Early complications and endoleaks after endovascular abdominal aortic aneurysm repair: Report of a multicenter study

Jacob Buth, MD, PhD, and R.J.F. Laheij, MSc, PhD, on behalf of the EUROSTAR Collaborators, *Eindhoven, The Netherlands, and Liverpool, United Kingdom*

Objective: The aim of this study was the identification of risk factors for adverse events and the assessment of the early success rate in 1554 patients with abdominal aortic aneurysms (AAAs) who underwent treatment with endovascular technique between January 1994 and March 1999. For this purpose, the clinical and procedural data were correlated with observed complications and endoleaks.
Methods: The data were collected from 56 European centers and submitted to a central registry. Patient characteristics, aortoiliac anatomic features, operative technical details, types of devices used, and experience of the teams of physicians were correlated with the occurrence of complications and endoleaks. The technical success rate was assessed according to the Society for Vascular Surgery / International Society for Cardiovascular Surgery, North American Chapter, guidelines. For the assessment of correlations between risk factors and adverse events, a multivariate logistic regression analysis was used.
Results: The operative complications were grouped into three categories: failure to complete the procedure (39 patients, of which 27 underwent a conversion to an open AAA repair; 2.5%); device-related or procedure-related complications (149 patients; 10%); and arterial complications (51 patients; 3%). The most important risk factors for failure to complete the procedure included an aneurysm diameter of 60 mm or more and the need for adjuvant procedures. The factors that predicted device-related and arterial complications were the experience of the team with endovascular AAA treatment and the need for adjuvant procedures. Forty patients (2.6%) died within 30 days after operation. American Society of Anesthesiologists III and IV operative risk classification results predicted higher mortality rates than did American Society of Anesthesiologists operative risk classification I and II results. The patients who underwent operation in 1994, the first year documented in this registry, and those who required adjuvant procedures also had an increased risk of perioperative death. The incidence rate of systemic complications within the first 30 days (279 patients; 18%) was higher in patients aged 75 years or more, in patients with an impaired cardiac status, and in patients considered unfit for an open procedure. An endoleak was detected at the completion of the procedure in 16% of the cases and was still present after 1 month in 9%. The risk factors for primary endoleaks were female gender and age of 75 years and older. The observed technical success rate in this patient series was 72%.
Conclusion: The learning curve of the doctors and the need for adjuvant procedures were independent risk factors of operative device-related and arterial complications. The importance of proper instruction during an institution's initial phase with this treatment is emphasized by these observations. Although the endovascular management of AAAs is less stressful than open surgery, systemic complications were still the most common adverse events during the first postoperative month. These complications were associat-

From the EUROSTAR Data Registry Center, Department of Vascular Surgery, Catharina Hospital, and the EUROSTAR Secretariat, Vascular Surgery Unit, Royal Liverpool University Hospital (see Appendix for list of EUROSTAR Collaborative Centers).
Competition of interst: nil.
Presented at the Forty-seventh Scientific Meeting of the International Society for Cardiovascular Surgery, North American Chapter, Washington, DC, Jun 8–9, 1999.
Reprint requests: Dr J. Buth, Department of Vascular Surgery, Catharina Hospital, PO Box 1350, 5602 ZA Eindhoven, The Netherlands.

0741-5214 / 2000 / $12.00 + 0 24 / 6 / 103605

ed with several patient-related factors, including advanced age, impaired cardiac status, and poor general medical condition. These observations may be a guide for improved patient selection for endovascular AAA repair. (J Vasc Surg 2000;31:134-46.)

The feasibility of endovascular repair of abdominal aortic aneurysms (AAAs) has been confirmed in many studies. However, the reported incidence rate of perioperative complications varies from 20% to 75%.[1-8] This is considerable and warrants further investigation. In the earliest series, some complications were attributable to inadequacies in the design and construction of prototype devices. With the evolution of improved endografts and delivery systems,[9-11] patient-related and doctor-related risk factors for adverse events become relatively more important and it is essential that these be identified if results are to be improved further.

A number of conditions may be expected to influence outcomes adversely (eg, the learning curve of the operating team). Risk factors for adverse events during the procedure might include need for adjunctive endovascular or surgical procedures. Potential patient-related factors that influence outcome include age, previous symptoms of myocardial ischemia, and anesthesia risk status. In addition, there are factors that are related to the anatomy of the aortoiliac segment.

