Long-term quality of life and acceptance of implantable cardioverter-defibrillator therapy: results of the European Heart Rhythm Association survey

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Structured Abstract and Keywords

Aims

Implantable-cardioverter-defibrillator (ICD) may impact patients' life significantly. The aim of this evaluation was to analyze the impact of the ICD on quality-of-life metrics from the patient's perspective.

Methods and results

"Living with an ICD" was a prospective, multicentre study with an online questionnaire submitted to the EHRA Research Network centers as well as patient associations from ten European countries; it was filled-in directly and personally by the patients that were proposed to participate, with a minimal interaction or influence from the healthcare professionals. Overall, the questionnaire was completed by 1809 patients (including 624 women, 34.5%). Patients in their 60s and 70s and from Western Europe were the most represented. The median time from first ICD implantation was 5 years (IQR 2-10). Device-related complications were reported by 505 patients (22.4%), including one or more inappropriate shocks (n = 209, 11.6%). Almost half of respondents reported improved QoL, with a more favorable impact for those receiving CRT-D, and only a tenth experienced a significant decrease in QoL. The occurrence of complications remained a major predictor of deteriorated QoL (odds ratio 2.1, 95% confidence interval 1.4-3.0, P<0.001).

Conclusion

Most patients have a globally positive view and acceptance of ICD therapy, reporting preserved to improved QoL after device implantation. Complications, namely inappropriate shocks, affect the expectation of living a normal life post-implant and are associated with a significant decrease in QoL. Our findings also highlight the importance of a detailed informed consent process and the involvement of the patient in the decision-making process.

Keywords (3-6)

Cardiac resynchronization therapy, patient attitude, patient fears, EHRA survey

Introduction

Implantable cardioverter-defibrillator (ICD) therapy is an established treatment for individuals at high risk of sudden cardiac death [1]. ICDs treat potentially lethal ventricular arrhythmias by antitachycardia pacing or high-voltage shock delivery. Appropriate and inappropriate shocks, however, are associated not only with worse prognosis but also with reduced quality of life (QoL) [2].

Despite the ongoing debate on ICD indications, there is still paucity of data on the impact of the device on patients' daily routine. ICDs may deliver a shock in the most unpredictable moment, that may save patient's life, but also impact dramatically on his lifestyle, forcing them to adapt [3]. Therefore, patient and physician engagement in a shared decision-making process is an inevitable element of a high-quality patient-centered care [4].

In this prospective evaluation, supported by the European Heart Rhythm Association (EHRA), we have assessed the impact on quality-of-life metrics, from the patient's perspective, and current needs of a large European cohort of unselected ICD recipients.

Methods

The study "Living with an ICD" was a prospective, multicentre, multinational research program specifically dedicated to evaluate patients with an ICD. The protocol was designed and approved by the members of the EHRA Scientific Initiatives Committee (SIC), and the final version of the questionnaire was accepted by all members. The questionnaire, consisting of 25 questions and available in multiple languages, was compliant with the GDPR rules and posted on an electronic platform. In the survey, basic demographic and device data were collected. The main part of the questionnaire aimed to assess essential aspects of ICD patients' lives: QoL, acceptance of ICD therapy, information received before device implantation and

need for further information about the device (Supplementary Material 1). As the questionnaire was intended for sharing with patients, plain and simple language was used whenever possible. The questionnaire was adapted and modified after a revision by an ESC Patient Forum member.

The link to the questionnaire was sent to the EHRA Research Network centers, with subsequent dissemination to the following countries: France, Poland, Germany, Spain, Italy, Latvia, United Kingdom, Serbia, Croatia, and Portugal. Patients were asked to answer the survey anonymously via the electronic form or in paper form and had access to technical guidance from medical staff if needed. The paper forms were uploaded online by each local center. Local ethics committee approval was obtained whenever needed according to the local policy. The study was conducted between April 12th 2021 and July 5th 2021. Patient associations working in each country were asked to collaborate whenever possible.

