EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE – SINGLE CENTRE EXPERIENCE

Thesis Submitted By

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In Partial Fulfillment of the Requirement for the Degree Of

MCh in Cardio Vascular and Thoracic Surgery

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We hereby certify that this thesis titled

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LIST OF ABBREVIATIONS

PPI – Permenant pacemaker implantation

MACE – Major Adverse Cardiac Events

NYHA – New York Heart Association

FC – Functional Class

BSA – Body surface area

ICR - Intra cardiac repair

ERI - Elective Replacement Indicator

DORV – Double outlet right ventricle

SSI – surgical site infection

SSS – sick sinus syndrome

LQTS – Long Q-T syndrome

CVA – Cerebrovascular Accident

PG – Pulse Generator

PM - Pacemaker

ABSTRACT

Background :

Permanent epicardial pacemaker have been utilized in clinical practice for several decades and the numbers of patients who require them are increasing. Pediatric pacemaker implants comprise < 1 % of all pacemaker implantations. The main indication for permanent pacemaker implantation in children is high-degree congenital atrioventricular block (AVB) with a frequency of about 1/ 2000. Another important indication is high-degree AVB following open-heart surgery, occurring with an incidence of 1 %. It is the main reason for placement of permanent epicardial pacemaker after congenital heart surgery. Although endocardial pacemaker have several advantages, such as longer battery life, better sensing and pacing thresholds, epicardial pacemakers are more suitable for infants and younger children who are still under somatic growth, especially for patients with complicated cardiac deformities. However, epicardial pacemakers are less durable and have a higher incidence of complications as compared to endocardial pacemakers. The current study aimed to review and analyze the experience in placement of permanent epicardial pacemaker and its outcomes. There is lack of data from the Indian subcontinent, with very few centres offering pediatric pacemaker implantation, especially regarding long term followup. Hence, our study will help to overcome this void.

Materials and Methods :

We prospectively followed up all children under18 years who underwent epicardial PPI in our institute from 2001 to 2020. Clinical data at baseline and at follow-up were assessed including need for reinterventions, pacing parameters and major adverse cardiovascular events (MACE).

Results:

A total of 84 patients underwent epicardial lead placement over a period of 20 years The mean age of implantation in the study population was 2.27 ± 3.58 years and for neonates (n=21) was 0.02 ± 0.03 years (0.24 ± 0.33 months. Mean birth weight for neonates was 2.31 ± 0.45 kg, Sex ratio was equal with 42 (50%) children were male and 42 (50%) children were female.. Most common indication for epicardial PPI insertion was post operative complete heart block(n=42 (50.00%)) followed by congenital complete heart block (CCHB) (n= 39 (46.43%)) ,sick sinus syndrome (SSS) (n=2) and Long QT Syndrome (n=1). 20 percent of congenital CHB children had maternal ANA positive. Congenital heart disease was noted in 26 CCHB children (60%), out of which PDA (51.16%) was the commonest. The most common surgery associated with post operative complete heart block was VSD| closure (73.8 %). VVI pacing mode was the most common mode of pacing, was seen in 61 patients followed by DDD mode in 21 and AAIR in 2 children.Most preffered approach for epicardial lead placement was lower midline sternotomy

(ministernotomy) (48%) followed by conventional sternotomy (27%), subxyphoid (10%) and lateral thoracotomy(7.14%). Rectus sheath in the anterior abdominal wall was the most preffered site for placing the pulse generator. The mean threshold at time of implantation was 1.43 ± 1V, and, at last follow up, it was 1.66 ± 1.08V (p=0.55). Average percentage of ventricular pacing was 87.17 ± 30.12 while mean impedance was 642±90.0 ohms, which remained relatively stable over all throughout follow-up but there was a statistically significant difference in median change in impedance between CCHB and post op group (P Value<0.05). Battery depletion, necessitating pulse generator change, was noted in 17 patients. The median time at PG Change occurs (in months) was 60 (46 to 120.50) in CCHB group and 84 (100 to 152) in post op group. Elevated lead threshold (>3V @ 0.4msec) was seen in 1 children beyond 6 months of follow-up who underwent ICR for DORV. Pacing induced LV dysfunction was noted in 5 patients at a mean age of 30 months . Ventricular dysfunction warranting upgradation to cardiac resynchronisation therapy (CRT) was done in 3 children. Change to endocardial pacing was seen in 8 children out of which 2 were because of lead fracture, 2 pacemaker malfunction. Total 4 deaths were seen and 2 were during the peri-operative period. Overall mortality is 4.7% and among neonates is 9.5% . Surgical site infection was seen in 5 patients (3 neonates) mostly seen within 3 months of implantation. There was no significant difference between the outcome of those

who underwent PPI for either indications in terms survival, heart failure, percentage of pacing requirement or duration of freedom from pulse generator replacement.

Conclusion :

Epicardial pacing outcome in pediatric age group have rarely been researched in south India. This study is among the few with the large number of participants analyzing the long term outcome epicardial pacing in a tertiary care centre. Epicardial permanent pacemaker implantation in pediatric population has become a relatively safe procedure with low mortality and morbidity with advent of newer implantation technique and sophisticated leads and pulse generators. There was no significant difference between the postoperative complete heart block patients and congenital heart block patients in terms of short and long term complications of epicardial pacing. Due to somatic growth in children conversion to endocardial leads becomes a necessity. Ventricular dysfunction due to pacing is a worrisome complication in children but CRT has shown promising results.

Keywords : Pacemaker • Children • Atrioventricular block • Epicardial pacing •

INTRODUCTION

Permanent epicardial pacemaker have been utilized in clinical practice for several decades and the numbers of patients who require them are increasing. Pediatric pacemaker implants comprise < 1 % of all pacemaker implantations[1]. The main indication for permanent pacemaker implantation in children is high-degree congenital atrioventricular block (AVB) with a frequency of about 1/ 2000.

Another important indication is high-degree AVB following open-heart surgery, occurring with an incidence of 1 %. It is the main reason for placement of permanent epicardial pacemaker after congenital heart surgery. Although endocardial pacemaker have several advantages, such as longer battery life, better sensing and pacing thresholds, epicardial pacemakers are more suitable for infants and younger children who are still under somatic growth, especially for patients with complicated cardiac deformities.

However, epicardial pacemakers are less durable and have a higher incidence of complications as compared to endocardial pacemakers. With the development of steroid-eluting leads appears to offer a better alternative to epicardial pacemaker. Its performance and longevity have been demonstrated to be comparable with the conventional endocardial leads.

Because of low economic statuses and undeveloped insurance systems, the single chamber pacemakers are utilized in many heart center for sick children in India. The current study aimed to review and analyze the experience in placement of permanent epicardial pacemaker and its outcomes.

REVIEW OF LITERATURE

Benrey et al , followed up 24 children in Texas, USA, with complete AV block, out of which 13 (54%) resulted from surgical complications, 9 had congenital AV block, and 4 had associated congenital heart disease. 20 children had syncope/convulsions while 4 had CHF, which led to pacemaker implantation in them. Mean age of the population at implantation was 9.7 years, and they were followed up for 1-12 years (average 5 years). Mortality rate was 25%, and seen in children with associated congenital heart defects, Pacemaker malfunction was seen 28 times in 12 patients, the leading cause being failure of PG, whereas wire fractures led to 12.5% of pacemaker failure.

Donahoo et al followed up 13 children in Baltimore, USA, with 27 pacemaker implantation, at a mean age of 6.8 years. Surgical induced CHB was seen in 11, while congenital CHB was seen in 2. Over an average period of 5 years (1-12 years), mortality rate 15%, and pacemaker was removed in 2 children, without any complication. Cohen et al [8], from Philadelphia, USA, evaluated 267 children with 385 pacemaker implantation (224 epicardial and 161 endocardial), implantation done at age of 8.4}6.2 years, following them up for a median of 29.4 months. Pacemaker infections were in seen in 30 patients (7.8%), majority being superficial infections, followed by pocket infections. Median time from implantation to infection was 16 days (range 2 days – 5 years). Multivariate analyses revealed trisomy 21 (RR – 3.9) and pacemaker revisions (RR – 2.5) as predictors of pacemaker infections.

Silvetti et al [9], from Rome Italy, reported 292 children, with mean age 8 years (range: 1 day – 18 years), who underwent pacemaker implantation. Endocardial leads were placed in 56.5%, and mean period of followup was 5 years. Pacing threshold was lower with endocardial leads as compared to epicardial leads (0.5}0.3V vs1.2}0.5V, $p<0.05$). 15 deaths were noted but none were related to pacing failure. Pacing upgradation was done to DDD in 6.5% patients, commonest indication being LV dysfunction (EF<40%) in VVI(n=10), followed by symptomatic AV block in AAI (n=4). Early complications (<3 months) included hemothorax (3.5%), infection (1-2%), lead dislodgments (5%), while late complications (>3 months) included infection (2%), lead failure (21.5%). There was no difference between lead type, except for lead failure which was higher in epicardial leads.

Paediatric pacemaker implants comprise < 1 % % of all pacemaker implants. When it is considered that the mean age of pacemaker implantation in the adult population is 75.5 years, compared with < 10% in the paediatric population, the problems of small size, growth and truly chronic pacing faced by the paediatric implanter are fully appreciated.

WHO NEEDS A PACEMAKER IN CHILDHOOD?

The American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/ AHA/HRS) 2008 guidelines for device-based therapy of cardiac rhythm abnormalities include up to date guidelines for implantation of pacemakers in children, adolescents and patients with congenital heart disease. The main indication for pacing in childhood is symptomatic or worrying bradycardia, the most common being complete heart block . Heart block may occur in children with structurally normal hearts (isolated heart block) or those with congenital heart disease.

Indication:

The most common indications for permanent pacemaker implantation in children with or without congenital heart disease are

1. Symptomatic sinus bradycardia
2. Bradycardia-tachycardia syndromes
3. Advanced second- or third-degree AV block, either congenital or after corrective surgery of congenital heart defects.

Acquired Heart Block:

An increasing number of young patients are long-term survivors of complex surgical procedures for congenital heart defects that result in palliation rather than correction of circulatory physiology. The residua of impaired ventricular function and abnormal physiology may result in symptoms due to sinus bradycardia or loss of AV synchrony at heart rates that do not produce symptoms in individuals with normal cardiovascular physiology. Surgical repairs involving the interventricular septum, namely ventricular septal defect and atrioventricular canal defects is the most common cause of acquired heart block in children with a rate of approximately 1-3% and a late mortality rate as high as

28 to 100%. With the advent of implantable pacemakers, the risk of late mortality appears diminished. Although with the advent of implantable pacemaker the risk is low still the presence of transient complete heart block following surgery is the strongest predictor for late sudden death after surgical repair of TOF. Percutaneous closure devices may obviate the need for cardiac surgery for patients with ventricular septal defects, but still carry a potential risk of injury to the conduction system with an incidence of permanent conduction changes in up to 10% of patients, with a need for permanent pacemaker implantation only in 3.8% of patients.

Congenital complete atrioventricular block (CHB):

Congenital complete heart block is usually associated with maternal lupus antibodies (anti-SSA/Ro and anti-SSB/La) and results in fetal and neonatal bradycardia. Although patient may be asymptomatic, the postnatal mortality rate is reported to be between 16 and 45%. A secondary dilated cardiomyopathy can develop in more severe forms, which appears to be related to fetal and neonatal heart rates; Progressive ventricular dysfunction despite ventricular pacing is uncommon. The actual incidence of ventricular dysfunction due to pacemaker-related chronic ventricular dyssynchrony remains undefined.

Sinoatrial Node Dysfunction (SND):

Isolated sinoatrial node dysfunction (SND) is not often seen in children with structurally normal hearts. However, this is a common sequel following certain types of palliation and completes repairs for congenital heart lesions. This is seen as a late complication after repair for tetralogy of Fallot, after Mustard or Senning repairs for transposition of the great arteries, or after a total cavopulmonary connection operation (Fontan) for single ventricle physiology. Current recommendations favor pacemaker implantation in children with

symptomatic bradycardia, relative to age. The evidence is conflicting, but implantation is considered reasonable in CHD patients with sinus bradycardia and recurrent atrial arrhythmias, and in patients with complex CHD who have resting sinus rates less than 40 s or prolonged pauses greater than 3 s, or those who have evidence of hemodynamic compromise that can be attributed to bradycardia or loss of atrioventricular synchrony.

Chronotropic Incompetence:

Another indication for pacing in children is chronotropic incompetence, as mentioned above; children with this problem receive rate-modulated (physiologic) pacing. Clinically, chronotropic incompetence refers to an inappropriately slow cardiac rate response to the body's physiologic demand (generally the stress caused by exercise). This terminology has gained added significance since "physiologic sensors" have been added to pacemakers. The best physiologic sensor is the sinus node, which responds to sensory and endocrine signals and determines the heart rate appropriate to a particular situation. Newly developed pacemaker performs similar function derived from algorithms programmed in its circuitry for the patients lacking in normal rate responsiveness of SA node.

