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Body image concerns in patients with an implantable cardioverter defibrillator:**A scoping review**

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Short running head: Body image concerns in ICD patients

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ABSTRACT

Background: Patients with an implantable cardioverter defibrillator (ICD) retain a scar and a bump at the site of implant. This may lead to body image concerns (BICs) that influence patients' quality of life. Few studies have examined the prevalence and impact of BICs post implant, prompting us to conduct a scoping review of the field.

Methods: We searched the Medline, Embase, PsycINFO and Cinahl databases in August 2016 and repeated May 2017. Included were studies reporting on patients ≥ 18 years, an ICD implant (transvenous, subcutaneous, or ICD with cardiac resynchronization therapy (CRT-D), reporting on BICs, and published in peer-reviewed English-language journals. We excluded non-systematic reviews, opinion pieces/letters, case-studies, conference-abstracts, PhD-dissertations, protocol papers, studies of ICD shock treatment of atrial fibrillation and of abdominally or submammary implanted ICDs.

Results: A total of 40 articles were included; 16 qualitative and 24 quantitative. None of the included studies had BICs as their primary endpoint. Results showed that BICs are present in various degrees in the ICD population and can be attributed to the visibility of the ICD (the scar and bump). Women and younger patients had greater problems with BICs, although men also had concerns. Two items of the "Florida Patient Acceptance Survey" were the most frequently used to assess BICs.

Conclusion: BICs were present among ICD patients, but the degree of impact on their lives varied. There is a need for developing a BICs questionnaire to examine the prevalence of BICs and the potential impact on patients' lives in longitudinal studies.

Keywords: Body image; Implantable Cardioverter Defibrillator; Prevalence; Florida Patient Acceptance Survey.

INTRODUCTION

Guidelines recommend the implantable cardioverter defibrillator (ICD) as the first line of treatment for the primary and secondary prevention of sudden cardiac death (1-3). Studies show that there has been an increase in ICD implantation rates until recently, with a plateau having been reached and some European countries even showing a decline (4). In the United States, the implant rate was 577 per million inhabitants in 2011 (5, 6), while the European Union had a total of 155 ICD implantations per million inhabitants (2013) (6, 7).

Body image concerns due to the scar and size of the ICD under the skin are device-related issues, which may impact patients' well-being and quality of life (8-11). Nowadays, the ICD is usually implanted under the skin in the subclavicular region. This procedure produces a visible scar and bump under the skin due to the size of the device (11, 12), which can lead to noticeable discomfort for some patients (13).

Aesthetic operation techniques, which aim to hide the bump from the ICD, such as subpectoral placement or submammary placement, have been tested in women with promising results (9-12, 14). However, subclavicular placement of the ICD is still standard practice, and little is known about the prevalence of body image concerns in patients with an ICD and the impact on patients' lives.

The scarce evidence on gender differences in body image concerns is conflicting. Some studies suggest gender differences, with women being more likely to report post-implant body image concerns as compared to men, in terms of concerns about how to make clothing fit to hide the bump from the device. Moreover, there is a risk of further scarring in

women because of the weight of the breasts (11). Others suggest that women have a higher risk for developing distress due to body image issues, but that more research is needed (15). A recent meta-synthesis (16) confirms that there is no consensus whether gender differences in body image concerns exist (17-20), and whether younger women are likely to have more concerns than older women (13, 21). As the literature is inconsistent, this issue deserves attention, as men and women potentially may benefit from different treatment (e.g. site of implant) and care in clinical practice, if gender differences exist.

Given the scarce and conflicting evidence on the prevalence and impact of body image concerns, and knowing that poor patient-reported health status is an independent predictor of mortality in ICD patients (22-24), we performed a scoping review of the available literature to examine the prevalence of body image concerns, possible questionnaires to measure BICs, and the potential impact on patients' lives.

A scoping review synthesizes research evidence and is also called a "mapping review". It is used for "reconnaissance" where the conceptual boundaries of a field are clarified. This is in contrast to a systematic review where a specific research question is addressed.

METHODS

Search strategy

A first exploratory search was performed in August 2016 and repeated in May 2017. The electronic databases Medline, Embase, PsycINFO and Cinahl were searched for the period between January 1980 (the introduction of the first commercially available ICD device) and May 2017. The search terms, including "Implantable cardioverter defibrillator", "Internal

defibrillator”, “Defibrillators, Implantable”, “Self-Concept”, “Self-Perception”, “Self-Esteem”, “Physical Appearance”, “Personal Appearance”, “Body Awareness” and “Body Image”, were used in various combinations, including MeSH terms and free text, with the adjacency (ADJ) operands being included in the “various combinations of search terms”. Reference lists of the included articles were examined to find further relevant articles as well as grey literature.

Study selection

Inclusion and exclusion criteria

Qualitative and quantitative studies were included, if they fulfilled the following criteria: (1) described patients ≥ 18 years with implantation of a transvenous ICD or subcutaneous ICD or ICD with cardiac resynchronization therapy (CRT-D), (2) reported body image concerns in the results, and (3) published in peer-reviewed English-language journals. We excluded (1) non-systematic reviews, opinion pieces/letters, case studies, conference abstracts, PhD dissertations, and protocol papers, (2) studies of ICD-AT (ICD shock treatment of atrial fibrillation), (3) studies on patients with abdominally implanted ICDs (as this implantation technique is no longer carried out) and (4) submammary implanted ICDs (as this technique is new).

Search outcomes

A total of 3,844 articles were identified. After eliminating duplicates, a total of 3,302 articles were screened, using the tool Covidence for Windows version 2017 (25). A refined and updated search was conducted in May 2017, yielding an additional 112 articles to screen after removing duplicates. Furthermore, one article was identified from the reference lists of included papers and inserted into Covidence. At first, a title/abstract screening was carried out individually by two reviewers (SJS and VSF), resulting in a total of 144 papers that were assessed for full text eligibility. In case of disagreement whether to include in the

review, SJS and VSF carried out a full text screening. If the two authors could not reach a consensus, the conflict was resolved by consulting a third reviewer (SSP or RNK). After full-text screening, 104 studies were excluded. Finally, a total of 40 articles were included after reading full text; 16 qualitative and 24 quantitative articles. We found 46.7% (7/15) qualitative studies using US samples, 46.7% (7/15) using European samples while 6.7% (1/15) was from Japan. The meta-synthesis is not included in these percentages (16). In the quantitative studies, we found 50% (12/24) studies using US samples, 41.7% (10/24) using European samples, 4.2% (1/24) from Japan and 4.2% (1/24) conducted in both USA/Australia. For an overview of the search process, see the PRISMA flowchart (Figure 1).

Data items and collection process

We included both qualitative and quantitative articles in this scoping review. An overview of the qualitative studies is listed in Table 1, while Table 2 presents an overview of the quantitative studies.

Assessment of study quality

The rationale for this scoping review was to provide a broader overview of the literature on body image concerns in patients with an ICD. Therefore, we included both qualitative and quantitative studies. There is no consensus in the literature whether a scoping review

should contain a quality assessment (26, 27). Due to the present lack of consensus about assessing quality in qualitative studies (28-30), and the fact that none of the quantitative studies had body image concerns as their primary focus, we therefore decided not to perform a quality assessment, as this would yield very little usable context to evaluate the studies (26).

RESULTS

Qualitative findings

Description of studies

Table 1 show 15 of the 16 qualitative studies included in the scoping review. We found one systematic review that included qualitative studies (16). We excluded this review as all the qualitative studies were already listed in Table 1. One of the studies also focused on family members, but only the results on patients are included (31). The studies were published between 1991 and 2016. A total of 294 patients with an ICD were included (range 3-54).

The interviews were conducted as individual interviews in the majority of the studies (in person or by telephone), although some studies used both focus group interviews and individual interviews (32, 33). Time of patient enrolment differed across studies. Some studies enrolled ICD patients directly after implantation, where others identified patients later from their outpatient clinics, recruitment brochures or from the internet. Time of interview also varied greatly, with recruited patients being interviewed anywhere from immediately after implantation up to 24 years after.

