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CARDIAC CONDUCTION SYSTEM PACING LEAD IMPLANTATION: DELIVERY TOOL IS THE CLUE TO SUCCESS

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Aim. To analyze the success rate and other intraprocedural parameters of implantation His bundle pacing lead using different approaches.

Methods. Since 2018 to 2022 we have tried His bundle lead implantation in 32 pts. During implantation 4 different approaches were used: on-stylet in 6 pts (19%), on-stylet over the delivery tool - in 9 pts (28%), over the C304 SelectSite (Medtronic, USA) delivery tool in 10 pts (31%), over the modified C304 SelectSite delivery tool in 12 pts (37%).

Results. Four studied implantation approaches did not differ by means of procedure duration as well as lead parameters. The success rate of implantation using modified C304 SelectSite delivery tool was higher than using other 3 techniques (91,7% vs 44%, p-0,006).

Conclusion. His bundle lead implantation success depends significantly on chosen implantation technique.

Key words: cardiac pacing; implantation technique; His bundle; introducer; bradycardia

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Stimulation of the cardiac conduction system is becoming a common method of permanent pacing. The first description of implanting an electrode in the bundle branch was made by P. Deshmuk et al. in 2000 [1]. The first procedures were performed with non-specialised instruments and were characterised by unsatisfactory intraoperative performance. Subsequently, papers appeared describing new implantation techniques using different introducers and electrodes. To determine the most effective technique for implanting electrodes in the bundle branch, we analysed our own experience with these procedures and compared it with data from other authors.

METHODS

Between 2018 and 2022, 32 patients underwent the pacemaker implantation with electrode insertion in the bundle branch at our institution. The mean age of the patients (22 (66%) were men) was 69±15 years.

Implantation techniques

1. Implantation on a stylet

This implantation technique uses endocardial electrodes with an active fixation mechanism. For implantation in the bundle branch, a standard J-shaped stylet with a relatively long knee is used, which is manually bent outwards and somewhat septally (Fig. 1). The electrode is inserted into the right atrial cavity, the shaped stylet is inserted and then mapping of the interatrial and interventricular septum in the atrioventricular (AV) sulcus is performed with longitudinal displacements and rotations about its axis, followed by standard electrode fixation in the area of recording of the bundle branch potential and selective or non-selective recording of the conduction system (Fig. 2) with stimulation from the distal pole of the implantable electrode. This technique allows relatively easy positioning of the electrode in the AV node and bundle branch, but the lack of rigidity of the system (even when using a rigid stylet) prevents insertion of the fixation spiral electrode directly into the tissue of the AV node or bundle branch. In our study, we attempted to implant Ingevity MRI 7742 (Boston Scientific, USA) electrodes in 1 patient, CapsureFix Novus 5076 (Medtronic, USA) in 3 patients, Crystalline Fix Pro (Vitatron, Netherlands) in 1 patient and Tendril STS 2088TC (Abbott, USA) in 1 patient using this technique.

2. Implantation on a stylet via a delivery introducer (DI)

Delivery introducers for the implantation of a left ventricular electrode into the venous system of the heart can also be used for bundle branch stimulation. The use of DIs gives the system sufficient rigidity and the use of a septal bend stylet allows the electrode to be implanted at almost straight angles to the endocardium. This improves the quality of electrode fixation and helps to reduce the stimulation threshold. An important consideration is to match the length of the DI to the length of the electrode [2]. Insufficient size of "cushioning" loop increases the risk of electrode dislocation or microdislocation during DI removal. In our study CapsureFix Novus 5076 (Medtronic, USA) - in 3 patients, Crystalline Fix Pro (Vitatron, Netherlands) - in 1 patient, Ingevity MRI 7742 (Boston Scientific, USA) - in 2 patients, Tendril STS 2088TC (Abbott, USA) - in 3 patients were implanted using this technique. Acuity Pro CS-EH coronary sinus electrode implantation devices (Boston Scientific, USA) were used as DI in this group.

3. Implantation of a stylet-free electrode through a controlled DI

In this technique, a 3830 SelectSecure 4Fr (Medtronic, USA) stylet-free electrode with a C304 SelectSite DI (Medtronic, USA) is inserted into the right atrial or right ventricular cavity and fixed in the area of the bundle branch electrogram registration. The DI is then removed by cutting.

