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Health-related quality of life of patients with implantable cardioverter defibrillators compared with that of pacemaker recipients

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Aims Studies indicate a poorer quality of life (QoL) for implantable cardioverter defibrillator (ICD) patients than for the general population. However, studies comparing the QoL of ICD patients with that of patients with other implantable cardiac devices are scarce. We hypothesized that ICD patients had a poorer QoL than pacemaker patients.

Methods and results All ICD patients living in Iceland at the beginning of 2002 (44 subjects), and a comparison group of 81 randomly selected patients with pacemakers were invited to participate. The Icelandic Quality of Life Questionnaire (IQL), the General Health Questionnaire (GHQ), the Beck Anxiety Inventory (BAI), and the Beck Depression Inventory (BDI) were submitted to measure QoL, psychiatric distress, and symptoms of anxiety and depression. The ICD and pacemaker groups did not differ on IQL, BAI, BDI, or GHQ scores. ICD patients were as a group more fearful of death ($P = 0.056$) and showed more concerns about returning to work ($P = 0.072$), although these items fell just short of statistical significance.

Conclusion Contrary to our expectations, ICD patients had a comparable QoL with pacemaker recipients and were not more likely to suffer from anxiety, depression, or general psychiatric distress. These findings are encouraging in view of expanding ICD indications.

Introduction

Indications for the use of implantable cardioverter defibrillators (ICDs) have been expanding in recent years following the publications of several large multi-centre trials and now include preventive implantation for patients with coronary artery disease and a severely depressed ejection fraction.[1–3] This has resulted in increased implantation rates and thus steadily growing numbers of ICD recipients worldwide.[4] At the same time, concerns remain regarding the quality of life (QoL) of these patients. Small observational studies have indicated a poor QoL for ICD patients.[5,6] More recently, a few of the large randomized preventive ICD implantation and ICD vs. anti-arrhythmic drug trials have evaluated QoL in subsamples of participants. These have generally shown a similar or even better QoL among ICD patients not receiving shocks than patients treated with drugs, but QoL scores decreasing with increasing numbers of shocks received from the device.[7] ICD recipients commonly report various physical and psychological symptoms, which they ascribe to the potentially life-saving cardioverter defibrillator itself.[8,9] The shocks from the ICD are reported as uncomfortable, are usually unexpected, their timing unpredictable, and they can occur under any circumstances.[9] As a consequence, ICD patients frequently report anxiety, lack of control, and powerlessness.[10] Taking these factors into account, it is quite possible that the device itself may provoke anxiety and thus result in reduction of the QoL of ICD patients.

Studies on the QoL of patients with pacemakers, who served as a control group in our study, indicate a similar QoL for this patient group to that of patients with other chronic medical illnesses.[11,12] Both ICD patients and pacemaker patients have an implanted cardiac device, but

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pacemaker patients are less likely to be aware of its function than ICD patients are of their defibrillator.

In this study, we examined the QoL of ICD patients compared with that of pacemaker patients. We hypothesized, given the potential of unexpected uncomfortable shocks, that the ICD group would score higher on subjective measures of anxiety, depression, and general psychiatric distress and report a poorer QoL than pacemaker recipients.

Methods

Design

This was a cross-sectional study where all living ICD patients in Iceland were compared with a group of pacemaker recipients attending the same outpatient clinic, at the University Hospital in Reykjavik. The study complied with the Declaration of Helsinki.

Subjects

Following review and approval by the Institutional Review Committee of Landspitali University Hospital and the Icelandic Data Protection Commission, a letter of invitation was sent to all ICD recipients in Iceland who were alive in January 2002. A similar letter was sent to a randomly selected comparison group of patients with pacemakers. The letter included information about the aims and possible benefits of the study, inclusion criteria for research and control subjects, and contact information if further details were required. To increase the power of the study and minimize the risk of age confounding the comparison, we divided both pacemaker and ICD patients into 10 year age bands and randomly selected approximately twice as many pacemaker patients as ICD recipients from each age band, hence broadly but not individually matching by age. Exclusion criteria included having major mental or physical disabilities and to be accordingly considered unable to answer the questionnaires by their caring physicians.

The subjects were offered participation during their next visit to the outpatient clinic at the University Hospital, but all ICD and the majority of pacemaker patients in Iceland are seen at this clinic. The ICD sample is therefore population based and the same applies to a similar degree to the comparison group.

