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Randomized clinical trial

Randomized clinical trial and follow-up study of cost-effectiveness of laparoscopic *versus* conventional Nissen fundoplication

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Background: **Laparoscopic Nissen fundoplication (LNF) has essentially replaced its conventional open counterpart (CNF). An economic evaluation of LNF compared with CNF based on prospective data with adequate follow-up is lacking.**

Methods: **Data from two consecutive studies (a randomized clinical trial (RCT) of 57 patients undergoing LNF and 46 undergoing CNF that was terminated prematurely, and a follow-up study of 121 consecutive patients with LNF) were combined to determine incremental cost-effectiveness 1 year after surgery.**

Results: **Mean operating time, reoperation rate and hospital costs of LNF were lower in the second series. The mean overall hospital cost per patient was €9126 for LNF and €6989 for CNF at 1 year in the initial RCT, and €7782 in the second LNF series. The success rate of both LNF and CNF at 1 year was 91 per cent in the RCT, and LNF was successful in 90·1 per cent in the second series. A cost reduction of €998 for LNF would cancel out the cost advantage of CNF. Similarly, if the reoperation rate after LNF decreased from 0·05 to below 0·008 and/or if the mean duration of sick leave after LNF was reduced from 67·2 to less than 61·1 days, the procedure would become less expensive than CNF. Complications, reoperation rate and quality of life after both operations were similar.**

Conclusion: **Including reinterventions, the outcome at 1 year after LNF and CNF was similar. In a well organized setting with appropriate expertise, the cost advantage of CNF may be neutralized.**

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Introduction

Laparoscopic Nissen fundoplication (LNF) is the leading surgical treatment for gastro-oesophageal reflux disease (GORD)[1–3]. Several authors have claimed that the laparoscopic procedure is as effective as conventional Nissen fundoplication (CNF), but with less morbidity, shorter hospital stay and earlier return to work[4–9]. These benefits need to be balanced against longer operating times and more expensive equipment (reusable and disposable) involved in laparoscopic surgery.

Proper economic evaluation should be part of the process of implementing new techniques and making final decisions about the standard of treatment[10]. Attempts have been made to assess the costs of LNF[11–15], although analysis of actual costs for LNF in randomized controlled studies with adequate follow-up is lacking. Most studies have reported short-term cost analyses with no clear definition of how costs were calculated, compromising the generality of such results[11–15].

In 2000, the results of a prematurely terminated randomized clinical trial (RCT) of LNF *versus* CNF were published[16]. It was decided to follow this population after the trial had ended and conduct a consecutive cohort study of at least 100 patients with GORD who were refractory to proton-pump inhibitor treatment. The aims of the study were to see whether the results obtained in the randomized trial could be improved upon and to carry out

The Editors have satisfied themselves that all authors have contributed significantly to this publication

an economic analysis. This paper contains an analysis of costs and cost-effectiveness, based on the RCT and the consecutive prospective cohort study, at 1-year follow-up.

Patients and methods

In January 1997, a multicentre RCT (Manchet I) comparing LNF with CNF was initiated in the Netherlands. The background, design and results have been reported previously[16]. At the time of the planned interim analysis, 103 patients had been randomized and operated on with a minimum follow-up of 3 months. Fifty-seven patients underwent laparoscopic and 46 open 360° fundoplication. At the time of the interim analysis, 11 patients in the laparoscopic group and one in the conventional group had reached a primary endpoint (dysphagia, recurrent GORD, intrathoracic hernia). In particular, there was a significant difference in the incidence of severe dysphagia (seven patients in the LNF group and none in the CNF group; $P = 0{\cdot}016$). The inclusion of new patients was stopped because of the poor early results of LNF. The follow-up of patients already included was, however, continued to determine long-term outcome. In addition, a consecutive cohort study on LNF was initiated (Manchet II) to investigate the effects of operator experience on the incidence of postoperative dysphagia and recurrent reflux. This study included 121 patients who underwent LNF performed by the same surgeons as in the RCT. Indications for surgery, technique, patient management and data analysis were similar to those in the RCT, such that the effect of experience was the only new variable. All procedures were performed in one of the six participating hospitals by two surgeons, with a minimum requirement of one local surgeon and one visiting surgeon involved in the overall study. Resource use over the year after the initial operation was determined for the 103 patients in the initial RCT and the 121 patients in the cohort study. Aiming at complete follow-up of at least 100 patients, 121 patients were included in the latter study, allowing for a drop-out rate of about 20 per cent.

