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ORIGINAL ARTICLE

Surgical Outcomes of Permanent Epicardial Pacing in Neonates and Young Infants Less Than 1 Year of Age

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Background Open surgical implantation of epicardial leads in neonates and infants remains the first option of treatment. We reviewed the long-term outcomes after epicardial pacemaker implantation in neonates and infants.

Methods From 1989 to 2016, 48 patients (16 neonates) underwent pacemaker implantation within the first year of life. Their median age and weight were 66.5 days (range: 0~319 days), and 4.2 kg (range: 1.9~9.3 kg), respectively, at the time of first pacemaker implantation. The indications for pacemaker implantation were post-operative or congenital atrioventricular block, sinus node dysfunction, and/or myocarditis-induced atrioventricular block. Forty-six (46) unipolar epicardial leads (non-steroid-eluting: 22; steroid-eluting: 24) and two bipolar leads (steroid-eluting) were inserted using a median sternotomy or subxiphoid approach.

Results The mean follow-up duration was 8.5 ± 7.9 years. The most commonly used generator mode at first implantation was VVI (n = 24, 50.0%). Eleven (11) generator mode changes from the initial VVI or VVIR to dual-chamber pacing were made at a mean of 7.0 ± 6.2 years after the first implantation for better inter-chamber synchrony and ventricular function. Freedom from reoperation for generator change after the first implantation was 95.3, 70.6, and 21.9% at 1, 5, and 10 years. Eighteen (18) lead malfunction events (34.1%) were detected. Freedom from reoperation for lead change was 97.8, 76.2, and 46.3% at 1, 5, and 10 years. The lead replacement rate was significantly higher in patients with non-steroid-eluting than steroid-eluting leads ($p = 0.045$).

Conclusions Neonates and infants require more frequent changes in pacemaker generator and leads than the older population. The use of steroid-eluting leads increased lead longevity and reduced the need for surgical re-interventions.

Keywords Pacemaker • Infant • Neonate • Pacing complications

Abbreviations: ASD, atrial septal defect; AV, atrioventricular; AVSD, atrioventricular septal defect; ccTGA, congenitally corrected transposition of great arteries; LV, left ventricle; RV, right ventricle; TGA, transposition of great arteries; VSD, ventricular septal defect

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Background

Over the past few decades, transvenous approaches required for various cardiovascular interventional treatments have improved dramatically [1]. However, due to anatomical barriers, growth potential, and small body size, the implantation of a permanent pacemaker via a transvenous approach in young patients, especially those with congenital cardiac disease, is not the first treatment option, unlike the situation in adults or adolescents [2,3]. The epicardial pacemaker lead approach is still the primary choice for young patients. Advances in lead and generator technology have improved the outcomes following implantation of permanent epicardial pacemakers [4]. However, the durability of lead and generator in neonates and small infants seemed to be less satisfactory than in adults. Thus we examined the long-term outcomes following epicardial pacemaker implantation in neonates and young infants in a single centre.

Methods

Patients

We retrospectively reviewed 48 patients who were less than 1 year of age, including 16 neonates (33.3%), and underwent epicardial pacemaker implantation between 1989 and 2016. The median age and weight of the patients were 66.5 days (range: $0 \sim 319$ days), and 4.2 kg (range: $1.9 \sim 9.3$ kg), respectively, at the time of the first pacemaker implantation. Indications for permanent pacemaker implantation were postoperative atrioventricular (AV) block (n = 24), congenital AV block (n = 18), sinus node dysfunction (n = 5), and myocarditis-induced AV block (n = 1). Twenty-eight (28) patients were male (58.3%).

This study was approved by the Institution Review Board of the Seoul National University Hospital.

Surgical Approaches

For the implantation of leads, a median sternotomy was employed in 32 patients, and sub-xiphoidal incision was employed in 16 patients. We placed unipolar epicardial leads in 46 patients, and bipolar epicardial leads in the most recent two patients. Initially, non-steroid-eluting leads were used, but, steroid-eluting leads were placed in all patients treated since 2002. Recently, we have sought to implant the ventricular leads in the apical area, as close to the left ventricle (LV) as possible, to minimise any dyssynchrony between LV and right ventricle (RV). This seeks to avoid RV-pacing-induced cardiomyopathy [5,6].

