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ECONOMIC EVALUATION OF THE TREATMENT OF GRADE II HAEMORRHOIDS: A COMPARISON OF STAPLED HAEMORRHOIDOPEXY AND RUBBER BAND LIGATION

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ABSTRACT

Objectives

Haemorrhoidal disease is a common condition causing considerable distress to individuals and significant cost to the health care service. This paper explored the cost-effectiveness of stapled haemorrhoidopexy (SH) compared with the standard non-surgical intervention, rubber band ligation (RBL), for grade II symptomatic circumferential haemorrhoids.

Methods

An economic evaluation alongside a randomised controlled trial conducted between October 2002 to February 2005. Adults were recruited from a single surgical centre in Scotland and randomised to either SH or RBL. The same surgeon performed all procedures and investigators were blinded until analyses was completed. Primary outcomes measured at 52 weeks were cumulative costs to the NHS, clinical diagnosis of recurrence and quality adjusted life years (QALYs).

Results

60 symptomatic men and women with confirmed clinical diagnosis of grade II symptomatic haemorrhoids were randomised. Loss to follow-up was up to 10% at 52 weeks.

The mean cost for SH was greater than RBL (mean difference - £1483, 95% CI £1339 to £1676); disease recurrence was lower (OR 0.18, 95% CI 0.03 to 0.86); and there was no evidence of a statistically significant difference in QALYs (-0.014, 95% CI –0.076 to 0.051). SH was associated with a modest incremental cost per recurrence avoided at 12 months follow-up (£4945). Based on current data it was considered highly unlikely to be cost-effective in terms of incremental cost per QALY.

Conclusions

There is insufficient evidence about the cost-effectiveness of SH for grade II haemorrhoids to recommend its use in place of RBL. Further information is needed from larger trials with a longer-term follow-up to inform subsequent economic evaluation.

INTRODUCTION

Haemorrhoidal disease is one of the commonest benign ano-rectal conditions and is associated with relapsing and remitting symptoms. The majority of patients (75%) diagnosed with second degree haemorrhoids require treatment within a few years[1]. Early intervention may avoid advanced disease and its associated complications. The current standard treatment for symptomatic grade II haemorrhoids, rubber band ligation (RBL), is readily available, can be performed as an out-patient procedure, is tolerated well and does not require general anaesthesia.[1] As a consequence the cost per procedure is relatively low This technique, however, is associated with a treatment failure rate of more than 40%[2,3] and the return of symptoms will reduce quality of life and require lead to further costly treatment,

Excisional haemorrhoidectomy (EH) is considered the 'gold standard' treatment for advanced (grade III and IV) haemorrhoids and remains the most commonly performed surgical intervention.[4] A systematic review comparing EH with RBL has shown no significant difference in the clinical effectiveness for grade II haemorrhoids. Furthermore EH was shown to be associated with increased incidence of complications.[5]

Stapled haemorrhoidopexy is an alternative surgical intervention accepted and performed widely because of its clinical success.[6,7,8] It shares a similar mechanism of action to RBL by addressing haemorrhoidal prolapse and bleeding whilst maintaining the presence of the anal cushions. It acts by relocating the haemorrhoidal cushions cranially into their original position by excising a strip of lower rectal mucosa (pain insensitive mucosa) and by interrupting the blood supply to the haemorrhoids. It is however more costly than RBL. There is very limited literature evidence available comparing stapled haemorrhoidopexy with RBL for grade III and IV haemorrhoids.[9] and there is no data available for grade II haemorrhoids.

In view of the relatively high recurrence rate for symptoms following RBL and the lack of comparative studies against stapled haemorrhoidopexy and the difference in treatment cost, we conducted a pilot study to compare these two techniques in a randomised controlled setting. This economic evaluation, conducted alongside the randomised controlled trial, sought to assess the cost-effectiveness of stapled haemorrhoidopexy compared with RBL for grade II symptomatic haemorrhoids.