Formula (Predicting Heart Rate): **IHRp = 139.5-(2.14 X age in years)**

Table 1 : Guidelines for Lower Limit of normal sinus heart rate children

By 24 Hours Ambulatory (Holter ECG) beats/min		**By standard ECG Beats/minute**	
Neonate And Infant	60 sleeping 80 awake	<3years	100
2-6 years	60	3-9 years	60
7-11 years	45	>9 years	50
>11 years	40		
Athelets	30		

ACC/ AHA Recommendations for Permanent Pacing in Children, Adolescents, and Patients with Congenital Heart Disease
1. PPI for advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output. (Level of Evidence: C)
2. PPI for symptomatic patients with age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate. (Level of Evidence: B)
3. PPI for postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery. (Level of Evidence: B)
4. PPI for congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction. (Level of Evidence: B)
5 PPI for congenital third-degree AV block in the infant with a ventricular rate less than 55 bpm or with congenital heart disease and a ventricular rate less than 70 bpm. (Level of Evidence: C)
Class IIa (PPI is reasonable)
1. PPI for patients with congenital heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial reentrant tachycardia; SND may be intrinsic or secondary to antiarrhythmic treatment. (Level of Evidence: C)
2. PPI for congenital third-degree AV block beyond the first year of life with an average heart rate less than 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence. (Level of Evidence: B)
3. PPI for sinus bradycardia with complex congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds. (Level of Evidence: C)
4. PPI for patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony. (Level of Evidence: C)
5. PPI for unexplained syncope in the patient with prior congenital heart surgery complicated by transient complete heart block with residual fascicular block after a careful evaluation to exclude other causes of syncope. (Level of Evidence: B)
Class IIb (PPI can be cosidered)
1. PPI for transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block. (Level of Evidence: C)
2 PPI for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex, and normal ventricular function. (Level of Evidence: B)
3 PPI for asymptomatic sinus bradycardia after biventricular repair of congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds. (Level of Evidence: C)
Class III (mostly not indicated)
1 PPI for transient postoperative AV block with return of normal AV conduction in the otherwise asymptomatic patient. (Level of Evidence: B)
2 PPI for asymptomatic bifascicular block with or without first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block. (Level of Evidence: C)
3 PPI is not indicated for asymptomatic type I second-degree AV block. (Level of Evidence: C)
4 PPI for asymptomatic sinus bradycardia with the longest relative risk interval less than 3 seconds and a minimum heart rate more than 40 bpm. (Level of Evidence: C)

Fig 1 : Guideliness for PPI

EPICARDIAL OR ENDOCARDIAL?

Epicardial

Epicardial leads are favoured by many for pacing in children weighing < 10 – 15 kg They have the advantage of being extravascular and are useful for patients where vascular access to the heart is compromised or for patients with a single ventricle where pacing the heart endocardially would mean pacing a systemic ventricle. Originally, epicardial leads used a hook or screw to attach onto the epicardium. Despite low pacing thresholds at implant, frequently there was a steep rise over time with a high incidence of exit block. This improved with the addition of steroid elution at the lead tip, but can still be a problem.

The Medtronic (Minneapolis, Minnesota, USA) CapSure Epi leads use steroid eluting 'button' electrodes that are sewn onto the surface of the epicardium. The bipolar version is in the shape of a Y, with each electrode at the tip of the arms of the Y. These leads tend to have lower, more stable chronic thresholds that compete well with endocardial leads. Overall, however, epicardial leads tend to have a higher fracture rate and earlier failure rate than endocardial leads. It has been our experience that the CapSure Epi bipolar lead can be prone to fracture in the Y arm of the indifferent electrode. When this occurs the lead may still function well if the pacemaker is programmed to unipolar sense/ pacing.

Endocardial

The overall poorer performance of epicardial leads has led, in some units, to the implantation of endocardial systems even in very small infants or patients with challenging venous and cardiac anatomy . In the very small child, even a redundant loop of ventricular lead made within the right atrium may not be enough to overcome lead stretch from many years of growth .

Some operators try to overcome this by opening up the site of lead implantation every 2-3 years and pushing forward the redundant extravascular lead into the vein and heart. This is not always successful as leads can become very adherent to the wall of the vein and heart, making it impossible to push them forward. Another important problem with endocardial leads is venous stenosis or occlusion. An incidence of 13% partial venous occlusion and 12% complete venous occlusion has been reported in children after a median of 6.5 years of pacing.

Usually venous stenosis is asymptomatic but can present with venous congestion and swelling of the ipsilateral arm. Importantly, it can make future endocardial implants more difficult, a serious consideration for a child facing 60-80 years of pacing. Complications related to implantation of endocardial systems are similar to those of adults but the incidence is higher in children. This probably reflects smaller patient size, more complex anatomy, fewer numbers and less experience of the paediatric compared with the adult operator.

Box 2 Epicardial versus endocardial pacing

Epicardial

Pros

Venous access not required, useful for:

- Patients weighing <10–15 kg
- Patients with compromised venous access
- Left ventricular pacing, even in small patients
- Dual chamber pacing in small patients

Steroid Eluting CapSure Epi leads (Medtronic) can give thresholds comparable to endocardial leads

Cons

Implantation procedure more invasive than endocardial

Cardiac surgeon required

Leads are more prone to failure than endocardial

Endocardial

Pros

Leads generally more reliable than epicardial

Implantation procedure less invasive than epicardial

Cardiologist can do implantation

Cons

Risk of:

- Venous stenosis/occlusion
- Perforation
- Endocarditis
- Risks associated with future lead removal

Fig2 : Pros and Cons – Epicardial and Endocardial pacing

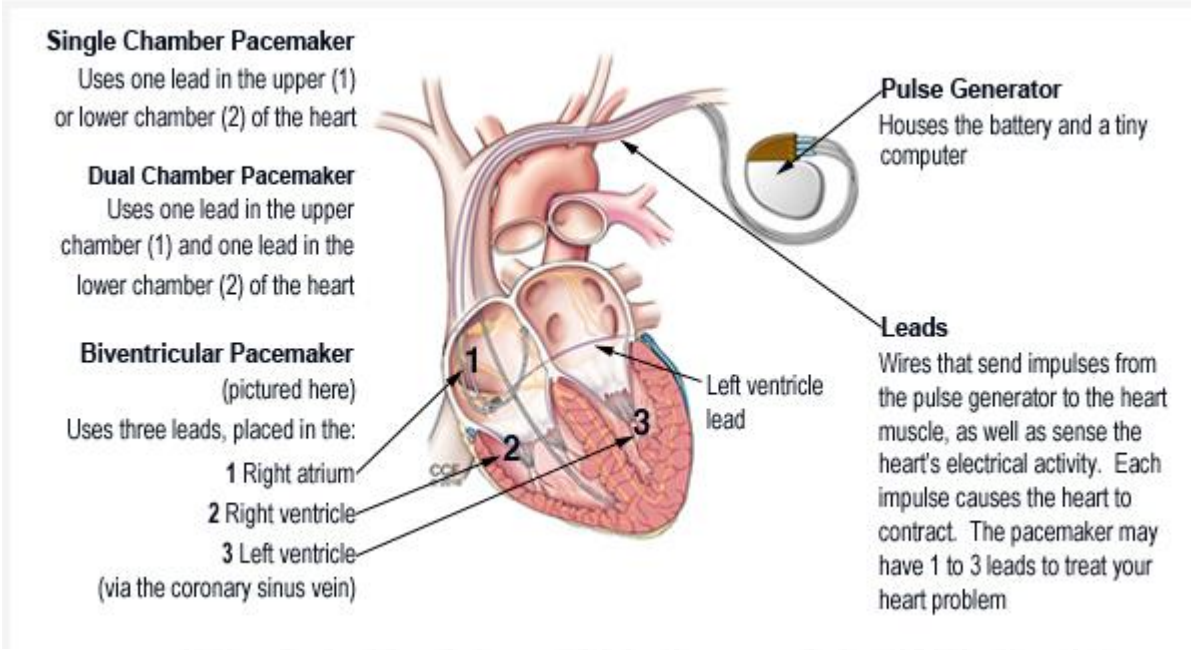


Fig 3: Description of Leads and PG and chambers

Modes and Codes:

In order to standardize and facilitate the use and understanding of pacemakers, the North American Society for Pacing and Electrophysiology (NASPE) and British Pacing and Electrophysiology Group (NASPE/BPEG) groups devised the standard pacemaker codes, the NBG coding system. The most recent iteration of the NBG code was revised in 2002. The NBG code has five positions that denote pacemaker function; however, the last position is rarely used and will not be included in this discussion.

In the context of the NBG code, “sensing” refers to the detection, by the pulse generator, of spontaneous cardiac depolarizations. The effect of a “sensed” event is either a “triggered” pacing stimulus or an “inhibited” pacing stimulus.

Table 2: Modes and Codes

I	II	III	IV
Chamber(s) **paced**	Chamber(s) **sensed**	**Response** to sensing	**Rate adaptive**
O = none	O = none	O = none	O = none
A = atrium	A = atrium	I = Inhibited	R = rate adaptive
V = ventricle	V = ventricle	T = Triggered	
D = dual	D = dual	D = dual	

Position I refers to the chambers that are paced. “A” refers to atrium, “V” to ventricle, and “D” or “dual” to both the atrium and the ventricle.

Position II refers to the chambers that are sensed. The letter codes are the same as above. In addition, the letter “O” refers to a mode in which there is no sensing, in other words, asynchronous pacing.

Position III refers to the pulse generator’s response to a sensed event. The letter “I” indicates that the pulse generator will inhibit a pacing stimulus in response to a sensed event. The letter “T” indicates that the pulse generator will trigger a pacing stimulus in response to a sensed event. The letter “D” is restricted to dual chamber systems and will both inhibit and trigger in response to sensed events. For example, a sensed event in the atrium will inhibit a pacing stimulus in the atrial channel, but triggers ventricular output. After the programmed AV delay, if the pulse generator senses a ventricular event, output will be inhibited in the ventricular channel. If the pulse generator does not sense a ventricular event, then a pacing stimulus will be triggered. The letter “O” indicates that there is no response to a sensed event and is most commonly used in the asynchronous pacing mode.

Position IV is unique in that it refers to the presence or absence of rate modulation or rate-adaptive pacing. If present, the letter “R” indicates that that the pulse generator incorporates a sensor, which uses a variable—such as mechanical vibration, minute ventilation, or acceleration—to adjust the programmed paced heart rate in response to a patient’s activity. If rate adaptive pacing is not used or is not available, rather than using the letter “O”, “R” is simply omitted. Numerous factors must be considered when programming the pacing mode, such as the patient’s age, exercise capacity, chronotropic response, medical comorbidities, and the intrinsic cardiac rhythm.

VVI or VVIR: VVI(R) is one of the more commonly used pacing modes. VVI(R) is ventricular demand pacing. The ventricle is paced, sensed, and the pulse generator inhibits pacing output in response to a sensed ventricular event. This mode of pacing prevents ventricular bradycardia and is primarily indicated in patients with atrial fibrillation with a slow ventricular response. However, since the pulse generator only paces and senses in the ventricle, there is loss of AV synchrony, which can potentially lead to pacemaker syndrome. This mode of pacing is available in every pacemaker system that has a ventricular lead.

AAI or AAI(R): AAI(R) is atrial demand pacing. The atrium is paced, sensed, and the pulse generator inhibits pacing output in response to a sensed atrial event. This mode is used for patients purely with sinus node dysfunction, yet maintain AV nodal function. This mode is being used in isolation uncommonly as the subsequent development of AV nodal conduction disease would render the patient vulnerable to bradycardia. This mode of pacing can be used in patients with dual chamber systems to minimize ventricular pacing along with an algorithm that can switch between AAI and DDD mode depending on sensed AV nodal conduction.

DDD or DDD(R): DDD or DDD(R) is a dual chamber system. It possesses pacing and sensing capabilities in both the atrium and the ventricle, and it is the most commonly used pacing mode. This mode is most appropriate for patients with combined sinus node dysfunction and AV nodal dysfunction. It is also appropriate for patients with sinus node dysfunction and normal AV node conduction, normal sinus node function with AV nodal conduction abnormalities, and carotid hypersensitivity with symptomatic cardio-inhibitory response.

There are four different rhythms that can be observed in DDD(R) pacing mode:

- Normal sinus rhythm (NSR) with no pacing (A sense, V sense).
- Atrial pacing with ventricular sensing and a native QRS (A pace, V sense).
- Atrial sensing with a native P wave and ventricular pacing (A sense, V pace).
- Atrial pacing and ventricular pacing (A pace, V pace).

The use of DDD(R) pacing mode in conjunction with an algorithm that minimizes ventricular pacing is preferred.

Asynchronous modes, VOO or DOO: These are asynchronous pacing modes in which the pulse generator delivers a pacing stimulus at a fixed rate, without any sensing capabilities. Therefore, the pacemaker is not “in sync” with the patient’s native rhythm and continues to deliver a pacing stimulus regardless of what the native conduction is doing.

These modes are rarely used for extended periods of time. They are typically used when a pacemaker dependent patient is undergoing a surgical procedure

that uses electrocautery that could be sensed by the pacemaker as native electrical conduction, which would inhibit pacemaker output and subsequently the patient could have profound bradycardia or even asystole. There is a small possibility that pacing in an asynchronous mode could induce a pacing stimulus in the vulnerable period (on the T wave), which could potentially induce a lethal ventricular tachyarrhythmia.

WHO SHOULD IMPLANT PACEMAKERS IN CHILDREN?

Epicardial pacing systems are implanted by cardiac surgeons, but there is variation when it comes to endocardial systems in children. In the USA and Australasia, endocardial systems usually are implanted by cardiac surgeons, but in the UK and Europe and Asia , the procedures are usually done by cardiologists. In most paediatric cardiology centres, the annual number of paediatric endocardial implants is often < 10 and unlikely to exceed 20 unless adult congenital patients are included. As a result, in some units, paediatric implants are done by adult cardiologists experienced in pacing.

IMPLANTATION TECHNIQUES

The basic principles of implantation are the same as for adults. For endocardial systems the subclavian vein is often favoured as the cephalic vein may be too small. In growing children, a loop of ventricular lead is usually made within the atrium to allow for growth . Sometimes the loop migrates across the tricuspid valve into the ventricle. Usually it does not cause problems, but occasionally it may interfere with tricuspid or even pulmonary valve function.

For endocardial systems most operators choose to place the generator in the pectoral region, either subcutaneously or subpectorally. A subpectoral pocket gives a less obvious bulge and better cosmetic result. In smaller children, sometimes the mass of the redundant extravascular lead is bigger than the

generator. Some operators 'use up' part of the redundant lead by making the generator pocket below the axilla and tunnelling the lead from the infraclavicular region to the subaxillary pocket, which is better cosmetically.

