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National Institute for Clinical Excellence

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11 Strand
London
WC2N 5HR

Web: www.nice.org.uk

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Technology Appraisal Guidance - No.17

National Institute for Clinical Excellence

Guidance on the Use of Laparoscopic Surgery for Colorectal Cancer

December 2000

This document has been circulated to the following:

- Health Authority Chief Executives in England and Wales
- NHS Trust Chief Executives in England and Wales
- PCG Chief Executives
- Local Health Group General Managers
- Medical and Nursing Directors in England and Wales
- Consultant Surgeons in England and Wales
- NHS Director Wales
- Chief Executive of the NHS in England
- NHS Executive Regional Directors
- Special Health Authority Chief Executives
- Community Health Councils in England and Wales
- Patient advocacy groups
- Commission for Health Improvement
- NHS Clinical Governance Support Team
- Chief Medical and Nursing Officers in England and Wales
- Medical Director & Head of NHS Quality – National Assembly for Wales
- Clinical Effectiveness Support Unit - Wales
- Representative bodies for health services, professional organisations and statutory bodies, Royal Colleges

This Guidance is written in the following context:
This guidance represents the view of the Institute's Appraisal Committee, the membership of which is set out in Appendix A, 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 about the use of laparoscopic surgery for colorectal cancer. 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.

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Guidance on the Use of Laparoscopic Surgery for Colorectal Cancer

1. Guidance

1.1 For colorectal cancer, open rather than laparoscopic resection should be the preferred surgical procedure.

1.2 Laparoscopic surgery should only be undertaken for colorectal cancer as part of a randomised controlled clinical trial (see 6.1).

This section, Section 1, constitutes the Institute's guidance on the use of Laparoscopic Surgery for Colorectal Cancer. The remainder of the document is structured in the following way:

The full document and a Summary of Evidence are available from our website at www.nice.org.uk or by telephoning 0541 555 455 and quoting the reference number 22956.

Mae'r adran hon (adran 1) hefyd ar gael yn Gymraeg ar ein gwefan neu drwy gysylltu â 0541 555 455, rhif cyfeirnod 22957.

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2 Clinical Need and Practice

2.1 Colorectal cancer (CRC) is second only to lung cancer as the most common malignancy in the western world. The incidence of colorectal cancer in England and Wales is 48/100,000 population per year, rising sharply with age to 300/100,000 per year among those aged 75 and over. CRC is the cause of around 16,000 deaths in England and Wales annually.

2.2 There has been only a modest improvement in survival over the last 30 years, despite improvements in adjuvant treatment, with an overall five-year survival of approximately 40%.

2.3 The only curative treatment in CRC is surgical resection. Traditionally, this has involved open resection requiring a laparotomy to enable both resection of the primary tumour with sufficient excision margins and an adequate, systematic lymphadenectomy. Additionally, for rectal cancer, a total mesorectal excision is performed to reduce the probability of local recurrence.

2.4 Excision of the tumour is the primary treatment for new cases of CRC with potential for cure in 80% of patients. In the remaining 20%, the disease is usually too far advanced at presentation for any curative intervention. These patients also frequently undergo surgery for palliation, where optimising quality of life is the main objective of treatment.

2.5 Stages of malignancy are based on a scheme described by Dukes in 1932. Firstly, the depth of the invasion of the cancer is assessed and secondly, whether or not the cancer has spread to regional lymph nodes or more distantly. In Dukes A the tumour is limited to the bowel wall, in Dukes B the tumour penetrates through the bowel wall into adjacent tissues, but does not involve the regional lymph nodes. Dukes C denotes a tumour with involvement of the regional lymph nodes and Dukes D is indicated by the presence of distant metastases.

2.6 The Dukes stages are highly prognostic of survival. The currently accepted stage-specific survival at two years for CRC patients undergoing open surgery are between 85-100% for Dukes A, 82-92% for Dukes B, 55-65% for Dukes C and around 20% for Dukes D, although survival rates following open resection vary between different centres.

3 The Technology

3.1 There are three laparoscopic approaches available to the surgeon: laparoscopic (intra-corporeal anastomosis), laparoscopically assisted (extra-corporeal anastomosis) and more recently hand-assisted laparoscopic resection (intra or extra-corporeal anastomosis).

