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ORIGINAL ARTICLE

A Pilot Study of a Mindfulness Based Stress Reduction Program in Adolescents with Implantable Cardioverter Defibrillators or Pacemakers

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Abstract Adolescents with implantable cardioverter defibrillators (ICDs) or pacemakers (PMs) face unique challenges that can cause psychosocial distress. Psychosocial interventions are effective for adults with cardiac devices and could potentially impact adolescents' adjustment to these devices. Mindfulness Based Stress Reduction (MBSR) is a structured psycho-educational program that includes meditation, yoga, and group support and has been studied extensively among adults. This study examined the feasibility of the MBSR program for adolescents with ICDs/PMs, a population previously unexamined in the research literature. The participants completed measures of anxiety and depression (Hospital Anxiety and Depression Scale) and coping (Responses to Stress Questionnaire) at baseline and after the six-session MBSR intervention. Mean age of the cohort ($n = 10$) was 15 ± 3 years, 6 were male, 6 had a PM, and 4 had an ICD. Feasibility was demonstrated by successful recruitment of 10 participants, 100 % participation and completion. Anxiety decreased significantly following the intervention, with a large effect size, $t[9] = 3.67$, $p < .01$, $\eta^2 = .59$. Anxiety frequency decreased from baseline to post-intervention (Fisher's exact test $p = .024$), and 90 % of participants reported decreased anxiety scores post-intervention. Coping skills related negatively to anxiety ($r = -.65$, $p = .04$) and depression ($r = -.88$, $p = .001$). Post-intervention, the group independently formed their own Facebook group and requested to continue meeting monthly. Although generalizability is limited due to the small sample size, this successful pilot study paves the way for larger studies to examine the efficacy of MBSR interventions in adolescents with high-risk cardiac diagnoses.

Keywords Adolescent · Cardiac · Anxiety · Pacemaker · Implantable cardioverter defibrillator

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Introduction

Sudden cardiac death (SCD) due to cardiac arrhythmia is a major health problem in the United States, causing approximately 180,000–450,000 deaths annually [32]. Implanted cardiac devices, i.e., implantable cardioverter defibrillators (ICDs) and pacemakers (PMs), are the treatment of choice for many types of heart rhythm abnormalities. These devices can deliver an electrical shock to treat a life-threatening ventricular arrhythmia and/or maintain the heart's rhythm. In the past decade, technological advances have reduced the size of the devices making them more available to the pediatric population. In an analysis of ICD and PM implantation in the United States between 1997 and 2004, implantation rates for these devices increased by 19 and 60 %, respectively [45]. Most SCDs are caused by ventricular arrhythmias, with only an estimated 7.9 % of patients treated by emergency medical services surviving to hospital discharge [35]. ICDs are the treatment of choice for life-threatening ventricular arrhythmias in adult and pediatric patients [2]. PMs are implanted cardiac devices primarily used to regulate the heart rhythm due to dysfunction of the sinoatrial or atrioventricular nodes. Implantation of a PM or an ICD in a patient may cause body image issues and problems in psychosocial adaptation

and quality of life (QOL) and contribute to the development of affective disorders [18].

This study was designed to test the feasibility of a Mindfulness Based Stress Reduction (MBSR) program for adolescents with ICDs or PMs and to evaluate levels of anxiety, depression, and coping before and after the 6-week MBSR program.

In recent years, the number of studies examining psychosocial issues following ICD or PM implantation has greatly increased; however, the vast majority of these studies pertain to adult patients. The study results cannot be generalized to children, given intellectual, developmental, and emotional differences between adults and children [13]. Survival rates from sudden cardiac arrest in pediatric patients with ICDs have increased to 98.5 % [21].This has shifted the focus of research from clinical outcomes to the evaluation of psychosocial factors related to the impact of living with this surgically implanted device. In a study of adult patients, the major psychological benefit of ICD implantation identified was the feeling of increased security due to the protection of having the device [38].

The experience of being shocked and/or the fear of being shocked during defibrillation is one of the most significant features of living with an ICD. Inappropriate shocks may also increase the incidence of psychiatric symptoms, and these shocks may occur more commonly in pediatric ICD patients [13]. Children with ICDs have high rates of inappropriate shocks due to lead fractures, higher heart rates, non-compliance with taking medications, and non-adherence to activity restrictions. In addition, children experience a high rate of surgical revisions of their devices. Devices are implanted at ages as early as 6 months and last approximately 4–6 years, even without complications [2].

The majority of research about the psychosocial impact of implanted devices has focused on the adverse psychological effects suffered by adults with ICDs, most commonly ICD-specific fears and symptoms of anxiety related to receiving shocks. Diagnosable levels of anxiety (13–69 %) and depression (7–41 %) in adults with ICDs are reported in various studies [4, 34, 39]. In a study of 16 patients aged 24–73 years, 69 % of ICD recipients who had received shocks had diagnosable levels of anxiety or depression [33]. In a review of published studies examining the effects of ICDs on anxiety and depression, significant numbers of ICD recipients remained anxious and depressed 1 year after ICD implantation [19]. Adolescent patients may exhibit even greater amounts of distress than adults due to fewer psychological resources [14]. Younger patients appear to be at increased risk for frequent shocks, have more interruptions in their daily life, develop more avoidant behaviors, and experience elevated anxiety levels [37]. Risk factors for psychosocial problems among adults with ICDs include younger age (<50 years), multiple ICD shocks, female gender, premorbid psychological difficulties, low social support, poor understanding of condition and device, and more severe medical conditions [19, 20, 38]. Depression and anxiety also are more common in adult patients with permanent PMs than in the general population [18].