Measures

We used four different questionnaires to assess anxiety, depression, psychiatric distress, and health-related QoL. An additional questionnaire was administered to address concerns, which might be of special relevance to ICD patients.

The Beck Anxiety Inventory (BAI) and The Beck Depression Inventory (BDI) were formulated by Beck *et al.*[13,14] Each questionnaire consists of 21 questions, which measure self-reported anxiety and depression.

The General Health Questionnaire (GHQ) is a screening tool to measure psychiatric distress (an indicator of psychiatric symptoms) related to general medical illness.[15,16] The questionnaire is available in four versions, differing in length. We used the 30-item version, which is the version recommended by the authors for screening purposes.

The Icelandic Quality of Life Questionnaire (IQL) was used to assess subjects' perception of their health-related QoL.[17,18] This is a recently developed generic 32-item questionnaire which measures 12 aspects of health-related QoL: general health, cognition, depression, social functioning, financial status, energy, anxiety, physical health, self-control, sleep, general well-being, and pain. It has in recent years been validated and used in a number of Icelandic studies.[17,19]

To address additional concerns of particular relevance to ICD patients, we used the ICD Psychosocial Index—a 14-item questionnaire formulated by McHugh-Schuster *et al.*[20] These authors used it in their study on QoL issues in ICD patients but have to our knowledge not validated it further. The inventory was translated into Icelandic and adjusted to our local clinical setting.

After signing an informed consent form, participants were asked to fill out these five questionnaires before they left the clinic.

Sampling and response rates

A letter of invitation with information about the study was sent to 44 ICD patients and 81 pacemaker patients in the beginning of 2002. ICD patients attend the outpatient clinic on average every 3 months and pacemaker patients on average every 6 months. We continued to enrol patients into the study for 17 months. One patient was excluded from the ICD group and three from the pacemaker group as they met the exclusion criteria. Two ICD patients and five pacemaker patients did not attend the clinic during the enrolment period, despite the invitation. Two pacemaker patients died during the study period.

All 41 ICD patients that attended the outpatient clinic during the study period accepted the invitation to participate in the study ($41/44 = 93\%$). Of 71 pacemaker patients who attended the clinic during the study period, 67 agreed to participate, but 6 patients who were allowed to complete the questionnaires at home failed to return them and therefore 61 responses were received ($61/81 = 75\%$).

Power

Power analysis indicated that the study should have >80% power to identify clinically relevant differences of 35 and 10% of either moderate or severe anxiety scores on the BAI among ICD patients and the comparison group of twice as many pacemaker recipients, respectively, at a 5% level of statistical significance. This is based on the assumption that 85–90% of the invited ICD and pacemaker patients accepted the offer of participation in the study.

Statistical analysis

All the questionnaires except the ICD Psychosocial Index rely on a summary of individual question scores rather than a mean score. In the event of missed answers on the IQL questionnaire, we corrected for such missed answers with mean scores for the relevant question from the patient's group as a whole (ICD or pacemaker patients). In line with authors' guidelines, missed answers on the GHQ, BAI, and BDI were given a score of 0. Questionnaires were excluded from the analysis if a patient failed to answer two or more questions on the relevant questionnaire.

The χ^2 test and Student's *t*-test were performed to evaluate differences in demographic data between the two groups. Mean values for BAI, BDI, and GHQ scores were compared between the groups using Student's *t*-test. Mean values for each aspect of the IQL and each question in the ICD Psychosocial Index were compared in the same manner. A conventional level of statistical significance was used ($\alpha = 0.05$) and all comparisons were two tailed. Because of the modest sample size, which limits the study's power to identify small or moderate effects, we did not correct for multiple testing. Results are presented as mean $\pm$ standard deviation (SD).

Results

Sample characteristics

Demographic comparisons are presented in *Table 1*. As shown in the table, the two groups were comparable and did not differ significantly with regard to age, sex, marital status, or occupational status. Time from implantation to the end of the study period was shorter among the ICD patients or 37.8 ± 28.6 months (range 11.6–154.9 months) compared with 76.6 ± 60.9 months for pacemaker patients (range 13.4–290.6 months) ($P < 0.001$).