We usually create a generator pocket in the rectus sheath or sub-costal area; however, retro-sternal space is currently being considered as another option for generator placement. We had used this space in four patients who were either neonates or whose body weight was too low to implant the generator in the subcostal or rectus sheath. We created space for the generator in the retro-sternal area by removing part of the thymus, which occupies a relatively larger proportion of the retrosternal space in neonates and young infants than in older subjects. Then, we fixed the generator to the anterior chest wall. Because we will need to replace the generator in the future because of battery exhaustion, we used to place some membranous materials to minimise the adhesion between the sternum, device and anterior surface of heart.

Results

We dealt with the clinical outcomes of the generator and lead which were implanted in the neonates and young infants whose age was less than 1 year old in this study. Therefore, we excluded the clinical data of the generator or leads which were newly added or replaced with previous one at the patients' age more than 1 year old after initial implantation in the neonatal or young infant period.

Indications for Permanet Pacemaker Implantation and Patients' Diagnoses

Twenty-three (23) patients exhibited postoperative AV block. All patients had various congenital cardiovascular anomalies with several types of ventricular septal defects (VSDs) except for one patient with an Ebstein anomaly who did not have VSD. All patients with VSDs exhibited complete AV block after VSD closure except for one patient with tricuspid atresia who underwent VSD extension procedure (Table 1).

Twenty-four (24) patients whose indications for permanent pacemaker implantation seemed not the postoperative AV block. We had 17 patients with congenital AV block. Among the patients with congenital AV block, six patients had structually normal hearts without any congenital intracardiac defects. Two patients had transposition of great arteries (TGA), two had VSD, two had atrial septal defect (ASD). We had one patient with congenitally corrected TGA patients, one with criss-cross heart, one with heterotaxy syndrome, and one with intra-cardiac tumour. We had six patients with sinoatrial node dysfucntion (five patients with heterotaxy syndrome, and one with ASD), and one patient with long QT syndrome with VSD (Table 1).

Besides congenital problems or postoperative complications, we had one patient with a developing AV block due to progressive myocarditis after vaccination.

Overall Follow-Up Outcomes

During 8.5 ± 7.9 years of mean follow-up, there were four early or in-hospital deaths (original diagnoses: abnormal origin of the right pulmonary artery in one, tetralogy of Fallot in one, VSD with long QT syndrome and AV block in one, and left isomerism in one). The causes of early deaths included intractable ventricular tachycardia attributable to the long QT syndrome, irreversible heart failure, septic shock, respiratory arrest, and biliary atresia. There were four late deaths during the same period (original diagnoses: interrupted aortic arch in one, congenitally corrected TGA in two, and left isomerism in one). One patient with complete AVSD

Table 1 Indications for permanent pacemaker implantation and structural diagnoses of the patients.

Indications for PPM	Diagnoses or structural anomalies		Number of the patients
Postoperative complication (n = 23)	VSD associated		21
	Isolated	*9*	
	TOF	*3*	
	IAA or CoA	*3*	
	TGA	*2*	
	ccTGA	*2*	
	DORV (TB anomaly)	*1*	
	AORPA	*1*	
	Tricuspid atresia		1
	Ebstein anomaly		1
Congenital (n = 24)	Long QT with VSD		1
	AV block		17
	Normal structure	*6*	
	TGA	*2*	
	VSD	*2*	
	ASD	*2*	
	others	*5*	
	SA node dysfunction		6
	Heterotaxy syndrome	*5*	
	ASD	*1*	
Myocarditis (n = 1)	Vaccin associated		1

Abbreviations: ASD, atrial septal defect; AORPA, abnormal origin of right pulmonary artery; AV, atrioventricular; cc-TGA, congenitally corrected transposition of great arteries; CoA, coarctation of aorta; DORV, double outlet of right ventricle; IAA, interrupted aortic arch; SA, sinoatrial; TB, Taussig-Bing; TGA, transposition of great arteries; TOF, tetralogy of Fallot; VSD, ventricular septal defect.

had never visited the hospital after the 1-year postoperative follow-up. The causes of late death included progressive heart failure and infective endocarditis. However, no death was associated with the surgical procedure used for permanent pacemaker implantation.

