

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedures overview of laparoscopic partial nephrectomy

#### ***Introduction***

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

#### ***Date prepared***

This overview was prepared in April 2005.

#### ***Procedure names***

- Laparoscopic partial nephrectomy.
- Laparoscopic nephron-sparing surgery.

#### ***Specialty societies***

- British Association of Urological Surgeons.
- Association of Laparoscopic Surgeons.

#### ***Description***

##### **Indications**

Indications for laparoscopic partial nephrectomy include a solid renal mass in a patient with a solitary kidney or compromised contralateral kidney, bilateral renal masses, small localised renal tumours in patients with a normal contralateral kidney. Most solid renal masses are renal cell carcinomas but a small proportion are benign tumours, such as oncocytoma.

Some small tumours may not be suitable for treatment by laparoscopic partial nephrectomy because of their position (centrally located lesions are more difficult to remove than peripheral lesions).

##### **Current treatment and alternatives**

The standard treatment for these indications would be an open partial nephrectomy. A flank extraperitoneal or an anterior subcostal incision is used to expose the kidney. The renal artery is identified and isolated using a vessel loop. If the tumour is small, it can be excised with a margin of normal tissue, and bleeding vessels are ligated with sutures. If the tumour is larger, temporary occlusion of the renal artery and hypothermia may be required. Iced saline slush is used to cool the kidney before the tumour is resected along with a margin of normal tissue. After the tumour is removed,

bleeding vessels are ligated with sutures. The renal capsule is closed, the arterial clamp is removed and the kidney is perfused. If extensive resection is required, an indwelling ureteral stent may be inserted intraoperatively or cystoscopically prior to surgery.

### **What the procedure involves**

A laparoscopic partial nephrectomy is performed under general anaesthetic, using a transperitoneal or retroperitoneal approach. In the transperitoneal approach, the abdomen is insufflated with carbon dioxide and three or four small abdominal incisions are made. In the retroperitoneal approach, a small incision is made in the back and a dissecting balloon is inserted to create a retroperitoneal space. After insufflation with carbon dioxide, two or three additional small incisions are made in the back. The renal vessels are identified and either isolated using vessel loops or clamped and the kidney is mobilised to allow exposure of the lesion. A laparoscopic ultrasound probe may be used to determine the line of incision and depth of tumour involvement. Bleeding vessels are sealed or ligated with sutures and the renal capsule is then closed. The specimen is enclosed in a bag and retrieved through an expanded port.

If the renal vessels are clamped during the procedure, the kidney may be cooled by surrounding it in a bag filled with ice slush, or by perfusing cold Ringer's lactate through the renal artery.

Hand-assisted laparoscopic partial nephrectomy allows the surgeon to place one hand in the abdomen while maintaining the pneumoperitoneum required for laparoscopy. A small incision is made that is just large enough for the surgeon's hand and an airtight 'sleeve' device is used to form a seal around the incision.

### **Efficacy**

Two non-randomised comparative studies reported statistically significantly shorter hospital stays for laparoscopic partial nephrectomy than for open partial nephrectomy. One study of 200 patients reported a median hospital stay of 2 days for laparoscopic partial nephrectomy compared with 5 days for open partial nephrectomy ( $p < 0.001$ ). The second study reported a mean hospital stay of 3 days for the laparoscopic procedure compared with 6 days for open surgery ( $p < 0.0002$ ). The first of these studies also reported a significantly shorter median convalescence time for the laparoscopic partial nephrectomy compared with open partial nephrectomy (4 weeks versus 6 weeks,  $p < 0.001$ ).

In one non-randomised comparative study, positive surgical margins were reported after 3% (3/100) of laparoscopic partial nephrectomies compared with 0% (0/100) of open nephrectomies ( $p = 0.1$ ). In a second non-randomised comparative study, positive surgical margins were reported in 0% (0/27) of laparoscopic procedures and 4% (1/22) of open procedures. Two case series reported positive surgical margins in 3% (1/37 and 3/100) of cases.

Three studies reported recurrence rates of 0% (0/100), 0% (0/79) and 4% (2/48) after mean follow-up periods of 15 months, 20 months and 38 months respectively.

The Specialist Advisors noted concern about the possibility of incomplete cancer clearance.

