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The psychological impact of permanent cardiac pacemakers on pediatric patients and their parents: A case control study

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ARTICLE INFO	A B S T R A C T
Article history: Received 31 August 2017 Accepted 28 February 2018 Available online 12 March 2018 Keywords: Cardiac devices Pacemakers Pediatrics Depression Anxiety	<i>Background:</i> This study assessed anxiety and depression in children with permanent pacemakers (PPM) and quality of life of their parents. <i>Methods:</i> Ninety children (63.3% males and 36.6% females) and their parents were included in the study and were divided into three groups. The control group (Group 1) included 30 normal healthy children (67.6%
	 (57% males and 43% females), the PPM group (Group 2) included 30 age-matched children (70% males and 30% females) with PPM and structurally normal heart, while the Group 3 included 30 children (63% males and 37% females) with PPM and congenital heart disease (PPM+CHD). Psychological assessment of children and their parents was carried out using an interview-based questionnaires. <i>Results:</i> Psychiatric disorders were more prevalent in PPM+CHD group including depression (P=0.04), anxiety (P=0.02) and lower parents' QoL (P=0.01). The PPM group had higher depression and lower parents' QoL than the control group. Family income was independent factor for depression (r2 = -6.3, with P<0.05). Sex of the child and CCU admission were independent factors for anxiety (r2 = -9.5, P<0.05 & r2 = 10.5, P=0.001) in PPM group. <i>Conclusion:</i> Children with pacemakers have higher psychiatric disorders and their parents have lower QoL. © 2018 Cardiological Society of India. Published by Elsevier B.V. This is an open access article under the CC
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1. Introduction

Pediatric pacemaker implantation (PPM) is performed to treat abnormalities of sinoatrial (SA) node or atrioventricular (AV) node function that leads to an insufficient heart rate.¹

In patients with congenital heart disease (CHD), pacemaker implantation may be due to cardiovascular malformations like transposition of great arteries (TGA), or more frequently, as a consequence of surgery.² Transient or permanent complete heart block is not a common complication after congenital heart surgery, and the frequency has been reported to range from 0.5% to 3% in wide series in the literature.³

Pacemaker therapy in children involves unique issues regarding patient size, growth, development, and possible presence of CHD.⁴ Also, the lifelong dependency on pacing therapy and the many future revisions therefore have to be considered.⁵

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The effect of these morbidities on pediatric patients' selfperception and behavioral characteristics remains poorly defined. Also the effect of these morbidities on their parents' quality of life (QoL) remains poorly studied.

Several studies found changes in scores of depression, anxiety and family functioning in children with implantable cardioverter defibrillators (ICDs).^{4,7,8} But most of them are limited due to reliance on self- report measures or computer based questionnaires.

Very few studies focused on patients with PPM, especially adults and older adults. 9,10

This study evaluated the psychological impact of having a PPM, on Egyptian children and their parents compared to healthy children and identified the socio-demographic and clinical correlates using a standardized structured psychiatric interview.

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2. Methods

2.1. Study design

This study was performed in Ain Shams university hospitals, Cairo, Egypt for a period of two years extending from March 2014 to March 2016.

The study consisted of 90 child-parents pairs (age ranged from 7 to 18 years) divided equally into three groups.

These groups were control group (30 subjects), PPM group (30 patients) and CHD+PPM group (30 patients). Control group represented normal healthy children without PPM who had completely normal echocardiographic and electrocardiographic findings with their respective parents. PPM group represented children with PPM who had completely normal echocardiographic findings (structurally normal hearts) with their parents and the CHD+PPM group included children with PPM and CHD as defined by Welke et al¹¹ with their parents.

Subjects were excluded from the study if they were younger than 7 years, older than 18 years, Critically ill patients (hospitalized in critical care unit, severe decompensated heart failure), handicapped or mentally retarded, hospitalized within 4 weeks of the study recruitment date (recent admission influences psychiatric

Table 1

Sociodemographic and clinical data among the study groups.

responses and QoL) or having their first PPM implanted less than 6 months from the study recruitment date (insufficient longitudinal exposure to the device effect).

