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LONG-TERM PERFORMANCE OF DOMESTIC ACTIVE-FIXATION ENDOCARDIAL PACING LEADS

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Aim. The aim of the study was to evaluate the long-term results of implantation of domestic endocardial leads (EL) with active fixation ELBI 233C-53 and ELBI 233C-58, implanted in the atrial and ventricular positions, respectively.

Methods. A total of 165 patients were included in the retrospective, single-center study. 239 EL were implanted from 2016 to 2018 (55 ELBI 233C-53 and 184 ELBI 233C-58). The median age was 78 years (43 to 92 years). 846 programming protocols were analyzed, which were carried out on the 1st day after implantation, and then every 6 months. Complications are divided into early (1-7 days) and late (8 days or more).

Results. In the EL ELBI 233C-53 group, there were no statistically significant changes in the pacing parameters during the observation period. There were 6 complications (10.9%): exit block (n=1, 1.8%), dislocation of the EL (n=3, 5.4%), damage to the EL structure (n=2, 3.7%). The number of reoperations was 3 (5.4%). In the ELBI 233C-58 group, a statistically significant increase in the pacing threshold was found (p=0.026). 13 (7.0%) complications were registered, including an increase in the pacing threshold (n=11.6%), exit block (n=1, 0.5%), damage to the EL structure (n=1, 0.5%). The number of reoperations in this group was 2 (1%).

Conclusion. EL ELBI 233C-53 and ELBI 233C-58 demonstrated acceptable pacing parameters and safety during observation. Complications occurred mainly in the first year after implantation. The number of repeated operations was low. There were no deaths caused by complications after lead implantation.

Key words: long-term results; active fixation endocardial pacing leads; early and late complications; parameters of ELBI 233C-53 and ELBI 233C-58.

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Every year, an increasing number of pacemakers (PM) are implanted worldwide [1]. Endocardial electrodes (EE) are the most vulnerable in the cardiac pacing system. With the advent of dual and triple chamber devices and the ability to upgrade the cardiac pacing system, the number of EEs implanted in one step is increasing. The longer the period after implantation of EE, the higher the risk of functional impairment (increase in stimulation threshold, blockage of impulse delivery, injury to insulation or breakage of electrode conductors) [2, 3]. Some of these problems can be solved by programming the PM, e.g. by increasing the stimulus amplitude when the stimulation threshold is high or by switching the PM to monopolar stimulation mode when one of the EE conductors is interrupted. However, in some cases, these measures have a temporary effect or are ineffective. In this case, the solution is repeated surgery, repositioning or replacement EE, which increases the risk of infectious complications [4]. Furthermore, when a new EE is implanted, the question arises of what to do with the remaining non-functioning electrode. Not all clinics, especially in Russia, have electrode-extraction systems at their disposal, and removal of an EE as early as 1 year after implantation by simple traction is associated with a high risk of complications [5]. Many countries maintain registries of patients with implanted devices as well as clinical trials to assess the reliability, durability and safety of implanted EEs [6]. This provides information about the 5-year "survival rate" of electrodes and the number of complications related to the technical component of EE, rather than the experience of a particular center or operator [7-9]. Based on the results of some studies, a decision can be made to withdraw certain EE models from the market [10].

EEs from different manufacturers and even different models from the same manufacturer differ in their technical characteristics (active or passive fixation, silicone or polyurethane coating, electrode diameter), so it is important to have reliable retrospective data to decide about implanting one or the other EE model. Under conditions of import substitution, demand for the products of domestic enterprises is forced to grow. We did not find any information in the literature on the long-term results of using Russian-made electrodes.

The aim of this study was to evaluate long-term outcomes after implantation of the ELBI 233C-53 and ELBI 233C-58 bipolar steroid-eluting devices with active fixation and silicone coating from Elystim-Cardio (Moscow, Russia), implanted in both atrial (right atrium) and ventricular (right ventricular apex) positions.

METHODS

A retrospective, single-center study included 165 patients who had 239 EEs implanted between 2016 and 2018: 55 ELBI 233C-53 and 184 ELBI 233C-58. The criterion for exclusion from the study was loss of communication with the patient or inability to conduct programming as planned. The endpoints were electrode replacement/removal or patient death. The mean follow-up time was 11.9±7.5 months (maximum 24 months). The clinical characteristics of the patients are shown in Table 1.

