Eur J Vasc Endovasc Surg (2015) 50, 313—319

Endovascular Treatment of Ruptured Abdominal Aortic Aneurysms with Hostile Aortic Neck Anatomy

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WHAT THIS PAPER ADDS

Patients with a ruptured AAA are often excluded from EVAR based on aortic morphology. This paper evaluates technical and clinical outcomes of emergency EVAR in patients with hostile infrarenal aortic neck anatomy and reports excellent results, suggesting that emergency EVAR in ruptured AAA with hostile aortic neck anatomy is technically feasible and safe in experienced hands.

Objective: To compare the mid-term results of endovascular aortic aneurysm repair (EVAR) for ruptured abdominal aortic aneurysms (RAAAs) in patients with favourable aortic neck anatomy (FNA) and hostile aortic neck anatomy (HNA).

Methods: Patients treated for a RAAA in a high volume endovascular centre in the Netherlands between February 2009 and January 2014 were identified retrospectively and divided into two groups based on aortic neck anatomy, FNA and HNA. HNA was defined as RAAA with a proximal neck of $<$10 mm, or a proximal neck of 10—15 mm with a suprarenal angulation (α) $>45^\circ$ and/or an infrarenal angulation (β) $>60^\circ$, or a proximal neck of $>$15 mm combined with $\alpha > 60^\circ$ and/or $\beta > 75^\circ$. Patient demographics, procedure details, 30 day and 1 year outcomes were recorded.

Results: Of 39 included patients, 17 (44%) had HNA. Technical success was 100% for FNA and 88% for HNA ($p = .184$). There were no type IA endoleaks on completion angiography in either group; however, more adjunctive procedures were necessary for intra-operative type IA endoleaks in the HNA group (24% vs. 0%, $p = .029$). Thirty day mortality rates were comparable, FNA 14% vs. HNA 12% ($p = 1.000$). There were no statistically significant differences at 1 year follow up in type I endoleaks, secondary endovascular procedures, or all cause mortality.

Conclusion: Emergency EVAR provides excellent results for treatment of RAAA patients with both FNA and HNA. EVAR in RAAAs with HNA is technically feasible and safe in experienced endovascular centres.

Article history:

Article history: Received 20 January 2015, Accepted 10 April 2015, Available online 28 May 2015
Keywords: Abdominal aortic aneurysm, Aortic rupture, Vascular surgical procedures

INTRODUCTION

A ruptured abdominal aortic aneurysm (RAAA) is fatal without emergency surgical intervention. The first report of a successful endovascular treatment of RAAA was published in 1994.[1] With doctors becoming more experienced in endovascular techniques, and also the improved availability of off the shelf endografts, an increasing number of RAAA patients undergo endovascular treatment. Endovascular aneurysm repair (EVAR) might improve short-term survival rates of RAAA patients compared with traditional open surgical repair (OR).[2] The implementation of an EVAR first strategy for RAAAs in experienced centres shows an improved clinical outcome.[3] However, according to the best available data, the IMPROVE trial, the AJAX trial, and a recent meta-analysis, there is no significant difference in short-term survival rates between EVAR and OR.[4—6]

The choice between OR and EVAR is based on operator preference, patient characteristics, and anatomical suitability. Anatomical suitability is defined in the instructions for use (IFU) of each endograft. With the evolution of endografts, the anatomical suitability for EVAR increased from 20% to approximately 46—64% with current devices.[4,5,7] Unfavourable aneurysm anatomy and adverse anatomical characteristics of the aortic neck could be

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http://dx.doi.org/10.1016/j.ejvs.2015.04.017

predictors of poorer short-term outcomes.[8] However, in experienced endovascular centres, an increasing number of patients with abdominal aortic aneurysms (AAA) are treated outside the IFU. In the authors' experience, this certainly includes RAAAs.

This study aimed to compare the 1 year results of EVAR for RAAA patients with favourable aortic neck anatomy (FNA) and hostile aortic neck anatomy (HNA).

