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Title **The Effectiveness and Cost Effectiveness of Minimal Access Surgery Amongst People with Gastro-Esophageal Reflux Disease - A UK Collaborative Study. The REFLUX Trial**

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Aim

To determine the clinical effectiveness, cost effectiveness, and safety of a policy of relatively early laparoscopic surgery versus medical management in people with gastroesophageal reflux disease (GORD) judged suitable for both.

Conclusions and results

The two randomized groups were well balanced at entry. Participants had been taking GORD medication for a median of 32 months; their mean age was 46 years, and 66% were men. Of 178 randomized to surgery, 111 (62%) actually had fundoplication. A mix of clinical and personal reasons (some related to long waiting times) were given for those not having surgery. A total or partial wrap procedure was performed, depending on surgeon preference. Complications were uncommon, and none was life threatening. By equivalent to 12 months after surgery, 38% in the randomized surgical group (14% among those who had surgery) were taking reflux medication compared to 90% in the randomized medical group. Substantial differences (a third to a half SD) favored the randomized surgical group across the health status measures, the size depending on assumptions about the proportion that actually had fundoplication. These differences were the same or somewhat smaller than differences observed at 3 months. The lower the reflux score at trial entry, the larger the benefit observed after surgery. A parallel group who wished to have surgery had the lowest reflux scores at baseline. These scores improved substantially after surgery, and by 12 months were better than in a fourth group who chose to continue medical management. The estimated within-trial cost per QALY was 19 000 pounds sterling (GBP) to GBP 23 000; modeling a range of longer-term scenarios indicated likely cost-effectiveness at a threshold of GBP 20 000 per QALY, but with wide uncertainty.

Recommendations

Among patients requiring long-term medication to control symptoms of GORD, surgical management significantly increases general and reflux-specific, health-related quality of life measures at least up to 12 months after surgery. Complications of surgery were rare. A surgical policy is, however, more costly. At a threshold of GBP 20 000 per QALY, it may well be cost effective, especially when putative longer-term benefits are taken into account, but this is uncertain. Hence, judgments are required about cost effectiveness. The more troublesome the symptoms, the greater the potential benefit from surgery.

Methods

See Executive Summary link at www.ncchta.org/project/1134.asp.

Further research/reviews required

Uncertainty about cost effectiveness would be greatly reduced by more reliable information about relative longer-term costs and benefits of surgical and medical policies in managing GORD. This could be through extended follow-up of the REFLUX trial cohorts (which is being undertaken) or by follow-up of other cohorts of fundoplication patients.

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