Fear of exercise and health-related quality of life in patients with an implantable cardioverter defibrillator

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Several studies have reported improved survival rates thanks to the use of an implantable cardioverter defibrillator (ICD) in the treatment of patients with life-threatening arrhythmia. However, the effects of the ICD on healthrelated quality of life (HR-QoL) of these patients are not clear. The aim of this study is to describe HR-QoL and fear of exercise in ICD patients. Eighty-nine ICD patients from the University Hospital in Groningen, the Netherlands, participated in this study. HR-QoL was measured using the Rand-36 and the Quality of Life After Myocardial Infarction Dutch language version guestionnaires. Fear of exercise was measured using the Tampa Scale for Kinesiophobia. Dutch version and the Fear Avoidance Beliefs Questionnaire, Dutch version. Association between outcome variables was analysed by linear regression analyses. Study results show that the HR-QoL of patients with ICDs in our study population is significantly worse than that of normal healthy people. Furthermore, fear of exercise is negatively associated with HR-QoL corrected for sex, age and number of years living with an ICD. After implantation of the ICD, patients with a clear fear of exercise should be identified and interventions should be considered in order to increase their HR-QoL.

Plusieurs études ont rapporté que les taux de survie avaient été améliorés grâce à l'usage d'un défibrillateur implantable (DI) pour traiter les patients avec une arythmie menaçant le pronostic vital. Cependant, on ne sait pas encore très bien quels effets le DI a sur la qualité de vie associée à la santé (QdV-AS) de ces patients. Cette étude a pour objectif de décrire la qualité de vie associée à la santé et la crainte de faire des exercices ressentis par les porteurs d'un DI. 89 patients porteurs d'un DI de l'hôpital universitaire de Groningen, aux Pays-Bas, ont participé à cette étude. La qualité de vie associée à la santé a été mesurée au moyen du Questionnaire Rand-36 et du Questionnaire sur la Qualité de vie après un infarctus du myocarde, Version en Hollandais (QoLMI-DLV). La crainte de faire des exercices a été mesurée au moyen de l'Echelle Tampa pour Kinesiophobie, Version hollandaise (TSK-DV) et le Questionnaire sur les Croyances en matière d'évitement de la crainte, Version hollandaise (FABQ-DV). L'association entre les variables relatives au dénouement a été analysée par des analyses de régression linéaire. Les résultats de l'étude montrent que la qualité de vie associée

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population étudiée est bien pire que celle des personnes saines normales. Qui plus est, la crainte de faire des exercices est négativement associée à la HR-QoL après avoir effectué les corrections tenant compte du genre, de l'âge et du nombre d'années de vie avec un DI. Après implantation du DI, les patients ressentant une véritable crainte des exercices devraient être identifiés et des interventions devraient être envisagées pour améliorer leur qualité de vie associée à la santé. In zahlreichen Studien wurde über verbesserte Überlebensraten bei der Behandlung von Patienten mit lebensbedrohlichen Arrhythmien dank der Verwendung eines implantierbaren Cardioverter-Defibrillators (ICD) berichtet. Jedoch sind die Auswirkungen des ICDs auf die gesundheitsbezogene Lebensqualität (HR-QoL) dieser Patienten unklar. Das Ziel dieser Studie ist die Beschreibung der gesundheitsbezogenen Lebensqualität und der Angst vor körperlicher Betätigung bei ICD-Patienten. An dieser Studie nahmen 89 ICD-Patienten der Universitätsklinik Groningen, Niederlande, teil. Die gesundheitsbezogene Lebensqualität wurde mit den niederländischen Versionen der Fragebogen Rand-36 und Quality of Life after Myocardial Infarction (QoLMI-DLV) ermittelt. Die Angst vor körperlicher Betätigung wurde mit der niederländischen Version der Fragebogen Tampa Scale for Kinesiophobia (TSK-DV) und Fear Avoidance Beliefs Questionnaire (FABQ-DV) gemessen. Der Zusammenhang der Parameter wurde mittels linearer Regressionsanalyse bestimmt. Die Studienergebnisse zeigen, dass die HR-QoL von Patienten mit ICDs in unserem Studienkollektiv signifikant schlechter ist als bei normal gesunden Menschen. Weiterhin ist die Angst vor körperlicher Betätigung negativ mit der um Geschlecht, Alter und Anzahl der Jahre mit ICD bereinigten HR-QoL assoziiert. Nach Implantation des ICDs sollte festgestellt werden, welche Patienten eine deutliche Angst vor körperlicher Betätigung haben und es sollten Maßnahmen überlegt werden um die gesundheitsbezogene Lebensqualität dieser Patienten zu erhöhen.

