transcutaneous non-invasive cardiac stimulation,
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NON-INVASIVE ELECTRO STIMULATION TECHNOLOGIES FOR THE DIAGNOSIS AND THERAPY OF CORONARY ARTERY DISEASE AND HEART ARRHYTHMIAS

The Centre of Excellence STIMCARD operating within the Institute of Medical Equipment and Technology ITAM develops Polish technologies of transesophageal, transcutaneous and transvenous cardiac stimulation as well as technologies supporting the supervision of patients undergoing electrocardiotherapy, such as in the case of an implanted pacemaker or cardioverter defibrillator. The paper reviews non-invasive electro stimulation techniques, as well as the diagnosis and therapy of the coronary artery disease (CAD) and arrhythmias. As far as CAD is concerned, the paper presents solutions applied in the construction of electrodes and pacemakers intended for both transesophageal and transcutaneous cardiac stimulation tests. The clinical value of the developed cardiac stimulation test has been assessed for the diagnosis of stable cardiac symptoms and management of patients with unstable cardiac disease, as well as for the identification of subjects in danger of sudden cardiac death. The system of stimulated ischemic preconditioning has also been discussed. Also, the paper demonstrates dedicated solutions used in ECG recording channels in the area of diagnosis and treatment of arrhythmias. The solutions make it possible to obtain stable and interpretable recordings during stimulation, both on the surface of the body and in the esophagus. Finally, the paper analyses solutions introduced in pacemakers which make it possible to induce (for diagnostic purposes) and stabilize quick paroxysmal heart arrhythmias, as well as the idea of supported hemodynamics, particularly useful during surgery.

1. INTRODUCTION

Invasive procedures in cardiology have made significant progress recently and the restoration of regular blood flow to the heart through subcutaneous angioplasty with stenting or surgical placement of „bridges” to enable permanent vascular access has been astoundingly effective. Considerable progress has also been made in removing lethal arrhythmia substrates (ablation). High costs are currently the substantial downside of these procedures even in countries that are more affluent than Poland. Costs can be reduced by appropriate selection of patients for expensive invasive diagnostic and treatment procedures. The increasingly advanced non-invasive techniques, such as MRI or multi-row spiral CT scans are also very costly and therefore cannot be extensively used, particularly in screening tests. Hence, affordable non-invasive diagnostic and treatment techniques are gaining in importance worldwide.

The Centre of Excellence STIMCARD operating within the Institute of Medical Equipment and Technology ITAM, develops Polish transesophageal, transcutaneous and transvenous cardiac stimulation technologies, taking account of both the optimal stimulation parameters and the recording of undisturbed ECG during diagnostic and treatment procedures. The paper gives an

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overview of non-invasive electrocardiostimulation technologies applied in the diagnosis and therapy of CAD and arrhythmias, as well as underlines all steps taken to use them broadly in the selection of patients who have to undergo costly invasive procedures.

2. NEW TECHNICAL SOLUTIONS

2.1. ELIMINATION OF ARTEFACTS CAUSED BY IMPULSES IN ECG RECORDINGS

The recording of an ECG signal without impulse artefacts is a prerequisite for diagnosis by means of non-invasive pacemakers. Artefacts in ECG recordings are caused by the impulse which amplitude is several times higher than the electric response of the heart to stimulation. Therefore, the interpretation of the obtained ECG recording is hampered for the purpose of diagnosis.

Several methods have been used so far to eliminate disturbances. An analogue system has been used for the elimination of impulse artefacts in the esophageal (cardiac stimulator SP-5, ITAM, Zabrze) [9,10] and in the surface ECG leads (cardiac stimulator NP-4D, ITAM, Zabrze) [11]. The system is compatible with analogue ECG recorders with a wide input range. The problem has been solved in the digital recorder DEK-631 (ITAM Zabrze) with the use of the software and thus high resistance to artefacts in transesophageal cardiac stimulation [14] has been obtained. The recorders manufactured by other companies are not prepared, in terms of software and hardware, to eliminate impulse artefacts during non-invasive cardio stimulation, so the quality of the obtained recordings usually makes it impossible to draw correct diagnostic conclusions.

