Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation

K McCormack,[1*] B Wake,[1] J Perez,[2] C Fraser,[1] J Cook,[1] E McIntosh,[3] L Vale[1,2] and A Grant[1]

[1] Health Services Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK
[2] Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK
[3] Health Economics Research Centre, Department of Public Health, University of Oxford, UK

* Corresponding author

Executive summary

Health Technology Assessment 2005; Vol. 9: No. 14

Health Technology Assessment
NHS R&D HTA Programme

Executive summary

Background

This review set out to determine: (1) whether laparoscopic methods are more effective and cost-effective than open mesh methods of inguinal hernia repair; and (2) whether laparoscopic transabdominal preperitoneal (TAPP) repair is more effective and cost-effective than laparoscopic totally extraperitoneal (TEP) repair of inguinal hernia. Where data allow, the patient population has been split by whether or not the hernia is recurrent or bilateral and whether or not the patient receives general anaesthesia.

Description of proposed service

Laparoscopic inguinal hernia repair is a minimal access surgical procedure. Small incisions are made for the operating instruments and for a laparoscope. A piece of prosthetic mesh is used to close the hernia defect. Laparoscopic repair is usually undertaken by means of the TAPP or TEP repair, the main variation being whether or not the instruments enter the peritoneal cavity.

Epidemiology and background

About 70,000 surgical repairs of inguinal hernia are performed each year in England, constituting approximately 0.14% of the population each year and accounting for over 100,000 NHS bed-days. Inguinal hernia can occur unilaterally or bilaterally and can recur after surgery, necessitating reoperation. The most effective method of repair of inguinal hernia is by means of a tension-free technique involving the use of prosthetic mesh to reinforce the abdominal wall in the region of the groin. This can be accomplished by open or laparoscopic techniques. The most common open method in use in the UK is the flat mesh technique. However, about 4% of primary inguinal hernia operations are currently carried out laparoscopically.

Methods

Effectiveness

Electronic searches of 17 databases were conducted to identify reports of trials of laparoscopic inguinal hernia repair, including TAPP and TEP procedures. Systematic reviews and other evidence-based reports were also identified. In addition, selected conference proceedings were handsearched, websites were consulted, reference lists of all included papers were scanned, experts were contacted for other potentially eligible reports and manufacturers' submissions to the National Institute for Clinical Excellence (NICE) were reviewed.

All published and unpublished randomised controlled trials (RCTs) and quasi-randomised controlled trials were eligible for inclusion if they compared (1) laparoscopic inguinal hernia repair with open mesh inguinal hernia repair or (2) laparoscopic TAPP with laparoscopic TEP methods of inguinal hernia repair.

Individual patient data (IPD) were obtained, where possible, from the responsible trialist for all eligible studies. Where IPD were unavailable, additional aggregate data were sought from trialists and published aggregate data were taken from the trial reports. Two reviewers independently extracted data and assessed study quality. For each outcome the results were derived from the best available source: if IPD reanalysis was not available, information from aggregate data provided by the trialist or data from the trial publications were used. Dichotomous outcome data were combined using the relative risk method and continuous outcomes were combined using the Mantel–Haenszel weighted mean difference method. Time to return to usual activities was described using hazard ratios derived from IPD reanalysis. Predefined subgroup analyses based on recurrent hernias and bilateral hernias were also carried out.

Cost-effectiveness

A review of economic evaluations was undertaken by NICE in 2001. This review was updated from 2000 until August 2003. Identified studies were quality assessed against the *BMJ* guidelines for reviewers and narratively synthesised along with those identified from the previous health technology assessment.

In addition to the review, an economic evaluation was performed. The estimation of ▶

cost-effectiveness focused on the comparison of laparoscopic repair with open flat mesh. Estimates for open plug and mesh and open preperitoneal mesh techniques are based on very limited data and are likely to be unreliable. A Markov model incorporating the data from the systematic review was used to estimate cost-effectiveness for a time horizon up to 25 years.

Number and quality of studies and direction of evidence

Effectiveness

Thirty-seven RCTs and quasi-RCTs met the inclusion criteria on effectiveness. Thirteen of these were newly identified for this update. The RCTs were of varying, generally moderate, quality, with sample sizes ranging from 18 to 928 randomised patients and with a mean or median follow-up from 1 week to 5 years.

Cost-effectiveness

Fourteen studies were included in the review of economic evaluations, seven of which were identified from the previous health technology assessment. Two of the new studies were industry submissions and one was based on a model. Of the other five studies, two were modelled data obtained from systematic reviews; the other three studies used poor methodology and were based on non-randomised evidence.

Summary of benefits

Laparoscopic repair is associated with a faster return to usual activities and less persisting pain and numbness. There also appear to be fewer cases of wound/superficial infection and haematoma. However, operation times are longer and there appears to be a higher rate of serious complications in respect of visceral (especially bladder) injuries. Mesh infection is very uncommon with similar rates noted between the surgical approaches. There is no apparent difference in the rate of hernia recurrence.

Costs

From the systematic review of economic evaluations, laparoscopic repair was more costly than open mesh in all but two of the 14 studies. Laparoscopic repair is more costly to the health service than open repair, with an estimated extra cost from studies conducted in the UK of about £300–350 per patient. The point estimates of cost provided by the economic model also suggest that the laparoscopic techniques are more costly (around £100–200 more per patient after 5 years).

