

# Major gaps in the information provided to patients before implantation of cardioverter defibrillators: a prospective patient European evaluation

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Received 7 November 2022; accepted after revision 6 December 2022

## Aims

Information provided to patients prior to implantable cardioverter-defibrillator (ICD) insertion and their participation in the decision-making process are crucial for understanding ICD function and accepting this lifelong therapy. The aim of this study is to evaluate the extent to which different aspects related to ICD and quality of life were transmitted to patients prior to ICD implantation.

## Methods and results

Prospective, multicenter European study with an online questionnaire initiated by the European Heart Rhythm Association. The questionnaire was filled-in directly and personally by the ICD patients who were invited to participate. A total of 1809 patients (majority in their 40s–70s, with 624 women, 34.5%) from 10 European countries participated in the study. The median time from first ICD implantation was 5 years (interquartile range 2–10). Overall, 1155 patients (71.5%) felt optimally informed at the time of device implantation, however many respondents received no information about ICD-related complications ( $n = 801$ , 49.6%), driving restrictions ( $n = 718$ , 44.5%), and possibility of end-of-life ICD deactivation ( $n = 408$ , 25.4%). Of note, women were less frequently involved in the decision-making process than men (47.3% vs. 55.9%,  $P = 0.003$ ) and reported to be less often optimally informed before ICD implantation than men (61.2% vs. 76.8%,  $P < 0.001$ ). More women mentioned the desire to have learned more about ICD therapy and the benefit/risk balance (45.4% vs. 33.7% of men;  $P < 0.001$ ).

## Conclusions

This patient-based evaluation provides alarming findings on the lack of information provided to patients prior ICD implantation, particularly for women.

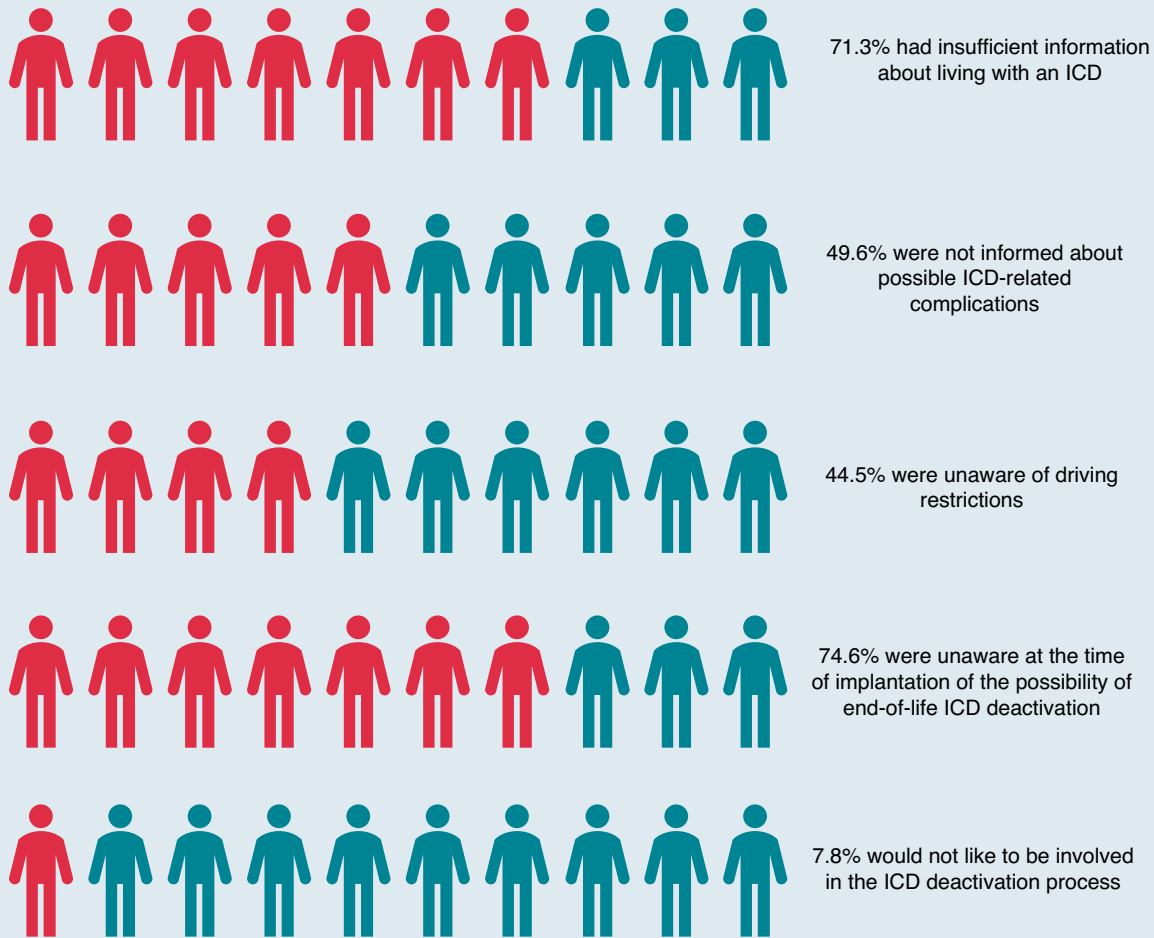
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## Graphical Abstract



