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5-6 DÉCEMBRE 2024

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Mon pire cauchemar

Dr Sonia MARRAKCHI

PH centre hospitalier de Versailles, attachée au CHU Pitié Salpêtrière- France, CHR

Marrakchi.sonia@yahoo.fr

- Patient de 89 ans a été hospitalisé en USIC à l'hôpital Saint Antoine à la suite d'un arrêt cardio-respiratoire résolutif après 5 minutes de massage cardiaque externe sur rythme non choquable.

Antécédant

- Infection à COVID19 avec PCR + en 12/2020
- Lymphome de Hodgkin en 2008 traité par chimiothérapie, en rémission depuis 2009
- AC/FA permanente sous Xarelto et bêta-bloquants
- TAVI pour Rétrécissement aortique serré syncopal en 2021
- Insuffisance rénale chronique modérée

Poids : 75 kg (02/12/2022), Taille : 170 cm (02/12/2022), IMC : 26 kg/m2, SC 1.9 m2

ECG: FA à 90/min, Axe gauche, HBAG, pas de trouble de la repolarisation

A la télémétrie: FA permanente

A l'ETT: aspect évocateur d'amylose, FEVG 60-65 %, SGL – 7 % avec avec relative préservation apicale. Bon fonctionnement du Bioprothèse TAVI. Dilatation biatriale. VD modérément dilaté, hypertrophié de fonction systolique conservée. HTAP importante avec PAPS 77 mmHg pour POD à 10 mmHg.

infection urinaire à E. Coli et E. Faecalis lors de son hospitalisation

Au vu de la forte probabilité de trouble conductif de haut degré paroxystique et du contexte d'amylose, il est retenu une indication d'implantation d'une pace maker monochambre (FA permanente) à distance de l'épisode infectieux.

Le patient est donc programmé pour implantation de PM sans sonde devant le risque haut risque infectieux

transféré au CHU de la Pitié salpétrière pour implantation de PM sans sonde

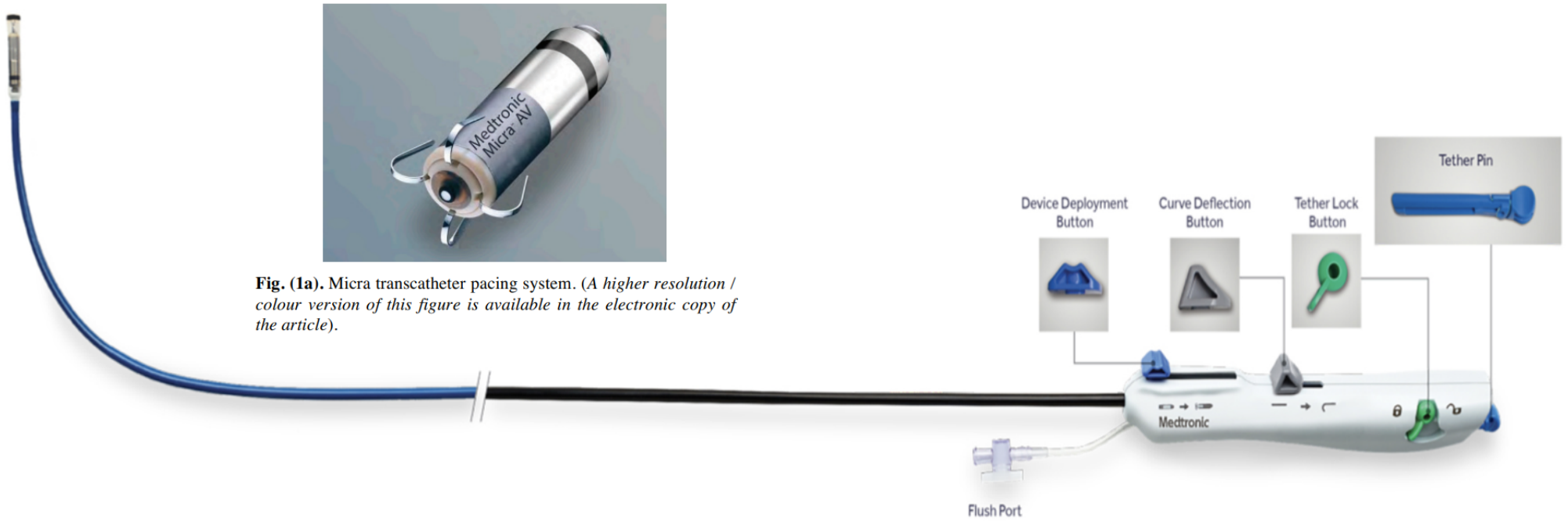
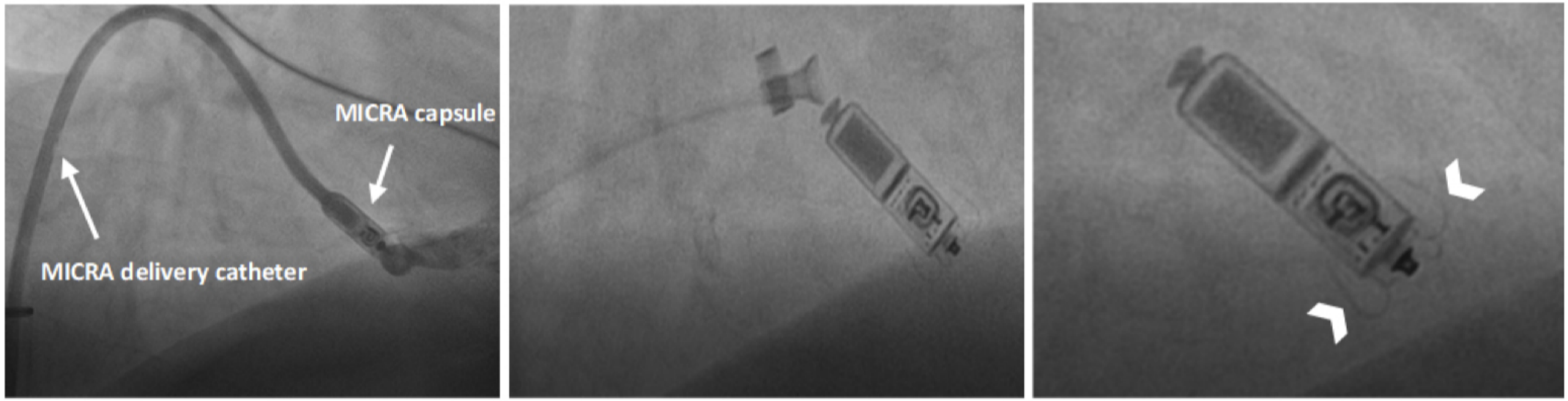


Fig. (1a). Micra transcatheter pacing system. (*A higher resolution / colour version of this figure is available in the electronic copy of the article*).

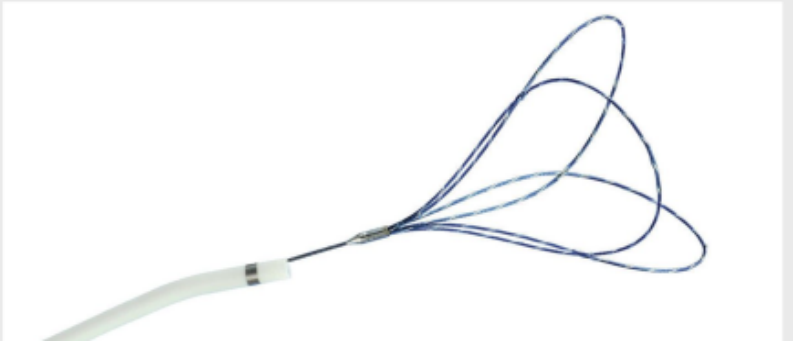
Fig. 1. Micra Integrated Delivery Catheter. 105 cm long catheter system with a handle that controls deflection and deployment of the Micra pacing capsule (23 Fr inner diameter/27 Fr outer diameter). Courtesy of Medtronic Inc.



- Procédure compliquée d'une perte de capture lors du retrait du fil et instabilité du MICRA lors de la traction douce

- Procédure compliquée d'une perte de capture lors du retrait du fil et instabilité du MICRA lors de la traction douce

EN Snare®
Endovascular Snare
System



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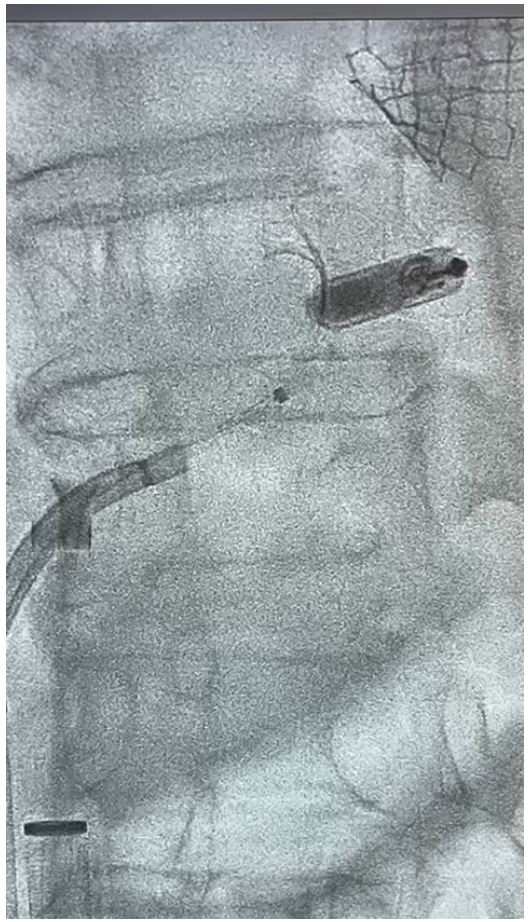

