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PERMANENT PACING IN CHILDREN: RESULTS OF FOLLOW-UP, ASSESSMENT OF COMPLICATIONS

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Aim. To present the experience and assess the complications of permanent pacing in children with bradyarrhythmias based on long-term follow-up.

Methods. Data of 145 children with structurally normal heart with implanted pacemakers at the age from 1 month to 18 years were retrospectively assessed. The follow-up was from 1999 to 2020 years. Epicardial pacemaker was implanted in 71 children, endocardial - in 74. The mean age of the primary implantation was 8.67±5.2 years.

Results. The following complications were disclosed: hemodynamic complications (heart chamber enlargement in dynamics and/or development of dyssynchrony, the appearance and increase in the regurgitation degree on the atrioventricular valves), bacterial endocarditis, hemopericardium, subclavian vein occlusion, pericarditis, infection of the pacemaker and its pocket, leads dislocation and fracture. With epicardial pacing various complications were detected in 24 (33.8%) examined patients, with endocardial - in 37 (50%). Hemodynamic complications with epicardial permanent pacing are associated with intraventricular dyssynchrony due to implantation of a ventricular lead on the lateral wall or the right ventricular outflow tract. Hemodynamic complications were not recorded in patients that performed the implantation of an epicardial lead at the left ventricular (LV) apex.

Conclusion. Children with pacemakers require careful follow-up. The most rational is the use of a primary epicardial pacemaker system with lead implantation on the apex of the LV. Such approach allows the veins to be preserved for endocardial stimulation at an older age, and to prevent hemodynamic complications. Neither epicardial nor endocardial pacemaker implantation guarantee the absence of complications. However, compliance with the above conditions will allow achieving high efficiency and safety of cardiac stimulation in children.

Key words: pacing; methods of lead implantation; complications; children

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Currently, pacemaker implantation is the only treatment option for bradyarrhythmias. Pacing in pediatric practice requires the high professionalism of specialists, especially in children, considering the prospect of lifelong pacing.

Continuous technical improvements in pacemakers have led to the emergence of modern physiological pacing systems that can be safely used in children of all ages due to their size and functionality [1]. When deciding on the optimal pacing system, the indications for permanent stimulation, the advantages and disadvantages of the different stimulation modes, and the implanting methods of pacemakers should be considered. Factors that determine the specifics of device implantation in children are: anthropometric data of the child and their correspondence to the size of the pacemaker and leads, the need for long-term (lifelong) pacemaker therapy, the high activity level of the child, intense physical development (the need for implantation of leads “with reserve” and their replacement), in some cases concomitant congenital heart defects, especially when intracardiac shunts are present, risks of possible complications that develop against permanent pacemaker [2-4].

Indications for pacemaker implantation have changed as new information about the efficacy and safety of permanent pacing has become available and because of improvements in medical technology [5, 6]. Today, many specialists use the indications for pacemaker implantation in children summarized in the 2013 review by the European Association of Arrhythmologists and Association of European Pediatric Cardiologists working group [7]. However, it should be noted that the level of evidence for these recommendations is low. Most recommendations for children requiring permanent pacemaker therapy are not supported by prospective studies and are based only on expert opinion. Generalizing the experience in the field

of pediatric pacing will allow specialists to make more informed decisions when choosing the implantation method in a particular patient, considering potential complications, planning dynamic monitoring, and clarifying indications for pacemaker implantation.

The purpose of this publication is to present the experience with the permanent pacemaker in children with bradyarrhythmia and to analyze the complications that arise from long-term follow-up.

MATERIALS AND METHODS

An analysis of pacemaker complications in children with structurally normal hearts was performed. The observation period is from 1999 to 2020, and the study included 145 patients aged 1 month to 18 years, including 103 patients with complete atrioventricular block (AVB), 25 children with sinus node disease (SND), and 17 with binodal disease. The mean age of the patients at the time of primary pacemaker implantation was 8.67±5.2 years. The age distribution was as follows: children under one year - 12 (8.3%) patients, from one to three years - 28 (19.3%) patients, from 3 to 10 years - 37 (25.5%) children. Most of the (68 (46.9%)) patients were children over 10 years of age. The division into age periods of childhood is due to the expediency of more detailed assessment of indicators in this study due to the peculiarities of the morphofunctional state of organs and systems in the process of growth and development of a child.

Inclusion criteria for patients:

- Presence of AVB, SND, or binodal pathology according to ECG and Holter monitoring (HM);
- Absence of evidence of a current inflammatory process according to blood tests;
- Absence of congenital heart disease.

On admission, all patients underwent a general clinical examination, including history, complaints, physical examination, blood cell count, urine tests, biochemical blood tests, coagulation profile, 12-lead ECG, daily ECG monitoring, echocardiography (Echo), and chest X-ray.

