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Cardiac Rehabilitation for Patients with an Implantable Cardioverter Defibrillator

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1. Introduction

Patients with an implantable cardioverter defibrillator (ICD) are not routinely referred to Cardiac Rehabilitation (CR) due to fears that exercise may induce ventricular tachyarrhythmias. Meta analyses and systematic reviews have shown that a CR program with an exercise component can improve survival, as well as non-fatal disease manifestations, functional capacity and quality of life (QOL) in patients with previous myocardial infarction or cardiac surgery (Ades 2001; Lewin et al., 2001; Wenger 2008).
Whether the same is true for patients with an ICD is not clear, especially as these patients may have ischaemic or non-ischaemic causes for their propensity for ventricular tachyarrhythmias, and are more likely to need treatment for heart failure. There is evidence that exercise programs can improve functional status and counter deconditioning in cardiac patients with heart failure (Smart and Marwick 2004).
Most previous studies which have examined the safety of exercising ICD patients have been small, with less than 100 patients in their studies (Belardinelli et al., 2006; Chinnaiyan et al., 2007; Dougherty et al., 2008; Fan et al., 2009; Fitchet et al., 2003; Vanhees et al., 2004) . A notable exception was the HF-ACTION cohort, in which 1285 patients had an ICD implanted before or during the trial and had at least one exercise test performed after ICD implantation (Keteylan et al., 2009). This large study clearly demonstrated the safety of exercise testing in ICD patients, but did not show the changes in workloads achievable during the course of a CR program, or examine QOL issues.
Exercise capacity at treadmill testing, expressed as peak metabolic equivalents (METS), has been shown to be of prognostic significance (Kokkinos et al., 2007), with each 1 MET increase in exercise capacity being associated with a 13% decrease in mortality (mean follow-up 7.5 years). This data suggests that exercise programs should aim to improve functional capacity in cardiac patients, and endeavour to help sustain this level of functional improvement over time.

2. Study aims

The current study was designed to document the safety and benefits of CR, which included exercise training and testing, in patients with an ICD. In addition to documenting morbidity

and mortality associated with the CR program, the study examined the increase in functional capacity achievable over the course of the CR program, as well as the potential improvements possible in QOL measures during the program.

3. Methodology

Consecutive patients with an ICD who entered a single comprehensive tertiary CR program in Sydney, Australia, from 1997 to 2010 were included. Prospective data was analyzed including demographics, past medical history, cardiac risk factors, medications, exercise days, dropout status, left ventricular ejection fraction by gated heart pool scan (LVEF,%), functional capacity, QOL and outcome indicators, program morbidity, and 1 year mortality post CR.

Exercise capacity was assessed in all patients by functional testing at the beginning of the CR program, and an exercise program, including both aerobic and resistive exercise regimes, was prescribed. All ICD patients were exercised with a wireless monitor linked to a central computer. Exercise capacity after the 6 week CR program was also assessed in patients completing the program.

All patients had education, assessment and counselling sessions as well as exercise training as previously described (Briffa et al., 2009; Zecchin et al., 1999). Secondary prevention strategies were also emphasized. All patients, including CR drop-outs, were followed-up by telephone contact for 1 year post CR.

Quality of Life (QOL) was objectively measured using two self-report questionnaires, the SF-36 (v1) and the DASS21, and was assessed before and after the program.

The SF-36 (v1) Health Survey is a widely used generic questionnaire with standardized scores used to measure physical and social functioning, physical and emotional roles, bodily pain, vitality, mental health and general health perceptions (Ware and Sherbourne 1992). For this questionnaire, a higher score indicates a better level of physical and social functioning, vitality, mental health status and general health. Conversely, a higher score indicates a lower level of bodily pain. Cronbach's scales of the SF-36 (v1) exceed alpha 0.8, except for social functioning (a = 0.76). The questionnaire can be compared to previously published data describing QOL in the normal Australian population – Australian Bureau of Statistics (ABS), 1995.

The DASS21 is a 21 item self-report inventory that yields 3 factors: depression (DEP), anxiety (ANX) and stress (STR) (Lovibond S.H. & Lovibond P.F. 1995). The DASS21 is a set of three self-report scales (7 items per scale) designed to measure the negative emotional states of depression, anxiety and stress.

The Depression Scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The Anxiety Scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The Stress Scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient. In this questionnaire, the higher the score the higher the level of depression, anxiety and/or stress.

The DASS Anxiety Scale correlates 0.81 with the Beck Anxiety Inventory and the DASS depression scale correlates 0.74 with the Beck Depression Inventory in its original form, DASS42 (Lovibond P.F.and Lovibond S.H. 1995).