Statistical analysis

The normal distribution of data was tested using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Values are expressed as numbers or percentages for categorical data or as mean ± standard deviation (SD) or as median (with 25th and 75th percentile) for continuous data. Distributions of categorical data were examined by the x2 test or Fisher's exact test, as appropriate. Continuous data were compared using Student's t-test or the Mann–Whitney U test, as appropriate. Univariate logistic regression was performed to test the association between predictor variables and QoL. Those with a $P < 0.10$ level of significance in univariate logistic regression were included in a subsequent multivariate logistic regression analysis (with results presented as odds ratio (ORs) with 95% CIs). A value of $P < 0.05$ was considered statistically significant. The statistical analysis was performed using SPSS software, version 23.0 (IBM Corporation, Armonk, NY, USA).

Results

Patient population

A total of 1809 patients from ten European countries participated in the study, including 624 (34.5%) women. Western Europe patients and in their 60s and 70s were the most represented. A total of 887 (49.0%) of patients were retired, and 726 (40.7%) either student or employed. The majority (74.7%) were married or living with a partner. Demographic data are described in Table 1.

Device data

Almost half of the patients (45.8%) had a transvenous single or dual chamber ICD, whereas 563 (31.1%) had a subcutaneous ICD (S-ICD) and 281 (15.5%) a cardiac resynchronization therapy defibrillator (CRT-D). Of note, 136 (7.5%) of patients were not aware of the type of ICD. The median time from first ICD implantation was 5 years (IQR 2-10). The most common indication for device implantation reported by patients was prevention of cardiac arrest (44.7%), with a third of the total cohort (32.2%) having a aborted cardiac arrest indication. Implantation for heart failure symptoms was reported as the main indication for the device by 36.8% of patients, and, importantly, 3% did not know why the device had been implanted (since multiple answers were allowed there was an overlap between options). A remote monitoring system was used in 1021 patients (56.4%), but 6.2% were unaware of whether their device was evaluated remotely or not (Table 1).

ICD-related complications

The majority of patients (n = 1404, 77.6%) declared no complications related to the ICD until the moment they participated in the questionnaire. However, device-related complications were reported by 505 patients (22.4%), including one or more inappropriate shocks (n = 209, 11.6%, representing an annual incidence of less than 2.5% per year), malfunctioning lead (n = 204, 11.3%), and unplanned re-operations (n = 128, 7.1%). There were no significant differences in complications across each device type (inappropriate shocks: ICD 12.5% vs. S-ICD 11.0% vs. CRT-D 10.7%, p=0.637; unplanned re-operations: ICD 6.9% vs. S-ICD 7.6% vs. CRT-D 6.8%, p=0.939; malfunctioning lead: ICD 11.5% vs. S-ICD 10.5% vs. CRT-D 13.2%, p=0.617). These complications occurred during a median follow-up of 5 years (IQR 2-10). Only 111 patients (6.1%) required unscheduled visits due to a device-related issue.

Quality of life

A total of 829 patients (45.8%) experienced a significant improvement in their QoL after device implantation, while a deterioration was reported by 183 (10.1%). More than a third (n = 675, 37.3%) had unchanged QoL and 122 (6.8%) were unsure. Nearly 65% of CRT-D recipients reported improved QoL compared with only slightly more than 40% of single, dual chamber ICD and S-ICD patients (p<0.001) (Figure 1). During a 5-year follow-up, approximately four out of every 10 patients (n = 704, 38.9%) had experienced at least one ICD shock (including the previously reported 209 patients with inappropriate shocks): 288 (40.9%) described it as more painful than expected, 127 (18.0%) as painful as expected, 172 (24.4%) not as painful as expected, and 117 (16.6%) were unaware of any shocks. Despite an overall improvement in QoL when considering the whole cohort as a group, almost half of the patients (42.8%) reported feeling depressed after ICD implantation, with 6% feeling very or extremely

depressed. Approximately 40% of patients were unaware of any support groups for patients with ICDs and 22.3% belonged to such a group and found it helpful.

Fears and daily life

Most of the respondents expressed fear regarding ICD shocks, device-related complications and limitations. The main concerns were the occurrence of an unexpected shock (80.1%), long-term device/electrode dysfunction (79.4%) and shock delivery in public (76.9%) (Figure 2). However, the majority (80.3%) of respondents feel safer with an ICD, and there was a good (69.3%) level of acceptance of the ICD limitations and necessary lifestyle changes. The use of remote monitoring contributed to patients' sense of safety in approximately two thirds of cases. Conversely, more than a third mentioned that the ICD had changed their lifestyle significantly, with 20% reporting a negative impact on their professional career (17.4% of patients had to change their job after implantation) and another 20% confirming that having an ICD has made them feel disabled. Overall, only 5.5% of patients regretted their decision of receiving an ICD (Figure 3A, 3B).

