How different from pacemaker patients are recipients of implantable cardioverter-defibrillators with respect to psychosocial adaptation, affective disorders, and quality of life?

F Duru, S Büchi, R Klaghofer, H Mattmann, T Sensky, C Buddeberg, R Candinas

Abstract

Objective—To assess differences in psychosocial adaptation, quality of life, and incidence of affective disorders between patients with pacemakers and those with implantable cardioverter-defibrillators (ICDs).

Design—Patients aged 40–70 years who underwent a first pectoral implantation of a pacemaker or an ICD system were studied. All subjects were asked to complete the hospital anxiety and depression scale (HAD), the short form general health survey (SF-36), and a specially designed device related questionnaire. Data analysis was performed for three patient groups: pacemaker (n = 76), ICD patients who received therapeutic shocks (n = 45), and ICD patients who did not receive shocks (n = 31).

Results—There were no differences between the three patient groups in HAD scores or in any of the SF-36 subscales or summary ratings. Probable depressive disorder (depression score > 10) was observed in 5.2%, 6.5%, and 6.6%, and probable anxiety disorder (anxiety score > 10) in 13.1%, 9.7%, 13.3% of the pacemaker, non-shocked ICD, and shocked ICD patients, respectively. There were no sex differences. However, patients in the shocked ICD group were more likely than those in the other groups to report limitations in their leisure activities, to perceive their device as a "life extender," and to admit anxiety about battery depletion and technical problems. Forty per cent of shocked ICD patients would be interested in joining a support group.

Conclusions—Despite having distinctly different medical histories and treatments, patients with pacemakers and ICDs responded similarly to validated tools of health status assessment. ICD patients who had received shocks perceived their device as prolonging their life and had greater anxiety about technical problems. Their endorsement of the potential benefits of a support group warrants further investigation.

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Arrhythmia Unit, Division of Cardiology, Department of Internal Medicine, University Hospital, Rämistr 100, 8091 Zurich, Switzerland
F Duru
H Mattmann
R Candinas

Department of Psychiatry and Psychosocial Medicine, University Hospital, Zurich
S Büchi
R Klaghofer
C Buddeberg

Division of Neurosciences and Psychological Medicine, Imperial College School of Medicine, West Middlesex University Hospital, Middlesex, UK
T Sensky

Correspondence to:
Dr Duru
firat.duru@dim.usz.ch

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Introducing a foreign body into the heart, a part of the human anatomy that symbolically represents emotions, may be considered a major life event. In this respect, implantation of a pacemaker or an implantable cardioverter-defibrillator (ICD) in a patient may result in a change in the body image, cause problems in psychosocial adaptation and quality of life, and contribute to the development of affective disorders.

Since the introduction of permanent pacemakers for the treatment of bradyarrhythmias in 1958, many investigators have studied psychological wellbeing in this patient group, and it has been found that, in general, the implantation of a permanent pacemaker improves health related quality of life.[1–5] The introduction of ICD treatment in 1980 opened a new era in the field of cardiac rhythm management. Clinical experience suggests that ICDs can reduce the incidence of sudden cardiac death in selected patients with malignant ventricular tachyarrhythmias.[6 7] Until recently, ICDs have been bulkier than pacemakers, but smaller devices are now available which, like pacemakers, are implanted in the pectoral region. Superficially, whether a patient receives a pacemaker or an ICD, they will ultimately have the experience of a foreign device implanted into the body. Moreover, the same clinicians tend to be involved in the implantation and follow up of both pacemaker and ICD patients. However, ICD discharges (shocks) are often painful and are delivered at unpredictable times, whereas pacemaker stimulation is hardly ever felt by the patients. These differences would be expected to influence the patients' perception of the implants and their appraisal of their quality of life.

