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Device and methods for performing transesophageal stimulation at reduced pacing current threshold

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Abstract. In order to reduce pacing current threshold in transesophageal stimulation, a novel multichannel transesophageal pacemaker and multichannel esophageal lead has been developed. Three different approaches to reduce pacing current threshold were clinically studied. Precise positioning of the pacing dipole allowed reduction of pacing current threshold on average by 20% over the standard bipolar transesophageal method in approximately 50% of patients. Use of a chest electrode lowered pacing current by up to 7 mA over standard bipolar transesophageal method in 60% of patients. A novel method of combining very short electrical pulses (splitting the impulse) from different locations, which gives desired current density and pulse length in the target tissue, has been elaborated. As a result, the stimulation is less painful for the patient than the routinely used single 10 ms current pulse. The proposed methods allowed successful atrial capture in all patients.

Key words: transesophageal pacing, threshold current, chest electrode.

1. INTRODUCTION

Transesophageal atrial stimulation (TAS) is widely used in evaluation and treatment of supraventricular (SV) arrhythmias. It can yield important information in most situations where invasive atrial stimulation is usually done, but is safe, rapid, inexpensive and can often be performed in an outpatient setting. TAS can initiate and terminate SV tachycardias [1,2] and atrial flutter [3], and predict the risk of potentially lethal SV arrhythmias in asymptomatic Wolff–Parkinson–White syndrome patients [4]. TAS has been recently implemented in surgery. SV arrhythmias represent an intraoperative risk factor during general anesthesia. The use of antiarrhythmic drugs is accompanied by intrinsic hazards, such as proarrhythmic and toxic effects as well as severe bradycardia immediately after the induction of anesthesia [5].

As the inducibility and causative mechanisms of arrhythmias induced by TAS have shown an excellent correlation with findings in a subsequent invasive electrophysiological study, it has become a simple, predictive, and inexpensive method of testing the antiarrhythmic/arrhythmogenic properties of drugs used for sudden cardiac death risk stratification and prediction of antiarrhythmic drug treatment benefits and drawbacks in various heart diseases [[6,7]]. Numerous reports have confirmed that TAS is a rapid, safe and effective means for evaluating and terminating SV arrhythmias in the pediatric population including infants [[8,9]], as well as for localization of ventricular preexcitation sites before ablation procedures [[10]].

The method is frequently used as a diagnostic option in coronary artery disease patients, as a modification of the stress test or in TAS stress echocardiography, which correlates well with myocardial perfusion stress scintigraphy and coronary angiography [[11,12]].

TAS is feasible because of the proximity of the esophagus to the posterior wall of the left atrium – the distance (approximately 5–6 mm) remains constant in patients of different age and weight [[13]]. Atrial capture can be obtained in more than 95% of patients. Pacing usually produces certain thoracic discomfort, mainly a burning chest sensation that most patients tolerate; nevertheless, minimizing of the pacing threshold is highly desirable and corresponding studies have been performed from the very early years of the development of this method [[14]]. The lowest threshold currents can be reached at pulse widths between 10 and 20 ms and are between 5 and 15 mA depending on the patient.

Widely studied methods of reducing the stimulus current include finding the optimal position for the pacing electrode, finding suitable position of the patient [[15,16]] and geometrical modification of the electrode. In this paper we propose a multichannel transesophageal pacemaker and three methods of utilizing it to reduce pacing current threshold and patient discomfort. Precise positioning of the pacing dipole allowed reduction of the pacing current threshold on average by 20% over the standard bipolar transesophageal method in approximately 50% of patients. Use of the chest electrode lowered pacing current up to 7 mA more than the standard bipolar transesophageal method in 60% of patients. We elaborated a novel method of combining very short electric pulses (splitting the impulse) from different locations, which resulted in desired current density and pulse length in the target tissue. As a result, the stimulation is less painful for a patient than the routinely used single 10 ms current pulse. The proposed methods allowed successful atrial capture in all patients with whom the standard bipolar transesophageal method was successful.

