Psychiatric Functioning and Quality of Life in Young Patients With Cardiac Rhythm Devices

WHAT'S KNOWN ON THIS SUBJECT: Initial studies in children and young adults have identified higher levels of anxiety and lower quality of life scores in patients with implantable cardioverter–defibrillators. Few studies are available looking at the same questions in young patients with pacemakers.

WHAT THIS STUDY ADDS: Anxiety is highly prevalent in young patients with ICDs, but the higher rates can be attributed to medical disease severity and age at implantation rather than type of device. Patients with pacemakers have depression and anxiety but at lower rates.

abstract

BACKGROUND: Less is known about depression, anxiety and quality of life (QoL) in children and adolescents with pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) than is known in adults with these devices.

METHODS: A standardized psychiatric interview diagnosed anxiety/depressive disorders in a cross-sectional study. Self-report measures of anxiety, depression and post-traumatic stress disorder were obtained. Medical disease severity, family functioning and QoL data were collected. A total of 166 patients were enrolled (52 ICD, 114 PM; median age 15 years).

RESULTS: Prevalence of current and lifetime psychiatric disorders was higher in patients with ICDs than PMs (Current: 27% vs. 11%, $P = .02$; Lifetime: 52% ICD vs. 34% PM, $P = .01$). Patients with ICDs had more anxiety than a healthy population (25% vs. 7%, $P < .01$). Patients with ICDs and PMs had similar levels of depression as a healthy population (ICD 10%, PM 4%, reference 4%, $P = .29$). In multivariate analysis including a medical disease score, demographics, exposure to beta-blockers, activity limitations, hospitalizations, shocks and procedures, the type of device (PM versus ICD) did not predict psychiatric diagnoses when age at implantation and the severity of medical disease were controlled for. Patients with ICDs and PMs had lower physical QoL scores (ICD 45, PM 47.5, Norm 53, $P \leq .03$), but similar psychosocial functioning scores (ICD 49, PM 51, Norm 51, $P \geq .16$) versus a normal reference population.

CONCLUSIONS: Anxiety is highly prevalent in young patients with ICDs, but the higher rates can be attributed to medical disease severity and age at implantation instead of type of device. *Pediatrics* 2014;133:e964–e972

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KEY WORDS

pacemaker, ICD, pediatrics, depression, anxiety

ABBREVIATIONS

BSI—Brief Symptom Inventory

DSI—Device Severity Index

DSM-IV—*Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*

ICD—implantable cardioverter–defibrillator

IFS—Impact on Family Scale

K-SADS-PL—Schedule for Affective Disorders and Schizophrenia in School Aged Children and Adolescents—Present and Lifetime Version

PM—pacemaker

PTSD—posttraumatic stress disorder

QoL—quality of life

RCMAS—Revised Children's Manifest Anxiety Scale, Version 2

Dr Webster designed the study, performed statistical analysis, supervised the study and drafted the manuscript. Dr Panek, Ms Martuscello, Dr Cecchin, Dr Berul and Dr DeMaso performed study design, data collection and manuscript revision. Ms Labella and Mr Taylor conducted K-SADS-PL interviews, and revised the manuscript. Dr Gauvreau performed univariate and multivariate analyses and reviewed and revised the manuscript for statistical analysis. Dr Walsh supervised data analysis and reviewed and revised the manuscript.

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Children and adolescents receive implantable cardioverter–defibrillators (ICDs) and pacemakers (PMs) for structural and electrical cardiac disease. Adults with ICDs have significantly higher levels of depression and anxiety,^{1–5} and frequent ICD discharges in adults have been associated with even higher risk for depression and anxiety.⁶ However, studies on children and adolescents with ICDs are limited.^{7–11} DeMaso and colleagues¹² found changes in scores for anxiety, depression, family functioning, and quality of life (QoL) in pediatric patients with ICDs (20 patients). Sears and colleagues¹³ examined a similar age group with ICDs and reported lower psychosocial and physical QoL scores compared with healthy children (60 patients). Koopman and colleagues¹⁴ found higher rates of depression and anxiety and found that the presence of shocks and a longer time since device implantation were associated with higher anxiety scores in young patients (30 patients). All these studies are limited by reliance on self-report measures. To date, no study has evaluated children for the presence of emotional or behavioral conditions using a standardized structured psychiatric interview.