An alternative approach is to make a subaxillary pocket and implant the lead via the axillary vein. This approach is likely to be preferred by image conscious children and teenagers as there are no scars over the anterior chest wall. In addition, a cephalic or axillary vein approach reduces the risk of crush fracture associated with implantation via the subclavian vein.

Technical Challenges (Trans venous Vs Epicardial lead placement):

Trans venous lead implantation:

Significant technical challenges may complicate device and transvenous lead implantation in very small patients or those with abnormalities of venous or intracardiac anatomy. The patients with transvenous pacemakers implanted at an early age had few complications and no venous occlusion noted on follow-up. Asymptomatic subclavian vein occlusion can occur in up to 10%- 13% of patients and wound related complications in 5-8%. Blood loss requiring blood transfusion is a rare but possible complication of trans venous PPI. For children undergoing trans venous lead implantation, future growth of the patient must be taken into account. A variety of techniques have been described to accommodate this important issue, with the most common method being to leave the redundant lead looped within the right atrium, with the expectation that the additional lead slack will avert tension as the child grows.

Epicardial pacemaker lead implantation:

It represents an alternative technique for the small kids or patient with CHD where trans venous lead placement is not possible. However, the risks associated with sternotomy or thoracotomy and the somewhat higher incidence of lead failure must be considered. This can often be performed without full sternotomy by using minimally invasive techniques, such as a subxiphoid approach or using thoracoscopic or robotic approaches.

Complications such as ventricular strangulation, coronary compression or post-pericardiotomy syndrome have been described, although these are quite rare findings. Generally blood loss during pacemaker insertion is small and does not necessitate blood transfusion. In general, the overall morbidity associated with epicardial lead implantation is low. In patients with complex CHD in who repeated sternotomy or thoracotomy carries excessive risk, prophylactic implantation of epicardial pacing leads appears to have a good rate of retrieval and successful pacing thresholds, reducing their surgical risk during subsequent procedures.

A major limitation is that these leads remain vulnerable to fracture and dislodgement. Complete lead failure was seen in up to 34% of epicardial leads in long-term follow-up, but increasing pacing thresholds were more commonly reported, often necessitating reintervention. The advent of steroid-eluting epicardial leads has certainly improved the long-term usability of these leads. Additional details that need to be considered in pacemaker implantation in young patients include risk of paradoxical embolism due to thrombus formation on an endocardial lead system in the presence of residual intracardiac defects and the lifelong need for permanent cardiac pacing

Precaution after pacemaker implantation:

After receiving a pacemaker an identification card is issued from the manufacturer that includes information about patient, specific model of pacemaker and the serial number. A medical identification bracelet or necklace can also be along with carrying the card by your child to alert others about the pacemaker in case of emergency.

Complications:

The risks associated with a pacemaker insertion are very low, but may be increased if the condition of child's heart or general health is poor. There is an overall risk of 1% to 2% for complications, which include

1.Pneumothorax (air leak around the lungs) Pneumothorax can heal by itself, or a chest drain may need to be inserted, to remove the air and allow the lung to fully inflate again.

2. Lead displacement. In the first few weeks after the procedure, there is a risk that the leads will move. In small children, an extra loop of lead is left in the heart so that the lead stays in place as they grow.

3. Hematoma (severe bruising).

4. Infection.

5. Vein thrombosis (clotting).

6. Pericardial effusion (blood leak around the heart).

7. Death. As with any procedure, there is also a risk of death. This is extremely rare, but it is important for you to be aware of this. X-ray scanning is used to guide placement of the lead. Although all x-rays are potentially harmful, only a very low dose is used.

SIZE MATTERS

The smallest pacemaker generator available is the Microny (St Jude Medical, California, USA), a single chamber device of 5.9 ml, weighing a mere 12.8 g, compared with 8-11 ml and 17-23 g for a standard single chamber generator. The small size of the Microny makes it an ideal choice for the tiniest of patients. The potential disadvantage is a smaller battery with reduced lifespan and a need for earlier replacement. However, the Microny has Autocapture, a programmable function that enables the pacemaker to measure ventricular capture threshold automatically and adjust the pacemaker output to run just above the threshold, thus preserving battery life.

Autocapture may be used successfully and safely in children, even with epicardial leads, although the leads must be bipolar. Our own experience has been a battery lifespan of up to 9 years in children requiring 100% pacing with the Microny programmed to VVIR using autocapture. With respect to endocardial leads, unipolar leads tend to be thinner than bipolar and, as such, have a theoretical advantage for small patients. However, they can be more difficult to remove and many operators choose to implant slightly bulkier bipolar leads. The Medtronic Select Secure leads are bipolar but only 4.1 F in diameter and are the lead of choice for some paediatric operators.

PACING TINY PATIENTS < 3kg

Pacing the tiniest patients presents real problems as pacemakers and leads are primarily designed for adults. Our own approach for those between 1.5-3 kg is to implant an epicardial unipolar CapSure 4965 Epi lead (Medtronic) with a unipolar Microny K SR (St Jude Medical). If the baby has abdominal problems such as necrotising enterocolitis, the generator may be implanted within the chest .

For even smaller patients, there simply may be no room for a permanent device until the baby grow. If the baby has a structurally normal heart and function with no major complications of prematurity, no immediate treatment for the heart block may be necessary. If the baby has a congenital heart condition or symptoms related to heart failure or low cardiac output, the prognosis usually is grim even if the heart rate is increased. Options for increasing the heart rate may include:

1. An infusion of isoprenaline (usually disappointing outcome with medical treatment alone)
2. Temporary epicardial ventricular leads, pacing with a temporary pacing box (probably the best option)
3. A temporary or permanent right ventricular endocardial lead, with a temporary pacing box or permanent generator placed externally (finding adequate venous access is a problem; risks include cardiac perforation, lead displacement, venous thrombosis and infection).

LEAD EXTRACTION IN CHILDREN

Most surgeons will simply cap off redundant epicardial leads and only attempt removal if they are infected. The indications for endocardial lead removal in children are as for adults and the techniques similar. An additional indication might be a lead that has become stretched with growth and is affecting tricuspid valve function. The risks of lead extraction are similar to those in adults, with the added risk of smaller patient size and relatively bulky equipment for lead removal.

Every attempt must be made to preserve venous access by using the same vein for the new device if at all possible. Lead extraction in children should only be undertaken by an experienced operator with surgical back-up immediately available. Some paediatric operators, unwilling to take the risks of lead explantation, cap off the proximal end of the lead and implant a new lead in the same or contralateral vein. This can result in a lot of leads in the cardiovascular system and increase the risk of infection and venous obstruction.

MORE PACING OR LESS PACING IN CHILDHOOD?

More pacing Overall, children's resting heart rates are faster than the rates in adults. The average heart rate of a baby is around 120-150 beats/min (bpm), compared with 70 bpm in an adult. Children tend to be more active, with higher mean daytime heart rates, than adults. It seems intuitive therefore that pacemakers in children should be programmed to reflect the normal higher heart rates of childhood.

Dual chamber pacemakers enable tracking of the sinus node rate and the normal variations of heart rate in childhood . However, most children on exercise achieve heart rates that are above the maximum programmable upper track rate on dual chamber pacemakers. The post-ventricular atrial refractory period (PVARP) and atrioventricular (AV) delay must be programmed to take this into account, otherwise symptomatic 2:1 block can occur at faster rates. An important problem with dual chamber pacing is that it requires a means of at least sensing the atrium as well as pacing the ventricle.

For epicardial implants this may mean a full sternotomy, rather than a simple limited lower sternotomy, to allow satisfactory positioning of an atrial lead. However, satisfactory positioning of both leads may also be achieved through a left thoracotomy. For endocardial systems, the veins may be too small to accommodate two leads easily. Some advocate using a single pass VDD lead to sense the atrium and pace the ventricle. However, most prefer to implant only a ventricular lead and pace the ventricle with rate response (VVIR). VVIR is the most common pacing mode in small children.

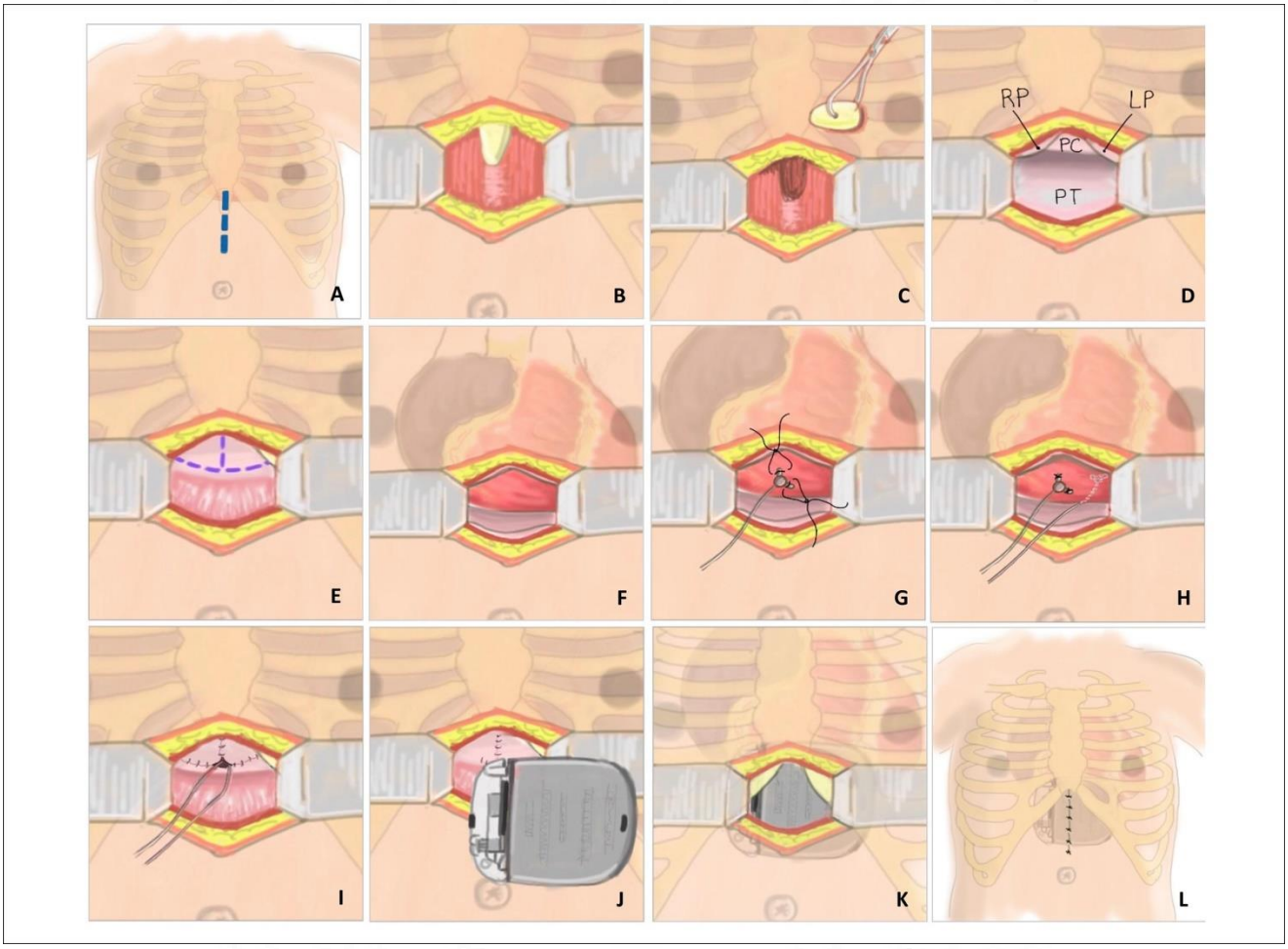


Fig4 : Placing of pulse generator in rectus sheath Pocket

The resting and upper heart rates are programmed and altered according to the child's age. A study comparing echocardiographic parameters in dual chamber versus ventricular pacing in children found no significant difference between the two pacing modes. There has been no study in children directly comparing exercise ability between the two pacing modes. Our own experience is that children with VVIR pacing for isolated complete heart block are able to compete well with their peers and even win at school sports day or in sporting competitions.

The technology used for detecting exercise and initiating rate response differs between different pacemaker brands, with claims of superiority of one technology over another by the pacing companies. In practice, the different technologies probably make little noticeable difference to exercise tolerance in children.

LESS PACING

The belief that dual chamber pacing is more 'physiological' has led to the practice by many of upgrading from VVIR to dual chamber pacing when the child is bigger and requiring pacemaker replacement for battery end of life or lead problems. However, because dual chamber pacing tracks the sinus rate, it will almost inevitably result in a higher mean 24 h heart rate than VVIR pacing. This will mean more ventricular pacing.

It is now recognised that in some individuals chronic right ventricular pacing can result in cardiomyopathy and heart failure. It is not clear whether this is a potential risk for anyone undergoing right ventricular pacing or whether there needs to be some sort of predisposition, such as an underlying problem within the myocardium. Some children with antibody positive isolated complete heart block are born with impaired ventricular function, believed to be secondary to

myocardial damage from maternal antibodies crossing the placenta. Pacing the right ventricle can be associated with worsening of ventricular function. It is observed improvement in cardiac function in some children paced for isolated complete heart block when the pacing rate has been reduced.

The DAVID (Dual Chamber and VVI Implantable Defibrillator) study in adults found a worse outcome for patients with dual chamber than ventricular pacing.w38 So, we need to think carefully about how we programme lower and upper pacing rates in children who truly do have a lifetime of chronic pacing.

For children with heart block where the concern is about pause related symptoms, consideration should be given to programming the pacemaker simply to an acceptable relatively slow back-up rate with rate response switched off. For VVIR systems, lower resting pacing rates and reduced upper rate responses than would be expected for a child's natural heart rate should be considered, provided that the child's exercise ability is not compromised. An example in a child >5 years 5 years might be a basic pacing rate of 60 bpm with an upper rate response 120-130 bpm.