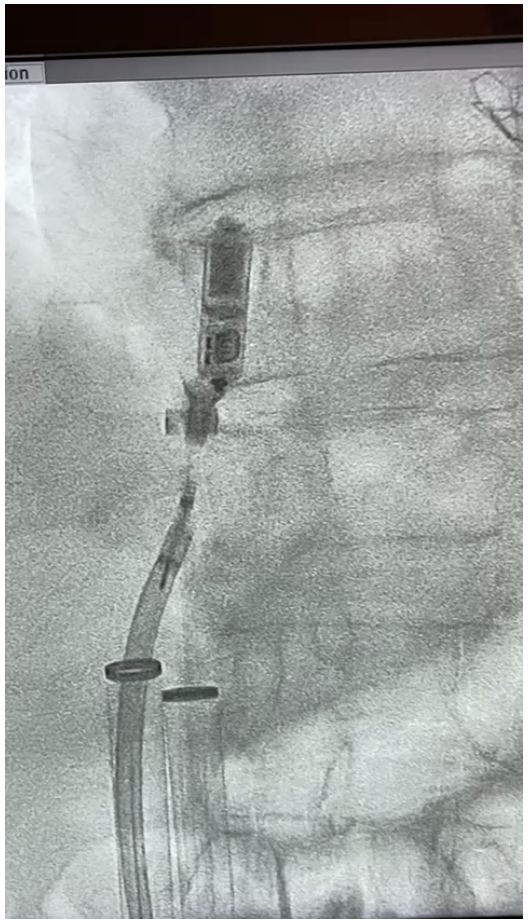

PM sans sonde retiré et Implantation d'un nouveau MICRA par nouvelle ponction fémorale droite

- Le boitier était entouré par le fil et présence d’un caillot sanguin à l’intérieur
- Qu’est ce qui était la cause de ce déplacement
  - Est-ce que c’était un bon candidat pour le PM sans sonde?
  - Problème d’anticoagulation?
  - Terrain: âge, amylose, insuffisance rénale

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Est-ce que c'était un bon candidat pour le PM sans sonde?

PM endovasculaire ou PM sans sonde

Circulation Journal
Circ J 2023; 87: 1809–1816
doi:10.1253/circj.CJ-23-0269

ORIGINAL ARTICLE
Devices

Safety and Performance of the Micra VR Leadless Pacemaker in a Japanese Cohort

— Comparison With Global Studies —

Kenji Ando, MD; Kanki Inoue, MD; Tomoo Harada, MD, PhD; Satoshi Shizuta, MD, PhD; Yukihiko Yoshida, MD, PhD; Kengo Kusano, MD, PhD; Tatsuya Onuki, MD, PhD; Yuji Watari, MD, PhD; Akio Fukui, MD, PhD; Shingo Sasaki, MD, PhD; Morio Shoda, MD, PhD; Nobuhiro Nishii, MD, PhD; Akira Shiose, MD, PhD; Junya Hosoda, MD, PhD; Chie Okai; Kurt Stromberg, MS; Jeffrey Murphy, MS; Thomas R. Holmes, PhD; Kyoko Soejima, MD, PhD

Table 3. Major Complications in MAP Japan

Type of major complication (no. of patients, %)	MAP Japan (n=300)	
	Acute	Total
Total major complications	11 (10, 3.33%)	11 (10, 3.33%)
Thrombosis	2 (2, 0.67%)	2 (2, 0.67%)
Deep vein thrombosis	2 (0.67%)	2 (0.67%)
Events at groin puncture site	2 (1, 0.33%)	2 (1, 0.33%)
Arteriovenous fistula	1 (0.33%)	1 (0.33%)
Vascular access site	1 (0.33%)	1 (0.33%)
Cardiac effusion/perforation	3 (3, 1.00%)	3 (3, 1.00%)
Cardiac perforation	1 (0.33%)	1 (0.33%)
Cardiac tamponade	1 (0.33%)	1 (0.33%)
Pericardial effusion	1 (0.33%)	1 (0.33%)
Pacing issues	4 (4, 1.33%)	4 (4, 1.33%)
Device dislocation	1 (0.33%)	1 (0.33%)
Device pacing issue	3 (1.00%)	3 (1.00%)

Abbreviations as in Table 1.

ESC European Society of Cardiology
Europace (2023) 25, 1–9
https://doi.org/10.1093/europace/euad269

CLINICAL RESEARCH

Comparison of in-hospital outcomes and complications of leadless pacemaker and traditional transvenous pacemaker implantation

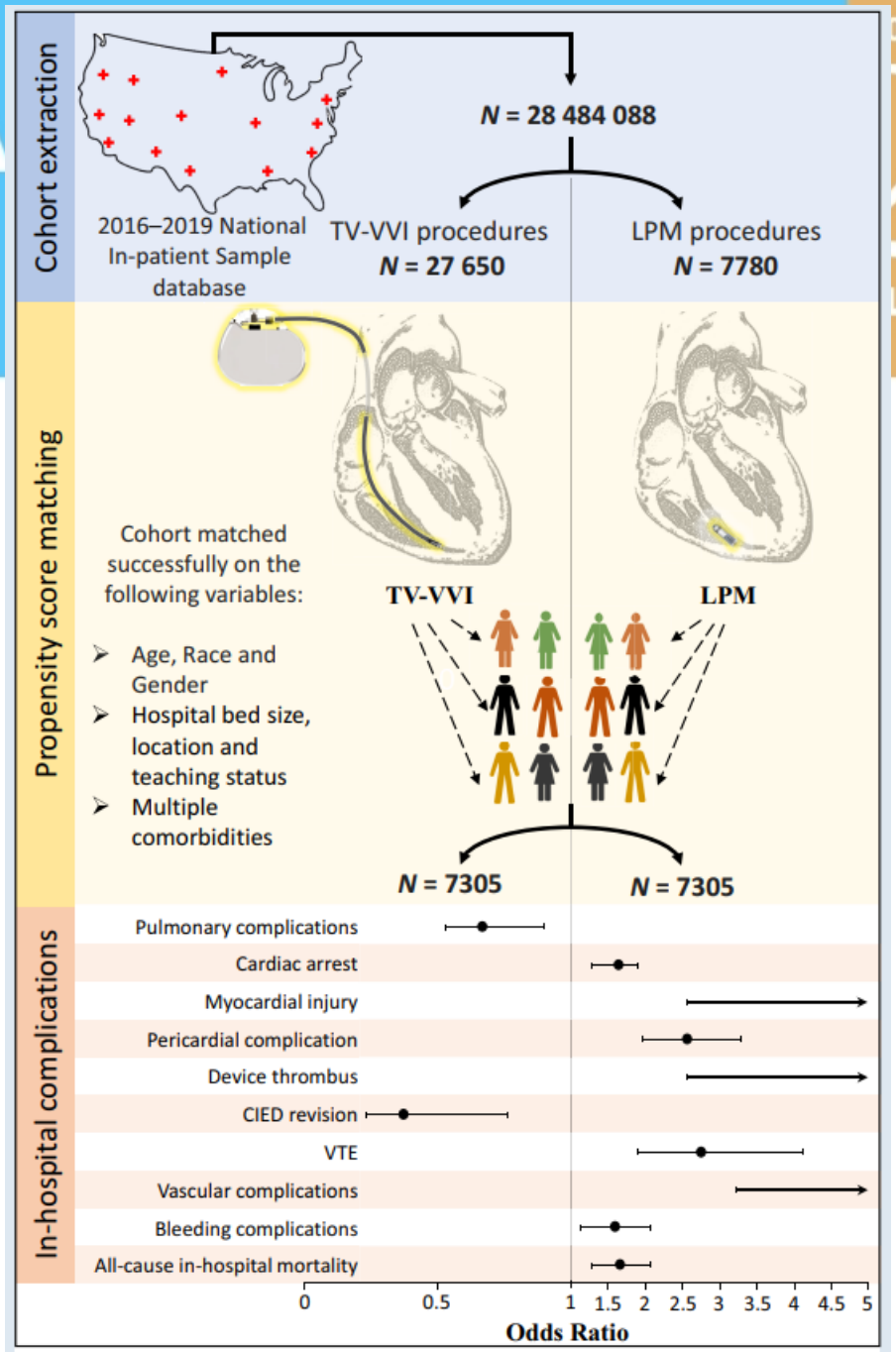
Majd Al Deen Alhuarrat [1†], Amrin Kharawala [1†], Sarath Renjithlal [2], Mohamed Magdi Eid [2], Dimitrios Varrias [1], Moghniuddin Mohammed [3], Michael Grushko[1], and Luigi Di Biase [4]*

[1]Division of Internal Medicine, Jacobi Medical Center, Albert Einstein College Medicine, Bronx, NY, USA; [2]Department of Internal Medicine, Rochester Regional Health/Unity Hospital,

Table 3 Breakdown of primary outcomes and logistic regression before and after propensity score matching