Clinicians are usually unaware of the psychosocial impact of implanted pacemakers and ICDs. Because of the complexity of these devices, there is a tendency for outpatient visits to be concentrated mainly on the technical aspects of device function, with the risk that psychosocial factors may be ignored. For this reason, a better understanding of factors likely to contribute to patients' perception of their health would be helpful in their management and in the training of clinicians.

In this study we aimed to investigate some of these factors. Given the difference in intrusiveness of the two devices, we expected that there would be reduced health related quality of life and increased anxiety and depression in the ICD group compared with the pacemaker group. The difference between ICD and pacemaker patients was expected to be greatest in

Table 1 Specially designed questionnaire used in the study

1	To what extent do you feel physically impaired by the implanted device (pacemaker, defibrillator)?				
	□ No impairment	□ Limited impairment	□ Considerable impairment	□ Disabling impairment	
2	How often do you think about the implanted device?				
	□ Never	□ Sometimes	□ Several days a week	□ Every day	
3	Did you feel depressed when you were informed about the necessity of a device implantation?				
	□ No	□ Yes, to some degree	□ Yes, considerably	□ Yes, very much	
4	Since implantation, to what extent are you preoccupied with your heart condition?				
	□ None	□ To some degree	□ Considerably	□ Very much	
5	Did the implanted device change your image of your body?				
	□ Yes	□ No			
6	To what extent do the visible changes at the implantation site disturb you?				
	□ Does not disturb	□ To some degree	□ Considerably	□ Very much	
7	Does the implanted device disturb you in daily life?				
	□ No	□ Yes, a little	□ Yes, considerably	□ Yes, very much	
8	Does the implanted device disturb you in your leisure activities?				
	□ No	□ Yes, a little	□ Yes, considerably	□ Yes, very much	
9	Do you have anxiety about premature battery depletion?				
	□ No	□ Yes, a little	□ Yes, considerably	□ Yes, very much	
10	Do you have anxiety about malfunction of the implanted device?				
	□ No	□ Yes, a little	□ Yes, considerably	□ Yes, very much	
11	How well are you informed about the implanted device?				
	□ Badly	□ Moderately	□ Well	□ Very well	
12	How well are you informed about your heart disease?				
	□ Badly	□ Moderately	□ Well	□ Very well	
13	Is the implanted device a source of security for you?				
	□ No	□ A little	□ Considerably	□ Very much	
14	Is the implanted device a life extender for you?				
	□ No	□ A little	□ Considerably	□ Very much	
15	Is the implanted device a source of anxiety for you?				
	□ No	□ A little	□ Considerably	□ Very much	
16	Would you rather have more frequent appointments with your physician?				
	□ Yes	□ No			
17	Would you rather have longer appointments with your physician?				
	□ Yes	□ No			
18	Would you also consider having psychological or psychotherapeutic support?				
	□ Yes	□ No			
19	Would you also consider being involved in a support group?				
	□ Yes	□ No			
20	Do you believe that the public should be better informed about the implantable devices for heart diseases?				
	□ Yes	□ No			
21	How do you feel now as compared to your status before the implantation?				
	□ Worse	□ Same	□ Better		
22	How long did it take you to adjust the implanted device?				
	□ Less than 1 month	□ Up to 6 months	□ Up to 1 year	□ Up to 2 years	□ Not yet
23	Overall, was it worthwhile having the device implanted?				
	□ No	□ Probably	□ Yes		

the subgroup of ICD patients who experienced therapeutic shocks from their ICD.

Methods

PATIENTS

We enrolled 210 patients, aged 40–70 years, undergoing their first pectoral implantation of a pacemaker (n = 124) or an ICD (n = 86) between 1993 and 1999 at the University Hospital of Zurich. Hospital ethics committee approval was obtained before the study. The physician or the pacemaker/ICD nurse informed the patients about the nature of the study, either during an outpatient visit or by telephone. All patients were studied more than six months after device implantation.

QUESTIONNAIRES

All subjects were asked to complete identical questionnaires, which were mailed to them. Quality of life and affective symptoms were assessed using validated instruments, as follows.

