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Development of a questionnaire to assess body image concerns in patients with an implantable cardioverter defibrillator: A qualitative study

Authors:
V S Frydensberg¹, J B Johansen¹, A Stromberg², S S Pedersen¹, ¹Odense University Hospital, Department B - Odense - Denmark, ²Linkoping University Hospital - Linkoping - Sweden,

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Background
The implantable cardioverter defibrillator (ICD) is an established intervention to prevent sudden cardiac death. The medical benefits of ICD therapy are unequivocal and the majority of patients adapt well to living with the device. However, a subset of patients experiences psychological complications, including anxiety, depression, and body image concerns (BICs). In a recent scoping review, we found that BICs are present in the ICD population, but given the lack of standardized questionnaires tapping into BICs it is not possible to determine the prevalence.

Purpose
To develop the "ICD Body Image Concerns Questionnaire" (I-BICQ) which can be used in clinical practice to assess the prevalence of BICs among ICD patients, with respect to initiating interventions that can help patients cope better.

Methods
A qualitative study design, including cognitive interviews with patients with an ICD is used in the development of the I-BICQ. The development is based on an iterative process: (i) themes from a scoping review on BIC in ICD patients are used to create preliminary items; (ii) cognitive interviews with ICD patients are performed to evaluate the validity of items and to ascertain if items are missing; (iii) healthcare professionals will review items to ensure content validity.

Results
So far, three patients and one statistician specialized in questionnaire development have validated the items in the questionnaire. The first version was changed after several construct considerations. The following interviews resulted in minor corrections and currently, we use version three. Interviewing will be performed until saturation is met and no new dimensions, items or corrections are suggested. We chose to use a 5-point Likert-type scale for all items.

Conclusion
Cognitive interviews led to the development of a conceptual framework containing four dimensions (see Figure 1): (1) behaviour, (2) emotions, (3) body perception and (4) assessment that includes 10 items in total.

Following additional cognitive interviews with patients and finalization of the I-BICQ questionnaire, it will be sent out together with other patient-reported outcome measures to 400 ICD patients identified through the "Danish Pacemaker and ICD Register", who have had their ICD for three months and up to 2 years. The data will be used to examine the I-BICQ psychometric properties and determine a clinically relevant cut-off for BICs.
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