The new version of the analogue system for the reduction of interferences in all surface ECG leads developed by the Centre also works for high-amplitude artefacts generated during transesophageal and transcutaneous pacing [12]. These systems have been installed in transesophageal cardiac stimulators SP-5, commonly used in Poland. Reliable recordings have been obtained both for digital and analogue ECG devices, in the whole range of amplitudes of stimulation impulses.

A hardware and software system for eliminating impulse artefacts has been used in the new ECG device CARDIS-210. The applied solution is aimed at disabling input adjustment and at appropriate software filtration in the digital signal processing channel. Examples of recordings are shown in Figs 3 and 4.

2.2. NEW CONFIGURATIONS OF THE TRANSESOPHAGEAL ELECTRODE

ITAM began research on new electrodes already in the 1980s. This is when a directional electrode, oval in cross-section, with spot poles [13] was developed and implemented. This electrode is characterised by resulting lower stimulation thresholds and may be inserted either through the mouth or nose. It took ITAM several years to optimize the material and the production technology for disposable electrodes. As a result, directional electrodes with carbon poles for diagnostic stimulation were designed, as well as anatomical electrodes intended for use in anaesthesiology. [16].

Fig. 1. Anaesthesiological electrode, the anatomically shaped part used for stimulation

Electrodes used in anaesthesiology must comply with additional requirements as they are inserted in subjects under general anaesthesia and should also enable stimulation of the ventricles.

This electrode, 28 F in diameter, has the appropriate shape in the stimulating part so that the poles cling to the esophagus wall. The electrode is inserted into the esophagus through the mouth or the inferior nasal passage and the insertion depth is calculated by means of the modified Roth formula which takes the following form for the atria:

- insertion through the mouth:

$$\textit{insertion depth [cm]} = \frac{height\ \ [cm]}{5} - 2$$

- insertion through the nose:

$$\textit{insertion depth [cm]} = \frac{height\ \ [cm]}{5} + 2$$

If the ventricles are stimulated, the electrode must be inserted 4 cm deeper than for the atria, as calculated above. During the tests, it took 48 s on average to insert the electrode through the nose and 98 s to begin stimulation and 25 s and 74 s, respectively, if the electrode was inserted through the mouth. The atrium excitation threshold at the level calculated by means of the modified Roth formula was equal to an average of 6.1 ± 3.7 mA.

2.3. THREE-ELECTRODE TRANSCUTANEOUS STIMULATION SYSTEM

Non-invasive transcutaneous cardiac pacing (NTCP) became widely used in the 1990s in Poland, after ITAM developed the NP-4D pacemaker. However, the patients' tolerance of NTCP was often unsatisfactory. The standard two-electrode system used in NTCP operates at 70 % efficiency in conscious subjects. The side effect of NTCP is the movement of the chest and/or abdomen caused by the excitation of skeletal muscles. The three-electrode system developed within the Centre is definitely more effective in this respect. The active electrode is placed above the apex of the heart, in point C3, whereas the two passive electrodes are placed in the sacral and gluteal region, on both sides of the backbone [7]. The new system is used with over 90 % efficiency in conscious subjects owing to less movement of skeletal muscles compared with the standard system.

The progress made has been confirmed by tests conducted in over 100 conscious patients. Most of them [4] demonstrated good tolerance of NTCP carried out by means of the three-electrode system, whereas they usually showed poor tolerance when the standard two-electrode system was applied. However, research in this area must be continued in order to achieve very good tolerance of NTCP in all subjects.

There is no problem with the efficiency of NTCP in subjects under general anaesthesia, although the movement of the operating field may be an obstacle for the surgeon. 100 % efficiency of NTCP was observed in subjects under general anaesthesia and with muscle relaxation, both in the two- and three-electrode systems. Yet, the obtained results and comparisons clearly indicate better properties of the three-electrode system, which can be observed both as a higher muscle excitation threshold (Table 1) and a lower ventricle excitation threshold (Table 2).

