

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedures overview of laparoscopic nephrectomy (including nephroureterectomy)

#### ***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 October 2004 and updated in March 2005.

#### ***Procedure name***

- Laparoscopic nephrectomy (including laparoscopic radical nephrectomy, laparoscopic simple nephrectomy, laparoscopic radical nephroureterectomy).

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

- British Renal Society.
- The Renal Association.
- British Association of Urological Surgeons.
- British Transplantation Society.

#### ***Description***

##### **Indications**

Indications for nephrectomy (including nephroureterectomy) include renal cell cancer, upper urinary tract urothelial cancer (transitional cell carcinoma) and benign conditions that lead to poor functioning or non-functioning of the kidney. These benign conditions may be due to or associated with symptomatic hydronephrosis, chronic infection, polycystic kidney disease, dysplastic kidney, hypertension and renal calculus. The most common type of kidney cancer is renal cell cancer. Other types include Wilm's tumour (a childhood cancer).

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

The standard treatment for an irreversibly damaged kidney or localised kidney cancer is an open nephrectomy. Under general anaesthesia, the kidney is removed through a large incision that may be made in the side of the body, in the front of the abdomen or in the back. A simple nephrectomy is the removal of just the kidney whereas a radical nephrectomy also involves the removal of the adrenal gland and sometimes the lymph nodes. A nephroureterectomy involves removal of the ureter and bladder

cuff along with the kidney and is used to treat transitional cell carcinoma of the upper urinary tract.

### **What the procedure involves**

A laparoscopic nephrectomy is performed under general anaesthetic. A transperitoneal or retroperitoneal approach may be used. 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 the balloon is removed, the space is insufflated with carbon dioxide and two or three additional small incisions are made in the back. These small incisions provide access for surgical instruments that are used to detach the kidney and to ligate the blood vessels. The intact kidney is enclosed in a bag and removed through one of the incisions, which is made slightly larger to accommodate it. Alternatively, the kidney may be placed in an impermeable sack, morcellated and removed through one of the port sites. The ureter and bladder cuff may also be excised and removed along with the kidney.

Hand-assisted laparoscopic nephrectomy allows the surgeon to place one hand in the abdomen while maintaining the pneumoperitoneum required for laparoscopy. A small incision is made which is just large enough for the surgeon's hand and an airtight 'sleeve' device is used to form a seal around the incision. At the end of the procedure, the intact kidney can be removed through the same incision.

### **Efficacy**

The main outcome measure for patients with renal tumours was disease-free survival rate. One non-randomised comparative study reported that there was no statistically significant difference in the estimated 5-year disease-free survival rate for laparoscopic and open nephrectomy (95.5% versus 97.5%). A case series of 157 patients with renal cell carcinoma reported an estimated 5-year survival rate of 91%.

Two non-randomised comparative studies, including 209 patients with upper urinary tract transitional cell carcinoma, reported no difference in recurrence rates between laparoscopic and open nephroureterectomy.

Four non-randomised comparative studies reported on analgesia and they all found that significantly less analgesia was required after laparoscopic nephrectomy than after open surgery. The mean hospital stay ranged from 5.2 to 12.6 days for open surgery, compared with 3.4 days and 9.3 days for laparoscopic surgery ( $p < 0.001$ ). The convalescence period was also significantly shorter for laparoscopic surgery; in three studies, the mean convalescence period was 19, 23 and 25 days for laparoscopic surgery and 25, 57 and 57 days for open surgery respectively ( $p < 0.001$ ).

The Specialist Advisors did not express any concerns about the efficacy of this procedure when it is performed by trained operators but they noted that there was a lack of randomised controlled trials.

### **Safety**

Two non-randomised comparative studies reported that the rate of complications for laparoscopic nephrectomy was not statistically significantly different to open nephrectomy. The complications reported in a large case series of 482 procedures (461 patients) included bleeding in 4.6% (22/481), re-intervention in 3.1% (15/481), bowel injury in 0.6% (3/481), hypercarbia in 0.4% (2/481), pulmonary embolism in 0.2% (1/481) and pleural lesion in 0.2% (1/481). Other complications reported in the

studies included ileus, urinary tract infection and injury to the arteries, spleen and adrenal gland. Two studies reported mortality rates of 0.7% (2/263) and 1.3% (2/157).

Seven studies reported the rate of conversion to open surgery, which ranged from 1.7% (1/60) to 12% (3/25) of procedures.

The Specialist Advisors stated that potential adverse events included major haemorrhage from renal vessels, bowel injury and the need for conversion to open surgery.

## **Literature review**

### **Rapid review of literature**

The medical literature was searched to identify studies and reviews relevant to laparoscopic nephrectomy. Searches were conducted via the following databases, covering the period from their commencement to February 2005: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. 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

### **Inclusion criteria for identification of relevant studies**

<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 or urethral cancer or non-functioning kidney.
Intervention/test	Laparoscopic 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 five non-randomised comparative studies and three case series. One non-randomised comparative study includes patients with benign kidney disease only.<sup>1</sup> Two non-randomised comparative study includes patients with upper urinary tract transitional cell carcinoma.<sup>2,3</sup> Two non-randomised comparative studies include patients with renal tumours only.<sup>4,5</sup> Two case series include patients with either benign or malignant disease, including one from a recent UK national audit, and one includes patients with renal cell carcinoma only.<sup>6,7,8</sup> These eight studies are summarised in Table 1.

