"CARDIOLOGIA DI PRECISIONE"

NOVARA, Venerdì 13 e Sabato 14 Settembre 2019

Pacing VVI leadless

Indicazione di nicchia

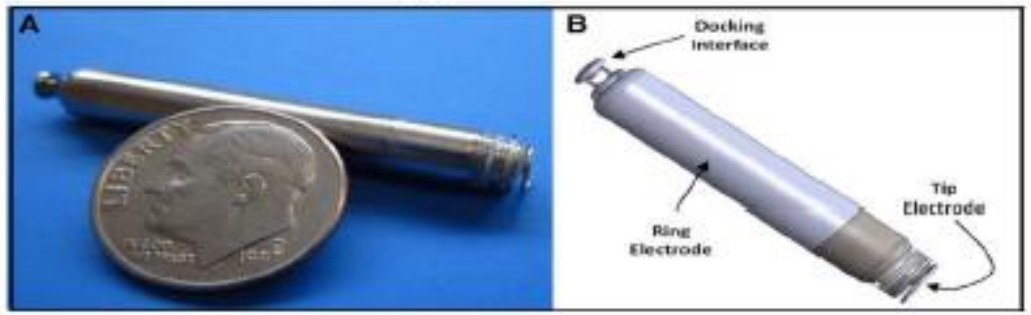
A. Ferraro – Rivoli (TO)

ORIGINAL ARTICLE

Percutaneous Implantation of an Enti… Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cant…, Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Toma…oni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes III, M.D., Jo…n Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Ra…sh Bari…, M.D., James Porterfield, M.D., James E. Ip, M.D., and S…nivas R. Dukki…, M.D., for the LEADLESS II Study I…estigators*

30. August 2015



ORIGINAL ARTICLE

…eadless Intracardiac Transcatheter Pacing System

…ds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D., …Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D., …Calambur…arasimhan, M.D., Clemens Steinwender, M.D., Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D., Venkata Sagi, M.D., Jo…Hummel, M.D., Maria Grazia Bongiorni, M.D., Reinoud E. Knops, M.D., Ch…topher R. Ellis, M.D., Charles C. Gornick, M.D., …Matthew A. Bernabei, M.D., …eda Laager, M.A., Kurt Stromberg, M.S., Eric R. …ns, B.S., J. Harriso…udnall, B.S., and Philippe Ritter, M.D., for the Micra Transcatheter Pacing Study Group*

9. November 2015

Reddy VY, NEJM, 2015
Reynolds D, NEJM, 2015

BENEFIT OF LEADLESS APPROACH

■Reduced invasiveness

- Percutaneus procedure
- Reduced hardware
- “Invisible to the patient”

■Improved Efficiency

- No pocket
- No system connection
- Reduced procedure time

■Improved Outcomes

- Fewer complications

Table 1. Comparison of Leadless Pacemakers.*

Device	Size	Means of Fixation	Patients	Successful Implantation	Major Complications	Perforation or Effusion	Device Dislodgement	Adequate Pacing Measures at 6 Mo
	*cm*³		*no.*	%	%	%	%	%
Nanostim	1.0	Helical wire screw	526	95.8	6.5	1.5	1.1	90.0
Micra	0.8	Tines	725	99.2	4.0	1.6	0	98.3

* Data in the table pertain to the total cohort in each study, with the exception of the rates of adequate pacing measures at 6 months, which are for the cohort used in the primary efficacy analysis.

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EDITORIAL COMMENT

Are Leadless Pacemakers a Niche or the Future of Device Therapy?*

Michael R. Gold, MD, PhD

There are a number of questions that remain to be answered regarding this new technology. Will the device continue to perform at a high level in the long term and match the reliability of current pacemaker pulse generators? Is this device retrievable in the long term, and how are patients managed when systemic infection develops or the device reaches elective replacement? Abandoning the device and

Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study

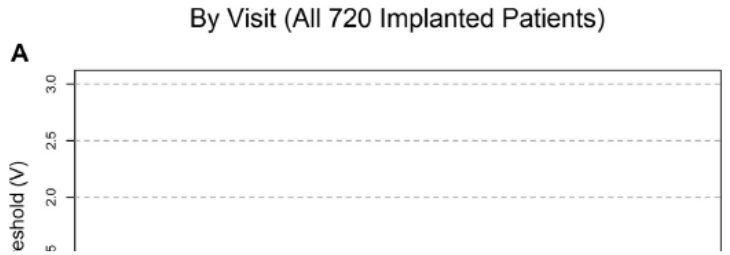
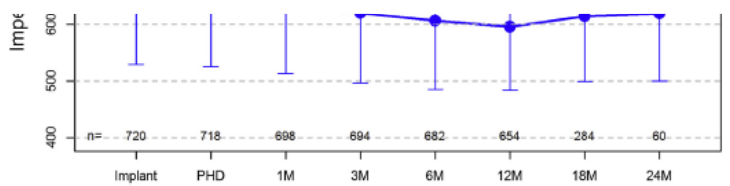


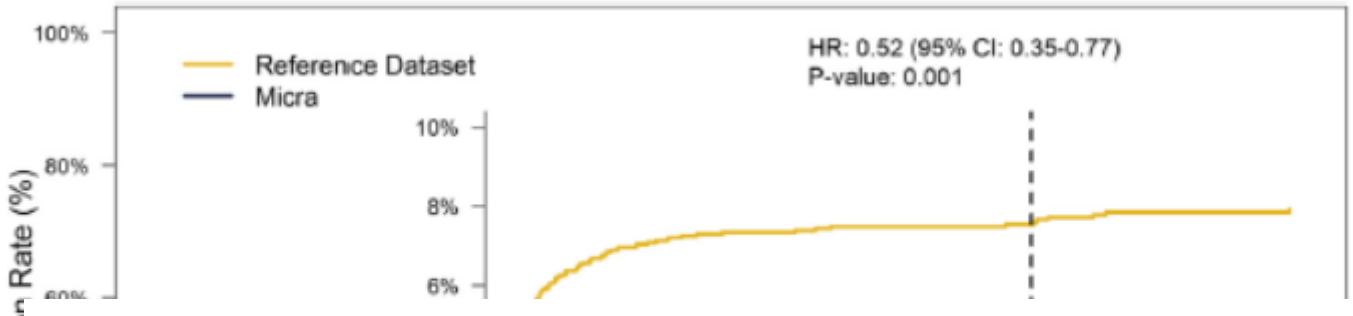
Table 1 Major complications (patients with an attempted Micra implant; N = 726)

