Lead Extraction and Registry Experiences in Europe

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KEYWORDS

• Infections • Malfunctions • Cardiac implantable electronic device • Lead extraction
• Clinical practice • Registry

KEY POINTS

- With the rise of Pacemakers and implantable cardiac defibrillators (ICDs), implantations, infections, and malfunctions related to these devices have increased.
- Transvenous lead extraction (TLE) is the gold standard treatment in case of cardiac implantable electronic device (CIED) infection or failing leads. This procedure was developed in terms of technology and techniques, improving success rates and showing its safety in experienced centers.
- The number of European hospitals performing TLE has increased in recent years. The European Heart Rhythm Society (EHRA) started to characterize them and published the results of 2 surveys about clinical practice of TLE in Europe. These surveys highlighted the need for a prospective registry for a better analysis of this procedure among European countries.
- ELECTRa (European Lead Extraction Controlled) Registry is the first large, prospective, multicenter registry for TLE in Europe. It will describe the European real world practice on TLE and will improve the quality of patient care.

INTRODUCTION

The number of cardiac implantable electronic device (CIED) implant procedures has grown considerably in recent years. Despite advances in technology, the number of infective and noninfective complications related to these devices has increased.[1,2]

Transvenous lead extraction (TLE) is the gold standard for treatment of CIED-related infective complications and is often required in the management of lead malfunction. TLE is a percutaneous procedure, which consists of extracting leads from the venous system used for CIED implantation. This procedure does not require surgical opening of the chest, and it is performed using appropriate instruments for operating in the veins of implantation.[3–5]

TLE has evolved enormously in the last 30 years since the early attempts, which were done with little expertise and inappropriate tools. Over time, numerous techniques and many instruments have been added to improve the results of TLE.[5–7]

TLE EVOLUTION

Mechanical Techniques

Since the beginning of TLE, traction on leads has played a significant role. The success rate of simple manual traction on leads is dwell time

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dependent; leads implanted for less than 6 months can often be removed by simple traction, whereas leads with implant times longer than 2 years have a low success rate, and traction has to be considered just one of the steps of a potentially complex extraction procedure.

To improve traction results, attention was focused on developing systems that allow traction energy to be applied at the tip of the lead and/or on a section of the lead, in order to free the lead while avoiding coil disruption or leaving the lead tip behind. Locking stylets engaging the lead tip were an essential part of the original mechanical technique and were used in combination with mechanical dilatation sheaths.[5–8] The use of a stylet makes the lead stiffer, thus helping dilatation or ablation (in case of powered sheaths) of scar tissue, independent of the energy used. One initial drawback of locking stylets was that once the stylet was locked, it was impossible to unlock and withdraw it. This was a significant problem in cases of failed extraction. Later, a new type of locking stylet was developed, allowing the stylet to be locked and unlocked when necessary; traction ability was not affected by this feature.

Other traction devices were developed in subsequent years.[9,10] The lead locking device (LLD) comes with a mechanism that expands a coil in the inner lumen of the lead, providing locking to the tip as well as to the length of the lead. Extraction tension is thus distributed, minimizing the risk of lead damage. Reports on LLD use suggest that the added ability to remove leads using a locking stylet compared with simple traction is limited.[11–13]

Published data also suggest that the success rate of pulling out leads with or without locking stylets not using sheaths can be estimated to be about 30% in the overall population of leads. These results support the opinion of many experienced centers, that the key point of transvenous extraction is freeing the lead tip and body from binding fibrous tissue, more than applying traction to pull out the lead.

At the end of the 1980s, Charles Byrd developed the first effective technique for transvenous extraction of chronic pacing leads.[8] This original technique used locking stylets and mechanical dilatation of fibrotic binding sites by means of dilating sheaths.[14] Later, his technique included a transfemoral approach by means of a transvenous workstation and several different tools (retrieval basket, snares) to approach lead fragments or free-floating leads.[14] The clinical results of mechanical dilatation described by Byrd were published using data from the US database on transvenous extraction.[15] The first report analyzed data from December 1988 to April 1994, relating the extraction of 2195 intravascular pacing leads from 1299 patients. Extraction was attempted via the implanted vein using locking stylets and dilator sheaths, via the femoral vein using snares, retrieval baskets, and sheaths, or via both approaches. Using this technique, 86.8% of leads were completely removed; 7.5% were partially removed, and 5.7% were not removed.[15] Fatal and near-fatal complications occurred in 2.5% of patients, including 8 (0.6%) deaths. The incidence of serious complications was found to be acceptable, particularly when compared with surgical removal techniques. In 1999, a new set of data from the US database on lead extraction was published.[16] It showed an increase in the number of procedures and also in success rate.

This experience refers to a period when extraction techniques were not undergoing development, and most of the limited numbers of active operators were well trained and experienced. From January 1994 through April 1996, extraction of 3540 leads from 2338 patients (mean age 64 years, range 5 to 96) was attempted at 226 centers. The conventional techniques for mechanical dilatation, including Cook Medical (Bloomington, Indiana) extraction kit tools, were used. Extraction was attempted via the implant vein using locking stylets and dilator sheaths, and/or transfemorally using snares, retrieval baskets, and sheaths. Complete removal was achieved in 93% of leads; partial removal was achieved in 5% of leads, and 2% of leads were not removed. Major complications were reported in 1.4% of patients (<1% at centers with >300 cases); minor complications were reported in 1.7%. The report underlined that the experience of operators played a key role in achieving a high success rate as well as in reducing the occurrence of major complications. Following these initial reports, many single-center experiences were published, but no significant contributions for improved techniques or results were added.

During the second half of the 1990s Maria Grazia Bongiorni and colleagues[17] developed a new transvenous approach using mechanical sheaths through the right internal jugular vein in cases of free-floating leads and leads difficult to expose, providing a significant contribution to developing techniques. Their modification of the technique of mechanical dilatation by polypropylene sheaths and the use of the jugular approach led to a significant improvement in results. In 2008, this group published the results of its single-center experience demonstrating the effectiveness of both the use of a single sheath technique and the use of the transjugular approach in presence of difficult