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Lead extraction: It is not where you go, but who you travel with

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The rate of transvenous lead extraction (TLE) procedures has steadily increased over time, firmly establishing itself as a foundational pillar of cardiac electrophysiology (EP) programs [1]. Technical improvements, enhanced imaging, and superior strategies have resulted in a safe and predictable experience that has lowered the threshold for elective TLE [2]. Unlike other cardiovascular procedures, however, the potential for a catastrophic complication and rapid exsanguination — not immediately manageable by most primary operators — still exists. Therefore, TLE mandates that a cardiac surgeon be immediately available for prompt surgical rescue, representing the final procedural failsafe. Additional societal recommendations related to safety include invasive blood pressure (BP) monitoring, central venous access, use of general anesthesia, access to echocardiography, high-quality fluoroscopy, and a preference for use of a hybrid operating room (OR); reflecting both the avoidance of, and response to, a serious complication [2]. While some of these safety measures are routine at modern cardiovascular centers, others may seem burdensome and can lead to a delay in definitive treatment. As encouraging TLE safety data continue to emerge, the rigid mandates of who, where, and how to perform TLE, have been challenged in an effort to balance safety and accessibility.

In this edition of *Kardiologia Polska (Kardiol Pol, Polish Heart Journal)* Kosior et al. [3] present the outcomes of a retrospective series of 2216 patients who underwent TLE over a 16-year period at 2 different hospitals by a single operator. Patients were retrospectively stratified into 3 “models” based on the era of the procedure. The “pioneering era” from 2006 to 2013

involved the use of an electrophysiology (EP) laboratory utilizing conscious sedation, with a surgeon on premises, and an OR available if needed, but without invasive BP monitoring or transesophageal echocardiography (TEE). The “in-between or safety staging era” from 2013 to 2016 utilized either an EP laboratory or an OR depending on multiple factors including lead dwell time, patient age at first implantation, female gender, the presence of multiple leads, and certain high-risk lead models. Strategies for patients in this group who had their procedures in the EP laboratory were similar to those in the pioneering era. Cases in the OR utilized a mobile C-arm X-ray machine, general anesthesia, invasive BP monitoring, but without TEE. A cardiac surgeon and perfusion team were similarly available as needed. The “modern era” from 2017–2021 was characterized by use of a hybrid OR, invasive BP monitoring, TEE, a surgeon functioning as a co-operator, and a pump and perfusion team on standby. Regardless of era, the procedures were performed in a similar manner, using a stepwise approach of simple traction, mechanical dilator sheaths, and rotational powered sheaths.

The overall rates of major complications and procedure-related deaths were 1.76% and 0.27%, respectively, with no significant differences between the study groups. Analysis of the mortality rate over a 3-year follow-up period after TLE showed that survival in the study groups was comparable regardless of the organizational model. The authors concluded that TLE performed in a hybrid OR by an electrophysiologist and cardiac surgeon, with invasive BP and TEE monitoring, appears to be the safest possible option for the patient.

The authors should be commended for their procedural success and impeccable record keeping over many years, when patients, pathology, and procedural aspects evolved considerably. Although multiple scales, scores, and time and escalation metrics were used to compare groups, these analyses are severely confounded, despite adjustments, and thereby limit the conclusions that can be drawn. Additional limitations include the lack of use of both the laser-powered sheath [4] and the vascular occlusion balloon, the latter of which has been associated with reduced mortality during TLE [5]. Lastly, all procedures were performed by a single operator, whose skills undoubtedly improved over many years as volume and experience both increased [6]. Notwithstanding, it is reassuring that the results regarding common risk factors for major complications including female gender, dwell time of the oldest extracted lead, and number of extracted leads, as well as overall rates of major complications and death, are consistent with other contemporary prospective lead extraction registries [4, 6].

