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Multicentre experience with the bidirectional rotational evolution RL mechanical sheath for lead extraction using a stepwise approach: safety, efficacy and outcome

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Background: In addition to the Evolution RL sheath, tools by Cook Medical, supporting lead extraction (LE), are available. Data on their use are not reported in detail in previous studies. Moreover, data regarding outcome are lacking. Purpose: To evaluate the safety and efficacy of the new Evolution sheath (Evolution RL, Cook Medical, USA) by using a stepwise approach with the available extraction tools and the outcomes after the procedure with chronically implanted leads. Methods: A total of 393 leads in 198 consecutive patients were removed with the Evolution RL sheath and ancillary tools using a stepwise approach. Results: The main indication for LE was infection in 125 (63.1%) cases. The mean implant duration was 95.4±59.7 months. According to our stepwise approach the Evolution Shortie RL sheath was used in all cases and complete LE was achieved in 24 (12.2%) cases. The Evolution RL was used in 174 (87.8%) cases and the SteadySheath Evolution tissue stabilization sheath in 87 (44%) cases because of tenacious fibrosis anchored targeted leads. Compression coil was used in 141 (71%) cases. Complete procedural success without the use of an additional snaring system was achieved with 379 (96.4%) leads. Clinical success rate was 99%. One major complications (0.5%) and 10 (5%) minor complications were encountered. During a mean time follow-up of 12±9 months, 14 (7%) patients died. Predictors of mortality included impaired renal function (HR 5.7; 95%CI 1.9-17.6; P=0.002), infection (HR 4.0; 95%CI 1.1-18.1; P=0.045) and diabetes (HR 3.2; 95%CI 1.1-9.8; P=0.036). Conclusions: The Evolution RL sheath with ancillary tools and by using a stepwise approach, is an effective and safe technique for LE. Infectious, renal impairment and diabetes are associated with a worse outcome.