METHODS

Patient selection

Patients with a proven RAAA were identified retrospectively based on the Dutch administrative code for RAAA (406) in the hospital records of a large, tertiary referral centre for cardiovascular disease in the Netherlands. Patients were included for this analysis if the RAAA had been treated by means of EVAR between February 2009 and January 2014. A RAAA was defined as bleeding outside the adventitia of a dilated aortic wall. The diagnosis of a ruptured AAA was based on clinical findings, an ultrasound (US) in the emergency department, followed by a contrast enhanced computed tomography angiography (CTA) to confirm the diagnosis and allow for precise treatment planning. Patients were excluded if there was no evidence of a rupture. Patients who underwent previous EVAR or OR were also excluded.

Patient clinical status, medical history, treatment and follow up data were collected through hospital, emergency department and operation records.

Patient management

All patients were treated by (or under the supervision of) an experienced endovascular surgeon. The type of treatment (OR or EVAR) was left to the discretion of the surgeon, although under an EVAR first strategy. All patients scheduled for endovascular treatment underwent pre-operative CTA to determine baseline aortic and aneurysmal dimensions. Both bifurcated and aorto-uni-iliac (AUI) devices were used, including Endurant (Medtronic Vascular, Santa Rosa, CA, USA) and Excluder (W.L. Gore and Associates, Flagstaff, AZ, USA). All endografts were implanted through the common femoral artery via a transverse surgical cutdown.

If the prognosis because of comorbidity was exceedingly poor or if treatment options were limited, patients were palliated.

Standard follow up of treated RAAA patients was performed at 1 month with a CTA scan, and yearly thereafter with CTA or duplex ultrasound.

Anatomical evaluation

Two trained researchers blinded for treatment outcome, reviewed all available pre-operative CTAs independently. Measurements were made using dedicated three dimensional (3D) sizing software (3mensio, 3mensio Vascular, Bilthoven, The Netherlands). The central lumen line (CLL) was generated manually. Measurements were taken perpendicular to the CLL, and suprarenal and infrarenal angulations were determined according to the method described by Van Keulen et al.[9] In case of a discrepancy of more than 2 mm neck length or 5° angulation, consensus was obtained by consultation with one of the endovascular surgeons. A common iliac artery (CIA) with a diameter $\geq$17 mm in males or $\geq$15 mm in females was considered aneurysmal.[10]

Definitions and outcomes

The study cohort of patients was divided into two groups based on infrarenal aortic neck anatomy. FNA was defined as a proximal neck of $\geq$15 mm combined with a suprarenal angulation (α) $\leq$60° and an infrarenal angulation (β) $\leq$75° or defined as a proximal neck of $\geq$10 mm combined with α $\leq$45° and β $\leq$60°. HNA was defined as RAAAs with a proximal neck of $<$10 mm, or a proximal neck of 10–15 mm with α $>$45° and/or β $>$60°, or a proximal neck of $>$15 mm combined with α $>$60° and/or β $>$75°. The limits correspond with the instructions for use (IFU) for the Endurant stent graft.

Technical success was defined as successful delivery and deployment of the endograft, without unintentional coverage of renal or visceral arteries, followed by successful removal of the delivery system, and the absence of either a type I or III endoleak. Completion angiography was performed to document any possible endoleaks and other endograft related complications. The duration of procedure was defined as the time between arterial cutdown and closure. Thirty day and 1 year outcomes included endograft related complications, mortality rates, and need for secondary interventions. Significant migration was defined as a displacement of the endograft of $\geq$10 mm. There was no loss to follow up at 1 year.

Statistical analysis

Statistical analyses were performed using SPSS version 21 for MAC (IBM Corporation, Armonk, NY, USA). Categorical variables are presented as frequencies with percentages. The χ^2 or Fisher's exact test were used for categorical variables depending on sample size. Continuous variables are presented as mean $\pm$ standard deviation (SD) or as median and interquartile range (IQR) in case of skewed data. Mean differences were assessed using independent group *t* tests and median differences were assessed using Mann–Whitney *U* tests. A *p* value $<$.05 was considered statistically significant. A per protocol analysis was performed for the technical endograft related observations. All other variables were evaluated on an intention to treat basis. Missing values were excluded for analysis. Follow up data were analysed by Kaplan–Meier life table analysis and the log-rank test.