Impact of the device on QoL and ICD acceptance

We assessed multivariate predictors of impact on QoL acceptance of the ICD after implantation (Table 2). Proper information provided to the patient before ICD implantation, as well as the patient's involvement in the decision-making process, was in general associated with favorable outcomes (e.g., proper pre-implantation information associated with improved QoL and lack of need of significant change in lifestyle or job). A longer period since first implantation and the use of remote monitoring were also associated with a feeling of safety

after ICD implantation and a better acceptance of the ICD limitations. The implantation of a CRT-D was also protective on patients' lifestyle and QoL.

Conversely, the occurrence of a complication had a negative impact on most metrics, including patients' QoL, feeling of safety, the need to change job after ICD implantation and lifestyle change. On univariate analysis the only predictor of regret post ICD implantation was the occurrence of complications.

Discussion

This prospective, international study provides valuable insight on the impact of the ICD on quality-of-life metrics from the patient's perspective. Almost half of respondents reported improved QoL after a median of 5 years post-ICD implantation, with a more favorable impact for those receiving CRT-D, and only a tenth experienced a significant decrease in QoL. This overall favorable QoL outcome might be the result of more regular follow-up appointments, improved clinical outcome particularly for patients with a CRT-D and the feeling of protection against sudden cardiac death after ICD implantation. Although most patients express fear of experiencing device-related complications or ICD shocks, and the occurrence of complications being a major predictor of deteriorated QoL, the majority feel safer with an ICD. Finally, this survey highlights the importance of informed consent and involving the patient in the decision-making process, both of which predict favorable QoL outcomes.

One of the strengths of this study is the fact that the questionnaire has been filled-in directly and personally by the patients that were proposed to participate, very often in their own environment, with not, or a minimal interaction or influence from the healthcare professionals. In addition, the median implantation duration of 5 years (IQR 2-10) looks long enough. We therefore believe that the answers provided by the patients have been sincere,

reflecting spontaneously their experience and feelings of living with an ICD. Of note, patients' perception of ICD indications may be different from the true medical indication. However, we could extrapolate that "prevention of cardiac arrest" (44.7%) is a primary prevention of sudden cardiac death, "cardiac arrest" (32.2%) is a secondary prevention of sudden cardiac death, and "fatigue, shortness of breath, heart failure" (36.8%) might be a partially primary prevention indication and CRT-D indication.

A previous systematic review found no evidence of impaired QoL in 5701 ICD patients included in randomized clinical trials [5], while a different one could not identify a trend for improved or decreased QoL in ICD patients [6], suggesting that different QoL responses might be explained by heterogenous populations including different cardiac conditions (i.e. ischemic cardiomyopathies, channelopathies), a broad age range of ICD recipients, and a varying rate of device-related complications.

Cardiac ICDs are one of the few cardiological implants which might be directly felt by patients under their skin. Due to this, and the ability to restore normal heart rhythm during sudden cardiac arrest, many patients regard the ICD as their *guardian angel* and treat this device very personally [7]. It is thus not surprising that the majority of surveyed patients feel safer with ICD. Nevertheless, patients with an ICD have to face multiple limitations associated with the implanted device, i.e. driving restrictions, avoidance of large magnetic fields, or specific high-voltage machines, although many may be unaware of the recommended driving restrictions and/or show poor adherence to them [8]. Our respondents recognized ICD limitations as significant for them and 53-70% exhibited at least a little level of fear regarding a possible negative impact of the device on their work/career, driving ability, and daily activities. However, almost 70% accepted the limitations of ICD and the necessary lifestyle changes, which is comparable to the 84.4% ICD acceptance reported by Morken et al. [9]. The