Primary outcome		Overall, *n* = 35 430 (%)	Baseline observations		Multivariate regression pre-match (OR [CI])	*P*-value	Univariate regression post-match (OR [CI])	*P*-value
			TV-VVI, *n* = 27 650 (%)	Leadless, *n* = 7780 (%)				
All-cause in-hospital mortality		550 (1.55)	355 (1.28)	195 (2.51)	1.97 [1.63–2.38]	<0.001	1.63 [1.29–2.05]	<0.001
Complications	Bleeding	340 (0.96)	230 (0.83)	110 (1.41)	1.54 [1.21–1.96]	<0.001	1.54 [1.14–2.07]	0.005
	Vascular	80 (0.23)	35 (0.13)	45 (0.58)	5.24 [3.23–8.49]	<0.001	7.54 [3.21–17.68]	<0.001
	VTE	225 (0.64)	125 (0.45)	100 (1.29)	2.96 [2.24–3.91]	<0.001	2.74 [1.84–4.10]	<0.001
	Device	525 (1.48)	385 (1.39)	140 (1.80)	1.23 [1.0–1.50]	0.055	1.56 [1.18–2.05]	0.002
	Cardiac	1385 (3.91)	885 (3.20)	500 (6.43)	2.06 [1.82–2.32]	<0.001	1.82 [1.56–2.13]	<0.001
	Pulmonary	755 (2.13)	635 (2.30)	120 (1.54)	0.68 [0.55–0.83]	<0.001	0.68 [0.54–0.87]	0.002
	Infection[a]	20 (0.06)	<11 (<0.04)	<11 (<0.15)	4.47 [1.75–11.42]	0.002	1	N/A
	Neurologic[a]	<11 (<0.04)	<11 (<0.04)	<11 (<0.15)	1	N/A	1	N/A
VTE breakdown	LE DVT	140 (0.40)	85 (0.31)	55 (0.71)	2.38 [1.66–3.41]	<0.001	1.93 [1.20–3.10]	0.007
	PE	120 (0.34)	55 (0.20)	65 (0.84)	4.24 [2.92–6.18]	0.001	3.55 [2.07–6.09]	<0.001
Cardiac complications breakdown	Pericardial	465 (1.31)	240 (0.87)	225 (2.89)	3.43 [2.82–4.17]	<0.001	2.55 [1.98–3.28]	<0.001
	Myocardial	95 (0.27)	45 (0.16)	50 (0.64)	4.9 [3.13–7.70]	<0.001	5.03 [2.55–9.92]	<0.001
	Intra- & post-operative	95 (0.27)	55 (0.20)	40 (0.51)	2.88 [1.87–4.44]	<0.001	2.68 [1.48–4.85]	0.001
	Cardiac arrest	850 (2.40)	570 (2.06)	280 (3.60)	1.74 [1.49–2.03]	<0.001	1.54 [1.26–1.88]	<0.001
	Shock[a]	30 (0.08)	<30 (<0.1)	<11 (<0.015)	0.88 [0.32–2.39]	0.798	1	N/A
Device-related complications breakdown	CIED revision	230 (0.65)	215 (0.78)	15 (0.19)	0.27 [0.16–0.45]	<0.001	0.42 [0.23–0.76]	0.004
	Device thrombus	85 (0.24)	30 (0.11)	55 (0.71)	5.70 [3.36–9.65]	<0.001	5.03 [2.55–9.92]	<0.001
	Device infection[a]	35 (0.10)	<11 (<0.04)	<35 (0.4)	17.46 [6.23–48.88]	<0.001	1	N/A
	Other mechanical complications[a]	<11 (<0.04)	<11 (<0.04)	<11 (<0.15)	4.72 [1.82–12.17]	0.001	1	N/A

[a]Unable to find a correlation in the propensity-matched cohort.
VTE, venous thromboembolism; LE, lower extremity; DVT, deep venous thrombosis; PE, pulmonary embolism; CIED, cardiac implantable electronic device.



TV-VVI, transvenous VVI pacemaker; LPM, leadless pacemaker; VTE, venous thromboembolism

ESC European Society of Cardiology
European Heart Journal (2024) 45, 1241–1251
https://doi.org/10.1093/eurheartj/ehae101
CLINICAL RESEARCH
Arrhythmias

Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry

Mikhael F. El-Chami [1]*, Christophe Garweg [2], Nicolas Clementy[3], Faisal Al-Samadi[4], Saverio Iacopino[5], Jose Luis Martinez-Sande[6], Paul R. Roberts[7], Claudio Tondo[8], Jens Brock Johansen [9], Xavier Vinolas-Prat[10], Yong-Mei Cha [11], Eric Grubman[12], Pierre Bordachar[13], Kurt Stromberg [14], Dedra H. Fagan[14], and Jonathan P. Piccini[15]

- Un total de 5,746 patients implanté par un Micra et 9,662 patients avec un PM monochambre
- Le taux de complication est similaire entre les deux groupes
- Micra est associé à un taux d'épanchement péricardique plus élevé mais un taux de complications lié au matériel plus bas (infection, de déplacement…)

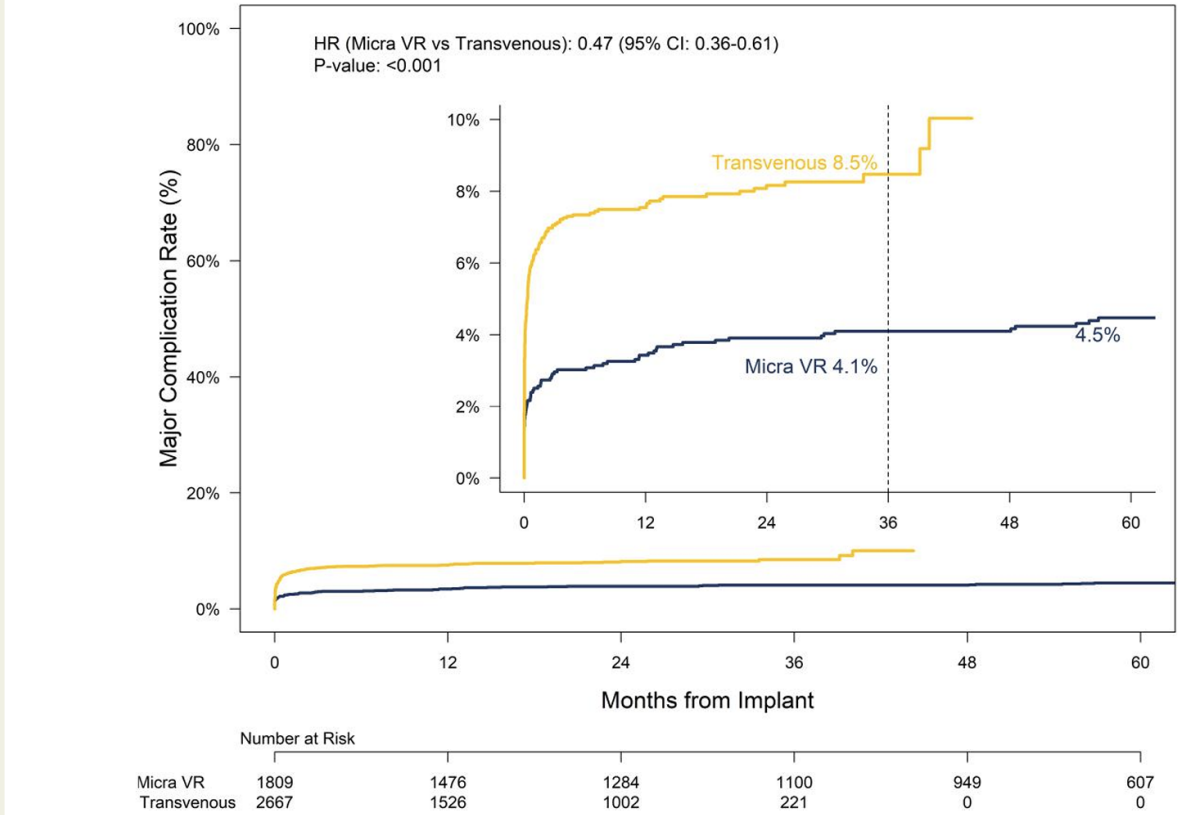


Figure 3 System or procedure-related major complication rates through 60 months post-implant for the Micra VR PAR and historical TV-PPM cohort. Sub-distributional hazard ratio based on data through 36-months post-implant as indicated by the dashed vertical line

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Indian Pacing and Electrophysiology Journal 22 (2022) 77–86

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Efficacy and safety of leadless pacemaker: A systematic review, pooled analysis and meta-analysis

Daniel Darlington [a], Philip Brown [a], Vanessa Carvalho [a], Hayley Bourne [a], Joseph Mayer [a], Nathan Jones [a], Vincent Walker [a], Shoaib Siddiqui [a], Ashish Patwala [a], Chun Shing Kwok [a, b, *]

- 18 études ont été inclus: 14 études prospectives et 4 retrospectives et 6 études internationales multicentriques
- Entre 2012 et 2019.
- 2496 patients avec PM sans sonde et 344 patients avec PM.
- Age moyen est de 80 ans

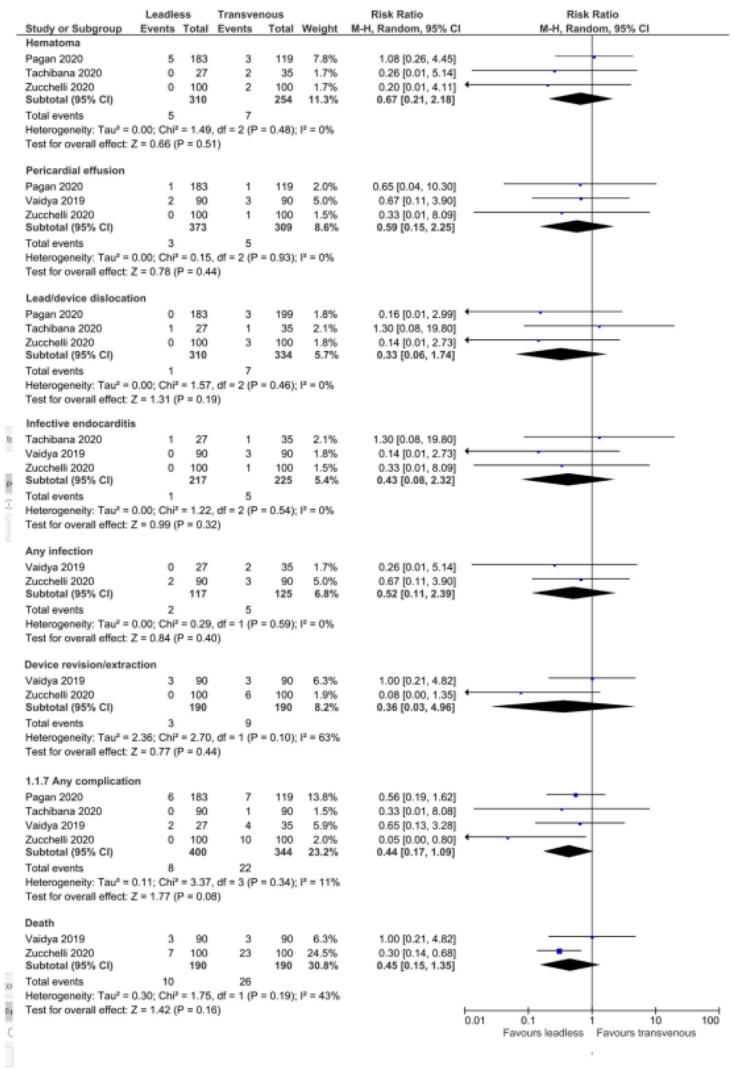

Fig. 2. Results of meta-analysis of studies comparing leadless to transvenous systems.