## Keywords

Patients' values • Shared decision-making • Patient-centred care • Sudden death • Complication

## Introduction

Implantable cardioverter-defibrillators (ICDs) are a life-saving therapy for patients at risk of sustained ventricular tachycardia or ventricular fibrillation.<sup>1</sup> Around 130 000 ICDs were implanted in Europe in 2020.<sup>2</sup> However, despite improving the prognosis of properly selected patients, this device also has its limitations and time-dependent related complications, which is a substantial concern given that implantable cardioverter-defibrillator (ICD) is usually implanted for life.<sup>3</sup>

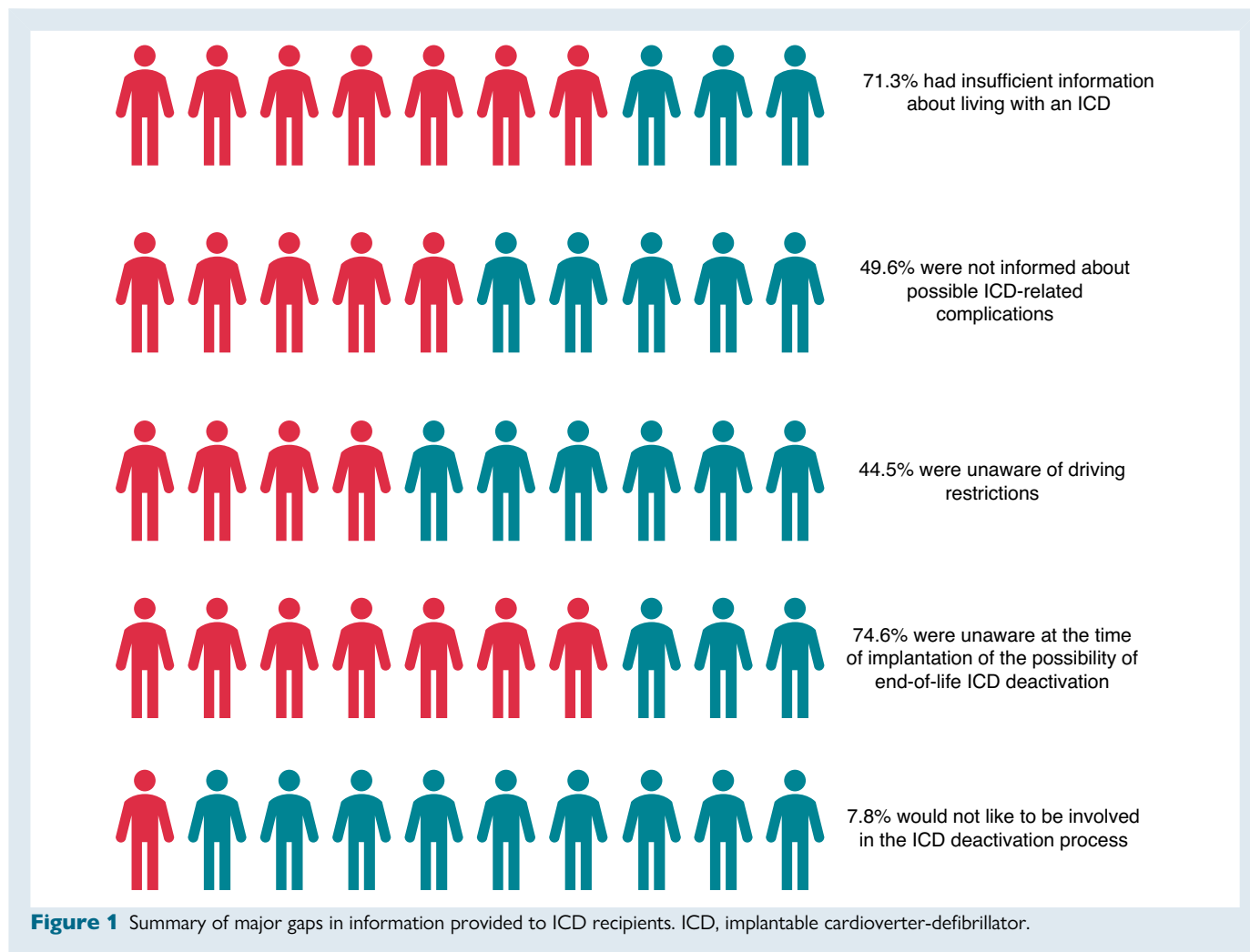
ICD eligible candidates are faced with a complex decision particularly in the setting of primary prevention of sudden cardiac death (SCD), which includes the majority of ICD recipients.<sup>4</sup> Prophylactic implantation may reduce risk of SCD but associates with a non-negligible risk of procedural complications, inappropriate shocks, and reduced quality of life in some patients.<sup>5,6</sup> The decision-making process requires comprehensive information given to the patient about anticipated risks and benefits from ICD therapy and alternative therapeutic options. The patient's preferences and expectations must be respected, so that adherence to the therapy is guaranteed.<sup>7</sup> Clinicians are responsible for this shared decision-making.<sup>8</sup>