Before an upgrade from ventricular to dual chamber pacing, consideration should be given to whether it is truly going to be beneficial for the child and worth the additional problems of a new lead and the potential deleterious effects of more chronic right ventricular pacing. In adults who require pacing for heart block, VVI pacing is associated with a higher risk of developing atrial fibrillation than dual chamber pacing. However, the risk is small and it is unknown whether it will be a late problem for children with VVIR pacing.

PACING AND VENTRICULAR SYNCHRONY IN CHILDHOOD

Select site pacing Pacing the right ventricle results in a wide QRS of left bundle branch morphology (LBBB) and associated dyssynchronous ventricular activation, which can lead to or exacerbate dilated cardiomyopathy. When pacing epicardially, the right ventricle tends to be the favoured site as it is immediately accessible from a lower sternotomy.

For endocardial systems, traditionally, the right ventricular apex has been the preferred position for the ventricular lead, because of its electrical stability. However, pacing from the right ventricular apical region is believed to be worst with respect to dysynchrony and development of ventricular dysfunction. Active fixation leads, which have a screw mechanism for attaching to the endocardium, allow stable positioning of leads in sites other than the right ventricular apex, but are associated with a higher incidence of cardiac perforation than passive fixation leads. There has been a move towards pacing sites other than the right ventricular apex in children in the hope that this will reduce dysynchrony and the risk of ventricular dysfunction from chronic pacing.

The Select Secure lead (Medtronic) uses a steerable delivery sheath to enable more accurate positioning of the lead on the septum. There is, however, no strong evidence that select site pacing of the right ventricle will reduce the risk of future cardiomyopathy.

CARDIAC RESYNCHRONISATION IN CHILDREN

In adults, cardiac resynchronisation therapy (CRT) has become an established treatment for selected patients with heart failure. The main criteria for selection are a wide QRS of left bundle morphology and left ventricular ejection fraction < 35. Whereas in adults the most common cause of heart failure is ischaemic heart

disease, in children the main causes are congenital heart disease and cardiomyopathies.

Very few of these children will have a wide QRS of left bundle morphology unless they have a pacemaker and are being paced from the right ventricle. Unlike the adult studies there are no randomised double blind controlled trials of CRT in children. The two largest published series of CRT in children are effectively multicentre multianecdotal studies where the indications for CRT and assessments of outcomes are not uniform.21 w41 Children with primary cardiomyopathy appear unlikely to benefit from CRT perhaps partly because of the underlying, often progressive, pathologies and partly because few will have a wide QRS of left bundle morphology.

CRT has not been clearly shown to benefit the failing right ventricle, which is often the failing ventricle in congenital heart conditions. It seems that the children most likely to benefit from CRT are those with impaired left ventricular function who are being paced from the right ventricle that is, those who have left bundle branch morphology on ECG. The improvement in ventricular function can be dramatic following an upgrade of right ventricular pacing to CRT, and every paediatric cardiac unit has its miracle story.

Pacing the left ventricle endocardially can be achieved either via the coronary sinus or by transeptal puncture, placing the lead directly into the left ventricle. However, the truly long term effects of a lead in the coronary sinus are unknown and anticoagulation with its attendant risks is required when a lead is positioned directly in the left ventricle. An alternative is to place the lead epicardially on the left ventricle through a left thoracotomy. Pacing the left ventricle alone might be beneficial for cardiac function, and some operators, when undertaking epicardial implants, are now choosing to site the lead on the left ventricle rather than the right.

LONG TERM OUTCOMES

Despite promising titles, the maximum mean or median follow-up of any of the studies of long term pacing in children is <10 years, a mere fraction of the life expectancy of a child. As yet, we do not know what will be the true long term outcome of decades of pacing beginning in childhood. We know that with current pacemaker technology, multiple implants will be required throughout life with the attendant risks of each procedure and eventual loss of vascular access for some.

We know that with current lead technology some children will experience unanticipated lead failure with risk of syncope, heart failure or even sudden death. We know that chronic pacing of the right ventricle will result in ventricular dysfunction for some. However, we also know that children with pacemakers are able to enjoy the activities of childhood with very few restrictions related to the pacemaker. The only activities that we advise against are rugby and martial arts. And our patients are always relieved to hear that digital music systems do not appear to interfere with pacemaker function.

THE FUTURE

Unfortunately the development of pacing systems specifically designed for children is not financially viable for the pacing companies. Paediatric operators have to keep looking over the shoulder of their adult counterparts to see what technology might be suitable or can be adapted for the small growing patient or the one with complex cardiac anatomy. The development of remote home monitoring systems allow pacemaker interrogation and early identification of problems to be done from home without the child having to miss school to attend a clinic.

The ‘Holy Grail’ for paediatric implanters, however, is a reliable leadless device. This has been achieved for implantable cardioverter defibrillators (ICD) in the form of the fully subcutaneous ICD, but the device is only suitable for those who do not require chronic pacing. The development of biological pacemakers is still in its early stages. The hope is that ongoing developments in wireless communications may make the leadless pacemaker a reality in the not too distant future.

STUDY DESIGN & PATIENTS

Study type – Retrospective Observational study with Prospective follow up of patients

Study design – Observational model

Patient data from medical records was collected, which includes pre-operative, Intra operative and post-operative follow up records of patient from OPD. Patients were followed up in OPD during their regularly yearly follow up and data was collected from OPD records.

Aim of study

To assess the long term outcome of epicardial pacemaker implantation in children less than 18 years of age.

Objectives of study

1. To study the indication of Epicardial Pacemaker Implantation in children less than 18 years of age, along with types of leads and pacing mode used.
2.To study various pacemaker parameters (impedance, amplitude, lead thresholds) and their trends during followup.
3.To study the type of complications in both early (<3 months after implantation) and late (>3 months after implantation) follow-up period
4. To study about any re-interventions or upgradation required in pacing mode in followup

Sampling method – Non Random

Study population – All pediatric cardiac surgery patients who had underwent epicardial pacemakerinsertion.

Eligibility Criteria

Inclusion Criteria –

1. Children who underwent epicardial permanent pacemaker implantation at SCTIMST
2. Patients who were less than 18 years of age at the time of pacemaker implantation
3. Patients being followed up in Cardiology/CVTS OPD since implantation

Exclusion Criteria –

1. Refusal of consent
2. Patients who were lost to followup after Pacemaker implantation.

Data collection procedure – All patients, who underwent pacemaker implantation in SCTIMST, the age of implantation being less than 18 years of age, will be included in the study. The patients will be recruited by the investigators considering the inclusion and exclusion criteria. The investigator will educate the patient regarding the proposed study. A consent form, written either in English or in Malayalam language, will be signed by the patient and witness of the patient (as per the SCTIMST norms). All patients will undergo a 12-lead electrocardiogram test and device interrogation as per standard protocol. An attempt will be made through the local governing bodies to contact the patient's/ family members who do not respond to the calls or to the letters sent to the address mentioned. Patients who have died subsequently would be identified by records maintained in the Medical Records Department with the help of the Medical social worker in the department. Details regarding indication of pacemaker implantation, technique involved, hardware used, initial mode of pacing and immediate post-procedural complications will be collected from Electronic Medical Records (EMR). Consent will be taken from the legal guardians prior to enrolment. During followup, details regarding NYHA functional class, pacemaker programming parameters and complications (if any) would be

recorded in a pre-designed proforma. Pacemaker interrogation would be performed using manufacturer provided Device Interrogator, and the following parameters would be noted:

- Pacing Mode
- Impedance of leads, including trend (in ohms)
- Pacing threshold (in volts)
- Pulse amplitude (in volts)
- Sensitivity of leads (in mV)
- Paced AV interval (in msec)
- Sensed AV delay (in msec)
- Post ventricular atrial refractory period (PVARP) (in msec)
- Post ventricular atrial blanking period (PVAB) (in msec)
- Upper tracking rate
- Upper sensing rate

Statistical Methods:

Descriptive analysis was carried out by frequency and proportion for categorical variables.

For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups) and Mann Whitney test was used in case of non-normally distributed parameters. Wilcoxon signed rank test was used to compare non-parametric parameters between the two pairs of observations.

Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.

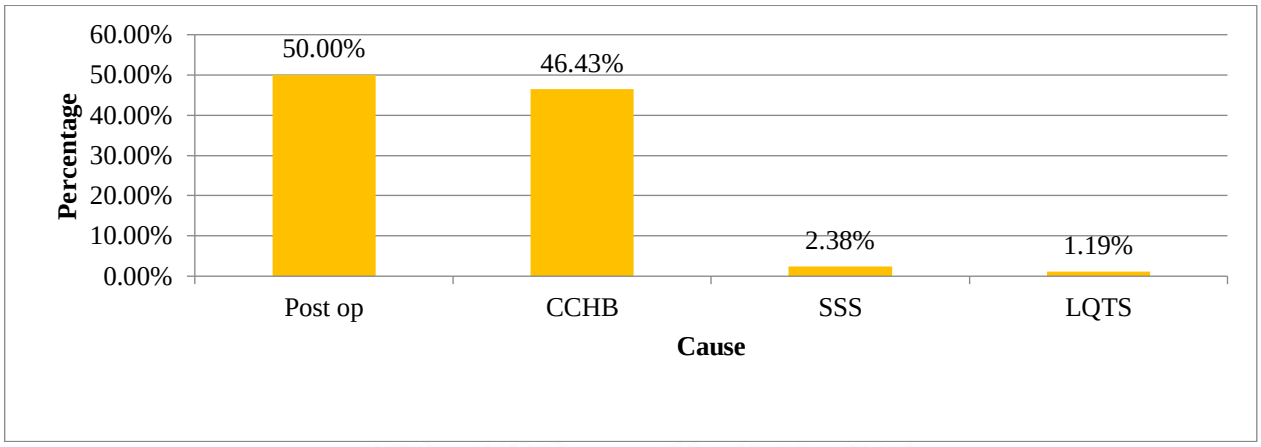
Data was also represented using pie chart and clustered bar chart and bar chart.

RESULTS

Patient Data:

A total of 84 patients underwent epicardial lead placement over a period of 20 years (2001 to 2020) were included in the final analysis. The mean age of implantation in the study population was 2.27 ± 3.58 years,(27.21 ± 43.01 months) and age for the congenital CHB group was 10.01 ± 14.89 months,. There were 21 neonates in the study and mean age at implantation was 0.02 ± 0.03 years (0.24 ± 0.33 months), ranged 0.0 years to 0.1 years (1 month) and the mean birth weight for neonatal babies was 2.31 ± 0.45 kg, ranged from 1.2 kg to 3.2 kg. Among the study population, 42 (50%) children were male and 42 (50%) children were female. Five percent were pre term. Most common indication for epicardial PPI insertion was post operative complete heart block(n=42 (50.00%)). The second common indication was congenital complete heart block (CCHB) (n= 39 (46.43%)) followed by sick sinus syndrome (SSS) (n=2) and Long QT Syndrome (n=1). One patient developed sick sinus syndrome after ASD closure at 12 years of age and other patient with SSS and neonatal seizures had implantation at 3 months of age.

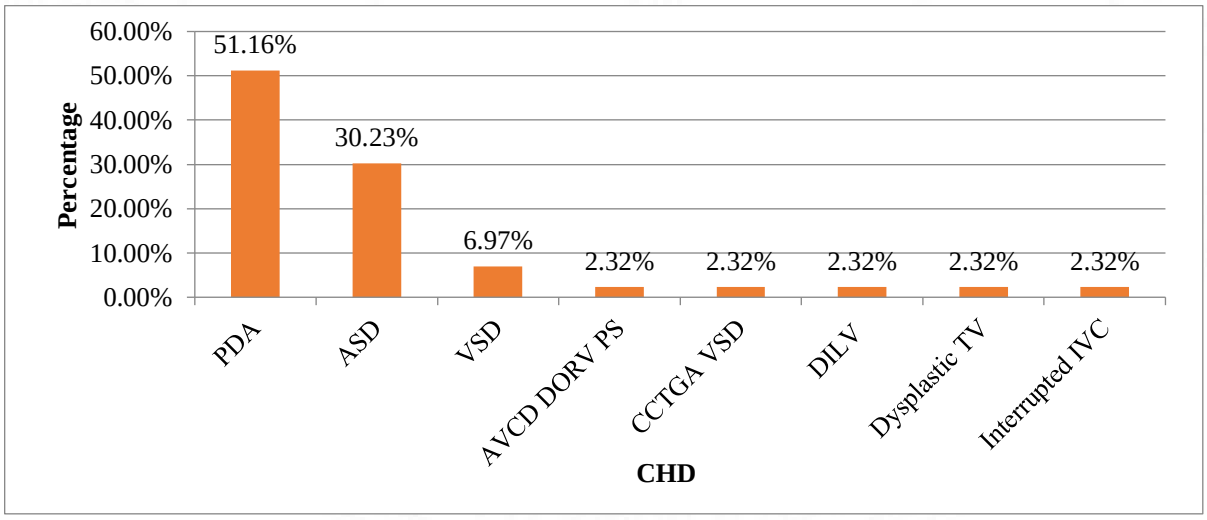
Figure 5: Bar Diagram for cause in study population



About 20 percent of congenital CHB children had maternal ANA positive. Other maternal risk factors were maternal diabetes (1) and hypothyroid (1).

Congenital heart disease was noted in 26 CCHB children (60%), out of which PDA (51.16%) was the commonest, followed by ASD (30.23%) and VSD (6.97%).