Electrodes were implanted through the brachial (141 EE, 59%), subclavian (86 EE, 36%), or external jugular vein (12 EE, 5.0%). In our study, the choice of the target vein was determined by the anatomical features of the patient and was staged. We started with isolation of the brachial vein (59% of implantations). In case of hypoplasia, it was impossible to lead two EEs through one vein, as well as in case of obstruction at the place of the confluence with the subclavian vein, puncture of the latter was performed (36% of cases). Finally, if puncture of the subclavian vein was impossible, access to the external jugular vein was made (5%) [11].

We analyzed 846 programming protocols that were performed on the first day after implantation and every 6 months thereafter. Programming was performed using the programmer Elystim-Cardio Progrex-060 (Version 5.20).

All complications were divided into early (1-7 days) and late (8 days or more). Electrode dislocation was diagnosed during PM programming by absence of myocardial capture or electrode stimulation of another heart chamber and confirmed by radiography. High stimulation thresholds included values greater than 2.5 V with a stimulus duration of 0.4 ms. EE structure damage was defined as impaired sensitivity/stimulation and/or significant changes in electrode impedance (<300 ohms, >2000 ohms, or impedance changes greater than 30% of the previous programming level).

Statistical analysis

Statistical analysis was performed using StatTech v. 1.2.0 (developer - StatTech LLC, Russia). Quantitative indices were evaluated for their correspondence to a normal distribution using the Kolmogorov-Smirnov criterion. Quantitative measures with a normal distribution were described using arithmetic mean (M) and standard deviations (SD), 95% confidence interval (95% CI) limits. In the absence of a normal distribution, quantitative data were described using median (Me) and lower and upper quartiles (Q1-Q3). One-factor analysis of variance with repeated measures was used to compare three or more related groups on a normally distributed quantitative trait. Statistical significance of changes in the index in dynamics was assessed using Pillai's Trace. When comparing three or more dependent populations whose distribution differed from normal, we used the nonparametric Friedman criterion with posterior comparisons using the Wilcoxon criterion with Holm correction.

RESULTS

The parameters of ELBI 233C-53 electrodes in the atrial position (right atrial auricle) on the first day after implantation and in subsequent observations are shown in Table 2. These values were comparable with published data on atrial electrodes from other manufacturers [9, 12, 13]. Analysis showed no statistically significant changes in threshold, sensitivity, and impedance during the observation period (p = 0.883, 0.714, and 0.421, respectively).

Parameters of ELBI 233C-58 electrodes in ventricular position (right ventricular apex) are shown in Table 2. They were comparable with the published data of other studies on ventricular electrodes with active fixation [3, 14]. During the analysis of the dynamics of the ES threshold, we found its statistically significant increase (p=0.026). At the same time, there were no statistically significant changes in sensitivity and impedance (p=0.72 and 0.922, respectively).

Complications

Six complications (10.9%) related to atrial electrodes were identified in 5 patients (2 complications were registered in one patient). Complications related to ventricular electrodes were registered in 13 patients (7.0%).

Electrodes ELBI 233C-53

In the early postoperative period, in 1 (1.8%) patient there was a block of the impulse output along the atrial electrode, which required a repeated operation - electrode replacement. Late complications were detected in 5 patients (9.0%). Three cases (5.4%) of electrode dislocation occurred between 8 days and 11 months and required repositioning in only 2 cases (3.6%), since in the third patient the atrial electrode was disconnected during programming due to development of a permanent form of atrial fibrillation. Also in 1-12 months, 2 (3.6%) electrode structure damage was detected (in 1 case, elec-

Table 1.

Clinical characteristics of patients

Indicator	Value
Age, years*	78 (43;70-81.5;92)
Male gender, n (%)	75 (45.4)
Coronary heart disease, n (%)	157 (95.2)
Arterial hypertension, n (%)	4 (2.4)
Chronic rheumatic heart disease, n (%)	4 (2.4)
Sinus node weakness syndrome, n (%)	40 (24.2)
AVB blockade II/III, n (%)	9 (5.4) / 24 (14.6)
Binodal disease, n (%)	27 (16.4)
AF, subtotal / complete AVB, n (%)	29 (17.6) / 32 (19.4)
AFt, subtotal / complete AVB, n (%)	2 (1.2) / 2 (1.2)

Note: * - values are presented as median (25 and 75 quartiles); AVB - atrioventricular block, AF - atrial fibrillation; AFt - atrial flutter.

trode impedance decreased to 150 ohms, and in 1 case, it increased to 3000 ohms in bipolar mode, 450 ohms in monopolar mode). These changes did not affect the functioning of the electrode and did not require surgical intervention, since the patient was not PM-dependent (Table 3). Thus, the number of reoperations in the atrial electrode group was 3 (5.4%).