Table 1 Demographic data for the ICD and pacemaker patient groups

	ICD patients	Pacemaker patients	*P*-value
Age			
Mean (SD)	61.8 (14.2)	63.8 (13.1)	NS
Range	23–85	19–82	
Gender (%)			
Male	28 (68.3%)	41 (67.2%)	NS
Female	13 (31.7%)	20 (32.8%)	NS
Time from implantation (months)[a]			
Mean (SD)	37.8 (28.6)	76.6 (60.9)	<0.001
Range	11.6–154.9	13.4–290.6	
Marital status (%)			
Married	31 (75.6)	41 (68.3%)	NS
Divorced	4 (9.8)	7 (11.7%)	NS
Single	4 (9.8)	4 (6.7%)	NS
Widowed	2 (4.9)	8 (13.3%)	NS
Occupation (%)			
Working	12 (29.3)	24 (40.7%)	NS
Disabled	12 (29.3)	7 (11.9%)	NS
Retired	15 (36.6)	24 (40.7%)	NS
Student	1 (2.4)	1 (1.7%)	NS
Unemployed	0 (0)	1 (1.7%)	NS
Domestic work	1 (2.4)	1 (1.7%)	NS
Sick leave	0 (0)	1 (1.7%)	NS

[a]Time from implantation of device till the end of the study period.

Outcome measures

As shown in *Figure 1*, the two groups did not differ significantly with regard to self-reported anxiety on the BAI (ICD patients: 8.0 ± 7.8; pacemaker patients: 7.7 ± 6.9; $P = 0.819$), self-reported depression on the BDI (ICD patients: 8.7 ± 6.3; pacemaker patients: 6.6 ± 6.7; $P = 0.121$), or overall psychiatric distress on the GHQ (ICD patients: 5.3 ± 5.9; pacemaker patients: 4.1 ± 5.3; $P = 0.320$). The 12 aspects of the IQL questionnaire did not show any significant difference between the two groups (*Figure 2*).

Some of the questions on the ICD Psychosocial Index revealed a marked numerical difference between ICD and pacemaker patients, although this fell just short of statistical significance (*Figure 3*). ICD patients expressed, for instance, more fear of device malfunction ($P = 0.084$), more fear of death ($P = 0.055$), greater concerns about not being able to work ($P = 0.061$), more worried about having sex ($P = 0.072$), and more worried about driving a car ($P = 0.080$). Nineteen of the 41 ICD patients (46.3%) had received shocks (median number of shocks 3, range 1–43). No statistical differences were found between ICD patients who had received shocks and those who had not on any of the inventories.

With the exception of more fear of death, fear of device malfunction, and fear of shocks on the ICD Psychosocial index, younger ICD patients (<60 years of age, $n = 16$) had better scores on the inventories than older ICD patients ($n = 25$). The difference was only statistically significant on the GHQ ($P = 0.002$).

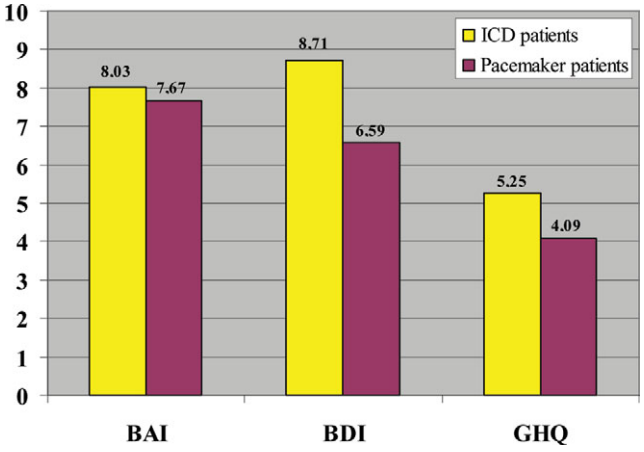

Figure 1 Scores for ICD and pacemaker patients on the BAI, BDI, and GHQ. No significant differences were found between the groups on any of the inventories.

