Transvenous lead extraction on continued oral anticoagulation

Editorial

Whereas it is accepted the oral anticoagulation (OAC) can be safely continued if deemed necessary in the setting of cardiomplantable electronic device (CIED) implantation [1], there is a paucity of data regarding this question on transvenous lead extraction (TLE). Risk of potentially fatal bleeding is higher with TLE, and data from randomized controlled studies performed in the setting of CIED implantation [2,3] cannot simply be extrapolated to these procedures. In a retrospective analysis from the Cleveland Clinic in 2,999 patients who underwent extraction of >5,500 CIED leads, an INR of ≥1.2 was associated with an odds ratio of 2.7 (95% CI 1.2–5.7, P = 0.0012) of risk of major complications by multivariate analysis [4]. Conversely, in the European Lead Extraction ConTRolled (ELECTRa) registry in 3,510 patients, the incidence of major and minor complications was not significantly different in patients with or without anticoagulation (interrupted or not) by uni- or multi-variate analyses [5].

The current data on TLE in patients on uninterrupted OAC is limited to two published series [5,6]. Zheng et al. reported data from a prospective TLE registry at the Brigham and Women’s Hospital in 62 patients who were on uninterrupted vitamin K antagonists (VKA) with a therapeutic INR (mean 2.5 ± 0.5; range 2.0–4.5). Procedural success was 98.4%, and there were only two complications (one small pericardial effusion which resolved spontaneously and once lacerated femoral vein which required vascular surgery and was not related to continued OAC). Mean estimated blood loss per procedure was 150 ± 105 mL. In a sub-analysis of the European Lead Extraction ConTRolled (ELECTRa) registry, out of 3,510 patients, 37% were on anticoagulants, indicating that this is a relatively frequent issue. Anticoagulation was interrupted (with or without heparin bridging) in the majority (93%) of these patients and continued in 87 patients. In this subgroup, there were two (2.3%) major complications (with one post-procedural death) and four (4.6%) minor complications (all being surgical site hematomas requiring revision). These incidences were not different compared to patients with interrupted anticoagulation.

Due to the paucity of data, the latest guidelines on TLE advocate that “peri-procedural anticoagulation strategies should be considered on a case-by-case basis, after assessing the thromboembolic risk during unprotected periods” [7].

In this issue of the journal, investigators from two tertiary centres performed a retrospective analysis on 121 TLE procedures performed over an 18-month period, of which 22(18%) were performed on uninterrupted VKA and a therapeutic INR (mean 2.2 ± 0.6, range 2–3.5) [8]. This subgroup was compared to 22 matched patients without OAC at the time of TLE. Infection was the indication in about half the cases. The mean lead dwell time in the groups was 7–8 years, and included defibrillator leads (44%), standard pacing leads (47%) and coronary sinus leads (9%). All procedures were performed with a superior approach using locking stylets, and, if necessary, rotational mechanical sheaths (femoral workstations were not required in any of the cases). The main findings were that there was no significant difference in procedural success — 43/45(96%) of leads were successfully extracted in patients under OAC — or complications between the groups. There were no reported immediate major complications, and over a 1-year follow-up, none of the patients died due to procedure-related causes.

This series, although of relatively limited size, is a very valuable addition to the two previously-mentioned reports [5,6] and contributes towards a total of 171 patients who are currently reported to have safely undergone TLE under uninterrupted OAC.