All analyses were based on an intention-to-treat principle. A decision analysis model was developed to compare the balance between costs and effects in the RCT for CNF with the results obtained in the consecutive cohort study on LNF (*Fig. 1*). In this way, the effect of several variables on the costs of LNF and CNF strategies was evaluated. A time frame of 1 year was chosen, on the basis that 80 per cent of recurrences of GORD occur during the first year after surgery[17]. The study was performed from a societal perspective, and included costs of hospital treatment and productivity loss.

Data on reflux control, patient satisfaction and quality of life were obtained by completion of a questionnaire

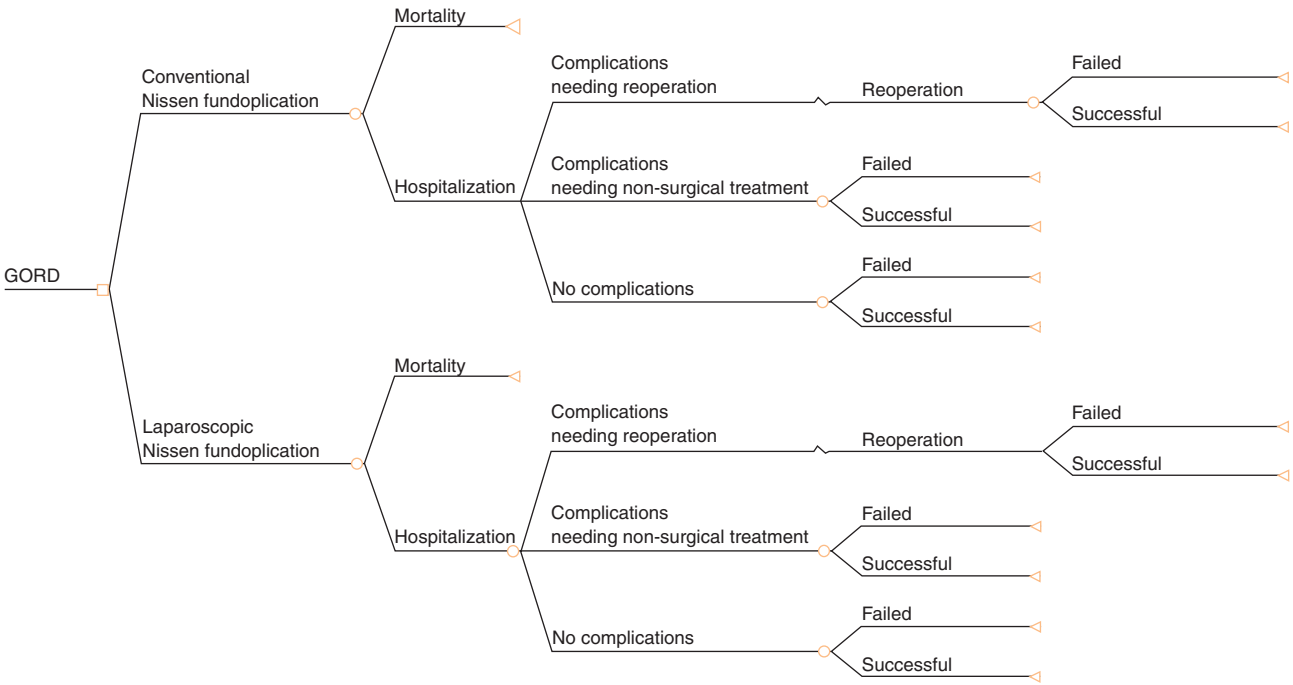

Fig. 1 Decision analysis model outlining the course in the first year after laparoscopic or conventional Nissen fundoplication for gastro-oesophageal reflux disease (GORD)