Figure 6 : Bar diagram of CHD in the study population

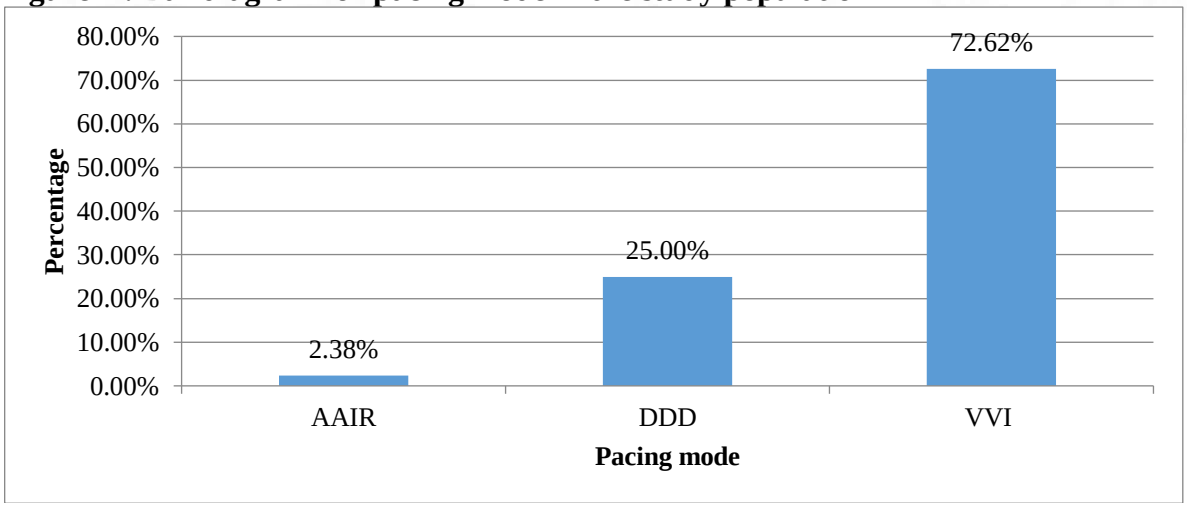


The most common surgery associated with post operative complete heart block was VSD| closure (73.8 %). Ten patients underwent isolated VSD closure, 8 Patients had VSD closure as part of intra cardiac repair , AVCD repair (4), ASO+VSD closure (3), Senning + VSD closure (2), SAM resection +VSD closure (1), Truncus arteriosus repair (1), Hemimustard + rastelli (1). Other surgeries not involving VSD closure were Bidirectional glenn shunt (3), Fontan completion (2), ASD clsoure + TV annuloplasty (1), PA banding (1), Kawashima procedure (1)

Pacing Characteristics:

VVI pacing mode was the most common mode of pacing, was seen in 61 patients followed by DDD mode in 21 and AAIR in 2 children. AAIR mode was used in 2 patients who had junctional rythm following fontan completion surgery and Kawashima operation.

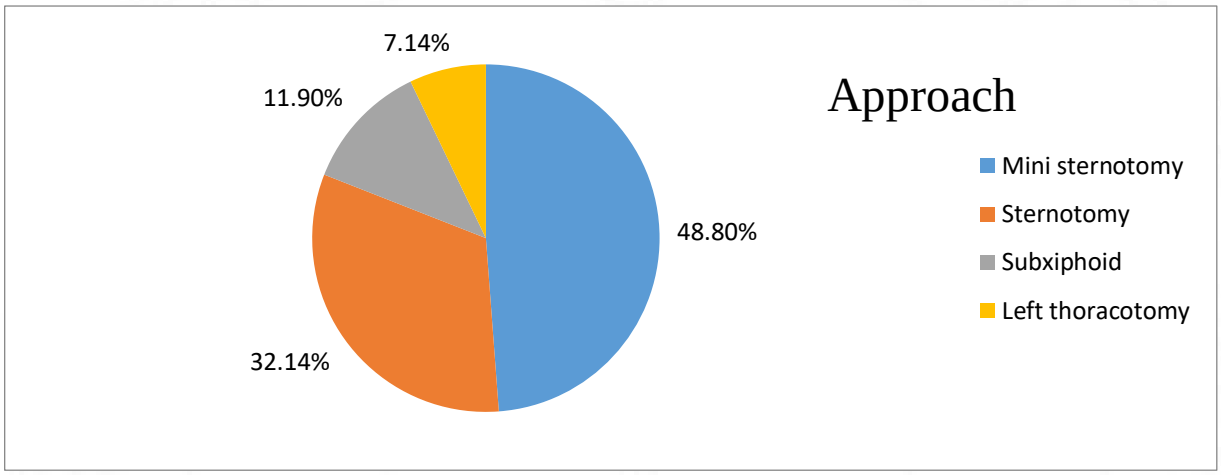
Figure 7 : Bar diagram for pacing mode in the study population



Approach and PG pocket:

Most preffered approach for epicardial lead placement was lower midline sternotomy (ministernotomy) (48%) followed by conventional sternotomy (27%), subxyphoid (10%) and lateral thoracotomy(7.14%). Rectus sheath in the anterior abdominal wall was the most preffered site for placing the pulse generator with very few exceptions (3.7%) where posterior chest wall in the thorax was used in whom lateral thoracotomy was done.

Figure 8: Pie chart of approach in the study population



Implant data:

At the time of implantation, the mean ventricular capture VP (in %) was 87.4 ± 27.31 (ranged from 0.8 to 100), Threshold was 1.43 ± 1 V (ranged from 0.3 V to 7.0 V), sensitivity was 2.58 ± 0.66 (ranged from 0.6 to 4.0) and impedance was 612.31 ± 132.32 ohms (ranged from 270 ohms to 1163 ohms).

Follow up Data

The Median duration of follow-up was 88±36 months . The mean threshold at time of implantation was 1.43 ± 1V, and, at last follow up, it was 1.66 ± 1.08V (p=0.55). Average percentage of ventricular pacing was 87.17 ± 30.12 while mean impedance was 642±90.0 ohms, which remained relatively stable over all throughout follow-up but there was a statistically significant difference in median change in impedance between CCHB and post op group (P Value<0.05). This can be accounted to the post procedural adhesions and myoepicardial inflammation at the local site of lead placement.

Table 3: Comparison of change in clinical parameters from the time of implantation to final follow up between cause (N=84):

Parameter	Cause [Median (IQR)]		P value
	CCHB (N=39)	Post op (N=42)	
Threshold	0.38 (0.0 to 1.00)	0.81 (0.0 to 1.21)	0.219#
Impedance	33 (0 to 154)	341 (0 to 643)	0.040#
Sensitivity	0 (0 to 2.8)	0 (0 to 0.97)	0.927#

Battery depletion, necessitating pulse generator change, was noted in 17 patients during the follow up period. The median time at PG Change occurs (in months) was 60 (46 to 120.50) in CCHB group and 84 (100 to 152) in post op group. There was no statistically significant difference in median time at PG Change occurs between cause (P Value>0.05

Table 4 : Comparison of time at PG change occurs between cause (N=16):

Parameter	Cause (Mean± SD)		P value
	CCHB (N=9)	Post op (N=7)	
Time at PG change occurs (in months)	60 (46 to 120.50)	84 (100 to 152)	0.142#

Elevated lead threshold (>3V @ 0.4msec) was seen in 1 children beyond 6 months of follow-up who underwent ICR for DORV. Pacing induced LV dysfunction was noted in 5 patients at a mean age of 30 months . Ventricular dysfunction warranting upgradation to cardiac resynchronisation therapy (CRT) was done in 3 children. Change to endocardial pacing was seen in 8 children out of which 2 were because of lead fracture, 2 pacemaker malfunction. Total 4 deaths were seen and 2 were during the peri-operative period. One child had PPI implantation on day 3 of life, developed severe acidosis and lead capture failure and had cardiac arrest on post op day 0 itself . Another child implanted on day 2 of life, died at post op day 2 following pulmonary infection ,sepsis and renal failure. Third child underwent PPI at 4 days of life, but developed LV dysfunction at 11 months after VSD closure at 6 years of age. He was suggested CRT upgradation, but child expired on post op day 0 due to capture failure and cardiac arrest. The last death was seen after 320 months when the child was admitted for SVT and cardioversion done when she developed bradycardia and arrested.That child developed junctional rhythm following sennings procedure for TGA. Overall mortality is 4.7% and among neonates is 9.5% .

Table 5 : Descriptive analysis of events in the study population

Events	Frequency	Percentages
PG Change	17	20%
Surgical Site Infection	5	5.9%
LV dysfunction	5	5.9%
Converted to endocardial PPI	8	9.5%
Lead fracture	2	2.3%
Failed arterial capture	1	1.1%
Pacemaker malfunction	2	2.3%
Elevated RV Threshold	1	1.1%
RV dysfunction	1	1.1%
Death	4	4.7%

Figure 9 : Bar chart for events in study population

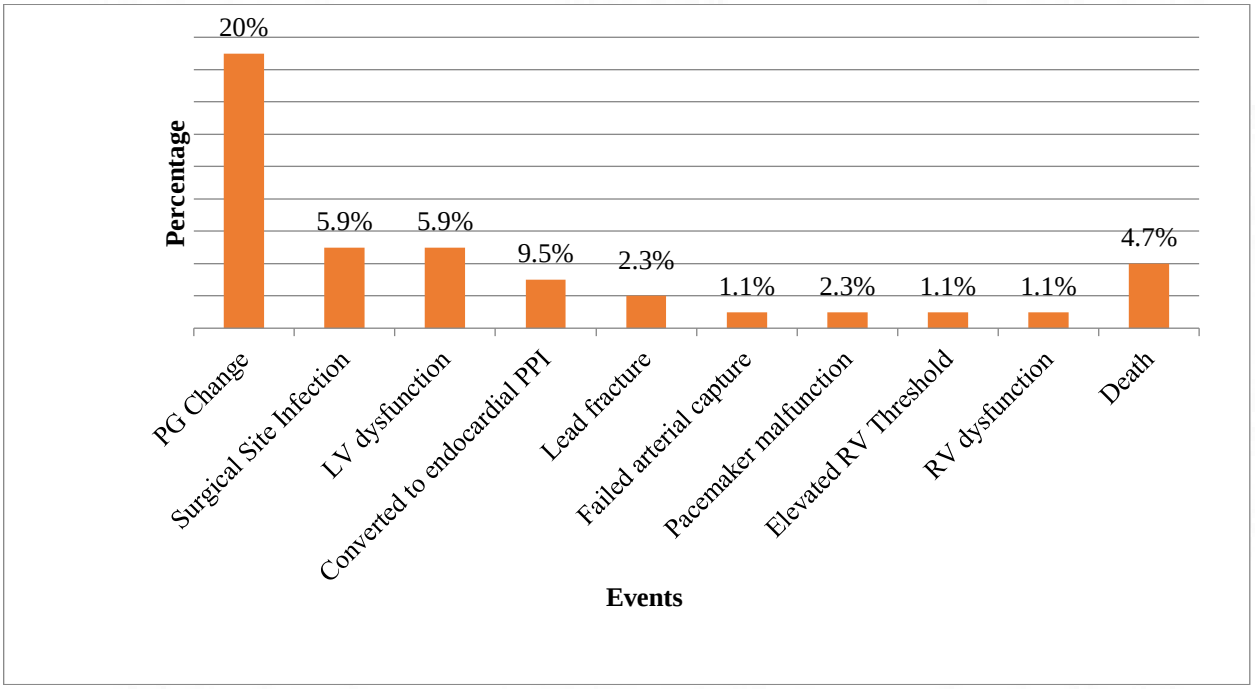
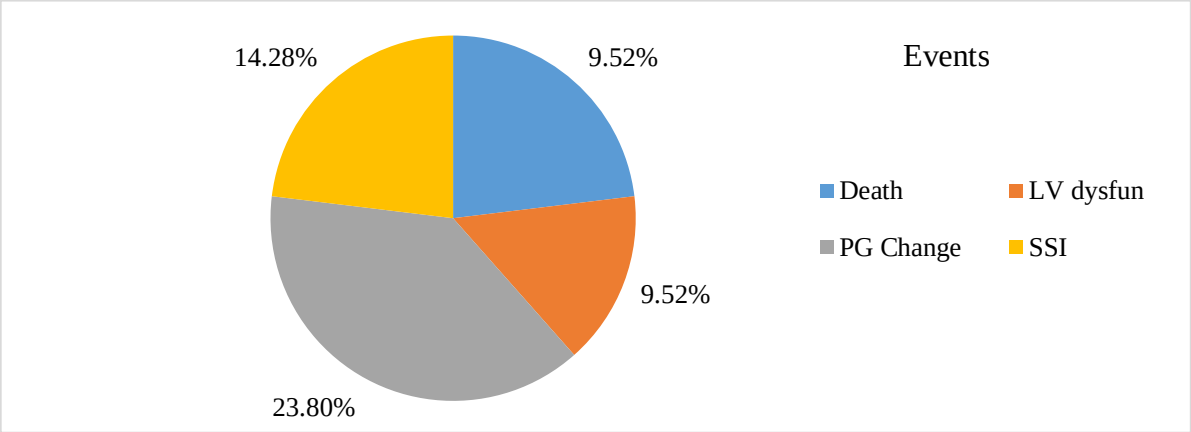


Table 6: Descriptive analysis of events (for neonatal babies) in the study population

Events	Frequency	Percentages
PG Change	5	23.80%
Surgical Site infection	3	14.28%
LV dysfunction	2	9.52%
Death	2	9.52%

Figure 10 : Pie chart for events (for neonatal babies) in study population



Surgical site infection was seen in 5 patients (3 neonates) mostly seen within 3 months of implantation. 2 patient required PG explantation and sinus tract excision, 2 patient had incision and drainage and other had wound debridment and resuturing. There was no significant difference between the outcome of those who underwent PPI for either indications in terms survival, heart failure, percentage of pacing requirement or duration of freedom from pulse generator replacement.

