Hospital in-service presentation References

- 1. Wilkoff, Bruce L., et al. How to treat and identify device infections. Heart Rhythm, Vol 4, No 11, 2007, 1467-1470.
- 2. Kleeman Thomas, et al. Annual Rate of Transvenous Defibrillation Lead Defect in Implantable Cardioverter-Defibrillators over a Period of >10 Years. Circulation 2007; 115:2474-2490.
- 3. Hauser, Robert, et. al., The Increasing Hazard of Sprint Fidelis Implantable Cardioverter-Defibrillator Lead Failuree, Heart Rhythm, Vol. 6, No 5, May 2009.
- 4. Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. Circ Arrhythm Electrophysiol. 2016; 9(8)
- Pokorney et al. Outcomes Associated with Extraction versus Capping and Abandoning Pacing and De brillator Leads Circulation 2017 Oct 10;136(15):1387-1395. doi: 10.1161/CIRCULATIONAHA.117.027636. Epub 2017 Aug 22.
- 6. Hussein et al. Microbiology of Cardiac Implantable Electronic Device Infections. J Am Coll Cardiol EP 2016;2:498–505 Circ Arrhythm Electrophysiol.
- 7. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
- 8. Fields, Michael E., et al. How to select patients for lead extraction. Heart Rhythm, Vol 4, Issue 7, July 2007.
- Worley, Seth J. Implant Venoplasty: Dilation of Subclavian and Coronary Veins to Facilitate Device Implantation: Indications, Frequency, Methods, and Complications. Journal of Cardiovascular Electrophysiology Vol. 19, No. 9, September 2008, 1004-7.
- 10. iData, MRG, Eucomed, EHRA White Book, Product Performance Reports (Biotronik, Boston Scientific, Medtronic, and St. Jude Medical), and internal estimates / analysis on file.
- 11. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
- 12. Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. Circ Arrhythm Electrophysiol. 2016; 9(8)
- 13. Tarakji, K, et al. Cardiac implantable electronic device infections: presentation, management, and patient outcomes, Heart Rhythm, Vol. 7, No. 8, 2010: 1043-7.
- 14. Hussein et al. Microbiology of Cardiac Implantable Electronic Device Infections. J Am Coll Cardiol EP 2016;2:498–505 Circ Arrhythm Electrophysiol.
- 15. Wazni, O et. al. Lead Extraction in the Contemporary Setting: The LExICon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579-586.
- 16. Bohm, Adam, et al. Complications Due to Abandoned Noninfected Pacemaker Leads. PACE, Vol 24, No 12, 2001, 1721-1724.
- 17. Byrd, CL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. PACE 1999; 22:1348-1357.
- 18. Levine, G, et al, "Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Devices: AHA statement from the Committee on diagnostic and interventional cardiac catherization, council on clinical cardiology, and the council on cardiovascular radiology and intervention. Circ 2007, pp 2878-2891
- 19. Sohal, M. et al. (2014). Laser lead extraction to facilitate cardiac implantable electronic device upgrade and revision in the presence of central venous obstruction. Europace, 16(1), 81-87.
- 20. Oginosawa Y, Abe H, Nakashima Y. The incidence and risk factors for venous obstruction after implantation of transvenous pacing leads. Pacing Clin Electrophysiol 2002;25:1605–1611.

- 21. Kutarski, A., Pietura, R., Młynarczyk, K., Małecka, B., & Głowniak, A. (2012). Pacemaker lead extraction and recapture of venous access: technical problems arising from extensive venous obstruction. Cardiology journal, 19(5), 513-517.
- 22. de Cock CC, et al. Long-term outcome of patients with multiple (> or = 3) noninfected leads: a clinical and echocardiographic study. PACE, Vol 23, No 4, 2000, 423-6
- 23. Raitt, Merritt H. "Implantable cardioverter-defibrillator shocks." (2008): 1366-1368.
- 24. Kern M. SCAI Interventional Cardiology Board Review Book. Lippincott Williams & Wilkins 2006; p.165.
- 25. Barbanti M, Petronio AS, Capodanno D, et al. Impact of balloon post-dilation on clinical outcomes after transcatheter aortic valve replacement with the self-expanding CoreValve prosthesis. JACC Cardiovasc Interv 2014;7:1014–21. 10.1016/j.jcin.2014.03.009
- 26. Doshi R, Decter DH, Meraj P. Incidence of arrhythmias and impact of permanent pacemaker implantation in hospitalizations with transcatheter aortic valve replacement. Clin Cardiol. 2018;41:640–645.
- 27. Culler, SD, Cohen, DJ, Brown, PP. Trends in aortic valve replacement procedures between 2009 and 2015: has transcatheter aortic valve replacement made a difference? Ann Thorac Surg 2018; 105: 1137–1143.
- 28. Poole, J. et. al., Complication Rates Associated with Pacemaker and ICD Generator Replacements when Combined with Planned Lead Addition or Revision, American Heart Association, November 15, 2009.
- 29. Elayi CS, Darrat Y, Suffredini JM, et al. Sex differences in complications of catheter ablation for atrial fibrillation: Results on 85,977 patients. J Intervent Cardiac Electrophysiol. 2018:1-7.
- 30. Khan MN, et al. Pulmonary-vein isolation for atrial fibrillation in patients with HF. N Engl J Med 2008;359(17):1778–1785.
- 31. Jones DG, et al. A randomized trial to assess catheter ablation versus rate control in the management of persistent atrial fibrillation in HF. J Am Coll Cardiol 2013; 61(18):1894–1903.
- 32. Hummel J, et al. Phased RF ablation in persistent atrial fibrillation. Heart Rhythm 2014;11(2):202–209.
- 33. Brignole, M. et. al., Defibrillation testing at the time of implantation of cardioverter defibrillator in the clinical practice: a nation-wide survey, Europace 2007 Vol. 9 No. 7: 540-543.
- 34. Ryan Azarrafiy, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circulation: Arrhythmia and Electrophysiology, August 2019.
- 35. ompared to common Teflon or polypropylene sheaths (D006341, Section 10.3.2)
- 36. Philips Data on File. D006339, Table 11.
- 37. Philips Data on File. D006339, Table 10.
- 38. Philips Data on File. D034042. It is a product requirement that the device must negotiate a 180 degree bend with a minimum radius of 0.75".