Evaluation of Performance & Complications of pacemakers in children; A single center study

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KEYWORDS
Cardiac pacing, Children, Complications, Outcome, Endocardial pacing.

ABSTRACT
Background: Permanent pacing is now a common treatment strategy used to treat rhythm abnormalities in pediatric patients with congenital heart disease (CHD). This study aimed to assess the outcome, effectiveness, and complications of permanent pacemakers.
Between March 2020 and February 2021, a total of 148 participants with permanent cardiac pacing were enrolled in the study. Their charts were reviewed pro- and retrospectively for anthropometric measurements, pacing indications, pacing measurements and pacing complications. Their mean age was 4.26 ± 3.56 years, their mean weight 16.38 ± 10.18 kg. There were 83 males (56.1%) and 65 females (43.9%). Post operative AV block was the most common pacing indication followed by congenital AV block. The majority of patients were paced using VVIR (ventricular pacing, ventricular sensing, inhibition response and rate adaptive) mode devices in 146 patients (98.6%). DDDR (dual chamber pacing, dual chamber sensing, dual chamber response and rate adaptive) mode device was used in 2 patients (1.35%). Endocardial pacing was done in 136 patients while epicardial pacing was done in 12 patients. During intensified follow up, lead failure related complications were detected in 8 patients (7.2 %). Lead failure related complications has occurred in 33.3 % of epicardial leads and in 4 % of endocardial leads
Conclusion: our findings suggest that endocardial pacing is associated with lower rates of lead related problems compared to epicardial pacing.

Introduction

Over the past few decades, pacemakers have become more and more common in clinical practice. Since the implantation of the first cardiac PM in 1958, enormous advancements have happened in both the technology of the devices and their indications. **(1)**
Pediatric pacemaker implants account for fewer than 1% of all pacemaker implants. It is vital to understand these qualities when assessing whether pacing is necessary, as well as when choosing the timing and how to implant. (**2)**
While permanent pacing is generally safe and has good long-term results for pediatric patients, lead performance-related issues still account for a large portion of the high rate of complications. Children that require a lifetime of pace with modern technologies should be especially concerned about this. (**3)**
Device management is a highly individualized skill due to the complexity and variability of pediatric patients with congenital cardiac disease. Certain obstacles, such as somatic growth, an active lifestyle, vulnerability to illness, and the typically expected long survival, are unique to pediatric pacing. (**4)**
The frequency of pacemaker follow up varies from center to center. Follow up can be divided into three phases: early surveillance, maintenance period, and intensified monitoring period. Typically, following hospital discharge, the first follow-up should occur four to six weeks later (early surveillance). Following pacing, follow-up will typically occur every six or twelve months (maintenance period). As the device gets closer to the end of its battery life, more thorough monitoring will be required. **(5).**
Therefore, our study aimed to assess the outcome, effectiveness and complications of permanent cardiac pacemakers in children

Patients & Methods

Study design and population.
The study was conducted at the pediatric cardiac Catheterization laboratory, Cairo University Children's Hospital, Cairo, Egypt between March 2020 and February 2021. A total of 148 participants with permanent cardiac pacing were enrolled in the study.
Patients were divided into 2 groups according to the duration of follow-up:

Group 1 included 37 patients (25 %) who were in maintenance period which is ≤ 12 months after pacemaker insertion. Group 2 included 111 patients (75 %) who were in intensified monitoring period which is ≥ 12 months after pacemaker insertion.
In each group patients were compared regarding the indication of pacing, anthropometric measures, complications depending on patient weight either ≤ 10 Kg or ≥ 10 Kg. The rational of this further classification according to ≤ 10 Kg or ≥ 10 Kg is due to the risk of venous occlusion, growth related lead problems, skin erosion at the generator site and the need for future lead extractions and replacements among patients weighing ≤ 10 Kg.
All patients were evaluated, regarding age, gender, weight and height Z-score, Symptoms of heart failure (dyspnea, hemoptysis, recurrent chest infection, dyspepsia, lower limb swelling), chest pain, syncope, low cardiac output symptoms (headache, dizziness, blurring of vision, exercise intolerance, syncopal attack) and family history of a similar condition, or maternal history of systemic lupus erythematosus (SLE). Vital signs including heart rate (HR), blood pressure (BP), Oxygen saturation (O2) and full cardiac examination were recorded**.** Any complications during insertion as pocket hematoma, hemothorax, pneumothorax, bleeding, other complications after insertion including venous thrombosis, lead fracture and loss of capture were recorded

