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Outcomes of Pacing in Egyptian Pediatric Population

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Abstract

Objectives: Permanent pacemakers are widely used in the pediatric population due to congenital and surgically acquired rhythm disturbances. The diversity and complexity of congenital heart diseases make device management a highly individualized procedure in pediatric pacing. We are also faced with special problems in pediatric age group as growth, children's activity and infection susceptibility. This study aimed to present our institute's experience in pediatric and adolescent pacemaker implantation and long-term outcomes.

Methods: This cross-sectional observational study included 100 pediatric patients who visited our outpatient clinics at Ain Shams University Hospitals for regular follow up of their previously implanted permanent pacemakers. All patients were subjected to history taking, clinical examination, ECG recording, echocardiography and elaborate device programming. Data about device types, device components' longevity, subsequent procedures, complications were collected, with comparison between epicardial and endocardial pacemakers.

Results: Our study population ranged in age from 8 months to 18 years (mean 13.12 ± 5.04 years), 51 were males and 53 patients had congenital heart disease. Epicardial pacing represented 26% of our total population using only VVIR pacemakers, while endocardial pacing represented 74% of our population with 58.1% of them being VVIR pacemakers. First battery longevity was higher in endocardial batteries (108 months vs. 60 months, p value: 0.007). First lead longevity was also higher in endocardial leads (105 months vs. 58 months, p value: 0.006). Complication rate was 25%; 8 patients had early complications (one insulation break in endocardial group). Late complications occurred in 17 patients (10 patients had lead fracture; 9 of them were endocardial, 2 insulation breaks in endocardial leads, 3 patients from epicardial group had lead failure of capture). In total, 16 patients had lead-related complications. There was no statistically significant difference between different lead models regarding lead-related complications.

Conclusion: Pacemakers in children are generally safe, but still having high rates of lead-related complications. Lead failure of capture was more common in epicardial leads. These complications had no relation to the model of the leads. Endocardial pacemakers showed higher first lead and first battery longevity compared to epicardial pacemakers.

Keywords: Permanent pacing, Pediatric age, Endocardial pacing, Epicardial pacing, Pacing complications

1. Introduction

Cardiac devices are an effective long-term treatment for a variety of bradyarrhythmias. Permanent pacemakers are widely used in the pediatric population due to congenital and surgically acquired rhythm disturbances [1,2]. The indications for pacing in children and patients with CHD are slightly different than in adults,

mainly reflecting the broad range of ages and concomitant structural heart disease involved [3].

Permanent pacing in pediatric patients is generally safe and has a favorable long-term outcome, but there remains a high rate of complications mainly related to lead performance. This is of particular concern in children who need a lifetime of pacing with modern technology [4,5]. The choice between endocardial or epicardial pacing is usually decided according to the presence of complex congenital

Received 27 December 2020; revised 6 February 2021; accepted 18 February 2021.
Available online 15 April 2021

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heart disease, type of corrective surgery and the size of the patient [6].

Permanent cardiac pacing in pediatric patients is performed in few cardiology centers in Egypt. So, the current study aims to present our institute's experience in pediatric and adolescent pacemakers and their long-term outcomes.

2. Methods

This study was a cross-sectional observational study. It was conducted on patients already attending in the pacemaker follow up clinic. They were undergoing regular routine follow up in pacemaker follow up clinics at Ain Shams University Hospitals. These visits are done regularly to all patients with implanted pacemakers including both adults & pediatrics. We selected the first 100 pediatric patients from those who presented in the clinic during the timeline of the study. Medical files were used for retrieving implantation data of the selected patients. Patients older than 18 years, handicapped or mentally retarded patients, or PPM implanted within 6 months of the study recruitment date were excluded from our study. Programming was done by an experienced cardiologist who received training on the programming of all types of cardiac devices. All patients were evaluated once. We enrolled in patients between July 2018 and December 2019. All parents & adolescent patients gave written informed consent that they accept the participation in this study. The study was approved by Ain Shams University ethical committee according to the ethical guidelines of the 1975 declaration of Helsinki as revised in 2008.

Full medical history was taken with special emphasis on demographic data including age, gender, weight, and indications of pacing, history of CCU admission, history of surgery or catheterization, family history of the same illness. All patients were subjected to thorough clinical examination.