Electrodes ELBI 233C-58

Early ventricular electrode complications were noted in 8 (4.3%) patients. Of these, in 6 cases (3.3%) there was an increase in the threshold (to a maximum of 3.75 V), which required reprogramming and prescription of anti-inflammatory therapy. In 1 (0.5%) case, impulse output block was detected (electrode repositioning was performed) and in another 1 patient (0.5%), impedance increase over 2000 ohms was noted, which did not affect electrode functioning; the patient is under dynamic observation. In 5 (2.7%) patients there were late complications (1-15 months) - increase of the threshold in all cases. Reoperation, namely replacement of the ventricular electrode, was required in 1 case (0.5%) due to increased threshold (Table 3). The total number of reoperations in the ventricular electrode group was 2 (1.0%).

DISCUSSION

Bipolar electrodes ELBI 233C-53 and 233C-58 have active fixation in the form of a microscrew on the distal end, covered with silicone insulation. The length of the electrodes is 53 and 58 cm, respectively. For easy orientation between the electrodes when implanting a dual-chamber PM, the connector part of the ELBI 233C-53 is marked with a green ring marker. The material of the anode is titanium covered with iridium oxide; the cathode is made of platinum-iridium alloy, also covered with iridium oxide. The amount of dexamethasone in the distal part of the electrode is 0.65 mg.

The electrodes are supplied with 3 styli - straight, 0.39 mm diameter (with a green tip) and 0.35 mm diameter (with a yellow tip), as well as a 0.35 mm diameter J-shaped stiletto (with a yellow-green tip). It is worth noting that the J-stilet for ELBI 233C-53 has an “anatomical” bend in 2 planes, frontal and sagittal, which greatly facilitates its positioning in the appendage of the right atrium.

The maximum electrode diameter is 7.5 French (Fr). This is larger than the diameter of silicone-coated electrodes from other manufacturers available on the market today (e.g., Beflex RF 45D and 46D (Sorin Group), and the Cary Fix Novus 5076 (Medtronic), which have a maximum diameter of 6 Fr). In the clinic, the diameter of the electrode matters in the choice of surgical access. For example, the size of the brachial vein often does not allow two 7.5 Fr electrodes to be inserted simultaneously, or after successful insertion, the electrodes are so closely spaced that free positioning inside the heart is difficult due to mutual friction reinforced by the silicone coating. Also, difficulties may arise when introducing additional electrodes with a large diameter through the subclavian vein, when there are already previously implanted electrodes in it and there is a narrowing of the vein lumen, making it difficult to pass additional electrodes. Therefore, the development and introduction of electrodes with a smaller diameter would solve a number of technical problems arising during the implantation procedure. The mechanism of active fixation implies greater stability of the electrode-endocardium contact, which is manifested by a lower percentage of dislocations in the early and late postoperative period. Our study revealed 5.4% of late atrial electrode dislocations, which is comparable or slightly higher than this in other studies [9, 12, 13]. At the same time, no dislocations were detected in ventricular electrodes, which is superior to similar data of foreign studies [14]. On the one hand, this can be explained by

Table 2.

