Outcome of endovascular abdominal aortic aneurysm repair in patients with conditions considered unfit for an open procedure: A report on the EUROSTAR experience

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Objective: **Endovascular abdominal aortic aneurysm repair (EAR) can be performed in patients whose conditions were previously considered unfit for conventional treatment of the aneurysm. However, because the life span in this category of patients often is limited because of serious comorbidity, the efficacy of EAR in prolonging life expectancy remains uncertain. This study involves the evaluation of preoperative risk classification and an assessment of the outcome of interventions.**
Methods: **The data of 3075 patients, who underwent operation in 101 European institutions that collaborated in the EUROSTAR Registry, were assessed. Only the patients who had been prospectively enrolled in the registry were used for this analysis. Patient characteristics, operative risk factors, procedural details, and types of devices were correlated with preoperative estimates of operative risk, early and late mortality, complications, and primary and secondary outcome success rates. In addition, the intermediate-term survival rates in patients with unfit conditions with EAR (observed series) and with conservative approaches of the aneurysms (rupture rates as derived from the literature) were compared in a mathematical model.**
Results: **Of the overall study group, 2525 patients were at "normal" risk for a surgical procedure (group A), 399 patients had conditions that were considered unfit for open surgery (group B), and 151 patients had conditions that were unfit for general anesthesia (group C). Both unfit categories had significantly more comorbid factors and larger aneurysms than did the patients in good medical condition. Differences were observed in comorbidities between the two high-risk categories, groups B and C. Factors that influenced the abdominal approach (previous laparotomies, hostile abdomen, and obesity) and local anatomic factors (eg, retroperitoneal fibrosis, inflammatory aneurysm, dissections, and enterostomy) were present in 19% of the patients with conditions that were unfit for open surgery and in only 1% of the category unfit for anesthesia. In contrast, severe pulmonary disease was present in 33% of the patients with conditions that were unfit for anesthesia as opposed to 11% of the patients with conditions that were unfit for open surgery. The early and late mortality rates were significantly higher in the unfit categories (groups B and C). Life table results showed a 3-year survival rate of 83% in patients at normal operative risk and of 68% in patients with unfit conditions ($P = .0001$). An independent correlation with late death was shown for the clinical classification into high-risk groups B and C, pulmonary disease, team experience of less than 60 procedures, and the diameter of the aneurysm. In groups B and C, aneurysms smaller than 6.0 cm were associated with a 2-year survival rate of 80% and larger aneurysms with a rate of 68% ($P = .02$). This difference was caused by an increased non–aneurysm-related mortality rate in the group with aneurysms of more than 6 cm. The mathematical model showed an advantage of EAR with regard to the reduction of the death rate in patients with unfit conditions as compared with no intervention after 1 year. The advantage of EAR was observed in patients with AAAs between 5 and 6 cm and with larger aneurysms.**
Conclusion: **Early and late mortality rates were increased in patients with the preoperative clinical diagnosis "unfit for open surgery and general anesthesia" as compared with patients at "normal" operative risk. EAR appeared of potential benefit in patients with unfit conditions, regardless of the aneurysm diameter. The life expectancy of patients at high risk who are considered for EAR should be longer than 1 year before any realistic gain in life span can be anticipated. (J Vasc Surg 2002;35:211-21.)**

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Because elective surgical repair of a large abdominal aortic aneurysm (AAA) is standard treatment to avert the risk of rupture, a proportion of patients has to be excluded from treatment because of too high a risk associated with major surgery.[1,2] The establishment of endovascular AAA repair (EAR) has changed the balance of risks and benefits considerably.[3] More patients with multiple comorbidities can undergo treatment with the advent of EAR because operative trauma, blood loss, and disturbance of circulation and ventilation is minimal. There is ample evidence that AAAs can now be successfully repaired in patients

Table I. Factors taken into account in categorization of unfit

1	Cardiovascular conditions (including cerebrovascular, status post heart transplant)
2	Pulmonary disorders
3	Combined cardiac and pulmonary diseases
4	Malignant diseases
5	Abdominal approach and local anatomic factors (eg, previous laparotomies, hostile abdomen, obesity, retroperitoneal fibrosis, abdominal irradiation, inflammatory aneurysm, aortitis, dissections, enterostoma, bladder substitute, uretherostoma, skin infections, osteomyelitis of sternum, peritoneal dialysis, kidney transplant, status post liver transplant, pancreatitis)
6	Specified general disorders (eg, hemotologic rheumatoid arthritis, connective tissue disease, hemodialysis, chronic renal failure, peritoneal dialysis, liver disorders, neurologic disorders, muscle dystrophy, myasthenia, Parkinson's disease, paraplegia, schizophrenia)
7	Poor condition: nonspecified general disorders (ASA 4, advanced age, multiple nonspecified comorbidity)

ASA, American Society of Anesthesiologists classification.

whose conditions were previously considered unfit for treatment.[4-6] However, because the life span in this category of patients often is limited because of serious comorbidities, the efficacy of EAR in prolonging life expectancy remains uncertain.[2] For the study of the mid-term outcome of EAR in patients who would have been rejected by their physicians for open repair, an analysis of the results obtained in patients in this category enrolled in the EUROSTAR database was performed. A preliminary account of the results obtained in the high-risk groups in the registry has previously been presented.[7,8] This study differs in several aspects from these previous communications. The study population consisted of prospectively enrolled patients only, and the database has increased by another 700 patients. We have assessed the various risk factors taken into account for the definition of a patient with unfit condition for open surgery or general anesthesia. In addition, the outcome of the clinical estimate of operative risks was compared with commonly used scored indices. Comparison of the outcome in patients at high risk and in patients at average risk who underwent EAR was performed. The follow-up data of patients at high risk with aneurysm who did not undergo operation, obtained from the literature, were analyzed with a mathematical model alongside the data of patients who underwent EAR.

