
Blood loss (in ml)	NR	NR
Operation time in min.	IG: 125; CG: 130; p=NS (2019)	IG: Ø 125 ±27 CG: Ø 130 ±25, p=NS
Transfusions	NR	NR
Drain duration (days)	NR	NR
Length of hospital stay (days)	IG: 2.2; CG: 2.5; p=NS (2019)	IG: Ø 2.2 ±1.5 CG: Ø 2.5 ±0.9, p=NS

Table A - 20: Extraction table Gallbladder/Liver/Spleen

	Hernia repair	**Hernia repair**	**Hernia repair**
Author, year [reference number]	**Costa et al. 2023 [54]**	**Prabhu et al. 2020 [56] & Miller et al. 2023 [59]**	**Olavarria et al. 2020 [57]**
Study characteristics			
Study design, indication	Single-blinded parallel-arm randomised controlled trial of patients with abdominal or pelvic incisional hernia	Multicentre, single-blinded, prospective randomised clinical pilot study (2020) and Follow-up (2023) of patients with inguinal hernia	Multicentre, multi-blinded, randomised controlled trial of patients with ventral hernia defect
Country	Brazil	USA	USA
Funding/Sponsor	No specific grant from funding agencies in the public, commercial, or not-for-profit sectors.	Intuitive Surgical (IUSI1602MR)	Intuitive Surgical
Intervention (IG) | Product	Robotic-assisted incisional hernia repair | da Vinci Si	Robotic transabdominal preperitoneal repair | NR	Robotic ventral hernia repair | NR
Comparator (CG)	Laparoscopic incisional hernia repair	Standard laparoscopic transabdominal preperitoneal repair	Laparoscopic repair
Experience of surgeon(s); time period	>50 minimal invasive hernia repairs before; May 2015 to September 2015 (recruitment)	>25 robotic and laparoscopic procedures before; April 2016 to April 2019 (enrollment)	Only surgeons experienced in minimally invasive hernia were allowed to participate in the study; April 2018 to February 2019
Number of randomised patients	40; IG: 20; CG:20	102; IG: 48; CG: 54	124; IG: 65; CG: 59

	Hernia repair	Hernia repair	Hernia repair
Author, year [reference number]	**Costa et al. 2023 [54]**	**Prabhu et al. 2020 [56] & Miller et al. 2023 [59]**	**Olavarria et al. 2020 [57]**
Inclusion criteria	• adult patients who met the criteria for any abdominal or pelvic incisional hernia •	• ≥21 yrs • no prior open abdominal surgery, presenting for primary or recurrent unilateral inguinal hernia repair • no previous preperitoneal mesh placement • BMI ≤40	• >18 yrs • Ventral hernia defect less than 12cm wide on physical examination, who would likely tolerate pneumoperitoneum • No history of open abdomen or extensive lysis of adhesions for bowel obstruction • No active infection (mesh infection)
Primary/secondary endpoints	• primary: length of time in the operating room, operative complications, postoperative length of hospital stay, hernia recurrence at 24-month follow-up • secondary: QoL and abdominal wall strength evaluation	• primary: was not selected because this study was designed as a pilot study (2020) • secondary: cost, surgeon ergonomics, multidimensional workload (2020)	• primary: number of days in hospital at 90 days after surgery (including postoperative and readmission length of stay) • secondary: operating room duration (incision to skin closure time), surgical site infections, surgical site occurrences, hernia recurrence, reoperation, Clavien-Dindo complication grades, emergency department visits, change in abdominal wall QoL, change in visual analogue scale pain scores, and costs from the healthcare system perspective
Follow-up (months)	In general: 7 days, 3 months, yearly and 2 yrs after surgery Hernia recurrence: 24 months after surgery QoL: 1 month and 24 months after surgery Abdominal wall strength: 24 months after surgery	7 days (±3 days) (2020) 1 month (±1 week) (2020) 12 months (± 1 month) after surgery (2023) 24 months (± 1 month) after surgery (2023)	1 month after surgery 90 days after surgery
Drop-outs (n (%))	Before Surgery: IG: 2 (10%); CG: 1 (5%)	30 days after surgery: IG: 3 (6.3); CG: 1 (1.9); (2020) 2 yrs after surgery: IG: 14 (29.2%); CG: 11 (20.4%); (2023)	At 90 days after surgery: IG: 0; CG: 1 (1.7%)
Patient characteristics			
Age of patients (yrs., mean)	*mean (SD);* p-value IG: 65.2 (10.8); CG 59.7 (12.7); NS	*mean (SD);* p-value IG: 56.1 (14.1); CG: 57.2 (13.3); NS	*IG vs CG; mean (SD); p-value* 50.1 (13.3) vs 48.0 (12.9); NS
Sex (% female)	IG: 61.1; CG: 68.4	IG: 4 (8.4); CG: 6 (11.1%)	IG: 74%; CG: 63%; NS

	Hernia repair	Hernia repair	Hernia repair
Author, year [reference number]	**Costa et al. 2023 [54]**	**Prabhu et al. 2020 [56] & Miller et al. 2023 [59]**	**Olavarria et al. 2020 [57]**
BMI (kg/m^2, mean)	*mean (SD)*; p-value IG: 30.5 (4.4); CG: 32.6 (6.6); NS	*mean (SD); p-value* IG: 24.9 (3.24); CG: 26.9 (4.42); **p=0.014**	*IG vs CG; mean (SD); p-value* 32.4 (4.6) vs 31.8 (5.4); NS
Disease	NR	NR	*IG vs CG; n (%);* p-value ASA: 1-2: 42 (65) vs 42 (71); NS 3-4: 23 (35) 17 (29); NS
Clinical classification	NR	NR	*IG vs CG; mean (SD); p-value* 50.1 (13.3) vs 48.0 (12.9); NS
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	*IG vs CG; n (%); p-value* Mortality (short-term, within 7 days): 0 vs 1 (5); NS	NR	NR
Recurrence (local, regional or distant)	IG: 2 (11.1); CG: 3 (15.75) (in 24-month-follow-up)	*IG vs CG; n;* p=NS NR (2020) Inguinal hernia recurrence: 2 yrs after surgery: 1 vs 1 (2023)	IG: 0 (0%); CG: 0 (0%); p=NS
Quality of life (e.g. measured by EQ-5D or SF-36)	*IG vs CG; mean (SD); p-value* Evaluated with the EORTC QLQ-C30 **30 days after surgery:** Global health: 77.36 (24.06) vs 71.00 (26.15); NS Functional: 78.93 (23.61) vs 73.36 (21.51); NS Symptoms: 23.13 (18.55) vs 29.07 (19.26); NS **2-yrs after surgery:** Global health: 72.07 (22.67) vs 67.69 (26.32); NS Functional: 77.27 (19.85) vs 67.19 (21.40); NS Symptoms: 22.13 (14.72) vs 30 (19.15); NS	*IG vs CG; mean (SD); p-value* Measured with the SF-36 **1 wk after surgery:** Physical component summary: -6.95 (8.64) vs -6.52 (8.50); NS Mental component summary: 0.00 (7.38) vs 0.80 (7.91); NS General Health: -1.72 (9.57) vs -1.98 (13.4); NS **30 days after surgery:** Physical component summary: -1.98 (8.90) vs -0.59 (8.91); NS Mental component summary: 0.71 (5.84) vs 0.65 (8.29); NS General Health: 1.55 (8.43) vs -2.31 (12.4); NS *IG vs CG; mean (SD); p-value*	*IG vs CG; median (IQR); difference in median (95% CI);* p-value Abdominal wall QoL measured by the modified Activity Assessment Scale: 52 (37-68) vs 65 (36-86); 8.25 (–1.75 to 20.00); NS

