

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 HALS¹, 468 minutes², and 7.7 hours³) than in the patients undergoing open surgery (136 minutes¹, 301 minutes², and 5.0 hours³ 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)⁴.

In one case series the mean operative time was 257 minutes (for HALS)⁵ and in a second case series operative time was 265 minutes for a totally laparoscopic aneurysm repair procedure, and 175 minutes with HALS⁶.

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)¹, 6.2 days², and 6.3 days³, following laparoscopic aneurysm repair, whereas it was 9.4 days¹, 10.0 days², and 10.2 days³ 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)⁴.

In one case series LOS was 5 days among 131 patients treated with totally laparoscopic aneurysm repair and 7 days in 215 patients with HALS⁶. 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) ($p=0.001$)⁵.

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) respectively³. 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)⁵ and 2% (1/60)³, myocardial infarction 2% (1/60)³, and pneumonia at between 0%(HALS)¹, 2% (2/131)⁶ and (3/122)(HALS)⁵, and 4% (1/24)(HALS)⁴.

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.

Table 1 Inclusion criteria for identification of relevant studies

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.

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

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

Abbreviations used: AAA - abdominal aortic aneurysm, HALS – hand assisted laparoscopic surgery.							
Study details	Key efficacy findings				Key safety findings		
Kolvenbach R (2001)¹ Non-randomised controlled trial Germany Study period: not stated n = 48 (29 laparoscopic repair, 19 open repair) Population: Not described Indications: Patients with abdominal aortic aneurysm, or aortic occlusive disease (not further defined). Technique: Anaesthesia not defined. HALS with a 6 cm incision, and 3-port access using a transperitoneal or retroperitoneal access. Tube graft used. Follow-up: not stated (to discharge) Conflict of Interest: Not stated	Surgical parameters				Complications		
	Group mean results				Group mean results		
	Outcome	Laparoscopic n=29	Open n=19	p=	Outcome	Lap. n=29	Open n=19
	Operative time (min)	180.67	135.79	NR	Mortality	3% (1/29)	5% (1/19)
	Aortic cross clamp time (min)	56.67	49.16	NR	Pneumonia	0%	11% (2/19)
	Blood loss (ml)	711.00	813.68	NR	Atelectasis	0%	5% (1/19)
	ICU stay (days)	1.30	2.11	NR	Sigmoid ischemia leus	3% (1/29)	0%
	Recovery				Distal embolisation	3% (1/29)	0%
	Group mean results				Incisional hernia	0%	5% (1/19)
	Outcome	Laparoscopic n=29	Open n=19	p=	Lymphatic fistula	3% (1/29)	5% (1/19)
	First solid food (days)	1.57	3.32	<0.05	Colitis	3% (1/29)	0%
	Length of stay (days)	5.93	9.37	<0.05	No details of statistical significance are provided		
	Postoperative temperature (C)	35.07	34.34	<0.05			

Abbreviations used: AAA - abdominal aortic aneurysm, HALS – hand assisted laparoscopic surgery.								
Study details	Key efficacy findings				Key safety findings			Comments
Edoga J K (1998) ² Non-randomised controlled trial USA Study period: Feb 1997 to Oct 1997 n = 122 (22 laparoscopic, 100 open repair) Population: Male = 75%, Age = 72 years, AAA size = 6.0 cm. Indications: Patients with infrarenal AAA who were not considered fit for open operation. Emergency presentations (patients with ruptured aneurysm) excluded. Technique: Under general anaesthesia a 1.5 cm incision, and 4 port access using retroperitoneal access. Woven dacron graft used. Follow-up: 1 month Conflict of Interest: Not stated	Surgical parameters Successful completion of laparoscopic procedure was achieved in 91% (20/22) of patients. In two patients the procedure was converted to an open retroperitoneal approach. Group mean results OutcomeLaparoscopicOpenp= n=20n=100 Anaesthesia468301NR time (min) Aortic cross14696NR clamp time (min) Blood loss (ml)17131387NR ICU stay (days)2.453.22NR Length of stay6.209.97NR (days)				Complications Group mean results OutcomeLap.open n=20n=100 Mortality10%4% (2/20)(4/100) Right-leg10%NR paresthesia(2/20) Oedema of right5% (1/20)NR buttock (All resolved spontaneously within 48 h) Declamping shock0%NR /acidosis Thrombi on graft5% (1/20)NR limb Required transfemoral thrombectomy Avulsion injury to5% (1/20)NR the left ureter Required left nephrectomy Worsening10%NR azotemia(2/20) Invasive5% (1/20)NR clostridium difficile enterocolitis Required total abdominal colectomy Postoperative ileus25%NR (5/20) Transient5% (1/20)NR paraparesis Full function recovery with 6 weeks of physical therapy			Outcome evaluation of patients undergoing the laparoscopic procedure is limited to the 20 patients in which the operation was successfully completed. Operator experience and number of operators are not stated. No statistical analysis comparing outcomes following the different procedures is undertaken.

