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1. BACKGROUND

- Gastro-esophageal reflux disease (GERD) affects 6.8M people in Spain, incurring €2.2M/year in healthcare costs<sup>1</sup>
- Standard-of-care (SOC) includes proton pump inhibitors (PPIs) and laparoscopic Nissen fundoplication (LNF) in select cases, both of which have disadvantages that undermine clinical utility<sup>2-6</sup>:
  - PPIs: Irresponsiveness, non-indicative use, and long-term use-associated adverse events (AEs)
  - LNF: Reoperations and complications
- RefluxStop restores the anti-reflux barrier without encircling the esophagus and confers long-term safety and efficacious GERD treatment, significant reduction in PPI dependency and the need for reoperations, and cost-effectiveness relative to SOC in the UK and multiple European countries<sup>6-9</sup>

Objective: To evaluate the cost-effectiveness of RefluxStop vs. PPI-based medical management (MM) and LNF for GERD treatment in Spain

2. METHODS

MODEL OVERVIEW

- Type: Markov/state-transition (adapted from UK, Norway, Switzerland cost-effectiveness models)
- Horizon: Lifetime
- Perspective: Spanish healthcare payor
- Cycle length: 1 month
- Annual discount rate: 3%
- Cost-effectiveness threshold: €30,000

INPUTS

- Clinical & QoL: Demographics, efficacy, safety, risks for AEs, Barrett’s esophagus (BE), and esophageal adenocarcinoma (EAC), mortality, utility decrements (HRQoL decline)
- Costs: Direct medical (PPIs, surgeries, and management of AEs, BE, EAC)

SOURCES

- Spanish DRG databases
- Peer-reviewed publications
- RefluxStop CE mark trial (3-year outcomes)

OUTCOMES

- Life years, quality-adjusted life-years (QALYs), total costs, incremental cost-effectiveness ratios (ICER), net health benefit (NHB), net monetary benefit (NMB), selected clinical outcomes