	Hernia repair	Hernia repair	Hernia repair
Author, year [reference number]	**Costa et al. 2023 [54]**	**Prabhu et al. 2020 [56] & Miller et al. 2023 [59]**	**Olavarria et al. 2020 [57]**
		1-yr after surgery: Physical component summary: 54.9 (7.3) vs 53.7 (8.2); NS Mental component summary: 55.9 (4.6) vs 54.8 (6.0); NS General Health: 82.6 (13.1) vs 76.8 (17.7); NS **2-yrs after surgery:** Physical component summary: 53.1 (8.1) vs 54.2 (6.1); NS Mental component summary: 53.9 (6.8) vs 53.4 (5.6); NS General Health: 77.8 (13.7) vs 77.8 (15.5); NS	
Time to resume work/daily activities	NR	NR	NR
Patient satisfaction	NR	NR	NR
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR	NR	NR
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* Complications (short-term, within 7 days): 3 (16.7) vs 2 (10.5); NS	*IG vs CG; n (%); p-value* 30-days after surgery: **Adverse Events:** 8 (16.7) vs 5 (9.3); NS Superficial surgical site infections: 0 (0.00) vs 1 (1.85); NS Purulent drainage from the wound: 0 (0.00) vs 1 (1.85); NS Seroma: 6 (12.5) vs 3 (5.6); NS Hematoma: 1 (2.08) vs 0 (0.00); NS Required Intervention: 0 (0.00) vs 1 (1.85); NS Oral Antibiotics: 0 (0.00) vs 1 (1.85); NS Urinary retention: 1 (2.08) vs 1 (1.85); NS	*IG vs CG; n (%); relative rate (95% CI); p-value* **Readmission:** 1 (2) vs 3 (5); 0.27 (0.03 to 2.43); p=NS **Emergency room visits:** 7 (11) vs 5 (9); 1.28 (0.43 to 3.75); p=NS **Wound complication:** 13 (20) vs 11 (19); 1.02 (0.51 to 2.08); p=NS Surgical site infection: 0 (0) vs 1 (2); NR; p=NS Seroma: 13 (20) vs 8 (14); NR; NS Hematoma: 0 (0) vs 2 (3); NR; NS **Clavien-Dindo complication:** 14 (22) vs 11 (19); 1.10 (0.54 to 2.24); NS 1-2: 14 (22) vs 10 (17); NR; NR 3-5: 0 (0) vs 1 (2); NR; NR

	Hernia repair	Hernia repair	Hernia repair
Author, year [reference number]	**Costa et al. 2023 [54]**	**Prabhu et al. 2020 [56] & Miller et al. 2023 [59]**	**Olavarria et al. 2020 [57]**
Reoperations/additional surgeries	None of these patients manifested a desire for reoperation at a 24-month follow-up	NR	*IG vs CG; n (%)* Reoperation: IG: 0 (0%); CG: 1 (2%); NS
Conversion	No conversion was registered.	One patient in the robotic group was converted to a laparoscopic procedure due to bleeding and was analysed based on intent to treat principles in the robotic group (2020).	*IG vs CG; n (%); relative rate (95% CI);* p-value Conversion to open repair: 1 (2) vs 1 (2); 0.76 (0.05 to 11.47); NS
Perioperative events & resource use			
Blood loss (in ml)	NR	NR	NR
Operation time in min.	*IG vs CG; mean (SD); p-value* 355.6 (89) vs 293.5 (89); **p=0.04**	*IG vs CG; median (25^{th}; 75^{th}); p-value* (2020) Time from skin incision to closure: 75.5 (59.0; 93.8) vs 40.5 (29.2; 63.8); **p<0.001** Time for dissection of the hernia: 18.0 (12.0; 27.0) vs 13.0 (7.00; 23.0); **p=0.012** Time for mesh fixation: 6.88 (5.00; 9.00) vs 1.00 (1.00; 3.00); **p<0.001** Time for peritoneal closure: 7.00 (5.00; 9.00) vs 2.00 (1.00; 3.00); **p<0.001**	*IG vs CG; mean (SD); relative rate (95% CI); p value* 141 (56) vs 77 (37); 62.89 (45.75 to 80.01); **p<0.001**
Transfusions	NR	NR	NR
Drain duration (days)	NR	NR	NR
Length of hospital stay (days)	*IG vs CG; mean (SD); p-value* 3.67 (1.78) vs 3.95 (2.66); NS	IG vs CG; hours; median (IQR); p=NS 5.75 (5.00; 7.00) vs 5.11 (4.00; 7.00) (2020)	*IG vs CG; n (%); p-value* Days in hospital at 90 days: 0 days 50: (77) vs 49 (84); NS 1 day 9: (14) vs 4 (7); NS 2 days: 4 (6) vs 1 (2); NS >3 days: 2 (3) vs 4 (7); NS

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
Study characteristics				

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
Study design, indication	Multicentre, blinded RCT of patients with ventral hernia	Registry-based, prospective, single-blinded RCT of patients with ventral hernia	International multicentre RCT of patients with gallbladder disease	Single-centre RCT of patients with gallbladder lithiasis or polyps with no evidence of choledocholithiasis
Country	USA	USA	7 institutions in the USA and 1 institution in Greece	Italy
Funding/Sponsor	Investigator-initiated grant from Intuitive Surgical; grants/payments from C-SATS and Activ Surgical reported by 1 author	Intuitive Surgical (IUSI1709AP)	Intuitive Surgical, Inc., Sunnyvale, CA, USA in association with the identified study investigators under a cooperative clinical trial agreement	None
Intervention (IG) | Product	Robotic ventral hernia repair | NR	Robotic ventral hernia repair | DaVinci Si or Xi	Robotic single-site cholecystectomy | da Vinci Single-Site Instruments	Single-incision laparoscopic robotic cholecystectomy | NR
Comparator (CG)	Laparoscopic ventral hernia repair	Laparoscopic ventral hernia repair	Multiport laparoscopic cholecystectomy	Four-port laparoscopic cholecystectomy
Experience of surgeon(s); time period	Each centre completed at least 50 standardised repairs as a ramp-up period; 50 cases were selected to ensure operating room staff and surgeons were optimised and to mitigate any possible effect of a learning curve of the standardised repair technique used; April 2018 – February 2019 (randomisation)	Training in advanced laparoscopy and complex abdominal wall reconstruction; robotic training and credentialing that was in line with requirements defined by Intuitive Surgical and our department of General Surgery; September 2017 to January 2020 (enrollment)	At the onset of the study, 8 of the 10 surgeons were new to the single-site technique; however, all 10 surgeons were experienced in laparoscopic and robot-assisted multiport techniques. The RSSC cases include procedures in which the surgeons were learning the technique Enrollment of patients occurred from September 2013-August 2015	Surgeons with prior experience with both operation techniques Operations were performed from September 2011-May 2013
Number of randomised patients	124; IG: 65; CG: 59	81; IG: 39; CG: 39[13] (2021)[14]	IG: 83 CG: 53	IG: 40 CG: 41
Inclusion criteria	• adult patients undergoing elective minimally invasive ventral	• ≥18 yrs • presenting in the elective setting with primary or incisional midline	Inclusion: • Age 18–80	Inclusion:

[13] There is an error in the CONSORT flow diagram in the study as 39+39=78.