METHODS

Patients and organization of registry. Details on the organization of the EUROSTAR Registry have been published in previous articles.[9,10] The objective of this registry is the collection and analysis of data from patients with endovascular treatment for AAA. The baseline data on suitable patients are recorded in a standardized fashion by participating institutions and are submitted for inclusion to the EUROSTAR Data Registry Center. The findings at follow-up examination, which involves clinical examination and computed tomographic (CT) scanning, are recorded on data forms and are returned at regular intervals to the Data Registry Center for processing and analysis. The follow-up visits are at 1, 3, 6, 12, 18, and 24 months and annually thereafter. The reminders for overdue follow-up data are regularly sent to the institutions participating in the project. No outside monitoring of the centers or a regular core laboratory for the evaluation of CT scan studies are involved.

Excluded from this analysis were 454 patients whose data had been enrolled retrospectively in the registry. Only the patients with prospective enrollment, which was at least 1 day before the EAR was performed, were included in this study. This cohort consisted of 3075 patients who underwent operation between June 1996 and March 2001. One hundred one centers were involved in patient treatment and data procurement (Appendix shows list of participating centers). The follow-up visits included a CT scan examination, with contrast enhancement of the abdominal blood vessels, in 94% of the patients and either contrast angiography, magnetic resonance angiography, or duplex scanning in the remainder of the patients.

Risk classifications, outcome events, and associated variables. Preoperative risk factors and risk classifications as recorded by the participating centers were used for correlation with perioperative and late morbidity and mortality rates. The American Society of Anesthesiology (ASA) physical status classification was used as a general risk indicator.[11] The scoring system proposed by the Society of Vascular Surgery and the International Society for Cardiovascular Surgery—North American Chapter (SVS/ISCVS-NA) was used to indicate more specific risk factors or the condition of different systems.[12] In addition to these specific risk categories, the physician's prospective assessment of risk according to one of the following broad categories was also taken into account: normal medical condition (group A), condition that was unfit for an open surgical repair of the AAA (group B), or condition that was unfit for general anesthesia as needed for open AAA repair (group C). Patients with unfit conditions for both open surgery and general anesthesia were categorized in group C. The Case Record Form allowed physicians to provide details in free text about the reasons a patient was allocated to the two defined unfit categories (groups B and C). On the basis of this detailed information, seven groups of factors that led to conditions being categorized as unfit were defined retrospectively (Table I). When a patient's condition was diagnosed as both unfit for open AAA repair and unfit for general anesthesia, the patient was allocated to the latter category.

Univariate analysis for the examination of the relationship between patient characteristics, aortoiliac morpho-

logic variables, and operative details with risk categories A, B, and C was performed with χ^2 test (for discrete variables) or with Mann-Whitney test (for continuous variables). The variables not obviously taken into account by EUROSTAR participants for the designation of group B or C were subjected to multivariate analysis for the delineation of those factors that independently correlated with these risk groups. Association between the most relevant clinical variables and different outcome events was subsequently assessed with multivariate analysis. If subgroup differences were statistically significant with the multivariate analysis results, *P* value and odds ratio (OR) were calculated. If outcome was an event that occurred during the follow-up period, a Cox proportional hazards regression model was used and the relative risk (RR) was calculated. Cumulative rates of patient survival, freedom from rupture, freedom from conversion, primary outcome success (freedom from death, rupture, conversion, and secondary intervention), secondary outcome success (freedom from death, rupture, and conversion), and freedom from systemic complications were estimated with life table analysis for each study group. With regard to the latter, if more than one systemic complication was experienced, the first in time was considered for the life table analysis. A *P* value of less than .05 was considered to represent a significant difference for all the tests. Statistical analysis was performed with SAS statistical software (version 6.12, SAS Institute Inc, Cary, NC).

The observed cumulative survival rate in patients with unfit conditions for open AAA repair or for general anesthesia who underwent EAR was compared with the expected survival rate in a theoretically similar cohort of patients without AAA treatment. It was intended to study the effect of aneurysm rupture–related mortality in untreated patients at high risk in addition to death from other causes. This analysis involved mathematic modeling of theoretic survival curves on the basis of the life table data (number of patients, patient years of follow-up examination until death or rupture, and rate of death) of the observed patients at high risk. An annual rupture rate of 11% for untreated patients with AAAs of 5 cm or more was derived from a report by Reed et al.[13] This rate was observed by these investigators in patients with aneurysms of 5 to 6 cm. Because the annual rupture rate for all patients with a AAAs 5 cm or more was not provided, we have applied the same rate in the mathematic model for patients with aneurysms 5 cm or more and for patients with aneurysms between 5 and 6 cm. In patients with aneurysms 6 cm or more, we have used an annual rupture rate of 26%, as reported by the same authors. We assumed that all untreated patients who had aneurysm rupture would have died from this rupture. A death rate was calculated from the observed data, with the discarding of 1st month deaths and the adding of deaths as the result of aneurysm rupture. Because the observed survival rate curve appeared approximately log linear, the survival rate in the theoretic group was assumed to be of the negative exponential type. The formula to describe such survival can be written as the exponential function: $\exp(-L \times t)$, in which t denotes follow-up time (in years) and L represents the annual death rate.

Table II. Patient characteristics and comorbid factors

	Group A	*Group B*	*Group C*
Mean age (years)	70.9	71.6	72.6*
Male gender	92.7	92.2	94
ASA physical status 3 or 4	48.8	81.8†	90.6†
SVS-ISCVS risk score			
Diabetes‡	9.9	13.5§	15.9§
Smoking‡	53	61.3*	67.0†
Hypertension‡	60.6	67.2§	61.5
Hyperlipemia‡	38.9	41.7	51.1*
Cardiac‡	56.9	75.3†	83.8†
Carotid‡	14.9	22.5†	21.4§
Renal‡	16.3	32.5†	27.8†
Pulmonary‡	34.2	59.9†	76.2†
Ankle-brachial pressure index < 0.87	19.4	25.7§	34.8†
Previous laparotomy	27	34.6*	26.5
Significant obesity	23.4	27.6	27.8

Figures represent percent of patients in each study group, unless stated otherwise.
All *P* values determined with group A as a reference.
*$P \leq .01$.
†$P \leq .001$.
‡Risk score ≥ 1.
§$P \leq .05$.
Group A, Patients at normal operative risk (n = 2525); *Group B,* patients with conditions unfit for open abdominal aortic aneurysm repair (n = 399); *Group C,* patients with conditions unfit for general anesthesia (n = 151); *ASA,* American Society of Anesthesiologists classification; *SVS-ISCVS,* Society of Vascular Surgery and the International Society for Cardiovascular Surgery.