A number of points deserve to be discussed. First, the results come from two high-volume TLE centres (defined as >30 procedures/year [9,10]), and may not be applicable to centres with less experience. Second, the mean age of patients was 66 years and the mean dwell time in the continued OAC group was 7 years, which is comparable to that of the previous series [5,6]. None of the patients required a femoral approach as a bailout solution, suggesting that the procedures may have been overall quite straightforward. The ELECTRa registry showed that a dwell time of >10 years was associated with a significantly increased risk of major complications, including death (OR 3.5, 95% CI 1.6–7.8, P = 0.0018). Therefore, outcome may have been different, had more patients with high-risk profiles been included in the study. Third, all patients were on VKA, and results may not be applicable to patients on direct oral anticoagulants (DOACs). These drugs were included in a minority of patients in the ELECTRa substudy (<20% of patients on OAC), but it was not reported whether any patients underwent TLE on uninterrupted DOACs [5]. Unlike VKA, where rapid reversal of anticoagulation is possible with infusion of concentrated coagulation factors, antidotes to DOACs are currently available only for dabigatran (albeit to a limited extent due to high cost). Therefore, there is currently insufficient evidence that TLE may be carried out safely in patients with uninterrupted DOACs. Finally, although strategies for managing antiplatelet therapy (APT) have been proposed for CIED implantation [1] this remains an open question in the setting of TLE. The only study reporting data in these patients is the ELECTRa substudy [5], in whom procedural outcome was similar regardless of OAC and APT status at baseline. APT was continued for TLE in 1042/1413 (74%) patients, of whom 81 were also on OAC. Roughly a quarter of
patients on APT were taking P2Y₁₂ inhibitors, but there was no separate analysis in this subgroup of patients with these more potent drugs.

Given the underlying high surgical risk, the variations in clinical practice across centres, and the overall relatively low event rate for bleeding or thromboembolic complications, we will most probably never witness a randomized trial comparing interrupted OAC/bridging heparin therapy vs. continued OAC in the domain of lead extraction. Large multicenter observational studies and meta-analyses will no doubt help in establishing the safety of periprocedural antithrombotic therapy (including DOACs and APT) during lead extraction. However, the currently available limited data give no alarming signal of increased risk with continued VKA, provided that these procedures are performed in selected patients (i.e. those at highest thrombotic risk, such as patients with mechanical prosthetic valves) and in experienced centres.

References

[1] Burri H, Starck C, Auricchio A, Biffi M, Burri M, D'Avila A, et al. EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter defibrillators. Europace 2021. In press.

[2] Birnie DH, Healey JS, Wells GA, Ayala-Paredes F, Coutu B, Sumner GL, et al. Continued vs. interrupted direct oral anticoagulants at the time of device surgery, in patients with moderate to high risk of arterial thrombo-embolic events (BRUISE CONTROL-2). Eur Heart J 2018;39:3973–9. https://doi.org/10.1093/eurheartj/ehy413.

[3] Birnie DH, Healey JS, Wells GA, Verma A, Tan AS, Kahn AD, et al. Pacemaker or defibrillator surgery without interruption of anticoagulation. N Engl J Med 2013;368:2084–93. https://doi.org/10.1056/NEJMoa1302946.

[4] Brunner MP, Cronin EM, Duarte VE, Yu C, Tarakji KG, Martin DO, et al. Clinical predictors of adverse patient outcomes in an experience of more than 5000 chronic endovascular pacemaker and defibrillator lead extractions. Heart Rhythm 2014;11:799–805. https://doi.org/10.1016/j.hrthm.2014.01.016.

[5] Di Cori A, Auricchio A, Regoli F, Blomström-Lundqvist C, Butter C, Dagres N, et al. Clinical impact of antithrombotic therapy in transvenous lead extraction complications: a sub-analysis from the ESC-EORP EHRA ELECTRa (European Lead Extraction ConTrolled) Registry. Europace 2019;21:1096–105. https://doi.org/10.1093/europace/eu062.

[6] Zheng Q, Maytin M, John RM, Killu AM, Epstein LM. Transvenous lead extraction during uninterrupted warfarin therapy: feasibility and outcomes. Heart Rhythm 2018;15:1777–81. https://doi.org/10.1016/j.hrthm.2018.07.018.

[7] Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14:e501–51. https://doi.org/10.1016/j.hrthm.2017.09.001.

[8] Vinit Sawhney, Vanessa Cobb, Alexander Breitenstein, Luisa Baca, Sarah Whittaker-Axon, Jan Steffel, et al. Transvenous lead extraction on uninterrupted anticoagulation: a safe approach? Indian Pacing Electrophysiol J 2021;21(4):201–6.

[9] Bongiorni MG, Burri H, Deharo JC, Starck C, Kennergren C, Saghly L, et al. 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS. Europace 2018;20:1217. https://doi.org/10.1093/europace/euy050.

[10] Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi GA, 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;38:2995–3005. https://doi.org/10.1093/eurheartj/ehx080.