Long-term outcome of permanent epicardial pacemaker implantation in neonates: Experience from an Indian center

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ABSTRACT

Introduction : **Permanent pacemaker implantation (PPI) in neonates is challenging with respect to indications, device selection, implantation technique, and long-term outcomes. Complex anatomy, the need for long-term pacing with high rates, and a problematic postoperative period are the major problems.**

Methods : **We prospectively followed up 22 newborns who underwent PPI below 28 days of life at our institute.**

Results : **The median age at implantation was 2 days (interquartile range 1–9 days), and 9% were born preterm. The average heart rate before implantation was 46.4 ± 7.2 bpm. Maternal lupus antibodies were positive in 8 (36.4%) neonates, whereas 11 (50.0%) had associated congenital heart disease. Nineteen neonates underwent single chamber (VVI) and three underwent dual chamber (DDD) pacemaker implantation. Over a median follow-up of 46 months (range 2–123 months), the average ventricular pacing percentage was 87.5 ± 24.9%, with a stable pacing threshold. Seven children underwent pulse generator replacement due to battery depletion at a median age of 47 months. Pacing-induced ventricular dysfunction was seen in five children at a median age of 23.6 months, and two underwent upgradation to cardiac resynchronization therapy. Overall mortality was 13.6%, all due to tissue hypoperfusion and lactic acidosis in the postimplantation period.**

Conclusions : **PPI in neonates has a favorable outcome with excellent lead survival. Overall mortality is 13.6%, which is predominantly in the postimplantation period and related to myocardial dysfunction.**

Keywords : Complete heart block, pacing thresholds, pacing-induced ventricular dysfunction, permanent pacemaker implantation

INTRODUCTION

Permanent pacemaker implantation (PPI) in neonates is challenging with respect to indications, device selection, implantation technique, and long-term outcomes. The major associated issues are complex anatomy,

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the need for long-term pacing with high rates, and challenging postoperative courses.[1] Predominant indications for PPI in neonates include congenital complete heart block (CCHB) with wide QRS escape, ventricular dysfunction, ventricular ectopy or significant bradycardia, or persistent postoperative complete heart block (CHB). The recommendations for pacemaker implantation in children are evolving and have been updated from the American College of Cardiology/American Heart Association/Heart Rhythm Society 2008 guidelines[2] to the recent Pediatric and Congenital Electrophysiology Society 2021 guidelines.[3]

The data regarding long-term outcomes of PPI in neonates are lacking, especially from the Indian subcontinent, and previous studies predominantly focused on older infants. Hence, we performed this study to assess the long-term outcomes of PPI in neonates aged below 28 days.

METHODS

This is a prospective observational longitudinal study in a tertiary care center in South India. The institutional ethics committee approved this study. Neonates with CHB (congenital or postoperative) who underwent epicardial PPI in the newborn period (age <28 days) between January 2009 and July 2021 were included in the study. Indications for PPI included CCHB with heart rate below 50/min or wide QRS escape and postoperative CHB persisting for more than 7 days. All of them underwent epicardial PPI through partial sternotomy; ventricular lead was placed on the anterior right ventricular free wall, and a pulse generator (PG) was placed in the rectus sheath. Steroid eluting bipolar suture leads (Medtronic Capsure 10366 or 4968, Minneapolis, MN) were used during implantation [Figure 1].

These neonates were prospectively followed up in a dedicated device care clinic, with biannual visits, thorough device interrogation, clinical examination, and periodic echocardiograms to assess left ventricular function. All device parameters were interrogated at each visit, including lead threshold and impedance, pacing percentage, amplitude, and any pacing-related problem.

Data entry and analysis were done using IBM SPSS v23.0 (statistical product and service solutions). (IBM, Chicago, Illinois, USA). Categorical variables were analyzed using the Chi-square test, and continuous variables were analyzed using the Student's *t*-test or Mann–Whitney *U* test. Kaplan–Meier analysis was used for survival analysis. $P < 0.05$ was considered statistically significant.

RESULTS

We followed up 22 neonates who underwent PPI in the aforesaid period [Table 1]. Out of them, 19 had CCHB, whereas 3 had postoperative CHB. All the neonates had wide QRS escape, with the mean heart rate before implantation being 46.4 ± 7.2/min. The median age at implantation was 2 days (interquartile range [IQR] 1–9 days) with a median weight of 3 kg (IQR 2.1–3.3 kg). None of them had any birth-related complications, and 9% were born preterm.

Out of three cases of postoperative CHB, two had undergone surgical closure of the ventricular septal defect, whereas 1 underwent ligation of patent ductus arteriosus. The mean interval to PPI was 16 ± 2 days after a trial of steroids.

