

References

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1. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. *N Engl J Med*. Sep 17 2015;373(12):1125-1135. PMID 26321198.
2. 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*. May 2012;9(5):728-735. PMID 22182495.
3. Haight, PP, Stewart, RR, Saarel, EE, Pettersson, GG, Najm, HH, Aziz, PP. Lateral thoracotomy for epicardial pacemaker placement in patients with congenital heart disease. *Interact Cardiovasc Thorac Surg*, 2018 Jan 5;26(5). PMID 29300890.
4. Cohen, MM, Bush, DD, Vetter, VV, Tanel, RR, Wieand, TT, Gaynor, JJ, Rhodes, LL. Permanent epicardial pacing in pediatric patients: seventeen years of experience and 1200 outpatient visits. *Circulation*, 2001 May 31;103(21). PMID 11382728.
5. Doll, NN, Piorkowski, CC, Czesla, MM, Kallenbach, MM, Rastan, AA, Arya, AA, Mohr, FF. Epicardial versus transvenous left ventricular lead placement in patients receiving cardiac resynchronization therapy: results from a randomized prospective study. *Thorac Cardiovasc Surg*, 2008 Jul 11;56(5). PMID 18615370.
6. Harake, DD, Shannon, KK, Aboulhosn, JJ, Moore, JJ. Transvenous pacemaker implantation after the bidirectional Glenn operation for patients with complex congenital disease. *J. Cardiovasc. Electrophysiol.*, 2017 Dec 15;29(3). PMID 29240293.
7. Tsutsumi, K. , Hashizume, K. , Kimura, N. , Taguchi, S. , Inoue, Y. , Kashima, I. and Takahashi, R. (2010), Permanent Pacemaker Implantation via the Iliac Vein: An Alternative in 4 Cases with Contraindications to the Pectoral Approach. *Journal of Arrhythmia*, 26: 55-61. doi:10.1016/S1880-4276(10)80037-7.
8. Healey JS, Toff WD, Lamas GA, et al. Cardiovascular outcomes with atrial-based pacing compared with ventricular pacing: meta-analysis of randomized trials, using individual patient data. *Circulation*. Jul 4 2006;114(1):11-17. PMID 16801463.
9. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Risk factors for lead complications in cardiac pacing: a population-based cohort study of 28,860 Danish patients. *Heart Rhythm*. Oct 2011;8(10):1622-1628. PMID 21699827.

10. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J*. May 2014;35(18):1186-1194. PMID 24347317.
11. Food and Drug Administration. FDA Executive Summary Memorandum. General Issues: Leadless Pacemaker Devices Prepared for the February 18, 2016 meeting of the Circulatory System Devices Advisory Panel Gaithersburg Hilton; Gaithersburg, MD. 2016;
<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM485093.pdf>. Accessed August 6, 2018.
12. American Heart Association. Statement of the American Heart Association to the Food and Drug Administration Circulatory System Devices Panel February 18, 2016: Leadless Cardiac Pacemaker Devices. 2016;
<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM486235.pdf>. Accessed August 6, 2018.
13. Reddy VY, Miller MA, Knops RE, et al. Retrieval of the leadless cardiac pacemaker: a multicenter experience. *Circ Arrhythm Electrophysiol*. Dec 2016;9(12). PMID 27932427.
14. Reddy VY, Knops RE, Sperzel J, et al. Permanent leadless cardiac pacing: results of the LEADLESS trial. *Circulation*. Apr 8 2014;129(14):1466-1471. PMID 24664277.
15. Knops RE, Tjong FV, Neuzil P, et al. Chronic performance of a leadless cardiac pacemaker: 1-year follow-up of the LEADLESS trial. *J Am Coll Cardiol*. Apr 21 2015;65(15):1497-1504. PMID 25881930.
16. Lakkireddy D, Knops R, Atwater B, et al. A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker. *Heart Rhythm*. Dec 2017;14(12):1756-1763. PMID 28705736.
17. Tjong FVY, Knops RE, Neuzil P, et al. Midterm safety and performance of a leadless cardiac pacemaker: 3-year follow-up to the LEADLESS Trial (Nanostim Safety and Performance Trial for a Leadless Cardiac Pacemaker System). *Circulation*. Feb 6 2018;137(6):633-635. PMID 28705736.