There is a dearth of data regarding information provided to patients before ICD implantation and their empowerment in the decision-making

process. In this report of the 'Living with an ICD' patient survey, proposed and performed by the European Heart Rhythm Association (EHRA), the current level of information provided to patients, end of life issues, and current needs of ICD recipients regarding ICD education were analysed.

## Methods

The prospective, multicenter, and multinational EHRA patient Survey 'Living with an ICD' included patients already implanted with an ICD. The survey was designed and approved by the members of the EHRA Scientific Initiatives Committee, as previously described.<sup>9</sup> In brief, the questionnaire (available in [Supplementary Material S1](#)), consisting of 25 questions and translated to all patients' native languages, was created on an electronic platform, and the link was sent to the EHRA Research Network centres via mailing lists and social media of national arrhythmia working groups. The collaboration of patient associations working in each participating country was obtained whenever possible. Each patient was asked to personally enter his/her replies directly via the electronic form or in paper form and had access to technical guidance from medical staff if needed (however, patients were encouraged to answer the survey autonomously whenever possible in order to reduce any potential bias arising from medical staff). The questionnaire aimed to



describe important aspects of ICD recipients' lives, including the information the patients received before device implantation and their need for further information about the device (see [Supplementary Material S1](#)). The understanding and ease of use of the questionnaire was tested by the Patients Forum of the European Society of Cardiology (ESC). Consequently, it was modified and adapted according to the suggestions provided by the Forum. The local ethics committee approval was obtained where needed according to the local policy. All data were collected anonymously, and compliant with the general data protection regulation policy. The study was conducted between 12 April 2021 and 5 July 2021.

### Statistical analysis

Values are expressed as numbers or percentages for categorical data or as mean  $\pm$  standard deviation or as median (25th to 75th percentile) for continuous data. Distributions of categorical data were examined using the Pearson's  $\chi^2$  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. The normal distribution of data was tested using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Sensitivity analysis was carried out in women, compared with men. A *P*-value  $<0.05$  was considered statistically significant. The statistical analysis was performed using SPSS software, version 23.0 (IBM Corporation, Armonk, NY, USA).

