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Endograft treatment of ruptured abdominal aortic aneurysms using the Talent aortouniiliac system: An international multicenter study

Noud Peppelenbosch, MD,[a] Robert H. Geelkerken, MD, PhD,[b] Chee Soong, MD, FRCS,[c] Piergiorgio Cao, MD, FRCS,[d] Oren K. Steinmetz, MD,[e] Joep A. W. Teijink, MD, PhD,[f] Mauri Lepäntalo, MD, PhD,[g] Jan De Letter, MD, PhD,[h] Frank E. G. Vermassen, MD, PhD,[i] Guy DeRose, MD, FRCSS, FACS,[j] Erik Buskens, MD, PhD,[k] and Jaap Buth, MD, PhD, FRCS,[a] *Eindhoven and Enschede, The Netherlands; Belfast, Northern Ireland; Perugia, Italy; Montreal, Quebec, Canada; Heerlen, The Netherlands; Helsinki, Finland; Brugge and Gent, Belgium; London, Ontario, Canada; Utrecht, The Netherlands*

Objective: To understand the potential of endovascular aneurysm repair (EVAR) in patients presenting with a ruptured abdominal aortic aneurysm (rAAA), the proportion in whom this procedure was applicable was assessed. Mortality and morbidity was also determined in patients treated with emergency EVAR (eEVAR) when anatomic and hemodynamic conditions allowed (ie, in the entire cohort with patients receiving endovascular and open repair combined). In addition, a comparison was made between the treatment group with eEVAR and open repair.

Methods: Between February 2003 and September 2004, 10 participating institutions enrolled a representative sample of 100 consecutive patients in whom eEVAR was considered. Patients in the New Endograft treatment in Ruptured abdominal aortic Aneurysm (ERA) trial were offered eEVAR or open repair in accordance with their clinical condition or anatomic configuration. Written informed consent was obtained from all patients or their legal representatives. The study included patients who were treated by stent-graft technique or by open surgery in the case of adverse anatomy for endoluminal stent-grafting or severe hemodynamic instability, or both. Data were collated in a centralized database for analysis. The study was sponsored and supported by Medtronic, and eEVAR was uniquely performed with a Talent aortouniiliac (AUI) system in all patients. Crude and adjusted 30-day or in-hospital and 3-month mortality rates were assessed for the entire group as a whole and the EVAR and open repair category separately. Complication rates were also assessed.

Results: Stent-graft repair was performed in 49 patients and open surgery in 51. No significant differences were observed between these treatment groups with regard to comorbidity at presentation, hemodynamic instability, and the proportion of patients who could be assessed by preoperative computed tomography scanning. Patients with eEVAR more frequently demonstrated a suitable infrarenal neck for endovascular repair, a longer infrarenal neck, and suitable iliac arteries for access than patients with open repair. The primary reason to perform open aneurysm repair was an unfavorable configuration of the neck in 80% of the patients. In patients undergoing eEVAR, operative blood loss was less, intensive care admission time was shorter, and the duration of mechanical ventilation was shorter ($P \leq .02$, all comparisons). The 30-day or in-hospital mortality was 35% in the eEVAR category, 39% in patients with open repair, and 37% overall. There was no statistically significant difference between the treatment groups with regard to crude mortality rates or rates adjusted for age, gender, hemodynamic shock, and pre-existent pulmonary disease. The cumulative 3-month all-cause mortality was 40% in the eEVAR group and 42% in the open repair group (no significant differences at crude and adjusted comparisons). The 3-month primary complication rate in the two treatment groups was similar at 59%.

Conclusions: In approximately half the rAAA patients, eEVAR appeared viable. An unsuitable infrarenal neck was the most frequent cause to select open repair. In dedicated centers using a Talent AUI system, eEVAR appeared to be a feasible method for treatment of a rAAA. The overall first-month mortality did not differ across treatment groups (patients with endovascular and open repair combined), yet was somewhat lower than observed in a recent meta-analysis reporting on open repair. (J Vasc Surg 2006;43:1111-22.)

Abdominal aortic aneurysms (AAAs) >5.5 cm in diameter have a significant risk of rupture, which again increases substantially when the aneurysm diameter is >6.5 cm.[1,2] Furthermore, open surgical repair of ruptured AAA (rAAAs) has typically been associated with an average in-hospital mortality of 50%[3-7] and only a modest improvement in the outcome of rAAA repair was documented in a recent meta-analysis in which the average mortality rate

achieved in the year 2000 was estimated at 41%.[8] Endovascular abdominal aortic aneurysm repair (EVAR) of elective patients has been demonstrated to be associated with lower 30-day mortality and morbidity rates than open repair.[9,10] Meanwhile, the use of emergency EVAR (eEVAR), as assessed in a number of studies,[11-25] has been associated with a mean first-month mortality rate of 18.4% (range, 0% to 45%). The improved outcomes in these reports may reflect selective patient recruitment, however, with patients selected for eEVAR constituting a lower-risk category because they would need to be stable for preoperative imaging and have a suitable anatomic configuration for EVAR. Thus, the favorable outcomes observed in the previous studies may simply reflect selection bias.

Several questions regarding the use of eEVAR in rAAAs remain. Among these uncertainties, the applicability rate for eEVAR is a key factor. In particular, the anatomy of the infrarenal neck and the patency of the iliac arteries may preclude successful endovascular repair. Additionally, primary outcome events that need to be addressed include the mortality rate of eEVAR in all patients who are candidates for endovascular treatment and the effect of a preferential eEVAR policy on mortality in an unselected group of patients with rAAA. Furthermore, the infrastructural requirements, such as the availability of rapid preoperative imaging and around the clock surgeons experienced in emergency endovascular aneurysm repair, need to be assessed.

The present observational study, which is designated the New ERA (Endograft treatment in Ruptured abdominal aortic Aneurysm) trial, was designed to overcome selection bias for an optimal assessment of eEVAR in the treatment of rAAA. This report describes an international multicenter cohort study of patients with rAAA who were treated preferentially by eEVAR using a Talent aortouniiliac (AUI) stent-graft (Medtronic, Santa Rosa, Calif). The outcome in the entire study group was assessed to allow a comparison with mortality rates in patients treated by conventional open surgery as reported in the literature. Additionally, the results observed in the eEVAR group were compared with those in the open repair group.

METHODS

The New ERA study is a prospective, multicenter European and Canadian study that is sponsored and supported by Medtronic and the Bakken Research Centre (Maastricht, the Netherlands). Ten centers participated in the study. Each participating clinical site had obtained approval of the protocol from the local ethics committee. Vascular surgeons and interventional radiologists with considerable experience in the diagnosis and open and endovascular treatment of rAAA were included as investigators in this study. A list of participating investigators is in the Appendix (online only). Patient data and procedural details were recorded in a structured case report form (CRF) and periodically monitored on-site by representatives of the organizing company. All adverse events, including device- and procedure-related events, and death were reviewed by
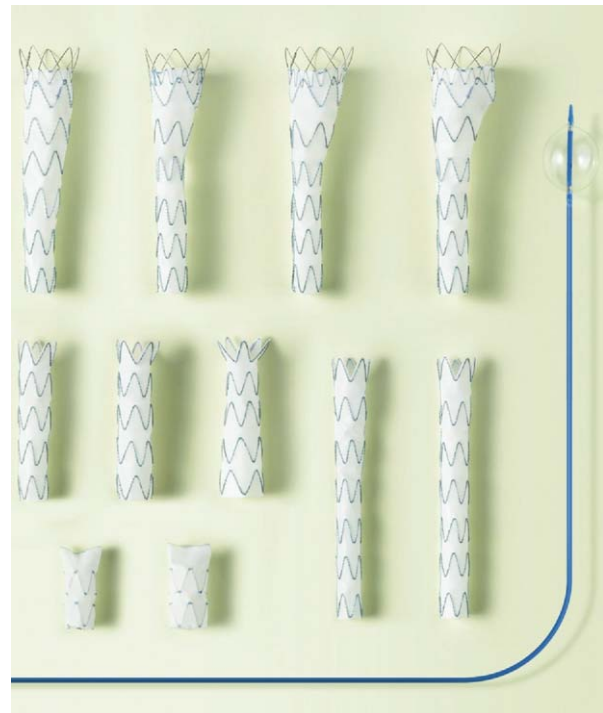

