Original article

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IMPLANTATION OF THE MICRA ELECTRODELESS MINIATURE ARTIFICIAL HEART GUIDE: EXPERIENCE AND CASE SERIES

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Advances in technology and medicine have brought new solutions to challenges encountered in everyday practice. Since the implantation of the first epicardial pacemaker about half a century ago, the refinement and miniaturization process of the device has resulted in the latest generation of artificial heart guides (VVS), which, with the help of sophisticated technology, overcomes the obstacles of conventional devices. The Micra pacemaker is a single-chamber device that weighs 2 g, has a volume of 0.8 cm², and is capsule-shaped, measuring 25.9 mm in length and 6.7 mm in outer diameter. The size of the device not only does not limit the functions of the device but also represents a significant advantage and novelty in the world of implantable devices.

This paper presents a series of the first 6 cases of transcatheter transvenous implantation of a miniature artificial heart guide Medtronic Micra (Medtronic, Minnesota, USA) device for permanent cardiac stimulation at the University Clinical Center Niš.

The Micra system without electrodes has proven in practice to be a safe and effective option for permanent cardiac pacing in adult patients. In certain patients in whom the usual venous access is impossible (multiple sternotomies, thoractomies, congenital or acquired anomalies), it has become the most useful alternative in the case of indication for permanent pacing.

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Key words: *Micra pacemaker, pacemaker implantation, complications*

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Introduction

Advances in technology and medicine have brought new solutions to challenges encountered in everyday practice. Since the implantation of the first epicardial pacemaker about half a century ago, the refinement and miniaturization process of the device has resulted in the latest generation of artificial heart guides (VVS), which, with the help of sophisticated technology, overcomes the obstacles of conventional devices. The Micra pacemaker is a single-chamber device that weighs 2 g, has a volume of 0.8 cm², and is capsule-shaped, measuring 25.9 mm in length and 6.7 mm in outer diameter. The size of the device not only does not limit the functions of the device, but also represents a significant advantage and novelty in the world of implantable devices. This system retains all the features of existing electrode systems (adaptive guidance concerning frequency and automatic threshold adjustment to extend battery life) (1). Micra (Medtronic, USA) is a single-chamber pacemaker system without electrodes; it is directly implanted transvenously into the right ventricle and passively fixed (2). The technology of VVS implanted transvenously directly into the ventricle was developed to compensate for the shortcomings of traditional VVS with electrodes. Although widely applicable, VVS with electrodes is not always implantable due to difficulties related to anatomical differences between patients, chronic infections of the device bed, and mediastinal tumors that complicate lead placement (3). Also, the presence of a traditional device is visible to the naked eye and the installation results in a scar, which is an aesthetic problem predominantly in younger patients. A less invasive approach favors older patients and facilitates recovery, does not limit movements and disrupts the quality of life less, while not detracting from efficiency (2, 3).

Aim

This paper presents a series of the first 6 cases of transcatheter transvenous implantation of

a miniature artificial heart guide Medtronic Micra (Medtronic, Minnesota, USA) device for permanent cardiac stimulation at the University Clinical Center Niš.

Materials and Methods

At the beginning of 2023, the first 6 Micra pacemakers were implanted at the Cardiology Clinic of the University Clinical Center in Niš. In this series, all patients were male with a mean age of 77 (SD 3.56) years. All patients had indications for implantation of a permanent artificial heart guide due to proven bradycardia and pauses in cardiac work. In 5 out of 6 patients, the basic rhythm was atrial fibrillation (AF), while in 1 patient, a tachycardia-bradycardia disorder was proven. All patients were elderly, of medium osteomuscular build. In the preparatory phase, anamnestic data were collected, complete basic and supplementary diagnostics were performed (electrocardiogram, echocardiographic examination, biohumoral status, antibodies to hepatitis B and C, HIV, treponema pallidum, INR, aPPT and coagulation factor screening). In order to plan the intervention and prevent vascular complications, all patients underwent a color-doppler ultrasound examination of the blood vessels of the femoral region with reference to the patency, diameter and length of the right femoral vein. Patients did not consume food or liquids for 12 hours before the intervention. Interventions were performed under local infiltration anesthesia (with a combination of Lidocaine and Marcaine). In addition, each patient received 0.2 mg Fentanyl IV (4).