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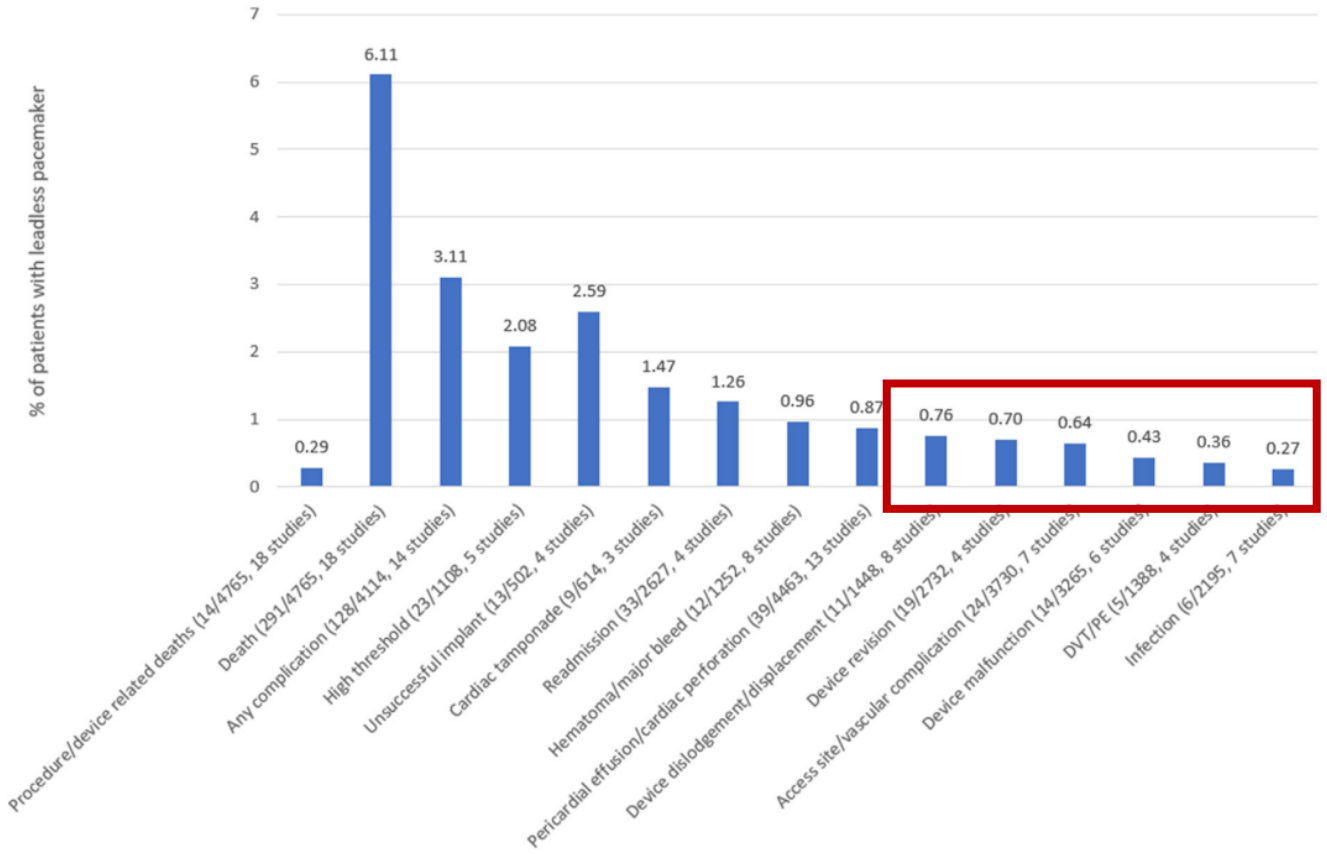

Fig. 1. Results of pooled analysis of studies of leadless pacemakers.

Quels types de PM sans sonde

Micra transcatheter pacing system (TPS) (Medtronic)

- Approuvé par FDA en 2016
- Micra: 25.9 mm de long, 0.8cc en volume, et poids 2 grams

Fig. (1a). Micra transcatheter pacing system. (*A higher resolution / colour version of this figure is available in the electronic copy of the article*).

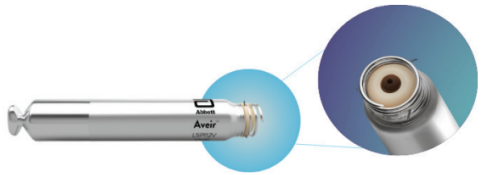

Fig. (1b). Aveir VR leadless pacemaker. (*A higher resolution / colour version of this figure is available in the electronic copy of the article*).

Aveir VR (Abbott) pacemaker

- Approuvé par FDA en 2022
- Aveir VR LP est 38 mm de long, moins de 3 grams,
- Utilise une gaine de 25 French de diameter interne
- une fixation active sous forme d'helix, permettant de mapper avant la fixation (onde R et impedance, test de stimulation)
- Possibilité d'extraction avec un système dédié
- Aveir DR i2i pivotal clinical study possibilité de stimuler oreillette

Current Cardiology Reviews, 2023, Vol. 19, No.

J Cardiovasc Electrophysiol. 2024 Oct 30. doi: 10.1111/jce.16485. Online ahead of print.

Device dislodgement and embolization associated with a new leadless pacemaker

Ali Bahbah [1], Jay Sengupta [1], Dawn Witt [1], Edwin Zishiri [1], Raed Abdelhadi [1], John Zakaib [1], Robert Hauser [1]

Affiliations + expand

PMID: 39474690 DOI: 10.1111/jce.16485

Abstract

Introduction: Currently, there are two approved single chamber leadless pacemakers (LP) in the United States (US), Micra VR™; approved since 2016 and AVEIR VR™; approved in 2022. A potential complication of LPs is dislodgement and/or embolization (D/E) during or after implant. According to the IDE trials, there appears to be a significant difference in D/E rates between the two LPs that have different fixation mechanisms; Micra uses nitinol tines, while AVEIR uses an active screw helix. The aim of this study was to determine if the AVEIR VR LP has continued to exhibit D/E in the United States since it was approved by the Food and Drug Administration (FDA) in April 2022.

Methods: The FDA Manufacturer and User Facility Device Experience (MAUDE) database was searched for US D/E reports communicated by the manufacturers of both LP devices. For AVEIR VR we reviewed reports from approval till December 2023, and for Micra VR we looked at reports from approval to April 2024. Excluded were reports based on information indirectly obtained from registries, journals, social media, or volunteers. Total number of US implants was acquired from the manufacturers' product performance reports.

Results: During a period of 21 months, 5990 AVEIR VR implants had been registered in the United States, of which 53 (0.88%) encountered D/E both during and after the procedure. More D/E (32; 60.4%) occurred during the implantation procedure, with device release problems being the most prominent procedural issue involved with these events. Within a 8-year period, 72 237 Micra VR implants have been registered in the United States, of which 211 (0.29%) showed D/E. The rate of D/E since the US approval of both devices was significantly higher for AVEIR VR compared to Micra VR (0.88% vs 0.29%; $p < .0001$).

Conclusion: AVEIR VR implants may be complicated by dislodgement with or without embolization. Currently, the estimated incidence is about 0.9%, which is significantly higher than Micra VR. Fixation issues and separation problems of the device from the delivery catheter appear to be responsible for most of these D/E events.

Keywords: device problems; dislodgement; leadless; permanent pacemaker; procedural outcomes.

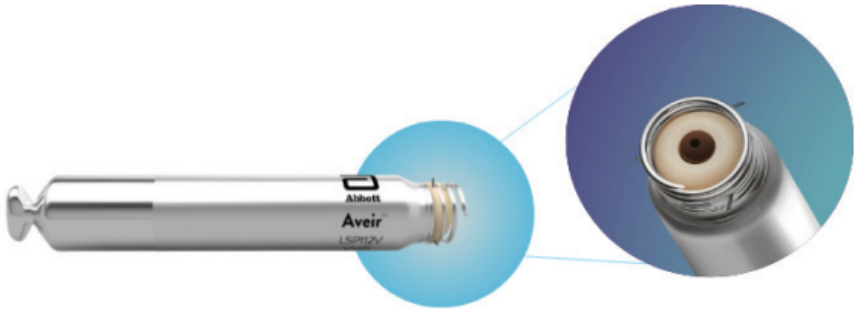

Fig. (1b). Aveir VR leadless pacemaker. (*A higher resolution / colour version of this figure is available in the electronic copy of the article*).

Table 1. Comparison of leadless pacemaker studies.