	No. of events (No. of patients, %)			
Adverse event key term	Within 30 d	30 d to 6 mo	>6 mo	Total major complications
Total major complications	**24 (21, 2.89%)**	**6 (6, 0.83%)**	**2 (2, 0.28%)**	**32 (29, 3.99%)**
Embolism and thrombosis	2 (2, 0.28%)	0 (0, 0%)	0 (0, 0%)	2 (2, 0.28%)
Deep vein thrombosis	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Pulmonary embolism	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Events at groin puncture site	5 (5, 0.69%)	0 (0, 0%)	0 (0, 0%)	5 (5, 0.69%)
Arteriovenous fistula	4 (4, 0.55%)	0 (0, 0%)	0 (0, 0%)	4 (4, 0.55%)
Vascular pseudoaneurysm	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Cardiac effusion/perforation	10 (10, 1.38%)	1 (1, 0.14%)	0 (0, 0%)	11 (11, 1.52%)
Pacing issues: elevated thresholds	2 (2, 0.28%)	0 (0, 0%)	0 (0, 0%)	2 (2, 0.28%)
Other	5 (5, 0.69%)	5 (5, 0.69%)	2 (2, 0.28%)	12 (12, 1.65%)
Acute myocardial infarction	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Cardiac failure	0 (0, 0%)	4 (4, 0.55%)	2 (2, 0.28%)	6 (6, 0.83%)
Metabolic acidosis	1 (1, 0.14%)*	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Pacemaker syndrome	1 (1, 0.14%)	1 (1, 0.14%)	0 (0, 0%)	2 (2, 0.28%)
Presyncope	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)
Syncope	1 (1, 0.14%)	0 (0, 0%)	0 (0, 0%)	1 (1, 0.14%)

*Led to procedure-related death in a patient with end-stage renal disease.



Heart Rhythm, Vol 14, No 5, May 2017



Conclusion

The Micra Transcatheter Pacing Study achieved its prespecified long-term safety objective with 96% freedom from major complications. Patients with Micra experienced a 48% reduction in the risk of major complication at 12 months compared to patients with transvenous systems from a historical control group, resulting in 82% fewer system revisions and 47% fewer hospitalizations. Pacing thresholds remained low and stable through 24 months of follow-up.

Tab

Maj

Total major complications	4.0% (2.8% to 5.8%)	7.6% (6.6% to 8.7%)	48% (23% to 65%)*
Death	0.1% (0% to 1.0%)	0.0% (NE)	NE
Hospitalization	2.3% (1.4% to 3.7%)	4.1% (3.4% to 5.0%)	47% (11% to 69%)†
Prolonged hospitalization	2.2% (1.4% to 3.6%)	2.4% (1.9% to 3.1%)	9% (−57% to 47%)
System revision	0.7% (0.3% to 1.7%)	3.8% (3.1% to 4.6%)	82% (55% to 93%)*
Loss of device function	0.3% (0.1% to 1.1%)	0.0% (NE)	NE

Not mutually exclusive as a single event may meet ≥1 major complication criteria.
CI = confidence interval; NE = not estimable.
*$P \leq .001$.
†$P < .05$.

Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control

Table 1 Baseline characteristics

Characteristic	Postmarket (n = 1817)	IDE (n = 726)	Total (N = 2543)	*P*
Sex: male	1111 (61.1)	427 (58.8)	1538 (60.5)	.26
Atrial arrhythmia	1370 (75.4)	548 (75.5)	1918 (75.4)	>.99
CHF	234 (12.9)	131 (18.0)	365 (14.4)	.001
COPD	176 (9.7)	92 (12.7)	268 (10.5)	.032
CAD	402 (22.1)	205 (28.2)	607 (23.9)	.001
HTN	1165 (64.1)	571 (78.7)	1736 (68.3)	<.001
Diabetes	480 (26.4)	207 (28.5)	687 (27.0)	.30
Prior CIED	265 (14.6)	0 (0.0)	265 (10.4)	<.001
Condition that precludes the use of a TV-PPM	435 (23.9)	45 (6.2)	480 (18.9)	<.001
Pacing indication				
Bradyarrhythmia with AF	1127 (62.0)	464 (63.9)	1591 (62.6)	<.001
Sinus node dysfunction	177 (9.7)	126 (17.4)	303 (11.9)	
AV block	211 (11.6)	109 (15.0)	320 (12.6)	
Syncope	243 (13.4)	16 (2.2)	259 (10.2)	
Other	50 (2.8)	11 (1.5)	61 (2.4)	
Not reported	9 (0.5)	0 (0.0)	9 (0.4)	

Values are presented as n (%).

AF = atrial fibrillation; AV = atrioventricular; CAD = coronary artery disease; CHF = congestive heart failure; CIED = cardiac implantable electronic device; COPD = chronic obstructive pulmonary disease; HTN = hypertension; IDE = Micra Investigational Device Exemption; TV-PPM = transvenous pacemaker.

Table 2 Major complications for patients with an attempted Micra implantation procedure (n=1817)

Complication	No. of events (no. of patients, percentage)		
	≤30 d	>30 d	Total major complications
Total major complications	41 (36, 1.98)	5 (5, 0.28)	46 (41, 2.26)
Embolism and thrombosis	2 (2, 0.11)	0 (0, 0)	2 (2, 0.11)
Deep vein thrombosis	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Pulmonary embolism	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Events at the groin puncture site	10 (10, 0.55)	1 (1, 0.06)	11 (11, 0.61)
Arterial injury/atrioventricular fistula	6 (6, 0.33)	1 (1, 0.06)	7 (7, 0.39)
Hematoma	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Incision site hemorrhage	2 (2, 0.11)	0 (0, 0)	2 (2, 0.11)
Retroperitoneal hemorrhage	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Cardiac effusion/perforation	8 (8, 0.44)	0 (0, 0)	8 (8, 0.44)
Pacing issues	12 (11, 0.61)	2 (2, 0.11)	14 (13, 0.72)
Device capturing issue/elevated thresholds	9 (9, 0.50)	2 (2, 0.11)	11 (11, 0.61)
Device dislodgment	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Device embolization during an implant attempt	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Undersensing	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Infection	3 (3, 0.17)	0 (0, 0)	3 (3, 0.17)
Abdominal wall infection	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Hematoma infection	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Sepsis	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Other	6 (6, 0.33)	2 (2, 0.11)	8 (8, 0.44)
Blood pressure decreased	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Cardiac failure	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Cardiomyopathy	0 (0, 0)	1 (1, 0.06)	1 (1, 0.06)
Complication of device removal	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Noncardiac chest pain	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Pacemaker syndrome	0 (0, 0)	1 (1, 0.06)	1 (1, 0.06)
Pulmonary edema	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)
Syncope	1 (1, 0.06)	0 (0, 0)	1 (1, 0.06)

