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Are Endoscopic Antireflux Therapies Cost-Effective Compared with Laparoscopic Fundoplication?

Background and Study Aims: A number of endoscopic antireflux therapies (EATs) have emerged as potential nonmedical treatment options for patients with gastroesophageal reflux disease (GERD). Concerns about clinical efficacy and costs have given rise to debate about their role in GERD management. The costs of laparoscopic fundoplication (LF) were compared with the costs of EAT when used in a sequential strategy that reserves the option of LF for EAT failure.

Methods: A simple mathematical criterion of direct medical costs was applied. Published articles concerning EAT were reviewed to assess its effectiveness, durability and costs, in order to estimate the parameters of the model. The costs of EAT and LF were evaluated from the perspective of a German third-party payer. Only direct medical costs were considered.

Results: Assuming that EAT has no impact on potential LF later on, the outcome of both strategies (LF, or EAT first with LF in case of failure of EAT) is identical and preference is a simple question of costs. The sequential strategy in nonmedical GERD treatment would be preferable if the long-term relief rate with EAT exceeds the ratio of the cost of EAT to the cost of LF. Long-term success rates of EAT do not exceed 0.65. At current prices EAT is clearly not cost-effective in Germany.

Conclusion: Our simple criterion indicates that EAT would only be cost-effective and beneficial in a sequential strategy if the costs of EAT were to be decreased to around 30% of current retail prices. However, long-term studies and randomized controlled trials are necessary to finally determine the role of EAT in GERD treatment, and the preference may change in either direction.

Introduction

Gastroesophageal reflux disease (GERD) is a common disorder with increasing incidence and prevalence in the industrialized countries and with a major impact on patient quality of life [1–4]. The prevalence of heartburn has been reported to be 29% of the population in the UK [5] and 22% in Finland [6]. Without treatment, potential sequelae of reflux esophagitis are ulcerations, esophageal stricture, or precancerous changes (Barrett esophagus) that are associated with a 30%–40% increase in the risk of esophageal cancer [7]. GERD treatment options comprise lifestyle modifications, pharmacological acid suppression, and antireflux surgery. The efficacy of GERD symptom control as well as of prevention or treatment of complications is variable [8–11]. Since GERD is a chronic relapsing disorder [12] substantial healthcare resources are at stake.

Proton-pump inhibitors (PPI) and (laparoscopic) antireflux surgery are currently the accepted treatment modalities for management of GERD. Since 82% of patients relapse after 6 months of PPI cessation [12] lifelong maintenance therapy is required [13]. A notable number of patients have relapsing GERD symptoms or resent dependence on lifelong PPI medication. Antireflux surgery is used as an alternative GERD therapy [14–16]. The

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open procedure has been replaced by the introduction of laparoscopic fundoplication (LF) [17,18] which can achieve long-term relief of symptoms [19] in about 90% of cases. However, LF requires hospital admission and is associated with significant morbidity and with a mortality of 0.1% – 0.3% [20 – 23]. Additionally, a comparative study has shown that after antireflux surgery 62% of patients were using antisecretory medication at a median follow-up of 6.3 years [10]. Comparing long-term PPI treatment with LF, the break-even point, where the costs of the two alternatives are equal, was calculated to be reached at 1.4 years of medical treatment [24].

In view of these risks and costs, investigators have sought less invasive endoscopic methods to augment the function of the gastroesophageal barrier and to prevent gastroesophageal reflux. Endoscopic antireflux therapies (EATs) have emerged as a potential alternative to LF in patients with an incomplete response to PPIs and/or for whom lifelong medication is not an acceptable treatment option. Three minimally invasive endoscopic approaches have recently been approved by the US Food and Drug Administration (FDA) for the management of GERD: endoscopic suturing (EndoCinch; CR BARD Endoscopic Technologies, Billerica, Massachusetts, USA) [25 – 29], delivery of temperature-controlled radiofrequency energy (Stretta; Curon Medical Inc. Sunnyvale, California, USA) [30 – 33], and injection of a biocompatible polymer (Enteryx; Boston Scientific, Natick, Massachusetts, USA) [34 – 37]. The long-term relief rate after EAT is not fully comparable with that of LF. Follow-up reports of patients after LF have shown an 87% to 91% overall success rate after 3 – 5 years [10,11,19,38]. For EAT the only available follow-up data are scarce and short-term. Published data indicate that, after 6 months to 1 year, the relief rate in terms of heartburn symptoms or reduction of PPI use is approximately 60% – 80% [26,27,30 – 32,34 – 37]. On the other hand, EAT procedures (not including the cost of the device) are cheaper and have a considerably lower extent of side effects (with no operation, less mental and physical strain, and no hospitalization). Two deaths have been reported with the Stretta procedure during the introductory period of the product, and for all EATs serious complications have been reported only very rarely, whereas LF shows a mortality of 0.2% – 1.0% in large series [39,40].