Studies that were considered relevant to this overview but that have not been summarised in the table are listed in Appendix A.

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

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Fornara P (2001)<sup>1</sup></p> <p>Non randomised comparative study</p> <p>1993–1997</p> <p>Germany</p> <p>249 patients:</p> <ul style="list-style-type: none"> <li>• 47% (118/249) open nephrectomy</li> <li>• 53% (131/249) laparoscopic nephrectomy</li> </ul> <p>Median age:</p> <ul style="list-style-type: none"> <li>• open nephrectomy = 58.5 years (range 8 to 89)</li> <li>• laparoscopic nephrectomy = 40 years (range 16 to 73)</li> </ul> <p>Indications: shrunken kidneys (n = 171), hydronephrosis (n = 69), other (n = 9)</p> <p>Exclusion criteria: suspected renal tumour, laparoscopic unilateral nephroureterectomy, laparoscopic bilateral nephrectomy</p> <p>Follow-up: 5 years</p>	<p>Median operative time (minutes):</p> <ul style="list-style-type: none"> <li>• open = 90 (range 30 to 240)</li> <li>• laparoscopic = 90 (range 41 to 210)</li> </ul> <p>p = 0.361</p> <p>Median analgesic consumption (milligrams morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>• open = 20 (range 1.5 to 75)</li> <li>• laparoscopic = 12 (range 0 to 43)</li> </ul> <p>p &lt; 0.001</p> <p>Median hospital stay (days):</p> <ul style="list-style-type: none"> <li>• open = 10 (range 2 to 79)</li> <li>• laparoscopic = 4 (range 2 to 46)</li> </ul> <p>p &lt; 0.001</p> <p>Median convalescence (days):</p> <ul style="list-style-type: none"> <li>• open = 36 (range 10 to 166)</li> <li>• laparoscopic = 24 (range 8 to 144)</li> </ul> <p>p &lt; 0.001</p>	<p><b>Complications</b></p> <p>All complications:</p> <ul style="list-style-type: none"> <li>• open = 25.4% (30/118)</li> <li>• laparoscopic = 20.6% (27/131)</li> </ul> <p>p = 0.45</p> <p>Haematoma:</p> <ul style="list-style-type: none"> <li>• open = 5.1% (6/118)</li> <li>• laparoscopic = 6.1% (8/131)</li> </ul> <p>Wound-related:</p> <ul style="list-style-type: none"> <li>• open = 6.8% (8/118)</li> <li>• laparoscopic = 3.0% (4/131)</li> </ul> <p>Gastrointestinal system:</p> <ul style="list-style-type: none"> <li>• open = 4.2% (5/118)</li> <li>• laparoscopic = 1.5% (2/131)</li> </ul> <p>Cardiovascular system:</p> <ul style="list-style-type: none"> <li>• open = 2.5% (3/118)</li> <li>• laparoscopic = 2.3% (3/131)</li> </ul> <p>Pulmonary system:</p> <ul style="list-style-type: none"> <li>• open = 4.2% (5/118)</li> <li>• laparoscopic = 2.3% (3/131)</li> </ul> <p>Blood transfusion required:</p> <ul style="list-style-type: none"> <li>• open = 18.6% (22/118)</li> <li>• laparoscopic = 9.9% (13/131)</li> </ul> <p>p &lt; 0.001</p> <p>Conversions to open surgery = 6.1% (8/131)</p>	<p>Retrospective comparison.</p> <p>The decision to perform open or laparoscopic nephrectomy depended on patient and surgeon preference.</p> <p>Laparoscopic nephrectomy was performed via a transperitoneal approach in 89% (117/131) of patients and a retroperitoneal approach in 11% (14/131).</p> <p>Age stratification did not reveal any differences regarding complication rate, analgesic consumption, hospital stay and convalescence.</p>

