# **EE296** A Nonactive Implant for the Treatment of Chronic Gastro-Esophageal Reflux Disease: **Cost-Effectiveness Analysis from an Italian Healthcare Payer Perspective**

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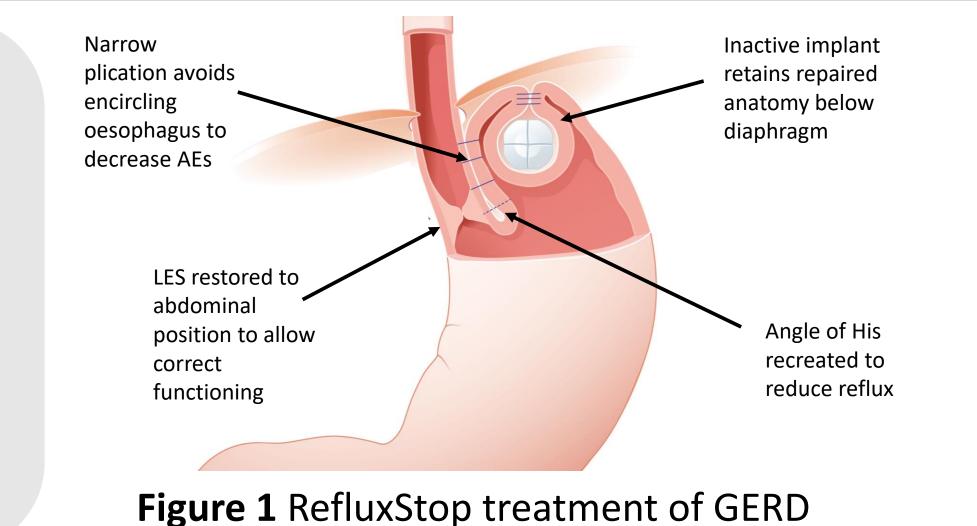
## INTRODUCTION

- Gastro-esophageal reflux disease (GERD) symptoms affects ~25% of the Italian population<sup>1</sup>
- First-line treatment is proton-pump inhibitors (PPIs) often continued indefinitely, with potential adverse effects (AEs)
- Medical failure or intolerance  $\rightarrow$  surgery: Typically, laparoscopic Nissen fundoplication (LNF) •

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Magnetic sphincter augmentation (MSA)

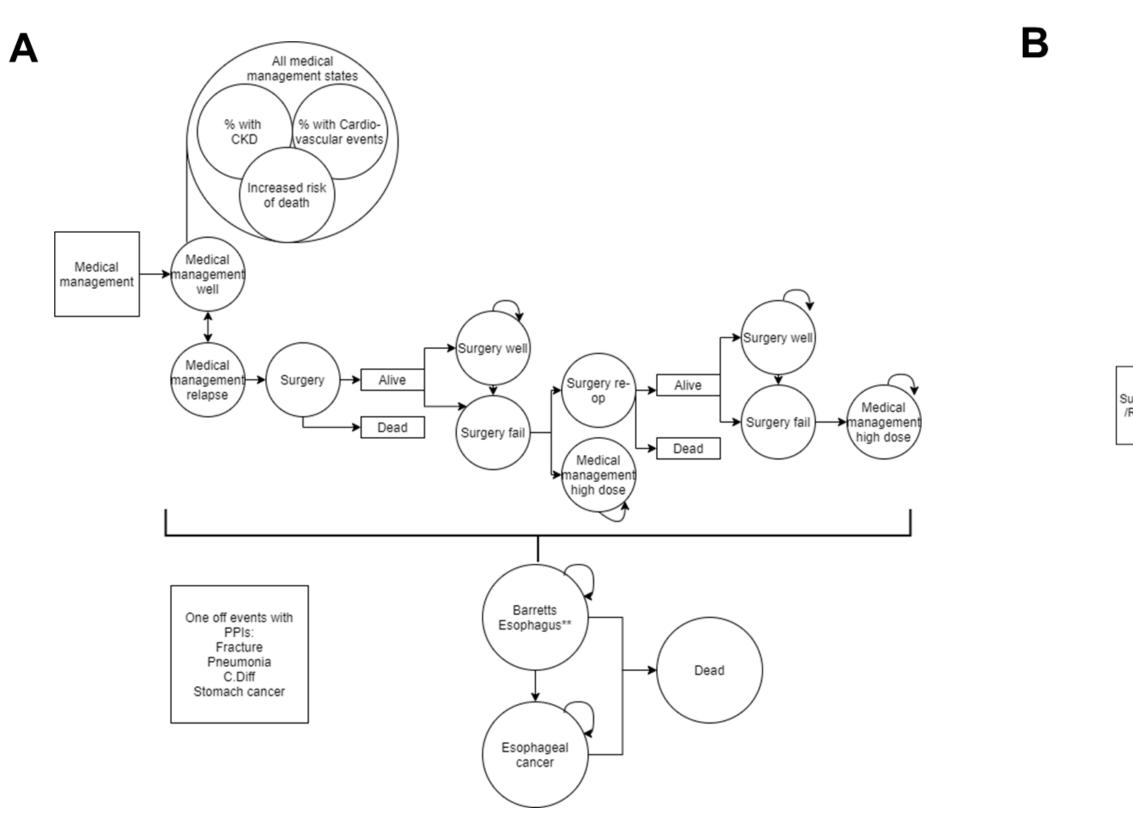
- Emergent surgical treatment (Figure 1) available at several Italian institutions RefluxStop: •  $\bullet$ 
  - Encouraging clinical safety and effectiveness to date<sup>2</sup>
  - Novel mechanism postulated to reduce adverse effects of surgery<sup>2</sup>