Reference values

For the BAI, BDI, GHQ, and IQL, we plotted scores for the two patient groups against reference values used for these inventories. As shown in *Figure 4*, the total score for the 21 questions on the BAI ranges from 0 to 63. User guidelines refer to scores of 0–9 as minimal anxiety, 10–16 as mild, 17–29 as moderate, and 30–63 as severe anxiety.[16] Six of 40 ICD patients who completed the inventory scored 17 or above (15.0%) and would thus be classified as having moderate or severe anxiety. Seven of the 55 pacemaker patients completing the questionnaire scored 17 points or more (12.7%), ranking accordingly as moderately or severely anxious. Also for the BDI, scores range from 0 to 63 and are interpreted in the same manner as for the BAI (0–9 minimal depression, 10–16 mild, 17–29 moderate, 30–63 severe depression).[16] Four of 41 ICD patients scored 17 or above (9.8%) on the BDI, as did 2 of the 54 pacemaker patients (3.7%) who completed the questionnaire (*Figure 4*). For the 30-item GHQ, scores range from 0 to 30 using the GHQ scoring system.[16] Patients scoring 5 points or more are considered probable psychiatric cases. Of 40 ICD patients completing the questionnaire, 14 scored 5 points or more (35.0%) and 19 of 57 pacemaker patients would also be classified as probable psychiatric cases (33.3%) using the same cut-off (*Figure 5*). Concerning the IQL Questionnaire, scores for the two patient groups are compared graphically with reference values for healthy subjects 50–69-year-old, retrieved from the authors of the questionnaire (*Figure 2*).

Discussion

Contrary to our initial hypothesis, no significant differences were observed between ICD recipients and pacemaker patients in our nationwide population-based sample on anxiety, depression, or QoL. Although the ICD Psychosocial Index did indicate some differences between the two groups, ICD patients expressed more concerns about death and more fear of device malfunction and greater concerns about working, having sex, and driving a car, but these differences fell just short of statistical significance. These differences were, however, all in the same direction and possibly of some clinical relevance.

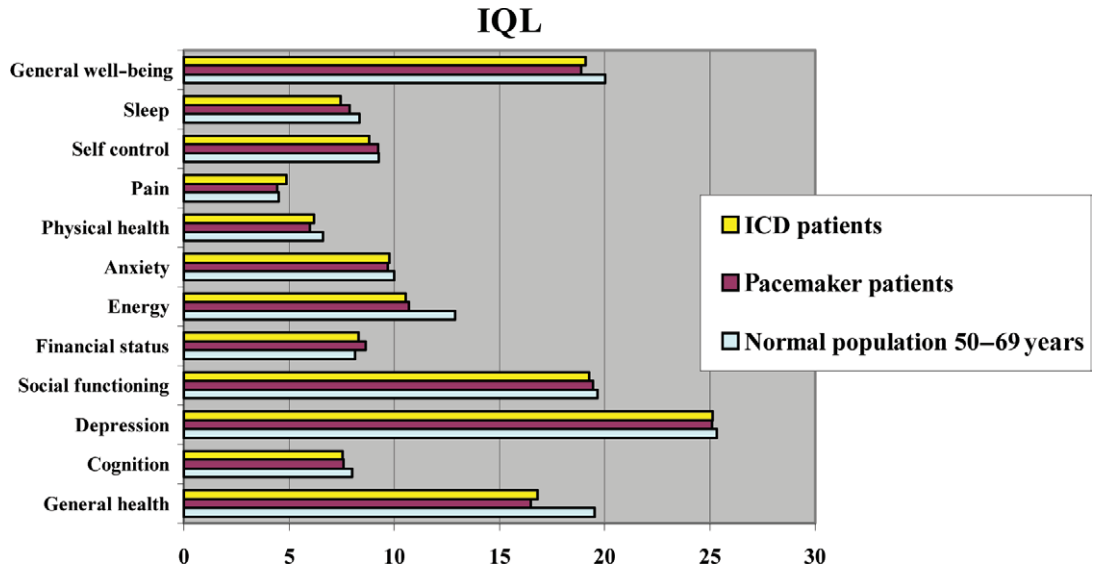

Figure 2 Outcome from the IQL. Unlike the BAI, BDI, GHQ, and ICD Psychosocial Index, the lower the score on the IQL, the worse the outcome. No significant differences were observed between ICD patients and pacemaker carriers on any of the 12 domains of the IQL. Comparisons with normal population values (age band 50–69 years) are shown.