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Hsueh T (2004)<sup>2</sup></p> <p>Non randomised comparative study</p> <p>1998–2003</p> <p>Taiwan</p> <p>145 patients:</p> <ul style="list-style-type: none"> <li>• 60% (87/145) open nephroureterectomy</li> <li>• 40% (58/145) laparoscopic nephroureterectomy</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• open nephroureterectomy = 67 (range 44 to 83)</li> <li>• laparoscopic nephroureterectomy = 68 (range 42 to 86)</li> </ul> <p>Indications: upper urinary tract transitional cell carcinoma</p> <p>Mean follow-up (months):</p> <ul style="list-style-type: none"> <li>• open nephroureterectomy = 35 (range 2 to 64)</li> <li>• laparoscopic nephroureterectomy = 16 (range 2 to 64)</li> </ul>	<p>Mean operative time (minutes):</p> <ul style="list-style-type: none"> <li>• open = 230 (range 125 to 535)</li> <li>• laparoscopic = 259 (range 75 to 505), p = 0.006</li> </ul> <p>Mean postoperative analgesia (mg morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>• open = 34.5 (range 5 to 129)</li> <li>• laparoscopic = 26.4 (range 5 to 148), p = 0.03</li> </ul> <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> <li>• open = 12.6 (range 7 to 34)</li> <li>• laparoscopic = 9.3 (range 4 to 20), p &lt; 0.001</li> </ul> <p>Mean convalescence (days):</p> <ul style="list-style-type: none"> <li>• open = 25.0 (range 15 to 50)</li> <li>• laparoscopic = 19.0 (range 11 to 30), p &lt; 0.001</li> </ul> <p>Bladder recurrence during follow-up:</p> <ul style="list-style-type: none"> <li>• open = 9% (8/87)</li> <li>• laparoscopic = 9% (5/58), p = 0.23</li> </ul> <p>Local recurrence during follow-up:</p> <ul style="list-style-type: none"> <li>• open = 3% (2/87)</li> <li>• laparoscopic = 0% (0/58), p = 0.35</li> </ul> <p>Systemic metastasis during follow-up:</p> <ul style="list-style-type: none"> <li>• open = 8% (7/87)</li> <li>• laparoscopic = 10% (6/58), p = 0.20</li> </ul>	<p>Ileus:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/87)</li> <li>• laparoscopic = 1.7% (1/58)</li> </ul> <p>Port-site metastasis 1 year after procedure:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/87)</li> <li>• laparoscopic = 1.7% (1/58)</li> </ul> <p>(patient had concomitant muscle-invasive bladder transitional cell carcinoma)</p> <p>Pleural effusion:</p> <ul style="list-style-type: none"> <li>• open = 1.1% (1/87)</li> <li>• laparoscopic = 0% (0/58)</li> </ul> <p>Mean blood loss (l):</p> <ul style="list-style-type: none"> <li>• open = 0.75 (range 0.5 to 4.0)</li> <li>• laparoscopic = 0.41 (range 0.1 to 10.0), p &lt; 0.001</li> </ul> <p>Mean blood transfusion (unit):</p> <ul style="list-style-type: none"> <li>• open = 2.2 (range 0 to 16)</li> <li>• laparoscopic = 1.6 (range 0 to 6)</li> </ul> <p>p = 0.813</p>	<p>Retrospective comparison</p> <p>Laparoscopic procedure was hand-assisted and used a retroperitoneal approach. The distal ureter and bladder cuff were excised using the traditional open method.</p> <p>A bag was not used to retrieve the specimen.</p> <p>Tumour stage and grade was similar in both groups.</p> <p>The mean follow-up period was longer for the open surgery group than for the laparoscopic group.</p>

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Bariol S (2004)<sup>3</sup></p> <p>Non randomised comparative study</p> <p>1992–1999</p> <p>UK</p> <p>64 patients:</p> <ul style="list-style-type: none"> <li>• 61% (39/64) open nephroureterectomy</li> <li>• 39% (25/64) laparoscopic nephroureterectomy</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• open nephroureterectomy = 69 (range 43 to 88)</li> <li>• laparoscopic nephroureterectomy = 70 (range 42 to 92)</li> </ul> <p>Indications: suspected upper tract transitional cell carcinoma</p> <p>Median follow-up (months):</p> <ul style="list-style-type: none"> <li>• open nephroureterectomy = 96 (range 46 to 136)</li> <li>• laparoscopic nephroureterectomy = 100 (range 41 to 138)</li> </ul>	<p>Incomplete ureterectomy:</p> <ul style="list-style-type: none"> <li>• open = 5% (2/39)</li> <li>• laparoscopic = 4% (1/25)</li> </ul> <p>Local recurrence:</p> <ul style="list-style-type: none"> <li>• open = 15% (6/39)</li> <li>• laparoscopic = 4% (1/25), p = 0.32</li> </ul> <p>Recurrence in contralateral kidney or ureter:</p> <ul style="list-style-type: none"> <li>• open = 3% (1/39)</li> <li>• laparoscopic = 8% (2/25), p = 0.34</li> </ul> <p>Bladder recurrence:</p> <ul style="list-style-type: none"> <li>• open = 42% (15/36)</li> <li>• laparoscopic = 28% (7/25), p = 0.21</li> </ul> <p>There were no port site or wound recurrences.</p> <p>Metastatic disease:</p> <ul style="list-style-type: none"> <li>• open = 18% (7/39)</li> <li>• laparoscopic = 28% (7/25), p = 0.26</li> </ul> <p>1 year metastatic-free survival rate:</p> <ul style="list-style-type: none"> <li>• open = 87%</li> <li>• laparoscopic = 80%, p = 0.33</li> </ul> <p>Disease specific survival at follow-up:</p> <ul style="list-style-type: none"> <li>• open = 82%</li> <li>• laparoscopic = 72%, p = 0.26</li> </ul> <p>Overall survival at follow-up:</p> <ul style="list-style-type: none"> <li>• open = 59%</li> <li>• laparoscopic = 56%, p = 0.51</li> </ul>	<p>Conversions to open surgery = 12% (3/25)</p>	<p>No randomisation.</p> <p>Patients with tumours of the upper ureter or renal pelvis and calices had initial transurethral resection of the intramural ureter.</p> <p>Laparoscopic nephroureterectomy was performed via a transperitoneal approach. The approach to the ureter was tailored according to the level of the tumour and distal lesions were removed with an open technique.</p> <p>The specimen was removed intact in an impermeable bag.</p> <p>3 patients in open surgery group had previous or simultaneous cystectomy.</p> <p>Advanced tumour stage and grade increased the risk of metastases and death.</p>