An informed consent was given by parents for children <12 years old and it was given by patients and their parents for children >12 years.

2.2. Clinical history and examination

Focused relevant history was taken from all study population included gender, family income, parenteral marital status and education level, and child school attendance.

Family income was classified into poor income (monthly income less than 1200 Egyptian pounds and the economic domain in QoL questionnaire less than two out of five), good income (monthly income ranged from 1200 to 3000 Egyptian pounds and the economic domain in QoL questionnaire two or three out of five) and excellent income (monthly income ranged more than 3000 Egyptian pounds and the economic domain in QoL questionnaire four or five out of five).

Then full medical history and physical examination were done for patients groups (PPM group and CHD+PPM group) included the indication for pacing, Time of the first device implanted, type of

	PPM group	CHD + PPM group	Control group	P value
Age (years)	11.9±2.7	11.8 ± 3.6	11.8 ± 3.1	0.99
Gender				
Male	21.0 (70%)	19.0 (63.3%)	17 (56.7%)	0.56
Female	9.00 (30%)	11.0 (36.7%)	13 (43.3%)	
School attendance				
Yes	30 (100%)	28 (93.3%)	26 (86.7%)	0.11
No	0 (0%)	2 (6.7%)	4 (13.3%)	
Family income				
Poor	7 (23.3%)	10 (33.3%)	5 (16.7%)	0.46
Good	22 (73.3%)	19 (63.3%)	22 (73.3%)	
Excellent	1 (3.3%)	1 (3.3%)	3 (10%)	
Type and mode of pacing				
VVI or VVIR	25 (83.3%)	25 (83.3%)		0.06
DDDR	4 (13.3%)	3 (10%)		
VDDR	1 (3.3%)	2 (6.7%)		
Indication of pacing				
Cong. CHB	30(100%)	0 (0%)		0.004
Post-op CHB	0 (0%)	24 (80%)		
TGA with CHB	0 (0%)	2 (6.6%)		
TOF with CHB	0 (0%)	4 (13.3%)		
Type of pacemaker leads				
Epicardial	25.0 (83.3%)	20.0 (66.7%)		0.01
Endocardial	5.00 (16.6%)	10.0 (33.3%)		
Device related complications				
Yes	8 (26.7%)	13 (43.3%)		0.176
No	22 (73.3%)	17 (56.7%)		
Presence of intrinsic rhythm				
Yes	15 (50%)	15 (50%)		1.0
No	15 (50%)	15 (50%)		
Time from diagnosis of disease to 1st device implantation (years)	$\textbf{0.62} \pm \textbf{1.8}$	0.99 ± 1.8		0.42
Time from 1st implanted device (years)	6.63 ± 3.22	5.03 ± 2.62		0.74
Previous surgical intervention				
Yes	0 (0%)	25(83.3%)		0.004
No	30 (100%)	5 (16.7%)		
Previous catheterization				
Yes	0 (0%)	23 (76.7%)		0.003
No	30 (100%)	7 (23.3%)		
Previous ICU admission				
Yes	11 (36.7%)	22 (73.3%)		0.004
No	19 (63.3%)	8 (26.7%)		
Presence of impaired LV systolic function				
Yes	1 (3.3%)	2 (6.7%)		0.554
No	29 (96.7%)	28 (93.3%)		

Cong.CHB: congenital complete heart block, Post-op CHB: postoperative complete heart block, TGA with CHB: Transposition of great vessels with CHB, TOF with CHB: tetralogy of fallot with CHB.

pacemaker and leads, a presence of intrinsic rhythm (pacemaker dependency), device related complications, number of hospitalization and history of any surgical intervention.

2.3. Psychiatric evaluation

Psychiatric interview based questionnaires were filled in by children in another room than their parents which took from 45 to 60 min.