acceptance of an ICD seems to be rather a complex process rather than a binary factor, and at least some level of uncertainty or fear might be inevitable for ICD recipients. Indeed, the majority of patients expressed a substantial level of fear regarding ICD therapy, potential ICD complications, and limitations. Patients mainly fear the possibility of sudden, unexpected shocks, possibly delivered in public, as well as long-term device/lead dysfunction. Notably, more than 40% of patients experiencing shocks regarded these as more painful than expected. The possibility of receiving high-voltage shocks is one of the most important aspects of living with an ICD. In qualitative studies, patients have compared shocks to "*an earthquake*", "*being kicked by a mule*", and even mentioned that during an ICD discharge "*they could see death*" [10, 11]. In our survey, nearly 40% of patients confirmed receiving an ICD shock within of 5 years of implantation, which is consistent with data from ICD registries [12, 13]. It is reassuring to observe that the percentages of global ICD interventions (i.e., both appropriate and inappropriate shocks) published in the literature are fully consistent with those declared by the patients. That means also that patients "remember" an ICD shock as a milestone, and they do not forget it even after many years.

Overall, more than 20% of patients experienced significant complications and almost 40% of these were inappropriate shocks. The self-reported complication rate is comparable with previous data (e.g., van der Heijden observed 12% rate of inappropriate shocks and 6% rate of lead failure within 4 years of follow-up) [12]. Undoubtedly, inappropriate shocks are one of the most important factors decreasing QoL and even increase mortality [2]. We observed a clear association between the occurrence of complications and reduced QoL. Unsurprisingly, we found that complications decreased the feeling of safety, associated with significant changes of lifestyle, the need to change job after ICD implantation, and increased chance of regretting ICD implantation. Adherence to expert consensus statement on optimal

ICD programming is crucial to achieve low rates of inappropriate shocks and mortality reduction [14, 15], and our data shows that reducing inappropriate shocks can also have a major impact on patients' QoL.

A total of 42.8% of patients felt depressed after ICD implantation, which is much higher than rates reported in the recently published DEFIB-WOMEN study or a previous meta-analysis [16, 17]. We did not use validated instruments for assessing depression and thus our results should be interpreted with caution, particularly when, overall, ICD implantation associated with favorable QoL outcomes and only very few patients regretted their decision of receiving an ICD. Psychological support and improved awareness of the existence of support groups might decrease the feeling of depression which so many patients report. Indeed, psychological support and the lack of contact with official patient associations have been reported as significant deficiencies by many ICD implanted patients, and should be offered much more often [18].

Finally, our results highlight the importance of providing patients with clear and detailed information on the ICD and involving them in the decision-making process. Patients who felt well informed were less likely to experience reduced QoL or significant changes in their lifestyles.

This study has typical limitations of all survey research. Since our data are patient-reported, there is a risk of both under- and overreporting and misclassification of events, i.e. complications and shocks. Moreover, we were unable to adjudicate reported events. We found, however, pretty good consistency with the literature data. We do not have information about device programming, which may influence the rates of reported events. There is also some risk that patients could have answered untruthfully. It is possible that patients might

misunderstood some questions, however the understanding and ease of use was confirmed with the ESC Patient Forum member.

Conclusion

This study provides insights to the well-being of patients receiving long-term ICD therapy. It reports global positive feedback with a majority of patients declaring being reassured and living better with the device. Complications, and especially inappropriate shocks, represent a turn in the natural feeling and are associated with a significant decrease in QoL. Given the impact of such adverse events, the prevention of complications, as well as being able to provide psychological support when these occur, should be considered a priority. Patient's involvement in shared decision making for ICD implantation is of high importance.

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EHRA Research Network centres participating in this survey

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Table 1 - Demographic data and device history of study population (N=1809)

	N (%)
Age	
0-20	7 (0.4)
21-40	271 (15.0)
41-60	682 (37.7)
61-80	784 (43.3)
>81	65 (3.6)
Sex (% female)	624 (34.5)
Countries	
Western Europe	877 (48.5)
France	550 (30.4)
Germany	248 (13.7)
United Kingdom	79 (4.4)
Central and Eastern Europe	563 (31.1)
Poland	410 (22.7)
Latvia	83 (4.6)
Serbia	50 (2.8)
Croatia	20 (1.1)
Southern Europe	369 (20.4)
Spain	228 (12.6)
Italy	138 (7.6)
Portugal	3 (0.2)
Education level	
Primary school	147 (8.1)
Secondary school	608 (33.6)
College	381 (21.1)
University	673 (37.2)
Employment status	
Student	21 (1.2)
Employed	715 (39.5)
Not employed	186 (10.3)
Retired	887 (49.0)
Marital status	
Married or living with a partner	1351 (74.7)
Single	320 (17.7)
Widower or widow	87 (4.8)
Living at home (as a child)	8 (0.4)
Living alone with children	43 (2.4)
Device type	
ICD	829 (45.8)
S-ICD	563 (31.1)
CRT-D	281 (15.5)
Do not know	136 (7.5)