4. Results

In the study period, 161 patients with an ICD commenced the CR program on 178 occasions. Mean age (± SD) was 61 ± 10 years, 85% of patients were male, and mean LVEF was 30 ± 10%.

Medical history included hyperlipidaemia 85%, hypertension 52%, previous myocardial infarction 48%, current smoking 29%, diabetes mellitus 26%, chronic obstructive airways disease 17%, previous cerebrovascular accident (CVA) 11% and depression 11%.

Cardioactive medications used were beta-blockers 85%, angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers 72%, specific antiarrhythmic drugs 17%, nitrates 15% and digoxin 10%. Adherence to medication was emphasized, and regularly checked with both patients and carers.

Functional capacity testing was performed in all patients prior to CR commencement. Treadmill exercise tests (EST) were performed in 78%, 6 minute walk tests (6MWT) in 21% and timed up and go tests in 1%. Mean number of exercise sessions attended during the CR program was 9 ± 7. Program completion rate was 62%, with the drop-out rate for non-medical reasons being 14%. For those patients who completed CR, the same functional test was repeated at the end of the program.

There were no deaths or ventricular tachyarrhythmias in study patients while they were exercising or undergoing a functional capacity test. There were 4 deaths in the study group at 1 year follow-up (mortality 2%). Two of these patients died 6 months post CR program, and 2 others died while on the program. These latter 2 patients were admitted to hospital with heart failure which proved refractory to treatment.

Other admissions to hospital while patients were on the CR program were for the following reasons – acute heart failure 3%, displaced lead 1%, percutaneous interventions 1%, CVA 0.5%, ICD activations 0.5% and miscellaneous causes 2%.

Functional capacity increased significantly in patients completing the CR program. For those undertaking EST assessment, MET levels rose from 6.9 ± 2.2 pre CR to 9.6 ± 2.8 post CR, $p < 0.001$. For the 6MWT group, distance walked increased from 373 ± 114 metres pre CR to 430 ± 126 metres post CR, $p = 0.04$.

Resting heart rate at the initial functional assessment was 75 ± 14 beats/min, rising to 109 ± 21 beats/min at peak exercise ($p < 0.001$). Systolic BP rose from a baseline of 111 ± 18 mmHg to a peak of 131 ± 25 mmHg ($p < 0.001$) during the initial functional assessment.

For patients completing the CR program, QOL indicators also improved between pre and post CR assessments, with respect to most SF-36 domains, and also the DASS[21] Depression and Anxiety Scales (Table 1).

5. Discussion

The patients in this study had significant left ventricular dysfunction, as well as propensity for ventricular tachyarrhythmias, but were clinically well enough to commence a CR program and to participate in the exercise component which was a key core feature of CR at Westmead Hospital. The majority of participants completed the program, and all patients were accounted for at follow-up. Standard antifailure therapy was taken by a clear majority of patients, with over 80% being on beta blockers and over 70% on ACEI or angiotensin receptor blockers.

SF-36 Domains (n=77)	Pre Program	Post Program	p-value	ABS 1995 Mean (n >18,500)
General Health	62±20	66±21	0.09	72
Physical Functioning	54±23	74±21	<0.001	83
Role-Physical	26±37	55±40	0.049	80
Bodily Pain	65±24	82±22	<0.001	77
Vitality	54±22	69±19	<0.001	65
Social Functioning	64±28	82±21	<0.001	85
Role-Emotional	48±44	72±40	<0.001	83
Mental Health	72±20	77±18	0.21	76
Total	108±17	120±16	<0.001	
DASS[21] (n=78)				
Depression	7.4±8.8	5.2±7.6	0.006	
Anxiety	6.9±6.8	5.2±6.1	0.005	
Stress	8.4±7.7	7.2±7.5	0.10	

Table 1. QOL assessments pre and post CR in ICD patients.

5.1 Safety of exercise

This study extended previous observations that exercise training as well as formal EST assessments are safe, and do not promote ICD activations.

There have been theoretical concerns that ventricular tachyarrhythmias can be provoked by adrenergic stimulation, such as occurs with exercise, but the present study and other studies of exercise testing or exercise training in patients with ICDs have now consistently shown that this concern is not warranted (Hussein & Thomas 2008). While this may in part be related to the high usage of beta blockers in the present study, there is data from both animal and clinical studies to suggest that exercise training might potentially reduce the incidence of ventricular tachyarrhythmias by shifting autonomic balance towards an

increase in vagal tone, and by reducing the frequency of ischaemic episodes which may trigger arrhythmias (see reviews by Hussein & Thomas 2008; Lewin, et al., 2001).

