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A scoping review

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ABSTRACT

Background: Patients with an implantable cardioverter defibrillator (ICD) retain a scar and a

30   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 the search May 2017. Included were patients ≥ 18 years, an ICD implant

35   (transvenous, subcutaneous, or ICD with cardiac resynchronization therapy (CRT-D),

reported on BICs, and published in peer-reviewed English-language journals. We excluded

non-systematic reviews, opinion pieces/letters, case studies, conference abstracts, PhD

dissertations, and protocol papers, studies of ICD shock treatment of atrial fibrillation, of

abdominally or submammary implanted ICDs.

40   **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. The two BICs items of the "Florida Patient Acceptance Survey" were

45   the most frequently used.

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 in order to examine the

prevalence of BICs and the potential impact on patients' lives.

50   Abstract (word count): 250

INTRODUCTION

55   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

60   Union had a total of 155 ICD implantations per million inhabitants (2013) (6, 7).

Despite the unequivocal medical benefits, ICD therapy is associated with increased risk of procedural and device-related complications, such as infection, lead fractures, and inappropriate therapies (i.e., shock therapy given in the absence of a life-threatening arrhythmia) (8), that may have a negative influence on patients' well-being and quality of life

65   (9). Additionally, body image concerns due to the scar and size of the ICD under the skin are device-related issues, that may also impact patients' well-being and quality of life (10-13). 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 (13, 14), which can lead to noticeable discomfort for some patients. As one patient stated: *"The*

70   *scar is huge and I don't wear tank tops or roll up my sleeves at all unless I'm in front of my close friends who know exactly what happened, my boyfriend or my family"*. Another women stated: *"I pick clothing that doesn't show the scars."* (15).

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

75   promising results (11-14, 16). 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.

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The scarce evidence is conflicting. Some studies suggest gender differences, where women may be more likely to report post-implant body image concerns compared to men, in terms

80   of concerns about how to make clothing fit to hide the bump from the device. Moreover, there is a risk of further scarring because of the weight of the breasts (13). Others suggest that women have a higher risk for developing distress due to body image issues, but that more research is needed (17). A recent meta-analysis (18) confirms that there is no consensus whether gender differences in body image concerns exist (19-22), and whether

85   younger women are likely to have more concerns than older women (15, 23).

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 (24-26), we performed a scoping review of the available literature to examine the prevalence of body image concerns and the potential impact on

90   patients' lives.

METHODS

Search strategy

A first exploratory search was performed in August 2016 and repeated in May 2017. The

95   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

100   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) body image concerns were reported 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 (27). 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. For an overview of the search process, see the PRISMA flowchart (Figure 1).

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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.

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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

140 contain a quality assessment (28, 29). Due to the present lack of consensus about assessing quality in qualitative studies (30-32), we decided not to assess the methodological quality.

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 (28).

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RESULTS

Qualitative findings

Description of samples

Table 1 show 15 of the 16 qualitative studies that we included in the scoping review. We
found one systematic review that included qualitative studies (18). 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 (33). 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 (34, 35). Time of patient enrolment differed across studies. Some
studies enrolled ICD patients directly after implantation, where others identified patients
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, mean age was not reported in all studies (e.g., (36-38). The
majority of patients were male (range 40-90.9%), and one study only reported that the
'typical subject' was male with no supporting statistics (37), and one study included only
women (36).

Patients' experiences with an ICD

The ICD recipients express an awareness of the ICD components inside their body. They feel
the physical presence of the ICD, see it, or are 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*

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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
175 *constant reminder that I may feel fine, but I am technically sick"* (36).

Visibility

The visibility of the scarring and the visible shape of the device give rise to feelings, in both men and women, of looking different, feeling disfigured, being uncomfortable and feeling
180 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"* (33). *"I also feel uncomfortable when I see the implant area"* (39). The ICD recipients report insecurity about their physical appearance both among
185 their family, friends and peers but also in personal 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"* (40).

Appearance

190 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"* (39). 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*
195 *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"* (10).

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Quantitative findings

Description of samples

200   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

205   e.g. pacemakers (PM) and ICD-AT (41), a combination of pacemakers and other implantable devices (42), and pacemakers (43, 44) and spouses (45).

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 (46), or via the

210   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 21 years after implantation.

Age across studies ranged from 13 to 98 years, however, age range was not reported in all studies (20-23, 41, 43, 46-53). The reported mean age ranged from 21.2 to 78 years,

215   although the mean age was not reported in two studies (53, 54). The studies included both men and women; mostly patients were male (range 43.8% - 90.0%), except from one study that included only women (22). Most of the studies used a cross sectional design except from four prospective studies (20, 23, 54, 55) and one observational longitudinal study (53).

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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) (20-22, 41, 46-48, 50, 51, 56, 57), the "Brodsky ICD Questionnaire" (54, 55), the "Implanted Device Adjustment Scale" (IDAS) (42, 44), "Low Treatment Satisfaction" (LTS) (49), the "Cleveland Clinic AICD Psychosocial Inventory" (45), the "Index of Subjective Concerns for People with ICDs" (ISCP-ICD), and the "Worries about ICD WAICD Scale" (WAICD) (52). There was also one study that used an "unspecified modification of the SF-36 questionnaire" (58) and five studies that used purpose-designed questionnaires (23, 43, 53, 59, 60).