RESULTS

Patients

69 patients presented with a RAAA at the emergency department between February 2009 and January 2014. Six patients were rejected for surgery based on extensive

comorbidities and four did not regain cardiac output after cardiopulmonary resuscitation. Of the 59 patients that underwent an intervention, 12 patients (20%) underwent OR. The primary reason for OR was the presence of a juxtarenal aneurysm. The remaining 47 patients (80%) underwent EVAR; eight of these patients were excluded because they had a secondary rupture after previous AAA repair (5 OR and 3 EVAR). The remaining 39 patients were included in the present study. The FNA group consisted of 22 patients (56%), and the remaining 17 patients (44%) were assigned to the HNA group.

Pre-operative clinical and anatomic features

Demographic data, haemodynamic status, serum creatinine, haemoglobin, and baseline risk factors of the study groups are outlined in Table 1. There were no significant differences in age, gender, haemodynamic stability, and risk factors. Mean pre-operative AAA measurements are listed in Table 2. The HNA group tended to have a larger maximum AAA diameter (HNA 86 $\pm$ 15 mm vs. FNA 70 $\pm$ 18 mm, $p = .004$). The shortest proximal neck was 4 mm, and the largest α and β were 85° and 90°, respectively. In the HNA group, seven (41%) patients had a proximal aortic neck length <10 mm, seven (41%) patients had a suprarenal angulation >60°, and 11 (65%) patients had an infrarenal angulation >75°.

Intra-operative results

Operation time was significantly longer for HNA (HNA 122 [IQR 88-179] min vs. FNA 87 [IQR 65-104] min $p = .021$). There was trend for implanting more AUI devices in HNA patients; however, the difference was not significant (Table 3). One HNA patient had no endograft implanted because of iliac access difficulties. Severe comorbidities meant that this patient was not converted to open surgery and died within 24 hours. Intra-operative type IA endoleaks were more frequent in the HNA group (Table 3). However, all endoleaks were addressed and resolved during the initial procedure. All intra-operative endoleaks required the use of a balloon expandable stent, and in one patient an extension cuff was added. Unintentional overstenting of both renal arteries occurred in one HNA patient. A hepato-renal bypass was performed to preserve blood flow to one kidney. Technical success was 100% (22/22) for FNA and 88% (15/17) for HNA ($p = .184$). Two FNA patients (9%) and two HNA patients (12%) died within 24 hours of surgery.

Table 1. Patient demographics and risk factors by neck anatomy.

Variables	FNA ($N = 22$)[a]	HNA ($N = 17$)[a]	p
Age, years	72.6 $\pm$ 8.2	75.6 $\pm$ 6.5	.230[b]
Female	18% (4/22)	18% (3/17)	1.000[c]
Admission data			
Pulse (beats per min)	85 $\pm$ 21	79 $\pm$ 13	.378[b]
Blood pressure (mmHg)			
Systolic	112 $\pm$ 29	114 $\pm$ 37	.920[b]
Diastolic	69 $\pm$ 19	67 $\pm$ 21	.843[b]
Haemoglobin (mmol/L)	7.3 $\pm$ 1.2	7.0 $\pm$ 1.4	.589[b]
Creatinine (μmol/L)	115 (82–130)	110 (98–138)	.573[d]
Risk factors			
Tobacco use	22% (4/18)	35% (6/17)	.471[c]
Hypertension	79% (15/19)	71% (12/17)	.706[c]
Hypercholesterolaemia	67% (12/18)	59% (10/17)	.631[e]
Diabetes	11% (2/18)	6% (1/17)	1.000[c]
Cancer	17% (3/18)	6% (1/17)	.603[c]
Cardiac disease	39% (7/18)	41% (7/17)	.890[e]
Pulmonary disease	17% (3/18)	29% (5/17)	.443[c]
Renal insufficiency	6% (1/18)	6% (1/17)	1.000[c]

Denominator differs when there are missing values.
[a] Values are reported as mean $\pm$ standard deviation, median and interquartile range (IQR), or as frequencies (%) (n/N).
[b] t test.
[c] Fisher's Exact test.
[d] Kruskal-Wallis test.
[e] Pearson chi-square.