### **Safety**

In two non-randomised comparative studies, postoperative complication rates were 11% (3/27) and 16% (16/100) for laparoscopic partial nephrectomy, compared with 14% (3/22) and 13% (13/100) for open partial nephrectomy. In one of these studies,

intraoperative complications were reported for 5% (5/100) of laparoscopic partial nephrectomies compared with 0% (0/100) of open partial nephrectomies ( $p = 0.03$ ).

Six studies reported urine leakage as a complication, affecting between 2% (2/100) and 10% (5/53) of patients. In three studies, postoperative haemorrhage was reported in 2% (4/200, 2/100 and 1/53) of patients and the rate of intraoperative haemorrhage ranged from 3% (3/100) to 8% (4/53) of patients. Other complications included renal failure, injury to the ureter, bowel and blood vessels, and urinary tract infection.

The main safety concerns listed by the Specialist Advisors were bleeding (intraoperative and postoperative) and urine leak.

## ***Literature review***

### **Rapid review of literature**

The medical literature was searched to identify studies and reviews relevant to laparoscopic partial nephrectomy; the search strategy is described in Appendix A. No language restriction was applied to the searches.

The following selection criteria were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

<b>Characteristic</b>	<b>Criteria</b>
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with renal tumours.
Intervention/test	Laparoscopic partial nephrectomy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### **List of studies included in the overview**

This overview is based on three non-randomised comparative studies and four case series, which are summarised in Table 1. Two non-randomised studies compare laparoscopic partial nephrectomy with open partial nephrectomy.<sup>1,2</sup> One non-randomised study compares laparoscopic partial nephrectomy with laparoscopic radical nephrectomy.<sup>3</sup> Two of the case series include 100 or more patients.<sup>4,5</sup> The remaining two case series include fewer patients but have a longer follow-up period.<sup>6,7</sup>