Table 1. Muscle excitation threshold (MET) in a two- and three-electrode system, respectively

	MET II [mA]	MET III [mA]	MET III – MET II [mA]
Mean value	40,3	50,5	-10,2 (p<0,001)
Min. – Max	30 - 63	33 – 79	

Table 2. Ventricle excitation threshold (VET) in a two- and three-electrode system, respectively

	VET II [mA]	VET III [mA]	VET III – VET II [mA]
Mean value	79,8	68,1	-11,7 (p<0,001)
Min – max	51 - 124	42 – 104	

2.4. OPTIMIZATION OF THE STIMULATION IMPULSE SHAPE

Following the development of the digital transcutaneous pacemaker NAP-601 (ITAM Zabrze), it became possible to investigate the influence of the stimulation impulse shape on the tolerance of transcutaneous stimulation in conscious subjects and subjects under general anaesthesia. The pacemaker generates stimulation impulses of various shapes programmed before and has an LCD display which enables the visualization of the surface ECG and pulse waveform or the transesophageal ECG.

In the course of research conducted within the STIMCARD Centre, the $\sin^2$ impulse turned out to be optimal from the point of view of stimulation tolerance in conscious subjects. This shape was chosen by 11 out of 13 subjects undergoing the tests [3].

The anaesthesiologist may apply stimulation impulses with much higher amplitude during NTCP in patients under general anaesthesia which increases the probability of effective pacing. However, the induced contraction of skeletal muscles results in the movements of the operating field.

As can be inferred from tests conducted with the use of NAP-601 in a three-electrode system (Fig. 2), the rectangular impulse is best for highly efficient hear excitation if hemodynamics has to be secured for a short period by means of NTCP. On the other hand, the $\sin^2$-shaped impulse assures the transfer of the smallest amount of cumulated electric power to the heart, which plays a significant role if longer pacing is necessary (Tab. 3).

Fig. 2. Placement of three electrodes during transcutaneous pacing (A) and the compared shapes of stimulation impulses (B).

Table 3. Examples of mean values for the determined parameters of the tested shapes of stimulation impulses in a group of patients consisting of 58 persons.

Impulse shape	rectangle	sin^2	$sin^{1/2}$
Effectiveness of stimulation	94 %	88 %	92 %
Muscle excitation threshold	40.5 mA	45.8 mA	47.8 mA
Ventricle excitation threshold	70.5 mA	74.9 mA	79.9 mA
Impulse energy for effective stimulation	99.7 mJ	44.0 mJ	65.2 mJ

The movement of the operating field during surgery under general anaesthesia mainly depends on the degree of relaxation of skeletal muscles.

3. DEVELOPED SOLUTIONS APPLIED TO CARDIAC DIAGNOSIS AND THERAPY

3.1. TRANSESOPHAGEAL OR TRANSCUTANEOUS CORONARY STIMULATION TESTS

ECG exercise tests used to assist in the diagnosis of CAD have shown, based on long-time observation, a life-threatening risk in those patients who exhibit ST segment depression ≥2 mm in several ECG leads in the first minute of exercise. A similar risk seems to be indicated by ST segment depression ≥2 mm after a 30-second stimulation of the atria or ventricles at a rate of 130 bpm. With such changes of the ST segment, stenosis exceeding 50% of the coronary artery lumen [2] is usually present in one or two coronary vessels. The transesophageal coronary stimulation test (Fig. 4A) is a recognised method; however, it cannot be used for large-scale screening tests as it is considered invasive under the valid law.

The transcutaneous, non-invasive coronary stimulation test (Fig. 4B) developed by STIMCARD seems to be a more appropriate method for identifying persons without complaints, but in danger of a myocardial infarction or sudden cardiac death. The test detects high ischemia already after a 30-second stimulation of the ventricles in the three-electrode system and guarantees that 100% of the calculated pulse limit will be achieved (which cannot be guaranteed by other methods). It is as effective and precise as the exercise test on a treadmill and the transesophageal coronary stimulation test, but it takes much less time and is much cheaper, especially compared with the fully non-invasive, although very costly spiral CT scan.