Age across studies ranged from 18 to 80 years. The reported mean age ranged from 23.7 to 63.7 years – however, not all studies reported mean age (e.g. (34-36)). The majority of patients were male (range 40 - 90.9%), one study only reported that the ‘typical subject’ was male with no supporting statistics (35), and one study included only women (34).

Patients’ experiences with an ICD

The ICD recipients express an awareness of the ICD components inside their body, either a physical awareness of the device, or a psychological awareness in terms of being reminded about the device. They feel the physical presence of the ICD, see it, or are made aware of it because other people notice it. However, these sensations seem to decrease over time. This awareness leads to feelings reported as intrusive that serve as a constant reminder of the ICD: *“Yeah, I mean just being that it is there and it should not be there and it shows itself all the time. I especially know it's there in the summer when you wear fewer clothes, especially bathing suits. To me it is constant reminder that I may feel fine, but I am technically sick”* (34).

Visibility

The visibility of the scarring and the visible shape of the device gives rise to feelings, in both men and women, of looking different, feeling disfigured, being uncomfortable and feeling embarrassed. Wearing swimsuits, shirtless or strapless dresses, feeling uncomfortable swimming in public, removing their shirts, or wearing clothing, which leaves the ICD site, exposed causes feelings of insecurity and awkwardness: *“It looks like a pack of cards sticking out. They can see it over my*

clothes" (31). *"I also feel uncomfortable when I see the implant area"* (37). The ICD recipients report insecurity about their physical appearance both among their families', friends and peers but also in personal intimate relationships. Body image and scarring can also interfere with intimacy: *"If someone leans against me and puts their head on my chest, it's uncomfortable"* (38).

Appearance

It is not clear whether all ICD recipients become accustomed to the appearance of their bodies after the ICD implantation. Some have continued problems with body image: *"I also feel uncomfortable when I see the implant area. I worry that these feelings have continued throughout my recovery"* (37). Others embrace their device and have no problems, showing their body, the scarring and lump - sometimes even proudly so: *"I don't try and cover it up at all, it's part of who I am. I'll take anyone's hand, they'll say 'what's that lump' and I say 'feel it, you can touch it'"* (8).

Quantitative findings

Description of samples

Table 2 shows the 24 quantitative studies included in the scoping review. In all studies, body image concerns were reported as a secondary outcome.

The studies were published between 1990 and 2015. A total of N = 3,173 patients with an ICD were included (range N = 16 - 566). However, the total number of included patients in Table 2 is 3,618, as some of the studies also included other patient groups with e.g. pacemakers (PM) and ICD-AT (39), a

combination of pacemakers and other implantable devices (40), and pacemakers (41, 42) and spouses (43).

Time of patient enrolment differed across studies. Some studies enrolled ICD patients directly after implantation, via registries, one study because of a world-wide advisory on specially manufactured ICDs that experienced rapid battery depletion (44), or via the internet, while others identified patients from their outpatient clinics / medical centers at follow-up. Patients were recruited in a time range of post-implantation up to 24 years after implantation.

Age across studies ranged from 13 to 98 years, however, age range was not reported in all studies (18-21, 39, 41, 44-51). The reported mean age ranged from 21.2 to 78 years, although the mean age was not reported in two studies (51, 52). The studies included both men and women; mostly patients were male (range 43.8% - 90.0%), except from one study that included only women (20). Most of the studies used a cross sectional design except from four prospective studies (18, 21, 52, 53) and one observational longitudinal study (51).

Questionnaires identified

The literature revealed the following questionnaires which contained items tapping into body image concerns (Table 3): the “Florida Patient Acceptance Survey/Scale” (FPAS) (18-20, 39, 44-46, 48, 49, 54, 55), the “Brodsky ICD Questionnaire” (52, 53), the “Implanted Device Adjustment Scale” (IDAS) (40, 42), “Low Treatment Satisfaction” (LTS) (47), the “Cleveland Clinic AICD Psychosocial Inventory” (43), and the “Worries about ICD Scale” (WAICD scale) adopted from the “Index of Subjective Concerns for People with ICDs” (ISCP-ICD) (50). One study used an

“unspecified modification of the SF-36 questionnaire” (56) and five studies used purpose-designed questionnaires (21, 41, 51, 57, 58). None of the scales was developed to assess body image concerns, let alone body image concerns in a medical population.

Gender and age

There was a trend for gender differences, with women reporting more body image concerns than men (18, 21, 40, 50, 56), however one study found no gender differences (45). Younger age was associated with more body image concerns (20, 21, 54). One study found an association between older age and higher device acceptance (19). However, another study found that women worried more than men about their appearance after receiving an ICD, with their scores remaining constant over time (21), while a third study showed that worries about body appearance, in both men and women, did not decrease with time (51). One study reported ethnic differences with Afro-American women having more concerns than Caucasian women (55).

Physical aspects of the ICD and body image concerns

The most frequent body image concern reported was the size of the ICD, which caused changes of the body's form and noticeability of the device (47, 53, 57), self-consciousness and apprehension about touching or looking at the implantations area (43). In one study, the majority deemed the appearance of the scar or bump acceptable, however, almost half of the patients admitted to covering up the wound or had negative opinions on the scar, or felt shame being intimate or undressed (58).

Additional findings from the BIC literature

Apart from the themes identified earlier, several other observations with regards to body image concerns were made. One study reported that patients scoring high on Type D personality were more likely to report body image concerns (49) while another study did not find an association (18). Some studies did not observe body image concerns in their group comparisons, e.g., ICD-Congenital versus ICD-non-Congenital (44, 45). One study's main focus was development of a questionnaire the "Implanted Device Adjustment Scale" (IDAS) and did not report results on body image concerns (42). One study found that ICD patients had more concerns than PM patients (39), while another study reported some level of body image concerns among the participants but with no significant differences between PM and ICD patients (41). One study reported body image concerns among secondary prevention patients when compared to primary prevention patients (46). Another study found that patients reporting more body image concerns would consider replacement of the ICD as compared to those that did not consider replacement of the ICD (48).

DISCUSSION

The purpose of the current study was to examine the prevalence of body image concerns in patients with an ICD and the potential impact on patients' lives. Given the scarce and conflicting evidence, we performed a scoping review (26, 27) rather than a systematic review of the available literature and allowed both for the inclusion of quantitative as well

as qualitative studies. We identified 16 qualitative and 24 quantitative studies that focused on body image concerns and their potential impact on patients' lives.

It is known that the mass-media exposure with body image ideals affects men and women and gives rise to body image concerns (59, 60). In this review, there was a trend in the majority of the studies to report on young women with body image concerns rather than men; however some studies also showed body image concerns among men. This implies that the focus should not only be women with an ICD, but that men also have body image concerns, although the extent of concerns in both genders needs to be further established.

Qualitative studies provide a more in-depth and detailed exploration of the individual patient's experience and comprise an important source of information in particular with respect to informing future research in fields that are underdeveloped (61) as the included qualitative studies in relation to body image concerns (8, 13, 16, 31-38, 62-66).

Most of the included quantitative studies were cross-sectional (19, 20, 39-50, 54-58) and therefore, it was not possible to determine whether body image concerns change over time. None of the included studies used body image concerns as their primary outcome. In addition, information about body image concerns was sometimes scarce and mostly found as supporting information in the text / tables. In most cases, information was also reported with insufficient clarity to extract data on, e.g., the content of the scales used and their psychometric properties. It was often impossible to retrieve the questionnaires being discussed, as many of them had not been formally published; an "Unspecified modification of SF 36 questionnaire" (56); an "Unspecified purpose-designed questionnaire" (57); the "Low Treatment Satisfaction questionnaire" (47); the "Cleveland Clinic AICD Psychosocial Inventory questionnaire" (43); a "Purpose designed questionnaire" (58); the "Brodsky

ICD Questionnaire” (52, 53), the “ICD Quality of Life questionnaire”(51) and the “ICD specific questionnaire” (21).