2. MATERIAL AND METHODS

2.1. Multichannel transesophageal pacemaker

The main goal of the study was to develop a laboratory device and methods suitable for programmed electrical stimulation protocols with reduced patient discomfort. The laboratory device implements a behavioural model and specifications developed and coordinated with specialists of the Estonian Institute of Cardiology. The laboratory device developed allows the energy of the stimulating current pulse to be split between multiple combinations of electrodes in space and time. Design of the device conforms to European standard EN 60601-1:1990 "Medical electrical equipment-Part 1: General requirements for safety" and to its amendments A1:1991, A11:1992, A12:1992, A2:1993 and A13:1995.

The main components of the laboratory device (Fig. 1) are a transesophageal catheter with multiple electrodes 1, body electrodes 2 and a programmable commutator 3 controlled by a programmator 5, which allows each electrode or combinations of electrodes to be connected to the current pulse generator 4. The current pulse generator 4 has interfaces to specify pulse current 9 and length 11. The main principles of the laboratory device are protected under useful model No. EE 00542 U1. A standard PC, National Instruments peripheral devices, programmable current pulse generator E53002-01 and self-made programmable commutator were used to implement the laboratory device. The application software was developed using the LabView development environment.

The laboratory device enables the current pulse to be split into 2 ms subpulses. Each subpulse may be applied to a different electrode or electrode set pair with desired polarity. The amplitude of each subpulse can be reduced from 0 to 100%, thus effectively altering the shape of the stimulus pulse. The maximum pulse current, voltage and duration are hardware-limited for safety considerations.

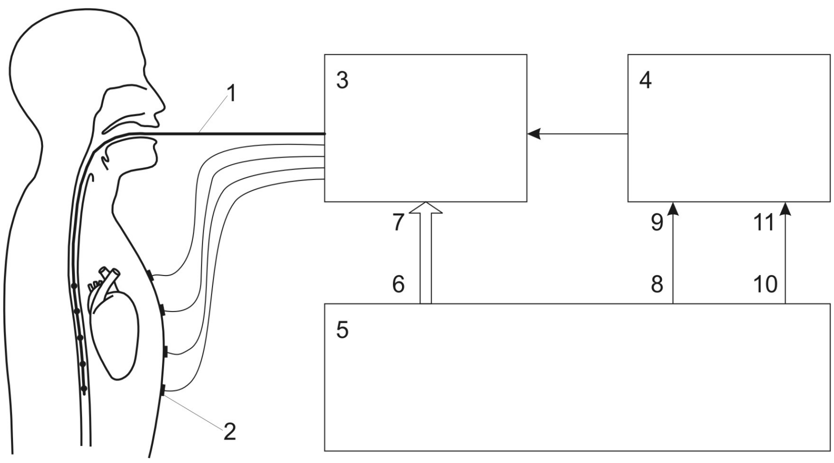

Fig. 1. Laboratory device.

2.2. Precise positioning of the pacing dipole

The optimal position of the esophageal pacing electrode has been a subject of continuous discussions since this method was invented. To evaluate the dependence of the pacing threshold current on the electrode position, a special study was performed on 15 patients. The intermediate electrode was positioned in the process of localization of maximal unipolar atrial electrogram (Fig. 2).

By gradually increasing the pacing current until stable capture of atrial pacing was confirmed by surface ECG, the pacing threshold of all 9 electrode positions was found.

2.3. Additional chest electrode

We evaluated use of the chest electrode in 34 patients aged from 19 to 66 years (22 with sick sinus syndrome, six with paroxysmal supraventricular tachycardia, five with Wolff–Parkinson–White syndrome and one with unexplained syncope), who underwent a routine TOE electrophysiological study in the Department of Cardiac Arrhythmias of the Estonian Institute of Cardiology. A standard bipolar transesophageal catheter was inserted through the mouth and pacing was performed at interelectrode spacing of 40 mm and pulse duration of 10 ms. Different interelectrode spacings and pulse durations were not studied as they have no considerable effect on the pacing threshold [[14]]. The current output was gradually increased until stable capture of atrial pacing was accomplished, which was confirmed by surface ECG.