Several complications after implantation, except the problems associated with a dysfunction of lead or generator, such as lead fracture, lead sheath erosion, or generator exhaustion, occurred in four patients. Complications included infection of the generator pocket (three cases), migration of a pulse generator from rectus sheath to the peritoneal cavity (two cases), skin necrosis at the generator pocket (two cases), and airway compression by the retrosternally placed generator (one case). One patient experienced all these complications, and the remaining three patients experienced two kinds of complication, respectively. Infection of a generator pocket occurred in three patients, two occurred in the late phase (4 years after operation, and 7 months after operation, respectively), and one occurred in the early phase (2 weeks after operation). All skin necrosis occurred in the early period after operation (less than 1 month). Two cases of generator migration occurred 7 months, and 6 years after previous generator placement, respectively. In the patients under suspicion of infection in the generator pocket, we changed both the generator and the leads, and also changed the generator pocket. Generator migration occurred in two patients. One patient underwent first-pacemaker implantation in the rectus sheath at the age of 40 days. We found the generator in the peritoneal cavity during an operation to change the generator 6 years after the first implantation. The migration of the generator in other patients was associated with infection, because the generator was migrated into the inside of the distal colon after perforation of peritoneal membrane and transverse colon. We changed the generator and leads, and placed the new generator in the left pleural cavity and fixed it to the rib after cleaning up the dirty wound and repairing the perforated colon. To avoid the complications of migration or skin necrosis, we recently implanted generators in the sub-sternal space after near-total thymectomy of three neonates and one young infant who were very thin and who thus had thin peritoneal membranes. However, as we mentioned above, one of them showed respiratory difficulty after sub-sternal generator implantation and had a difficult postoperative course during the follow-up. One patient, who underwent VVI type permanent pacemaker implantation, recovered spontaenously from postoperative complet AV block, which was developed after VSD repair. Now, we are considering removing the generator and leads for this patient.

Mid- and Long-Term Follow-Up of Generators and Leads

The VVI mode was most commonly applied in pulse generators at the time of first implantation (n = 24, 50%) and followed by DDD (n = 14, 29.2%), VVIR (n = 6, 12.5%), AAIR (n = 3, 6.3%), and AAI (n = 1, 2.1%) modes. Because of the patient's body size in this young population, a smaller size of device, a single chamber generator, VVI or AAI type rather than the dual chamber generator, is preferred to avoid several problems such as skin necrosis, infection, lead fracture or generator migration. However, if a patient shows severe cardiac dysfunction due to AV dyssynchrony, we have tried to apply a dual chamber generator. The longevity of a pulse generator between a single chamber and a dual chamber mode did not show significant difference (p = 0.774, Log Rank test) during the follow-up. We changed the mode to the dual-chamber mode in 11 patients 7.0 ± 6.2 years after VVI or VVIR mode implantation for better cardiac output by atrio-ventricular dyssynchrony if the patient's body size permitted.

The main reasons for generator change were battery exhaustion or malfunction, and the need for a mode change. In one patient, we suspected infection of the generator pocket, and therefore changed both the generator and the leads simultaneously. Generator changes were performed in 26 patients during follow-up. Freedom from generator replacement after the first implantation was 95.3, 70.6, and 21.9% at 1, 5, and 10 years (Figure 1A), respectively. The mean generator longevity was 49.0 ± 44.9 months.

In terms of leads, lead replacement was required 28 times in 16 patients during follow-up because of a need for a generator mode change or bipolar lead conversion (n = 10), or deteriorating lead function including an increased threshold (n = 10). Lead fractures (n = 4) or sheath erosions (n = 1) occurred in five patients, and we changed the leads and the generator of one patient with suspected infection in the generator pocket (n = 3). Freedom from lead replacement was 97.8, 76.2, and 46.3% at 1, 5, and 10 years (Figure 1B), respectively. The mean lead longevity after the first implantation was 62.4 ± 63.8 months.

Steroid-Eluting Versus Non-Steroid-Eluting Leads

As mentioned earlier in the text, all epicardial leads placed early in the study were of the non-steroid-eluting type (n = 22; 17 hook-type, 5 patch-type). However, since 2002, we have placed only steroid-eluting epicardial leads in all patients (n = 26; 2 hook-type, 24 patch-type) including the cases with replacement of previous non-steroid-eluting type after initial implatation in the same patients. In terms of longevity, steroid-eluting leads were significantly better than non-steroid-eluting leads (Figure 2, p = 0.045.

