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Correspondence: Authors' reply to Critical appraisal of "Goetz G, Wernly B, Wild C (2023) Wearable cardioverter defibrillator for preventing sudden cardiac death in patients at risk: An updated systematic review of comparative effectiveness and safety. IJC Heart & Vasculature 45 (2023) 101189" by M. Nürnberg, F. Semrau

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Authors' reply to Nürnberg and Semrau

Nürnberg and Semrau question the validity of our systematic review [1]. We respectfully disagree with their claim of errors [2].

First, our conclusion is based on the only available randomised controlled trial (RCT). In this trial, the pre-defined null hypothesis of no treatment effect (h0) could not be rejected [3].

Second, we are not convinced that we should have used our chosen methods or reported on the available evidence differently. We have addressed the non-statistical trend towards improvement of depression scores [4] in patients with a WCD. Although in disagreement, we acknowledge that Nürnberg and Semrau judge our risk of bias (RoB) scaling (IHE-20 checklist [5]) as unbalanced. Single-arm trials are, per se, of very limited value when assessing comparative effectiveness [6]. Regarding GRADE [7], it is correct that the certainty of endpoints should be evaluated separately, which is also the case in our assessment. Respective judgements on the endpoint level can be found within the footnotes. Subsequent per-protocol and other post-hoc analyses [8] are included in our review. However, we focused on the primary analysis of VEST [3] within our GRADE assessment as the effect of assignment to intervention [9] was assessed in our SR.

Third, it is essential to clarify that we did not accuse any researchers of academic misconduct: VEST [3] was methodologically strong, but had strengths and limitations. RoB concerning arrhythmic mortality was judged to be high due to "deviations from intended intervention" (low compliance), following the Cochrane RoB algorithm [10]. Further ratings (D4: we found no red flags, but upholding blinding was considered highly complex; D5: some secondary outcomes planned in the study protocol were not reported in currently available peer-reviewed publications) of some concerns were not causal for up- or downgrading the overall RoB for any of the endpoints.

We want to stress that the efficacy of a treatment is not the same as the comparative effectiveness of a treatment strategy. In post-MI patients, the WCD is part of a treatment strategy evaluated in the only available RCT [3], which did not demonstrate a statistically significant reduction in their primary endpoint arrhythmic mortality.

Fourth, the SR by Masri et al. [11] included 28 studies, while the SR by Aidelsburger et al. [12] included 46 studies. Both SRs had similar in- and exclusion criteria and used the same search period. Hence, it is reasonable to believe that Aidelsburger et al. [12] counted publications instead of studies (e.g., WEARIT-II). Of note, a recent HTA from Wales (HTW) came to similar conclusions as we did [13].

We acknowledge different opinions on the utility of the WCD for most high-risk patients among cardiologists [14,15]. We believe evidence from both sides has been presented to allow the medical community to form their own judgments.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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