We were particularly interested in comparing epicardial and endocardial pacemakers regarding pacemaker types, device data, first battery & lead longevity, second or third procedures, complications (whether early or late complications) and device interrogation.

2.1. Device data

We collected data regarding indication of pacemaker implantation (sinus node dysfunction, congenital heart block or post-operative heart block), age of first implantation, first implantation technique whether (endocardial or epicardial), device data

List of abbreviations

| | |
|----------|---|
| CCU | Cardiac care unit |
| CHB | Complete heart block |
| CHD | Congenital heart disease |
| CHF | Congestive heart failure |
| CRT-P | Cardiac resynchronization therapy pacemaker |
| DDD/DDDR | Dual chamber pacemaker |
| ECG | Electrocardiogram |
| LVEF | Left ventricular ejection fraction |
| PDA | Patent ductus arteriosus |
| PPM | Permanent pacemaker |
| VVI/VVIR | Single chamber pacemaker |

including its type (VVIR or DDD), manufacturer, model name, lead type, site of pulse generator implantation. Data about number of battery replacement, PPM replacement or device & lead extraction procedures since first implantation, their timing as well as their indication, were also collected.

2.1.1. Important definitions

- Battery replacement: exchange of the pulse generator only with keeping the previously implanted leads in place.
- PPM replacement: exchange of the pulse generator in addition to exchanging the previously implanted leads (whole device replacement).
- Lead extraction: removal of at least one previously implanted lead with the assistance of specialized equipment.

Device related complications were recorded, whether early complications which occurred in the first 3 months after implantation or late complications occurring after more than 3 months of implantation.

ECG was done to all patients to assess heart rate & rhythm, detect any arrhythmias & assess pacemaker function. Echocardiography was done to detect presence or absence of structural heart diseases or congenital heart diseases. LVEF measurement by modified Simpson's method was performed using the standard technique [7].

2.2. Device interrogation & programming

Device interrogation & programming were performed using the appropriate programmer for battery information including voltage, battery impedance, remaining longevity in addition to lead integrity (impedance measurements considered normal between 300 and 1200 Ohms) with detection of any signs of lead fracture or insulation break.

Sensing function evaluation was done measuring ventricular and atrial spontaneous electrograms amplitudes (P wave & R wave amplitudes were tested & recorded with reported normal value above 1.5mv & 5mv respectively). Pacing threshold testing of atrial and ventricular leads was done.

2.3. Statistical analysis

Data were collected, coded, revised and entered the Statistical Package for Social Science (IBM SPSS) version 21. The data were presented as mean, standard deviations and ranges for the quantitative data with the parametric distribution. The comparison between groups with qualitative data was done by using the Chi-square test and/or Fisher exact test only when the expected count in any cell found less than 5%. The comparison between two independent groups with quantitative data and parametric distribution was done by using an independent *t*-test. The comparison between more than two groups with quantitative data was done by using One Way Analysis of Variance (ANOVA). The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *p*-value was considered significant as the following: $p > 0.05$: Non-significant (NS), $p < 0.05$: Significant (S), $p < 0.01$: Highly significant (HS).

3. Results

3.1. Patient's clinical and demographic data

Our study included 100 patients ranging from 8 months to 18 years of age (mean 12.58 ± 5.27 years). We had 51 males and 49 females. Forty-seven patients had structurally normal hearts, while 53 patients had congenital heart disease (Table 1). Types of congenital heart diseases were shown in Fig. 1.

From 53 patients having congenital heart diseases, 50 patients had history of cardiac surgery for repair of their congenital defects. Two patients had done PDA coil closure. Only one patient in our study had a history of a cardiac diagnostic hemodynamic study.

3.2. Device data

Epicardial pacing represented 26% of our total population using only VVIR pacemakers, while endocardial pacing represented 74% of our population with 58.1% of them being VVIR pacemakers, with a highly significant difference between both techniques (p -value= <0.01). The details of device manufacturer's data are detailed in Table 2.