Some of the quantitative studies used purpose-designed questionnaires (41, 57, 58), which among other things tapped into body image concerns. Other studies used validated questionnaires as the FPAS (18-20, 39, 44-46, 48, 49, 54, 55), and the IDAS (40, 42); however mostly these had only one or two questions tapping into body image concerns, and often only a total sum score was reported. The most commonly used questionnaire was the “Florida Patient Acceptance Survey” (FPAS) (39). FPAS was designed to measure overall device acceptance with two items tapping into body image concerns. However, two validation studies in Danish (49) and Dutch patients (67) comprised of three different cohorts, show that a 12- rather than a 15-item FPAS consisting of three factors is more psychometrically sound. Of note, the 12-item scale does not contain the items on body image concerns. In the original 15-item FPAS version, the two body image concerns items also explain very little variance (6-7%) in device acceptance in the Danish and Dutch cohorts likely due to too few items (49, 67)

We did not provide a quality assessment of the individual studies (26) as this is a scoping review. In addition, given that none of the studies focused on body image concerns as the primary outcome and the lack of systematic use of questionnaires that are standardized and validated and specifically designed to tap into body image concerns, it was not possible to determine the true prevalence of body image concerns in the ICD population.

Some studies found that older age at implantation was associated with fewer concerns, where others showed that concerns did not decrease with increasing age. With respect to gender differences, it has been proposed that women are more likely to report body image concerns post implantation due to the scar as compared to men (11), which we also found in this scoping review.

Apart from reporting more body image concerns among women, previous studies have shown that women with an ICD may be more vulnerable for experiencing reduced quality of life than men (68), and may therefore be more vulnerable for developing depression as the two are related (69). However, evidence for this was mixed in this scoping review (19, 21, 70-75), probably due to comparable mixed effects in gender differences.

Our results showed that experiences of embarrassment due to altered body image (a visible scar and bump under the skin) have an impact on patient's social lives. The connection with body image concerns and psychosocial issues has also been shown to be evident in other patient populations, and importantly, that this is not related to the severity of the disfigurement (69). Hence, this factor is an important finding, as studies show that mental health and symptoms of anxiety and depression are independent factors that increases the risk of ventricular tachyarrhythmia's and mortality (76), as well as general noncompliance with medical treatment (77).

CLINICAL IMPLICATIONS

The results of this scoping review show that some ICD patients are affected by body image concerns. Given the available evidence, it is difficult to determine whether body image concerns are more prevalent in women or in men. Nowadays, the standard implantation site of the ICD is the subclavicular area, leaving the scar / bump visible. Intramuscular implantation still leaves a scar, but not a visible bump (78).

Body image concerns may not be on the patient's mind when discussing implantation and it is known that an individualistic and holistic involvement and communication with patients from the health care professionals plays a crucial role for patient's satisfaction with the healthcare system and treatment (79). Therefore we recommend that health providers ask patients about body image

concerns before, and after the ICD is implanted, regardless of patients' gender (11), as such involvement may lead to a decision to submammary implantation and increase patient satisfaction due to reduced body image concerns (9, 10, 12). However this requires an adoption of the method by the clinicians, as this is currently not the standard implantation technique for ICDs, and perhaps not a possible solution for some patients. If it is not possible to change the implantation site, or until new techniques are introduced, health care professionals have to be aware of patients reporting distress associated with body image concerns related to their ICD and provide, or refer to psychosocial care.

LIMITATIONS

The results of this scoping review have some limitations and need to be interpreted with some caution. Firstly, the results may be subject to bias, as body image concerns was not the primary outcome in the included studies, which resulted in a limited amount of information on body image concerns in the primary papers. Second, a potential selection bias could be present as we only included papers published in the English language.

CONCLUSION

As we know that even relatively small disfigurements can have a large impact on psychosocial outcomes (69), it is paramount that we further elucidate the link between body image concerns and psychosocial outcomes. There is also an urgent need for prospective studies with long-term follow-up to determine whether patients adapt to the scar / bump at the site of implant, whether subsets of patients (e.g. younger and female patients) are at greater risk of developing body image concerns

and, whether the impact of these concerns on patients' well-being and quality of life varies across patients.

The scoping review also shows that the most frequently used questionnaire to tap into body image concerns in ICD patients is the FPAS (39). However, the FPAS has only two items measuring body image concerns, which precludes any psychometric analysis. Hence, in order to advance our knowledge of the prevalence and impact of body image concerns in the ICD population, it seems paramount that we develop a questionnaire that contains more items that specially tap into body image concerns and is psychometrically robust.

Using a participatory design, involving both patients and health care professionals (80), in developing the questionnaire could be a way forward, using the themes identified in this scoping review as a guide in the development. There are also a number of body image concerns questionnaires that can be used to inform the development of a new questionnaire for ICD recipients, e.g. for breast cancer patients (81) or patients living with problems of appearance (82). Healthcare providers should give attention to potential body image concerns and discuss this with patients prior to, and after ICD implantation.

AUTHOR CONTRIBUTIONS

Study concept and design: VSF, SSP, RNK, SJS

Acquisition, analysis or interpretation of data: VSF, SSP, RNK, SJS

Drafting the manuscript: VSF, SSP, RNK, SJS

Critical revision of the manuscript for important intellectual content: VSF, SSP, RNK, SJS

Statistics: Not applicable

Approval of article: SSP, RNK, SJS, VSF

Administrative, technical or material support: Not applicable

Study supervision: SSP, RNK

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FIGURE LEGEND:

Figure 1: PRISMA Flowchart

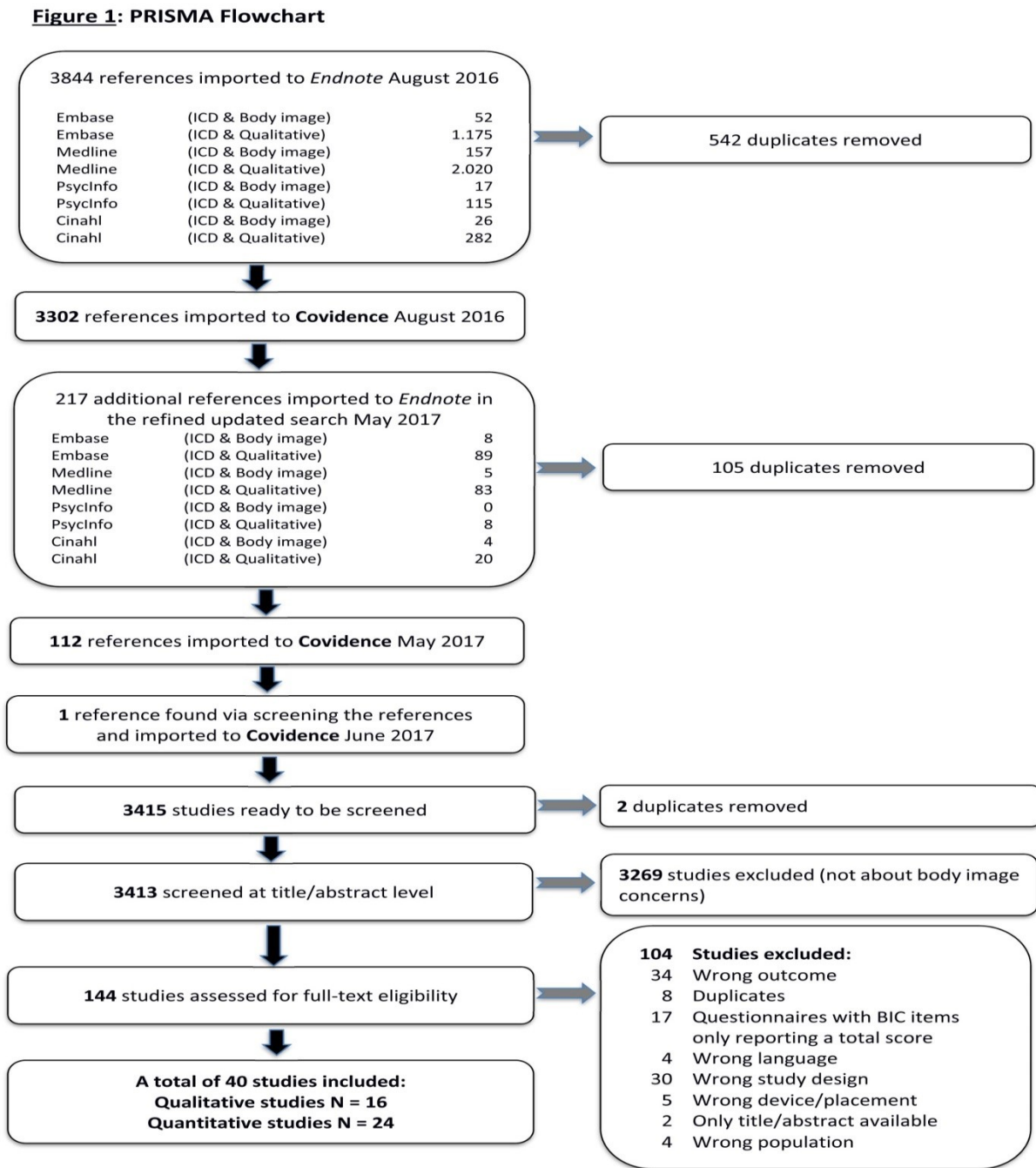


Table 1: Overview of qualitative studies – body image concerns

Reference	Participants N (% men)	Age (years) Mean (SD)	Time since implantation	Design (Interview time points post- implantation)	Results (Impact of body image concerns)
Burke (1996) (62)	N = 24 (58% men)	59 (x) years Range: 22 - 78 years	Up to 6 months	Qualitative study. Interviews at baseline, at 3 and 6 months.	Physical sensations were about awareness of the ICD inside the body, which decreased over time in most of the patients. The associated emotions were reported as intrusive: <i>“First week: Of looking different”. “Three months: Of feeling disfigured”.</i>
Cinar (2013) (63)	N = 54 (79.6% men) <u>Experimental group:</u> N=27 (78% men) <u>Control group:</u> N=27 (82% men)	<u>Experimental group:</u> 63.41 (11.37) years Range: x <u>Control group:</u> 63.74 (11.00) years Range: x	<u>6 months and less :</u> Mean (SD): <u>Experimental group:</u> 17 (63.0) <u>Control group:</u> 15 (55.6) <u>≥7 months:</u> Mean (SD):	Mixed-methods study. <u>Experimental group:</u> A total of 4 semi- structured interviews: Timepoint: Baseline; 15 days (education); 3 months (same education); 6 months.	In the months following the implantation, some of the patients were accustomed to the appearance of their body and maintained normal activities.

			Experimental group: 10 (37.0)	Control group: 12 (44.4)	Control group: A total of 2 interviews: Timepoint: At baseline and after 6 months.	
Conelius (2015) (34)	N = 3 (0% men)	α Range: 34-50 years	More than 1 year		Qualitative descriptive phenomenology study. Individual interviews. Timepoint: α	The women reported that they were continually reminded of the presence of their ICD. Although the actual incision was “hardly noticeable”, all women felt that the ICD was a constant reminder, either directly (awareness of its presence, feeling or seeing it physically present) or indirectly (through family members noticing it, or physically coming into contact with it).
Dougherty (2000) (31) ¹	N = 15 sudden cardiac arrest survivors. (86.7% men) & one family	57 (11) years Range: 31-72 years Family members:	0-12 months		Qualitative study. Grounded theory. Semi-structured interviews. Timepoint: At hospitalization,	First, the ICD gave rise to discomfort: <i>“This box is finding a place of rest in me, and there’s an irritation where the box is stuck in the muscles”</i> . <i>“It looks like a pack of cards sticking out. They can see it over my clothes”</i> .

	member each.	53 (9) years. Range: 31-72 years		1, 3, 6 and 12 months	Patients were also fighting with impatience and getting “back to normal”.
Flemme (2011) (64)	N = 16 (56.25% men)	57.6 (13.6) years Range: 31-78 years	6-24 months	Qualitative study. Grounded theory approach. Interviews by telephone or in the informant’s home. Timepoint: After 6-24 months	The bulge and scar from the ICD implantation was something the ICD recipients had to accept: <i>“The device is visible. I found it really hard to wear something sleeveless in the beginning, but now I don’t care, it’s kind of part of me...”</i> (Woman aged 48 years).
Fridlund (2000) (65)	N = 15 (66.6% men)	61.8 (x) years Range: 33-76 years	Mean time: 33 months Range: 23 - 55 months	Qualitative study. Holistic perspective, Phenomenography. Open and semistructured interviews. Timepoint:	Body image concerns and their ICD feeling as an intrusion were emphasized but also that they sometimes were able to forget that they had an ICD: “I don’t like it. Sometimes I forget about it and then I’m glad that I’ve succeeded in forgetting about it”. “An alien thing has entered my body”. “It’s the fact that it’s something alien

				α	that disturbs me sometimes, but I forget about it when I'm together with other people".
Hallas (2010) (66)	N = 13 (76.9% men)	58.46 (13.65) years Range: 35-80 years	6 months to 5 years	Qualitative study. Semi-structured interviews. Timepoint: α	The majority of patients had a negative perception of their body due to the scar at the implant site. The primary feeling was embarrassment.
Hauptman (2013) (32)	N = 41 (48.8% men)	61.4 (14.7) years Range: α	α	Qualitative study. Eight patient focus group interviews were conducted. Timepoint: α	The prevalent perception of body image was negative due to the cosmetic changes associated with the ICD. Body discomfort including " <i>pulling sensations</i> " and discomfort when " <i>lying on the side</i> " might have contributed to this negative perception.
Humphreys (2016) (8)	N = 18 (61.1% men) 13 non- shock participants	55.7 (α) years Range: 28 – 68 years	3 - 24 months	Qualitative study. Semi-structured interviews. Individually conducted.	Most patients were physically aware of the device inside their bodies, and some described it as a physical obstacle: "... <i>its 'incredulous' size once implanted</i> ".

	(53.8% men) 5 shock participants (80% men)			Timepoint: α	Others mentioned that they were unprepared of its protrusion: "...was clearly visible under the skin and some complained that the arm adjacent to the implant was painful with restricted movement". A female non-shock patient embraced her device and proudly showed its protrusion. The participant wore a t-shirt which clearly revealed the device: "I don't try and cover it up at all it's part of who I am. I'll take anyone's hand, they'll say 'what's that lump' and I say 'feel it, you can touch it'."
Kuiper (1991) (35)	N = 20 (α)	α Range: 39 - 75 years	1 - 12 months Mean (SD): 8.75 (5) months	Mixed-method. A quantitative instrument "JC" (Jaloweic Coping Scale) and a semi-structured interview guide. Timepoint: α	Based on the content analysis of the semi-structured interviews, aspects as clothing adjustments and appearance were mentioned.
Larimer (2016) (38) ²	N = 6	23.7 (α) years	15 months to 24 years	Descriptive qualitative	The participants had challenges in terms of insecurity about their

	(50% men)	Range: 18 - 28 years		research design. Purposive sampling. In-person interview. Semi-structured interviews. Timepoint: x	physical appearance. Embarrassment arose due to the attention their family, friends and peers had to the visibility and scar from the implantation. The visibility of the ICD was obvious when wearing a swimsuit and clothes that was either shirtless or strapless. This can interfere with interpersonal relationships, intimacy and closeness.
McDonough (2009) (13)	N = 20 (40% men) <u>Telephone group:</u> N=6 (33.3% men) <u>Internet group:</u> N=14 (42.9% men)	<u>Total group:</u> 33.5 (6.7) years Range: 21 - 40 years <u>Telephone group:</u> 35.2 (7.4) years Range: 21 - 40 years <u>Internet group:</u> 32.9 (6.4)	Post ICD implantation. Mean (SD) years: 3,9 (x) years Range: 3 months to 17 years (only one for 17 years)	Qualitative study. Interviews (telephone and Internet) Interview guide with open-ended questions. Timepoint: x	All expressed body image concerns. Leaving the ICD site exposed made the participants feeling uncomfortable as in situations like swimming, not having their shirt on or clothes that revealed the ICD. Some felt that others would look at them differently, but this dissipated within a few months. Women tended to choose clothing that covered the ICD site.

		years Range: 21 - 40 years			
Mert (2012) (33)	N = 19 (78.9% men)	53.57 (13.44) years Range: α	15.47 (9.82) months	Qualitative descriptive approach. Four focus-group interviews with groups of 4 - 5 patients. Semi-structured interviews with open-ended questions. Timepoint: α	Among the most frequently reported emotional change due to the ICD were changes in body image.
Saito (2012) (37)	N = 22 (90.9% men)	61.26 (13.4) years Range: 35 - 79 years	14 months	Qualitative descriptive study. Semi-structured interviews. Timepoint:	Patients were aware of the physical existence of the ICD, leading to physical discomfort. Being confronted with the ICD area also caused discomfort.

