The Amsterdam Acute Aneurysm Trial: Suitability and Application Rate for Endovascular Repair of Ruptured Abdominal Aortic Aneurysms

L.L. Hoornweg, 1 W. Wisselink, 2 A. Vahl 3 and R. Balm 1*
On behalf of the Amsterdam Acute Aneurysm Trial Collaborators

1Department of Vascular Surgery, Academic Medical Center, Amsterdam, The Netherlands, 2Department of Vascular Surgery, Vrije Universiteit Medical Center, Amsterdam, The Netherlands, and 3Department of Vascular Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Purpose. To evaluate anatomical suitability and application rate for endovascular repair of patients with a ruptured abdominal aortic aneurysm (RAAA).

Methods. The Amsterdam Acute Aneurysm trial is a multicenter randomised trial comparing open with endovascular treatment in patients with a RAAA (International Standard Randomized Controlled Trial Number (ISRCTN) 66212637). Between April 2004 and January 2006, all consecutive patients with clinical suspicion of a RAAA at presentation were assessed prospectively. Anatomical suitability for endovascular repair was based on use of an aorto-uni-iliac endovascular graft and assessed in patients with a proven aortic rupture on CT angiography (CTA).

Results. In 128/256 patients, presenting with clinical suspicion of a ruptured aneurysm, RAAA was diagnosed. 105 patients were brought to a trial center and CTA confirmed RAAA in 83 patients. In 38 of 83 patients (45.8%) with positive CTA, the anatomy of the aorta and iliac arteries was considered suitable for endovascular repair. Exclusion from endovascular repair was due to unsuitable infrarenal neck or iliac anatomy (37 and 8 patients respectively). Overall, endovascular treatment was applicable in 38/128 patients (29.7%) with a RAAA in the Amsterdam region and in 38 out of 105 patients (35.5%) admitted to the trial centers.

Conclusion. In this prospective cohort of all patients with a RAAA in the Amsterdam Acute Aneurysm Trial region, the suitability for endovascular repair in patients with a RAAA confirmed on CTA is 45.8%, but the application rate was lower.

Keywords: Ruptured aortic aneurysms; Endovascular repair; Suitability.

Introduction

The mortality rate for open surgical repair in patients with a ruptured abdominal aortic aneurysm (RAAA) who reach the hospital alive is approximately 40 to 55%. 1–5 Despite improved peri- and postoperative care, Bown et al. 6 report in their meta-analysis a very limited improvement in outcome for open surgical repair during the last 5 decades.

Endovascular repair might improve the outcome of patients with RAAA. Initial reports of endovascular repair for RAAA are promising, although to date no results from completed randomised trails are available. 7–10 A recent report on an aborted randomized trial that compared open and endovascular repair concluded that there was no superiority of one technique over the other. Therefore, it continues to be ethical to randomize patients between the two techniques. 11

The option of either open surgical or endovascular repair is only possible in a selected group of patients. The feasibility of endovascular repair for RAAA depends on distinctive anatomical criteria such as size of the infrarenal neck and iliac arteries and haemodynamic stability sufficient to perform pre interventional CT angiography (CTA).

The purpose of the present study is to evaluate anatomical suitability and application rate for endovascular repair in a prospective cohort of patients with a RAAA.
Methods

The Amsterdam Acute Aneurysm trial is a multicenter randomized trial comparing open with endovascular treatment in patients with a RAAA (ISRCTN 66212637). Collaborating centres and trial centres are listed in the Appendix. Background, design and methods of this trial have been described previously and patient enrolment continues.

An important aspect of the trial is close cooperation between 10 hospitals in the Amsterdam region and the regional ambulance services, serving 1.3 million inhabitants. Part of this cooperation is installation of an acute aneurysm rotation in which the 3 trial centres alternate on a weekly basis. All patients with clinical suspicion of a RAAA are sent to the trial centre on call. For inclusion into the randomized trial, there must be proof of aneurysm rupture. We defined rupture as an acute haemorrhage from the infraaortic aneurysm outside the true aortic wall with the presence of intraperitoneal and/or retroperitoneal blood at CTA. If patients are considered suitable for either open or endovascular treatment, patients are randomized by computer and patients treated immediately after randomization. The study is performed according to the World Medical Association’s declaration of Helsinki and the study protocol was approved by the Central Committee on Research on humans in the Netherlands and the ethical committees of all the trial centres involved.