RESULTS

Of the 3075 patients who constituted the study cohort, 2525 were considered to be of normal operative risk (group A), 399 had conditions that were indicated as unfit for open surgical repair of the AAA (group B), and 151 had conditions that were unfit for the general anesthesia that would have been necessary for surgical repair (group C). The mean follow-up period for the entire study population was 13.0 months (range, 0 to 57 months).

The patients in group C were older than the patients in group A. ASA classification of III or IV had a higher prevalence in groups B and C as compared with group A. This is in agreement with the expected greater operative risk in patients classified in groups B and C. The individual systemic risk scores generally were higher in groups B and C than in group A. With regard to abdominal approach factors, previous laparotomies had been more frequently performed in group B but not in group C (Table II). Groups B and C had less favorable morphologic and procedural factors in that the preoperative aneurysm diameters were larger, the infrarenal neck was more often angulated (only group C), adjunct procedures were more frequently performed, and blocking of side branches was more frequently needed. In addition, the experience of the teams was limited to less than 60 procedures in an appreciably larger proportion of cases in

Table III. Variables representing aneurysm morphology device brands used and procedural details

	Group A	*Group B*	*Group C*
Neck diameter (mean ± SD; mm)	22.9 ± 3.0	23.2 ± 3.2	23.3 ± 3.2
AAA diameter (mean ± SD; mm)	56.2 ± 10.6	58.3 ± 11.9*	59.5 ± 13.8*
Significant angulation of the infrarenal neck	22	25.3	31.8†
Configuration of device straight or aortouniiliac	5.9	9.3‡	11.3*
Adjunct procedures	31.9	46.1*	44.4*
Team experience < 60 procedures	63.7	69.4†	81.5*
Endoleak present at completion of operation	17.1	18.0	19.2
Blocking of side branches	18.5	27.8*	31.8*
Regional/local anesthesia	23.6	28.1	64.8*

Figures represent percent of patients in each study group, unless stated otherwise.
All *P* values determined with group A as reference.
*$P \leq .001$.
†$P \leq .05$.
‡$P \leq .01$.
Group A, Patients at normal operative risk (n = 2525); *Group B,* patients with conditions unfit for open abdominal aortic aneurysm repair (n = 399); *Group C,* patients with conditions unfit for general anesthesia (n = 151); *SD,* standard deviation; *AAA,* abdominal aortic aneurysm.

groups B and C. Straight or aortouniiliac devices were more frequently used in the unfit categories. Local or regional anesthesia was more frequently used in group C than in group A or B (Table III). The different devices used are represented in Table IV. There were no statistical differences in the frequency of any device used in patients at high risk.

Risk factors for patients with unfit conditions for open surgery or anesthesia. The disorders that were observed in groups B and C included significantly more conditions that complicated the abdominal approach and factors associated with adverse retroperitoneal anatomy in group B (in 19%) and more pulmonary disorders in group C (in 33%; Fig 1). Fig 1 also shows that there was a considerable overlap in groups B and C in systemic and abdominal approach/anatomic factors. For this reason, these groups were combined as B/C in most of the following analyses.

Multivariate analysis was performed for the following patient factors not obviously taken into account for designation of group B/C: age, gender, diabetes, current smoking, obesity, and ankle-brachial blood pressure index. Of these factors age, diabetes, obesity, and ankle-brachial blood pressure index correlated with classification into group B/C (Table V).

Perioperative morbidity and mortality rates. In 533 patients (17.3%), an endoleak was observed on the completion angiographic results. There were no differences in the overall prevalence of endoleaks nor in the prevalence of individual types of endoleak between the study groups. There were slightly more procedure-related complications, such as problems in the advancement or deployment of the device, iliac limb stenosis or occlusion, and device migration, in groups B (10.3% of patients) and C (11.3%) as compared with group A (7.1%; $P = .02$). Cardiac complications during admission occurred more frequently in group B (7.5%) and group C (9.9%) than in group A (2.8%; $P = .001$). Overall, there were 52 patients (1.7%) who needed conversion to an open procedure during the primary operation or within the 1st month. Conversions were needed in six patients (1.5%) in group B, in two patients (1.3%) in group C, and in 44 patients (1.7%) in group A, which represented a comparable prevalence in the study groups. Mortality rate during the 1st month was higher in group B (19 patients; 4.8%) and in group C (eight patients; 5.3%) than in group A (50 patients; 2.0%; both $P = .001$).

Multivariate analysis results, including preoperative and operative variables and risk groups A, B, and C, showed a significantly higher 1st-month mortality rate in: 1, patients in the combined risk groups B/C as compared with group A ($P = .039$; OR, 1.8); 2, patients with ASA classification of 3 or 4 ($P = .03$; OR, 1.9); 3, patients with renal insufficiency ($P = .0003$; OR, 2.5); and 4, age of 70 years and more ($P = .0004$; OR, 3.0). Other variables, such as a history of cardiac symptoms, pulmonary disorders, diabetes, ankle-brachial index of less than 0.87, obesity, and experience of the team did not correlate significantly with operative mortality rate.

Late morbidity and mortality rates. Nonfatal systemic complications (cardiac, pulmonary, vascular, neurologic, cancer, and other) occurred in 281 patients in the whole series. The cumulative incidence rates of systemic complications at 3 years in groups A and B/C were 19.4% and 25.1%, respectively ($P = .009$). Conversions to an open procedure, including procedures in the 1st month, were needed in a total of 94 patients (81 in group A and 13 in group B/C), and rupture of the aneurysm occurred in 20 patients (17 in group A and three in group B/C). There were no statistically significant differences between the study groups relating to the cumulative incidence rates of these two events.