**Table 1 Summary of key efficacy and safety findings on laparoscopic partial nephrectomy**

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Gill I (2003)<sup>1</sup></p> <p>Non-randomised comparative study (retrospective)</p> <p>Ohio, USA</p> <p>1999–2002</p> <p>200 patients:</p> <ul style="list-style-type: none"> <li>100 laparoscopic partial nephrectomy</li> <li>100 open partial nephrectomy</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>laparoscopic = 65.1</li> <li>open = 58.8</li> </ul> <p>p &lt; 0.001</p> <p>Median tumour size (cm):</p> <ul style="list-style-type: none"> <li>laparoscopic = 2.8</li> <li>open = 3.3</li> </ul> <p>p = 0.005</p> <p>Inclusion criteria: solitary, localised sporadic renal tumour ≤ 7 cm</p> <p>All tumours were clinical stage T1a-b N0 M0-1</p> <p>Follow-up: 30 days</p>	<p>Mean warm ischaemia time (mins):</p> <ul style="list-style-type: none"> <li>laparoscopic = 27.8</li> <li>open = 17.5, p &lt; 0.001</li> </ul> <p>Median estimated blood loss (ml):</p> <ul style="list-style-type: none"> <li>laparoscopic = 125.0</li> <li>open = 250.0, p &lt; 0.001</li> </ul> <p>Median operative time (mins):</p> <ul style="list-style-type: none"> <li>laparoscopic = 180.0</li> <li>open = 231.5, p &lt; 0.001</li> </ul> <p>Median analgesic requirement (mg morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>laparoscopic = 20.2</li> <li>open = 252.5, p &lt; 0.001</li> </ul> <p>Median hospital stay (days):</p> <ul style="list-style-type: none"> <li>laparoscopic = 2.0</li> <li>open = 5.0, p &lt; 0.001</li> </ul> <p>Median convalescence (weeks):</p> <ul style="list-style-type: none"> <li>laparoscopic = 4.0</li> <li>open = 6.0, p &lt; 0.001</li> </ul> <p>Positive surgical margin:</p> <ul style="list-style-type: none"> <li>laparoscopic = 3% (3/100)</li> <li>open = 0% (0/100)</li> </ul> <p>All kidneys functioned postoperatively except one removed for postoperative haemorrhage in laparoscopic group</p> <p>There were no significant differences in serum creatinine levels between the groups</p>	<p><b>Complications</b></p> <p>Total intraoperative complications:</p> <ul style="list-style-type: none"> <li>laparoscopic = 5% (5/100)</li> <li>open = 0% (0/100), p = 0.03</li> </ul> <p>Renal haemorrhage:</p> <ul style="list-style-type: none"> <li>laparoscopic = 3% (3/100)</li> <li>open = 0% (0/100)</li> </ul> <p>Ureteral injury:</p> <ul style="list-style-type: none"> <li>laparoscopic = 1% (1/100)</li> <li>open = 0% (0/100)</li> </ul> <p>Bowel laceration during port closure:</p> <ul style="list-style-type: none"> <li>laparoscopic = 1% (1/100)</li> <li>open = 0% (0/100)</li> </ul> <p>Total postoperative complications:</p> <ul style="list-style-type: none"> <li>laparoscopic = 16% (16/100)</li> <li>open = 13% (13/100), p = 0.55</li> </ul> <p>Urine leakage:</p> <ul style="list-style-type: none"> <li>laparoscopic = 3% (3/100)</li> <li>open = 1% (1/100)</li> </ul> <p>Renal haemorrhage:</p> <ul style="list-style-type: none"> <li>laparoscopic = 2% (2/100)</li> <li>open = 0% (0/100)</li> </ul> <p>[1 patient ultimately required nephrectomy]</p> <p>Perirenal haematoma:</p> <ul style="list-style-type: none"> <li>laparoscopic = 1% (1/100)</li> <li>open = 0% (0/100)</li> </ul> <p>Haematuria:</p> <ul style="list-style-type: none"> <li>laparoscopic = 1% (1/100)</li> <li>open = 0% (0/100)</li> </ul> <p>Ureteropelvic obstruction:</p> <ul style="list-style-type: none"> <li>laparoscopic = 0% (0/100)</li> <li>open = 1% (1/100)</li> </ul>	<p>Same centre as Ramani et al (2005).</p> <p>No randomisation.</p> <p>Comparison of first 100 laparoscopic cases with consecutive contemporary series of 100 open cases.</p> <p>Follow-up data were obtained by telephone contact or patient completed questionnaires.</p> <p>Patients in the laparoscopic group were older and had smaller tumours than patients in the open group.</p> <p>One patient in the laparoscopic group had a previously resected solitary metastasis and no evidence of disease other than the primary renal tumour.</p> <p>Ice slush was used to cool the kidney in one patient in the laparoscopic group and four patients in the open group. The rates of vascular clamping were similar in the two groups.</p> <p>Intraoperative ultrasound was used in 76% of laparoscopic cases and 15% of open cases.</p> <p>Histopathology confirmed the diagnosis of renal cell carcinoma in 70 laparoscopic and 85 open cases. The rest were benign.</p>

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Beasley K (2004)<sup>2</sup></p> <p>Non-randomised comparative study (retrospective)</p> <p>Canada</p> <p>1999–2003</p> <p>49 patients:</p> <ul style="list-style-type: none"> <li>• 27 laparoscopic partial nephrectomy</li> <li>• 22 open partial nephrectomy</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 53.5</li> <li>• open = 51.1</li> </ul> <p>Mean tumour size (cm):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 2.4</li> <li>• open = 2.9</li> </ul> <p>Inclusion criteria: renal tumours ≤ 4 cm</p> <p>Indications: renal cell carcinoma, complex cyst, other benign tumours</p> <p>Mean follow-up period not stated</p>	<p>Mean warm ischaemia time (mins):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 41</li> <li>• open = 28, p = not significant</li> </ul> <p>Mean blood loss (ml):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 250</li> <li>• open = 334, p = not significant</li> </ul> <p>Mean operative time (mins):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 210</li> <li>• open = 144, p &lt; 0.001</li> </ul> <p>Mean analgesic requirement (mg morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 43</li> <li>• open = 187, p &lt; 0.001</li> </ul> <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 2.9</li> <li>• open = 6.4, p &lt; 0.0002</li> </ul> <p>Positive surgical margin:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 0% (0/27)</li> <li>• open = 4.5% (1/22)</li> </ul> <p>Postoperative serum creatinine (mg/dl):</p> <ul style="list-style-type: none"> <li>• laparoscopic = 1.1</li> <li>• open = 1.1, p = not significant</li> </ul>	<p><b>Complications</b></p> <p>Total postoperative complications:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 11% (3/27)</li> <li>• open = 14% (3/22)</li> </ul> <p>p = not significant</p> <p>Pulmonary embolism:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 3.7% (1/27)</li> <li>• open = 0% (0/22)</li> </ul> <p>Urinary tract infection:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 3.7% (1/27)</li> <li>• open = 0% (0/22)</li> </ul> <p>Urine leak:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 3.7% (1/27)</li> <li>• open = 4.5% (1/22)</li> </ul> <p>Acute renal failure:</p> <ul style="list-style-type: none"> <li>• laparoscopic = 0% (0/27)</li> <li>• open = 4.5% (1/22)</li> </ul>	<p>No randomisation.</p> <p>Cases and controls were matched by tumour size.</p> <p>There were no significant differences in age, ASA scores or body mass index between the two groups.</p> <p>Intraoperative ultrasound was used in 15 laparoscopic cases.</p> <p>The renal artery and vein were clamped in cases associated with central masses and heminephrectomy procedures. Renal hypothermia was not used.</p> <p>The rates of vascular clamping were similar in the two groups.</p>