Table 1. Patient clinical demographic data.

| | No. = 100 |
|-------------------------------------|--------------------|
| Age (years) | |
| Mean \pm SD | 12.58 \pm 5.27 |
| Range | 0.8–18 |
| Gender | |
| Female (no. %) | 49 (49.0%) |
| Male (no. %) | 51 (51.0%) |
| Weight (kg) | |
| Mean \pm SD | 48.98 \pm 21.78 |
| Range | 8–85 |
| Height (cm) | |
| Mean \pm SD | 137.07 \pm 31.74 |
| Range | 49–172 |
| Body surface area (m ²) | |
| Mean \pm SD | 1.35 \pm 0.45 |
| Range | 0.39–1.96 |
| Echocardiography data EF (%) | |
| Mean \pm SD | 60.90 \pm 6.24 |
| Range | 44–77 |
| Pacing indication (no., %) | |
| Sinus node dysfunction | 2 (2.0%) |
| Cong. CHB | 52 (52.0%) |
| Post-operative CHB | 46 (46.0%) |

CHB: congenital heart block.

The mean age for epicardial pacemakers was significantly lower than that for endocardial pacemakers (p -value= <0.01). The smallest weight and height for endocardial pacing reported were 12 kg and 69 cm, which were significantly higher compared to epicardial pacing (p -value= <0.01 and < 0.01 , respectively).

The devices used in our studied population were St. Jude Medical devices in (69.0%) of patients compared to other manufacturers (Medtronic 25%, Biotronik 4%, Boston Scientific 2%), with no statistically significant difference between epicardial and endocardial devices (73.1% vs. 67.6% respectively) (p -value = 0.523) as shown in Table 2.

3.3. Device implantation & multiple procedures data

In our study, all patients were pacemaker dependent. The age of patients at 1st device implantation ranged from 2 months to the age of 14 years.

3.3.1. Second procedure

A total of 39 patients needed a second procedure prior to the study; one patient with DDDR pacing was upgraded to CRT-P due to LV dysfunction, while 19 patients were switched from epicardial to endocardial pacing after 3–7 years from first implantation (Table 3).

Device battery was replaced in 12 patients due to battery end of life and the pacing system was

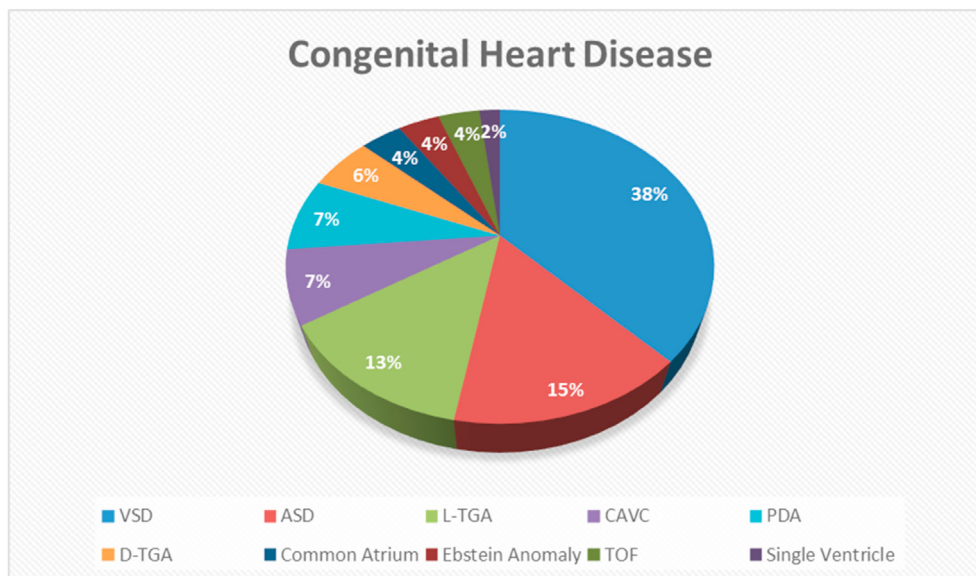


Fig. 1. Types of congenital heart diseases. ASD: atrial septal defect, CAVC: common AV canal, D-TGA: dextro-transposition of great arteries, L-TGA: levo-transposition of great arteries, PDA: patent ducts arteriosus, TOF: Tetralogy of Fallot, VSD: ventricle septal defect.

replaced in 9 patients due to lead problems and battery end of life with a device age ranging between 2 and 12 years after device implantation with mean of 5.92 ± 3.04 years, five of them were switched from epicardial to endocardial pacing. Two

patients with endocardial pacing had successful lead extraction to allow for implantation of a new device with new leads, and two patients had changed their leads with epicardial pacing due to lead failure of capture (Table 3).