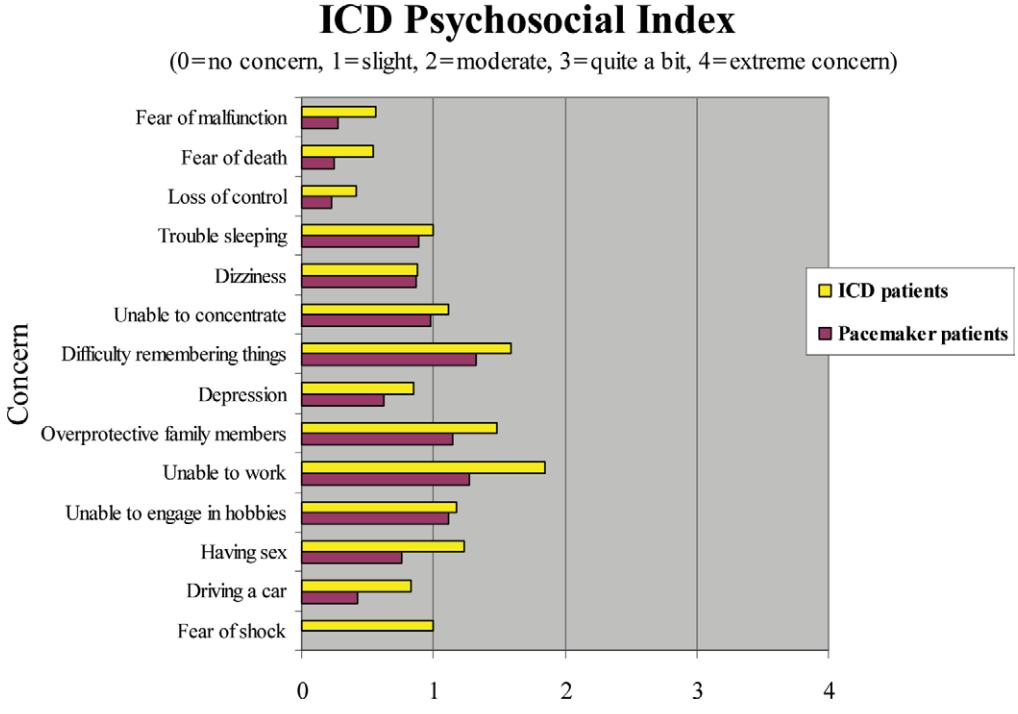

Figure 3 Outcome from the ICD Psychosocial Index. No items revealed a statistical difference between the two groups in our relatively modest sample.

The main strength of this study is the fact that it was population based and very high recruitment was attained for the ICD group, 93% of all living ICD recipients in Iceland taking part. Furthermore, several instruments were used to measure anxiety, depressive symptoms, general psychiatric distress, QoL, and concerns of particular relevance to patients with implanted cardiac devices.

Limitations

The present study had several limitations. First, and perhaps most significantly, the size of the study was modest. This limits the power to identify small- and medium-sized effects. Second, the response rate was somewhat lower in the pacemaker group (75 vs. 93%) and questions not answered were also more frequent in that group. This might partly be explained by the fact that the study was designed to evaluate anxiety, depression, and QoL among ICD patients, and as a result, the pacemaker group might not have been enthusiastic about participation. Third, we did not record underlying cardiac illnesses and co-morbidity for the patients, so any such differences between the two groups are unrevealed. For the same

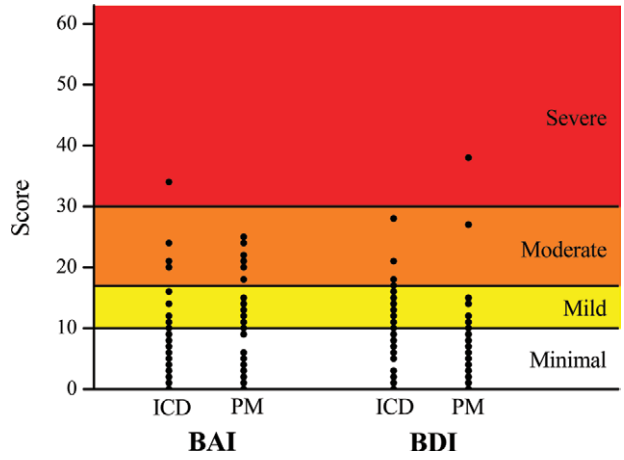

Figure 4 Score distributions for ICD and pacemaker patients on the BAI and BDI. According to reference values, patients scoring 17 points or more would be considered as having moderate or severe anxiety/depression. ICD, ICD patients; PM, pacemaker patients.