The prevalence of 1st month and late deaths combined was 286 in the whole series and 83 in group B/C. The causes of death in patients in group B/C were related to cardiac disorders in 28 patients, malignant diseases in 10, stroke in seven, pulmonary disorders in eight, miscellaneous causes in 19, unknown causes in seven, and causes

Table IV. Device brands used in patients with normal operative risk and conditions unfit for open surgery

	All	*Group A*	*Group B/C*
Device brand			
Vanguard	910	758 (83.3%)	152 (16.7%)
AneuRx	794	653 (82.2%)	141 (17.8%)
Talent	525	426 (81.1%)	99 (18.9%)
Zenith	464	368 (79.3%)	96 (20.7%)
Excluder	216	178 (82.4%)	38 (17.6%)
EVT/Ancure	65	55 (84.6%)	10 (15.4%)
Other	101	87 (86.1%)	14 (13.9%)

Figures represent patient numbers. There were no statistical differences in proportions of any device brand used between groups A and B/C.
Device manufacturers are: Vanguard, Boston Scientific, Natick, Mass; AneuRx, Medtronic AVE, Cupertino, Calif; Talent, World Medical & Medtronic AVE, Sunrise, Fla; Zenith, Cook, Bjaeverskov, Denmark; EVT & Ancure, Guidant, Menlo Park, Calif; Excluder, Gore, Flagstaff, Ariz.
Group A, Patients at normal operative risk (n = 2525); *Group B/C,* patients with conditions unfit for open repair or anesthesia (n = 550).

Table V. Results of multivariate analysis that correlated preoperative patient characteristics with high risk classification (group B/C)

	Coefficient	*SE*	*Odds ratio*	P *value*
Age (years)	0.02	0.008	1.02	.048
Diabetes	0.46	0.18	1.58	.011
Obesity	0.29	0.14	1.34	.037
Ankle-brachial blood pressure index ≤0.87	0.49	0.14	1.64	.0005

SE, Standard error.

related to the aneurysm in four. The 2-year cumulative survival rate was significantly lower in group B (75.7%) and group C (74.3%) than in group A (88.5%; $P = .0001$; Fig 2). Aneurysms of 60 mm or larger were associated with lower survival rates than were smaller aneurysms in the study population as a whole. The group A and group B/C 2-year survival rates for aneurysms 60 mm or more and less than 60 mm in the entire cohort were 79.9% and 89.5%, respectively ($P = .0001$), in group A were 82.8% and 91.0%, respectively ($P = .0001$), and in group B/C, were 68.5% and 80.0% respectively ($P = .023$).

With the exclusion of the early deaths at multivariate analysis, the following factors were found to be independently associated with late death: 1, the preoperative risk classification in groups B and C ($P = .001$; RR, 1.8); 2, pulmonary disorders ($P = .005$; RR, 1.6); 3, team experience of more than 60 procedures ($P = .02$; RR, 0.6); and 4, aneurysm diameter ($P = .0002$; RR, 1.8).

The 2-year primary outcome success rates in groups A, B, and C were 70.0%, 61.7%, and 59.0%, respectively ($P = .0001$ for group A versus groups B and C). The secondary outcome success rates in groups A, B, and C were 88.2%, 78.2%, and 79.9%, respectively ($P = .0001$ for group A versus group B/C).

Comparison of patient survival rate with endovascular abdominal aortic aneurysm repair and without treatment of aneurysm (mathematical model). The cumulative survival rate in patients with unfit conditions who underwent EAR as observed in groups B and C combined was compared with that of a hypothetically similar group of patients at high risk who did not undergo treatment with an estimated rate of rupture of aneurysms more than 5.0 cm on the basis of the outcome reported in the literature. The mean period of follow-up in the 550 patients in group B/C was 9.8 months. Eighty-three deaths were observed, including 27 patients who died within the 1st month. With the exclusion of the latter 27 patients, the annual rate of deaths not related to the procedure was calculated to be 56 deaths per 449 person-years (0.12). With the addition of an annual rupture rate of 0.11 (derived from the report of Reed et al[13]) to this figure, an overall theoretic annual death rate in the survival formula of 0.12 + 0.11 = 0.23 is obtained. Fig 3 illustrates observed overall survival rate in the group of 550 patients and the theoretic survival rate curve on the basis of an annual death rate of 0.23. From this figure, it appears that in the early postoperative period avoidance of operative mortality outweighs the advantage of a reduced rupture rate in patients who undergo EAR. However, from 12 months after surgery, an increasing difference in survival rate in favor of patients with EAR is observed. After 2 years, survival rate in the observed (EAR) group was 75% and in the theoretic group was 63%.

When similar analyses were performed separately on patients in group B/C with initial aneurysm diameters less than 6.0 cm and 6.0 cm or more, the observed annual death rates not related to the aneurysm were 0.11 and 0.15 per person-year, respectively. Intrapolated death-from-rupture rates in the groups with aneurysms less than 6.0 cm and 6.0 cm or more in diameter were 0.11 and 0.26 per person-year, respectively.[13] Observed cumulative survival rate with EAR and theoretic survival rate without EAR showed differences in favor of patients who underwent EAR after 12 months of follow-up examination (Fig

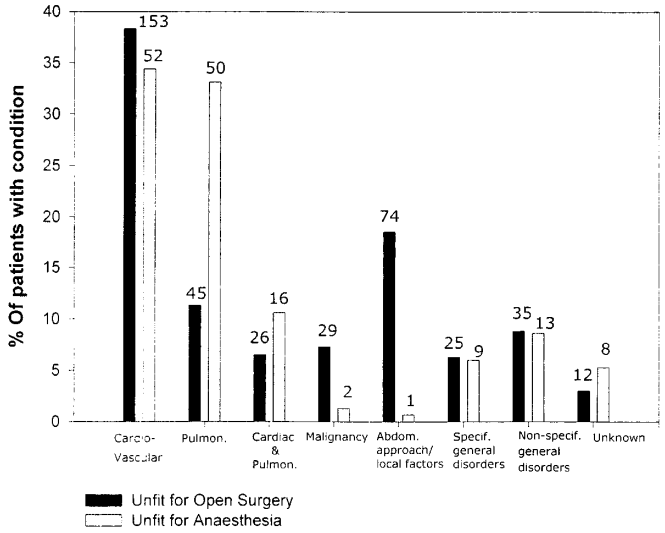


Fig 1. Distribution of factors taken into account in classifications of unfit for open surgery and unfit for anesthesia. In this graph, main risk factor in each patient is represented.