Table 2. Baseline aneurysm characteristics by neck anatomy.

Variable	FNA ($N = 22$)[a]	HNA ($N = 17$)[a]	p-value
Suprarenal angulation (α), degrees	27 $\pm$ 17	47 $\pm$ 19	.002[c]
Infrarenal angulation (β), degrees	50 $\pm$ 15	73 $\pm$ 16	<.001[c]
Neck length, mm	35 $\pm$ 14	22 $\pm$ 16	.016[c]
Neck diameter, mm	23 $\pm$ 4	22 $\pm$ 4	.595[c]
Maximum AAA[b] diameter, mm	70 $\pm$ 17	86 $\pm$ 15	.004[c]
Right iliac diameter, mm	22 $\pm$ 18	16 $\pm$ 5	.184[c]
Left iliac diameter, mm	19 $\pm$ 9	17 $\pm$ 8	.639[c]
Right femoral diameter, mm	10 $\pm$ 4	9 $\pm$ 2	.144[c]
Left femoral diameter, mm	10 $\pm$ 2	9 $\pm$ 2	.356[c]
Iliac aneurysm	55% (12/22)	35% (6/17)	.232[d]

[a] Values are reported as mean $\pm$ standard deviation or as frequencies (%) (n/N).
[b] Abdominal aortic aneurysm.
[c] t test.
[d] Pearson chi-square.

Thirty day outcome

Within 30 days of implant, three FNA patients (13%) died, versus two HNA patients (12%, $p = 1.000$), including the direct post-operative deaths. One month imaging was performed in 33 implanted patients (85%), one patient was diagnosed with metastasised cancer therefore no follow up was planned. Table 4 presents the 30 day clinical and technical outcomes. One FNA patient developed a type IA endoleak on post-operative day one, which required open surgical correction. Unfortunately, the patient died during this procedure. One HNA patient was converted to open repair because of an AAA re-rupture based on a type IA endoleak on post-operative day three. One type IB endoleak was reported in an HNA patient, requiring an extension cuff just to the level of the hypogastric artery. An endograft limb occlusion was observed in an FNA patient, which was corrected by converting the bifurcated graft to an AUI graft in combination with a femoro-femoral bypass. A total of four HNA patients (24%) versus zero FNA patients developed an abdominal compartment syndrome, which required decompression laparotomy ($p = .029$).

Table 3. Initial procedural data and evaluation by neck anatomy.

Variable	FNA ($N = 22$)[a]	HNA ($N = 17$)[a]	p
Duration of procedure (min)	87 (65–104)	122 (88–179)	.021[c]
Anaesthesia used			.584[d]
General	50% (11/22)	59% (10/17)	
Local or regional	50% (11/22)	41% (7/17)	
Configuration endograft			.147[e]
Bifurcated	95% (21/22)	76% (13/17)	
AUI[b]	5% (1/22)	24% (4/17)	
Device name			1.000[e]
Endurant	95% (21/22)	100% (17/17)	
Excluder	5% (1/22)	0% (0/17)	
Adjunctive procedures			
Resolve endoleak type IA	0% (0/22)	24% (4/17)	.029[e]
Resolve endoleak type III	0% (0/22)	6% (1/17)	.436[e]
Completion angiography			
Endoleak type IA	0% (0/22)	0% (0/17)	—
Endoleak type III	0% (0/22)	0% (0/17)	—
Unintentional overstenting of renal artery	0% (0/22)	6% (1/17)	.436[e]
Basic outcome			
Technical success	100% (22/22)	88% (15/17)	.184[e]
No implant	0% (0/22)	6% (1/17)	.436[e]
Conversion to open surgery	0% (0/22)	0% (0/17)	—
Dead within 24 hours	9% (2/22)	12% (2/17)	1.000[e]

[a] Values are reported as median and interquartile range (IQR) or as frequencies (%) (*n*/*N*).
[b] Aorto-uni-iliac.
[c] Kruskal–Wallis test.
[d] Pearson chi-square.
[e] Fisher's Exact test.

