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LETTER

Comments on the authors' reply to the critical appraisal concerning "Wearable cardioverter defibrillators for the prevention of sudden cardiac arrest: a health technology assessment and patient focus group study"

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Dear editor

Since the authors' reply to our critical appraisal did not properly address the points we raised, we still see need for further clarification.

The wearable cardioverter defibrillator (WCD) is not an adequate substitute for an implantable cardioverter defibrillator (ICD). The authors state that both can be compared immediately post-myocardial infarction (MI). According to the current guidelines, primary prevention of sudden cardiac death with the ICD within 40 days after MI is generally not indicated.[1] Therefore, we disagree with the authors' proposal of conducting such a trial. In this context, the authors mentioned the VEST trial, which compares a WCD population and one receiving medical treatment. There is explicitly no comparison to an ICD population.

We agree that randomized controlled trials (RCTs) are important for the evaluation of effectiveness. However, health technology assessments (HTAs) explore all elements of a technology, not just those that can be demonstrated in RCTs.[2] RCTs have important limitations in terms of sample size, length of follow-up, and generalizability. Not considering all available relevant information across the full spectrum of study designs and not weighing the evidence according to its estimated validity and generalizability will result in potentially incorrect and biased assessments.[2] The European Network for Health Technology Assessment (EUnetHTA) guidelines, which the authors refer to as the basis of their HTA, state that observational studies should be included for the evaluation of effectiveness and efficacy if the research question cannot be answered in RCTs.[3] Thus, it is not justifiable to exclude observational studies for the evaluation of effectiveness when there is no RCT. Furthermore, it is erroneous to claim that no data is available, even though thousands of patients have been excluded.

The argument that the inclusion of retrospective studies may mislead manufacturers to believe that RCTs are not necessary is an unusual and non-acceptable explanation for the exclusion of non-randomized studies.

The authors' intention to identify less frequent types of risk in terms of safety might have been better addressed by considering large patient populations, for example,

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large registry studies, which they have excluded. Contrary to their study methodology, the EUnetHTA guidelines for safety recommend to evaluate a broad range of studies to obtain an exhaustive assessment of adverse reactions with wider generalizability.[4]

The focus group does not fulfill the criteria of a properly conducted qualitative study. There is a lack of a theoretically justified sampling strategy that could allow for drawing substantial conclusions. In particular, the general idea of saturation in qualitative research has not been taken into consideration by the authors: only one focus group was conducted consisting of only five participants, no women were included, and none of the participants had any experience in using a WCD. However, the benefit of a WCD should be judged by a less selected patient population having experiences in using such a device. Thus, we conclude that the authors' approach does not fulfill the intended purpose of conducting a qualitative study.

This study combined a systematic review with a group interview, which does not constitute a HTA. The authors' conclusions are not supported by their findings, and therefore, should be interpreted with caution.

Disclosure

Johannes Sperzel is employed by Hospital Kerckhoff Klinik GmbH, Ingo Staudacher is employed by Medical University Hospital Heidelberg, Olaf Goeing is employed by Sana-Hospital Lichtenberg, Martin Stockburger is employed by Havelland Kliniken GmbH, and Thorsten Meyer is employed by Universität Bielefeld; none of these authors received financial support for contributing to the writing of this letter. Ana Sofia Oliveira Gonçalves, Hanna Sydow, Tonio Schoenfelder, and Volker Amelung are employed by inav – privates Institut für angewandte Versorgungsforschung GmbH [inav – Institute for Applied Health Services Research GmbH]; these four authors received financial support from Zoll GmbH for contributing to the writing of this letter. The authors report no other conflicts of interest in this communication.

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