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Kim F (2003)<sup>3</sup></p> <p>Non-randomised comparative study (retrospective)</p> <p>Maryland, USA</p> <p>1998–2002</p> <p>114 patients:</p> <ul style="list-style-type: none"> <li>79 laparoscopic partial nephrectomy</li> <li>35 laparoscopic radical nephrectomy</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>partial nephrectomy = 58.3 (range 32 to 82)</li> <li>radical nephrectomy = 57.5 (range 37 to 86)</li> </ul> <p>Mean tumour size (cm):</p> <ul style="list-style-type: none"> <li>partial nephrectomy = 2.5 (range 1.0 to 4.5)</li> <li>radical nephrectomy = 2.8 (range 0.9 to 4.5)</li> </ul> <p>Inclusion criteria: single, localised unilateral sporadic renal tumour size &lt; 4.5 cm and normal contralateral kidney.</p> <p>Mean follow-up (months):</p> <ul style="list-style-type: none"> <li>partial nephrectomy = 19.8 (range 7 to 53)</li> <li>radical nephrectomy = 18.6 (range 8 to 54)</li> </ul>	<p>Mean estimated blood loss (ml):</p> <ul style="list-style-type: none"> <li>partial = 391.2 (range 50 to 1500)</li> <li>radical = 372.4 (range 50 to 1900) p = 0.42</li> </ul> <p>Mean operative time (mins):</p> <ul style="list-style-type: none"> <li>partial = 181.9 (range 67 to 370)</li> <li>radical = 166.9 (range 85 to 329), p = 0.12</li> </ul> <p>Mean analgesic requirement (mg morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>partial = 7.6 (range 0.2 to 46.2)</li> <li>radical = 9.0 (range 0.8 to 27.8), p = 0.30</li> </ul> <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> <li>partial = 2.8 (range 1 to 6)</li> <li>radical = 3.2 (range 1 to 9), p = 0.14</li> </ul> <p>Positive surgical margin:</p> <ul style="list-style-type: none"> <li>partial = 3.4% (2/59)</li> <li>radical = 0% (0/29)</li> </ul> <p>Mean postoperative serum creatinine (mg/dl) :</p> <ul style="list-style-type: none"> <li>partial = 1.03 (range 0.4 to 2.7)</li> <li>radical = 1.51 (range 0.9 to 2.4), p = 0.02</li> </ul> <p>No patient had local or port site recurrence, or metastatic disease</p>	<p><b>Complications</b></p> <p>Conversions to open surgery:</p> <ul style="list-style-type: none"> <li>partial = 1.3% (1/79)</li> <li>radical = 2.9% (1/35)</li> </ul> <p>Bleeding requiring transfusion:</p> <ul style="list-style-type: none"> <li>partial = 5.1% (4/79)</li> <li>radical = 5.7% (2/35)</li> </ul> <p>Injury to mesentery, liver, serosa, lumbar vein or splenic capsule:</p> <ul style="list-style-type: none"> <li>partial = 2.5% (2/79)</li> <li>radical = 11.4% (4/35)</li> </ul> <p>Ureteral injury:</p> <ul style="list-style-type: none"> <li>partial = 1% (1/79)</li> <li>radical = 0% (0/35)</li> </ul> <p>Urine leakage:</p> <ul style="list-style-type: none"> <li>partial = 2.5% (2/79)</li> <li>radical = 0% (0/35)</li> </ul> <p>Acute renal failure:</p> <ul style="list-style-type: none"> <li>partial = 1% (1/79)</li> <li>radical = 0% (0/35)</li> </ul> <p>Ileus:</p> <ul style="list-style-type: none"> <li>partial = 0% (0/79)</li> <li>radical = 5.7% (2/35)</li> </ul> <p>Atelectasis:</p> <ul style="list-style-type: none"> <li>partial = 1% (1/79)</li> <li>radical = 0% (0/35)</li> </ul> <p>Foley catheter clot:</p> <ul style="list-style-type: none"> <li>partial = 1% (1/79)</li> <li>radical = 0% (0/35)</li> </ul> <p>Wound infection:</p> <ul style="list-style-type: none"> <li>partial = 0% (0/79)</li> <li>radical = 2.9% (1/35)</li> </ul> <p>Pleural effusion:</p> <ul style="list-style-type: none"> <li>partial = 0% (0/79)</li> <li>radical = 2.9% (1/35)</li> </ul>	<p>Same study centre as Allaf et al (2004).</p> <p>No randomisation.</p> <p>The procedure was chosen according to surgeon and patient preference.</p> <p>There were no significant differences between the two groups in terms of age, ASA grade, body mass index or tumour size.</p> <p>75% (59/79) of tumours in partial nephrectomy group were diagnosed as renal cell carcinoma (56 stage pT1 and 3 stage pT3). 83% (29/35) of tumours in radical nephrectomy group were diagnosed as renal cell carcinoma (23 stage pT1, 4 stage pT2 and 2 stage pT3).</p> <p>Renal artery and vein were clamped in 66% (52/79) of partial nephrectomy cases. Ureteral catheterisation was performed in 70% (55/79) of cases.</p>