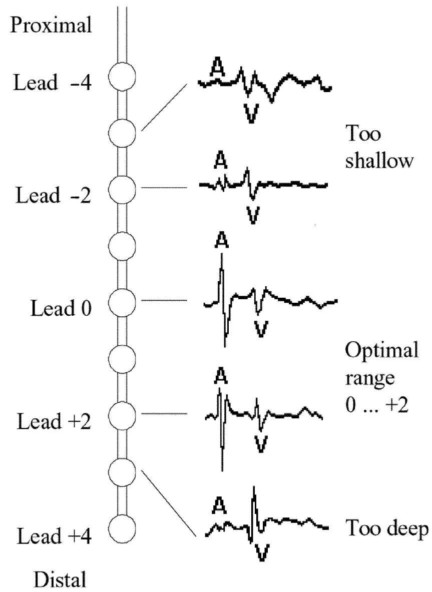

Fig. 2. Positioning catheter.

The second part of the study included the use of an external chest electrode (defibrillator electrode of 100 mm diameter), placed beneath the back between scapulae. It was electrically connected to the distal electrode of the esophageal catheter and the pacing threshold was determined again. In all tests the overall voltage of the pulse as well as the current distribution between the chest electrode and the distal esophageal electrode were measured using a multichannel oscilloscope.

2.4. Split stimulus pulse

In clinical practice, transesophageal cardiac pacing usually causes patients discomfort or pain. The level of discomfort is highly individual and depends on the tolerance to electrical current. The idea behind the proposed method is based on the hypothesis that discomfort and pain could be reduced by shortening the duration of the electrical stimulus.

The study was performed in 17 patients aged 22 to 54 years (nine with sick sinus syndrome, four with paroxysmalsupraventricular tachycardia, three with Wolff–Parkinson–White syndrome and one with unexplained syncope) who underwent routine transesophageal study.

The catheter, with a diameter of 3.5 mm, had 9 electrodes with interelectrode distance 10 mm and 5.5 mm stainless steel balls laser-soldered to the original electrodes (Fig. 3). Initial catheter depth of insertion (DOI) was calculated using the formula DOI = patients height/5 + 5 cm for the middle electrode (Lead 0). Lead 0 was connected to the ECG and A-wave was maximized on the electrogram by gradually withdrawing the catheter (Fig. 2).

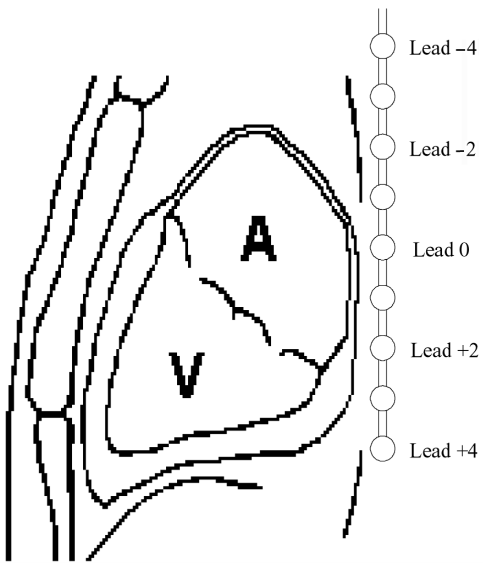

Fig. 3. Modified multilead catheter.