Implantation Procedure
Prior to every single lead insertion, the central venous access is assessed by contrast venography for detection of venous stenosis or occlusion. Depending on the result of examination, the operation is planned (simple implantation versus interventional approach with dilatation, stenting with subsequent surgery or alternative access).
All procedures were performed with the patient under general anesthesia. The endocardial pacing leads were inserted in the catheterization laboratory thorough Subclavian vein cannulation using 6 FR sheath followed by placing the guide wire through the subclavian vein into the right ventricle (RV). The ventricular leads were positioned in the non-systemic ventricular apex, from which adequate values of the pacing threshold and impedance were achieved.
Epicardial pacing leads were inserted in the operation theater by positioning the pacing lead in the RV through sternotomy or thoracotomy. The pacing threshold and impedance were evaluated during the implant procedure until adequate values were achieved. The voltage stimulation threshold and pacing impedance were rechecked on the second day, and patients were discharged from the hospital 4 to 6 days after implantation.

Follow-up Evaluation
The patients were followed up 1, 3, and 6 months after implantation, then every 6 months or as needed. Evaluation included routine clinical examination, electrocardiography, chest X-ray, echocardiography, and a full analysis of the pacing system measurements.
12-lead resting ECG was done for all children, transthoracic echocardiographic examination with a simultaneous ECG tracing was performed for all children included in the study in both supine and left lateral position using a commercially available device (GE vivid s5) with a phased array probe (3-7 MHz) according to the American society of echocardiography recommendations. **(6)**
Full analysis of pacing system measurements was done including pacing indication, pacing type pacing mode, pacing rate, pacing output, pacing threshold, pulse width, lead impedance, ventricular sensing, pacing & sensing polarity.

Ethical Issues:
Our study was approved by the research ethics committee of Assiut University (IRB No.: 17200400). All methods and protocols of our work were performed in accordance with the relevant guidelines and regulations of declaration of Helsinki and Assiut University. All Caregivers of all participants have given their informed written consent.

Statistical Analysis:
The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 26 (IBM SPSS Statistics for Window Version 26. Armonk, NY: IBM Corp). Qualitative variables were expressed as number and percentage and quantitative variables as mean ± standard

deviation, Comparisons between different groups in the study were performed using student t-test. The level of significance in this study was set to P-value less than 0.05.

Results

The current study shows that patients' age ranged from 3 month to 12 years with a mean of 4.26 ± 3.56, the weight ranged from 4 – 55 kg with a mean of 16.38 ± 10.18, the height ranged from 59 – 162 cm with a mean of 96.93 ± 24.16. In terms of gender of the studied group, there were 83 males (56.1%) and 65 females (43.9%).

Table 1 reveals significant improvement among patients of maintenance studied group (Group 1) weighing less than 10 Kg regarding pre-pacing and (≤ 1yr) post-pacing weight (p <0.001) and weight Z -score (p 0.004). Also, there was significant improvement among patients weighing ≥ 10 Kg regarding pre-pacing and (≤ 1 yr) post-pacing weight (p <0.001) and weight Z-score (p 0.004).

Table 2 clarifies that most common pacing indication among patients of maintenance studied group (Group 1) weighing less than 10 kg is post ventricular septal defect (VSD) closure heart block (n=8, 47.1%) followed by post complete atrio-ventricular canal (CAVC) repair heart block (n= 3, 17.6%) and congenital complete heart block (CHB) (n=3, 17.6%) then post tetralogy of Fallot (TOF) repair heart block (n=2, 11.7%).