Gender and age

There was a trend for gender differences, with women reporting more body image concerns than men (20, 23, 42, 52, 58), however one study found no gender differences (47). Younger age was associated with more body image concerns (22, 23, 56). One study found an association between older age and higher device acceptance (21). However, another study found that women worried more than men about their appearance after receiving an ICD, with their scores remaining constant over time (23), while a third study showed that worries about body appearance, in both men and women, did not decrease with time (53). One study reported ethnic differences with Afro-American women having more concerns than Caucasian women (57).

Types of 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 (49, 55, 59), self-consciousness

245 and apprehension about touching or looking at the implantations area (45). 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 (60). One study reported that patients scoring high on

Type D personality were more likely to report body image concerns (51) while another study

250 did not find an association (20). Some studies did not observe body image concerns in their

group comparisons, e.g., ICD-Congenital versus ICD-non-Congenital (46, 47). 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 (44). One study found that ICD

patients had more concerns than pacemaker (PM) patients (41), while another study

255 reported some level of body image concerns among the participants but with no significant

differences between PM and ICD patients (43). One study reported body image concerns

among secondary prevention patients when compared to primary prevention patients (48).

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

260 (50).

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

265 conflicting evidence, we performed a scoping review (28, 29) 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. Qualitative studies

provide a more in-depth and detailed exploration of the individual patient's experience and

270   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 (10, 15, 18, 33-40, 62-66).

Most of the included quantitative studies were cross-sectional (21, 22, 41-52, 56-60)

and therefore, it was not possible to determine whether body image concerns change over

275   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 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 and it

was often impossible to retrieve the questionnaires being discussed, as many of them had

280   not been formally published (e.g., a "Unspecified modification of SF 36 questionnaire" (58); a

"Unspecified purpose-designed questionnaire" (59); the "Low Treatment Satisfaction

questionnaire" (49); the "Cleveland Clinic AICD Psychosocial Inventory questionnaire" (45); a

"Purpose designed questionnaire" (60); the "Brodsky ICD Questionnaire" (54, 55), the "ICD

Quality of Life questionnaire"(53) and the "ICD specific questionnaire" (23).

285   Some of the quantitative studies used purpose-designed questionnaires (43, 59, 60),

which among other things tapped into body image concerns. Other studies used validated

questionnaires as the FPAS (20-22, 41, 46-48, 50, 51, 56, 57), and the IDAS (42, 44); however

mostly there were only one or two questions tapping into body image concerns and often

just a total sum score was reported. The most commonly used questionnaire was the

290   "Florida Patient Acceptance Survey" (FPAS), which has only 2 items that tap into body image

concerns (41). We did not provide a quality assessment of the individual studies (28) 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. Taken together, these findings show that that there is no good and standardized questionnaires that tap into body image concerns for ICD patients and that there is a need to develop a new one.

It is known that the massive media exposure with body image ideals affects men and women and gives rise to body image concerns (67, 68). 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. 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 (13), 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 (9), 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 (21, 23, 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) could 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 it is not related to the severity of

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the disfigurement (69). Hence this factor is an important finding, as studies show that mental health, symptoms of anxiety and depression are independent factors that increases the risk of ventricular tachyarrhythmia's and mortality (76) as well as noncompliance with medical treatment (77).

Clinical implications

The results of this scoping review showed, 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 standard implantation site of the ICD is at the subclavicular area, leaving the scar / bump visible. Intramuscular implantation still leaves a scar, but not a visible bump (78). 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). Discussions about implantation site and offering of an alternative implantation area should therefore be offered to all ICD patients. The importance of patient involvement in this decision is crucial in terms of avoiding psychosocial issues. Novel studies have revealed a new submammary implantation technique that leaves patients satisfied in terms of body image concerns (11, 12, 14) however this requires an adoption of the method by the clinicians, as this is currently not the standard implantation technique for ICDs.

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

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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.

Future research

345   As we know that even relatively small disfigurements can have a large impact on psychosocial outcomes (69), more research on the link between body image concerns and psychosocial outcomes is warranted. More long-term research could help detecting changes in body image concerns and potential gender differences in ICD patients. We found that the most frequently used questionnaire in this scoping review was the FPAS (41), however, the

350   FPAS has only two items measuring body image concerns which precludes any psychometric analyses. Based on the current scoping review, the use of a questionnaire with more items specially tapping into body image concerns appears to be a more convincing predictor of the prevalence and impact on patients' lives than a generic questionnaire. There is a knowledge gap with regard to assessment tools of body image concerns in ICD patients and further

355   research is warranted to create a more comprehensive scale tapping into body image concerns. To entail more thorough information about body image concerns, the use of mixed-methods could be a recommendation for future research. Using a participatory design, involving both patients and health care professionals (80) could be a method to develop a more specific questionnaire tapping into body image concerns. Furthermore,

360   there is an urgent need for prospective studies with long-term follow-up in order 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.