As LF is still possible after EAT [41,42], it may be both beneficial and cost-effective to adopt a conditional strategy, namely to carry out EAT as the first-line treatment and leave the option of LF as a last resort, only to be done if the results of EAT are unsatisfactory. We used a simple decision-tree model scenario to elucidate the circumstances under which long-term relief rates and costs are optimal in the management of GERD patients. We determined how great the rate of long-term relief after EAT needed to be if the conditional strategy was to be beneficial, expressing this rate as a function of the cost advantage of EAT over LF.

Methods

We reviewed all available publications regarding the efficacy, and durability of the new EndoCinch, Stretta, and Enteryx antireflux procedures.

Table **1** Comparison of costs of endoscopic antireflux therapy (EAT) and laparoscopic fundoplication (LF)

Procedure	*GOÄ number*	*Cost, €*
EndoCinch		1942.12
Gastroscopy	684	160.87
Sedation	450	10.19
EndoCinch device	–	1771.06
Stretta		2021.06
Gastroscopy	684	160.87
Sedation	450	10.19
Stretta devices	–	1850.00
Enteryx		1671.06
Gastroscopy	684	160.87
Sedation	450	10.19
Enteryx kit	–	1500.00
LF		992.68
Fundoplication	3280	371.35
General anesthesia	462	68.37
Additional 30 min	463	46.65
"Hotel" cost (average 5 days)	–	101.26 (506.32)

GOÄ, GebührenOrdnung für Ärzte.

Patient Selection Criteria

Most studies included patients with uncomplicated GERD. Patients considered here had to meet all of the following inclusion criteria: moderate to severe reflux more than five times a week; at least a partial response to PPIs; abnormal findings at 24-hour esophageal pH monitoring; hiatal hernia smaller than 3 cm; and no significant co-morbidity. The hernia size criterion was imposed in order to guarantee the applicability of all procedures. Patients who were aged less than 18 years or had dysphagia, previous thoracic surgery, or esophageal varices were excluded.

Model Considerations

To evaluate the costs, EAT was compared with LF from the perspective of the third-party payer. Direct medical costs associated with EAT and LF consisted of those of uncomplicated operation and of medication and the "hotel" costs of hospitalization. The hotel costs for inpatient-days were obtained from the accounting center of the 20 participating hospitals by calculating the mean values (Table **1**). For comparable costs, the GOÄ (GebührenOrdnung für Ärzte, 2.3-fold average cost multiplies in a national reimbursement schedule for German doctors) was used to provide a nationwide cost-covering measuring unit. Direct nonmedical costs, for example transportation, and indirect costs such as loss of production due to endoscopy (1 day) or operation (5 days) were not included, to the disadvantage of EAT.

Our scenario was based on the following assumptions:

- (i) that EAT does not affect the probability of success of a second-line LF; and
- (ii) that no patient could be cured by means of EAT who could not also be cured with an LF procedure. (This assumption was to the disadvantage of EAT.)

Figure **1** illustrates two treatment options in patients with mild to moderate GERD, that is, LF as first-line treatment, or EAT as the first-line treatment with LF carried out only in those patients in whom EAT failed.

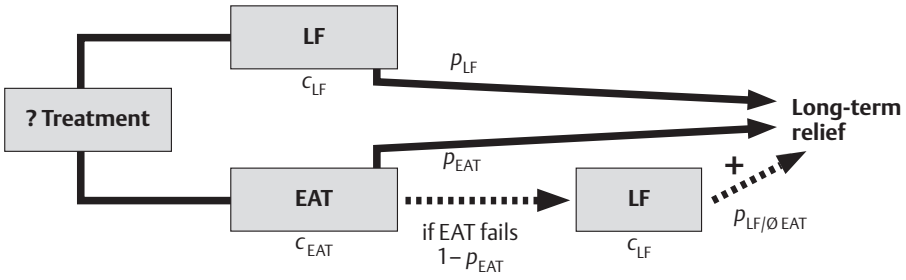

Figure **1** Considered treatment strategies for gastroesophageal reflux disease (GERD): laparoscopic fundoplication (LF) as first-line treatment, or endoscopic antireflux therapy (EAT) as first-line treatment followed by LF in those patients in whom EAT fails.

Key:	
LF	laparoscopic fundoplication
EAT	endoscopic antireflux therapy
p_{LF}	long-term relief rate following LF
P_{EAT}	long-term relief rate following EAT
$p_{LF/Ø\,EAT}$	long-term relief rate following LF after EAT failed
c_{LF}	cost of LF
c_{EAT}	cost of EAT

The costs of EAT and LF are designated by C_{EAT} and C_{LF}, respectively and the costs of the conditional strategy by $C_{EAT<fail>\rightarrow LF}$. The long-term relief rates for EAT and for LF are denoted by p_{EAT} and p_{LF}, respectively.

