Emergency Treatment of Acute Symptomatic or Ruptured Abdominal Aortic Aneurysm. Outcome of a Prospective Intent-to-treat by EVAR Protocol

N. Peppelenbosch¹, N. Yilmaz¹, C. van Marrewijk¹, J. Buth¹, Ph. Cuypers¹, L. Duijm² and A. Tielbeek²

Departments of ¹Surgery and ²Radiology, Catharina Hospital Eindhoven, Eindhoven, The Netherlands

Objective: outcome of treatment of patients with ruptured or symptomatic non-ruptured aneurysm (rAAA and snrAAA), preferentially treated by emergency endovascular repair was assessed. The outcome was compared with a historical group of patients treated by open repair.

Patients and methods: two groups of patients presenting with acute symptomatic AAA were compared. Group I (study group) consisted of 40 consecutive prospectively enrolled patients from May 2001 until June 2002, in whom emergency endovascular abdominal aortic aneurysm repair (e-EVAR) was the preferential management. Short or wide neck or profound hypovolemic shock were exclusion criteria for e-EVAR. Group II (control group) consisted of 28 patients, retrospectively analysed, all treated by conventional surgical repair between January 1999 and May 2001. In group I, 26 patients had rAAA and in group II 22 patients. The other patients had snrAAA.

Results: in group I, 14 patients were treated by open repair. Unsuitable anatomy or profound hypovolemia was the cause of open repair in eight patients, while logistic reasons were the reasons for use of open repair in six patients (off-protocol use of open surgery). Thus, in this prospective series the feasibility of EVAR was 80% (32/40). Patient characteristics, proportion rAAA or hemodynamically unstable patients were comparable in group I and II. Volume of blood loss and need for fluid transfusion were significantly less in group I compared to group II. The perioperative mortality in group I was significantly less than in group II (20% vs. 43%, respectively, p = 0.04). If patients with rAAA were considered the mortality was 31% in group I and 50% in group II, which difference did not reach the level of statistical significance.

Conclusion: e-EVAR was a feasible treatment in the majority of patients with rAAA and snrAAA. Blood loss and the requirements of fluid transfusion were significantly decreased. Most importantly in this institutional series significantly lower first-month mortality was observed in the group with preferential e-EVAR compared to a control group. A multicenter study assessing the outcome of preferential use of e-EVAR in patients with acute symptomatic AAA is required.

Key Words: Ruptured abdominal aortic aneurysm; Acute symptomatic aneurysm; Emergency endovascular repair.

Introduction

A ruptured aneurysm of the abdominal aorta (rAAA) is the 6th leading cause of acute death in the US.¹ The only treatment that may save a patient’s life consisted of emergency surgery with replacement of the ruptured aorta by a vascular prosthesis. Most published data indicate a perioperative mortality of conventional open surgery, which ranges from 32 to 70%.²-⁸ In a recently published paper a gradual reduction of the operative mortality over time was demonstrated until a current rate of 41%.⁹ During the previous decade the development of endovascular abdominal aortic aneurysm repair (EVAR) has changed the practice pattern of elective treatment in asymptomatic patients considerably. EVAR has become a routine procedure in many institutions, although statistical evidence of decreased perioperative mortality is currently not available. Nevertheless, it is considered by many the treatment of choice in patients with increased risk of conventional open surgery. In emergency repair of patients with symptomatic non-ruptured abdominal aortic aneurysms (snrAAA) stentgraft treatment may have several advantages compared to an open procedure. One aspect is the use of local anaesthesia rather than general anaesthesia. It is believed that the induction of general anaesthesia, which is associated with the loss of arterial sympathetic tone, frequently causes complete circulatory collapse in a patient with severe hypovolemia and compensated shock. In addition

¹ Please address all correspondence to: Dr J. Buth, Department of Surgery, Catharina Hospital Eindhoven, P.O.Box 1350, 5602 ZA Eindhoven, The Netherlands.

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relaxation of the abdominal wall may cause a contained retroperitoneal rupture to turn into an open intraperitoneal haemorrhage. The operative and perioperative mortality increase dramatically with massive blood loss in patients with a free intraperitoneal rupture. The type of anaesthesia may be one of the reasons of a possibly better outcome in endograft-treated patients with ruptured AAA.

In the present report an analysis of our experience with emergency-EVAR (e-EVAR) is presented. This work differs from a previous preliminary publication from our institution in that more patients were included and the study group has been redefined. The objective of the present study involved the assessment of the outcome of treatment in a consecutive group of patients with symptomatic or ruptured AAA. This approach allowed us to evaluate (1) the applicability of e-EVAR, and (2) the possible impact of e-EVAR on the early mortality in an unselected cohort of patients with acute symptomatic aneurysms.

