CLINICAL ETHICS

Views of patients with heart failure about their role in the decision to start implantable cardioverter–defibrillator treatment: prescription rather than participation

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Background: There is a shortage of reports on what potential recipients of implantable cardioverter–defibrillators (ICDs) need to be informed about and what role they can and want to play in the decision-making process when it comes to whether or not to implant an ICD.
Aims: To explore how patients with heart failure and previous episodes of malignant arrhythmia experience and view their role in the decision to initiate ICD treatment.
Patients and methods: A qualitative content analysis of semistructured interviews was used. The study population consisted of 31 outpatients with moderate heart failure at the time of their first ICD implantation.
Setting: The study was performed at Sahlgrenska University Hospital, Göteborg, Sweden.
Results: None of the respondents had discussed the alternative option of receiving treatment with anti-arrhythmic drugs, the estimated risk of a fatal arrhythmia, or the expected time of survival from heart failure in itself. Even so, very little criticism was directed at the lack of information or the lack of participation in the decision-making process. The respondents felt that they had to rely on the doctors' recommendation when it comes to such a complex and important decision. None of them regretted implantation of the ICD.
Conclusions: The respondents were confronted by a matter of fact. They needed an ICD and were given an offer they could not refuse, simply because life was precious to them. Being able to give well-informed consent seemed to be a matter of less importance for them.

Treatment with automatic implantable cardioverter–defibrillators (ICDs) has been shown to be more effective than medical treatment in preventing sudden cardiac death among patients who have survived life-threatening ventricular arrhythmias (ventricular tachycardia/fibrillation).[1] As a result, international guidelines recommend the ICD as the treatment of choice for these patients.[2–4] The risk of fatal arrhythmias recurring in the absence of a clear reversible cause ranges from 30% to 50% at the 2-year follow-up.[4]

Approximately one-third of the patients who receive an ICD experience heart failure.[1] Chronic heart failure is a common syndrome caused by reduced cardiac function that leads to the failure of the heart to pump blood. This in turn gives rise to disabling symptoms including breathlessness and fatigue. Depending on the degree of impaired exercise tolerance in daily life, the patients are classified according to the New York Heart Association (NYHA) in one of four classes (I–IV). This is a serious condition with high mortality. Approximately half the patients who develop severe heart failure corresponding to NYHA class IV will die within a year. Even in the milder or moderate stages of heart failure, the 5-year mortality is almost 50%. However, it is difficult to estimate the short-term prognosis due to various clinical courses. About one-third of the patients will die suddenly and unexpectedly, one-third will die suddenly in conjunction with a period of deterioration or a myocardial infarction, and one-third will die following a progressive deterioration in heart failure symptoms.[3 5]

Patients with reduced ventricular function (ejection fraction <35–40%) and advanced heart failure (NYHA≥ III) obtain the greatest benefit from ICD treatment in terms of survival.[1] In one study, mortality was reduced by 29% in patients treated with ICDs over a period of 3 years compared with those who received the best medical treatment for the prevention of arrhythmias (anti-arrhythmics).[6] Alternately, it could be said that though the device would save these patients from a sudden, dramatic, painless and somewhat premature death due to arrhythmia, thereby leading to a limited prolongation of life, the price that is paid for this effect could also be a more painful end, due to symptoms of progressive heart failure and the potential negative effects related to the treatment itself.

Treatment with ICD from the patients' perspective

The impact of an ICD on the patients' quality of life is small in overall terms, unless numerous shocks are delivered. In fact, most patients who have received an ICD feel confident with the device and adapt to their new situation.[7–10] However, there are side effects associated with the treatment that need to be taken into consideration, in particular when the patient's expected time of survival is short, due to advanced age and/or severe underlying disease. For instance, anxiety related to the unpredictable shocks is common, in particular the first time this happens after implantation (24–87%).[7] Some recipients of an ICD actually begin to avoid certain activities, objects and places, even though these precautions are not medically motivated.[11] The way in which patients describe their feelings about being subjected to a shock vary from a mild and tolerable chest sensation that rapidly disappears to a very painful, unpredictable and scary experience, sometimes associated with a feeling that their heart is going to explode in their chest. Some patients will also take some time to recover physically and mentally. There is no medical risk associated with the shocks in terms of causing damage to the heart or other organs. However, shocks can be inappropriately triggered by more benign disturbances in cardiac rhythm—that is, supraventricular arrhythmias.[1] Adverse events after implantation that require additional intervention may also occur.[12] In one survey, 5% of

Abbreviations: ICD, implantable cardioverter–defibrillator

patients receiving treatment with ICDs said that they would prefer to be without an ICD and take their chances.[13]

