# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

# INTERVENTIONAL PROCEDURES PROGRAMME

# Interventional procedures overview of laparoscopic

# live donor simple nephrectomy

## Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

# Date prepared

This overview was prepared by ASERNIP-S in November 2002

### Procedure name

- Laparoscopic live donor nephrectomy (LLDN).
- Laparoscopic transperitoneal simple nephrectomy.
- Live donor laparoscopic nephrectomy.
- Laparoscopic donor nephrectomy.

## Specialty society

• British Association of Urological Surgeons.

## Description

#### Indications

The aim of laparoscopic live donor nephrectomy (LLDN) for retrieving kidneys from live donors is to make the donation process more attractive to potential donors by decreasing donor morbidity. In turn this should increase the availability of kidneys for transplantation, the best option for treating patients with end-stage renal disease. Kidneys from live donors are also considered to offer recipients more advantages than cadaveric renal transplants.<sup>1</sup>

#### What the procedure involves

LLDN can be performed via a retroperitoneal approach or a transperitoneal approach. The transperitoneal approach is preferred because it allows more laparoscopic working space and also makes it easier to remove the kidney from the abdomen through a relatively low-pain, midline incision.<sup>2</sup> Usually four ports are introduced into the peritoneal cavity for the laparoscope and the dissecting

instruments. A pneumo-peritoneum with CO<sub>2</sub> is usually created.<sup>3</sup> Sometimes an endocatch bag is used to deliver the kidney, which enables a shorter midline incision.<sup>4</sup>

Only the left kidney is generally removed in the laparoscopic procedure because the vessels are likely to be longer than the vessels for the right kidney, thus avoiding potential problems with the recipient's graft.<sup>5</sup> However, some authors believe that concerns about right laparoscopic nephrectomy are no longer justified.<sup>7,8</sup>

For hand-assisted LLDN (LLDN-HA), a tranverse Pfannenstiel incision, similar to the LLDN incision, is made in the lower abdomen. The operating surgeon's left hand is inserted through the hand-assisting apparatus and used to retract the viscera, expose the renal vascular pedicle and retract the kidney laterally during vessel transection and kidney extraction.<sup>6</sup> LLDN is now preferred over open live donor nephrectomy (OLDN) in some centres.<sup>6</sup>

#### Efficacy

Donor operating time was usually longer for LLDN (including hand-assisted procedures) than for OLDN. Conversely, donor hospital stay was generally shorter for LLDN and, in one study, LLDN-HA was significantly shorter than LLDN. LLDN donors generally returned to work earlier than OLDN donors. Costs were slightly higher for LLDN and LLDN-HA in one study. No difference was detected between LLDN and OLDN for recipient early and late graft function, graft survival and recipient survival, although follow-up is still short.

#### Safety

LLDN did not appear to have obviously worse results than OLDN although numbers of individual complications were small in both groups, and some studies did not report their OLDN results for comparison. Recipient complications also appeared to be similar, but these were even less reported than the donor complications.

## Literature reviews

#### Rapid review of literature

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, covering the period from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports (2002), relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English-language evidence base, and could be translated in the time available.

Studies were excluded: if they were historical rather than concurrent comparisons; if they did not state that the LLDN procedure was transperitoneal; and if the LLDN

procedure was hand-assisted. Included studies are highlighted in bold in the reference list. Studies for which data were not tabulated are listed in the Appendix.

#### List of studies found

Total number of studies:

- Systematic reviews 1 (data extracted only from the 10 studies that compared LLDN using a transperitoneal approach with OLDN)
- Non-randomised comparative studies 19 (in addition to the studies in the systematic review) 4 included.

#### **RCTs in progress**

None located.

#### Summary of key efficacy and safety findings

See following tables.

#### Abbreviations

GIA	gastrointestinal anastomosis.
LD	live donor.
LLDN	laparoscopic live donor nephrectomy.
LLDN-HA	laparoscopic live donor nephrectomy (hand-assisted).
OLDN	open live donor nephrectomy .
pns	statistically nonsignificant.
TP	transperitoneal.
[]	standard deviation.
{ }	variance measure not specified.

