



## Correspondence



**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”**

Dear Editors,

With great interest we read the systematic literature review (SLR) of Goetz et al. (*IJC Heart & Vasculature 45 (2023) 101189*) [1]. Goetz et al. from the Austrian aihta conducted a highly disputed HTA update on the WCD [2], which forms the basis for the publication in *IJC Heart & Vasculature*. In fact, there is a long list of inconsistencies, which were already addressed in detail. The full discussion can be followed on the website of the aihta institute (<https://eprints.aihta.at/1407/>).

We would like to address several limitations within this publication in *IJC Heart & Vasculature*.

First, an SLR or HTA should be factual, neutral and rather free of personal opinion. The opposite is true in this article. About two thirds of the discussion deal with authors' opinion that health care systems lack correct hurdles for patient therapies, that physicians do not understand principles of scientific evidence and that industry cannot be trusted. On the other hand, it is obvious that the authors have difficulty to understand and discuss the evidence of the wearable cardioverter-defibrillator (WCD) appropriately.

Second, the authors' view on the WCD is strongly biased, leading to selective reporting and manipulation of results.

The discussed study of Weiss et al. investigated a potential impact of the WCD on anxiety and depression. The investigators reported that there was a higher anxiety level prior to wearing the WCD in a patient cohort selected to receive the WCD [3]. Goetz et al. use this “side-note” information as the main result of the study and repeatedly state about this study, “*a statistical (positive) association between WCD and baseline anxiety was found when comparing both anxiety score and rate of anxiety between patients wearing a WCD and patients not wearing a WCD.*” However, the truth is exactly the opposite. In fact, Weiss et al. reported that, “*...the WCD is clearly not associated with increased anxiety and depression, but may have also positive impact on depressive symptoms. [...] In contrast to ICD treatment, [...], the WCD might enable patients to feel more secure.*” [3].

Goetz et al. used the Institute of Health Economics (IHE) tool assessing the risk of bias with observational studies [4]. However, they made two methodical mistakes, which downgraded *all* of the investigated studies unrelated to their quality. They included questions, the inventor of the IHE tool recommended to skip in single arm observational studies. Furthermore, Goetz et al. created a non-intuitive, unbalanced assessment scale, which guaranteed that most studies would be rated low quality. If one deletes only one inappropriate question without changing the non-intuitive scale, the assessments result was seven studies with moderate and only three studies with high risk of bias instead of seven studies with high risk of bias. With an appropriate scale, some studies reach a low risk of bias level and there is almost no study

left with a high risk of bias. (See the website of the aihta for details.).

Furthermore, the GRADE assessment was inappropriately done. While the GRADE group suggests as a core element that every parameter is assessed separately over a body of evidence [5], Goetz et al. put together the two most important outcomes (arrhythmic mortality and total mortality), although the confidence in the reliability of those outcomes is very different. While total mortality is the most reliable outcome ever, arrhythmic mortality (SCD) most often is linked with unwitnessed events with unreliable data, which additionally have to be adjudicated from remote. Goetz et al. adjudicated both outcomes of a large randomized trial with “low confidence”. They justify their low confidence in the RCT results with cross overs and low compliance. Of note, both reasons reduce the effect of the verum, which means, the true effect would be even greater without these limitations. Corresponding results were achieved by analyses using an “as-treated” as well as a “per-protocol” approach [6,7].

Third, authors bring forth accusations against investigators and adjudication committees in order to downgrade certain studies and publications.

As Goetz et al. often use general terms instead of being specific, one has to perform a more detailed analysis, why the RCT was considered having an overall low confidence level. Apart from crossover and low compliance, Goetz et al. say, “*...and some concerns were further found with regard to bias in measurement of outcomes and selection of reported results (see Fig. 2).*” But in Fig. 2, we find only general categories without explanations. When we look at the original HTA-Update, we find explanations for the serious concerns (crossover, compliance) in Domain 2. In Domain 4, a footnote states, “*Outcome assessors may have been aware of the intervention received.*” This means Goetz et al. accuse the VEST investigators and VEST's adjudication committee of deception. - This is not only a groundless accusation, because data adjudication was blinded, but it also demonstrates lack of respect for the study's investigators and its adjudication committees. The reason for “some concerns” in Domain 5 was the fact that Quality of Life (QoL) data was not reported in the first VEST publication. Of note, when Goetz et al. did their literature research, those data had already been presented at an important congress and those results were published in *Circulation* [8]. Furthermore, missing QoL data do not have an impact on the confidence in mortality endpoints. In conclusion, the two limitations of the RCT Goetz et al. mention, lead to lower effectiveness (reduction of mortality) and with this to an effect underestimation. This is in line with results of a meta-analysis of Masri et al., who found higher appropriate shock rates in observational trials compared with the RCT [9].

Instead of discussing available results more seriously, Goetz et al. disparage the WCD as a falsely adopted therapy, although the WCD is a

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world-wide accepted, useful approach to save lives by defibrillation of deadly VT/VF events until a permanent ICD therapy is clearly indicated or considered unnecessary. Furthermore, defibrillation is one of the rare therapies, which researchers of evidence-based medicine certify a so-called “dramatic effect” [10].

Goetz et al. also discredit the so far most comprehensive SLR on the WCD [11]. Goetz et al. limited their own SLR to one RCT and 11 prospective, observational studies. Thereby, they neglected the evidence of ten thousands of published patients, including large registries with several thousand patients in one indication, each [12], comprehensive European registries [13], indirect comparative studies [14], as well as studies in smaller but nevertheless important indications [15]. Goetz et al. disparagingly state about the large SLR, “...it is highly likely that the number of “studies” in fact refers to the number of available publications.” One could assume, Goetz et al. did not read this SLR. In fact, Aidelburger et al. found 535 citations and screened 350 publications for title and abstract. In their analysis, they finally included one RCT, one non-randomized comparative trial, 16 prospective and 28 retrospective observational studies.

We believe that the contribution of Goetz et al. is an offending work, discrediting authors and serious publications.

Science and criticism should be based on facts and logic – not on prejudice and opinion.

#### 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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