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Transvenous lead extraction in low volume centre linked to doubled risk of death

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Extraction in a low volume centre was associated with a doubled risk of death

Cardiac lead extraction is safer in high volume centres, according to the largest study of contemporary practice in Europe published today in *European Heart Journal*. Extraction in a low volume centre was associated with a doubled risk of death while in hospital.

The European Lead Extraction ConTRolled (ELECTRa) registry of transvenous lead extraction (TLE) outcomes was conducted by the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC) under the EURObservational Research Programme (EORP).

TLE is the gold standard treatment for infections related to cardiac implantable electronic devices such as pacemakers or defibrillators. It may also be required when leads malfunction. It is a percutaneous procedure during which leads are extracted from the veins. The rate of cardiac device implantation is on the rise leading to a parallel growth of the TLE procedure. It is estimated that 10 000 to 15 000 leads are extracted each year worldwide, including up to 5 000 in Europe.

"Indications for TLE are expanding as lead extraction technology improves and extractors become increasingly skilled," said lead author Dr Maria Grazia Bongiorni, director of the Cardiology, Cardio Thoracic and Vascular Department, University Hospital of Pisa, Italy. "In Europe, most centres have only recently started performing TLE and data is lacking on indications, techniques, success rates, safety, and follow-up."

The ELECTRa registry included 73 centres from 19 countries who enrolled 3 555 consecutive patients, of whom 3 510 underwent TLE. The primary objective was to evaluate the acute and long-term safety of TLE. Secondary objectives were to describe the characteristics of patients, leads, indications, techniques, and outcomes. The complication rate in low and high volume (30 or more TLE per year) centres was compared.

Data was collected using a web based system. No specific protocol for the procedure, materials, techniques of extraction, or treatment after the procedure was mandated during this observational study. Patients were followed up 12 months after discharge to assess long-term safety and efficacy of TLE.

The rate of in-hospital procedure-related major complications (the primary endpoint) was 1.7%, including a mortality rate of 0.5%, with no significant differences between high and low volume centres. High volume centres had significantly lower overall in-hospital major complications (2.4% vs 4.1%) and deaths (1.2% vs 2.5%) compared to low volume centres. In multivariable analysis, extraction in a low volume centre was associated with a doubled risk of death from all causes during the hospital stay and a doubled risk of clinical failure of the procedure.

Dr Bongiorno said: "Patients who undergo TLE in a low volume centre are more likely to die or have a major complication during the hospital stay. The outcome of TLE is not confined to the TLE procedure per se but is dependent on multiple patient factors and co-morbidities that require an advanced and highly skilled multidisciplinary team management that may only be facilitated in high volume centres. In the event of cardiac major complications occurring after the procedure, patients may often be saved, if complications are recognised and treated promptly."

She added: "The ELECTRa registry was not designed to define the minimum number of procedures needed to reduce complications and increase success, but if we extrapolate from the data it appears that centres should perform at least 40 to 50 TLE per year."

The overall efficacy of TLE was high, with 97% clinical and 96% complete radiological success rates. High volume centres achieved radiological (96.2% vs 93.4%) and clinical (97.3% vs 94.3%) success more frequently than low volume centres. "The success of contemporary TLE is high, independent from the technique used, but aggressive tools like powered sheaths are less safe," said Dr Bongiorno. "Infection was the most common reason for TLE (53% of cases), followed by lead malfunction."

Procedure-related major complications and deaths were more common in women (odds ratio [OR] 2.11), and lead dwell time more than ten years (OR

3.54). Predictors of clinical failure included female gender (OR 1.81), three or more leads for extraction (OR 2.47), and lead dwell time more than ten years (OR 4.0). Dr Bongiorno said: "Women have smaller and weaker blood vessels which are more vulnerable to damage. When leads are in the body for a long time, the risk of fibrosis increases, the adhesions become tenacious, and the operator needs more energy to detach them from the veins which may cause complications."

She concluded: "TLE is safe and effective, with a low incidence of life-threatening complications. Outcomes may improve even further if centres perform at least 40 to 50 procedures per year."

Source:

<https://www.escardio.org/The-ESC/Press-Office/Press-releases/cardiac-lead-extractions-safer-in-high-volume-centres?hit=wireag>
