# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of laparoscopic

## repair of abdominal aortic aneurysm

An abdominal aortic aneurysm is a bulge in the section of the aorta that travels down through the abdomen. It occurs because of a weakness in the wall of the aorta. If the aneurysm bursts (ruptures), it causes internal bleeding, and this can be rapidly fatal. The damaged section of the aorta can be repaired preventatively using a synthetic tube stitched into the artery by video keyhole surgery.

## 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 January 2007

## **Procedure name**

Laparoscopic repair of abdominal aortic aneurysm

## **Specialty societies**

- Vascular Society of Great Britain and Ireland
- Association of Laparoscopic Surgeons of Great Britain and Ireland

## Description

#### Indications

Abdominal Aortic Aneurysm. Dilatation of the aorta, to form an aneurysm, occurs in about 2% of men over the age of 65 (it is less common in women). In some cases aneurysms continue to enlarge and there is then a risk that they may leak or rupture, causing internal bleeding and death. Some patients

with a ruptured aneurysm will survive long enough to have surgery for ruptured aortic aneurysms but the mortality is high. If a large aneurysm is detected, then preventive treatment is often advised to remove the risk of rupture.

#### Current treatment and alternatives

The traditional treatment for abdominal aortic aneurysm is open surgical repair. The aneurysm is opened and a graft is then sewn in above and below the weakened area to allow normal blood flow. A less invasive approach is now commonly used, involving endovascular stent graft placement via catheters in the femoral arteries, but not all aneurysms are suitable for endovascular treatment.

#### What the procedure involves

The procedure requires general anaesthesia. A midline minilaparotomy incision is made for insertion of one of the surgeon's hands for hand assisted laparoscopic surgery (HALS). Three or more small skin incisions are made for insertion of a laparoscope and instruments. Clamps are applied above and below the aneurysm and its sac is opened. Thrombus is removed and patent lumbar arteries are sutured from the inside of the aneurysm. A prosthetic vascular graft is anastomosed to the proximal and distal ends of the aorta Grafting may be extended into the iliac arteries if necessary. The aneurysm wall and the posterior parietal peritoneum are closed to cover the graft. The abdominal cavity is rinsed with warm saline and closed.

## Efficacy

Specialist Advisers considered the key efficacy outcomes of this procedure to be successful complete repair, open conversion rates, operative time, intensive care unit and overall length of stay, patient quality of life criteria, renal function, return to theatre, and 30 day survival.

The majority of the outcomes reported in the studies included in this overview concern the characteristics of the procedure and the immediate recovery period. No evidence from randomised controlled trials is available.

#### Operative time

In three non-randomised controlled trials which compared laparoscopic aneurysm repair with open surgery, the mean operative time was longer in the laparoscopic groups (181 minutes using HALS<sup>1</sup>, 468 minutes<sup>2</sup>, and 7.7 hours<sup>3</sup>) than in the patients undergoing open surgery (136 minutes<sup>1</sup>, 301minutes<sup>2</sup>, and 5.0 hours<sup>3</sup> respectively). Statistical significance levels were not stated in any of these three studies. A fourth non-randomised controlled study comparing laparoscopic aneurysm repair (HALS) with endovascular stenting reported that operative time was again longer in the laparoscopic repair group (198 minutes and 149 minutes respectively - not a statistically significant difference)<sup>4</sup>.

In one case series the mean operative time was 257 minutes (for HALS)<sup>5</sup> and in a second case series operative time was 265 minutes for a totally laparoscopic aneurysm repair procedure, and 175 minutes with HALS <sup>6</sup>.

#### Length of Stay

Conversely to operative time, hospital length of stay (LOS) was lower following laparoscopic aneurysm repair than open surgery. In three non randomised controlled trials LOS was 5.9 days (HALS)<sup>1</sup>, 6.2 days<sup>2</sup>, and 6.3 days<sup>3</sup>, following laparoscopic aneurysm repair, whereas it was 9.4 days<sup>1</sup>, 10.0 days<sup>2</sup>, and 10.2 days<sup>3</sup> respectively following open repair. One non-randomised controlled study reported that LOS was broadly similar following HALS (7.4 days) and endovascular stenting (6.4 days)<sup>4</sup>.