There has been no systematic study of anxiety and depression in young patients with PMs. The few studies in the literature have focused on adults and older adults.^{15,16} Patients with PMs are an important comparison group for patients with ICDs because they too have an implanted cardiac rhythm device, yet they do not experience the ICD shocks postulated to promote heightened anxiety and depression in adults. These devices lie under the patient's skin. The implantation leaves visible scars, and the edges of the device are palpable. Surgery for generator changes is necessary every few years, and occasional lead revisions are

needed. Patients with ICDs may receive sudden, unexpected, and painful shocks from the device. A PM or ICD also may introduce the concept of being “dependent on a machine” into a child's understanding of his or her body. For all these reasons, these devices may decrease psychiatric functioning and QoL in children and young adults.

This study examined psychiatric functioning and QoL in pediatric patients living with cardiac arrhythmias and a cardiac rhythm device. We hypothesized that young patients with ICDs would have a higher prevalence of psychiatric disorders, along with more symptoms of depression and anxiety, and lower QoL when compared with young patients in the community and those with cardiac PMs.

METHODS

Subjects

All subjects were evaluated once, creating a cross-sectional study. We enrolled subjects between August 2009 and October 2010 at Boston Children's Hospital. We used a clinical database to identify patients with a functioning ICD or PM who were between 6 and 20 years of age and received clinical care at our institution. We applied the following exclusion criteria: absence of English language fluency (many measures did not have alternative-language offerings), hospitalization within 4 weeks of the study administration date (recent admission influences psychiatric responses and QoL), and having one's first ICD or PM implanted within 6 months of the study administration date (insufficient longitudinal exposure to the device). All remaining patients in the database were sent a written invitation to participate in the study. Follow-up phone calls were made to request participation. Patients from the group who agreed to

participate and were willing to attend a single study session were included in the study.

This study was approved by the hospital's institutional review board, registered with clinicaltrials.gov (identifier NCT01040988), and conducted in accordance with institutional guidelines. Eligible patients gave written informed consent or assent; parents gave written informed consent for patients under 18 years of age.

Assessments

Study visits were scheduled in 2-hour blocks and were performed in a location separate from the subject's clinical evaluation. The assessment consisted of a standardized structured psychiatric interview and self-report questionnaires for subjects and parents. Interviewers were experienced pediatric psychiatry researchers, trained in administering these scales by the Department of Psychiatry for this and other studies. All interview results were reviewed with a child and adolescent psychiatrist (K.A.P. and D.R.D.) to determine a specific diagnosis. A random subset of the interviews were audio recorded and reviewed to maintain consistency between reviewers. Most subjects finished the written questionnaires within the time allotted for their visit. For those who did not, completed questionnaires were retrieved by mail or in person at a later date.

Measures

Cardiac Arrhythmia and Severity of Illness

Medical data on each study subject, including current medications, hospitalizations, procedures, and shocks, were gathered from medical chart review and were confirmed by direct interview with the patient or parent. In cases where chart review and parent

information differed, a cardiac electrophysiologist helped resolve the discrepancy. Congenital heart disease was defined as an anatomic or structural abnormality present at birth, typically necessitating surgical intervention. Subjects whose structural diagnoses were considered variants of normal (primarily patent foramen ovale or a history of isolated peripheral pulmonary stenosis) were not classified as having congenital heart disease.

The Device Severity Index (DSI) is a modification of the 8-item Defibrillator Severity Index, a scale with excellent published interrater agreement designed to allow cardiologists to classify patients with ICDs according to the underlying severity of their disease.¹² The DSI was modified to apply to both ICDs and PMs to minimize confounding effects of medical variables that influence device selection. Items regarding ICD indications, ventricular arrhythmia diagnosed, and number of appropriate ICD discharges were dropped and replaced with recent hospitalizations, failure to thrive (based on documentation in the medical record), and developmental delay (Supplemental Information Table 7). Developmental delay for purposes of the DSI measure was determined by either parental report or a score of <70 on the Scales of Independent Behavior–Revised, a well-established, comprehensive, norm-referenced assessment of functional independence and adaptive functioning.¹⁷

Primary Outcome Measure

The Schedule for Affective Disorders and Schizophrenia in School Aged Children and Adolescents–Present and Lifetime Version (K-SADS-PL) is a standardized structured psychiatric interview yielding *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV) psychiatric

diagnoses.¹⁸ Modules evaluating depressive and anxiety disorders were administered to the subject and a parent or guardian. Adequate interrater (93%–100%) and test–retest reliability, as well as convergent and discriminant validity, have been established for use of the K-SADS-PL with children 6 to 17 years of age. Information from both modules was combined and scored according to published K-SADS-PL standards.