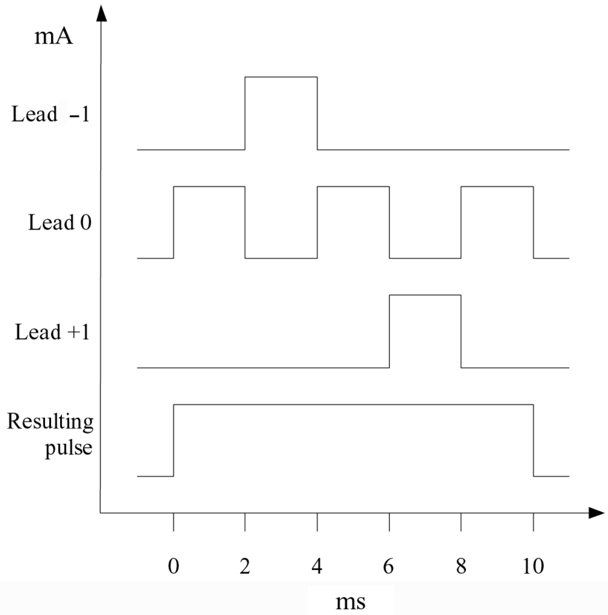

Fig. 4. Pulse splitting.

The lead set, exhibiting minimum pacing threshold, was determined (Fig. 3). The effect of splitting the stimulating pulse between multiple leads on atrial pacing threshold was studied (Fig. 4).

The current pulse with length of 10 ms was split as follows:

1) 2 ms at the lead, exhibiting the minimum atrial pacing threshold, determined in phase I of the study;
2) 2 ms at the proximal lead, adjacent to the lead exhibiting the minimum atrial pacing threshold, determined in phase I of the study;
3) 2 ms at the lead, exhibiting the minimum atrial pacing threshold, determined in phase I of the study;
4) 2 ms at the distal lead, adjacent to the lead, exhibiting the minimum atrial pacing threshold, determined in phase I of the study;
5) 2 ms at the lead, exhibiting the minimum atrial pacing threshold, determined in phase I of the study.

Again, the pacing current was gradually increased until stable atrial capture was confirmed by surface ECG. After completing the stimulation protocol, the stability of the intermediate Lead 0 at the position of maximal unipolar atrial electrogram was re-confirmed.

3. RESULTS

3.1. Precise positioning of the pacing dipole

The results show that optimal position of the esophageal lead is 1 cm distal to the maximal unipolar atrial electrogram registration point (Fig. 5, Table 1). Anode position 0 denotes the intermediate electrode, positioned at the localization maximal unipolar atrial electrogram. Positive numbers represent anode positions

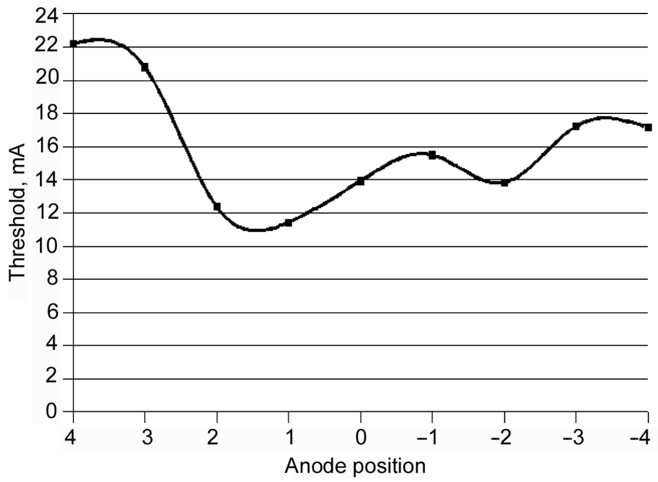

Fig. 5. Pacing threshold dependence on the anode position.

Table 1. Optimal lead position dependence on the patient

Patient No.	Lead position			Reduction, %
	–2	–1	0	
1	8	9	12	12.5
2	16	13	25	
3	13	13	15	
4	9	14	14	55.6
5	13	13	25	
6	12	10	9	11.1
7	11	12	17	9.0
8	13	8	7	14.3
9	12	13	11	18.2
10	10	17	16	
11	20	18	15	20.0
12	14	13	25	
13	13	9	16	
14	13	11	12	
15	22	17	20	
Tot/Avg	4	7	4	20.10

distal to position 0 in centimeters. Negative numbers represent anode positions proximal to position 0 in centimeters. Stimulation points 1 cm to distal or proximal to optimal position also assure acceptable pacing thresholds. Removal of anode position in the proximal direction is accompanied by significant elevation of the pacing threshold; the same is observed if the anode is placed more than 2 cm distal from the maximum atrial electrogram location. The optimal position of esophageal lead is patient-dependent (Table 1).