4. Implantation of a stylet-free electrode through a modified guided DI

The creation of a septal bend on the C304 Select Site MD significantly facilitates bundle branch mapping and reliable electrode fixation. Due to the loss of septal curvature after 5-7 min of DI stay in the vascular bed, in some patients the re-modification of the delivery device was performed up to 2-4 times.

Implantation success

The final point for implantation of the electrode in the bundle branch was a reliable (no signs of intraoperative dislocation, even after provocation tests with coughing and deep breathing) fixation of the electrode with a satisfactory threshold for stimulation of the bundle branch (not higher than 3.5 V at a pulse duration of 0.4 ms). If it was not possible to implant the electrode in the bundle branch with the described parameters, the electrode was fixed in the area of the interventricular septum. After fixation of the electrode in the bundle branch, different combinations of bundle branch and ventricular myocardium were observed at different amplitudes of stimulation (Fig, 2).

Statistical processing

Data were statistically analysed using SPSS Statistics 26.0 software (IBM, USA). The normality of the definition was analysed using the Shapiro-Wilk test. Quantitative data are presented as arithmetic mean and standard deviation. Categorical data are presented as number of patients and proportion in percent. Comparison of groups by categorical parameters was done using Fisher's exact test. Quantitative comparisons were made using the Mann-Whitney test. The Kruskal-Wallis test was used for comparisons of more than two groups. Differences were considered statistically significant if $p<0.05$.

RESULTS

Characteristics of patients and implant procedures performed

The indications for implantation of the pacemaker were:

- acquired AV block of grade 1-3 - 22 (70%) patients: 15 (48%) on a background of sinus rhythm, 7 (22%) on a background of atrial fibrillation;
- pacemaker implantation prior to radiofrequency ablation of the AV node for tachysystole atrial fibrillation - 7 (22%) patients;
- vasovagal syncope due to VASIS 2B-type cardioinhibitory mechanism - 1 patient (3%);
- syndrome of sinus node weakness - 1 patient (3%);
- 3rd degree congenital AV block - 1 patient (3%).

The mean left ventricular ejection fraction was 56±11%. A single chamber pacemaker was implanted in 10 patients (30%), a dual chamber pacemaker in 19 (60%) and a biventricular device in 1 patient (3.3%). Safety electrodes were implanted in the interventricular septum in 4 patients (3 with dual-chamber and 1 with biventricular pacemak-

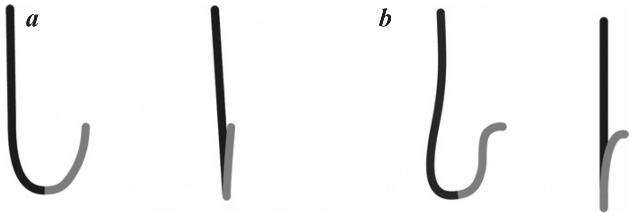

Fig. 1. Modification of the standard J-shaped stylet for implantation into the bundle branch: a - standard J-shaped stylet for electrode implantation with active fixation in the atrial position, b - modified stylet with additional curvature outwards and in the septal direction for implantation into the bundle branch.