The *medical outcomes study general health survey short form questionnaire* (SF-36), which has accepted validity and reliability, was administered to assess the general health status. The SF-36 comprises eight multi-item scales, including physical functioning, social functioning, role limitations because of physical problems, role limitations because of emotional problems, mental health, energy and vitality, pain, and general perceptions of health. All these subscales contribute to physical and mental summary scores.[8]

Anxiety and depression were assessed using the *hospital anxiety and depression scale* (HAD), a reliable measure in people with physical illness.[9]

In order to assess the patients' perceptions of an implanted device, a specifically designed questionnaire was also used (table 1). This questionnaire addressed 23 device specific questions, which would apply to both the pacemaker and the ICD populations, and aimed to assess different aspects of an implanted device, such as perceptions of the device, technical concerns, and individual needs of patients. The questions used in the questionnaire were developed by the clinical team, based on their previous experience of work with patients with implanted devices.

Table 2 Sociodemographic characteristics of the three groups

	Pacemaker	ICD (no shock)	ICD (shock)
Number of patients	76	31	45
Male	50	27	37
Female	26*	4	8
Age (years) (mean (SD))	59.4 (9.9)	56.2 (12.8)	59.7 (13.0)
Civil status (n)			
Married	54	27	34
Divorced/separated	12	0	6
Widowed	4	2	3
Single	6	2	2
Work status (n)			
Full time	16	14	9
Part time	9	4	6
Unemployed	2	1	1
Retired	33	8	18
Invalid	8	2	10

*$p < 0.05$ *v* the other two groups.
ICD, implantable cardioverter-defibrillator.

STATISTICS

Besides descriptive statistics, χ^2 analysis and one way analysis of variance with Scheffé post hoc tests were performed to assess any differences in the characteristics of the comparison groups. A probability value of $p < 0.05$ was considered significant.

Table 3 Results of hospital anxiety and depression (HAD) scale and short form 36 (SF-36) general health survey in the three patient groups

	Pacemaker	ICD (no shock)	ICD (shock)	p Value
HAD scale				
Anxiety score	5.4 (4.0)	6.0 (4.3)	5.8 (3.8)	NS
Depression score	4.1 (3.8)	3.9 (4.0)	4.4 (3.9)	NS
SF-36 general health survey				
Physical functioning	67.3 (27.4)	72.2 (30.4)	71.2 (20.1)	NS
Physical role	57.6 (30.2)	60.3 (25.5)	59.0 (24.8)	NS
Bodily pain	49.8 (26.8)	54.4 (23.8)	49.9 (23.2)	NS
General health	57.9 (14.0)	57.3 (10.7)	58.1 (12.1)	NS
Vitality	49.8 (12.4)	50.3 (9.7)	49.6 (11.2)	NS
Social functioning	29.0 (13.9)	27.0 (8.0)	28.4 (9.1)	NS
Emotional role	69.2 (43.9)	71.3 (38.6)	83.8 (31.1)	NS
Mental health	61.7 (8.1)	61.8 (6.7)	58.0 (13.9)	NS
Mental component score	41.1 (5.3)	39.5 (4.9)	41.3 (6.8)	NS
Physical component score	42.3 (6.9)	45.0 (3.8)	42.4 (6.2)	NS

Values are mean (SD).
ICD, implantable cardioverter-defibrillator.