Methods

From May 2001 onward, patients with symptomatic snrAAA and rAAA of the abdominal aorta presenting at the Catharina Hospital, Eindhoven, The Netherlands, were treated according to a well-defined management protocol involving intent-to-treat by e-EVAR. Aneurysms were considered symptomatic non-ruptured (snrAAA), if there were no CT signs of haemorrhage outside the wall of the aneurysm, but with acute pain in the abdomen and an abdominal aneurysm, which was painful at palpation. Aneurysms were defined ruptured (rAAA) if there was extravasation of blood surrounding the aneurysm at CT examination. In patients that did not undergo CT examination a retroperitoneal haematoma at open surgery was the criterion for rupture of the aneurysm. During the study period all patients who were referred to our hospital with a symptomatic aneurysm of the abdominal aorta, were prospectively analysed and included in this study.

On arrival in the emergency ward the intravenous fluid infusion rate was minimised. The protocol involved that patients were taken to the radiology department for emergency CT examination with intravenous contrast infusion to opacify the aorta. An exception was made for patients in profound shock (systolic blood pressure <60 mmHg not responding to rapid infusion of fluid) or who had a cardiac arrest during transportation to the hospital, diameter and length of the infrarenal neck of the aneurysm were measured and the decision whether endovascular repair was feasible was taken and communicated with the operating room staff. Exclusion criteria for e-EVAR were a short neck (less than 10 mm length), a wide neck (over 30 mm in diameter) and inaccessible iliac arteries. Following CT examination patients were quickly transported to the operating room for the selected emergency procedure, or taken to the intensive care unit (ICU) for further optimisation (only in snrAAA). Patients with rupture of their aneurysm were preferentially treated with an aorto-uni-iliac endograft, combined with a crossover bypass (Fig. 1).

Details on the devices used were described in a previous paper of our group.

The study group described above was compared with a control group of patients with a symptomatic aneurysms, who were treated by open procedure, between January 1999 and May 2001. This historical control group was retrospectively analysed by hospital chart review. Primary outcome events that were compared included: 30-day or in-hospital mortality, morbidity, length of hospital and ICU stay, intraoperative blood loss, requirement of blood products and overall fluid infusion during operation.

The follow-up protocol consisted of routine CT-scanning at 1, 3, 6 and 12 months and hereafter every year for patients treated with e-EVAR. Patients treated by open surgery were seen back after 1 month and 3 months, hereafter yearly. Patients sent in from other hospitals were readmitted back and have the same schedule.

Statistical analysis was performed using SPSS® for Windows® version 9.0. Chi-square and Fisher tests were used for the comparison of discrete variables and the Mann–Whitney test was used for continuous variables. Continuous variables are presented as the mean (range). A p-value of <0.05 was considered significant.

Account of patient cohort in the present study and control group relative to previous publication

Of the 24 patients treated e-EVAR in the previous assessment six were not considered in the present study as they consisted a pilot phase and were selected on favourite aspects. The cohort with consecutive enrolment with intend-to-treat by EVAR was increased by eight EVAR patients (44% of previous EVAR group), while 14 patients treated by open surgery enrolled under the same protocol were also
Fig. 1. (a) Intraoperative angiogram demonstrating ruptured AAA. (b) Intraoperative angiogram demonstrating deployment of proximal component of aorto-uni-iliac device. (c) Intraoperative angiogram demonstrating bilateral iliac arteries. (d) Postoperative CT-examination, demonstrating functioning aorto-uni-iliac device with complete exclusion of the aneurysm.
included for a total of 40 patients in the study group. Six of these 14 patients were new enrolled patients since the previous study.

The previous article included 40 patients with open surgery of which eight felt within the intend-to-treat by EVAR study period. Four additional patients with open surgery were excluded (one because he had a suture-line aneurysm and three with snrAAA because they had been admitted longer than 24 h before treatment), for a total of 28 patients constituting the present control group of consecutive enrolled patients use open surgery.

### Results

**Patients**

From May 2001 until June 2002, 40 consecutive patients in the study group were admitted and treated in our hospital because of a ruptured or symptomatic infrarenal abdominal aneurysm (group I, Table 1). Twenty-six patients received endovascular repair (EVAR subgroup), and 14 patients conventional open surgery (COS subgroup, Table 2). There was a trend that patients in the conventional group were hemodynamic less stable and had larger aneurysms, however, these group differences in patient characteristics were not significant (Table 2). The control group with routine open repair consisted of 28 patients treated between January 1999 and April 2001 (group II).