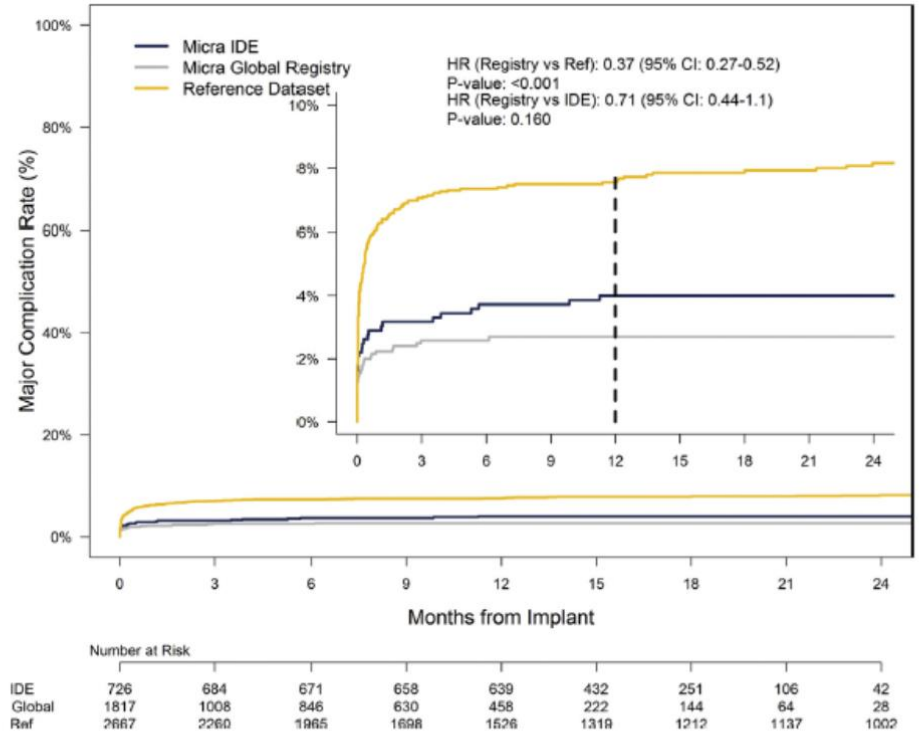


Figure 3 Major complication rates through 24 months postimplantation for Micra PAR, Micra IDE study, and transvenous reference cohorts. Subdistributional hazard ratio derived from data through 365 days postimplantation for each cohort by comparing the cumulative incidence functions given to the left of the *dashed line*. CI = confidence interval; HR = hazard ratio; IDE = Micra Investigational Device Exemption; PAR = Post-Approval Registry.

Table 3 System- or procedure-related major complication breakdown for Micra and transvenous control patients

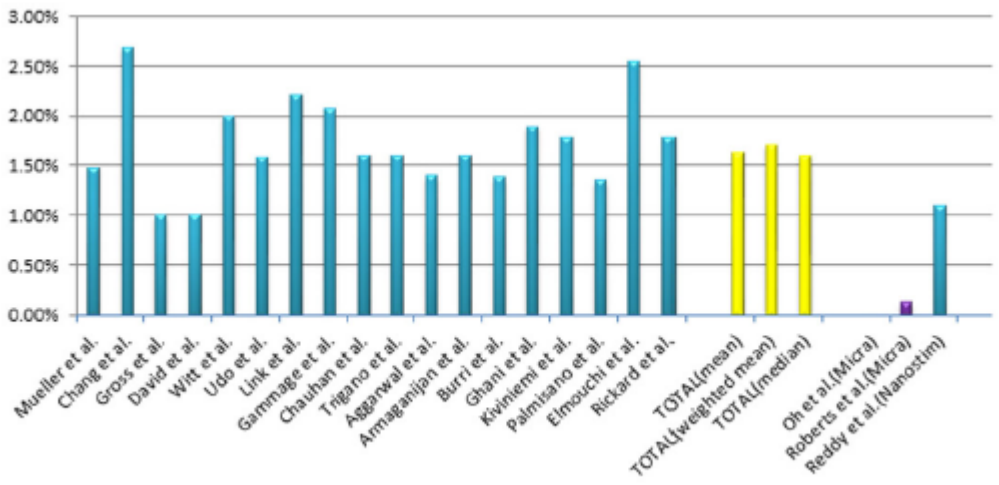
	Micra (n = 1817)		Transvenous historical control (n = 2667)			
Major complication criterion	No. of events (no. of patients, percentage)	12-mo KM estimates (95% CI) (%)	No. of events (no. of patients, percentage)	12-mo KM estimates (95% CI) (%)	Relative risk reduction (95% CI) (%)	*P*
Total major complications	46 (41, 2.26)	2.7 (2.0 to 3.7)	230 (196, 7.35)	7.6 (6.6 to 8.7)	63 (48 to 73)	<.0001
Death	5 (5, 0.28)	0.3 (0.1 to 0.8)	0 (0, 0.00)	0.0	NE	.0109
Hospitalization	17 (16, 0.88)	1.3 (0.8 to 2.1)	124 (106, 3.97)	4.1 (3.4 to 5.0)	71 (51 to 83)	<.0001
Prolonged hospitalization	33 (29, 1.60)	1.9 (1.3 to 2.7)	68 (64, 2.40)	2.4 (1.9 to 3.1)	24 (−18 to 51)	.2278
System revision	15 (13, 0.72)	0.9 (0.5 to 1.6)	102 (95, 3.56)	3.8 (3.1 to 4.6)	74 (54 to 85)	<.0001
Loss of device function	9 (9, 0.50)	0.7 (0.4 to 1.3)	0 (0, 0.00)	0.0	NE	.0003

Major complication end point criteria are not mutually exclusive. For example, an event resulting in a system revision may also result in hospitalization.
CI = confidence interval; KM = Kaplan-Meier; NE = not estimable.

