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experience and case series

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Implantation of the Micra electrodeless miniature artificial heart guide - experience and case series

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 weighing 2g, volume 0.8cm², capsule-shaped, 25.9mm long and 6.7mm 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, 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.

Key words: Micra pacemaker, pacemaker implantation, complications

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Implantacija minijaturnog pejsmejкера Micra bez elektroda – iskustvo i serija slučajeva

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Napredak tehnologije i medicine doneo je nova rešenja za izazove sa kojima se susreće u svakodnevnoj praksi. Od ugradnje prvog epikardijalnog pejsmejкера pre oko pola veka, proces tehničkog napretka i minijaturizacije uređaja rezultirao je najnovijom generacijom vodiča za veštački vodič srca (VVS), koji uz pomoć sofisticirane tehnologije prevazilazi prepreke konvencionalnih uređaja. Micra pejsmejker je jednokomorni uređaj težine 2 g, zapremine 0,8 cm², u obliku kapsule, dužine 25,9 mm i spoljašnjeg prečnika 6,7 mm. Veličina uređaja ne samo da ne ograničava funkcije uređaja, već predstavlja značajnu prednost i novinu u svetu implantabilnih uređaja.

U ovom radu je prikazana serija od prvih 6 slučajeva transkateterske transvenske implantacije minijaturnog aparata odn. pejsmejкера Medtronic

Micra (Medtronic, Minesota, SAD) za trajnu srčanu stimulaciju u Univerzitetском kliničkom centru Niš.

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

Ključne reči: Micra pejsmejker, ugradnja pejsmejкера, komplikacije

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1. 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 weighing 2g, volume 0.8cm², capsule-shaped, 25.9mm long and 6.7mm 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 with respect to frequency and automatic threshold adjustment to extend battery life) (1). Micra (Medtronic, USA) is a single-chamber pacemaker system without electrodes that 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).

2. Aim of the paper

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.

3. Patients, preoperative preparation and intervention protocol

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 an intravenous injection of Fentanyl (0.2 mg). 6

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 10-12-14-16-18F, and the advancement of larger dilators was supported by "super stiff" wires for better support. A 27F external diameter (23F 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 is 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. Adequate position achieved from the first attempt in 5 out of 6 cases. The parameters were measured using telemetry reading of the device. The recommended threshold values $<1\text{mV}$, at 0.25ms were achieved in all patients. After adequate apposition, fixation and obtaining stable impedance and satisfactory parameters, the device was released. The system was constructed that until the final release, repositioning of the device can be carried out unhindered until adequate parameters are achieved. After the device has been implanted, the implantation catheter is inserted and hemostasis is 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 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 atrial fibrillation	Permanent atrial fibrillation, 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 atrial fibrillation, 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, chronic obstructive pulmonary disease, asthma	Type II diabetes	Type II diabetes, arterial hypertension, benign prostatic hyperplasia	Hypertension, benign prostatic hyperplasia	Arterial hypertension	
Implantation-site	The central part of the right	1. Apex of the right	The apical part of the septum of	The apical part of the septum of	The central part of the right	Apex of the right ventricle

	ventricular septum	ventricle 2. Apical part of the septum of the right ventricle	the right ventricle	the right ventricle	ventricular septum	e
Treshold at implantation (on 0,24ms)	0,4V	0,5V	0.4V	1.1 V	1,3V	0,8V
Impedance at implantation	650 Om	1. > 3000Om 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
Treshold on the control after 1 month	0,6 mV	0,8mV	0,5 mV	0,8 mV	1,0mV	0,8 mV
Impedance at the control after 1 month	540 Om	600 Om	550 Om	800 Om	600 Om	500 Om
The height of R wave at control after 1 month	7mV	11mV	11,2 mV	8,9 mV	12,2 mV	8,5mV
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

4. 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, represent a therapeutic problem and often require 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* have the ability to create biofilms on implanted materials that are a source of reinfections, so even after 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 impantation 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 slightly 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 (11).

In a study (12), the effectiveness of the Micra pacemaker after implantation was investigated in 1801 patients. Data obtained from the IDE study (Investigational Device Exemption) (13) and the PAR registry (Post-Approval Registry) (14) 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 (15).

5. Conclusions

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.

