

Laparoscopic radical prostatectomy

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic radical prostatectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic radical prostatectomy should inform the clinical governance leads in their trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.
- 1.2 Patients should be informed that radical prostatectomy by any technique can control local symptoms of prostate cancer, but that it can also have significant complications. They should be informed that there is no reliable evidence showing whether or not radical prostatectomy improves survival (see 2.5).
- 1.3 Laparoscopic radical prostatectomy requires specialist training before it is undertaken. The British Association of Urological Surgeons has agreed to produce training standards.

2 The procedure

2.1 Indications

- 2.1.1 The indication for laparoscopic radical prostatectomy is localised prostate carcinoma with no evidence of spread beyond the prostate or of systematic metastases. It is an alternative to open radical retropubic prostatectomy.

2.2 Outline of the procedure

- 2.2.1 This procedure involves the insertion of a laparoscope and trocars through the abdominal wall. The prostate, adjacent tissue and lymph nodes are separated and removed, and the urethra is reconnected.

2.3 Efficacy

- 2.3.1 The evidence relating to this procedure was based largely on case series from a few specialised centres. No data on clinical recurrence of cancer were available. The studies showed rates of continence of 57% (35/61) to 89% (750/841) 1 year after surgery.
- 2.3.2 All the Specialist Advisors thought that this was definitely a novel procedure. They noted that extensive training is required.

Interventional Procedure Guidance 16

This guidance is written in the following context:

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.

2.4 Safety

- 2.4.1 There was very little good-quality comparative data available to compare laparoscopic radical prostatectomy with open retropubic radical prostatectomy. Total postoperative complication rates for laparoscopic radical prostatectomy were 17% in one study (with 20% of these complications considered to be major) and 20% in another study. Conversion rates to open surgery were low, ranging from 0 to 4%.
- 2.4.2 Following the procedure, continence rates (defined as either no pads or one pad required daily) ranged from 84% (43/51) at 3 months to 78% (29/37) at 1 year. One study reported that 11% (7/63) of patients had spontaneous erections at 1 year.
- 2.4.3 The Specialist Advisors commented that a high rate of complications was likely, given the novelty of the procedure and the steep learning curve involved. One Specialist Advisor said that the effects on incontinence and impotence are controversial.

2.5 Other comments

- 2.5.1 Existing NICE cancer service guidance, *Improving Outcomes in Urological Cancer*, is available from the Institute's website (www.nice.org.uk). It includes recommendations on laparoscopic radical prostatectomy.
- 2.5.2 Some studies compare the results of laparoscopic radical prostatectomy with those from other treatment carried out some years ago. The stage of disease may be different in patients in the earlier studies, making the comparison invalid.

Andrew Dillon
Chief Executive
October 2003

Information for the Public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG016publicinfoenglish and in English and Welsh from www.nice.org.uk/IPG016publicinfowelsh.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional Procedure Overview of Laparoscopic Radical Prostatectomy, November 2002.

Available from: www.nice.org.uk/IP039overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference: N0321. *Information for the Public* can be obtained by quoting reference number N0322 for the English version and N0323 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG016distributionlist

Published by the National Institute for Clinical Excellence, October 2003 ISBN: 1-84257-392-6

© National Institute for Clinical Excellence October 2003. All rights reserved. This material may be freely reproduced for educational and not for profit purposes within the NHS. No reproduction by or for commercial organisations is permitted without the express written permission of the Institute.

National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

N0321 1P 20k Oct 03 (ABA)