For each diagnosis assessed, the main endpoint was binary: diagnostic criteria met, yes or no. The measure reports a diagnosis for 2 time perspectives. The first time perspective is “current diagnosis,” which was our primary outcome measure. The K-SADS-PL reports that the subject has a current diagnosis when his or her answers meet criteria for a psychiatric diagnosis at the time of the interview. The K-SADS-PL reports a second time measure: “lifetime diagnosis.” The subject qualifies for a lifetime diagnosis on the K-SADS-PL when his or her answers meet criteria that demonstrate that he or she carried a qualifying psychiatric diagnosis currently or at any previous time. This outcome has been defined and validated in the K-SADS-PL; it is intended to screen for the presence of these diagnoses over the subject’s entire lifetime, not just on the day that the K-SADS-PL is administered. These distinctions exist within the K-SADS-PL and were applied in this study according to the K-SADS-PL guidelines.

Where K-SADS-PL was compared against normative values, we used median estimates of prevalence from a meta-analysis of 21 epidemiologic studies; comparison rates for lifetime diagnosis were from the clinical reappraisal sample of the National Comorbidity Survey of Adolescents.^{19,20} The National Comorbidity Survey of Adolescents is a nationally representative survey of 10 123 American youth that used

a combination of structured adolescent interviews and parent report forms to yield DSM-IV diagnoses. Its clinical reappraisal sample ($n = 347$), weighted to represent the larger sample, was also assessed by using K-SADS-PL.

Patient Measures of Anxiety, Depression, and Stress

To elucidate psychiatric functioning in this population, the following self-report measures were selected to capture the symptoms of depression and anxiety in addition to the presence or absence of a psychiatric disorder.

The Revised Children’s Manifest Anxiety Scale, Version 2 (RCMAS) is a well-established 49-item self-report questionnaire for children ages 6 to 19 that evaluates anxiety symptom severity. The RCMAS contains an embedded lie scale, designed to detect bias in favor of socially desirable responses. Items have a reliability estimate of 0.83.²¹

The Reynold’s Child Depression Scale for ages 7 to 12 and the Reynold’s Adolescent Depression Scale, Version 2 for children ages 13 to 20 are well-established self-report measures designed to assess depressive symptoms. With a 4-point Likert-type response format, these measures are reliable and valid. Ratings from the child and adolescent measures were transformed into T scores and combined into 1 subject pool, according to previously published methods.²²

Given concern about impact of painful device shocks, a specific measure for posttraumatic stress disorder (PTSD) was specifically selected. The University of California, Los Angeles Posttraumatic Stress Disorder Reaction Index is a reliable, validated self-report scale for patients 6 to 17 years old. It assesses symptoms of PTSD from the DSM-IV on a 5-point frequency scale, used to identify full or partial DSM-IV

diagnoses.²³ The scale first asks symptom probes to determine what traumas have been present before requesting descriptions of any additional traumatic experiences the subject has had. For the purposes of this study, we added a query to the list of symptom probes, “having an operation in the hospital to treat a heart condition,” to assess whether participants found this particular experience traumatic.

Parent Measures of QoL, Family Impact, and Parental Functioning

To fully understand the QoL in these youth, measures that capture illness impact on family and parental psychological distress were selected in addition to a measure of QoL.

The Child Health Questionnaire-50 is a well-validated 50-item parent report of QoL that has physical and psychosocial summary scores.²⁴ For the Child Health Questionnaire-50, internal consistency estimates from a normative US sample showed a median reliability estimate of 0.84.²⁴

The Impact on Family Scale (IFS) is a well-established 27-item parent questionnaire that assesses the financial, social, and personal impact of a child's heart condition on the family. Originally developed to assess functioning in families with children who have chronic health conditions, the IFS has been found to be a reliable and valid measure of the effect of a child's illness that can be used across diagnostic groups.^{25,26}

The Brief Symptom Inventory (BSI) is a well-established 53-item parent questionnaire used to screen adults for current psychological distress.²⁷ Normed on a population of 974 non-patient adults, the BSI consists of items reflecting a wide range of psychiatric symptoms; parents rated how problematic each symptom (on a scale from 0 to 4) had been during the previous

week. The BSI generates a Global Severity Index, which is a cumulative measure of symptom severity. Scores in the clinically elevated range on the Global Severity Index identify presumptive psychiatric cases.