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CONCLUSION

Body image concerns were prevalent among ICD patients however the degree of impact on their lives varied. The studies in this review did not investigate body image concerns as their primary endpoint. Future research is warranted in terms to explore the prevalence of body

370   image concerns and the potential impact on patients' lives.

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AUTHOR CONTRIBUTIONS

380 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

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

Statistics: Not applicable

Approval of article: SSP, RNK, SJS, VSF

390 Administrative, technical or material support: Not applicable

Study supervision: SSP, RNK

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Table 1: Overview of qualitative studies – body image concerns

	Reference	Participants N (% men)	Age (years)	Time since implantation	Design (interview time points post-implantation)	Results (Impact of body image concerns)
1	Burke (1996) (62)	N = 24 (58% men)	Mean (SD) age: 59 (-) 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: *"First week: Of looking different". "Three months: Of feeling disfigured".*
2	Cinar (2013) (63)	Experimental group: N=27 (78% men) Control group: N=27 (82% men)	Experimental group: Mean (SD) age: 63.41(11.37) years Range: - Control group: Mean (SD) age:	6 months and less : E:17 (63.0) C: 15 (55.6) ≥7 months: E: 10 (37.0) C: 12 (44.4)	Mixed-methods study. Experimental group: A total of 4 semi-structured interviews: • 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.

			63.74(11.00) years Range: -		Control group: A total of 2 interviews: • Baseline; 6 months.	
3	Conelius (2015) (36)	N = 3 (0% men)	Mean (SD) age: - Range: 34-50 years	More than 1 year	Qualitative descriptive phenomenology study Individual interviews Timepoint: -	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).
4	Dougherty (2000) (33)[1]	N = 15 sudden cardiac arrest survivors. (86.7% men) & One of their family	Mean (SD) age: 57(11) years Range: 31-72 years Family members:	0-12 months	Qualitative study. Grounded theory. Semi-structured interviews: • Hospitalization, 1, 3, 6 and 12 months	First the ICD gave rise to discomfort: *"This box is finding a place of rest in me, and there's an irritation where the box is stuck in the muscles".* *"It looks like a pack of cards sticking out. They can see it over my clothes".* Patients were also fighting with impatience and getting "back

		members: (86.7% men)	Mean (SD) age: 53(9) years. Range: 31-72 years			to normal".
5	Flemme (2011) (64)	N = 16 (56.25% men)	Mean (SD) age: 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: *"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…"* (Woman aged 48 years).
6	Fridlund (2000) (65)	N = 15 (66.6% men)	Mean (SD) age: 61.8 (-) years Range:	Mean time: 33 months Range:	Qualitative study. Holistic perspective, Phenomenography.	Body image concerns and their ICD feeling as an intrusion were emphasized but also that they are sometimes 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".

			33-76 years	23-55 months	Open and semistructured interviews.	"An alien thing has entered my body". "It's the fact that it's something alien that disturbs me sometimes, but I forget about it when I'm together with other people".
					Timepoint:	
					-	
7	Hallas (2010) (66)	N = 13 (76.9% men)	Mean (SD) age: 58.46 (13.65) years	6 months to 5 years.	Qualitative study.	The majority of patients had a negative perception of their body due to the scar at the implant site. The primary feeling was embarrassment.
					Semi-structured interviews.	
			Range: 35-80 years		Timepoint:	
					-	
8	Hauptman (2013) (34)	N =41 (48.8% men)	Mean (SD) age: 61.4 (14.7) years	-	Qualitative study.	The prevalent perception of body image was negative due to the cosmetic changes associated with the ICD. Body discomfort including "pulling sensations" and discomfort when "lying on the side" might have contributed to this negative perception.
			Range: -		First eight patient focus group interviews were conducted.	
					Timepoint:	
					-	

| 9 | Humphreys (2016) (10) | N = 18

13 non-shock participants

(53.8% men)

5 shock participants

(80% men) | Mean (SD) age:

55.7 (-) years.

Range:

28 – 68 years | 3-24 months. | Qualitative study.

Semi-structured interviews.

Individually conducted.

Timepoint:

- | Most patients were physically aware of the device inside their bodies, and some described it as a physical obstacle: "…. *its 'incredulous' size once implanted"*.

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'."* |
| 10 | Kuiper (1991)(37) | N = 20

(- % men) | Mean (SD) age:

-

Range:

39-75 year | 1 -12 months.

