Patients' knowledge and attitudes about living with implantable electronic devices: Results from a multicentre, multinational patient survey conducted by the European Heart Rhythm Association

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Abstract

The purpose of this patient survey was to analyse the knowledge, experiences and attitudes regarding cardiac implantable electronic devices (CIED) in patients with pacemakers, implantable cardioverter defibrillators or cardiac resynchronization devices. Of 1644 patients with CIEDs from seven European countries, 88% were over 50 years of age. Most patients (90%) knew what device they were implanted with, and felt sufficiently informed about the indications for the therapy. As many as 42% of patients, needed additional information on the battery replacement and limitations in physical activity. The self-reported incidence of complications was 9%, and among these 9%, one quarter felt insufficiently informed about the possibility of complications and their management. The vast majority of patients (83%) were followed by face-to-face visits, which was the most commonly preferred follow-up strategy by the patients. Nearly 75% of patients reported improved quality of life after device implantation, but still about 40% had worries about their device. Less than 20% had discussed with their physician or thought about the device handling in the end of life circumstance or end-stage disease. Notably, almost 20% of the ICD patients did not wish to answer the question about what they wanted to be done with their ICD in case of end stage disease, indicating the challenges in approaching these issues.

Introduction

Cardiac implantable electronic devices (CIED), including pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT) are the standard of care in various cardiac conditions and are used in a growing number of patients. CIEDs are effective in improving survival and quality of life. While indications, implantation rates and complications are well described among centres in Europe [1], patients' experiences of being implanted and living with a CIED are less well explored. Being implanted with a device is a significant encounter for the individual, both physically and psychologically. Not only the diagnosis and implantation, but also the function of the device may affect and worry the patient. Furthermore, important questions of how to live with the device and what to do with the device in a situation of severe or end-stage disease may rise. Patients' beliefs and knowledge about their illness are important determinants of their coping responses to their illness and their treatment[2].

In the second patient survey performed by the European Heart Rhythm Association (EHRA)[3], we explored the knowledge, perception of information and attitude towards the device among patients implanted with a CIED.

Methods

The prospective, multicentre, multinational snapshot survey included patients with CIEDs, implanted either recently or in the past. The survey was designed and approved by the EHRA Scientific Initiatives Committee (SIC). Patients with CIEDs were offered to participate in the survey by anonymously answering the questionnaire posted on an electronic platform and available via Internet or in the paper form. The questionnaire contained 18 questions in the patients' native language. The survey was sent to the EHRA Electrophysiology (EP) Research

Network centres. The local ethic committee approval was obtained where needed, as per local policy. The EP Network centres were invited to participate on a voluntary basis. Patients were asked to submit their replies via the internet or in a paper form, either without any help or with technical guidance from medical staff or family members. The paper forms were subsequently uploaded online by the SIC staff. Data were collected anonymously. The study was conducted from November 2016 to February 2017.

Results

Patient population

A total of 1644 patients (61% males) from 7 European countries participated in the survey. The number of patients from each country was as follows: 812 (49%) from Poland, 435 (26%) from Italy, 175 (11%) from France, 86 (5%) from Denmark, 55 (3%) from Norway, 32 (2%) from Romania, 16 (1%) from Spain and 33 (2%) were from other countries. There were 688 patients (42%) aged >75 years, 755 patients (46%) aged 50-75 years and 199 patients (12%) aged < 50 years. Most patients were living with a partner (77%), while 20% were living alone and 3% lived in a nursing home. Regarding the patients' education level, 37% of patients had a primary school education, 43% had graduated a secondary school and 21% of patients had a higher level of education. Almost half of patients filled the questionnaire by themselves (49%), 31% were helped by a health care professional and 20% used help from a friend or a family member.