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Ono Y (1999)<sup>4</sup></p> <p>Non randomised comparative study</p> <p>1992–1998</p> <p>Japan</p> <p>100 patients:</p> <ul style="list-style-type: none"> <li>• 40% (40/100) open radical nephrectomy</li> <li>• 60% (60/100) laparoscopic radical nephrectomy</li> </ul> <p>Mean age:</p> <ul style="list-style-type: none"> <li>• open nephrectomy = 60 years (range 29 to 81)</li> <li>• laparoscopic nephrectomy = 58 years (range 34 to 83)</li> </ul> <p>Indications: localised small (&lt; 5 cm in diameter) renal cell carcinoma</p> <p>Median follow-up: 24 months (range 2 to 70)</p>	<p>Calculated 5-year disease-free rate:</p> <ul style="list-style-type: none"> <li>• open = 97.5%</li> <li>• laparoscopic = 95.5%</li> </ul> <p>p = not significant</p> <p>Mean operative time (hours):</p> <ul style="list-style-type: none"> <li>• open = 3.3 (range 1.8 to 5.6)</li> <li>• laparoscopic = 5.2 (range 3 to 7.6)</li> </ul> <p>p &lt; 0.001</p> <p>Mean postoperative analgesia (mg):</p> <ul style="list-style-type: none"> <li>• open = 68</li> <li>• laparoscopic = 31</li> </ul> <p>p &lt; 0.001</p> <p>Mean convalescence (days):</p> <ul style="list-style-type: none"> <li>• open = 57</li> <li>• laparoscopic = 23</li> </ul> <p>p &lt; 0.001</p> <p>No local recurrence or seeding to the port sites was observed</p>	<p><b>Complications</b></p> <p>All complications:</p> <ul style="list-style-type: none"> <li>• open = 8% (3/40)</li> <li>• laparoscopic = 13% (8/60)</li> </ul> <p>p = not significant</p> <p>Injury to arteries:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/40)</li> <li>• laparoscopic = 3.3% (2/60)</li> </ul> <p>Injury to renal vein:</p> <ul style="list-style-type: none"> <li>• open = 2.5% (1/40)</li> <li>• laparoscopic = 0% (0/60)</li> </ul> <p>Injury to spleen:</p> <ul style="list-style-type: none"> <li>• open = 2.5% (1/40)</li> <li>• laparoscopic = 1.7% (1/60)</li> </ul> <p>Injury to adrenal gland:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/40)</li> <li>• laparoscopic = 1.7% (1/60)</li> </ul> <p>Injury to duodenum:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/40)</li> <li>• laparoscopic = 1.7% (1/60)</li> </ul> <p>Paralytic ileus:</p> <ul style="list-style-type: none"> <li>• open = 2.5% (1/40)</li> <li>• laparoscopic = 3.3% (2/60)</li> </ul> <p>Pulmonary thrombosis:</p> <ul style="list-style-type: none"> <li>• open = 0% (0/40)</li> <li>• laparoscopic = 1.7% (1/60)</li> </ul> <p>Blood transfusion required:</p> <ul style="list-style-type: none"> <li>• open = 7.5% (3/40)</li> <li>• laparoscopic = 3.3% (2/60)</li> </ul> <p>p = not stated</p> <p>Mean blood loss (ml):</p> <ul style="list-style-type: none"> <li>• open = 513 (range 70 to 1334)</li> <li>• laparoscopic = 255 (range 50 to 1096)</li> </ul> <p>p &lt; 0.001</p> <p>Conversion to open surgery = 1.7% (1/60)</p>	<p>Retrospective comparison.</p> <p>The choice of treatment was made by the patient.</p> <p>Laparoscopic nephrectomy was performed via a transperitoneal approach in 75% (45/60) of patients and a retroperitoneal approach in 25% (15/60).</p> <p>The kidney was fractionated before removal in 57% (34/60) of the laparoscopic procedures, all of which used the transperitoneal approach. The remaining 43% (26/60) of kidneys were removed intact.</p> <p>The authors state that the retroperitoneal approach will be used only in patients with a history of previous abdominal surgery.</p>