Mean (SD):

8.75(5) months | Mixed-method

A quantitative instrument (JC: Jaloweic Coping Scale)

and | Based on the content analysis of the semi-structured aspects as clothing adjustments and appearance were mentioned. |

					a semi-structured interview guide. Timepoint: -	
11	Larimer (2016) (40)[2]	N = 6 (50% men)	Mean (SD) age: 23.7 (-) years. Range: 18- 28 years	15 months to 24 years.	Descriptive qualitative research design Purposive sampling. In-person interview. Semi-structured interviews. Timepoint: -	The participants had challenges in terms of insecurity about their 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 either was shirtless or strapless. This can interfere with interpersonal relationships, intimacy and closeness.
12	McDonough (2009) (15)	N = 20 (40% men). Telephone group: N =6 (33.3% men)	Total group: Mean (SD) age: 33.5 (6.7) years. Range:	Post ICD implantation. Mean (SD) years:	Qualitative study. Interviews (telephone and Internet) Interview guide with open ended questions.	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.

			21-40 years	3,9 (-) years		Women tended to choose clothing that covered the ICD site.
		Internet group:			Timepoint:	
		N= 14	Telephone group:	Range:	-	
		(42.9% men)	Mean (SD) age:	3 months – 17		
			35.2(7.4) years	years (only one		
			Range:	for 17 years)		
			21-40 years			
			Internet group:			
			Mean (SD) age:			
			32.9(6.4) years.			
			Range:			
			21-40 years.			
13	Mert (2012) (35)	N = 19 (78.9% men)	Mean (SD) age: 53.57 (13.44) years Range: -	15.47(9.82) months.	Qualitative descriptive approach. 4 focus-group interviews with groups of 4-5 patients. Semi-structured interviews	Among the most frequently reported emotional change due to the ICD were changes in body image.

| | | | | | | with open ended questions.

Timepoint:

14	Saito (2012) (39)	N = 22 (90.9% men)	Mean (SD) age: 61.26 (13.4) years Range: 35-79 years.	14 months	Qualitative descriptive study. Semi-structured interviews.

Timepoint:

14 months | Patients were aware of the physical existence of the ICD, leading to physical discomfort. Being confronted with the ICD area also caused discomfort. |
| 15 | Tagney (2003) (38) | N = 8 (75% men) | Mean (SD) age: -

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 |

400

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 PMs and 3 had PM/ICD's.

27

Table 2: **Overview of quantitative studies – body image**

	Reference	Participants N (% men)	Response rate %(send/ responded)	Age	Time since implantation	Design	Instrument (Total # items / # items on body image concerns)	Key findings with respect to body image concerns (BIC)
CROSS SECTIONAL								
1	Bedair[1] (2015)(47)	N=193 (56.5% men) 147 ACHD Hereof 59 ICD patients with congenital disease (59.2 % men) & 46 non-ACHD: Hereof	61.0% (319/193)	Mean (SD) age: 45.0(14.7) years Range: -	Patients with congenital disease: 5.7 (6.1) years Patients with non-congenital disease: 5.1 (4.8) years	Cross sectional	FPAS (18/2)	BIC Median (interquartile range) ICD-Congenital: 25 (0, 50) ICD-Non-Congenital: 0 (0, 25) There was no body image concerns observed between groups.

28

		34 ICD patients with non-congenital disease (73.9% men)						
2	Beery (2005)(44)[2]	N=45 (66.7% men) Hereof Pacemaker = 18 ICD = 27	97.8% (45/44) Test-retest after 2 weeks: 95.6% (45/43)	Mean (SD) age: 67.0(7) years Range: 30 - 98 years	Mean (SD) years: 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 development of the IDAS. The IDAS contains two items tapping into body image concerns. No results are reported on the patients' endorsements on these items.
3	Beery (2007)(42)[3]	N=173 ICD=102 (83.3% men in the ICD sample)	- (-/173)	For the whole sample: Mean (SD) age: 69 (-) years Range: 35-91.	Mean (SD) years: 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: Body awareness mean(SD): Women 6.53 (2.8) Men 5.48 (1.8)

| 4 | Birnie (2009)(46) | N (total group)=180

Advisory group:
N= 86
(83.6% men)

Non-advisory group:
N= 94
(76.6% men) | 70.3 % (256/180)

Advisory group:
70.5% (86/122)

Non-advisory group:
70.1% (94/134) | Advisory group:
Mean (SD) age: 67.7(9.75) years.

Non-advisory group:
Mean (SD) age: 65.0(11.8) years.

Range:
- | Mean (SD) months:

Advisory group:
52.4(9.0) months

Non-advisory group:
50.6(13.3) months

P-value 0.29 | Cross sectional | FPAS (18/2) | FPAS scores in body image concerns:
Advisory group:
13.11(23.68)