Highlighted cells show the optimal lead position for each patient. In 8 of 15 patients, the individual optimal position differs from the average. By selecting lead configuration according to the individual patient, pacing current threshold was reduced in 8 of 15 patients by 9 to 55%, 20% on average.

3.2. Additional chest electrode

Main results are presented in Table 2. The patient count denotes the number of cases where the given current threshold was sufficient for successful atrial capture. Success rate denotes cumulative percentage of cases where the given current threshold would be sufficient for successful atrial capture. Both figures are given both for reference study, i.e. using transesophageal lead only, and for simultaneous use of transesophageal lead and chest electrode.

The results show that successful atrial capture at pulse current 16 mA or less was feasible in more than 80% of patients, and the current of 19 mA would have been sufficient for capture in 100% of patients (Fig. 6a).

Using a external chest electrode, connected in parallel with distal esophageal electrode, allowed effective atrial capture in more than 80% of patients at pacing pulse current 13 mA or less, while 19 mA was required for 100% capture (Fig. 6b).

Table 2. Pacing thresholds

Threshold, mA	Reference		With chest electrode	
	Patient count	Success rate, %	Patient count	Success rate, %
7	1	3		0
8	0	3	4	12
9	1	6	5	26
10	1	9	5	41
11	5	24	5	56
12	6	41	4	68
13	5	56	5	82
14	4	68	2	88
15	2	74		88
16	7	94	2	94
17	1	97		94
18		97	2	100
19	1	100		100

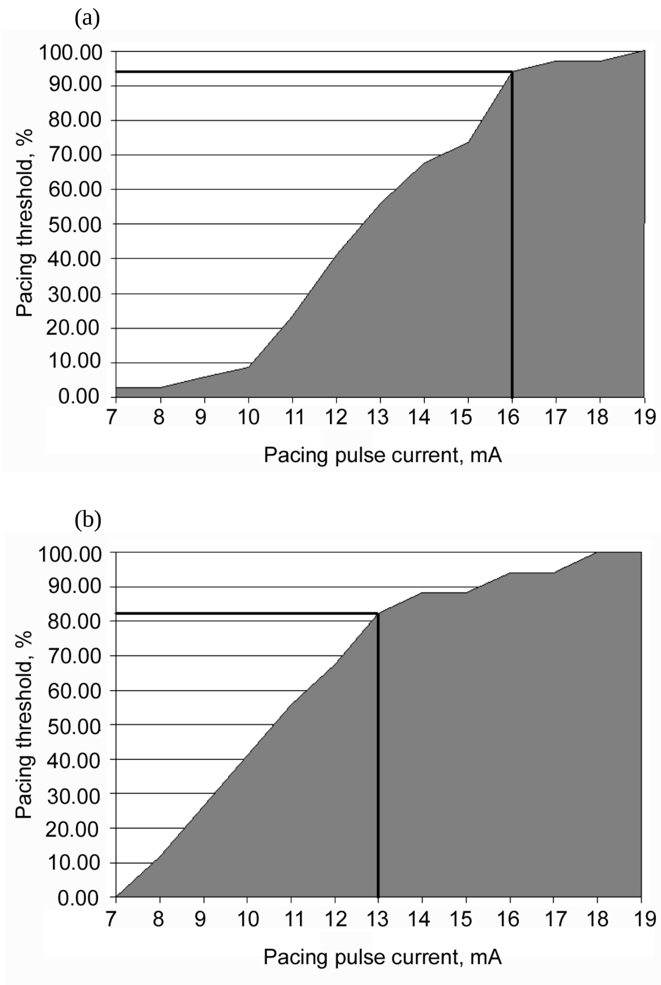

Fig. 6. Pacing threshold (minimum pacing current required to perform TOE) with transesophageal lead only (a) and transesophageal lead with chest electrode (b).

