EDUCATIONAL INTERVENTION FOR PATIENTS WITH AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

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ABSTRACT

Objective:

The aim of this pilot study was to evaluate the feasibility of a brief educational intervention administered two weeks after Automatic Implantable Cardioverter Defibrillator (AICD) implantation on subsequent levels of anxiety, depression, stress and hostility.

Design:

A randomised controlled design was used.

Subjects and setting:

Twenty-two patients hospitalised for implantation of an AICD were recruited for the study. Thirteen patients were randomised to attend the intervention and nine to the standard care control group.

Intervention:

The educational intervention was delivered by a nurse and psychologist. It comprised one 60-90 minute session in which the patient and a significant other received detailed information about the AICD (including practical and psychological aspects), and had the opportunity to ask questions, express concerns and receive reassurance.

Main outcome measure:

The DASS was used to measure anxiety, depression and stress at two, four and six months after AICD insertion.

Results:

Patients who attended the intervention showed no significant improvements or trend toward improvement on any of the measured psychological domains.

Conclusions:

The findings suggest that a single educational session delivered to recent AICD recipients is not sufficient to improve patients' psychological adjustment.

BACKGROUND

The Automatic Implantable Cardioverter Defibrillator (AICD) is a small electronic device that is implanted in patients at high risk for sudden cardiac death due to ventricular arrhythmias. The device monitors heart rhythm and can deliver cardioversion pacing or defibrillation, depending on the type of arrhythmia that occurs. In the last decade AICDs have become the dominant therapeutic modality for patients with life threatening ventricular arrhythmias that cannot be adequately controlled with antiarrhythmic medications. (Crespo et al 2005; Swygman et al 1999). Their efficacy in terminating ventricular fibrillation and tachycardia and preventing sudden cardiac death has been well established (Crespo et al 2005; Ezekowitz 2003; Moss et al 2002).

While the majority of AICD recipients are able to resume their normal activities (Bainger et al 1995) and experience improved quality of life after implantation (Irvine et al 2002), a substantial proportion experience physical and psychological difficulties (Dunbar 2005;

Schron et al 2002; Bourke et al 1997; Hegel et al 1997, 1994). One important factor is related to the therapeutic effect of the device. High energy shocks aimed at halting tachyarrythmias are often not well received by recipients, with some describing them as painful or like 'a bolt of lightning' (Dunbar et al 1993). Uncertainty of device discharge is one of the most frequent psychological concerns expressed by many patients (Kuiper et al 1991). Other common problems include side effects of medication; changes in body image; reduced energy levels; sleep difficulties; physical discomfort; reduced ability to exercise, work, do house chores or maintain sexual activity; driving restrictions; and worry over the possibility of device failure (Schron et al 2002; Gallagher et al 1997; Sears et al 1999).

The reported prevalence of psychological disorders among AICD recipients ranges from 15% to 60%, with anxiety disorders (panic attacks, agoraphobia and generalised anxiety disorder), depression, anger and adjustment disorder being frequently cited problems (Bourke et al 1997; Dunbar et al 1996; Pycha et al 1990; Vlay et al 1989). Factors that have been found to increase the risk of psychopathology among AICD patients include poor functional status (Dunbar et al 1999), maladaptive cognitive appraisal and coping style (Dunbar et al 1999; Godemann et al 2001), sporadic (Schron et al 2002) or frequent shocks (Bourke et al 1997; Dougherty 1995; Godemann et al 2001; Goodman et al 1999; Irvine et al 2002), and family problems and inadequate social support (Morris et al 1991).

Because of this increased vulnerability, many hospitals offer support group meetings for AICD patients. Groups are run weekly, fortnightly, monthly or quarterly and aim to provide information, emotional reassurance and social support (DeBasio and Rodenhausen 1984). Reported evaluations of AICD patient support groups suggest they are positively appraised by participants (Badger and Morris 1989; DeBasio and Rodenhausen 1984; Dickerson et al 2000; Molchany and Peterson 1994), however to date there is little evidence that attending such groups leads to enhanced psychological adjustment (Edelman et al 2003).

Given the increased risk of psychopathology within this cohort, some researchers have suggested that AICD recipients should be routinely screened for anxiety, depression and social functioning (Edelman et al 2003; Bourke et al 1997) and patients displaying symptoms of psychopathology should be offered appropriate psychological treatment for their condition. This type of intervention is often referred to as 'secondary', in that it is offered to patients at the secondary stage, after problems have developed. An alternative approach is a 'primary' intervention, directed at all patients during an early or 'primary' stage, before psychological difficulties emerge.