At the present time, only one known study examined QOL data in adolescents with ICDs. In this pilot study of 20 patients aged 9–19 years (mean 14.8), there were significant associations among measures of anxiety, depression, family functioning, and QOL. Patients with ICDs had significantly lower scores on physical functioning, social emotional-behavioral roles, self-esteem, parent emotional impact, and higher depression scores than a normative sample [13].

In four studies, nursing interventions improved psychosocial recovery of adult patients following ICD implantation [12, 15, 16, 29]. These interventions included the following: a cognitive behavioral therapy (CBT) intervention [29]; a relaxation training, biofeedback, and health education intervention [12]; a randomized control trial with usual care or telephone counseling [16]; and a telephone intervention delivered by expert cardiovascular nurses post-ICD [15]. All of these studies reported significant reductions in anxiety, indicating that psychological interventions effectively decrease distress in adult patients with ICDs or PMs.

MBSR is a structured 8-week group psycho-educational intervention program which affects positive changes in perspectives toward health and disease [27]. The MBSR content focuses on the attainment of mindful, non-judgemental self-awareness of thoughts, physical sensations, and environment in the present moment, with the intent of fostering calmness and centering. Evidence of the benefits of the two-decade established MBSR program in adults is reported in two meta-analyses [24, 25]. Consistent and strong effect sizes were found across samples of adults with chronic pain, fibromyalgia, cancer, anxiety disorders, and depression [24]. In addition, MBSR interventions for health care professionals found empirical evidence to support benefits in mental and physical health in this population [25].

Researchers are just beginning to investigate the feasibility, application, and effectiveness of MBSR interventions in children and adolescents. The largest published review of MBSR studies in children and adolescents to date includes fifteen studies with sample sizes ranging from 1 to 228 and ages from 4 to 19 years [8]. Each of these studies investigated feasibility and acceptability of MBSR interventions, and overall conclusions indicate that these interventions were well tolerated, acceptable, and safe with no adverse events reported. Analyses of changes in post-treatment outcome measures range from non-significant to significant, with reported effect sizes ranging from small to large ($d = -0.2$–1.4) [8]. Clinical samples investigated consisted of substance abuse and sleep disorders [7], ADHD [47], conduct disorder [41], Prader–Willi syndrome

[42], externalizing disorders [6], mixed psychiatric disorders [3], and anxiety [40].

Adolescents with ICDs or PMs face unique challenges such as the experience of getting shocked, school absence, physical limitations and restrictions, social isolation, peer issues, and body image changes due to the appearance of the cardiac device and body scar.

The social, emotional, and behavioral problems which may occur with prolonged stress can interfere with interpersonal relationships, school success, and potential to become competent adults and productive citizens [23]. Medications used to treat mental health problems such as anxiety and depression can increase the risk of arrhythmias which could lead to ICD shocks. These findings suggest that adding the unusual stresses experienced by this population of adolescents with ICDs or PMs and other life-threatening cardiac illnesses may compound the long-term issues faced by this already at-risk population.

To date, there are no published studies investigating MBSR interventions in children or adolescents with ICDs, PMs, or any pediatric heart disease. While there is no generalized empirical evidence of the efficacy of MBSR interventions in children and adolescents, there is evidence to support the feasibility of these interventions in these age groups. It is time for research to shift to adopting standardized intervention formats which will allow replication and comparison studies, in an effort to develop a strong base of evidence in this population [8].

The small but growing research literature on MBSR interventions in adolescents shows promise of a positive effect on outcomes of anxiety, depression, and coping though not yet established in adolescents with ICDs or PMs. Teaching adolescents to think positively, cognitively restructure their thoughts, distraction, and acceptance through positive interventions may improve clinical outcomes [10].

The primary aim of the current study was to establish the feasibility of an MBSR program for adolescents with ICDs and/or PMs. Secondary aims were to measure coping strategies, anxiety, and depression pre and post the 6-week MBSR intervention and the association between secondary control engagement coping strategies and levels of anxiety and depression following the MBSR intervention.

Materials and Methods

Study Design and Sample

A descriptive, prospective, one-group, pretest–posttest design was used to establish the feasibility of the MBSR intervention in adolescents with ICDs or PMs. The study was approved by the IRBs at the Children's National Health System and the University of Maryland Baltimore. The participants completed measures of coping, anxiety, and depression, on week one of the six-session MBSR intervention and week six at the end of the MBSR intervention. The intervention occurred in one 6-week series, and the group members participated simultaneously. Participants were recruited from the Cardiology Clinic at Children's National Health System in Washington, DC. At least five participants were required to complete all six sessions and the pre- and post- intervention questionnaires to demonstrate feasibility; therefore, 10 participants were enrolled to account for possible participant dropout.

Inclusion criteria included being age 12 through 18 years at the time of enrollment and having a functioning ICD or PM that was implanted at least 4 weeks before the start of the MBSR intervention, a diagnosis of cardiac disease with potential life-threatening arrhythmias in the setting of structural or non-structural heart disease, and a parent/caregiver who was aged 18 years or older. Exclusion criteria were a lack of English language fluency in patient or caregiver, or the patient was unable to complete the measurement tools.

Data Collection

The following demographic and health data were collected from each participant: age, gender, diagnosis, current medications, type of device, and length of time since the device was implanted; experience with their device including had the patient ever been shocked, number of shocks, and date of last shock; and the number of shocks the patient received during the study period. Patient records were screened for inclusion/exclusion criteria. Clearance from the patient's cardiologist was obtained prior to approaching eligible patients. Patients were approached by the first author, a clinician at the site, about study participation during a scheduled outpatient clinic visit. If a patient was willing to participate, the parent/guardian was approached for written informed consent. Patients who were 12–17 years of age provided written assent. Both informed consent and assent forms were IRB approved.