à la santé (HR-QoL) des patients porteurs d'un DI dans la

Varios estudios han informado de mejoría de las tasas de supervivencia con la utilización de un desfibrilador cardioversor implantable (DCI) para el tratamiento de pacientes con arritmias peligrosas para la vida. Sin embargo, los efectos del DCI en la calidad de vida relacionada con la salud (CdV-RS) de estos pacientes no están claros. El objetivo de este estudio es describir la calidad de vida relacionada con la salud y el miedo al ejercicio físico en los pacientes con DCI.

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DOI: 10.1097/01.mrr.0000070758.63544.2c

En este estudio participaron 89 pacientes con DCI del Hospital Universitario de Groninga, Países Bajos. La calidad de vida relacionada con la salud se midió utilizando los cuestionarios Rand-36 y la versión en neerlandés del Cuestionario de calidad de vida después de un infarto de miocardio (QoLMI-DLV). El miedo al ejercicio físico se midió utilizando las versiones en neerlandés de la Escala de cinesiofobia de Tampa (TSK-DV) y del Cuestionario sobre las creencias que evitan el miedo (FABQ-DV). La asociación entre las variables de valoración se determinó mediante análisis de regresión lineal.

Los resultados del estudio muestran que la CdV-RS de los pacientes con DCI en la población de nuestro estudio es significativamente peor que la de las personas sanas normales. Además, el miedo al ejercicio físico está inversamente relacionado con la CdV-RS corregida para

Introduction

An implantable cardioverter defibrillator (ICD) has been used frequently since the 1990s in the treatment of patients with life-threatening arrhythmia (Carroll et al., 1999). The ICD is used to pace, convert and defibrillate survivors of sudden cardiac arrest, ventricular tachycardia and ventricular fibrillation or in prophylaxis for patients with a left ventricular ejection fraction lower then 35% or with past myocardial infarction (Connolly, 1998; McHugh-Schuster et al., 1998). There have been a number of studies reporting improved ICD patient survival compared to patients without ICD (Bainger and Fernsler, 1995; Wever et al., 1996; Cappato, 1999; Hider, 1999; Connolly et al., 2000). The device, however, may have major effects on the health-related quality of life (HR-QoL) of those patients. HR-QoL consists of different domains that refer to areas of behaviour or experience. These domains include physical, psychological, social and occupational functioning (and other roles) and perceptions about health status (Swenson and Clinch, 2000).

One would think that an ICD would make patients less fearful than other cardiac patients. Although implantation relieves much of the fear of sudden death and is welcomed by patients, Lewin *et al.* (2001) indicate it also imposes new fears and has its own set of negative effects. The most potent source of distress that is unique to ICD patients is the effect of experiencing or anticipating firings. A firing is usually highly aversive and is accompanied by acute pain and anxiety. Often the patient becomes unconscious. Many patients report a feeling of dread or helplessness that can persist for hours or even days after a firing.

In some patients, the unpredictability of firings can produce an almost permanent state of anticipatory tener en cuenta el género, la edad y el número de años vividos con un DCI.

Tras la implantación del DCI, debe identificarse a los pacientes que tienen un miedo manifiesto al ejercicio físico y hay que considerar las intervenciones que puedan aumentar su calidad de vida relacionada con la salud. *International Journal of Rehabilitation Research* 26:117–122 © 2003 Lippincott Williams & Wilkins.