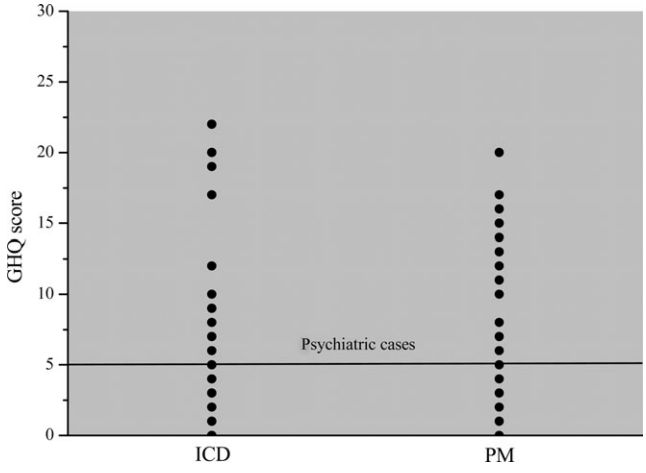

Figure 5 Score distributions for ICD and pacemaker patients on the GHQ, viewed against reference values. Subjects scoring 5 points or more are considered probable psychiatric cases. 35.0 and 33.3% of the ICD and pacemaker patients, respectively, scored 5 points or more ($P = \text{NS}$).

reason, the extent to which the underlying cardiac illness rather than the device itself affects QoL of the patients remains unknown. Other differences between the two study groups, such as circumstances leading to device implantation, age at implantation, time from implantation to conduction of the study, and the mere size of device implanted, may also be confounding factors. Fourth, the relatively low incidence of shocks received in the ICD group might partly explain the lack of difference between the two groups, but previous studies have indicated that it may affect the psychological well-being of ICD recipients.[21–24] Fifth, the fact that all of the measurements used in this study, apart from the ICD Psychosocial Index, are well known and widely used generic measures and not disease specific, could have affected the observed outcome. The use of such generic measures will, though, facilitate comparisons with other patient groups.

Anxiety

Most studies examining psychological disorders among ICD patients agree on anxiety being the one most commonly encountered in this patient group, with diagnostic rates for clinically significant anxiety ranging from 13 to 38%.[5,25] To our knowledge, only one study has previously been published, which compares QoL and signs of affective disorders between pacemaker and ICD patients. Duru *et al.*[26] evaluated QoL and signs of anxiety and depression in 76 patients with ICDs, compared with 76 patients with pacemakers in a recent paper. Probable anxiety disorder was encountered in 13.1, 9.7, and 13.3% of the pacemaker, non-shocked, and shocked ICD patient groups, respectively.[26] This is similar to the findings in our study, where 15.0% of the ICD patients and 12.7% of the pacemaker patients would be classified as having moderate or severe anxiety by means of their BAI scores. These relatively low percentages, compared with previous studies, might be partly explained by the fact that ICD technology has improved considerably over the last 10 years, with more arrhythmias being terminated by anti-tachycardia pacing techniques, resulting in fewer shocks actually being felt by the patients.[27]

Depression

A recent study by Ruo *et al.*,[28] on QoL among patients with coronary artery disease, showed that depression is a stronger indicator of poor QoL among this patient population than physiological measures of cardiac function, such as ejection fraction. In their study, 20% of the patient population had symptoms of major depression. In another study on depressive symptoms among patients with coronary artery disease, ~12% showed signs of moderate or severe depression by means of the BDI, at 18 months after myocardial infarction.[29] In our study, 9.8% of the ICD patients and 3.7% of the pacemaker patients met cut-off levels for moderate or severe depression by means of the BDI. Probable depressive disorder observed in the study of Duru *et al.*[26] were even lower, with 5.2% of the pacemaker patients and 6.5% ICD patients suffering from depression.

Quality of life

Originally, studies on QoL among ICD patients were mostly observational studies of limited size with no comparative groups.[6] More recently, QoL data have been emerging from the large randomized preventive ICD implantation and ICD vs. anti-arrhythmic drug trials, where QoL has been evaluated in subsamples of the patient populations and compared with medically treated patients.[7] Duru *et al.* evaluated QoL in their paper, with the ICD patients further divided into two groups, depending on whether they had received shocks. As in our study, no significant differences were observed on measurements of QoL between the two groups.