Fig 1. The components of the Talent aortouniiliac stent-graft system used for emergency endovascular aneurysm repair.

an independent Adverse Event Advisory Committee (Appendix, online only). Study conduct was supervised by a Steering Committee (Appendix, online only). The first author and the principal investigator had access to all CRFs at the end of the study period. The evaluation of the study objective required 100 patients, each with a follow-up of 3 months. Enrollment into the study started in February 2003 and ended in September 2004.

The protocol specified that in each of the participating centers, a consecutive series of patients treated for ruptured infrarenal AAAs, who had given their informed consent, were expected to be included in the study. The preferential treatment was EVAR. The protocol recommended that open surgery was only to be selected as the treatment when anatomic criteria precluded effective exclusion of the aneurysm or if the patient was in profound hypovolemic shock (see the definition of *severe hemodynamic instability* below) that did not allow a preoperative computed tomography (CT) examination, fluoroscopy, or the use of intravascular ultrasound (in one of the institutions) to evaluate feasibility for EVAR. In other words, included in the study were patients treated by stent-graft technique or by open surgery in the case of adverse anatomy for endoluminal stent-grafting or severe hemodynamic instability.

Patients who were suitable for EVAR were treated with a uniform technique and a single endovascular device, the Talent AUI stent-graft system (Fig 1) combined with a femorofemoral bypass. The number and outcome of the treatment of patients who did not give their informed

consent or were otherwise not enrolled, for example, because the surgeon did not ask them to participate, and the reasons for exclusion, were obtained from each of the participating institutions by a questionnaire at the end of the study.

Purpose and objectives. The New ERA study had three main purposes. The first was to assess the proportion of patients presenting with rAAA in whom EVAR by the Talent AUI device could be used. The second was to determine the operative mortality and morbidity in a cohort of patients treated with eEVAR when possible, according to present anatomic and hemodynamic criteria. This analysis comprised the entire study group with patients who underwent endovascular or open surgery. Finally, the mortality and morbidity in the eEVAR and open repair groups was compared. Study end points included *operative mortality,* defined as death ≤30 days or during the same hospitalization, and *major morbidity,* defined as serious adverse events. Secondary end points included death from all causes and major morbidity ≤3 months after the procedure.

Patient selection, inclusion, exclusion criteria, and management. Details of the inclusion and exclusion criteria, management of the patient, and the technical execution of the eEVAR by implanting the Talent AUI device were described previously in an article on the design and planning of this study.[26] Each participating center was expected to enroll its series of patients with rAAA that met the inclusion criteria consecutively throughout the study period.

Briefly, the protocol required that on arrival in the emergency department, intravenous fluid infusion was minimized, and if necessary, medication to lower blood pressure was administered. If the hemodynamic situation allowed an emergency CT examination, this was performed. *Aneurysm rupture* was defined as hemorrhage outside the aortic wall or by direct observation in case of laparotomy. By protocol, when there was still doubt after treatment whether the aneurysm was ruptured, extravasation was to be confirmed by postoperative CT examination or by autopsy. The patient or his or her relatives were informed about the study and asked permission to participate by a written informed consent. The main exclusion criteria for enrollment in the study were not consenting to participate and comorbidities with a life expectancy of <1 year. Thus, the study group consisted only of patients who met the inclusion criteria and had signed (or their relatives or legal representative) the informed consent.

An urgent CT examination was done in patients in stable hemodynamic condition or with *moderate hemodynamic instability,* referred to in this analysis when the patient had a systolic blood pressure between 60 and 100 mm Hg, was conscious, and had no episodes of cardiac arrest. The selection of patients for CT examination and subsequently for EVAR or open repair was according to the algorithm represented in Fig 2. This flow sheet dictated the decisions to be taken at initial management, although it was left to the discretion of the participating surgeon to deviate

from these suggested guidelines. The algorithm advised that *severely hemodynamically unstable* patients with a systolic blood pressure of <60 mm Hg, decreased consciousness, or with episodes of cardiac arrest, should be taken to the operating room and, if possible, undergo fluoroscopic assessment to establish whether an EVAR or open surgical procedure should be performed. The use of intra-aortic balloon inflation to increase a low blood pressure was again left to the discretion of the attending surgeon.

The suggested anatomic criteria for treatment by open surgery included an infrarenal aortic neck of <10 mm or a diameter of >32 mm, or both. In addition, an angulation of the infrarenal neck of >85° was considered an exclusion criterion for EVAR, as were bilateral iliac artery occlusions or stenosis (<6 mm diameter) not amenable to balloon angioplasty.

After CT examination, patients were quickly transported to the operating room for the selected emergency procedure. In endovascularly treated patients, the preferred operative technique in rAAA was an AUI stent-graft implantation. The reasons for this preference, which is shared with several other groups, include a larger application rate of the stent-graft technique because of less anatomic restrictions and a quicker decompression of the bleeding aneurysm.[14,16,21,22] AUI endografting was combined with a crossover bypass and the deployment of an Occluder cuff in the contralateral iliac artery. The standard emergency set of AUI stent-grafts and distal extender iliac device limbs (Talent®, Medtronic, Santa Rosa, CA) represented in Fig 1 was permanently available in the ten centers.

It was recommended that eEVAR be commenced under local anesthesia of the groin at the selected access site. The rational for using local anesthesia in the initial part of the procedure has been described previously by our group and by others.[26,27] The general idea is to avoid a severe circulatory collapse associated with the induction of general anesthesia in the patient with extensive retroperitoneal blood loss because of vasomotor relaxation.[28] In addition, the loss of abdominal tone, which increases the risk of a contained rupture becoming an intra-abdominal hemorrhage, is minimized by the use of local anesthesia.

After the AUI device was inserted and the antegrade flow into the ruptured aneurysmal sac was blocked, general anesthesia could be given to perform the subsequent operative steps, which consisted of exploration of the contralateral common femoral artery, deployment of the common iliac Occluder cuff at this side, and performing the crossover femorofemoral bypass. Also with regard to the technical execution of the procedure, the managing team could deviate from any of the suggested steps except implantation of the Talent AUI device when the patient was treated by endovascular technique.