# Table 2 Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Appraisal/comments
Systematic review			
Merlin et al. 2000 <sup>9,10</sup>	<b>Donor operating times</b> (4 studies) – OLDN statistically significantly shorter than LLDN in 3	<b>Donor mortality</b> – none reported in any of the comparative studies, case series or	Potential for bias: OLDN complications likely to be underreported; small studies
Australia	studies, with no statistically significant difference found in the fourth study	case reports	lacked power to detect any differences should they exist, short follow-up times;
10 studies (relevant to this	Donor analgesia (3 studies) – analgesia	Donor complication rates (5 studies)	lack of rigorous study designs;
overview) – all nonrandomised, mixed concurrent and	amount or duration was significantly less for LLDN than OLDN	study LLDN OLDN 1 11% (n = 9) 15% (n = 27)	inappropriate or no statistical testing done for some outcomes in some studies.
retrospective comparisons	Donor hospital stay (6 studies) – statistically	2 14% (n = 70) 35% (n = 65)	
	significantly less for LLDN than OLDN in five	3 5% (n = 19) 0% (n = 20)	Outcome measures and their validity:
Selection criteria: all forms of	studies (LLDN range of means 2.2–3.1 days;	4 17% (n = 12) 5% (n = 21)	most outcomes appeared to be reasonably
LLDN, but data extracted only	OLDN 3.8 –5.7 days)	5 20% (n = 30) 3% (n = 30)	objective, although less stringent
for the 10 studies comparing	Donor resumption of employment (5 studies)		measurement was applied to OLDN
LLDN with OLDN for the	<ul> <li>more rapid for LLDN than OLDN in all five</li> </ul>		outcomes in some studies.
purposes of this overview	studies (LLDN range of means 2.3–3.9 weeks; OLDN 5.3–7.4 weeks)	<b>Donor blood loss</b> (3 studies) no clinically significant differences	
Follow- p: ranged from 6 months to 2 years (when	<b>Donor conversion rates</b> (5 studies) – 0%, 0%, 5.7%, 8.3%, 13.3%	between LLDN and OLDN	
stated)	<b>Recipient creatinine levels</b> (3 studies) – no statistically significant difference found between	<b>Recipient ureteral complication rates</b> (3 studies)	
	LLDN and OLDN (at 3 and/or 12 months)	LLDN: ranged from 3.3% to 10.8%	
	Recipient delayed graft function (4 studies) – no statistically significant difference found	OLDN: ranged from 3.0% to 6.3%	
	between LLDN and OLDN in 2 studies; statistical		
	testing not conducted in the other 2 studies		
	Recipient graft survival (6 studies) – no		
	statistically significant difference found between LLDN and OLDN in 4 studies; statistical testing		
	not conducted in the other 2		
	<b>Recipient survival</b> (3 studies) – no statistically		
	significant difference found between LLDN and		
	OLDN in 3 studies		