Table 4. Patient outcome within 30 days by neck anatomy.

Variable	FNA ($N = 22$)[a]	HNA ($N = 17$)[a]	p[e]
Technical outcome[b]			
Endoleak type IA	5% (1/19)	7% (1/14)	1.000
Endoleak type IB	0% (0/19)	7% (1/14)	.424
Endoleak type III	0% (0/19)	0% (0/14)	—
Endograft occlusion	5% (1/19)	0% (0/14)	1.000
Endograft migration	0% (0/19)	0% (0/14)	—
Clinical outcome[c]			
Secondary surgical procedures			
Endovascular procedure	5% (1/22)	6% (1/17)	1.000
Laparotomy for ACS[d]	0% (0/22)	24% (4/17)	.029
Conversion to open surgery	5% (1/22)	6% (1/17)	1.000
Aneurysm rupture	0% (0/22)	6% (1/17)	.421
All cause mortality	14% (3/22)	12% (2/17)	1.000

[a] Values are reported as frequencies (%) (*n*/*N*).
[b] Per protocol analysis. Only patients with 30 day imaging were included in the analysis.
[c] Intention to treat analysis. All patients were included in the analysis.
[d] Abdominal compartment syndrome.
[e] Fisher's Exact test.

One year outcome

One year imaging was available for 28 (72%) patients (Table 5). No new type I endoleaks were reported in either group. One FNA patient developed a type III endoleak, which was corrected endovascularly with an interposition graft. Freedom from device related secondary interventions at 1 year was comparable between groups (FNA 85% vs. HNA 87%, $p = .962$, Fig. 1). In addition, there were no significant differences in estimated freedom from all cause mortality (FNA 77% vs. HNA 65%, $p = .413$, Fig. 2). Within 1 year, four HNA patients died (urosepsis, sepsis of unknown origin, cardiac, incarcerated femoral hernia). In the FNA group two patients died (metastasised cancer, pulmonary insufficiency). In all patients there were no stent graft related complications.

DISCUSSION

To the authors' knowledge, this is the first report that evaluates the outcomes of EVAR in RAAAs with hostile aortic neck anatomy. Encouraging results are reported with

Table 5. Patient outcome at 1 year by neck anatomy.

Variable	FNA ($N = 22$)[a]	HNA ($N = 17$)[a]	p[c]
Endograft related complications[b]			
Endoleak type IA	0% (0/16)	0% (0/12)	—
Endoleak type IB	0% (0/16)	0% (0/12)	—
Endoleak type III	6% (1/16)	0% (0/12)	1.000
Endograft occlusion	0% (0/16)	0% (0/12)	—
Endograft migration	0% (0/16)	0% (0/12)	—

[a] Values are reported as frequencies (%) (*n*/*N*).
[b] Per protocol analysis. Only patients with 1 year imaging were included in the analysis.
[c] Fisher's Exact test.

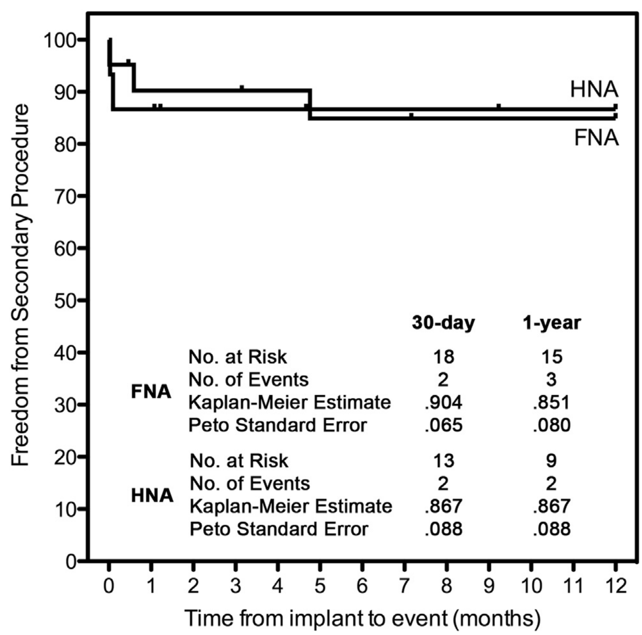

Figure 1. Kaplan—Meier curves representing the 1 year freedom from device related secondary interventions (log-rank, $p = .962$). Five patients in the FNA group and six patients in the HNA group died within 1 year and were censored.

no differences in clinical and technical outcomes between FNA and HNA patients.