For this study on suitability and application rate for endovascular repair of RAAA, we registered prospectively all consecutive patients in the Amsterdam region between April 2004 and January 2006, with clinical suspicion of a RAAA at presentation in the ambulance or on arrival in the emergency room. All haemodynamically stable patients who could be brought to one of the 3 trial centres and, in which the diagnosis RAAA was not rejected at presentation, underwent immediate CT-scanning for firm diagnosis of RAAA and assessment of anatomical suitability for endovascular repair. In the Amsterdam region all ambulance and hospital protocols are based on controlled hypotension. If the low blood pressure in controlled hypotension could not be maintained, patients were declared haemodynamically unstable and brought to the operating theatre for acute open repair.

Immediately after CT scanning was performed an experienced endovascular team, consisting of a vascular surgeon and an interventional radiologist, evaluated suitability for endovascular repair. Anatomical suitability was assessed in all patients with a proven aortic rupture on CTA and based on use of a standard set of aorto-uni-iliac endovascular grafts (Talent, Medtronic, Santa Rosa, CA). The following anatomical guidelines were used: the infrarenal aortic neck cranial to the aneurysm must have a diameter between 20 and 32 mm and a length of at least 10 mm; at least one iliac artery should be able to accommodate the endovascular graft and have a diameter of 8 to 18 mm; the contra-lateral common iliac artery diameter should have a diameter between 8 and 20 mm. The vascular surgeon in charge made the ultimate decision on suitability. Emergency endovascular aorto-uni-iliac grafts were available in all trial centres. Application rate was defined as the percentage of all patients with a RAAA that could be treated with an endovascular graft.

Patient characteristics and CTA data were recorded in a database with use of SPSS 11.0 data editor (Microsoft Corporation, USA) and continuous data were expressed in mean ± standard deviation.

Results

During the study period a total of 256 patients with clinical signs of aneurysm rupture presented in the Amsterdam region. These patients mainly were referred by general practitioners (101) and by ambulance staff (79). The diagnosis of RAAA was confirmed in 128 out of a total of 256 patients with clinical signs suggestive of an aneurysm rupture. Twenty-three patients with RAAA could not be brought to one of the trial centres due to haemodynamic instability: RAAA was confirmed in 128 out of a total of 256 patients with clinical signs suggestive of an aneurysm rupture. Twenty-three patients with RAAA could not be brought to one of the trial centres due to haemodynamic instability. Of the 105 patients (mean age 76.1 yrs (range 52–98), 89 male) admitted at the trial centres, 3 patients could not be evaluated for treatment by CTA and rupture was diagnosed by ultrasound: 2 because of severe co morbidities and 1 died in the emergency room. CTA confirmed RAAA in 83 of the remaining 102 patients. In 19 patients no CTA data were available due to haemodynamic instability: RAAA was confirmed at open repair.

Among the 83 patients whose CTA data could be analysed, we found anatomy suitable for endovascular repair of the aorta and iliac arteries in 38 patients (45.8%). Mean age was 77.2 years SD 10.5 and 32 were men. Thirty seven patients were unfit for endovascular repair due to unsuitable infrarenal neck and 8 due to iliac anatomy. (Fig. 1)

Overall, endovascular treatment was applicable in 38/128 patients (29.7%) with a RAAA in the Amsterdam region. Considering only the 105 patients with a RAAA admitted at the trial centres, the application rate was 35.5% (38/105).
Discussion

Implementing endovascular management of patients with a RAAA is a complex process. First there is the logistic challenge of offering an endovascular service 24 hr per day and 7 days per week. This was solved by the introduction of a RAAA rotation in 3 centres. Nevertheless 23 patients could not be transported to the trial centres. Twenty-one patients were hemodynamically unstable and the ambulance staff decided to bring the patients to the nearest hospital. In 2 patients the trial centre on call was busy with another major vascular procedure resulting in unavailability of the vascular surgeon. These 2 patients received open repair at the referring hospitals.