Table 4 Responses to the specifically designed questionnaire

	Pacemaker	ICD (no shock)	ICD (shock)	p Value
1. Physical discomfort/limitations	1.65 (0.78)	1.74 (0.78)	1.93 (0.70)	NS
2. Constant awareness of a device	2.15 (0.71)	2.58 (0.89)	2.44 (0.99)	NS
3. Depressed because of device need	1.85 (0.89)	2.03 (1.05)	1.96 (1.00)	NS
4. Preoccupation with heart	1.87 (0.79)	2.23 (0.62)	2.32 (0.88)	NS
5. Change in body image	1.74 (0.44)	1.65 (0.49)	1.66 (0.48)	NS
6. Dislike of new body image	1.46 (0.74)	1.52 (0.63)	1.49 (0.55)	NS
7. Limitations in daily living	1.47 (0.79)	1.52 (0.72)	1.73 (0.91)	NS
8. Limitations in leisure activities	1.47 (0.76)	1.45 (0.72)	1.91 (0.87)	< 0.05
9. Anxiety about battery depletion	1.43 (0.64)	1.19 (0.40)	1.60 (0.75)	< 0.05
10. Anxiety about technical failure	1.50 (0.70)	1.19 (0.40)	1.69 (0.87)	< 0.05
11. Well informed about device	3.00 (1.53)	3.06 (0.73)	3.20 (0.67)	NS
12. Well informed about disease	3.07 (0.75)	3.07 (0.58)	3.13 (0.73)	NS
13. Device as "source of security"	2.91 (0.91)	3.20 (0.71)	3.11 (0.86)	NS
14. Device as "life extender"	2.51 (1.10)	2.45 (0.99)	3.07 (0.91)	< 0.05
15. Device as "source of anxiety"	1.26 (0.57)	1.47 (0.68)	1.53 (0.73)	NS
16. Request for more follow ups	7.9%	0.0%	2.2%	NS
17. Request for longer follow ups	9.3%	6.5%	6.7%	NS
18. Request for psychotherapy	9.2%	6.5%	8.9%	NS
19. Request for support group	19.7%	20.0%	42.2%	< 0.05
20. Need for better public awareness	67.1%	73.3%	64.4%	NS
21. General wellbeing				NS
Worse	10.5%	9.7%	20.0%	
Same	31.6%	48.4%	26.7%	
Better	57.9%	41.9%	53.3%	
22. Duration of adjustment				NS
< 1 month	44.7%	29.0%	22.2%	
< 6 months	35.5%	38.7%	48.9%	
< 1 year	14.5%	22.6%	22.2%	
< 2 years	2.6%	3.2%	4.4%	
Never	2.6%	6.5%	2.2%	
23. Implantation worthwhile in general	77.7%	67.7%	86.7%	NS

Values are mean (SD).

Results

Seventy six patients in the pacemaker group and 76 in the ICD group returned the questionnaires. Response rate was 61.3% in the pacemaker group and 88.4% in the ICD group ($p < 0.05$). Time since implantation was 3.1 years in the pacemaker group and 2.3 years in the ICD group ($p < 0.05$). The calculated body mass index was comparable in both populations (pacemaker group 26.4, ICD group 26.1).

The main indication for pacemaker implantation was atrioventricular block in 42 patients, sick sinus syndrome in 28, and atrial fibrillation with bradycardia in six. Fifty six patients received dual chamber pacemakers (DDDR), 16 received single chamber pacemakers (VVIR), and four had VDD systems with single pass leads. In the ICD group, 49 patients had coronary artery disease, 10 had idiopathic cardiomyopathy, six had arrhythmogenic right ventricular dysplasia, three had hypertrophic cardiomyopathy, and five had other underlying cardiac pathologies. In the remaining three patients, ventricular tachyarrhythmias were idiopathic.

For purposes of this study, ICD patients were analysed in two separate groups—those who had and those who had not experienced device discharges (shocks). The mean (SD) number of shocks, as determined by the stored event data in the ICDs, was 5.4 (11.3) per patient (range 0–66); 42.1% of the sample had received no shocks, 13.2% had received one shock, 15.8% two to four shocks, 13.2% five to 10 shocks, and 17.1% more than 10 shocks.