Device types and indications for implantations

As self-reported, 41% of patients were implanted with antibradycardia pacemaker, 33% with an ICD, 8% with CRT and 7% of patients with CRT-D, whilst 10% of patients did not know the

type of device they were implanted with. The device was implanted 0-1 years, 1-3 years, 4-6 years or 7-15 years ago each in approximately 25% of patients.

Among the self-reported indications for device implantation, slow heart rhythm was the most common reason for device implantation (36%), followed by atrial fibrillation (23%), cardiac arrest or syncope (23%), prophylactic implantation due to high risk of cardiac arrest (20%) and heart failure (25%); 5% of patients did not know why they were implanted with their device.

Device monitoring and follow-up

Face-to-face regular hospital follow-up visits were the most common follow-up strategy (83% of patients), while 17% were followed remotely, with either not-so-frequent onsite visits (11%) or onsite visits scheduled as needed (4%). Most patients (51%) preferred to be followed by regular onsite visits, while 27% left the choice of follow-up strategy to their physician; 15% of participants wished to be monitored remotely, with less frequent face-to-face visits.

Complications-related information

Most patients (57%) reported that they were extensively informed about possible complications before the implantation, 29% reported that they had received some information, and 14% reported that they have been supplied with insufficient information. The self-reported incidence of complications was 9% (91% of patients reported no complication). Infections constituted half of the complications (4%). If a complication had occurred, 72% of patients felt sufficiently informed about it, while the remaining 28% of patients felt insufficiently informed about the complication and its management.

Overall, most patients (44%) felt sufficiently informed, while the device battery capacity and possible limitations in physical activity (21% each) were the issues which patients would like to be more informed about (Figure 1).

Quality of life with the device

The vast majority of patients (69%) had never regretted to have received the device, while 24% of them had not given this question a second thought. A small proportion (7%) regretted or had sometimes regretted to have been implanted, usually because of complications and insufficient information about daily-life restrictions.

In 68% of patients, the device had never caused any difficulties; however, 12% of patients reported difficulties regarding diagnostic procedures (e.g.., cardiac magnetic resonance), 7% regarding private life (e.g., travelling, relationship with partner), 4% of patients experienced professional problems (e.g., limitations to drive, etc.), 2% had insurance issues, and 0.4% of patients reported difficulties regarding pregnancy.

Sixty-four percent of patients had no device-related worries; however, 36% of the patients were concerned about the delivery of shock, possible primary or daily activities-induced malfunctioning of the device, or had other worries (Figure 2).

Only 6% of patients reported that the device affected their daily life. Restrictions in physical activity and the possibility of sleeping on the left side were the most commonly reported complaints. The quality of life after device implantation was clearly or slightly improved in the majority of patients, while it was impaired in only 5% of patients (Figure 3).

Information and attitude in case of end-stage disease

Eighty-four percent of patients had not discussed what to do with their device in the end-of-life situation; 12% had briefly discussed the issue and 5% reported they have been thoroughly informed about possible alternatives by their physician. Of patients with an ICD, 66% had never thought about how would they wish their device to be handled in the case of an end-stage disease; 6% of patients would prefer that their ICD remains active, 5% would consider to ask for the ICD inactivation, while 2% of patients reported that they had thought about the question but they did not have a clear preference. Notably, 18% of participants preferred not to answer this question.

Discussion

This prospective, international, multicentre patient survey conducted in 7 European countries provided important insights into the contemporary patients' knowledge, information and attitudes regarding living with a CIED. The survey revealed the unmet need for more information with respect to battery replacement and physical activity. Nevertheless, the survey showed that European patients implanted with a CIED were well informed of the device indication and the type of device they were implanted with. In most patients, the quality of life increased or remained unchanged after device implantation, and only a very few patients regretted the device implantation. Only a minority of patients had discussed with their physician what to do with the device in the case of end-stage disease or end-of-life situation, and there was a tendency among patients to avoid this question.