Statistical analysis. A priori, the applicability of the endovascular technique was considered unsatisfactory if it would be <50% of the patients. The intention was to demonstrate that the mortality rate of consecutively enrolled patients with rAAA, treated by preferential EVAR, would be <50%. As for secondary study end points, a
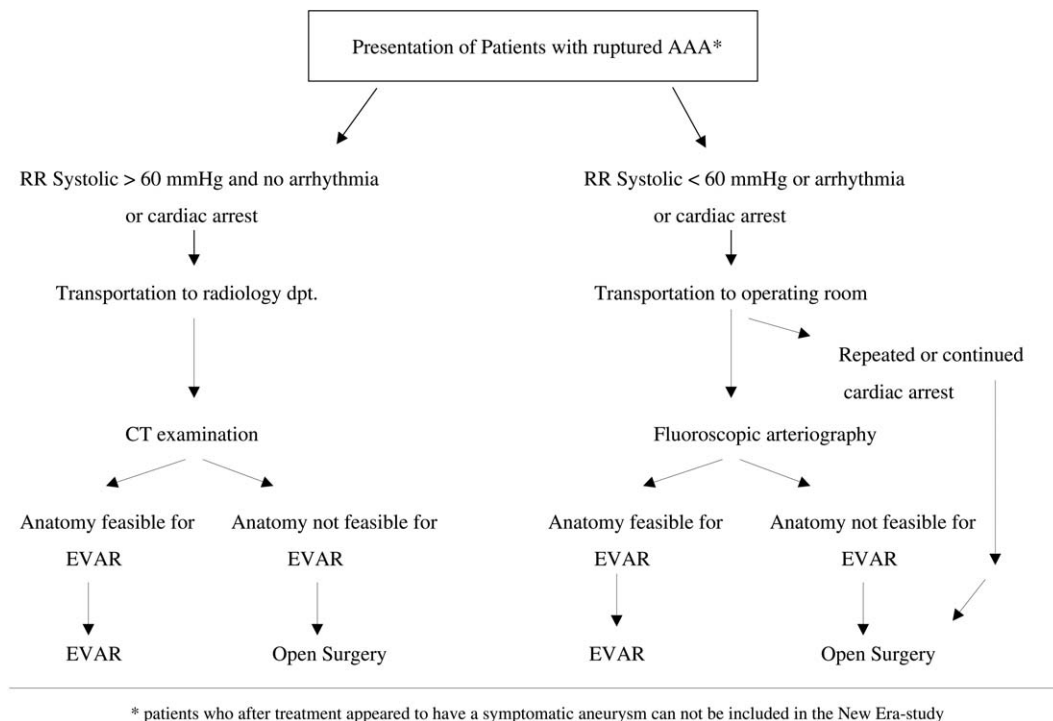
Fig 2. Flow sheet for patients with ruptured abdominal aortic aneurysms *(AAA)* entering the hospital. In patients with stable hemodynamic condition (systolic blood pressure of >100 mm Hg) and with moderate hemodynamic instability (systolic blood pressure, 60 to 100 mm Hg without cardiac arrhythmia), preoperative computed tomography *(CT)* examination was to be performed. Patients with severe hemodynamic instability (systolic blood pressure <60 mm Hg, with arrhythmia) were immediately taken to the operating room. *EVAR,* Endovascular aneurysm repair.

comparative analysis between the eEVAR and open repair groups was powered to demonstrate a statistically significant 30-day or in-hospital mortality of ≤25% in the patients that had received eEVAR compared with 50% in the open repair group.

Crude and adjusted hazard ratios with the 95% confidence intervals (CI) and *P* values were assessed for differences in mortality rates in the subgroups. The factors for which adjustment was made included advanced age, male gender, hemodynamic shock (systolic tension ≤100 mm Hg), and a history of pulmonary disease. These factors were previously observed to influence outcome in patients undergoing rAAA repair.[3,5]

The data processing and analysis were performed by the first author and the principal investigator, with the technical assistance of Medtronic. A statistician (E. B.) reviewed the manuscript and the validity of the conclusions. Results were reported as means, standard deviation, or ranges. Differences in findings between treatment groups were assessed by χ^2 or Fisher exact tests for discrete variables and by Mann-Whitney tests for continuous variables. Selected variables were entered in a multivariate regression analysis, and a Cox analysis was used to assess independent associations with the 3-month mortality rate. Only moderate or severe adverse postoperative events[29,30] were taken into account. Per patient, the initial or most severe complica-

tion, or both, was considered for the analysis. All analyses were performed by SAS 9.1 statistical software (SAS Institute, Inc, Cary, NC).

RESULTS

Between February 2003 and September 2004, 100 patients (83 men and 17 women) with a mean age of 74 years (range, 58 to 90) were enrolled in the study. The number of study patients from different centers varied between 2 and 23 (mean, 10 patients) (see the Appendix [online only] for the number of patients from each center). Forty-nine patients underwent eEVAR, and 51 had operative repair. Table I summarizes the baseline characteristics of the patients in the two treatment groups. Hemodynamic instability at presentation was observed in 43 patients (43%), and the mean systolic blood pressure was 100 mm Hg (range, 0 to 200 mm Hg). There were no differences between the treatment groups with regard to any of the assessed preoperative variables, including the presence and severity of hemodynamic instability.

Preoperative use of an occluding aortic balloon to prevent severe hemodynamic collapse was needed in seven patients: three in the eEVAR group and four in the open repair group. The median time from admission to the procedure was 90 minutes (range, 10 to 3060) for the endovascular group and 60 minutes (range, 12 to 1440) for

Table I. Baseline characteristics of patients presenting with ruptured abdominal aortic aneurysm treated by emergency endovascular repair or open repair

	eEVAR (n = 49) (%)	Open repair (n = 51) (%)	All patients (n = 100) (%)
Demographic details			
Male/female	42/7	41/10	83/17
Age ± SD (years)	75.1 ± 7.1	73.8 ± 7.9	74.4 ± 7.5
History (% of group)			
Cardiac	9 (18)	8 (16)	17 (17)
Pulmonary	14 (29)	13 (25)	27 (27)
Renal	7 (14)	11 (22)	18 (18)
Carotid	4 (9)	12 (24)	16 (16)
Details at admission			
Abdominal pain	45 (92)	45 (88)	90 (90)
Collapse of patients	27 (55)	26 (51)	53 (53)
Hemodynamic instability	21 (43)	22 (43)	43 (43)
Moderate*	16 (33)	19 (37)	35 (35)
Severe†	5 (10)	3 (6)	8 (8)
Lowest systolic BP mean ± SD in mm Hg	100 ± 41	101 ± 42	101 ± 42

eEVAR, Emergency endovascular aneurysm repair; *BP,* blood pressure.
Figures indicate number of patients (%) unless indicated otherwise.
*Systolic blood pressure, 60 to 100 mm Hg.
†Systolic blood pressure <60 mm Hg.

Table II. Preoperative imaging

	eEVAR (n = 49) (%)	Open repair (n = 51) (%)	All patients (n = 100) (%)
US	1 (2)*	6 (12)	7 (7)
CT scanning (with/ without US)	43 (88)	44 (86)	87 (87)
IVUS	5 (10)	—	5 (5)
MRA	—	1 (2)	1 (1)

eEVAR, Emergency endovascular aneurysm repair; *US,* ultrasound; *CT,* computed tomography; *IVUS,* intravascular ultrasound; *MRA,* magnetic resonance angiography.
*This patient had a preoperative US study and later underwent intraoperative fluoroscopy and endovascular repair.