4). The advantage of EAR indicated by the proportional death-from-rupture rate relative to the rate of death from all causes at 2 years was comparable in patients with AAAs less than 6.0 cm and 6.0 cm or more (44% and 43%, respectively).

DISCUSSION

The proportion of patients for treatment of AAA who will be turned down for surgical repair depends, in part, on the type of practice attracted by some institutions. In one regional referral practice, the proportion of patients rejected for surgical AAA treatment was recently reported as 30%, which indicates the importance of the problem.[14] Endovascular repair of AAAs is applicable in patients at high risk of complications associated with conventional surgery. Several series that have been published in the recent years suggest that technical success can be obtained in those patients with unfit conditions for open aneurysm repair at low risk of mortality and morbidity.[4-6,15-17] However, one must question to what extent the benefit of aneurysm rupture prevention is undermined by a high incidence rate of non–aneurysm-related deaths, perhaps resulting in a mid-term survival rate not appreciably different to that if the patients had not undergone treatment.[2,18] Direct comparison of patients at high risk who underwent EAR or without any intervention has not been performed previously.

In this study, patients with conditions considered unfit for open aneurysm repair were identified from a large registry that consisted of more than 3000 prospectively enrolled patients. In addition to ASA classification and the SVS/ISCVS-NA system-based scoring schedule, a clinical assessment was recorded in detail for all enrolled patients. A distinction was made between patients with conditions unfit for conventional aneurysm repair (group B) and those patients with conditions unfit for prolonged general anesthesia (group C). Pulmonary disorders were more frequently associated with a diagnosis of unfit for general anesthesia, and factors regarding laparotomy and intraabdominal anatomic factors had a higher prevalence in patients with conditions considered unfit for open surgery. However, analysis results of the other reasons for classification as unfit showed a considerable overlap of comorbid medical conditions in these two categories. Therefore, groups B and C were combined for correlation with the main outcome events.

Clinical risk assessment by physicians participating in the registry according to groups A and B/C will correspond with other classifications, such as the ASA and SVS/ISCVS-NA risk scores. Of a number of other factors, the presence of diabetes, obesity, and advanced age correlated with the clinical diagnosis of high risk (group B/C). In addition, the presence of peripheral arterial occlusive disease indicated with an ankle-brachial index of less than 0.87 also correlated with a diagnosis unfit for surgery or anesthesia, a finding that confirmed a recently reported observation by Powell et al.[19]

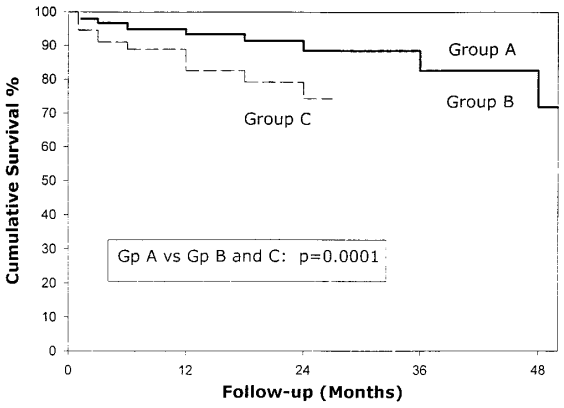
Patient selection appeared to be influenced by the experience of the clinical team. A total experience of less than 60 EAR procedures per surgical team was associated with a significantly higher proportion of group C patients, which suggests that these surgeons reserved EAR procedures primarily for patients otherwise considered at high risk for open aneurysm repair. This assumption is also supported by our observation that limited experience correlated with a higher late mortality rate. It would seem to be the case that more patients with better risk are accepted for treatment as teams gain experience and overcome their learning curves.

The mortality rate during the 1st month was significantly higher in patients classified as having high operative risk as compared with other patients. Variables in addition

to clinical assessment (groups A and B/C) that correlated with increased perioperative mortality rates were ASA classification, age, and renal insufficiency. Notably, the factors usually associated with an increased risk of death in relation to open aneurysmal repair, such as cardiac disease and pulmonary disease, did not have an independent effect on operative mortality rate in this series of patients with endovascular treatment. It might be possible, though, that in the multivariate model the effects of these factors were already absorbed by the fit–unfit categorization. On the other hand, it was observed previously that EAR is associated with less challenge of the respiratory system and decreased cardiac stress.[20,21]

The reported series of patients with untreated AAAs in which rupture rates were studied invariably involve relatively small numbers. The earliest observed series of 127 patients with untreated AAAs of more than 5 cm was reported by Szilagyi, Elliott, and Smith.[1] That study emphasized the relation between the risk of rupture and the size of the aneurysm. In patients with aneurysms larger than 6.0 cm, 42% of the deaths were caused by rupture, and in smaller aneurysms, this figure was 36%. We have investigated the effect of EAR on mortality rate with the intrapolation in our current life table data of patients with unfit conditions of a rupture rate of 0.11 (incidence rate of rupture per person-year) documented in untreated aneurysms between 5.0 and 6.0 cm.[13] There was an appreciable benefit in terms of survival rate resulting from minimization of the risk of rupture with endovascular aneurysm exclusion, with this rupture rate for comparison. The advantage of EAR became apparent after approximately 1 year. Thus, the life expectancy of patients at high risk who opt for EAR should be longer than 1 year before any realistic gain in life span can be anticipated.