Outcomes in Neonates

Of the 48 patients, 16 were less than 1 month of age. Their mean age was 11.3 ± 9.9 days and their mean body weight was 3.4 ± 0.6 kg. The reasons for permanent pacemaker implantation were congenital AV block (n = 14), and sinus node dysfunction (n = 2). The VVI mode was most commonly applied in pulse generators for the neonates (n = 11), and followed by the DDD mode (n = 3) and the AAI mode (n = 2) at the time of first implantation. The size of the pulse generator for DDD mode was too large to place for the neonates, however, we should consider the DDD mode pacemaker for one neonate with a long QT syndrome and two neonates with a heterotaxy syndrome accompanying with a moderate degree of AV valve regurgitation which was supposed to be due to AV dyssynchrony. Freedom from replacement for generator in neonates was 100%, 61%, and 15.2% at 1, 5, and 10 years, respectively and, the freedom from replacement of generator in patients aged more than 1 month was 93.2%, 67.6%, and 24.3% at 1, 5, and 10 years, respectively. The figures for both groups did not differ significantly (Figure 3A, p = 0.62). In terms of leads, the freedom from replacement in neonates were 100%, 66.7%, and 50% at 1, 5, and 10 years; the figures for patients older than 1 month of age were 96.8%, 75.6%, and 45.9% at 1, 5, and 10 years, respectively. The figures for both groups did not differ significantly (Figure 3B, p = 0.49).

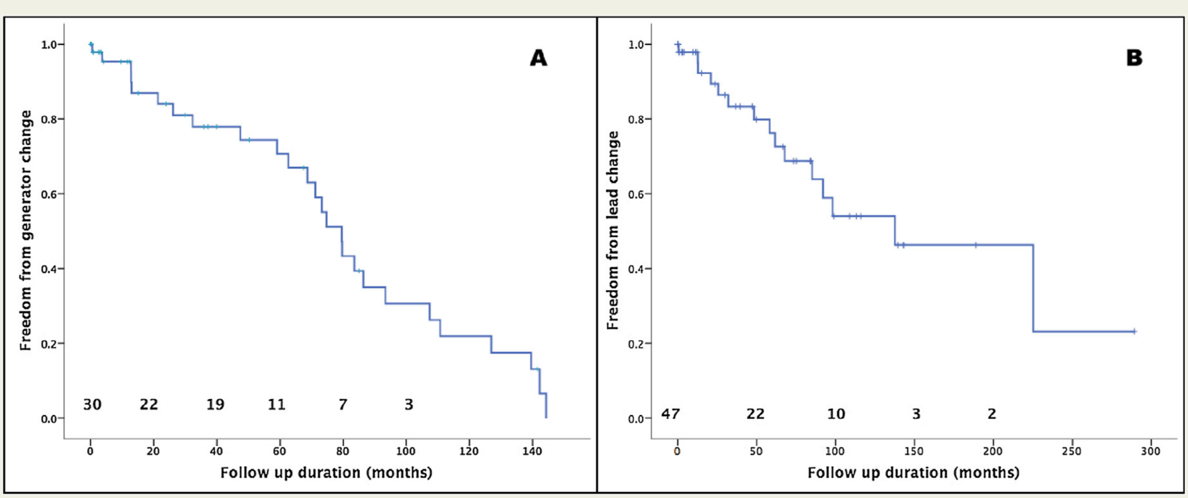

Figure 1 A Overall freedom from the need to change generators; B. Overall freedom from the need to change leads.