Fifteen participants who met inclusion/exclusion criteria were approached during their outpatient clinic visits, 10 of whom enrolled in the study (66 %). After these 10 were enrolled, recruitment ceased. Of the 5 who did not enroll, reasons for non-participation included ongoing Saturday activities at the same time as the intervention sessions ($n = 2$), no available transportation ($n = 1$), and lack of interest ($n = 2$).

Procedures

Each patient participated in the intervention for 6 weeks. The weekly sessions each lasted 1½ –2 h and were led by

the first author who was trained in the MBSR curriculum. The MBSR intervention began approximately 4 weeks following signed consent, allowing ample time for questions to be asked and answered. All sessions were held in a meeting room outside of the cardiology clinic at Children's National Medical Center. The intervention included sessions to train the participant in deep breathing exercises, guided imagery, meditation, and yoga. Each session also included group discussion and discussions between pairs of participants about pleasant and unpleasant events and issues related to their stressors. Yoga mats, yoga blocks, and CDs of sitting meditation, body scan (guided imagery), and sitting and standing yoga poses were given to each participant to use for home practice between sessions.

Study questionnaires were completed at the first MBSR intervention session prior to the intervention and again at week 6 of the MBSR intervention to assess levels of anxiety, depression, and coping mechanisms. Interview questions and final evaluation forms were completed at the final session of the MBSR intervention. One patient could not attend the final MBSR intervention session, so the measures were e-mailed to the participant for completion; the forms were returned to the PI 2 days later. Each participant received $100 worth of gift cards over the course of the study which were distributed at the end of each session. If a participant missed a session, the gift card was given at the next session.

Instruments

Patient anxiety, depression, and coping strategies were assessed before (pre) and after (post) the intervention via self-report scales. Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS), and coping strategies were measured using the Responses to Stress Questionnaire (RSQ).

Hospital Anxiety and Depression Scale—The HADS [46] is a brief self-report screening scale, developed to examine the prevalence of emotional distress among patients at general medical outpatient clinics. The scale consists of two subscales (anxiety and depression), each consisting of 7 items (range 0–21). A score of eight or higher on each scale is indicative of distress, and this cut point was used in this study. The HADS has been used extensively and was developed for people ages 16–65. In a literature review of studies using the HADS, the Cronbach's alpha for HADS-A varied from .68 to .93 (mean .83) and for HADS-D from .67 to .90 (mean .82) [5]. The HADS also was administered to a population of adolescents ages 12–16 and was found to be reliable, with adequate sensitivity and specificity [44]. Therefore, the HADS is a useful tool for screening adolescents. The use of the HADS in a population of adolescents with ICDs or PMs has not been previously reported in the literature. The HADS takes approximately 5 min to complete.

Responses to Stress Questionnaire—The RSQ [11] assesses types of coping strategies used by adolescents. The items were developed to represent responses to stress in three dimensions: voluntary versus involuntary, engagement versus disengagement, and primary versus secondary control. However, this study focused on two of the voluntary coping factors: primary control engagement coping (nine items measuring problem solving, emotional modulation, and emotional regulation) and secondary control engagement coping (nine items measuring positive thinking, cognitive restructuring, acceptance, and distraction). Respondents were asked to identify specific coping strategies that they actually used, allowing a more comprehensive analysis of associations of type of coping strategies (i.e., primary control engagement vs. secondary control engagement) and symptoms.

The first ten items in the version of the RSQ used in this study were designed to be specific to adolescents with ICDs or PMs (i.e., feeling afraid of getting a shock, concerns about not being able to play sports). For this study, the PI worked with the author of the RSQ (Bruce Compas, PhD) to word the scale specifically for this patient population. A separate scale was worded for both the ICD participants and the PM participants. These items are measured on a 4-point Likert scale (1 = not at all, 4 = very) and have a total score of 40 (higher scores indicate higher levels of perceived stress); 57 subsequent items assess the adolescents' responses to the stressors identified in the first 10 questions. These items are also measured on a 4-point Likert scale (1 = not at all, 4 = a lot). These 57 items are divided into 19 categories of 3 questions each, which represent responses to stress. The range of total scores for each category is 3–12, with higher scores indicating higher levels of what is being measured in the particular category. Individual primary and secondary control engagement strategies were quantified as ratio scores calculated by dividing the number of primary or secondary coping strategies by the total number of coping strategies used, respectively.

Previous studies using the RSQ demonstrated that the measure has good reliability and validity [10]. A study of adolescents with Type 1 diabetes found that internal consistency was $\alpha = 0.75$ for primary control coping, $\alpha = 0.71$ for secondary control coping, and $\alpha = 0.70$ for disengagement coping [26]. Individual differences in overall coping strategies are determined by obtaining ratio scores (dividing the number of primary and secondary control engagement strategies by total number of coping strategies used by each adolescent). The RSQ had not yet been administered to adolescents with heart disease, but has been used in populations of pediatric cancer patients, Type I diabetes patients, and chronic abdominal pain

patients and worded specifically for those groups [10, 26]. The RSQ takes approximately 20 min to complete.

Open-ended questions were asked at the conclusion of the last session to further examine the adolescents' issues related to their cardiac disease/device status. Responses were intended to inform development of future studies. The questions were asked verbally, and the responses were written down by the interviewer.