Maternal lupus antibodies (antinuclear antibody [ANA]) were positive in 8 (36.4%) patients, whereas 11 (50.0%)

Table 1: Baseline characteristics (*n*=22)

Characteristics	*n* (%) or median (IQR)
Etiology	
CCHB	19 (86.4)
Postoperative CHB	3 (13.6)
Median age at implantation	2 days (IQR 1–9 days)
Preterm	2 (9.1)
Associated congenital heart disease	11 (50.0)
VVI pacemaker	19 (86.4)
DDD pacemaker	3 (13.6)

CHB: Complete heart block, CCHB: Congenital CHB, IQR: Interquartile range, VVI: Single chamber ventricular pacemaker, DDD: dual chamber pacemaker

Table 2: Follow-up events

Event	*n* (%)
Pulse generator replacement	7 (31.8)
Pacing-induced ventricular dysfunction	5 (22.7)
Lead dysfunction	2 (9.1)
Mortality	3 (13.6)

Table 3: Differences in children who died and survived

Parameter	Died (*n*=3), *n* (%)	Survived (*n*=19), *n* (%)	*P*
Age at implantation (days), median (IQR)	3 (1–26)	2 (1–8)	0.69
Single-chamber (VVI) pacemaker implantation	3 (100)	16 (84.2)	0.46
CHD	2 (66.7)	9 (47.4)	0.53
Positive maternal lupus antibodies	2 (66.7)	6 (31.6)	0.24
Ventricular dysfunction on follow-up	3 (100.0)	2 (10.5)	<0.01

IQR: Interquartile range, CHD: Congenital heart disease, VVI: Single chamber ventricular pacemaker

Table 4: Predictors of mortality

Parameter	OR	*P*
VVI pacemaker implantation	1.48 (0.07–35.69)	0.80
CHD	2.22 (0.17–28.86)	0.54
Positive maternal lupus antibodies	4.33 (0.33–57.65)	0.46
Postoperative CHB	9.00 (0.39–206.54)	0.17
Ventricular dysfunction	49.00 (1.91–1258.77)	0.01

OR: Odds ratio, CHD: Congenital heart disease, CHB: Complete heart block, VVI: Single chamber ventricular pacemaker

had associated congenital heart disease (CHD), the atrial septal defect being the most common (31.8%) followed by a ventricular septal defect (9.1%). Nineteen underwent single chamber (VVI) and three underwent dual chamber (DDD) pacemaker implantation. Four children had surgical site infections postimplantation, which were managed conservatively.

The median duration of follow-up was 46 months (range 2–123 months), during which the average threshold changed from 1.0 ± 0.5 V to 1.4 ± 0.7 V (P = 0.10). The average ventricular pacing percentage was 87.5% ± 24.9%, with the average impedance being 604 ± 98 ohms.

Seven children underwent PG replacement due to battery depletion at a median age of 47 months. Elevated lead threshold (>3V@0.4 ms) beyond 6 months of age was seen in two children [Table 2].

Pacing-induced ventricular dysfunction was seen in five children at a median age of 23.6 months with no significant association with pacing mode, rate, or site of lead implantation. Two children underwent upgradation to cardiac resynchronization therapy, as they remained symptomatic despite optimal medical therapy.

Overall mortality was 13.6% at a median of 46 months of follow-up, which were all in the postoperative period with tissue hypoperfusion and lactic acidosis [Table 3]. Maternal ANA [Figure 2] and postoperative CHB [Figure 3] did not impact mortality [Table 4]. However, the development of ventricular dysfunction postimplantation of the pacemaker was significantly associated with mortality (P < 0.01).

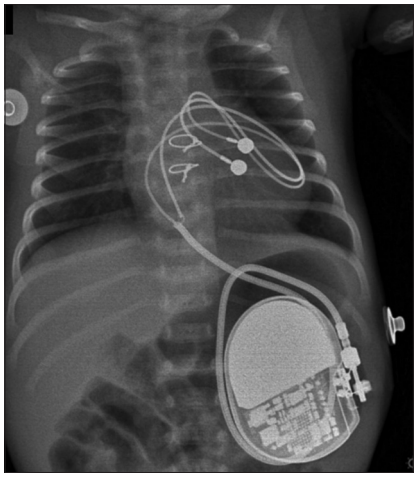

Figure 1: Chest X-ray (AP view) showing pulse generator in the rectus sheath and bipolar epicardial leads

DISCUSSION

This is one of the largest cohorts of neonatal pacemaker implantation with a relatively long follow-up duration

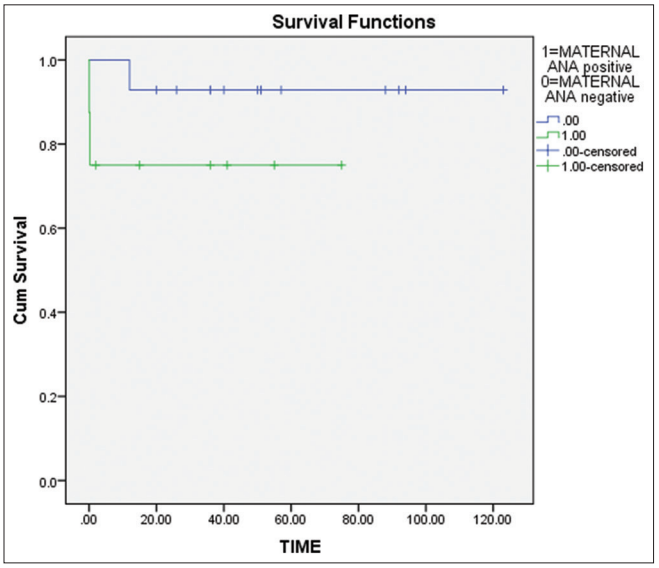

Figure 2: Kaplan–Meier curve showing survival of population with respect to maternal antinuclear antibody positivity (P = 0.196). ANA: Antinuclear antibody