Non-advisory group:
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. |
| 5 | Burns (2005)(41)[4] | N=238
ICD= 58
(66.7% male) | 72% (238/338) | ICD group:
Mean (SD) age: 72.0 (9.6) years.
Range:
- | At least 3 months | Cross sectional | FPAS (18/2) | ICD patients had lower scores than pacemaker patients. Mean FPAS score:
(76.0 – 85.4)
P<0.001 |

| 6 | Dubin (1996)(58)[5] | N=16 (43.75% men) | 88% (16/18) | Time of age at implantation: *The 25 implanted patients:* Mean (SD) age: 28(8.7) years Range: 13-40 years | Assessment: 3.3 (1.5) years after ICD implantation | Cross-sectional | Unspecified modification of SF36 | Perceived attractiveness was not an issue for patients, however, a majority of patients reported issues with clothing and specifically with bathing wear (mostly women). |
| 7 | Duru (2001)(43) | N=152 Pacemaker group: N=76 (65.58% men) ICD total group: | N total =210 Pacemaker: (n = 124) ICD: (n = 86) | Mean (SD) age. ICD no shock group: 56.2 (12.8) years. ICD shock group: | Time since implantation was: Pacemaker group: 3.1 years. ICD group: 2.3 years. | Cross sectional | Purpose-designed device questionnaire. (23/2) | All patients reported some level of body image concerns, but there were no significant differences between pacemaker patients and ICD patients who had and had not received shocks. |

		N=76 (84.21% men) ICD no shock group: N= 31 (87.01% men) ICD shock group: N= 45 (82.22% men)	Response rate: Pacemaker 61.3% (76/124) ICD 88.4% (76/86)	59.7 (13.0) years Range: -	P< 0.05			
8	Groeneveld (2007)(48)	N=120 (73% men) Primary prevention: N= 45 (62% men) Secondary prevention:	100% (120/120)	Mean (SD) age: Total group: 60 (15) years. Primary prevention: 58 (16) years.	Patients receiving ICDs for secondary prevention of SCD had a longer time since implantation (median duration	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.

		N= 75 (80% men)		Secondary prevention: 61 (15) years. Range: -	3 years vs 1 year, P < 0.0001)			
9	Heller (1998)(59)	N=58 (72% men)	43% (58/135)	Mean (SD) age: 64 (11) years Range 37-84 years	20 (14) months	Cross sectional	Unspecified purpose- designed questionnaire	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).
10	James[6] (2012)(56)	US N=86 (44.19 % men)	- % (-/-)	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)	Body image concerns subscale 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
11	Ladwig (2005)(49)[7]	N=195, (83,6 % men)	91.5% (195/213)	Mean (SD) age: 59.8 (12.6) years Range: -	Months (SD): 28.2 (21.9)	Cross sectional	Low satisfaction with ICD treatment items. • ICD feels like a foreign body • Disturbed by changes of body form	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 approximately 18 % of the patients (estimated from Figure 2).
12	Lewis (2014)(50)	N=106 (75.47 % men) Would consider non replacement	72% (106/147)	Mean (SD) age: Would consider non replacement	Mean (SD) years: Would consider non replacement	Cross sectional	FPAS (18/2)	Patients who would consider replacement of their ICD had a higher score on BIC (= less acceptance) than those that the Non replacement cohort.

		cohort: N= 15 (60 % men). Would consider replacement cohort: N=91 (78 % men). P-value: 0.13		cohort: 61.1 (16.8) years. Would consider replacement cohort: 68.0 (12.3) years. P-value: 0.06 Range: -	cohort: 9.3 (3.5) Would consider replacement cohort: 9.1 (3.4) P-value: 0.88			Would consider replacement cohort: Mean (SD) years: 88.7 (22.9) Would consider non replacement cohort: Mean (SD) years: 73.3 (34.7) P = 0.03
13	Pedersen (2008)(51)	N=566 (82.2 % men)	86.3% (624/723)	Mean (SD) age: 61.9(14.3) years Range: -	Mean (SD) years: 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 group but only stratified by Type D personality. Type D patients were more likely to report body image concerns as compared to non-type D

								patients:
								Type D patients:
								Mean (SD):
								29.86 (29.84)
								Non-Type D patients
								10.62 (21.86)
								P < 0.001)
14	Pycha (1990)(45)	N=42 (90 % men)	60.9% (42/69)	Mean (SD) age: 57.7(-) years Range: 34-76 years	Mean (SD) months: 17.6 (-) months Range: 1-52 months	Cross-sectional	The Cleveland Clinic AICD Psychosocial Inventory	83.3% of patients reported a successful incorporation of the ICD into their body image. However, altered body perceptions were also frequently reported. 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.
15	Rahmawati	N=179	- % (-/-)	Mean (SD) age:	-	Cross	Worries about ICD	Females reported higher body image

	(2013)(52)	(81 % men)		60.5 (15.9) years Range: -		sectional	(WAICD) scale. 26/2	concerns than men. However, body image concerns were not the most important worries the about ICD in this sample. WAICD Scores <u>Mean (SD):</u> Female: 40.6 (18.6) Male: 31.0 (18.8) P < 0.05
16	Spindler (2009)(21)	N =535. (81.9% men).	86% (624/723)	Mean (SD) age: 61.54 (14.4) years. Range: -	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. Total FPAS score: Mean (SD): 78.04(17.0) P = 0.930

| 17 | Vazquez (2008)(22) | N=88. (0 % men) | - % (-/-) | Mean (SD) age: 57.76 (15.33) years Range: - | Mean (SD) time: 3.1 (2.8) years | Cross sectional | FPAS but only used the Body Image Concerns scale. | Higher body image concerns were associated with living in the US, being younger (≤ 50 years), having a history of non-ischemic cardiomyopathy and using psychotropic medication. Body image concerns: Means (SD) of Females by Age Group: Young: 25.8 (28.2) Middle: 11.5 (23.2) Older: 9.7 (20.1) |
| 18 | Wilson (2013)(57) | N= 101. (66 % men) | - % (-/-) | Mean (SD) age: 65 (12.8) years Range: 29-88 years | Years (%): < 1 y: 12 (12) 1 ≤ 2 y: 9 (9) 2 -5 y: 45 (45) > 5 y: 35 (34) | Cross sectional | FPAS | Body Image Concerns Mean (SD): 10.6 (22.2) Racial and Gender differences related to Body Image Concerns: Mean (SD). |