Many researchers have advocated an educational intervention delivered to all AICD patients soon after surgery (Shaffer 2002; Wolbrette and Naccarelli 2001; Dougherty 1997; Burke 1996; Dunbar et al 1993) in order to prevent psychological problems and therefore the need for more intensive treatment at a later stage. Providing information helps dispel misconceptions and provides coping strategies. Brief educational interventions have been shown to reduce anxiety among medically ill patients, including patients attending an examination visit for colposcopy (Walsh et al 2004), women referred for colonoscopy (Marteau et al 1996), women with abnormal Pap smears (Stewart et al 1993) and women awaiting mastectomy (Belleau et al 2001). Brief educational interventions have also been associated with reduced depression among depressed female patients in primary care (Jacob et al 2002) and when delivered via the internet, among individuals with depressive symptomology (Christensen et al 2004).

Patients who are hospitalised to receive an AICD need to assimilate a lot of new information within a short period of time. Information about management of the AICD, prescribed lifestyle changes and recommended action following a shock is usually presented while the patient is in hospital, immediately before or within a few days after surgery. The nature of changes that patients need to accommodate and the volume of information provided can be overwhelming for some, particularly for those who did not know much about AICDs prior to their hospitalisation.

Whether patients are adequately prepared for what lies ahead depends partly on their ability to assimilate new information, the type of adjustments they will need to make (eg retirement; not driving) and their inherent personality characteristics. As anxiety (Ashcraft and Kirk 2001; Hope et al 1998; Hill and Vandervoort 1992), and depression (Kizilbash et al 2002) can impair the ability to retain new information, the material provided to patients in the period immediately following surgery may not be well assimilated. In addition, anxiety can lead to recall bias toward threat related material (Coles and Heimberg 2002; Reidy and Richards 1997), which may interfere with objective processing of new information.

As the length of hospital stay has shortened in recent years, there may also be limited opportunity to provide comprehensive information and respond to patient concerns while they are in hospital. Further, some issues may not arise until after patients have gone home. Inadequate preparation may contribute to subsequent problems with management of the device and/or psychological adjustment, particularly if difficulties arise.

Educational interventions

While many researchers have argued that educational interventions should be part of routine hospital care, to date very few evaluations of such interventions have been reported. In an extensive search of on-line databases (including Medline, PsychInfo, HealthStar, Current Contents and CINAHL) we were able to locate only one pilot study that evaluated educational interventions with AICD recipients (Carlsson et al 2002). In this study 20 patients were randomly allocated to either a nurse-led educational intervention or a standard care control group. The intervention was delivered over two sessions, before and after surgery, with relatives also being able to attend. Assessment using the Nottingham Health Profile (Hunt and McKenna 1992) revealed no significant differences between groups on health-related quality of life. Although the authors report a significant reduction in sleep disturbances among study group participants following the intervention, the summary measures reported suggest that greater reductions in sleep disturbances occurred in the control group.

Two other non-randomised studies examined psychological outcomes of patients attending support groups that included an educational component (Badger and Morris 1989; Molchany and Peterson 1994). While support group participation was not associated with significant benefits, the self-selected nature of the groups, lack of randomised design and poorly defined intervention limit the usefulness of these reports.

Pilot Study

We report on a pilot study that evaluated a brief educational intervention with recent recipients of an AICD. Although patients already receive basic information about the AICD while they are in hospital, this information is standardised and does not address all of the concerns of each individual patient. By providing information two weeks after AICD implantation it was presumed that some of the obstacles to patient attention and engagement in the early hospitalisation period might be avoided. It was hypothesised that comprehensive information about the medical and psychosocial aspects of living with an AICD delivered at this time would help to dispel some of the uncertainties and fears that patients and their family members typically experience in the aftermath of AICD implantation. We expected that if this were the case, it would be reflected in reduced scores on anxiety, depression and stress levels in the intervention group, in the period following the educational program.

METHOD

Sample

Patients scheduled for implantation of an AICD at the Royal North Shore Hospital and the North Shore Private Hospital, Sydney, Australia were recruited for the study. Those with a psychotic disorder or cognitive deficit or with inadequate English to complete the questionnaires were excluded from participation. Patients were approached by a cardiac nurse following their admission to hospital for AICD implantation and were given details about the aims of the study, what their participation would involve and information about approval for the study by the hospital Ethics Committee. Those who provided informed consent were given a set of questionnaires and were asked to complete the forms prior to their surgery. Before the initial questionnaires were processed patients were randomly allocated either to the educational intervention or to a standard care control group. Patients who were randomised to the intervention were invited to attend the hospital with a family member or significant other approximately two weeks following their surgery. Those in the control group received standard care, which included verbal information from the cardiologist and an AICD booklet produced by the device manufacturer.

