Complete Summary

GUIDELINE TITLE

Laparoscopic surgery for inguinal hernia repair.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Laparoscopic surgery for inguinal hernia repair. London (UK): National Institute for Clinical Excellence (NICE); 2004 Sep. 33 p. (Technology appraisal; no. 83).

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Inguinal hernia

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

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

TARGET POPULATION

Patients with inguinal hernia

INTERVENTIONS AND PRACTICES CONSIDERED

1. Laparoscopic surgery
    - Transabdominal preperitoneal (TAPP) repair
    - Totally extraperitoneal (TEP) repair
2. Open mesh inguinal repair (considered but not specifically recommended)

MAJOR OUTCOMES CONSIDERED

- Outcomes of interest, against which the effectiveness of laparoscopic and open surgery were assessed, were primary outcomes of recurrence and persistent pain, and secondary outcomes of the rate of complications and persistent numbness, the duration of the operation, length of hospital stay, time to return to normal activities, and quality of life.
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Health Services Research

Unit and the Health Economics Research Unit (see the "Companion Documents" field).

Search Strategy

Electronic searches were conducted to identify reports of trials of laparoscopic inguinal hernia repair, including transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP) procedures. Systematic reviews and other evidence-based reports were also identified. The original Technology Assessment Report had searched MEDLINE and EMBASE up to 2000; therefore these databases were searched only from 2000 onwards using a revised strategy to reflect the scope of the new review. Since the original strategies used had not specifically searched for studies comparing TAPP with TEP procedures, supplementary searching of these databases for all years was also undertaken. The following databases were searched, and full details of the strategies used are documented in Appendix 1 of the technology assessment.

- MEDLINE (2000- Week 1 June 2003) Additional TAPP vs. TEP search (1966 to Week 1 June 2003)
- MEDLINE Extra (13th June 2003)
- EMBASE (2000 to Week 23 2003) Additional TAPP vs. TEP search (1980 to Week 23 2003)
- CINAHL (1985 to Week 1 June 2003)
- BIOSIS (1985 to 18th June 2003)
- Science Citation Index (1981 to 21st June 2003)
- Web of Science Proceedings (1990 to 21st June 2003)
- Cochrane Controlled Trials Register (Cochrane Library Issue 2 2003)
- Cochrane Database of Systematic Reviews (Cochrane Library Issue 2 2003)
- Database of Abstracts of Reviews of Effectiveness (June 2003)
- HTA Database (June 2003)
- Journals@Ovid Full Text (July 16th 2003)
- SpringerLink (July 16th 2003)
- National Research Register (Issue 2 2003)
- Clinical Trials (June 2003)
- Current Controlled Trials (June 2003)
- Research Findings Register (June 2003)

In addition, selected conference proceedings were hand-searched and Web sites consulted, details of which can also be found in Appendix 1 of the technology assessment. Reference lists of all included papers were scanned and experts contacted for other potentially eligible reports.

Inclusion Criteria and Exclusion Criteria

All titles and, where possible, abstracts identified by the search strategies were assessed to identify potentially relevant reports. A total of 1,421 citations were identified from electronic searching and a further 23 abstracts from hand-searching. Two hundred thirteen (213) reports (180 papers; 33 abstracts) were assessed as potentially relevant for which full text papers were then obtained where available. These were formally assessed independently by two researchers to check whether they met the inclusion criteria, using a study eligibility form developed for this purpose (Appendix 2 of the technology assessment). Any

disagreements that could not be resolved through discussion were referred to an arbiter. The following inclusion criteria were applied:

Types of Studies

All published and unpublished randomised controlled trials 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. Trials were included irrespective of the language in which they were reported.

Types of Participants

The trials included all patients with a clinical diagnosis of inguinal hernia for whom surgical management was judged appropriate. Where possible, analyses based on individual patient data from randomised patients were included in the meta-analysis, including data obtained for any patients excluded from the original published analyses. Where data allowed, the patient population was split by whether or not the hernia was recurrent or bilateral and whether or not the patient was fit enough for general anaesthesia. Data from children aged 12 years and older were included where these patients were included in a trial of adults; however, trials specifically relating to children were not included.