Table 2. Device data at time of follow up.

| | | Epicardial | Endocardial | Test value | p- value |
|-------------------------------------|-------------------|--------------------|--------------------|------------|----------|
| | | No. = 26 | No. = 74 | | |
| Type | VVIR | 26 (100%) | 43 (58.1%) | 15.785* | <0.01 |
| | DDDR | 0 (0.0%) | 31 (41.9%) | | |
| Age (years) | Mean \pm SD | 6.10 \pm 2.23 | 14.85 \pm 3.97 | -10.639 | <0.01 |
| | Range | 0.8–8 | 4–18 | | |
| Weight (kg) | Mean \pm SD | 20.85 \pm 4.81 | 56.77 \pm 19.00 | -9.504• | <0.01 |
| | Range | 8–25 | 12–85 | | |
| Height (cm) | Mean \pm SD | 101.81 \pm 28.26 | 148.76 \pm 20.52 | -9.054• | <0.01 |
| | Range | 49–128 | 69–172 | | |
| Body surface area (m ²) | Mean \pm SD | 0.76 \pm 0.19 | 1.52 \pm 0.37 | -9.935• | <0.01 |
| | Range | 0.39–0.94 | 0.48–1.96 | | |
| Manufacturer | ST. Jude Medical | 19 (73.1%) | 50 (67.6%) | 2.245 | 0.523 |
| | Medtronic | 7 (26.9%) | 18 (24.3%) | | |
| | Boston Scientific | 0 (0.0%) | 2 (2.7%) | | |
| | Biotronik | 0 (0.0%) | 4 (5.4%) | | |
| Model Name | Microny | 4 (15.4%) | 2 (2.7%) | 16.873* | 0.010 |
| | Endurty | 9 (34.6%) | 36 (48.6%) | | |
| | Relia | 3 (11.5%) | 0 (0.0%) | | |
| | Sensia | 4 (15.4%) | 17 (23.0%) | | |
| | Verity | 2 (7.7%) | 7 (9.5%) | | |
| | Sustain | 4 (15.4%) | 8 (10.8%) | | |
| | Talos | 0 (0.0%) | 4 (5.4%) | | |
| Model Lead | Tendril | 15 (57.7%) | 50 (67.6%) | 30.789* | <0.01 |
| | Capsurefix | 2 (7.7%) | 16 (21.6%) | | |
| | Capsure EPI | 9 (34.6%) | 0 (0.0%) | | |
| | Boston angipity | 0 (0.0%) | 2 (2.7%) | | |
| | Salox SR53 | 0 (0.0%) | 6 (8.1%) | | |

Table 3. Types of implantation procedures including indications of second & third procedures.

| | | No. = 100 | |
|---|----------------------|-----------------------|--|
| Age of first implantation (years) | | | |
| Mean \pm SD | | 5.29 \pm 3.99 | |
| Range | | 0.2–14 | |
| Device Dependency | | 100 (100.0%) | |
| Route of implantation | | | |
| Epicardial | | 26 (26.0%) | |
| Lt. subclavian | | 59 (59.0%) | |
| Rt. Subclavian | | 15 (15.0%) | |
| Timing of second procedure (years) | | | |
| Mean \pm SD | | 5.92 \pm 3.04 | |
| Range | | 0.60–12.00 | |
| Total number of leads | | 147 (100%) | |
| Number of functioning lead (%) | | 133 (90.5%) | |
| Number of non- functioning lead (%) | | 14 (9.5%) | |
| Type of second & third procedures | Epicardial N = 26 | Endocardial N = 74 | Duration (years) From previous implantation |
| 2nd procedure n = 39 | 25 (25%) | 14 (14%) | 3–8 |
| Pacing system replacement n = 9 | 4 (4%) | 5 (5%) | 2–12 |
| Battery replacement n = 12 | 4 (4%) | 8 (8%) | 3–8 |
| Lead replacement n = 2 | 2 (2%) | 0 (0%) | 0.6 |
| PM upgrading to CRT-P n = 1 | 0 | 1 (1%) | 8 |
| Switch from epicardial to endocardial pacing n = 19 | 0 | 2 | 3–7 |
| History of lead extractions n = 2 | 0 | 2 | 3–4 |
| 3rd procedure n = 7 | 0 | 7 (7%) | 2–8 |
| Pacing system replacement n = 7 | 0 (0%) | 7 (7%) | 2–8 |
| PM upgrading VVI to DDD n = 4 | 0 (0%) | 4 (4%) | 7–8 |

3.3.2. Third procedure

A total of 7 patients needed a third procedure prior to the study within 2–8 years from 2nd procedure. Four of them needed pacing system upgrade from VVI pacing to DDD with ventricular lead replacement due to lead fracture; while the other 3 patients needed pacing system replacement only due to insulation breaks within 2–3 years which resulted in premature battery depletion (Table 3).