[14] Assumed Data in Petro et al. 2021

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
	hernia repair with a defect less than 12 cm wide, and • likely able to tolerate pneumoperitoneum	ventral hernias of an anticipated width of 7 cm or less who were candidates for minimally invasive hernia repair	• Diagnosis of symptomatic gallbladder disease Exclusion: • Requirement of emergency procedure, acute cholecystitis, pregnancy, presence of upper midline visible abdominal scar(s) or keloid • Presence of umbilical hernia or prior umbilical hernia repair • Inability of the patient to tolerate the Trendelenburg position • Pneumoperitoneum • Cirrhosis • Mental impairment	• Diagnosis of gallbladder lithiasis or polyps with no evidence of choledocholithiasis • Age 18- 80 • BMI < 30 kg/m2, • Ability to adhere to the protocol Exclusion • Evidence of acute cholecystitis or stones in the common duct as assessed by liver function tests and abdominal ultrasound • Gallbladder stone > than 3 cm • Previous abdominal surgery through a midline or a right subcostal laparotomic incision • Ongoing pregnancy • Liver cirrhosis • ASA>II • Known allergy to the analgesic drugs adopted in the study protocol
Primary/secondary endpoints	• clinical outcomes: wound complication, hernia recurrence, port site hernia, readmission, reoperation • patient-reported outcomes: functional status, pain, satisfaction	• primary: pain on the first postoperative day and 1, 7, 30, and 365 days after surgery • secondary: measured preoperatively, at a mean (SD) of 30 (15) days and a mean (SD) of 12 (3) months, included pain as measured by the Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Intensity short form 3a and abdominal-wall–specific QoL	• Patient-perceived cosmesis, patient-reported satisfaction (BIQ, PSQ) and quality of life (QoL-SF 12) • Secondary endpoint: perioperative outcomes	• To evaluate the reduction by 50% of SIRC patients with moderate to severe pain at 24 h after surgery compared to the laparoscopy group • Secondary endpoints: VAS score and cosmetic outcome (subjective min 0-max 10) of the surgical scars. Further objectives: operative times, intra and postoperative morbidity, rate of incisional hernia.

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
		using the hernia-specific QoL (HerQLes) survey; operating room time, PACU opioid consumption measured in morphine equivalents, rates of same-day discharge, hospital LOS, as well as surgical site infection, surgical site occurrence, surgical site occurrence requiring a procedural intervention, ventral hernia recurrence, and cost.		
Follow-up (months)	12-months postoperative	30-days postoperative (2021) 12 months postoperative (2022)	Max. 3 months	IG: M 32.0 IQR [22.4-30.1] CG: M 36.8 IQR [26.9-39.5], p=NS
Drop-outs (n (%))	IG: 5 (8%); CG: 6 (10%)	After allocation (2021): IG: 3 (7.7); CG: 3 (7.7) By 12 months after surgery (2022): NR	at 2 weeks IG: 6/83 (7.2%) CG: 1/53 (1.9%) at 6 weeks IG: 16/83 (19.3%) CG: 3/48 (6.3%) at 12 weeks IG: 17/83 (20.5%) CG: 5/53 (9.4%)	IG: 10/40 (25.0%) CG. 10/41 (24.4%)
Patient characteristics				
Age of patients (yrs., mean)	IG: 50.1; CG: 48.0	*IG vs CG; median (IQR); p-value* 56 (50-70) vs 55 (49-60); NS	IG: Ø 46.8 ±15.5 CG: Ø 46.5 ±17.3, p=NS	NR, but it was reported "the groups were comparable in terms of age, sex and BMI"
Sex (% female)	IG: 74%; CG: 63%	IG: 41%; CG: 58%; p=NS	IG: 78% CG: 92%, p<0.05	
BMI (kg/m^2, mean)	IG: 32.4; CG: 31.8	*median (IQR); p-value* IG: 35 (31-39); CG: 31 (27-36); **p=0.02**	IG: Ø 30.4 ±6.5 CG: Ø 31.7 ±6.7, p=NS	
Clinical classification	ASA (IG vs CG) p=NS I: 8% vs 8%	ASA (IG vs CG; n (%) p=NS I: 1 (3) vs 1 (3)	ASA (IG vs. CG), p=NS I: 20% vs. 21%	NR

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
	II: 57% vs 63% III: 35% vs 29%	II: 7 (18) vs 2 (19) III: 29 (74) vs 27 (75) IV: 2 (6) vs 1 (3)	II: 63% vs. 64% III: 16 vs. 15% IV: 1 vs. 0	
Patient-relevant outcomes				
Survival (overall and disease-specific or disease-free)	NR	NR	NR	NR
Recurrence (local, regional or distant)	Hernia recurrence: 4 (7%) vs 5 (9%); NS; relative risk (95% CI): 0.68 (0.17 to 2.68)	*IG vs CG; data captured; n/N (%); p-value* 12-months postoperative: Hernia recurrence at 1 y: 13/38 (34) vs 6/33 (18); 71/75 (95); NS Clinical recurrence at 1 y: 5/20 (25) vs 0/17 (NR); 37/75 (49); **p=0.03** Composite recurrence at 1 y: 9/38 (24) vs 2/33 (6); 71/75 (95); **p=0.04** (2022)	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	*Median (IQR); p-value* **Measured by Hernia-specific quality of life Survey** 30-days postoperative: IG: 67 (45-79); CG: 75 (41 to 81); NS (2021) *n (95%CI); p-value* 1-y postoperative: IG: 92 (82-100); CG: 77 (49-93); **p=0.04** (2022)	SF-12: at 2 weeks, IG vs. CG (Ø±SD): 39±4.19 vs. 39.5±3.95,p=NS at 6 weeks, IG vs. CG: 39.23 ±3.79 vs. 40±3.41, p=NS at 3 months, IG vs CG: 40.45±3.05 vs. 41.18±5.53, p=NS	VAS (IG vs. CG), p=NS @ 24h: M 3 IQR [1-8] vs. CG: M 4 IQR [1-9], Δ-1 $CI_{95\%}$1 [-5;3] @ 7 days: M 0 IQR [0-2] vs. M 0 IQR [0-2], Δ 0 $CI_{95\%}$[-2;2], ns @ 30 days: M 0 IQR [0-0] vs. M 0 IQR [0-0], Δ 0 (NA)
Time to resume work/daily activities	NR	NR	NR	NR
Patient satisfaction	*IG vs CG; median (interquartile range); p-value; mean difference (95% CI)*	NR	BIQ (IG vs. CG) at 2 weeks	Cosmetic outcome (IG vs. CG) M 9 IQR [8-10] vs. M 8 IQR [7-8], Δ 1 $CI_{95\%}$[0 to 2], p=<0.01