Statistical Analyses

Data were double-entered into a custom-designed database and independently cross-checked for accuracy. Analysis was performed by using SPSS Version 12.0 for Windows (IBM SPSS Statistics, IBM Corporation). Patient characteristics were compared by using Fisher's exact test for categorical variables and either the *t* test or Wilcoxon rank-sum test for continuous variables. Comparisons against published population norms were made using 1-sample *t* tests, but all other continuous comparisons were made using 2-sample *t* tests. For regression analysis, variables significant at the 0.1 level in univariate analysis were considered for inclusion in a multivariable logistic regression model. Forward selection was used, and *P* < .05 was required for retention in the final model. In a prespecified analysis, univariate and multivariate regression were performed on factors that may have contributed to the differences between these 2 populations. Age at implantation, age at the time of the study, total score on the DSI, any shocks, frequent shocks (>3 shocks), frequent surgeries (>3 surgeries), frequent hospitalizations (>3 hospitalizations), frequent invasive procedures (>5 procedures), the presence of activity limitations, and current use of β -blocking agents were eligible for inclusion in the model. Once this model was determined, “ICD or pacemaker” was added as a binary covariate to determine whether type of device was associated with diagnosis after other risk factors were adjusted for.

RESULTS

Patient Characteristics

A total of 166 patients were enrolled, ranging in age from 6 to 20 years, with a median of 15 years (Fig 1). ICDs were present in 52 patients (31%), and PMs were present in 114 patients (69%). Compared with patients with PMs, ICD subjects were older, took more medications, including β -blockers, had more familial heart disease, and had more activity restrictions (*P* < .01) (Table 1).

Anxiety and Depression, Psychiatric Interview (K-SADS-PL)

The current prevalence of any anxiety or depression disorders was 27% in patients with ICDs and 11% in patients with PMs (*P* = .02, Table 2). The lifetime prevalence of anxiety or depressive disorders was 52% in patients with ICDs and 32% in patients with PMs (*P* = .01, Table 2). Compared with those with PMs, subjects with ICDs had higher rates of current anxiety diagnoses (25% vs 8%, *P* < .01) and lifetime anxiety diagnoses (42% vs 24%, *P* < .02). Rates of depression were not significantly different between groups, either currently (10% vs 4%) or over the subject's lifetime (27% vs 18%).

Compared with rates reported from community samples, patients with ICDs showed higher rates of anxiety disorders, both current and lifetime, but no significant difference in depressive disorders (Table 3).^{19,20} Rates of anxiety and depressive disorders were not significantly different between the PM group and community samples.

Anxiety, Depression, and Stress

In contrast to the psychiatric interview, there were no significant differences between patients with ICDs and those with PMs in self-reported measures of anxiety and depression. In both groups, self-reported anxiety and depression

FIGURE 1

Patients screened for study enrollment. The dotted enclosure represents all patients who were excluded because they were not current device patients or because they met exclusion criteria. Exclusion criteria: absence of English language fluency, hospitalization within 4 weeks of the study administration date, and first device implanted within 6 months of the study administration date.

TABLE 1 Characteristics of Pediatric Patients With Cardiac Rhythm Devices

Characteristic	ICD Group (n = 52)	Pacemaker Group (n = 114)	P
Age, yr (SD)	16 (3.6)	14 (4.5)	<.01
Female gender, %	39	49	.24
Median age at implant, yr	13.8	4.5	<.01
Structural congenital heart disease, %	12	48	<.01
Taking β -blockers, % ^a	69	19	<.01
Taking any medication, %	92	61	<.01
Cardiac family history, %	60	27	<.01
Cardiac death in family, %	12	2	<.01
Moderate to severe exercise restrictions, %	48	1	<.01
Developmental delay, %	13	4	.10
Surgeries, mean number	2.1	3.2	<.01
Catheterizations, mean number	2.2	3.3	.03
Total procedures (include noncardiac surgeries), mean number	3.3	5.7	<.01

^a β -blocker use includes antiarrhythmic drugs with β -blocker properties (amiodarone, sotalol).

scores were lower (indicating lower symptoms) than published community norms for the measures (Table 4).^{19,20} However, we noted that 28% of our subjects scored in the clinical range on the RCMAS internal bias scale, compared with an expected 15%.