Table 5: Summary of previous studies related to permanent pacemaker implantation in neonates

Author (country) (year)	Sample size	CHD (%)	Indication of PPI	Follow-up duration	Events
Aellig *et al.*[4] (Switzerland) (2007)	22	77.3	7 CCHB 11 postoperative CHB 4 sinus node dysfunction	Median 4.6 years	Device replacement - 7 Mortality - 18.2%
Cho *et al.*[5] (Korea) (2015)	44 (15 neonates)	N/A	16 CCHB 23 postoperative CHB	Mean 9 years	11 PG change 15 lead failure
Kwak *et al.*[6] (Korea) (2019)	48 (16 neonates)	N/A	18 CCHB 24 postoperative CHB 6 sinus node dysfunction	Mean 8.5 years	11 PG change 18 lead failure
Wildbolz *et al.*[7] (Switzerland) (2020)	52	84.6	12 CCHB 34 postoperative CHB 6 sinus node dysfunction	Median 40 months	10 PG change, 3 lead dysfunction No mortality
Mikulski *et al.*[8] (USA) (2023)	573	29	All had CCHB	In-hospital stay	Mortality 16.3% Major predictors - low birth weight, associated CHD, prematurity, and nonwhite race

CHB: Complete heart block, CCHB: Congenital CHB, CHD: Congenital heart disease, PG: Pulse generator, PPI: Permanent pacemaker implantation, N/A: Not available

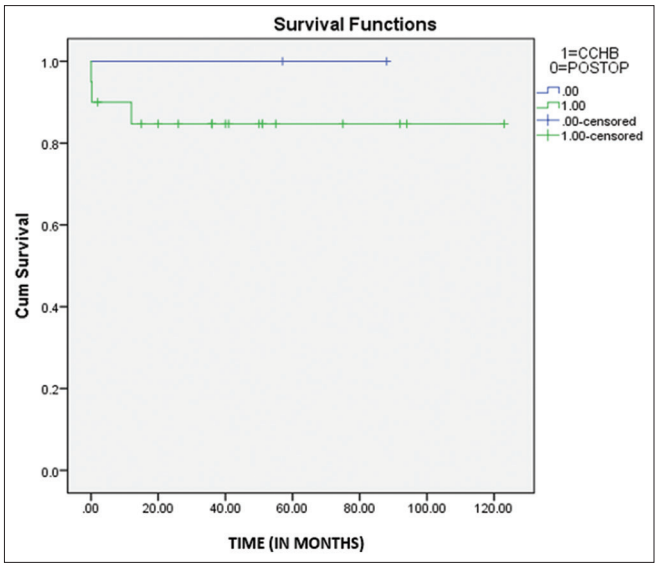

Figure 3: Kaplan–Meier curve showing survival of population with respect to etiology of complete heart block (*P* = 0.570). CCHB: Congenital complete heart block

described in the literature. Previous studies[3-8] [Table 5] have included mainly older infants and only a small proportion of neonates. These studies also had predominantly infants with postoperative CHB. Mikulski *et al.* also reported an inhospital mortality of 32.6% in neonates with CCHB undergoing PPI, among whom low birth weight, associated CHD, prematurity, and nonwhite race were significant predictors.[8] The prevalence of CHD in this cohort was less than in previously published studies, with atrial septal defect being the most common (31.8%). Surgical site infection was seen in 18.2% but was unrelated to body weight or device size, as reported by Ergün *et al.*[9]

The pacing threshold remained relatively stable throughout follow-up, with lead failure seen in only two children, which is relatively low compared to previous cohorts. The incidence of pacing-induced ventricular dysfunction was 22.7%. The ventricular pacing percentage was relatively high due to the CHB, and battery depletion was seen earlier than in adults, which can be attributed to higher pacing requirements and high pacing rates.

Overall mortality was 13.6%, which was comparable to the previous studies and predominantly due to myocardial dysfunction in the immediate postoperative period. As our cohort had more CCHB than postoperative CHB and less prevalence of CHD, the mortality was numerically lower than the existing data. No significant association was found between maternal ANA positivity, pacing mode or rate, and site of lead implantation with mortality.

CONCLUSIONS

PPI in neonates has a favorable outcome with excellent lead survival. Overall mortality is 13.6%, which is predominantly in the postimplantation period and related to myocardial dysfunction.

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Conflicts of interest

There are no conflicts of interest.

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