DISCUSSION

Cardiac pace makers in pediatric patients with congenital heart disease offers great challenge for surgeons as there are several complications as these subjects carry body size, age, somatic growth, long duration of pacing and lifestyle as a trial.[1],[2] In addition to this these subjects pose a number of anatomical irregularities for an example situs anomalies, vein malformations, septal/ valvular defects, AV /ventriculo-arterial disconcordance and sequelae from prior surgical interferences, which make inserting a pacemaker (PM), an intricate technique, with a high risk of acute and chronic problems. In literature there are many studies which have studied the complication of pacemaker in adult subjects [3],[4] however, very less groups have studied the complication s of pace makers in pediatric subjects with CHD. [5],[6]

A study by Silvetti, M et al,[6] had the greatest number of paediatric patients with a PPI and other CHD that has ever been published to date. Showing the results of pacing in children and adolescents with CHD, this study demonstrated the outcomes of these patients in the early phases of their life, as previous papers focused on adult patients with CHD implanted in the third or fourth decade of life.[7],[8] This large cohort of patients, implanted in paediatric age in the great majority of cases, followed by a long and complete follow-up, shows that the incidence of complications that cause the pacing system to fail is significantly higher in patients with the epicardial system, compared with the transvenous system. Therefore, when not contraindicated due to anatomical or surgical

characteristics, or in neonates and infants, transvenous implantation should be preferred. In fact, the epicardial implant presents a risk of failure approximately five times greater than the endocardial implant. Other predictors for the failure of the pacing system are the younger age of the implanted patient, a higher number of heart operations, and a greater number of leads implanted.

In our study we retrospectively studied 84 subjects. The mean age of implantation in the study population was 2.27 ± 3.58 years, ranged from 0 to 14.50 years. There was an equal proportion of male and female babies. The mean birth weight in our study population was 2.49 ± 0.59 kg, ranged from 1.2 kg to 4.2 kg. A similar study by Samir, R et al,[9] involved 32 subjects with median age ranging of 0.16–15years of age with male predominance (56.3%) and female with 43.7%. the mean weight of the study population was 6–74 (21.6 ± 13.8) kg. Another study by Silvetti, et al,[6] had involved 287 with mean age 1-11years with male proportion more. Further, a retrospective study by Costa, R et al,[10]with 16 neonates with female neonates comparatively greater. In contrast to all the studies mentioned and to the present study Cohen, M et al,[3] involved paediatric age, neonates up to adult (21years) in their study with mean weight showing 1.4-87kg, was contrast to present study findings due to the disparity in the involvement in the age of the study subject. The mean age at implantation for neonatal babies was 0.02 ± 0.03 years, ranged 0.0 to 0.1 and the mean birth weight for neonatal babies was 2.31 ± 0.45 kg, ranged from 1.2 kg to 3.2 kg.

In Ali A et al,[11] study the mean age of the epicardial pacemaker implantation was

6.10 ± 2.23 years and mean weight was 20.85 ± 4.81kg.

Table 7 : comparing the sociodemographic details across various studies with present study

Studies	**Study population (n=)**	**Mean age**	**Gender**		**Mean weight**
			Male	**female**	
Samir, R et al,[9]	32	0.16–15years	56.3%	43.7%	21.6 ± 13.8 range 6-74 kg
Silvetti, et al,[6]	287	1-11years	58%		-
Cohen, M et al,[3]	123	1day-21years	-	-	1.4 - 87kg
Costa, R et al,[10]	16	4.7 ± 5.3 days (range, 1 to 23 days). neonates	43.75%	56.25%	-
Present study	84	2.27 ± 3.58 years	50%	50%	2.49 ± 0.59 kg range

Majority 84.52% of neonates mothers did not have maternal risk factor, in 10.71% of neonates mothers had SLE, 3.57% had gestational diabetes and 1.19% had mothers with hypothyroidism.

Pacing characteristics

Epicardial pacing is usually established because of either cardiac anatomy or small body size. In a study Ali A et al,[11] epicardial pacing was only limited to small children, single ventricle physiology, or early post- operative CHB. As also found in our study subjects. In the present study the pacing mode was majority

for VVI in 72.62% followed by DDD in 25% and AAIR in 2.38%. Most 95.24% of the study participants were asymptomatic and in 3.57% the symptoms were incidental and 1.19% had syncope. In a study by Cohen, M et al,[3] found the initial pacing mode used VVI in majority followed by DDD and AAI. This finding was concordance with our study.

Table 8 : comparing the mode of pacing among the participants across the various studies to present study

Studies	**VVI**	**DDD**	**AAI**
Cohen, M et al,[3]	60.9%	34.14%	4.87%
Samir, R et al,[9]	62.5%	12.5%	-
Walker, F et al,[8]	43.92%	-	49.35% AAI+DDD
Present study	72.62%	25%	2.38%

All our participants had epicardial pacemakers (100%). The approach used for implanting epicardial PPI in our study was mini sternotomy in 48.8% followed by sternotomy in 32.14%, subxiphoid in 11.9% and left thoracotomy in 7.14%. In a study by Cohen et al,[3] had epicardial leads implanted by a subxiphoid approach (14%, 4 atrial/25 ventricular), a lateral thoracotomy (29%, 22 atrial/38 ventricular), or a sternotomy (57%, 34 atrial/84 ventricular).

The most common indication for epicardial pacemaker was postoperative complete heart block in 50%, CCHB in 46.43%, SSS for 2.38% and LQTS for 1.19%. In a study by Ali Aet al,[11] found indication for epicardial PPI to be Sinus node

dysfunction in 2%,Cong. CHB in 52%,post op CHB in 46%. A study by Samir, R et al,[9] the indication for pacemaker included postoperative CHB in 50%, congenital AV block in 40.6%, SND in 9.4%. Surgically repaired VSD in 40.6%, L-TGA (Levo-transposition of great arteries) in 9.4%,Valvular PS (pulmonary stenosis)in 3.1%, , Repaired AV canal in 3.1% in each and Single ventricle (fontan) 6.2%. In another study by Costa, R et al,[10] the indications for cardiac pacing included signs of low cardiac output in 25%, heart rate < 55 beats/minute in 18.7%, and both conditions in 56.3% patients. Patent ductus arteriosus were detected in 75.0% infants, and atrial septal defects were detected in 25.0% of them. In 25.0% neonates, congenital heart defects were not detected before pacemaker implantation. One child had moderate-to-severe tricuspid regurgitation, and another had pulmonary stenosis.[10]

The most common surgery associated with post operative complete heart block was VSD closure (73.8 %). Ten patients underwent isolated VSD closure, 8 Patients had VSD closure as part of intra cardiac repair , AVCD repair (4), ASO+VSD closure (3), Senning + VSD closure (2), SAM resection +VSD closure (1), Truncus arteriosus repair (1), Hemimustard + rastelli (1). Other surgeries not involving VSD closure were Bidirectional glenn shunt (3), Fontan completion (2), ASD clsoure + TV annuloplasty (1), PA banding (1), Kawashima procedure (1)

Post- operative complications

Among the study population, the event was PG Change for 17 (20%) participants, Surgical Site infection and LV dysfunction for 5 (5.9%) participants each, Converted to endocardial PPI for 8 participants(9.5%) Lead fracture for 2 (2.3%) participants each, Failed arterial capture, Pacemaker malfunction, Elevated RV Threshold and RV dysfunction for 1 (1.1%) participant each and death for 4 (4.7%) participants.

Regardless of the surgical approach and pacing mode, device-related complications are common during follow-up. Although pocket-related complications, in particular, erosions or thinning of the skin are more frequent when the device is implanted in the chest wall, abdominal pockets may also be associated with complications. [12],[13]. But in our study rectus sheath was the choice of PG pocket in most (96.43%) of the participants and posterior chest wall in thorax in 3.57% participants. Hence all PG pocket related complications were noted in rectus sheath pockets only.

It is worth highlighting that lead fracture is an important determinant of lead survival and is directly associated with the patient's growth. [14],[15] But our study showed only 2 cases (2.3%) . In general, standard epicardial leads has been linked with a high incidence of increased pacing thresholds following implantation, requiring early lead or pulse generator replacement. Few studies have shown that steroid-eluting leads are related with a lesser rate of lead

failure.[16],[4] A study by Walker et al,[8]found the incidence of lead complications to be 3% per patient-years, and wound infections or pulse generator erosion in 5% of patients in total. In a series of 119 epicardial pacemakers implanted at a mean age of 1.8 years with a median follow-up of 6.4 years, there were pocket complications in 6.7% and lead fractures or exit block in 20%.18 Other procedural complications included hemothoraces and pericardial effusion

In our study, the mean time at PG change occured (in months) was 111.88 ± 81.01, ranged from 39 months to 322 months. A study by Ali A et al,[11] found the age of patients at 1st device implantation ranged from 2 months to the age of 14 years. The present study found the mean time at PG change occured (in months) was 80.33 ± 45.19 in CCHB group and 122.43 ± 76.15 in post op group. There was no statistically significant difference in mean time at PG Change occurs between cause (P Value>0.05).

Among the study population, event for neonatal babies was PG Change for 5 (38.46%) participants, Surgical Site infection for 3 (23.08%) participants, LV dysfunction for 2 (15.38%) participants and death for 2 (15.38%) participants.

The mean time at PG Change occurs (in months) for CCHB group was 57.60 ± 23.3 months, ranged from 39 months to 97 months.

There was an average increase of 0.5 ± 10.6 in volts from implantation to last followup. There was an average decrease of 0.62 ± 1.22 in threshold from implantation to last followup. There was an average decrease of 1.48 ± 1.92 in ampere from implantation to last followup. There was an average decrease of

258.05 ± 349.31 in impedance from implantation to last follow-up. There was an average decrease of 0.54 ± 1.42 in sensitivity from implantation to last follow-up. (Table 36) Average percentage of ventricular pacing was 87.17 ± 30.12 while mean impedance was 642±90.0 ohms, which remained relatively stable over all throughout follow-up but there was a statistically significant difference in median change in impedance between CCHB and post op group (P Value<0.05). This can be accounted to the post procedural adhesions and myoepicardial inflammation at the local site of lead placement

In a study Costa, R et al,[10] all operations were successful, and there were no perioperative complications. In addition, there were no complications related to surgical technique during the follow-up period (maximum of 12 years). In particular, there were no pocket-related complications (infection or skin erosion); lead-related complications (lead fracture), increases in pacing thresholds, or early battery depletion. Finally, measurements of sensing, pacing, and impedance remained satisfactory during the follow-up period. [10] In a study by Noiseux, N et al ,[20]with a total study pediatric population with CHD found reintervention was required in 75 patients out of 122 subjects, after 5.0 ± 3.2 years, due to depletion of the battery in 45 patients (60%), fracture or dysfunction of electrodes in 27 patients (36%), and infection in 3 patients (4%). In univariate analyses, risk factors for reintervention were an approach via a median sternotomy, with a relative risk of 2.3 (p = 0.0087), and an indication for pacing other than atrioventricular block, with a relative risk of 1.7 (p = 0.0314). In

multivariate analyses, the approach via the mediansternotomy independently predicted the need for reintervention, with a relative risk of 2.1, and 95% confidence intervals from 1.1 to 4.1 (p = 0.0256). The authors found epicardial pacing beneficial in children as it was associated with low mortality and morbidity. The use of leadless epicardial PM in paediatric CHD can possibly reduce the need for reintervention and can prolong their longetivity.

CONCLUSIONS:

Epicardial permanent pacemaker implantation in pediatric population has become a relatively safe procedure with low mortality and morbidity with advent of newer implantation technique and sophisticated leads and pulse generators. There was no significant difference between the postoperative complete heart block patients and congenital heart block patients in terms of short and long term complications of epicardial pacing. Due to somatic growth in children conversion to endocardial leads becomes a necessity. Ventricular dysfunction due to pacing is a worrisome complication in children but CRT has shown promising results.

LIMITATIONS AND RECOMMENDATIONS:

- This was a retrospective study which limit the assessment of perioperative complications.
- The results of this study cannot be generalized due to marked heterogenicity of the underlying diseases and the variety of the age of patients.
- The study presented only one single medical center experience.
- The study included a limited number of cases.

REFERENCES:

1. Silvetti MS, Drago F, De Santis A, Grutter G, Ravà L, Monti L, et al. Single-centre experience on endocardial and epicardial pacemaker system function in neonates and infants. Eur Eur pacing, arrhythmias, Card Electrophysiol J Work groups Card pacing, arrhythmias, Card Cell Electrophysiol Eur Soc Cardiol. 2007 Jun;9(6):426–31.
2. Fortescue EB, Berul CI, Cecchin F, Walsh EP, Triedman JK, Alexander ME. Patient, procedural, and hardware factors associated with pacemaker lead failures in pediatrics and congenital heart disease. Hear Rhythm. 2004 Jul;1(2):150–9.
3. Cohen MI, Bush DM, Vetter VL, Tanel RE, Wieand TS, Gaynor JW, et al. Permanent epicardial pacing in pediatric patients: Seventeen years of experience and 1200 outpatient visits. Circulation. 2001;103(21):2585–90.
4. Udink ten Cate F, Breur J, Boramanand N, Crosson J, Friedman A, Brenner J, et al. Endocardial and epicardial s0.teroid lead pacing in the neonatal and paediatric age group. Heart. 2002 Oct;88(4):392–6.
5. HEINEMANN MK, GASS M, BREUER J, ZIEMER G. DDD Pacemaker Implantation After Fontan-Type Operations. Pacing Clin Electrophysiol [Internet]. 2003 Jan 1;26(1p2):492–5. Available from: https://doi.org/10.1046/j.1460-9592.2003.00079.x
6. Silvetti MS, Drago F, Di Carlo D, Placidi S, Brancaccio G, Carotti A. Cardiac pacing in paediatric patients with congenital heart defects: Transvenous or

epicardial? Europace. 2013;15(9):1280–6.