Remote monitoring	
Yes	1021 (56.4)
No	675 (37.3)
Do not know	113 (6.2)
ICD indication	
Post-cardiac arrest (secondary prevention)	583 (32.2)
Prevention of sudden death	808 (44.7)
Heart failure symptoms	665 (36.8)
Do not know	54 (3.0)
Complications	
None	1404 (77.6)
Inappropriate shocks	209 (11.6)
Malfunctioning lead	204 (11.3)
Unplanned re-operations	128 (7.1)
Unscheduled visit due to device problem	111 (6.1)

ICD – implantable cardioverter-defibrillator

S-ICD – subcutaneous implantable cardioverter-defibrillator

CRT-D – cardiac resynchronization therapy/defibrillator

Table 2 - Multivariate analysis

Endpoints ***Independent predictors for each endpoint***	**OR (95% CI), p-value**
Feeling of safety after ICD implantation	
Years since first implantation	1.02 (1.0-1.05), 0.03
Remote monitoring system	1.8 (1.1-3.0), 0.02
Inappropriate shocks	0.7 (0.4-1.0), 0.03
Acceptance of ICD limitations	
Years since first implantation	1.03 (1.02-1.05), <0.001
Remote monitoring system	2.0 (1.2-3.2), 0.004
Full explanation of available treatment options before ICD implantation	1.8 (1.1-2.8), 0.01
The need to change job after ICD implantation	
Feeling of being well informed before ICD implantation	0.6 (0.4-0.9), 0.04
Complications	1.3 (1.0-1.9), 0.04
Significant change of lifestyle after ICD implantation	
Feeling of being well informed before ICD implantation	0.6 (0.4-0.7), <0.001
CRT-D	0.6 (1.0-2.3), 0.04
Active involvement in the decision-making about ICD implantation	0.7 (0.5-0.98), 0.03
Complications	1.5 (1.1-1.9), 0.004
Reduced quality of life after ICD implantation	
CRT-D	0.3 (0.2-0.6), 0.001
Feeling of being well informed before ICD implantation	0.4 (0.3-0.6), <0.001
Complications	2.1 (1.4-3.0), <0.001