On the University of California, Los Angeles Posttraumatic Stress Disorder Reaction Index, 7 subjects (4%) met criteria for “probable partial diagnoses” and 2 subjects (1%) for “probable full diagnoses.” These 2 subjects both had ICDs and were also identified as having current PTSD in their psychiatric interview. Both patients reported that the stress symptoms were related to being shocked multiple times by their ICDs. However, the small number of subjects

with PTSD is too small to statistically correlate PTSD and shocks.

QoL, Family Impact, and Parental Functioning

There were no significant differences between patients with ICDs and PMs reports of psychosocial QoL (ICD 47.9 ± 13.9 vs PM 44.7 ± 14.8) or physical QoL (ICD 44.6 ± 21.6 vs PM 39.7 ± 21.3). The IFS did not show statistically different family functioning for families of patients with PMs versus families of patients with ICDs (mean score 1.76 vs 1.85, $P = .34$).

Compared with healthy normative groups, patients with ICDs and PMs had significantly lower physical QoL scores but comparable psychosocial functioning (Table 4).²⁴ The IFS was

developed with normative values for parents of patients with significant chronic disease. Parents in the current study reported significantly less family strain than the published comparison sample ($P < .01$).^{25,26} Parent distress was measured with the BSI. The global severity scores for parents of patients with ICDs and PMs were indistinguishable from scores of healthy normative samples (Table 4).

Multivariate Analysis and Psychiatric Disorders

In the univariate model, patients with ICDs were more likely than patients with PMs to have depression or anxiety disorders (Table 5). However, in multivariate analysis, type of device did not demonstrate a statistically significant influence on the prevalence of anxiety or depression, either at the time of evaluation (current diagnosis) or in lifetime analysis, when age at implantation and total DSI score were controlled for (Table 6). The presence of any shocks, frequent shocks, frequent surgeries, frequent hospitalizations, frequent invasive procedures, the presence of activity limitations, and current use of β -blocking agents were not significantly associated with depression or anxiety in either the univariate or multivariate models. In multivariate analysis, an increase of 1 unit on the DSI carried an odds ratio of

TABLE 2 Current Prevalence and Lifetime Prevalence of Psychiatric Diagnoses in Young Patients With ICDs and PMs

	Current Prevalence ^a			Lifetime Prevalence ^a		
	ICD (%)	PM (%)	<i>P</i>	ICD (%)	PM (%)	<i>P</i>
Any psychiatric diagnosis	14 (27)	13 (12)	.02	27 (52)	36 (32)	.02
Anxiety disorders	13 (25)	9 (8)	.01	22 (42)	27 (24)	.02
Social phobia	6 (12)	5 (4)		10 (19)	13 (11)	
Generalized anxiety disorder	6 (12)	2 (2)		7 (14)	3 (3)	
Separation anxiety disorder	2 (4)	4 (4)		7 (14)	10 (9)	
Simple phobia	2 (4)	3 (3)		2 (4)	6 (5)	
Posttraumatic stress disorder	2 (4)	0		6 (12)	7 (6)	
Agoraphobia	1 (2)	1 (1)		2 (4)	3 (3)	
Panic disorder	1 (2)	1 (1)		2 (4)	3 (3)	
Acute stress disorder	0	0		0	0	
Adjustment disorder with anxious mood	0	0		1 (2)	4 (4)	
Depressive disorders	5 (10)	5 (4)	.29	14 (27)	21 (18)	.22
Major depressive disorder	2 (4)	4 (4)		8 (15)	15 (13)	
Dysthymia	2 (4)	0		3 (6)	4 (4)	
Depressive disorder not otherwise specified	1 (2)	1 (1)		5 (10)	2 (2)	
Adjustment disorder with depressed mood	0	0		3 (6)	4 (4)	

^a Columns do not sum evenly because of patients with multiple diagnoses.

TABLE 3 Current and Lifetime Prevalence of Psychiatric Diagnoses in Cardiac Device Groups, as Compared With Healthy Normative Samples

	Population Norms ^b	ICDs	Effect Size ^a	<i>P</i>	PMs	Effect Size ^a	<i>P</i>
Current disorder							
Anxiety disorder (%)	7 ¹⁹	25	18	<.01	8	1	.5
Depressive disorder (%)	4 ¹⁹	10	6	.08	4	0	.64
Lifetime disorder							
Anxiety disorder (%)	25 ²⁰	42	17	<.01	24	1	.37
Depressive disorder (%)	24 ²⁰	27	3	.37	18	6	.19

^a Effect sizes are expressed as the difference in means between the sample population and the reference population.