In one case series LOS was 5 days among 131 patients treated with totally laparoscopic aneurysm repair and 7days in 215 patients with HALS<sup>6</sup>. In a second case series overall LOS following HALS was reported as 4.4 days. However, subgroup analysis showed a statistically significant difference between the first 30 patients treated at one institution (5.3 days) and the last 92 patients treated (4.1 days) (p=0.001)<sup>5</sup>.

#### Safety

The important safety outcomes by which to evaluate this procedure were highlighted by Specialist Advisers to be death within 30 days and late mortality, and major complications such as blood loss, infection, multiple organ failure, and leg ischemia / limb loss.

The rate of postoperative death following laparoscopic aneurysm repair has been reported at between,  $3\% (1/29)(HALS)^1$ ,  $4\% (1/24)(HALS)^4$ ,  $5\% (3/60)^3$ , and  $10\% (2/20)^2$ .

One non-randomised controlled trial reported that the rate of respiratory insufficiency was 3% (2/60) following laparoscopic aneurysm repair compared to 7% (7/100) following open repair, the rate of renal insufficiency was also lower, 2% (1/60) and 11% (11/100) respectively<sup>3</sup>. The rate of infection following laparoscopic aneurysm repair has been reported between 2%  $(1/60)^3$  (one case leading to multiple organ failure and death) and 5%  $(1/20)^2$ .

Other complications reported following laparoscopic aneurysm repair include bleeding at between <1% (1/122)(HALS)<sup>5</sup> and 2% (1/60)<sup>3</sup>, myocardial infarction 2% (1/60)<sup>3</sup>, and pneumonia at between 0%(HALS)<sup>1</sup>, 2% (2/131)<sup>6</sup> and (3/122)(HALS)<sup>5</sup>, and 4% (1/24)(HALS)<sup>4</sup>.

## Literature review

#### Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic repair of abdominal aortic aneurysm. Searches were conducted via the following databases, covering the period from their commencement to 19-12-2006: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix C for details of search strategy.)

The following selection criteria (Table 1) 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.

Characteristic	Criteria
Publication type	Clinical studies were 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 abdominal aortic aneurysm(s)
Intervention/test	laparoscopic repair or hand assisted laparoscopic repair
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.

#### Table 1 Inclusion criteria for identification of relevant studies

#### List of studies included in the overview

This overview is based on four non randomised controlled studies  $^{1,2,4,3}$ , and two case series  $^{5,6}$ .

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) have been listed in Appendix A.

#### Existing reviews on this procedure

There were no published reviews with meta analysis or evidence based guidelines identified at the time of the literature search.

## Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

#### Interventional procedures:

IPG163 Stent-graft placement in abdominal aortic aneurysm - guidance

#### Technology appraisals:

None

#### **Clinical guidelines:** None

Public health: None

Kolvenbach R (2001) <sup>1</sup> Surgical parameters Group mean results       Complications Group mean results       Outcome       Laparoscopic n=29       Open n=19       Open n=29       Open n=19       Outcome       Lap. Notality       Outcome       Lap. N=29       Open n=19       Open n=29       Open n=19       Open n=29       Open n=29       Open n=19       Open n=19       Open n=29       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=29       Open n=19       Open n=29       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=29       Open n=19       Open n=29       Open n=19       Open n=19       Open n=19       Open n=29       Open n=19       Open n=19       Open n=19       Open n=29       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19       Open n=19	Study details	Key efficacy find	ings			Key safety find	ings		Comments
stated.	Kolvenbach R (2001) <sup>1</sup> <b>Non-randomised controlled trial</b> Germany Study period: not stated <b>n = 48 (29 laparoscopic repair, 19</b> <b>open repair)</b> Population: Not described Indications: Patients with abdominal aortic aneurysm, or aortic occlusive disease (not further defined). Technique: Anaesthesia not	Key efficacy find Surgical paramet Group mean resul Outcome Operative time (min) Aortic cross clamp time (min) Blood loss (ml) ICU stay (days) Recovery Group mean resul Outcome First solid food (days) Length of stay (days) Postoperative	ings ters Laparoscopic n=29 180.67 56.67 711.00 1.30 tts Laparoscopic n=29 1.57 5.93	Open n=19 135.79 49.16 813.68 2.11 Open n=19 3.32 9.37	p= NR NR NR NR p= <0.05 <0.05	Key safety find Complications Group mean res Outcome Mortality Pneumonia Atelectasis Sigmoid ischemia leus Distal embolisation Incisional hernia Lymphatic fistula Colitis No details of sta	sults Lap. n=29 3% (1/29) 0% 3% (1/29) 3% (1/29) 3% (1/29) 3% (1/29)	n=19 5% (1/19) 11% (2/19) 5% (1/19) 0% 5% (1/19) 5% (1/19) 0%	Outcomes not reported separately for AAA patients and the number of AAA patients is unclear Control patients came from a concurrent group of patients having open surgery. Patient selection method not described Authors state that obesity was not a contraindication for laparoscopic treatment. The number of operators and their experience is not stated. It is unclear whether the operator(s) for both techniques were the same. Criteria of choice of approach n

