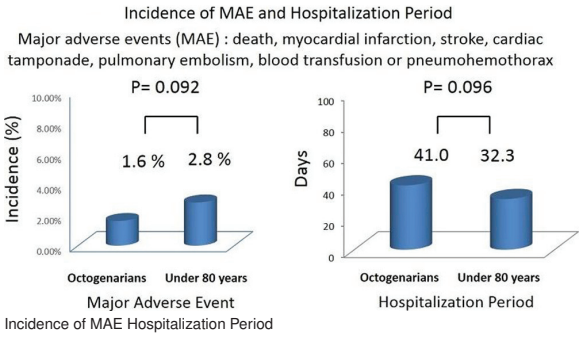

Incidence of MAE Hospitalization Period

Conclusions: In elderly patients, percutaneous transvenous lead extraction could be performed safely without prolonged hospital stay.

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Chronic tissue encapsulation profile and extraction of extravascular versus transvenous leads

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Background: Extravascular (EV) ICDs may prove to be a valuable alternative to transvenous (TV) ICDs. A novel EV ICD system is proposed that places a customized lead in the space between the sternum and pericardium to preserve standard energy defibrillation and ATP capability. Tissue encapsulation, with bearing on both lead stability and extractability, has not been well characterized for this space.

Purpose: Evaluate the chronic encapsulation profile of EV leads and compare extraction efficacy using simple traction and extraction tools.

Methods: Two chronic studies were conducted. A 12-week study in five swine was designed to compare histology of a novel EV lead to a market-released TV ICD lead implanted in the RV apex. The EV and TV leads were of similar construction, diameter, and outermost insulation material. A second study was conducted in four ovine (n=3 animals for extraction and n=1 animal for encapsulation evaluation), with two of the novel EV leads implanted in each animal for one year. Extraction was performed using either simple extraction tools or by simple traction utilizing a locking stylet or the integral conductor cables.

Results: Histological comparison of EV and TV leads from the 12-week study revealed tissue capsules of similar thickness, maturity and inflammatory response. EV leads had fibrous capsules of advanced but not yet complete maturity; TV capsules were composed of paucicellular fibrous tissue and frequently had thrombus adhered. EV capsule thicknesses ranged from 20–1,740 mm (average: 518 mm); TV capsules ranged from 50–1,970 mm (average: 476 mm).

The one-year study showed mature tissue capsules with low cellularity and inflammation–an expected finding for the implant duration. Simple extraction tools were used on n=3 leads (one per animal) without initial use of traction, and all leads were extracted without complications. Traction was attempted first for n=3 leads (one per animal) and successful for two, with an average pull force of 3.0 kgf; for the remaining lead, traction was abandoned at 4.1 kgf, and simple tools used to extract the lead successfully thereafter, without complication.

Conclusion: At 12 weeks, histomorphological characteristics of the perilead encapsulation were similar between EV and TV leads, even though the distal portion of the EV lead was implanted within a tissue environment and the TV lead within a hematogenous environment. Importantly, the tissue capsules were of similar thickness and comparable in their maturity and inflammatory response. In the one-year specimens, no further remodeling or additional biologic response was observed. Lead extraction was performed without complications using traction and simple tools.

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