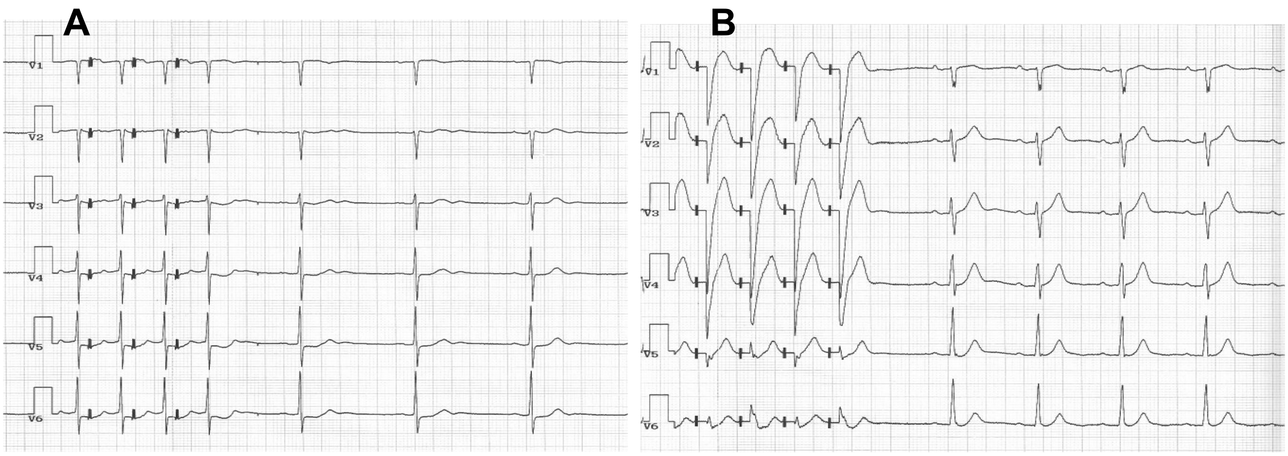

Fig. 3. The final fragment of the 30-second pacing A- transesophageal, B- transcutaneous, at a rate of 130 bpm. Visible depressions of the ST segment in leads V3-V6 in record A and no depressions in record B.

3.2. ADAPTIVE PROTECTION OF HEART FROM ISCHEMIA

A non-invasive method of activating the adaptive protection of heart from ischemia [1] has found several useful applications in clinical practice. Tests were conducted within the STIMCARD Centre on a group of subjects with documented, stable CAD (CCS 2-3). The tests were aimed at answering the question whether the repeated 30-second transesophageal pacing of atria at a constant rate of 130 bpm makes it possible not to provoke coronary pain and to what extent and with what dynamics the heart is protected from ischemia if this method is applied [5]. The protocol included 30-second stimulation intervals with the use of NAP-601 pacemaker and, alternately, 60-second periods of sinus rhythm. As a result of breaks in pacing, the ECG symptoms of ischemia subsided. The mean atria excitation threshold was 7 mA (4÷12 mA) which enabled unnoticeable pacing in 75 % of the tested subjects. The following stimulation intervals were repeated until the maximum depression of the ST segment was reduced by 50 %, which was assumed to be the activation of protection of the heart from ischemia. From then on, subsequent stimulation intervals were repeated after 3, 5 and 25 minutes.

The adaptive protection of the heart from ischemia was becoming increasingly stronger in time and the obtained image of positive ECG and clinical changes occurring after the eighth stimulation interval on average indicates that this method is a simple tool which safely activates the adaptive protection from ischemia in patients with stable CAD. It seems that this mechanism of activating resistance to ischemia may be broadly applied in patients before treatment causing acute ischemia (PTCA), as well as serve as a special function of the implanted pacemaker in patients with CAD without the possibility of revascularization. If adaptive protection is activated in these persons through programmed series of stimulations carried out by the pacemaker, particularly in the morning, their quality of life may improve because the activated protection from ischemia holds (as can be inferred from our tests) at an almost unchanged level for at least 36 minutes.