Types of Interventions

Methods of surgical repair of inguinal hernia:

a. Laparoscopic inguinal hernia repair (TAPP and TEP)
b. Open mesh inguinal hernia repair (including open flat mesh, open pre-peritoneal mesh and open plug and mesh)

Types of Outcome Measures

The following data items were sought for all trials:

<u>Primary Outcomes</u>

- Hernia recurrence
- Persisting pain

<u>Secondary Outcomes</u>

- Duration of operation
- Opposite method initiated
- Conversion
- Post-operative pain
- Haematoma
- Seroma
- Wound/superficial infection
- Mesh/Deep infection
- Port site hernia

- Vascular injury
- Visceral injury
- Length of hospital stay
- Time to return to usual activities
- Persisting numbness
- Quality of life

Data Extraction Strategy

The titles and abstracts of all papers identified by the search strategy were screened. Full text copies of all potentially relevant studies were obtained and two reviewers independently assessed them for inclusion. Reviewers were not blinded to the names of studies' authors, institutions, or publications. Any disagreements were resolved by consensus or arbitration.

A data extraction form was developed to record details of trial methods, participants, interventions, patient characteristics, and outcomes (Appendix 3 of the technology assessment). Two reviewers extracted data independently. Any differences that could not be resolved through discussion were referred to an arbiter.

Quality Assessment Strategy

Two reviewers working independently assessed all studies that met the selection criteria for methodological quality. Any disagreements were resolved by consensus or arbitration. The system for classifying methodological quality of controlled trials was based on an assessment of four principal potential sources of bias. These were: selection bias from inadequate concealment of allocation of treatments; attrition bias from losses to follow-up without appropriate intention-to-treat analysis, particularly if related to one or other surgical approaches; detection bias from biased ascertainment of outcome where knowledge of the allocation might have influenced the measurement of outcome; and selection bias in analysis (Appendix 3 of the technology assessment).

NUMBER OF SOURCE DOCUMENTS

Twenty-four trials from the original review compared laparoscopic with open mesh procedures and were included in this updated review. In addition, from the searching conducted for this update, 37 new reports of trials met the criteria for inclusion. These comprised 20 reports relating to the originally included trials and 17 reports relating to 13 new trials. Thus, in total 37 eligible trials were identified. A list of these studies with their associated references is given in Appendix 4 of the technology assessment.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Health Services Research Unit and the Health Economics Research Unit (see the "Companion Documents" field).

Data Synthesis

For each outcome the results were derived from the best available source: if individual patient data (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 (RR) method and continuous outcomes were combined using the Mantel-Haenszel weighted mean difference (WMD) method. Time to return to usual activities was described using hazard ratios (HR) derived from IPD reanalysis. The hazard ratio is defined as the ratio of the instantaneous adverse event rates of the groups, i.e., the ratio of the adverse event rate of the treatment group to that of the control group. Unlike the odds ratio, the HR can allow for the fact that some patients were not followed up for the full time period (censored). Even when the instantaneous adverse event rates of the groups both change with time the ratio of the two is always assumed to be constant (i.e., the HR assumes the survival curves are proportional and do not cross over). A HR of one indicates no difference between comparison groups. For undesirable outcomes a HR that is less than one indicates that the intervention was effective in reducing the risk of that outcome. In the context of meta-analysis Peto's formula gives an estimate of the odd ratio and this is also usually a close approximation to the HR. The results are all reported using a fixed effects model. Chi-squared tests were used to explore statistical heterogeneity across studies and where a significant result was found, possible reasons were explored using sensitivity analyses.

The review was conducted using the standard Cochrane software 'RevMan 4.1'. Appendix 7(1) of the technology assessment considers TAPP versus open mesh repair. Within this analysis, the trials were ordered by the method of open mesh repair (open flat mesh, open pre-peritoneal mesh, and open plug and mesh). Appendix 7(2) of the technology assessment considers TEP versus open mesh repair and the trials were similarly ordered by the method of open repair (open flat mesh, open pre-peritoneal mesh, and open plug and mesh). Appendixes 7(3)-7(4) and 7(5)-7(6) of the technology assessment repeat this but only include patients with recurrent and bilateral hernias respectively.