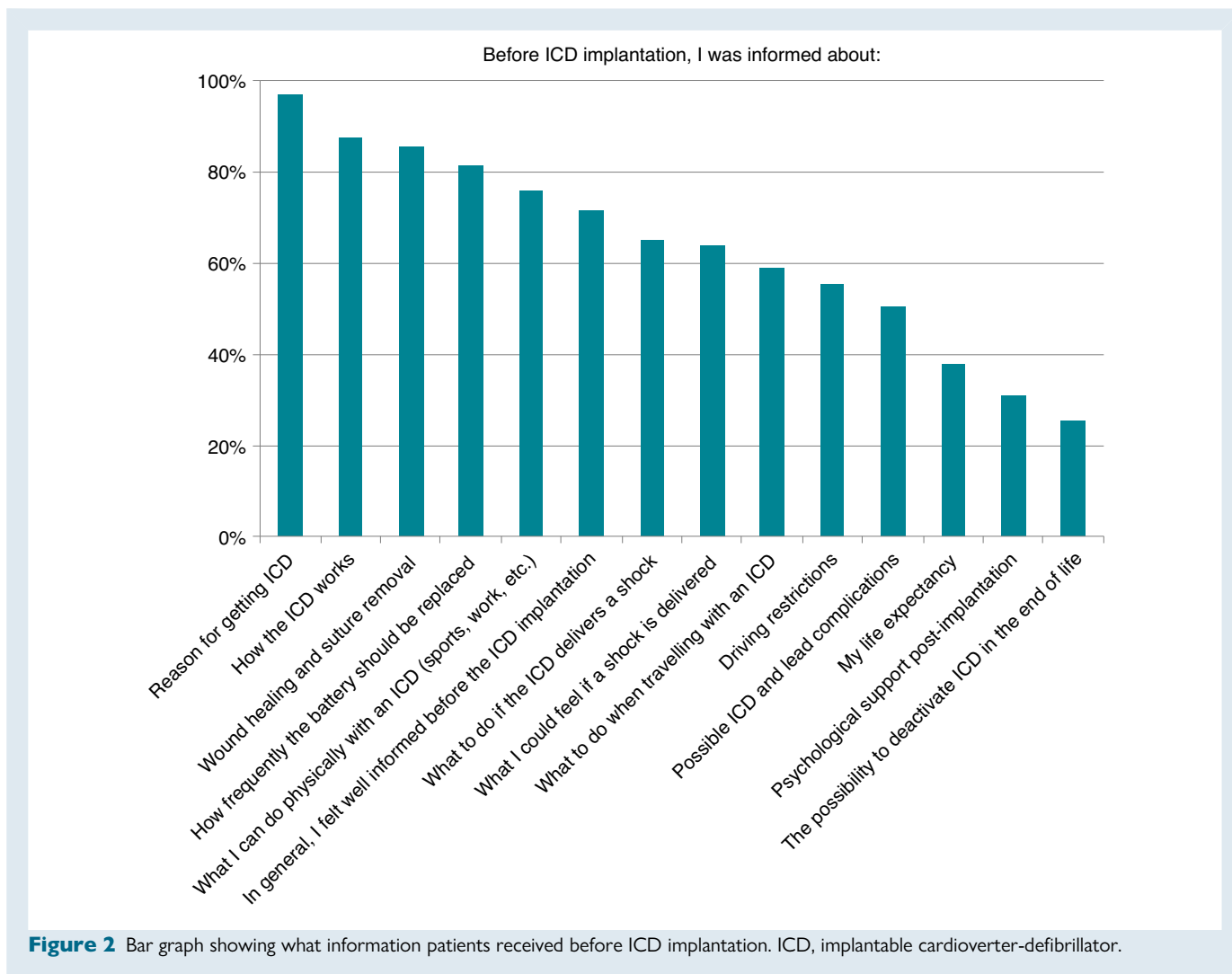
## Results

### Patient characteristics

The study population and device data have been described elsewhere.<sup>9</sup> In brief, of 1809 patients participating in the study, 624 (34.5%) were women; the majority of the respondents were in their 40s–70s; France, Poland, and Germany were the most represented countries (see [Supplementary Material S2](#)). The median time from first ICD implantation was 5 years (interquartile range 2–10). The majority of the patients (77.0%) had a transvenous single or dual chamber ICD or a subcutaneous ICD, while 281 (15.5%) received a cardiac resynchronization therapy defibrillator. Of note, 136 (7.5%) patients were not aware of what device they had. Prevention of sudden death was mentioned as an indication for ICD implantation by 44.7% of respondents, followed by heart failure symptoms (36.8%) and an aborted cardiac arrest (32.2%) (note: multiple answers were allowed). Importantly, 3.0% were unaware of the reason why the device had been implanted.

### Information provided to patients before implantation

The vast majority of patients ( $n = 1569$ , 97.0%) mentioned knowing the reason for getting an ICD, and 71.5% ( $n = 1155$ ) felt optimally informed at the time of device implantation. However, half ( $n = 801$ , 49.6%)



reported receiving no information on possible device-related complications, while almost half ( $n = 718$ , 44.5%) were unaware of driving restrictions and only a fourth ( $n = 408$ , 25.4%) were aware at the time of implantation of the possibility of end-of-life ICD deactivation (Figures 1 and 2). Less than a third ( $n = 500$ , 31.0%) were offered psychological support post-implantation.

A total of 1086 (66.9%) patients reported that the available treatment options and potential alternatives (if any) to the ICD had been 'fully explained', while 400 (24.7%) and 136 (8.4%) mentioned this had only been 'somewhat explained' or 'not explained at all', respectively (Figure 3A). Moreover, 859 subjects (53.0%) had been actively involved in the decision-making process about ICD implantation, whereas 461 (28.4%) had only been somewhat involved and 302 (18.6%) not at all involved in the decision (Figure 3B).