Meta-analysis of the incidence of lead dislodgement with conventional and leadless pacemaker systems

TABLE 2 Characteristics of leadless pacemaker systems in the included studies

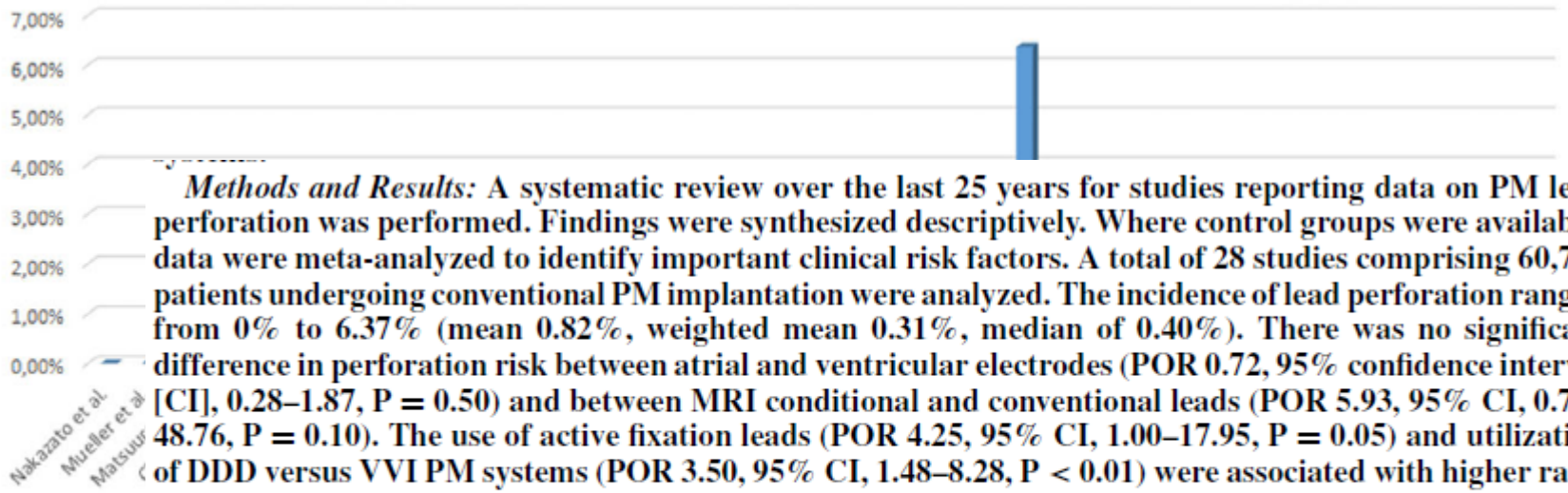
Study	Subjects (N)		Incidence	Age (Years)	Sex (Female)	Follow-up	Devices implanted	Dislodgement defined as	Quality
	Total	Dislod-gement							
Oh et al.[25]	725	0	0	75.9 ± 10.9	41.2%	1 year	Micra TPS	No dislodgement	High
Roberts et al.[12]	795	1	0.13%	75.2 ± 14.2	62.3%	1 months	Micra TPS	2 tines were observed to not be embedded in tissue and 2 tines were positioned between the wall and papillary muscle	High
Reddy et al.[13]	526	6	1.1%	75.8 ± 12.1	385	6.9 +−4.2 months	Nanostim-LCP	Device migration to the pulmonary artery or right femoral vein occurred in 4 and 2 patients, respectively	High



Methods and results: A total of 18 studies which included 17,321 patients undergoing conventional single- or dual-chamber pacemaker implantation and three studies which included 2,116 patients undergoing LCP device implantation were reviewed. The incidence of lead dislodgement ranged from 1% to 2.69% in individual studies with a mean of 1.63%, weighted mean of 1.71%, and median of 1.60 %. There was a relatively higher lead dislodgement rate between atrial and ventricular electrodes (odds ratio [OR], 3.56; 95% confidence interval [CI], 1.9–6.70; P = 0.6; I^2 = 0%), and between magnetic resonance imaging conditional and conventional leads (OR, 2.79; 95% CI, 1.30–5.99; P = 0.16; I^2 = 46%). The use of active fixation leads (OR, 1.06; 95% CI, 0.66–1.70; P = 0.29; I^2 = 20%) showed no significant difference in dislodgement risk compared to passive fixation leads. The incidence of LCP device dislodgement was 0%, 0.13%, and 1% in three leadless pacemaker studies.

Conclusions: The incidence rates of conventional pacemaker lead dislodgement vary in individual studies with an overall high incidence. Use of the currently available LCP systems appears to result in a lower rate of device dislodgement. This may reflect the effectiveness of this novel technology and the fixation design of LCP devices.

Incidence of Cardiac Perforation With Conventional and With Leadless Pacemaker Systems: A Systematic Review and Meta-Analysis



Methods and Results: A systematic review over the last 25 years for studies reporting data on PM lead perforation was performed. Findings were synthesized descriptively. Where control groups were available, data were meta-analyzed to identify important clinical risk factors. A total of 28 studies comprising 60,744 patients undergoing conventional PM implantation were analyzed. The incidence of lead perforation ranged from 0% to 6.37% (mean 0.82%, weighted mean 0.31%, median of 0.40%). There was no significant difference in perforation risk between atrial and ventricular electrodes (POR 0.72, 95% confidence interval [CI], 0.28–1.87, P = 0.50) and between MRI conditional and conventional leads (POR 5.93, 95% CI, 0.72–48.76, P = 0.10). The use of active fixation leads (POR 4.25, 95% CI, 1.00–17.95, P = 0.05) and utilization of DDD versus VVI PM systems (POR 3.50, 95% CI, 1.48–8.28, P < 0.01) were associated with higher rates of perforation. In the 2 leadless PM studies, the incidence of cardiac perforation was 1.52% for each.

Conclusion: PM lead perforation rates vary in individual studies with an overall low incidence. Leadless PMs seem to be associated with a slightly higher perforation risk, most likely reflecting a learning curve effect of this novel technology. *(J Cardiovasc Electrophysiol, Vol. 28, pp. 336-346, March 2017)*

Perforation with

Perforation rat
less PMs appear
rate of perforation was higher compared to the conventional systems, the incidence is still reasonably low. On the other hand, the consequences of cardiac perforation due to the implantation of conventional leads appear to be different from those occurring in leadless PM implantation. In the former group, the vast majority of perforations are associated with mild symptoms or even asymptomatic while in the leadless PM studies more than 50% of patients with evidence of perforation developed tamponade. These differ-

TABLE 2
Characteristics of Leadless Pacemaker Systems Studies

Study	Study Design	Subjects (N)		Incidence	Age (Years)	Sex (Female)	Follow-Up	Manufacturer	Devices Implanted	Myocardial Injury Defined as	Onset	Tamponade	Lead / Surgical Revision	Quality
		Total	Perforation											
Reddy *et al.* (Nanostim)[33]	Multicenter, prospective, nonrandomized study	526	8	1,52%	75.8 ± 12.1	38%	6.9 ± 4.2 months	SJM	VVI 100%	Radiographic evidence, pericardial fluid, cardiac tamponade, or symptoms of pericarditis	n.a.	62.5%	12.5%	High
Reynolds *et al.* (MICRA)[34]	Multicenter, prospective, nonrandomized study	725	11	1.52%	75.9 ± 10.9	41%	4 months	Medtronic	VVI 100%	Cardiac injury including cardiac perforation or pericardial effusion	n.a.	63.6%	18.2%	High