							White (n=59):
							Men: 7.0 (15.0)
							Women: 9.1 (21.0)
							Total: 7.4 (16.1)
							African American (n=42):
							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.
19	Wojcicka (2008)(60)	N=45 (55.7% men)	81.8% (45/55)	Mean (SD) age: 21.2 (4.3) years Range: 14-29 years *A total of 35*	4.3 (2.7) years Range: 5 months to 11 years	Cross-sectional	Purpose designed questionnaire:	The implantation site was visible to most patients, but a majority deemed the appearance of the scar or bump acceptable. Almost half of the patients admitted to covering up the wound, and

				subjects ≥18 years				half had negative opinions on the scar. Some issues with shame, being intimate and being undressed were reported.

PROSPECTIVE								
20	Carroll (2005) (55)	N=59 No shock group: N= 43 (67.44% men) Shock group: N= 16 (81.25% men)	After 1 year: 84.3% (59/70)	Mean (SD) age: No shock group: 64.8(12,9) years Shock group: 57.5(18,3) years Both groups: Range: 21 – 84 years	1 year.	Prospective:1 year follow up; Brodsky Cross sectional at follow up.	Brodsky ICD Questionnaire (46/5)	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. No shock group: Mean (SD) 6.8 (2.2) Shock group: Mean (SD) 7.9 (2.8)
21	Flemme[8]	N= 56	67.5%	Mean (SD) age:	After 3 and 12	Prospective/	The Patient	The Wishes subscale of the Brodsky

	(2001)(54)	(75 % men)	(56/83)	- (-) years Range: 25 – >75 years	months	Longitudinal	Implantable Cardioverter Defibrillator Questionnaire of Brodsky.	questionnaire decreased from 3 months to 12 months, but the change was not significant. Wishes after 3 months (N=54): Sum (range)[8] 349 (216-648) Wishes after 12 months (N=53): Sum (range). 339 (212-848) P = 0.504.
22	Hegel (1997)(53)	N=38 (86 % men)	(N= 25 responded after 1 year) (66%)	Age (SD) mean: 62.2 (-) years (at time of implantation).	4.22 (2-8) years	Observational, longitudinal, 1 and 2 years follow up	The ICD Quality of Life questionnaire.	Worries about body appearance did not decrease with time, and were not associated with depression, trait anxiety and anxiety sensitivity.

			(N= 21 responded after 2 years) (55%)	Range: 29-78 years (at time of implantation)				Appearance: 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.
23	Marshall (2012)(23)	N= 47. (70% men)	67% (47/70)	Mean (SD) age: 58 (16.44) years Range: -	Post implantation to 12 months	Prospective study Questionnaires at: Baseline and 4, 8 and 12 months.	ICD specific questionnaire adopted from Hegel et al 1997. Contains 15 items.	Women worried more than men about their looks after receiving an ICD and their scores remained constant. Younger women worried more than older women at both time points. Men were less worried about their looks and their scores were significantly reduced over time. Worrying about looks:

								At discharge mean scores were:
								Females: 1.07
								Males: 0.36
								(P = 0.0013)
								At 4 months mean scores were:
								Females: 1.07
								Males: 0.24
								(P = 0.0017)
								At 12 months mean scores were:
								Females: 1.21
								Males: 0.27
								(P = 0.0013)
24	Starrenburg (2014)(20)	N=300 (82.3 % men)	86.5% (300/347)	Mean (SD) age: 62.0 (11.1) years Range: -	12 months.	Prospective quantitative study. Questionnaires	FPAS	In the domain Body image concerns women had higher levels of concerns as compared to men and thereby gender as an independently association with

| | | | | | prior implantation, 2, 5, 8, and 12 months post implantation. However results on FPAS are cross sectional after 1 year | | poorer device-related acceptance. (P = 0.043, Cohen's effect size (ES) = 0.27) Age, type D personality, ICD indication, comorbidity, shocks, ejection fraction and age were not significantly related to body image. |
| | P = | | | | | | |

405

Footnotes:

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

2-4. Mix of pacemaker and ICD patients

410   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 (Arrhytmogenic right ventricular dysplasia/cardiomyopathy)