Abbreviations used: AAA - abdominal aortic aneurysm, HALS – hand assisted laparoscopic surgery.																																																								
Study details	Key efficacy findings			Key safety findings	Comments																																																			
Kolvenbach R (2001a) ⁴ Non randomised controlled trial Germany, UK, Brazil Study period: Jan 1998 to Oct 2001 n = 37 (24 laparoscopic, 13 EVAR) Population: Male = NS, Age = NS. Indications: Patients with AAA who were referred for endovascular stenting. Technique: Anaesthesia not described Hand Assisted Laparoscopic repair via a 6 to 7 cm incision, and 3-port access using transperitoneal access. Various grafts used. Vs endovascular stent graft placement. Follow-up: 1 month Conflict of Interest: None	Surgical parameters Successful completion of laparoscopic procedure was achieved in 96% (23/24) of patients, with one conversion to open surgery due to intraoperative bleeding from the lumbar vein. Conversion of endoscopic stent graft procedure not stated although one patient required a laparoscopy for clip legation of a type II endoleak. <table><tr><td colspan="3">Group mean results</td></tr><tr><td>Outcome</td><td>Laparoscopic n=24</td><td>Endovascular Stent n=13</td></tr><tr><td>Operative time (min)</td><td>198.1</td><td>149.2*</td></tr><tr><td>Aortic cross clamp time (min)</td><td>59.2</td><td>15.7</td></tr><tr><td>Blood loss (units)</td><td>2.2</td><td>1.1</td></tr><tr><td>Postoperative body temperature (C)</td><td>35.2</td><td>34.8</td></tr><tr><td>Length of stay (days)</td><td>7.4</td><td>6.4*</td></tr></table> * p= NS. Otherwise p= NR All patients following laparoscopic repair were monitored in ICU, whereas 'most' patients in the endovascular stent group were transferred to the vascular ward (p<0.001).			Group mean results			Outcome	Laparoscopic n=24	Endovascular Stent n=13	Operative time (min)	198.1	149.2*	Aortic cross clamp time (min)	59.2	15.7	Blood loss (units)	2.2	1.1	Postoperative body temperature (C)	35.2	34.8	Length of stay (days)	7.4	6.4*	Complications Group mean results <table><tr><td>Outcome</td><td>Lap. n=24</td><td>Stent n=13</td></tr><tr><td>Mortality</td><td>4% (1/24)</td><td>0%</td></tr><tr><td>Limb thrombosis</td><td>0%</td><td>8% (1/13)</td></tr><tr><td>Pneumonia</td><td>4% (1/24)</td><td>0%</td></tr><tr><td>Arrhythmia</td><td>4% (1/24)</td><td>0%</td></tr><tr><td>Ileus</td><td>4% (1/24)</td><td>0%</td></tr><tr><td>Graft thrombosis</td><td>0%</td><td>8% (1/13)</td></tr><tr><td>Thype II endoleak</td><td>0%</td><td>8% (1/13)</td></tr><tr><td>Lymphatic fistula</td><td>4% (1/24)</td><td>8% (1/13)</td></tr><tr><td>Transient renal failure</td><td>0%</td><td>8% (1/13)</td></tr></table>	Outcome	Lap. n=24	Stent n=13	Mortality	4% (1/24)	0%	Limb thrombosis	0%	8% (1/13)	Pneumonia	4% (1/24)	0%	Arrhythmia	4% (1/24)	0%	Ileus	4% (1/24)	0%	Graft thrombosis	0%	8% (1/13)	Thype II endoleak	0%	8% (1/13)	Lymphatic fistula	4% (1/24)	8% (1/13)	Transient renal failure	0%	8% (1/13)	Choice of endovascular stenting or laparoscopic repair based on shape of aneurysm. Potentially some of the same patients as included in Kolvenbach (2001), although this report appears to include patients from 3 centres. Prospective study. Analysis on intention to treat basis. Adjunctive intraoperative procedures were performed in 4 patients in the Laparoscopic repair group, making comparison between groups difficult. Authors state that given the small number of patients in the endovascular stent graft group comparison of complication rates is not possible Clinical and demographic characteristic not reported, and these may have been different between groups at baseline. 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.
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Study details	Key efficacy findings		Key safety findings	Comments																																													