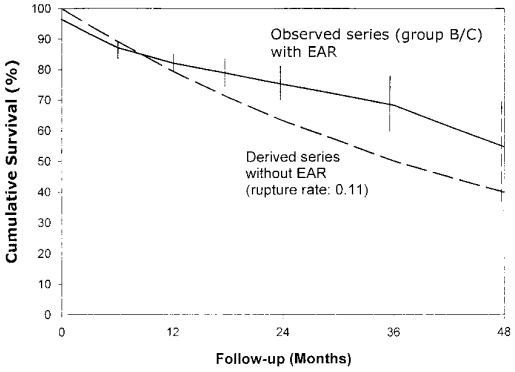
The risk of rupture varies with the size of the aneurysm, being minimal in aneurysms with a diameter less than 5 cm, becoming clinically significant in untreated aneurysms of 5.0 to 5.9 cm, and increasing dramatically in aneurysms with diameters more than 6.0 cm.[1,2,13,18,22,23] In recognition of this relationship, some authors advocate operative treatment only in those patients with AAAs larger than 6.0 cm.[24] There may be justification for a lower threshold diameter for intervention in patients with conditions that are suitable for EAR. From this analysis, it is apparent that in patients who undergo EAR (in which group the rate of rupture was low) the nonrupture death rate was significantly higher in patients with aneurysms 6.0 or more as compared with patients with smaller aneurysms. This pattern was similar for patients at normal and high operative risk. Thus, aneurysm size appeared to correlate strongly with the probability of both late death related to the aneurysm and death from comorbidity. The benefits from EAR appeared comparable in patients with aneurysms less than 6 cm and in those patients with aneurysms 6 cm or more in diameter, as the proportion of death from rupture relative to death from all causes after 2 years was 44% and 43% for aneurysms less than 6 cm and 6 cm or more, respectively. When these data are taken in account, it may be argued that the optimal threshold for endovascular interventions is definitely less than 6.0 cm. The data suggest that endovascular repair is justifiable in aneurysms larger than 5 cm, provided the patient is expected to survive for more than 1 year. These findings are in agreement with conclusions drawn previously from a predictive model reported by Finlayson et al.[3] These authors recommended lowering the size threshold for interventional treatment of aneurysms suitable for EAR to less than 6 cm, which was hitherto the conventionally accepted threshold for open AAA repair in patients at high risk.[24] Finlayson et al[3] observed also that the greatest potential impact of EAR was in patients at high risk.



	0	12	24	36	48 months
Group A					
Cumulative %	100	93.3	88.5	82.6	71.7
No. at risk	2525	1360	706	296	46
No. of deaths	50*	132	175	196	203
Group B					
Cumulative %	100	82.0	75.7	66.3	53.0
No. at risk	399	150	55	21	4
No. of deaths	19*	50	56	59	60
Group C					
Cumulative %	100	82.6	74.3	-	-
No. at risk	151	66	30	-	-
No. of deaths	8*	19	23	-	-

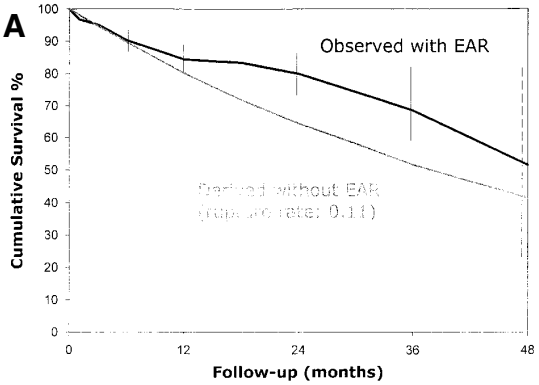
Fig 2. Survival curves in patients at normal operative risk (group A), in patients with conditions unfit for open surgery (group B), and in patients with conditions unfit for anesthesia (group C). *Deaths during the first postoperative month.

This study has several limitations. First, a prospective registry is not a rigorously monitored study, and the assessment of preoperative factors and determination of the indications for EAR are undertaken independently by a large number of institutions and physicians with inevitable variability. A small number of patients in the group with conditions identified as unfit for surgery had AAAs smaller than 5 cm, which would obviate the need for any intervention. However, in review of the details of this category, it appeared that most of these aneurysms were between 4.5 and 5.0 cm, and additional indications, such as rapid growth, a saccular configuration, or large iliac aneurysms, although not reported, may have been present. Secondly, one third of the patients classified in group C still underwent general anesthesia. This seemingly erroneous patient grouping can be explained by the fact that exploration of

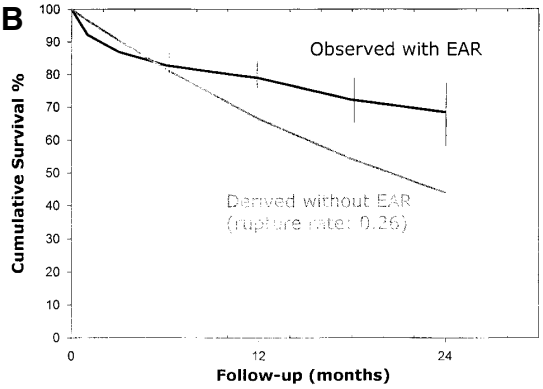


	0	12	24	36	48 months
Observed survival with EAR					
Cumulative %	100	82.1	75.1	68.3	54.6
No. at risk	550	216	85	30	4
No. of deaths	27*	69	79	82	83
Derived survival without EAR					
Cumulative % (when rupture rate = 0.11)	100	79.4	63.1	50.1	39.8

Fig 3. Observed survival rate curve in patients with unfit conditions who underwent endovascular abdominal aortic aneurysm repair (*EAR;* group B/C) and in theoretically similar cohort of patients with untreated abdominal aortic aneurysms and assumed annual rupture rate of 0.11. *Deaths during the first postoperative month.