Table III. Anatomic characteristics in patients, who had preoperative imaging*

Anatomic characteristic†	eEVAR (n = 49)	Open repair (n = 44)	All patients (n = 93)
Aneurysmal neck suitable (%)‡	49 (100)‡	11 (25)‡	60 (65)
Proximal neck length (mm)§	21 ± 12§	9 ± 12§	16 ± 13
Proximal neck diameter (mm)	25 ± 3	25 ± 8	25 ± 6
Iliac arteries suitable (%)	47 (96)	35 (80)	82 (88)
Aneurysm diameter (mm)	75 ± 16	80 ± 15	78 ± 15

eEVAR, Emergency endovascular aneurysm repair.
Data are given in numbers (%) or mean ± SD.
*Either computed tomography examination, magnetic resonance angiography, intravascular ultrasound or ultrasound scan followed by fluoroscopy.
†More than one factor per patient was possible.
‡$P < .0001$.
§$P < .0001$.

Forty-nine patients had a suitable anatomy and were treated with eEVAR (Table III) for an overall applicability rate for eEVAR of 49%. Three additional patients, according to their CT findings in retrospect, appeared suitable for eEVAR. At the time of admission, however, unavailability of experienced endovascular staff (in two) or severe hemodynamic instability (in one) precluded eEVAR. Taking these cases into account, at least 52% of the study cohort had a vascular morphology that would have allowed an EVAR procedure.

The principal reason to perform an open aneurysm repair was an adverse configuration of the neck in 40 patients: the neck was too short in 34 patients, too angulated in two, and the diameter too wide for available devices in four. It should be noted that accepted criteria for neck length in EVAR were not followed rigorously, as endovascular repair was performed in five patients with a neck <10 mm. Other adverse anatomic factors included small diameter or occluded iliac arteries in two patients and iliac arteries that were too angulated in 14 patients. Moreover, moderate or severe hemodynamic instability precluded EVAR in seven patients (14%).

At statistical comparison, a number of anatomic characteristics were different in the treatment groups. Patients with eEVAR more frequently demonstrated an infrarenal neck suitable for EVAR and longer necks (Table III). No significant differences were observed in aneurysm diameter, neck diameter, angulation of the neck, iliac arteries suitable for EVAR, and angulation of iliac arteries. This comparison did not include patients with open repair who were not examined by CT because of severe hemodynamic instability.

The procedure and early course. The anesthetic technique involved general anesthesia in all patients with open repair compared with 33 patients with eEVAR ($P < .05$). In this latter category, 21 patients had local anesthesia during the initial part of the procedure and general anesthesia after deployment of the AUI device, whereas re-

the open repair group; thish difference was not statistically significant. Preoperative CT examination was performed in 87 patients (87%) (Table II). In seven patients (7%), an ultrasound examination revealed a rAAA, but the patients were severely hemodynamically unstable and the surgeon elected not to perform CT scanning. These patients were directly transported to the operating room, where six underwent open repair and the seventh underwent fluoroscopic assessment followed by endovascular repair. In five patients (5%), all in one institution, intravascular ultrasonography (IVUS) was performed. In this center, it was the policy that IVUS was used instead of preoperative CT examination. One patient (1%) was reported to have had a magnetic resonance angiography to assess the vascular anatomy.

Table IV. Operative details in patients with emergency endovascular aneurysm repair

	eEVAR (n = 49) (%)
Use of supra-renal balloon	3 (6)*
Deployment success	45 (92)
Conversion to open repair	3 (6)
Fluoroscopic time, mean ± SD (min)	19 ± 9
Postoperative completion angiogram endoleak	11 (22)
Type I proximal	3
Type I distal	4
Type II	4
Type III	—
Operation time (min)	173 ± 60
Replaced blood volume (mL)†	1322 ± 1494†
I.C.U. stay (days)‡	5.8 ± 9.4‡
Mechanical ventilation (hours)§	71 ± 159§
Hospital stay (days)	14.9 ± 16.4

eEVAR, Emergency endovascular aneurysm repair.
Data are given in numbers (%) or mean ± SD.
*P < .001 compared with suprarenal clamping in open repair Table V.
†P = .001 compared with open repair Table V.
‡P = .019 compared with open repair Table V.
§P = .001 compared with open repair Table V.

Table V. Operative details in patients with open repair

	Open repair (n = 51)
Suprarenal clamping	22 (43%)*
Aortic cross-clamp time (min)	56 ± 27
Tube graft/bifurcated graft used	35/16
Operation time (min)	177 ± 54
Replaced blood volume (mL)†	2411 ± 2159†
ICU stay (days)‡	9.4 ± 14.6‡
Mechanical ventilation (hours)§	165 ± 317§
Hospital stay (days)	22.2 ± 28.2

ICU, Intensive care unit.
Data are given as numbers (%) or mean ± SD.
*P = .001 compared with eEVAR Table IV.
†P = .001 compared with eEVAR Table IV.
‡P = .019 compared with eEVAR Table IV.
§P = .001 compared with open repair Table V.

gional or local anesthesia exclusively was used in 16 eEVAR patients. Twelve patients had general anesthesia for the entire procedure. Procedural details for each of the two treatment modalities are shown in Tables IV and V. Suprarenal control by clamping during the procedure in patients with open repair was significantly more frequent than suprarenal balloon occlusion in patients with eEVAR (P = .001). The volume of replaced blood was less in the eEVAR group (P = .001). A primary conversion to open repair was required in three eEVAR patients (6%) because of device migration that caused a persistent type III endoleak in two and because the device could not be advanced as a result of too narrow iliac arteries in one. The distal landing zone in the other 46 patients with endovascular repair was in the common iliac artery in 36 and in the external iliac artery in 10 patients. Endoleaks at completion angiography were identified and accepted in 11 patients (22%).

No group differences were observed with regard to the duration of the procedure; however, the intensive care unit stay was significantly shorter in the eEVAR group than in the open repair group (Tables IV and V). The same was true for time on the ventilator. There was no statistically significant difference in hospital stay between the groups.

Mortality. The overall 30-day or in-hospital mortality was 37 (37%) for the entire study group; 17 (35%) died in the eEVAR group and 20 (39%) in the open repair group. There was no statistically significant difference between the type of operation and crude or adjusted mortality rates (Table VI).

The all-cause mortality at 3 months was 40% in patients with eEVAR and 42% in the open repair category (difference not statistically significant) (Fig 3). The adjusted 3-month mortality was not different for the treatment groups (Table VI). Independent associations were found between hemodynamic shock at admission (systolic blood pressure < 90 mm Hg) and a history of pulmonary disease and mortality. The causes of death are listed in Table VII and included hemorrhage, cardiac arrest, respiratory insufficiency, and multiorgan failure as the most frequent causes of death. No statistically significant differences were found between the participating centers and the overall mortality.

Complications. The primary postoperative complications in 24-hour survivors and reinterventions that occurred ≤30 days and from 1 to 3 months are summarized in Table VIII. There was no difference with regard to the overall number of complications or the different types of complications between the treatment groups. Of the 85 24-hour survivors, 50 patients (59%) experienced one or more complications: 24 patients (59%) in the eEVAR group and 26 patients (59%) in the open repair group. Reinterventions by laparotomy in the eEVAR group included a banding at the infrarenal neck 4 days postoperatively for a type I endoleak that had caused a secondary rupture. In another patient, a secondary conversion to open repair findings after the procedure was performed because of a type I proximal endoleak. Notably, paraplegia developed in four patients (4%), two in each treatment group.