There were significantly more female patients in the pacemaker group than in the ICD groups ($p < 0.05$). A history of previous myocardial infarction was present in nine patients in the pacemaker group (12%), 17 in the non-shocked ICD group (55%), and 28 in the shocked ICD group (62%) ($p < 0.01$). There were more patients with heart failure (New York Heart Association functional class II or higher) in the ICD group (58% in the non-shocked patients and 76% in the shocked patients) than in the pacemaker group (19%) ($p < 0.01$). Other sociodemographic properties of the three groups were comparable (table 2).

There was no difference between the three groups with respect to scores on any aspect of the HAD and SF-36 (table 3). Probable depressive disorder (HAD depression score > 10) was observed in 5.2%, 6.5%, and 6.6% of the pacemaker, non-shocked ICD, and shocked ICD patients, respectively (NS). Somewhat higher prevalences were encountered for probable anxiety disorder (HAD anxiety score > 10) (pacemaker group 13.1%, non-shocked ICD group 9.7%, shocked ICD group 13.3%) (NS). The derived physical and mental component scores were also comparable in all three groups. Similarly, no differences were found when the combined ICD group (shocked and non-shocked) was compared with the pacemaker group. There were no differences with respect to sex.

The responses to the specially designed questionnaire revealed some differences between the groups (table 4). Patients in the

shocked ICD group reported more limitation in their leisure time activities than patients in the other two groups ($p < 0.05$). They perceived the device as a "life extender" ($p < 0.05$), and were particularly anxious about the battery running out ($p < 0.05$) and about technical failure of their device ($p < 0.05$). There was a greater demand for a support group in the shocked ICD group (42.2%) than in the non-shocked ICD group (20.0%) or the pacemaker group (19.7%) ($p < 0.05$).

Discussion

This is the first reported comparative evaluation of psychosocial adaptation and affective disorders in patients with pacemakers and ICDs. From their demographic and clinical profile, the patients recruited into this study were representative of the typical patient population of an urban tertiary care centre pacemaker/ICD clinic. The response rate to the questionnaires among our pacemaker patients (63.1%) compares well with that in previous studies.[10 11] The response rate among ICD patients (88.4%) was significantly higher ($p < 0.05$), which is to be expected. While pacemaker patients attend the clinic only every 9–12 months, those with ICDs usually attend every three months, or exceptionally less often, and are encouraged to contact the clinic between their scheduled visits when experiencing problems. As a result, ICD patients are likely to feel more closely linked with the clinic and may therefore be keen to cooperate, and in some cases may even feel dependent on the clinic.

The SF-36 is a widely used instrument, validated across different clinical conditions. Contrary to expectations, no difference was found in SF-36 scores between the pacemaker and the ICD groups. There are several reasons why ICD patients might rate their health status more favourably than expected. First, these patients might make comparisons between themselves and people who are seriously ill, notably those with cardiac arrhythmias who are not candidates for ICD implantation. Secondly, among those who experience therapeutic shocks from their devices, these unpleasant experiences may serve as reminders of how the device has a life preserving function in the presence of arrhythmias.

It is well recognised that permanent pacemakers improve health related quality of life.[1–5] In contrast, improvement in health status in ICD recipients is somewhat controversial. Lüderitz and colleagues suggest that in the majority of patients who receive an ICD there is improvement in quality of life 12 months after implantation.[12–14] However, Herrmann and associates found that a subgroup of about 15% of patients—particularly those who had frequent therapeutic shocks from their ICDs—experienced psychological distress and reduced quality of life, and suggested that these patients should receive special care.[15] More recently, Heller and colleagues have identified depressive responses and heightened health concern in 20–58% of ICD patients, which adversely affects their quality of life.[11]

Depression and anxiety are reported to be more common in patients with permanent pacemakers than in the general population. Aydemir and colleagues, using a modified Hamilton depression rating scale, reported that 19.1% of pacemaker patients warranted a psychiatric diagnosis, and 10.7% were clinically depressed.[16] In ICD patients depression of moderate severity was identified in 35% of cases using the Beck depression inventory (BDI).[10] In our study population, the prevalence of affective disturbance was relatively low. Though it was anticipated that shocked ICD patients would have higher levels of anxiety and depression than non-shocked ICD patients or patients with pacemakers, no such differences were found. These results also contradict earlier findings.[17 18] Unlike the BDI and the Hamilton scale, the HAD used in our study was specifically designed for use in samples with physical illness, and does not involve rating somatic features of depression. It is possible that previous studies have overestimated the prevalence of affective disorders. Also, to the extent that affective disturbance may be related to the severity of the patient's physical state, anxiety or depression may have been associated more with older devices (that is, first or second generation ICDs) than with the more modern ones used in our study.