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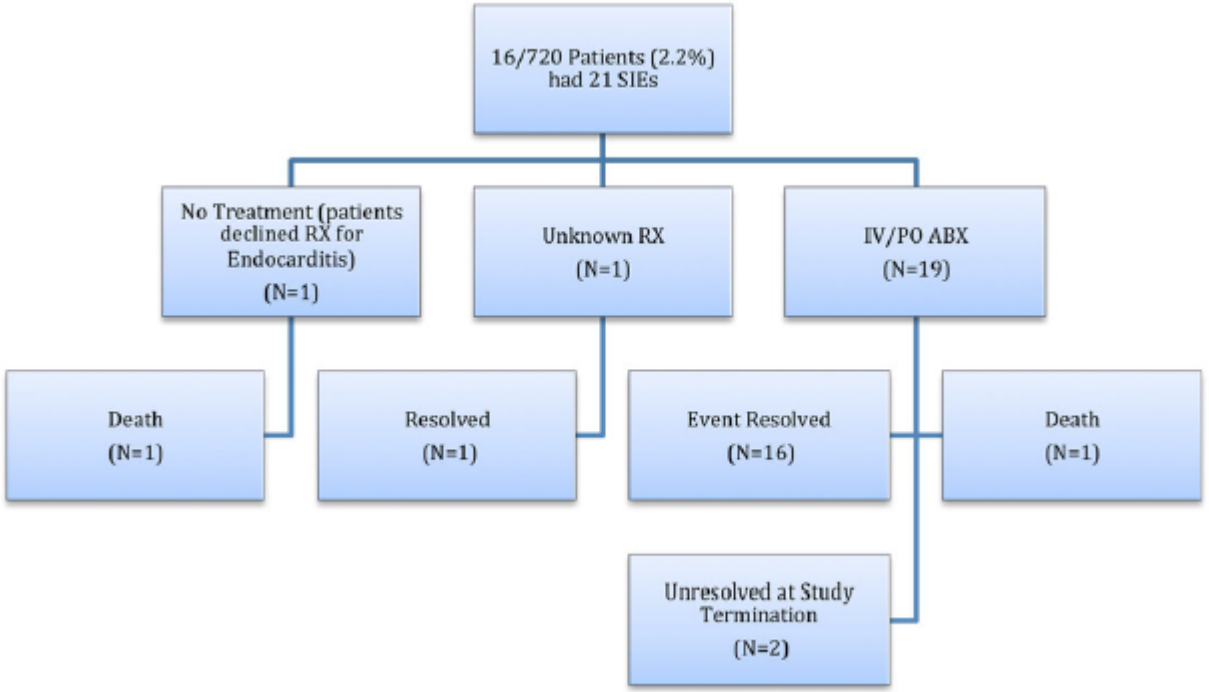
PACE WILEY

Incidence and outcomes of systemic infections in patients with leadless pacemakers: Data from the Micra IDE study

TABLE 1 Baseline characteristics of patients with and without systemic infection

Subject characteristics	Developed sepsis (N = 16)	Did not develop sepsis (N = 704)	*P* value
Age (years)			
Mean ± standard deviation	71.9 ± 11.7	75.9 ± 11.0	.15
Male, *n* (%)	10 (62.5%)	415 (58.9%)	1.00
Atrial arrhythmias, *n* (%)	13 (81.3%)	531 (75.4%)	.77
CHF, *n* (%)	8 (50.0%)	121 (17.2%)	.003
COPD, *n* (%)	4 (25.0%)	87 (12.4%)	.13
CAD, *n* (%)	6 (37.5%)	195 (27.7%)	.40
HTN, *n* (%)	13 (81.3%)	552 (78.4%)	1.00
Dialysis, *n* (%)	2 (12.5%)	26 (3.7%)	.13
Diabetes, *n* (%)	4 (25.0%)	201 (28.6%)	1.00
Preclusion for transvenous	4 (25.0%)	41 (5.8%)	.014
Pacing indication (%)			
Bradyarrhythmia with AF	9 (56.3%)	451 (64.1%)	.11
Sinus node dysfunction	4 (25.0%)	121 (17.2%)	
AV block	1 (6.3%)	107 (15.2%)	
Syncope	2 (12.5%)	14 (2.0%)	
Other	0 (0.0%)	11 (1.6%)	

AF = atrial fibrillation; AV = atrioventricular; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; HTN = hypertension.



5 | CONCLUSION

The Micra leadless pacemaker may have unique characteristics that make it more resistant to bacterial seeding in the setting of bacteremia than conventional pacemakers. Prospective multicenter studies are needed to confirm these preliminary findings.

Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry

TABLE 1 Baseline characteristics and prior CIED system information

Subject characteristics	Subjects, *N* = 105
Age, y	
Mean ± standard deviation	72.7 ± 14.7
Sex (% male)	69 (65.7%)
Cardiovascular disease history (n, %)	
Atrial arrhythmias	60 (57.1)
Cardiomyopathy	28 (26.7)
Congestive heart failure	16 (15.2)
Coronary artery disease	26 (24.8)
Hypertension	51 (48.6)
Myocardial infarction	6 (5.7)
Pulmonary hypertension	3 (2.9)
Coronary artery intervention	17 (16.2)
Pacemaker dependent	33 (31.4)
Other comorbidities n (%)	
COPD	17 (16.2)
Chronic lung disease	18 (17.1)
Diabetes	34 (32.4)
Renal dysfunction	29 (27.6)
Dialysis	13 (12.4)
Condition precluding transvenous system	83 (79.0)
Pacing indication n (%)	
Bradyarrhythmia with AF	52 (49.5)
Sinus node dysfunction	11 (10.5)
AV block	23 (21.9)
Syncope	12 (11.4)
Other	6 (5.7)
Not reported	1 (1.0)
Previous CIED system (%)	
Pacemaker	74 (70.5)
CRT-pacemaker	10 (9.5)
ICD	5 (4.8)
CRT-ICD	8 (7.6)
Not reported	8 (7.6)
Prior system status (%)	
All components explanted	98 (93.3)
Partially explanted	7 (6.7)

Abbreviations: AV, atrioventricular; CIED, cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.