This study highlights an important question concerning appropriate safeguards to mitigate risk

and improve outcomes during TLE, above and beyond emerging tools and techniques [7–9]. Some routine safety measures such as invasive BP monitoring and the use of TEE are practical, and may reassure that no injury is present during transient hypotension, or alternatively, rapidly identify an injury early in the course. Importantly, this includes complications such as myocardial avulsion, which can occasionally be managed percutaneously, or tricuspid valve injury, which rarely requires immediate surgical intervention. If a severe injury such as vascular laceration does occur, surgical response time is of the essence, and repair must take place without transferring the patient to another location. To this extent, use of a hybrid OR is an appealing venue for TLE in large part due to its close proximity to a covering surgeon. However, its use must be balanced carefully with the possibility of logistical delays, which have been associated with worse outcomes.(10) It is incumbent upon an extraction team to construct a system that can provide surgical rescue in the EP laboratory, including rapid use of the vascular occlusion balloon, surgical tool procurement, identification of support personnel, and participation in mock codes that encourage multidisciplinary collaboration. Ultimately, rescue is less dependent upon where you are, but rather who is present, and how prepared they are.

Researchers continue to recalibrate what is considered safe during TLE, including operating on uninterrupted warfarin therapy [11] and utilizing a same day discharge protocol [12]. Whether surgical back-up can be omitted completely based on a pre-operative risk assessment has also been the subject of recent study [13, 14], similar to the early evolution of percutaneous coronary intervention [15]. However, more information is required to reach definitive conclusions, particularly since most of these procedures performed without surgical back-up resulted in no injuries, rendering it impossible to judge outcomes if they did. Regardless of location or surgical coverage, TLE success will continue to be dominated by operator skill, judgement, and experience, metrics that tend to be much harder to quantify.

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REFERENCES

1. Deshmukh A, Patel N, Noseworthy PA, et al. Trends in use and adverse outcomes associated with transvenous lead removal in the United States. *Circulation*. 2015; 132(25): 2363–2371, doi: [10.1161/CIRCULATIONAHA.114.013801](https://doi.org/10.1161/CIRCULATIONAHA.114.013801), indexed in Pubmed: [26534954](https://pubmed.ncbi.nlm.nih.gov/26534954/).
2. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm*. 2017; 14(12): e503–e551, doi: [10.1016/j.hrthm.2017.09.001](https://doi.org/10.1016/j.hrthm.2017.09.001), indexed in Pubmed: [28919379](https://pubmed.ncbi.nlm.nih.gov/28919379/).
3. Kosior J, Jacheć W, Polewczyk A, et al. To grade or not to grade the application of safety requirements for transvenous lead extraction: Experience with 2216 procedures. *Kardiol Pol*. 2022 [epub ahead of print], doi: [10.33963/KP.a2022.0266](https://doi.org/10.33963/KP.a2022.0266), indexed in Pubmed: [36446069](https://pubmed.ncbi.nlm.nih.gov/36446069/).
4. Wazni O, Epstein LM, Carrillo RG, et al. Lead extraction in the contemporary setting: the LEXiCon study: an observational retrospective study of consecutive laser lead extractions. *J Am Coll Cardiol*. 2010; 55(6): 579–586, doi: [10.1016/j.jacc.2009.08.070](https://doi.org/10.1016/j.jacc.2009.08.070), indexed in Pubmed: [20152562](https://pubmed.ncbi.nlm.nih.gov/20152562/).
5. Azarrafiy R, Tsang DC, Wilkoff BL, et al. Endovascular occlusion balloon for treatment of superior vena cava tears during transvenous lead extraction: a multiyear analysis and an update to best practice protocol. *Circ Arrhythm Electrophysiol*. 2019; 12(8): e007266, doi: [10.1161/CIRCEP.119.007266](https://doi.org/10.1161/CIRCEP.119.007266), indexed in Pubmed: [31401856](https://pubmed.ncbi.nlm.nih.gov/31401856/).
6. Bongiorno MG, Kennergren C, Butter C, et al. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes. *Eur Heart J*. 2017; 38(40): 2995–3005, doi: [10.1093/eurheartj/ehx080](https://doi.org/10.1093/eurheartj/ehx080), indexed in Pubmed: [28369414](https://pubmed.ncbi.nlm.nih.gov/28369414/).
7. Muhlestein JB, Dranow E, Chaney J, et al. Successful avoidance of superior vena cava injury during transvenous lead extraction using a tandem femoral-superior approach. *Heart Rhythm*. 2022; 19(7): 1104–1108, doi: [10.1016/j.hrthm.2022.02.024](https://doi.org/10.1016/j.hrthm.2022.02.024), indexed in Pubmed: [35245690](https://pubmed.ncbi.nlm.nih.gov/35245690/).
8. Schaller RD, Sadek MM, Cooper JM. Simultaneous lead traction from above and below: A novel technique to reduce the risk of superior vena cava injury during transvenous lead extraction. *Heart Rhythm*. 2018; 15(11): 1655–1663, doi: [10.1016/j.hrthm.2018.05.022](https://doi.org/10.1016/j.hrthm.2018.05.022), indexed in Pubmed: [29803849](https://pubmed.ncbi.nlm.nih.gov/29803849/).