Figure 1

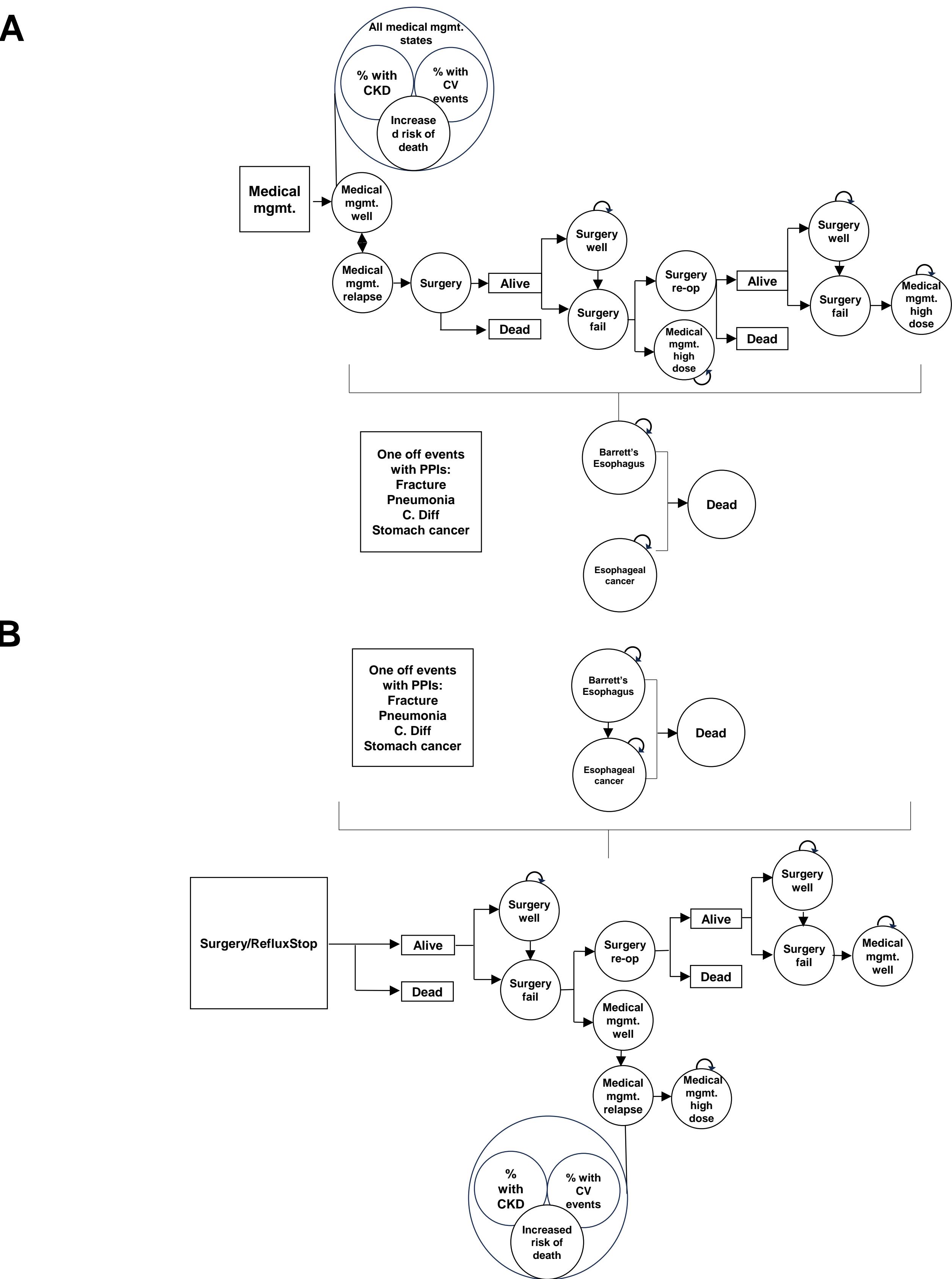


Figure 1: Model structure applied to medical management (A) and surgical treatment options (B)

3. RESULTS

- Over lifetime horizon, RefluxStop led to incremental per-patient:
  - Cost difference of €1,472 (vs. MM), €2,111 (vs. LNF)
  - QALY gains of 2.64 (vs. MM), 0.88 (vs. LNF)
- In the base case analysis, the ICERs per QALY gained for RefluxStop were €557 and €2,393 against MM and LNF, respectively
- At the €30,000 cost-effectiveness threshold, RefluxStop was cost-effective with a probability of:
  - 100% against MM
  - 95% against LNF
- RefluxStop improved clinical outcomes vs. LNF (per 1,000 patients) evidenced by:
  - Fewer surgeries: 1.03 vs. 1.05
  - Fewer surgical failures: 0.26 vs. 0.51
  - Fewer endoscopic dilations: 0 vs. 0.84