				14 months	
Tagney (2003) (36)	N = 8 (75% men)	∅ Range: 36 - 75 years	5 - 20 months	Qualitative study. Semi-structured interview Timepoint: ∅	Some adjustment concerns seemed to be associated with body image for patients having their ICD implanted a year or more earlier. Both men and women had concerns about altered appearance

∅. Information was not provided.

1: The ICD could be implanted abdominal or under the shoulder. Both sudden cardiac arrest survivors and a family member were interviewed.

2: All participants had PM's and 3 had PM/ICD's.

Table 2: Overview of quantitative studies – body image concerns

Reference	Participants N (% men)	Response rate (% sent/ responded)	Age Mean (SD)	Time since implantation	Design	Instrument (Total # items / # items on body image concerns)	Key findings with respect to body image concerns (BIC)
CROSS SECTIONAL							
Bedair (2015) (45) ¹	N = 193 (56.5% men) <u>147 ACHD</u> Hereof N = 59 ICD patients with congenital disease (59.2 % men) & <u>46 non-ACHD:</u> Hereof N = 34 ICD patients with non-congenital disease (73.9% men)	61.0% (319/193)	45.0 (14.7) years Range: α	<u>Patients with congenital disease:</u> 5.7 (6.1) years <u>Patients with non-congenital disease:</u> 5.1 (4.8) years	Cross sectional	FPAS (18/2)	<u>BIC</u> Median (interquartile range): <u>ICD-Congenital:</u> 25 (0, 50) <u>ICD-Non-Congenital:</u> 0 (0, 25) There was no body image concerns observed between groups.

Beery (2005) (42) ²	N = 45 (66.7% men) ICD = 27 (x)	97.8% (45/44) <u>Test- retest after 2 weeks:</u> 95.6% (45/43)	67.0 (7) years Range: 30 - 98 years	Mean (SD) time: 6.29 (7) years Range: 1 – 11 years	Cross sectional + test re-test validation	IDAS (Implanted Device Adjustment Scale) (20/2)	This study focused on the developmen t of the IDAS. The IDAS contains two items tapping into body image concerns. No results were reported on the patients' endorsemen ts on these items.
Beery (2007) (40) ³	N = 173 ICD=102 (83.3% men)	x	For the whole sample: 69 (x) years Range: 35 - 91	Mean (SD) time: 4.3 years (3.8) years Range: 3 months to 21 years	Cross sectional	IDAS (Implanted Devices Adjustment Scale) (21/2)	On the “body awareness subscale” women scored significantly higher: Mean (SD): <u>Women:</u> 6.53 (2.8) <u>Men:</u> 5.48 (1.8)
Birnie	N = 180	70.3 %	<u>Advisory</u>	Mean (SD)	Cross	FPAS (18/2)	FPAS scores in body

(2009) (44)	(80% men) <u>Advisory group:</u> N = 86 (83.6% men) <u>Non-advisory group:</u> N = 94 (76.6% men)	(256/180) <u>Advisory group:</u> 70.5% (86/122) <u>Non-advisory group:</u> 70.1% (94/134)	<u>group:</u> 67.7 (9.75) years <u>Non-advisory group:</u> 65.0 (11.8) years Range: α	time: <u>Advisory group:</u> 52.4 (9.0) months <u>Non-advisory group:</u> 50.6 (13.3) months P = 0.29	sectional	image concerns: Mean (SD): <u>Advisory group:</u> 13.11 (23.68) <u>Non-advisory group:</u> 17.95 (26.60) (No significant between-group differences) Multivariate analysis of correlates of FPAS Body image concerns with demographic or clinical variables did not find significant correlations.
Burns (2005) (39) ⁴	N = 238 (62.7% men)	72% (238/338)	<u>ICD group:</u> 72.0 (9.6) years	At least 3 months	Cross sectional	FPAS (18/2) ICD patients had lower scores than pacemaker patients.

	ICD = 58 (66.7% men)		Range: α				Mean FPAS score: (76.0 – 85.4) P < 0.001
Dubin (1996) (56) ⁵	N = 16 (43.75% men)	88% (16/18)	Time of age at implantation: The 25 implanted patients: 28 (8.7) years Range: 13-40 years	Mean (SD) time: 3.3 (1.5) years	Cross-sectional	Unspecified modification of SF36 (α)	Perceived attractiveness was not an issue for patients, however, a majority of patients reported issues with clothing and specifically with bathing wear (mostly women).
Duru (2001) (41)	N = 152 (14% men) <u>ICD total</u>	N total = 210 ICD:	<u>ICD no shock group:</u> 56.2 (12.8)	<u>ICD group:</u> 2.3 years P < 0.05	Cross sectional	Purpose-designed device questionnaire	All patients reported some level of body image concerns, but there were no

	<u>group:</u> N = 76 (84.21% men) <u>ICD no shock group:</u> N = 31 (87% men) <u>ICD shock group:</u> N = 45 (82.22% men)	(N = 86) Response rate: ICD: 88.4% (76/86)	years <u>ICD shock group:</u> 59.7 (13.0) years Range: x			(23/2)	significant differences between pacemaker patients and ICD patients who had and had not received shocks.
Groeneveld (2007) (46)	N = 120 (73% men) <u>Primary prevention:</u> N = 45 (62% men) <u>Secondary prevention:</u> N = 75	100% (120/120)	<u>Total group:</u> 60 (15) years <u>Primary prevention:</u> 58 (16) years <u>Secondary prevention:</u>	Patients receiving ICDs for secondary prevention of SCD had a longer time since implantation. (Median duration 3 years vs 1 year; P < 0.0001)	Cross sectional	FPAS (18/2)	Overall, ICD recipients reported little distress or body image concerns. Secondary prevention patients reported more concerns about body image, but this difference was not significant.

	(80% men)		61 (15) years Range: \bar{x}				
Heller (1998) (57)	N = 58 (72% men)	43% (58/135)	64 (11) years Range 37 - 84 years	Mean (SD) time: 20 (14) months	Cross sectional	Unspecified purpose- designed questionnai re (\bar{x})	Patients (33%) reported worrying about the size of the ICD. Less worry about ICD size was associated with high levels of satisfaction with the ICD (Spearman's R=0.38; P=0.007).
James ⁶ (2012) (54)	N = 86 (44.19% men)	\bar{x}	Mean (SD) age: 45.8 (12.9) years Range: 18 - 79 years	Median: 3.2 years Range: 0.2 - 20.1 years	Cross sectional	FPAS (18/2)	<u>"Body image concerns subscale"</u> : Mean (SD): 17.9 (23.5) The subscale body image concerns were most sensitive to differences in age.