#### Table 2 Summary of key efficacy and safety findings on laparoscopic repair of abdominal aortic aneurysm

Abbreviations used: AAA - abdominal ac	ortic aneurysm, HAL	S – hand assiste	ed laparosco	pic surge	ry.			
Study details	Key efficacy find	ings			Key safety findings			Comments
Edoga J K (1998) <sup>2</sup> Non-randomised controlled trial USA	Surgical parameter Successful completer achieved in 91% ( the procedure was retroperitoneal ap	etion of laparoso 20/22) of patien s converted to a proach.	its. In two pa		Complications Group mean results Outcome Mortality	Lap. n=20 10% (2/20)	open n=100 4% (4/100)	Outcome evaluation of patients undergoing the laparoscopic procedure is limited to the 20 patients in which the operation was successfully completed.
Study period: Feb 1997 to Oct 1997	Group mean resul Outcome	Laparoscopic n=20	Open n=100	p=	Right-leg pareasthesia Oedema of right	10% (2/20) 5% (1/20)	NR NR	Operator experience and number
<ul> <li>n = 122 (22 laparoscopic, 100 open repair)</li> <li>Population: Male = 75%, Age = 72 years, AAA size = 6.0 cm.</li> <li>Indications: Patients with intfarenal AAA who were not consideredfit for open operation. Emergency presentations (patients with ruptured aneurysm) excluded.</li> <li>Technique: Under general anaesthesia a 1.5 cm incision, and 4 port access using retroperitoneal access. Woven dacron graft used.</li> <li>Follow-up: 1 month</li> <li>Conflict of Interest: Not stated</li> </ul>	Anaesthesia time (min) Aortic cross clamp time (min) Blood loss (ml) ICU stay (days) Length of stay (days)	n=20 468 146 1713 2.45 6.20	•	NR NR NR NR NR	Oedema of right buttock (All resolved sponta Declamping shock /acidosis Thrombi on graft limb Required transfemo Avulsion injury to the left ureter Required left nephro Worsening azotemia Invasive clostridium difficile enterocolitis Required total abdo Postoperative ileus Transient paraparesis Full function recove physical therapy	5% (1/20) neously with 0% 5% (1/20) ral thrombed 5% (1/20) ectomy 10% (2/20) 5% (1/20) minal colect 25% (5/20) 5% (1/20)	NR NR NR NR NR NR Omy NR	Operator experience and number of operators are not stated. No statistical analysis comparing outcomes following the different procedures is undertaken.