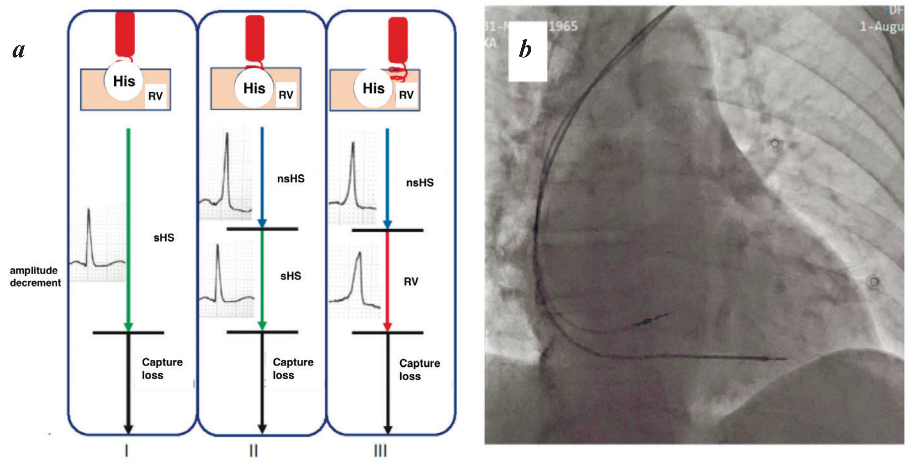

Fig. 2. Variants of bundle branch (BB) and ventricular myocardium capture at different amplitudes of stimulation (a): I - true selective BB stimulation (SBB), II - ventricular myocardium stimulation threshold above SBB threshold, III - SBB threshold above ventricular myocardium stimulation threshold, where RV is right ventricular myocardium, sSBB - selective SBB, nSBB - non-selective SBB. Direct projection X-ray imaging of a patient with electrodes implanted in the bundle branch and right ventricular apex (b).

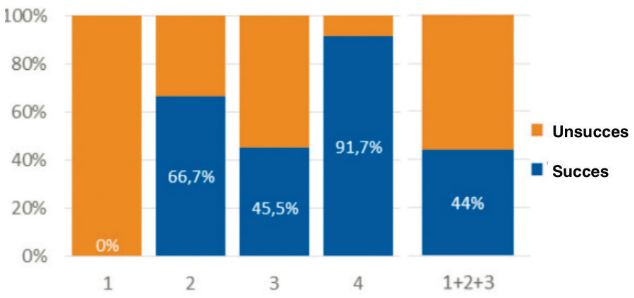

Fig. 3. Successful implantation of the electrode in the bundle branch using different techniques. Note: here and hereafter, DI refers to delivery introducer, 1 - on stylet, 2 - stylet+DI, 3 - controlled DI, 4 - modified controlled DI.

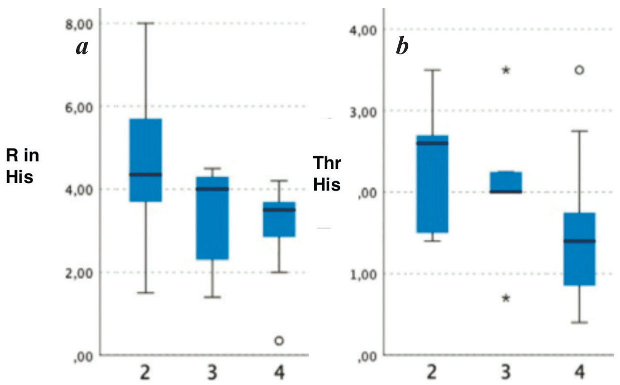

Fig. 4. Parameters of spontaneous activity detection (a) and bundle branch capture (b) during electrode implantation using different techniques.

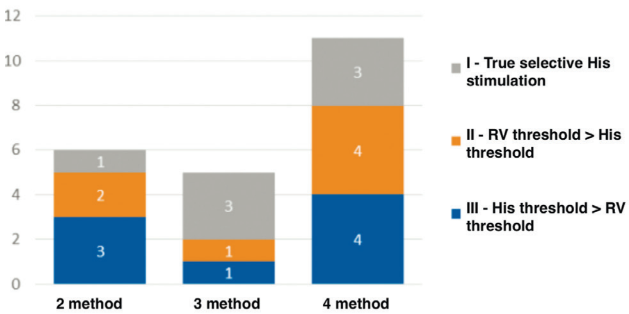

Fig. 5. Distribution of patients according to the type of bundle branch capture for 2, 3 and 4 implantation techniques.

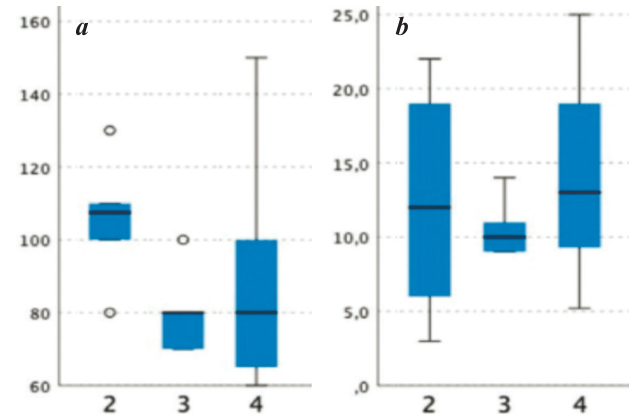

Fig. 6. Length of operation (a) and X-ray control (b) with the different techniques of electrode implantation.

er). In the remaining patients, the electrode in the bundle branch was the only one stimulating the ventricles.