before, and 3, 6, 9 and 12 months after surgery. Incomplete questionnaires were returned for completion and, if data were still missing, the forms were completed by telephone interview. Effectiveness was expressed as a successful or failed procedure, determined by the patient's opinion after 12 months. Patients were asked whether they felt that their reflux disease was cured, improved (no need for acid-suppressing medication), unchanged or worse. Based on this clinical outcome, operations were divided into successful (reflux symptoms cured or improved) or failed (symptoms unchanged or deteriorated) in the decision analysis. Utilities were estimated with a visual analogue scale (VAS) that ranged from 0 to 100. Utility measures are preference-based measures of health-related quality of life that can be used in economic evaluations. Generally, these measures evaluate subjective preferences for multidimensional health-related quality of life on a scale of 0 to 100, where 0 represents worst possible health and 100 represents perfect health. Values for successful or failed outcome, determined at 1 year, were calculated for patients in six groups (LNF – successful, LNF – failed, CNF – successful and CNF – failed in the RCT, and LNF – successful and LNF – failed in the cohort study) and presented graphically. Quality-adjusted life-years (QALYs) were estimated by calculating the area under the curve.

A general quality of life questionnaire (Short Form 20) was also completed before and at 12 months after operation. In this questionnaire, 20 questions represent six dimensions of quality of life: physical functioning, role function, social function, mental health, general health and bodily pain perception. On each scale 0 represents the worst score and 100 the best, except for bodily pain perception, where 0 represents no pain and 100 severe pain.

DATA 3.5™ (TreeAge Software, Boston, Massachusetts, USA) was used to perform decision analysis (*Fig. 1*). After the initial operation, patients were divided into three categories, based on the occurrence of complications within the first year after surgery: no complications, complications leading to reoperation and complications leading to non-surgical treatment. After treatment for complications, patients were subdivided into successful or failed outcome based on the clinical outcome at 12 months. Probabilities used in the model were based on the actual number of events observed in the clinical studies. The model was driven by the clinical outcome at 1 year. Costs and benefits both pertain to 1 year, so no discount rate was applied.

All resource use was recorded prospectively and completed with review of medical records. Variables scored for each patient included preoperative investigation (visits to the outpatient clinic, diagnostic tests related to GORD and routine preoperative screening), in-hospital resources (operating time, hospital stay and in-hospital complications) and postoperative follow-up (complications after discharge, reinterventions, follow-up visits and diagnostic tests). Additional diagnostic tests or procedures, type and amount of medication, and time to return to work were documented.

All 103 patients from the RCT and 121 patients from the cohort study were included in the cost analysis. Calculation of unit costs was based on data from the University Medical Centre Utrecht in 2004 and was considered representative of all other participating centres. Costs of nursing and medical personnel involved were based on the duration of the procedure. Costs of materials and anaesthesia were based on average consumption. Depreciation and interest costs of equipment were calculated, distinguishing between specific laparoscopic instruments and instruments routinely used in laparotomy. A minimum package consisting of five trocars (Versaport™), a dissecting instrument (EndoPeanut™), a liver retractor (EndoPaddle™) and a roticulating Endograsper™ or EndoBabcock™ (€1603 in the RCT, €1303 in the cohort study) was used in the model (all above equipment supplied by Tyco Healthcare, Zaltbommel, The Netherlands). In the later study, the Endograsper™ and EndoBabcock™ were no longer used routinely. The costs of medical staff, administration and management, costs of other hospital departments (cleaning, maintenance, services), housing and general overheads were also incorporated. Costs per day in hospital, hours of recovery and outpatient visits were calculated based on the yearly cost data per department. The costs of other diagnostic or therapeutic procedures were supplied by the local finance department. If no cost information was available, charges were used as a proxy for real costs. Average retail prices for medication in the Netherlands were used with the pharmacist's fee[18]. Costs for productivity losses were based on the friction cost method[19] estimating the production loss over time, by assuming that loss in production will be restricted to a period needed for the company to adapt to the situation changed because of the patient's absence (the friction period). Sex- and age-dependent friction costs are available for the Netherlands[20]. This friction period was 123 days in 2003–2004, implying that absence of work beyond 123 days would not lead to further productivity losses. All costs were calculated in euros.