Study details Key efficacy findings Key safety findings Comments Kolvenbach R (2001a)<sup>4</sup> Surgical parameters Complications Choice of endovascular stenting Successful completion of laparoscopic procedure was Group mean results or laparoscopic repair based on achieved in 96% (23/24) of patients, with one shape of aneurysm. Non randomised controlled trial conversion to open surgery due to intraoperative Outcome Stent Lap. bleeding from the lumbar vein. Conversion of Potentially some of the same n=24 n=13 Germany, UK, Brazil endoscopic stent graft procedure not stated although patients as included in Mortality 4% (1/24) 0% one patient required a laparoscopy for clip legation of Kolvenbach (2001), although this Limb 0% 8% (1/13) Study period: Jan 1998 to Oct 2001 a type II endoleak. report appears to include thrombosis patients from 3 centres. 4% (1/24) 0% Pneumonia n = 37 (24 laparoscopic, 13 Arrhythmia 4% (1/24) 0% Group mean results Prospective study. Analysis on EVAR) 0% lleus 4% (1/24) Outcome Laparoscopic Endovascular intention to treat basis. Graft 8% (1/13) 0% n=24 Stent n=13 Population: Male = NS, Age = NS. thrombosis Operative time (min) 198.1 149.2\* Adjunctive intraoperative Thype II 0% 8% (1/13) Aortic cross clamp 59.2 15.7 procedures were performed in 4 Indications: Patients with AAA who endoleak time (min) patients in the Laparoscopic were referred for endovascular Lymphatic 4% (1/24) 8% (1/13) Blood loss (units) 2.2 repair group, making comparison 1.1 fistula stenting. Postoperative body 35.2 34.8 between groups difficult. 8% (1/13) Transient renal 0% temperature (C) failure Technique: Anaesthesia not Length of stay (days) 7.4 6.4\* Authors state that given the \* p= NS. Otherwise p= NR described Hand Assisted small number of patients in the endovascular stent graft group Laparascopic repair via a 6 to 7 cm All patients following laparoscopic repair were comparison of complication rates incision, and 3-port access using monitored in ICU, whereas 'most' patients in the is not possible transperitoneal access. Various endovascular stent group were transferred to the grafts used. Vs endovascular stent vascular ward (p<0.001). Clinical and demographic graft placement. characteristic not reported, and these may have been different Follow-up: 1 month between groups at baseline. Conflict of Interest: None Study states that the aim was to evaluate whether laparoscopic AAA resection can be offered to patients unsuitable for endovascular repair, but some patients then selected to undergo endovascular stent grafting. Authors state that a prospective randomised trial would be ideal to compare techniques.

Abbreviations used: AAA - abdominal aortic aneurysm. HALS - hand assisted laparoscopic surgery.

Abbreviations used: AAA - abdominal aortic aneurysm, HALS - hand assisted laparoscopic surgery.