The psychological assessment consisted of the following questionnaires:

2.3.1. Child depression inventory (CDI)

CDI was an Arabic validated questionnaire consisted of 27-item, self-rated, symptom-oriented scale suitable for youths aged 7 to 17.¹² CDI gave two outcomes: CDI scale and CDI raw score. CDI scale compared the study group to the normative values while the raw score compared one study group to other groups. The higher the CDI score the higher the depressive symptoms.

2.3.2. Child modified form of Taylor manifest anxiety scale (TMAS)

TMAS is a 36-item questionnaire used for assessment of anxiety for adults¹³ but in 1956 a children's form was developed by Castaneda et al¹⁴ In this study, we used an Arabic validated form from this child modified form.

TMAS gave two outcomes: TMAS scale and TMAS raw score. TMAS scale compared the study group to the normative values while the raw score compared one study group to other groups. The higher the TMAS score the higher the anxiety symptoms.

2.3.3. The PCASEE quality of life scale for parents

The PCASEE QoL scale is a clinical instrument provides information on symptoms and functioning over the last month and is used for assessment of the QoL for the subjects' Parents. An Arabic validated form was used with 30-items rated from 0 to 5. It covered (P) Physical component, (C) cognitive component, (A) affective component, (S) social component, (E) economic component and (E) Ego functioning.^{15,16} PCASEE gave two outcomes: PCASEE scale and PCASEE raw score. PCASEE scale compared the study group to the normative values while the raw score compared one study group to other groups. The lower the PCASEE score the lower the QoL i.e. more affection of parents' QoL.

Table 2

Comparison between the study groups regarding Depression, Anxiety and their parents' quality of life.

		PPM Gro	PPM Group		PPM+CHD Group		Control Group	
		No.	%	No.	%	No.	%	P value
CDI scale	Non or minimal	17	56.6%	13	43.3%	22	73.3%	0.179
	Mild	11	36.6%	11	36.6%	7	23.3%	
	Moderate	2	6.7%	5	16.7%	1	3.3%	
	Severe	0	3.3%	1	3.3%	0	0%	
	Depression	12	40%	17	56.7%	8	26.7%	
TMAS scale	Low anxiety	18	60%	15	50%	24	80%	0.042
	High anxiety	12	40%	15	50%	6	20%	
CDI score	Mean \pm SD	14.03 ± 6	.00	15.83 ± 6.2	29	$12.07 \pm 5.$	17	0.049
	Range	6-29		5–27		4–26		
TMAS score	Mean \pm SD	15.8 ± 6.7	76	16.53 ± 6.1	2	$12.50 \pm 5.$	45	0.029
	Range	8-31		8-31		5–29		
PCASEE	Mean \pm SD	101.1 ± 19	9.54	90.63 ± 25	.43	108.47 ± 1	16.07	0.005
	Range	51-124		32-130		78–130		

CDI: Child Dehpression Inventory, TMAS: Taylor Manifest Anxiety Scale, PCASEE: The PCASEE Quality of Life Scale for parents.

3. Statistical analysis

Data were revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Quantitative non parametric variables were expressed as mean and SD. Median and Interguartile range (IOR). Qualitative variables are expressed as frequencies and percentage. Student t Test was used to compare a continuous variable between two study groups. ANOVA and post hoc test were used to compare a continuous variable between more than two study groups. Fisher's exact test was used to examine the relationship between Categorical variables when the expected count is less than 5 in more than 20% of cells. Correlation analysis using Pearson's method was used to assess the strength of association between two quantitative variables. Linear regression was used to test and estimate the dependence of a quantitative variable based on its relationship with a set of independent variables. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *p*-value < 0.05 was considered significant and P value <0.01 was considered highly significant.

4. Results

4.1. Sociodemographic characteristics

The main demographic and medical characteristics of the three groups are outlined in Table 1. No differences in gender were found among all study groups. All patients attended schools except two (6.7%) from CHD + PPM group due to their cardiac condition, and four (13.3%) from control group but there were no statistical differences among study groups regarding school attendance (*p* value 0.11) and family income (*p* value 0.46), reflecting good sample selection.