Castronuovo J J (2000)³ Non-randomised controlled trial USA Study period: Feb 1997 to May 1999 n = 160 (60 laparoscopic repair, 100 open repair) Population: Age = 71 years, Male = 85%, Mean AAA diameter = 57 mm Indications: Patients with abdominal aortic aneurysm of at least 50mm diameter or that had increased by 5 mm on CT scan (period not stated). After the first 12 cases, high risk patients were excluded from the study Technique: Anaesthesia not defined. Laparoscopic assisted surgery with retroperitoneal approach with 5-port access. CO2 insufflation to a maximum of 15 mm Hg. Bifurcated woven Dacron graft used. Follow-up: Unclear, probably to 1 month Conflict of Interest: None	Surgical parameters Conversion to open surgery was required in 5% (3/60) of patients. Group mean (range) results <table><tr><td>Outcome</td><td>Laparoscopic n=60</td><td>Open n=100</td></tr><tr><td>Operative time (hours)</td><td>7.7 (1.5 to 11.5)</td><td>5.0 (2.6 to 9.7)</td></tr><tr><td>Aortic cross clamp time (min)</td><td>112 (43 to 286)</td><td>90 (38 to 243)</td></tr><tr><td>Ventilator support (days)</td><td>0.8 (0 to 19)</td><td>2.2 (0 to 38)</td></tr><tr><td>ICU stay (days)</td><td>2.4 (1 to 24)</td><td>3.3 (0 to 17)</td></tr><tr><td>Total length of stay (days)</td><td>6.3 (1 to 25)</td><td>10.2 (2 to 83)</td></tr><tr><td>First solid food (days)</td><td>1.8 (1 to 19)</td><td>5.4 (1 to 77)</td></tr></table> p= NR for all. Aortic cross clamp time decreased with experience with a mean of 146 in the first 20 patients and a mean of 95 minutes in the last 25 patients.		Outcome	Laparoscopic n=60	Open n=100	Operative time (hours)	7.7 (1.5 to 11.5)	5.0 (2.6 to 9.7)	Aortic cross clamp time (min)	112 (43 to 286)	90 (38 to 243)	Ventilator support (days)	0.8 (0 to 19)	2.2 (0 to 38)	ICU stay (days)	2.4 (1 to 24)	3.3 (0 to 17)	Total length of stay (days)	6.3 (1 to 25)	10.2 (2 to 83)	First solid food (days)	1.8 (1 to 19)	5.4 (1 to 77)	Complications Outcome All patients n=60 Postoperative death to 5% (3/60) 30 days 1 patient sepsis and multiple organ failure after <i>Clostridium Difficile</i> infection 1 patient cardiogenic shock following myocardial infarction. 1 patient required reoperations for bleeding and respiratory and renal insufficiency developed. As a comparator authors compared the mortality rate for cases treated by open repair at the same institution. Mortality rate among patients treated by open aneurysmectomy was 4% (4/100). <table><tr><td>Outcome</td><td>Laparoscopic n=60</td><td>Open n=100</td></tr><tr><td>Respiratory insufficiency</td><td>3% (2/60)</td><td>7% (7/100)</td></tr><tr><td>Renal insufficiency</td><td>2% (1/60)</td><td>11% (11/100)</td></tr><tr><td>Paraparesis</td><td>2% (1/60)</td><td>1% (1/100)</td></tr><tr><td>Ureteral injury</td><td>2% (1/60)</td><td>0%</td></tr><tr><td>Graft thrombosis</td><td>2% (1/60)</td><td>2% (2/100)</td></tr><tr><td>Infection (C Difficile)</td><td>2% (1/60)</td><td>6% (6/100)</td></tr><tr><td>Deep vein thrombosis</td><td>2% (1/60)</td><td>1% (1/100)</td></tr></table> p= NR	Outcome	Laparoscopic n=60	Open n=100	Respiratory insufficiency	3% (2/60)	7% (7/100)	Renal insufficiency	2% (1/60)	11% (11/100)	Paraparesis	2% (1/60)	1% (1/100)	Ureteral injury	2% (1/60)	0%	Graft thrombosis	2% (1/60)	2% (2/100)	Infection (C Difficile)	2% (1/60)	6% (6/100)	Deep vein thrombosis	2% (1/60)	1% (1/100)	Consecutive patients at one institution. Prospective data collection via a registry established. Patient outcomes are compared to those undergoing open aneurysm surgery, from a contemporary consecutive series. The clinical characteristics or patients in either treatment group were not described. It is not clear whether the cases that were converted to open surgery were discounted from subsequent analysis or evaluated on intention to treat basis. No classification of exclusion criteria for high risk patients is provided other than they were ruled out after cardiac respiratory and renal function evaluation