^b Normative values have been previously published and are referenced in the Methods section for each scale.

TABLE 4 Patient- and Parent-Completed Measures Compared With Healthy Normative Samples

	Healthy Norms ^a Mean	ICD Mean (SD)	Effect Size	<i>P</i> (norms versus ICD)	Pacemaker Mean (SD)	Effect Size	<i>P</i> (norms versus PM)
Patient measures							
Total anxiety (RCMAS)	50	43.2 (10.4)	6.8	<.01	42.7 (10.1)	7.3	<.01
Total depression (RADS/RCDS)	50	42.9 (7.7)	7.1	<.01	42.7 (8.5)	7.3	<.01
Parent measures							
Physical quality of life (CHQ-50)	53	45.0 (11.5)	8.0	<.01	47.5 (11.8)	5.5	.03
Psychosocial quality of life (CHQ-50)	51	49.0 (10.0)	2.0	.16	51.2 (10.3)	0.2	.84
Parent distress, global severity (BSI)	0.30	0.39 (0.41)	0.09	.12	0.32 (0.33)	0.02	.52

CHQ-50, Child Health Questionnaire; RADS, Reynold's Adolescent Depression Scale, Version 2; RCDS, Reynold's Child Depression Scale; RCMAS, Revised Children's Manifest Anxiety Scale, Version 2

^a Normative values have been previously published and are referenced in the Methods section for each scale.

1.54 (95% CI, 1.17–2.02; *P* = .03) in favor of having a depression or anxiety disorder. An increase of 1 year of age at implantation carried an odds ratio of 1.09 (95% CI, 1.01–1.18; *P* = .03).

DISCUSSION

Children and adolescents with ICDs were found to have higher rates of anxiety disorders than children and adolescents with PMs. Rates of anxiety

disorders were higher on the day that patients performed our study (“current diagnoses”) and when we looked back at their whole lives (“lifetime diagnoses”). In addition, young patients with ICDs showed higher prevalence rates of current and lifetime anxiety disorders than have been found in community samples. The higher levels of anxiety among patients with ICDs may seem to implicate unique stresses associated with its defibrillating function. However, the new contribution from this article is that the association with higher anxiety may not be related to whether the patient receives a PM or ICD. When analyses controlled for age at device implantation and severity score on the DSI, the type of device did not predict the presence of diagnosable psychiatric disorder, either at the time of evaluation or over the subject's lifetime. These findings suggest that patients with more medical disease and those who are older at device implantation may have higher anxiety levels, regardless of whether they receive a PM or ICD.

Patients who receive devices at an older age have an opportunity to see these devices as intrusive and foreign. However, many children have devices placed in infancy or before school age, in some cases on the very first day of life. These children have experienced only life with a device. This experience may protect them from some of the maladaptive responses that eventually lead to anxiety and depression disorders. A higher burden of psychiatric disease has been found in many patients with medical diseases, so the coupling between medical disease and a psychiatric diagnosis is less surprising, but it has profound implications for patient care: Patients with significant medical disease who receive a device are at high risk and should receive early intervention for psychiatric comorbidities.

TABLE 5 Univariate Regression Model for Subjects With Any Diagnosis of Psychiatric Disease (by K-SADS-PL) Compared With Patients With No Diagnosis of Psychiatric Disease

	Any Diagnosis (<i>n</i> = 63)	No Diagnosis (<i>n</i> = 103)	<i>P</i>
Type of device			.01
PM	36 (57%)	78 (96%)	
ICD	27 (43%)	25 (24%)	
Previous shocks	10 (16%)	10 (10%)	.33
Total score, DSI	4 (range 1–8)	4 (range 0–8)	.01
0	0 (0%)	6 (6%)	
1	3 (5%)	4 (4%)	
2	3 (5%)	9 (9%)	
3	12 (19%)	29 (28%)	
4	15 (24%)	22 (21%)	
5	16 (25%)	21 (20%)	
6	6 (10%)	8 (8%)	
7	4 (6%)	1 (1%)	
8	4 (6%)	3 (3%)	
Age at implantation (y)	10.6 (range 0–19.7)	5.9 (range 0–18.3)	.007
Age at study (y)	16.5 (range 7.5–21.0)	14.7 (range 6.0–20.9)	.04
Many hospitalizations	3 (5%)	0 (0%)	.05
Many surgeries	18 (29%)	29 (28%)	1.0
Many procedures	15 (24%)	27 (26%)	.85
Many shocks	6 (10%)	3 (3%)	.08
Activity limitations	21 (33%)	21 (20%)	.07
β -blockers	24 (28%)	34 (33%)	.51