5.2 Effects of exercise on functional capacity

Exercise prescription and training can also improve general physical fitness, and this in turn can decrease the likelihood of an early inappropriately fast sinus tachycardia with exercise, which could potentially lead to inappropriate ICD discharges if heart rate cut-offs for ICD shocks are exceeded. The heart rate response to exercise noted during the CR program can, in turn, help optimize the setting of heart rate cut-offs for ICD activation, so helping to reduce inappropriate ICD discharges.

Functional capacity improved substantially during the course of the 6 week CR program in this study, but MET levels achieved were still short of the 11-14 MET workloads achieved at the Westmead Hospital CR program in patients without ICDs (Kovoor, et al., 2006). The improvement in MET levels achieved in the Westmead ICD patients was 2-3 METS on average, which could potentially translate to a substantial reduction in mortality (up to 13% reduction for each increase in workload of 1 MET – Kokkinos et al., 2007), particularly if the improved functional capacity can be maintained after completion of the CR program.

Exercise training in patients with heart failure have demonstrated that most of the benefit appears to be the result of peripheral adaptations, although some improvements in cardiac function have also been documented (Briffa et al., 2009; Haykowsky et al., 2007). The present study did not re-evaluate LVEF at 1 yr post CR, and it is not known whether the low 1 year mortality observed was due to improvement in left ventricular function.

Demonstration to patients that they can safely exercise to relatively high workloads without setting off the ICD is an important way of building patient confidence and self esteem, as well as ensuring that they have improved endurance, reduced fatigue and increased muscular strength (Lampman & Knight 2000). This reinforces the desirability of continuing a regular exercise program after the CR program has been completed.

5.3 Effects on quality of life measures

Psychosocial problems of patients with ICDs include anxiety, depression, insomnia, fear of either shocks from the device or device malfunction, and reduced quality of life in general (Hussein & Thomas 2008; Sears et al., 2005; Sola & Bostwick 2005). As shown in Table 1, QOL in ICD patients in this study was poor when compared with the general Australian population, but did improve significantly over the course of the 6 week CR program. This study showed significant improvements in QOL indicators as assessed by both the SF-36 domains and DASS[21] scales.

The improvements in QOL documented in the present study were in the SF-36 domains of physical functioning, social functioning, physical and emotional roles, bodily pain and vitality. Anxiety and Depression DASS Scales also showed favourable outcomes during the course of the CR program. These major benefits probably derive from a combination of factors, including exercise training, and active educational and counselling sessions giving guidance on general health matters, secondary prevention, lifestyle change and psychosocial support. There may be a differential benefit for older and younger age groups (Crossmann et al., 2010) but this was not examined in the present study.

ICD patients are a heterogeneous group, both from the physical and psychological points of view. CR programs should have certain core components including exercise, education and psychological interventions. The individual needs of patients will have to be addressed by having sufficient flexibility of CR programs so as to tailor the individual programs to the needs of the patients.

6. Conclusion

This study shows that exercise testing and exercise training is safe in ICD patients who are clinically stable, and that exercise does not provoke ventricular tachyarrhythmias. The ICD patients also gain significant improvements in functional capacity and QOL outcomes.
Future studies will need to evaluate whether these benefits are maintained over time.

7. Acknowledgements

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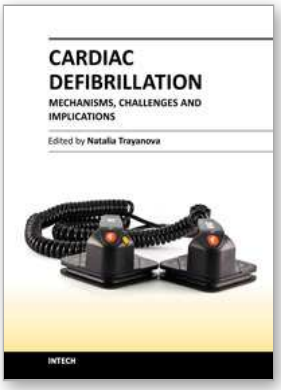

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The only known effective therapy for lethal disturbances in cardiac rhythm is deï¬brillation, the delivery of a strong electric shock to the heart. This technique constitutes the most important means for prevention of sudden cardiac death. The efficacy of defibrillation has led to an exponential growth in the number of patients receiving implantable devices. The objective of this book is to present contemporary views on the basic mechanisms by which the heart responds to an electric shock, as well as on the challenges and implications of clinical defibrillation. Basic science chapters elucidate questions such as lead configurations and the reasons by which a defibrillation shock fails. Chapters devoted to the challenges in the clinical procedure of defibrillation address issues related to inappropriate and unnecessary shocks, complications associated with the implantation of cardioverter/defibrillator devices, and the application of the therapy in pediatric patients and young adults. The book also examines the implications of defibrillation therapy, such as patient risk stratification, cardiac rehabilitation, and remote monitoring of patient with implantable devices.

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