TABLE 3 Major complications in 105 patients with prior CIED infection and extraction who underwent Micra implant attempt

Adverse event keyterm	No. events (No. subjects, %)
Total major complications	**6 (4, 3.81)**
Cardiac effusion/perforation	**1 (1, 0.95)**
Pacing issues	**1 (1, 0.95)**
Elevated thresholds	1 (1, 0.95)
Infection	**1 (1, 0.95)**
Abdominal wall infection	1 (1, 0.95)
Other	**3 (3, 2.86)**
Complication of device removal	1 (1, 0.95)
Pacemaker syndrome	2 (2, 1.90)

Abbreviation: CIED, cardiac implantable electronic device.
The first bold is number of subjects and second one is percentage.

6 | CONCLUSION

The Micra leadless pacemaker is a safe and feasible pacing option in patients with history of CIED infection. Its intracardiac location, small surface area, and tendency for encapsulation might provide an advantage in this patient population at risk of recurrent infections.

ESC European Society of Cardiology
Europace (2019) 21, 1229–1236
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Micra pacemaker implant after cardiac implantable electronic device extraction: feasibility and long-term outcomes

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Table 1 Baseline characteristics

	Overall population ($n = 83$)	Group 1 Post-extraction patients ($n = 23$)	Group 2 Naïve patients ($n = 60$)	*P*
Age (years)	77.27 ± 9.96	73.83 ± 10.29	78.58 ± 9.6	0.042
Male gender, *n* (%)	65 (78.31)	20 (86.96)	45 (75)	0.24
Ejection fraction (%)	56.45 ± 7.5	57.4 ± 8.34	56.04 ± 7.17	0.18
Pacing indication, *n* (%)				
AV block with permanent atrial fibrillation, *n* (%)	39 (46.98)	7 (30.43)	32 (53.33)	0.22
Sinus-node dysfunction	19 (22.89)	10 (43.48)	9 (15)	0.002
Sinus rhythm with intermittent AV block, *n* (%)	20 (24.09)	4 (17.39)	16 (26.67)	0.27
Other reasons, *n* (%)	5 (6.04)	2 (8.7)[a]	3 (5)[b]	0.67
Comorbidities, *n* (%)				
Coronary artery disease, *n* (%)	16 (19.28)	5 (21.74)	11 (18.33)	0.64
Hypertension, *n* (%)	59 (71.08)	15 (65.22)	44 (73.33)	0.69
Diabetes, *n* (%)	16 (19.28)	3 (13.04)	13 (21.67)	0.43
Renal impairment, *n* (%)	12 (14.46)	2 (8.7)	10 (16.67)	0.40
Chronic obstructive pulmonary disease, *n* (%)	11 (13.25)	4 (17.4)	7 (11.67)	0.43

AV, atrioventricular block.
[a]One carotid sinus syndrome and one suspected bradycardia without definite diagnosis.
[b]Three syncope with bifascicular bundle branch block.

Table 3 Implant procedure data

	Overall population ($n = 83$)	Group 1 Post-extraction patients ($n = 23$)	Group 2 Naïve patients ($n = 60$)	*P*
Deployments, *n* (%)				
1	49 (59.04)	16 (69.56)	33 (55)	0.22
>1	34 (40.96)	7 (30.44)	27 (45)	
Implant site, *n* (%)				
Apical	23 (27.7)	5 (21.74)	18 (30)	0.42
Septum	60 (72.3)	18 (78.26)	42 (70)	
Fluoroscopy time (min)	13.32 ± 7.79	13.88 ± 10.98	13.15 ± 6.64	0.45
Impedance (Ohm)	714 ± 165.8	689.09 ± 125.05	723.67 ± 178.46	0.54
Pacing threshold (V)[a]	0.56 ± 0.34	0.59 ± 0.34	0.54 ± 0.35	0.34
Ventricular sensing (mV)	10.02 ± 4.52	9.92 ± 5.16	10.05 ± 4.31	0.62

[a]Duration 0.24 ms.

Clinical follow-up

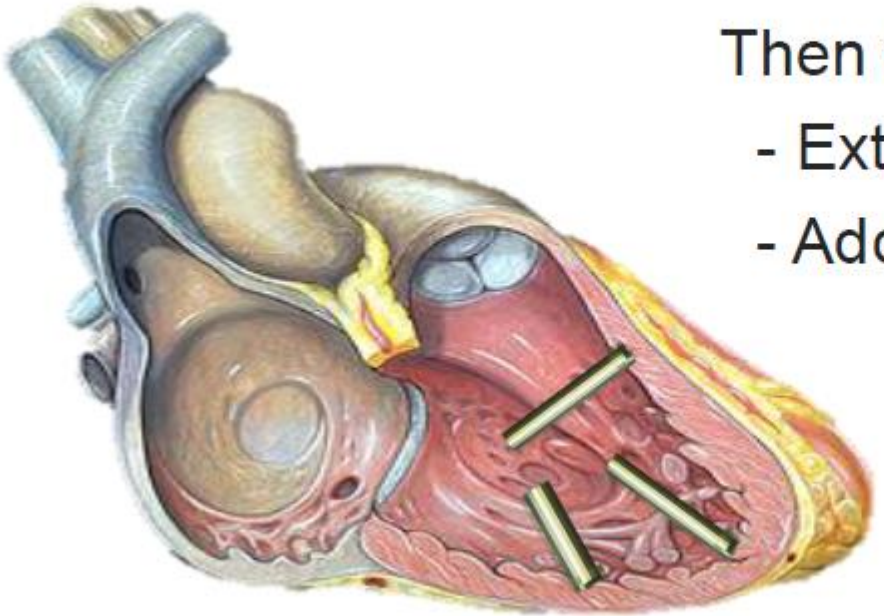
sion due to epicardial PM infection). Anyway, no patients required a system upgrade due to a PM syndrome.

Conclusions

Micra implant appears to be a safe and effective procedure even in the post-extraction setting, and with electrical performance and outcomes comparable with naïve patients at long-term follow-up.

Battery Longevity

- Current **projected** Battery Longevity: 8-10 years



Then what?

- Extraction and Reimplant?
- Add another one?