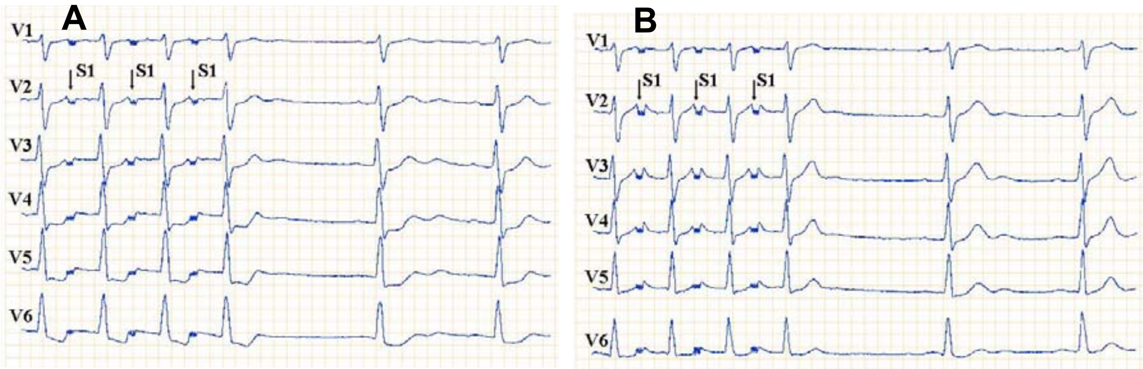

Fig. 4. **A** – ECG recording of surface leads after the first interval of atrial pacing at a rate of 130 bpm. ST depressions' meeting the criteria for ischemia are visible during pacing and after it is turned off.
B - ECG recording of surface leads after activation of protection of heart from ischemia in the same patient. Only a slight depression of ST is visible in leads V5, V6.
Recording speed: 50 mm/s. S1-S1 – stimulation impulses with a visible marker of the artefact reduction period.

3.3. STIMULATING SUPPORT OF HEMODYNAMICS

Non-invasive heart stimulation techniques are used to support of hemodynamics during bradycardia or asystolia occurring in patients in cardiology wards and in the operating rooms [6]. Routine activities of the surgeon and anaesthesiologist during surgery often lead to excessive bradycardia, which causes impaired tissue flow and drop in arterial blood pressure. Impaired hemodynamics has a negative impact on the surgery itself and the patient's distant future after the surgery. Excessive bradycardia during surgery under general anaesthesia with negative hemodynamic impact occurs in 30-70% of the subjects. A lack of or delayed reaction of the body to pharmacological treatment has a negative effect on the patients whose key organs were impaired already before the surgery. Invasive pacing is very difficult in the sterile operating room or usually impossible as trained cardiologists are not available there.

3.3.1. HEMODYNAMICS SUPPORTED BY TRANSCUTANEOUS CARDIAC PACING

Transcutaneous cardiac pacing is the simplest method of supporting hemodynamics in patients under anaesthesia and may be carried out by the anaesthesiologist. The process consists in exciting the ventricles with broad stimulation impulses (above 30 ms) by means of electrodes glued to the skin of the chest in a two-electrode or preferably three-electrode system. Supporting hemodynamics with transcutaneous cardiac pacing is less hemodynamically efficient than the transesophageal pacing of atria which lose their transporting function.

3.3.2. HEMODYNAMICS SUPPORTED BY TRANSESOPHAGEAL CARDIAC PACING

Transesophageal pacing of atria or cardiac pacing is the most beneficial method of supporting hemodynamics in patients under anaesthesia. An electrode with two stimulation poles is inserted into the esophagus either through the nose or through the mouth and the insertion depth is calculated by means of the modified Roth formula. Pacing is carried out by means of a new generation directional electrode with a modified shape, developed by STIMCARD Centre, and assures 100 % efficiency in the pacing of atria, a stable operating field and does not hamper any anaesthesiological activities. The effectiveness of this electrode amounts to 98% in transesophageal cardiac pacing under general anaesthesia.

3.4. PROGRAMMED PACING OF VENTRICLES AND ATRIA

Research carried out so far has demonstrated particular usefulness of transcutaneous pacing in stabilizing monomorphic ventricular tachycardia and atrial and ventricular tachycardia [8]. Transcutaneous pacing used for this purpose is simple, quick, non-invasive and comes in handy also in therapy. The overdrive technique or programmed cardiac pacing with one, two or three impulses is usually used for rhythm stabilization.