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Dunn M (2000)<sup>5</sup></p> <p>Non randomised comparative study</p> <p>1990–1999</p> <p>USA</p> <p>93 patients:</p> <ul style="list-style-type: none"> <li>35% (33/93) open radical nephrectomy</li> <li>65% (60/93) laparoscopic radical nephrectomy</li> </ul> <p>Mean age:</p> <ul style="list-style-type: none"> <li>open nephrectomy = 61.8 years</li> <li>laparoscopic nephrectomy = 63.5 years</li> </ul> <p>Indications: suspected renal cell carcinoma</p> <p>Mean follow-up:</p> <ul style="list-style-type: none"> <li>open nephrectomy = 27.5 months (range 7 to 90)</li> <li>laparoscopic nephrectomy = 25 months (range 3 to 73)</li> </ul>	<p>Mean operative time (hours):</p> <ul style="list-style-type: none"> <li>open = 2.8</li> <li>laparoscopic = 5.5</li> </ul> <p>p &lt; 0.001</p> <p>Mean analgesic consumption (milligrams morphine sulphate equivalent):</p> <ul style="list-style-type: none"> <li>open = 78.3</li> <li>laparoscopic = 28.0</li> </ul> <p>p &lt; 0.001</p> <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> <li>open = 5.2</li> <li>laparoscopic = 3.4</li> </ul> <p>p &lt; 0.001</p> <p>Mean time to normal activity (weeks):</p> <ul style="list-style-type: none"> <li>open = 8.1</li> <li>laparoscopic = 3.6</li> </ul> <p>p &lt; 0.001</p> <p>Mean time to 100% recovery (weeks):</p> <ul style="list-style-type: none"> <li>open = 29.3</li> <li>laparoscopic = 8.2</li> </ul> <p>p = 0.001</p> <p>The difference in recurrence-free survival between the two groups was not statistically significant</p>	<p><b>Complications</b></p> <p>All complications:</p> <ul style="list-style-type: none"> <li>open = 55% (18/33)</li> <li>laparoscopic = 37% (23/60)</li> </ul> <p>Major complications:</p> <ul style="list-style-type: none"> <li>open = 9% (3/33)</li> <li>laparoscopic = 3% (2/60)</li> </ul> <p>Injury to superior mesenteric artery:</p> <ul style="list-style-type: none"> <li>open = 3.0% (1/33)</li> <li>laparoscopic = 1.7% (1/60)</li> </ul> <p>Haemorrhage:</p> <ul style="list-style-type: none"> <li>open = 3.0% (1/33)</li> <li>laparoscopic = 1.7% (1/60)</li> </ul> <p>Pulmonary embolus:</p> <ul style="list-style-type: none"> <li>open = 3.0% (1/33)</li> <li>laparoscopic = 0% (0/60)</li> </ul> <p>Injury to colon:</p> <ul style="list-style-type: none"> <li>open = 3.0% (1/33)</li> <li>laparoscopic = 0% (0/60)</li> </ul> <p>Minor complications:</p> <ul style="list-style-type: none"> <li>open = 45% (15/33)</li> <li>laparoscopic = 34% (21/60)</li> </ul> <p>Blood transfusion required:</p> <ul style="list-style-type: none"> <li>open = 15.2% (5/33)</li> <li>laparoscopic = 12% (7/60)</li> </ul> <p>Mean blood loss (ml):</p> <ul style="list-style-type: none"> <li>open = 451</li> <li>laparoscopic = 172</li> </ul> <p>p = 0.01</p> <p>Conversions to open surgery = 1.7% (1/60)</p>	<p>All laparoscopic cases were compared to a contemporary cohort of open nephrectomy cases from the same institute.</p> <p>One patient underwent a bilateral radical laparoscopic nephrectomy for metachronous renal tumours.</p> <p>Early in study, 15 patients underwent ureteral stent placement but this was later abandoned.</p> <p>Laparoscopic nephrectomy was performed via a transperitoneal approach in 90% (55/61) of procedures, a retroperitoneal approach in 5% (3/61) and a combined approach in 5% (3/61).</p> <p>The kidney was morcellated before removal in 66% (40/61) of the laparoscopic procedures, all of which used the transperitoneal approach. The remaining 34% (21/61) of kidneys were removed intact.</p> <p>73% (44/60) of patients treated laparoscopically had renal cell carcinoma, 3% (2/60) had transitional cell carcinoma and 23% (14/60) had benign disease.</p> <p>91% (30/33) of patients treated with open surgery had renal cell carcinoma, 3% (1/33) had transitional cell carcinoma and 6% (2/33) had benign disease.</p>



Study Details	Key efficacy findings	Key safety findings	Comments
<p>Rassweiler J (1998)<sup>6</sup></p> <p>Case series</p> <p>1992–1996</p> <p>Germany, Austria and Switzerland</p> <p>461 patients (482 laparoscopic nephrectomies)</p> <p>Age range: 6 months to 82 years</p> <p>Indications: benign renal disease (n = 444), renal tumours (n = 38)</p> <p>Follow-up period not stated</p>	<p>Mean hospital stay = 5.4 days (range 3 to 9), excluding patients with major complications, conversion or re-intervention</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Bleeding = 4.6% (22/482)</li> <li>• Bowel injury = 0.6% (3/482)</li> <li>• Hypercarbia = 0.4% (2/482)</li> <li>• Pulmonary embolism = 0.2% (1/482)</li> <li>• Pleura lesion = 0.2% (1/482)</li> <li>• Re-intervention = 3.1% (15/482) for bleeding (n = 7), abscess (n = 4), intestinal stenosis (n = 2), pancreatic fistula (n = 1), port hernia (n = 1).</li> </ul> <p>Conversions to open surgery = 9.5% (46/482)</p>	<p>Data were obtained from the initial 461 patients undergoing a laparoscopic nephrectomy at 14 centres.</p> <p>Laparoscopic nephrectomy was performed via a transperitoneal approach in 71% (344/482) of procedures and a retroperitoneal approach in 29% (138/482).</p> <p>The authors note that there is a significant learning curve.</p>
<p>Keoghane S (2004)<sup>7</sup></p> <p>Case series</p> <p>2001–2002</p> <p>UK</p> <p>263 procedures</p> <p>Indications: non-functioning kidney (45%), renal cell carcinoma (32%), transitional cell carcinoma (11%), other (12%)</p>	<p>Mean operative time = 173 minutes (range 89 to 335)</p> <p>Median length of hospital stay = 4 days</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Mortality = 0.7% (2/263)</li> <li>• Mean conversion rate = 5.7%</li> <li>• Mean complication rate = 16.8% (range 0–60)</li> <li>• Diarrhoea = 1.1% (3/263)</li> <li>• Perihepatic collection = 0.4% (1/263)</li> <li>• Wound infection = 1.1% (3/263)</li> <li>• Labial haematoma = 0.4% (1/263)</li> <li>• Sepsis = 1.1% (3/263)</li> <li>• Bowel perforation = 0.4% (1/263)</li> <li>• Nausea = 1.5% (4/263)</li> <li>• Incisional hernia = 1.1% (3/263)</li> <li>• Neuropraxia = 0.4% (1/263)</li> <li>• Gastrointestinal bleed = 0.4% (1/263)</li> <li>• Haematuria = 0.4% (1/263)</li> <li>• Acute renal failure = 0.4% (1/263)</li> <li>• Laparotomy = 0.4% (1/263)</li> <li>• Fistula = 0.4% (1/263)</li> <li>• Respiratory = 1.1% (3/263)</li> <li>• Other = 1.5% (4/263)</li> </ul>	<p>National audit (25 centres), including members of the British Association of Urological Surgeons (BAUS).</p> <p>Included 20 hand-assisted nephrectomy procedures.</p> <p>The mean complication rates were no higher in centres undertaking fewer than five cases per year than in the centres with a greater volume.</p> <p>One concern is the completeness of the audit dataset. Data submission was voluntary and there may have been some selection bias.</p>