After scarification of the access site, a puncture of the femoral vein was performed, and the intravascular position of the puncture needle was verified by aspiration of venous blood and a good return jet. A J guide wire was placed through the puncture needle and advanced into vena cava inferior. After securing the access road, dilation of the access site was performed by successive changes of dilators of increasing dimensions 10-12-14-16-18-F, and the advancement of larger dilators was supported by super stiff wires for better support. A 27-F outer diameter (23-F internal diameter) Micra system implantation catheter was advanced to the right ventricle by manual advancement, and then the tip of the catheter was directed toward the mid-septal area using a fluoroscopy-guided curve-making mechanism on the system's handle. After achieving an adequate position (verified by giving contrast through the system in at least two positions (RAO and LAO 30), the device was positioned by the release mechanism towards the central part of the septum of the right ventricle and fixed to the trabeculae by fixing at least 2 of the 3 apical hooks. An adequate position was achieved on the first attempt in 5 out of 6 cases. The parameters were measured using the telemetry reading of the device. The recommended threshold of < 1 mV, at 0.25 ms was achieved in all patients. After adequate apposition, fixation and obtaining stable impedance and satisfactory parameters, the device was released. The system was constructed so that until the final release, repositioning of the device could be carried out unhindered until adequate parameters were achieved. After the device was implanted, the implantation catheter was inserted, and hemostasis was achieved with a figure-of-eight suture, manual compression for about 20 minutes and compression with a gauze roll for about 4 hours post-intervention. Out of 6 patients, 1 patient developed a minor inguinal hematoma that healed spontaneously in the following weeks.

Patient characteristics, indications, implantation details, and implantation parameters at 1-month follow-up are given in Table 1.

Table 1. Patient characteristics, measured and monitored parameters

Patient	1.	2.	3.	4.	5.	6.
Age (years)	74	74	75	76	84	79
Indication for pacemaker implantation	Permanent AF with 8 defined pauses over 2 sec (longest 3.88 sec)	Permanent AF with 3 defined pauses over 2 sec and average night frequency 34 (longest 2.3 sec)	Sinus node disease with 10 defined pauses longer than 2 sec and episodes of AF	Permanent AF, average frequency during the day 47/min, frequent syncope	Syncope, sinus node disease (minimum frequency 30), transient AV block II degree, episodes of AF	Permanent AF, a large number of pauses in the heart's work longer than 2 seconds
Comorbidities	Hypertension for the past 10 years, benign prostatic hyperplasia, type II diabetes	Type II diabetes	Type II diabetes, arterial hypertension, benign prostatic hyperplasia	Hypertension, benign prostatic hyperplasia	Arterial hypertension	

	chronic obstructive pulmonary disease, asthma					
Implantation-site	The central part of the right ventricular septum	1. Apex of the right ventricle 2. Apical part of the septum of the right ventricle	The apical part of the septum of the right ventricle	The apical part of the septum of the right ventricle	The central part of the right ventricular septum	Apex of the right ventricle
Threshold at implantation (on 0.24 ms)	0.4 V	0.5 V	0.4 V	1.1 V	1.3 V	0.8 V
Impedance at implantation	650 Om	1.>3000 Om 2. 580 Om	485 Om	920 Om	990 Om	399 Om
The height of R wave at implantation	6.8 mV	11.9 mV	10.2 mV	7.8 mV	14.5 mV	8.7 mV
Threshold at 1-month follow-up	0.6 mV	0.8 mV	0.5 mV	0.8 mV	1.0 mV	0.8 mV
Impedance at 1-month follow-up		600 Om	550 Om	800 Om	600 Om	500 Om
The height of R wave at 1-month follow-up	7 mV	11 mV	11.2 mV	8.9 mV	12.2 mV	8.5 mV
Complications	without	without	without	Hematoma at the puncture site	without	without
Duration of the procedure	70 min	45 min	90 min	60 min	50 min	40 min
Duration of the fluoroscopy	26 min	17 min	38 min	22 min	20 min	15 min
Number of implantation attempts	2 (inadequate fixation)	2 (impedance > 2000 Om)	1	1	1	1

Discussion

The elimination of leads and pockets by the introduction of leadless pacemakers provides potential advantages over conventional transvenous systems. Lead and pocket-related complications are the major complications after implantation of standard lead pacemaker systems.

Pacing electrodes and a pacemaker as a foreign body of large volume are an ideal ground for the emergence of infections that usually persist for a long time, representing a therapeutic problem and often requiring a complete extraction of the system. After the extraction of the system, the venous access path is often changed by fibrosis, narrowed, and even during the eradication of the infection, the next system with an electrode cannot be adequately placed. Common causative agents of lodge infections such as *S. Aureus, S. Epidermidis* can create biofilms on implanted materials that are a source of reinfections, so even after the reimplantation of new systems, infections recur and potentially progress to endocarditis as well as systemic infections. In such cases, the Micra pacemaker is a necessity and the only possible solution for permanent heart stimulation (2, 4).