METHODS

Description of trial

The trial was a pragmatic randomised controlled trial comparing stapled haemorrhoidopexy with rubber band ligation for grade 2 haemorrhoids. Further details of the trial are reported elsewhere[9] but in brief 60 participants were recruited from one centre in Aberdeen Scotland, between October 2002 and February 2005, and randomised to either stapled haemorrhoidopexy (n = 30) or RBL (n = 30). Patients with associated colonic malignancy, symptomatic anal sphincter damage or ano-rectal sepsis were excluded from the trial. Written informed consent was obtained from all eligible participants and the Grampian Research Ethics Committee approved the study (Ethics committee approval code – GREC 01/0297). Participants who were randomised to stapled haemorrhoidopexy would, if symptoms had not resolved, be eligible for two repeat procedures. This was assessed at a 6 week, a 26 or a 52 week follow-up or at a re-presentation. RBL patients were eligible for a maximum of four repeat procedures. Longer-term recurrence rates for both treatments were assessed at 40.7 (±6.3) months. All analyses were conducted on an intention to treat basis.

Measurement of costs

Costs included health care resource costs (from the perspective of the NHS) for initial treatment and follow up events, both for secondary care and primary care. As detailed below resource usage was recorded as part of the trial for each individual patient and wherever possible, unit costs for these resources were identified at the individual patient level. At initial treatment visits and all scheduled follow up visits at 6, 26 and 52 weeks hospital resource use was recorded using data collection forms for each patient. Information recorded included the anaesthetic time (for stapled haemorrhoidopexy), length of time for the procedures, recovery time and post procedure stay in ward, duration of any in-patient stay and medications. Details of any unscheduled hospital visits, primary care contacts, over the counter medications and prescriptions were obtained from a self-reported patient questionnaire completed at 6, 26 and 52 weeks post randomisation. Details of the methods used to derive resource used to provide the two procedures are described below.

Operative Costs

The resources required for RBL were based on the procedure being performed in an outpatient setting. Details of the staff involved were recorded on a case report form completed at the time of surgery. Also included on this form were details of the post discharge medication and the use of consumables (disposable rubber band applicator, disposable proctoscope) required for the procedure.

Resource costs for stapled haemorrhoidopexy included theatre running costs, assumed to include an element for recovery facilities, were derived from published sources[10] to establish a theatre cost. The cost of staff involved in theatre were based upon the number and grade specific health care professionals necessary for each procedure. Operative costs relating to surgical repair of haemorrhoids (including consumables, drugs, equipment and sterilisation) for the two interventions studied were sourced from the hospital pharmacy and measured prospectively. The cost of reusable items were converted into annual costs (when it was believed the equipment would last more than 1 year using a discount rate of 3.5%[11]). This value was divided by the amount of time the equipment would be used used in a year to give a cost per patient.

In the instance that a patient experienced a recurrence, the overall resource use of the repeat surgery was assumed to be the mean value of the original surgical procedure across all patients.

A summary of the costs used in the analysis is provided in Table 1. All costs are at calculated in 2004 prices and inflated to 2006/7 prices using the hospital pay and prices inflation index.[12]

Effectiveness

Clinical effectiveness was measured in terms of whether or not the treatment had failed over the 52 weeks following initial treatment. At the 52 week follow-up a clinical assessment was made using proctoscopy and symptom enquiry. This was performed by an experienced consultant colorectal surgeon who was blinded to the original intervention. Further assessment of clinical effectiveness was undertaken at a mean follow-up of 40.7 (± 6.3) months.

Quality of life was measured using the EQ-5D questionnaire. Each patient was asked to complete the EQ-5D at baseline, 3, 6, 26 and 52 weeks. Quality adjusted life years (QALYs) were calculated from the EQ-5D responses using UK population tariffs.[13] Differences between groups were based on linear regression adjusting for the EQ-5D score at baseline.[14]

Cost-effectiveness

The incremental cost per recurrence avoided was estimated by combining the estimates of incremental costs and the difference in recurrence rates. Similarly, using the estimates of

incremental cost and QALYs, the incremental cost per QALY was estimated. No discounting of costs and effects was performed, as the time horizon was only one year. Non-parametric Bootstrap methods were used for statistical inference on total costs, QALYs and cost per QALY because of skewed distributions.[15]

Sensitivity Analysis

In economic evaluation sensitivity analysis is used to address concerns which might relate to such issues as whether the methods of estimating data influence the conclusions or whether data are generalisable to other settings. In this analysis there is uncertainty about the magnitude of any difference in cost. The total cost per patient was recalculated using alternative values for the procedure cost. This was done separately for stapled haemorrhoidopexy and RBL. For stapled haemorrhoidopexy the initial procedure cost (and similarly the cost per re-treatment) was reduced by 25% and by 50%. For RBL, initial procedure cost (and cost per re-treatment) was increased by 50% and by 100%.