Study details	Key efficacy findings			Key safety fir	ndings		Comments
Castronuovo J J (2000) <sup>3</sup>	Surgical parameters			Complication	S		Consecutive patients at one
· · · · ·	Conversion to open surge	ery was required	d in 5%				institution.
Non-randomised controlled trial	(3/60) of patients.			Outcome	All p	atients	
					n=60	C	Prospective data collection via
USA	Group mean (range) resu			Postoperative	e death to 5% (	(3/60)	registry established.
00/1	Outcome	Laparoscopic	Open n=100	30 days		. ,	
Study pariod: Eab 1007 to May		n=60			sis and multiple		Patient outcomes are compare
Study period: Feb 1997 to May	Operative time (hours)	7.7	5.0	failure after C	lostridium Diffic	cile infection	to those undergoing open
1999		(1.5 to 11.5)	(2.6 to 9.7)		liogenic shock f	ollowing	aneurysm surgery, from a
	Aortic cross clamp time	112	90	myocardial in			contemporary consecutive
n = 160 (60 laparoscopic repair,	(min)	(43 to 286)	(38 to 243)		ired reoperatio		series. The clinical
100 open repair)	Ventilator support	0.8	2.2		respiratory and	renal	characteristics or patients in
	(days)	(0 to 19)	(0 to 38)	insufficiency (	developed.		either treatment group were no
Population: Age = 71 years, Male =	ICU stay (days)	2.4	3.3				described.
85%, Mean AAA diameter = 57 mm	<b>-</b>	(1 to 24)	(0 to 17)		tor authors com		
	Total length of stay	6.3	10.2		or cases treate		It is not clear whether the case
Indications: Patients with	(days)	(1 to 25)	(2 to 83)		ame institution.		that were converted to open
	First solid food (days)	1.8	5.4		atients treated b		surgery were discounted from
abdominal aortic aneurysm of at		(1 to 19)	(1 to 77)	aneurysmecto	my was 4% (4/	100).	subsequent analysis or
least 50mm diameter or that had	p= NR for all.						evaluated on intention to treat
increased by 5 mm on CT scan							basis.
(period not stated). After the first 12	Aortic cross clamp time d						
cases, high risk patients were	with a mean of 146 in the		s and a mean	Outcome	Laparoscopic		No classification of exclusion
excluded from the study	of 95 minutes in the last 2	25 patients.			n=60	n=100	criteria for high risk patients is
				Respiratory	3% (2/60)	7% (7/100)	provided other than they were
Technique: Anaesthesia not				insufficiency			ruled out after cardiac respirate and renal function evaluation
defined. Laparoscopic assisted				Renal	2% (1/60)	11%	
surgery with retroperitoneal				insufficiency		(11/100)	
approach with 5-port access. CO2				Paraparesis	2% (1/60)	1% (1/100)	
insufflation to a maximum of 15 mm					00/ (4/00)	00/	
				Ureteral	2% (1/60)	0%	
Hg. Bifurcated woven Dacron graft				injury	00/ (4/00)	00/ (0/460)	
used.				Graft	2% (1/60)	2% (2/100)	
				thrombosis	00/ /4/00)	00/ (0/400)	
Follow-up: Unclear, probably to 1				Infection (C	2% (1/60)	6% (6/100)	
month				Difficile)	00/ (4/00)	40/ (4/400)	
				Deep vein	2% (1/60)	1% (1/100)	
Conflict of Interest: None				thrombosis			
				p= NR			

Study details	Key efficacy finding	S			Key safety findings		Comments
Ferrari M (2006) <sup>5</sup>	Surgical parameters	;			Complications		Unusually low mortality rate of
	Conversion to open s						0% among 122 patients treated
Case series	of the 122 patients tre				No post-operative deat	hs reported.	for abdominal aortic aneurysm
	incision was extended			for			
taly	repair of concomitant	iliac aneury	sms.		Overall morbidity rate w	vas 12%	Patient selection was
lary					(15/122).		conditioned by practicality as
Study pariod: Oct 2000 to Mar 2004	Overall outcomes						only two surgeons at the
Study period: Oct 2000 to Mar 2004	Mean ± standard devi	iations			Bleeding from the hypo		institution were trained in the
	Outcome		All patients	n=122	occurred in <1% (1/122		HALS technique.
n = 122			057 ( 70)		thrombosis of a bifurcat		
	Operative time (min)	• 、	257 (± 70)		occurred in <1% (1/122		A consecutive cohort of patient
Population: Age = 68 years, Male =	Laparoscopic time (m		64 (± 32)		Both required emergen		fulfilling criteria for HALS at one
98%, Mean AAA diameter = 56 mm	Aortic cross clamp tin	76 (± 26)		but without extending the length of the		institution.	
	Blood loss (ml)		1136 (± 71		incision made for HALS	6	
ndications: Patients with	ICU length of stay (ho		14.3 (± 13)				No details of outcome
abdominal aortic aneurysm.	Time to bowel moven				Blood transfusions were	e required in 7%	assessment by independent
Patients whose AAA had increased	Time to first solid mea	ai (nours)	27.4 (± 15)		(8/122) of patients		clinicians.
Icm in last 12 months were also	'Postoperative recover	and longth	4 4 ( , 4 7)				
candidates.	of stay (days)	ery / ierigin	$4.4(\pm 1.7)$		Other complications		
anuluales.	UI Stay (Uays)				Outcome	All patients	
	Neither AAA size (gre	ator or less	than 60 mm	) or		n=122	
Technique: Anaesthesia not	patient BMI (greater c			) 01	Longer IV crystalloid	2% (3/122)	
lefined. HALS with a 7 to 8 cm	significantly influence				support for ileus	00/ (0/400)	
nidline incision, and 3-port access.		u operative	unio.		Arrhythmia	2% (3/122)	
Synthetic woven Dacron prostheses	Group mean results g	rouped by a	operator expe	erience	Pneumonia Muse andial la sherria	2% (3/122)	
ised.	Outcome	First 30	Second 92		Myocardial Ischemia	2% (2/122)	
		patients	patients	F	Renal dysfunction	2% (2/122)	
Follow-up: 29 months (mean)	Operative time (min)			<0.001	Incisional hernia (in	2% (3/122)	
•	Laparoscopic time	98 (± 35)	52 (±21)	<0.001	obese patients) Long lasting wound	0%	
Conflict of Interest: None	(min)	,			<b>u</b>	0%	
	Aortic cross clamp	90 (± 28)	71 ( ±24)	<0.001	pain		
	time (min)	. ,	. ,				
	Blood loss (ml)	1077	1101	0.917			
		(± 726)	(± 711)	(NS)			
	'Postoperative	5.3 (± 2)	4.1 (±1)	0.001			
	recovery' / length of						
	stay (days)						