Programmed pacing of atria is effectively used for the detection of fast atrial and ventricular dysrhythmias [17], as shown in the examples below.

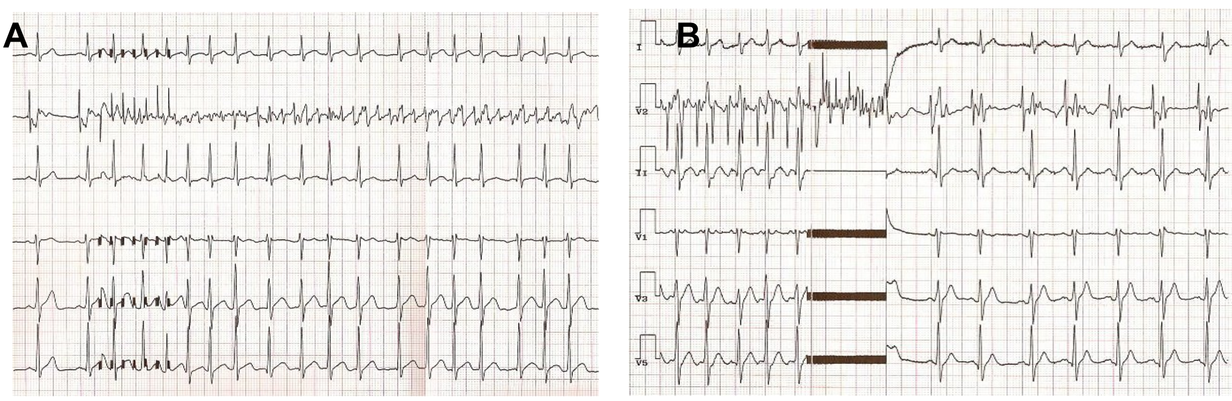

Fig. 5. An ECG recording made: **A** – during a diagnostic procedure when fibrillation is released, and **B** – during stabilization of atrial flutter by means of transesophageal cardiac pacing.

3.5. SUPPORTING THERAPY CONDUCTED BY MEANS OF AN IMPLANTED CARDIOVERTER DEFIBRILLATOR (ICD)

The quantity of tachycardias in the patient after implanting an ICD may be reduced by means of antiarrhythmic treatment or by decreasing the arrhythmia substrate. However, this sometimes leads to ventricular tachycardia (VT) at a rate outside the ICD range, which prevents the ICD from releasing an electric shock. In order to obtain an effective charge, a VT episode at a rate of 150 bpm lasting longer than 36 seconds may be imitated with the use of the transcutaneous external pacemaker (Fig. 6). Sin² impulses with a base 60 ms wide were applied in clinical practice. The amplitude of impulses was set at a level hardly noticeable for the patient (10 mA) and insufficient to excite the heart muscle [15].

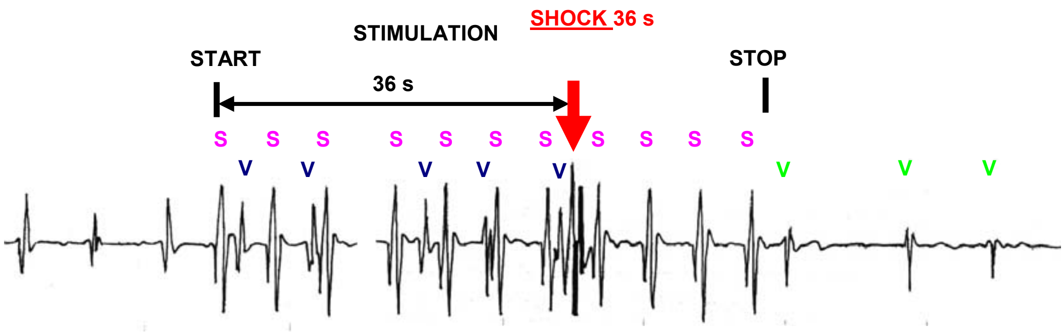

Fig. 6. A record of the imitation of the VT episode at a rate of 150 bpm released by non-invasive pacing and enabling the ICD to interrupt tachycardia at a rate outside its detection range.

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