There were no significant differences with regard to patient characteristics, presence of preoperative shock or previous cardiac and/or pulmonary events, between group I and II.

In the study group 14 (35%) patients had snrAAA and 26 (65%) a rAAA, in the control group 6 (21%) patients had a snrAAA and 22 (79%) a rAAA (Table 1). The differences were not statistically significant. Of the patients with a snrAAA two of the control group and two of the study group were taken to the ICU and treated within 24 h with an urgent operation. All other 16 snrAAA patients were treated without delay by emergency operation.

In the study group 33 (83%) patients underwent an emergency CT-scanning. Seven patients did not undergo CT-scanning, three in the EVAR and four in the COS subgroup. Reasons for not performing a CT-scanning were profound hypovolemic shock (in two patients) and logistic reasons in five patients. All these patients were immediately transported to the operating room. In the three patients who received e-EVAR fluoroscopic assessment was performed with calibrated catheters to establish the diameter of the neck and neck length. In case open surgery was performed fluoroscopic assessments were not performed. The mean neck length was significantly longer in the EVAR subgroup compared with the COS subgroup, 18.0 (6±36) and 7.5 (0–15) mm, respectively (p = 0.004). The neck diameter in the two subgroups was not statistically different, 23.8 (17–33) and 27.8 (20–34) mm in EVAR and COS, respectively.

<table>
<thead>
<tr>
<th>Table 1. Patient characteristics in group I and II.</th>
<th>Group I study group (40 patients)</th>
<th>Group II control group (28 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female</td>
<td>N</td>
<td>34/6</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>Years</td>
<td>73.0 (56.8–90.0)</td>
</tr>
<tr>
<td>SnrAAA/rAAA</td>
<td>N</td>
<td>14/26</td>
</tr>
<tr>
<td>Mean ○ AAA (range)</td>
<td>cm</td>
<td>7.0 (3.6–10.0)</td>
</tr>
<tr>
<td>Systolic &lt;100 mmHg</td>
<td>N (%)</td>
<td>16 (40)</td>
</tr>
<tr>
<td>History of cardiac events</td>
<td>N (%)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>History of pulmonary events</td>
<td>N (%)</td>
<td>7 (18)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Patient characteristics of subgroups in group I (40 patients).</th>
<th>Subgroup with EVAR (26 pts)</th>
<th>Subgroup with COS (14 pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female</td>
<td>N</td>
<td>23/3</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>Years</td>
<td>74.1 (56.8–90.0)</td>
</tr>
<tr>
<td>SnrAAA/rAAA</td>
<td>N</td>
<td>10/16</td>
</tr>
<tr>
<td>Mean ○ AAA (range)</td>
<td>cm</td>
<td>6.7 (3.6–8.8)</td>
</tr>
<tr>
<td>Systolic &lt;100 mmHg</td>
<td>N (%)</td>
<td>8 (31)</td>
</tr>
<tr>
<td>History of cardiac events</td>
<td>N (%)</td>
<td>8 (31)</td>
</tr>
<tr>
<td>History of pulmonary events</td>
<td>N (%)</td>
<td>6 (23)</td>
</tr>
</tbody>
</table>
Applicability of e-EVAR

EVAR was performed in 26 of the 40 patients in the study group. Reasons for COS were unavailable endovascular specialists in six patients and unsuitable anatomic (dimensions of the infrarenal neck, five patients), or technical (profound hypovolemia, three patients), reasons in eight patients. Thus the feasibility of EVAR based on an acceptable aortoiliac anatomy and hemodynamics was 80% (32/40). The overall applicability of e-EVAR in this study was 65% (26/40).

Procedural details

The intraoperative and hospital aspects in group I and II are summarised in Table 3. In the EVAR subgroup no conversions to open surgery were required. Most often an aorto-uni-iliac device was used in combination with a femorofemoral crossover bypass (19 patients). Two patients received a tube-endograft and five received a bifurcated stentgraft. Of the patients who received a bifurcated stentgraft two had a snrAAA. In 25 patients, a Talent\textsuperscript{1} stentgraft was used. In one patient a bifurcated Excluder\textsuperscript{1} stentgraft was used. In 88% of the cases in the EVAR subgroup, local (in 15 patients) or regional (in eight patients) anaesthesia was used. Two patients with snrAAA and one with a rAAA received general anaesthesia. The patient with ruptured aneurysm was in deep hypovolemic shock at arrival in the hospital. It was felt by the responsible anaesthesiologist that in this patient a more rapid control of the hemodynamic situation might be obtained by general anaesthesia. Mean operation time was 155 (80–270) min in group I, and 176 (100–240) in group II, which was not a significant difference. Mean blood loss in group I was 1800 (100–6000) ml, and in group II 3900 (300–120000) ml. This difference was statistically significant ($p \leq 0.01$). In addition, there was a significant difference between group I and II with regard to total fluid infusion (blood components, fresh frozen plasma and crystalloids combined; $p \leq 0.004$). Administration of blood components was comparable in the two groups.