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
	Visual analogue scale satisfaction at 1-y: 10.0 (8.0, 10.0) vs 10.0 (7.5, 10.0); NS; 0.3 (-0.7 to 1.3) *Median (interquartile range); p-value; mean difference (95% CI)* **Cosmetic satisfaction at 1-y:** 10.0 (5.0, 10.0) vs 10.0 (6.5, 10.0); NS; -0.2 (-1.4 to 1.0)		Questions 1-5: Ø 5.5 ±1.0 $CI_{95\%}$[5.3;5.8] vs. Ø 6.4 ±1.80 $CI_{95\%}$[5.9;6.9], p<0.01 Questions 6-8: Ø 20.5 ±3.3 $CI_{95\%}$[19.8;21.3] vs. Ø18.5 ±4.5 $CI_{95\%}$[17.3;19.7], p<0.01 at 6 weeks Questions 1-5: Ø 5.5 ±1.2 $CI_{95\%}$[5.2;5.8] vs. Ø 6.2 ±2.2 $CI_{95\%}$[5.5;6.9], p=NS Questions 6-8: Ø 21.2 ±3.2 $CI_{95\%}$[20.4;22.0] vs. Ø 19.8 ±3.8 $CI_{95\%}$[18.7;21.0], p=NS at 12 weeks Questions 1-5: Ø 5.4 ±1.4 $CI_{95\%}$[5.1;5.8] vs. Ø 6.1 ±1.5 $CI_{95\%}$[5.6;6.5], p<0.05 Questions 6-8: Ø 22.3 ±2.3 $CI_{95\%}$[21.7;22.8] vs. Ø 20.2 ±3.5 $CI_{95\%}$[19.2;21.2], p<0.01 PSQ (IG vs. CG) at 2 weeks Questions 1: Ø 8.3 ±2.0 $CI_{95\%}$[5.3;5.7] vs. Ø 7.2 ±2.1 $CI_{95\%}$[5.9;6.9], p<0.01 Questions 5: Ø 7.8 ±2.7 $CI_{95\%}$[7.1;8.4] vs. Ø 6.6 ±2.4 $CI_{95\%}$[5.9;7.3], p<0.05 at 6 weeks Questions 1: Ø 8.8 ±1.6 $CI_{95\%}$[8.4;9.2] vs. Ø 8.1 ±1.9 $CI_{95\%}$[7.6;8.7], p<0.05 Questions 5: Ø 8.9 ±1.6	

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
			$CI_{95\%}$[8.6;9.3] vs. Ø 8.2 ±1.8 $CI_{95\%}$[7.7;8.8], p<0.05 at 12 weeks Questions 1: Ø 9.2 ±1.1 $CI_{95\%}$[9.0;9.5] vs. Ø 8.1 ±1.9 $CI_{95\%}$[7.5;8.6], p<0.01 Questions 5: Ø 9.4 ±1.1 $CI_{95\%}$[9.2;9.7] vs. Ø 8.2 ±1.8 $CI_{95\%}$[7.6;8.7], p<0.01	
Safety-related outcomes				
Intraoperative complications (e.g. air-leakage)	NR	*IG vs CG; n (%); p-value* **Intraoperative complications (2021):** 2 (6) vs 2 (6); NR Bowel serosal injury: 1 (3) vs 2 (6); NS Liver injury: 1 (3) vs 0; NS	IG: 0 CG: 0, p=NS	IG vs. CG, p=NS Major adverse events: 0 vs. 0 Bile spillage: 2/30 (6.7%) vs. 5/30 (16,7%), ns Minor bleeding: 3/30 (10.0%) vs. 4/30 (13.3%), ns Liver damage at gallbladder fossa: 1/30 (3.3%) vs. 3/30 (10.0%)
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value; relative risk (95% CI)* **Wound complication:** 9 (15%) vs 8 (15%); NS; 0.93 (0.32 to 2.74)	*IG vs CG; n (%); p-value* **Postoperative complications (2021):** 2 (6) vs 3 (8); NS Pulmonary embolism 1 (3) vs 0; NS SSO: 0 vs 1 (3); NS Readmission: 1 (3) vs 1 (3); NS	Total IG 4/83 (5%) vs. CG 2/53 (4%) at 3 months, p=NS • Bile leakage: 0 vs. 1/53 (1.9%) • Wound infection: 2/83 (2.4%) vs. 1/53 (1.9%) • Inflammatory bowel disease: 1/83 (1.2%) vs. 0 Deep vein thrombosis/pulmonary embolism: 1/83 (1.2%) vs. 0	IG vs. CG @ 6 months Wound infection: 2/30 (6.7%) (of these 1 required incisional hernia) vs. 0, p=NS
Reoperations/additional surgeries	*IG vs CG; n (%); p-value; mean difference (95% CI)* **Reoperation:** 0 vs 5 (9%); **p=0.020**; NR	*IG vs CG; n (%); p-value* **Reoperation**: 0 vs 1 (3); NS (2021) **Reoperation:** 3 vs 4 (NR); NS (2022)	NR	NR

Gallbladder/Liver/Spleen				
	Hernia repair	**Hernia repair**	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Dhanani et al. 2021 [55]**	**Petro et al. 2021 & 2022 [53, 58]**	**Kudsi et al. 2017 [70]**	**Pietrabissa et al. 2016 [71]**
Conversion	NR	*IG vs CG; n (5); p-value* **Conversion to laparoscopy**: 2 (6) vs NA; NA (2021) **Conversion to robotic repair:** NA vs 0; NA (2021)	IG: 0 CG: 0	IG: 0 CG: 0, p=NS
Perioperative events & resource use				
Blood loss (in ml)	NR	NR	IG: 13.1 CG: 15.8, p=NS	NR
Operation time in min.	NR	*IG vs CG; median (IQR); p-value* 146 (123-192) vs 94 (69 -116); **p<0.001** (2021)	IG: Ø 61.0 ±27.5 CG: Ø 44.0 ±19.9, p<0.01	IG: Ø 98 ±34 CG: Ø 87 ±30, p=NS
Transfusions	NR	NR	IG: 0 CG: 0	NR
Drain duration (days)	NR	NR	NR	NR
Length of hospital stay (days)	NR	*Median (IQR); p-value* IG: 25 (10 to 30); CG: 10 (8 to 31); NS (2021)	IG: 16.7 hours CG: 13.9 hours, p=NS	IG: M 1.2 (R 1-3) CG: M 1.2 (R 1-3), p=NR

	Hepatectomy	**Cholecystectomy**	**Cholecystectomy**
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
Study characteristics			
Study design, indication	Randomised controlled trial of patients with synchronous colorectal liver metastases	Single centre RCT	Single centre RCT
Country	China	Netherlands	Switzerland
Funding/Sponsor	NR	NR	None
Intervention (IG) | Product	Robot-assisted laparoscopic hepatectomy | da Vinci	Robot-assisted single-site cholecystectomy| da Vinci telemanipulation system (Intuitive Surgical Inc, Mountain View, CA)	Robot-assisted single-site cholecystectomy | da Vinci single-site ™ cholecystectomy robotic system (Intuitive Surgical Inc, Sunnyvale, CA)