EP CASE EXPRESS

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Safety and usefulness of a second Micra transcatheter pacemaker implantation after battery depletion

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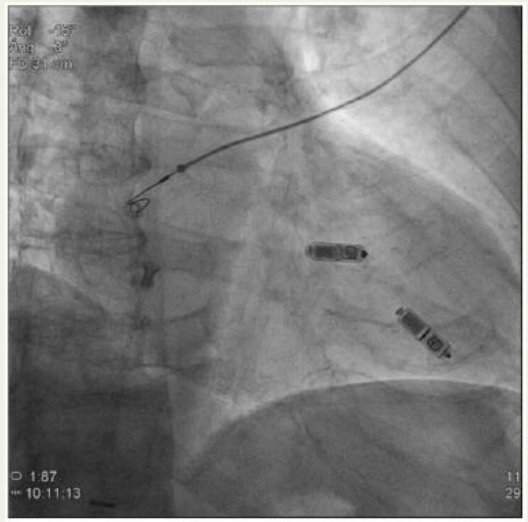
Techniques to manage the end of life of the Micra transcatheter pacing system (Medtronic Micra TPS) are not well standardized. It has been suggested that the best option is to leave the old device in the heart and implant a new one. Nevertheless, to date no double implant has successfully been reported in humans.

We present the case of a 78-year-old man who had reached the elective replacement time of the pacemaker after having received a Micra TPS in 2014 due to atrioventricular block. Reasons for early battery depletion were high right ventricular pacing threshold and 100% right ventricle (RV) pacing. A new Micra TPS was implanted through right femoral vein access. The new pacemaker was placed in the mid-septum of the RV, distant from the first pacemaker (*Figure*). The parameters of the new device (sensing, impedance, and threshold) were achieving within acceptable limits. No interactions were observed between the two devices. An echocardiography ruled out a negative impact of RV function by the implantation of the two devices. To our knowledge, this study is the first successful case of multiple implants of a Micra TPS with correct sensing and capture and no negative effects on RV function.



The full-length version of this report can be viewed at: https://www.escardio.org/Education/E-Learning/Clinical-cases/Electrophysiology

To retrieve, or not to retrieve: System revisions with the Micra transcatheter pacemaker

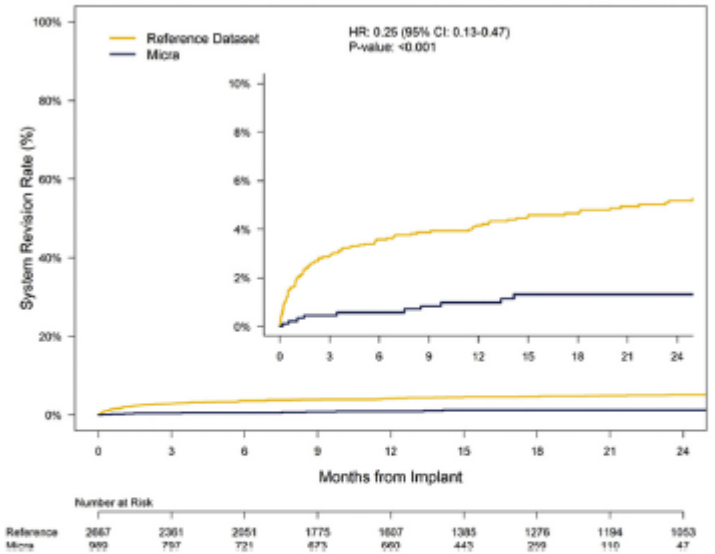


Figure 2 System revision rate for Micra vs transvenous control cohort. Subdistributional HR derived from data through 24 months postimplant for each cohort by comparing the cumulative incidence (rate) of system revision using the Fine-Gray competing risk model in the presence of competing risk of death for any reason. The inset shows the same data on an enlarged y-axis. For the 1:1 propensity-matched subset, the HR was 0.27 (95% CI 0.14–0.54; $P < .001$). CI = confidence interval; HR = hazard ratio.

Conclusion

In this study of patients undergoing leadless pacemaker implantation, the need for system revision was extremely low and was 75% lower than the rate for patients with transvenous pacemakers. In those patients requiring revision, the device could safely be either disabled and left in place or removed, as late as 14 months after implantation.

ITORIAL COMMENT

Are Leadless Pacemakers a Niche or the Future of Device Therapy?*

Michael R. Gold, MD, PhD

Achilles' Lead: Will Pacemakers Break Free?

Mark S. Link, M.D.