There were significant differences regarding pre-pacing and post-pacing left ventricle posterior wall (LVPW) Z-score (p <0.001), left atrium (LA) Z-score (p <0.005) and tricuspid annular plane systolic excursion **(**TAPSE) Z-score (p <0.01) among patients of maintenance studied group (Group 1).

There were no significant differences between initial pacing and post-pacing pacemaker parameters among maintenance studied group (Group 1) regarding pacing threshold (0.66±0.18 vs. 0.61±0.16, p=0.073), pacing sensing (6.64±0.65 vs. 6.58±0.67, p=0.252) and lead impedance (548.7±92.5 vs.510.73±100.74, p=0.28).

Endocardial pacing was done in 37 patients (100 %). pacing mode was VVIR in 37 patients (100%) at the first and last follow up. Bi-polar pacing was started in 37 patients (100%) till the last follow up.

There were no complications had happened among the maintenance studied group (Group 1).

As shown in table 3, there was significant improvement among patients of intensified studied group (Group 2) weighing ≤ 10 Kg regarding pre-pacing and (≥ 1 yr) post-pacing weight, height and weight Z -score (p <0.001). Also, there was significant improvement among patients weighing ≥ 10 Kg regarding pre-pacing and (≥ 1 yr) post-pacing weight and height (p <0.001)

Table 4 reveals that the most common indication of pacing among patients of maintenance studied group (Group 2) weighing less than 10 kg is congenital CHB (n=14, 42.4%) followed by post (VSD) heart block (n=8, 24.4%) then post CAVC repair (n=6, 18.1%). While most common indication of pacing among patients with weight more than 10 kg is congenital CHB (41%) followed by post VSD repair (n=20, 25.6%) then post TOF repair (n=11, 14.1%).

There was significant difference regarding pre-pacing and post-pacing inter-ventricular septum (IVS) Z-score, left ventricular posterior wall (LVPW) Z-score, left atrium (LA) Z-score, fractional shortening (FS) and tricuspid annular plane systolic excursion **(**TAPSE) (p <0.001) among patients of maintenance studied group (Group 2).

There were no significant differences between initial pacing and post-pacing pacemaker parameters among intensified studied group (Group 2) regarding pacing threshold (0.88±0.48 vs.0.92±0.48, p=0.053), pacing sensing (6.68± 0.87 vs.9.71± 0.89, p=0.156) and lead impedance (481.81±179.47 vs.508.05 ± 136.58, p=0.060).

Out of 111 patients, endocardial pacing was done in 99 patients (89.1%) while epicardial pacing was done in 12 patients (10.8%). At last follow up, endocardial pacing was done in 106 patients (95.4%) while epicardial pacing was done in 5 patients (4.5%). Pacing mode was VVIR in 109 patients (98.1%) and DDDR in 2 patients (1.8%) during first and last follow up. Bi-polar pacing was started in 111 patients (100%), 3 patients (2.7 %) had lead problems necessitating the shift to unipolar pacing at last follow up.

About 22 patients (19.8 %) among the intensified studied group (Group 2) required a second pacemaker procedure. Device battery was replaced in 13 patients (11.7 %) due to battery end of life; lead replacement was done in 2 patients (1.8 %) as a result of lead fracture. Switching from epicardial to

endocardial pacing was performed in 7 patients within 3.5 - 7 years from first implantation due to battery depletion (n=4, 3.6 %) and lead fracture (n=3, 2.7%).
Among intensified studied group (Group 2), the most common complication among patients with weight less than 10 kg lead fractures (n=2 , 6%) followed by loss of capture (n=1, 3 %), lead exposure (n=1, 3 %), and chronic venous occlusion(n=1, 3 %), while most common complication among patients weighing more than 10 kg was lead fractures (n=3, 3.8%) followed by chronic venous occlusion (n=2, 2.5%) and finally lead exposure (n=1,1.2%) and pocket infection (n=1, 1.2%).

Table (1): Anthropometric data of maintenance studied group (Group 1) according to weight.