4.2. Clinical and medical data

Twenty-five of 30 children in PPM group (83.3%) had epicardial PPM while 20 out of 30 children in CHD+PPM group (66.7%) had epicardial PPM (*p value 0.01*).

CHD + PPM group had more surgical interventions compared to PPM group who had no surgeries (83.3% versus 0% respectively, p*value 0.004*). As regard catheterization, 23 children in CHD+PPM group had a previous history of catheterization while no child in PPM group had any history of catheterization (76.7% versus 0% respectively, *p value 0.003*).

Cardiac care unit (CCU) admission was significantly higher in CHD + PPM group than PPM group (73.3% versus 36.7%, respectively, *p* value 0.004).

4.3. Child depression inventory (CDI)

As regards CDI score, CHD+PPM group had the highest prevalence of depression (mean 15.83 ± 6.29 ; 95% CI = 13.49-18.18) followed by PPM group (mean 14.03 ± 6.0 ; 95% CI = 11.79-16.27) and control group (12.07 ± 5.17 ; 95% CI = 10.14-14.00) with *P* value 0.049 (Table 2).

By using Post Hoc analysis, there was a significant difference between PPM + CHD group versus control group and also between PPM group versus control group (Table 2).

As regards degree of depressive symptoms (CDI scale), in CHD +PPM group: 13 patients (43.3%) had none or minimal depressive symptoms, 11 patients (36.6%) had mild depressive symptoms, five patients (16.7%) had moderate depressive symptoms and one patient (3.3%) had severe depressive symptoms. While, in PPM group: 17 patients (56.6%) had none or minimal depressive symptoms, 11 patients (36.6%) had mild depressive symptoms, two patients (6.7%) had moderate depressive symptoms.

In control group: 22 patients (73.3%) had none or minimal depressive symptoms, seven patients (23.3%) had mild depressive symptoms, one patient (3.3%) had moderate depressive symptoms.

4.4. Taylor manifest anxiety scale (TMAS) child form

As regards TMAS score, PPM+CHD group had the highest prevalence of anxiety (mean 16.53 ± 6.12 ; 95% CI = 14.25-18.82) compared to PPM group (mean 15.80 ± 6.76 ; 95% CI = 13.28-18.32) and control group (mean 12.50 ± 5.45 ; 95% CI = 10.46-14.54) with *P* value 0.029 (Table 2).

Post hoc analysis showed a significant difference between PPM + CHD group versus control group but no difference between PPM group versus control group.

As regards degree of anxiety symptoms (TMAS scale), in PPM group, 18 patients (60%) suffered from low levels of anxiety while 12 patients (40%) had higher levels. While in CHD+PPM group, 15 patients (50%) had low levels of anxiety while the rest (50%) had higher levels. In control group: 24 patients (80%) had low levels of anxiety, and only 6 patients (20%) had higher levels (Table 2).

4.5. Parents' quality of life (PCASEE)

Table 3

As regards PCASEE score, PPM +CHD group had the lowest quality of life (mean 90.63 ± 25.43 ; 95% CI = 81.14-100.13) compared to PPM group (mean 101.10 ± 19.54 ; 95% CI = 93.80-108.40)

and control group (mean 108.47 \pm 16.07; 95% CI = 102.47–114.47) with *P* value 0.005 (Table 2).

Post hoc analysis showed a significant difference between PPM group versus control group and also between PPM+CHD group versus control group.

4.6. Correlations

4.6.1. Sociodemographic data among PPM group

There was more prevalence of anxiety in children > 12 years than children <12 years based on TMAS score (19.09 ± 7.53 versus 14.47 \pm 5.01 respectively, *p* value 0.006).

Also, Anxiety was prevalent in females compared to males (17.8 \pm 7.05 versus 11.1 \pm 2.47 respectively, *p* value 0.01).