	0	12	24	36	48 months
Observed survival with EAR					
Cumulative %	100	84.4	80.0	68.6	51.5
No. at risk	323	132	47	18	3
No. of deaths	10*	33	36	39	40
Derived survival without EAR					
Cumulative %	100	80.2	64.4	51.7	41.5



	0	6	12	18	24 months
Observed survival with EAR					
Cumulative %	100	82.7	78.9	72.1	68.5
No. at risk	227	119	84	53	38
No. of deaths	17*	32	36	41	43
Derived survival without EAR	100	81.5	66.3	54.1	44.0
Cumulative %					

Fig 4. Survival rate curves in patients with unfit conditions who underwent endovascular abdominal aortic aneurysm repair (*EAR*; group B/C) and in theoretically similar group of patients without treatment of abdominal aortic aneurysm (AAA) in (a) patients with AAAs less than 6.0 cm and in (b) patients with AAAs 6.0 cm or more. *Deaths during the first postoperative month.

the femoral artery and catheter intervention requires a lighter anesthesia than does a major abdominal procedure. Thirdly, assessment of clinical risk according to groups A, B, and C was largely subjective rather than a formal scoring system. Although this is the same principle that was used to exclude patients from AAA repair before endovascular treatment was an option,[1,2,18,25] a system with standardized objective parameters may be preferable. POSSUM (Physiologic and Operative Severity Score for enUmeration of Mortality and morbidity) scoring system is a proven method for the estimation of the risk of death or complications in individuals after major surgery, and this system has been adapted successfully for vascular surgical procedures.[26] The system is quantitative and was found to correlate well with postoperative mortality after aneurysm surgery. This system may become applicable to studies of the type described here, although some additional modifications may be necessary for endovascular interventions.[27] The POSSUM predictor equation or other predicting rules may well be useful in future auditing projects of EAR procedures.[26,28] Fourthly, we assumed in the theoretic model of patients who did not undergo treatment that all aneurysm ruptures occurring during the follow-up period would result in death and disregarded the option of emergency surgery. This assumption may seem reasonable because the overall fatality rate after AAA rupture (including patients at normal risk) is reported to be 80% to 90%.[29,30] The chance of aneurysm rupture survival by patients with conditions previously declared unfit for open repair indeed seems almost negligible. Finally, the mathematic model we used to estimate the relative gain in survival rate after EAR was on the basis of the presently observed outcome during follow-up examination and of rupture rates derived from reports on the natural history of aneurysms. The reported annual risk of rupture varies between 0.03 and 0.14 in AAAs of 5 to 5.9 cm.[13,22,23,25,31,32] In this size range, we investigated a rate of 0.11, which appeared in accordance with life table data of patients with untreated AAAs, published in two large recent studies.[2,18] It was not methodologically sound to use the mathematic model for the assessment of the statistical

significance of calculated differences in mortality rates between patients with EAR and no intervention.

CONCLUSION

Early and late mortality rates after EAR were increased in patients at high risk for open surgery as compared with patients at normal risk. Subjective clinical assessment of risk correlated as well or better with early and late survival rates than scored classifications. However, there is a need to develop better standardized systems for the prediction of outcome after EAR. Our estimate that endovascular repair will offer a significant reduction in all cause death rates in patients at high risk with AAAs beyond 1 year after operation requires confirmation by a prospective randomized trial that compares EAR with a conservative treatment in this category of patients.

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Appendix. Participants of 101 institutions that contributed data to this EUROSTAR study

Austria: Vienna: Prof G. Kretschmer.
Belgium: Bonheiden: Dr P.M.A.J. Peeters; Bruxelles: Dr R. Verhelst; Gilly: Dr H. Massin; Leuven: Prof A. Nevelsteen; St Truiden: Dr F. van Elst; Turnhout: Dr P. Stabel; Wilrijk/Antwerpen: Dr M. van Betsbrugge.
France: Draguignan: Dr C. Mialhe; Grenoble: Dr Magne; Lille cedex: Dr M.A. Vasseur; Lyon: Dr B. Age; Marseille: Dr Piquet; Montpellier: Prof Marty-Ane; Nancy: Dr C. Amicabile; Nanterre: Dr J. Marzella; Nimes: Dr Cardon; Paris cedex: Prof J.C. Gaux; Paris Creteil Cedex: Prof J.P. Becquemin; St Etienne: Prof J.P. Favre; St Laurant du Var: Prof P. Kreitmann; Toulouse: Prof H. Rousseau; Toulouse Cedex: Dr C. Giraud.
Germany: Bonn: Dr A. Viehofer; Dusseldorf: Dr R. Kolvenbach; Frankfurt: Prof W. Stelter; Frankfurt: Prof H. Sievert; Freiburg: Dr Uhrmeister; Hamburg: Prof H. Kortmann; Hanover: Dr G. Voshage; Kempten: Dr Antoni; Koblenz: Dr R. Wickenhoefer; Mainz: Dr C. Duber; Marburg: Prof M. Storck; Munchen: Prof P.C. Maurer; Oldenburg: Dr Ratusinski; Ulm: Dr Pamler.
Greece: Psihico Athens: Prof P. Balas.
Ireland: Dublin: Dr S. Sultan.
Israel: Tel Aviv: Prof B. Morach.
Italy: Perugia: Prof P. Cao; Roma: Dr M. Scoccianti.
Luxembourg: Luxembourg: Dr P. Berg.
Monaco: Monaco: Dr C. Mialhe.
The Netherlands: Alkmaar: Dr H. van Dijk; Amsterdam: Dr R. Balm; Amsterdam: Dr A. Vahl; Amsterdam: Dr W. Wisselink; Arnhem: Dr W.R. de Vries; Delft: Dr J. Koning; Den Haag: Dr J.C.A. de Mol van Otterloo; Den Haag: Dr H. van Overhagen; Dordrecht: Dr R.P. Tutein Nolthenius; Eindhoven: Dr J. Buth; Enschede: Dr R.H. Geelkerken; Groningen: Dr H.R. Dop; Groningen: Dr E. Verhoeven; Leiden: Prof J.H. van Bockel; Maastricht: Dr G.W.H. Schurink; Nieuwegein: Dr F. Moll; Nijmegen: Dr W.B. Barendrecht; Nijmegen: Prof J. van Vliet; Rotterdam: Dr A.C. van der Ham; Rotterdam: Dr van Sambeek; Rotterdam: Dr A. de Smet; Tilburg: Dr J.F. Hamming; Tilburg: Dr S. Kranendonk; Utrecht: Dr J. Blankensteijn; Veldhoven: Dr J.A. Charbon; Zwolle: Dr P. Jörning.
Norway: Oslo: Prof A. Kroeze; Oslo: Dr K. Krohg-Soerensen; Trondheim: Prof H. Myhre.
Poland: Lublin: Prof Michalak.
Spain: Barcelona: Dr M. Cairols; Barcelona: Dr J. Escudero Rodriguez; Barcelona: Dr V. Riambau; Donostia San Sebastian: Dr M. de Blas; Leon: Dr R. Fernandez-Samos Gutierrez; Lugo: Dr J.R. Pulpeiro; Madrid: Dr F. Acin; Madrid: Dr E. Criado; Madrid: Dr Sanchez-Corral; Madrid: Dr D. Tagarro; Madrid: Dr J. Urbano; Pamplona: Dr L. Fernandez Alonso; Valladolid: Dr C. Vaquero-Puerta.
Sweden: Lund: Prof L. Norgren; Orebro: Dr Th. Nordh Larzon; Stockholm: Prof J. Swedenborg.
Switzerland: Bern: Dr J. Schmidli; Zurich: Dr M. Enzler.
United Kingdom: Bournemouth: Dr S. Darke; Bristol: Dr R. Baird; Chester: Dr G. Abbott; Glasgow: Dr R. Edwards; Hull: Dr D. Ettler; Liverpool: Dr P. Harris; London: Dr J. Wolfe; Manchester: Dr R. Asleigh; New Castle-Upon-Tyne: Dr M.G. Wyatt.