This report documents the early results from a multicenter registry of endovascular procedures for aneurysm repair that was organized by the EUROSTAR (EUROpean collaborators on Stent-graft Techniques for Abdominal aortic aneurysm Repair) Collaborators Group. The purpose of the registry was the assessment of the relative importance of these factors for different categories of adverse outcome. To allow the comparison of our results with those of other studies, technical success was assessed according to previously defined guidelines for standardized reporting.[12]

MATERIALS AND METHODS

Study population and organization of the registry. In 1996, the EUROSTAR Registry was established for the purpose of the collation and analysis of data from patients who undergo endovascular treatment for AAA. A study protocol and case record forms were designed by an international steering committee.[13] Regular collaborators' meetings were organized to coincide with the annual congresses of the European Society for Vascular Surgery. The secretariat of the EUROSTAR organization is located at the Royal Liverpool and University Hospital in Liverpool, United Kingdom, and the Data Registry Center at the Catharina Hospital in Eindhoven, The Netherlands. Fifty-six centers in 15 European countries have contributed data regularly to the registry.

Data on patients who underwent treatment before September 1996 were collected and entered onto the database retrospectively. This cohort of 362 patients was identified separately as the retrospective part of the registry. After September 1996, the pretreatment registration of the patient became compulsory. These patients (1192 until the closure of the study file) all constituted the prospective part of the registry, which accounts for 77% of the present data. All the commercially available devices with a CE mark (European Union regulatory approval) have been included. According to the study protocol, the following information was recorded: (1) preoperative patient and anatomic characteristics, (2) operative details, (3) types of devices used, and (4) outcome of the angiogram at the completion of the procedure. The data collected at follow-up examination included clinical and imaging studies, with contrast-enhanced computed tomography (CT) as the primary index examination. The data were entered onto a computerized database (written in Microsoft Access, version 2.0, Seattle, Wash) by a research secretary, and the data analysis was undertaken by a data manager (R.J.F.L.), who is a health scientist. The data manager is in regular communication with the participating centers to encourage maximum compliance with data returns. He is also responsible for verifying the accuracy of the information submitted. The activity of the Data Registry Center is overseen by a consultant vascular surgeon, who reports regularly to the steering committee. To date, financial constraints have precluded site visits by registry center staff and the establishment of a regular core laboratory for standardized analysis of radiographic and CT images. Although the absence of outside monitoring is undesirable in that it may lead to variable standards of reporting, it was considered by the steering committee that know-how in the evaluation of CT scanning and other imaging studies is widely available in institutions involved in the EUROSTAR project. The financial support for this project was initially from a Dutch government and a hospital grant. However, most of the support has been provided by fees charged for contracted reports for a number of companies involved in stent-graft manufacturing (Boston Scientific, Natick, Mass; Medtronic, Sunnyvale, Calif; and World Medical, Sunrise, Fla).

Table I. Operative complications (during stent graft procedures) in 1554 patients

	No. of patients (%)	*No. of complications (%)*
Failure to complete procedure	39 (2.5)	
Conversion to open procedure		27 (2)
Extra-anatomic bypass grafting		9 (0.6)
Other (abandoning the procedure)		3 (0.2)
Device-related complications	149 (10)	
Inability to advance delivery system		32 (2)
Inability to deploy device		26 (2)
Device / device limb occlusion, stenosis, or kinking		16 (1)
Device migration		25 (2)
Balloon burst or other problem		24 (2)
Delivery sheath tear, device stuck in sheath		18 (1)
Other		28 (2)
Arterial complications	51 (3)	
Arterial damage, perforation, rupture, dissection		23 (1.5)
Thrombus, obstruction, stenosis		12 (0.7)
Emboli		5 (0.3)
Occlusion of renal artery		2 (0.1)
Other		10 (0.6)

The inclusion criteria for this study, as defined in the registry's protocol, comprised an elective AAA operation and an anatomic configuration suitable for the implantation of a stented tube or a bifurcated prosthesis. This configuration included an infrarenal neck with a minimal length of 15 mm and iliac arteries of adequate dimensions to admit the delivery system. The exclusion criteria involved juxta or suprarenal extension of the aneurysm, strong indications for combined reconstruction of other intra-abdominal vessels, patients younger than 21 years, connective tissue diseases, and active infection. The baseline, demographic information collected included the medical history, the preoperative vascular operative risk factors according to the Society for Vascular Surgery / International Society for Cardiovascular Surgery, North American Chapter (SVS / ISCVS) system,[14] brachial and ankle pressures, and anatomic details of the aortoiliac segments. For the assessment of the abdominal aorta and the iliac arteries, the patients underwent contrast-enhanced CT scanning and usually also angiography. The operative data included details about the types of devices used, the need for adjuvant procedures, device-related or procedure-related problems, arterial complications, and the findings on completion angiography. In a small number of patients, one or more items of data were either missing or uninterpretable. Nevertheless, the available data were sufficient to address most questions in this study. Therefore, it was elected to use all the available case record forms for this analysis.