While children with poor family income showed the highest CDI score in comparison to other children with good and excellent family income (17.78 ± 6.28 versus 13.06 ± 5.38 versus 12.78 ± 6.29 respectively, *p* value 0.009) indicating the highest prevalence of depression (Table 3).

4.6.2. Sociodemographic data among PPM + CHD group

No significant correlation between sociodemographic data and psychiatric scores among subjects of PPM + CHD group was found (Table 4).

4.6.3. Clinical and medical data among PPM group

Children with endocardial PPM showed a higher prevalence of depression than those who have epicardial PPM [CDI score 23.5 \pm 0.70 versus 13.4 \pm 5.62 respectively; with *p* value 0.018]. Parents of children who had a history of previous admission to CCU had a lower QoL when compared to parents of children who had never been admitted [PCASEE score 95.3 \pm 20.4 versus 111.2 \pm 13.4 respectively; with *P* value 0.029]. (Table 5)

4.6.4. Clinical and medical data among PPM + CHD group

Children without intrinsic cardiac rhythm (IR) showed a higherprevalence of depression and poorer parent QoL than those who had IR [CDI score 19.8 ± 5.6 versus 11.9 ± 4.1 , respectively with *p* value 0.001] and [PCASEE score 79.9 ± 26.2 versus 101 ± 20.2 , respectively with *p* value 0.018]. Children with a previous history of CCU admission showed higher anxiety scores as compared to those who were never admitted. [TMAS score 20.2 ± 3.11 versus 15.2 ± 6.43 , respectively with *p* value 0.043]. Also, children with a previous history of surgical intervention had higher anxiety scores as compared to children without. (TMAS score 22 ± 2 versus 15.4 ± 6.09 , respectively with *P* value 0.026). (Table 6)

After adjustment for all factors using linear regression, we found that:

In PPM group, family income was the only independent factor affecting CDI (regression coefficient $(R^2) = -6.305$, CI = -12.1 to

ociodemographic data correlation with psychiatric scores in PPM group.											
		CDI score Mean ± SD	Independ t	lent <i>t</i> -test P value	TMAS score Mean \pm SD	Independ t	lent <i>t-</i> test P value	PCASEE Mean ± SD	Independ t	lent <i>t</i> -test P value	
Age	< = 12 years > 12 years	$\begin{array}{c} 14.29 \pm 6.22 \\ 16.05 \pm 6.04 \end{array}$	1.065	0.291	$\begin{array}{c} 14.47 \pm 5.01 \\ 19.09 \pm 7.53 \end{array}$	2.85	0.006	$\begin{array}{c} 95.08 \pm 23.96 \\ 97.23 \pm 22.01 \end{array}$	0.345	0.732	
Sex	Male Female	$\begin{array}{c} 13.72 \pm 6.09 \\ 14.42 \pm 5.84 \end{array}$	0.537	0.593	$\begin{array}{c} 11.01 \pm 2.47 \\ 17.08 \pm 7.05 \end{array}$	2.237	0.01	$\begin{array}{c} 98.07 \pm 21.88 \\ 103.52 \pm 21.44 \end{array}$	1.146	0.255	
Family Income	Poor Good Excellent	$\begin{array}{c} 17.78 \pm 6.28 \\ 13.06 \pm 5.38 \\ 12.78 \pm 6.92 \end{array}$	4.965	0.009	$\begin{array}{c} 17.17 \pm 7.56 \\ 14.48 \pm 5.94 \\ 13.78 \pm 5.87 \end{array}$	1.456	0.239	$\begin{array}{c} 89.94 \pm 19.12 \\ 102.57 \pm 22.26 \\ 102.78 \pm 19.03 \end{array}$	2.518	0.086	

CDI: Child Depression Inventory, TMAS: Taylor Manifest Anxiety Scale, PCASEE: The PCASEE Quality of Life Scale for parents.

Table 4

Sociodemographic data correlation with psychiatric scores in PPM+CHD group.