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

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

415

420

Table 3: Questionnaires identified

Instrument	Study	Language	Internal consistency (Cronbach's alpha):		Test-retest Reliability: Correlation coefficient	Factor analysis
			Total	Body Image Concerns (BIC)		
Florida Patient Acceptance Survey	Bedair (2015) (47)	English	-	-	-	-
Description: Florida Patient Acceptance Survey (FPAS) is disease specific to patients with implanted devices (Burns 2005).	Birnie (2009) (46)	English	-	-	-	-
It consists of 18 items rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Only 15 items	Burns(2005) (41)	English	α = 0.83	α = 0.74	-	1. Return to function 2. Device-related Distress 3. Positive Appraisal 4. Body Image Concerns
contribute to the total score as 3 items are filler items.	Groeneveld	English	-	-	-	-

	(2007) (48)					
Starrenburg (2014) used a 5-point Likert scale 0 (strongly disagree) to 4 (strongly agree). With a score range 0-60.	James (2012) (56)	English	-	-	-	-
It is composed of 4 consistent factors: - Return to Life [RTL] - 4 items	Lewis (2014) (50)	English	-	-	-	-
- Device-related distress [DRD] – 5 items - Positive appraisal [PA] - 4 items - Body Image Concerns [BIC] – 2 items A high score on DRD and BIC means less acceptance. A high score on RTF and PA means more acceptance.	Pedersen (2008) (51)	Danish	α = 0.85	α = 0.73		The four factors accounted for 64.3% of the variance: Factor I (*Device related distress*) = 33.0% Factor II (Positive appraisal) = 13.8% Factor III (Return to function) =11.1% Factor IV (Body image concerns) = 6.4%
	Spindler (2009) (21)	Danish	-	-	-	-
Both the total and the subscale scores range from 0–100.	Starrenburg (2014) (20)	Dutch	-	-	-	-
	Vazquez (2008) (22)	English	-	α = 0.79	-	-

	Wilson (2013) (57)	English	0.85	α =0.82	-	-
Brodsky ICD Questionnaire Brodsky 1988 (81) *Description:* The questionnaire measures the concerns of ICD patients. It consists of 46 items rated on a 3-point Likert scale from 1 (not at all), 2 (some) to 3 (a lot). It is composed of 8 subscales: - Their level of fear – 5 items - Embarrassment – 5 items - Suffering – 5 items - Worry about the ICD – 5 items - Wishes – 5 items - Experience with ICD – 3 items - Concerns regarding relationship with spouse / significant other – 11 items - The extent of lifestyle changes – 8 items	Carroll (2005) (55)	Norway - language not stated	-	Subscales in the interval α = 0.75 - 0.85	-	-

Body image concerns are present in the subscale "Wishes". *I wish the ICD were:* A. smaller B. less rigid C. less noticeable D. elsewhere on my body E. more trustworthy Higher scores indicate more concerns about the ICD.						
Brodsky ICD Questionnaire *Description:* The questionnaire measures the concerns of ICD patients. It consists of 43 items rated on a 3-point Likert scale from 1 (not at all), 2 (some) to 3 (a lot). It is composed of 7 subscales:	Flemme (2001) (54)	Sweden - language not stated	-	Subscales in the range α = 0.76 to 0.85	-	Factor analysis was performed within each statement (cumulatively varied between 53% and 74 % of total variance, factor loadings ranging 0.51-0.91).

- 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					
Body image concerns are present in the subscale **"Wishes":**					
I wish the ICD were:					
A. smaller					
B. less rigid					
C. less noticeable					
D. elsewhere on my body					
E. more trustworthy					

Higher scores indicate more concerns about the ICD.						
Flemme et al have used the Brodsky questionnaire in a modified version.						
IDAS (the Implanted Device Adjustment Scale)	Beery	English	0.90	-	0.92	
Description:	(2005) (44)		N=45		N= 43	
(Beery 2005):						
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).						
It was composed by 4 scale dimensions: "1. Attitude toward the device" "2. Body image" "3. Relief of symptoms"						

"4. Effective device function" Scores can range from 20 to 100. Higher numbers indicate poorer adjustment.						
IDAS (the Implanted Device Adjustment Scale) *Description:* (Beery 2007): 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) Scores can range from 21 to 105. Higher numbers indicate poorer adjustment. (This is an adaption of the 2005 IDAS scale).	Beery (2007)(42)	English	0.89	-	-	Four subscales were described by the categories: - Fear/anxiety - Attitude - Preparation - **Body awareness** Three items were included in the Body awareness subscale: **9. I do not like the way my body looks** **since I have had my device implanted** (Item loading 0.844) 14. I am concerned that my device will not work properly) (Item loading 0.369)

						16. I am troubled by my physical appearance since I have had my device (Item loading 0.812)
LTS (Low Treatment Satisfaction) *Description:* The LTS has 11 dichotomous items. Items concerning due to the ICD: -A mistrustful attitude - Low appraisal - A negative body image The total treatment satisfaction score ranged from 0 to 11 (0 = very satisfied, 11 = most dissatisfied) and was markedly skewed to the right. A negative body image subscale: - ICD feels like a foreign body - Disturbed by changes of body form	Ladwig (2005)	Germany - language not stated	0.73	-	-	-