Treatment. The operative details were recorded according to the fixed format of the case record form. The surgeons and radiologists were free to use any device available for the endovascular exclusion of AAAs. Included in this series were straight tube, modular, and unipiece bifurcated and aortouniiliac devices, either produced by commercial firms with CE mark or fabricated in the institution itself. Most participating centers were assisted during their first series of cases by a vascular surgeon or radiologist with extensive experience with the type of device used. Most commonly, the procedures were performed in the operating room with mobile fluoroscopy equipment. Completion angiograms were performed for the assessment of the immediate result of the procedure. In the great majority of centers, vascular surgeons and radiologists worked together in teams. There were differences between centers with regard to the use of systemic or regional heparinization and the application of coil embolization of aortic side branches before endograft implantation.

Postoperative examination. The period of interest for this study was limited to the first postoperative month. Information was recorded at the end of the procedure, before discharge, and at 1 month. The results of the treatment were assessed with clinical examination and with radiographic imaging of the aneurysm and the endograft. All the clinical complications were recorded together with the presence and location of endoleaks. The assessment at the end of the operation was performed with completion angiography. CT examination with contrast enhancement of the abdominal blood vessels was carried out before discharge or at 1 month after discharge. In a number of cases, CT imaging was carried out at both of these intervals. Contrast angiography, duplex scanning, and magnetic resonance angiography examinations were used at the discretion of the responsible physicians. In case more than one examination was used, the ranking order of the methods for analysis was: (1) CT, (2) angiography, (3) magnetic resonance angiography, and (4) duplex scanning. The highest ranking method used was the recorded examination.

Outcome events. The outcome events that were registered in the case record forms were operative complications (events occurring during the procedure) and postoperative complications (events occurring during admission or within the first postoperative month). The operative complications were

subdivided into three categories: (1) failure to complete the procedure, (2) device-related, and (3) arterial complications. The different adverse events within these categories are specified in Table I. The postoperative complications were categorized into: (1) systemic, (2) procedure-related and device-related, and (3) access site and lower limb complications. The details of these outcome events are presented in Table II. The 30-day mortality rate was recorded as a separate outcome event.

Endoleaks were analyzed at two points of time—at the end of the procedure as documented with completion angiography and during the first postoperative month. If a patient underwent two examinations within the first 30 days, one before discharge from the hospital and the other at the scheduled 1-month visit, the findings of the second CT scan were recorded. Endoleaks are categorized into four types as described by White et al.[15] Type I endoleaks involve proximal and distal attachment site endoleaks, and type II represent reperfusion via lumbar or inferior mesenteric arteries. Type III are graft-site endoleaks, including leakage at the connection of the separate iliac limb to the body of the device and fabric holes. Type IV include blushing via the pores of the device fabric. The overall technical success rate was calculated with the guidelines of the advisory committee of the SVS / ISCVS.[12] The key elements included in technical success are: successful access, successful deployment (with persisting perigraft endoleakage other than transgraft extravasation considered failure), and patent endoluminal graft.

Table II. Postoperative complications (during admission and in the first postoperative month)

	No. of patients (%)	*No. of complications (%)*
Systemic complications	279 (18)	
Cardiac		71 (5)
Pulmonary		50 (3)
Renal		54 (3)
Cerebral		24 (1.5)
Hepatobiliary		5 (0.3)
Gastrointestinal		34 (2)
Sepsis, prolonged fever		52 (3)
Other		71 (5)
Laparotomy for systemic complications		8 (0.5)
Procedure-related and device-related complications	76 (5)	
Graft migration		7 (0.5)
Graft stenosis		6 (0.4)
Graft (limb) thrombosis		24 (1.5)
Bleeding perianeurysmal (rupture or perforation)		—
Secondary interventions transfemoral		25 (1.6)
Secondary interventions transabdominal		14 (0.9)
Secondary interventions extra-anatomic		13 (0.8)
Access site and lower limb complications	143 (9)	
Bleeding, hematoma, false aneurysm		86 (5)
Arterial thrombosis		6 (0.4)
Peripheral emboli		10 (0.6)
Intermittent claudication		5 (0.3)
Limb loss		2 (0.1)
Femoral nerve neuralgia		6 (0.4)
Wound infection, lymphocele, lymphatic fistula		20 (1)
Other		9 (0.6)