	Hepatectomy	Cholecystectomy	Cholecystectomy
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
Comparator (CG)	Laparoscopic hepatectomy	Standard laparoscopy cholecystectomies[15]	Single-port laparoscopic cholecystectomy
Experience of surgeon(s); time period	NR; May 2015 to June 2018 (selection)	3 experienced surgeons and assisting team with experience of >15 robotic procedures performed IG procedures; 5 surgical residents under the supervision of a qualified surgeon, performed laparoscopic cholecystectomies	Operations were performed by three senior surgeons with training and experience in both surgical techniques.
Number of randomised patients	122; IG: 61; CG: 61	IG 10 CG 10	IG 30; CG 30
Inclusion criteria	• Patients with synchronous colorectal liver metastases confirmed by clinicopathological diagnosis • treated with radical resection of colorectal cancer, no tumour residue was found • no large blood vessel infiltration, hepatic vein, or portal vein tumour thrombus was found by imaging examination • Child-Pugh liver function class was A or B • No severe organ dysfunction was observed	• Elective symptomatic cholelithiasis patients with cholecystolithiasis confirmed by ultrasound.	Inclusion: adults with benign gallbladder disease admitted for elective cholecystectomy • Exclusion: pregnant or breastfeeding, systemic disease, mental or organic disorders affecting consent/participation, malignant disease, previous abdominal surgery, obesity (BMI > 35.0 kg/m²).
Primary/secondary endpoints	• clinical manifestations (operation time, intraoperative blood transfusion, intraoperative blood loss, average intraoperative blood transfusion, hepatic porta occlusion time • Stress response indicators • Energy metabolism • Complications • Survival	• Procedure time	• Surgeon's physical and mental stress load. Secondary: intraoperative outcomes, complications, health-related quality of life, cosmesis
Follow-up (months)	1x/month within the first yr 1x/3 months within the second yr 1x/6 months in the third yr	None	1 year

[15] Not clearly stated but probably multi-port laparoscopy

	Hepatectomy	Cholecystectomy	Cholecystectomy
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
Drop-outs (n (%))	3 yrs after surgery IG: 30 (49.2%); CG: 35 (57.4%); p=NS	None	IG: 0 vs. CG 3/30 (10%) (three patients did not return the HRQoL and BIC questionnaires in the CG group at 1-year follow-up and were therefore excluded from the analyses)
Patient characteristics			
Age of patients (yrs., mean)	*IG vs CG; mean (±SD); p-value* 57.13 (± 5.86) vs 57.51 (± 6.27); NS	IG: M 46 (R 29-72) CG: M 54 (R 24-87), p=NR	IG Ø 52.4 (R 26-82) vs CG Ø 51.5 (R 30-78), p=NS
Sex (% female)	IG: 27.9%; CG: 37.7%	IG: 80% CG: 80%, p=NR	IG 67% vs. CG 53%, p=NS
BMI (kg/m^2, mean)	*IG vs CG; mean (±SD); p-value* 23.45 ± 2.32 vs 23.59 ± 2.22; NS	IG: 26[16] (R 18-47) CG: 25 (22-30), p=NR	IG Ø 27.3 ± 3.9 vs. CG Ø 27.3 ± 4.2, p=NS
Clinical classification	*IG vs CG; n (%); p-value* ASA 1-2: 49 (80.33) vs 44 (72.13); NS 3: 12 (19.67) vs 17 (27.87); NS	Cholecystolithiasis (chronic in IG 4/10 and CG 1/20)	Cholecystolithiasis: IG 29/30 vs. CG 29/30 Galbladder polyps: IG 1 vs. CG 1
Patient-relevant outcomes			
Survival (overall and disease-specific or disease-free)	*IG vs CG; n (%); p-value* **At 1-yr follow-up:** 52 (85.25) vs 48 (78.69); NS **At 2-yrs follow-up:** 43 (70.49) vs 40 (65.57); NS **At 3-yrs follow-up:** 31 (50.82) vs 26 (42.62); NS	NR	NR
Recurrence (local, regional or distant)	NR	NR	NR
Quality of life (e.g. measured by EQ-5D or SF-36)	NR	NR	Gastrointestinal Quality of Life Index: 1 month post-op: IG M 123 (R 83-140) vs. CG M 120 (R55-142), p=NS.

[16] Not stated if mean or median

	Hepatectomy	Cholecystectomy	Cholecystectomy
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
			12 months post-op: IG 123 (R 105-141) vs. CG 128 (94-143), p=NS
Time to resume work/daily activities	NR	NR	
Patient satisfaction	NR	NR	Body Image Questionnaire: 1 month post-op: IG M 37 (R 24-40) vs. CG 38 (19-40), p=NS 12 months post-op: IG M 35.5 (R 20-40) vs. CG M 39 (22-40)NR
Safety-related outcomes			
Intraoperative complications (e.g. air-leakage)	NR	NR	EAES grade: • No complications: IG 18/30 (60%) vs. CG 16/30 (53%), p=NS • Grade I: IG 8/30 (27%) vs. CG 11/30 (37%), p=NS • Grade II: IG 4/30 (13%) vs. CG 3/30 (10%), p=NS • Grade III-IV: IG 0 vs, CG 0. Type of complication, p=NS • Peritoneal tear (EAES Io): IG 8/30 (27%) vs. CG 11/30 (37%) • Minor bleeding (EAES IIo): IG 4/30 (13%) vs.CG 3/30 (10%) • Major bleeding (EAES > 11º): IG 0 vs. CG 0 Bile duct injury: IG 0 vs. CG 0
Postoperative complications (e.g. infections)	*IG vs CG; n (%); p-value* **Total complications**: 2 (3.3) vs 8 (13.1); **p=0.048** Intestinal obstruction: 1 (1.6) vs 2 (3.3); NR Bile leakage: 0 (0.0) vs 2 (3.3); NR Pleural effusion: 1 (1.6) vs 2 (3.3); NR Abdominal haemorrhage: 0 (0.0) vs 1 (1.6); NR Incision infection: 0 (0.0) vs 1 (1.6; NR)	NR	Complications within 30 days: IG 4/30 (13%) vs. CG 7/30 (23%), p=NS Dindo-Clavien IG vs. CG, p=NR: • No complications: 25/30 (83%) vs. 23/30 (77%) • Grade I: 2/30 (7%) vs. 4/30 (13%) • Grade II: 2/30 (7%) vs. 1/30 (3%) • Grade IIIa: 0 vs. 1/30 (3%) • Grade IIIb: 0 vs. 0 • Grade IVa: 0 vs. 0