Patients' knowledge, need of information and quality of life after device implantation

The patients participating in this survey were generally well informed about their type of device and the indication for the implantation, with less than 10% of them not able to answer these questions. Of note, almost half of the patients were >75 years of age, indicating a good

knowledge also in the elderly. However, the need of information about the device was still not met, because only 40% of patients felt they had no unresolved questions and 40% had worries regarding their device.

Patient information is of uppermost importance, as it will reduce stress of living with a CIED and the disappointments in case of complications. Information on the device should be ideally given orally, during face-to-face conversations, and in written form, with the possibility to discuss further questions with an appropriate health care provider. This survey showed that patients felt well informed about complications concerning the implantation procedure. However, among those who reported to have had complications, as many as a quarter of subjects felt insufficiently informed about potential complications and their management. Furthermore, even questions concerning the way of life with the device during the follow up were less well answered. The need for further information was most often related to device functioning (e.g., battery replacement, etc.) and to physical activity. Physical activity is an important question to address when living with a CIED, and, of course, it has to be individualized in accordance with the type of device and the underlying diseases. Current international recommendations only suggest moderate leisure-time physical activity to patients with an ICD [4, 5]. Recent studies have indicated that the device *per se* should not restrict physical activity. In patients used to an active life-style, restrictions in activity are particularly limiting. A multinational registry showed that many athletes with ICDs engage in competitive sports, without physical injury, or failure to terminate the arrhythmia[6]. Physicians should carefully consider the patients need for activity, when choosing leads, devices programming, preventive bradycardic medication, physical rehabilitation and psychological counselling, in order to allow the maximum benefit and the minimum harm for physically active ICD patients[7].

Interestingly, 73% of patients reported to have improved their quality of life after device implantation. Considering that 56% of our population received a pacemaker (pacemaker: 41%; CRT devices: 15%), also a substantial proportion of ICD patients had an increase in their quality of life. This may be explained by improved medical treatment, regular follow-up visits and psychological effects. However, patients worried about their devices and 40% reported concerns about technical problems. In particular, 10% of patients were frightened to receive a shock from the ICD. Although focus has been paid to reduce appropriate and inappropriate shocks, this problem still seems to be considerable.

Only a very small minority of patients regretted the device implantation. The reasons given by these patients were most frequently associated with device complications and with restrictions of physical activity.

Monitoring of the device

Most patients followed regular onsite- visits and only a minority was followed remotely. Remote follow-up of devices allows for fewer in-office visits in combination with earlier detection of relevant findings[8, 9]. However, most patients wished to continue regular onsite-visits, and only 15% wanted more extensive remote monitoring with less onsite visits. This result may reflect a lack of awareness about potential benefits of remote monitoring. The cost-benefit ratio of remote follow-up is actively debated and the reimbursement issue is one of the significant barriers to its practical implementation[8, 9].