Analysis of dynamics of electrostimulation threshold, sensitivity and impedance of ELBI 233C-53 and ELBI 233C-58 electrodes

Indicator	Stages of observation										p
	1 day		2 days-6 months		7-12 months		13-18 months		19-24 months		
Electrodes ELBI 233C-53											
Pacing threshold, V, M±SD	0.85 ±0.56	0.69-1.01	1.02 ±0.52	0.83-1.2	1.01 ±0.39	0.82-1.19	1± 0.26	0.8-1.2	0.89 ±0.44	0.75-1.03	0.883
Sensitivity, mV, M±SD	2.7 ±1.81	2.17-3.22	2.61 ±1.79	1.97-3.24	2.09 ±1.15	1.55-2.63	2.97 ±2	1.46-4.48	2.35 ±1.66	1.84-2.85	0.714
Impedance, Ohm, Me, Q1-Q3	624	550-723	650	552-788	592	554-711	613	550-766	630	546-750	0.421
Electrodes ELBI 233C-58											
Pacing threshold, V, M±SD	0.62 ±0.21	0.38-0.87	0.83 ±0.13	0.68-0.98	1.1 ±0.87	0.1-2.1	1.15 ±0.38	0.71-1.58	1.23 ±0.39	0.78-1.68	0.026
Sensitivity, mV, M±SD	13.2	7.28-14.4	14.4	8-14.4	14.4	8-14.4	14.4	9.6-14.4	14.4	14.4-14.4	0.72
Impedance, Ohm, Me, Q1-Q3	752 ±241	475-1030	678 ±96.7	567-789	675 ±128	528-823	715 ±196	489-941	722 ±152	547-897	0.922

Note: ES - electrocardiostimulation.

the fact that in our study all ventricular electrodes were in the apex of the right ventricle, which initially suggests greater stability of the electrode, although even in this case there remains the possibility of its dislocation in the following situations: in the early postoperative phase due to the lack of control of good contact of the electrode with the endocardium in the implantation phase (control of screw exit from the electrode by X-ray marker, test with breathing and coughing, careful fluoroscopic control of the movement of the electrode tip after unscrewing the screw, endogram shape); in the early and late postoperative phase due to external causes (Tweedler or Reel syndrome, closed thoracic trauma with electrode traction, and some others) [15].

Considering the clinical relevance of these data, the low probability of ventricular electrode displacement is certainly favorable in terms of patient safety, especially if the patient is PM-dependent.

The relatively high frequency of dislocations of atrial electrodes, as shown in various studies [13, 16], can be explained by the absence of a J-shape at the distal part of the electrode, which is characteristic of passive electrodes where such a pre-shape is a fixation mechanism in the trabeculae of the right atrium. The atrial electrode with active fixation is fixed only by a microscrew, and its stability is not maintained by the curved shape. It can be assumed that the criteria described above for the stability of an electrode with active fixation should be observed even more strictly when implanting an electrode in the atrial position to reduce the number of dislocations and thus the number of repeated surgical interventions.

It is well known that implantation of an electrode through the subclavian vein carries the risk of pneumothorax as well as damage to the electrode in the subclavian vein, as it runs through the riboclavicular ligament [17, 18]. When analyzing the causes of electrode damage, we found that both atrial electrodes that had impedance changes were implanted through the subclavian vein. At the same time, both ventricular electrodes, which also had impedance changes, were implanted through the brachial vein. Thus, there was no clear correlation between the probability of electrode damage and the vein through which the implantation was performed. This may be due to both the small sample of patients and the small number of electrode lesions (two in each group). In the case of ventricular electrodes, it is not possible to talk conclusively about where the electrodes are damaged and the possible causes before the revision. In our experience with electrodes from other manufacturers, even access via venipuncture of the brachial vein does not guarantee long-term preservation of the electrode insulation, as excessive forces when tightening the ligature around the vein without using a coupling can also lead to damage to the insulation early after implantation.

The main complication in the ventricular lead group was a significant increase in pacing threshold, found both early (7 cases, 3.8%) and to a lesser extent late (5 cases, 2.7%) after surgery. Conservative methods, i.e. increasing the stimulus amplitude and prescribing anti-inflammatory therapy, reduced the stimulus threshold in 10 cases (5.4%), but two patients underwent repeated surgery - repositioning and electrode replacement - due to the ineffectiveness of conservative therapy. Several possible reasons for the increase in the threshold of irritation have been described in the literature, and the relationship between the development of the complication and the timing after surgery provides the key to understanding these reasons [15, 19]. If there is an increase in pacing threshold or blockage of output hours or days after implantation, electrode displacement or cardiac perforation are the most likely causes. Loss of traction several weeks or months after surgery is mainly due to the fouling of the electrode with connective tissue sleeve. This variant is rare nowadays, as all modern electrodes have a steroidal coating on the distal end. Finally, an increase in the stimulation threshold after several months or years is most often associated with damage to the metal conductor or electrode insulation, and possibly with depletion of the pacemaker battery. In addition, reversible causes must be ruled out in all cases, such as metabolic disorders, myocardial ischaemia and the use of various pharmacological drugs that can increase the stimulation threshold [20].