-	Leadless II- Phase 1 [14]	Leadless II-Phase 2 [15]	Micra IDE [6]	Micra PAR [10]	Micra CED [44]
N	526	200	725	1826	5746
Implant Success (%)	95.8	98	99.2	99.1	N/A
Perforation (%)	1.6	1.5	1.5	0.77	0.8
Dislodgment (%)	1.1	1	0	0.05	N/A
Groin Complication (%)	1.2	0.5	0.7	0.61	N/A
Infection	0	0	0	0	N/A

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Les risques thromboemboliques

Journal of *Clinical Medicine*

MDPI

Article

Peri-Procedural Management of Direct-Acting Oral Anticoagulants (DOACs) in Transcatheter Miniaturized Leadless Pacemaker Implantation

François Diederik Regoli [1,2,*], Ardan M. Saguner [3], Angelo Auricchio [2], Andrea Demarchi [2], Elena Pasotti [2], Giulio Conte [2], Maria Luce Caputo [2], Tardu Özkartal [2] and Alexander Breitenstein [3]

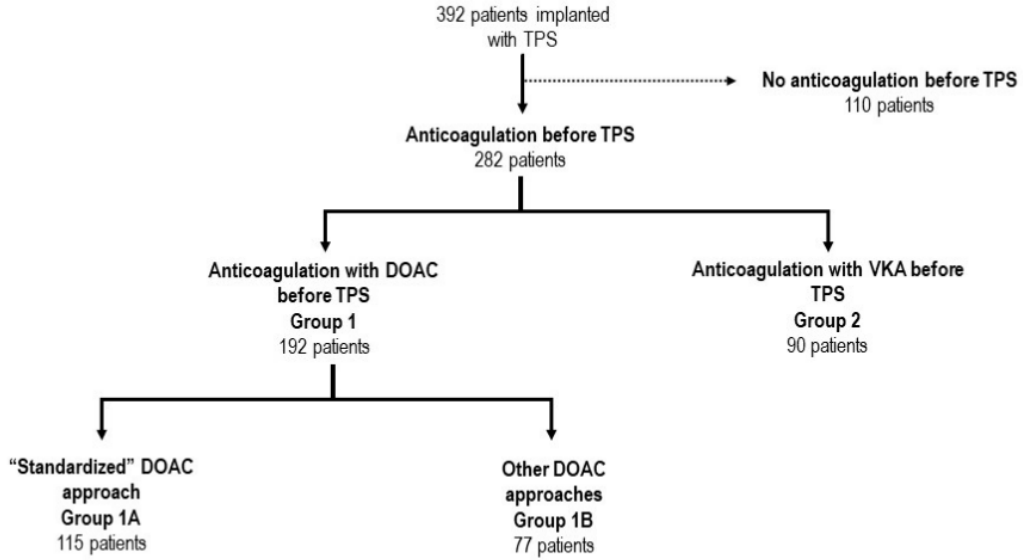

Figure 1. Study flow diagram presenting the different groups based on the type of anticoagulation therapy prescribed. Patients under chronic anticoagulation therapy with a DOAC (Group 1) were divided according to the standardized approach (Group 1A) or other DOAC management strategies (Group 1B).

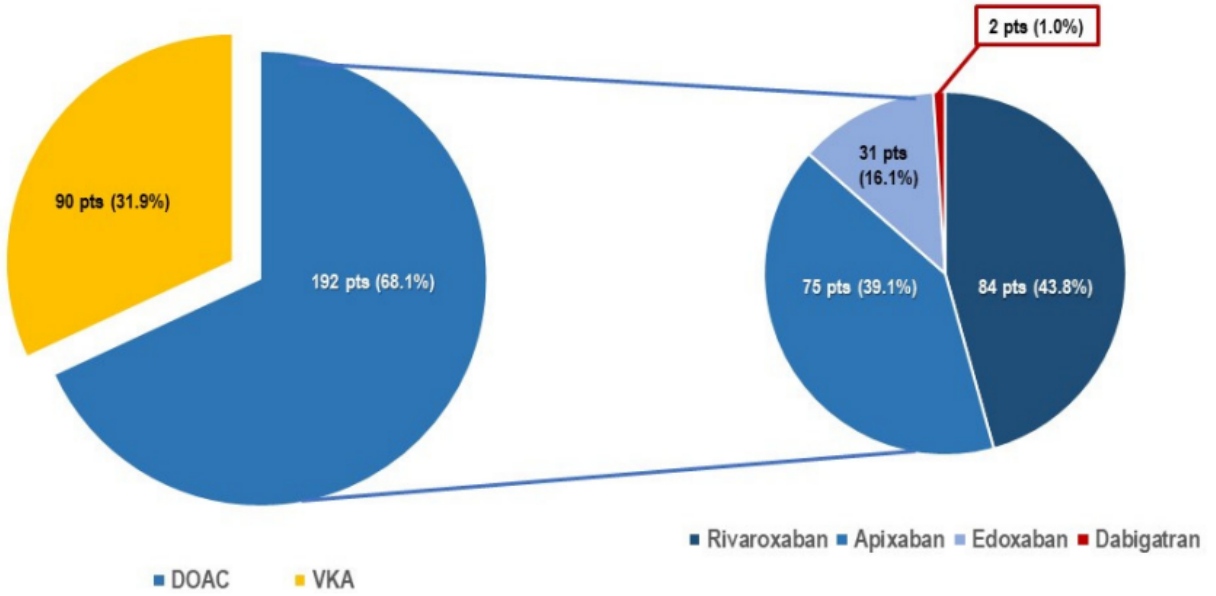

Figure 2. On the left, the pie graph presents the distribution of patients under chronic anticoagulation therapy divided into either DOAC or VKA. The pie graph on the right highlights the specific distribution of DOAC drug agents.

Prise en ch… …s

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Groupe 1A

- Interruption sur la dernière prise et reprise dans les 6 à 12 heures après la procédure

Groupe 1B

- Interruption precise sur au moins deux prises et reprise plus tardive des AOD au delà de 24 heures
- Interruption avec relais HNF
- Pas d'interruption d'AOD en périprocédure

Patients sous AVK (Groupe 2)

- Interruption avec relais : suspension AVK 72 heures avant avec INR<1.5 HNF ou HF en périprocédure
- Interruption sans relais: suspension AVK 72 heures avant avec INR<1.5 reprise en post opératoire
- Sans interrupetion avec INR sous AVK< 3.
- Position allongée pendant 8 heures incluant 6heures sous pansement compressif

Journal of *Clinical Medicine*

MDPI

Article

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- Pas de différence en terme de complications hémorragiques

Table 3. Procedural and pre-discharge characteristics.

	Standardized DOAC (Gp 1A, *n*= 115)	Other DOAC Regimens (Gp 1B, *n* = 77)	*p* Value
Procedure duration, min	45.1 ± 14.0	56.2 ± 27.6	<0.001
Fluoroscopy time, min	7.0 ± 6.1	9.2 ± 7.5	0.027
Implant success rate	115 (100)	77 (100)	1.000
DOAC management			
DOAC stopped (hours)	21.4 ± 5.2	27.0 ± 27.1	0.032
DOAC reinitiation (hours)	14.8 ± 9.3	35.7 ± 33.4	<0.001
Complications			
Major			
Intraprocedural bleeding	3 (2.6)	3 (3.8)	0.685
Pericardial effusion	1	2	
Major femoral access bleeding	2	1	
Minor			
Puncture site hematoma (<6 cm)	6 (5.2)	3 (3.9)	0.743
Length of hospital stay, days (IQR)	3.0 (2.0:3.8)	4.0 (3.0:12.5)	<0.019

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Terrain: Comorbidités

Rev Esp Cardiol. 2020;73(4):307–312

Original article

Performance of the Micra cardiac pacemaker in nonagenarians

Amine El Amrani, Bieito Campos, Concepción Alonso-Martín, José M. Guerra-Ramos, Enrique Rodríguez-Font, Zoraida Moreno-Weidmann, Óscar Alcalde-Rodríguez, Francisco J. Méndez-Zurita, Miguel Santaló, Hildemari Espinosa-Viamonte, and Xavier Viñolas*

Unidad de Arritmias, Servicio de Cardiología, Hospital de la Santa Creu i Sant Pau, Instituto de Investigación Biomédica Sant Pau, Universidad Autónoma de Barcelona, CIBERCV, Barcelona, Spain

- But: évaluation de la performance de PM sans sonde chez les patients âgés
- Faisabilité et inocuité de la pose chez les patients de plus de 90 ans

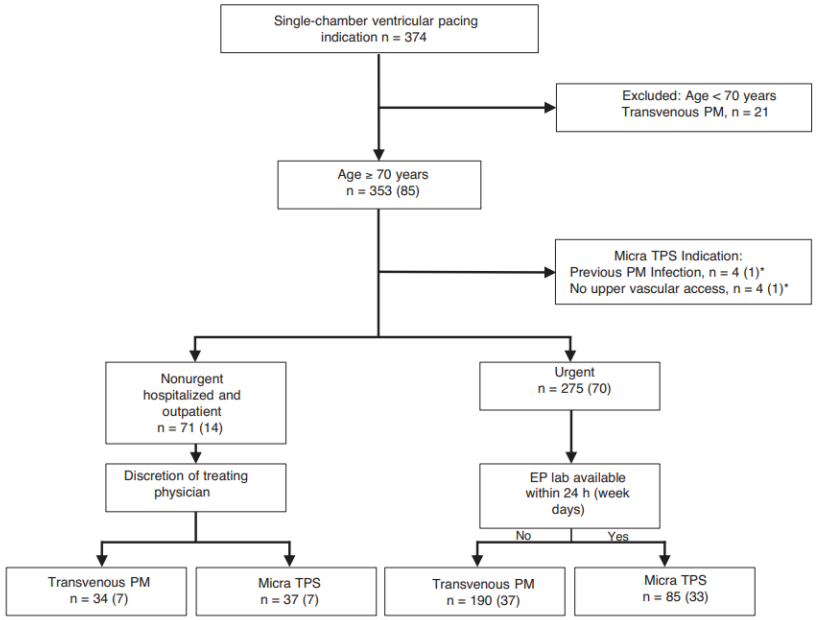

Figure 1. Flowchart of the decision-making process between the Micra and conventional transvenous pacemaker in patients with an indication for single-chamber ventricular pacing. The values in brackets represent the number of patients aged ≥ 90 years. EP lab, electrophysiology laboratory; PM, pacemaker; TPS, transcatheter pacing system. Figures in parentheses indicate patients aged ≥ 90 years. *One patient aged ≥ 90 years had both a previous pacemaker infection and absence of upper vascular access.