Costs per QALY gained and per additional patient with a successful outcome were estimated at 1 year. The incremental cost–utility ratio was estimated by dividing the difference in expected costs by the difference in expected QALYs and likewise by the difference in number of successfully operated patients.

Multiple one-way sensitivity analyses were performed to determine whether outcome was affected by variability in the parameters used in the model. In particular, values for variables known to differ from estimates of previous studies were subjected to sensitivity analyses. Operating time, laparoscopic disposable materials, hospital stay, total costs of operation, return to work after laparoscopy (sick leave time) and reoperation rate were tested in one-way sensitivity analyses. Data from other studies comparing CNF with LNF were used as high or low estimates and the present data as opposing estimates, thus reflecting the range for the one-way sensitivity analyses. Two-way sensitivity analyses were performed with a combination of two of the following variables: total cost of operation, duration of sick leave and reoperation rate.

Statistical analysis

Student's t test was used for comparison of results with normal distribution. The Mann–Whitney U test was used for comparison of skewed data. The significance level was set at $P < 0{\cdot}050$.

Results

Resource use was recorded for 57 patients who had LNF and 46 who had CNF in the RCT (Manchet I), and for 121 who had LNF in the following cohort study (Manchet II). Indication for operation and baseline characteristics were comparable (*Table 1*). One patient in the RCT was lost to follow-up at 12 months, but was free of symptoms at 6 months. It was assumed this patient would also have been free of symptoms at 1 year and so no extra costs after the first 6 months were taken into account. Detailed results of the interim analysis of the RCT have been reported elsewhere[16].

Clinical outcome, complications after discharge and reoperations are summarized in *Table 2*. LNFs in five patients in the RCT and four in the consecutive follow-up study were converted to open surgery. These patients were analysed on an intention-to-treat basis. Probabilities of events used in the decision tree are shown in *Table 3*. At 1 year after surgery, the outcome was successful in 52 (91 per cent) of 57 patients after LNF and 42 (91 per cent) of 46 after CNF in the RCT (*Table 2*). In the cohort study on LNF, a successful outcome was noted in 109 (90·1 per cent) of 121 patients.

Reasons for failure of LNF in the RCT (five patients) were persistent dysphagia after reoperation for an intrathoracic herniation of the wrap (one patient), persistent reflux symptoms and pathological reflux on 24-h pH monitoring after reoperation for recurrent GORD (one), recurrent GORD with dysphagia (one) and severe epigastric pain awaiting reoperation (one); the fifth patient did not have complications or objective reflux, but was dissatisfied with the result. Of the four patients with a failed CNF in the randomized trial, one had objective recurrent GORD despite a further Nissen procedure, one had no reflux symptoms but was reoperated twice for an incisional hernia, and one was reoperated for persistent dysphagia 9 months after the initial fundoplication but still complained of bloating 3 months after the second procedure. The fourth patient had persistent pulmonary tract infections, which overshadowed adequate reflux control. Of 12 patients in the consecutive cohort study who had a failed LNF, seven had persistent dysphagia, three had recurrent GORD, and two had both recurrent dysphagia and GORD. Reoperation was undertaken in six of 12 patients who had a failed procedure.

