NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA83 Laparoscopic surgery for inguinal hernia repair

This guidance was issued in September 2004
The review date for this guidance is September 2010

Recommendation

- This guidance should be moved to the static list

Consideration of options for recommendation:

Options	Recommendation	Comment
A review of the guidance should be planned into the appraisal work programme.	No	No new evidence that suggests the guidance should be updated.
The decision to review the guidance should be deferred [to a specified date].	No	No anticipated new evidence to indicate the guidance should be deferred.
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	No	No related technologies
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No	None have been referred
A review of the guidance should be incorporated into an on-going clinical guideline.	No	No ongoing clinical guideline
A review of the guidance should be updated into an on-going clinical guideline.*[1]	No	No ongoing clinical guideline
A review of the guidance should be	**Yes**	**No new evidence available that is likely to**

[1] See Appendix A on page 4

transferred to the 'static guidance list'.		**change the current guidance. Therefore, the guidance should be transferred to the static list**

Original remit(s)

Objective: to assess the clinical and cost effectiveness of laparoscopic surgery relative to current standard treatments in the NHS, and to update if and as necessary, guidance issued to the NHS in England and Wales in January 2001[1].

Current guidance

1.1. Laparoscopic surgery is recommended as one of the treatment options for the repair of inguinal hernia.

1.2. To enable patients to choose between open and laparoscopic surgery (either by the transabdominal preperitoneal [TAPP] or by the totally extraperitoneal [TEP] procedure), they should be fully informed of all of the risks (for example, immediate serious complications, postoperative pain/numbness and long-term recurrence rates) and benefits associated with each of the three procedures. In particular, the following points should be considered in discussions between the patient and the surgeon:

• the individual's suitability for general anaesthesia

• the nature of the presenting hernia (that is, primary repair, recurrent hernia or bilateral hernia)

• the suitability of the particular hernia for a laparoscopic or an open approach

• the experience of the surgeon in the three techniques.

1.3. Laparoscopic surgery for inguinal hernia repair by TAPP or TEP should only be performed by appropriately trained surgeons who regularly carry out the procedure.

Relevant Institute work

Published
Nothing

In progress
Nothing

Suspended/terminated
Nothing

In topic selection
Nothing

On-going trials

Trial name and contact	Details
NCT00311935 Laparoscopic vs Open Hernia Mesh Repair for Inguinal Hernia Other Study ID Numbers: Hernia repair study Contact: Michael Rodgers, MBCHB, FRACS +64 9 486 8920 ext 3152 michael.rodgers@waitematadhb.govt.nz Hisham Hammodat, MBCHB, FRACS +64 9 486 8920 ext 2459 hisham.hammodat@waitematadhb.govt.nz	Enrolment: 350 Status: Currently recruiting Study start date: April 2006; Expected recruitment completion: May 2010
NCT00226161 Chronic Pain After Inguinal Herniorrhaphy Other Study ID Numbers: 171178 Contact: Emilie Øberg, Medical student +45 39 77 33 68 emilieberthelsen@hotmail.com Jacob Rosenberg, professor,chief consultant +45 39 77 33 65 jaro@gentoftehosp.kbhamt.dk	Enrolment: not specified Status: Currently recruiting participants Study first alerted: September 22, 2005

Proposal for updating the guidance

If the guidance is to be updated as an appraisal, it would be scheduled into the work programme accordingly.

New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References

from 2007 onwards were reviewed. The results of the literature search are discussed in the 'Appraisals comment' section below.

Implementation

A submission from Implementation is attached at the end of this paper.

At the time of publication of the original guidance in 2004, expert opinion indicated that uptake of laparoscopic hernia repair would reach 20-40% of all hernia repairs performed. Implementation data indicates that this projection is broadly accurate and NICE guidance is being taken up. As such, there has been an increase in use of laparoscopic surgery for hernia repairs since the original guidance was issued. In 2008/2009, the uptake of laparoscopic hernia repair stood at about 17% and this continues to rise, although at a much slower rate than it was before 2007. The uptake is much higher for recurrent hernia repairs than for primary hernia repairs.