Informed consent

It is widely established that informed consent is an inevitable element of good clinical practice.[14]

For example, the Convention of Human Rights and Biomedicine from the Council of Europe states: ''An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. The person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.''[15] Doctors should promote understanding and facilitate participation in the decision-making process to give their patients a real chance to make choices in their best interests. To provide a nuanced description and analysis of the concept of informed consent, we feel that it should be discussed in the light of how things are in the real world. Moreover, consent procedures should be adapted to match patients' capacity to understand and their preferences in terms of information and the degree of involvement in the decision.[16]

Patients who have survived a life-threatening arrhythmia are generally offered treatment with an ICD during their period of hospitalisation after the event. At the time of a decision to implant an ICD, patients may be in a state of a psychological or existential crisis, after having come so close to death. Their mental capacity may be diminished due to sequelae from cerebral hypoxia related to a cardiac arrest. Under these circumstances, they are expected to give their consent to the recommended treatment. It is considered too risky to send patients home without an ICD or to postpone the decision, as the fatal arrhythmia may recur at any time. However, as the patients remain in hospital for the continuous monitoring of cardiac rhythm while waiting for the implantation, there will be opportunities, in some cases, to repeat and add information and thereby obtain more valid informed consent.

As far as we know, there is a shortage of reports and commentaries on what potential recipients of ICD need to be informed about and the extent to which they should, can and want to influence the decision.

Objective

The main aim of this study was to explore (1) how patients with heart failure and previous episodes of malignant arrhythmia experienced the consent procedure, including the information they had been given and the role they had played in the decision-making process, (2) the extent to which they want and feel that they are able to influence the decision to initiate ICD treatment, and (3) their current attitudes towards the treatment. On the basis of the results, the conditions that should be met in order to claim that the patient's right to influence a decision has been complied with in this particular context are discussed.

METHODS

Patients

To be included in the study, patients had to meet the following criteria: (1) have received an ICD, as a secondary preventive measure at Sahlgrenska University Hospital, Göteborg, Sweden, and (2) have chronic heart failure corresponding to NYHA classification III and/or a left ventricular ejection fraction (EF) estimated by echocardiogram to be <40% at the time of the first implantation.

The reason for choosing patients with moderate to severe heart failure for the study was because it can be particularly difficult to estimate whether the potentially beneficial effects of an ICD outweigh the negative effects associated with the treatment for these patients. Therefore, it might be particularly important to provide information on the facts that make this a difficult decision in order to give them a real chance of making an autonomous choice.

Patients who met the inclusion criteria and had a planned follow-up visit at the clinic were approached. To obtain a sample that would reflect a diverse range of individuals and include as many factors as possible that might influence the results, patients with different ages, backgrounds and experiences of ICD treatment were included (purposive sampling). For the last three interviews, females were searched for and selected, as only three women had previously been included. Two patients declined to participate, referring to a lack of time. The final study group consisted of 31 outpatients, 25 men and 6 women. All the participants gave their informed consent to the interviews. Table 1 presents further characteristics of the study group.

Data collection

A semistructured interview made up of open-ended questions was used to collect data related to the objectives of the study. The respondents were therefore asked about their experiences and views when it came to the disclosure of information and their role in the decision on whether to start ICD treatment. Their current attitudes towards the treatment were also addressed. One complementary question with fixed reply alternatives (yes/no/uncertain) was asked: If you had known what you know today when you were offered the ICD, would you still have opted for it?

The interviewer occasionally intervened by asking the respondents to clarify what they meant or by asking them to go into more detail. The interviews took place at the hospital and they were all carried out in May–September 2004 by A Å, who was not involved in the medical care of these patients. The interviews were tape-recorded. The first 13 were transcribed verbally, whereas only selected parts including quotes that were considered essential were transcribed from the remainder as the contribution of new qualitative data was limited. They

Table 1 Demographical characteristics of the study group

Patients	
N	31
Men/women	25/6
Mean (range) age (years)	65 (44–79)
ICD indication	
VT/VF	20/11
Aetiology of heart failure	
Ischaemic cardiomyopathy	19
Non-ischaemic cardiomyopathy	12
NYHA class at first implantation	
I*	4
II*	12
III	15
Duration of ICD treatment	
Mean (range) number of months	40 (1–126)
Number of shocks	
0	19
1–5	10
>5	2

ICD, implantable cardioverter–defibrillator; NYHA, New York Heart Association; VF, ventricular fibrillation; VT, ventricular tachycardia.
*Ejection fraction estimated by echocardiogram to be <40% at the time of their first implantation.

varied in length between 20 and 60 min (mean 35 min). The local Research Ethics Committee at Sahlgrenska University Hospital, Göteborg, Sweden, approved the study (Dnr S 439–00).