Mean(s.d.) skin-to-skin operating times were 2·5(0·7) and 1·6(0·5) h for LNF and CNF respectively in the RCT, and 1·5(0·4) h in the cohort study on LNF. Mean(s.d.) hospital stay was 4·5(1·5), 5·8(1·3) and 4·2(3·4) days respectively ($P = 0{\cdot}029$). Proportions of patients in

Table 1 Patient characteristics at baseline

	Manchet I laparoscopy ($n = 57$)	Manchet I laparotomy ($n = 46$)	Manchet II laparoscopy ($n = 121$)
Age (years)*	40·5(12·8)	42·5(10·9)	41·0(11·1)
Sex ratio (M : F)	36 : 21	34 : 12	78 : 43
Weight (kg)*	80·3(15·5)	81·1(12·7)	79·5(14·6)
Height (cm)*	176(12)	176(10)	174(15)
Clinical presentation			
Heartburn	53	42	98
Regurgitation	20	21	47
Duration of symptoms (years)*	4·1(4·7)	3·5(4·5)	7·0(8·7)
Indication for operation			
Insufficient response to medical treatment	46	40	81
Medication stopped because of adverse effects	6	1	7
Unwilling to take lifelong medication	5	5	33
Short Form 20*			
Physical functioning	39·7(33·6)	44·6(30·6)	36·0(28·1)
Role function	42·7(47·5)	43·3(46·0)	42·6(47·5)
Social function	66·3(31·8)	64·8(27·7)	51·9(25·8)
Mental health	69·1(21·7)	64·2(19·7)	48·3(30·7)
General health	36·7(28·0)	32·0(23·8)	27·5(29·4)
Bodily pain perception†	65·5(32·8)	62·0(24·6)	44·8(30·0)
General quality of life (VAS score 0–100)*	53·2(25·2)	49·4(21·4)	50·8(26·7)

*Values are mean(s.d.). †Score 0, no pain; 100, severe pain; VAS, visual analogue scale. In other domains of the Short Form 20, 100 represents the best score.

Table 2 Events and outcome at 1 year after operation

	Manchet I laparoscopy ($n = 57$)	Manchet I laparotomy ($n = 46$)	Manchet II laparoscopy ($n = 121$)
Complications after discharge			
Persistent dysphagia	7 (12; 5, 24)	1 (2; 0, 12)	9 (7·44; 3·46, 13·71)
Recurrent GORD	3 (5; 1, 15)	2 (4; 0, 15)	4 (3·31; 0·91, 8·25)
Dysphagia and recurrent GORD	1 (2; 0, 9)	1 (2; 0, 12)	1 (0·83; 0·02, 4·52)
Epigastric pain	1 (2; 0, 9)	0 (0; 0, 8)	2 (1·65; 0·20, 5·84)
Cicatricial hernia	0 (0; 0, 6)	1 (2; 0, 12)	1 (0·83; 0·02, 4·52)
Reoperation			
Nissen	7 (12; 5, 24)*	2 (4; 0, 15)	5 (4·13; 1·36, 9·38)†
Belsey Mark IV	2 (4; 0, 12)	1 (2; 0, 12)	1 (0·83; 0·02, 4·52)
Cicatricial correction	0 (0; 0, 6)	1 (2; 0, 12)	0 (0·00; 0·00, 3·00)
Success rate			
After initial operation	46 (81; 68, 90)	41 (89; 76, 96)	105 (86·78; 80·72, 92·80)
At 12 months	52 (91; 80, 97)	42 (91; 79, 98)	109 (90·08; 83·30, 84·81)

Values in parentheses are percentages with 95 per cent confidence intervals. *Includes two patients reoperated on for an intrathoracic herniation of the wrap, directly after the initial procedure; †includes two patients reoperated on for an intrathoracic herniation of the wrap, within 1 month after the initial procedure. GORD, gastro-oesophageal reflux disease.

