Cost-Effectiveness of the Absorbable Antibacterial Envelope for Infection Control in Cardiac Implantable Electronic Device Implantation in Spain.

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Background

- Infection is a serious complication of the implantation of cardiac implantable electronic devices (CIED), which can be difficult to diagnose and treat. This complication not only requires the extraction of the device but is also associated with high morbidity and mortality.
- The extraction procedure generates significant healthcare costs and, in addition, prolongs hospital stays, further worsening the patient's situation. Consequently, infection in patients with CIED poses a significant challenge for healthcare professionals, as it involves complex management and can have a considerable impact on the quality of life of those affected.

Objective

• Our aim is to model the cost-effectiveness of the Absorbable Antibacterial Envelope (AAE) for infection prevention in patients undergoing a CIED implantation in the context of the Spanish healthcare system.

Methods

- A decision tree model (Figure 1) with a lifetime horizon was populated to compare standard of care (SoC), consisting of one course of pre-operative antibiotic prophylaxis only, versus SoC plus the envelope in patients undergoing a CIED implantation.
- The model considers clinical inputs for infection (REINFORCE¹) and mortality rates (AdaptResponse², WRAP-IT³) at 12-, 24- and 36-months post-implant; costs (€, 2023) from Spanish databases and benefits in quality-adjusted life-years (QALY) gained using the EQ-5D-5L data from WRAP-IT.
- The incremental cost-effectiveness ratio (ICER) is presented per device type and aggregated according to the current Spanish treatment mix [77% pacemaker (PM), 15% Implantable Cardiac Defibrillator (ICD), 5% Cardiac Resynchronization Therapy-Defibrillator (CRT-D), 3% Cardiac Resynchronization Therapy-Pacemaker (CRT-P)].
- Probabilistic sensitivity analysis (PSA) was conducted to test the robustness of the analysis.

Results

- For CRT-D and ICD patients, the envelope is a dominant alternative, and cost-effective for PM (€18,160/QALY) and CRT-P (€14,627/QALY) when compared to the SoC considering a willingness to pay (WTP) threshold of €25.000/QALY⁴. Averaging across all devices, the ICER was €10,798/QALY (Table 1) (Figure 2).
- PSA corroborates the base-case results as the envelope remained cost-effective for all-devices in 69%, 80%, 89% of model replications at €20,000/QALY, €30,000/QALY and €50,000/QALY WTP thresholds, respectively, compared with SoC (Figure 3).
- The results from the one-way sensitivity analysis, represented in the tornado diagram (Figure 4), confirm the robustness of the analysis. All variables show low impact on the all devices ICER, besides the infection rate hazard ratio for the envelope.