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Ramani A (2005)<sup>4</sup></p> <p>Case series</p> <p>Ohio, USA</p> <p>1999 onwards</p> <p>200 patients</p> <p>Mean age = 61.6 years (range 17 to 87)</p> <p>Mean tumour size = 2.9 cm (range 1 to 10)</p> <p>Indications: solitary renal tumour</p>	<p>Mean ischaemia time (mins) = 28.7</p> <p>Mean blood loss (ml) = 247 (range 25 to 1500)</p> <p>Mean operative time (mins) = 199</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Total perioperative complications = 33% (66/200)</li> <li>• Conversions to open surgery = 1% (2/200)</li> <li>• Reoperation = 2% (4/200)</li> <li>• Intraoperative haemorrhage = 3.5% (7/200)</li> <li>• Postoperative haemorrhage = 2% (4/200)</li> <li>• Delayed haemorrhage (after discharge) = 4% (8/200)</li> <li>• Transfusion required = 9% (18/200)</li> <li>• Urinary leakage = 4.5% (9/200)</li> <li>• Transient renal insufficiency = 2% (4/200)</li> <li>• Inferior epigastric artery injury = 0.5% (1/200)</li> <li>• Epididymitis = 0.5% (1/200)</li> <li>• Transient haematuria = 0.5% (1/200)</li> <li>• Ureteral injury = 0.5% (1/200)</li> <li>• Pulmonary complications = 5% (10/200)</li> <li>• Cardiovascular complications = 4.5% (9/200)</li> <li>• Gastrointestinal complications = 2% (4/200)</li> <li>• Sepsis = 1% (2/200)</li> <li>• Wound infection = 2% (4/200)</li> <li>• Gluteal fasciotomy = 0.5% (1/200)</li> </ul>	<p>Same study centre as Gill et al (2003).</p> <p>Consecutive patients.</p> <p>Intraoperative data were prospectively entered into a database. Postoperative data were collected by personal or telephone interviews with the patient and/or referring physician.</p> <p>Renal vessels were clamped and intraoperative ultrasound was used for all cases.</p> <p>Haemorrhage was defined as bleeding requiring transfusion or therapeutic intervention.</p> <p>Urine leakage was defined as urinary extravasation requiring therapeutic intervention or that identified radiographically on 1-month postoperative excretory urogram.</p>