Table 3 Probabilities of events in the decision tree and comparison with published values

	Manchet I laparoscopy ($n = 57$)	Manchet I laparotomy ($n = 46$)	Manchet II laparoscopy ($n = 121$)	Published values	
				Laparoscopy	Laparotomy
Probability of death	0·00 (0·00, 0·06)	0·00 (0·00, 0·07)	0·00 (0·00, 0·03)	0·00, 0·14	0·00, 0·01
Probability of complications needing reoperation	0·16 (0·08, 0·30)	0·09 (0·02, 0·21)	0·05 (0·02, 0·11)	0·00, 0·10	0·00, 0·25
Intrathoracic herniation	0·04 (0·00, 0·12)	0·00 (0·00, 0·07)	0·02 (0·00, 0·06)	0·07	–
Persistent dysphagia	0·05 (0·01, 0·15)	0·02 (0·00, 0·12)	0·03 (0·00, 0·07)	0·00, 0·24	0·00, 0·17
Recurrent GORD	0·05 (0·01, 0·15)	0·02 (0·00, 0·12)	0·00 (0·00, 0·03)	0·00, 0·09	0·04, 0·05
Recurrent GORD + dysphagia	0·02 (0·00, 0·09)	0·02 (0·00, 0·12)	0·01 (0·00, 0·05)	–	–
Cicatricial hernia	0·00 (0·00, 0·06)	0·02 (0·00, 0·12)	0·00 (0·00, 0·03)	–	–
Probability of success after reoperation	0·66 (0·31, 0·93)	0·20 (0·01, 0·81)	0·67 (0·22, 0·96)	0·83, 0·92	0·83, 0·92
Probability of complications needing non-surgical treatment	0·09 (0·03, 0·19)	0·02 (0·00, 0·12)	0·08 (0·04, 0·15)	0·26	0·32
Persistent dysphagia	0·07 (0·02, 0·17)	0·00 (0·00, 0·07)	0·05 (0·02, 0·11)	0·05, 0·40	0·03, 0·43
Recurrent GORD	0·00 (0·00, 0·06)	0·02 (0·00, 0·01)	0·02 (0·00, 0·06)	0·05	0·02, 0·03
Epigastric pain	0·02 (0·00, 0·09)	0·00 (0·00, 0·07)	0·02 (0·00, 0·06)	0·17	0·12
Probability of success after complications	0·80 (0·28, 0·99)	1·00 (0·58, 1·00)	0·20 (0·03, 0·60)	–	–
Probability of no complications	0·75 (0·62, 0·86)	0·89 (0·76, 0·96)	0·87 (0·81, 0·93)	0·86, 0·93	0·84, 0·90
Probability of success without complications	0·98 (0·88, 0·99)	0·98 (0·87, 0·99)	0·98 (0·96, 1·00)	0·84, 1·00	0·86, 0·97

Values in parentheses are 95 per cent confidence intervals. GORD, gastro-oesophageal reflux disease.

employment before surgery and duration of sick leave after successful and unsatisfactory procedures are summarized in *Table 4*.

Mean hospital costs, productivity losses (sick leave) and total costs of treatment are shown in *Table 5*. Mean total costs for LNF were lower in the later study than in the RCT. Hospital costs were €2137 higher for LNF than for CNF in the randomized trial. In the cohort study, however, this difference was reduced to €793. These extra hospital costs were partly compensated by lower productivity losses for LNF (€600 in RCT and €391 in cohort study).

Table 4 Sick leave

Costs	Manchet I laparoscopy	Manchet I laparotomy	Manchet II laparoscopy	Unit costs (€)
Proportion in paid work (%)	63	63	68	–
Mean duration of sick leave (days)				
Successful outcome	71·8	79·2	67·2	136
Failed outcome	98·3	101·3	112·4	136