Information and attitude in case of patients' end-stage disease

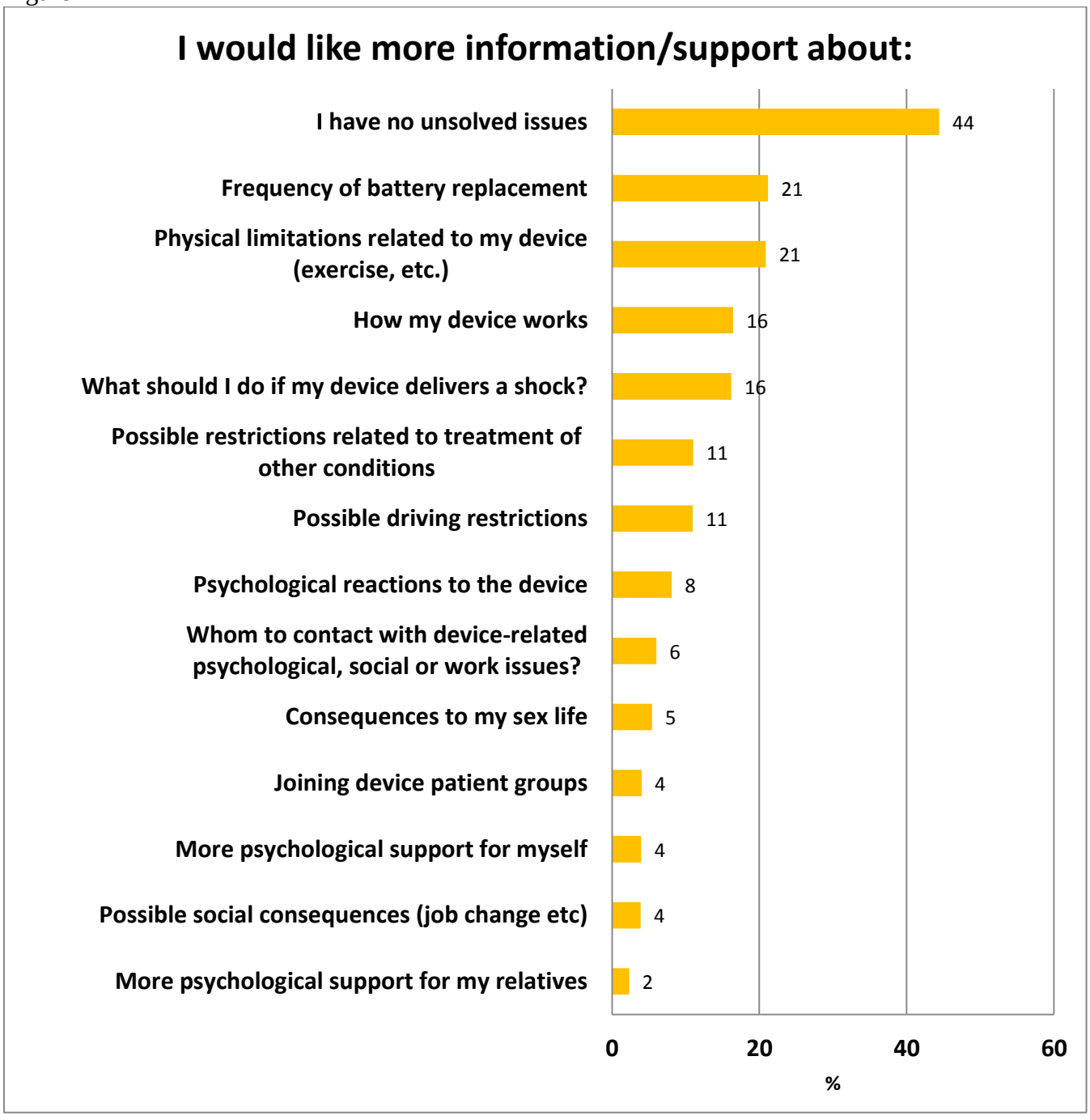
Although nearly half of patients were > 75 years of age, only a minority of them had discussed with their physician or, even, thought about what to do when end of life is approaching.

Physicians and patients may be reluctant to discuss these problems, particularly when the clinical situation seems to be far away. Most physicians have experienced the dilemma of turning off a pacemaker or an ICD in terminal patients. For many years, the ethical debate about pacemakers has focused on whether and under what circumstances they may be turned off in end of life care[10]. Interestingly, and of note, almost 20% of the ICD patients in this survey did not want to answer the question about what they wanted to do with their device in such a situation. This may reflect an unwillingness to approach the argument. The current guidelines on prevention of sudden cardiac death give only a IIa class recommendation to the discussions of end-of-life issues with patients, both before ICD implantation and at significant points along the illness trajectory[11]. Furthermore, recommendations class IIa state that ICD deactivation should be considered when clinical conditions deteriorate[11]. This issue remains difficult and requires attention and awareness among physicians and health care personnel. Incorporation of patients' values and preferences in these questions should be considered as an integral part of the decision-making process[2].