Data Analysis

Descriptive statistics were used to characterize the participants according to demographic and health status. Frequencies and Fisher's exact tests were used to summarize variables measured on nominal or ordinal scales, and means and standard deviations were used to summarize variables assessed on interval or ratio scales. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. Paired-samples *t* tests were used to examine the significance of changes in mean of each outcome from baseline (Time 1) to post-intervention (Time 2). Pearson's *r* was used to examine the relationship of post-intervention primary and secondary control engagement coping strategies to post-intervention anxiety and depression and ICD-specific anxiety. The strength of the relationship was evaluated using Cohen's (1988) guidelines for eta squared small: $r = .10$–$.29$, medium: $r = .30$–$.49$, large: $r = .50$–1.0 [9]. All quantitative statistical analyses were performed with SPSS version 17.

Data from the open-ended interview questions were analyzed by grouping the responses to each question into themes and categories.

Results

Study Sample

Demographic and clinical characteristics of the study sample ($N = 10$) are summarized in Table 1. The mean age of the study population was 15 (±3) years, 60 % were male, mean age at device implant was 8.0 (SD = 6.0) years, and mean time device implanted was 7.31 (SD = 6.1, range = .25–13.6) years. Six participants had a PM and four had an ICD. Of those with an ICD, two (50 %) had been shocked through their device. One participant had received over ten shocks 1 month prior to the intervention and all in 1 day, and the other participant had only ever received one shock 3 years ago. Four participants were taking antiarrhythmic medications, five were taking heart failure medications, and two were taking warfarin. None of the participants were taking psychotropic medications or had a previously diagnosed psychiatric illness.

Table 1 Demographic and clinical characteristics of patients enrolled in the study ($N = 10$)

Characteristic	*N*	Range	Mean	SD	%
Demographics					
Age (years)		12–18	15.0	1.94	
Age at implant (years)		.05–17	8.0	5.98	
Number of shocks		1–15	7.5	6.85	
Gender					
Male	6				60
Type of device					
PM	6				60
Ever been shocked by ICD ($N = 4$)					
Yes	2				50
Last ICD shock ($N = 2$)					
< 2 months	1				50
Months since implant		3–163	87.8	60.90	
Type of heart disease					
Structural	7				70
Long QT syndrome	1				10
AVB/SSS	1				10
Clotting disorder	1				10
Psychiatric diagnosis					
No	10				100
Antiarrhythmic medications					
Yes	4				40
Heart failure medications					
Yes	5				50
Warfarin					
Yes	2				20

ICD implantable cardioverter defibrillator, *HD* heart disease, *AVB* atrioventricular block, *SSS* sick sinus syndrome

$N = 10$ unless otherwise specified

Seven participants had structural heart disease, while one had Long QT syndrome, one had genetic autoimmune disease, and one had primary conduction system disease.

Baseline Psychosocial Factors

Baseline intervention psychosocial variable scores are included in Table 2. The mean baseline HADS anxiety score was 8.9 (SD = 5.13), and six patients (60 %) had HADS scores greater than or equal to 8 indicating anxiety. The mean baseline HADS depression score was 2.9 (SD = 3.1), and one patient (10 %) had a HADS score greater than or equal to eight indicating depression.

Feasibility

The primary aim of this study was to establish the feasibility of an MBSR program for adolescents with ICDs and/

Table 2 Psychosocial characteristics of patients ($N = 10$) enrolled in the study pre and post-MBSR intervention

Characteristic	Mean	SD	t	df	p	η^2
Anxiety			3.67	9	.005**	.59
Pre	8.9	5.13				
Post	7.1	4.86				
Depression			−.68	9 .51	.04	
Pre	2.9	3.07				
Post	3.4	2.91				
Total stress score			1.35	8 .21	.17	
Pre	2.02	.68				
Post	1.89	.60				
Primary engagement control						
Coping			−.85	8	.42	.07
Pre	.18	.042				
Post	.19	.037				
Secondary engagement control						
Coping			.35	8	.73	.01
Pre	.28	.05				
Post	.28	.04				

Significant ** $p < .01$

or PMs. All 10 (100 %) of the enrolled participants completed the MBSR intervention. One participant attended four out of six sessions (missed due to illness and out of town), and three participants attended five out of six sessions. These sessions were missed due to being out of town ($n = 1$), illness ($n = 2$), and previous social engagement ($n = 1$). All of these occurrences, except for the illnesses, were made known to the PI prior to the study beginning, and the illnesses were reported to the PI the day before the next session. Six participants attended 100 % of the sessions. All participants completed 100 % of study measures. Feasibility for this MBSR intervention with this sample of adolescents was demonstrated by successful recruitment of ten participants, 100 % participation with no dropouts and 100 % completion of study measures.

Changes in Psychosocial Variables

The frequency of anxiety decreased significantly from the baseline to the post-intervention assessment with the HADS (Fisher's exact test $p = .024$; $\eta^2 = .59$; Fig. 1). Mean anxiety also decreased significantly from baseline to post-intervention ($p < .01$); Fig. 2). The frequency of depression did not change significantly over the course of the intervention (Fisher's exact test $p = .90$; $\eta^2 = .04$). One patient no longer met the criteria for depression at the post-intervention assessment and another had become depressed. There were no significant changes in mean depression from baseline to post-intervention ($p = .51$).