Table 5 Mean treatment costs

	Mean cost (€)		
	Manchet I laparoscopy ($n = 57$)	Manchet I laparotomy ($n = 46$)	Manchet II laparoscopy ($n = 121$)
Preoperative visits and diagnostics	1 261	1 257	1 112
Preoperative screening	286	274	233
Operation			
Personnel	430	279	261
Materials	1 603	491	1 303
Depreciation	79	15	48
Overheads	197	160	156
Hospitalization	1 150	1 483	1 075
Additional procedures	26	22	26
Consultations	43	58	43
In-hospital complications excluding reoperations	1 716	1 205	1 804
Non-surgical treatment of complications	57	21	58
Complications needing reoperation, excluding reoperation	262	112	87
Reoperations	473	241	128
Postoperative visits and diagnostics	1 419	1 302	1 389
Medication (1st year after operation)	124	69	59
Total hospital cost	9 126	6 989	7 782
Sick leave from paid work	6 351	6 951	6 560
Overall cost	15 477	13 940	14 342

Symptoms and complaints at 1 year were similar in all groups (*Table 2*). Changes in VAS scores during the first year for patients with a successful or failed procedure in each of the three groups are shown in *Fig. 2*. The mean number of QALYs was 0·63 for the laparoscopic group and 0·59 after a conventional procedure in the RCT, and 0·66 after LNF in the cohort analysis. Further comparisons

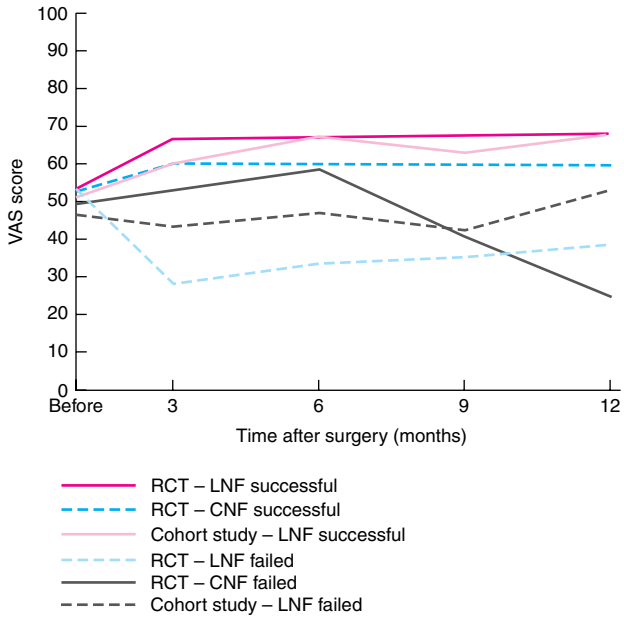

Fig. 2 Utilities affecting general quality of life were estimated using a visual analogue scale (VAS, 0–100) before, and 3, 6, 9 and 12 months after surgery in patients subgrouped according to success or failure of each treatment within each study. RCT, randomized clinical trial; LNF, laparoscopic Nissen fundoplication; CNF, conventional Nissen fundoplication

regarding quality of life revealed no significant differences in postoperative outcome between studies or individual groups. The incremental cost–utility ratio for LNF in the cohort study compared with CNF in the RCT was €40 254 per QALY gained.

Several sensitivity analyses were performed. If the total cost of LNF was reduced by €998, but the costs of CNF remained unchanged, the cost advantage of CNF would be cancelled out. Similarly, if the reoperation rate after LNF was decreased from 0·05 to below 0·008 and/or if the mean duration of sick leave was reduced from 67·2 to below 61·1 days, the cost advantage of CNF would be cancelled out. Two-way sensitivity analyses were performed with a combination of two of the above variables. If total costs for LNF were less than €950 and duration of sick leave after LNF was less than 52·8 days, laparoscopy would become cost-saving.

Discussion

This study analysed direct and indirect costs associated with Nissen fundoplication with follow-up of 1 year. The consecutive series of 121 patients with LNF was added to eliminate the effect of the learning curve, which seemed

apparent in the RCT. By the time of the later study surgeons had experience of more than 30 laparoscopic fundoplications.

The results of the original trial indicated that CNF yielded better outcomes at lower cost. The present analysis showed that complication rates and operating times were lower in the cohort study than in the original RCT. Time to return to work was slightly in favour of LNF. Thus, with a well organized set-up and experienced surgeons, the total cost of LNF was reduced by €1135, although it remained €402 more expensive than CNF. LNF and CNF were equally effective and safe in both studies, comparable to published findings[2,3,6].