		CDI score Mean \pm SD	Independe T	ent <i>t-</i> test P value	TMAS score Mean \pm SD	Independe T	ent <i>t</i> -test P value	PCASEE Mean \pm SD	Independ T	ent <i>t-</i> test P value
Age	< = 12 years > 12 years	$\begin{array}{c} 15.29 \pm 6.22 \\ 16.05 \pm 6.04 \end{array}$	1.065	0.346	$\begin{array}{c} 16.47 \pm 5.01 \\ 19.09 \pm 7.53 \end{array}$	2.158	0.254	$\begin{array}{c} 95.08 \pm 23.96 \\ 97.23 \pm 22.01 \end{array}$	0.345	0.732
Sex	Male Female	$\begin{array}{c} 15.8 \pm 5.86 \\ 15.9 \pm 7.26 \end{array}$	0.537	0.961	$\begin{array}{c} 16.2 \pm 5.08 \\ 17.2 \pm 7.83 \end{array}$	2.024	0.667	$\begin{array}{c} 86.5 \pm 23.1 \\ 97.7 \pm 28.8 \end{array}$	1.146	0.252
Family Income	Poor Good Excellent	$\begin{array}{c} 16.30 \pm 6.34 \\ 15.60 \pm 6.41 \\ 15.78 \pm 6.92 \end{array}$	0.345	0.779	$\begin{array}{c} 14.2\pm5.87\\ 15.48\pm5.94\\ 17.7\pm6.04 \end{array}$	1.456	0.142	$\begin{array}{c} 90.5 \pm 17.1 \\ 90.7 \pm 22.26 \\ 90.7 \pm 29.1 \end{array}$	2.518	0.984

CDI: Child Depression Inventory, TMAS: Taylor Manifest Anxiety Scale, PCASEE: The PCASEE Quality of Life Scale for parents.

Table 5

Clinical and medical data correlation with psychiatric scores in PPM group.

		CDI score Mean \pm SD	Independent <i>t</i> -test P value	TMAS score Mean \pm SD	Independent <i>t</i> -test P value	PCASEE Mean \pm SD	Independent <i>t</i> -test P value
CCU admission	Yes	$\begin{array}{c} 13\pm 6.68\\ 14.6\pm\end{array}$	0.483	13.2 ± 5.02	0.108	111.2 ± 13.4	0.029
	No	5.68		17.3 ± 7.28		95.3 ± 20.4	
Presence of intrinsic rhythm (IR)	IR No IR	$\begin{array}{c} 14.3 \pm 6.64 \\ 13.8 \pm 5.52 \end{array}$	0.836	$\begin{array}{c} 17.3 \pm 6.79 \\ 14.3 \pm 6.63 \end{array}$	0.241	$\begin{array}{c} 105 \pm 21.1 \\ 96.7 \pm 17.4 \end{array}$	0.227
Type of lead and access	Epicardial Endocardial	$\begin{array}{c} 13.4 \pm 5.62 \\ 23.5 \pm 0.70 \end{array}$	0.018	$\begin{array}{c} 15.4 \pm 6.81 \\ 21.5 \pm 2.12 \end{array}$	0.223	$\begin{array}{c} 101.1 \pm 19.7 \\ 100.5 \pm 24.7 \end{array}$	0.965
Device related complications	Yes No	$\begin{array}{c} 14.2 \pm 7.72 \\ 14 \pm 5.46 \end{array}$	0.908	$\begin{array}{c} 14.9 \pm 4.76 \\ 16.1 \pm 7.42 \end{array}$	0.659	$\begin{array}{c} 104.3 \pm \ 10.4 \\ 100.0 \pm 22.0 \end{array}$	0.603

CDI: Child Depression Inventory, TMAS: Taylor Manifest Anxiety Scale, PCASEE: The PCASEE Quality of Life Scale for parents, CCU: coronary care unit, IR: intrinsic rhythm.

Table 6

Correlation of clinical and medical data with psychiatric scores in PPM+CHD group.