Regret of ICD implantation *Complications*	 2.0 (1.3-3.2), 0.003

Figure 1 Bar graph showing patients' quality of life after ICD implantation

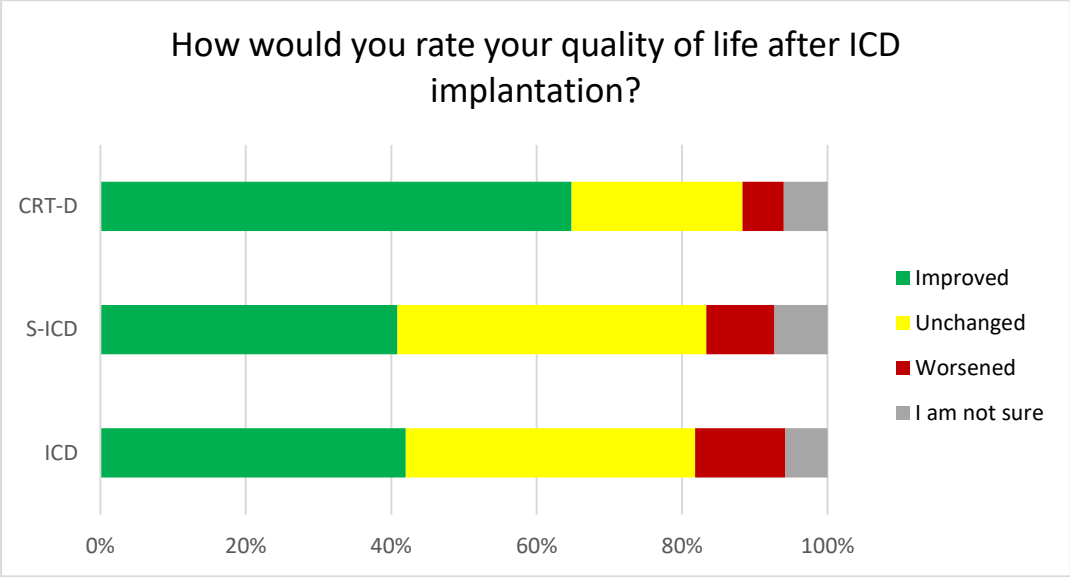

Figure 2 Bar graph showing patients' fears regarding living with an ICD.

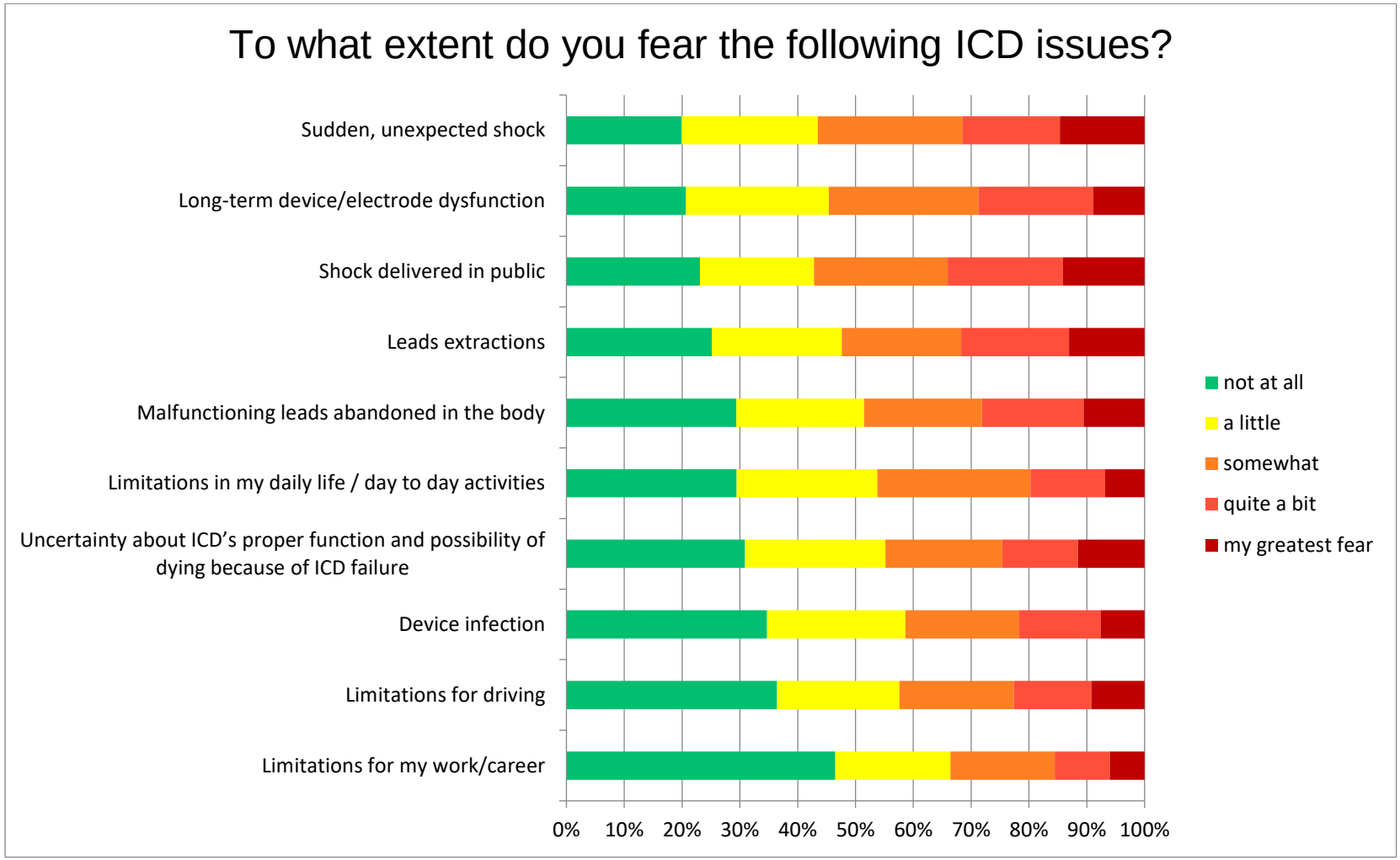

Figure 3 Daily feelings reported by ICD implanted patients.
Figure 3A Positive aspects