Figure 1: Decision tree

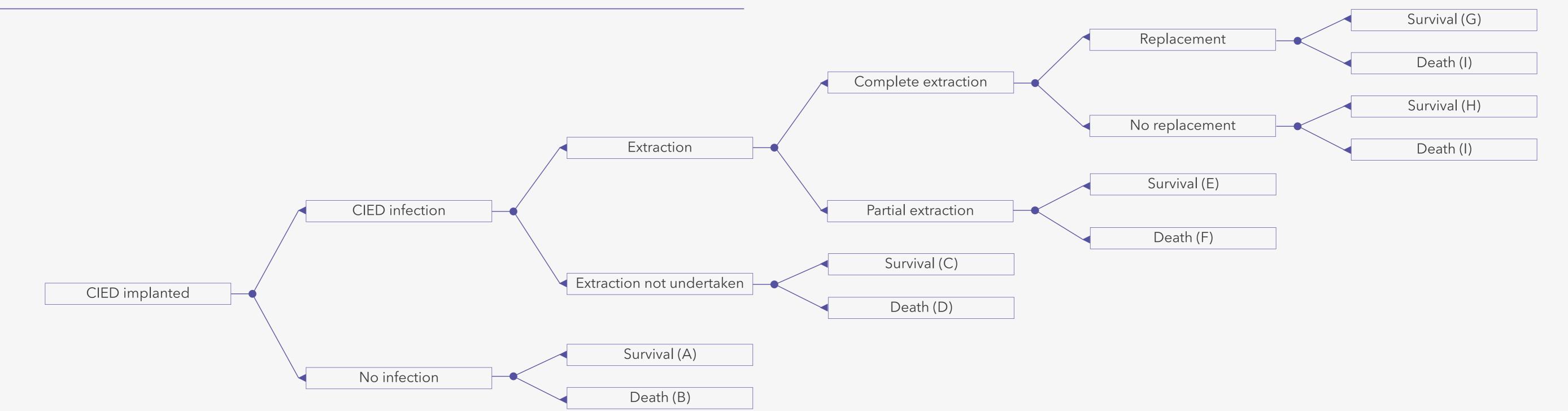
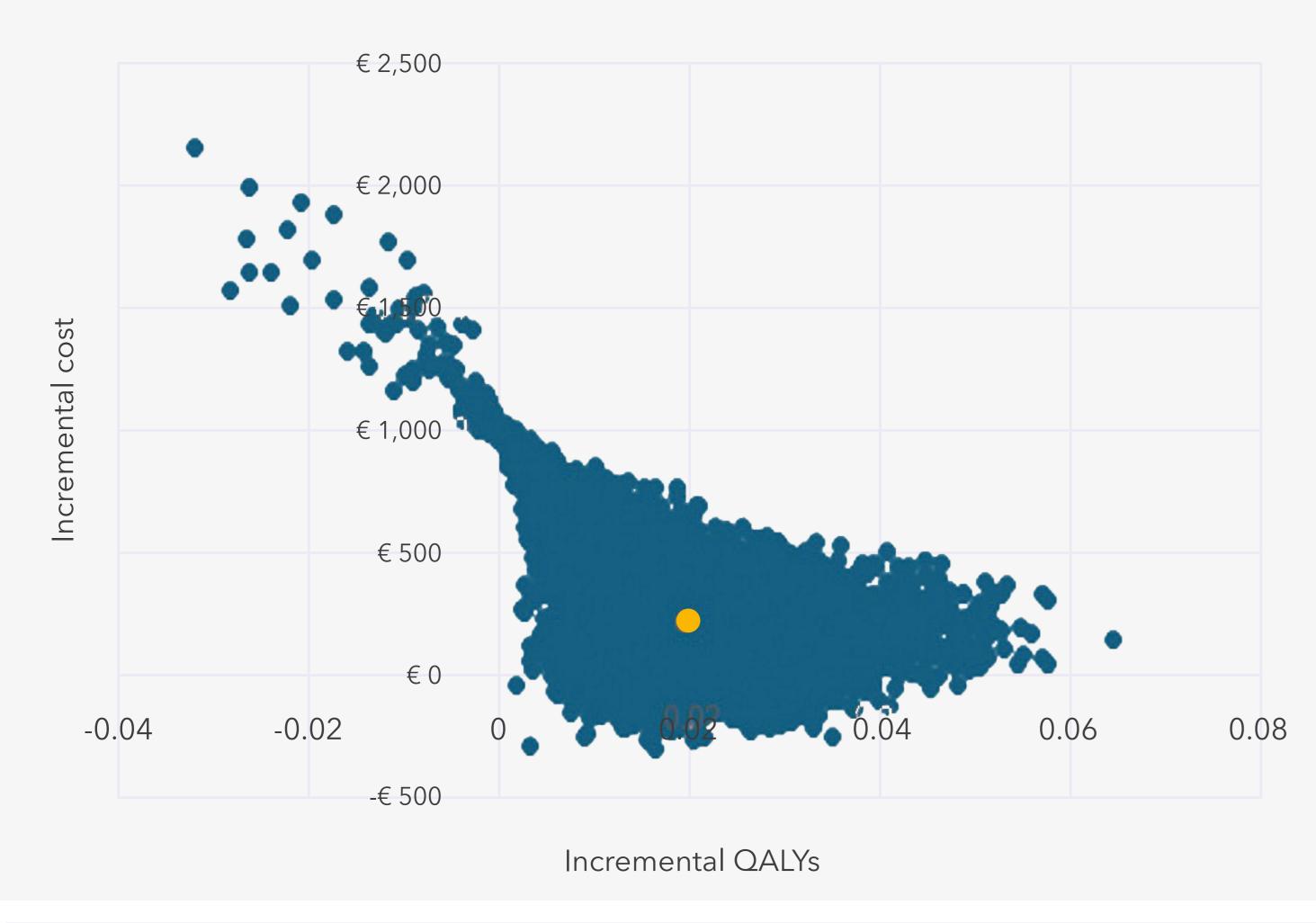


Table 1: Cost-effectiveness results.