Study Details	Key efficacy findings	Key safety findings	Comments
<p>Cadeddu J (1998)<sup>8</sup></p> <p>Case series</p> <p>1991–1997</p> <p>USA, Canada, Japan, Austria</p> <p>157 patients</p> <p>Mean age: 61 years (range 27 to 92)</p> <p>Indications: clinically localised, pathologically confirmed renal cell carcinoma</p> <p>Mean follow-up: 19.2 months (range 1 to 72)</p>	<p>5-year actuarial disease-free rate for all patients (n = 156) = 91%</p> <p>5-year actuarial disease-free rate for patients clinical stage T2 disease (n = 124) = 89%</p> <p>No evidence of disease recurrence at last follow-up = 96.8% (151/156)</p> <p>No deaths due to cancer occurred</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• Mortality = 1.3% (2/157), one patient died intraoperatively; the cause of death was not determined but a carbon dioxide embolus could not be ruled out. The second patient died a month after the surgery due to congestive heart failure</li> <li>• Ileus = 2.5% (4/157)</li> <li>• Urinary tract infection = 1.3% (2/157)</li> <li>• Pulmonary embolism = 1.3% (2/157)</li> <li>• Congestive heart failure = 0.6% (1/157)</li> <li>• Transfusion = 0.6% (1/157)</li> <li>• Incisional hernia = 0.6% (1/157)</li> <li>• Wound infection = 0.6% (1/157)</li> <li>• Seroma = 0.6% (1/157)</li> <li>• Haemorrhage requiring exploratory laparotomy = 0.6% (1/157)</li> <li>• Duodenal perforation = 0.6% (1/157)</li> <li>• Splenic injury = 0.6% (1/157)</li> </ul> <p>Conversions to open surgery = 3.8% (6/157)</p>	<p>Retrospective study.</p> <p>This study includes patients from the same centres as Rassweiler et al, 1998 and Ono Y et al, 1999.</p> <p>Laparoscopic nephrectomy was performed via a transperitoneal approach in 88% (139/157) of procedures and a retroperitoneal approach in 12% (18/157).</p> <p>The adrenal gland was removed in 56% (88/157) of procedures.</p> <p>The kidney was morcellated or fragmented in 90% (142/157) of procedures.</p> <p>64% (101/157) of patients were followed up for at least 12 months.</p> <p>Subclinical recurrences could not be excluded.</p> <p>The authors note that longer follow-up is needed to determine the true risk, if any, of port seeding after the procedure.</p>

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

- The studies included patients with different indications and different outcomes were reported. Recurrence-free survival is an important efficacy outcome for patients with malignant disease whereas outcomes such as length of hospital stay and convalescence are more important for patients with benign disease.
- In two non-randomised comparative studies, the patient and the surgeon chose the treatment option.<sup>1,4</sup> This may have introduced a bias.
- Most of the studies used a combination of transperitoneal and retroperitoneal approaches for laparoscopic nephrectomy.
- Two studies reported results of nephroureterectomies for upper urinary tract transitional cell carcinoma.<sup>2,3</sup> The approach for removing the ureter and bladder cuff varied within and between the studies.
- Three studies reported that the kidneys were fractionated or morcellated before removal.<sup>4,5,8</sup>
- Two studies reported results from multiple centres and there is likely to be some overlap in the patient populations.<sup>6,8</sup>
- One study reported results from a voluntary audit.<sup>7</sup> There may be some selection bias in the data selected for submission to the audit database.

## ***Specialist Advisors' opinions***

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

- This procedure is established practice and no longer new.
- Training is important and the laparoscopic experience of the operator is a major concern.
- The key efficacy outcomes are length of hospital stay, postoperative pain levels, recovery time and cosmetic result.

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

NICE has previously produced guidance for laparoscopic live donor simple nephrectomy. The guidance was issued in May 2004 and stated that "Current evidence on the safety and efficacy of laparoscopic live donor simple nephrectomy appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance." (Interventional Procedure Guidance No. 57).

A prospective randomised controlled trial of laparoscopic versus open nephrectomy was carried out in the UK between 2001 and 2003. The trial included 60 patients requiring nephrectomy for benign or malignant diseases.

Another prospective randomised controlled trial of laparoscopic versus open nephrectomy started in the UK in May 2002 and was due to finish in December 2004. The trial included patients requiring a nephrectomy for benign or malignant disease.