Data analysis. A set of 16 variables was correlated with the outcome events described previously. These variables were: patient factors (gender, age, American Society of Anesthesiologists [ASA] classification,[16] consideration as unfit for open surgery, ankle and arm blood pressure index, and cardiac status and smoking—both scored according to the SVS / ISCVS risk scoring system[14]), anatomic dimensions (infrarenal neck diameter, maximum aneurysm diameter, severe angulation of the iliac arteries), procedural aspects (need for adjuvant procedures, duration of the procedure, which was only considered for correlation if it was likely not to be a result of the outcome event), physician-related factors (level of experience of the team), study period (retrospective versus prospective part of the study, calendar year 1994 to 1999), and type of device (company label). Experience with the procedures in each institution was calculated on the basis of the sequence and number of patients enrolled in the EUROSTAR Registry. Experience was ranked into three grades: first to 10th operation, 11th to 30th operation, and more than 30 operations performed. Discrete variables are presented in absolute numbers or percentages of each subgroup. Continuous variables are expressed as median values and interquartile ranges (IQRs). These variables were first correlated with univariate analysis with the outcome events by means of χ^2 test. The Mann-Whitney test was used for continuous parameters. Significantly associated variables were subsequently selected stepwise (backward selection) for a multivariate logistic regression model, which was tested for stability of the coefficients and their standard errors.[17] The results of the different variable-to-outcome event correlations are expressed as odds ratio (OR) with corresponding 95% confidence interval (CI). Statistical significance was reached if the *P* value was less than .05. All the analyses were performed with SAS statistical software (version 6.12, SAS Institute, Inc, Cary, NC).

Table III. Risk factors in 1554 patients who underwent stent graft treatment for abdominal aortic aneurysm

	SVS/ISCVS risk score			
	0	*1*	*2*	*3*
Associated diseases	Percent of patients			
Diabetes mellitus	90	8	2	0.2
Smoking	43	30	18	9
Hypertension	43	38	16	3
Hyperlipidemia	60	26	5	9
Cardiac status	39	30	26	5
Carotid disease	84	11	3	2
Renal status	83	14	2	1
Pulmonary status	64	21	12	3
ASA physical status classification	No. of patients (%)*			
ASA I	128 (8)			
ASA II	594 (39)			
ASA III	677 (45)			
ASA IV	108 (7)			

SVS/ISCVS, Society of Vascular Surgery / International Society of Cardiovascular Surgery, North American Chapter; *ASA*, American Society of Anesthesiologists classification.
Overall reporting rate of the different risk scores was 95%.
*The ASA classification was not retrieved in 47 patients.

Table IV. Adjuvant procedures in 1554 patients who underwent stent graft treatment for abdominal aortic aneurysm (n = 444)

	No. of procedures
Percutaneous transluminal angioplasty (or stent)	250
Endarterectomy, arterial reconstruction, or repair of CFA / iliac artery damage	57
Embolization of side branches	66
Femoropopliteal bypass graft	6
Decoiling of iliac arteries	11
Iliofemoral bypass graft for access	8
Banding of iliac arteries	3
Crossover femorofemoral bypass graft	26
Ligation of common iliac arteries	5
Intentional crossing of renal arteries by uncovered stent	23
Hypogastric arterial bypass graft or reimplantation	11
Ligation of hypogastric artery	4
Other (arterial procedures)	35
Other nonarterial procedures	3

CFA, Common femoral artery.