Battery and pacing system replacements were significantly higher in the VVIR group (p-value = <0.01, 0.018 respectively). The timing of second procedures in DDDR patients was significantly later compared to VVIR patients with mean timing of 7.91 \pm 2.20 years vs. 5.19 \pm 3.01 years respectively with (p-value = 0.008).

Meanwhile, third procedures in the form of pacing system replacement were only done in VVIR group.

3.4. Device battery and lead measurement data

Lead measurements including lead impedances, pacing thresholds and sensing function measurements of all ventricular leads, were similar with no statistical difference between epicardial and endocardial group. The longevity of some device batteries was short because of lead problems

necessitating pacing system replacement; three patients had insulation breaks needed pacing system replacement after 2–3 years and one patient with epicardial PPM had lead fracture after 2 years needed to replace the device after 2 years.

3.5. First battery longevity

The longevity of PPM batteries (endocardial Vs epicardial), independently from pacing mode and battery manufacturer is presented by Kaplan-Meier survival estimate curve (Fig. 2).

There was statistically significant difference among the two survival curves with median of 108 months in endocardial batteries compared to a median of 60 months in epicardial batteries, using (Log-rank chi-squared = 15.408, df = 1, p-value = 0.007*).

3.6. First ventricular lead longevity

The longevity of ventricular leads independently from pacing mode is represented by Kaplan-Meier survival curve in endocardial versus epicardial leads. There was statistically significant difference among two survival curves with median of 105 months in endocardial leads compared to median of 58 months in epicardial leads using (Log-rank chi-squared = 18.965, df = 1, p-value = 0.006*) (Fig. 3).

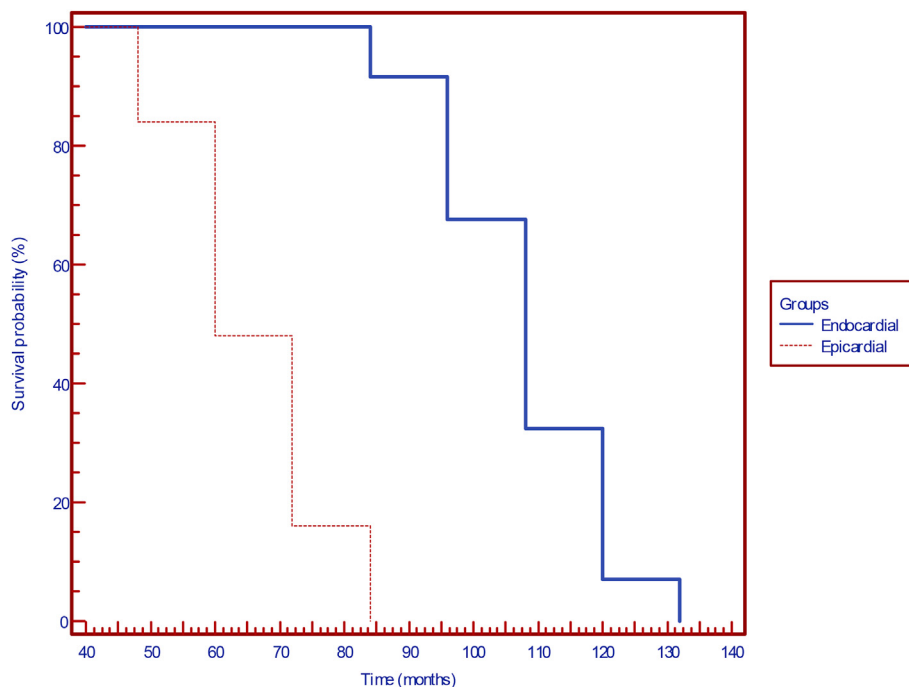


Fig. 2. Kaplan-Meier survival curves in endocardial versus epicardial pacemakers' batteries (Log-rank chi-squared = 15.408, $df = 1$, p -value = 0.007*).

