

Issue date: **January 2006**

Laparoscopic partial nephrectomy

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG151

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0961 (full guidance)
- N0962 (information for the public).

National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

ISBN 1-84629-133-X

© National Institute for Health and Clinical Excellence, January 2006. 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 allowed without the express written permission of the National Institute for Health and Clinical Excellence.

Contents

About this information	4
About the procedure	5
How well the procedure works	5
Risks and possible problems with the procedure	7
What has NICE decided?	8
What the decision means for you	9
Further information	10

About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called laparoscopic partial nephrectomy. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether laparoscopic partial nephrectomy is safe enough and works well enough for it to be used routinely for the removal of certain types of tumour in the kidney (see below).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of laparoscopic partial nephrectomy and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

The NICE guidance concerns a new procedure to remove kidney tumours. These are usually cancerous tumours, but may sometimes be non-cancerous (benign).

The standard operation to remove a section of kidney containing a tumour is called an open partial nephrectomy. The surgeon carries out the operation through a large opening in the area of the kidney under general anaesthesia. The new operation NICE has looked at is called laparoscopic partial nephrectomy. This procedure is also carried out under general anaesthesia and involves making small 'keyhole' openings, either in the back or in the abdomen. Through these openings, a telescope-like instrument (endoscope) is inserted to look inside the abdomen, and specially designed surgical instruments are inserted to remove the section of kidney that contains the tumour. The surgeon may also use a special ultrasound probe to find the exact location of the tumour. In some cases, the surgeon may create an extra opening so that he or she can fit a hand into the abdomen to help with the operation.

The new procedure may not be suitable for some people with small tumours in the centre of the kidney that are difficult to reach.

How well the procedure works

What the studies said

One study of 200 patients reported that patients who had the laparoscopic procedure stayed in hospital for a shorter time (2 days on average) compared to people who had the standard operation (5 days on average). A second study of 49 patients found a similar pattern (an average of 3 days compared with 6 days). The first of these studies also reported that patients who had a laparoscopic procedure recovered faster than those who had the standard procedure (an average of 4 weeks convalescence time compared to 6 weeks).

The success of the laparoscopic procedure was assessed by looking at the removed portion of kidney under a microscope to see if the edges (or margins) contained any tumour cells. If tumour cells were found in the margins, this meant that not all of the tumour was removed and that further surgery would be needed. In one study, tumour cells were found in the margins in 3% (3 out of 100) of patients who had the laparoscopic procedure, whereas no tumour cells were found in the margins in the 100 patients who had the standard operation. In a second study, the findings were reversed with no tumour cells found in the margins in the 27 patients who had the laparoscopic procedure, whereas tumour cells were found in the margins in 1 patient out of 22 (5%) who had the standard operation. In two studies that followed what happened in people who had the laparoscopic procedure, tumour cells were found in the margins in 1 out of 37 patients in one study, and in 3 out of 100 patients in another study (3% in each study).

The success of the laparoscopic procedure was also assessed by looking at whether the tumour returned. In a study that checked on 100 patients after 15 months, there were no cases of tumour recurrence. Similarly, in a second study that checked on 79 patients after 20 months, there were no cases of tumour recurrence. In a third study, which checked on patients after 38 months, the tumour had returned in 2 out of 48 patients (4%).

What the experts said

The experts said there were concerns about the possibility that cancerous tumours wouldn't be removed completely with the laparoscopic procedure.

Risks and possible problems with the procedure

What the studies said

Six studies reported urine leakage as a problem affecting people who had had the laparoscopic procedure (that is, urine leaked from the remaining part of the kidney). The numbers of patients who were affected ranged from 2 out of 100 patients (2%) in one study to 5 out of 53 patients (9%) in another. Further surgery may be needed if a person has urine leakage.

Three studies reported bleeding (haemorrhage) in patients during or after the laparoscopic procedure. The number of patients who had bleeding during the procedure ranged from 3 out of 100 patients (3%) in one study to 4 out of 53 patients (8%) in another study. The numbers of patients who had bleeding after the procedure in the three studies were 4 out of 200 patients, 2 out of 100 patients and 1 out of 53 patients (about 2% of patients in each study).

Other problems included kidney failure; damage to the bowel, blood vessels, and ureter (the tube that carries urine from the kidney to the bladder); and urinary infection.

What the experts said

The main concerns listed by the experts were bleeding during and after the procedure and urine leakage.

What has NICE decided?

NICE has considered the evidence on laparoscopic partial nephrectomy. It has recommended that when doctors use this procedure for people with kidney tumours, they should be sure that:

- the patient understands what is involved and the risks linked to the procedure, particularly the risk of serious bleeding (haemorrhage)
- the patient agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has also said that surgeons who carry out laparoscopic partial nephrectomy should have been specifically trained to do the operation and should be carrying it out regularly so that they have experience.

Finally, NICE has encouraged surgeons to send information about every patient who has the operation and what happens to them afterwards to a central store of information run by the British Association of Urological Surgeons (www.baus.org.uk) so that the safety of the procedure and how well it works can be checked over time.

Other comments from NICE

The studies NICE looked at were carried out in very specialist units where the staff had a lot of experience of caring for patients who have laparoscopic surgery on the kidney. The surgeons in the studies were very experienced in carrying out this type of surgery.

What the decision means for you

Your doctor may have offered you laparoscopic partial nephrectomy. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS as long as it is carried out by surgeons who are trained and experienced in doing it. Nonetheless, you should understand the benefits and risks of laparoscopic partial nephrectomy before you agree to it. In particular, you should understand that there is a risk of serious bleeding (haemorrhage). Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has also encouraged doctors to collect details about every patient who has this procedure. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have laparoscopic partial nephrectomy, you may be asked to agree to your details being entered into an electronic database for this purpose. A clinician looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be allowed to have the procedure.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on laparoscopic partial nephrectomy that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on kidney cancer on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





**National Institute for
Health and Clinical Excellence**

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk
N0962 1P Jan 06
ISBN 1-84629-133-X