Intervention

The intervention was delivered by a cardiac nurse and a psychologist over 60 to 90 minutes. Whenever possible, patients were invited to attend with a partner or ‘significant other’. The aim of the session was to provide information, normalise their experiences and give reassurance. The following information was provided:

1. About the AICD: Growing use of AICD for control of ventricular dysrhythmias. Advantages of AICD implantation over medication; types of therapy that it performs (ATP and defibrillation); length of battery life, etc.
2. High level of satisfaction: majority of people who have an AICD are very happy with it, and would recommend it to others; majority resume their previous lifestyle.
3. About device discharge: what to expect; experiences of others with shocks.
4. What to do if the AICD discharges.
5. Safety and potential hazards of the AICD: Objects and places that may generate environmental electromagnetic interference and should be avoided; discourage over-cautious avoidance that is not medically recommended; encourage return to normal lifestyle, within the limits of patients’ particular medical status (eg participation in hobbies, exercise, social activities, etc).
6. Discussion of lifestyle changes following AICD implantation: work, driving, exercise, sexual activity, etc; initial lifestyle restrictions are often temporary, and with time most people resume their normal activities; some patients need to modify aspects of lifestyle in the longer term.
7. Encourage patients to continue regular exercise: eg come to rehabilitation exercise classes, regular walking, gardening, etc.
8. Encourage open communication with family and friends about the AICD.
9. Normalise the feelings and concerns of patients and their family members: eg ‘It is normal to feel anxious or depressed following a major event like having an AICD implanted, however most people tend to recover over time’.

10. Encourage patients to telephone the cardiac nurse should any questions or problems arise.

Instruments:

The primary outcomes of interest (anxiety, depression and stress) were measured using the DASS (Lovibond and Lovibond 1995), which was administered at the time of recruitment (prior to AICD insertion), and at two, four and six months after surgery. The DASS is a self-report measure consisting of subscales on depression, anxiety and stress that has been widely used in research with clinical populations, including patients with heart disease (Lovibond and Lovibond 1995). The scales have high internal consistency, adequate convergent and discriminant validity (Brown et al 1997; Crawford and Henry 2003) and excellent reliability (Brown et al 1997; Crawford and Henry 2003). In addition, a Hostility scale (Koskenvuo et al 1988) consisting of three 5-point semantic differential items was used. The measure has been found to be strongly associated with the incidence of cardiac events and death among men with coronary heart disease (Koskenvuo et al 1988).

Statistical Analysis

Scores on depression, anxiety, stress and hostility were entered into repeated measures ANOVA analysis using age, sex and group as potential predictors.

Table 1: Characteristics of patients enrolled in the study at baseline

Number	22
Males/females	19/3
Married or living with partner	86%
Occupational Status	
Full time work	32%
Part time work	9%
Not working	59%
Received treatment for psychological problems in last 5 years	9%
Shortness of breath	
Not at all	27%
With more strenuous activity	46%
With ordinary activity	23%
Chest pain or palpitations	
Not at all	82%
With more strenuous activity	18%
Trouble breathing in bed at night	14%
DASS anxiety score – mean (SD)	7.5 (7.4)
% in the clinically significant range	18%
DASS depression score – mean (SD)	7.0 (7.8)
% in the clinically significant range	14%
DASS stress score- mean (SD)	10.6 (9.0)
% in the clinically significant range	14%
Hostility Scale Score	6.4

RESULTS

Twenty-seven patients were recruited for the study however five of these stated that they would not be able to attend an intervention (due to distance), and were therefore not randomised. The remaining 22 patients were randomly allocated either to the educational intervention (n=13) or to a standard care control group (n=9). Table 1 summarises the background characteristics of the patients registered in the study at the baseline assessment.

Table 2: Comparison of Psychological Scores of Groups at Baseline Mean (SD)

Measure	Intervention	Control
DASS depression	8.9 (6.3)	8 (10.8)
DASS anxiety	6.3 (5.2)	9.8 (12.2)
DASS stress	11.2 (6.9)	10.0 (12.1)
Hostility	7.2 (2.6)	5.2 (3)

Psychological Outcomes

No significant differences in depression, anxiety, stress or hostility were found between the Intervention and Control groups at baseline (table 2). Age, sex and group were tested for association with changes in the DASS and Hostility scores over the four occasions. The critical alpha was set at 0.0125 to account for the four variables tested. There were no significant relationships between participation in the intervention and subsequent scores on psychological outcomes on any occasion of measurement, and there was no trend suggesting psychological benefits associated with the intervention (table 3). There were no interaction effects between age, sex, group and psychological outcomes.