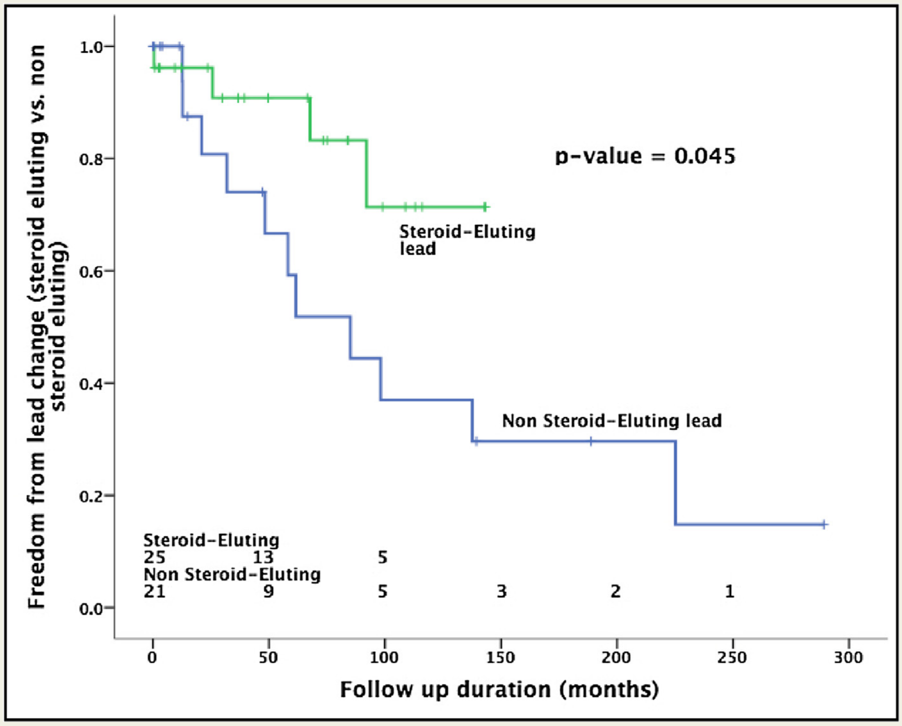

Figure 2 Comparison of freedom from replacement of initially implanted leads between steroid-eluting type and non-steroid-eluting type in terms of lead longevity.

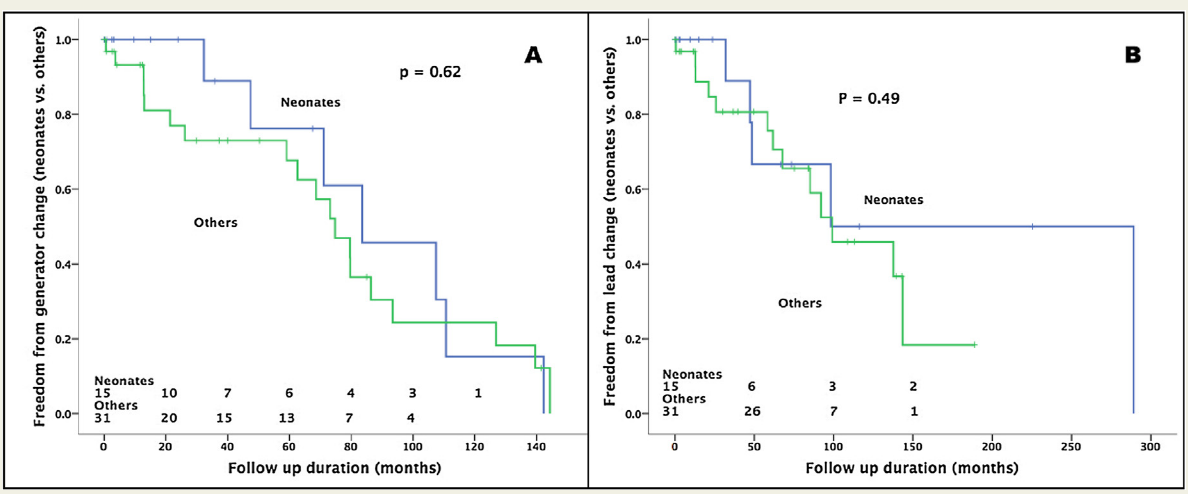

Figure 3 A BA. Comparison of freedom from the need to change of the initially implanted generators and leads between the neonates and the others (age > 1 month).

Discussion

Generator and Lead Longevities in Young Infants and Neonates

Some physicians have used endocardial pacemaker implantation in small infants [1,7], but the epicardial approach is preferred as the first option for young infants or neonates who require a permanent pacemaker for various reasons. The mid- and long-term results following implantation of epicardial pacemakers in children differed in several studies. However, most studies found that generator and lead longevities in children were not as good as in adults, and also that steroid-eluting leads lasted longer than non-steroid-eluting leads [3,7,8].

In this study, we limit our description and analysis to patients aged less than 1 year, including neonates. The generator and lead longevities were both poorer than that