Excluded patients. During the study period, 134 patients were not enrolled in the study (data obtained by questionnaire). The number of patients excluded from each participating center ranged from 2 to 39, and the proportion of excluded patients ranged from 12% to 94%. Four centers were responsible for 113 (84%) of all patients not enrolled. The reasons that patients were not enrolled included informed consent not obtained or asked for, endovascular team unavailable, suprarenal aneurysm (which was in fact an exclusion criteria for this study), severe hemodynamic instability (which condition would have allowed inclusion with the option of allocating the patient to immediate open repair), and the use of a bifurcated stent-graft system of a different brand (one patient). Frequently, more than one reason was reported. The mean perioperative mortality in the patients excluded was 41%.

Table VI. Mortality in patients with emergency endovascular aneurysm repair and open repair

	eEVAR (n = 49)	*Open repair (n = 51)*		*OR and HR; 95% CI, P value* adjusted†*
30-day or in-hospital mortality†	17 (35%)	20 (39%)	operation type	1.14 (0.46-2.80; *P* = .78)
			age	1.05 (0.98-1.12; *P* = .19)
			gender	1.91 (0.55-6.64; *P* = .31)
			shock	3.85 (1.57-9.47; *P* = .003)
			Hx pulmonary	1.41 (1.00-1.97; *P* = .05)
3-month all cause mortality†‡	20 (40%)	22 (42%)	operation type	1.20 (0.65-2.24; *P* = .56)
			age	1.02 (0.98-1.08; *P* = .35)
			gender	1.51 (0.66-3.46; *P* = .33)
			shock	2.69 (1.52-5.58; *P* = .0013)
			Hx pulmonary	2.22 (1.19-4.14; *P* = .0121)

eEVAR, Emergency endovascular aneurysm repair; *CI,* Confidence interval.
*Odds ratios *(OR)* and hazard ratios (HR) from multivariate regression models.
†Adjusted for operation type, age, gender, shock (systolic blood pressure ≤ 90 mm Hg) and pulmonary history.
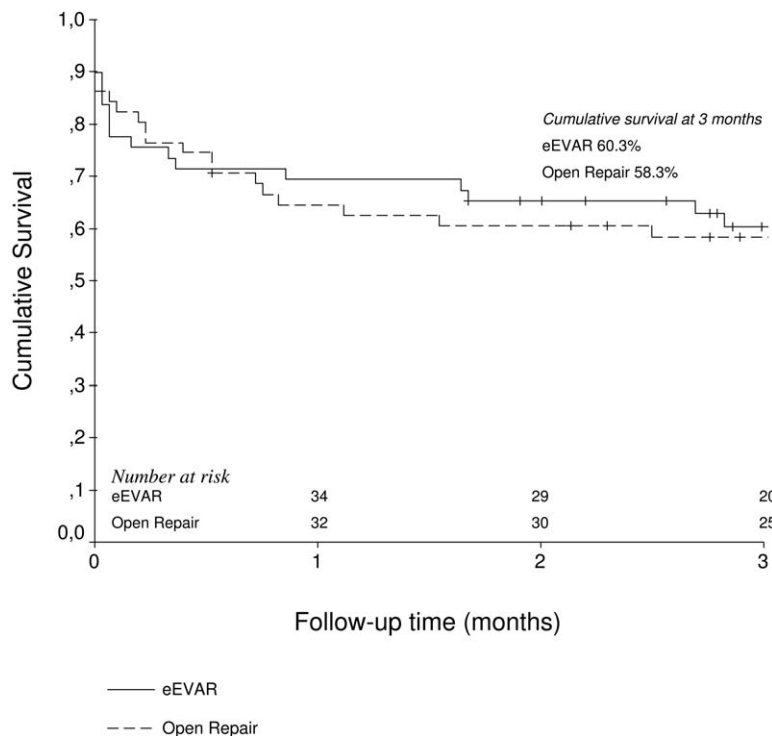‡Adjusted for follow-up time (see Fig 3).

Fig 3. Kaplan-Meier survival curve for emergency endovascular aneurysm repair *(eEVAR)* patients and open repair patients.

DISCUSSION

Although an immense increase in the expertise with EVAR in elective cases was observed during the last decade, only a limited number of centers have thus far published their experience with EVAR in rAAAs.[11-27] The present study was organized in cooperation with Medtronic. It was intended to systematically assess the outcome of treatment in a consecutive patient cohort undergoing either endovascular or open repair. This design, which differed from previous studies on emergency use of EVAR, was chosen to evaluate the following aspects: the applicability rate or the proportion of patients with anatomy that would allow endovascular repair, the overall perioperative mortality rate, and the mortality and morbidity rates in the endovascular and open repair groups separately. The study was organized as multicenter project to assess emergency rAAA repair using endovascular techniques where applicable. A broad range of institutions participated to accumulate a sufficiently large cohort in a short period, to realistically reflect current practice, and to allow for generalization of our

Table VII. Causes of death

	eEVAR (n = 49)	*Open repair* (n = 51)	*All patients* (n = 100)
30-day or in-hospital total	17 (35%)	20 (39%)	37 (37%)
Hemorrhage	6	6	12
Cardiac	3	3	6
Pulmonary	3	4	7
Bowel	2	2	4
MOF*	3	4	7
Miscellaneous	—	1	1
1- to 3-month total	3 (6%)	2 (4%)	5 (5%)
Cardiac	—	1	1
Pulmonary	1	1	2
MOF*	1	—	1
Miscellaneous	1	—	1

eEVAR, Emergency endovascular aneurysm repair.
*Multiorgan failure (failure of ≥ three organs).

findings. The study was set up as a feasibility study, and a number of notable findings evolved from this effort.

The proportion of patients with anatomic dimensions allowing endovascular repair reported in previous reports varied from 28% to 83%.[15,17,21,24,25] In the present study group, half of the patients underwent eEVAR. Adverse anatomy appeared to be the most frequent reason for selecting open repair. Logistic factors such as unavailable endovascular expertise precluded eEVAR in the study group in only 6% (three patients) of the open repair group. The potential effects of the relatively large number of excluded patients (often also because of logistic factors) will be considered at the end of this discussion.

Lower eligibility rates (23% to 37%) indicated in a number of previous reports[15,17,20-22] were probably associated with more restrictive anatomic criteria than recommended in our study protocol.[26] Five patients in the EVAR group (10%) had necks of <10 mm (our recommended threshold), and another 11 patients (22%) had necks of <15 mm (often suggested as a contraindication for elective EVAR). These observations signify that the anatomic criteria for eEVAR were applied liberally in the present study. Rigid application of generally recommended anatomic guidelines, well justified in elective EVAR, seems counterproductive in emergency treatment of rAAA. However, the safety and efficacy of the expanded criteria remain to be determined even though our outcomes appear generally favorable.

A preoperative CT examination was performed in 87% of the patients in an almost equal proportion of the two treatment groups. Hemodynamic status (ie, severe or moderate instability on average) was comparable in the two treatment groups; however, hemodynamic instability precluded any other imaging than ultrasound scans in 12% in the open repair group. In retrospect, our categorization into moderate and severe hemodynamic instability, meant to assist in decision-making, did not correlate with the selected treatment. Apparently, the response to hemodynamic shock varies from one surgeon to another. Some will prefer open repair in a critical situation, whereas others will

proceed with EVAR if the arterial morphology allows. In the eEVAR-group, 10% underwent preoperative IVUS (all in one center) instead of CT examination. In only one patient, the alternative pathway of triage between eEVAR or open repair by fluoroscopic arteriography immediately before the intervention was used. Thus, a CT examination is possible in almost all patients with rAAA. This is in agreement with the findings of Lloyd et al,[31] who observed that of patients who did not undergo repair of their aneurysm, 87.5% survived for more than 2 hours after admission in hospital.