		CDI score Mean \pm SD	Independent <i>t</i> -test P value	TMAS score Mean \pm SD	Independent <i>t</i> -test P value	$\begin{array}{c} \text{PCASEE} \\ \text{Mean} \pm \text{SD} \end{array}$	Independent <i>t</i> -test P value
Previous CCU admission	Yes No	$\begin{array}{c} 16.2\pm7.0\\ 14.9\pm3.9 \end{array}$	0.623	$\begin{array}{c} 20.2 \pm 3.11 \\ 15.2 \pm 6.43 \end{array}$	0.043	$\begin{array}{c} 88.0 \pm 26.7 \\ 15.2 \pm 6.43 \end{array}$	0.356
Previous catheterization	Yes No	$\begin{array}{c} 17.4 \pm 4.5 \\ 15.3 \pm 6.7 \end{array}$	0.453	$\begin{array}{c} 19.3 \pm 5.25 \\ 15.7 \pm 6.22 \end{array}$	0.178	$\begin{array}{c}92.6\pm22.2\\84.1\pm35.5\end{array}$	0.450
Previous surgical intervention	Yes No	$\begin{array}{c} 16.4 \pm 6.75 \\ 13.0 \pm 1.22 \end{array}$	0.277	$\begin{array}{c} 22.0 \pm 2.00 \\ 15.4 \pm 6.09 \end{array}$	0.026	$\begin{array}{c} 87.6\pm26.1\\ 106\pm16.2 \end{array}$	0.153
Presence of intrinsic rhythm (IR)	IR No IR	$\begin{array}{c} 11.9\pm4.1\\ 19.8\pm5.6\end{array}$	0.001	$\begin{array}{c} 16.3 \pm 6.69 \\ 16.7 \pm 5.71 \end{array}$	0.862	$\begin{array}{c} 101 \pm 20.2 \\ 79.9 \pm 26.2 \end{array}$	0.018
Type of lead and access	Epicardial Endocardial	$\begin{array}{c} 15.4 \pm 8.07 \\ 16.0 \pm 5.41 \end{array}$	0.795	$\begin{array}{c} 13.7 \pm 5.17 \\ 18.0 \pm 6.18 \end{array}$	0.072	$\begin{array}{c} 101.1 \pm 19.7 \\ 90.8 \pm 24.6 \end{array}$	0.972
Device related complications	Yes No	$\begin{array}{c} 16.8\pm7.04\\ 15.1\pm5.77\end{array}$	0.485	$\begin{array}{c} 17.3 \pm 6.33 \\ 15.9 \pm 6.08 \end{array}$	0.554	$\begin{array}{c} 82.4 \pm 25.6 \\ 96.9 \pm 24.1 \end{array}$	0.122

CDI: Child Depression Inventory, TMAS: Taylor Manifest Anxiety Scale, PCASEE: The PCASEE Quality of Life Scale for parents, CCU: coronary care unit, IR: intrinsic rhythm.

-0.48, with *p* value 0.035) while sex and previous admission in CCU were the independent factors affecting TMAS score. Females showed higher TMAS score compared to males ($R^2 = -9.55$, CI = -13.8 to -5.26 with *p* value 0.0001), while children with a history of the previous admission had higher TMAS score compared to non-admitted children ($R^2 = 10.566$, CI = 4.992 to 16.140 with *p* value 0.001). Previous admission in CCU was the only independent factor affecting PCASEE score ($R^2 = -21.055$, CI = -41.65 to -0.464 with *p* value 0.045).

In PPM+CHD group, Absence of IR was the only independent factor affecting both CDI score ($R^2 = -9.234$, CI = -14.033 to -4.435

with *p* value 0.001) and PCASEE score ($R^2 = 21.400$, CI = 3.902 to 38.898 with *p* value 0.018).

5. Discussion

In the last decade, there has been an increasing use of pacemaker therapy in Egypt although still, no registries are available. The current study was the first conducted in Egypt to evaluate the psychological impact of having a PPM on Egyptian children and their parents and to identify the socio-demographic and clinical correlates affecting their psychology.