Mortality is of the utmost importance in the discussion of whether patients with hostile anatomical features should be treated with EVAR. In this study, following an EVAR first strategy, the overall 30 day or in hospital mortality was 13%. This is in line with reports showing an improvement in 30 day mortality in various centres that changed from an OR first to an EVAR first approach.[11] When taking aneurysm

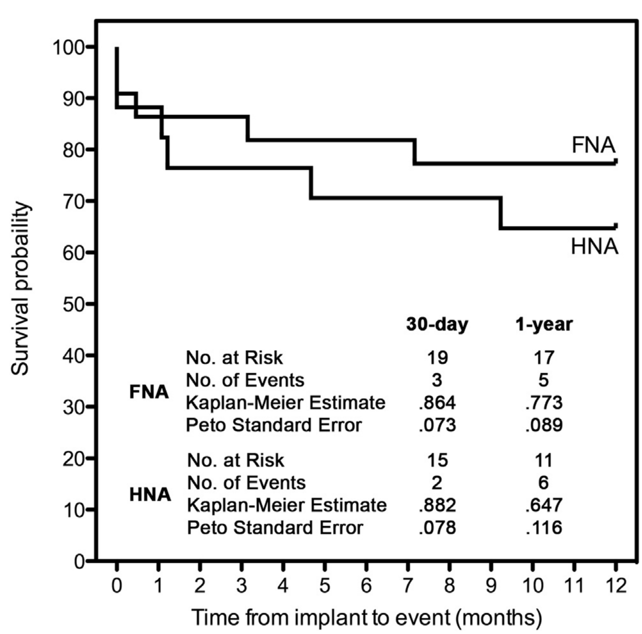

Figure 2. Kaplan—Meier curves representing the 1 year freedom from all cause mortality (log-rank, $p = .413$).

morphology into account, it has been shown that especially short infrarenal neck length influences mortality, as it does in OR.[12] In OR this is most likely caused by the need for high cross clamping, impairing circulation of the visceral arteries. In this study the mortality rates were not influenced by the suitability for EVAR (FNA 14% vs. HNA 12% $p = 1.000$). This supports the authors' view that patients should not be denied endovascular surgery based on hostile anatomical features alone, especially when considering that data on emergency EVAR in HNA are limited and OR in this population shows no survival benefit.[12]

In this study, 44% of patients undergoing EVAR had HNA. This is in contrast with reports estimating that 17—30% of elective patients are treated outside IFU.[13,14] Anatomical unsuitability for EVAR remains one of the main reasons to treat AAAs via open surgery, and there have been reports stating that up to 80% of RAAAs are regarded as not suitable for EVAR.[7] However, unsuitability is based on pre-clinically obtained test data and defined by the manufacturer. With increasing experience, off label use of several stent grafts has become widely accepted in elective surgery.

The discrepancy between the present results and those from previous reports on suitability can be explained partly in that juxtarenal AAAs underwent OR and were not included in this analysis. However, this does not account for the difference between elective and emergency EVAR. One reason for the high number of patients treated with HNA may be the diameter of the AAA. In this study, the mean AAA diameter was significantly larger for HNA patients. Besides increasing the risk of a rupture, a large AAA diameter may also negatively influence infrarenal neck length or shape, or both, which can result in a higher percentage of RAAAs regarded as unsuitable for EVAR.[7] Although the present study shows no difference between HNA and FNA at 1 year, the larger AAA diameter could contribute to a higher re-intervention rate at long-term follow up as has been previously described.[15]

