The role of laparoscopic fundoplication in management of chronic gastro-oesophageal reflux disease

Z H Krukowski PhD FRCS FRCP

University of Aberdeen & Aberdeen Royal Infirmary

The symptoms of gastro-oesophageal reflux disease (GORD) are one of the commonest reasons for referral to both primary and secondary care[i]. The majority of patients with GORD is managed medically with advice on life style management and medical therapy. The former often comprises the conflicting advice to stop smoking and lose weight and the latter acid suppression therapy and prokinetic agents[ii]. Weight loss is the single most effective non-medical component in management but only a handful of individuals successfully implement it. Although medication with proton pump inhibitors (PPI) is very effective in controlling symptoms in the majority this is achieved not by abolishing reflux but by raising the pH of the refluxate and reducing oesophageal inflammation. Furthermore PPIs are not free of side effects[iii] or concerns about long term acid suppression therapy[iv]. Despite optimal medical therapy as defined by the Genval Convention[v] a minority suffer persistent symptoms, often due to volume regurgitation and such failures of medical treatment merit consideration of surgery. More problematic is to know how to advise patients who are well controlled but wish to stop medication. Surgery to reconstruct the hiatus combined with some form of fundoplication has long been an option as an alternative to long-term medical therapy. The introduction of the minimal access laparoscopic approach in the early 1990s profoundly changed the perception of surgery amongst patients, physicians and surgeons and resulted in a dramatic increase in

the number of operations. The operation involves partial or total wrapping of the fundus of the stomach around the lower oesophagus and repair of the oesophageal hiatus. Laparoscopic fundoplication produces resolution of reflux symptoms in 90% of patients[vi],[vii] but there is a lack of consensus on the optimal form of fundoplication viz: total, partial anterior or partial posterior fundoplication. In addition there is uncertainty about the safety, side effects, durability and cost effectiveness of surgery. Increasing evidence from small randomised studies have gone some way to answering these concerns. The REFLUX trial[viii] was conceived to address this important issue in the context of the NHS.

The REFLUX trial was funded by NHS Health Technology and run by the University of Aberdeen Health Services Research Unit, a 5 star rated research centre. The study which was described as “elegant” and “a role model for future research” was a multicentre, pragmatic randomised trial with parallel non-randomised preference groups to contextualise the results and augment them, particularly in respect of surgical complications). The principal objective was to evaluate the clinical effectiveness, safety and costs of a policy of relatively early laparoscopic surgery compared with optimised, continued medical management of GORD for people judged suitable for both policies. Clinically the study was a collaboration between gastroenterologists, who were largely responsible for identifying, recruiting and randomisation, and experienced surgeons. Despite funding each centre to carry out additional operations during the study the competition from malignant disease and waiting time targets delayed recruitment. Nevertheless recruitment in the 21 UK centres, between March 2001 and June 2004 comprised 357 participants to the randomised component (178 allocated surgery and

179 medical management) and 453 to the preference component (261 choosing surgery and 192 medical management).