Table 4
Major complications at implantation and within 30-day after implantation

	≥ 90 years	< 90 years	Total
Patients, No.	41	88	129
Total major complications	0	3 (3.4)	3 (2.3)
Events at groin puncture site	0	2 (2.3)	2 (1.5)
Incision site hematoma	0	1 (1.1)	1 (0.8)
Pseudoaneurysm	0	1 (1.1)	1 (0.8)
Cardiac perforation	0	1 (1.1)	1 (0.8)

The data are expressed as No. (%).

HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society SM

Leadless pacemakers in patients with different stages of chronic kidney disease: Real-world data from the updated i-LEAPER registry

Gianfra
Giovan
Luca Bo
Pietro P
Mauro
Maurizi
Giovan

MD,[6]
[6]
MD,[10]

Table 2 LPM implantation features and outcomes in the study cohort stratified for kidney function according to CKD-EPI score for eGFR and significances between groups

Variable	Overall (N = 1748)	Normal kidney function (n = 1007)	CKD stage G3a/G3b (n = 577)	CKD stage G4/G5 (n = 164)	P G3a/G3b vs NKF	P G4/G5 vs NKF	P G4/G5 vs G3a/G3b
Duration of the procedure (min)	50 (40–68)	45 (38–60)	50 (40–70.5)	53 (40–75)	.032	.025	.713
Radiological time (min)	6 (3.2–9)	5.25 (3.2–8.1)	6 (3–9)	6.1 (4.1–8.5)	.464	.037	.494
In-hospital stay (d)	3 (2–5)	3 (2–4)	3 (2–5)	6 (4–8)	.944	<.001	<.001
Deployments							
1	1465 (83.8)	849 (84.3)	475 (82.3)	141 (86)	.304	.584	.273
2	222 (12.7)	128 (12.7)	77 (13.3)	17 (10.4)	.718	.399	.314
3	40 (2.3)	18 (1.8)	16 (2.8)	6 (3.7)	.196	.125	.557
≥4	21 (1.2)	12 (1.2)	9 (1.6)	0	.538	.685	.582
LPM final positioning							
Proximal septum	716 (41)	414 (41.1)	211 (36.6)	91 (55.5)	.075	<.001	<.001
Distal septum	889 (50.9)	520 (51.6)	310 (53.7)	59 (36.0)	.423	<.001	<.001
RVOT	43 (2.5)	22 (2.2)	14 (2.4)	7 (4.3)	.756	.118	.216
Apex	100 (5.7)	51 (5.1)	43 (7.5)	6 (3.7)	.054	.440	.092
LPM-related complications*	75 (4.3)	39 (3.9)	31 (5.4)	5 (3)	.144	.698	.228
Pericardial effusion	11 (0.6)	7 (0.7)	2 (0.3)	2 (1.2)	.870	.482	.208
Cardiac tamponade	5 (0.3)	1 (0.1)	3 (0.5)	1 (0.6)	.151	.198	.889
LPM dislodgment/ embolization	1 (0.1)	0	1 (0.2)	0	.501	.999	.872
Battery premature depletion	3 (0.2)	2 (0.2)	1 (0.2)	0	.904	.813	.772
Periprocedural stroke	2 (0.1)	0	1 (0.2)	1 (0.6)	.640	.567	.747
Femoral artery injury	9 (0.5)	3 (0.3)	6 (1.0)	0	.076	.800	.537
Groin hematoma	37 (2.1)	22 (2.2)	14 (2.4)	1 (0.6)	.752	.208	.178
Systemic/LPM infection	1 (0.1)	1 (0.1)	0	0	.763	.846	.866
Other	6 (0.3)	2 (0.2)	3 (0.5)	1 (0.6)	.291	.359	.889
Major complications	39 (2.2)	18 (1.8)	17 (2.9)	4 (2.4)	.135	.570	.730
Minor complications	36 (2.1)	21 (2.1)	14 (2.4)	1 (0.6)	.654	.226	.179
Intraprocedure	37 (2.1)	18 (1.8)	16 (2.8)	3 (1.8)	.196	.871	.503
Early postprocedure	32 (1.8)	19 (1.9)	11 (1.9)	2 (1.2)	.978	.562	.556
Late postprocedure	6 (0.3)	2 (0.2)	4 (0.7)	0	.141	.777	.490
All-cause mortality	207 (11.8)	99 (9.8)	76 (13.2)	32 (19.5)	.042	<.001	.044

Values are presented as median (interquartile range) or n (%).
CKD = chronic kidney disease; CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration; eGFR = estimated glomerular ejection fraction; LPM = leadless pacemaker; NKF = normal kidney function; RVOT = right ventricular outflow tract.
*Not mutually exclusive.

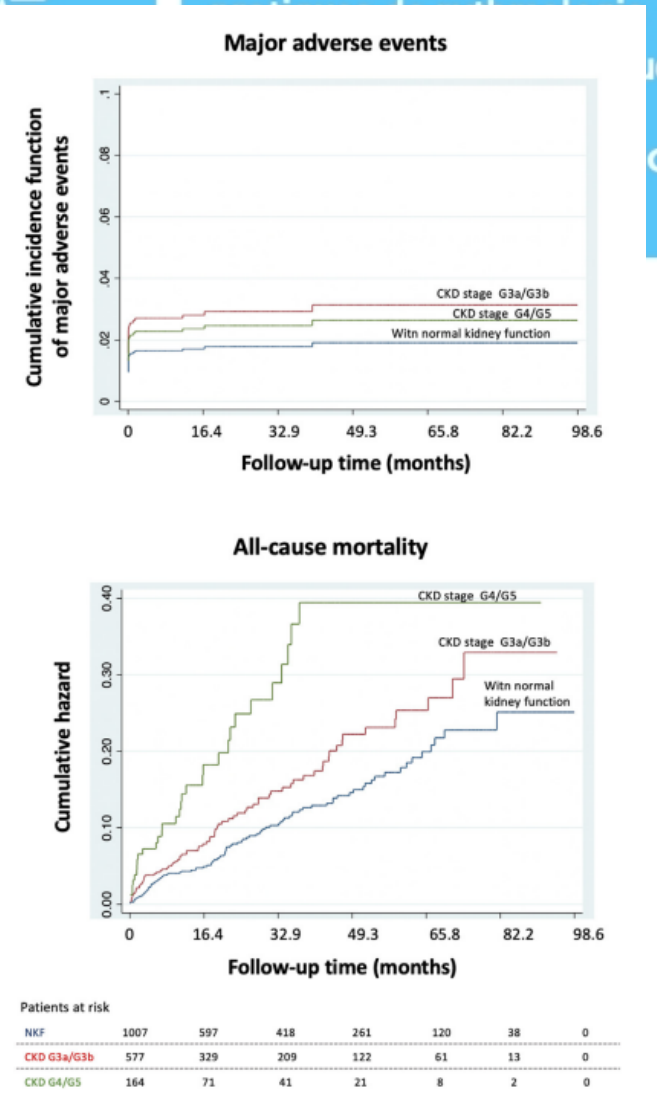

Figure 1
Top: Cumulative incidence function of major adverse events by patients grouped according to kidney function, taking into account the competing risk of death. **Below:** Cumulative hazard of all-cause mortality by patients grouped according to kidney function. CKD = chronic kidney disease; NKF = normal kidney function.

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Impact of comorbidity on complication rates and life expectancy in patients with a leadless pacemaker

Tardu Özkartal [a,*,1], Alessia D'Alto [b,1], Marco Bergonti [a], Maria Luce Caputo [a], Giulio Conte [a,b], Alexander Breitenstein [c], Christian Sticherling [d], Andreas Haeberlin [e], Jolie Bruno [e], Peter Ammann [f], Christian Grebmer [g], Luca Schöni [d], Elia Rigamonti [a], Catherine Klersy [h], Angelo Auricchio [a,b]

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[h] [illegible]

Table 3
Peri-procedural and long-term complications. CCI – Charlson Comorbidity Index. CRT – Cardiac Resynchronization Therapy. IQR - Interquartile range. LV – Left ventricular.

	Peri-procedural and long-term complications			
	All pts. (n = 863)	CCI ≤ 5 (n = 500)	CCI > 5 (n = 363)	P value
In-hospital death, n (%)	16 (1.9)	3 (0.6)	13 (3.6)	p = 0.002
Peri-procedural complications requiring intervention, n (%)	19 (2.2)	13 (2.6)	6 (1.7)	p = 0.482
Pericardial effusion requiring pericardiocentesis	8 (0.9)	5 (1.0)	3 (0.8)	
Vascular complication necessitating intervention, n (%)	6 (0.7)	4 (0.8)	2 (0.6)	
Others	5 (0.6)	4 (0.8)	1 (0.3)	
Long-term complications	16 (1.9)	6 (1.2)	10 (2.8)	p = 0.12
Pacing induced LV dysfunction	7 (0.81)	3 (0.6)	4 (1.1)	
of which upgraded to CRT	6 (0.70)	3 (0.69	3 (0.83)	
Increased threshold and premature battery depletion	9 (1.04)	3 (0.6)	6 (1.7)	
of which implant of new pacemaker	5 (0.58)	2 (0.4)	3 (0.83)	

2.3. Definition of comorbidity groups

Comorbidities were collected according to age-adjusted Charlson Comorbidity Index (CCI): age, sex, history of myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease (including transitory ischemic attack), dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease (divided into severe, defined as cirrhosis with portal hypertension and variceal bleeding history, moderate defined as cirrhosis with portal hypertension but no variceal bleeding history, or mild, defined as chronic hepatitis or cirrhosis without portal hypertension), diabetes mellitus (divided into uncomplicated or complicated with end-organ damage), hemiplegia, moderate to severe chronic kidney disease (defined as creatinine level > 3 mg/dl, presence of signs of uremia, and patient on dialysis or with previous kidney transplant), solid tumor (with or without metastasis), leukemia, lymphoma, and AIDS (acquired immunodeficiency syndrome).