## References

- 1 Fornara P, Doehn C, Friedrich HJ, et al. Nonrandomized comparison of open flank versus laparoscopic nephrectomy in 249 patients with benign renal disease. *European Urology* 2001; 40: 24–31.
- 2 Hsueh TY, Huang Y, Chiu AW, et al. A comparison of the clinical outcome between open and hand-assisted laparoscopic nephroureterectomy for upper urinary tract transitional cell carcinoma. *BJU International* 2004; 94: 798–801.
- 3 Bariol SV, Stewart GD, McNeill SA, et al. Oncological control following laparoscopic nephroureterectomy: 7-year outcome. *The Journal of Urology* 2004; 172: 1805–8.
- 4 Ono Y, Kinukawa T, Hattori R, et al. Laparoscopic radical nephrectomy for renal cell carcinoma: a five-year experience. *Urology* 1999; 53: 280–6.
- 5 Dunn MD, Portis AJ, Shalhav AL, et al. Laparoscopic versus open radical nephrectomy: a 9-year experience. *The Journal of Urology* 2000; 164: 1153–9.
- 6 Rassweiler J, Fornara P, Weber M, et al. Laparoscopic nephrectomy: the experience of the laparoscopy working group of the German Urologic Association. *The Journal of Urology* 1998; 160: 18–21.
- 7 Keoghane SR, Keeley FX, Timoney AG, et al. The British Association of Urological Surgeons Section of Endourology audit of laparoscopic nephrectomy. *BJU International* 2004; 94: 577–81.
- 8 Cadeddu JA, Ono Y, Clayman RV, et al. Laparoscopic nephrectomy for renal cell cancer: evaluation of efficacy and safety: a multicenter experience. *Urology* 1998; 52: 773–7.