### Patient need for information

Regarding the need for information, only 28.7% ( $n = 520$ ) mentioned they had sufficient information (Figure 1). Patients would mostly like to know what bystanders should do in the case of an ICD shock ( $n = 628$ , 34.7%), discuss the possibility of end-of-life ICD deactivation ( $n = 587$ , 32.4%), and learn more about possible ICD complications and how to avoid them ( $n = 539$ , 29.8%) (Figure 4). More than half of the subjects would prefer to receive this information during face-to-face appointments,

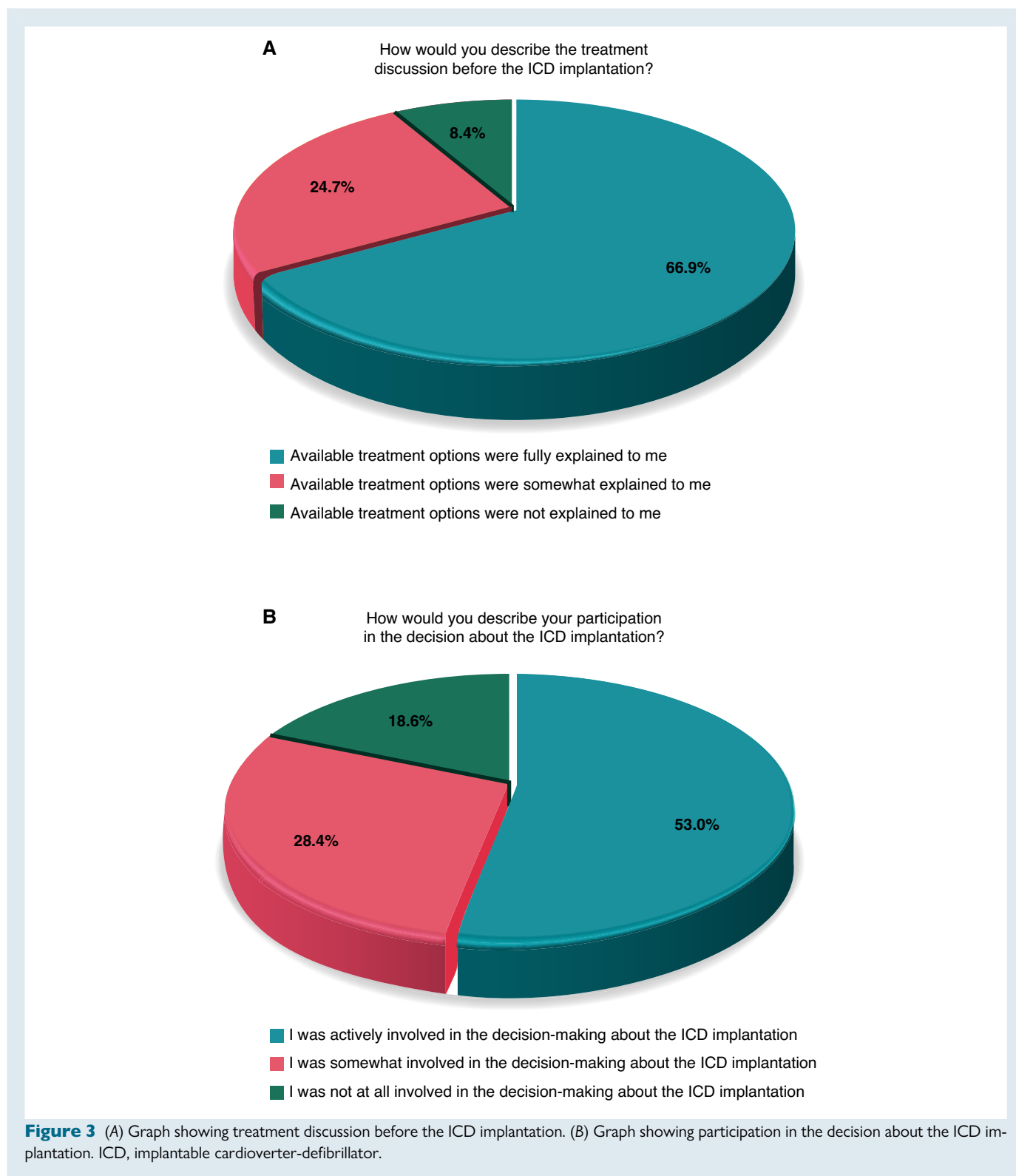
followed by internet content (30.6%), printed material (28.2%), video presentation (18.7%), mobile apps (17.6%), and audio content (8.1%).