In the discussion, costs may be interpreted from two perspectives: a) the monetary costs for the procedures, or b) the subjective "costs", which include side effects and the stress caused to the patient by the procedures. While monetary costs can be assessed by adding the expense of the material used, operations, and hospitalization etc., the assessment of subjective costs depends on clinical judgment. Both perspectives are important and the equations in their general form apply to both.

Results

Model

Applying the assumptions of the model, the final long-term relief rates of both strategies, that is, LF or EAT with LF only in case of failure, are identical. As the outcomes may thus be assumed to be eventually the same, preference between the strategies is a straightforward question of costs.

The monetary cost of the conditional strategy is simply:
$C_{EAT<fail>\rightarrow LF} = C_{EAT} + (1 - p_{EAT}) * (C_{second} + C_{LF})$.

Here C_{second} denotes the additional cost or stress associated with the experience and the diagnosis of failure of EAT and the need to face a second intervention.

Thus the conditional strategy is cheaper, i.e.
$C_{LF} > C_{EAT<fail>\rightarrow LF}$,

if and only if
$p_{EAT} > (C_{second} + C_{EAT})/(C_{second} + C_{LF})$.

Monetary values for C_{EAT} and C_{LF} are estimated below. C_{second} is more difficult to assess.

If one disregards C_{second}, the conditional strategy is cheaper, i.e.
$C_{LF} > C_{EAT<fail>\rightarrow LF}$

if and only if
$p_{EAT} > C_{EAT}/C_{LF}$

or, rearranging,
$C_{EAT} < p_{EAT} * C_{LF}$.

Thus the conditional strategy would be preferable if the long-term relief rate provided by EAT exceeds the ratio of the cost of EAT to the cost of LF.

In order to have a rough upper boundary for p_{EAT}, we set the additional costs C_{second} of needing a second procedure as being equal to C_{EAT}. Thus assuming that the additional expense of needing a second procedure is in the order of the costs for EAT, the conditional procedure is cost-effective if
$p_{EAT} > 2C_{EAT}/(C_{LF} + C_{EAT})$

or, rearranging,
$C_{EAT} < p_{EAT}C_{LF}/(2 - p_{EAT})$.

The main conceptual insight from this result is that, given the costs of the procedures, we can calculate a break-even threshold for p_{EAT}. Also, given values for C_{LF} and p_{EAT}, we can calculate values for the cost C_{EAT} at which the sequential procedure would become cost-effective.

Monetary Costs

The costs C_{EAT} and C_{LF} can be crudely estimated by adding the cost of performing the procedures to the costs for hospitalization (Table **1**). LF is clearly cheaper than any of the EAT alternatives. A fortiori, the sequential strategy is far from cost-effective at current prices.

In order to determine at what price EAT might become cost-effective we assessed effectiveness as the percentage of patients who were satisfied at 6 months without PPI (Table **2**). Less opti-

Table 2 Economic evaluation of alternative strategies in (GERD), data from [19, 26, 31, 38, 44] and non-published data

Procedure	Total no. of patients in study	No. of patients with symptom relief	Ratio of cost to outcome, € per successful treatment German healthcare system	Ratio of cost to outcome, € per successful treatment US healthcare system
EndoCinch	193	115 (60%)	3259.38	4342.68
STRETTA	94*	64 (68%)	2968.43	3999.73
ENTERYX	85	55 (65%)	2582.55	4134.80
EAT (all)	372	234 (63%)	2985.67	4244.68
LF	218	180 (83%)	1202.25	7259.40

* 94/118 were available for follow-up.

mistic long-term rates would be preferable, but are currently unavailable.

Since the mean success rates of all EAT do not exceed 0.63 (mean $P_{EAT} = 0.63$; range 0.60 – 0.68) and $C_{LF} =$ € 992.68, the break-even threshold for C_{EAT} is as low as € 675.02 if C_{second} is disregarded and € 511.38 if it is assumed that $C_{second} = C_{EAT}$. Thus current prices are around three times too high.

Subjective Costs: the Patient's Perspective

The side effects of an ambulatory EAT compare favorably with those associated with a full operation and 5 days of hospitalization with LF. The subjective cost ratio is probably more favorable for EAT than is the monetary cost ratio. Although experiencing a failure of EAT is certainly stressful, we think that the subjective break-even threshold is smaller than or equal to the monetary break-even threshold.

Discussion

We derived a simple criterion for the cost-effectiveness of endoscopic antireflux therapy used within a sequential treatment strategy. Based on success rates published so far, EAT could be a cost-effective initial treatment option compared with laparoscopic fundoplication if costs of EAT decreased to around 30% of current retail prices.