It may be the case that in spite of the ICD's ability to produce uncomfortable and unpredictable shocks, ICD patients are relatively positive towards their devices, because of their life-saving quality.[6] This might affect ICD patients' overall perspective and subjective QoL and nurture optimism, despite the seriousness of the underlying disease.

Even though QoL as a whole was not significantly different between our patient groups, various aspects of daily life,

affecting ICD patients' ability to adapt socially, seem to be of concern to this patient group. The ICD patients expressed somewhat more concerns about activities such as driving a car and having sex, about device malfunction, and about dying, with differences between the groups falling just short of statistical significance but being in the same direction for all items. This may not be surprising, because the ICD is literally a life-saving device and thus the possible consequences of device malfunction would be expected to be more distressing than for pacemaker patients. The unpredictability and discomfort of shocks are also probably an important contributing factor when considering concerns about driving a car and having sex. Studies have also shown that the recommended abstinence from driving after ICD implantation is very distressing for many ICD patients, as it hampers their ability to return to previous routines in their life.[30]

The observed difference between our two study groups and the normal population reference values on 'energy' and 'general health' aspects of the IQL questionnaire (*Figure 2*) is probably explained by the fact that the reference values are based on largely healthy individuals as opposed to individuals often with severe medical illnesses in our study groups. Conclusions about this difference must be drawn with some caution, because the populations also differ in other aspects, including age and sex to some degree.

ICD patients receiving shocks vs. those not having received a shock

When reviewing the literature, the majority of studies comparing QoL for shocked vs. non-shocked ICD patients reports a worse outcome for shocked ICD patients.[21–24] The AVID Trial (Antiarrythmics Versus Implantable Defibrillators Trial), CIDS (Canadian Implantable Defibrillator Study), and CABG Patch Trial research groups all reported either a stable or declining QoL for shocked ICD-patients over a 12 month follow-up period after ICD implantation, compared with that for non-shocked patients, with sample sizes ranging from 317 to 905 patients.[21–23] In our sample of 41 ICD patients, however, no statistical differences were observed on any of the questionnaires administered between shocked and non-shocked ICD patients. The risk of type II error has to be kept in mind when making such subgroup comparisons.

General psychiatric distress

Approximately 35% of both our patient groups showed signs of general psychiatric distress by means of the GHQ. This is compatible with psychiatric symptoms detected among patients seeking primary care.[31,32] Previous studies have shown that administering relatively simple measurement tools such as the GHQ can help to detect psychological symptoms that may otherwise not reach diagnostic thresholds, but which are associated with an increased risk of later developing psychiatric illness and disability.[32,33]

Future implications

Earlier studies and our own study indicate that both ICD patient and pacemaker patient populations include individuals at high risk of developing common mental disorders. To which extent the device itself, on one hand, and the underlying cardiac illnesses, on the other hand, play a role remains unanswered. Either way, it is necessary for healthcare personnel to be aware of signs and symptoms of anxiety and depression when attending to these patients. Preventive measures are also very important, with adequate patient education and awareness, support groups for patients, and family members having shown beneficial results for their psychological well-being.[34,35] We are therefore pleased to report that in the wake of this study, an ICD patient support network was set up among ICD patients in Iceland.

The fact that the ICD patients in our study expressed somewhat more concerns about specific activities such as driving a car and having sex, about device malfunction, and about dying raises the question whether this patient group might need a more standardized approach to prepare them for life with a defibrillator. A randomized controlled trial on whether specified patient education prior to implantation of an ICD might help to reduce these concerns is a highly relevant topic for further research.

Conclusions

Our study indicates that health-related QoL appears to be similar among ICD patients and pacemaker recipients. This is of importance in the light of the expanding use of ICDs in patients with coronary artery disease and a decreased ejection fraction. Nevertheless, individuals are found among both ICD and pacemaker patients who seem to suffer substantially from anxiety or depression. This study therefore supports the suggestions set out by others[28] that psychiatric co-morbidity is prevalent and perhaps more important among cardiac patients than previously acknowledged. Medical personnel attending these patients need to be aware of signs and symptoms of psychological distress and react to the patients' needs accordingly. More information prior to device implantation, improved access to psychiatric care resources during follow-up, and patient support groups might help to meet those needs. As a consequence, such resources could help to improve the health-related QoL of these patient groups.

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