### End of life issues

While only 25% of patients were informed before implantation on the possibility of ICD deactivation on request, this proportion had increased to almost half of the respondents at the time of filling out the questionnaire ( $n = 779$ , 49.2%). The vast majority of respondents ( $n = 1494$ , 94.0%) declared that all patients should be explicitly informed about the possibility of deactivation in specific contexts and would like to be involved in the ICD deactivation process ( $n = 1462$ , 92.2%) (Figure 1). Four of ten patients had thought what to do with their ICD in case of terminal illness ( $n = 633$ , 40.0%). According to patients, the best time to have a discussion on ICD deactivation is when health deteriorates ( $n = 637$ , 40.1%), followed by the period before implantation ( $n = 555$ , 39.4%) and during stable condition ( $n = 317$ , 19.9%).

### Sex analysis

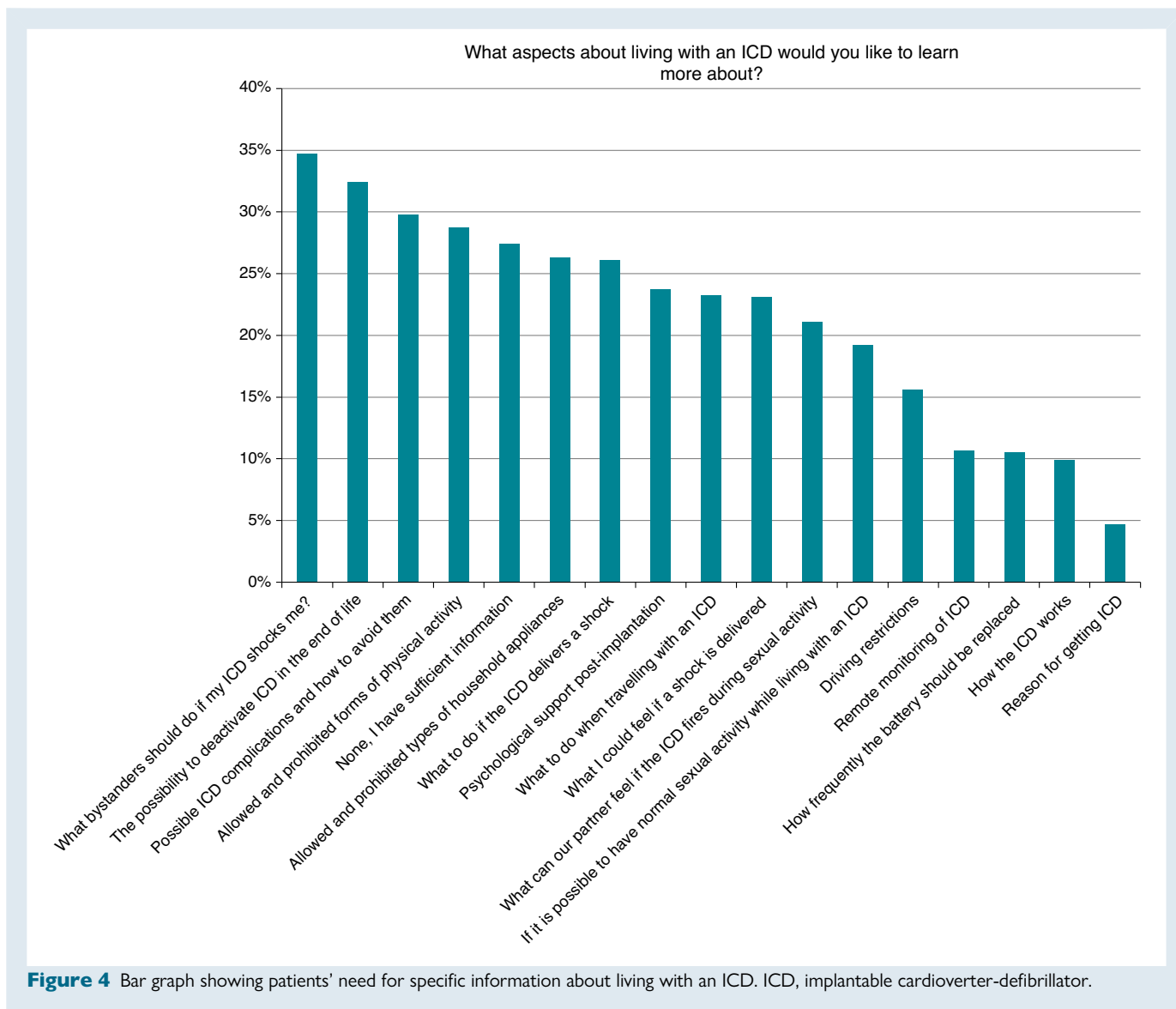
Women declared receiving a full explanation on available treatment options and potential alternatives (if any) to ICD less often than men (60.3% vs. 70.4%,  $P < 0.001$ ). Likewise, women were less likely involved in the decision-making process than men (47.3% vs. 55.9%,  $P = 0.003$ )