With respect to the precision surrounding estimates of the incremental cost per recurrence avoided the cost effectiveness results were re-estimated using the extreme values of the 95% confidence intervals for the difference in total costs and recurrence rates. This was done using *best case* and *worst case* scenarios for the stapled haemorrhoidopexy procedure.

A further area addressed in the sensitivity analysis was the impact of imputing missing quality of life data. In the base case analysis the mean difference in QALYs was estimated using information from those trial participants who had utility scores available at each time point. The drawback of this approach is that a participant would be excluded if data for that participant were only available for only three of the four time points, approximately 10% of responses were missing. A second approach was therefore also adopted. In this, the missing data were imputed from the most recent previous score that was available.

RESULTS

A total of 69 patients were identified from clinic or direct access endoscopy, of which two patients were subsequently, deemed unsuitable (One recent RBL and another unsuitable for anaesthesia). Details of the trial were presented to the remaining 67 patients, 66 of whom chose to participate. Of these, 64 were considered suitable for randomisation. Four patients were then excluded (one could not attend hospital due to personal commitment and three were not recruited for want of base line data due to technical reasons) leaving a total of 60 eligible patients who were randomised (by computer) to either RBL or stapled haemorrhoidopexy. Complete data were available for 54 patients at the end of the trial period (2 withdrew early, four moved and forwarding addresses were not obtainable before the final follow-up). The baseline characteristics and clinical outcomes for this trial are reported elsewhere.[9]

Health Care Costs

The mean total cost per patient, both in aggregate and separately for each element of health care is presented in Table 2. These are rounded to the nearest pound. The mean cost per patient treated using stapled haemorrhoidopexy was significantly higher than that for RBL (£1757 compared to £273). Much of this difference can be attributed to the initial procedure cost which is relatively high for stapled haemorrhoidopexy (£1647 vs £102 for RBL) due to the cost of the disposable stapling gun (£336) along with drugs and staff costs incurred in theatre, plus the hospital stay requirement.

Incremental Cost per Recurrence

Recurrence rate at 52 weeks was significantly higher in the RBL treatment group than the stapling group [11 (41%), n =27, compared to 3 (11%), n = 27) OR 0.18 (95% CI 0.03, to 0.86), P = 0.028). This gave an incremental cost per recurrence avoided from stapled haemorrhoidopexy of £4945. At a mean follow-up of 40.7 (±6.3) months the recurrence rates were 12 out of 22 patients for whom data were available in the RBL group and 4 out of 24 patients in the stapling group, OR 0.22 (95% CI 0.04, to 0.92). This give an incremental cost per recurrence of £3917. This estimate excludes treatment costs incurred after the first year.

Incremental cost per QALY

Quality Adjusted Life Years and the EQ-5D scores at baseline and at 52 weeks are reported in Table 4. Four patients in each treatment group had missing values for EQ-5D data at one or more time points. The mean value for QALYs was higher for the RBL patients than those treated with stapled haemorrhoidopexy although the confidence intervals were wide. In

terms of mean incremental cost per QALY, RBL dominated stapled haemorrhoidopexy (RBL was associated with lower mean cost and greater mean QALYs than the stapled haemorrhoidopexy group).

Sensitivity analysis

The results of the sensitivity analyses described in the methods are presented in Table 3. Under each scenario for procedure costs and also for the best case scenario based on confidence intervals for costs, RBL was the dominant procedure in terms of the incremental cost per recurrence avoided.

Table 5 shows that the base case results for incremental cost per QALY were also robust in terms of RBL being the dominant intervention for variations in procedure costs.

DISCUSSION

With stapled haemorrhoidopexy for grade II haemorrhoids we found that at 52 weeks there was a statistically significant reduction in recurrences which was associated with a relatively modest incremental cost per recurrence avoided, although it is a matter of judgement as to this additional benefit is worth the extra cost. However, there was no evidence that this difference in the risk of recurrence translated into differences in quality of life. Furthermore, it was unlikely that stapled haemorrhoidopexy would be considered cost-effective at threshold values for society's willingness to pay for a QALY based upon the 12 month data.