3.3. Split stimulus pulse

The main results are presented in Table 3.

Table 3. Pacing thresholds

Change in pacing threshold, %	Number of patients
–15–0	4
1–15	5
16–30	6
>30	2

In 4 patients, the use of the proposed method was not accompanied by increased atrial capture current. On the contrary, in some cases the atrial capture current was even reduced. In 5 patients, a somewhat higher (from +7 to +13%) pacing threshold was recorded. Significantly higher pacing thresholds were recorded in 6 patients and unexpectedly high thresholds were assessed in 2 patients. The reason behind the dramatic increase of pacing requires further study.

4. DISCUSSION

There are two main sources of discomfort in the TOE electrophysiological study – the initial introduction of the pacing catheter into the esophagus and the burning sensation caused by the pacing current. The pacing threshold (and current strength) can be reduced by modifying certain parameters: the position of pacing electrodes, construction of electrodes, distance between electrodes and the duration and shape of the pulse. The proposed multichannel transesophageal pacemaker with multichannel catheter allows the best position of electrodes for successful atrial pacing to be quickly achieved without moving the catheter inside the esophagus. Incorporating an ECG module in the pacemaker would make it possible to find the best position fully automatically. We introduced the simultaneous use of multiple esophageal and chest electrodes as a way to reduce the pacing threshold. Utilization of an additional chest electrode connected electrically in parallel with a distal esophageal electrode resulted in pacing threshold reduction of 2 to 7 mA in 50% of cases (Fig. 7), and more than 80% of patients were found to have a pacing threshold of 13 mA or less (Fig. 6b). It is worth mentioning that during atrial stimulation the current through chest electrode was 82 ± 13% (M ± SD) of total pacing current. The voltage required dropped from 19.8 ± 5.8 V (the reference study) to 14.2 ± 2.6 V (M ± SD) using the chest electrode.

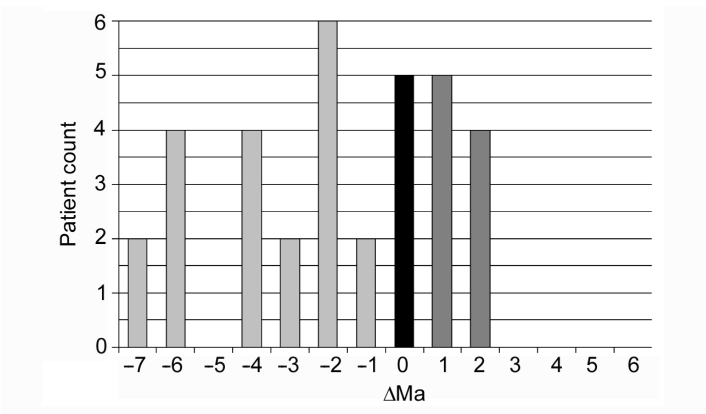

Fig. 7. Pacing threshold reduction using esophageal lead with chest electrode compared to using only esophageal lead. Negative numbers denote reduction in mA (desired effect), positive numbers denote growth of the pacing threshold.

It is generally accepted that stimulus duration reduction results in elevated threshold levels if the duration of stimulus is less than 10 ms. Enlargement of the electrode surface area results in smaller current density in surrounding tissue. At the same time, a current density of 5 mA/cm^2 in heart tissue is required for successful capture [17]. We suggest that combining very short electric pulses from different locations results in the desired current density and pulse length in the target tissue.

As the result, the stimulation could be less painful to the patient than the use of a single 10 ms current pulse. The tissue inside the 2.5 mm circle, shown in Fig. 5, is considered to be the subject to at least 5 mA/cm^2 current density [18].