3.2 Laparoscopic techniques have been adopted for a range of colorectal conditions. Laparoscopic-assisted right hemi-colectomy was first performed in 1990 and a left sided colonic laparoscopic resection was reported later that year.

3.3 Widespread uptake of laparoscopic surgery for CRC has been limited because of concern about its long-term effectiveness and oncological safety. There are fears that the laparoscopic technique may increase the risk of developing local metastases, either within the abdomen or at the instrument port sites, or that resection may be incomplete. The techniques allow visualisation but not direct palpation of the liver for metastases and the primary tumour for fixity to and involvement of adjacent organs, and may therefore compromise the ability to accurately stage the tumour. In addition, there may be a reduced ability to control bleeding and identification of some vital structures may be difficult because of inadequate retraction thus increasing the risk of intra-operative damage.

3.4 At present most experts advocate the use of laparoscopic surgery for CRC only in an evaluative context until more data is available. Few centres in the UK, outside the MRC funded CLASICC (Conventional versus Laparoscopic-Assisted Surgery in Colorectal Cancer) trial currently use laparoscopic techniques for curative excision of CRC.

3.5. Guidelines on the use of laparoscopic surgery for CRC have been published, and recommend that surgeons undertaking these minimally invasive techniques should be appropriately trained and experienced, in both open and laparoscopic colorectal surgery, and their results carefully audited [1,2,3].

4 Evidence

4.1 The important criteria in the assessment of the clinical effectiveness of colorectal surgery for cancer are long-term (5 years or more) survival (overall and disease-free), recurrence (local and distant) and patient related quality of life. The risk of port site metastases (and their likely adverse effect on overall survival) is also of primary concern.

4.2 Sixty-nine papers were considered for the review of clinical effectiveness. Fifty-seven case series (17 of which include comparative data for some outcomes) reported long-term (follow-up range 8-42 months) outcomes (survival, disease-free survival, cancer related deaths, local recurrences, distant metastases, port site metastases). Twenty-two papers [randomised controlled trials (RCTs)] and prospective cohort studies (PCSs) reported short-term (post-operative) outcomes (conversion rate, complications, length of stay, duration of operation, blood loss, analgesia use, time to mobilisation, time to restart diet, time to bowel movement, number of lymph nodes harvested). The quality of the studies and reporting of data was generally poor.

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[1] Royal College of Surgeons of England and Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of Colorectal Cancer. RCS Guidelines 1996.

[2] Association of Surgeons of Great Britain and Ireland and Association of Coloproctologists of Great Britain and Ireland. Consensus Statement. ASGBI 1998.

[3] Scottish Intercollegiate Guidelines Network. Colorectal cancer: a national clinical guideline. Scottish Cancer Therapy Network 1997.

4.3 There was no evidence of long-term harms or benefits from laparoscopic compared to open surgery but the existing evidence cannot exclude the possibility of clinically important benefits or harms, in particular reduction in survival time.

4.4 Most short-term outcomes (length of stay, blood loss, time to restart diet and time to bowel movement) were significantly and consistently reduced, indicating benefit in the laparoscopic groups. There was a significant and consistent increase (95% CI: 45 to 65 minutes) in duration of operation for laparoscopic surgery although because of variation in laparoscopic techniques it is difficult to estimate the significance of this difference in practice. However length of hospital stay was significantly and consistently shorter (95%CI: 2.5 to 3 days) for laparoscopic surgery. There was no difference in the number of lymph nodes harvested at operation between open and laparoscopic techniques. The complication rates (major and minor) were not consistent across studies.

4.5 No formal economic evaluations (i.e. cost-effectiveness, cost utility, or cost benefit analyses) comparing laparoscopic versus open surgery for CRC were identified.

4.6 The additional cost of laparoscopic surgery compared to open surgery was estimated to be £227 per admission, which mainly reflected the extra cost of theatre consumables since the increase in theatre time was approximately balanced by a reduction in the length of stay compared to open surgery. However the net increase in the cost was sensitive to changes in operating time and length of stay and may range widely (i.e. -£221 to £678).

4.7 The overall conversion rate, from a laparoscopic to an open procedure was 13.0% (95% CI: 7.8% to 21.0%). Conversions will increase the average cost difference between laparoscopic and open surgery since the consumable costs of laparoscopic surgery and some increase in operating time will be incurred without the reduction in length of stay.