	Hepatectomy	Cholecystectomy	Cholecystectomy
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
			• Grade IVb: 0 vs 1/30 (3%) • Grade V: 0 vs. 0 Type of complication (IG vs. CG), p=NS • Superficial wound infection: 2/30 (3%) vs. 1/30 (3%) • Periumbilical hematoma: 1/30 (3%) vs. 0 • Self-limiting fever episode: 0 vs 1/30 (3%) • Bowel paralysis: 0 vs 1/30 (3%) • Renal function impairment: 0 vs. 1/30 (3%) • Urinary retention: 1/30 (3%) vs. 0 • Nausea: 0 vs. 1/30 (3%) • Common bile duct stones: 0 vs. 1/30 (3%) • Multi-organ failure: 0 vs. 1/30 (3%) Incisional hernia (within 1 post-op year): IG 2/30 (7%) vs. CG 2/30 (7%), p=NS
Reoperations/additional surgeries	NR	NR	Rate of postoperative complications requiring re-intervention (Dindo-Clavien grade ≥IIIa): IG: 0 vs CG 2/30, p=NS
Conversion	NR	IG 0, CG: 0	Conversion to conventional laparoscopy: IG 2 (7%) vs. CG 3 (10%), p=NS Conversion to open surgery: IG 0 vs. CG 0
Perioperative events & resource use			
Blood loss (in ml)	*IG vs CG; mean (±SD); p-value* 203.11 (± 10.98) vs 356.00 (± 32.00); **p<0.001**	NR	IG: M 5.0 (R 0-150) vs. CG: M 3.5 (R 0-300), p=NS
Operation time in min.	*IG vs CG; mean (±SD); p-value* 156.34 (± 15.97) vs 184.18 (± 18.03); **p<0.001**	[17] IG: M 144 (R 111-234) vs. CG M 119 (R 71-189), p=NS	IG: M 85.5 (R 48-148) vs. CG: M 74 (R 31-135), p=NS
Transfusions	*IG vs CG; mean (±SD); p-value* 608.31 (± 117.08) vs 656.21 (± 103.75); **p=0.018**	NR	NR

[17] Defined as time between entry of the patient into the OR and departure from OR

	Hepatectomy	Cholecystectomy	Cholecystectomy
Author, year [reference number]	**Li et al. 2022 [60]**	**Ruurda et al 2003 [73]**	**Grochola et al. 2019 [72]**
Drain duration (days)	If no biliary leakage or bleeding was found, the abdominal drainage tube was placed and the operating table was restored to a horizontal position before the abdominal cavity was closed until the end of the operation. (duration NR)	NR	NR
Length of hospital stay (days)	NR	NR	IG: Ø 1.9 (R 1-4) vs. CG Ø 3.06 (R 1-26) Median: IG 2 (R 1–4) vs CG: 2 (R 1–26) p<0.05

Abbreviations: ASA = American Society of Anesthesiologists, BMI = body mass index, CG = control group, CI = confidence interval, CRM = circumferential resection margin, d = day, EORTC QLQ-C30 = European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire, EQ-5D = EuroQol 5 Dimension 5 Level, FU = follow-up, GERD = gastroesophageal reflux disease, GORD HRQOL = Gastro-oesophageal Reflux Health-Related Quality of Life scale, GORD = gastro-oesophageal reflux disease, GSRS = Gastrointestinal Symptom Rating Scale, HR = hazard ratio, ICU = intensive care unit, IG = intervention group, IQR = interquartile range, LN = lymph node, M = median, MD = mean difference, min = minutes, mL = millilitres, n = number of patients, NA = not applicable, NE = not evaluable, NR = not reported, NS = not significant, NSCLC = non-small cell lung cancer, PPI = proton pump inhibitor, PSQ = photograph series questionnaire, pts = patients, QoL = Quality of Life, QOLRAD = Quality of Life in Reflux and Dyspepsia, R = range, RATS = Robot-assisted thoracic surgery, RCT = randomised controlled trial, SD = standard deviation, SF-36 = 36-Item Short Form Health Survey, SIRC = single-incision robotic cholecystectomy, TNM = tumour (T), node (N), and metastasis (M), USA = United States of America, VAS = visual analogue scale, VATS = Video-assisted thoracic surgery, vs = versus, wk = week, wks = weeks, y = year, yrs = years, Ø = mean.

9.4. Literature search strategies

Medline

Database: Ovid MEDLINE(R) ALL <1946 to April 18, 2023>
Search Strategy:
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1 exp Robotic Surgical Procedures/ (15400)
2 robot*-assisted*.mp. (19709)
3 (robot* adj5 (surger* or surgical*)).mp. (27135)
4 1 or 2 or 3 (34479)
5 ((pulmonary or lung*) adj5 (segmentectom* or lobectom*)).mp. (5574)
6 ((excis* or resect*) adj5 (lobe* or lung*)).mp. (26301)
7 5 or 6 (30124)
8 4 and 7 (540)
9 limit 8 to clinical trial, all (11)
10 ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti.) not (exp animals/ not humans.sh.) (1396957)
11 8 and 10 (30)
12 9 or 11 (34)
13 limit 12 to (english or german) (33)
14 limit 13 to dt = 20180626-20230417 (19)
15 limit 13 to ed = 20180626-20230417 (12)
16 14 or 15 (19)
17 exp Mediastinum/su [Surgery] (1016)
18 (mediastin* adj5 (surg* or resect*)).mp. (5255)
19 exp Thymectomy/ (8272)
20 thymectom*.mp. (11057)
21 exp Thymus Gland/su [Surgery] (517)
22 (thymus adj5 (surg* or resect* or excis* or remov*)).mp. (879)
23 17 or 18 or 19 or 20 or 21 or 22 (17421)
24 4 and 23 (383)
25 limit 24 to clinical trial, all (5)
26 10 and 24 (17)
27 25 or 26 (20)
28 limit 27 to (english or german) (19)
29 limit 28 to dt = 20180704-20230417 (10)
30 limit 28 to ed = 20180704-20230417 (8)
31 29 or 30 (11)
32 exp Gastroesophageal Reflux/ (29103)
33 reflux.mp. (69499)
34 GER.mp. (3725)
35 GERD.mp. (10376)
36 GORD.mp. (909)
37 (plication* or fundic wrap*).mp. (4337)
38 anti-reflux.mp. (1764)
39 anti?reflux.mp. (4842)
40 exp FUNDOPLICATION/ (5080)
41 fundoplication*.mp. (7847)
42 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 (78723)
43 4 and 42 (506)
44 limit 43 to clinical trial, all (18)
45 10 and 43 (34)