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Johnston W (2005)<sup>5</sup></p> <p>Case series</p> <p>Michigan, USA</p> <p>100 cases</p> <p>Mean tumour size = 2.5 cm</p> <p>Mean follow-up = 15 months</p>	<p>Mean warm ischaemia time = 26 minutes.</p> <p>Positive surgical margins = 3% (3/100)</p> <p>Recurrences = 0% (0/100)</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Urinary leakage = 2% (2/100)</li> <li>• Haemorrhage = 9% (9/100)</li> </ul>	<p>Consecutive cases.</p> <p>Review of first 100 laparoscopic partial nephrectomies performed.</p> <p>Renal hilar clamping was used in 43% (43/100) of procedures.</p> <p>A sutureless approach was used for first 74 cases. In the last 25 cases, the collecting system and renal sinus were usually sutured.</p>
<p>Rassweiler J (2000)<sup>6</sup></p> <p>Case series</p> <p>Germany, France, Austria</p> <p>1994 onwards</p> <p>53 cases</p> <p>Mean age = 61.5 years (range 39 to 80)</p> <p>Mean tumour size = 2.3 cm (range 1.1 to 5)</p> <p>Median follow-up = 24 months (range 6 to 36)</p>	<p>Mean operative time = 190.9 minutes (range 90 to 320)</p> <p>Mean estimated blood loss = 725 ml (range 20 to 1500)</p> <p>Mean hospital stay = 5.4 days (range 3 to 28)</p> <p>Regional relapse at follow-up = 0% (0/53)</p> <p>Distant metastases at follow-up = 0% (0/53)</p> <p>Cumulative overall disease-free survival rate after 3 years for patients with renal cell carcinoma = 100% (37/37)</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Conversions to open surgery = 8% (4/53)</li> <li>• Intraoperative bleeding = 8% (4/53)</li> <li>• Postoperative bleeding = 2% (1/53)</li> <li>• Urinary leakage = 10% (5/53)</li> <li>• Reintervention = 12% (6/53)</li> </ul> <p>[2 percutaneous drainage, 1 indwelling stent, 2 open revisions, 1 nephrectomy]</p>	<p>Includes patients from four centres – technique was not standardised.</p> <p>Transperitoneal or retroperitoneal approach was used, according to surgeon preference.</p> <p>Final histology showed 70% (37/53) stage T1 renal cell carcinoma, 28% (15/53) benign tumours and 2% (1/53) malignant lymphoma.</p> <p>The authors state that this procedure is technically difficult and should be performed in centres with expertise.</p>

Abbreviations used: ASA = American Society of Anaesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Allaf M (2004)<sup>7</sup></p> <p>Case series</p> <p>Maryland, USA</p> <p>1996–2001</p> <p>48 patients</p> <p>Mean age = 59.7 years (range 32 to 81)</p> <p>Mean tumour size = 2.4 cm (range 1.0 to 4.0)</p> <p>Indications: renal cell carcinoma</p> <p>88% (42/48) stage pT1, 12% (6/48) stage pT3a</p> <p>Mean follow-up = 37.7 months (range 22 to 84)</p>	<p>Positive surgical margin = 2.7% (1/37)</p> <p>Recurrence at follow-up = 4.2% (2/48)</p> <p>(One recurrence was in a patient with von Hippel-Lindau disease rather than sporadic renal cell carcinoma and the report states that it is unclear if the recurrence represents de novo cancer or a previously undetected neoplasm. The other recurrence occurred approximately 4 years postoperatively).</p>	<p><b>Complications</b></p> <p>Not reported.</p>	<p>Same centre as Kim et al (2003).</p> <p>Retrospective review of cases.</p> <p>Preoperative cystoscopy and stent placement were performed at the discretion of the surgeon.</p> <p>Intraoperative ultrasound was used to define tumour extent.</p> <p>Artery and vein were occluded of just isolated, according to surgeon preference.</p> <p>23% (11/48) of specimens were morcellated. The decision to morcellate was made preoperatively, based on patient preference. The margin status of these cases could not be assessed.</p>

## **Validity and generalisability of the studies**

- Several study centres have published a number of articles and it is difficult to ascertain the number of patients that have been reported on more than once.
- There are several variations of the technique, including the use of hypothermia, vascular clamping and intraoperative ultrasound. The methods used varied within and between the studies.
- None of the studies included a randomised control group.
- Three studies reported a very short or no follow-up period.<sup>1,2,4</sup>
- In one non-randomised comparative study, patients in the laparoscopic group were statistically significantly older than those in the open surgery group and had significantly smaller tumours.<sup>1</sup>
- Two studies stated that they included the initial series of patients to be treated with laparoscopic partial nephrectomy.<sup>1,5</sup>

## ***Specialist advisors' opinions***

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.*

- Laparoscopic partial nephrectomy is definitely novel and of uncertain safety and efficacy.
- The appropriate comparator is open partial nephrectomy.
- The potential impact of this procedure on the NHS, in terms of patients eligible for treatment and use of resources is minor to moderate.
- Training and experience in laparoscopic nephrectomy are important.