							Younger individuals (the youngest quartile 35 or younger) had a significantly worse mean score on this measure (30.1 versus 13.7) than the older population
Ladwig (2005) (47) ⁷	N = 195, (83.6% men)	91.5% (195/213)	59.8 (12.6) years Range: α	Mean (SD) time: 28.2 (21.9) months	Cross sectional	Low satisfaction with ICD treatment items (11/2)	Complaints of a dissociated perception ("ICD feels like a foreign body") in 30.3% of the patients. Complaints of ("Disturbed by changes of body form") in approximatel y 18% of the patients (estimated from Figure 2).
Lewis (2014) (48)	N = 106 (75.47% men)	72% (106/147)	<u>Would</u> <u>consider</u> <u>non</u> <u>replace</u>	Mean (SD) time:	Cross sectional	FPAS (18/2)	Patients who would consider replacement

	<p><u>Would consider non replacement cohort:</u></p> <p>N = 15 (60% men)</p> <p><u>Would consider replacement cohort:</u></p> <p>N = 91 (78% men)</p> <p>P-value: 0.13</p>		<p><u>ment cohort:</u></p> <p>61.1 (16.8) years</p> <p><u>Would consider replacement cohort:</u></p> <p>68.0 (12.3) years</p> <p>P = 0.06</p> <p>Range: α</p>	<p><u>Would consider non replacement cohort:</u></p> <p>9.3 (3.5) years</p> <p><u>Would consider replacement cohort:</u></p> <p>9.1 (3.4) years</p> <p>P = 0.88</p>			<p>of their ICD had a higher score on BIC (= less acceptance) than those who would not consider replacement.</p> <p><u>Would consider replacement cohort:</u></p> <p>Mean (SD) years: 88.7 (22.9)</p> <p><u>Would consider non replacement cohort:</u></p> <p>Mean (SD) years: 73.3 (34.7)</p> <p>P = 0.03</p>
Pedersen (2008) (49)	N = 566 (82.2% men)	86.3% (624/723)	61.9 (14.3) years Range: α	Mean (SD) time: 4.7 (3.3) years	Cross-sectional	FPAS (18/2)	No information was provided on the mean score on body image concerns for the total

							<p>group but only stratified by Type D personality.</p> <p>Type D patients were more likely to report body image concerns as compared to non-type D patients:</p> <p><u>Type D patients:</u></p> <p>Mean (SD): 29.86 (29.84)</p> <p><u>Non-Type D patients</u></p> <p>10.62 (21.86)</p> <p>P < 0.001</p>
Pycha (1990) (43)	N = 42 (90% men)	60.9% (42/69)	57.7 (x) years Range: 34 - 76 years	Mean (SD) time: 17.6 (x) months Range: 1-52	Cross-sectional	The Cleveland Clinic AICD Psychosocial Inventory (x)	83.3% of patients reported a successful incorporation of the ICD into their body image. However, altered body

				months			<p>perceptions were also frequently reported.</p> <p>One-third of patients felt self-conscious and some were apprehensive about touching or looking at themselves in the area where the ICD was implanted.</p>
Rahmawati (2013) (50)	N = 179 (81% men)	α	60.5 (15.9) years Range: α	α	Cross sectional	<p>Worries about ICD (WAICD) scale (26/2)</p>	<p>Females reported higher body image concerns than men. However, body image concerns were not the most important worries the about ICD in this sample.</p> <p><u>WAICD Scores:</u> Mean (SD): Female: 40.6</p>

							(18.6) Male: 31.0 (18.8) P < 0.05
Spindler (2009) (19)	N = 535 (81.9% men)	86% (624/723)	61.54 (14.4) years Range: α	Mean (SD) time: 4.6 (3.2) years	Cross sectional	FPAS (18/2)	No gender differences in body image concerns were found, however, older age showed an association with an increased device acceptance. <u>Total FPAS score:</u> Mean (SD): 78.04 (17.0) P = 0.930
Vazquez (2008) (20)	N = 88 (0% men)	α	57.76 (15.33) years Range: α	Mean (SD) time: 3.1 (2.8) years	Cross sectional	FPAS - but only used the Body Image Concerns scale (18/2)	Higher body image concerns were associated with living in the US, being younger (≤ 50 years), having a

							<p>history of non-ischemic cardiomyopathy and using psychotropic medication.</p> <p><u>Body image concerns of Females by Age Group:</u></p> <p>Mean (SD):</p> <p>Young: 25.8 (28.2)</p> <p>Middle: 11.5 (23.2)</p> <p>Older: 9.7 (20.1)</p>
Wilson (2013) (55)	N = 101 (66% men)	α	<p>65 (12.8) years</p> <p>Range: 29 - 88 years</p>	<p>Years (%):</p> <p>< 1 y: 12 (12)</p> <p>1 ≤ 2 y: 9 (9)</p> <p>2 - 5 y: 45 (45)</p> <p>> 5 y: 35 (34)</p>	Cross sectional	FPAS (18/2)	<p><u>Body Image Concerns:</u></p> <p>Mean (SD): 10.6 (22.2)</p> <p><u>Racial and Gender differences related to Body Image Concerns:</u></p> <p>Mean (SD):</p> <p><u>White (n=59):</u></p> <p>Men: 7.0</p>

							(15.0) Women: 9.1 (21.0) Total: 7.4 (16.1) <u>African American (n=42):</u> Men: 8.3 (20.6) Women: 20.3 (32.5) Total: 15.2 (28.4) In particular, differences between African American men and women were considerable.
Wojcicka (2008) (58)	N = 45 (55.7% men)	81.8% (45/55)	21.2 (4.3) years Range: 14 - 29 years <i>A total of 35</i>	Mean (SD) time: 4.3 (2.7) years Range: 5 months to 11 years	Cross-sectional	Purpose designed questionnaire (x)	The implantation site was visible to most patients, but a majority deemed the appearance of the scar or bump acceptable. Almost half

			subjects ≥18 years				of the patients admitted to covering up the wound, and half had negative opinions on the scar. Some issues with shame, being intimate and being undressed were reported.
PROSPECTIVE							
Carroll (2005) (53)	N = 59 (71% men) <u>No shock group:</u> N = 43 (67.44% men) <u>Shock group:</u> N = 16 (81.25% men)	After 1 year: 84.3% (59/70)	<u>No shock group:</u> 64.8 (12.9) years <u>Shock group:</u> 57.5 (18.3) years <u>Both groups:</u> Range: 21 – 84 years	1 year	Prospective: 1 year follow up; Brodsky Cross sectional at follow up.	Brodsky ICD Questionnaire (46/3)	Some concerns about the size, place or noticeability of the device were noted by all patients. Specifically, patients who had received a shock were more likely to wish that the device was less rigid or in another position.

							<u>No shock group:</u> Mean (SD): 6.8 (2.2) <u>Shock group:</u> Mean (SD): 7.9 (2.8)
Flemme ^s (2001) (52)	N = 56 (75% men)	67.5% (56/83)	\bar{x} Range: 25 to >75 years	After 3 and 12 months	Prospective/ Longitudinal	The Patient Implantable Cardioverter Defibrillator Questionnaire of Brodsky (46/3)	The Wishes subscale of the Brodsky questionnaire decreased from 3 months to 12 months, but the change was not significant. <u>Wishes after 3 months (N=54):</u> Sum (range) 349 (216 - 648) <u>Wishes after 12 months (N=53):</u> Sum (range). 339 (212 -

							848) P = 0.504
Hegel (1997) (51)	N = 38 (86% men)	(N= 25) Responded after 1 year (66%) (N= 21) Responded after 2 years (55%)	62.2 (x) years (at time of implantatio n) Range: 29-78 years (at time of implantatio n)	4.22 (2 - 8) years	Observati onal, longitudin al, 1 and 2 years follow up	The ICD Quality of Life questionnai re. (16/1)	Worries about body appearance did not decrease with time, and were not associated with depression, trait anxiety and anxiety sensitivity. <u>Appearance:</u> Mean (SD): Baseline: 0.63 (1.13) 1 year: 0.67 (1.09) 2 year: 0.62 (1.02) Appearance was not associated to depression or anxiety.
Marshall (2012)	N = 47 (70% men)	67% (47/70)	58 (16.44) years	Post implantati on to 12	Prospectiv e study	ICD specific questionnai re adopted	Women worried more than