The Talent AUI stent-graft was adopted as the single endovascular device in this study to reduce a large variation in operative technique and device characteristics. The use of an AUI stent-graft reduces intra-aneurysm sac pressure more effectively than bifurcated devices, as was confirmed in model study by Gawenda et al.[32] This advantage is greatest in unstable patients. Moreover, in patients with elective EVAR, AUI devices increased the proportion of patients treatable by endovascular technique by 19% to 45% because an unilateral access problem did not preclude the endovascular repair.[33,34] This aspect applies also to ruptured aneurysms. An additional advantage is the shorter learning curve with AUI stent-grafts compared with bifurcated stent-grafts, which may increase the number of centers that can perform eEVAR in rAAA.[35]

The use of a femorofemoral prosthetic bypass is considered a disadvantage by some. Potential risks include late occlusion or infection of the prosthetic bypass.[36] In the present study, only one patient had a prosthetic infection, which was successfully treated by replacing the crossover bypass by a vein graft. In an overview of the literature, it was concluded that the complication rate of femorofemoral bypasses in combination with AUI devices was low, and the long-term patency was excellent.[36-38]

Of 24-hours survivors, 59% had moderate or severe postoperative complication (Table VIII). Others have reported a comparable high figure,[23] but in other series this rate was lower (22% to 46%).[14,16,17,24] A likely explanation for the higher major morbidity is that the present study was prospective, which usually accounts for a higher reported rate of complications. Similar to most reports on open and endovascular repair, multiorgan failure, limb ischemia requiring thrombectomy, and cardiac and respiratory events were frequent complications in both treatment groups. Although we anticipated that eEVAR might be associated with fewer complications than open repair, the incidences in both groups were similar. The 4% rate of paraplegia was surprising. An assessment of the pathogenesis and risk factors of this complication after eEVAR was recently published by some of the present authors.[39]

The 30-day mortality in the present trial was considerably higher compared with some published single institution series in which this rate in eEVAR patients was 8% to 14%.[18,22-24] There may be several explanations for this difference:

First, selection bias seems a reasonable explanation of the seemingly favorable results observed in previous stud-

Table VIII. Primary complications

	30-day or in-hospital*		1- to 3-month period[†]	
	eEVAR (n = 41) (%)	*Open repair (n = 44) (%)*	*eEVAR (n = 29) (%)*	*Open repair (n = 29) (%)*
Cardiac	5 (12)	5 (11)	—	1 (4)
Pulmonary	2 (5)	4 (9)	—	—
Renal (with dialysis)	1 (2)	1 (2)	—	—
Bowel ischemia	2 (5)	3 (7)	—	—
Paraplegia	2 (5)	2 (5)	—	—
Reintervention (total)	3 (7)	3 (7)	1 (4)	—
Thrombectomy	1	2	—	—
Ffx infection[‡]	—	—	1	—
Late conversion	1	—	—	—
Laparotomy	1	1	—	—
Multiorgan failure[§]	5 (12)	5 (11)	1 (4)	—
Miscellaneous	—	—	2 (7)	2 (7)
Total	20	23	4	3

Ffx, femorofemoral prosthesis.
Data are number of patients and percentages (%), unless indicated otherwise.
Patients are categorized to their most severe complication.
*Of 24-hour survivors.
[†]Of 30-day or in-hospital survivors.
[‡]Femorofemoral crossover bypass replaced by vein.
[§]Failure of ≥ three organs.

ies. In particular, a small number of patients underwent endovascular treatment, and the outcome in patients with open surgery for their ruptured aneurysms in the same period was not reported.

Second, the presence of severe or multiple comorbidities may cause different outcomes between series. Notably, medical eligibility for open repair was not a prerequisite for enrolment in the present study, which may have resulted in the acceptance of patients with quite severe comorbidities for endovascular repair.

Third, hemodynamic status is strongly associated with the overall outcome. In a recent series by Hechelhammer et al,[24] only 22% of their patients were in hemodynamic shock preoperatively, as opposed to twice as many (43%) in the present study (systolic blood pressure of <100 mm Hg in both studies).

The higher percentage of patients treated by endovascular repair in combination with less favorable prognostic factors (confounders), compared with most of the previously reported series, may very well explain the higher mortality in the present study. Nevertheless, the 35% mortality rate in the eEVAR group and the 37% mortality in the study group overall still compare favorably with the often-observed 40% to 50% perioperative mortality in open repair series.

One may consider that essentially three types of patients with rAAA will present for treatment. The first category includes the patient who will not survive the first postoperative month irrespective of whether the operation is by endovascular or by open surgical technique. Death in this patient category appears unpredictable; no single pre-existing risk factor can reliably indicate the expected clinical course, as was assessed in earlier open repair series.[3,5] Patients in the second category may be assumed to survive

any type of repair. For these two categories, the introduction of EVAR will not be of decisive importance. At most, the duration of the intensive care unit admission or the number of days on the ventilator may be less with eEVAR. Finally, a third category may be recognized. This group consists of patients that will not tolerate the initial challenge of a laparotomy, aortic clamping, lower-limb ischemia, hypothermia, and systemic and coagulation disturbances. This may be the patient who survives the perioperative period because of the lesser challenge of the endovascular procedure. How large this proportion of patients is cannot be estimated at the present time.

The large number of patients who were excluded because no informed consent was obtained was disturbing and, at first sight, appears to undermine the validity of this study. In fact, 134 nonenrolled patients underwent open repair, except one in whom implantation of a bifurcated endograft from another company was performed. However, since informed consent was not obtained or asked for (largely because the attending surgeon was inexperienced in eEVAR) for most of the nonenrolled patients, selection leading to a bias is not an issue. Not asking for informed consent in an emergency situation or because personnel requirements were not met may be considered a random phenomenon with regard to patients being admitted for rAAA, that is, it did not result in systematic inclusion of patients with exceptionally good or poor prognosis. In fact, this observation signifies the large organizational challenges even in dedicated centers with the endovascular management of emergency cases.

The proportion of nonenrolled patients with an unsuitable anatomy for EVAR could not be examined because CT examination was rarely performed. Still we have no reason to assume that the EVAR application rate is different from

the group that was included. In particular, the first-month mortality was very much similar in patients enrolled undergoing open repair (39%) and nonenrolled (41%) patients, virtually all of whom underwent open repair (*P* value of 2% difference with 95% CI). This again corroborates comparability between the enrolled and nonenrolled groups. Thus, we believe that that our conclusions, which were based on the patients enrolled, may still be generalizable to the larger population of rAAA patients.

CONCLUSIONS

Questions that were answered in the present study included that eEVAR appeared to be a feasible method for most dedicated vascular centers to treat rAAA. Also, a good outcome may be anticipated for most patients. The mortality after eEVAR was 35% and the overall mortality was 37%, which compared favorably with most previously published results of open repair.[3-7] In the simultaneously nonenrolled group, mortality was 41% after open repair. Half of the patients with rAAA in our study were treated by endovascular technique, which is higher than in most previous studies.