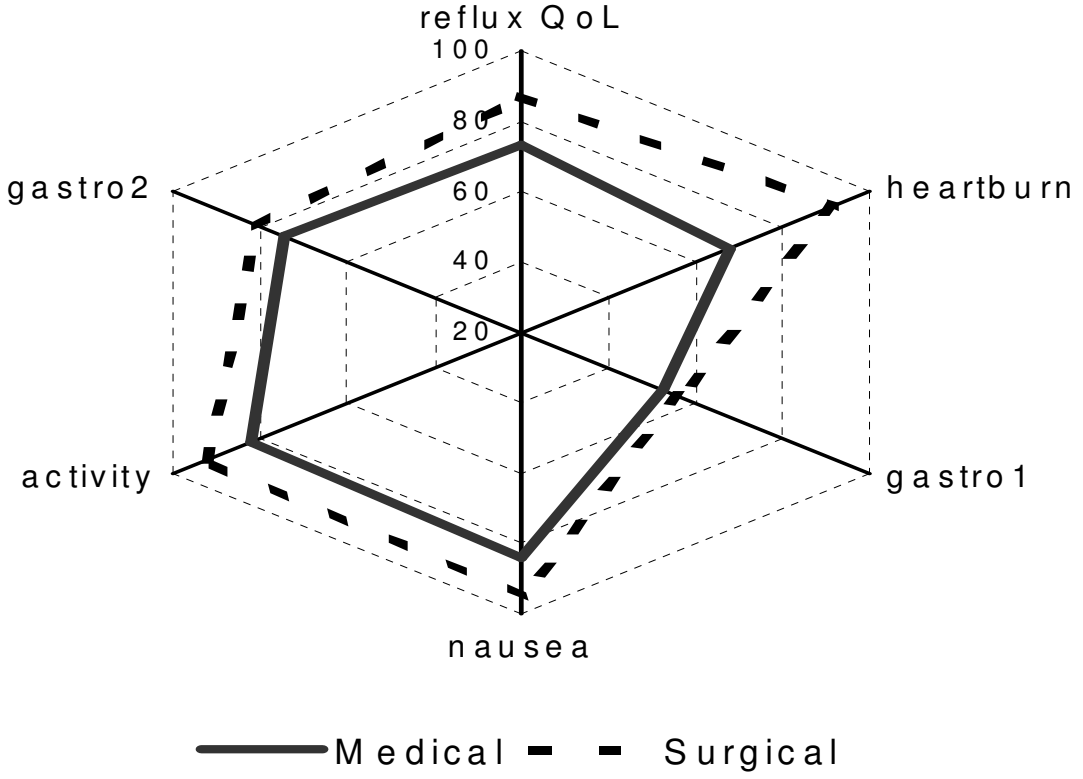
The outcome measures were those judged important to patients and health services. The primary outcome was the REFLUX questionnaire, a validated 'disease-specific' measure incorporating assessment of reflux and other gastro-intestinal symptoms, including the side effects and complications of both therapies (score range 0 to 100 – the higher the score the better the patients felt). Secondary outcomes used standard tools for assessing quality of life: health status – EQ-5D and SF-36; serious morbidity, such as operative complications; mortality; and costs to the NHS. Health services resource use data included in-patient days in hospital wards and high dependency units, diagnostic tests, duration in theatre, out-patient and GP visits, re-admissions and use of reflux-related pharmaceuticals. These were costed using routine NHS unit costs and prices.

The characteristics of the randomised participants were similar and lay between the preference groups; surgical preference participants were younger and had been prescribed medication for GORD for longer; medical preference participants were older, more likely to be women, and more likely to be taking medication. Three participants, none of whom had surgery, died during the trial. It was notable that only 62% of those randomised to surgery and 84% of surgical preference participants actually received fundoplication. The reasons for not having surgery were a surgeon's decision that symptoms were not sufficiently severe, not being fit for surgery, patients' change of mind for work or home related reasons, concerns about surgery, a wish to avoid pre-operative tests, and symptomatic improvement reflecting

the “|real world” pragmatic nature of the study. The conversion rate to open surgery was only 0.6% in the 329 operations reflecting the expertise of the participating surgeons .

By 12 months after surgery, 38% of the randomised surgical participants were taking medication compared with 90% of the randomised medical participants. Amongst those who had surgery, use of anti-reflux medication dropped to 14% 12 months after surgery. There were substantial differences across all symptom domains between the randomised intention to treat groups in the REFLUX score with the surgery group having better scores than the medical group. The differences between groups were even larger when only the per protocol participants were considered. All results showed strong evidence of increases in REFLUX scores favouring surgery (Figure)

Figure: difference in REFLUX scores between Medical and Surgical randomised groups at 12 months. (higher score is better)



Similar patterns in the randomised groups were seen in the SF-36 scores where the biggest differences favouring surgery were observed in the general health and bodily pain dimensions.

In the randomised comparison, mean costs up to one year after surgery were: surgery £1768 and medical £507 (63)

In the preference groups those opting for surgery had lower mean REFLUX scores (i.e worse GORD) at baseline compared to the medical (55.8 v 77.5). Despite this, at follow up at 12 months, the REFLUX and other QoL scores favoured the preference surgical group .

This large study showed that laparoscopic fundoplication is safe with low morbidity. There was a highly statistically significant differences between the surgical and medicvally treated patients at one year. Predictably there was no significant improvement in patients continuing on medical treatment, having been on it for at least 12 months before entering the study, Whereas patients undergoing surgery whether by random or choice reported improved quality of life. The lower the reflux scores at entry, i.e. the worse the symptoms, the larger were the improvements following surgery.

The protocol allowed surgeons to use the type of fundoplication with which they were familiar, to avoid any learning effects, and found no difference in outcomes between total versus partial fundoplication.

The costs of laparoscopic fundoplication appear to be equivalent to 2-3 years of maintenance treatment with proton pump inhibitors The costs of surgery related to the incidence of complications/length of hospital stay and the number of patients requiring long-term medication after surgery. The outstanding issue remains whether the benefits of surgery are sustained and these cohorts of patients will befollowed up in the long term. For the present when dicussing surgery with a patient with uncomplicated GORD who is considering

laparoscopic fundoplication it can reasonably be stated that the operation will improve quality of life but the durability remains uncertain.

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