RESULTS

Patients, devices, and procedures. Between January 1994 and March 1999, 1554 patients from 56 centers were included in the registry (from three to 287 patients per center). Of these patients, 1421 were male and 133 were female. In this study group, 362 patients were included in the retrospective part of the registry and 1192 in the prospective part. At the time of the closing of the patient file for this analysis, 43 additional patients who were included in the prospective part had been registered more than 3 months earlier, but operative data had not yet been received. These patients could not be considered for this study. The mean age of the patients was 70 years (range, 37 to 90 years). The median size of the aneurysms was 56 mm (range, 28 to 150 mm). The baseline medical characteristics and the risk factors were fairly typical for patients with AAA who undergo treatment, except for the fact that 7% of the study population was classified as ASA IV (Table III).

Of the patients, 1387 underwent placement with a modular bifurcation device, 42 with a one-piece bifurcation device, 98 with an aorto-aortic straight tube endograft, and 27 with an aortouniiliac device combined with a femorofemoral bypass graft. The commercial devices used were: Stentor (Mintec, Freeport, Bahamas; 330 patients), Vanguard (Boston Scientific; 741 patients), EVT (Endovascular Technologies, Menlo Park, Calif; 52 patients), Talent (World Medical; 160 patients), AneuRx (Medtronic; 215 patients), and other labels or physician-constructed devices (56 patients). Straight tube devices were used in the Stentor group in 33 patients (10%), in the Vanguard group in 30 patients (4%), in the EVT group in 12 patients (23%), in the Talent group in 16 patients (10%), in the AneuRx group in two patients (1%), and in the other devices group in five patients (9%). In 444 patients, 508 adjuvant procedures were performed (Table IV).

Complications during the procedure. One hundred ninety-one patients (12%) had operative complications: 146 had complications in one category, 42 had complications in two categories, and three had complications in three categories (Table I). Failure to complete the endovascular procedure was reported in 2.5%. Conversion to an open procedure was necessitated by device migration, inability to cannulate the short limb, aortic rupture, arterial dissection, and perforation. Primary extra-anatomic bypass grafting was undertaken for iliac artery or device limb occlusion. The procedure was abandoned on three occasions when the device fell back into the sack or because it impacted during deployment (Table I). In the multivariate analysis results, the aneurysm diameter was the only anatomic variable that had an adverse independent correlation with outcome. Age of 75 years or older, the need for adjuvant procedures, and two of the device types used had a negative influence on this outcome event (Table V). There were 9.6% (5 of 52) failures to complete the procedure in patients with EVT and 7.5% (12 of 160) with Talent as opposed to

Table V. Results of multivariate analysis relating risk factors to the probability of categorized complications observed during procedures

Variable			*P value*	*Odds ratio*	*95% Confidence interval*
Failure to complete the procedure	Patient age (years)	≤65	—	1	1
		65 - 75	.44	1.48	0.54 - 4.06
		≥75	.02	3.28	1.25 - 8.61
	Aneurysm diameter (mm)	<60	—	1	1
		≥60	.005	2.72	1.36 - 5.45
	Adjuvant procedure	No	—	1	1
		Yes	.0003	4.48	2.24 - 8.98
	Type of device	Vanguard	—	1	1
		Stentor	.8	0.87	0.28 - 2.75
		AneuRx	.5	0.64	0.18 - 2.32
		Talent	.0006	4.40	1.90 - 10.23
		EVT	.0003	8.21	2.64 - 25.55
		Other devices	.5	1.65	0.35 - 7.84
Device-related complications	Smoking risk score	0	—	1	1
		1	.75	1.07	0.71 - 1.60
		2 & 3	.01	0.46	0.25 - 0.83
	Adjuvant procedure	No	—	1	1
		Yes	.001	1.79	1.25 - 2.55
	Experience of team (procedures)	≤10	—	1	1
		10 - 30	.006	1.80	1.18 - 2.74
		≥30	.4	0.84	0.53 - 1.31
Arterial complications	Adjuvant procedure	No	—	1	1
		Yes	.0001	3.83	2.10 - 7.01
	Experience of team (procedures)	≤10	—	1	1
		10 - 30	.5	0.82	0.42 - 1.58
		≥30	.006	0.34	0.16 - 0.74

The odds ratio is relative to the variable's reference class, which is indicated by odds ratio = 1.
Smoking risk score is indicated according to the Society of Vascular Surgery / International Society of Cardiovascular Surgery, North American Chapter Ad Hoc Committee.[14]

1.6% (22 of 1342) with all other devices combined. For the assessment of whether different proportions of straight tube or aortouniiliac graft device diameters were responsible for the difference in outcomes, graft configuration was entered as an additional variable into the logistic regression model. The expanded model failed to show device configuration as a significant factor in procedural failure, and the other correlations were similar to those in the original model.