Equality and diversity issues

No equality issues have been identified relating to this guidance

Appraisals comment:
The original guidance on this technology was produced in 2004. In 2007, the Guidance Executive recommended that a review of this technology should be postponed to 2010 because no new evidence was identified that could have changed the recommendations issued in the original guidance. Since 2007, several studies have been published that evaluated the efficacy of laparoscopic hernia repair compared with open hernia repair. The majority of the studies evaluated the difference in hernia recurrence, post operative pain and recovery time between the two techniques. Nearly all of these studies concluded the laparoscopic hernia repair is comparable or better than open hernia repair in all these outcomes. A study by Champault et al (2007) (n=410) evaluated the 2-year incidence of recurrence and pain between people undergoing Lichtenstein repair (a method of open repair) and laparoscopy (totally extraperitoneal approach or TEP), and two types of mesh, polypropylene mesh and beta-d-glucan-coated mesh (Glucamesh). It concluded that the choice of prosthesis was more determinant than choice of technique. No studies were identified that specifically evaluated the efficacy or cost effectiveness on the two laparoscopic hernia repair techniques (TEP and TAP).

TA83 recommended further research into chronic pain and numbness following surgery. Two studies specifically evaluated this outcome. One study by Beldi et al (2008) evaluated the incidence of chronic pain and hypoesthesia after inguinal hernia repair using three types of operation: open suture, open mesh, and laparoscopic. The study found the incidence of chronic pain and hypoesthesia to be lower in laparoscopic repair than the other two techniques. Another study by Eklund et al (2010) concluded that chronic pain at 5 years was lower after laparoscopic surgery than after open repair. As such, the

results of these studies are unlikely to change the recommendations of the current guidance.

Three economic evaluation studies were identified that compared laparoscopic surgery with open hernia surgery. All the studies considered open surgery more cost effective compared to laparoscopic surgery. A study by Bender et al (2009) (n=40) evaluated systematic inflammatory response after Kugel (a method of open repair) hernia surgery compared with laparoscopic hernia surgery. The study compared operation time, length of hospital stay, pain severity, time to return to normal activities, cost, and systemic inflammatory responses to surgical trauma between the two surgical techniques. The study found that Kugel technique provided the same outcomes as laparoscopic surgery at a lower cost. It concluded that Kugel technique was more cost effective compared with laparoscopic surgery. However, it is highlighted in the study that this technique has not been well studied. A study by Butler et al (2007) (n=66), reported that post operative pain was the same between laparoscopic and open repair while the cost of open repair was significantly lower than laparoscopic surgery. It concluded that the higher operative costs noted for the laparoscopic hernia repairs were not offset by a shortened convalescence. A cost minimisation study by Eklund et al (2010) during follow-up of 5 years concluded that laparoscopic inguinal hernia repair had a small but significant increase in overall costs compared with open repair. All the three studies were conducted in the USA and none were undertaken as cost-utility analysis. As such there is uncertainty over the relevance of the results for the UK setting.

There are three ongoing clinical trials relevant to this review. One trial (NCT00226161) undertaken in Denmark (expected completion date not stated) is evaluating whether laparoscopic inguinal hernia repair leads to a lower incidence of chronic pain compared with open herniorrhaphy. The second trial (NCT00311935) which is being undertaken in New Zealand (expected date of completion May 2010) is evaluating whether laparoscopic and open hernia repair have the same recurrence and complication rates in the under 60 year old age group. The study will also compare the overall financial costs of each repair. The third trial (NCT00788554) which is being under taken in Holland (**-**expected date of completion not stated) is comparing laparoscopic total extraperitoneal with open mesh repair of inguinal hernia, with regard to outcomes such as hospital stay, postoperative pain, quality of life, postoperative recovery and return to daily activities. None of the studies are evaluating any different outcomes to those reported extensively in the trials included TA 83.

In view of the available evidence and the absence of upcoming studies that evaluate different outcomes from those considered in TA 83, there appears to be no new evidence available that is likely to change the current guidance. It is therefore recommended that this guidance be moved to the static list.

Key issues

There is no new evidence available that is likely to change the current guidance. It is therefore recommended that this guidance be moved to the static list.

GE paper sign off: Frances Sutcliffe 17th September 2010

Contributors to this paper:

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[1] *Guidance on the use of laparoscopic surgery for inguinal hernia* (Technology Appraisal Guidance no.18), National Institute for Clinical Excellence, January 2001).