3.7. Complications

A total of 25 patients (25%) of our studied population developed complications including 16 lead-related complications (Table 4). Early complications occurred in only 8 patients (all from endocardial group) with only one lead-related complication

(insulation break which occurred one month after endocardial pacemaker implantation).

As far as late complications, ten patients had lead fractures within 1 year–8 years after device implantation due to external trauma, only one of them was epicardial. Three patients developed lead failure of capture after 6 months with epicardial

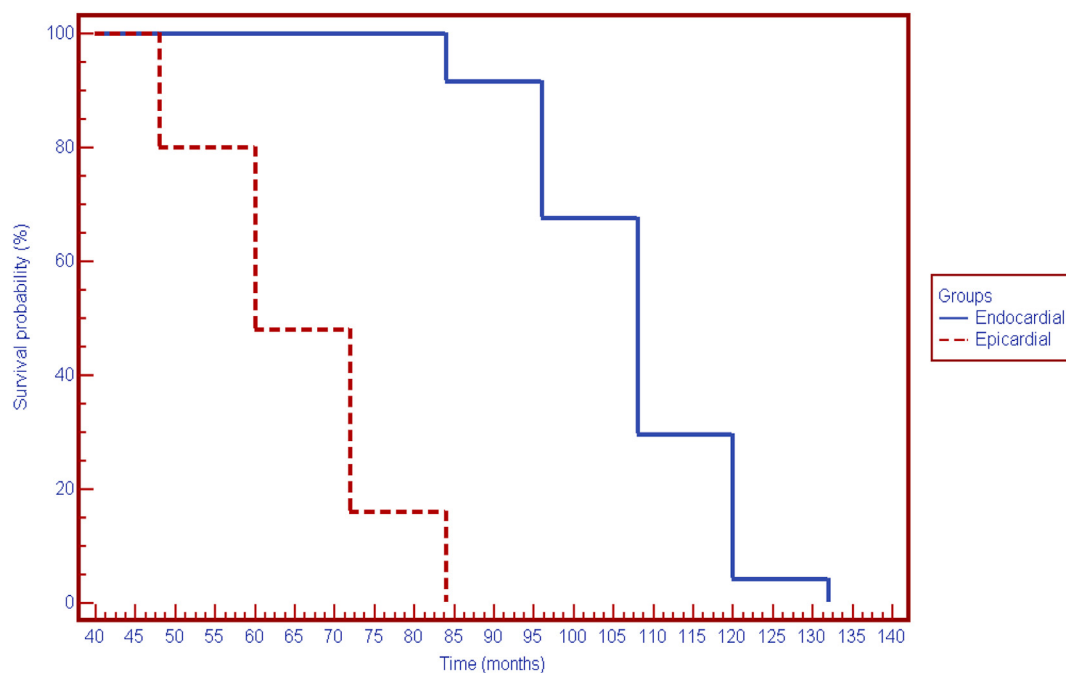


Fig. 3. Kaplan-Meier survival curves in endocardial versus epicardial ventricular leads (Log-rank chi-squared = 18.965, $df = 1$, p -value = 0.006*).

Table 4. Complications among studied patients.

| | Epicardial No. = 26 | Endocardial No. = 74 | Test value | p- value |
|---------------------------------|------------------------|-------------------------|------------|----------|
| Early complications | | | | |
| Superficial infection n., (%) | 0 (0.0%) | 2 (2.7%) | 0.717 | 0.397 |
| Painful pocket n.,(%) | 0 (0.0%) | 2 (2.7%) | 0.717 | 0.397 |
| Pocket hematoma n., (%) | 0 (0.0%) | 2 (2.7%) | 0.717 | 0.397 |
| Trauma to apex of lung n., (%) | 0 (0.0%) | 1 (1.35%) | 0.355 | 0.551 |
| Insulation break n., (%) | 0 (0.0%) | 1 (1.35%) | 0.355 | 0.551 |
| Timing (month) | – | 1 | – | – |
| Late complications | | | | |
| Lead fracture n., (%) | 1 (3.8%) | 9 (12.2%) | 1.478 | 0.224 |
| Timing (years) | 2 | 1–8 | – | – |
| Mean ± SD | 2.00 ± 0.00 | 3.56 ± 2.65 | | |
| Lead failure of capture n., (%) | 3 (11.5%) | 0 (0.0%) | 8.803 | 0.003 |
| Timing (months) | 6 | – | – | – |
| Insulation break n., (%) | 0 (0.0%) | 2 (2.7%) | 0.717 | 0.397 |
| Timing (months) | – | 6 | | |
| Others | 0 (0.0%) | 2 (2.7%) | 0.717 | 0.397 |

pacemakers. Two patients had insulation breaks 6 months after pacemaker implantation (both were endocardial).