The availability and number of endovascular teams with experience in emergency endovascular repair needs to improve to include most patients with a ruptured infrarenal abdominal aneurysm in a preferential treatment by EVAR protocol. In a well-organized setting, the advantages of less blood loss, avoiding of laparotomy, and shorter time in the intensive care unit and on mechanical ventilation should translate into a further decrease of the perioperative mortality.

AUTHOR CONTRIBUTIONS

Conception and design: NP, JB
Analysis and interpretation: NP, EB, JB
Data collection: NP, RHG, CS, PC, OKS, JAWT, ML, JDL, FEGV, GD
Writing the article: NP, JB
Critical revision of the article: EB, RHG, CS, PC, OKS, JAWT, ML, JDL, FEGV, GDR, JB, NP
Final approval of the article: EB, RHG, CS, PC, OKS, JAWT, ML, JDL, FEGV, GDR, JB, NP
Statistical analysis: NP, EB, JB
Obtained funding: JB
Overall responsibility: JB

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DISCUSSION

Mr Kevin Burnand (London, UK). I wonder whether you'd tell us how many people were excluded from this study, because that's obviously a very important piece of information. Could you tell us how many people died during the assessment period? Finally, could you tell us whether there was any difference in outcome between patients with a short neck, because one would expect these patients to have a poorer outcome.

Dr Noud Peppelenbosch. With regard to the exclusion of patients, we retrieved this information from the participating institutions by questionnaire at the end of the study period.

As many as 134 patients were excluded from this study. The main cause for exclusion was no available patient consent, and the second cause was no unavailable staff with endovascular experience at the time of presentation at the hospital. Of those 134 patients, all except one were treated with open repair. One patient received endograft treatment with a bifurcated system of another company, and this patient was excluded. The 30-day mortality in the excluded group was 41%.

Mr Burnand. So, could you give us a rough idea of how many people it would be appropriate for? My guess is 20% to 30%; is that right?

Dr Peppelenbosch. I think the application rate remains 50%, comparable with the rate in the included patients. We cannot be certain about this estimate because the majority of excluded patients did not receive a CT examination. However, because the primary reasons for exclusion from this study regarded logistic factors (not anatomic), there is no indication that the proportion of patients with anatomy feasible for endovascular repair will be different than in the included category.

Dr Munier Nazzal (Toledo, Ohio). I have two questions. The first one, you did not tell us about the surgical group, what type of aneurysm (in relation to the renal artery)? I assume that they had shorter necks. As you know, these are expected to be difficult from the surgical point of view, with higher complication rates. The second question is how do you explain the similarity in hospital stay?

Dr Peppelenbosch. To start with your last question, it may not be the treatment modality that determines the occurrence of complications and the duration of the hospital admission. It is most likely the disease itself. General patient characteristics, risk factors, and hemodynamic situation were the same for patients with endovascular and open repair. We did not present these data here, but the morbidity figures in both treatment groups were similar. When we consider the overall high morbidity rate in this cohort, an operative (one-month) survival of over 60% can be considered acceptable.

Dr Donald P. Spadone (St. Louis, Mo). Was abdominal compartment syndrome a problem in ruptured aneurysm patients treated with EVAR? How many patients required a secondary procedure to treat abdominal compartment syndrome or other problems with intra-abdominal thrombosis?

Dr Peppelenbosch. Approximately 12% of the patients received a secondary intervention. The most frequent reinterventions included thrombectomy and device extensions and other procedures, such as coiling of side branches, to treat type I and II endoleaks. Two patients had an abdominal compartment syndrome.

Dr John Hallett (Charleston, SC). Was there a difference in time from the arrival and diagnosis to when treatment was completed for the two? First question. And second, is there a difference in the cost and total cost of hospitalization between the two.

Dr Peppelenbosch. There was no difference in time period from the arrival at the hospital until the operation. In both treatment groups, it was approximately 1.5 hours. Most patients in the open repair group received also a CT examination, explaining the similar time interval until operation.

Dr William Jordan Jr (Birmingham, Ala). Recently, we presented our own single-institution experience of UAB at the Peripheral Vascular Surgery Society. Our findings were similar to yours, with similar survival in both groups, but our conclusions were a little different. Specifically, we have taken the approach, if the ruptured aneurysm arrives and the anatomy is suitable, we prefer endografting because the endograft makes a relatively unstable or an emergency situation stable that can be converted later if we need to. My real preference is to go with endovascular repair. Ultimately then, my question is, can we really support or do you really think we should push ahead with a randomization protocol? I mean, we have a minimally invasive approach that can at least stabilize the patient and has similar short-term outcome.

Dr Peppelenbosch. Our protocol included the option of the use of an occluding aortic balloon, which was used in about 8% of the reported patients preoperatively. In addition, the protocol included taking severely unstable patients directly, without a CT scan, to the operating room. When the condition permits, we can use fluoroscopy for further triage. When CT or fluoroscopy is not possible, an open repair is performed.

Dr Jordan. So you are demonstrating our same practice pattern, but I am asking if you think we should do a randomization protocol based upon what you—and it sounds like the practitioners in your group—practice. Do we need to go and push for randomization for this problem?

Dr K. Craig Kent (New York, NY). Dr Buth, do you want to comment?

Dr Jaap Buth. We think that the present study is not the final answer on what is the best approach. There is still equipoise on what is the best treatment for a ruptured AAA. A randomized comparative study with two treatment arms, the first preferential EVAR and the second standard open surgery, seems a proper next step to our present report. In this randomized trial, the preferential EVAR group subsequently needs to be divided into two subgroups, one where EVAR can be performed on the basis of anatomy and hemodynamic situation and the second subgroup where anatomy is unfavorable and an open repair is required. In our view, a randomized trial of this design will be the best way to find out which treatment is best in patients with a ruptured AAA.

Dr Takao Ohki (Bronx, NY). We have been proponents of this approach also, and we do have some experience. And from our own experience, I can tell you that some patients were hurt by insisting on endovascular repair in the presence of unfavorable anatomy. Although you did select out some unfavorable anatomy in terms of the length and the diameter of the proximal neck, you didn't take into account the tortuosity and other anatomic factors that may make endovascular repair difficult. The selection process in your trial most likely negatively impacted the mortality of the open repair, because the unstable patients preferentially got the open repair and the patients with more difficult anatomy got the open repair. So the open repair suffered from the fact that they were dealing with more challenging patients, yet there was no difference in mortality. So there is a possibility that the endovascular repair was, in fact, hurting the patients.

Have you done some analysis looking at outcome in comparable groups of patients in terms of anatomy and hemodynamic stability? I hate to say this, because I do believe endovascular repair is the way to go, but there is a possibility that endovascular repair may be harmful if used inappropriately.

Dr Peppelenbosch. We didn't perform a separate comparison for hemodynamically stable and unstable patients. We believe that the endovascular technique is also feasible in the majority of unstable patients. We observed that both patient groups were comparable with regard to hemodynamic instability and general risk factors, including cardiac disease, renal disease and pulmonary disease. We have not expected this to be the case. An important difference with previous published studies was that in our series two-thirds of the patients were hemodynamically unstable. In most other reports, approximately 20% was unstable. This difference in

patient selection explains a higher mortality in the present study compared with previous studies.

Dr Kent. Tak, stay at the podium for a second. Your group has published a number of articles suggesting that mortality can be reduced fairly dramatically with endovascular repair, and now we are hearing data that suggests the contrary. Since I have both of you at opposite microphones, is there any way to reconcile this? Tak, what do you think is the secret that you might have that Dr Peppelenbosch was not able to demonstrate in this multicenter trial?