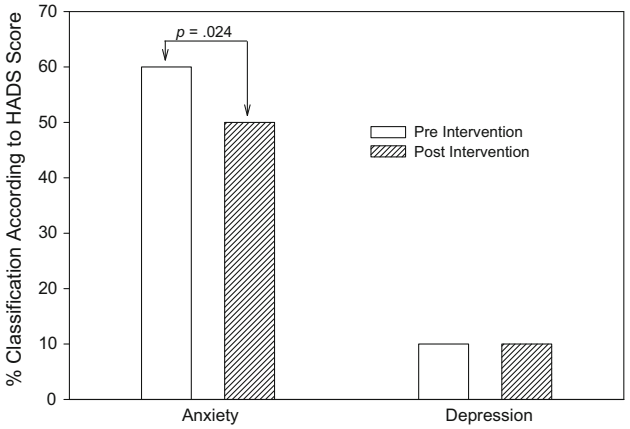

Fig. 1 Percent of participants ($N = 10$) classified as anxious and depressed on the Hospital Anxiety and Depression Scale (HADS) pre and post the six-session MBSR intervention

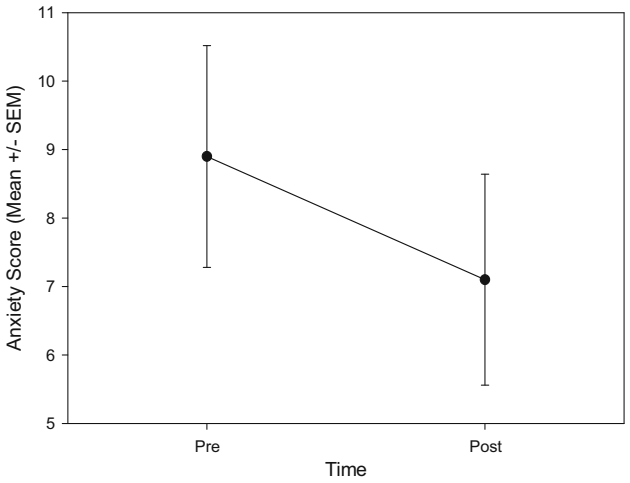

Fig. 2 Mean anxiety score on the Hospital Anxiety and Depression Scale (HADS) pre and post the six-session MBSR intervention ($N = 10$)

Changes in Stress and Coping

Stress scores were slightly, but not significantly, lower after the MBSR (Table 2). The mean post-intervention total stress score of 1.89 (SD = .60) was not significantly ($p = .21$) lower than the baseline score.

Types of coping strategies used did not change significantly over the course of the study. The adolescents reported using secondary control coping strategies most often, explaining 28 % of their total stress response both at baseline and post-intervention (mean ratio scores for secondary control engagement coping = .28, SD = .05 and .28, SD = .04, ($p = .73$)). Primary control engagement coping strategies accounted for 18 % of the total stress response at baseline (mean ratio score = .18, SD = .043)

Table 3 Correlations between anxiety, depression, and coping scores pre- and post-MBSR intervention ($N = 10$)

	Anxiety (baseline)	Anxiety (post)	Depression (baseline)	Depression (post)
Primary control engagement coping				
Baseline	$r = -49$, $p = .15$	$r = -55$, $p = .10$	$r = -65$, $p = .04$***	$r = -19$, $p = .62$
Post	$r = .19$, $p = .63$	$r = .20$, $p = .60$	$r = -19$, $p = .62$	$r = -65$, $p = .06$
Secondary control engagement coping				
Baseline	$r = -59$, $p = .07$	$r = -65$, $p = .04$***	$r = -80$, $p = .005$**	$r = .41$, $p = .24$
Post	$r = -37$, $p = .29$	$r = -42$, $p = .22$	$r = -75$, $p = .01$***	$r = -88$, $p = .001$**

** $p < .01$; *** $p < .05$, two tailed

and 19 % post-intervention which did not significantly differ (mean ratio score = .19, SD = .047, ($p = .42$)). Type of coping was not related to post-intervention anxiety scores, but was related to post-intervention depression scores. There was no significant correlation between post-intervention anxiety scores and post-intervention ($p = .60$) primary engagement control coping scores (see Table 3). Lower levels of depression post-intervention were associated with higher levels of primary engagement control coping post-intervention ($p = .059$) (Table 3). Lower levels of post-intervention depression were strongly associated with higher levels of secondary engagement control coping ($p < .01$) (Table 3).

Responses to Interview Questions

Most patients' responses to a question about how they viewed their devices indicated that they viewed their devices as positive presences in their lives. Forty percent of the patients indicated that their device was their friend and 40 % reported their device being both a friend and an enemy. Two respondents (20 %) said their device was their enemy, preventing them from doing everything they wanted to do.

In response to a question about importance of activities and restrictions, 40 % of the participants said that the restrictions from having the device bothered them very much, while 40 % said they used to hate the restrictions but have gotten used to them. Two participants (20 %) reported that they have always had some activity restrictions, so this was nothing new.

In relation to their scar and device bump, four participants (40 %) said their scar/device bump does not bother them as they have never known their body any differently and/or their scar is "no big deal," while two other participants (20 %) reported that their scar makes them feel self-conscious. Two participants (20 %) said that they feel "great" about their scar.

Discussion

The findings of this study clearly support the feasibility of this intervention with this group of adolescents. The positive outcomes from the quasi-experimental pilot study suggest that adolescents with chronic diseases will experience psychological benefit from MBSR.

The finding that MBSR is feasible in this population is consistent with other studies of MBSR in adolescents. A review of 15 studies of MBSR interventions with adolescents found that all of these studies investigated feasibility and acceptability of mindfulness-based interventions, and overall conclusions indicated that interventions were well tolerated, acceptable, and safe with no adverse events reported in clinical and non-clinical populations [8]. Currently, there are no known published studies evaluating an MBSR intervention in a group of adolescents with ICDs or PMs.