Other late complications included developing LV dysfunction in one patient after 8 years with dual pacemaker device due to prolonged RV pacing which was upgraded to CRT device. Another patient developed psychological problems.

As regards lead model, there was no statistically significant difference between different lead models as regards lead related complications as shown in Table 5.

4. Discussion

Treatment with permanent pacemakers has significantly improved survival in patients with life-threatening bradyarrhythmias [8]. However, complication rates and incidence of infection appear to be greater in children than adults [9].

Pediatric population represent a unique subset of patients with special characteristics including anatomical variations depending on the type of CHD, small vascular access, somatic growth, higher frequency of infections and traumatic events making them more prone to complications.

Still, pacemaker implantation in children and adolescents is a procedure with a generally favorable outcome. The indications for pacing in children and patients with CHD are slightly different than in adults, mainly due to differences in age groups and concomitant structural heart diseases involved. The natural history of bradyarrhythmias in these palliated or repaired CHD patients and the specifics of surgical approach are major determinants influencing the need for pacing. In our study a big proportion of patients (53%) had CHD and a 46% of patients had postoperative CHB.

Epicardial pacing is usually established because of either cardiac anatomy or small body size. In our study, epicardial pacing was only limited to small children, single ventricle physiology, or early postoperative CHB. Also, patients who received endocardial pacing in our study were significantly older & bigger in size compared to patients who received epicardial pacemakers. The youngest age, smallest size (i.e. weight and height) for endocardial pacing were 4 years, 12 kg and 69 cm, respectively, which showed significantly higher values compared to epicardial pacing (p-value=<0.01, <0.01 and < 0.01, respectively).

Table 5. Difference between model leads according to complications.

| | Tendril No. = 65 | Capsurefix No. = 18 | Capsure EPI No. = 9 | Others No. = 8 | Test value | p-value |
|-------------------------|---------------------|------------------------|------------------------|-------------------|--------------------|---------|
| Lead fracture | 8 (12.3%) | 0 (0.0%) | 0 (0.0%) | 2 (25.0%) | 5.385 ^a | 0.146 |
| Lead failure of capture | 3 (4.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1.665 ^a | 0.645 |
| Insulation break | 3 (4.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1.665 ^a | 0.645 |

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant.

^a Chi-square test; ∴ One Way ANOVA test.

In our study, the lowest weight for endocardial pacing was a body weight of 12 kg due to concerns about the development of venous thrombosis resulting from disproportion between vessel and lead size in smaller patients as well as the lifelong need for permanent pacing in these patients. In our institute, we believe that endocardial pacing could be preferable due to better lead & battery performances in older pediatric population.

Despite recent technical progress, pacing leads remain the weakest point of the permanent pacing system, especially in a growing patient. In our study the complication rate was 25% and more than half of it was lead-related complications or failure (16%) that necessitated re-intervention and lead abandonment in the majority of cases. Nearly similar rates of complications were demonstrated in similar studies on the same age group [10–12].

In our study there was no statistical difference between endocardial & epicardial pacing in lead related complications except for lead failure of capture which was significantly higher in epicardial pacemakers ($p = 0.003$). This might be related to the limited experience of some of cardiac surgeons with epicardial pacing in this age group. These findings were similar to what was found previously in a similar study [13] that showed higher lead failure in epicardial group.

One of the most serious complications encountered in epicardial pacemakers is the development of coronary artery compression with epicardial leads. It can lead to potentially lethal outcomes including sudden cardiac arrest [14]. Although it is thought to be a rare complication, a higher incidence (5.5%) of coronary compression caused by epicardial leads was found in a patients' cohort which was noted by either coronary angiography and/or computed tomography (CT) of the coronary arteries [15].

Our study showed that there was no relation between lead model and incidence of lead related complications. Although Tendril leads showed a higher incidence of complications (8 lead fractures, 3 failures of capture, 3 insulation breaks) among all leads in this study, but still it did not reach statistical significance. It is the first study in literature to address the issue of the relation between lead model and occurrence of lead related complications, our hypothesis was trying to see if there's a relation between structural properties of the lead and incidence of lead related complications.