References

1. Reynolds D, Duray G, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. 2016; 374(6): 533–541, doi: 10.1056/nejmoa1511643.
2. Grabowski M, Michalak M, Gawałko M, Gajda S, Cacko A, Januszkiewicz Ł, Kołodzińska A, Mitkowski PP, Duray GZ, Opolski G. Implantation of the Micra transcatheter pacing system: Single Polish center experience with the real costs of hospitalization analysis. *Cardiol J*. 2020;27(1):47-53. doi: 10.5603/CJ.a2018.0075. Epub 2018 Aug 29. PMID: 30155871; PMCID: PMC8086506.
3. Piccini JP, Stromberg K, Jackson KP, Kowal RC, Duray GZ, El-Chami MF, Crossley GH, Hummel JD, Narasimhan C, Omar R, Ritter P, Roberts PR, Soejima K, Reynolds D, Zhang S, Steinwender C, Chinitz L; Micra Transcatheter Pacing Study Group. Patient selection, pacing indications, and subsequent outcomes with de novo leadless single-chamber VVI pacing. *Europace*. 2019 Nov 1;21(11):1686-1693. doi: 10.1093/europace/euz230. PMID: 31681964.
4. Sohail MR, Hussain S, Le KY, et al. Management and outcome of permanent pacemaker and implantable cardioverter-defibrillator infections. *J Am Coll Cardiol*. 2007;49(18):1851–1859.
5. Johar S, Luqman N. Initial experience with a leadless pacemaker (Micra™) implantation in a low volume center in South East Asia. *Future*

Cardiol. 2018 Sep;14(5):389-395. doi: 10.2217/fca-2017-0106. Epub 2018 Sep 25. PMID: 30251546; PMCID: PMC6190239.

6. Udo EO, Zuithoff NP, Van Hemel NM et al. Incidence and predictors of short-and long-term complications in pacemaker therapy: the FOLLOWPACE study. *Heart Rhythm* 9, 728–735 (2012).

7. Mahapatra S, Bybee KA, Bunch TJ et al. Incidence and predictors of cardiac perforation after permanent pacemaker placement. *Heart Rhythm* 2(9), 907–911 (2005).

8. Kypta A, Blessberger H, Kammler J, et al. Leadless cardiac pacemaker implantation after lead extraction in patients with severe device infection. *J Cardiovasc Electrophysiol*. 2016;27(9):1067–1071. doi: 10.1111/jce.13030.

9. Ritter P, Duray GZ, Steinwender C, et al. Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study. *Eur Heart J*. 2015;36(37):2510–2519. doi:10.1093/eurheartj/ehv214.

10. Breatnach CR, Dunne L, Al-Alawi K, Oslizlok P, Kenny D, Walsh KP. Leadless micra pacemaker use in the pediatric population: device implantation and short-term outcomes. *Pediatr Cardiol*. 2020; 41:683–686. doi: 10.1007/s00246-019-02277-y.

11. Reynolds D, Duray G, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. 2016; 374(6): 533–541, doi: 10.1056/nejmoa1511643.

12. El-Chami MF, Al-Samadi F, Clementy N, Garweg C, Martinez-Sande JL, Piccini JP, Iacopino S, Lloyd M, Viñolas Prat X, Jacobsen MD, Ritter P, Johansen JB, Tondo C, Liu F, Fagan DH, Eakley AK, Roberts PR. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart Rhythm*. 2018 Dec;15(12):1800-1807. doi: 10.1016/j.hrthm.2018.08.005. Epub 2018 Aug 10. PMID: 30103071.

13. Duray GZ, Ritter P, El-Chami M, Narasimhan C, Omar R, Tolosana JM, Zhang S, Soejima K, Steinwender C, Rapallini L, Cicic A, Fagan DH, Liu S, Reynolds D; Micra Transcatheter Pacing Study Group. Long-term performance of a transcatheter pacing system: 12-Month results from the

Micra Transcatheter Pacing Study. Heart Rhythm. 2017 May;14(5):702-709. doi: 10.1016/j.hrthm.2017.01.035. Epub 2017 Feb 10. PMID: 28192207.

14. [Study Details | Micra Transcatheter Pacing Study | ClinicalTrials.gov](#)
[Last accessed: 09.12.2023.]

15. Shah MJ, Borquez AA, Cortez D, McCanta AC, De Filippo P, Whitehill RD, Imundo JR, Moore JP, Sherwin ED, Howard TS, Rosenthal E, Kertesz NJ, Chang PM, Madan N, Kutalek SP, Hammond BH, Janson CM, Ramesh Iyer V, Williams MR. Transcatheter Leadless Pacing in Children: A PACES Collaborative Study in the Real-World Setting. Circ Arrhythm Electrophysiol. 2023 Apr;16(4):e011447. doi: 10.1161/CIRCEP.122.011447. Epub 2023 Apr 11. PMID: 37039017.

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