Perioperative morbidity and mortality

The hospital and ICU-stay in the study group and control group was not statistically different (Table 3). The perioperative mortality rate in the study group with preferential EVAR was significantly lower than in group II, 20 and 43%, respectively, ($p \leq 0.04$, Table 4). If only patients with rupture of their aneurysms were considered the mortality rate in group I was 31% and in group II 50%. This difference did not reach the level of statistical significance ($p \leq 0.10$). Causes of death included continued bleeding, cardiac failure, multi organ failure, respiratory insufficiency and bowel ischaemia. The latter constituted 50% (two patients) of the causes of death in the EVAR subgroup. The rate of postoperative morbidity among survivors was in the study group higher than in the control group (44% versus 25%, respectively) (Table 4). However, this difference did not reach statistical significance.

Follow-up of patients

In the EVAR subgroup, three patients demonstrated an endoleak during follow-up from 30 days to 14 months: two patients had a type I and one patient
a type II endoleak. The latter patient is still under survey and an intervention for coiling has been planned. Both patients with type I endoleak refused further intervention because of their age of, respectively, 90 and 80 years. The 90-year old patient has a follow-up time of 14 months and he remains without symptoms. The 80-year old patient was discharged from further follow-up on his own request.

Follow-up was achieved in 90% of the patients in the study group and 86% in the control group. The patients, with recorded follow-up data, were followed in the hospitals from where they originally were referred. The six-month survival in group I was 74% and in group II 52% (Fig. 2). The difference of 22% already existed after the first postoperative month and there was no further change

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**Table 4. Mortality and morbidity in group I and II.**

<table>
<thead>
<tr>
<th></th>
<th>Study group (40 patients)</th>
<th>Control group (28 pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total (40 pts)</td>
<td>EVAR (26 pts)</td>
</tr>
<tr>
<td>Mortality (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>8 (20) *</td>
<td>4</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Continued bleeding</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Multiorgan failure</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Bowel ischaemia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Postoperative morbidity (%)</td>
<td>14 (44) **</td>
<td>8</td>
</tr>
<tr>
<td>Cardiac</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Multiorgan failure</td>
<td>1</td>
<td>–</td>
</tr>
<tr>
<td>Coagulation disorder</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>CVA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Re-operation</td>
<td>3</td>
<td>–</td>
</tr>
<tr>
<td>Wound infection/haematoma</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

![Diagram](image_url)

**Fig. 2.** Kaplan–Meier survival curves of patients in the study group and in the control group. Initially existing difference sustains during the first months of follow-up. Numbers below figure indicate patients at risk.

\[ p = 0.04, \]
\[ p = 0.3. \]
of this difference in the subsequent follow-up period.

Discussion

Conventional open surgery has been the gold-standard for the treatment of acute symptomatic aneurysms for five decades. During this period the perioperative mortality and morbidity has improved only modestly. After the successful introduction of elective stent graft repair of asymptomatic abdominal aneurysms, this technique now is also considered appealing for the treatment of acute symptomatic aneurysms. Mortality rates in these studies range from 10 to 45%, which is promising considered the prohibitive mortality in open surgery. However, none of these studies was based on an intention-to-treat by EVAR protocol or on a consecutively enrolled patient group. Rather, patients were selected on the basis of availability of experienced staff and other practical aspects. Also in the previous report from our group, Yilmaz assessed the outcome in a consecutive series with regard to the treatment received.

In the present study, the larger and redefined study group allowed to assess the overall impact of e-EVAR.

In the present study, group I consisting of both patients with EVAR and COS and group II including patients with open surgery, demonstrated less difference in preoperative characteristics than in our previous study because of redefined study groups. No differences in operating time and ICU admission time were noted between group I and II. Patient selection criteria for EVAR involved in the first place the presence of a suitable infrarenal neck. This was apparent in the study group from a significantly shorter neck in the subgroup with COS compared to the subgroup with EVAR.