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	ICERs (AAE vs. SoC)				
	CRT-D	CRT-P	IPG	ICD	All devices
Incremental costs	- € 266	€ 258	€ 320	- € 219	€ 208
Incremental QALYs	0,0210	0,0177	0,0176	0,0274	0,0192
ICER	AAE Dominates	€ 14,627	€ 18,160	AAE Dominates	€10,798

AAE: Absorbable Antibacterial Envelope

Figure 2: All-devices cost-effectiveness plane (AAE vs. SoC).





€ 40,000

€ 60,000

Willingness-to-pay threshold

€ 80,000

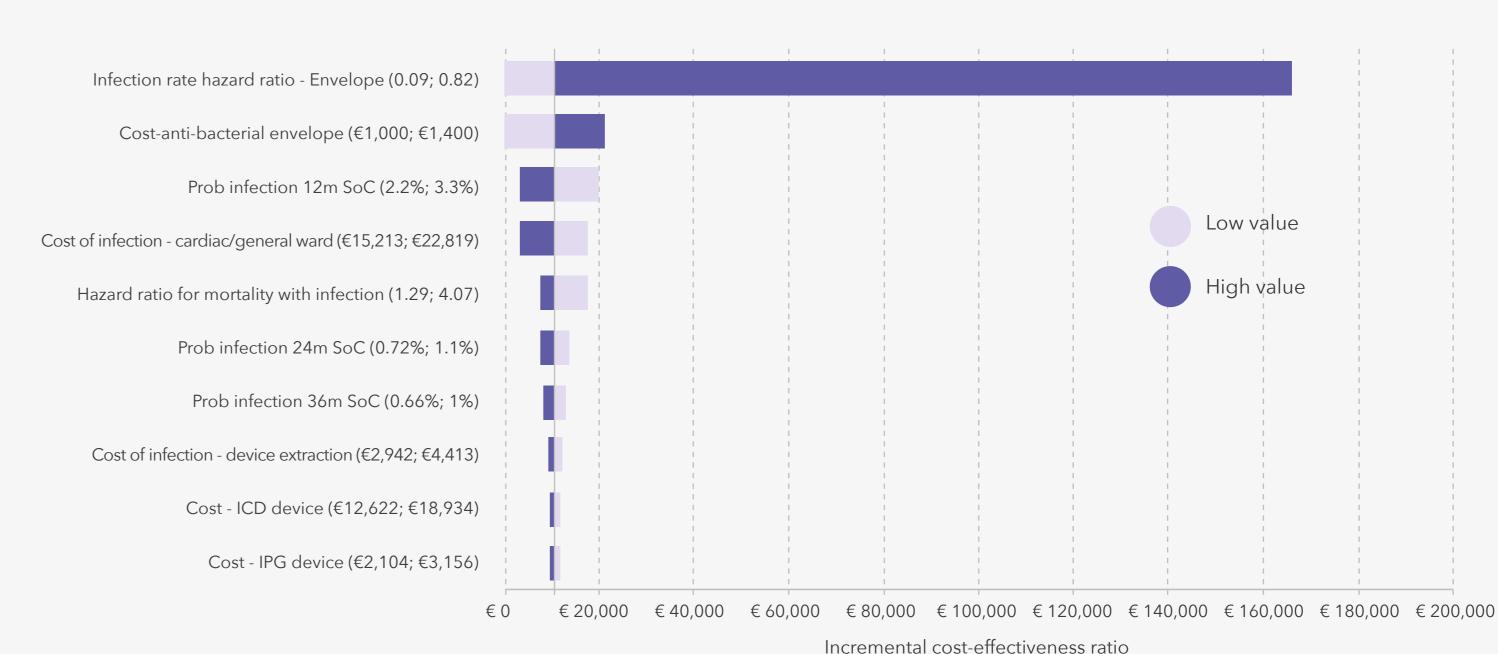
€ 100,000

Figure 4: All-devices tornado diagram.

€0

Figure 3: All-devices acceptability curve (AAE vs. SoC).

€ 20,000



Conclusion

The absorbable antibacterial envelope was associated with ICER values below the Spanish WTP regardless of the implanted CIED, suggesting the envelope provides value for the Spanish healthcare system by preventing CIED infections.

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