18. Sperzel, JJ, Defaye, PP, Delnoy, PP, Garcia Guerrero, JJ, Knops, RR, Tondo, CC, Deharo, JJ, Wong, TT, Neuzil, PP. Primary safety results from the LEADLESS Observational Study. *Europace*, 2018 Jan 25;20(9). PMID 29365073.
19. Zuckerman B, Shein M, Paulsen J, et al. Circulatory System Devices Panel Meeting: Leadless Pacemakers. FDA Presentation. 2016; <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM486733.pdf>. Accessed August 6, 2018.
20. Ritter P, Duray GZ, Zhang S, et al. The rationale and design of the Micra Transcatheter Pacing Study: safety and efficacy of a novel miniaturized pacemaker. *Europace*. May 2015;17(5):807-813. PMID 25855677.
21. Ritter P, Duray GZ, Steinwender C, et al. Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study. *Eur Heart J*. Oct 1 2015;36(37):2510-2519. PMID 26045305.
22. Tjong, FF, Beurskens, NN, de Groot, JJ, Waweru, CC, Liu, SS, Ritter, PP, Reynolds, DD, Wilde, AA, Knops, RR. Health-related quality of life impact of a transcatheter pacing system. *J. Cardiovasc. Electrophysiol.*, 2018 Sep 1;29(12). PMID 30168233.
23. Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. *N Engl J Med*. Feb 11 2016;374(6):533-541. PMID 26551877.
24. Lloyd M, Reynolds D, Sheldon T, et al. Rate adaptive pacing in an intracardiac pacemaker. *Heart Rhythm*. Feb 2017;14(2):200-205. PMID 27871854.
25. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Micra Transcatheter Pacing System (PMS P150033). 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150033B.pdf. Accessed August 6, 2018.
26. Transcript of the United States of America Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Medical Devices Advisory Committee: Circulatory System Devices Panel Meeting Meeting. February 18, 2016. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM489547.pdf>. Accessed August 6, 2018.

27. Medtronic. Meet Micra (brochure). n.d.; http://www.medtronic.com/content/dam/medtronic-com/01_crhf/brady/pdfs/medtronic-micra-transcatheter-pacing-system-hcp-brochure.pdf. Accessed August 6, 2018.
28. Grubman, EE, Ritter, PP, Ellis, CC, Giocondo, MM, Augustini, RR, Neuzil, PP, Ravindran, BB, Patel, AA, Omdahl, PP, Pieper, KK, Stromberg, KK, Hudnall, JJ, Reynolds, DD. To retrieve, or not to retrieve: System revisions with the Micra transcatheter pacemaker. *Heart Rhythm*, 2017 Jul 18;14(12). PMID 28713024.
29. Roberts PR, Clementy N, Al Samadi F, et al. A leadless pacemaker in the realworld setting: The Micra Transcatheter Pacing System Post-Approval Registry. *Heart Rhythm*. Sep 2017;14(9):1375-1379. PMID 28502871.
30. El-Chami MF, Brock Johansen J, Zaidi A, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Paper presented at: Heart Rhythm Scientific Sessions. 2018 May 10; Boston, MA.
31. El-Chami, MM, Al-Samadi, FF, Clementy, NN, Garweg, CC, Martinez-Sande, JJ, Piccini, JJ, Iacopino, SS, Lloyd, MM, Viñolas Prat, XX, Jacobsen, MM, Ritter, PP, Johansen, JJ, Tondo, CC, Liu, FF, Fagan, DD, Eakley, AA, Roberts, PP. 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 Aug 14;15(12). PMID 30103071.
32. Duray GZ, Ritter P, El-Chami M, et al. Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. *Heart Rhythm*. May 2017;14(5):702-709. PMID 28192207.
33. El-Chami, MM, Johansen, JJ, Zaidi, AA, Faerstrand, SS, Reynolds, DD, Garcia-Seara, JJ, Mansourati, JJ, Pasquie, JJ, McElderry, HH, Roberts, PP, Soejima, KK, Stromberg, KK, Piccini, JJ. Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry. *J. Cardiovasc. Electrophysiol.*, 2019 Jan 21;30(4). PMID 30661279.
34. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Jan 22 2013;61(3):e6-75. PMID 23265327.

35. Gillis AM, Russo AM, Ellenbogen KA, et al. HRS/ACCF expert consensus statement on pacemaker device and mode selection. *J Am Coll Cardiol.* Aug 14 2012;60(7):682-703. PMID 22854177.

36. Centers for Medicare & Medicaid Services. Decision Memo for Leadless Pacemakers (CAG-00448N). 2017; <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=285&bc=ACAAAAAAQAAA&>. Accessed August 31, 2018.