The use of local rather than general anaesthesia may be one of the important factors determining outcome of treatment. In our study group, 58% received local or regional anaesthesia. These types of anaesthesia do not influence the tone of the abdominal wall. Relaxation of the abdominal musculature during general anaesthesia may change a contained rupture into an intraperitoneal or free rupture, reducing the chance of survival significantly. Local anaesthesia has the additional advantage of leaving the sympathetic tone of the arterioles unchanged. Patients with ruptured AAA usually are in a state of compensated shock with maximal vasoconstriction. Release of the sympathetic tone at induction of general anaesthesia may cause complete cardiovascular collapse, as most of the surgeons know from practical experience. Reduction of blood loss and fluid administered during operation in the EVAR subgroup are likely related to the avoidance of general anaesthesia as much as to avoiding open surgery.

Preoperative CT-scanning on the one hand appears quite useful for ascertaining whether endovascular treatment is feasible, and for measuring anatomical dimensions. A drawback may be the time delay until the treatment commences. In the present series only two patients had too low blood pressures to allow an additional delay of 10–15 min, which is the usual time an emergency CT-scan takes in our institution. During CT-examination the operating room is prepared for the operative procedure, making the actual time delay even less.

The use of aorto-uni-iliac rather than bifurcated endografts is a matter of debate. During our institutional experience we have developed a strong preference for AUI-endografts. The advantages of this device type include a quick introduction and deployment, which rapidly lowers intra-aneurysmal blood pressure and provides control on the intra-abdominal bleeding. Only one groin needs to be explored under local anaesthesia, which seems more easily tolerated by the patient in emergency circumstances than bilateral groin exploitation. An additional advantage of AUI grafts seems that patients with complex iliac artery anatomy can more frequently be treated by aorto-uni-iliac devices as only one suitable side is needed. Nevertheless, Orend et al. and Lachat et al. used bifurcated stentgrafts in their selected patient population with comparable operating times and excellent results.

To demonstrate the impact of endograft treatment on the first-month mortality of acute AAA requires a careful analysis. Simple assessment EVAR-treated patients will lead to a skewed outcome, as patients with short necks or in profound shock will have the highest risk, but will be excluded for EVAR. It is of note that the present study is also the first to demonstrate a significant difference in first-month mortality in favour of e-EVAR compared to conventional surgery in a combined group of patients with ruptured and symptomatic AAAs. The advantage of e-EVAR continues during the first postoperative months. Apparently there is no catch-up of mortality by delayed events and the favourable effect on survival seems durable. Admittedly, our present follow-up periods were still rather short. It is of note that the incidence of postoperative complications among survivors in group I was somewhat higher than in group II. A plausible explanation may be that the occurrence of complications in the first group was
assessed prospectively and in the latter retrospectively. Nevertheless, this finding also may indicate that complications occur in patients with e-EVAR that may cause death when open surgery would have been performed.

The present study has several flaws. First, a relatively small number of patients were included and the follow-up period was short. Secondly, despite the intent-to-treat by EVAR protocol six patients (15%) received conventional open repair because of an unavailable endovascular specialist at the time of admission. When these patients also would have been treated by EVAR, the difference in early mortality might have been even greater. Thirdly and perhaps most importantly, the control group in this study was analysed retrospectively, which may influence the comparability with the study group as well as accuracy of recording events. A large scale multicenter study is needed to confirm, that emergency EVAR for acute symptomatic and ruptured aneurysms is associated with improved survival. Once our findings are confirmed by such a study, additional evidence will be required from a randomised controlled trial comparing EVAR and open surgery for clearly delineated indications, distinguishing patients with truly ruptured and symptomatic non-ruptured AAA. The importance of a trial monitoring committee that terminates the study as soon as a statistical significant difference in operative survival is obtained at regular interim analyses is obvious in such a RCT.

Late complications associated with e-EVAR included the occurrence of endoleaks. In the present study three endoleaks (12%) of survivors were present after one month. Two patients had a type I proximal endoleak, but refused further treatment. So far they remained without symptoms. Nevertheless, these endoleaks in our opinion should be treated either by the use of a giant Palmaz-stent, an aortic extension endograft or by laparoscopic banding of the aorta. The policy in type II endoleaks may be similar as in elective EVAR and intervention should be dependent on eventual increase in size of the aneurysm.20

In conclusion, emergency endovascular repair of ruptured and acute symptomatic abdominal aortic aneurysms is justified when the patient has a suitable anatomy, most importantly an adequate infra-renal neck. The first-month mortality in the present study was significantly lower than in a control group receiving surgical repair. Further study of a larger study population to confirm our findings is needed.

References