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

The following table outlines studies that are considered potentially relevant to the overview but were not included in the main data extraction table and is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Abbou C, Cicco A, Gasman D, et al. Retroperitoneal laparoscopic versus open radical nephrectomy. <i>Journal of Urology</i> 1999; 161: 1776–80.	58 patients. Mean follow-up = 13 months.	Case series. Renal cancer.	Patients with laparoscopic procedures had significantly less blood loss and less analgesia.
Desai M, Strzempkowski B, Matin SF, et al. Prospective randomized comparison of transperitoneal versus retroperitoneal laparoscopic radical nephrectomy. <i>Journal of Urology</i> 2005; 173: 38–41.	102 patients.	RCT comparing 2 different approaches.	No open conversions. Both approaches were similar in terms of blood loss, hospital stay, complications and analgesia requirements.
Fugita O, Chan D, Roberts W, et al. Laparoscopic radical nephrectomy in obese patients: outcomes and technical considerations. <i>Urology</i> 2004; 63: 247–52.	101 patients.	Case series.	No significant differences between obese and non-obese patients.
Gill I, Meraney A, Schweizer D, et al. Laparoscopic radical nephrectomy in 100 patients: a single center experience from the United States. <i>Cancer</i> 2001; 7: 1843–55.	100 patients. Mean follow-up = 16 months.	Case series. Renal cancer.	No local or port site recurrence.
Gill I, Kavoussi L, Clayman R, et al. Complications of laparoscopic nephrectomy in 185 patients: a multi-institutional review. <i>Journal of Urology</i> 1995; 154: 479–83.	185 patients.	Case series.	16% (30/185) complications. No mortality.
Goel H, Hemal A, Gupta N. Retroperitoneal laparoscopic radical nephrectomy and nephroureterectomy and comparison with open surgery. <i>World Journal of Urology</i> 2002; 20: 219–23.	43 patients.	Non-randomised comparison. Renal cancer.	Retroperitoneal laparoscopic approach was associated with less morbidity and faster recovery.
Hemal A, Talwar M, Wadhwa S, et al. Retroperitoneoscopic nephrectomy for benign disease of the kidney: prospective nonrandomized comparison with open surgical nephrectomy. <i>Journal of Endourology</i> 1999; 13: 425–31.	86 patients.	Non-randomised comparison. Benign disease.	Major complications: laparoscopic 5% open 2% Minor complications: laparoscopic 21% open 33%.
Hemal A, Goel A, Kumar M, et al. Evaluation of laparoscopic retroperitoneal surgery in urinary stone disease. <i>Journal of Endourology</i> 2001; 15: 701–5.	67 patients.	Case series. Calculous disease.	1 colon injury, 1 injury to artery.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Janetschek G, Al Zachrani H, Vrabec G, et al. Laparoscopic radical nephrectomy. <i>Urologe</i> 2002; 41: 101–6.	121 patients. Mean follow-up = 13 months.	Case series. Renal cancer. Article in German.	No cancer recurrence within follow-up period. No conversion to open surgery.
Jeschke K, Wakonig J, Pitzler C, et al. Laparoscopic radical nephrectomy: a single-center experience of 51 cases. <i>Techniques in Urology</i> 2000; 6: 9–11.	51 patients. Mean follow-up = 8 months.	Case series. Renal cancer.	Major complications in 4% of patients. No conversion to open surgery. No local recurrences or metastases.
Kawauchi A, Fujito A, Ukimura O, et al. Hand assisted retroperitoneoscopic nephroureterectomy: comparison with the open procedure. <i>Journal of Urology</i> 2003; 169: 890–4.	68 patients. Mean follow-up = 13 months.	Non-randomised comparison. Hand-assisted. Renal cancer.	Complication rate 12% (4/34) in each group. 1 conversion to open procedure. 12% (4/34) recurrence.
Kawauchi A, Fujito A, Soh J, et al. Hand-assisted retroperitoneoscopic radical nephrectomy and nephroureterectomy. <i>Journal of Endourology</i> 2004; 18: 365–9.	149 patients.	Case series. Hand-assisted. Renal and upper urinary tract cancer.	Nephrectomy: Complication rate = 8% Recurrence rate = 5% Nephroureterectomy: Complication rate = 9% Recurrence rate = 23%.
Keeley FX, Tolley D. A review of our first 100 cases of laparoscopic nephrectomy. <i>British Journal of Urology</i> 1998; 82: 615–8.	100 patients.	Case series. Benign and malignant disease.	Major complications = 3%, minor complications = 15%.
Kuriki O, Ono Y, Kinukawa T, et al. Laparoscopic radical nephrectomy for renal cell carcinoma. <i>Aktuelle Urologie</i> 2003; 34: 244–6.	185 patients. Follow-up = 1 to 108 months.	Case series. Renal cancer.	Recurrences in 3% (6/185) of patients.
Lee S, Ku J, Kwak C, et al. Hand assisted laparoscopic radical nephrectomy: comparison with open radical nephrectomy. <i>Journal of Urology</i> 2003; 170: 756–9.	104 patients. Follow-up not stated.	Non-randomised comparison. Renal cancer.	No significant difference in complication rate. Significantly lower mean blood loss and shorter hospital stay for laparoscopic group.
Makhoul B, de la Taille A, Vordos D, et al. Laparoscopic radical nephrectomy for T1 renal cancer: the gold standard? A comparison of laparoscopic vs open nephrectomy. <i>BJU International</i> 2004; 93: 67–70.	65 patients. Mean follow-up = 20 months.	Non-randomised comparison. Renal cancer.	No recurrence or tumour progression. Less blood loss, less analgesia and shorter hospital stay for laparoscopic procedure.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Nambirajan T, Jeschke S, Al-Zahrani H, et al. Prospective, randomized controlled study: transperitoneal laparoscopic versus retroperitoneoscopic radical nephrectomy. <i>Urology</i> 2004; 64: 919–24.	40 patients.	RCT comparing 2 different approaches.	No open conversions. No significant differences between the approaches in terms of patient morbidity.
Patel V, Leveillee R. Hand-assisted laparoscopic nephrectomy for stage T1 and large stage T2 renal tumors. <i>Journal of Endourology</i> 2003; 17: 379–83.	100 patients.	Comparing T1 and T2 tumours. Hand-assisted procedure.	There is a learning curve. With increased expertise, larger tumours can be removed safely.
Poddoubnyi I, Dronov A, Kovarskyi S, et al. Laparoscopic nephrectomy and nephroureterectomy in 90 pediatric patients. <i>Pediatric Endosurgery &amp; Innovative Techniques</i> 2003; 7: 135–9.	90 patients	Children. Case series. Benign kidney disease.	No intraoperative complications.
Rabets J, Kaouk J, Fergany A, et al. Laparoscopic versus open cytoreductive nephrectomy for metastatic renal cell carcinoma. <i>Urology</i> 2004; 64: 930–4.	64 patients.	Non-randomised comparison. Metastatic renal cancer.	Kaplan-Meier 1-year survival estimates: 61% in laparoscopic group and 65% in open group
Rassweiler J, Frede T, Henkel T, et al. Nephrectomy: a comparative study between the transperitoneal and retroperitoneal laparoscopic approach versus the open approach. <i>European Urology</i> 1998; 33: 489–96.	54 patients.	Non-randomised comparison. Benign disease.	No significant difference between the 2 laparoscopic approaches.
Stifelman M, Handler T, Nieder A, et al. Hand-assisted laparoscopy for large renal specimens: a multi-institutional study. <i>Urology</i> 2003; 61: 78–82.	95 patients Mean follow-up = 12 months	Case series. Hand-assisted. Renal cancer.	Patients with larger lesions required longer recovery period.
Wille A, Roigas J, Deger S, et al. Laparoscopic radical nephrectomy: techniques, results and oncological outcome in 125 consecutive cases. <i>European Urology</i> 2004; 45: 483–8.	125 patients. Mean follow-up = 23.5 months.	Case series. Renal cancer.	1.6% conversion to open surgery. (1 bleeding, 1 bowel injury). No local recurrence or port metastasis.

## Appendix B: Literature search for laparoscopic nephrectomy

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1. \*laparoscopy/
2. laparoscop\$.tw.
3. nephrectomy/
4. nephrectomy.tw.
5. 1 or 2
6. 3 or 4
7. 5 and 6
8. laparoscopic nephrectomy.tw.
9. (laparoscopic adj2 nephrectomy).tw.
10. (laparoscop\$ adj2 nephroureterectomy).tw.
11. or/7-10
12. exp kidney neoplasms/
13. kidney neoplasm\$.tw.
14. kidney cancer.tw.
15. ureteral neoplasms/
16. ureteral neoplasm\$.tw.
17. ureteral cancer.tw.
18. malignant kidney\$.tw.
19. carcinoma, transitional cell/
20. transitional cell carcinoma.tw.
21. exp kidney diseases/
22. kidney disease\$.tw.
23. or/12-22
24. 11 and 23
25. limit 24 to english language
26. limit 25 to human