Conclusion

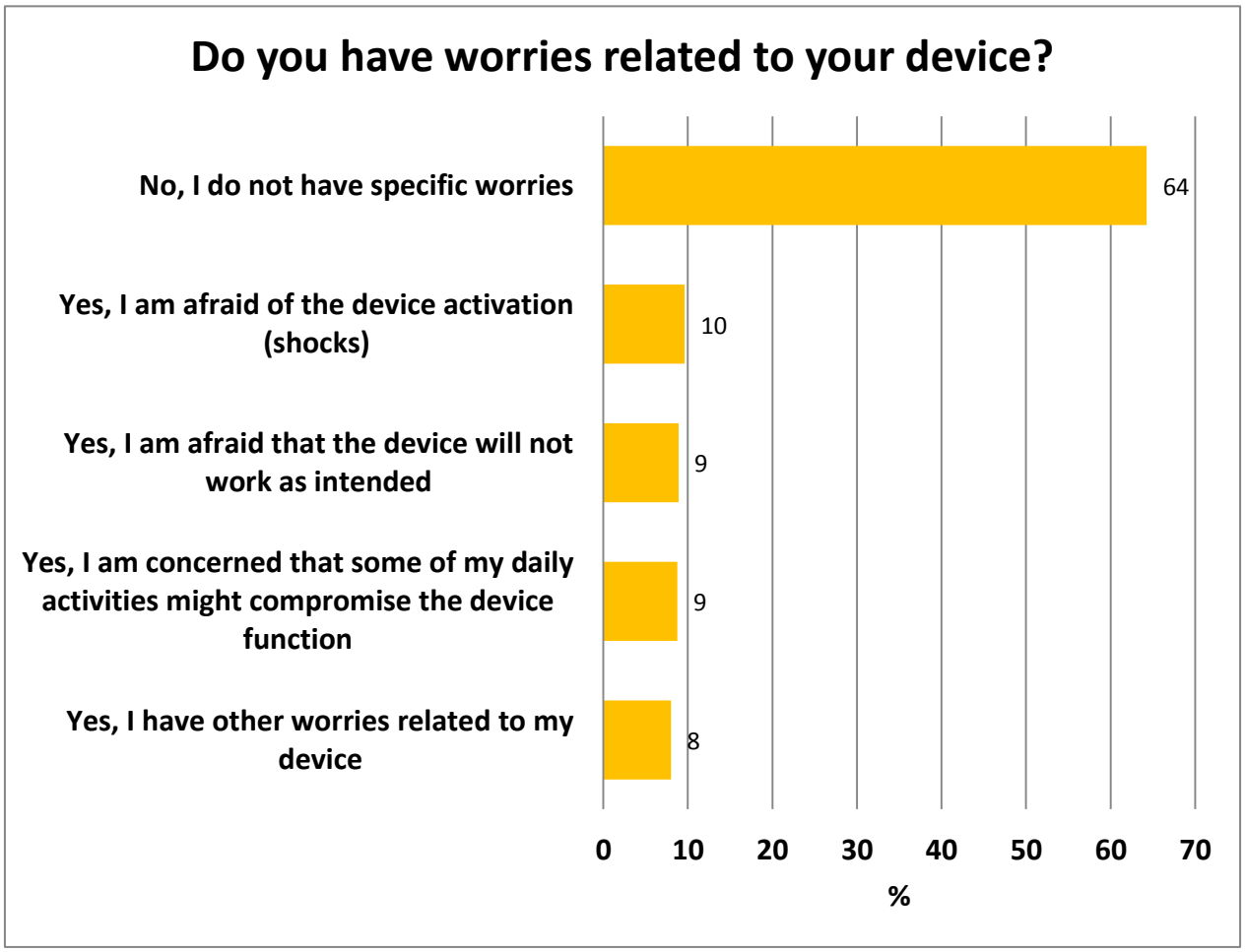
Patients were generally well informed about their device and indications. However, there was further need for information, mainly regarding device functioning, battery replacement and physical activity. Quality of life improved in the majority of patients, also including ICD patients. Questions about what to do with the device at the patient's end of life were rarely discussed by patients and physicians.