## ***Issues for consideration by IPAC***

IPAC has previously issued guidance on laparoscopic live donor simple nephrectomy (IPG0057) and has recently considered laparoscopic nephrectomy (in progress).

NICE has published Urological Cancer Service guidance, which states that "Patients with small tumours for whom nephron-sparing surgery may be possible, should be discussed with a surgeon from a specialist multidisciplinary team. Referral to a specialist cancer centre is likely to be appropriate for these patients." ([www.nice.org.uk/pdf/Urological\\_Manual.pdf](http://www.nice.org.uk/pdf/Urological_Manual.pdf))

## References

- 1 Gill IS, Matin SF, Desai MM, et al. Comparative analysis of laparoscopic versus open partial nephrectomy for renal tumors in 200 patients. *Journal of Urology* 2003; 170: 64–8.
- 2 Beasley KA, Omar MA, Shaikh A, et al. Laparoscopic versus open partial nephrectomy. *Urology* 2004; 64: 458–61.
- 3 Kim FJ, Rha KH, Hernandez F, et al. Laparoscopic radical versus partial nephrectomy: assessment of complications. *Journal of Urology* 2003; 170: 408–11.
- 4 Ramani AP, Desai MM, Steinberg AP, et al. Complications of laparoscopic partial nephrectomy in 200 cases. *Journal of Urology* 2005; 173: 42–7.
- 5 Johnston WK, Wolf JS. Laparoscopic partial nephrectomy: technique, oncologic efficacy, and safety. *Current Urology Reports* 2005; 6: 19–28.
- 6 Rassweiler JJ, Abbou C, Janetschek G, et al. Laparoscopic partial nephrectomy. *Urologic Clinics of North America* 2000; 27: 721–36.
- 7 Allaf ME, Bhayani SB, Rogers C, et al. Laparoscopic partial nephrectomy: evaluation of long-term oncological outcome. *Journal of Urology* 2004; 172: 871–3.

## Appendix A: Literature search for laparoscopic partial nephrectomy

Database	Version searched (if applicable)	Date searched
Cochrane Library	2005 Issue 1	7/03/2005
CRD Databases		7/03/2005
Embase	1980 to 2005 Week 10	7/03/2005
Medline	1966 to February Week 4 2005	7/03/2005
Premedline	MEDLINE(R) In-Process & Other Non-Indexed Citations March 04, 2005	7/03/2005
CINAHL		7/03/2005
British Library Inside Conferences (limited to current year only)		7/03/2005
National Research Register	2005 Issue 1	7/03/2005
Controlled Trials Registry		7/03/2005

### Search strategy used in Medline

1. laparoscopy/
2. laparoscop\$.tw.
3. 1 or 2
4. nephrectomy/
5. nephrectom\$.tw.
6. nephroureterectom\$.tw.
7. or/4-6
8. 3 and 7
9. partial.tw.
10. (nephron\$ adj3 sparing).tw.
11. 9 or 10
12. 8 and 11
13. kidney neoplasms/
14. (renal adj3 cancer\$.tw.
15. (renal adj3 neoplasm\$.tw.
16. carcinoma, renal cell/
17. solid renal mass\$.tw.
18. (renal adj3 tumo?r).tw.
19. or/13-18
20. 12 and 19
21. limit 20 to humans