The tactics for managing a patient with this complication in our study was as follows. If an output blockage occurred early after implantation, an urgent repositioning or electrode replacement was performed. In the case of the early output blockade of ELBI 233C-53, the electrode was replaced. The surgeon's motivation to perform the replacement instead of reducing the EE remained unknown (there were no records in the medical history).

If the stimulus threshold was high, non-steroidal anti-inflammatory drugs were administered early and the stimulus amplitude was increased threefold, followed by programming every 1-2 days until there was a ten-

Table 3.

Complications of ELBI 233C-53 and ELBI 233C-58 electrodes

Complications	Timeline	n	%	Treatment
Electrodes ELBI 233C-53				
Exit Block	Up to 8 days.	1	1.8	Electrode replacement
Dislocation	8 days. -11 months.	3	5.4	Repositioning/ replacement
Damage to the EE structure	1-12 months.	2	3.6	Surveillance, RP
Electrodes ELBI 233C-58				
Exit Block	1-7 days.	1	0.5	Repository
Impedance >2000 Ohms	1-7 days.	1	0.5	Observation
High stimulation threshold	1-7 days.	6	3.3	RP, NSAIDS
	1-15 months.	4	2.2	RP
	2 months.	1	0.5	Electrode replacement

Note: EE - endocardial electrode; RP - reprogramming; NSAIDs - non-steroidal anti-inflammatory drugs.

dency for this parameter to decrease. Further programming was performed as usual (in 3-6, 9-12 months). If the complication occurred after 2 months and later, the electrode was replaced/repositioned if it was not possible to programme a double amplitude reserve. In this case, dislocation and/or damage to the electrode was ruled out in the initial phase by the chest X-ray in the "hard" X-ray mode. We replaced one ELBI 233C-58 at a late date (2 months after implantation) due to an increased stimulation threshold. The former electrode was removed without technical difficulties by traction, and there was no damage to it.

With the experience gained in implanting the ELBI 233C-53 and ELBI 233C-58 electrodes, we had a request to the manufacturer to improve the design and facilitate the implantation of these electrodes. This applies first and foremost to the stylet supplied with the electrodes. As stated above, these are 2 straight stylets with different thicknesses and therefore different degrees of stiffness. It was observed that in some cases it was impossible to position the lead in the right ventricle with a straight stylet, even with the least stiffness, because the stylet could not be passed along the course of the lead through the tricuspid valve into the right ventricle. The stylet as if "straightened" the electrode, which resulted in its dislocation into the right atrium. The problem was solved by replacing the stylet with imported analogues, smaller in diameter and "softer". Therefore, we believe that adding another stylet of lower stiffness to the kit would solve this problem and use only the "native" stylets during the operation.

The second design feature concerns the active locking micro-screw. In some situations, when the electrode is implanted through the brachial vein, especially when it is obstructed by tortuosity or an inconvenient angle of entry into the subclavian vein and the electrode has to be pushed along the vein with some force, an unintended unscrewing of the screw and entrapment of the screw into the venous wall has been observed. This hindered the further free movement of the lead and required the screw to be screwed back, which not only prolonged the operation time and made the work more difficult, but also posed a certain risk to the patient (vein perforation, possible damage to the tricuspid valve). We believe that the fixation mechanism should be improved to avoid such complications.

CONCLUSION

ELBI 233C-53 and ELBI 233C-58 electrodes demonstrated acceptable parameters of sensitivity, acute and chronic stimulation thresholds, and safety during the observation period. With a relatively high rate of early and late postoperative complications, which occurred predominantly in the first year after implantation, the rate of reoperation was low (5.4% in the atrial group and 1% in the ventricular electrode group). A somewhat higher number of complications in ELBI 233C-53 electrodes in the atrial position is explained by their more frequent dislocation, which is probably due to the peculiarities of electrode fixation in the ear of the right atrium with the formation of a J-shaped loop. No deaths caused by complications after electrode implantation were detected.

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