5 Implications for the NHS

5.1 There may be cost implications of this guidance in those centres currently carrying out laparoscopic surgery but not in the context of the CLASICC trial (see 6.1). In those centres a switch of laparoscopic to open may produce cost savings. It is difficult to determine this saving as reliable figures on the number of laparoscopic operations performed in centres out with this trial are not known.

6 Further Research

6.1 There is a need for higher quality evidence about long-term outcomes of laparoscopic surgery for CRC with adequate precision to detect clinically important differences to the open technique. The MRC funded CLASICC Trial, a multi-centre study in the UK, and the American National Institute of Health Trial are randomising over 2000 patients. Their results are likely to be reported in 2005.

6.2 The NHS Cancer Research Network (NCRN) will seek to double the number of cancer patients in clinical trials. The MRC funded CLASICC trial is still recruiting patients and therefore surgeons are recommended to support active recruitment.

7 Implementation

7.1 Trusts should review their current practice against this guidance. Laparoscopic resection for colorectal cancer should only be carried out in the context of properly conducted trials.

8 Clinical Audit Advice

8.1 Surgeons should be encouraged to collect prospective long-term outcome data on those colorectal cancer patients who will in the future undergo, or who have to date undergone, either open or laparoscopic surgery.

9 Review of Guidance

9.1 This guidance will be reviewed in August 2003

Andrew Dillon
Chief Executive
December 2000

APPENDIX A

Appraisal Committee Members

The Appraisal Committee is a Statutory Committee whose members sit for 3 years. They are supplemented by technology specific experts as indicated in Appendix B.

Professor R. L. Akehurst
Dean, School of Health Related Research
Sheffield University

Professor David Barnett (Chairman)
Professor of Clinical Pharmacology
University of Leicester

Professor Sir Colin Berry
Professor of Morbid Anatomy
St Bartholomew's and Royal London School of Medicine

Dr Sheila Bird
MRC Biostatistics Unit, Cambridge

Professor Martin Buxton
Director of Health Economics Research Group
Brunel University

Professor Yvonne Carter
Professor of General Practice and Primary Care
St Bartholomew's and Royal London School of Medicine

Dr Karl Claxton
Lecturer in Economics
University of York

Professor Duncan Colin-Jones
Professor of Gastroenterology
University of Southampton

Ms Sarah Cowley
Professor of Community Practice Development
Kings College, London

Dr Nicky Cullum
Reader in Health Studies
University of York

Mr Chris Evennett
Chief Executive
Mid-Hampshire Primary Care Group

Ms Jean Gaffin
Formerly Executive Director
National Council for Hospice and Specialist Palliative Care Service

Mrs Sue Gallagher
Chief Executive
Merton, Sutton and Wandsworth Health Authority

Dr Trevor Gibbs
International Medical Operations Director
Glaxo-Wellcome R&D Ltd

Mr John Goulston
Director of Finance
The Royal Free Hampstead NHS Trust

Professor Philip Home
Professor of Diabetes Medicine
University of Newcastle

Dr Terry John
General Practitioner
St James Health Centre, London

Dr Diane Ketley
Clinical Governance Programme Leader
Leicester Royal Infirmary

Dr Mayur Lakhani
General Practitioner, Highgate Surgery, Leicester and
Lecturer, University of Leicester

Mr M Mughal
Consultant Surgeon
Chorley and South Ribble NHS Trust

Mr James Partridge
Chief Executive
Changing Faces

Professor Philip Routledge
Professor of Clinical Pharmacology
University of Wales

Professor Andrew Stevens
Professor of Public Health
University of Birmingham

APPENDIX B

Sources of Evidence

1. The following documentation and opinion was made available to the Committee:

a. Assessment Reports:

- prepared by the Royal College of Surgeons of England, Division of Surgery, Anaesthetics and Intensive Care, London School of Hygiene and Tropical Medicine, National Institute for Clinical Excellence (A Systematic Review of the Effectiveness and Cost-effectiveness of Laparoscopic Surgery for Colorectal Cancer, July 2000)
- prepared by the Health Services Research Unit and the Health Economics Research Unit, University of Aberdeen (Systematic Review of the Effectiveness and Cost-effectiveness of Laparoscopic versus Open Repair of Inguinal Hernia, July 2000)

b. Sponsor submissions:

- The Association of Endoscopic Surgeons of Great Britain and Ireland

c. Manufacturer submissions:

- Ethicon Endo-Surgery and
- Tyco Healthcare Ltd. (Joint submission)
- Karl Storz Endoscopy (UK) Ltd.

d. Professional/specialist group, patient/carer group and trade association submissions:

- Arthritis Care
- The Association of Operating Department Practitioners
- Association of Surgeons of Great Britain and Ireland
- British Medical Association
- Cancer Research Campaign
- Marie Curie Cancer Care
- Oesophageal Patients Association
- Royal College of Surgeons

e. External expert and patient advocate submissions:

- Professor Michael Bailey, Professor of Surgery & Director of Minimal Access Therapy Training, Guildford Nuffield Hospital
- Professor Ara Darzi, Professor of Surgery, Imperial College of Medicine
- Ms. Claire Taylor, Macmillan Colorectal CNS, Macmillan Cancer Unit, Northwick Park Hospital

APPENDIX C

Guidance on the use laparoscopic surgery for the treatment of colorectal cancer – patient information

The patient information in this appendix has been designed to support the production of your own information leaflets; you can download it from our web site (www.nice.org.uk) where it is available in English and Welsh. A printed version of this text is available in English/Welsh or English alone. If you would like copies of the printed leaflet please contact 0541 555 455, and quote the reference number 22959 for the English/Welsh version and 22958 for the English only version.

What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical & surgical procedures and where they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients.

NICE was asked to look at the available evidence on the use of laparoscopic surgery and provide guidance that would help the NHS in England and Wales decide where it should be used in the treatment of colorectal cancer.

What is colorectal cancer?

Cancer is a disease of the body's cells. Normally, all cells divide and reproduce themselves in an orderly and controlled manner. In cancer, the cells multiply without proper control. Colorectal cancer is a cancer of the large intestine. The type of treatment given for a cancer depends on many factors. These include:

- the type of cancer,
- where in the body it started,
- what the cancer cells look like under the microscope,
- how far they have spread, if at all
- the general health of the patient

Colorectal cancer (CRC) is the second most common cancer in the western world. It causes around 16,000 deaths in England and Wales each year. Around 48 in every 100,000 people per year get colorectal cancer this increases to about 300 out of every 100,000 people aged 75 and over.

An operation is carried out to remove the cancerous part of the intestine, the tumour and cancerous cells. This operation can cure around 8 out of 10 people with colorectal cancer, however for 2 out or 10 patients the cancer is usually too far advanced for any effective cure. These patients often have an operation to reduce the symptoms of the cancer and improve their quality of life.

What is laparoscopic surgery?

Laparoscopic surgery is often referred to as 'key-hole' surgery. This is where small cuts are made in the patient's stomach and then a harmless gas is pumped in to create a working space. Through additional small cuts, a rod shaped telescope, attached to a camera, and other long and narrow surgical instruments are placed into the newly formed space. The surgeon then uses these instruments to perform the surgery and remove the cancer.

Key-hole surgery is used for other types of operations, but its use in colorectal cancer surgery has been limited because of concerns as to how well it works in the long term and concerns that it may cause a spread of the cancer cells. Also because the surgeon can't put his hand directly on the liver and other body organs he/she cannot feel if the cancer has spread and may not be able to confirm how serious the cancer is.

What has NICE recommended about the use of laparoscopic surgery for colorectal cancer?

NICE has recommended that people with colorectal cancer should have ordinary (open) surgery rather than laparoscopic surgery to remove their cancer.

People should only have laparoscopic surgery as part of a clinical trial. If you have this type of operation, then your surgeon will discuss the details of the clinical trial with you before you agree to have the operation.

What should I do?

If you, or someone you care for, are diagnosed with colorectal cancer then they should discuss this advice with their doctor or nurse.

Will NICE review its guidance?

Yes. This guidance will be reviewed in August 2003.

Further Information

Further information on NICE, and the full guidance issued to the NHS is available on the NICE web site (www.nice.org.uk). It can also be requested from 0541 555 455, quoting reference 22956.