In the present cost analysis the cost of a 'minimum package' of disposables was used, which differed between the two studies. With growing experience, fewer laparoscopic instruments were used routinely in the cohort study. Hospital stay, another important cost-increasing factor, was significantly shorter after LNF, although somewhat higher than reported in a recent meta-analysis of antireflux surgery (mean 5·2 days after CNF and 3·1 days after LNF)[21]. No specific criteria were applied to hospital discharge, which was determined locally, reflecting prevailing attitudes among Dutch surgeons. The impact of these somewhat longer admission times is unlikely to influence significantly the conclusions of this study, as it is the difference in hospital stay between techniques that is relevant to the analysis.

In the RCT, the reoperation rate was higher after LNF than CNF during the first 3 months[16], although this difference had diminished by 1 year. The reoperation rate at 1 year after LNF in the cohort study was lower than that after LNF and CNF in the randomized trial (5·0, 16 and 9 per cent respectively). Reoperation rates varying from 0 to 25 per cent have been reported after antireflux surgery. In the sensitivity analysis, however, reducing the reoperation rate had only a marginal effect on mean total costs.

It was nearly 2·5 months (7·4 days in favour of the laparoscopic procedure in the RCT and 12 days in the cohort study) before patients resumed paid work after uncomplicated fundoplication. Sick leave in the present study was longer than that in other reports (mean 35·8 (range 17·0–44·0) days after CNF and 20·1 (range 15·3–21·0) days after LNF)[21]. Although a substantial proportion of the patients had physically strenuous jobs, this cannot fully account for the prolonged absence. Company doctors decide upon return to work in the Netherlands and probably base their advice on experience with conventional abdominal procedures. This long period of sick leave is not easily understood nor does it seem acceptable. In a recent study by Bisgaard *et al.*[22], pain, fatigue and dysphagia contributed to prolonged convalescence after uncomplicated LNF. It was also emphasized that application of well defined criteria for recovery may shorten sick leave after LNF[22].

Only one randomized cost analysis of CNF *versus* LNF has been published, with a follow-up of only 3 months[11], a period too short to determine outcome and costs associated with treatment of complications. Most comparative cost and cost-effectiveness analyses of antireflux surgery have major methodological flaws. Apart from improper definition of cost measurements and resources obtained in different time intervals, some studies have reported only hospital charges or provided incomplete data[12–15]. The present study included all extra costs for treatment of complications. The fact that patients can have a successful outcome after experiencing a complication was also taken into account. The majority of hospital cost was the operation itself. Costs related to the treatment of complications were of less importance. Preoperative tests are generally accepted, but after operation most patients accept invasive tests only if they develop symptoms. In the present study the cost of routine postoperative examinations was not taken into account.

As for utilities, these were obtained using a VAS[23]. Only a small improvement was found after operation compared with preoperative values (*Fig. 2*). The utilities based on the VAS scores indicated that there were no significant differences in general quality of life between LNF and CNF in both studies. More interesting was the pattern of scores over time, notably a decrease in VAS score for both LNF groups at 3 months and for the CNF group in the RCT after 6 months. This might be explained by the fact that failure occurred during the first 3 months after LNF but slightly later after conventional surgery. After treatment of these complications, VAS scores increased without significant differences and, in addition, these results were comparable at 12 months. The area under the curve, which represents the QALYs, did not appear to differ significantly between the strategies at 1 year.

Similar clinical outcomes may be expected after LNF and CNF, although the laparoscopic procedure was calculated to be more expensive even when performed by experienced surgeons with accelerated recuperation after surgery. Not until prices of laparoscopic equipment decrease and sick leave is shortened will LNF become an economically viable alternative. Adjustment of the Dutch sick leave policy might make LNF the procedure of choice in the surgical treatment of refractory GORD from both a clinical and an economic perspective.

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