All patients underwent primary pacemaker implantation. In the postoperative period, repeated examinations including ECG, Echo, HM, chest X-ray in 2 projections, and control of pacemaker parameters were performed 5-7 days after the procedure. Follow-up examination, including ECG, Echo, HM, control of pacemaker parameters was performed after 6 and 12 months and then annually. Chest X-ray in two projections was performed once every 3 years after primary pacemaker implantation or more frequently, depending on the indications.

The indications for pacemaker implantation were determined considering the national recommendations developed on the basis of the recommendations of the European Association of Arrhythmologists and Pediatric Cardiologists [7]. The methods of implantation and the modes of pacing according to the age of the patients are shown in Table 1. In 5 patients with atrial pacing (AAI), a stimulator was implanted because of SND associated with symptomatic bradycardia, and 118 patients with complete AVB and binodal pathology were implanted with dual-chamber pacing systems. One patient with complete AVB and left bundle branch block was implanted with a three-chamber pacemaker system. Single-chamber ventricular pacemaker systems were implanted in 21 patients, 3 of whom were less than 1 year of age. In choosing the VVI pacing mode during primary pacemaker implantation, we were guided by the goal of minimizing the risk of complications related to excessive lead length in both endo- and epicardial approaches, avoiding sternotomy, and using a subxiphoid approach in epicardial pacing. In addition, VVI pacing at minimal frequency does not suppress AV junction function in patients with partially preserved AV conduction.

Most patients with dual-chamber epicardial pacing underwent partial sternotomy, whereas patients with single-chamber epicardial pacing used a subxiphoid approach without sternotomy.

Epicardial pacemaker implantation was performed in 71 children and endocardial implantation in 74 children. The mean age of patients with an epicardial ECS system at the time of primary implantation was 3.86±3.35 years; the mean age of patients with an endocardial ECS system at the time of primary implantation was 13.28±3.39 years. The mean duration of pacing from the time of primary implantation to the detection of complications was 2.10±2.7 years.

Statistical analysis. Statistical processing of data was performed with Statistica 10 software. Quantitative indicators are presented as M±σ, where M is the arithmetic mean and σ is the standard deviation. Differences in qualitative indicators were assessed using the $\chi 2$ criterion. Differences were considered significant at a significance level of $p<0.05$.

RESULTS

In patients with epicardial pacemaker implantation, various complications were noted in 24 (33.8%) subjects and in 37 (50%) with endocardial implantation (Table 2). The following complications were noted: hemodynamic complications (increase in ventricular dynamics and/or development of interventricular dyssynchrony, occurrence and increase in the degree of regurgitation at the atrioventricular valves), bacterial endocarditis, hemopericardium, usually associated with perforation of the right atrium, occlusion of the subclavian vein, pericarditis, infection of the pacemaker and its pocket, pacemaker dislocation, and lead failure.

In the endocardial implantation method, the ventricular lead was placed mainly in the right ventricular (RV) apex region. In epicardial pacing system, the ventricular lead was localized in the left ventricular (LV) apex and RV apex in 27 (38%) patients, and in 44 (62%) patients - in the RV free wall. It should be noted that in the “old era” (before 2013), when an epicardial pacing system was implanted, the ventricular lead was localized in the free RV wall. Most Russian clinics are still oriented to this approach. In recent years, in our clinic, during primary epicardial pacing, the ventricular lead is localized in the LV apex or RV apex.

In epicardial implantation, the most frequent complications were related to the development of hemodynamic changes in the form of signs of pacemaker-induced cardiomyopathy due to stimulation of the RV free wall. Stimulation of the above-mentioned zone leads to the development of electrical and mechanical dyssynchrony and LV dysfunction. It should be noted that the patients who under-

went primary epicardial lead implantation in the LV apex (n=27, 38%) did not have hemodynamic complications.

In the early postoperative period after epicardial pacemaker implantation, two patients were diagnosed with pericarditis and 1 patient was found to have hemopericardium. In the remote postoperative period, lead dislocation and their integrity failure were noted in 4 patients, including cardiac strangulation in one patient with congenital AVB. This complication was discovered 2 years after primary epicardial pacemaker implantation, which was performed at 1 year of age.

In the single-chamber epicardial pacing mode of VVI, only hemodynamic complications related to LV dyssynchrony were observed. In the dual-chamber pacing (DDD) mode, complications directly related to the epicardial leads were noted in addition to hemodynamic complications (Table 2).