## Appendix B: Additional papers on laparoscopic partial nephrectomy not included in the summary tables

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Bermudez H, Guillonneau B, Gupta R, et al. Initial experience in laparoscopic partial nephrectomy for renal tumor with clamping of renal vessels. <i>Journal of Endourology</i> 2003; 17: 373–8.	19 patients. Median follow-up = 3 months.	Case series. Clamping and renal cooling were used.	10.5% (2/19) transfusion Mean operating time reduced with increasing experience.
Bhayani S, Rha K, Pinto P. et al. Laparoscopic partial nephrectomy: effect of warm ischaemia on serum creatinine. <i>Journal of Urology</i> 2004; 172: 1264–6.	118 patients. Median follow-up = 28 months.	Non randomised comparison of no renal occlusion versus < 30 minutes warm ischaemia time versus > 30 minutes warm ischaemia time.	Warm ischaemia time did not significantly influence long-term renal function as measured by serum creatinine levels.
Bove P, Bhayani S, Rha K, et al. Necessity of ureteral catheter during laparoscopic partial nephrectomy. <i>Journal of Urology</i> 2004; 172: 458–60.	103 patients. Mean follow-up = 20 months.	Retrospective study, comparing patients with and without an external ureteral catheter.	No open conversions. Urinary leakage detected in 3% (1/33) of patients with a catheter and 4% (1/26) of patients without a catheter.
Brown J, Hubosky S, Gomella L, et al. Hand assisted laparoscopic partial nephrectomy for peripheral and central lesions: a review of 30 consecutive cases. <i>Journal of Urology</i> 2004; 171: 1443–6.	30 patients. Mean follow-up = 9 months.	Case series. Hand-assisted technique.	3% (1/30) urine leakage 7% (2/30) intraoperative haemorrhage 3% (1/30) delayed haemorrhage 20% (6/30) transfusion 3% (1/30) re-intervention No short-term local recurrences.
Desai M, Gill I, Kaouk J, et al. Laparoscopic partial nephrectomy with suture repair of the pelvicaliceal system. <i>Urology</i> 2003; 61: 99–104.	64 patients.	Non randomised comparison of cases requiring and not requiring caliceal repair.	No open conversions. No significant differences in mean postoperative serum creatinine between 2 groups.
Guillonneau B, Bermudez H, Gholami S, et al. Laparoscopic partial nephrectomy for renal tumor: single center experience comparing clamping and no clamping techniques of the renal vasculature. <i>Journal of Urology</i> 2003; 169: 483–6.	28 patients. 1 month follow-up.	Case series. 12 patients underwent surgery without renal vasculature control, 16 patients had surgery with renal pedicle clamping and renal cooling.	Clamping the renal vessels was associated with less blood loss and shorter operative time.
Jeschke K, Peschel R, Wakonig J, et al. Laparoscopic nephron-sparing surgery for renal tumors. <i>Urology</i> 2001; 58: 688–92.	51 patients. Mean follow-up = 34 months.	Case series.	No open conversions. Urinary leakage = 6% (3/51) Bleeding = 2% (1/51) No distant or local recurrences seen by last follow-up date.
Kane C, Mitchell J, Meng M, et al. Laparoscopic partial nephrectomy with temporary arterial occlusion: description of technique and renal functional outcomes. <i>Urology</i> 2004; 63: 241–6.	27 patients.	Case series. Hand assisted technique. Renal artery was occluded in 15 cases.	Temporary arterial occlusion did not affect short-term renal function adversely.
Orvieto M, Chien G, Laven B, et al. Eliminating knot tying during warm ischemia time for laparoscopic partial nephrectomy. <i>Journal of Urology</i> 2004; 172: 2292–5.	32 patients. Mean follow-up = 5 months.	Case series. Clips used instead of knot tying.	No postoperative bleeding or urine leaks. Conversions = 6% (2/32)

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Robinson B, Snow B, Cartwright P, et al. Comparison of laparoscopic versus open partial nephrectomy in a pediatric series. <i>Journal of Urology</i> 2003; 169: 638–40.	22 patients (all children).	Non randomised comparison of open versus laparoscopic approach. Heminephroureterectomy was performed in 15 cases. Main indications were ectopic ureter and ureterocele.	Laparoscopic surgery took significantly longer to perform. Patients in laparoscopic group required significantly less analgesia than those in the open group.
Seifman B, Hollenbeck B, Wolf S. Laparoscopic nephron-sparing surgery for a renal mass: 1-year minimum follow-up. <i>Journal of Endourology</i> 2004; 18: 783–6.	40 patients. Mean follow-up = 24 months.	Case series.	No recurrences on follow-up. 3% (1/40) haemorrhage 3% (1/40) urinary fistula