Outcome	Laparoscopic n=60	Open n=100																																															
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Abbreviations used: AAA - abdominal aortic aneurysm, HALS – hand assisted laparoscopic surgery.						
Study details	Key efficacy findings			Key safety findings	Comments	
Ferrari M (2006) ⁵ Case series Italy Study period: Oct 2000 to Mar 2004 n = 122 Population: Age = 68 years, Male = 98%, Mean AAA diameter = 56 mm Indications: Patients with abdominal aortic aneurysm. Patients whose AAA had increased >1cm in last 12 months were also candidates. Technique: Anaesthesia not defined. HALS with a 7 to 8 cm midline incision, and 3-port access. Synthetic woven Dacron prostheses used. Follow-up: 29 months (mean) Conflict of Interest: None	Surgical parameters Conversion to open surgery was not required in any of the 122 patients treated. In 7% (9/122) the midline incision was extended to up to 12 cm to allow for repair of concomitant iliac aneurysms. Overall outcomes Mean ± standard deviations OutcomeAll patients n=122 Operative time (min)257 (± 70) Laparoscopic time (min)64 (± 32) Aortic cross clamp time (min)76 (± 26) Blood loss (ml)1136 (± 711) ICU length of stay (hours)14.3 (± 13) Time to bowel movement (hours)32.8 (± 12) Time to first solid meal (hours)27.4 (± 15) 'Postoperative recovery' / length of stay (days)4.4 (± 1.7) Neither AAA size (greater or less than 60 mm) or patient BMI (greater of less than 30 kg/m ²) significantly influenced operative time. Group mean results grouped by operator experience OutcomeFirst 30 patientsSecond 92 patientsp= Operative time (min)306 (± 81)241 (± 59)<0.001 Laparoscopic time (min)98 (± 35)52 (±21)<0.001 Aortic cross clamp time (min)90 (± 28)71 (±24)<0.001 Blood loss (ml)1077 (± 726)1101 (± 711)0.917 (NS) 'Postoperative recovery' / length of stay (days)5.3 (± 2)4.1 (±1)0.001			Complications No post-operative deaths reported. Overall morbidity rate was 12% (15/122). Bleeding from the hypogastric artery occurred in <1% (1/122) of patients, and thrombosis of a bifurcated leg graft occurred in <1% (1/122) of patients. Both required emergency re-operations but without extending the length of the incision made for HALS Blood transfusions were required in 7% (8/122) of patients Other complications OutcomeAll patients n=122 Longer IV crystalloid support for ileus2% (3/122) Arrhythmia2% (3/122) Pneumonia2% (3/122) Myocardial Ischemia2% (2/122) Renal dysfunction2% (2/122) Incisional hernia (in obese patients)2% (3/122) Long lasting wound pain0%		Unusually low mortality rate of 0% among 122 patients treated for abdominal aortic aneurysm Patient selection was conditioned by practicality as only two surgeons at the institution were trained in the HALS technique. A consecutive cohort of patients fulfilling criteria for HALS at one institution. No details of outcome assessment by independent clinicians.

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

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 McGuinness, 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, robotically-assisted).

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) Laparoscopic-assisted 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 endoaneurysmorrhaphy: 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 Endosc</i> 9 (8): 905-907.	Case report n=1 FU=6 days	Total operative time 4 hours, and blood loss 1l. 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	Laparoscopically 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
Strategy 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	(endovascu\$ 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
Comments:	