Feasibility was demonstrated in this study as evidenced by 100 % participation with no dropouts and 100 % completion of study measures. Key findings were that every participant had positive comments about the MBSR program. For most participants, the ideas and practices of meditation and yoga were quite novel. Some participants said that they were "nervous" or "didn't know what to expect" initially. While several participants enjoyed some types of MBSR practices more than others, all participants found at least one method they really enjoyed and practiced each week. Several participants commented on the effects that the MBSR program had on their psychological and physical well-being. These participants reported feeling "more energetic and awake" and "less stressed," with fewer physical complaints such as back pain, headache, and nervousness.

In addition, without prompting from the PI (group leader), the participants expressed a desire to continue meeting as a group even after the study ended. The participants also formed their own Facebook group to maintain contact with each other.

Anxiety, Depression, and Coping

At baseline, 60 % of the adolescents with ICDs or PMs reported elevated anxiety. In comparison, a study of 119 adolescents (age 12–20) with congenital heart disease found that 27 % ($n = 32$) had scores indicating anxiety [43]. Anxiety tended to be more common (Fisher's exact test $p = .063$) in the adolescents with cardiac devices in the current study than among the adolescents with congenital heart disease alone. In this sample, levels of anxiety

were equally distributed among participants with PMs ($n = 3$) and ICDs ($n = 3$). Therefore, the increase in anxiety could be explained by the added stress of having a cardiac device, independent of the device type. The mean decrease in HADS-A scores was 1.8 with a 95 % confidence interval of the difference ranging from .69 to 2.91. Ninety percent of the participants demonstrated a decrease in anxiety scores, including five participants with PMs and 4 with ICDs with a large effect size ($\eta^2 = .59$), again demonstrating in this sample that type of device did not change the significant decrease in anxiety scores. These findings related to decreases in anxiety are supported in the literature regarding MBSR interventions for children and adolescents. Significantly decreased levels of anxiety were found in a group of 34 adolescents with learning disabilities following a 5-week mindfulness meditation intervention [1]. A review of 15 studies of mindfulness-based approaches, with children and adolescents with a wide range of clinical diagnoses, states that analyses of changes in post-treatment psychosocial outcome measures range from non-significant to significant, with reported effect sizes ranging from small to large ($d = -0.2$–1.0) [8].

In contrast to anxiety, depression was not prevalent in this sample; therefore, it is not known if this program would have a positive impact on depression in this population based on the results of this study. Baseline prevalence of depression in this study (10 %) was similar to the prevalence (9 %) in a study of adolescents with congenital heart disease [43]. Mean depression scores on the HADS-D were not significantly different from baseline to post-intervention. Since 90 % of the participants did not report elevated baseline depression scores, it would be difficult to detect changes over time. Further studies need to be done with participants who meet criteria for depression at baseline. This finding is similar to two other MBSR intervention studies of adolescents [3, 31]. It is possible that this program or other psycho-educational interventions will be more beneficial for those adolescents who have higher levels of anxiety and/or depression at baseline. In addition, these individuals may be more likely to participate in programs such as MBSR. Further studies need to be done to address these questions.

Coping was evaluated based on the total mean stress score on the RSQ and total factor scores for primary engagement control coping and secondary engagement control coping. Total mean stress scores on the RSQ are a global score for stress. Primary control engagement coping scores on the RSQ are reflective of emotional expression, emotional reflection, and problem solving. Primary control engagement coping ratio score increased from baseline to post-intervention, but this was not a statistically significant difference. Secondary control engagement coping ratio scores on the RSQ are reflective of cognitive restructuring, acceptance, positive thinking, and distraction. Secondary control engagement coping score was unchanged from baseline to post-intervention. Therefore, the adolescents in this sample used secondary control coping strategies more frequently than primary control coping strategies (28 vs. 18 %) to deal with ICD- or PM-related stress. The non-significant findings of no change in primary or secondary control coping scores over the 6-week intervention period suggests that the MBSR intervention did not change the participants' overall coping strategies; however, the use of these strategies may have had an effect on the overall outcome of anxiety. The intervention may not have been long enough to change overall coping strategies. Follow-up measures at 3 or 6 months might have shown differences in coping strategies over time. Future studies will include longer follow-up.

Relationship Between Coping Strategy and Psychosocial Outcomes

In this study, greater use of primary engagement control coping was associated with lower levels of depression. Adolescents who were more emotionally expressive and had better problem-solving strategies had lower levels of depression before the intervention. The negative relationship between post-intervention depression and post-intervention primary control engagement coping approached significance with higher levels of primary engagement control coping associated with lower levels of depression. The negative relationship of emotional expression, emotional regulation, and problem solving to depression was consistent with the literature. Two studies reported that increased use of primary engagement coping strategies such as emotional expression and problem solving was associated with better QOL and increased resilience [22, 26].

Secondary control engagement coping scores on the RSQ are reflective of cognitive restructuring, acceptance, positive thinking, and distraction. In this study, the association between secondary engagement control coping and anxiety approached significance with a strong, negative correlation between the two variables. Cognitive restructuring, acceptance, positive thinking, and distraction at baseline were associated with lower anxiety and lower depression levels post-intervention. There was a strong, negative correlation between post-intervention depression scores and post-intervention secondary engagement control coping scores, with higher levels of post-intervention secondary engagement control coping associated with lower levels of post-intervention depression. These findings imply that methods to enhance the use of these coping strategies may offer tools for the adolescents to decrease their anxiety and depression. In other clinical populations, greater use of secondary control coping strategies was

associated with positive health outcomes such as better asthma control and less pain [36, 46]. Greater use of secondary control coping strategies including distraction and acceptance was associated with higher QOL and better metabolic control in adolescents with Type 1 diabetes [26].