Data analysis

A qualitative content analysis of the textual data was performed.[17 18] Meaning units—that is, statements that provided essential information related to the research questions—were interpreted with respect to their underlying meaning and grouped on the basis of their similarity in content into categories. Statements that contradicted these common patterns were also searched for (''deviant cases''). Table 2 exemplifies the analysis. Three main themes—facing a matter of fact, an offer you cannot refuse, and a life insurance worth paying a price for—were thought to sum up a large part of the data, and to capture the essence of respondents' experiences and views on information and their role in the decision-making process. The authors reached agreement on the interpretation of the qualitative data and how to present them.

RESULTS

Facing a matter of fact

The key message received at the time of the decision was that an ICD was recommended for the treatment of severe disturbances in heart rhythm were likely to recur in future. The respondents understood that they had had a serious event and that it was important for them to get something called an ICD, but not much more than that. Three respondents who had been resuscitated from a cardiac arrest even said that they were hardly able to grasp any information at all before the implantation. There was no single recall of discussions about the alternative option of receiving treatment with anti-arrhythmic drugs, or about the estimated risk of a fatal arrhythmia or the expected time of survival from heart failure in itself. Even so, the respondents felt that they had been told what they needed to know to opt for the ICD.

> ''If my heart stopped again, it would come into effect, thereby making my heart start beating again. That was all I needed to know'' (respondent 29: male, 73 years, ICD for 117 months)

Three respondents had some initial doubts about whether they really needed an ICD, but they were soon convinced to opt for it after receiving further information that clarified why the treatment was regarded as medically indicated (respondents 5, 9 and 26). Apart from these cases, the decision was not questioned and the discussion between doctors and patients mainly consisted of one-way communication. However, having had several complications after the implantation, one respondent criticised the information provided.

> ''The information and dialogue could have been better. Now, having had these experiences, I think they should have gone through the risks and benefits in more detail. They should have made an effort to explain instead of just saying that they were about to go for this thing'' (respondent 27: male, 66 years, ICD for 3 months)

An offer you cannot refuse

As life was precious to these patients, in spite of symptoms related to a reduction in cardiac function there was no other real option than to opt for the ICD when their doctors, who were regarded as knowing what was best for them, recommended the device in order to save or prolong their lives. The standard argument was that, as laymen, they could not possibly have an opinion about a complex medical decision such as this. Therefore, they had to rely on the doctors' skill and also expected these professionals to make the right decision for them. They simply had to face the fact; there was a need for an ICD. As a result, very little criticism was directed at the lack of participation in the decision-making process.

> ''It was a precautionary measure. I didn't feel that it was something that needed to be discussed'' (respondent 2: male, 76 years, ICD for 30 months)
>
> ''I didn't want to experience such episodes again. As the ICD could save my life, there was no choice for me and I didn't get any other choices either'' (respondent 3: male, 71 years, ICD for 63 months)
>
> ''He told me what was going to happen and about the things that had been decided. I didn't really need to know more, this is something for the professionals to deal with. The fact that they should inform people about what they are planning to do is something else'' (respondent: male, 63 years, ICD for 6 years)
>
> ''I got the impression that the decision had already been made. I realised that I had to accept it, as I was in such a high-risk situation. It wasn't possible for me to understand the basis for their decision'' (respondent 26: male, 52 years, ICD for 13 months)

Table 2 Examples of how the text was being analysed in terms of meaning units, condensed meaning units and categories

Meaning unit	Underlying meaning	Category (condensed meaning unit)
''In case I would get another heart stop, thereby making my sufficient heart beating again. That was all I needed to know.	No need for further information	A limited amount of information being regarded as sufficient
I got the impression that the decision had already been made.	One-way communication	
I realised that I had to accept it, while being in such a high-risk situation.	No real choice as life is being threatened	Accepting a passive role in the decision-making process
It was not possible for me to understand the basis for their decision.	Having to rely on the medical expertise	
I didn't want to experience such episodes again.	No real choice as life is being threatened	A choice with no real alternatives since life is at stake
ICD could save my life, there was no choice for me and I wasn't given any other choices either	One-way communication	
I have received twelve and shocks from it. If I hadn't had the ICD, I wouldn't have experienced the things that I have. It's as simple as that.	A price to pay for staying a live	The device is worth all the trouble and inconvenience

ICD, implantable cardioverter–defibrillator.

A life insurance worth paying a price for

Four respondents had undergone surgical procedures beyond what was normal because of device dysfunction or infectious complications, five were worried about shocks, and six felt that the device sometimes caused local discomfort. Despite these negative effects, none of them regretted the ICD, no matter whether shocks had been given or not. As the device increased their chance of staying alive, it was worth all the trouble and inconvenience.