	Weight					
	Less than 10 kg (n=17)			**More than 10 Kg (n=20)**		
	pre-pacing	**(≤ 1yr) post-pacing**	**P. value**	**pre-pacing**	**(≤ 1yr) post-pacing**	**P. value**
Weight	8.93±1.33	10.88±1.51	**<0.001***	16.35±7.0	17.63±7.47	**<0.001***
Weight Z score	-2.15±1.26	-1.44±1.16	**0.004***	-0.63±1.36	-0.33±1.23	**0.004***
Height	77.0±5.3	78.85±3.84	0.242	99.05±18.23	99.82±18.3	0.64
Height Z score	-2.2±1.16	-2.92±1.15	0.126	-0.89±1.2	-1.2±1.17	0.37

The level of significance in this study was set to P-value less than 0.05

Table (2): Indications for pacemaker insertion among maintenance studied group (Group 1) according to weight.

Indication	**Weight**	
	Less than 10 kg (n=17)	**More than 10 kg (n=20)**
Congenital AV block	**3 (17.65%)**	**9 (45%)**
Post-operative AV block	**14 (82.35%)**	**11 (55%)**
Post complete AV canal repair	3 (17.65%)	2 (10%)
Post ASD repair	1 (5.88%)	0 (0%)
Post fallout repair	2 (11.76%)	1 (5%)
Post sub-aortic membrane resection / VSD repair	0 (0%)	5 (25%)
Post VSD repair	8 (47.06%)	3 (15%)

AV: atrio-ventricular, ASD: atrial septal defect, VSD: ventricular septal defect

Table (3): Anthropometric data of intensified studied group (Group 2) according to weight.

	Weight					
	Less than 10 kg (n=17)			**More than 10 Kg (n=20)**		
	pre-pacing	**(≥1yr) post-pacing**	**P. value**	**pre-pacing**	**(≥1yr) post-pacing**	**P. value**
Weight	8.34 ± 1.6	22.5 ± 9.0	**<0.001***	21.09 ± 10.6	38.16 ± 14.2	**<0.001***
Weight Z score	-1.77 ± 1.35	-0.10 ± 0.9	**<0.001***	-0.41 ± 1.42	-0.25 ± 0.82	0.33
Height	75.30 ± 7.75	110.6 ± 20.5	**<0.001***	109.2 ± 23.0	136.68± 19.1	**<0.001***
Height Z score	-1.12 ± 1.55	-1.16 ± 1.06	0.9	-0.74 ± 1.83	-1.18 ± 0.78	0.52

The level of significance in this study was set to P-value less than 0.05

Table (4): Indications for pacemaker insertion among intensified studied group (Group 2) according to weight.

Indication	Weight	
	Less than 10 kg (n=33)	More than 10 Kg (n=78)
Congenital AV block	**14 (42.4%)**	**28 (35.8 %)**
Sick sinus syndrome	**0 (0%)**	**4 (5.1%)**
Post-operative AV block	**19 (57.5%)**	**46 (58.9%)**
Post complete AV canal repair	6 (18.1%)	6 (7.6%)
Post ASD repair	0 (0%)	2 (2.5%)
Post DORV + PS correction	0 (0%)	1 (1.2%)
Post Fallot repair	5 (15.1%)	11 (14.1%)
Post PDA repair	0 (0%)	1 (1.2%)
Post senning operation	0 (0%)	1 (1.2%)
Post valve replacement	0 (0%)	1 (1.2%)
Post VSD & SAM repair	0 (0%)	3 (3.8%)
Post VSD repair	8 (24.2%)	20 (25.6%)

AV: atrio-ventricular, ASD: atrial septal defect, VSD: ventricular septal defect, DORV: double outlet right ventricle, PS: pulmonary stenosis, PDA: patent ductus arteriosus, SAM: sub-aortic membrane