Anecdotal Data

During the final session of the MBSR intervention, each participant spoke to the group about why they initially came to the program and what kept them coming each week. Two participants said that they initially "came for the money" but stayed because they liked what they were learning and liked the meeting and getting to know group. One participant said that she came for the yoga mat and to meet other kids who shared similar problems and stayed because of the mindfulness techniques and the rest of the group. The other seven participants said that they came to learn how to relax and lower their stress and stayed because they thought the techniques were working and because they liked being with the group.

During the 5th session, the entire group asked if they could continue meeting with the PI after the study was over. It was agreed that the group would continue to meet monthly after the final session was completed. Parents of the participants agreed to bring their children to the monthly group as often as possible. In addition, nine of the participants exchanged contact information in order to be able to form their own Facebook group after the sessions ended. One of the participants agreed to put the Facebook group together. One participant (the youngest) was not a Facebook member and therefore did not join the Facebook group.

Limitations

Due to the small sample size and lack of control group, it is difficult to determine whether the significant decrease in anxiety at the end of the MBSR intervention was due to the basic elements of the MBSR program, or the peer-group, social support aspects of the program. In addition, the PI was a respected clinician who was well known by all participants. All non-significant results must be viewed with caution due to the small sample size, as there was not enough power to prove non-significance.

Conclusion

These results reveal that the adolescents who participated in this intervention had significant decreases in anxiety scores and significant associations between coping strategies and levels of anxiety and depression after the intervention. In addition, qualitative data showed perceived improvement in ability to manage psychological stress and to decrease physical symptoms associated with stress with the formal and informal MBSR practices such as meditation and yoga. As in other studies previously described, the findings of this study suggest that coping strategies may make a difference in how adolescents cope with health issues. Teaching adolescents to think positively, cognitively restructure their thoughts and beliefs about their illness and distract and to use acceptance may lead to more adaptive outcomes [10]. The data reported here are encouraging for continuing to evaluate the effectiveness of the MBSR intervention for groups of adolescents with ICDs, PMs, and other congenital heart disease. The results of this successful pilot study were used to design a randomized control trial utilizing the MBSR intervention with a comparison group (support group without the MBSR intervention). Power analysis using data from the pilot study determined the needed sample size for adequate power. This study is currently underway.

As of this writing, there are no published studies utilizing psycho-educational interventions in this patient population. However, several meta-analyses [17, 28, 30] have described the need for psycho-educational interventions aimed at reducing distress in adolescents with ICDs and/or congenital heart disease as well as the need for research to determine the effectiveness of these interventions.

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Conflict of interest The authors declare that they have no conflicts of interest.

References

1. Beauchemin J, Hutchins TL, Patterson F (2008) Mindfulness meditation may lessen anxiety, promote social skills, and improve academic performance among adolescents with learning disabilities. Complement Health Pract Rev 13(1):34–45
2. Berul CI, Van Hare G, Kertsz N et al (2008) Results of a multicenter retrospective implantable cardioverter defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol 51:1685–1691
3. Biegel GM, Brown KW, Shapiro SL, Schubert CM (2009) Mindfulness-based stress reduction for the treatment of adolescent psychiatric outpatients: a randomized clinical trial. J Consult Clin Psychol 77(5):855
4. Bilge AK, Ozben B, Demircan S et al (2006) Depression and anxiety status of patients with implantable cardioverter defibrillator and precipitating factors. Pacing Clin Electrophysiol 29(6):619–626
5. Bjelland I, Dahl AA, Haug TT, Neckelmann D (2002) The validity of the hospital anxiety and depression scale: an updated literature review. J Psychosom Res 52(2):69–77