Endoscopic antireflux therapies are an innovative treatment approach to GERD. Due to their minimal invasiveness EATs are associated with less morbidity and require a shorter hospital stay or only ambulatory treatment.

Although several endoscopic techniques are under investigation, EndoCinch, Stretta, and Enteryx are the most advanced devices and are FDA approved, and therefore only these three techniques were considered here. Success rates have been reported for all three EATs (on the basis of symptom relief and PPI reduction of at least 50%), that range from 60% to 80% [26, 27, 30 – 32, 34 – 37]. Although these results are promising, they should be viewed with great caution because only a few studies with a limited number of patients and limited follow-up have been published. At this point it remains unclear whether one or all of the EATs will evolve into an evidence-based treatment approach for GERD. Although the EndoCinch, Stretta, and Enteryx methods vary in their mechanism of action and potential side effects, the sequential model of cost-effectiveness is applicable since LF can be performed after all three EAT procedures in the case of treatment failure [41,42; personal communication, P. Meier, Hannover, May 2004].

We modelled the trade-off between higher long-term relief rates with LF versus lower hospitalization costs and less side effects with EAT, using simple conditional probability calculations and assuming that LF was a backup treatment option after failed EAT, as suggested by the literature [43]. We considered both a monetary and a subjective patient-centred perspective. We derived an order of magnitude value for the break-even threshold for the long-term relief rate with EAT as a function of the costs of EAT and LF, and vice versa. Our simple trade-off scenario conceptualizes what is involved in choosing between LF or a conditional strategy with EAT as the first-line treatment. The cost estimates provided suggest that there may only be a role for EAT in the management of GERD patients requiring intervention if prices are drastically reduced.

The short-term results of limited trials with EATs and our own experience with 43 patients with EndoCinch (64% success at 3 months) suggest that the mean long-term relief rate following EAT treatments does not exceed 0.63 (range 0.60 – 0.68) (for example, EndoCinch, 64% patients with reduced medication at 12 months [27]; Enteryx, 70% with no medication at 12 months [37]; Stretta, 61% with no medication at 12 months [31]). Based on the crude cost estimates that we provide and the published success rates, a conditional strategy would appear to be both cost-efficient and beneficial only if costs of EAT were to decrease to around 30% of present values.

Cost assessment is notoriously difficult. Nevertheless we think that our estimates define well the order of magnitude of the break-even threshold. All the cost estimations were done on the basis of current wholesale prices for EAT and published cost estimates for LF. Since costs for the EAT devices will probably decline in the future, the potential cost-effectiveness of EAT may rise.

Several general comments about this conceptual model need to be emphasized:

a) The time horizon of our model is limited by the currently published data on EAT which do not relate to follow-up of more than 1 year.
b) The values assigned to the model parameters were based on the best available evidence. There are no data from randomized controlled clinical trials to support the response rates we used.
c) The morbidity, mortality and efficacy estimates for EAT are based on limited data of relatively small series from centers where experience is considerable, to the extent that when EAT procedures are performed by less skilled endoscopic operators, the results may be less favorable.

We took the perspective of a third-party payer and calculated the cost based on customary reimbursement by a German health insurance company using a nationwide cost-covering measuring unit (the GOÄ). Although the cost structure of reimbursement for gastrointestinal procedures has undergone several changes, the GOÄ values represent the average payments in the present German healthcare system. However, relative reimbursements for EAT and LF procedures in the United States followed an opposite pattern, with LF being more expensive [44] (Table **2**). Our model allows country-specific calculations of cost estimates by simple replacement of regional reimbursement parameters. Since we did not explicitly consider indirect medical costs (e.g. transport, days of work lost) in our calculation, the overall cost estimate may be biased towards LF as hospital stay and number of working days lost are greater after LF. The aim of our analysis was to increase awareness of the cost of modern interventions in the early stages of clinical use, and we wished to analyse the procedures themselves, not taking indirect or nonmedical costs into account.

Although medical PPI therapy is the gold standard of treatment for GERD, our calculations did not include a comparison with medical treatment. According to existing opinion in the literature, EAT and LF are considered to be a treatment option for GERD only in patients with a partial response to PPIs, with side effects from PPI, or, most commonly, who reject long-term medical therapy [10].

In summary, this simple sequential model of nonmedical GERD treatment suggests that EAT as a first-line treatment, followed by LF if needed, may be cost-effective in patients with mild to moderate reflux, if costs of EAT decrease to around 30% of current retail prices (in the German healthcare system). Alongside its potential clinical superiority, due to lower morbidity, improved patient satisfaction, and shorter hospital stay, EAT is not superior from the perspective of health economics, even assuming favorable long-term efficacy data. Given that long-term data are awaited, as well as data from randomised controlled trials, the results from our simple model could change in either direction.

Based on our findings, further cost-effectiveness analyses of EAT versus LF should be performed as part of clinical trials.

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