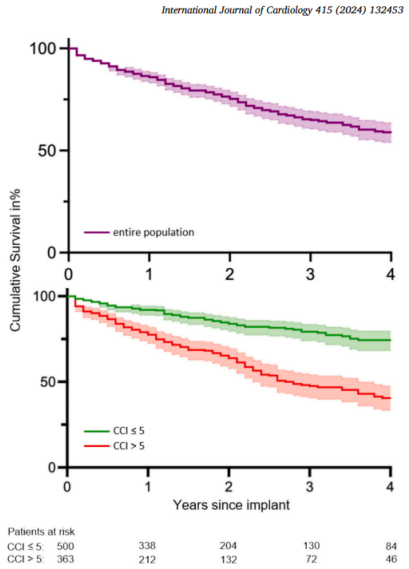

Fig. 1. Cumulative survival according to CCI. Upper panel: purple line – cumulative survival of the entire population over 4 years. Lower panel: green line – cumulative survival of the low comorbidity group with a CCI ≤ 5, red line – cumulative survival of the high comorbidity group with a CCI > 5. CCI – Charlson Comorbidity Index. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

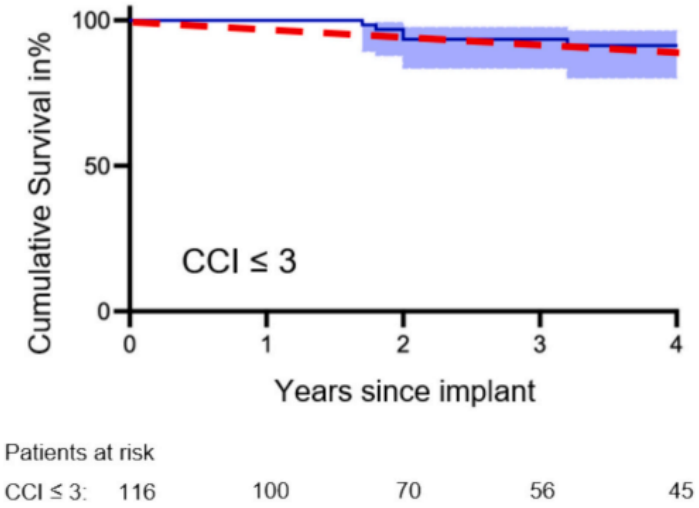

Fig. 2. Cumulative survival in patients with a CCI ≤ 3 compared to the general Swiss population, adjusted for age and sex. Red dashed line: expected survival; blue line - observed survival with 95%CI for CCI ≤ 3. CCI – Charlson Comorbidity Index. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

medicina

MDPI

Article

Leadless Pacemaker Implantation in the Emergency Bradyarrhythmia Setting: Results from a Multicenter European Registry

Marco Schiavone [1,2,*], Annalisa Filtz [1], Alessio Gasperetti [1,3,4,*], Alexander Breitenstein [5], Pietro Palmisano [6], Gianfranco Mitacchione [7], Simone Gulletta [8], Gian Battista Chierchia [9], Elisabetta Montemerlo [10], Giovanni Statuto [11], Giulia Russo [12], Michela Casella [13], Francesco Vitali [14], Patrizio Mazzone [8], Daniel Hofer [5], Gianmarco Arabia [7], Fabrizio Tundo [4], Diego Ruggiero [1], Nicolai Fierro [8], Massimo Moltrasio [4], Matteo Bertini [14], Antonio Dello Russo [13], Ennio C. L. Pisanò [12], Paolo Della Bella [8], Giovanni Rovaris [10], Carlo de Asmundis [9], Mauro Biffi [11], Antonio Curnis [7], Claudio Tondo [4,15], Ardan M. Saguner [5] and Giovanni B. Forleo [1]

The main findings of our study can be summarized as follows:

(1) LPM implantation is a feasible procedure for the treatment of severe bradyarrhythmias in an urgent setting, in patients admitted from the ED;

(2) Emergency LPM implantation was not correlated with an increase in the rate of major complications compared to the control group (6.9% for ED+ vs. 4.2% for ED−, $p = 0.244$);

(3) LPM implantation for severe bradyarrhythmia is associated with longer procedural times (60 (45–80) mins vs. 50 (40–65) mins, $p < 0.001$), even when controlling for confounders (OR 5.156, CI (4.610–24.872), $p = 0.004$).

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Prise en charge du déplacement de PM sans sonde

EP CASE REPORT

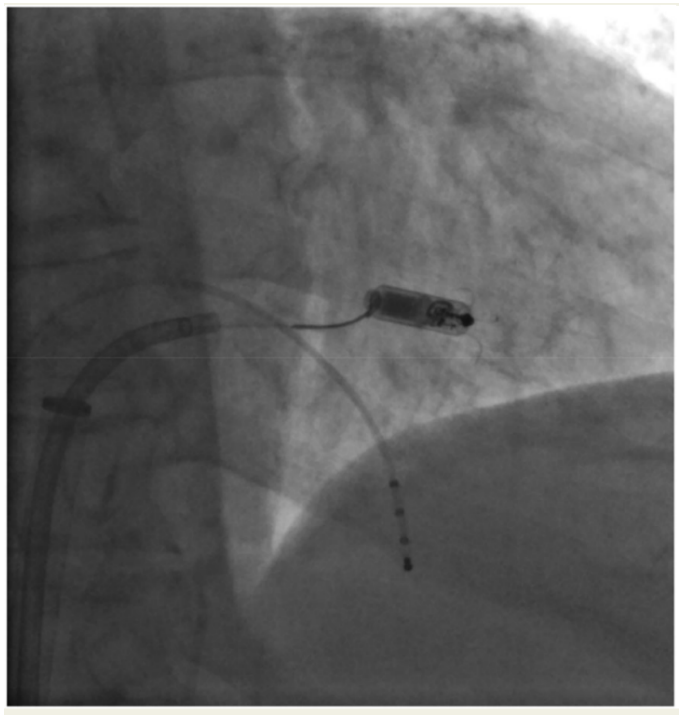
Retrieval of a Medtronic Micra Transcatheter Pacing System after tether removal

Christian Gerdes* and Jens Cosedis Nielsen

Arrhythmia Section, Department of Cardiology, Aarhus University Hospital, Skejby, Denmark

* Corresponding author. Tel: +45 2720 3530; fax +45 7845 2052. *E-mail address:* chr.gerdes@dadlnet.dk

An interaction of the steerable Agilis™ NxT steerable introducer (St. Jude Medical, St. Paul, MN, USA) and snare released the device



6F 20 mm amplatz goose neck snare kit

EP CASE REPORT

Retrieval of a Medtronic Micra Transcatheter Pacing System after tether removal

Christian Gerdes* and Jens Cosedis Nielsen

Arrhythmia Section, Department of Cardiology, Aarhus University Hospital, Skejby, Denmark

* Corresponding author. Tel: +45 2720 3530; fax +45 7845 2052. *E-mail address:* chr.gerdes@dadlnet.dk

- Dans la gaine du stimulateur cardiaque sans sonde ,
  - d'abord, un désilet court de 14F pour l'hémostase ;
  - Deuxièmement, un introducteur orientable en grande courbe (Agilis, Abbott, Abbott Park, Illinois, États-Unis) ;
  - troisièmement, un cathéter de diagnostic 6 F (Amplatz Goose Neck 20 mm)

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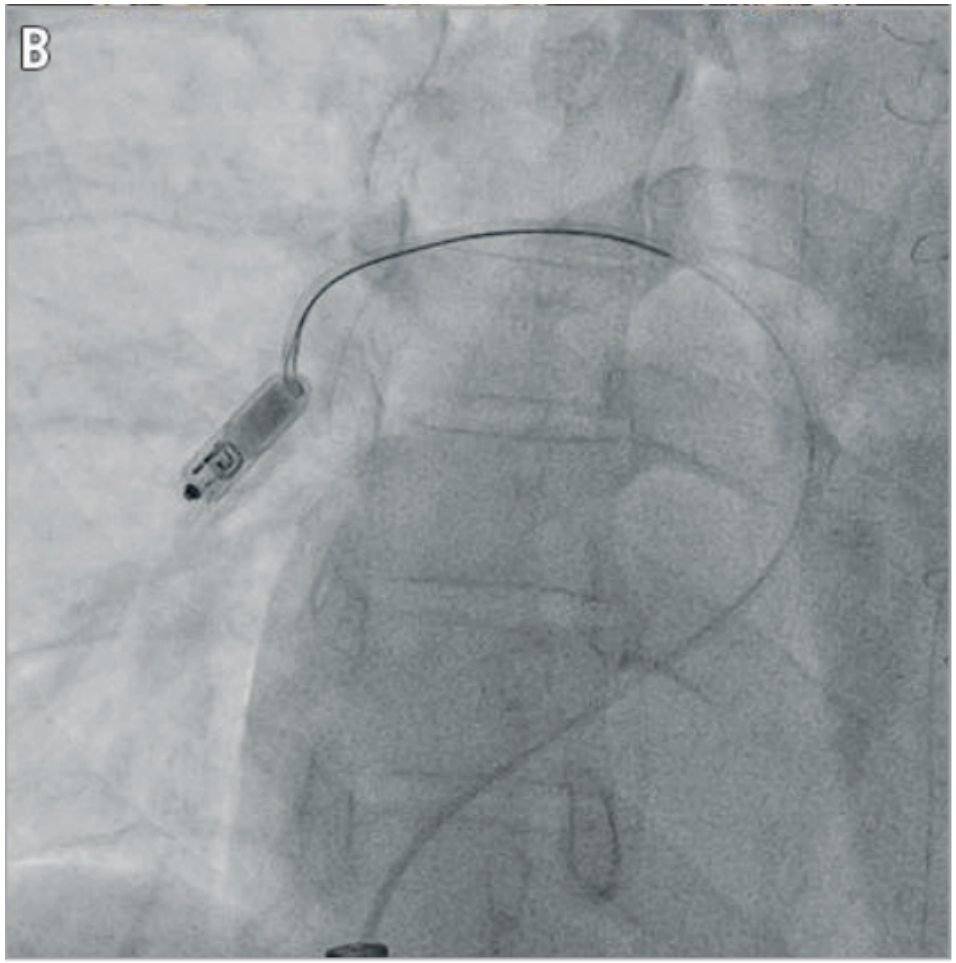
Percutaneous extraction of a leadless Micra pacemaker from the pulmonary artery in a patient with complex congenital heart disease and complete heart block