The following techniques were used to implant the electrode in the bundle branch:

- on stylet - 6 (19%) patients;
- on stylet through DI - 9 (28%) patients;
- via controlled DI - 10 (31%) patients;
- via modified DI - 12 (37%) patients.

Two techniques were used in 5 patients: after ineffective stylet implantation (1 technique), implantation was attempted with an introducer and a stylet (2 techniques).

Implantation success

Patients were divided into 4 groups according to the techniques used. The efficacy of the different techniques for implanting the electrode in the bundle branch ranged from 0% for stylet implantation (group 1) to 92% for implantation with a modified controlled DI (group 4), although the differences found were not statistically significant (Fig. 3). The efficacy of implanting the electrode in the bundle branch with the modified C304 SelectSite CI was higher than with the other techniques (91.7% vs. 44%, p=0.006) (Fig. 3).

Electrode parameters for successful implantation

In this section, only the results of successful implantation of an electrode in the bundle branch region were examined. The amplitude of ventricular activity (p=0.203) and the bundle branch threshold (p=0.161) as well as the ratio of bundle branch threshold to ventricular myocardium were not significantly different between the groups (Fig. 4 and 5).

Length of surgery and X-ray control

There were no statistically significant differences when comparing patient groups in terms of duration of surgery (p=0.07) and X-ray control time (p=0.519) (Fig. 6).

DISCUSSION

Choosing an implantation technique

Since the first description of permanent pacemaker implantation in the bundle branch by Deshmukh et al. in 2000, the surgical technique has changed considerably [1]. In the first procedures, electroanatomical mapping was used to clarify the localisation of the bundle branch. The additional use of three-dimensional electroanatomical navigation increased the duration and cost of surgery without improving efficiency. Our clinic has also attempted electro-anatomical mapping of the bundle branch, but this technique was not routinely used because of the long duration of the procedure and the need for additional vascular access for insertion of the mapping catheter.

The first surgeries performed with the stent-implantation technique had low efficacy (35-67%) and required a large amount of time for surgery and X-ray control (1, 3-5). This is most likely since the stylet cannot ensure adequate contact of the electrode with the endocardium and reliable penetration of the fixation coil into the myocardium. The main advantage of stylet electrode implantation is the cost, which is comparable to that of a conventional permanent pacing system. The appearance of the C304 SelectSite controlled delivery system and the 3830 SelectSecure stylet-free electrode has made it possible to simplify and speed up the implantation technique considerably, although the characteristic feature of bundle branch pacing is still the high pacing threshold [6], which is most likely related to the absence of septal curvature. This feature prevents effective fixation of the electrode perpendicular to the endocardium. Nevertheless, thanks to the possibility of changing the curvature, the controlled CI C304 SelectSite allows to reach the AV sulcus in different anatomical features, especially in cases of marked atriomegaly.

The development of a specialized delivery uncontrolled DI with an additional curvature in the direction of interventricular septum C315His (Medtronic, USA) made the procedure highly effective, fast and simple [2, 7, 8]. At the same time, in some patient's anatomical peculiarities (especially dilatation of the right atrium) do not allow effective implantation of the lead into the conduction system, as C315His DI is not manageable and only applicable in relatively small hearts.

The limitations of available delivery systems have led to the development of new techniques for implanting electrodes in the bundle branch. One of these is the use of a telescopic system with the insertion of an uncontrolled C315His septal bend DI via a coronary sinus DI [9]. Another alternative implantation technique proposed by Orlov et al. 2019 involves the simultaneous use of a DI and a stylet [10]. The obvious advantage of this technique is the ability to implant any endocardial lead with active fixation. On the other hand, the use of DI increases the cost of the procedure, and the need for simultaneous control of DI, stylet and electrode during fixation of the latter greatly increases the complexity of the manipulation and the risk of complications. In recent years, the possibility of implanting Solia (Biotronik, Germany) stylet electrodes with a retractable coil into the conductive system has been reported, using special DIs with a Selectra 3D (Biotronik, Germany) septal bend [11, 12].