Data from our specifically designed device related questionnaire show that the shocked ICD patients were more likely to regard their device as essential to keeping them alive and also expressed greater anxiety about battery depletion and technical failure than the pacemaker patients and the non-shocked ICD patients. Several factors might contribute to this. Device discharges in ICD recipients who are awake at the time of the shock create an unpleasant experience, whether the shocks are appropriately delivered or not. The shock experience is often described as a "lightning-like blow" to the chest or likened to "being kicked by a horse."[19] The most distressing aspects of receiving a shock are the lack of warning, multiple shocks, and progressively increased sensations with multiple shocks.[20] Generalised nervousness and fear, dizziness, weakness, nausea and vomiting, palpitations, and chest soreness have often been reported.[20] These circumstances may create a constant anticipation of further shocks at unpredictable times. They also display a constant struggle between experiencing unpleasant shocks and fear of sudden death. Thus these devices are sources of anxiety but are also perceived as offering an opportunity to prolong survival.

Psychosocial interventions may be helpful in reducing psychopathology and its potential consequences in pacemaker and ICD patients after device implantation. The shocked ICD group in particular endorsed the need for a support group, suggesting that this intervention might appropriately focus on mechanisms of coping with the anticipation of receiving unpleasant shocks. Heller and colleagues have shown that 96% of ICD patients who attended

support groups found them very helpful.[11] Support group participants reported feeling healthier than before implantation, better able to work, and more interested in attending social occasions. In addition, those patients who were most enthusiastic about the help derived from the group were happier and less preoccupied with thoughts of dying. On the other hand, approximately 20% of the pacemaker and the non-shocked ICD patients also requested support group participation. Therefore, as an integral part of routine clinical management, clinics might aim to organise support groups for all device recipients who wish to take advantage of such groups. Educational interventions might incorporate knowledge about the effects of devices, to facilitate anticipatory guidance and strengthen preparation of both the patient and family members for ICD device discharge. Whether such groups can demonstrate their clinical effectiveness remains to be seen, but the patients' perceived need for them should encourage appropriate outcome studies to be undertaken.

LIMITATIONS

Our study was cross sectional and was based on self report questionnaires. Being cross sectional, no inferences can be drawn from the study of how health status or affective disturbances might change over time. Although the response rate to the questionnaires compared favourably with those in previously published studies, it remains possible that our sample was self selected to some extent. However, against this is the fact that the sociodemographic and clinical profiles of the three groups studied resemble those of the clinic as a whole and also accord with patient profiles in other clinical studies of similar patients. To the extent that the patients' responses are dependent on their recollection of the actual implantation of their device, it may be important that the time since implantation was significantly greater for pacemaker patients than for those with ICDs. This is to be expected given that in recent years the rate of pacemaker implantation has remained fairly constant, while that of ICD implantation has risen considerably.

CONCLUSIONS

Despite having distinct differences in underlying heart disease and types of treatment delivered, patients with pacemakers and ICDs (whether they experienced shock delivery or not) responded similarly to validated tools of health status assessment. However, shocked ICD patients perceived their device as prolonging their lives, and admitted higher levels of anxiety over the device's functioning. A large proportion of the patients, particularly in the shocked ICD group, indicated that they would like to join a support group if one were available. It would be appropriate to evaluate whether such a support group might be of benefit to patients' families as well as to the patients themselves.

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