International Journal of Rehabiliation Research. 2003, 26:117-122

Keywords: health-related quality of life, fear of exercise, myocardial infarction, implantable cardioverter defibrillator, arrhythmia

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anxiety. Some may become reluctant to socialize and even become reclusive because of the social embarrassment a firing may cause. Approximately 90% of patients attribute each firing to a specific preceding cause. It is most commonly attributed to a physical activity such as walking or gardening, or related to stress or excitement, as can be the case when watching a football match or simply worrying. Attributing a cause this way can lead to an increasingly restricted and unsatisfying lifestyle as more and more activities are struck off the patients' repertoire by themselves or their spouses (Lewin *et al.*, 2001).

HR-QoL of ICD patients has been studied before but the results of these studies are not conclusive. In some studies an improvement in HR-QoL was found after ICD implantation (Lüderitz *et al.*, 1994; May *et al.*, 1995; Chevalier *et al.*, 1996), but Bainger and Fernsler (1995) found no change and Carroll *et al.* (1999) found a decline in HR-QoL.

The outcomes of the different studies that compared quality of life of ICD patients, to that of normal healthy individuals are not consistent either. One study (Sauvé, 1995) reported a significantly poorer physical function in ICD patients but no differences in psychological functioning. Arteaga and Windle (1995) found quality-of-life scores in patients with an ICD similar to those of normal healthy individuals. Gallagher *et al.* (1997), on the other hand, found that recipients of an ICD are more depressed, stressed, confused and angry than the normal population. This suggests a poorer mental health of patients with an ICD than of normal individuals.

Fear of exercise is common in all types of patients. For example, patients with low back pain refrain from exercise and sports because they are afraid of recurring pain (Keen *et al.*, 1999). Cancer patients are unwilling to exercise because of their weakened physical and emotional condition (Courneya *et al.*, 2000). This is a particularly important quality-of-life aspect for patients with cardiovascular disease, who often perceive anxiety, depression and deceptive health beliefs. They resort to unhelpful coping strategies and avoidance of activity, which can lead to poor adjustment (Lewin *et al.*, 2001).

In the case of ICD patients, tachyarrhythmias may occur during exercise testing or training and require special attention (Vanhees *et al.*, 2001). However, according to Lampman and Knight (2000) most ICD patients are able to exercise safely if given appropriate clinical guidelines. In many cases, patients with an ICD can resume relatively normal exercise routines and can even participate in rather vigorous activities (Kelly, 1995). This is even more important because physical activity is considered a potential important determinant of HR-QoL.

Until now, the relationship between fear of exercise and HR-QoL in ICD patients has not been studied explicitly. The aim of this study is to describe HR-QoL, fear of exercise and their relationship in ICD patients.

Materials and methods Participants

Patients treated with an ICD between December 1995 and May 2001 at the Groningen University Hospital were eligible for participation in this study. Excluded were those under the age of 18, non Dutch-speakers and patients with severe comorbidity or other factors that may influence the results of the study. Of the 179 eligible patients, 95 consented to participate. Of these 95, six were excluded because of the above-mentioned criteria.

Procedure

After informed consent, participants were asked to fill in a set of questionnaires. The questionnaires were completed at an undefined point in the treatment. HR-QoL was quantified using two questionnaires, the Rand-36 and the Quality of Life After Myocardial Infarction Dutch language version (QoLMI-DLV), originally composed by T.K. Hillers et al. in 1994. The Rand-36 consists of the following components: physical functioning, emotional functioning, mental health, pain, general health belief, change in health, restricted role due to physical problems, restricted role due to emotional problems and vitality. The higher a score on the Rand-36, the better the HR-QoL of the patient. The Cronbach's α of the Rand-36 varies between 0.71 and 0.92 for the different subscales. The scores on this questionnaire in our population were compared with the scores in a normal population (van der Zee and Sanderman, 1993). The QoLMI-DLV scale consists of three components: emotional, social and physical. The higher the score on this questionnaire, the better the HR-QoL.