7. McLeod CJ, Attenhofer Jost CH, Warnes CA, Hodge D 2nd, Hyberger L, Connolly HM, et al. Epicardial versus endocardial permanent pacing in adults with congenital heart disease. J Interv Card Electrophysiol an Int J Arrhythm pacing. 2010 Sep;28(3):235–43.
8. Walker F, Siu SC, Woods S, Cameron DA, Webb GD, Harris L. Long-term outcomes of cardiac pacing in adults with congenital heart disease. J Am Coll Cardiol. 2004;43(10):1894–901.
9. Samir R, Diab OA, Morttada A, Aboulmaaty M. Permanent pacing in infants and children: A single center experience in implantation and follow up. Egypt Hear J [Internet]. 2011;63(3–4):183–9. Available from: http://dx.doi.org/10.1016/j.ehj.2011.08.012
10. Costa R, da Silva KR, Martinelli Filho M, Carrillo R. Implante de marca-passo epicárdico por acesso minimamente invasivo em neonatos com bloqueio atrioventricular congênito. Arq Bras Cardiol. 2017;109(4):331–9.
11. Ali AN, Wafa SS, Arafa HH, Samir R. Outcomes of pacing in egyptian pediatric population. J Saudi Hear Assoc. 2021;33(1):61–70.
12. Lichtenstein BJ, Bichell DP, Connolly DM, Lamberti JJ, Shepard SM, Seslar SP. Surgical approaches to epicardial pacemaker placement: does pocket location affect lead survival? Pediatr Cardiol. 2010 Oct;31(7):1016–24.
13. Motonaga KS, Dubin AM. Cardiac resynchronization therapy for pediatric patients with heart failure and congenital heart disease: a reappraisal of

results. Circulation. 2014 May;129(18):1879–91.

14. Villain E, Martelli H, Bonnet D, Iserin L, Butera G, Kachaner J. Characteristics and results of epicardial pacing in neonates and infants. Pacing Clin Electrophysiol. 2000 Dec;23(12):2052–6.

15. Silvetti M, Carlo D, Ammirati A, Placidi S, Mambro C, Ravà L, et al. Left ventricular pacing in neonates and infants with isolated congenital complete or advanced atrioventricular block: Short- and medium-term outcome. Europace. 2014 Aug 12;17.

16. Silvetti MS, Drago F, De Santis A, Grutter G, Ravà L, Monti L, et al. Single-centre experience on endocardial and epicardial pacemaker system function in neonates and infants. Europace. 2007;9(6):426-31. doi: 10.1093/ europace/eum043.

STUDY CONSENT FORM (ENGLISH)

TITLE OF THE STUDY: - SINGLE CENTRE EXPERIENCE OF EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE.

Participant's name: Date of Birth / Age (in years):
I_____ _____,
son/daughter of _____ (Please tick boxes).

[ ] Declare that I have read the above information provide to me regarding the study- **SINGLE CENTRE EXPERIENCE OF EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE.** and have clarified any doubts that I had.

[ ] I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

[ ] I understand that the study. Staff and institutional ethics committee members may be not need my permission to look at my health records even if I withdraw from the trial. I agree to this access.

[ ] I understand that my identity may be not be revealed in any information released to third parties or published.

[ ] I voluntarily agree to take part in this study.

[ ] I received a copy of this signed consent form.

Name:
Signature:
Date:

Name of witness:
Relation to participant:
Date:

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____
Name and Signature of Person Obtaining Consent
Dr. Selvaraj Anbu
Senior resident
Dept. of Cardiovascular and Thoracic surgery, SCTIMST

For any technical clarifications please contact **Dr. Srinivas G, Member Secretary, I E C**, SCTIMST, & Scientist - F, Department of Biochemistry, SCTIMST, (email iec.mem.sec@sctimst.ac.in).

ASSENT FORM (ENGLISH)

TITLE OF THE STUDY: SINGLE CENTRE EXPERIENCE OF EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE

Participant's name: Date of Birth / Age (in years):

I _____ _____,
FATHER/MOTHER/LEGAL GUARDIAN of _____ (Please tick boxes).

[ ] Declare that I have read the above information provide to me regarding the study**: LONG TERM OUTCOME OF CARDIAC PACEMAKER IMPLANTATION IN PEDIATRIC POPULATION** and have clarified any doubts that I had.

[ ] I also understand that the participation of my child in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

[ ] I understand that the study. Staff and institutional ethics committee members may be not need my permission to look at my health records even if I withdraw consent from the study. I agree to this access. [ ] I understand that my child's identity may be not be revealed in any information released to third parties or published.

[ ] I voluntarily agree for my child to take part in this study.

[ ] I received a copy of this signed consent form.

Name:
Signature:
Date:

Name of witness:
Relation to participant:
Date:

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____

Name and Signature of Person Obtaining Consent

Dr.Selvaraj Anbu

Senior resident

Dept. of CVTS, SCTIMST

For any technical clarifications please contact **Dr. Srinivas G, Member Secretary, I E C**, SCTIMST, & Scientist - F, Department of Biochemistry, SCTIMST, (email iec.mem.sec@sctimst.ac.in).

PATIENT INFORMATION SHEET (ENGLISH)

TITLE: SINGLE CENTRE EXPERIENCE OF EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE.

Name of Investigators:

D r Selvaraj Anbu, Dr Sabarinath Menon, Dr Baiju S Dharan, Dr KK Narayanan Namboodiri

Dear Patient,

We welcome you and thank you for your interest in your participation in this research project titled **SINGLE CENTRE EXPERIENCE OF EPICARDIAL PACEMAKER INSERTION IN PATIENTS WITH CONGENITAL HEART DISEASE.**

. We hope to include as many patients as possible in the study. Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomforts, the precautions and the information about how this project will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are free to ask the study personnel or the contact person mentioned below before you give your consent and also at any time during the entire course of the project.

What is Pacemaker?

The normal human heart contracts as a result of electrical impulses generated by the Sino Atrial Node (SAN), which is transmitted to myocardium by the Atrioventricular node and specialized conducting tissues.

In patients, where there is problem with impulse generation or impulse conduction, artificial pacemaker is implanted to enable proper heart contraction. The pacemaker consists of a pulse generator (PG) and electrical leads which may be implanted by open surgery or through intravascular route. Proper functioning of the pacemaker is tested using periodic electrocardiogram (ECG) and device interrogation.

What does the present study involve?

The records of the previous procedure that you/your child has undergone will be collected from the hospital database. You will be contacted by phone/ by mail to visit the hospital on a particular day. You will usually come in to hospital on the day of appointment. A specialist doctor will explain the proposed study design to you and ask you to sign the consent form to confirm that you understand the procedure and agree to go ahead with it. Please ask any questions you want. Following enrolment into the study, you will undergo the following tests- usually done as part of routine follow up evaluation:

- Functional status- History
- Electrocardiogram

- Interrogation of Implanted Pacemaker
- Any other test deemed necessary as part of evaluation

How long does it take?

The hospital visit will be a routine consultation, and the tests done will be part of routine follow up. This may take upto 2-3 hours. Please be prepared to be in the hospital OPD during that time.

What are the responsibilities of participants?

Your decision to allow your child to participate in this study is voluntary, your own personal choice. You may choose not to continue at any time, for any reason, without notice.

What are the expected risks for the participants?

The study involves collection of previous data from case records, and a follow up evaluation to assess the functional status and outcome, along with pacemaker parameters by device interrogation. There will be no risks for the participants because of participation in the study. They will be managed according to the hospital protocol. No specific intervention will be done.

What are the expected benefits of the research to the participants?

The participants are evaluated in detail for any cardiac cause for functional impairment. Since the operations undertaken are palliative in nature, a follow up examination and evaluation may be helpful in identification of any risk factors for poor outcomes or functional deterioration. It may be helpful in detecting patients who require early intervention or addition of medical therapy.The data derived from the study may be helpful in planning appropriate timing and surgical strategies for patients with similar conditions in the future.

Will participants be compensated for participation in this trial?

You will not be paid for participation in the study.

Will mine/my child's participation in this study be kept confidential?

All records of your study will be kept confidential. Your personal identity will not be revealed in any publication or release of results. Study records will be kept indefinitely for analysis and follow-up.

Can i withdraw from the study at any time during the study period?

Yes, you can. Your decision will not affect your regular medical care.

If there are any new findings / information, would i be informed?

Yes.

What happens in case of a study related injury?

There will be no study related injury.

Is there any alternative to the treatment mentioned?

Not applicable.

If you have any further questions, please ask: Dr. Selvaraj Anbu (Principal investigator), Senior Resident, Department of CVTS (Email: anbu@sctimst.ac.in Ph No: 9894526698)

For any technical clarifications please contact **Dr. Srinivas G, Member Secretary, I E C**, SCTIMST, & Scientist - F, Department of Biochemistry, SCTIMST, (email iec.mem.sec@sctimst.ac.in).

CONSENT FORM (MALAYALAM)

പഠന സമ്മതപത്രം
(പങ്കെടുക്കുന്നവരുടെ പ്രായം 7 വയസ്സിൽ കൂടുവാണെങ്കിൽ)

ശീർഷകം: കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം.

പങ്കെടുക്കുന്നയാളുടെ പേര്..... ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)

ഞാൻ ..... അച്ഛൻ/അമ്മ/രക്ഷകർത്താവ് .....

(ദയവായി കോളങ്ങളിൽ അടയാളപ്പെടുത്തുക)

[ ] കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം എന്ന പഠനസംബന്ധമായി മുകളിൽ എനിക്കുനൽകിയ വിവരങ്ങൾ ഞാൻ വയിക്കുകയും എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിക്കുകയും ചെയ്തു എന്ന് ഞാൻ പ്രഖ്യാപിക്കുന്നു.

[ ] എന്റെ കുട്ടിയുടെ പഠനത്തിലുള്ല പങ്കാളിത്തം സ്വമേധയാ ആണെന്നും എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ എനിക്ക് ഏതു സമയത്തും പഠനത്തിൽനിന്നും പിൻവാങ്ങാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനസംഘാംഗങ്ങൾക്കും നൈതീക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ കുട്ടിയുടെ ചികിത്സാരേഖകൾ പരിശോധിക്കാൻ എന്റെ പ്രത്യേക അനുമതി ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു, അതിന് ഞാൻ സമ്മതിക്കുന്നു.

[ ] വിവരങ്ങൾ മൂന്നാംകക്ഷികൾക്ക് നൽകുമ്പോഴോ പ്രസിദ്ധീകരിക്കുമ്പോഴോ എന്റെ കുട്ടിയുടെ വ്യക്തിവിവരങ്ങൾ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു

[ ] ഈ സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു

പേര് സാക്ഷിയുടെ പേര്
ഒപ്പ് പങ്കെടുക്കുന്നയാളുമായുള്ള ബന്ധം
തീയതി തീയതി

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണ പദ്ധതിയെപ്പറ്റി സാങ്കേതികതകരമായ പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേരും ഒപ്പും

ഡോ. സെൽവരാജ് അൻപു

സീനിയർ റെസിഡന്റ്

സിവിറ്റിഎസ്, ഡിപ്പാർട്ട്മെന്റ് SCTIMST

സാങ്കേതിക വിശദീകരണങ്ങൾക്ക്, ദയവായി ബന്ധപ്പെടുക ഡോ. ശ്രീനിവാസ് ജി, മെമ്പർ സെക്രട്ടറി, IEC, SCTIMST, പ്രൊഫസർ AMCHSS, SCTIMST (ഇമെയിൽ. iec.mem.sec@sctimst.ac.inഫോൺ 0471-2524234)

ASSENT FORM (MALAYALAM)

അനുവാദപത്രം
7 വയസ്സിൽ കൂടുതൽ പ്രായമുള്ളവർക്ക്

ശീർഷകം: കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം.

പങ്കെടുക്കുന്നയാളുടെ പേര്..... ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)....

ഞാൻ ..... അച്ഛൻ/അമ്മ/ രക്ഷകർത്താവ് .....
.....

(ദയവായി കോളങ്ങളിൽ അടയാളപ്പെടുത്തുക)

[ ] കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം എന്ന പഠനസംബന്ധമായി മുകളിൽ എനിക്കുനൽകിയ വിവരങ്ങൾ ഞാൻ വയിക്കുകയും എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിക്കുകയും ചെയ്തു എന്ന് ഞാൻ പ്രഖ്യാപിക്കുന്നു.

[ ] എന്റെ കുട്ടിയുടെ പഠനത്തിലുള്ള പങ്കാളിത്തം സ്വമേധയാ ആണെന്നും എന്റെ പതിവ് ചികിത്സയെയോ നിയപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ എനിക്ക് ഏതു സമയത്തും പഠനത്തിൽനിന്നും പിൻവാങ്ങാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനസംഘാംഗങ്ങൾക്കും നൈതീക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ കുട്ടിയുടെ ചികിത്സാരേഖകൾ പരിശോധിക്കാൻ എന്റെ പ്രത്യേക അനുമതി ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു, അതിന് ഞാൻ സമ്മതിക്കുന്നു.

[ ] വിവരങ്ങൾ മൂന്നാംകക്ഷികൾക്ക് നൽകുമ്പോഴോ പ്രസിദ്ധീകരിക്കുമ്പോഴോ എന്റെ കുട്ടിയുടെ വ്യക്തിവിവരങ്ങൾ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു

[ ] ഈ സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു

പേര്
ഒപ്പ്
തീയതി

സാക്ഷിയുടെ പേര്
പങ്കെടുക്കുന്നയാളുമായുള്ള ബന്ധം
തീയതി

(ദയവായി കോളങ്ങളിൽ അടയാളപ്പെടുത്തുക)

[ ] കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥാപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം എന്ന പഠനസംബന്ധമായി മുകളിൽ എനിക്കുനൽകിയ വിവരങ്ങൾ ഞാൻ വയിക്കുകയും എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിക്കുകയും ചെയ്തു എന്ന് ഞാൻ പ്രഖ്യാപിക്കുന്നു.

[ ] എന്റെ പഠനത്തിലുള്ള പങ്കാളിത്തം സ്വമേധയാ ആണെന്നും എന്റെ പരിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ എനിക്ക് ഏതു സമയത്തും പഠനത്തിൽനിന്നും പിൻവാങ്ങാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനസംഘാംഗങ്ങൾക്കും നൈതീക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ചികിത്സാരേഖകൾ പരിശോധിക്കാൻ എന്റെ പ്രത്യേക അനുമതി ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു, അതിന് ഞാൻ സമ്മതിക്കുന്നു.