(21)			Range: α	months	Questionnaires: At baseline and 4, 8 and 12 months	from Hegel et al 1997 (15/α)	<p>men about their looks after receiving an ICD and their scores remained constant.</p> <p>Younger women worried more than older women at both time points.</p> <p>Men were less worried about their looks and their scores were significantly reduced over time.</p> <p><u>Worrying about looks:</u></p> <p>At discharge mean scores were:</p> <p>Females: 1.07</p> <p>Males: 0.36</p> <p>P = 0.0013</p>
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							<p>At 4 months mean scores were:</p> <p>Females: 1.07</p> <p>Males: 0.24</p> <p>P = 0.0017</p> <p>At 12 months mean scores were:</p> <p>Females: 1.21</p> <p>Males: 0.27</p> <p>P = 0.0013</p>
Starrenburg (2014) (18)	N = 300 (82.3% men)	86.5% (300/347)	62.0 (11.1) years Range: x	12 months	Prospective quantitative study. Questionnaires prior implantation, 2, 5, 8, and 12 months post implantation. However results on	FPAS (18/2)	In the domain Body image concerns women had higher levels of concerns as compared to men and thereby gender as an independently association with poorer device-related acceptance. (P = 0.043, Cohen's

					FPAS are cross sectional after 1 year		effect size= 0.27) Age, type D personality, ICD indication, comorbidity, shocks, ejection fraction and age were not significantly related to body image.
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Footnotes:

α. Information was not provided.

1. Comparison of Adults with Congenital Heart Disease (ACHC): ICDs, pacemakers, no devices and non-ACHD patients with ICDs.

2-3. Mix of pacemaker and ICD patients.

4. Mix of pacemaker, ICD-AT and ICD patients.

5. Age and range are from the original sample of the 25 implanted recipients from 1987 – 1993. A total of 14 patients were > 18 years old.

6. The population were patients with ARVD/C (Arrhythmogenic right ventricular dysplasia/cardiomyopathy).

7. One of the exclusion criteria was age < 16 years.

8. Statistics are reported in total summation scores, not averages.

Table 3: Questionnaires identified

Instrument	Study	Language	Number s of body image specific questio ns	Internal consistency		Test- retest Reliability (Correlatio n coefficient)	Factor analysis
				Total	Body Image Concern s (BIC)		
<p>Florida Patient Acceptance Survey</p> <p><i>Description:</i></p> <p>Florida Patient Acceptance Survey (FPAS) is disease specific to patients with implanted devices (Burns; 2005).</p> <p>It consists of 18 items rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Only 15 items contribute to the total score as 3 items are filler items.</p> <p>Starrenburg (2014) used</p>	Bedair (2015) (45)	English	2	α	α	α	α
	Birnie (2009) (44)	English	2	α	α	α	α
	Burns (2005) (39)	English	2	α = 0.83	α = 0.74	α	1. Return to function 2. Device-related Distress 3. Positive Appraisal 4. Body Image Concerns
	Groeneveld (2007) (46)	English	2	α	α	α	α
	James (2012)	English	2	α	α	α	α

<p>a 5-point Likert scale 0 (strongly disagree) to 4 (strongly agree). With a score range 0 - 60.</p> <p>It is composed of 4 consistent factors:</p> <ul style="list-style-type: none"> - Return to Life (RTL) - 4 items - Device-related distress (DRD) – 5 items - Positive appraisal (PA) - 4 items - Body Image Concerns (BIC) – 2 items <p>A higher score on DRD and BIC means lower acceptance.</p> <p>A higher score on RTL and PA means higher acceptance.</p> <p>Both the total and the subscale scores range from 0 – 100.</p> <p>Body Image Concerns subscale items:</p> <ul style="list-style-type: none"> - I feel less attractive because of my device - I feel that others see me as disfigured by my device. 	(54)						
	Lewis (2014) (48)	English	2	α	α	α	α
	Pedersen (2008) (49)	Danish	2	α = 0.85	α = 0.73	α	<p>The four factors accounted for 64.3% of the variance:</p> <p>Factor I (<i>Device related distress</i>): 33.0%</p> <p>Factor II (Positive appraisal): 13.8%</p> <p>Factor III (Return to function): 11.1%</p> <p>Factor IV (Body image concerns): 6.4%</p>

	Spindler (2009) (19)	Danish	2	α	α	α	α
	Starrenburg (2014) (18)	Dutch	2	α	α	α	α
	Vazquez (2008) (20)	English	2	α	α = 0.79	α	α
	Wilson (2013) (55)	English	2	α = 0.85	α = 0.82	α	α
<p>Brodsky ICD Questionnaire Brodsky 1988 (83)</p> <p><i>Description:</i></p> <p>The questionnaire measures the concerns of ICD patients.</p> <p>It consists of 46 items rated on a 3-point Likert scale from 1 (not at all), 2 (some) to 3 (a lot).</p> <p>It is composed of 8 subscales:</p> <ul style="list-style-type: none"> - Their level of fear – 5 items - Embarrassment – 5 items - Suffering – 5 items - Worry about the ICD – 5 items 	Carroll (2005) (53)	USA - language not stated	3	α	Subscales in the interval α = 0.75 - 0.85	α	α

<p>- Wishes – 5 items</p> <p>- Experience with ICD – 3 items</p> <p>- Concerns regarding relationship with spouse / significant other – 11 items</p> <p>- The extent of lifestyle changes – 8 items</p> <p>Body image concerns are present in the subscale “Wishes”:</p> <p>I wish the ICD were:</p> <p>A. Smaller</p> <p>B. Less rigid</p> <p>C. Less noticeable</p> <p>D. Elsewhere on my body</p> <p>E. More trustworthy</p> <p>Higher scores indicate more concerns about the ICD.</p>							
<p>Brodsky ICD Questionnaire</p> <p><i>Description:</i></p> <p>The questionnaire measures the concerns of ICD patients.</p> <p>It consists of 43 items rated on a 3-point Likert</p>	<p>Flemme (2001) (52)</p>	<p>Sweden</p> <p>- language not stated</p>	<p>3</p>	<p>α</p>	<p>Subscales in the range</p> <p>α = 0.76 to 0.85</p>	<p>α</p>	<p>Factor analysis was performed within each statement (cumulatively varied between 53% and 74</p>

<p>scale from 1 (not at all), 2 (some) to 3 (a lot).</p> <p>It is composed of 7 subscales:</p> <ul style="list-style-type: none"> - Their level of fear – 5 items - Embarrassment – 5 items - Suffering – 5 items - Worry about the ICD – 5 items - Wishes – 5 items - Concerns regarding relationship with spouse / significant other – 11 items - The extent of lifestyle changes – 8 items <p>Body image concerns are present in the subscale “Wishes”:</p> <p>I wish the ICD were:</p> <ul style="list-style-type: none"> A. Smaller B. Less rigid C. Less noticeable D. Elsewhere on my body E. More trustworthy 							<p>% of total variance, factor loadings ranging 0.51 - 0.91).</p>
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<p>Higher scores indicate more concerns about the ICD.</p> <p><i>*Flemme et al. have used the Brodsky questionnaire in a modified version.</i></p>							
<p>IDAS (the Implanted Device Adjustment Scale)</p> <p><i>Description:</i></p> <p>(Beery 2005):</p> <p>The IDAS is a 22-item, 5-point Likert-scale from 1 (Strongly agree), 2 (Agree), 3 (No preference), 4 (Disagree) to 5 (Strongly disagree).</p> <p>It was composed by 4 scale dimensions:</p> <ol style="list-style-type: none"> 1. Attitude toward the device 2. Body image 3. Relief of symptoms 4. Effective device function 	Beery (2005) (42)	English	2	α = 0.90 N = 45	α	α = 0.92 N = 43	α