Cost-effectiveness

From the review of economic evaluations, the estimates of incremental cost per additional day at usual activities were between £86 and £130. Where productivity costs were included, they eliminated the cost differential between laparoscopic and open repair.

For the management of unilateral hernias, the base-case analysis and most of the sensitivity analysis suggest that open flat mesh is the least costly option but provides less quality adjusted life years (QALYs) than TEP or TAPP. TEP is likely to dominate TAPP (on average TEP is estimated to be less costly and more effective). The results of the base-case analysis and much of the sensitivity analysis suggest that the mean incremental cost per QALY for TEP compared with open mesh is less than £10,000 and that there is approximately an 80% chance that TEP is the most cost-effective intervention should society's maximum willingness to pay for an additional QALY be £20,000.

For recurrent hernias and treatment choice guided by gender and age, the data were sparse and results may be unreliable. In this circumstance, extrapolation from the base-case analysis for primary repair may provide the best available evidence. It is likely that, for management of symptomatic bilateral hernias, laparoscopic repair would be more cost-effective as differences in operation time (a key cost driver) may be reduced and differences in convalescence time are more marked (hence QALYs will increase) for laparoscopic compared with open mesh repair. When possible repair of contralateral occult hernias is taken into account, TEP repair is most likely to be considered cost-effective at threshold values for the cost per additional QALY above £20,000. Nonetheless, the results are sensitive to changes in estimates of prevalence and risk of progression of occult hernias, for both of which data are limited.

Sensitivity analyses

The results of the base-case analysis were most sensitive to assumptions about the disutility associated with persisting pain and numbness. When persisting pain and numbness were ▶

excluded from the analysis, then the results obtained are similar to those that formed the basis of the 2001 assessment, and it is unlikely that laparoscopic repair would be associated with an incremental cost per QALY of less than £50,000. Use of patient utility data derived from a discrete choice experiment, which put weight on avoiding rare intraoperative complications, indicated that both TAPP and TEP were unlikely to be associated with net benefits compared with open flat mesh.

Supplementary report

In April 2004, a further large trial was published. This trial reported data on 2164 randomised participants compared with the 5560 randomised participants in the 37 eligible trials considered by the main Assessment Report. The main change from the main Assessment Report is that recurrence is now statistically significantly more likely following TEP repair. The findings of the supplementary analysis for the other outcomes were essentially similar to those in the original report. On incorporation of these data into the economic model, it was found that, in terms of incremental cost per QALY, laparoscopic repair at levels of willingness to pay for an additional QALY accepted by decision-makers in the past is still likely to be considered cost-effective.

Limitations of the calculations (assumptions made)

Effectiveness

The meta-analyses were conducted using a fixed-effects model although subsequent reanalysis using a random effect model did not greatly alter effect estimates. The main limitations related to the quantity and quality of the data available. For example, few data pertaining to longer than 5-year follow up were available and only one small randomised trial was identified comparing TAPP with TEP repair.

Cost-effectiveness

The nature of the data available also had an impact on the economic evaluation, which extrapolated outcomes for up to 25 years. Assumptions were made by extrapolation about how baseline rates would change over time and about how long relative effects would persist. As far as possible these assumptions were in accordance with available data, and the results were insensitive to changes in the assumed duration of effects.

TAPP and TEP were indirectly compared. In reality, the difference in cost and outcomes between the two procedures may be much smaller than those suggested using data derived from indirect comparisons. For example, the TEP data may relate to more experienced surgeons than the data available for TAPP.

Other important issues regarding implications

The increased adoption of laparoscopic techniques may allow patients to return to usual activities faster. This may, for some people, reduce any loss of income.

For the NHS, increased use of laparoscopic repair would lead to an increased requirement for training which may be costly. During the training period, laparoscopic repair is likely to have higher costs (and hence be less cost-effective). Furthermore, the risk of serious complications may be higher, although adequate supervision and training might minimise these risks.

Notes on the generalisability of the findings

The 37 trials considered in the clinical effectiveness review were mounted in a wide range of settings. Nonetheless, very limited data were available about rare complications and for the subgroup analyses of recurrent and bilateral hernias; although data are presented, these have questionable reliability and hence limited generalisability.

Need for further research

A liberal definition of ‘persisting pain’ was used in the meta-analyses with the consequence of widely varying prevalence rates across trials. Ideally, the issue of chronic pain should now be addressed prospectively using standard definitions and allowing assessment of the degree of pain. Furthermore, more evidence is required on the loss of utility caused by persisting pain and numbness.

Rare, serious complications are an important consideration in the context of minor surgery. Prospective population-based registries of new surgical procedures may be the best way to address this, as a complement to randomised trials assessing effectiveness.

Further research relating to whether the balance of advantages and disadvantages changes when hernias are recurrent or bilateral is also required as current data are limited.

Questions remain about the relative merits and risks of TAPP and TEP. Ideally there should be more data from methodologically sound RCTs.

Laparoscopic groin hernia repair is technically challenging and performance is likely to improve with experience. This issue is important in its evaluation and further methodological research related to this is warranted in the context of both trials and meta-analyses of trial data.

Publication

McCormack K, Wake B, Perez J, Fraser C, Cook J, McIntosh E, *et al*. Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation. *Health Technol Assess* 2005;**9**(14).

NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, consumer groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a limited time period.

Criteria for inclusion in the HTA monograph series
Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned and funded by the HTA Programme on behalf of NICE as project number 03/31/01. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme, NICE or the Department of Health.

ISSN 1366-5278

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.