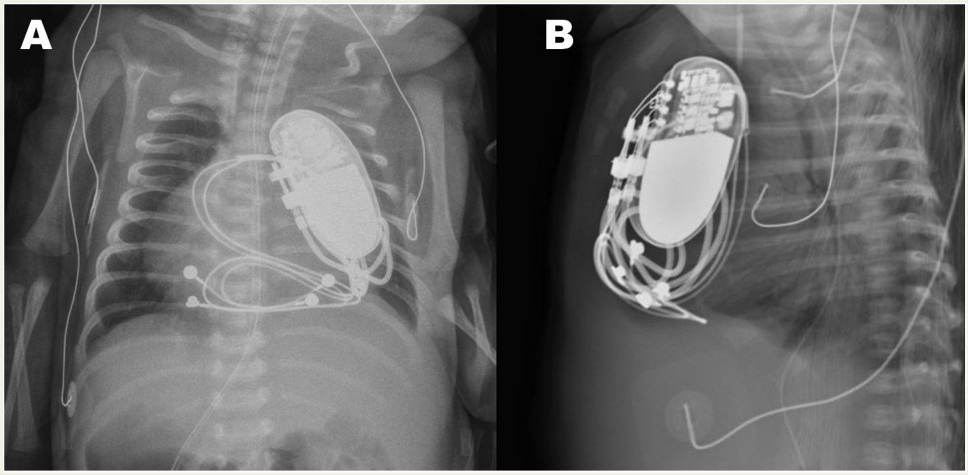

Figure 4 Pulse generator in retrosternal space. A. A chest postero-anterior X-ray; and B: chest lateral X-ray.

reported in previous studies on general child populations (usually older than our study population). Events compromising generator and lead longevities were also frequent in these younger populations. However, steroid-eluting leads exhibited better longevity (Figure 2) than non-steroid-eluting leads.

As the heart rates of younger patients are usually faster than those of older patients, we expected that neonates would require more frequent replacements than older patients; but in fact, we found no significant difference in the longevity of either the generators or leads (Figure 3) between neonates and older patients. When we compared the longevities of generators or leads in our older children (older than 1 month of age) and those of a previous study [9], the longevities were comparable (poorer in generator longevity, better in lead longevity).

Location of the Pulse Generator Pocket

Generally, the epicardial pulse generator was placed above the peritoneum or the rectus sheath. However, neonates and premature babies of low body weight frequently have very thin peritoneal membranes and rectus muscles. In such cases, the generators were externally obvious, and this may be a reason lead fracture or lead sheath erosion was more common in young infants who crawl on their abdomens. In fact, we encountered more lead damage cases in our group (n = 5 of 48, 10.4%) compared with older children than were encountered in a cohort slightly larger than this study that included only nine patients less than 1 year of age (3 out of 53, 5.7% [9]). In addition to this practical problem, the visibility of the generator caused parents to frequently state that they were nervous when handling their babies especially after the babies started to crawl on their abdomens. Sometimes, we encountered skin thinning or necrotic changes resulting in exposure of the generator through the skin, attributable to underlying pressure from the relatively large device, especially in low-birth weight babies. We also experienced two instances of generator migration into the abdominal cavity, which were discovered 6 years and 7 months, respectively, after implantation in the rectus sheath in the neonatal period; the generator had penetrated the peritoneal membrane. In these patients, it was difficult to change the generator because of severe adhesion of the pacemaker to abdominal tissue in one patient, and because of contamination by fecal material after colon perforation by the generator in another patient. Aellig et al. also reported dislocation of generators placed in the abdominal cavity in some patients [10], and Kelle et al. placed pulse generators just above the posterior rectus sheath after opening the linea alba and dissecting the rectus muscle from the posterior sheath, to avoid such complications [11]. To prevent such problems, we considered using the retro-sternal space instead of the rectus sheath for generator placement (Figure 4) in highly selected cases [12]. As neonates and young infants have a relatively large thymus, the removal of some thymus tissue created a space sufficient for generator placement. However, we still should be careful of possible compression of the mediastinal structures by a pulse generator, such as pulmonary arteries, pulmonary veins, trachea, or bronchus. Fortunately, the patients with generators in the retrosternal space did well except one patient who experienced respiratory difficulty attributable to airway compression; we had to change the positioning of the generator pocket. Considering a cosmetic benefit, we did not need an additional extensive incision to make the generator pocket. When the patient with a retrosternal generator pocket grows up enough to have adequate abdominal tissue to embed the generator, we can move the generator pocket to its usual place, a rectus sheath. We need a further follow-up and observation for these patients, because this approach method cannot be the primary option for the generator pocket.

Conclusions

In conclusion, epicardial pacing in young infants and neonates was associated with poorer lead and generator longevities than noted in previous studies on slightly older patients. However, steroid-eluting leads were more long-lasting compared to non-steroid-eluting leads. The retrosternal space may be considered an another option for generator placement in highly selected small patients with thin peritoneal membrane and skin.

Declarations

This topic was presented in the 25th World Society of Cardiothoracic Surgeons Annual Meeting and Exhibition 2015, in Edinburgh, Scotland.

Dr. Cho and Kwak contributed for this study as the first author equally.

No conflicts of interests.

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