> ''I have received twelve shocks from it. If I hadn't had the ICD, I wouldn't have experienced the things that I have. It's as simple as that. However, the heart failure makes me tired'' (respondent 8: female 44 years, ICD for 58 months)

Furthermore, the device was sometimes given the credit for more than it could possibly have accomplished. For instance, even though no shocks had been delivered, four respondents believed that they had the ICD to thank for their lives, that it had relieved symptoms or prevented further cardiac events.

DISCUSSION

None of the 31 participants in this study said that they had been informed about the alternative treatment with antiarrhythmic drugs or about the estimated risk of a fatal arrhythmia. Despite this, very little criticism was directed at the lack of information or their passive role in the decision-making process. Participants generally felt that they only needed to know that they ran a high risk of life-threatening arrhythmias to give their consent.

The results of this study need to be interpreted in the light of the fact that it may be difficult for the respondents to recall in detail what they were informed about, understood and felt at the time of the decision. Moreover, there is probably considerable variation in the way consent procedures are carried out, depending on the setting and the individual doctor. However, we believe that the kinds of experiences, views and concerns related to being offered an ICD are quite similar in this study group and among other patients with heart failure who are faced with this offer.

So, what can be said about the fact that the respondents' basis for the decision may have been incomplete and that they felt they did not need more information to opt for the ICD implantation? Firstly, patients do not always request knowledge of details in order to be sure of what decision to make, in particular when it comes to decisions associated with life or death, or where only one medically reasonable alternative exists.[16 19] Secondly, many patients have a great desire to live and are therefore willing to accept highly technological interventions in spite of a poor prognosis, risks and inconvenience.[20] During the course of 20 years, NE has actually not met a single patient who has refused the offer of an ICD. Thirdly, many patients trust the judgement of their doctors and they therefore do not hesitate to opt for the treatment when it is recommended.[21]

Nevertheless, in order to be able to claim that the patient's right to influence the decision has been met, a certain degree of patient (or proxy) involvement is needed. The question is whether it is possible to define a minimal level of information and understanding that needs to be achieved for what can be defined as substantially informed consent.[22] Moreover, our own values and experiences influence the way in which we look upon the informed consent procedures. We feel that patients have a right to be adequately informed about their health and to participate in medical decisions relating to their own bodies. However, patients' preferences about information and their capacity to comprehend information should guide the type and amount of information provided to them. Correspondingly patients' preferences and their capacity should guide the degree to which they participate in the decision-making process. Patients' right to be adequately informed and to participate in medical decisions should also be balanced against health providers' professionals responsibility to do good and avoid harm.

It has been recommended that checklists, which define what constitutes essential information for adequate informed consent in particular clinical contexts, should be drawn up.[23 24] However, to our knowledge there are no official guidelines that explicitly state what the potential ICD recipient should be informed about. In our opinion, potential ICD recipients need to know that they run a high risk of life-threatening arrhythmias (30–50% within 2 years), which are best treated with an ICD. They should have a fair perception of the effect of an ICD compared with medical treatment, as well as a fair perception of the potential risks and inconvenience associated with the treatment. Information should also include the fact that the device can be switched off or removed at their request. In addition to the difficulties associated with calculating the prognosis for an individual on the basis of statistical results from large populations with similar characteristics, studies have shown that many patients do not want detailed information about their prognoses.[25 26] As a result, information about prognoses should be adapted to match the patient's preferences.

To reach a satisfactory decision in terms of whether a patient with moderate to severe heart failure will benefit from ICD treatment, the doctors must take the following medical and ethical questions into consideration. Does the patient meet the criteria for an ICD according to the existing guidelines? Is the patient's expected time of survival long enough and the risk high enough to justify an ICD?[27] How will the treatment influence the patient's life? Are the costs in reasonable proportion to the medical benefits?[28] Could pharmacological treatment be considered as a reasonable alternative?[6 29] And, finally, how much information does the patient need, or wish to have in order to make a well-founded decision?

CONCLUSIONS

None of the respondents felt that they needed additional information to opt for the treatment at the time of the decision, apart from the fact that an ICD was a device that could rescue them from life-threatening arrhythmias. They felt that the decision was too complex for them to have their own opinion on and they therefore had to rely on the doctors' judgement and recommendations. As the respondents wanted to live, it was quite simply an offer they could not refuse.

In our opinion, healthcare professionals are faced with a challenging task in providing information considered essential for their potential ICD recipients, while at the same time being sensitive in terms of how much information the patients are capable of handling and want to handle, and the degree to which they are capable of influencing and want to influence decisions on whether to have an ICD implanted.

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