The population in the trial was representative of those seen in practice and were all treated by a single surgeon with considerable experience in performing both procedures. Therefore, it might be expected that if there were benefits to stapled haemorrhoidopexy in terms of quality of life then these would be seen within this study. However, the relatively small size of the RCT on which this economic evaluation was based would render the results imprecise. Furthermore, the time horizon over which costs and effects were considered was only 52 weeks, although further information of recurrence rates was available for a mean follow-up of 40.7 months. Given the finding of increased recurrences in the rubber band ligation arm the difference in cost might fall over a longer time horizon and that the quality of life associated with the rubber band ligation arm would be reduced. Given that the benefits from stapled haemorrhoidopexy may persist into the future it is possible to consider under what circumstances stapled haemorrhoidopexy might be considered worthwhile. For example, if society's maximum value willingness to pay for a QALY was £20,000[11] and the difference in cost was unchanged then stapled haemorrhoidopexy would need be associated

with an average gain of 0.07 QALYs compared with RBL over the expected life time of a patient. This might occur if, on average, patients who initially received RBL spent at least 0.6 years more with a recurrence (and patients with a recurrence returned to their pre-treatment quality of life). Numerous factors, including the long-term performance of both procedures will affect estimates of cost-effectiveness but should differences in recurrence rates persist then it is possible that the cost-effectiveness of stapled haemorrhoidopexy might improve but further long-term data would need to incorporated into a well designed economic model to explore this fully.

The results of the analysis were sensitive to the costs associated with stapled haemorrhoidopexy. Changes in management as well as in equipment can result in improvements in the cost-effectiveness of this procedure. In terms of future research a further larger scale RCT would be required. The design of this study might be informed by a modelling exercise in which value of information methods are used to determine an optimal design and sample size.

CONCLUSIONS

Based upon the data presented in this paper it is unlikely that stapled haemorrhoidopexy would be considered a cost-effectiveness treatment for grade II haemorrhoids and hence there is no basis to recommend its use in place of rubber band ligation. However, the risk of recurrence at 52 weeks and at a mean follow-up of 40.7 months following surgery is lower. Further information is needed from larger trials with a longer term follow-up before this conclusion should be revisited.

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Table 1 Unit Costs

Operative Event - Stapled haemorrhoidopexy Procedure		Unit Cost	Source
Operative event	Equipment and Drugs	£389.32	Hospital pharmacy
	Cost per min in pre-op (anaesthetic room)	£1.47	15
	Cost per min in theatre	£3.37	15
	Cost per min in recovery	£0.29	15
	Cost per min for theatre overheads	£9.74	15
Hospital Stay	Day case	£28.19	10
	In-patient	£138.12	10
Operative Event - Rubber Band Ligation Procedure			
Operative event	Equipment and Drugs	£26.97	Hospital pharmacy
Hospital Stay	Out-patient	£74.82	10
Post discharge events (for both Rubber Band Ligation and stapled haemorrhoidopexy)			
	GP visit	£17.35	15
Contact with health professionals	Visits by nurse	£11.93	15
	Out-patient visits	£74.82	15
	Telephone consultation	£20.60	15
	GP home visit/out of hours visits	£54.22	15
	Sanitary pad	£2.05	Chemist and Druggist
		£0.00	
Discharge medication	Laxative	£2.64	16
	Antibiotic	£0.67	16
	haemorrhoidal cream	£7.32	16
	Analgesic	£1.84	16
	Anaesthetic	£1.52	16
			16
Prescriptions	Antihistamine	£0.34	16
	Analgesic	£1.03	16
	Laxative	£2.52	16
	Antibiotics	£0.67	16
	Anti-inflammatory	£2.85	16
	haemorrhoidal cream	£5.81	16
	Anti-fungal cream	£2.58	16
Repeat RBL		Mean RBL	
Repeat Stapled haemorrhoidopexy		Mean Stapling	
Hospital Stay	Day-case	£28.19	10
	In-patient	£138.12	10

Table 2 Mean health care costs per patient (costs rounded to nearest £)