Fear of exercise was measured by the Fear Avoidance Beliefs questionnaire Dutch version (FABQ-DV) and the Tampa Scale for Kinesiophobia Dutch version (TSK-DV) (Vlayen *et al.*, 1995; Vendrig *et al.*, 1998). The FABQ-DV is divided into two parts. The first part consists of seven items on fear-avoidance beliefs with regard to work, the second part consists of four items and measures fearavoidance beliefs regarding physical activity. The Cronbach's α of the first part when used in patients with low back pain is 0.90 and that of the second part 0.71, pointing out a satisfactory validity. The higher the score, the more fear-avoidance beliefs play a part (Vendrig *et al.*, 1998).

The TSK-DV consists of four components: harm, fear of (recurring) injury, avoidance of activity and importance of exercise. The higher the score on a component of the TSK-DV, the greater the role that component has in the fear of exercise. The Cronbach's α was 0.77, which is fair. This information underscores the reliability of the TSK-DV when used in patients with low back pain (Vlayen *et al.*, 1995).

These two scales have been designed for measuring fear of exercise and fear-avoidance beliefs in patients with low back pain. For this study they were modified so as to be applicable to patients with an ICD. Both the FABQ-DV and the TSK-DV consist of statements regarding chronic low back pain, such as 'physical activity would damage my back', 'because of my daily work my low back pain becomes worse' and 'because of my low back pain, my body is in danger for the rest of my life'. Respondents have to react to these statements by filling in the degree to which they agree or disagree with the statement. In the original statements, the words 'pain' and 'back' recur often. We changed these words to 'complaints' and 'heart' or 'ICD', respectively.

The internal consistency of the modified TSK-DV we used in our study was tested by the Cronbach's α and compared with the TSK-DV used by Vendrig *et al.* (1998) and the internal consistency of the modified version of the FABQ was tested and compared with the original English version (Waddell *et al.*, 1993). In different studies the internal consistency of the TSK-DV ranges between 0.68 and 0.80, the internal consistency of the modified TSK-DV in our study is 0.80. The internal consistency of the FABQ work domain in the original English version is 0.88 and for the modified FABQ-DV in our study it is 0.87; the internal consistency of the original FABQ physical activities is 0.77 and for the modified version in our study it is 0.80.

Statistical analyses

Data were analysed using SPSS-10. Means, SDs, medians and ranges were calculated. Association between outcome variables was analysed through linear regression. Statistical significance was defined at P < 0.05.

Results

The general composition of the study population was as follows. Full data-sets of 83 patients were taken for analysis (67 men and 16 women). The mean age (SD) was 58.1 (13.2) years. The mean (SD) number of years the patients had been living with the ICD was 2.2 (1.2) years (see also Table 1).

Table 2 shows the means, SDs and 95% confidence intervals of the Rand-36, the QoLMI-DLV, the TSK-DV and the FABQ-DV in our study population.

The 95% confidence intervals of the difference between our scores and those from a study on a normal population by van der Zee and Sanderman (1993) are shown in

 Table 1
 General characteristics of the participating implantable cardioverter defibrillator patients

	Study population
Number of patients	83
Men/women (%)	81/19
Mean (SD) age (years)	58.1 (13.2)
Mean (SD) number of years with implantable cardioverter defibrillator	2.2 (1.2)

Table 2 Scores on the questionnaires and their 95% confidence intervals

	n	Mean (SD)	95% confidence interval
Rand-36			
General health	83	57.3 (22.8)	52.3-62.3
Physical functioning	80	72.3 (22.3)	67.3-77.3
Social functioning	82	80.0 (22.0)	75.2-84.8
Mental health	81	76.8 (19.3)	72.5-81.1
Pain	82	87.5 (18.4)	83.5-91.5
Vitality	81	64.3 (20.8)	59.7-68.9
Restricted role (emotional)	80	77.1 (36.2)	69.0-85.2
Restricted role (physical)	80	59.4 (42.4)	50.0-68.8
Health change belief	83	53.9 (25.8)	48.3-59.5
QoLMI-DLV			
Total score	80	130.8 (24.0)	125.0-136.0
Physical	83	52.9 (12.1)	50.3-55.5
Emotional	83	59.4 (12.0)	56.8-62.0
Social	80	39.7 (7.8)	38.0-41.4
TSK-DV			
Total score	78	38.3 (8.3)	36.4-40.2
Harm	83	7.4 (2.8)	6.79-8.01
Fear of (recurring) injury	83	3.8 (1.7)	3.43-4.17
Avoidance of activity	81	8.3 (2.9)	7.66-8.94
Importance of exercise	80	6.7 (2.0)	6.25-7.15
FABQ-DV			
Regarding work	73	16.9 (13.3)	13.8-20.0
Regarding physical activity	80	10.9 (6.4)	9.48-12.3