Discussion

The current study showed that the mean age among the maintenance group during initial pacemaker implantation was 3.26 ± 2.42 yr, the mean weight was 12.94 ± 6.43 kg, and the mean height was 88.78 ± 17.76 cm. The youngest patient with endocardial pacemaker insertion in the same studied group was 15 months old and weighed 8 kg. On the other hand, the intensified group revealed that mean age during initial pacemaker implantation was 4.61 ± 3.8 yr, the mean weight was 17.53 ± 10.94 kg, and the mean height was 99.65 ± 25.44 cm. The youngest patient with endocardial pacemaker insertion in the same studied group was 3 months old and weighed 3 kg at time of pacemaker insertion

A study done by Nolasco et al. **(7)** showed that the youngest patient with endocardial pacemaker insertion was 1 month old and weighed 2.3 kg. Similarly, Kammeraad et al. **(8)** inserted endocardial pacemaker in 2 days old child weighing 2.3 kg

The current study stated that the most common indication among maintenance group was post-operative complete heart block (n=25, 67.6%) followed by isolated congenital CHB (n=12, 32.4%). The maintenance group had 14 patients (82.3 %) with post-operative AV block and 3 patients (17.6 %) with congenital complete heart block weighing ≤ 10 kg for whom PM implantation was indicated. Similarly, post-operative complete heart block (58.5%) was the most common indication among intensified group followed by isolated congenital CHB (37.8%). Among the intensified group, there were 19 patients (57.5 %) with post-operative AV block and 14 patients (42.5 %) with congenital complete heart block weighing ≤ 10 kg for whom PM implantation was indicated. This was due to the high incidence of congenital heart diseases that need surgical correction and may be complicated by post-operative AV block.

This agrees with Lotfy et al. **(9)** who stated that the most common indication for pacing was postoperative complete heart block in 54 patients (52.4 %) of their patients followed by congenital heart block in 31 patients (33.2 %) of their patients.

Also, another study by Samir et al. **(4)** showed that postoperative CHB was the most common indication for pacing in (50%) of their patients (n=16) followed by congenital AV block in (40%) of their patients (n=13).

While a study done by Kammeraad et al. **(8)** showed that indications for pacing was congenital AV block in 53.8% in their patients (n=21) followed by postoperative AV block in 30.7% in their patients (n=12). The interpretation of our findings regarding the more frequent postoperative AV block could be that the population of our study was too small and too heterogenous to identify postoperative

prognostic factors for recovery of AV block such as the underlying defect, surgical techniques or immediate postoperative period.

In this study, VSD closure (29.7%, n=11) was the most common surgical intervention in the maintenance group complicated by complete heart block and hence indicating a permanent pacing as VSD is the most common congenital heart disease in pediatrics, followed by complete AV canal repair (13.5%, n=5) and sub-aortic membrane resection (13.5%, n=5). On other hand, the most common surgical intervention complicated by complete heart block among intensified group was VSD closure (25.2%, n=28) followed by Fallot tetralogy repair (14.4%, n=16)

This agreed with Murray et al. **(10)** who showed that each VSD closure and complete AV canal repair represented (n=129, 10.8%) of their cases and finally repair tetralogy of Fallot represented (n=119, 9.9 %) of their cases. The development of CHB after these surgeries might be due to injury to the AV node and bundle of Hiss due to anatomical proximity. Furthermore, prolonged aortic clamp time and prolonged cardio bypass time may result in ischemia and myocardial insult.

In this study, the maintenance group showed significant differences regarding pre-pacing and post-pacing LVPW Z-score, LA Z-score, TAPSE Z-score. On other hand the intensified group revealed significant differences regarding pre-pacing and post-pacing IVS Z-score, LVPW Z-score, LA Z-score, FS. The current study showed no significant differences regarding pre-pacing and post-pacing LVEDD Z-score, LVESD Z-score. This may be explained by the significant increase in the growth parameters of the children's post pacing. Thus, the Z-score is related to higher body weight and height post pacing. In agreement with the current study, Gebaur et al. **(11)** showed no statistically significant difference regarding pre-pacing and post-pacing LVEDD Z score for both endocardial and epicardial pacing.