Maciej Sterliński*, MD, PhD; Marcin Demkow, MD, PhD; Karolina Plaskota, MD, PhD; Artur Oręziak, MD, PhD

Institute of Cardiology, Warsaw, Poland



ESC European Society of Cardiology
European Heart Journal - Case Reports (2019) 3, 1–4
doi:10.1093/ehjcr/ytz113
CASE REPORT
Arrhythmias/Electrophysiology

Percutaneous extraction of a leadless Micra pacemaker after dislocation: a case report

Stephanie Fichtner [1]*, Heidi L. Estner [1], Michael Näbauer[1], and Jörg Hausleiter[1,2]

- Patient présentant une amylose cardiaque

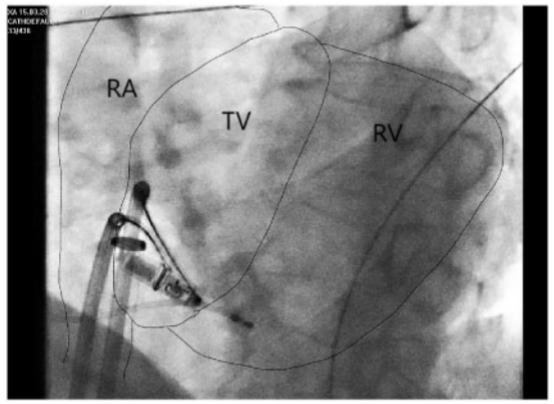


Figure 3 (left anterior oblique) view: extraction of the Micra. One snare is holding a fixation tine (right side) and the other snare is holding the Micra body. In addition, temporary pacing lead. RA, right atrium; RV, right ventricle; TV, tricuspid valve.

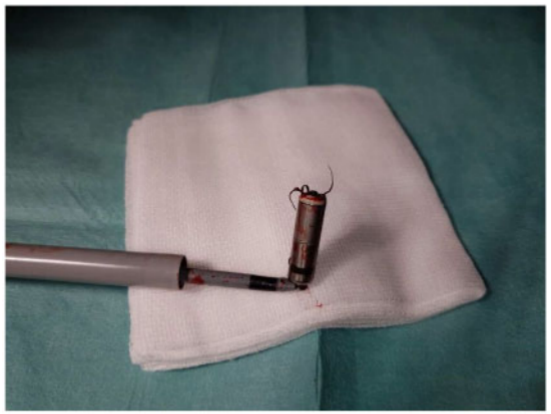


Figure 4 Explanted Micra, snared through an Agilis stearable introducer which is located in the Micra sheath.

VASCULAR AND ENDOVASCULAR TECHNIQUES

Peter F. Lawrence, MD, Section Editor

Three new techniques for creation of a steerable sheath, a 4F snare, and bidirectional sheath inversion using existing endovascular materials

Alexandros Mallios, MD, Willy Yankovic, MD, Benoit Boura, MD, and Myriam Combes, MD, *Paris, France*

The 4F snare device. A 0.018-inch Terumo guidewire (Terumo, Guyancourt, France) is passed through a straight 4F diagnostic catheter and then looped back on itself through the catheter (Fig 3). This creates a loop snare that can be greatly modified in size and easily rotated and positioned with the use of the 4F introducer sheath (Fig 4).

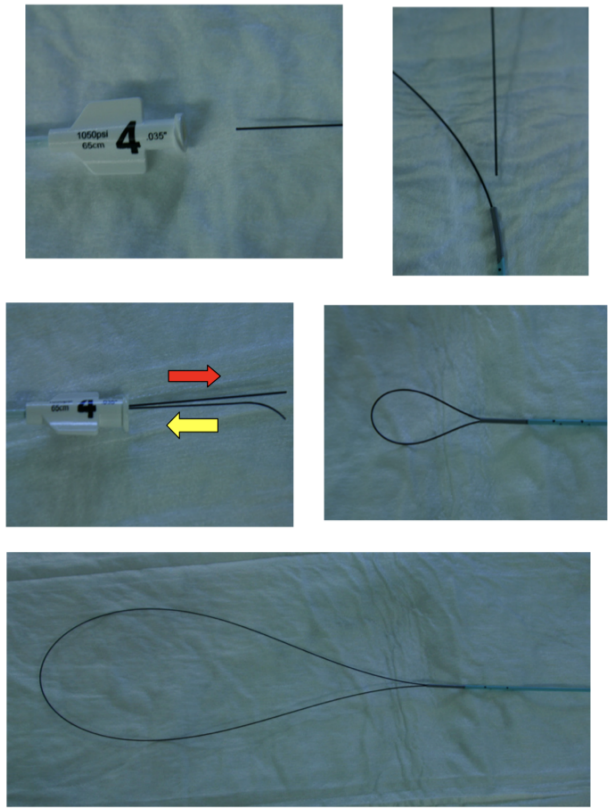


Fig 3. Creation of the snare. From *left* to *right*: Insertion of a 0.018-inch Terumo wire into the 4F catheter (straight–stiff tip first). After it exits from the other side of the catheter, we reinsert it to create the loop. The size can be greatly modified. If we need to undo the snare at some point during the procedure, we can push one of the two sides of the wire and pull the other (*red* and *yellow arrows*).

VASCULAR AND ENDOVASCULAR TECHNIQUES

Peter F. Lawrence, MD, Section Editor

Three new techniques for creation of a steerable sheath, a 4F snare, and bidirectional sheath inversion using existing endovascular materials

Alexandros Mallios, MD, Willy Yankovic, MD, Benoit Boura, MD, and Myriam Combes, MD, *Paris, France*

A 10F nonflexible sheath was used for the initial vascular access. An 8F long flexible sheath was inserted through the 10F sheath, constituting the steerable element of the "device." A 0.035-inch wire was introduced into the 8F sheath, exiting between the 8F and the 10F sheath. A 6F sheath was then inserted through the 8F sheath and used for the renal artery cannulation (Fig 2).

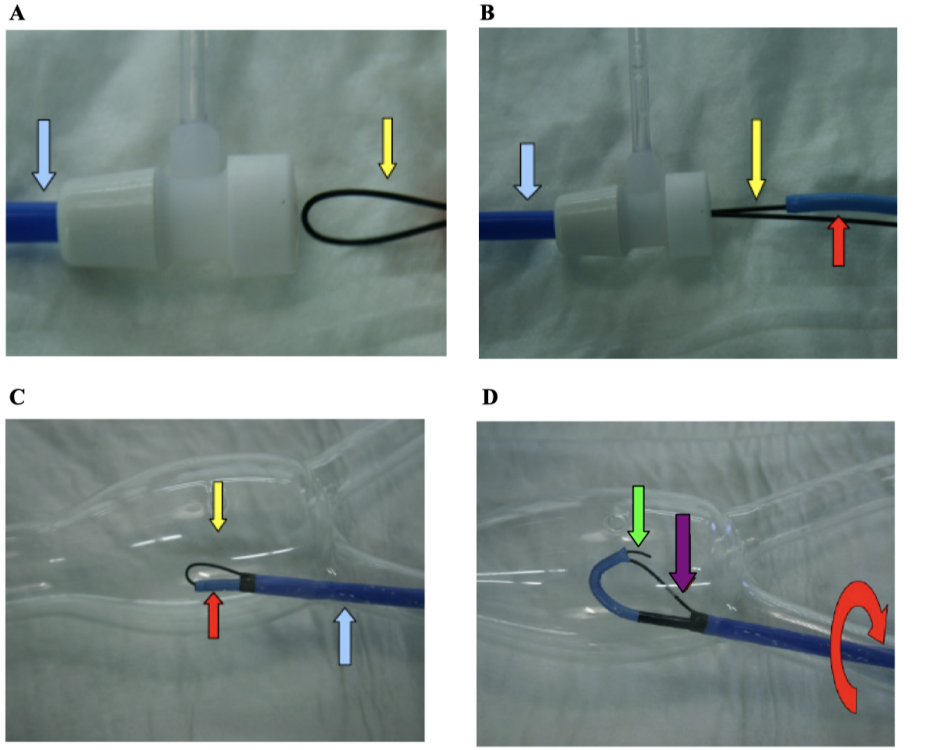


Fig 1. A-C, A guidewire (*yellow arrow*) is passed through a flexible sheath (*red arrow*), folded back on itself, and introduced into a nonflexible wider sheath (*light blue arrow*). The steerable element may exit the nonflexible sheath at the required level for use. **D**, Pulling the wire (*purple arrow*) that returns back to us achieves the desired angulation. Rotating the larger nonflexible sheath also rotates the guiding system (*circular arrow*). A vertebral catheter with a cannulating wire can be inserted into the flexible sheath to cannulate the target vessel (*green arrow*).

En conclusion

- Le déplacement des PM sans sonde reste une complication rare
- L'extraction reste un challenge

Table 3. Patient selection for leadless pacemakers.

First Choice	Reasonable	Avoid
Occluded upper extremity vascular access	Right ventricular only pacing	Atrial pacing needed
End stage renal disease	Bridging pacemaker during lead extraction	Cardiac resynchronization therapy indicated
Recent bacteremia	As part of ablate and pace strategy	Defibrillator indicated
Intravenous drug use	-	Young patients
Bioprosthetic tricuspid valve	-	-

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