Figure 2

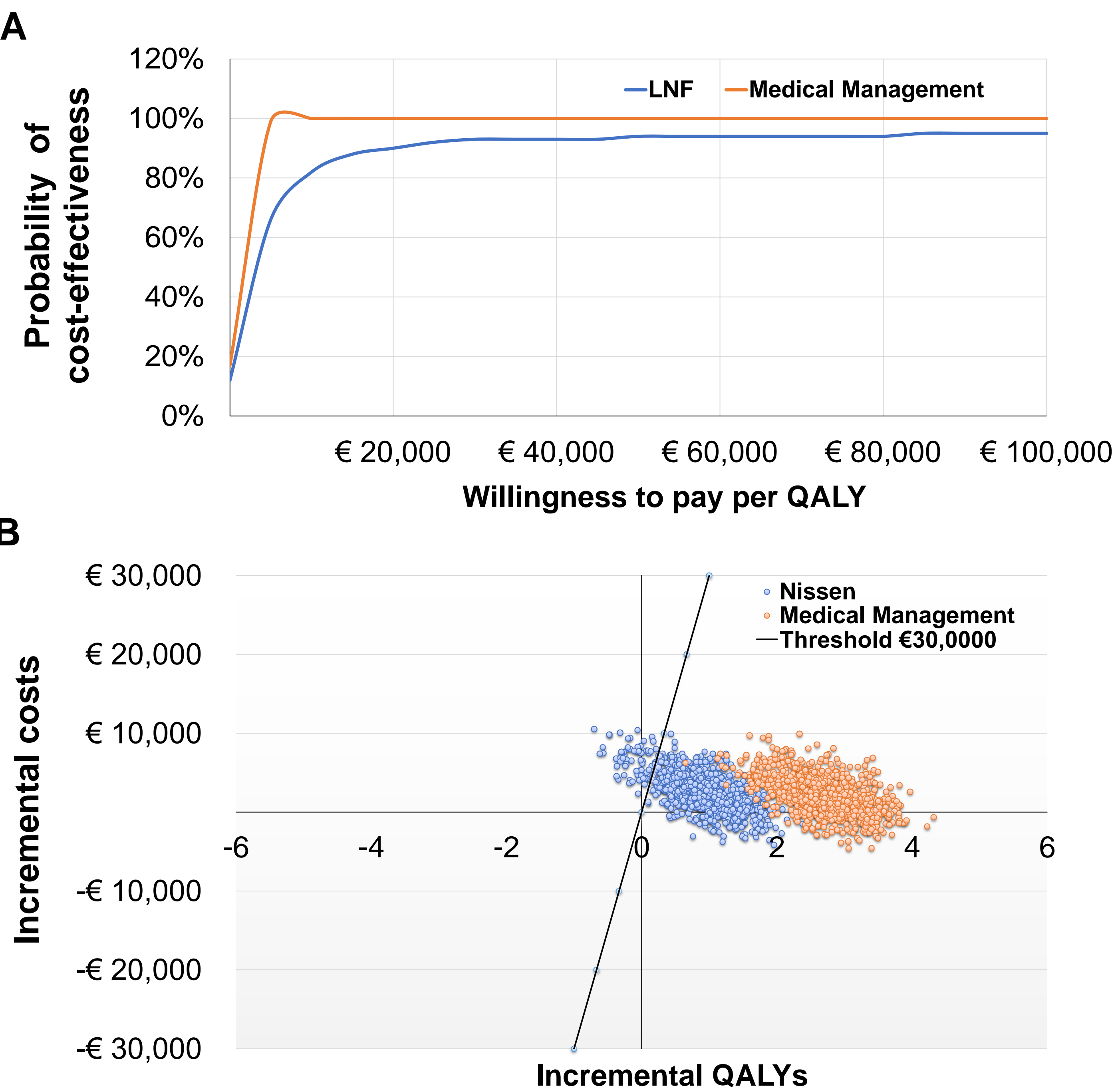


Figure 2: Probabilistic sensitivity analyses against the two comparators presented as cost-effectiveness acceptability curves (A) and as a cost-effectiveness plane showing the spread of the individual iterations (B)

Table 1

Cost-effectiveness outcomes estimated in the base case analysis, per patient					
Summary results	RefluxStop	MM	Incremental vs MM	LNF	Incremental vs LNF
Cost (€)	20,296.66	18,825.03	1,471.63	18,185.25	2,111.41
QALYs	14.20	11.56	2.64	13.32	0.88
Life years (undiscounted)	30.64	29.05	1.59	29.99	0.65
Life years (discounted)	18.24	17.59	0.65	18.00	0.24
ICER		€557.12		€2,392.83	
NMB		€233,056.63		€72,891.58	
NHB		2.62		0.86	

4. CONCLUSIONS

RefluxStop has a high probability of being cost-effective relative to SOC for treating adult GERD patients in the Spanish healthcare system. This aligns with findings from multiple European countries and the UK, demonstrating its value for payers across diverse healthcare settings.

References

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Abbreviations

AE, adverse event; BE: Barrett’s esophagus; C.diff, *C. difficile*; DRG, diagnostic-related group; GERD, gastro-esophageal reflux disease; ICER, incremental cost-effectiveness ratio; MM, medical management; NHB, net health benefit; NMB, net monetary benefit; PPI, proton pump inhibitor; QALY, quality-adjusted life-year; reop, reoperation.