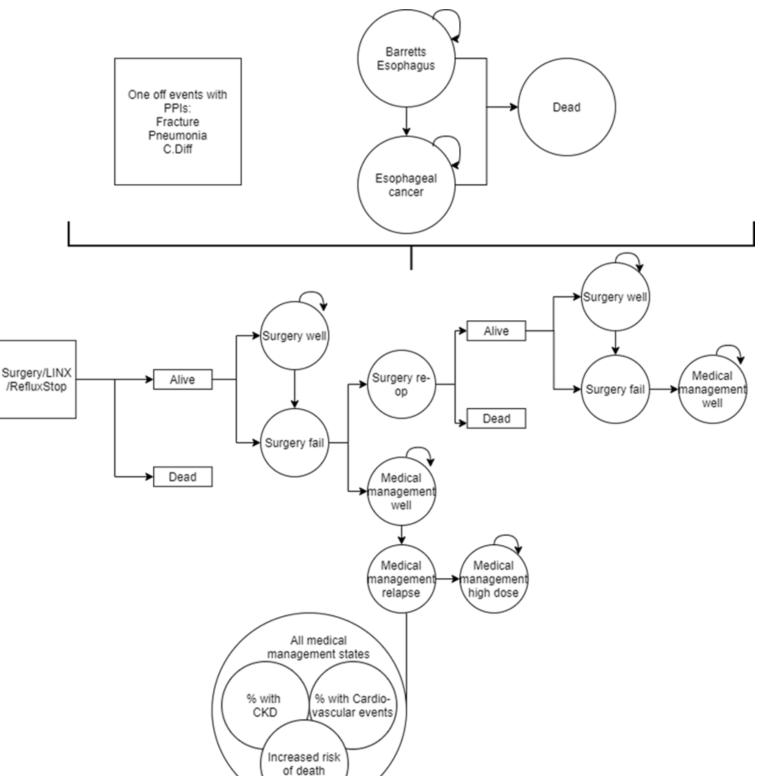


## **METHODS**

### **OVERVIEW**

- Markov/state transition model adapted from model used in the UK, Switzerland, and Sweden (Figure 2)
- Perspective: Italian healthcare payer
- Horizon: Lifetime
- Discount rate: 3% annual
- Direct medical costs only
- Cycle length: 1 month
- Sources: medical literature, Italian DRG databases
- Cost-effectiveness threshold: €50,000

