LETTER TO THE EDITOR

To the editor: S-ICD eligibility in adult congenital heart disease

We read with concern the recent article by Zormpas *et al.*, 'Eligibility for subcutaneous implantable cardioverter-defibrillator in adults with congenital heart disease'.[1] The authors reported a high (83%) rate of eligibility for subcutaneous implantable cardioverter-defibrillator (S-ICD) in the adult congenital heart disease (ACHD) population, which is in sharp contrast to several previous ACHD studies: by Wang *et al.*[2] (60% eligibility), by Alonso *et al.*[3] in mixed ACHD (75% eligibility) and tetralogy of Fallot (77% eligibility),[4] and by Garside *et al.*[5] (75% eligibility; left-sided only).

One discrepancy is between the reported data in figures and what is discussed in the results section. Figure 1 in the manuscript[1] shows that 22% of patients failed the left-sided automated screening test and 25% of patients failed the right-sided automated test. The authors stated that only 'two patients were found eligible in the left parasternal but not in the right parasternal position, while all patients found eligible in the right parasternal position were also eligible in the left parasternal position'. Mathematically, it is not possible to achieve the reported 83% rate of eligibility per written findings, but, instead, figure 1 provides results more consistent with previous studies.[2–4]

The authors[1] did not discuss possible reasons for disagreement of their findings with previous studies. It is essential to discuss the limitations of the study in order for the reader to gain perspective of the study.

The methods included the use of an automated Boston-Scientific screening test. However, details about the Boston-Scientific programmer settings of the test and whether or not SMART Pass S-ICD function (ECG filtering settings)[6] was considered were not included. Furthermore, it is unusual for the automated screening test to yield 'no results.' Further details of the automated test with 'no results' would be helpful for troubleshooting and meaningful interpretation. It would be necessary if the authors compared their results with a previous comprehensive evaluation of the automatic screening tool.[7]

An important limitation of the study was that a single investigator performed the ECG-based screening test, and therefore, inter-rater and intra-rater agreement has not been investigated. There was also no mention of investigator blinding, suggesting that there was no blinding/masking of investigators performing the assessment of two different tests: automated and ECG-based. It is well-recognized that there is always some degree of inter-rater and intra-rater disagreement. For appropriate assessment of measurement bias, it is essential to assess the magnitude of disagreement in each study. An absence of investigators' blinding/masking can further increase measurement bias. The limitations in the study design and conduct could at least partially explain the difference in the reported results with other studies.[2–4]

Also, the study[1] raised questions about the appropriateness of utilized statistical analyses. For appropriate paired comparison of S-ICD ineligibility in different positions (standing and supine) on the left and right sides, McNemar's χ^2 statistic has to be used. Furthermore, the authors reported confusing results of the logistic regression. Table 4 shows that a QRS duration $\geq$148 ms was the 'only independent parameter predicting failure of the automated screening test' with an odds ratio (OR) of 0.102. The OR value below 1 indicates that a QRS $\geq$ 148 ms is *less* likely to fail an automated S-ICD screening test and is actually protective, which is the opposite of their result interpretation.

Additionally, Zormpas *et al.*[1] missed an opportunity to provide a meaningful discussion of the clinical implications of S-ICD eligibility. The study screened for S-ICD eligibility using both standard ECG-based screening and automated S-ICD screening but did not provide any reason for the difference in eligibility rates and even stated, 'the aim of the present study was to assess S-ICD eligibility utilizing the automated screening test and not to compare the two methods'. We suggest, on the contrary, that such a comparison might be useful for clinical practice. While the authors emphasized that their study is 'the first' to assess the automated S-ICD screening tool, they did not compare their results with previous comprehensive evaluation of the automatic screening tool.[7]

While the study reported that all patients underwent a transthoracic echocardiogram, there were no reports of the echocardiographic findings. Arguably, analysis of echocardiographic findings, including the size of the heart chambers, the presence, and degree of systolic and diastolic

dysfunction, can provide valuable insight into possible reasons for S-ICD ineligibility. For various reasons, ACHD patients with the same anatomical defect may have very different functional capacities. Available echocardiographic data provided a unique opportunity for the data analyses, which was missed by the study investigators.

Recently, Wang et al.[2] observed important sex differences in S-ICD eligibility and showed that female ACHD patients had a nearly 6-fold greater odds of S-ICD eligibility. Sex differences in clinical characteristics and outcomes in the ACHD population are insufficiently studied, and any available data contribute to the knowledge base. Zormpas et al.[1] did not include looking at how sex affected S-ICD eligibility in their study.

In sum, the reported methodology of the S-ICD eligibility assessment[1] raised concerns about the transparency, accuracy, and reproducibility of the results. The ACHD population continues to grow in the United States and worldwide, emphasizing a need for greater research on this group. In ACHD patients, sudden cardiac death is the most frequent cause of death, and S-ICD can be an important life-saving treatment option. Further studies and technological developments are needed to improve S-ICD technology and reduce the number of ineligible S-ICD ACHD patients. Similar to the discussed study, previous studies of S-ICD eligibility in ACHD are relatively small.[2–5] To summarize research evidence, future systematic reviews and meta-analyses will likely be needed. An accurate, detailed, and reproducible methods and results have the greatest impact on what new studies can expand on in the ACHD population.

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