9. Schaller RD, Sadek MM, Schaller RD, et al. Utility of intracardiac echocardiography during transvenous lead extraction. *Heart Rhythm*. 2017; 14(12): 1779–1785, doi: [10.1016/j.hrthm.2017.08.023](https://doi.org/10.1016/j.hrthm.2017.08.023), indexed in Pubmed: [28843419](https://pubmed.ncbi.nlm.nih.gov/28843419/).
10. Lee JZ, Majmundar M, Kumar A, et al. Impact of timing of transvenous lead removal on outcomes in infected cardiac implantable electronic devices. *Heart Rhythm*. 2022; 19(5): 768–775, doi: [10.1016/j.hrthm.2021.12.023](https://doi.org/10.1016/j.hrthm.2021.12.023), indexed in Pubmed: [34968739](https://pubmed.ncbi.nlm.nih.gov/34968739/).
11. Zheng Qi, Maytin M, John RM, et al. Transvenous lead extraction during uninterrupted warfarin therapy: Feasibility and outcomes. *Heart Rhythm*. 2018; 15(12): 1777–1781, doi: [10.1016/j.hrthm.2018.07.018](https://doi.org/10.1016/j.hrthm.2018.07.018), indexed in Pubmed: [30010055](https://pubmed.ncbi.nlm.nih.gov/30010055/).
12. Atteya G, Alston M, Sweat A, et al. Same-day discharge after transvenous lead extraction: feasibility and outcomes. *Europace*. 2022 [Epub ahead of print], doi: [10.1093/europace/euac185](https://doi.org/10.1093/europace/euac185), indexed in Pubmed: [36575941](https://pubmed.ncbi.nlm.nih.gov/36575941/).
13. Issa ZF. Transvenous lead extraction in 1000 patients guided by intraprocedural risk stratification without surgical backup. *Heart Rhythm*. 2021; 18(8): 1272–1278, doi: [10.1016/j.hrthm.2021.03.031](https://doi.org/10.1016/j.hrthm.2021.03.031), indexed in Pubmed: [33781982](https://pubmed.ncbi.nlm.nih.gov/33781982/).
14. Kancharla K, Acker NG, Li Z, et al. Efficacy and Safety of Transvenous Lead Extraction in the Device Laboratory and Operating Room Guided by a Novel Risk Stratification Scheme. *JACC Clin Electrophysiol*. 2019; 5(2): 174–182, doi: [10.1016/j.jacep.2019.01.001](https://doi.org/10.1016/j.jacep.2019.01.001), indexed in Pubmed: [30784687](https://pubmed.ncbi.nlm.nih.gov/30784687/).
15. Dehmer GJ, Blankenship JC, Cilingiroglu M, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. *Circulation*. 2014; 129(24): 2610–2626, doi: [10.1161/CIR.0000000000000037](https://doi.org/10.1161/CIR.0000000000000037), indexed in Pubmed: [24637561](https://pubmed.ncbi.nlm.nih.gov/24637561/).