The advantages and disadvantages of the techniques for implanting electrodes in the bundle branch that we used in this study are listed in Table 1.

Implantation success

In the early years of bundle branch implantation in our clinic, different techniques were used, from implantation of standard electrodes with active fixation on a modified stylet [2] to the use of a modified guided insertion system. The main reason for changing the technique is the intraoperative success of the implantation. According to F. Zanon et al. implantation with DI is more likely to be successful than implantation with a stylet [7]. This correlation was also confirmed in our clinic (Fig. 3). Due to the lack of success of implantation with a stylet DI (group 2) and using the C304 SelectSite DI (group 3), attempts were made to manually modify the guided delivery system by giving it a septal bend. This increased implantation efficiency to 92% in 12 subsequent operations and made this technique more effective than the others. In the only implantation that was found to be ineffective in group 4, selective stimulation of the bundle branch was achieved, but due to a stimulation threshold above 3.5 V, the electrode was repositioned to the left bundle branch with satisfactory parameters.

In some patients in groups 2 and 3, implantation was attempted against a background of grade 3 AV block with an idioventricular replacement rhythm. They contributed significantly to the statistics of ineffective implantations due to the lack of antegrade potential of the bundle branch. Mapping of the bundle branch in the absence of spontaneous AV conduction is a significant physiological pacing problem for which there is currently no clear solution. Methods for mapping retrograde activation during ventricular pacing have been described, but are difficult to apply in daily practise [13].

Electrode parameters

The electrode parameters are significantly influenced by the fixation point of the electrode [14-16]. For example, O. Tang et al. have shown that a more distal (ventricular) electrode position is associated with a higher amplitude of ventricular signal than the atrial side of the tricuspid valve annulus [14]. Similar results were obtained by X. Liu et al, patients with more distal electrode fixation showed a higher amplitude of the R wave as well as a lower pacing threshold [15]. In our study, the amplitude of spontaneous activity was only marginally lower in groups 3 and 4. Considering the studies described above, this could be due to a more proxi-

Table 1.

Advantages and disadvantages of different techniques for implanting an electrode into the bundle branch

	Technique			
	1	2	3	4
Advantages	Price, standard tools	Fixation perpendicular to the endocardium	Curvature adaptable to different anatomies	Curvature adaptable to different anatomies, fixation perpendicular to the endocardium, possibility of implantation in the left bundle branch
Disadvanteges	Implantation time, difficult to manipulate, low probability of success, proximal electrode positioning, no possibility of implantation in the left bundle branch	High price, additional tool, difficult to manipulate, two tools (stylet and DI)	High price	High price

mal (atrial) electrode position. Furthermore, these differences may be due to anatomical features of the location of the bundle branch in relation to the endocardium [17] and the different depth of insertion of the fixation coil.

The type of bundle branch capture also depends on the location where the electrode is fixed. According to Y. Hu et al. implantation in the distal (ventricular) part of the bundle branch reduces the probability of selective capture compared to stimulation of the proximal part [18].

In our data, isolated selective capture of the bundle branch (without the possibility of ventricular myocardial pacing) was most common in the C304 SelectSite DI implantation group. Given the rather high threshold of bundle branch stimulation in this group and the relatively low amplitude of the R-waves, we assume that in this technique the electrode is attached at an acute angle and rather superficially in the area of the penetrating part of the bundle branch.

Length of surgery and X-ray control

The duration of the procedure to implant an electrode in the bundle branch depends on several factors: the surgeon's experience in performing electrophysiological studies and knowledge of the X-ray anatomy of the heart, experience in implanting electrodes in the bundle branch, and technical equipment. While the first operations described in the literature lasted up to 3 hours and required careful X-ray control (up to 35 minutes of X-ray) [1, 6], according to some authors, today the duration does not differ from traditional pacemaker implantation with minimal use of X-rays to performing the operation with the X-ray-free technique [19]. In our study, there was no significant difference in the duration of surgery and X-ray time, most likely due to the small group size.

CONCLUSION

The effectiveness of implanting an electrode into the bundle branch depends to a large extent on the surgical technique. Implantation of electrodes into the bundle branch by means of delivery devices opens the possibility of using conduction stimulation as an alternative to conventional electrocardiostimulation.

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