Abbreviations used: AAA - abdominal aortic aneurysm, HALS - hand assisted laparoscopic surgery.

Study details	Key efficacy findings			Key safety fin	dings		Comments
Kolvenbach R (2006) <sup>6</sup> Case series	Surgical parameters Perioperative data			Complications Outcome	Totally Laparoscopic	Lap. assisted	Possibly some of the same patients as included in Kolvenbach (2001) or (2001a).
Case series Germany Study period: 1996 to 2005 n = 346 (131 total laparoscopic approach, 215 HALS) Population: Not reported Indications: Patients with abdominal aortic aneurysm (not further defined). Technique: Anaesthesia not defined. Totally laparoscopic approach with 7-port access, or laparascopic assisted procedure with mini incision. Tube graft used where possible, not further defined Follow-up: 8 months (mean) Conflict of Interest: None	Group median results (a Outcome Operative time (min) Aortic cross clamp time (min) Blood loss (ml) Body temperature (C) Length of stay (days) ITU Length of stay (days) Conversion to open repair * p= <0.05. Otherwise p	Totally Laparoscopic n=131 265 (145 to 405) 95 (30 to 160) 1100 (250 to 3000) 36 (34.5 to 37.0) 5 (3 to 21) 2 (1 to 16) 18% (23/131)	Laparascopic assisted n=215 175 (85 to 290)* 55 (25 to 130)* 850 (150 to 1800)* 35 (34.0 to 36.9) 7 (5 to 18) 2 (0 to 8) 5% (11/215)*	Mortality Major complication Cardiovascular complication Cerebral ischemia Colonic ischemia Bowel perforation Pancreatitis Transient renal failure Renal failure Pneumonia Operative bleeding Postoperative bleeding Bowel obstruction Peripheral ischemia Embolisation Compartment syndrome Renal artery thrombosis Spleen injury Heparin induced thromboyctope	Laparoscopic n=131 3% (4/131)* 18% (23/131)* <1% (1/131) <1% (1/131) 2% (2/131) <1% (1/131) 2% (2/131) 2% (2/131) 2% (2/131) 2% (2/131) 2% (2/131) <1% (1/131) <1% (1/131) <1% (1/131) <1% (1/131) <1% (1/131) <1% (1/131)	assisted n=215 2% (4/215) 7% (14/215) <1% (1/215) 0% <1% (1/215) 0% <1% (2/215) 0% 1% (3/215) 0% 2% (4/215) <1% (1/215) 0% 2% (4/215) <1% (1/215) 0% 0% 0%	Kolvenbach (2001) or (2001a). All operations undertaken by one of seven surgeons who had beer trained in the totally laparoscopic technique Protocol changed in 2000 to undertake purely laparoscopic procedures. The first 20 cases were evaluated as the learning curve. Study report also provides outcomes for patients with aortic occlusions. Data not presented here.