Second patients need pre-operative CTA examination to confirm rupture of the aneurysm and more importantly to assess anatomical suitability. This potentially introduces a delay. Lloyd et al. described that 12.5% of the patients who did not undergo repair of their ruptured aneurysm due to severe co-morbidity died within 2 hours after admission. In a recent report Hinchcliffe et al. concluded that the concerns that CT scanning prior to surgery caused detriment to the patients appeared to be misplaced. This implies that in most patients who reach the hospital alive anatomical suitability can be assessed by CTA. In all patients with a possible RAAA we applied the principles of hypotensive resuscitation. Nevertheless 19 patients (18%) could not undergo CTA because the
surgeon decided that the patient was too unstable to justify further delay of surgery. One patient died immediately after admission before CTA.

Peppelenbosch et al. concluded that even if moderate and severe hemodynamic instability are defined in advance, different surgeons tend to respond differently to a patient with hypovolemic shock. These variations in haemodynamic thresholds will lead to varying suitability rates among different studies. In our study, the suitability rate for patients with RAAA was 45.8%. Reichart et al. reported a potential 42% suitability rate, also using the Talent® aorto-uni-iliac emergency set. Peppelenbosch et al. recently published a 49% suitability rate, but patients with a neck length less than 10 mm were included in his study.

The debate on whether to use a bi-furcated or an aorta-uni-iliac stent continues. The choice of an aorto-uni-iliac endovascular graft was made for several reasons. First, the technical ease results in a shorter learning curve which makes this technique accessible for a broader range of vascular surgeons. A study reporting on elective endovascular repair showed a significant increase in suitability rate using an aorta-uni-iliac stent because an unilateral iliac access problem did not prevent endovascular repair. Second it can be deployed quickly, resulting in a rapid control of the intra-abdominal bleeding. Third only a minimal supply of stent-grafts is needed to treat most patients.

Complications of the femoro-femoral bypass such as thrombosis and infection are often mentioned as a possible disadvantages of the aorta-uni-iliac stent but the literature indicates a similar perioperative morbidity to bifurcated endovascular stentgrafts and acceptable long term patency of femoro-femoral bypasses after aorta-uni-iliac endovascular aneurysm repair.

In our study, like previous studies, most patients deemed unfit for endovascular repair had an unsuitable infrarenal aortic neck (37/45 patients (82%)). In contrast to intact aneurysms, patients with ruptured aneurysms appear to have a larger aneurysm diameter and shorter and narrower proximal necks.

Finally we want to emphasise that the literature on this subject mostly describes selected patient series.

Conclusion

In this study, suitability for endovascular repair in patients with a RAAA, confirmed by CTA, was 45.8%, the application rate in all identified RAAA patients in the Amsterdam region was 29.7%, but 35.5% for patients admitted to the specialist trial centres.

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Appendix.

Trial collaborators; R. Balm, D.A. Legemate, M.M. Idu, C. Kox, J.A. Reekers, K.P. van Lienden, O.M. van Delden (Academic Medical Center), W. Wisselink, J.A. Rauwerda, F.G. van den Berg (Vrije Universiteit Medical Center), A.C. Vahl, M.J.T Visser, F.H.W.M van der Heijden, C. de Vries, V.P.M. van der Hulst, A.D. Montauber van Swijndregt (Onze Lieve Vrouwe Gasthuis).

Trial coordinator; L.L. Hoornweg (Academic Medical Center).

Trial centers, Amsterdam, The Netherlands; Academic Medical Center, Vrije Universiteit Medical Center, Onze Lieve Vrouwe Gasthuis.


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Scan protocols

Academic Medical Center

Siemens® Somatom Sensation 4, Erlangen, Germany
slice thickness 5 mm, collimation 10 mm, reconstruction increment 2.5 mm, pitch 1.5
Contrast protocol: power injection 100 ml Visipaque 320, 3 ml/s, bolus tracking

Vrije Universiteit Medical Center

Siemens® Somatom Sensation 64, Erlangen, Germany
slice thickness 1.5 mm, collimation 6 mm, reconstruction increment 1 mm, pitch 1.2
Onze Lieve Vrouwe Gasthuis
Philips® Tomoscan AVE 1, Philips Medical Systems, Eindhoven, The Netherlands
Contrast protocol: power injection 100 ml Ultravist 300, 5 ml/s, bolus tracking

References