Table 3: Effects of intervention (Interaction Contrast of Group by Occasion)

Measure	2 months	4 months	6 months
DASS depression	F[1,15] = 0 p = 1	F[1,16] = 0.67 p = 0.43	F[1,12] = 0.02 p = 0.89
DASS anxiety	F[1,15] = 0.3 p = 0.59	F[1,16] = 0.3 p = 0.59	F[1,12] = 2.3 p = 0.16
DASS stress	F[1,15] = 0.04 p = 0.85	F[1,16] = 0.08 p = 0.78	F[1,12] = 0.26 p = 0.62
Hostility	F[1,15] = 0.23 p = 0.64	F[1,16] = 0.003 p = 0.96	F[1,12] = 0.13 p = 0.72

DISCUSSION

Although many health professionals have advocated that comprehensive patient education should be provided to all AICD recipients and their family members, very few educational programs have been quantitatively evaluated. The aim of this pilot study was to examine the feasibility of a brief educational intervention delivered two weeks after surgery, and to examine its potential for improving patients' level of adjustment. While the procedures were straight forward, the analysis revealed no reduction in anxiety, depression, stress or hostility at any of the assessment periods.

A major limitation of the current study was the small sample size. It is possible that a similar intervention with a substantially larger sample may have identified benefits on psychological outcomes. However the absence of a trend towards psychological improvement following the intervention suggests that a significant benefit was unlikely to emerge, or at the very least, an extremely large sample size would be required to detect any possible benefits. The finding is also consistent with those of a pilot study (Carlsson et al 2002) and two small non-randomised studies (Badger and Morris 1989; Molchany and Peterson 1994) with AICD patients.

While there is little evidence that a purely educational program can improve psychological outcomes in AICD recipients, it is possible that a more targeted and sustained intervention, with greater emphasis on psychological coping strategies could produce more substantial benefits (Kohn et al 2000).

One factor that may account for the failure of the intervention to influence psychological outcomes is its brevity. It is possible that a more intensive intervention run over several sessions in group or individual format might have yielded a measurable benefit. However even if this were the case, the relative costs and benefits of an intensive primary intervention may need to be weighed up against those of a more targeted secondary intervention, particularly if psychological adjustment is the main issue under consideration.

As to date there is little evidence that brief educational interventions can reduce the risk of psychological dysfunction among AICD patients it may be that well-targeted secondary interventions are more effective for the management of mental health problems that arise within this cohort. Few studies have evaluated psychological interventions with distressed AICD patients (Edelman et al 2003), however one randomised trial with this cohort (Kohn et al 2000) and other trials that targeted cardiac patient groups (Berkman et al 2003; Freedland et al 1996; Friedman et al 1986) suggest that evidence based psychotherapy such as Cognitive Behaviour Therapy (CBT) is an effective treatment for psychological problems. It is therefore possible that an intervention of this type may prove to be a suitable treatment for AICD patients who develop psychological distress.

The failure to find improvements on psychological outcomes does not imply that educational interventions are not useful. It is The AICD is a technologically complex device used in the management of life-threatening illness, and has major implications for patients' lifestyle and quality of life. It is important that patients have a clear understanding of how the AICD works, safe versus potentially hazardous situations, problems that may arise and how to deal with them, and psychosocial issues associated with the device.

Educational interventions have been found to improve compliance to treatment and survival time among cancer patients (Richardson et al 1990). While there is no similar evidence for AICD patients, education about the device is at the very least important for effective management and minimisation of problems. As stated by Dougherty (1997) 'educational programs should focus on the provision of new information required to effectively manage illness at home and new behaviours that are required to live safely with the AICD and prevent complications' (p.47).

Support for patient education programs comes not only from health care professionals but also from patients. In a survey of 78 patients who had received an AICD at least one month previously, nearly two thirds stated that they would have liked to have had attended a hospital teaching program on AICDs (Reid et al 1999). The desire to learn more about the AICD is also one of the factors underlying the increasing popularity of support groups run at many suburban hospitals (DeBasio and Rodenhausen 1984). Without comprehensive information patients may otherwise be confused about aspects of management of their AICD. Indeed, there is evidence that AICD patients frequently avoid activities, objects and places for which no medical recommendation had been made (Lemon et al 2004).

CONCLUSION

The findings suggest that a single educational session delivered to recent AICD recipients is not sufficient to improve patients' psychological adjustment. While educational programs may not directly affect psychological adjustment, they may never the less affect patients' quality of life and willingness to participate in wide range of life-enhancing activities.

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