Many shocks is >3 shocks, many surgeries is >3 surgeries, many hospitalizations is >3 hospitalizations, and many invasive procedures is >5 procedures.

TABLE 6 Multivariate Regression Model for Subjects With Any Diagnosis of Psychiatric Disease (by K-SADS-PL) Against Patients With No Diagnosis of Psychiatric Disease

	Odds Ratio	95% Confidence Interval	<i>P</i>
Age at implantation (increase by 1 y)	1.08	1.01–1.16	.02
Total DSI score (increase by 1 score)	1.31	1.06–1.61	.01
ICD present	1.11	0.48–2.58	.81

Self-reported anxiety and depression scores for both groups were lower than published norms. This discrepancy between self-report and a structured interview is more likely to be the result of underreporting by subjects than overdiagnosis by K-SADS-PL, which is considered the gold standard for child and adolescent psychiatric diagnosis. Previous research suggests that children with chronic medical conditions, such as asthma and cancer, tend to score themselves lower than healthy controls on self-report measures of anxiety and depression and higher on scales of defensiveness, suggesting a bias in favor of socially desirable responses.^{28–31} Our findings show the same self-report bias found in these populations, suggesting that self-

report measures may not be sufficient to assess psychiatric morbidity in this population.

Compared with the general population, young patients with cardiac rhythm devices have lower parent-reported physical QoL (Table 4).²⁴ Impaired physical functioning probably reflects direct impact of medical disease in patients with cardiac disorders. We report psychosocial scores that are statistically similar to those of the general population, which may reflect good psychosocial functioning in the majority of patients who do not have a current psychiatric disorder.

Despite elevated rates of anxiety disorders, families were found to be less affected than anticipated based on the

caregiver-completed IFS. Families with PMs and ICDs were not distinguishable from one another on the overall scale or on any subscale. Both scored significantly better than the validation sample, consisting predominantly of low-income mothers of children with diverse chronic conditions, including severe asthma and myelomeningocele.²⁵ These results are corroborated by the BSI, which shows no difference in psychosocial adjustment between the parents of these patients and normative samples. These data suggest that families of children with cardiac devices function well despite the challenges inherent in having a young family member with a cardiac rhythm device.

LIMITATIONS

Despite being the largest sample we are aware of for psychiatric outcomes in children with cardiac devices, the sample remains underpowered to determine how other factors influence psychiatric disease, including hospitalizations, procedures, use of β -blockers, and, most importantly for the ICD subgroup, whether shocks in children influence psychiatric disease or QoL. The study is a cross-sectional analysis of a population with devices; data were gathered at a single point in time. The rates of depression and anxiety that preceded device placement cannot be determined from this study. Although this study is unique because it uses standardized structured psychiatric interviews and questionnaires to determine diagnoses and symptoms, only depression and anxiety disorders and symptoms were the target of this study. The potential impact of other neurobehavioral disorders and symptoms was not accessed. QoL was assessed by parent report only, as opposed to that of the youth. In addition, it is a single-center study at a large pediatric

tertiary referral hospital, which limits the generalizability of the results. Finally, this study did not obtain data on social support or socioeconomic class, both of which have been shown to be predictors of QoL.

CONCLUSIONS

Our study showed that patients with ICDs have significantly higher rates of anxiety disorders than peers with PMs. They also have higher rates of anxiety

disorders than a community population. However, knowing the type of device (PM or ICD) may not be sufficient to determine who is at highest risk of having depression and anxiety disorders. Older age at device implantation and more severe medical disease are better predictors of anxiety and depression diagnoses than the type of device that the patient received.

Fortunately, the young patients we studied have largely been an adaptive

group. Psychosocial QoL scores are the same as those of normative groups, and although patients with cardiac rhythm devices have lower physical QoL scores, this difference is probably related to their underlying disease and not to the type of device.

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