Applying short current pulses to the shaded electrodes as described in Fig. 4 results in the following:

- Tissue in area A is stimulated for a total of 10 ms with the desired current density level (5 mA/cm^2).
- Tissue in area B is stimulated for a total of 8 ms with the desired current density level.
- Tissue in area C is stimulated for a total of 2 ms with the desired current density level.

The area of highest current density levels (and the most probable source of pain) is in near proximity to the electrode surface. Depending on electrode geometry, current density levels can easily reach 100 mA/m^2. The utilization of the proposed method allows a limited duration of a single painful stimulus. The critical mass of heart tissue still receives the required current density level and pulse duration (Fig. 8).

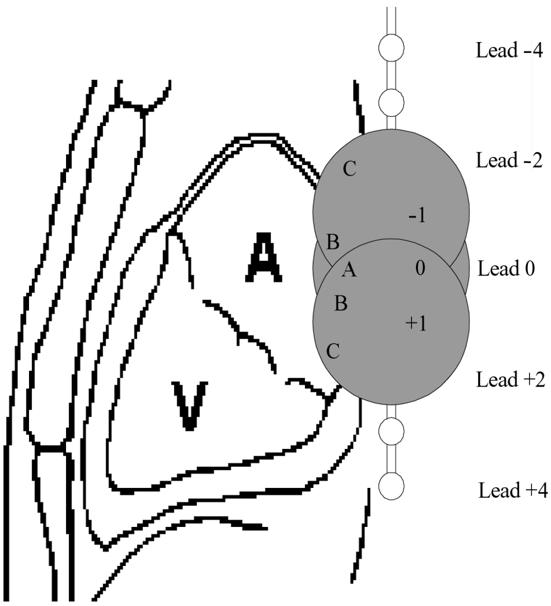

Fig. 8. Splitting the pulse.

5. CONCLUSIONS

The multichannel transesophageal pacemaker developed allows quickly to find the best position of electrodes for successful atrial pacing without removing the esophageal catheter. Application of additional (external) electrode(s) in TOE atrial stimulation can be used to reduce the pacing current threshold. Optimal number and location(s) of additional electrodes and current distribution between them is subject to further study. We demonstrated the possibility of utilizing a split stimulus pulse to achieve successful atrial capture. In more than half of the cases using the proposed method there was no accompanying significant increase of atrial pacing threshold. We expect to find an optimal combination of pulses to reduce the pain sensation during transesophageal pacing.

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Seade ja meetod söögitorukaudse südamestimulatsiooni teostamiseks langetatud stimulatsiooniläve tingimustes

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Eesmärgiga langetada söögitorukaudsel südamestimulatsioonil stimuleeriva voolu läve on välja töötatud mitmekanaliline söögitorukaudne südamestimulaator ja multipolaarne söögitorukaudne elektrood. On teostatud kliinilised uuringud kolme erineva stimulatsiooniläve alandamise lähenemisviisi kohta. Stimuleeriva dipooli täpne positsioneerimine on umbes pooltel patsientidest võimaldanud vähendada stimulatsiooniläve keskmiselt 20% võrra standardse bipolaarse stimulatsioonimeetodiga võrreldes. Rindkerel paiknevate elektroodide kaasamine söögitorukaudsel südamestimulatsioonil on umbes 60%-l patsientidest võimaldanud vähendada stimuleeriva voolu tugevust keskmiselt 7 mA võrra standardse meetodiga võrreldes. On välja töötatud väga lühikeste elektriimpulsside kombineerimise meetod, mis võimaldab saavutada vajaliku voolutiheduse ja impulsi kestvuse stimuleeritavas koes. Seega on osutunud võimalikuks muuta stimulatsioon patsiendile vähem valulikuks standardselt kasutatava (kestusega 10 ms) üksikimpulsiga stimuleerimisega võrreldes. Väljatöötatud meetodid tagasid eduka kodade stimuleerimise kõigil patsientidel.