Non-lead related complications were only seen in endocardial devices including early pocket hematoma, superficial infection, painful pocket and trauma to apex of lung during venous puncture and

late LV dysfunction, which required upgrading to CRT.

In our study, the longevity of ventricular leads, independently from pacing approach was significantly longer in endocardial ventricular leads which coincides with the findings of similar studies in literature that reported better longevity of endocardial leads in infants [10,13,16].

In contrast *Samir et al.* [17] proven no significant difference in survival between epicardial and endocardial leads and this discrepancy in results might be explained by small number of patients included in this study (32 patients). Also, in a retrospective review chart on 158 epicardial leads, lead survival at 10 years was 92.4%, with only 7.5% lead failure (due to lead failure) [18].

The probable reasons behind better performance of endocardial leads might include trauma or traction imposed on epicardial leads by thoraco-abdominal movement and the numerous cardiac operations that patients with CHD often undergo with consequent presence of inflamed or scarred epicardium.

Also, in our study the battery longevity, independently from pacing mode and battery manufacturer, showed significantly longer median endocardial batteries longevity. Similar results were shown in different previous studies with the same or even longer longevity for endocardial batteries [12,19].

In our series, a longer average endocardial battery survival compared to epicardial ones could be explained by the fact that the patients in the epicardial group were significantly younger demanding a higher pacing rate, and in this group, the number of patients with operated congenital heart disease was higher assuming an epicardial surface with variable degrees of fibrosis from scar tissue formation or pericardial adhesions causing higher stimulation thresholds. These two factors may contribute to early battery depletion, too.

The patient's individual characteristics is the basis upon which the decision on whether to implant either endocardial or epicardial leads, rather than on different technical aspects as lead performance or longevity. Other factors should be considered, as preservation of vascular access, expected operations or reoperations and the spacial considerations for leaving a pacing lead reserve to compensate the patient's growth, when choosing an acceptable route for pacemaker [18].

Although *Konta et al.* conducted a study that proved that transvenous pacing in infants weighing less than 10 kg is favorable because it showed better short and long clinical outcomes (in patients

weighing less than 5 kg, subclavian vein occlusion was an important complication) [20], but actually these data cannot be generalized in general practice. Even the largest congenital heart centers do not have enough volume of patients or enough practice variation to determine optimal device use for each type of pediatric or congenital heart patient [21].

However, the emergence of leadless pacemakers' technology offers a promising tool for effective pacing and avoiding problems that are sometimes encountered from epicardial & endocardial pacing discussed previously [22,23]. In a retrospective review by *Breatnach et al.* in 2020 on leadless pacemaker in children, they concluded that it is feasible to implant a leadless pacemaker in pediatric patients. Of course, these data are encouraging, but further studies and long-term follow-up are needed to ensure device longevity and complication rates [24].

Study Limitations:

1. The results of this study cannot be generalized due to marked heterogeneity of the underlying diseases and the variety of the age of patients.
2. The study presented only one single medical center experience.
3. The study included a limited number of cases.

5. Conclusion

Pacemakers in children are generally safe with favorable long-term outcomes. But still, we found high rates of complications; mainly lead-related. Epicardial pacemakers were associated with higher incidence of lead failure of capture when compared to endocardial pacemakers. These lead-related complications had no relation to the model of the leads. First battery longevity was higher in endocardial batteries. First lead longevity was also higher in endocardial leads.

Author contributions

Ahmed Nabil Ali: Conception and design of Study; Literature review; Acquisition of data; Research investigation and analysis; Drafting of manuscript; Analysis and interpretation of data; Data preparation and presentation; Research coordination and management. **Samir S. Wafa:** Conception and design of Study; Literature review; Analysis and interpretation of data; Data collection; Revising and editing the manuscript critically for important intellectual contents; Supervision of the research. **Hosni Hosni Arafa:** Literature review; Acquisition of data; Analysis and interpretation of

data; Research investigation and analysis; Data collection; Data preparation and presentation. **Rania Samir A:** Literature review; Research investigation and analysis; Revising and editing the manuscript critically for important intellectual contents; Supervision of the research; Research coordination and management.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interests

All authors have none to declare.

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