[ ] വിവരങ്ങൾ മൂന്നാംകക്ഷികൾക്ക് നൽകുമ്പോഴോ പ്രസിദ്ധീകരിക്കുമ്പോഴോ എന്റെ വ്യക്തിവിവരങ്ങൾ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.

[ ] ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു

[ ] ഈ സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു

പേര്
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തീയതി

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തീയതി

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണ പദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേരും ഒപ്പും

ഡോ. സെൽവരാജ് അൻപു
സീനിയർ ഓഫീഡന്റ്
സിവിറ്റിഎസ്, ഡിപ്പാർട്ട്മെന്റ് SCTIMST

സാങ്കേതിക വിശദീകരണങ്ങൾക്ക്, ദയവായി ബന്ധപ്പെടുക ഡോ. ശ്രീനിവാസ് ജി മെമ്പർ സെക്രട്ടറി, IEC, SCTIMST, പ്രൊഫസർ AMCHSS, SCTIMST (ഇമെയിൽ. iec.mem.sec@sctimst.ac.inഫോൺ 0471-2524234)

PATIENT INFORMATION SHEET **(MALAYALAM)**

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുനന്തപുരം

രോഗികൾക്കുള്ള കാര്യവിവരണ പത്രം

ശീർഷകം: കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം.

ഗവേഷകരുടേ പേര്: ഡോ. സെൽവരാജ് അൻപു, ഡോ ശബരിനാഥ് മേനോൻ, ഡോ. ബൈജു എസ് ധരൻ ഡോ. കെ കെ നാരായണൻ നമ്പൂതിരി,

പ്രിയപ്പെട്ട പങ്കാളി/പങ്കാളിയുടെ രക്ഷകർത്താവേ,

കുട്ടികളിൽ ഹൃദയത്തിന്റെ പേസ്മെക്കർ സ്ഥപിക്കുന്നതിനാലുണ്ടാകുന്ന ദീർഘകാല നേട്ടം എന്ന പഠനത്തിൽ പങ്കെടുക്കാനുള്ള താത്പര്യത്തിന് താങ്കൾക്ക് സ്വാഗതവും നന്ദിയും പറയുന്നു.

പരമാവധി രോഗികളെ പഠനത്തിൽ ഉൾപ്പെടുത്താമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു. പഠനത്തിൽ പങ്കെടുക്കുന്നതിനുമുമ്പ് എന്തുകൊണ്ടാണ് ഈ ഗവേഷണം നടത്തുന്നത് എന്ന് താങ്കൾ മനസ്സിലാക്കേണ്ടത് പ്രധാനമാണ്. ഈ ഗവേഷണത്തെപ്പറ്റിയുള്ള പ്രസക്തമായ എല്ലാ വിവരങ്ങളും ഈ പത്രിക താങ്കൾക്ക് നൽകും. ഈ പദ്ധതിയുടെ സ്വഭാവം, നേട്ടങ്ങൾ, അപായങ്ങൾ, അസ്വസ്ഥതകൾ, മുൻകരുതലുകൾ എങ്ങിനെ ഇത് നടപ്പാക്കുന്നു എന്നീ വിവരങ്ങൾ ഈ പത്രിക വിശദീകരിക്കും. ഈ പത്രികയിലെ ഉള്ളടക്കം ശ്രദ്ധാപൂർവ്വം വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേണ്ടത് പ്രധാനമാണ്. ഈ പത്രികയിൽ ചില ശാസ്ത്ര പദങ്ങളുണ്ടായേക്കാം, അതിനാൽ താങ്കൾക്കെന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിലോ, കൂടുതൽ വിവരങ്ങളാവശ്യമുണ്ടെങ്കിലോ പഠനംനടത്തുന്നവരോടോ ബന്ധപ്പെടാനായി താഴെ നൽകിയിരിക്കുന്നയാളോടോ, സമ്മതം നൽകുന്നതിനു മുമ്പോ, പഠനകാലത്ത് ഏതു സമയത്തോ ചോദിക്കാൻ താങ്കൾക്ക് സ്വാതന്ത്യമുണ്ട്.

പേസ്മേക്കർ എന്നാലെന്ത്?

സിനോ എട്രിയൽ നോഡ് (എസ്എഎൻ) പുറപ്പെടുവിക്കുന്ന വൈദ്യുത പ്രേരണകൾ എട്രിയോവെൻട്രിക്കുലാർ നോഡും പ്രത്യേക പ്രസരണ കലകളും വഴി മയോകാർഡിയത്തിലേയ്ക്ക് പ്രസരിപ്പിക്കുന്നതിന്റെ ഫലമായാണ് മനുഷ്യഹൃദയം സാധാരണയായി സങ്കോചിക്കുന്നത്.

പ്രേരണകൾ സൃഷ്ടിക്കുന്നതിലോ പ്രസരണം നടത്തുന്നതിലോ പ്രശ്നങ്ങളുള്ള രോഗികളിൽ കൃത്രിമമായ പേസ്മേക്കർ സ്ഥാപിക്കുകയും വേണ്ടുംവിധമുള്ള ഹൃദയ സങ്കോചത്തിന് ശേഷിയുണ്ടാക്കുകയും ചെയ്യുന്നു. പേസ്മേക്കറിൽ പ്രേരണ സൃഷ്ടിക്കുന്ന (പിജി) ഒരു ഭാഗവും ധമനിക്കുള്ളിലൂടെ ശസ്ത്രക്രിയവഴി സ്ഥാപിക്കുന്ന വൈദ്യുതപ്രസരണ മാർഗ്ഗവും ഉണ്ടാകും. പേസ്മേക്കറിന്റെ വേണ്ടുംവിധമുള്ള പ്രവർത്തനം കാലാകാലങ്ങളിലുള്ള ഇലക്ട്രോകാർഡിയോഗ്രാം (ഇസിജി), ഉപകരണ പരിശോധന എന്നിവ വഴി ഉറപ്പാക്കും.

ഇപ്പോഴത്തെ പഠനത്തിൽ ഉൾപ്പെടുന്നതെന്ത്?

താങ്കൾ/താങ്കളുടെ കുട്ടി വിധേയമായ നടപടികൾ സംബന്ധമായ വിവരങ്ങൾ ആശുപത്രി രേഖകളിൽ നിന്നും ശേഖരിക്കും. ആശുപത്രിയിൽ ഒരു പ്രത്യേക ദിവസം സന്ദർശിക്കാനായി ഫോൺ/ഇമെയിൽ വഴി താങ്കളെ ബന്ധപ്പെടും. താങ്കൾ സാധാരണയായി നിശ്ചിത ദിവസം ആശുപത്രിയിൽ വരും. ഒരു വിദഗ്ദ്ധ ഡോക്ടർ പഠനരൂപരേഖയുടെ ഉദ്ദേശം വിശദീകരിക്കുകയും താങ്കൾക്ക് നടപടികൾ മനസ്സിലായെന്നും അതിന് സമ്മതിക്കുന്നു എന്നും ഉറപ്പാക്കാൻ ഒരു സമ്മതപത്രത്തിൽ ഒപ്പിടാനാവശ്യപ്പെടുകയും ചെയ്യും. താങ്കൾക്കു വേണ്ടുന്ന ചോദ്യങ്ങൾ ദയവായി ചോദിക്കുക.

പഠനത്തിൽ ഉൾപ്പെടുത്തിയ ശേഷം പതിവ് തുടർചികിത്സയിലെ വിലയിരുത്തലിന്റെ ഭാഗമായ താഴെപ്പറയുന്ന പരിശോധനകൾക്ക് താങ്കൾ വിധേയമാകും.

- പ്രവർത്തനസംബന്ധമായ അവസ്ഥ- ചരിത്രം
- ഇലക്ട്രോകാർഡിയോഗ്രാം
- സ്ഥാപിച്ചിട്ടുള്ള പേസ്മേക്കറിന്റെ പരിശോധന
- വിലയിരുത്തലിന്റെ ഭാഗമായി അവശ്യമായ മറ്റ് പരിശോധനകൾ

ഇതിന് എത്ര സമയമെടുക്കും?

ആശുപത്രി സന്ദർശനം പതിവ് ചികിത്സയ്ക്കും, പരിശോധനകൾ പതിവ് തുടർചികിത്സയുടെ ഭാഗവുമാണ്. ഇതിന് 2-3 മണിക്കൂർ വേണ്ടിവന്നേക്കാം. ആ സമയത്ത് ആശുപത്രിയിലെ ഒപിഡിയിൽ എത്താൻ ദയവായി തയാറാകുക.

പങ്കെടുക്കുന്നവരുടെ ഉത്തരവാദിത്വങ്ങളെന്തെല്ലാം?

താങ്കളുടെ കുട്ടിയുടെ പഠനത്തിൽ പങ്കെടുക്കാനുള്ള തീരുമാനം സ്വമേധയായുള്ളതും താങ്കളുടെ വ്യക്തിപരമായ പരിഗണനയുമാണ്. മുന്നറിയിപ്പില്ലാതെ ഏതു സമയത്തും താങ്കൾക്ക് പഠനത്തിൽ തുടരാതിരിക്കാം.

പങ്കടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കപ്പെടുന്ന അപായങ്ങളെന്തെല്ലാം?

ചികിത്സാ രേഖകളിൽ നിന്നും മുൻകാല വിവരങ്ങളുടെ ശേഖരണവും, തുടർചികിത്സയുടെ ഭാഗമായുള്ള പ്രവർത്തനപരമായ വിലയിരുത്തലും നേട്ടങ്ങളും അതിനൊപ്പം പേസ്മേക്കറിന്റെ പ്രവർത്തന ഘടകങ്ങളുടെ പരിശോധനയുമാണ് ഈ പഠനത്തിൽ ഉൾപ്പെടുന്നത്. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊണ്ട് പങ്കെടുക്കുന്നയാൾക്ക് അപായമൊന്നും ഇല്ല. ഉണ്ടായാൽ അവ ആശുപത്രി നടപടിക്രമപ്രകാരം ചികിത്സിക്കും. പ്രത്യേകിച്ച് ഒരു ഇടപെടലും നടത്തില്ല..

ഗവേഷണം കൊണ്ട് പങ്കെടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കപ്പെടുന്ന നേട്ടങ്ങളെന്തെല്ലാം?

പങ്കെടുക്കുന്നവരിൽ പ്രവർത്തനപരമായ തകരാറിന് ഹൃദയസംബന്ധമായ കാരണങ്ങളുണ്ടോയെന്ന് വിശദമായി വിലയിരുത്തും. ശസ്ത്രക്രിയ ഒരു ആശ്വാസ (പാലിയോറ്റീവ്) സ്വഭാവത്തോടെയുള്ളതായതിനാൽ പ്രവർത്തനപരമായ അധഃപതനം, കുറഞ്ഞ നേട്ടങ്ങൾ എന്നിവയ്ക്കുള്ള അപായ കാരണങ്ങൾ കണ്ടെത്തുന്നതിൽ തുടർ പരിശോധനയും വിലയിരുത്തലും സഹായകരമായേക്കാം. മുൻകൂട്ടിയുള്ള ഇടപെടലുകളോ, മരുന്നുചികിത്സ വർദ്ധിപ്പിക്കേണ്ടതോ ആവശ്യമായ രോഗികളെ കണ്ടെത്തുന്നതിന് അത് സഹായകരമായേക്കാം. സമാനമായ രോഗാവസ്ഥയുള്ളവർക്ക് അനുഗുണമായ സമയക്രമവും ശസ്ത്രക്രിയാ തന്ത്രവും ആസൂത്രണം ചെയ്യുന്നതിന് ഭാവിയിൽ സഹായകമായേക്കാം.

ഈ പരിശോധനയിൽ പങ്കെടുക്കുന്നവർക്ക് നഷ്ടപരിഹാരം നൽകുമോ?

പങ്കെടുക്കുന്നതിന് താങ്കൾക്ക് പണം നൽകില്ല.

എന്റെ/എന്റെ കുട്ടിയുടെ ഈ പഠനത്തിലെ പങ്കാളിത്തം രഹസ്യമായി സൂക്ഷിക്കുമോ?

താങ്കളുടെ പഠനസംബന്ധമായ രേഖകളെല്ലാം രഹസ്യമായിരിക്കും. പ്രസിദ്ധീകരണങ്ങളിലോ ഫലങ്ങൾ പ്രസിദ്ധീകരിക്കുമ്പോഴോ താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ ഉണ്ടാകില്ല. പഠനരേഖകൾ വിലയിരുത്തലിനും തുടർചികിത്സയ്ക്കുമായി അനന്തമായി സൂക്ഷിക്കും.

പഠനകാലത്ത് ഏതു സമയത്തും എനിക്ക് പഠനത്തിൽ നിന്നും പിൻമാറാമോ?

അതേ, താങ്കൾക്കാകും, താങ്കളുടെ തീരുമാനം പതിവ് വൈദ്യപരിചരണത്തെ ബാധിക്കില്ല.

പുതിയതായി എന്തെങ്കിലും കണ്ടെത്തിയാൽ/വിവരങ്ങളുണ്ടെങ്കിൽ അറിയിക്കുമോ?

അറിയിക്കും.

പഠനസംബന്ധമായി പരുക്കുണ്ടായാലെന്ത് സംഭവിക്കും?

പഠനസംബന്ധമായി പരുക്കൊന്നും ഉണ്ടാകില്ല.

സൂചിപ്പിച്ച ചികിത്സയ്ക്ക് പകരമെന്തെങ്കിലുമുണ്ടോ?

ബാധകമല്ല.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക. ഡോ. സെൽവരാജ് അൻപു (പ്രധാന ഗവേഷകൻ), സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ് (ഇമെയിൽ. anbuism@yahoo.com ഫോൺ. : 9894526698)

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