In the current study, Depression was more prevalent with pacemaker implantation whether the child had structurally normal hearts or CHD (p value 0.049), with higher degrees of depression in the presence of CHD as well as anxiety disorders which was significantly evident among children with CHD (p value 0.029). This could be explained by the added morbidities associating CHD and the psychological impact of interventional & surgical procedures. These findings were similar to other reports like Koopman et al⁷ but their study included only children with implantable cardioverter defibrillator (ICD) and Aydemir et al⁹ whose reported that 19.1% of PM patients warranted a psychiatric diagnosis, and 10.7% were clinically depressed but this study was done on adults with PPM. Pycha et al¹⁷ identified depression of moderate severity in 35% of ICD patients while Heller et al¹⁸ reported it in 20-58%. But in these last two studies, the study populations were adults, not children having ICDs.

Other reports have shown different findings, reporting that depressive disorders were not significantly different between the PPM group and community samples (p value 0.64).^{19,20}

Social withdrawal, body image perception due to device' pocket and presence of surgical incisions, and also activity restriction were the main concerns in the current study population. Also, there were concerns about their future marital life, especially adolescents.

Fear of battery depletion or repeated hospital admissions and body image perception were the main concerns in the current study population

As regard QoL of their parents, the current study is one of few studies that shed light on the affection of parents' QoL in the pediatric population with cardiac devices.

5.1. Correlations

5.1.1. Sociodemographic data

In our study, older age (> 12 years) was associated with higher levels of anxiety after pacemaker implantation, as Older patients were more aware of these foreign devices in their body, their complications, and physical restrictions and so liable to higher levels of anxiety.

Although females in the studied group represented only 30% of children with pacemakers, they had significantly higher levels of anxiety compared to males with pacemakers. They were more anxious due to body image perception (surgical wounds and pocket), and fear of battery depletion.

Children with poor income had higher prevalence of depression due to social withdrawal, the economic burden of these procedures in lack of good medical insurance in Egypt. There were two patients rejected from many schools due to their cardiac condition.

5.1.2. Clinical and medical data

Depression was more prevalent in children with endocardial pacemakers than those with epicardial devices. The explanation is that many children had epicardial devices placed in infancy or before school age, in some cases on first few days 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 depression. While patients with endocardial pacemakers received these devices at older age so they have an opportunity to see these devices as intrusive and foreign.

Parents of children who were admitted to CCU showed a lower QoL than those without admission because of fear of their children's death.

In PPM+CHD group, depression and lower parents' QoL were more prevalent in children with no IR as compared to those who have IR due to their concern about being dependent on pacemakers for life. However, Richard et al²¹ stated that device dependency has no correlation with lower pediatric QoL. However, in the current study a higher number of patients were dependent on pacemaker (with no IR) than those in the trial by Richard et al (50% of children with pacemakers versus only 9%, respectively).

Family income was the only independent factor affecting CDI score, sex and previous admission in CCU were the independent factors affecting TMAS score, while the previous admission in CCU was the independent factor affecting PCASEE score.

6. Study limitations

Limitations of the current study are that it comes from a single medical center with a relatively small number of patients which limits the generalization of the results.

Data were collected at a single point in time. The rates of depression and anxiety that preceded device placement cannot be determined from this study. The study evaluated only depression and anxiety scores while other neurobehavioral disorders and symptoms were not accessed as a potential impact.

7. Conclusion

Children with pacemakers have significantly higher prevalence of anxiety and depression than healthy children and their parents report a much lower QoL. Presence of structural CHD further adds to the risk for having these psychiatric disorders.

Age, sex, family income, an absence of IR and repeated surgical interventions can be predictors for anxiety and depression scores for these patients.

Compliance with ethical standards

This study was approved by our ethical committee and an informed consent was obtained from all patients prior to their inclusion in the study.

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Disclosures

The authors declare that they have no conflict of interest.

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