QoLMI-DLV, quality of life after myocardial infarction Dutch language version; TSK-DV, Tampa scale for kinesiophobia Dutch version; FABQ-DV, fear avoidance beliefs questionnaire, Dutch language version. Table 3. The table shows that our population scored significantly worse than a normal population on general health, physical functioning, social functioning, pain and restricted role due to physical problems.

For each regression analysis, sex, age, number of years of living with the ICD and one of the components of the four questionnaires were used as independent variables. The dependent variable every time was one of the HRQoL domains of the Rand-36 and the QoLMI-DLV. Pearson correlation coefficients of these regression analyses were calculated. Thus, the correlation coefficients presented in Table 4 show the association between fear of exercise and HR-QoL, corrected for the influence of age, sex and amount of years that a patient has lived with the ICD.

Discussion

The results of our study show that HR-QoL is lower in patients with an ICD than in the normal population. The patients in our study scored significantly worse than the normal population on the following components of the Rand-36: general health, physical functioning, social functioning and restricted role due to physical problems. This is partly in accordance with the results of the study by Sauvé (1995), who also found that ICD patients have diminished general health and physical functioning. However, no difference in problems in social functioning was found in that study.

In our study population there were a considerable number of patients who reported a fear of exercise. This is an important finding, although our scores on the two fear-of-exercise questionnaires present a large range.

Next, HR-QoL in ICD patients appear to be negatively associated with fear of exercise. The regression analyses performed show relatively high correlation coefficients between these two variables. In our calculation of the correlation coefficients we had already excluded the influence that sex, age and amount of years of living with the ICD can have on this relationship. Our hypothesis that fear of exercise negatively influences HR-QoL in patients with an ICD is confirmed by this analysis.

Finally, because a cross-sectional study has been performed here, no causal relationships between variables can be taken from our data. To be able to do so, prospective cohort trials need to be carried out.

Nevertheless, our findings could be very important for planning treatment of ICD patients. Earlier studies have made it clear that several ICD patients benefited from joining social support groups that offer guidance and meet the psychosocial needs of patients with an ICD (Badger and Morris, 1989; Dickerson *et al.*, 2000; Eads *et al.*, 2000).

Table 3 Comparison of Rand-36 scores with a normal population	Table 3
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	п	Mean (SD)	<i>n</i> (van der Zee and Sanderman, 1993)	Mean (SD) (van der Zee and Sanderman, 1993)	95% confidence interval of the difference
General health	83	57.3 (22.8)	1063	72.2 (22.7)	10.3-20.5 ^a
Physical functioning	80	72.3 (22.3)	1063	81.9 (23.2)	4.33-14.9 ^a
Social functioning	82	80.0 (22.0)	1063	86.9 (20.50)	2.23-11.5ª
Mental health	81	76.8 (19.3)	1063	76.8 (18.4)	-4.17-4.19
Pain	82	87.5 (18.4)	1063	79.5 (25.6)	-13.2-1.89
Vitality	81	64.3 (20.8)	1063	67.4 (19.9)	-1.44-7.6
Restricted role (emotional)	80	77.1 (36.2)	1063	84.1 (32.3)	-0.39-14.4
Restricted role (physical)	80	59.4 (42.4)	1063	79.4 (35.5)	11.8-28.2 ^a
Health change belief	83	53.9 (25.8)	1063	52.4 (19.4)	-5.97-2.93

^aSignificant at the 0.05 level.