The Cleveland Clinic AICD Psychosocial Inventory	Pycha (1990) (45)	English	-	-	-	-
Description: The Psychosocial Inventory elicit information gathered from multiple choice questions on: -Demographics - Medical history - Patient attitudes towards the device - Body image distortions - Lifestyle alterations -Impact on family and marriage - General quality of life - Device-specific concerns						
The Worries About ICDs Scale (WAICD)	Rahmawati (2013) (52)	Japanese	0.89	-	-	-
Description: The WAICD examines quality-of-life issues associated with having an ICD and reflects the degree to which the						

respondent experiences the problem.						
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.						
It consists of 26 items rated on a 5- point 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).						
The score is determined by the total of the 26 items, with a scoring range of 0 to 104.						
Lower scores are reflective of less worry. Higher scores indicate heightened worry.						
Body image concerns are present in the following questions:						

"9. It bothers me that there is a "bump" where the ICD is." *"10. It bothers me that I have to wear clothes that cover* *up the place where the ICD sticks out"*						
Unspecified modification of SF 36 *Description:* The questionnaire assessed quality of life in 4 areas:(82) - Demographics - Education and work status - Health and exercise - Self-image and social interaction	Dubin (1996) (58)	English	-	-	-	-
Purpose-designed device questionnaire *Description:* The questionnaire was specifically designed to assess the 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	Duru (2001) (43)	Zürich, Switzerland Middlesex, UK - language not stated	-	-	-	-

some also dichotomous. Questions regarding Body image concerns: *"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 some degree, Considerably, Very much)*						
Unspecified purpose-designed questionnaire *Description:* 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	Heller (1998) (59)	English	-	-	-	-

- Compliance variables, 6. 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.						
Purpose designed questionnaire *Description:* In order to asses patients quality of life a questionnaire was developed to asses important issues and problems of patients with ICDs. It consisted of four parts. Part 1: Functioning of patients with ICDs (e.g. shock) Part 2: Various psychological problems Part 3: Everyday activities Part 4: Future plans and advantages/disadvantages of living with an ICD Unknown number of items.	Wójcicka (2008) (60)	Poland - language not stated	-	-	-	-

Some of the questions were closed questions, with suggested answers, i.e. yes or no, while some of the questions were open. Questions regarding Body image concerns: (Part 4) "The appearance of the implantation area" "Question about sexual life"?						
ICD specific questionnaire *Description:* The questionnaire is adopted from "Hegel et al 1997" with 15 questions. In contrast to Hegel (1997) it is measured on a 5-point Likert scale. The questions focused on impact of the device and shock therapy upon: - Driving - Comfort	Marshall (2012) (23)	English	-	-	-	-

- Worry and anxiety						
- Physical and sexual activity						
- Sleep						
- Financial and family issues".						
Higher scores indicate worse outcome.						
Questions regarding Body image concerns:						
"Worry about looks".						
Reported was the Cronbach's alpha coefficient from Hegel of 0.79.						
The ICD Quality of Life questionnaire _Description:_ The questionnaire was purpose designed with 15 questions measured on a 6-point Likert scale: 0 (Not at all) to 5 (Very much so).	Hegel (1997)(53)	English	0.79	-	-	-

"The questions focused on 16 variables:						
- 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 the occurrence of shock						
- 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".						

Footnotes:

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

2. Items assigned to a factor are presented in bold

<u>Figure 1</u>: PRISMA Flowchart

3844 references imported to *Endnote* August 2016	
Embase	(ICD & Body image)	52
Embase	(ICD & Qualitative)	1.175
Medline	(ICD & Body image)	157
Medline	(ICD & Qualitative)	2.020
PsycInfo	(ICD & Body image)	17
PsycInfo	(ICD & Qualitative)	115
Cinahl	(ICD & Body image)	26
Cinahl	(ICD & Qualitative)	282

→ 542 duplicates removed

3302 references imported to **Covidence** August 2016

217 additional references imported to *Endnote* in the refined updated search May 2017	
Embase	(ICD & Body image)	8
Embase	(ICD & Qualitative)	89
Medline	(ICD & Body image)	5
Medline	(ICD & Qualitative)	83
PsycInfo	(ICD & Body image)	0
PsycInfo	(ICD & Qualitative)	8
Cinahl	(ICD & Body image)	4
Cinahl	(ICD & Qualitative)	20

→ 105 duplicates removed

112 references imported to **Covidence** May 2017

1 reference found via screening the references
And imported to **Covidence** June 2017

3415 studies ready to be screened → **2** duplicates removed

3413 screened at title/abstract level → **3269** studies excluded (not about body image concerns)

144 studies assessed for full-text eligibility →

104	**Studies excluded:**
34	Wrong outcome
8	Duplicates
17	Questionnaires with BIC items only reporting a total score
4	Wrong language
30	Wrong study design
5	Wrong device/placement
2	Only title/abstract available
4	Wrong population

A total of 40 studies included:
Qualitative studies N= 16
Quantitative studies N = 24

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