DISCUSSION

Dr Frank J. Veith (Bronx, NY). I rise to question your assumption that aneurysms that are untreated, even if they are over 5 cm, have an 11% to 14% rupture rate within whatever period of time you claimed they had it. We have recently made the point that not all large aneurysms, that is, over 5.5 cm, need to be treated either openly or endovascularly, particularly if they are very unfavorable for an endovascular approach.

And we base that on a series of 72 patients presented at the Eastern Vascular Society that were followed from 6 to 72 months without operative treatment. In that group of patients, when the aneurysms enlarged or became symptomatic, 53 of them ultimately underwent a repair with an 11% mortality. In addition, of the entire group, 19 not requiring any repair at all and 53 requiring repair, there was only a 4% mortality from rupture with this conservative treatment. So, we question the premise that all large aneurysms, that is, over 5.5 cm, need to be treated, particularly when their anatomy is unfavorable for endovascular repair and they are at very high risk for open repair.

I would ask you the question: did you look at the unfit group that had endovascular treatment to see if they had a very high incidence of unfavorable factors that might have caused the high mortality that you observed in that group?

Dr Jacob Buth. Thank you very much, Dr Veith. These were good questions, as they bring up the matter of what is the appropriate comparative group with conservative treatment? The rupture rates that we used in this analysis were derived from the literature. The available reports are on the fate of patients during a time that endovascular repair was not an option. The choice was between no treatment or open surgical treatment. It might well be that these comparisons differ from a comparison in the more recent period, where endovascular treatment is the alternative for no treatment. If one would analyze outcome in a group at high risk with unfavorable anatomy not eligible for EAR, rupture rates may differ from previously described series wtih a conservative approach. However, the main risk factors for rupture will remain: size of the aneurysm, age of the patient (high age corresponds with more deaths from nonaneurysmal causes), and perhaps female gender.

One may conclude that new studies comparing risk of rupture and death from comorbidities in EAR and conservatively treated patients need to be performed.

Dr Roy Greenberg (Cleveland, Ohio). I again enjoyed your paper and always value the input of the EUROSTAR Registry because of the numbers that you have. My question relates to the fact that your conclusions include the fact that one of the acute benefits for all endovascular repairs was a fairly low morbidity and mortality. However, the incidence of device-related, more than 30-day complications were high in the endovascular group. Is there a trend over time demonstrating that our ability to treat these patients has improved, or has this been a fairly steady thing where we have seen a stable rate of 5% 30-day mortality?

Dr Buth. Thank you for your question, Dr Greenberg. We have made an adjustment for the year in which the patients were treated. In this analysis, we have left out a cohort of approximately 600 patients that were retrospectively enrolled in the

EUROSTAR Registry. So, we only have taken the prospectively enrolled patients into account. In the multivariate analysis, the year of operation was not a significant variable. Thus, the answer is that the 1st month mortality remains fairly constant over the years of the study in both the unfit and in the normal risk groups. The operative mortality was significantly higher in unfit patients treated early and late during the study.

Dr Alun H. Davies (London, United Kingdom). I would just like to ask you the question about the difference between the ASA classification and your fitness for general anesthesia. Because we all know that when it is a physician decision as to whether somebody is fit for anesthesia, there is a lot of variation. And one of the problems with the EUROSTAR data is that it has very much been left to the individual investigators. So, do you really feel that your claims are justified when there is not a fixed protocol for the actual determination of fit and unfit? Because the other question must be, if you have not found a relationship with respect to the ASA classification, there must be some degree of variability.

Dr Buth Mr Davies, preoperative risk scoring is a subject in which there is little consensus. The ASA score is a commonly used system today. However, this is a broad indicator, although we found a significant correlation with clinical assessment by the participants in the registry. In the literature, clinical estimate of high operative risk was the most commonly used method in articles studying outcome of conservatively treated patients with large-size aneurysms. This was also the case in a number of studies performed in the UK.[2,18]

I am aware of the fact that the POSSUM score is, at the present time, quite popular in England. However, this initially was not a practical preoperative risk score as it required findings made by open surgery to fit into the equation. To my knowledge, there is as yet no validated modification of the POSSUM score for endovascular treatment of aneurysms. Your question, why no uniform validated scoring method was used for assessment of operative risk, is quite justified. The answer is: there was none during the time of our study as far as I know.