Figure 1



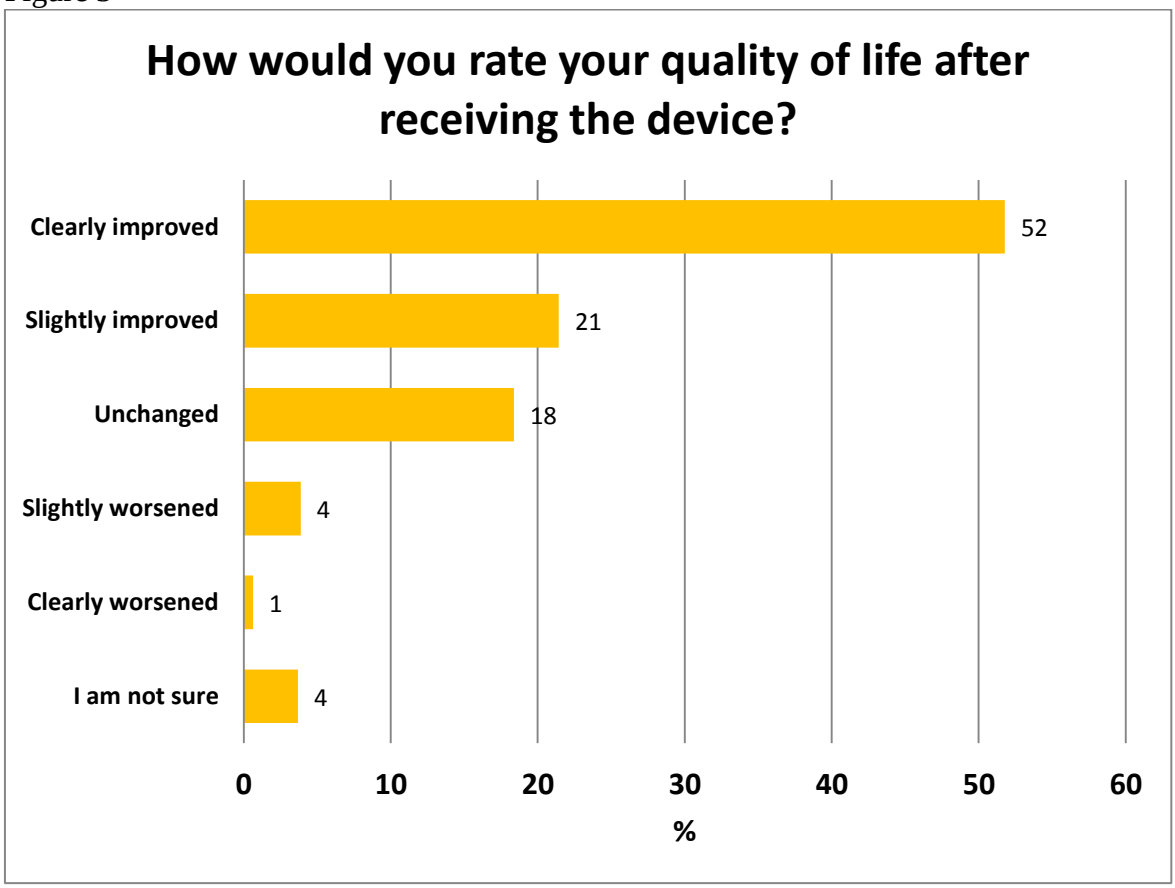
Bar graph showing the need of information or support among 1644 patients with implantable electronic devices (multiple answers possible).

Figure 2



Bar graph showing device-related worries among 1644 patients with implantable electronic devices

Figure 3



Bar graph showing quality of life after device implantation among 1644 patients with implantable electronic devices

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