

PD101 Evaluating The Budget Impact Of Introducing RefluxStop™ As A Novel Treatment Option For Gastroesophageal Reflux Disease In Italy

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Introduction: In Italy, the first-line treatment for gastroesophageal reflux disease (GERD) is proton pump inhibitors (PPIs). Other options considered after PPI failure include Nissen fundoplication and magnetic sphincter augmentation. RefluxStop is a novel device for treating GERD. The aim of this study was to evaluate the budget impact of introducing RefluxStop into the Italian National Health Service (SSN).

Methods: The analysis, which used a five-year time horizon, one-year cycle length, and Italian payer perspective, was developed in line with ISPOR recommendations. Estimates for the Italian population and growth projections, GERD prevalence and incidence rates, and rates of anti-reflux surgery were obtained from relevant literature sources. The current market share of those requiring surgery was based on market research by Implantica (Zug, Switzerland). The cost of treatment was based on an adaptation of an economic model from the UK applied to the Italian setting. Unit costs were derived from available literature and diagnosis-related groups averaged across five Italian regions. Extensive sensitivity analyses involving key model inputs were also conducted.

Results: The overall one-year, three-year, and five-year financial impacts of introducing RefluxStop were EUR 242,641, EUR 710,651, and EUR 1,004,946 per year, respectively, corresponding to 0.063 percent, 0.197 percent, and 0.316 percent annual increases in overall Italian SSN expenditure for GERD. Use of more optimistic and pessimistic market uptake and surgery rates (i.e., doubled and halved) for RefluxStop led to one-year increases in Italian SSN expenditure of 0.126 percent and 0.032 percent and five-year increases of 0.636 percent and 0.155 percent, respectively. In our study, introducing RefluxStop avoided 95 surgical failures, 11 reoperations, and 64 endoscopic esophageal dilatations over five years.

Conclusions: The introduction of RefluxStop is likely to provide substantial benefits for patients with GERD at the cost of a marginal budget impact on the Italian healthcare system. Though Italian health

care is organized at a regional level, this study is an example of a health technology assessment using budget impact analysis at a national level.

PD102 Evaluating The Clinical Effectiveness Of Portable Ultrasonic Scalpels For Urological Surgery

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Introduction: Ultrasonic scalpels are widely used in urological surgery. Although portable ultrasonic scalpels are convenient to use and install, the existing evidence on their safety and effectiveness is scarce. This study aimed to compare the safety and effectiveness of portable ultrasonic scalpels in urological surgery with traditional ultrasonic scalpels to aid clinical decision-making.

Methods: A multicenter, prospective, non-randomized controlled trial was conducted from February to August 2023 in three tertiary hospitals in China. The intervention group included 90 prospectively enrolled patients undergoing urological surgery during the same period of hospitalization: 45 with portable ultrasonic scalpels and 45 with traditional scalpels. Demographic and clinical data of patients in the study were collected. Data on quality of life were obtained using the EuroQol EQ-5D-5L scale preoperatively, at discharge, and one month and three months after surgery. Descriptive analysis and a generalized linear model were used in the data analysis.

Results: A total of 82 patients were included in the study: 39 in the intervention group and 43 in the control group. The average hospital stay and intraoperative and postoperative blood loss in the intervention group were lower than in the control group ($p > 0.05$). From baseline to discharge, the decrease in quality-adjusted life-years (QALYs) in the intervention group was smaller (-0.134 versus -0.287 ; $p < 0.05$) than in the control group. During the follow-up period, there were no significant differences in the changes in QALYs between the two groups. The decline in QALYs was significantly influenced by variables such as intraoperative blood loss and surgical site.

Conclusions: There were no significant differences in baseline characteristics or changes in QALYs between the intervention and control groups. Portable ultrasonic scalpels in urological surgery may be as equally effective as traditional scalpels with respect to clinical outcomes, with additional benefits in reducing QALY decline at discharge. Further research with large samples and long-term follow-up should be conducted.