Evolution RL effective, efficient, and safe for TLE

Clinical success: 98.7% of procedures

Complete success: 96.3% of leads

Zero isolated SVC injuries

No device related mortality

RELEASE study conclusion: This prospective clinical study demonstrates that use of mechanical TLE tools, especially bidirectional rotational sheaths, are effective, efficient, and safe tools for TLE.[1]

1. Saumya Sharma S, Byron K. Lee B, Anuj Garg A, et al. Performance and and Outcomes of Transvenous Rotational Lead Extraction: Results from a Prospective, Monitored, International Clinical Study. *Heart Rhythm*. 2021;S2666-5018(21)00040-4.

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Study Design

Prospective clinical data is limited regarding the safety and effectiveness of rotational lead extraction tools. The objective of the RELEASE study was: "to prospectively investigate the safety and effectiveness of mechanical TLE in real-world usage."

Methods

Patients were enrolled at 10 sites internationally, in the United States (7) and Europe (3) to evaluate the use of mechanical TLE devices. Clinical success, complete procedural success, and complications were evaluated through follow-up (median, 29 days). Patient data were source verified and complications were adjudicated by an independent clinical events committee.

Prospective study comparison

	RELEASE	ELECTRa
Patients	230	3510
Leads	460	6493
Clinical success per patient	98.7% (227/230)	96.7% (3395/3510)
Median indwell time	7.4 years	5.0 years
Cardiac avulsion or tear	2/230	30/3510
Procedure related mortality	1/230	17/3510

Patient Demographics

Patient Characteristics	Mean ± Std (N, Min – Max)
Age (years)	64.3 ± 14.4 (230, 22 - 92)
BMI†	29.6 ± 6.7 (227, 16.5 - 59.1)
	Percent of patients (n/N)
Male	67.4% (155/230)
Pacing dependency (HR under 40 bpm)	20.0% (46/230)

† BMI information was unavailable for three patients.

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