Table 4 Co	orrelation	coefficients	of	linear	regression	anal	yses
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	TSKtot	TSKh	TSKf	TSKaa	TSKi	FABQw	FABQp
QoLMI-DV	0.587 ^a	0.645 ^a	0.478 ^a	0.580 ^a	0.258	0.550 ^a	0.329
QoLphys	0.587 ^a	0.643 ^a	0.454 ^a	0.547 ^a	0.179	0.464 ^a	0.414 ^a
QoLemo	0.543 ^a	0.613 ^a	0.490 ^a	0.525 ^a	0.291	0.422 ^a	0.254
QoLsoc	0.484 ^a	0.515 ^a	0.395 ^a	0.527 ^a	0.279	0.614 ^a	0.279
Rand-36	0.572 ^a	0.657 ^a	0.402 ^a	0.488 ^a	0.169	0.451 ^a	0.441 ^a
Rand-pf	0.512 ^a	0.568 ^a	0.460 ^a	0.434 ^a	0.299	0.381 ^a	0.399 ^a
Rand-sf	0.428 ^a	0.507^{a}	0.352 ^a	0.411 ^a	0.206	0.362 ^a	0.219
Rand-mh	0.511 ^a	0.593 ^a	0.457^{a}	0.500 ^a	0.338	0.367 ^a	0.285
Rand-p	0.405 ^a	0.487 ^a	0.388 ^a	0.322	0.259	0.330	0.332
Rand-v	0.571 ^a	0.665^{a}	0.473 ^a	0.510 ^a	0.210	0.381 ^ª	0.350 ^a
Rand-re	0.434 ^a	0.466 ^a	0.297	0.399 ^a	0.157	0.276	0.194
Rand-rp	0.471 ^a	0.507 ^a	0.344 ^a	0.412 ^a	0.203	0.409 ^a	0.332
Rand-hcb	0.312	0.329	0.236	0.306	0.232	0.342	0.339

Tampa Scale for Kinesiophobia Dutch version (TSK-DV) components: TSKtot, total score on TSK-DV; TSKh, harm; TSKf, fear of (recurring) injury; TSKaa, avoidance of activity; TSKi, importance of exercise. Fear Avoidance Beliefs questionnaire (FABQ-DV) components: FABQw, work; FABQp, physical activity. Quality of Life After Myocardial Infarction Dutch language version (QoLMI-DLV) components: QoLtot, total score on QoLMI-DLV; QoLphys, physical; QoLemo, emotional; QoLsoc, social. Rand-36 components: Rand-gh, general health; Rand-pf, physical functioning; Rand-sf, social functioning; Rand-mh, mental health; Rand-p, pain; Rand-v, vitality; Rand-re, restricted role emotional; Rand-rp, restricted role physical; Rand-hcb, health change belief.

^aSignificant at the 0.05 level.

Cardiac rehabilitation is proven to result in improved quality of life in patients with conditions like myocardial infarction (Badger and Morris, 1989). Although researchers have stated that for most ICD patients it is safe to exercise (Lampman and Knight, 2000; Kelly, 1995), until now very little has been known about the guidelines and benefits of rehabilitation programmes or exercise training for such patients. Menard-Rothe and Callahan (1986) suggested patients who received an ICD be considered as an appropriate population to participate in cardiac rehabilitation programmes. According to Menard-Rothe and Callahan (1986), the guidelines for ICD patients should be similar to those used for individuals who have undergone coronary bypass surgery and valve replacement. Others believe that ICD patients need a specifically defined exercise programme and careful medical supervision during exercise by skilled staff (Friedman et al., 1996; Lampman and Knight, 2000; Vanhees et al., 2001). Further research on this topic, with a larger number of patients, is needed if one is to prescribe an exercise programme that fits the needs of ICD patients.

This study paid special attention to the relationship between HR-QoL of patients with an ICD and fear of exercise. There are probably other factors contributing to the quality of life of our patients that can affect our findings. For example, depression or fatigue can be highly relevant to quality of life as well as to fear of exercise. We have also learned from previous research that the number of ICD firings patients have experienced influences their emotional state (Gallagher *et al.*, 1997). These factors should be considered in further research.

Conclusion

Fear of exercise is a significant determinant of HR-QoL in ICD patients. After implantation of an ICD, patients with a fear of exercise should be identified. Appropriate rehabilitation and interventions should be considered in patients with a clear fear of exercise in order to optimize their HR-QoL.

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