In the transvenous (endocardial) pacing mode, complications related to hemodynamic disturbances were noted in the same number of patients as in the epicardial pacing group (Table 2). However, there were several differences in the quality of hemodynamic complications. Whereas in the epicardial pacing group, all patients with hemodynamic complications had evidence of pacemaker-induced cardiomyopathy, in the endocardial pacing group, hemodynamic complications were represented by pacemaker-induced cardiomyopathy in only 8 (47%) patients and by tricuspid regurgitation in 9 (53%) patients. The more frequent occurrence of pacemaker-induced cardiomyopathy in children with epicardial pacing compared to patients with endocardial pacing was statistically significant (p=0.047) and was observed only in patients with epicardial implantation of the ventricular lead in the region of the RV free wall.

In the group of patients with endocardial pacing, the early postoperative period was complicated by hemopericardium associated with perforation of the right atrium in 3 patients. Pericarditis was observed in one patient. In the remote postoperative period, one of the most serious complications of endocardial cardiac pacing was registered - the development of infective endocarditis. This complication occurred 10 years after primary pacemaker implantation and required open heart surgery with artificial circulation, deimplantation of the entire endocardial system, tricuspid plastic surgery followed by epicardial pacemaker implantation. In addition, remote postoperative complications of endocardial pacing were observed in two other patients: in one case - occlusion of the subclavian vein, in the other - infection of the pacemaker pocket.

DISCUSSION

One of the controversial and unresolved issues in pediatric pacing remains the choice of implantation method:

Table 1.
Pacing modes and methods of implantation of a pacemaker system in children with a structurally normal heart depending on age, n (%)

	Implantation approach							
	Endocardial, n=74 (51.03%)				Elicardial, n=71 (48.97%)			
	AAI n=5 (3.45%)	DDD n=57 (39.31%)	VVI n=12 (8.27%)	Всего n=74 (51.03%)	DDD n=61 (42.07%)	DDD-biV n=1 (0.69%)	VVI n=9 (6.21%)	Всего n=71 (48.97%)
< 1 year					9 (6.21)		3 (2.07)	12 (8.28)
1-3 years		1 (0.69)		1 (0.69)	23 (15.86)	1 (0.69)	3 (2.07)	27 (18.62)
3-7 years	1 (0.69)		1 (0.69)	2 (1.38)	16 (11.03)		3 (2.07)	19 (13.1)
7-10 years	1 (0.69)	6 (4.14)	2 (1.38)	9 (6.21)	7 (4.83)			7 (4.83)
> 10 years	3 (2.07)	50 (34.48)	9 (6.2)	62 (42.75)	6 (4.14)			6 (4.14)

Table 2.
Complications during epicardial and endocardial stimulation depending on the stimulation mode, n (%)

	Implantation approach					
	Endocardial, n=74 (51.03%)			Elicardial, n=71 (48.97%)		
	AAI n=5 (3.45%)	DDD n=57 (39.31%)	VVI n=12 (8.27%)	DDD n=61 (42.07%)	DDD-biV n=1 (0.69%)	VVI n=9 (6.21%)
Hemodanamical		12 (21.05)	5 (41.6)	14 (22.58)		3 (33.3)
Dislodgement*		11 (19.29)	2 (16.6)	4 (6.45)		
Pericarditis		1 (1.75)		2 (3.22)		
Hemopericardium		3 (5.26)		1 (1.61)		
Endocarditis			1 (8.33)			
Pacemaker infection		1 (1.75)				
Vein occlusion			1 (8.33)			
Overall		28 (49.12)	9 (75)	21 (33.87)		3 (33.3)

Notes: * - a lead disintegrates

epicardial or endocardial, depending on the age of the patient. Each method has its own advantages and disadvantages [8, 9]. Our analysis confirms this and shows that neither the epicardial nor the endocardial approach guarantees the absence of complications.

With endocardial pacing, complications include isolation failure, lead dislocation, cardiac perforation, tricuspid regurgitation, and the development of bacterial endocarditis. Endocardial pacing systems carry a high risk of venous occlusion and venous thrombosis in children, and therefore venous accesses cannot be reused in the future, leading to more complicated patient management [10, 11]. The increase in the degree of tricuspid regurgitation is related to both the excessive lead loops required due to patient growth and the number of leads passed through the patient's orifice due to transvenous reimplantation during the patient's lifetime. And because pacemaker has been required for several decades, a large number of leads passing through the transvenous valve only exacerbates intracardiac hemodynamic disturbances. Complications related to infection of the implanted devices range from 1% to 19% according to various authors [12]. At the same time, the patient can be definitively cured only if the infected leads and the pacemaker are completely removed, which concretizes the unsolved problem of endocardial lead extraction in children.