Study details	Key efficacy findings	Key safety findings	Appraisal/comments
Non-randomised comparative	studies		
Non-randomised comparative Hawasli et al. 2001 <sup>11</sup> USA January 1997 to February 2000 59 donors: 30 LLDN; 29 OLDN 46 recipients (*see Appraisal/comments): 24 LLDN; 22 OLDN Selection criteria: not stated Follow up: not stated	StudiesDonor operating time, mean (hours:mins)LLDN 3:01 (range 1:54–5:21)OLDN 2:30 (range 1:55–2:59)Donor hospital stay, mean (days)LLDN 1.3 (range 1–3)OLDN 4.1 (range 3–7) $p < 0.001$ Donor return to work, mean (days)LLDN 14.8 (range 7–30)OLDN 28.4 (range 7–100) $p < 0.01$ Donor pain – OLDN patients needed an epiduralcatheter; LLDN patients required only intramuscular or oral analgesiaDonor conversions from LLDN to OLDN: 1 (3.3%) – to control bleedingRecipient creatinine level at 1 month was similar for LLDN and OLDN patientsRecipient kidney function – all kidneys in both groups functioned immediately postoperatively, none suffered	<ul> <li>Donor complications <ul> <li>LLDN:</li> <li>2 (6.7%) intraoperative bleeding <ul> <li>no ureteral complications;</li> <li>4 (13.3%) postoperative complications</li> <li>1 pancreatitis,</li> <li>1 flank ecchymosis,</li> <li>2 wound haematomas</li> </ul> </li> <li>OLDN: <ul> <li>no intraoperative or ureteral</li> <li>complications</li> <li>4 (13.8%) postoperative complications</li> <li>4 (13.8%) postoperative complications</li> <li>1 incisional hernia</li> <li>1 pneumothorax</li> <li>2 atelectasis</li> </ul> </li> <li>Donor blood loss, mean (ml) <ul> <li>LLDN: 125 (10–2000)</li> <li>OLDN: 130 (25–350)</li> </ul> </li> </ul></li></ul>	<ul> <li>Potential for bias: patients were consecutive, but method of allocation to OLDN or LLDN was not stated; LLDN complications gathered prospectively, bujt OLDN complications were gathered from a retrospective chart review</li> <li>Outcome measures and their validity Although most outcome measures appeared to be objective, some were gathered differently for LLDN and OLDN patients (see above).</li> <li>Other comments: *13 recipients either required re-operation or were diagnosed with vascular rejection; all LLDN performed by an experienced laparoscopic surgeon – learning curve stated to be 7 cases</li> </ul>
Montgomery et al. 2001 <sup>12</sup> ; Ratner et al. 2000 <sup>4</sup>	from acute necrosis and no kidneys were lost post- transplantation Donor conversion rate – 5 (10%) Recipient hospital stay – median was 7 days for both	<b>Donor complications</b> LLDN: 34 (17%) OLDN: not stated	<b>Potential for bias</b> : retrospective review of all living donor nephrectomies; the majority of OLDN were performed early
USA	LLDN and OLDN groups	Specific complications for LLDN:	in the study period, and the LLDN later, so this is partly an historical
January 1995 to July 1999	<b>Recipient acute rejection</b> (first month) LLDN (n = 110): 30.1%	4 retroperitoneal haematoma (1 required reoperation), 2 splenic	comparison.
Recipients: 248–200 LLDN; 48 OLDN	OLDN (n = 48): 31.3%, pns	capsule injury, 6 wound complications, 5 thigh paresthesia, 2 pneumonia, 3	Outcome measures and their validity Most outcome measures appeared to

Study details	Key efficacy findings	Key safety findings	Appraisal/comments
Selection criteria: all paediatric and adult LD recipients during the study period Follow up: 3 years	Recipient graft lossLLDN: 8 (16%) (*see Appraisal/comments): - 3secondary to vascular thrombosis, 2 rejection, 1haemolytic uremic syndrome, 1 cholesterol emboli, 1patient non-complianceOLDN: 4 (8.3%), pnsRecipient graft functionLLDN – creatinine clearance at 36 months 69.3 [27.2]ml/min	bowel injury (1 delayed open repair), 1 epigastric artery injury, 1 thrombophlebitis, 4 open conversions – early (1 stapler malfunction, 1 GIA malfunction, 1 renal vein tear, 1 loss of pneumoperitoneum), 6 transfusions <b>Recipient deaths</b> LLDN: 7 (14%) – 4 sepsis, 2 cardiovascular, 1 haemorrhage OLDN: 1 (2.1%) – 1 sepsis	be objective, although not all OLDN outcomes (e.g. complications) were reported; rejection was diagnosed histologically. <b>Other comments:</b> *all 3 grafts lost to vascular thrombosis occurred with donation of right kidneys (authors believe thrombosis was due to short donor renal vein and now avoid using right kidneys if possible)
		<b>Recipient ureteral complications</b> LLDN 13 (26%) OLDN 3 (6.3%)	Authors make the observation that LLDN has increased the numbers of people prepared to make live kidney donations
Ruiz-Deya et al. 2001 <sup>13</sup> , Slakey et al. 2002 <sup>14</sup>	<b>Operating time</b> , mean (hours) LLDN (TP) 3.59 [0.2] LLDN-HA 2.75 [0.2]	Donor complications LLDN-HA • 1 adrenal vein injury, not	<b>Potential for bias</b> : Laparoscopic procedures were consecutive; method of allocating patients to LLDN and
USA	Donor conversion rates – 1 LLDN-HA	repairable endoscopically, was converted to open	OLDN was not stated; small patient numbers in each of 3 groups
Dates: not stated, but LLDN was introduced in 1997 and LLDN-HA in 1998	<b>Donor pain</b> – none of the LLDN (TP or HA) patients required parenteral narcotics	<ul> <li>2 postoperative ileus</li> <li>LLDN (TP) –</li> <li>1 deep venous thrombosis</li> </ul>	Outcome measures and their validity: Most outcome measures appeared to be objective, although OLDN outcomes
Donors (and recipients): 48 • 11 LLDN (TP) • 23 LLDN-HA • 14 OLDN	<b>Donor hospital stay</b> (days) LLDN (TP) 1.6 [1.3] LLDN-HA 2 [0.1] pns	<ul> <li>1 incarcerated hernia</li> <li>Donor blood transfusions – none required in any of the 3 groups</li> </ul>	were often not reported
• 14 OLDIN	<b>Recipient serum creatinine</b> – similar in all 3 groups at 12 months	Recipient ureteral complications – none reported for any of the 3 groups	
Selection criteria: donors with more than 1 year follow up and complete charts	<b>Recipient graft function</b> – all grafts harvested laparoscopically functioned well	<u>.</u>	
Follow up: 1 year	<b>Recipient graft rejection</b> – acute LLDN (TP) 1 (9%) LLDN-HA 4 (17%) OLDN 2 (14%)		