46 44 or 45 (41)
47 45 or 46 (41)
48 limit 47 to (english or german) (38)
49 limit 48 to dt = 20180801-20230417 (7)
50 limit 48 to ed = 20180801-20230417 (6)
51 49 or 50 (8)
52 exp Esophagectomy/ (12349)
53 Oesophagectom*.mp. (1886)
54 Esophagectom*.mp. (16999)
55 ((Trans?hiat* or Trans-hiat*) adj3 (Oesophagectom* or Esophagectom*)).mp. (885)
56 ((oesophag* or esophag*) adj3 (remov* or excis* or resect*)).mp. (7310)
57 52 or 53 or 54 or 55 or 56 (22011)
58 4 and 57 (516)
59 limit 58 to clinical trial, all (18)
60 10 and 58 (55)
61 59 or 60 (59)
62 limit 61 to (english or german) (56)
63 limit 62 to dt = 20180808-20230417 (39)
64 limit 62 to ed = 20180808-20230417 (31)
65 63 or 64 (40)
66 exp Esophageal Perforation/ (4518)
67 ((oesophag* or esophag* or Heller*) adj3 (repair* or perforat* or myotom*)).mp. (8833)
68 exp Heller Myotomy/ (266)
69 LHM.ti,ab. (383)
70 exp Esophageal Achalasia/ (7667)
71 achalasia*.mp. (9614)
72 ((oesophag* or esophag*) adj3 (swallow* adj3 (disorder* or difficult* or problem* or impair*))).mp. (73)
73 ((oesophag* or esophag*) adj3 dysphagia*).mp. (1632)
74 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 (19055)
75 4 and 74 (124)
76 limit 75 to clinical trial, all (4)
77 10 and 75 (20)
78 76 or 77 (23)
79 limit 78 to (english or german) (20)
80 limit 79 to dt = 20180822-20230417 (6)
81 limit 79 to ed = 20180822-20230417 (4)
82 80 or 81 (6)
83 exp Gastrectomy/ (40644)
84 Gastrectom*.mp. (53232)
85 Pylorectom*.mp. (72)
86 ((stomach or pylor*) adj3 (remov* or excis* or resect*)).mp. (3690)
87 83 or 84 or 85 or 86 (55443)
88 4 and 87 (744)
89 limit 88 to clinical trial, all (32)
90 10 and 88 (90)
91 89 or 90 (103)
92 limit 91 to (english or german) (100)
93 limit 92 to dt = 20180824-20230417 (45)
94 limit 92 to ed = 20180824-20230417 (44)
95 93 or 94 (48)
96 exp Bariatric Surgery/ (32998)
97 bariatric*.mp. (28876)
98 (Gastric adj3 (bypass* or band* or stimul*)).mp. (24245)

99 Roux*.mp. (17459)
100 RYGB.ti,ab. (4111)
101 (sleeve* adj3 gastrectom*).mp. (8481)
102 96 or 97 or 98 or 99 or 100 or 101 (56710)
103 4 and 102 (527)
104 limit 103 to clinical trial, all (8)
105 10 and 103 (32)
106 104 or 105 (35)
107 limit 106 to (english or german) (33)
108 limit 107 to dt = 20180830-20230417 (13)
109 limit 107 to ed = 20180830-20230417 (16)
110 108 or 109 (17)
111 exp Intestine, Small/ (167611)
112 ((small bowel* or small intestine*) adj3 (remov* or excis* or resect*)).mp. (4527)
113 111 or 112 (169737)
114 4 and 113 (230)
115 limit 114 to clinical trial, all (2)
116 10 and 114 (7)
117 115 or 116 (9)
118 limit 117 to (english or german) (8)
119 limit 118 to dt = 20180831-20230417 (2)
120 limit 118 to ed = 20180831-20230417 (4)
121 119 or 120 (4)
122 exp Colectomy/ (23301)
123 colectom*.mp. (26877)
124 procto?colectom*.mp. (5407)
125 hemi?colectom*.mp. (5017)
126 sigmoidectom*.mp. (1226)
127 transversectom*.mp. (31)
128 ((colon* or hemi*colon* or sigmoid*) adj3 (remov* or excis* or resect*)).mp. (11062)
129 122 or 123 or 124 or 125 or 126 or 127 or 128 (41939)
130 4 and 129 (829)
131 limit 130 to clinical trial, all (15)
132 10 and 130 (62)
133 131 or 132 (68)
134 limit 133 to (english or german) (66)
135 limit 134 to dt = 20180904-20230417 (33)
136 limit 134 to ed = 20180904-20230417 (28)
137 135 or 136 (35)
138 polypectom*.mp. (5810)
139 proctectom*.mp. (2870)
140 rectopex*.mp. (1014)
141 ((rect* or colo?rect* or meso?rect* or polyp* or sphincter*) adj3 (remov* or excis* or resect*)).mp. (28659)
142 colo?rectom*.mp. (25)
143 rectom*.mp. (48)
144 138 or 139 or 140 or 141 or 142 or 143 (35415)
145 4 and 144 (1214)
146 limit 145 to clinical trial, all (35)
147 10 and 145 (149)
148 146 or 147 (163)
149 limit 148 to (english or german) (153)
150 limit 149 to dt = 20180907-20230417 (78)
151 limit 149 to ed = 20180907-20230417 (68)

152 150 or 151 (88)
153 ((gallbladder* or gall bladder*) adj3 (remov* or excis* or resect*)).mp. (2035)
154 exp Cholecystectomy/ (30690)
155 cholecystectom*.mp. (42635)
156 153 or 154 or 155 (43380)
157 4 and 156 (541)
158 limit 157 to clinical trial, all (27)
159 10 and 157 (49)
160 158 or 159 (55)
161 limit 160 to (english or german) (50)
162 limit 161 to dt = 20180911-20230417 (16)
163 limit 161 to ed = 20180911-20230417 (21)
164 162 or 163 (23)
165 exp Herniorrhaphy/ (11070)
166 herniorrhaph*.mp. (13072)
167 hernioplast*.mp. (1888)
168 (hernia* adj3 repair*).mp. (16769)
169 165 or 166 or 167 or 168 (24152)
170 4 and 169 (626)
171 limit 170 to clinical trial, all (18)
172 10 and 170 (37)
173 171 or 172 (41)
174 limit 173 to (english or german) (40)
175 limit 174 to dt = 20180914-20230417 (32)
176 limit 174 to ed = 20180914-20230417 (27)
177 175 or 176 (33)
178 remove duplicates from 177 (32)
179 ((liver* or hepat*) adj3 (remov* or excis* or resect*)).mp. (31575)
180 exp Hepatectomy/ (34106)
181 Hepatectom*.mp. (43721)
182 179 or 180 or 181 (58840)
183 4 and 182 (645)
184 limit 183 to clinical trial, all (4)
185 10 and 183 (27)
186 184 or 185 (31)
187 limit 186 to (english or german) (29)
188 limit 187 to dt = 20180913-20230417 (20)
189 limit 187 to ed = 20180913-20230417 (17)
190 188 or 189 (22)
191 16 or 31 or 51 or 65 or 82 or 95 or 110 or 121 or 137 or 152 or 164 or 178 or 190 (310)

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17.04.2023

Cochrane

Search Name: Robotic Surgery (Update 2023) Gesamt
Last Saved: 19/04/2023 17:27:20
Comment: LG 19.04.2023