Mean cost per case*	Stapled haemorrhoidopexy (sd)	RBL (sd)	Mean difference*	P	95% confidence interval
N	30	30			
Valid N	30	30			
Procedure cost	£1647 (-£227)	£102 (£0)	-£1545	<0.000	-£1630 to –£1461
Re-treatment cost	£31 (-£174)	£64 (-£105)	£33	0.380	-£42 to £107
Discharge medication	£18 (-£2)	£14 (-£2)	-£4	<0.000	-£5 to - £3
Prescription costs	£3 (-£5)	£1 (-£3)	-£2	0.122	-£4 to £0
Primary care contacts	£15 (-£30.36)	£4 (-£11)	-£12	0.053	-£24 to £0
Secondary Care contacts	£41 (-£121)	£91 (-£152)	£50	0.165	-£22 to £123
TOTAL COST PER CASE	£1,757 (-£346)	£273 (-£246)	-£1483	**<0.000**	**-£1676 to -£1339**†

* costs are rounded to nearest £ pound. Summation errors may be attributed to rounding.

† based on the 2.5 and 97.5 percentile from the bootstrapping

Table 3 Sensitivity analysis on increment al cost per recurrence avoided*

Sensitivity analysis	Scenario	RBL	Stapled haemorrhoidopexy	Incremental cost	Incremental recurrence avoided	Incremental cost per recurrence avoided
Adjustment to procedure cost	Cost of Stapled haemorrhoidopexy 25% lower; Base case value for RBL	£273	£1337	£1064	0.296	£3595
	Cost of Stapled haemorrhoidopexy 50% lower; Base case value for RBL	£273	£917	£644	0.296	£922
	Cost of RBL 50% higher; Base case value for stapled haemorrhoidopexy	£356	£1757	£1401	0.296	£4732
	Cost of RBL 100% higher; Base case value for Stapled haemorrhoidopexy	£439	£1757	£1318	0.296	£4451
Extreme value of confidence interval	Best case scenario for Stapled haemorrhoidopexy	£439	£917	£478	0.395 **	£1210
	Worst case scenario for Stapled haemorrhoidopexy	£273	£1757	£1483	0.057	£26,008

* all costs rounded to nearest £ pound

** based on extreme values from confidence intervals

Table 4 EQ-5D and estimated Quality adjusted life years*

Scenario	Treatment	EQ-5D score				QALYs(95% CI)***
		Baseline	6 weeks	26 weeks	52 Weeks	
Available data only**	SH	0.75	0.87	0.88	0.85	0.863
	RBL	0.79	0.85	0.90	0.88	0.876
	Difference	0.041	0.027	0.038	0.059	-0.0135 (-0.067 to 0.066)
Imputed data	SH	0.73	0.84	0.86	0.83	0.866
	RBL	0.80	0.85	0.91	0.89	0.880
	Difference	0.065	0.011	0.026	0.026	-0.014 (-0.076 to 0.051)

* based on adjustment for baseline EQ-5D score

** based on cases with complete data for *all* EQ-5D scores. RBL (n = 26) and Stapled haemorrhoidopexy (n =26)

*** 95% CI based on results of bootstrapping exercise

Table 5 Incremental cost per QALY for the base case and sensitivity analyses

Scenario	Surgery	Cost (£)	QALYs	Incremental cost per QALY	Probability cost-effectiveness for different threshold values for society's willingness to pay for a QALY			
					£10,000	£20,000	£30,000	£50,000
QALYs based on cases with complete EQ-5D data	SH	£1757	0.863	Dominated	0.0%	1.2%	7.0%	17.8%
	RBL	£273	0.876		100.0%	98.8%	93.0%	82.2%
QALYs where missing EQ-5D data has been imputed	SH	£1757	0.866*	Dominated	0.0%	0.5%	2.7%	9.9%
	RBL	£273	0.880		100.0%	99.5%	97.3%	90.1%
Costs of haemorrhoidopexy 75% of base case	SH	£1318	0.866*	Dominated	0.1%	2.4%	7.6%	16.6%
	RBL	£273	0.880		99.9%	97.6%	92.4%	83.4%
Costs of haemorrhoidopexy 50% of base case	SH	£878	0.866*	Dominated	1.3%	9.8%	16.6%	23.9%
	RBL	£273	0.880		97.7%	91.2%	83.4%	76.1%

SH = Stapled haemorrhoidopexy; RBL = Rubber band ligation

* based on the mean value for RBL and the adjusted difference reported in Table 4