Study details	Key efficacy findings	Key safety findings	Appraisal/comments
	<b>Recipient graft rejection</b> – chronic LLDN (TP) 1 (stabilised by adjusting immunosuppression)		
Velidedeoglu et al. 2002 <sup>6</sup> . Velidedeoglu et al. 2001 <sup>15</sup> USA Donors (and recipients): 150 50 OLDN 40 LLDN 60 LLDN-HA Dates: June 1997 to May 2001	<b>Donor operating time</b> (mins) – based on 125 donors only OLDN: 185 {5.7} (n = 50) LLDN: 258 {5.4} (n = 40) LLDN-HA: 260 {7.1} (n = 35) p < 0.001 (OLDN compared with either LLDN or LLDN- HA) <b>Donor length of hospital stay</b> (days) OLDN: 4.4 LLDN: 3.2 {0.2} LLDN-HA: 2.6 {0.1} p < 0.001 (OLDN compared with either LLDN or LLDN-	Donor complications OLDN: • 1 arterial injury • 1 reoperation for sponge removal LLDN: • no complications LLDN-HA: • 2 mild postoperative ileus • 1 kidney suffered an arterial intimal injury	<b>Potential for bias</b> : Demographics similar for all 3 groups; retrospective record review – not clear whether cases were sequential; not stated how patients were allocated to the three groups, although the authors state that laparoscopic procedures were offered mainly on renal arterial anatomy; not all results presented for all groups;
Selection criteria: not stated Follow up: probably 6 weeks	HA) Donor conversion LLDN 3/40 (7.5%)	<b>Donor blood loss</b> , mean (ml) LLDN + LLDN-HA: 118.5 {11.3} range 50-1100)	<b>Other comments</b> : All laparoscopic procedures were for left kidneys. Operating time is presented as a graph in the later paper with 150 donors;
	LLDN-HA 1/60 (1.7%) Recipient graft function mean serum creatinine less than 1.5 (units not given) for all groups by 6 weeks Costs	<b>Recipient complications</b> OLDN: 1 thrombosis of the renal vein LLDN: 1 thrombosis of the renal artery (needed to remove graft 2 days after transplantation); 2 urine leaks LLDN-HA: 1 death (pulmonary fibrosis)	however variances are not given, so the results based on only 125 donors have been shown here. The mean operating times are very similar in both papers.

# Specialist Advisor's opinions

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

One Advisor commented that it had not been proven that recovery rates were quicker and post-operative pain lower than for open surgery. The other Advisors did not raise any concerns regarding the efficacy of this procedure.

The Specialist Advisors considered the main safety concerns to be bleeding, injury to nearby organs and conversion to open surgery.

# Issues for consideration by IPAC

No further issues noted.

### References

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- 12. Montgomery RA, Kavoussi LR, Su L-M, Sinkov V, et al. Improved recipient results after 5 years of performing laparoscopic donor nephrectomy. *Transplantation Proceedings 2001*;33(11):1108–10
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- 14. Slakey DP, Hahn JC, Rogers E, Rice JC, et al. Single-center analysis of living donor nephrectomy: hand-assisted laparoscopic, pure laparoscopic, and traditional open. *Progress in Transplantation* 2002;12(3):206–11
- 15. Velidedeoglu E, Williams N, Brayman KL, Desai NM, et al. Surgical options for live-donor nephrectomy. *Transplantation Proceedings* 2001;33:3789–90

# Appendix: Additional studies not included in the summary table

Berney T, Malaise J, Mourad M, Morel P, et al. Laparoscopic and open live donor nephrectomy: a cost/benefit study. *Transplantation International* 2000;13(1):35–40 - *mostly cost outcomes* 