#### Validity and generalisability of the studies

- Studies describe a mixture of interventions, some with hand assistance, and one series with a small number of patients treated with robotic assistance.
- Few long-term clinical outcomes are reported, most studies concentrate on surgical parameters. This could probably be considered appropriate for the type of the treated condition, nevertheless more long-term data would have been re-assuring.
- Controlled studies compare laparoscopic repair to either open repair or endovascular stenting.
- There is some degree of variation between studies in the criteria used for case selection, with high-risk patients excluded in some studies. This makes comparison between studies difficult.
- Both retroperitoneal and transperitoneal access have been reported in the studies included.

## Specialist advisers' opinions

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

Mr J Earnshaw, Miss Cathy McGuiness, Mr R Vohra, Mr D Nott.

- All four advisers were unanimous in their opinions on the current status of the procedure, that it is novel and with uncertain safety and efficacy profile.
- The proposed benefit of the procedure is to effect a complete repair of the aorta avoiding the need for open surgery and reducing the length of hospital stay
- The adverse events known to advisers or reported in the literature include death, bowel perforation, bleeding, vascular embolisation, long ischemia times and the need to convert to open surgery.
- Additional theoretical adverse events may include long operations, particularly early in the learning curve.
- One adviser suggested that if the repair can be completed successfully it is assumed to be as safe as an open repair.
- The advisers suggested that there is a steep learning curve with this operation, and practitioners require advanced laparoscopic training and expertise in vascular surgery. In addition, appropriate hardware must be available.
- Advisers were divided in their opinions as to the likely impact of this procedure on the NHS, with two suggesting that it is likely to be used in fewer than 10 specialist centres, one that it would probably be used in a minority of hospitals but at least 10, and one was unable to predict the likely spread at the present time.
- Advisers considered a lack of training in laparoscopic vascular surgery as a potential limitation to the development of this procedure.

## **Issues for consideration by IPAC**

- There is potentially some double counting between Kolvenbach 2001 papers, but this is likely to be minimal
- Non-English studies excluded owing to sufficient data being available in the English language.
- Variation in techniques described (totally laparoscopic, HALS, roboticallyassisted).

## References

- 1 Kolvenbach R. (2001) Hand-assisted laparoscopic abdominal aortic aneurysm repair. *Semin Laparosc.Surg* 8: 168-177.
- 2 Edoga JK, Asgarian K, Singh D et al. (1998) Laparoscopic surgery for abdominal aortic aneurysms. Technical elements of the procedure and a preliminary report of the first 22 patients. *Surg Endosc* 12: 1064-1072.
- 3 Castronuovo JJ, Jr., James KV, Resnikoff M et al. (2000) Laparoscopicassisted abdominal aortic aneurysmectomy. *J Vasc.Surg* 32: 224-233.
- 4 Kolvenbach R, Ceshire N, Pinter L et al. (2001) Laparoscopy-assisted aneurysm resection as a minimal invasive alternative in patients unsuitable for endovascular surgery. *J Vasc.Surg* 34: 216-221.
- 5 Ferrari M, Adami D, Corso AD et al. (2006) Laparoscopy-assisted abdominal aortic aneurysm repair: Early and middle-term results of a consecutive series of 122 cases. *Journal of Vascular Surgery* 43: 695-700.
- 6 Kolvenbach R, Puerschel A, Fajer S et al. (2006) Total Laparoscopic Aortic Surgery versus Minimal Access Techniques: Review of More than 600 patients. *Vascular* 14 (4): 186-192.