EDITORIAL COMMENT

The paradox of innovation with leadless pacing

EDITORIAL COMMENTARY

Leadless cardiac pacemakers: Paradigm shift in cardiac pacing

Patients Treated

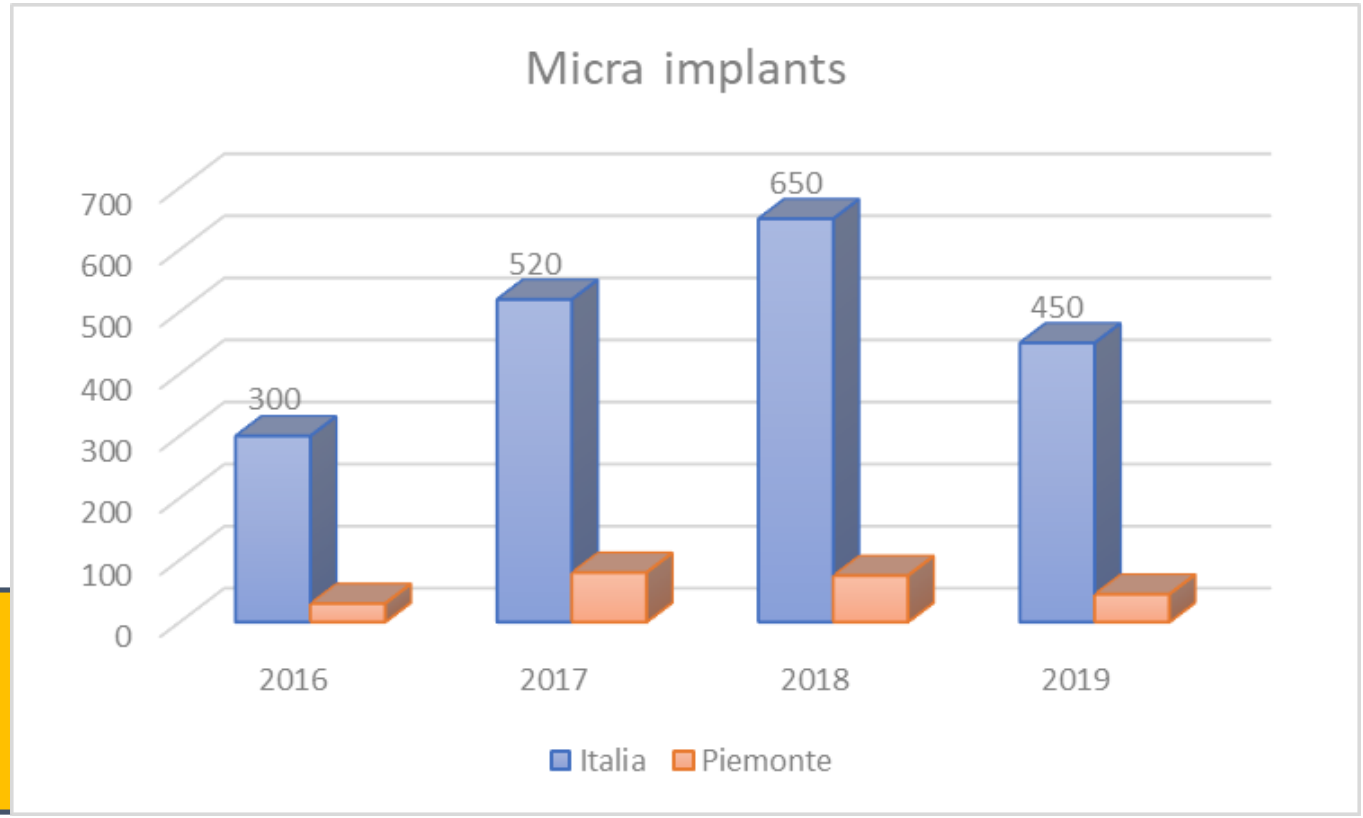
More than
37,000
Worldwide

More than
13,000
In Europe

Geography

In **> 40** countries

More than
2,000
In Italy



Who is the optimal candidate for leadless Pacing?

- ✓ Permanent AF
- ✓ Patient not expected to survive Battery Longevity

Who is the worst candidate for standard pacing?

- x Hemodialysis
- x Previous device infections
- x Anatomy I: Vascular access occlusions
- x Anatomy II: pediatric patients

JACC: Clinical Electrophysiology

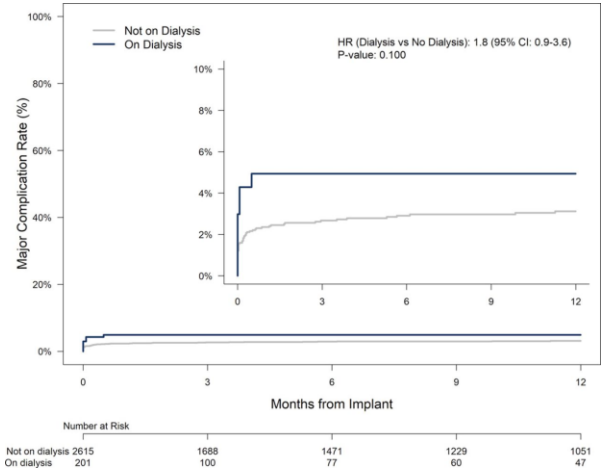
Volume 5, Issue 2, February 2019DOI: 10.1016/j.jacep.2018.12.008 **PDF Article**

NEW OBSERVATIONS IN CIED THERAPY

Leadless Pacemaker Implantation in Hemodialysis Patients

Experience With the Micra Transcatheter Pacemaker

Mikhael F. El-Chami, Nicolas Clementy, Christophe Garweg, Razali Omar, Gabor Z. Duray, Charles C. Gornick, Francisco Leyva, Venkata Sagi, Jonathan P. Piccini, Kyoko Soejima, Kurt Stromberg and Paul R. Roberts



Hemodialysis International 2018; **22**:E57–E59

Case Report

Leadless pacemaker placement in a patient with chronic kidney disease: A strategy to preserve central veins

IJC Heart & Vasculature 23 (2019) 100349

Contents lists available at ScienceDirect

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journal homepage: http://www.journals.elsevier.com/ijc-heart-and-vasculature

The use of a single chamber leadless pacemaker for the treatment of cardioinhibitory vasovagal syncope

Received: 26 February 2019 | Revised: 12 April 2019 | Accepted: 29 April 2019

DOI: 10.1111/jce.13961

INNOVATIVE TECHNIQUES

Initial experience with transcatheter pacemaker implantation for adults with congenital heart disease

Received: 16 May 2018 | Revised: 21 July 2018 | Accepted: 7 August 2018

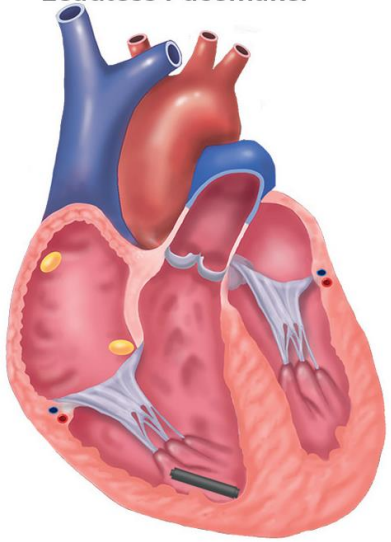
DOI: 10.1111/pace.13496

DEVICES

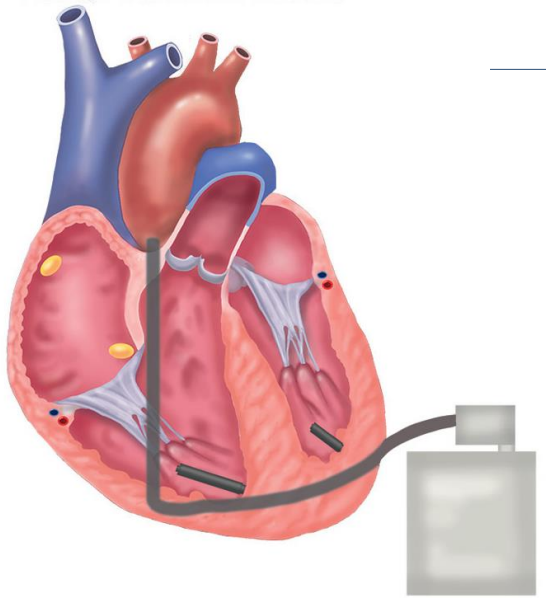
Acute and long-term outcomes of simultaneous atrioventricular node ablation and leadless pacemaker implantation

Conclusions

Leadless Pacemaker



Future Universal Device



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EDITORIAL COMMENT

Are Leadless Pacemakers a Niche or the Future of Device Therapy?*

Michael R. Gold, MD, PhD

anticoagulation is unclear, but the development of smaller pellets with a transducer could be coupled with a subcutaneous energy source for cardiac resynchronization with defibrillation therapy if appropriate (Figure 1). All of these possibilities point toward a bright future for leadless pacing with the likely possibility that the devices of the future will belargely devoid of intravascular leads, and many will not require subcutaneous pulse generators. As such, these devices should become the future of pacing in many types of devices rather than persist as a niche to compete in the single-chamber pacemaker market.

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GRAZIE PER L'ATTENZIONE!