and declared to receive less information before ICD implantation (61.2% of women vs. 76.8% of men felt well informed before the procedure  $P < 0.001$ ). Moreover, a larger percentage of women mentioned the desire to have known more about the ICD before implantation (45.4% vs. 33.7% of men,  $P < 0.001$ ). The most relevant results of a sex-specific analysis are presented in *Table 1*.

## Discussion

This prospective, international patient survey points out a general lack of information delivered to patients before ICD implantation. Moreover, women are less likely than men to receive complete information on the device and to be involved in the decision-making process.



**Figure 4** Bar graph showing patients' need for specific information about living with an ICD. ICD, implantable cardioverter-defibrillator.

In a previous EHRA Cardiac implantable electronic devices Patient Survey, not specifically ICDs, approximately half of respondents reported having been extensively informed about possible complications before implantation, but almost a third felt insufficiently informed about them.<sup>10</sup> This ICD survey suggests that patients receive a lower level of specific information regarding various aspects of life with an ICD compared with Danish and Dutch cohorts from previous studies.<sup>11,12</sup> Therefore, it seems that, during the last years, there has been no improvement at all regarding adequate information provided to patients before cardiac device implantation procedures in Europe. Also, the percentages of respondents who are not aware of the device type (7.5%) or indication (3.0%), albeit low, are still too high. As we showed recently, the feeling of being well informed before ICD implantation is associated with improved quality of life,<sup>9</sup> and lower satisfaction with provided information associates with higher anxiety levels.<sup>12</sup> Face-to-face consultations and didactic and educative tools for understanding benefits and risks of ICD therapy are certainly useful prior to device implantation, according to Center for Medicare and Medicaid Services.<sup>13</sup>

Fair and reliable information about the risks and benefits of ICD therapy is a key element in the decision-making process, considering of

course the patient's preferences and values. However, in our study, only half of ICD recipients were actively involved in the decision-making process, which is not dissimilar to what a previous study has shown.<sup>14</sup> This emphasizes a clear need for better communication between physicians and patients, with the former dedicating more time to explain the procedure, risks, and implications of the ICD, as well as the possibility of device deactivation in particular cases. A transition from a paternalistic healthcare system to patient-empowerment whenever possible is necessary.

Before ICD implantation, only a fourth of patients participating in this survey were aware of the possibility of ICD deactivation at the end-of-life, and this increased to only around 50% at the time of the survey (a median of 5 years after implantation). This is consistent with a previous report.<sup>15</sup> In addition, although more than half of patients did not understand why ICD deactivation could be helpful at the end-of-life, when explicitly asked about this almost everyone believed they should be informed about the ICD deactivation process and be involved in the decision. This represents a major gap which should be addressed. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure<sup>16</sup> recommend that this information is provided to patients. The importance about continued communication between

**Table 1** Sex analysis

	Female (n = 624)	Male (n = 1185)	P value
How would you describe the treatment discussion before the ICD implantation?			<b>&lt;0.001</b>
Available treatment options were fully explained to me	60.2%	70.3%	
Available treatment options were somewhat explained to me	28.6%	22.7%	
Available treatment options were not explained to me	11.2%	7.0%	
How would you describe your participation in the decision about the ICD implantation?			<b>0.003</b>
I was actively involved in the decision-making about the ICD implantation	47.2%	55.9%	
I was somewhat involved in the decision-making about the ICD implantation	30.6%	27.3%	
I was not at all involved in the decision-making about the ICD implantation	22.2%	16.8%	
In general, I felt well informed before the ICD implantation	61.2%	76.8%	<b>&lt;0.001</b>
I would like to learn more about:			
None, I have sufficient information	20.7%	33.0%	<b>&lt;0.001</b>
Psychological support post-implantation	34.3%	18.1%	<b>&lt;0.001</b>
Driving restrictions	17.6%	23.0%	<b>0.008</b>
The possibility to deactivate ICD in the end of life	36.2%	30.5%	<b>0.013</b>

ICD, implantable cardioverter-defibrillator.