A retrospective study done by Lotfy et al. **(9)** showed statistically significant improvement occurred in the LV dimensions after pacing. Shalganov et al. **(12)** revealed no significant difference regarding pre-pacing and post-pacing FS among 99 pediatric patients.

The current study showed optimum pacing parameters with no significant difference between initial pacing and post-pacing parameters regarding pacing thresholds, pacing sensing and lead impedance. This could be explained by strict evaluation and follow-up protocols.

This agreed with Burri et al. **(13)** who stated that capture thresholds should be < 1.5 V@0.5 ms, with sensing amplitudes > 4m V for the ventricle and lead impedances should be within normal limits (usually 400–1200 Ohms).

Among the studied patients, transvenous endocardial PM insertion was performed in 37 patients (100 %) of the maintenance studied group and in 99 patients (89%) of the intensified studied group. This can be explained by availability of thinner endocardial pacing leads, small pulse generators, patent venous access and experienced cardiologists. However, transthoracic epicardial insertion was performed in 12 patients (11 %) intensified studied group. In children, especially in neonates and infants, the epicardial route was chosen because of early post-operative heart block or small body size until the advancement of smaller generators, lead implantation techniques that allowed growth of the child without lead displacement. During the follow up period, 7 patients were switched from epicardial to endocardial pacing due to battery depletion (n=4, 3.6 %) and lead fracture (n=3, 2.7%).

A study done by Ali et al. **(14)** included 100 patients and assessed the outcomes of pacing in the Egyptian pediatric population, showed that epicardial pacing represented 26% of studied group (n=26) while endocardial pacing represented 74% of same studied group (n=74%).

Another retrospective study by Samir et al. **(4)** included 32 patients, they assessed both endocardial & epicardial pacing in infants and children and showed that endocardial pacing was performed in 21 patients (65.6%), while epicardial pacing was performed in 11 patients (34.4%)

There were no reported complications among the maintenance studied group. This was due to strict evaluation, follow up protocol, prophylactic antibiotics for 3 days and good infection control during procedure. However, the intensified group had 12 patients (10.8 %) who developed complications. Lead failure related complications were detected in 8 patients (7.2 %). Lead failure related complications has occurred in 33.3 % of epicardial leads and in 4 % of endocardial leads. This was explained by the small number of epicardial leads and large number of endocardial leads included in the study. The most significant patient risk factor related to lead failure was the young age at initial pacemaker implantation, children are undergoing rapid growth and are very active, both of which can place additional mechanical stress on the leads.

This agreed with Ali et al. **(14)** who showed that a total of 25 patients (25%) of their studied population developed complications including 16 lead-related complications, this due to external trauma, traction and mechanical stress exerted on leads. Lead failure related complications has occurred in 15.3 % of epicardial leads (n=4) and in 16 % of endocardial leads (n=16).
Similarly, a study by Samir et al. **(4)** showed that a total of 12 patients (37.5%) developed complications during the study. Lead related complications occurred in 6 patients (18.7%), while non-lead related complications occurred in 6 patients (18.7%). Lead failure related complications has occurred in 20 % of epicardial leads (n=2) and in 9.6 % of endocardial leads (n=2). This finding is congruent with several articles related to lead complications such as a retrospective study by Fortescue et al. **(15)** who noted lead failure in 15 % (n= 155) of their patients, with significantly higher lead failure in epicardial placed leads.

Limitations

Our study has some limitations. First, it is a cross-sectional study with a limited number of patients. Second, the retrospective nature of the study is a limitation. Third, our research is a single center study.

Conclusion and recommendations

Children who have transvenous endocardial pacemaker implantation can expect a good long-term prognosis and a safe operation with few problems. Transvenous endocardial pacing is a lifesaving procedure. It can result in a significant improvement in cardiac output, which has an impact on the children's growth rates. Compared to endocardial pacemakers, epicardial pacemakers had greater incidence of lead-related issues. Endocardial leads exhibited a longer lead lifespan in comparison to epicardial leads.

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