The present results did show a significantly higher rate of adjunctive procedures for intra-operative type IA endoleaks in HNA patients. Comparable results can be found in studies reporting the outcome of EVAR in elective AAA patients with hostile infrarenal necks. A recent meta-analysis of these studies also concluded that patients with hostile neck anatomy required significantly more adjunctive procedures to resolve intra-operative type IA endoleaks (FNA 9% vs. HNA 22%, $p < .001$).[16] Remarkably, however, the present study reported a comparable rate of adjunctive procedures of 24% in HNA patients, even though there was notably less time for procedure planning compared with elective surgery. This indicates that emergency planning by an experienced vascular surgeon was adequate, and did not lead to an increased need for adjunctive procedures.

Although EVAR requires lifelong follow up and has an increased secondary intervention rate compared with OR, no differences were found in the need for secondary interventions between HNA and FNA within 1 year. This finding is in line with previous reports on AAAs with challenging aortic necks treated with comparable devices in an elective setting.[17–19] This implies that the need for secondary interventions within 1 year of follow up was not influenced by the emergency setting and the higher number of adjunctive procedures in the present study.

A marked advantage of EVAR is that its physiological impact is notably reduced compared with OR, because of the possibility of local anaesthesia and the avoidance of aortic cross clamping. A recent study by Gupta et al. supports this theory, with an improved mortality in unstable patients who received EVAR.[20] On the other hand, the AJAX trial and IMPROVE trial did not show any significant differences in 30 day mortality between EVAR and OR.[4,5] However, it should be noted that these two randomised trials reported only on a selected group of patients with RAAA and are not necessarily generalisable to the general population. Moreover, the nature of these trials did not permit surgeons to perform the procedure they personally prefer.

Although the present study suggests that a hostile infrarenal neck is not necessarily a reason for OR, there are limitations to the use of a "regular" endograft, depending on the extent of neck hostility. Several techniques have been developed to increase EVAR suitability, one of which is the chimney technique introduced by Greenberg et al.[21] This is a cheap and readily available procedure and therefore ideal for RAAAs. However, evidence is scarce and consists of small studies, and case reports without long-term follow up.[22]

Even without advanced techniques, a low percentage (14%) of RAAA patients were rejected for intervention. This finding may inform the debate on rejection for repair, which is considered to be subject to many influencing factors. In the current literature, rejection rates vary greatly between centres and countries, ranging from 20% to up to 42%.[23] These differences arise because of the wide variation in criteria used to decide whether or not to operate on a patient. Some patients are rejected for any form of surgery because anatomy does not allow EVAR and comorbidity precludes OR.

At the authors' hospital, treatment decisions are based on a multitude of anatomical and patient characteristics. Therefore, the present patient sample ranges from small haemodynamically stable retroperitoneal haemorrhaging to large free intraperitoneal ruptures. While open surgery is probably lethal in the latter patients, they may potentially survive EVAR in combination with optimised in hospital logistics (availability of pre-operative CT scan, an experienced endovascular team, and immediate availability of a variety of endografts) and the use of permissive hypotension.[3]

In clinical practice, a CT scan is essential, even in an emergency setting, to determine the best surgical care and to make a substantiated decision to perform open or endovascular surgery. A previous study suggests that, in the majority of RAAA patients, there is enough time to obtain CT imaging, assess AAA morphology and EVAR suitability, and transfer the patient to the operating theatre.[24]

This study is limited by the small sample size and the single centre design. Because of the low rate of complications, modern stent grafts require a large patient sample in which to detect significant differences. The results of emergency EVAR were described in a hospital with three vascular surgeons performing over 100 EVARs annually and these results may not be generalisable to centres with less experience in EVAR. Further prospective studies, with a larger group of patients, and longer follow up are necessary to evaluate the safety and durability of EVAR in patients with RAAAs and hostile infrarenal aortic neck anatomy.

CONCLUSION

EVAR in RAAAs with hostile infrarenal aortic necks appears technically feasible and safe in experienced hands. Endograft related complication rates and secondary intervention rates were not significantly higher in RAAA patients with HNA at 1 year.

CONFLICT OF INTEREST

None.

FUNDING

None.

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