<p>Scores can range from 20 to 100.</p> <p>Higher numbers indicate poorer adjustment.</p> <p>Body image (item):</p> <p>(9) I do not like the way my body looks since I've had my implanted device.</p> <p>(16) I am troubled by my physical appearance since I have had my device.</p>							
<p>IDAS (the Implanted Device Adjustment Scale)</p> <p><i>Description:</i></p> <p>(Beery 2007):</p> <p>The IDAS is a 21-item, 5-point Likert-scale from 1 (Strongly agree), 2 (Agree), 3 (No preference), 4 (Disagree) to 5 (Strongly disagree)</p> <p>Scores can range from 21 to 105.</p> <p>Higher numbers indicate poorer</p>	<p>Beery (2007) (40)</p>	<p>English</p>	<p>2</p>	<p>$\alpha = 0.89$</p>	<p>α</p>	<p>α</p>	<p>Four subscales were described by the categories:</p> <ul style="list-style-type: none"> - Fear/anxiety - Attitude - Preparation - Body awareness <p>Three items were included in the Body</p>

<p>adjustment.</p> <p>(This is an adaption of the 2005 IDAS scale).</p>							<p>awareness subscale:</p> <p>9. I do not like the way my body looks since I have had my device implanted (Item loading 0.844)</p> <p>14. I am concerned that my device will not work properly) (Item loading 0.369)</p> <p>16. I am troubled by my physical appearance since I have had my device (Item loading 0.812)</p>
<p>LTS (Low Treatment Satisfaction)</p>	<p>Ladwig (2005) (47)</p>	<p>Germany - language not stated</p>	<p>2</p>	<p>$\alpha = 0.73$</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>

<p><u>Description:</u></p> <p>The LTS has 11 dichotomous items.</p> <p>Items concerning due to the ICD:</p> <ul style="list-style-type: none"> -A mistrustful attitude - Low appraisal - A negative body image <p>The total treatment satisfaction score ranged from 0 to 11 (0 = very satisfied, 11 = most dissatisfied) and was markedly skewed to the right.</p> <p>A negative body image subscale:</p> <ul style="list-style-type: none"> - ICD feels like a foreign body - Disturbed by changes of body form 							
<p>The Cleveland Clinic AICD Psychosocial Inventory</p> <p><u>Description:</u></p> <p>The Psychosocial Inventory elicit information gathered from multiple choice questions on:</p> <ul style="list-style-type: none"> -Demographics 	<p>Pycha (1990) (43)</p>	<p>English</p>	<p>#</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>

<ul style="list-style-type: none"> - Medical history - Patient attitudes towards the device - Body image distortions - Lifestyle alterations - Impact on family and marriage - General quality of life - Device-specific concerns 							
<p>The Worries About ICDs Scale (WAICD)</p> <p><i>Description:</i></p> <p>The WAICD examines quality-of-life issues associated with having an ICD and reflects the degree to which the respondent experiences the problem.</p> <p>The WAICD is a modification of the 26-item "Index of Subjective Concerns for People with ICD's" (ISCP-ICD) (Vitale and Funk 1995) suitable for adults.</p> <p>It consists of 26 items rated on a 5- point</p>	<p>Rahmawati (2013) (50)</p>	<p>Japanese</p>	<p>2</p>	<p>$\alpha = 0.89$</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>

<p>Likert scale from 0 (not at all true), 1 (a little true), 2 (sort of true), 3 (quite a bit true) and to 4 (extremely true).</p> <p>The score is determined by the total of the 26 items, with a scoring range of 0 to 104.</p> <p>Lower scores are reflective of less worry.</p> <p>Higher scores indicate heightened worry.</p> <p>Body image concerns (items):</p> <p>9. It bothers me that there is a “bump” where the ICD is.</p> <p>10. It bothers me that I have to wear clothes that cover up the place where the ICD sticks out.</p>							
<p>Unspecified modification of SF 36</p> <p><i>Description:</i></p> <p>The questionnaire (84), assessed quality of life in 4 areas:</p> <ul style="list-style-type: none"> - Demographics - Education and work 	<p>Dubin (1996) (56)</p>	<p>English</p>	<p>#</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>	<p>✕</p>

status - Health and exercise - Self-image and social interaction							
Purpose-designed device questionnaire <u>Description:</u> The questionnaire was designed to assess patients' perceptions of an implanted device. It consists of 23 items rated on several scales. Some items were rated on a 3- point Likert scale and others on a 4-point Likert scale – (with different answer categories) and some also dichotomous. Body image concerns (items): 5. Did the implanted device change your image of your body? (yes/no) 6. To what extent do the visible changes at the implantation site disturb you? (Does not disturb, To	Duru (2001) (41)	Zürich, Switzerland & Middlesex, UK - language not stated	2	✕	✕	✕	✕

some degree, Considerably, Very much)							
Unspecified purpose- designed questionnaire <i>Description:</i> The questionnaire was subjective and experiential demographic and biopsychosocial and comprised of 7 categories: - Psychiatric variables, - Patient attitudes toward the ICD and their illness - ICD discharges - Patient-perceived family attitudes toward the ICD - Compliance variables - Quality-of-life variables - History and symptoms of cardiac illness The questions were designed in a Likert scale fashion. Unknown number of questions in total and on body image concerns.	Heller (1998) (57)	English	#	α	α	α	α

<p>Purpose designed questionnaire</p> <p><i>Description:</i></p> <p>In order to assess patients' quality of life, a questionnaire was developed to assess important issues and problems of patients' with ICDs.</p> <p>It consisted of four parts:</p> <p>Part 1: Functioning of patients with ICDs (e.g. shock)</p> <p>Part 2: Various psychological problems</p> <p>Part 3: Everyday activities</p> <p>Part 4: Future plans and advantages/disadvantages of living with an ICD</p> <p>Unknown number of items.</p> <p>Some of the questions were closed questions, with suggested answers, i.e. yes or no, while some of the questions were open.</p>	<p>Wójcicka (2008) (58)</p>	<p>Poland - language not stated</p>	<p>#</p>	<p>¤</p>	<p>¤</p>	<p>¤</p>	<p>¤</p>
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<p>Questions regarding Body image concerns: (from Part 4) The appearance of the implantation area</p>							
<p>ICD specific questionnaire</p> <p><i>Description:</i> (2012) (21)</p> <p>The questionnaire is adapted from “Hegel et al. 1997” with 15 questions. In contrast to Hegel (1997), it uses a 5-point Likert scale.</p> <p>The questions focused on impact of the device and shock therapy upon:</p> <ul style="list-style-type: none"> - Driving - Comfort - Worry and anxiety - Physical and sexual activity - Sleep - Financial and family issues <p>Higher scores indicate worse outcome.</p> <p>Questions regarding</p>	<p>Marshall (2012) (21)</p>	<p>English</p>	<p>#</p>	<p>α</p>	<p>α</p>	<p>α</p>	<p>α</p>

<p>Body image concerns:</p> <p>Worry about looks</p> <p>Reported was the Cronbach's alpha coefficient from Hegel of 0.79.</p>							
<p>The ICD Quality of Life questionnaire</p> <p>Hegel (1997) (51)</p> <p><i>Description:</i></p> <p>The questionnaire was purpose designed with 16 questions measured on a 6-point Likert scale: 0 (Not at all) to 5 (Very much so).</p> <p>The questions focused on 16 variables:</p> <ul style="list-style-type: none"> - Frequency of shock - The occurrence of warning signals before shock - The ability to prevent shock - The ability to control the intensity and frequency of shock - The ability to predict shock - Levels of anxiety about 	Hegel (1997) (51)	English	1	$\alpha = 0.79$	⌘	⌘	⌘

<p>the occurrence of shock</p> <ul style="list-style-type: none"> - Levels of discomfort secondary to shock - Interference in daily activities - Time spent worrying about shock - Interference in sexual functioning - Financial difficulties secondary to the ICD - Overprotectiveness from significant other - Worries about appearance with the ICD - Feeling like a burden to the family - Quality of sleep - Avoidance of activities secondary to the ICD 							
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Footnotes:

#. Information was not provided (i.e., the specific item(s) tapping into body image concerns was not provided in the published article)

α. Information was not provided

1. Correlated item-total correlations. Abbreviation: MICC = mean inter-item correlation

2. Items assigned to a factor are presented in bold-face