Brown SL, Biehl TR, Rawlins MC, Hefty TR. Laparoscopic live donor nephrectomy: a comparison with the conventional open approach. *Journal of Urology* 2001;165(3):766–9 - *not clear whether approach is transperitoneal; historical comparison* 

Koffron A, Herman C, Gross O, Ferrario M, et al. Laparoscopic donor nephrectomy: analysis of donor and recipient outcomes. *Transplantation Proceedings* 2001;33:1111 - not clear whether approach is transperitoneal; historical comparison

Kuo PC, Johnson LB. Laparoscoic donor nephrectomy increases the supply of living donor kidneys: a center-specific microeconomic analysis. *Transplantation* 2000;69(10):2211-3 - *historical comparison* 

Kuo PC, Johnson LB, Sitzmann JV. Laparoscopic donor nephrectomy with a 23-hour stay: a new standard for transplantation surgery. *Annals of Surgery* 2000;231(5):772–9

- not clear whether approach is transperitoneal; historical comparison

Lennerling A, Blohme I, Ostraat O, Lonroth H, et al. Laparoscopic or open surgery for living donor neohrectomy. *Nephrology Dialysis Transplantation* 2001;16:383–6 - *not clear whether approach is transperitoneal* 

Leventhal JR, Deeik RK, Joehl RJ, Rege RV, et al. Laparoscopic live donor nephrectomy – is it safe?: analysis of 80 consecutive cases and comparison with open nephrectomy.

Transplantation 2000;70(4):602–6

historical comparison

Lindstrom P, Haggman M, Wadstrom J. Hand-assisted laparoscopic (HALS) for live donor nephrectomy is more time- and cost-effective than standard laparoscopic nephrectomy. *Surgical Endoscopy* 2002;16:422–5

- not clear whether approach is transperitoneal; historical comparison

Malaise J, Mourad M, Squifflet J-P. Video-assisted live donor nephrectomy: a comparison with open surgery. *Transplantation Proceedings* 2000;32:473–4

- concurrent but retrospective comparison; smaller numbers than included studies

Rudich SM, Marcovich JC, Magee JC, Punch JD, et al. Hand-assisted laparoscopic donor nephrectomy: comparable donor/recipient outcomes, costs, and decreased convalescence as compared to open donor nephrectomy. *Transplantation Proceedings* 2001;33:1106–7

- concurrent comparison of hand-assisted laparoscopic versus open (no LLDN arm); same patients as Wolf et al. 2001

Sasaki TM, Finelli F, Bugarin E, Fowlkes D, et al. Is laparoscopic donor nephrectomy the new criterion standard? *Archives of Surgery* 2000;135(8):943–7

- - not clear whether approach is transperitoneal; historical comparison

Shalhav AL, Siqueira TM, Gardner TA, Paterson RF, Stevens LH. Manual specimen retrieval without a pneumoperitoneum preserving device for laparoscopic live donor nephrectomy. *Journal of Urology* 2002;168(3):941-4

- historical comparison

Stifelman MD, Hull D, Sosa RE, Su L-M, Hyman M, Stubenbord W, Shichman S. Hand assisted laparoscopic donor nephrectomy: a comparison with the open approach. *Journal of Urology* 2001;166(2):444-8

- concurrent comparison of hand-assisted laparoscopic versus open (no LLDN arm)

Waller JR, Hiley AL, Mullin EJ, Veitch PS, Nicholson ML. Living kidney donation: a comparison of laparoscopic and conventional open operations. *Postgraduate Medical Journal* 2002;78(917):153-7

- historical comparison

Wolf JS, Marcovich R, Merion JW, Konnak RM. Prospective case matched comparison of hand assisted laparoscopic and open surgical live donor nephrectomy. *Journal of Urology* 2000;163(6):1650-3

- concurrent comparison of hand-assisted laparoscopic versus open (no LLDN arm); same patients as Rudich et al. 2001

Wolf JS, Merion RM, Leichtman AB, Campbell DA, Magee JC, Punch JD, Turcotte JG, Konnak JW. Randomized controlled trial of hand-assisted laparoscopic versus open surgical live donor nephrectomy. *Transplantation* 2001;72(2):284-90

RCT of hand assisted laparoscopic versus open live donor nephrectomy (no LLDN arm)