Conventional cardiac pacing devices are associated with significant complications that are not uncommon. It is estimated that 9.5−12.6% of interventions are related to complications. Complications are divided into local lodge complications, lead-related complications, and systemic complications. The most common local complications are hematomas, bed infections, skin erosions and decubitus changes and difficult healing. In the FOLLOW-PACE study, the highest percentage of early (9.2%) and late complications (12.6%) was recorded. The frequency of infections after the implantation of conventional devices, which reaches 16.4% in some centers, is particularly noteworthy. However, large centers record about 1% of lodge infections in the first 3 months after implantation (5, 6).

During the implantation of conventional pacemaker systems with an electrode, there is a

constant risk of effusion caused by perforation of the myocardium with the electrode, which is about 1.2% (7).

Micra's small size, reduced surface area and lack of an electrode significantly reduce the risk of early infection after implantation (8). During long-term follow-up, these characteristics of the device condition early encapsulation and stabilization, which additionally ensures the effectiveness of pacing (8, 9).

An early report on Micra implantation showed a very high procedural success rate of 100% (10). This success rate was reduced to 99.2% in a study involving 725 patients, where 719 patients had the device successfully implanted. Also, this study showed a high rate of device efficiency of 98.3% and safety of 96.0%, which far exceeds the expected values of the mentioned parameters. The septal position of the device has also been shown to bring advantages in terms of reducing mechanical complications (1).

In a study by El-Chami et al. (11), the effectiveness of the Micra pacemaker after implantation was investigated in 1801 patients. Data obtained from the IDE study (Investigational Device Exemption) (12) and the PAR registry (Post-Approval Registry) (13) showed exceptional safety and efficacy. Therefore, the study by El-Chami et al. aimed to substantiate the evidence and confirm on a live model the efficacy and safety of the device. Device implantation was successful in 99.1% of cases. Within 12 months, the complication rate was 2.7%, and the overall risk of major complications was 63% lower than in patients with conventional transvenous systems. Only 3 patients had a reported infection that did not result in device complications or lead to system extraction.

Due to the mentioned advantages, this system is also applied in the pediatric population to patients with multiple open heart interventions in whom it is not possible to place a pacemaker system with electrodes (14).

Conclusion

The Micra system without electrodes has proven in practice to be a safe and effective option for permanent cardiac pacing in adult patients, and in certain patients in whom the usual venous access is impossible (multiple sternotomies, thoractomies, congenital or acquired anomalies) it has become the most useful alternative in the case of indication for permanent pacing.

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IMPLANTACIJA *MICRA* MINIJATURNOG PEJSMEJKERA BEZ ELEKTRODA: ISKUSTVO I SERIJA SLUČAJEVA

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Napredak tehnologije i medicine doneo je nova rešenja za izazove sa kojima se medicinski radnici susreću u svakodnevnoj praksi. Nakon ugradnje prvog epikardijalnog pejsmejkera pre oko pola veka, proces tehničkog napretka i minijaturizacije uređaja rezultirao je najnovijom generacijom veštačkih vodiča srca (VVS), koji uz pomoć sofisticirane tehnologije prevazilazi prepreke konvencionalnih uređaja. *Micra* pejsmejker je jednokomorni uređaj težak dva grama, čija zapremina iznosi 0,8 cm^2. U obliku je kapsule, ima dužinu od 25,9 mm i spoljašnji prečnik od 6,7 mm. Ne samo da veličina uređaja ne ograničava funkcije uređaja već i predstavlja značajnu prednost i novinu u svetu implantabilnih uređaja.

U ovom radu je prikazana serija prvih šest slučajeva transkateterske transvenske implantacije minijaturnog aparata, odnosno pejsmejkera *Medtronic Micra* (Medtronic, Minesota, SAD) za trajnu srčanu stimulaciju u Univerzitetskom kliničkom centru u Nišu.

Micra sistem bez elektroda pokazao se u praksi kao bezbedna i efikasna opcija za trajni pejsing kod odraslih bolesnika. Kod pojedinih bolesnika kod kojih uobičajeni venski pristup nije moguć (zbog višestruke sternotomije, toraktomije, urođene ili stečene anomalije) postao je najkorisnija alternativa u slučaju indikacije za trajni pejsing.

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***Ključne reči**: Micra pejsmejker, ugradnja pejsmejkera, komplikacije*