Dr Ohki. Can I speak my mind?

Dr Kent. Oh, I'm afraid of the consequences, but let's give it a try.

Dr Ohki. Maybe better surgeons, better endografts. I think our patients were equally unbiased in terms of the hemodynamic instability since we treated all comers. One major difference includes the fact that we used the occlusion balloon more often than you did. Also, we preferentially used the balloon-expandable stent, which performs better in angulated and short necks than the self-expanding-type device that you used. Finally, single-center trials usually produce a better outcome than multicenter trials. I think these are the major differences that I can come up with, short of the fact that we were better surgeons.

Dr Kent. Dr Buth, why don't you respond to this.

Dr Buth. The issue of which device is better is difficult to prove. Obviously, there are subjective preferences here. Our view is that the aortouniiliac device of Medtronic is quite suitable for the treatment of ruptured abdominal aortic aneurysms. In this series, many patients had shorter necks than usually would be considered, eg, criteria were more liberal in the endovascular group than in an elective EVAR group. In this regard, I may respond to one of the previous discussants who asked whether the open repair cases in this study were technically more difficult. We didn't have that impression from our data. We believe that the open repairs were rather standard, without a frequent need for supraceliac clamping. Also, the reimplantation rate of visceral arteries was low, with approximately 5%. There was, however, an increased rate of suprarenal clamping, which was approximately 40%, if compared to the literature.

To come back to Tak Ohki's comments. These re-emphasize the need for a randomized study. Indeed, we may harm an individual patient, but we don't know how many. At present, the mortality rates in our and other studies are lower than in classic open repair series. Therefore, we feel confident that more patients will benefit from the endovascular procedure. The only way to find out is a sufficiently powered randomized study.

Dr Michael Golden (Philadelphia, Penn). You mentioned that you had separated out the patients that were hemodynamically unstable and they went to open repair, and also that about half, or more than half, of the endovascular-treated group was actually treated without general anesthesia. However, it appears that your postoperative ventilatory support requirement was actually an appreciable amount of time for EVAR patients also, as was the hospital stay. Can you comment on the respiratory complications of the EVAR group? Was it a small number of the EVAR patients that had a high level of morbidity, with very long ventilatory requirements, or was the respiratory morbidity relatively common with EVAR patients, but of shorter duration?

Dr Peppelenbosch. The morbidity rates in the endovascular and open repair groups were fairly similar. Statistically significant differences were observed in the intensive care unit stay and the time on mechanical ventilation in favor of the endovascular group. In addition, probably related to time on the ventilator, pulmonary complications were less frequent in patients with endovascular treatment. However, the latter was not statistically significant. Other complications that arose included renal failure, with two patients who required dialysis. Cardiac problems occurred more in the open repair group, but none were statistically significant, which we found surprising. Perhaps the high proportion of patients with hemodynamic instability explains why the morbidity rate was 26 independent of the type of treatment.

INVITED COMMENTARY

James May, MD, MS, FRACS, FACS, *Sydney, Australia*

Since the mortality rate for open repair of ruptured abdominal aortic aneurysm (AAA) is 40% to 50%, vascular surgeons have felt intuitively that it should be possible to improve on these results by using the endovascular method of repair (EVAR). It has not, however, been easy to find objective evidence and statistical proof of the superiority of EVAR in this situation. The impact of EVAR on ruptured AAA has also been disappointing in terms of the number of cases treated. Veith[1] has reported 442 cases with a mortality of 20% from an international survey conducted over a 5-year period. This perhaps should not surprise us since Greenhalgh's group[2] have reported that only 24 of 103 patients whose AAA ruptured during ultrasound surveillance were able to be treated by operation. This figure would, in all probability, be halved again if anatomical criteria for endovascular repair were applied.

The report of Peppelenbosch et al[3] of the first multicenter study comprising 100 patients is therefore welcome. It should be seen in the context of the obstacles in conducting such a study, not least of which is the logistic difficulty in providing skilled endovascular, radiology, anesthetic, and nursing teams around the clock. Not withstanding this, however, the limitations of this study must be considered.

One hundred patients were enrolled in the study, and 134 were excluded. There is much information on the 100 patients in study group but very little on the 134 who were excluded, and what information the authors have on this group is according to a survey by questionnaire conducted at the end of the study. Not all of the exclusion criteria are provided, but the main criteria are stated to be "not consenting to participate in the study and comorbidities with a life expectancy less than one year." Additionally, 14% of enrolled patients in the EVAR group were excluded from EVAR because of moderate or severe hemodynamic instabil-

ity and were transferred to the open group. Under these circumstances, despite reassurance by statisticians, the study group and the subgroup treated by EVAR are highly selected. It is therefore difficult to know what relevance the outcome of these two groupings has to the practical day-to-day management of patients presenting with rupture to emergency departments.

The major finding of equality of survival between the group treated by EVAR and that treated by open repair is difficult to interpret. Since the EVAR group was favored by exclusion of 14% of patients as a result of hemodynamic instability and the open repair group was additionally disadvantaged by inclusion of patients with anatomically unfavorable or absent proximal necks, it is difficult to understand why the outcome of the open group was so good and that of the EVAR group was so comparatively bad.

The relationship of the investigators and device manufacturers, although common practice, is not ideal. The study was sponsored and supported by the manufacturers and periodically monitored on site by them. Data processing and analysis were performed by the first author and principal investigator with the technical assistance of the manufacturers.

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APPENDIX (online only)

Participants of the New ERA study

Medisch Spectrum Twente, Enschede, the Netherlands, R.H. Geelkerken, A.B. Huisman, D.J. Gerrits, E.D.P. Volker, R. van Det, P. de Smit (23); Regional Endovascular Centre, Belfast, Northern Ireland, C. Soong, C. Boyd, W. Loan (18); Catharina Hospital, Eindhoven, the Netherlands, J. Buth, Ph. Cuypers, N. Peppelenbosch (14); Policlinico Monteluce, Perugia, Italy, P. Cao, F. Verzini, S. Mosca (11); Royal Victoria Hospital, Montreal, Quebec, Canada, O.K. Steinmetz, K. MacKenzie, D. Obrand, B. Montreuil (11); Atrium Medisch Spectrum, Heerlen, The Netherlands, J. Teijink, H. Odink, R. Welten (8); Meilahti Hospital/HUCH, Helsinki, Finland, M. Lepäntalo, P. Keto, W. Roth, P. Aho (5); AZ St. Jan AV, Brugge, Belgium, J. de Letter (5); University Hospital, Gent, Belgium, F.E.G. Vermassen, Ivan Herzeele (3); London Health Sciences Centre, London, Ontario, Canada, G. DeRose, T.L. Forbes, S.W. Kribs (2).

Adverse Event Advisory Committee

B. Barbieri, Medtronic, Maastricht, the Netherlands; J. van den Berg, Lugano, Italy; P. Cao, Policlinico Monteluce, Perugia, Italy; S. Zannetti, Medtronic, Santa Rosa, Calif.

Steering Committee

B. Barbieri, Medtronic, Maastricht; J. Buth, Ph. Cuypers, and J. Jakimowicz, Catharina Hospital, Eindhoven, The Netherlands; and S. Zannetti, Medtronic, Santa Rosa, Calif.