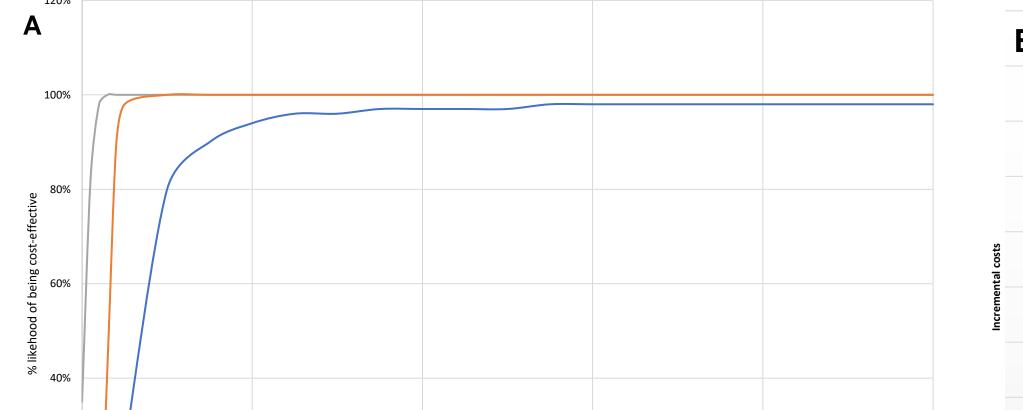


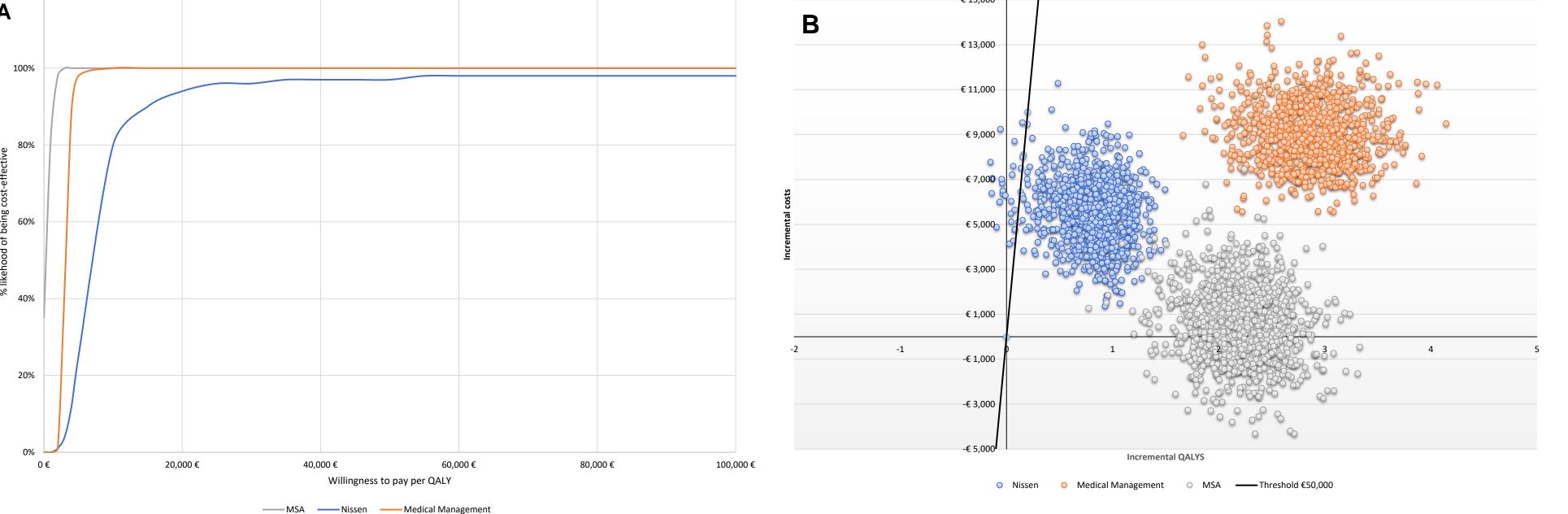


**Figure 2** Model structure. **A** PPI-based medical management, **B** Surgical treatment options: LNF and MSA

### **Table 1** Cost-effectiveness outcomes from base case analysis, per patient

Summary results	RefluxStop	MM	Incremental vs MM	LNF	Incremental vs LNF	MSA	Incremental vs MSA
Cost per patient	€13,122.51	€4,334.15	€8,788.35	€7,810.48	€5,312.03	€12,746.50	€376.01
QALYs per patient	11.66	8.79	2.87	10.87	0.79	9.46	2.20
Life years per patient (undiscounted)	18.38	16.48	1.90	17.84	0.54	16.73	1.66
Life years per patient (discounted)	12.97	11.90	1.07	12.68	0.28	12.09	0.88
Incremental cost-effectiveness ratio (ICER)		€3,066.90		€6,712.37		€170.97	
Net monetary benefit (NMB)		€277,767.01		€73,825.84		€219,547.02	
Net health benefit (NHB)		2.78		0.74		2.20	





- **Base-case analysis showed ICERs** per QALY gained with RefluxStop of €3,067 vs PPIs, €6,712 vs LNF, and €171 vs MSA - well below threshold of €50,000 per QALY
- More QALYs in RefluxStop arm than comparator arms
- Costs incurred with RefluxStop partially offset by savings from:
  - Lower PPI requirement
  - Fewer PPI-associated AEs
  - Fewer intraoperative events and complications requiring surgery
  - Fewer endoscopic dilatations
  - Fewer device removals
- At threshold of €50,000 per QALY gained, **RefluxStop had a high**

probability of being costeffective against PPIs (100%), Nissen fundoplication (97%), and **MSA (100%)** 

**Figure 3. A** Cost-effectiveness acceptability curves, **B** Cost-effectiveness plane showing distribution of individual iterations in probabilistic sensitivity analysis, confirming model robustness

# **CONCLUSION:** Implementation of RefluxStop in the Italian national health service is highly cost-effective against standard-of-care medical and surgical management of GERD.

#### References

- 1. Zagari RM, Fuccio L, Wallander MA et al. Gastro-oesophageal reflux symptoms, oesophagitis and Barrett's oesophagus in the general population: the Loiano-Monghidoro study. Gut. 2008;57(10):1354-9.
- 2. Harsányi L, Kincses Z, Zehetner J, Altorjay Á. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surg Endosc. 2024;https://doi.org/10.1007/s00464-024-11114-0.

#### Abbreviations

AE, adverse effect; DRG, diagnostic-related group; GERD, gastro-esophageal reflux disease; ICER, incremental costeffectiveness ratio; LES, lower esophageal sphincter; LNF, laparoscopic Nissen fundoplication; MM, medical management; MSA, magnetic sphincter augmentation; NHB, net health benefit; NMB, net monetary benefit; PPI, proton pump inhibitor; QALY, quality-adjusted life-year.