Duration of operation was defined as time from first incision to last suture or, where this was not available, time in theatre. "Opposite" method initiated was defined as a laparoscopic repair initiated when an open repair was allocated, or vice versa. A conversion was defined as a procedure initiated as a laparoscopic but converted to an open repair, or vice versa. "Postoperative pain" could include data collected on the second or third day, if no data were reported for the first post-operative day. Haematoma included wound or scrotal haematoma or ecchymosis but not bruising. Seroma included hydrocele. Wound/superficial infection was defined as wound related infections only and included pus from wound, fistula, and sinus formation. Length of postoperative stay was defined as time from admission to discharge. Time to return to usual activities was defined as number of days to resumption of normal social activities or work where this was not available. Persisting pain was defined as groin pain of any severity (including testicular) persisting at one year after the operation, or at the closest timepoint to one year providing this was at least three months after surgery. Persisting numbness included paresthesia, dysesthesia, and discomfort persisting at one year after the operation, or at the closest timepoint to one year providing this was at least three months after surgery. Hernia recurrence data were based on the methods of ascertainment used in individual trials.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and

the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients, and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Literature Review

The literature review identified seven economic evaluations of laparoscopic surgery for inguinal hernia repair--three based on economic models and four based on primary studies. Only two studies (submitted by Ethicon Endo-Surgery and BARD Ltd) were relevant to the United Kingdom setting.

Summary

The guideline development committee reviewed the data on the cost effectiveness of laparoscopic repair compared with the different methods of open repair, and considered the open flat mesh (OFM) technique to be the most clinically relevant comparator because it is the most common method of open repair and because of the absence of long-term data on the costs and outcomes of newer techniques (open preperitoneal mesh [OPPM] and open plug and mesh [OPM]). The Committee considered that, taking all data reviewed into account, laparoscopic surgery (transabdominal preperitoneal [TAPP] and totally extraperitoneal [TEP]) is

a cost-effective alternative to OFM repair. However, they noted that the choice of disposable or reusable equipment for use in laparoscopic hernia repairs had a significant effect on the incremental cost-effectiveness ratio (ICER) of the procedure. The Committee were therefore persuaded that, wherever possible, the use of reusable equipment was to be preferred.

See Section 4.2 of the original guideline document for a detailed discussion and more information.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Laparoscopic surgery is recommended as one of the treatment options for the repair of inguinal hernia.
- 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
- Laparoscopic surgery for inguinal hernia repair by TAPP or TEP should only be performed by appropriately trained surgeons who regularly carry out the procedure.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of laparoscopic surgery for the repair of inguinal hernia
- The potential benefits of using a laparoscopic approach include reduced postoperative pain, earlier return to normal activities, and a reduction in long-term pain and numbness.

POTENTIAL HARMS

- Complications of surgery, including haematoma, seroma, wound-related infection, mesh infection, vascular or visceral injuries and port-site hernia
- Post-operative pain/numbness

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- Surgical services in National Health Service organizations should review their current practice and policies to take account of the guidance set out in Section 1 of the original guideline document (and the "Major Recommendations" field).
- Local guidelines or care pathways for people who undergo surgery for repair of inguinal hernia should incorporate the guidance, considering the availability

of a surgeon who is trained and experienced in laparoscopic surgery for the repair of inguinal hernia.

- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - Laparoscopic surgery is considered as one of the treatment options for the repair of inguinal hernia. In choosing between open and laparoscopic surgery (either the transabdominal preperitoneal [TAPP] or the totally extraperitoneal [TEP] procedure), the following are considered:
        - The suitability of the individual for general anaesthesia
        - The nature of the presenting hernia
        - The suitability of the particular hernia for a laparoscopic or open approach
        - The experience of the surgeon in the three techniques
    - The individual undergoing repair of inguinal hernia is fully informed of all the risks and benefits associated with open surgery and laparoscopic surgery by both the TEP and TAPP procedures as part of the informed consent process.
    - Laparoscopic surgery for inguinal hernia repair by TAPP or TEP is performed only by a surgeon who has received appropriate training and regularly carries out the procedure.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Laparoscopic surgery for inguinal hernia repair. London (UK): National Institute for Clinical Excellence (NICE); 2004 Sep. 33 p. (Technology appraisal; no. 83).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan (revised 2004 Sep)

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Laparoscopic surgery for inguinal hernia repair. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Sep. 2 p. (Technology appraisal 83). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Systematic review of the clinical effectiveness and cost-effectiveness of laparoscopic surgery for inguinal hernia repair. Assessment report. Aberdeen (UK): Health Services Research Unit and Health Economics Research Unit; 2003 Dec 10. 248 p. (Technology appraisal 83). Electronic copies: Available in PDF from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- Laparoscopic surgery for inguinal hernia repair: understanding NICE guidance - information for people with inguinal hernia, their families and carers, and the public. London: National Institute for Health and Clinical Excellence. 2004 Sep. 10 p. Available in English and Welsh in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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Date Modified: 9/15/2008