ID Search

#1 MeSH descriptor: [Robotic Surgical Procedures] explode all trees
#2 (robot* assisted*) (Word variations have been searched)
#3 robot* near surg* (Word variations have been searched)
#4 (#1 OR #2 OR #3)
#5 (pulmonar* or lung*) near (segmentectom* or lobectom*) (Word variations have been searched)
#6 (excis* or resect*) near (lobe* or lung*) (Word variations have been searched)
#7 #5 or #6
#8 #4 AND #7 with Cochrane Library publication date Between Jun 2018 and Apr 2023, in Trials
#9 (conference proceeding):pt
#10 (abstract):so
#11 (clinicaltrials OR trialsearch OR ANZCTR OR ensaiosclinicos OR Actrn OR chictr OR cris OR ctri OR registroclinico OR clinicaltrialsregister OR DRKS OR IRCT OR Isrctn OR rctportal OR JapicCTI OR JMACCT OR jRCT OR JPRN OR Nct OR UMIN OR trialregister OR PACTR OR R.B.R.OR REPEC OR SLCTR OR Tcr):so (Word variations have been searched)
#12 #9 OR #10 OR #11
#13 #8 NOT #12
#14 MeSH descriptor: [Mediastinum] explode all trees
#15 mediastin* near (surg* or resect*) (Word variations have been searched)
#16 MeSH descriptor: [Thymectomy] explode all trees
#17 thymectom* (Word variations have been searched)
#18 MeSH descriptor: [Thymus Gland] explode all trees
#19 thymus near (surg* or resect* or excis* or remov*) (Word variations have been searched)
#20 #14 or #15 or #16 or #17 or #18 or #19 (Word variations have been searched)
#21 #4 and #20 with Cochrane Library publication date Between Jul 2018 and Apr 2023, in Trials
#22 #21 NOT #12
#23 MeSH descriptor: [Gastroesophageal Reflux] explode all trees
#24 gastro*esophageal reflux (Word variations have been searched)
#25 GER:ti,ab,kw
#26 GERD:ti,ab,kw
#27 GORD:ti,ab,kw
#28 (anti*reflux or reflux) near (surg* or operat* or management) (Word variations have been searched)
#29 MeSH descriptor: [Fundoplication] explode all trees
#30 fundoplication* (Word variations have been searched)
#31 plication* or fundic wrap* (Word variations have been searched)
#32 #23 or #24 or #25 or #26 or #27 #28 or #29 or #30 or #31
#33 #4 and #32 with Cochrane Library publication date Between Aug 2018 and Apr 2023, in Trials
#34 #33 NOT #12
#35 MeSH descriptor: [Esophagectomy] explode all trees
#36 Oesophagectom* (Word variations have been searched)
#37 Esophagectom* (Word variations have been searched)
#38 (Transhiat* OR Trans-hiat*) NEAR (Oesophagectom* OR Esophagectom*) (Word variations have been searched)
#39 (oesophag* OR esophag*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)
#40 #35 OR #36 OR #37 OR #38 OR #39 (Word variations have been searched)
#41 #4 AND #40 with Cochrane Library publication date Between Aug 2018 and Apr 2023, in Trials
#42 #41 NOT #12
#43 MeSH descriptor: [Esophageal Perforation] explode all trees
#44 ((oesophag* OR esophag* OR Heller*) NEAR (repair* OR perforat* OR myotom*)) (Word variations have been searched)
#45 MeSH descriptor: [Heller Myotomy] explode all trees
#46 (LHM):ti,ab,kw
#47 MeSH descriptor: [Esophageal Achalasia] explode all trees

#48 (achalasia*) (Word variations have been searched)
#49 ((oesophag* OR esophag*) NEAR (swallow* NEAR (disorder* OR difficult* OR problem* OR impair*))) (Word variations have been searched)
#50 ((oesophag* OR esophag*) NEAR dysphagia*) (Word variations have been searched)
#51 #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50
#52 #4 AND #51 with Cochrane Library publication date Between Aug 2018 and Apr 2023, in Trials
#53 #52 NOT #12
#54 MeSH descriptor: [Gastrectomy] explode all trees
#55 (Gastrectom*) (Word variations have been searched)
#56 (Pylorectom*) (Word variations have been searched)
#57 (stomach OR pylor*) NEAR (remov* OR excis* OR resect*)
#58 #54 OR #55 OR #56 OR #57 (Word variations have been searched)
#59 #4 AND #58 with Cochrane Library publication date Between Aug 2018 and Apr 2023, in Trials
#60 #59 NOT #12
#61 MeSH descriptor: [Bariatric Surgery] explode all trees
#62 (bariatric*) (Word variations have been searched)
#63 ((Gastric*) NEAR (bypass* OR band* OR stimul*)) (Word variations have been searched)
#64 (Roux*) (Word variations have been searched)
#65 (RYGB):ti,ab,kw
#66 (sleeve* NEAR gastrect*) (Word variations have been searched)
#67 #61 OR #62 OR #63 OR #64 OR #65 OR #66
#68 #4 AND #67 with Cochrane Library publication date Between Aug 2018 and Apr 2023, in Trials
#69 #68 NOT #12
#70 MeSH descriptor: [Intestine, Small] explode all trees
#71 (small bowel* OR small intestine*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)
#72 #70 OR #71
#73 #4 AND #72 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#74 #73 NOT #12
#75 MeSH descriptor: [Colectomy] explode all trees
#76 colectom* (Word variations have been searched)
#77 procto*colectom* (Word variations have been searched)
#78 hemi*colectom* (Word variations have been searched)
#79 sigmoidectom* (Word variations have been searched)
#80 transversectom* (Word variations have been searched)
#81 (colon* OR hemi*colon* OR sigmoid*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)
#82 #75 OR #76 OR #77 OR #78 OR #79 OR #80 OR #81 (Word variations have been searched)
#83 #4 AND #82 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#84 #83 NOT #12
#85 colo*rectom* (Word variations have been searched)
#86 rectom* (Word variations have been searched)
#87 polypectom* (Word variations have been searched)
#88 proctectom* (Word variations have been searched)
#89 rectopex* (Word variations have been searched)
#90 (rect* OR colo*rect* OR meso*rect* OR polyp* OR sphincter*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)
#91 #85 OR #86 OR #87 OR #88 OR #89 OR #90 (Word variations have been searched)
#92 #4 AND #91 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#93 #92 NOT #12
#94 MeSH descriptor: [Cholecystectomy] explode all trees
#95 Cholecystectom* (Word variations have been searched)
#96 (gallbladder* OR gall bladder*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)

#97 #94 OR #95 OR #96 (Word variations have been searched)
#98 #4 AND #97 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#99 #98 NOT #12
#100 MeSH descriptor: [Herniorrhaphy] 1 tree(s) exploded
#101 Herniorrhaph* (Word variations have been searched)
#102 Hernioplast* (Word variations have been searched)
#103 hernia* NEAR repair* (Word variations have been searched)
#104 #100 OR #101 OR #102 OR #103 (Word variations have been searched)
#105 #4 AND #104 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#106 #105 NOT #12
#107 (liver* OR hepat*) NEAR (remov* OR excis* OR resect*) (Word variations have been searched)
#108 MeSH descriptor: [Hepatectomy] explode all trees
#109 Hepatectom* (Word variations have been searched)
#110 #107 OR #108 OR #109 (Word variations have been searched)
#111 #4 AND #110 with Cochrane Library publication date Between Sep 2018 and Apr 2023, in Trials
#112 #111 NOT #12
#113 #13 OR #22 OR #34 OR #42 OR #53 OR #60 OR #69 OR #74 OR #84 OR #93 OR #99 OR #106 OR #112

174 Hits

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