In contrast to endocardial pacemaker implantation, the most common mechanical complications associated with epicardial pacing are lead fractures, less lead "survival," and risks associated with thoracic surgery [13]. However, the problem of epicardial leads "survivability" observed in the early era of pacing is less relevant today. Steroid coating limits the inflammatory response at the contact site between the lead and cardiac tissue, resulting in lower acute and chronic pacing thresholds and longer battery life. When comparing modern steroid-coated endocardial and epicardial leads, it has been shown that there is almost no difference in the "survival rate" of the leads. Mechanical complications of epicardial pacing include rare but very serious cardiac strangulation, which is limited to the pediatric population. As the child grows, dislocation of the lead loop causes strangulation of the heart and, depending on where maximal compression occurs, can lead to coronary artery stenosis, valve insufficiency, or ventricular dysfunction, followed by myocardial infarction, which can be fatal. Particular attention should be paid to children implanted before 6 months of age because they have more intense physical development and a high likelihood of cardiac strangulation due to the excessive length of the leads in the mediastinum. Annual Echo and control chest X-ray in 2 projections every 3 years in asymptomatic patients are recommended to diagnose this complication [14-16]. To date, only 20 cases of cardiac strangulation have been described in the world literature [17, 18]. Our hospital has experience of treating such a complication in 2 patients: one of them had a pacemaker implanted at 1.5 months of age due to complete AVB after surgical correction of congenital heart disease [19]; the other patient had a pacemaker implanted at 1 year of age due to congenital AVB; 2 years after primary epicardial implantation, lead dislocation was detected. In the first clinical case, surgical correction was performed (pacemaker and leads replacement). In the second clinical case, a similar surgical procedure is planned.

It should be noted that the RV apex is the most common stimulation zone when a transvenous (endocardial) approach is used, which ensures a stable position of the lead and the absence of its displacement. However, prolonged apical endocardial pacing of the RV may lead to pacemaker-induced cardiomyopathy [20]. His bundle pacing seems promising to prevent this complication. It improves the function of the LV and alleviates the symptoms of heart failure due to ventricular dyssynchrony. This technique is currently gaining popularity in adult patients requiring cardiac resynchronization therapy, but experience with its use in children, although limited, is very promising [21].

In recent years, publications have discussed the areas of ventricular pacing for both types of lead implantation. Stimulation of the "optimal site" should aim to prevent pacemaker-induced mechanical dyssynchrony, especially in children implanted with a stimulator in early childhood with the prospect of lifelong pacing. Stimulation of LV apex and lateral wall during epicardial pacing has been shown to have the greatest potential to prevent dyssynchrony and reduce LV contractile function, whereas LV exit and lateral wall pacing is associated with a high risk of LV dysfunction [22, 23], consistent with our findings. Pacemaker-induced cardiomyopathy was noted only in patients with epicardial pacing of the LV free wall, and no hemodynamic complications were noted in patients with apical LV pacing.

The indications for pacemaker implantation in children do not provide clear recommendations for the choice of implantation method. For example, the 2013 consensus recommendations of the European Association of Arrhythmologists and the Association of European Pediatric Cardiologists recommend implantation of systems using only epicardial leads in children weighing up to 10 kg; in other patients, it is recommended to use predominantly transvenous systems [7]. However, considering the current global trends and the experience of leading foreign hospitals, epicardial lead implantation techniques are increasingly used, both because of the more serious complications of transvenous pacemaker implantation and because of the possibility of selecting the hemodynamically optimal pacing zone in the epicardial technique to prevent pacemaker-induced dyssynchrony [22, 23]. The epicardial approach is preferable for any initial pacemaker implantation in a child because it allows postponing as much as possible the installation of an endocardial pacing system, the use of which updates the previously unsolved problem of endovascular lead extraction in children. In most cases of complications, endocardial lead extraction is performed during open-heart surgery with the use of an artificial circuit, and the techniques of minimally invasive laser or mechanical lead removal in children have not yet achieved positive results not only in Russia but also worldwide [25-28].

Study limitations. In our study, direct statistical comparison of patients with epi- and endocardial pacing was difficult because these patients were not initially comparable in terms of age and type of complications. This factor contributed to the fact that no differences were found in the

number of complications of epi- and endocardial pacing in different age groups in our study.

CONCLUSION

The presence of a permanent pacemaker in children, in contrast to adult patients, requires more thorough dynamic monitoring, including HM, detailed Echo, chest X-ray in 2 projections, evaluation of pacemaker parameters. Currently, there are still unresolved issues in pediatric pacemaker therapy. The most important of these are the choice of implantation method and the prevention of complications occurring during continuous pacing.

According to recent studies and our experience, the use of a primary epicardial pacing system with lead implantation at the LV apex makes the most sense. It allows saving veins for endocardial pacing in older age and preventing the development of hemodynamic complications. It should be considered that neither epicardial nor endocardial methods of cardiac pacing guarantee the absence of complications, but compliance with the above conditions allows high efficiency and safety of cardiac pacing in children. The resolution of these issues is of great importance for the development of pediatric pacing.

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