6. Bögels S, Hoogstad B, van Dun L et al (2008) Mindfulness training for adolescents with externalizing disorders and their parents. Behav Cogn Psychother 36(02):193–209
7. Bootzin RR, Stevens SJ (2005) Adolescents, substance abuse, and the treatment of insomnia and daytime sleepiness. Clin Psychol Rev 25(5):629–644
8. Burke CA (2010) Mindfulness-based approaches with children and adolescents: a preliminary review of current research in an emergent field. J Child Fam Stud 19(2):133–144
9. Cohen J (1988) Statistical power analysis for the behavioral sciences. Psychology Press, Hove
10. Compas BE, Boyer MC, Stanger C et al (2006) Latent variable analysis of coping, anxiety/depression, and somatic symptoms in adolescents with chronic pain. J Consult Clin Psychol 74(6):1132
11. Connor-Smith JK, Compas BE, Wadsworth ME (2000) Responses to stress in adolescence: measurement of coping and involuntary stress responses. J Consult Clin Psychol 68:976–992
12. Cowan MJ, Pike KC, Budzynski HK (2001) Psychosocial nursing therapy following sudden cardiac arrest: impact on two-year survival. Nurs Res 50(2):68–76
13. DeMaso DR, Lauretti A, Spieth L, Van Der Feen JR, Jay K, Gauvreau K et al (2004) Psychosocial factors and quality of life in children and adolescents with implantable cardioverter-defibrillators. Am J Cardiol 93:582–587
14. DeMaso DR, Neto LB, Hirshberg J (2009) Psychological and quality-of-life issues in the young patient with an implantable cardioverter-defibrillator. Heart Rhythm 6(1):130–132
15. Dougherty CM, Thompson EA, Lewis F (2005) Long-term outcomes of a telephone intervention after an ICD. Pacing Clin Electrophysiol 28(11):1157–1167
16. Dunbar SB, Langberg JJ, Reilly CM et al (2009) Effect of a psychoeducational intervention on depression, anxiety, and health resource use in implantable cardioverter defibrillator patients. Pacing Clin Electrophysiol 32(10):1259–1271
17. Dunbar S, Dougherty C, Sears S et al (2012) Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter defibrillators and their families: a scientific statement from the American Heart Association. Circulation 126:2146–2172
18. Duru F, Buchi S, Klaghofer R et al (2001) How different from pacemaker patients are recipients of implantable cardioverter-defibrillators with respect to psychosocial adaptation, affective disorders, and quality of life? Heart 85(4):375–379
19. Freedenberg V, Thomas SA, Friedmann E (2011) Anxiety and depression in implanted cardioverter-defibrillator recipients and heart failure: a review. Heart Fail Clin 7(1):59–68
20. Friedmann E, Thomas SA, Liu F et al (2006) Relationship of depression, anxiety, and social isolation to chronic heart failure outpatient mortality. Am Heart J 152(5):940 e1,940. e8
21. Gradaus R, Wollmann C, Kobe J et al (2004) Potential benefit from implantable cardioverter-defibrillator therapy in children and young adolescents. Heart 90(3):328–329
22. Graue M, Wentzel-Larsen T, Bru E et al (2004) The coping styles of adolescents with type 1 diabetes are associated with degree of metabolic control. Diabetes Care 27(6):1313–1317
23. Greenberg MT, Domitrovich C, Bumbarger B (2001) The prevention of mental disorders in school-aged children: current state of the field. Prev Treat 4(1):1a
24. Grossman P, Niemann L, Schmidt S, Walach H (2004) Mindfulness-based stress reduction and health benefits: a meta-analysis. J Psychosom Res 57(1):35–43
25. Irving JA, Dobkin PL, Park J (2009) Cultivating mindfulness in health care professionals: a review of empirical studies of mindfulness-based stress reduction (MBSR). Complement Ther Clin Pract 15(2):61–66
26. Jaser SS, White LE (2011) Coping and resilience in adolescents with type I diabetes. Child Care Health Dev 37(3):335–342
27. Kabat-Zinn J, Hanh TN (2009) Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness. Random House LLC, New York
28. Karsdorp P, Everaerd W, Kindt M (2007) Psychological and cognitive functioning in children and adolescents with congenital heart disease: a meta-analysis. J Pediatr Psychol 32(5):527–541
29. Kohn CS, Petrucci RJ, Baessler C et al (2000) The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. Pacing Clin Electrophysiol 23(4):450–456
30. Lane DA, Millane TA, Lip GY (2013) Psychological interventions for depression in adolescent and adult congenital heart disease. Cochrane Database Syst Rev. doi:10.1002/14651858.CD004372.pub2
31. Lee J, Semple RJ, Rosa D, Miller L (2008) Mindfulness-based cognitive therapy for children: results of a pilot study. J Cogn Psychother 22(1):15–28
32. Lloyd-Jones D, Adams RJ, Brown TM et al (2010) Executive summary: heart disease and stroke statistics–2010 update: a report from the American Heart Association. Circulation 121(7):948–954
33. Maryniak A, Szumowski Ł, Orczykowski M, Przybylski A, Walczak F (2009) Anxiety and depression among the patients with frequent implantable cardioverter–defibrillator discharges. Int J Cardiol 132(2):e80–e81
34. Newall EG, Lever NA, Prasad S et al (2007) Psychological implications of ICD implantation in a new zealand population. Europace 9(1):20–24
35. Nichol G, Thomas E, Callaway CW et al (2008) Regional variation in out-of-hospital cardiac arrest incidence and outcome. JAMA 300(12):1423–1431
36. Schreier H, Chen E (2008) Prospective associations between coping and health among youth with asthma. J Consult Clin Psychol 76(5):790
37. Sears SF, Conti JB (2002) Quality of life and psychological functioning of ICD patients. Heart 87(5):488–493
38. Sears SF, Conti JB (2006) Psychological aspects of cardiac devices and recalls in patients with implantable cardioverter defibrillators. Am J Cardiol 98:565–567
39. Sears S, Eads A, Marhefka S (1999) The US national survey of ICD recipients: examining the global and specific aspects of quality of life. Eur Heart J 20:232
40. Semple RJ, Reid EF, Miller L (2005) Treating anxiety with mindfulness: an open trial of mindfulness training for anxious children. J Cogn Psychother 19(4):379–392
41. Singh NN, Lancioni GE, Joy SDS, Winton AS, Sabaawi M, Wahler RG et al (2007) Adolescents with conduct disorder can be mindful of their aggressive behavior. J Emot Behav Disord 15(1):56–63
42. Singh NN, Lancioni GE, Singh AN et al (2008) A mindfulness-based health wellness program for an adolescent with prader-willi syndrome. Behav Modif 32(2):167–181
43. Wang Q, Hay M, Clarke D, Menahem S (2012) The prevalence and predictors of anxiety and depression in adolescents with heart disease. J Pediatr 161(5):943–946.e1
44. White D, Leach C, Sims R et al (1999) Validation of the hospital anxiety and depression scale for use with adolescents. Br J Psychiatry 175:452–454
45. Zhan C, Baine WB, Sedrakyan A, Steiner C (2007) Cardiac device implantation in the United States from 1997 through 2004: a population-based analysis. J Gen Intern Med 23:13–19
46. Zigmond AS, Snaith RP (1983) The hospital anxiety and depression scale. Acta Psychiatr Scand 67(6):361–370
47. Zylowska L, Ackerman DL, Yang MH et al (2008) Mindfulness meditation training in adults and adolescents with ADHD: a feasibility study. J Atten Disord 11(6):737–746