# Appendix A: Additional papers on laparoscopic repair of abdominal aortic aneurysm not included in summary Table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Alimi YS, Di Molfetta L., Hartung O. et al. (2003) Laparoscopy-assisted abdominal aortic aneurysm endoaneurysmorraphy: early and mid- term results. <i>J Vasc.Surg</i> 37 (4): 744- 749.	Case series n=24 FU=17 months	One patient (4%) died in the immediate postoperative period. Clamp time decreased from 275 minutes in first 10 patients to 195 minutes in the last 14	Have larger series included in table 2
Chen MH, Murphy E.A., Halpern V. et al. (1995) Laparoscopic-assisted abdominal aortic aneurysm repair. <i>Surg</i> <i>Endosc</i> 9 (8): 905-907.	Case report n=1 FU=6 days	Total operative time 4 hours, and blood loss 1I. An uncomplicated operative course and the patient was discharged in day 6	Have larger series included in table 2 Have series with longer follow up included in table 2
Coggia M, Javerliat I., Di C., I et al. (2004) Total laparoscopic infrarenal aortic aneurysm repair: preliminary results. <i>J Vasc.Surg</i> 40 (3): 448-454.	Case series n=30 FU=12 months	Median operative time was 290 minutes, and blood loss 1680 ml. Conversion to minilaparotomy in 2/30 patients, and lethal MI in 2/30 patients.	Have larger series included in table 2
Kline RG, D'Angelo A.J., Chen M.H. et al. (1998) Laparoscopically assisted abdominal aortic aneurysm repair: first 20 cases. <i>J Vasc.Surg</i> 27 (1): 81-87.	Case series n=20 FU=12 months	Laparascopically assisted repair possible in 18 /20 patints. Mean operative time was 4.1 hours, and length of stay 5.8 days. One patient required colotomy for colon ischemia, there were no deaths	Have larger series included in table 2
Kolvenbach R, Schwierz E, Wasilljew S et al. (2004) Total laparoscopically and robotically assisted aortic aneurysm surgery: a critical evaluation. <i>J Vasc.Surg</i> 39: 771-776	Case series n = 47 FU=8 months	Successful completion of laparoscopic procedure was achieved in 83% (39/47) of patients. Ten patients treated with robotic assistance No deaths were reported	Same patients as included in Kolvenbach (2006)

# Appendix B: Related published NICE guidance for laparoscopic repair of abdominal aortic aneurysm

Guidance programme	Recommendation
Interventional procedures	IPG163 Stent-graft placement in abdominal aortic aneurysm – guidance
	1.1 Current evidence on the efficacy and short- term safety of stent–graft placement in abdominal aortic aneurysm appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
	1.2 Clinicians should ensure that patients fully understand the long-term uncertainties and the potential complications associated with this procedure. In particular, patients should understand: the risks of endovascular leaks; the possibility of secondary intervention; and the need for lifelong follow-up. Patients should be provided with clear written information.
	1.3 Patient selection is important, particularly for patients who would normally be considered unfit for surgery.
	1.4 Publication of long-term data would be useful. It is recommended that all patients who have the procedure are entered onto one of the existing registries.
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

# Appendix C: Literature search for laparoscopic repair

## of abdominal aortic aneurysm

IP: 382 laparoscopic repair of abdominal aortic aneurysms					
Database	Date searched	Version searched			
Cochrane Library	19/12/2006	2006, Issue 4			
CRD databases (DARE & HTA)	19/12/2006	2006, Issue 4			
Embase	15/12/2006	1980 to 2006 Week 49			
Medline	14/12/2006	1966 to November Week 3 2006			
Premedline	18/12/2006	1966 to present			
CINAHL	18/12/2006	1982 to December Week 2 2006			
British Library Inside Conferences	19/12/2006	-			
NRR	18/12/2006	2006 Issue 4			
Controlled Trials Registry		-			

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

#### **Database: Medline**

Str	ategy	used	:

- 1 Aortic Aneurysm, Abdominal/
- 2 (aort\$ adj3 abdom\$).tw.
- 3 AAA.tw.
- 4 iliac.tw.
- 5 or/2-4
- 6 aneurysm\$.tw.
- 7 5 and 6
- 8 1 and 7
- 9 exp Laparoscopy/
- 10 exp Laparoscopes/
- 11 exp Surgical Procedures, Minimally Invasive/
- 12 laparoscop\$.tw.
- 13 endoscop\$.tw.
- 14 percutan\$.tw.
- 15 or/9-14

16	8 and 15				
17	Stents/				
18	(endovascul\$ adj3 (repair\$ or staple\$)).tw.				
19	or/17-18				
20	16 and 19				
21	Animals/				
22	Humans/				
23	21 not (21 and 22)				
24	20 not 23				
25	from 24 keep 1-242				
Corr	Comments:				
•					