the patient and healthcare professionals is highlighted also in ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of SCD.<sup>17</sup> Our study provides additional data on when patients feel is the right time to have this discussion: before implantation or at the time of health deterioration, but not during stable condition. This is a sensitive topic to discuss with patients, and some may not want to engage in this discussion.<sup>18</sup> On the other hand, improving patients' knowledge on ICD function may also further facilitate the decision-making process at the end-of-life.<sup>19</sup>

The sex bias in cardiology has been studied across various areas and it has been shown that women less often than men receive guideline-based therapies.<sup>20–22</sup> We explored sex disparities regarding information provided before ICD implantation, and this survey clearly highlights the fact that women receive less information than men. Interestingly, their concerns also seem slightly different from those of male patients, with the latter focusing more often on driving restrictions while women are more often worried about (the lack of) psychological support post-implantation, which may be explained by their higher level of anxiety and depression.<sup>23,24</sup> Insufficient information provided by physicians plays a considerable role in the well-documented higher anxiety and depression reported in women.<sup>25</sup> However, despite the fact that there has been a greater attention paid to heart disease prevention and treatment in women in the last years, there is still a large room for improvement in this area. Effective strategies to reduce sex inequality in ICD treatment are a matter of great importance.

This study has the typical limitations of survey research. First, there is a bias due to the format of the questionnaire which is purely declarative. Additionally, there is a second bias since patient information may differ from centre to centre and even more from country to country. Differences related with age, education level, gender, culture, and religion are difficult to anticipate and evaluate. Finally, there is a potential bias in that patients may remember information differently, and this may vary depending on how long they have had their device and whether they have already experienced any complication.

## Conclusion

The results of this survey should raise awareness among the European medical community for the incomplete and insufficient information

which is provided to patients before ICD implantation, especially women. A large proportion of patients is unaware of ICD-related complications, driving restrictions, and possible end-of-life decisions. A better understanding and knowledge on device function, benefits, and potential limitations, as well as end-of-life decisions, should help to improve the acceptance of the device and adherence to treatment and the patients' quality of life.

## Supplementary material

Supplementary material is available at *Europace* online.

## Acknowledgements

The authors acknowledge Axel Verstrael, Patient from the ESC Patient Forum who consulted the questionnaire. The authors would like to thank Vanessa Meyen for her significant support in co-ordinating the project. The authors acknowledge EHRA Research Network centres participating in this survey. The authors acknowledge the European Heart Network and its members for the dissemination and promotion of the survey. We acknowledge the Patient Associations: APODEC—Association de Porteurs de Dispositifs Electriques Cardiaques and DAIPP from France, Arrhythmia Alliance from UK, ICDefibrilatorzy—Stowarzyszenie na rzecz osób ze wszczepionymi urządzeniami kardiologicznymi from Poland, Defibrillator (ICD) Deutschland e.V., The Irish Heart Foundation, The Lithuanian Heart Association, The German Heart Foundation (Deutsche Herzstiftung), The Swiss Heart Foundation (Schweizerische Herzstiftung), The Spanish Heart Foundation (Fundación Española del Corazón), The Finnish Heart Association (Suomen Sydänliitto), Fondazione Italiana per il Cuore, and Conacuore ODV Coordinamento Nazionale Associazioni Del Cuore from Italy. The production of this document is under the responsibility of the Scientific Initiatives Committee of the European Heart Rhythm Association: Serge Boveda (Chair), Giulio Conte (Co-Chair), Ante Anic, Sergio Barra, Julian K.R. Chun, Carlo de Asmundis, Nikolaos Dages, Michal M. Farkowski, Jose Guerra, Konstantinos E. Iliodromitis, Kristine Jubele, Jędrzej Kosiuk, Eloi Marijon, Rui Providencia, and Frits Prinzen.

## Funding

None declared.

**Conflict of interest:** Ł.J. has received speaker/consultant fees from Biotronik, Medtronic. E.M. has served as a consultant for Medtronic,



Boston Scientific, Abbott, and Zoll. Research grants from Medtronic, Abbott, Boston Scientific, Biotronik, and Microport. M.M.F. has received speaker/proctoring fees from Abbott Medical Poland and Medtronic Poland. G.C. has received research grants from the Swiss National Foundation and research grants and speaker fees from Boston Scientific. S.B. has served as consultant for Medtronic, Boston Scientific, Microport, and Zoll. All the other authors have no conflict of interest to declare.

## Data availability

The data underlying this article will be shared on reasonable request to the corresponding author with permission of EHRA Scientific Initiatives Committee.

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