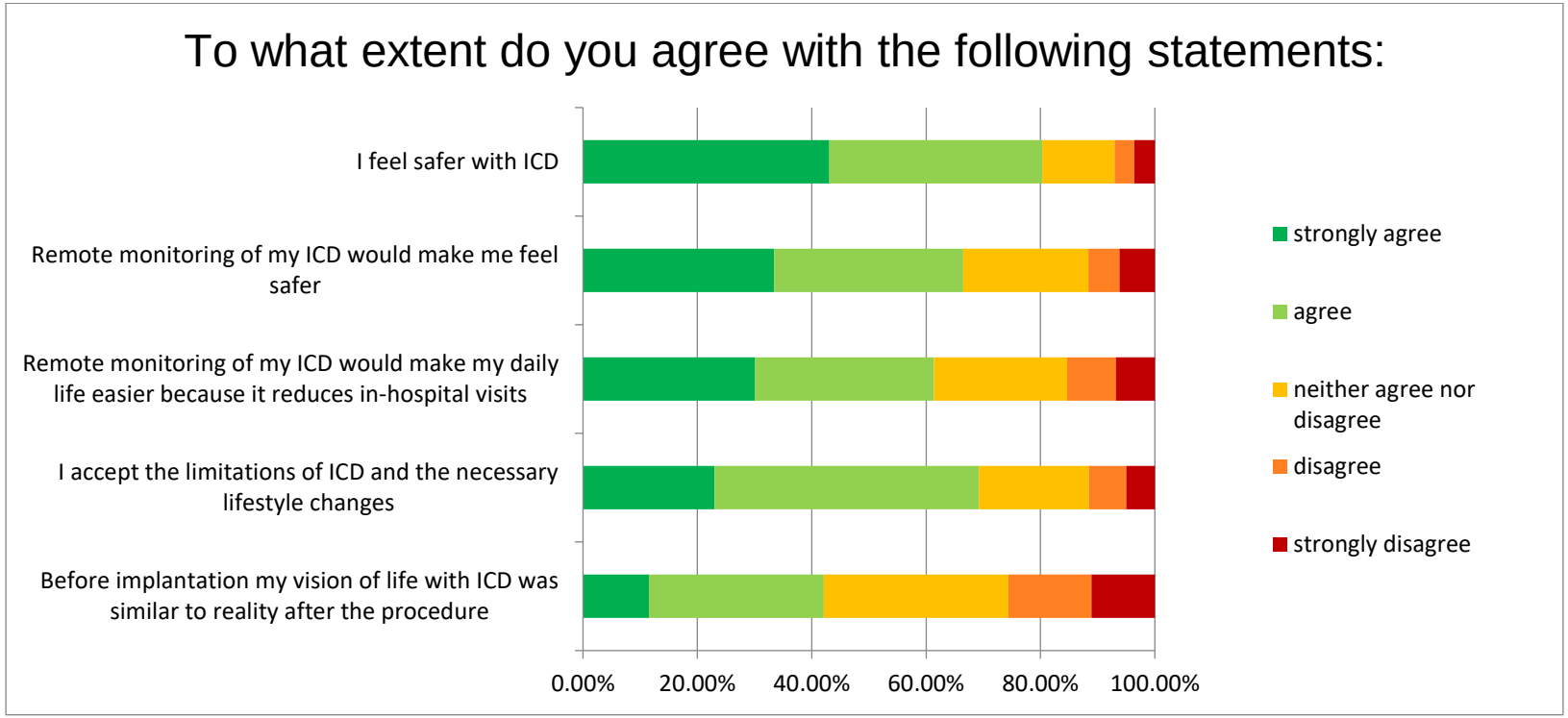

Figure 3B Negative aspects