In device-related complications, which occurred in 10% of the patients, the following variables correlated significantly with outcome: current smoking, the need for adjuvant procedures, and experience of the team (Table V). Institutional experience was associated with an increase in complications (incidence rate, 14%) between the 10th and the 30th procedure as compared with the initial 10 operations (incidence rate, 7%). After 30 patients underwent treatment, the incidence rate of complications (7%) was similar to that of the initial patient group.

Arterial complications were observed in 3% of the patients. In the multivariate regression model results, the experience of the operating team and the need for adjuvant procedures correlated independently with the occurrence of arterial complications. The frequency of arterial complications decreased significantly with growing experience, the incidence rate being lowest after 30 operations (Table V). ASA class IV and aneurysmal diameter also had an adverse effect on the rate of arterial complications, although this did not reach statistical significance.

Mortality and other complications within the first postoperative month. There were 40 deaths within the first postoperative month, for a perioperative mortality rate of 2.6%. The causes of death included cardiac failure (the most frequent cause of death with 12 patients [30%]), multiorgan failure / sepsis, adult respiratory distress syndrome, aortic perforation, pulmonary failure, and stroke. Six of the deaths (15% of the total deaths) occurred in patients who had undergone conversion to open repair. The mortality rate in the patients in whom conversion was necessary was 22% (6 of 27). In the multivariate model, ASA classes 3 and 4 ($P = .04$ and $P = .0001$; OR, 2.3 and 6.8; 95% CI, 1.0 to 5.2 and 2.7 to 17.4, respectively), the need for adjuvant procedures ($P = .008$; OR, 2.49; 95% CI, 1.3 to 4.9), and the calendar year 1994 ($P = .001$; OR, 8,8; 95% CI, 2.5 to 32.5) were found to

Table VI. Results of multivariate analysis relating risk factors to the probability of categorized complication within the first postoperative month

Variable			*P value*	*Odds ratio*	*95% Confidence interval*
Systemic complications	Age (years)	≤65	—	1	1
		65 - 75	.03	1.56	1.28 -1.91
		≥75	.0008	2.00	1.63 - 2.47
	Cardiac status	0	—	1	1
		1	.3	1.23	1.01 - 1.49
		2 & 3	.01	1.60	1.32 - 1.92
	Unfit for open surgery	No	—	1	1
		Yes	.0005	2.01	1.65 - 2.46
	Adjuvant procedure	No	—	1	1
		Yes	.005	1.57	1.34 - 1.85
	Duration of procedure*		.0001	—	—
Procedure-related and device-related complications	Year of procedure	1998 - 1999	—	1	1
		1997	.8	1.07	0.59 - 1.93
		1996	.003	2.40	1.35 - 4.27
		1995	.277	0.51	0.15 - 1.72
		1994	.8	0.77	0.10 - 5.89
Access site and lower limb complications	Adjuvant procedures	No	—	1	1
		Yes	.0001	3.54	1.96 - 6.39
	Experience of team (procedures)	≤10	—	1	1
		10 - 30	.8	0.92	0.48 - 1.77
		≥30	.03	0.42	0.20 - 0.91

The odds ratio is relative to the variable's reference class, which is indicated by odds ratio = 1.
*Continuous parameter.

Table VII. Endoleaks at completion angiogram and within the first month after surgery

	At completion angiography	*Within first month after surgery*
Total no. of patients	1554	1471*
Patients with first observation of endoleak	250	86
Patients with a persistent endoleak	—	63
Patients with resolved endoleak	—	(186)
Proportion of patients with endoleak	250 (16%)	149 (10%)

*Of patients who underwent initial treatment, 83 had end of their follow-up period within the first month because of death (34 patients), early conversion (21 patients), death and early conversion (six patients), and missing imaging study (22 patients).

have an independent correlation with death within 30 days. In patients with ASA class IV, there were 11 deaths (10.2%), as opposed to 29 deaths (2.1%) for the patients with a lower ASA classification (P = .001). There was a progressive increase in mortality risk with ascending ASA grading. For patients in ASA I, there were no deaths, and for those in ASA II and III, the mortality rates were 1.5% and 2.9%, respectively. The mortality rate was higher during the calendar year 1994, when the first cohort of 31 patients included in this registry underwent treatment (mortality rate, 12.9% [4 of 31 patients]; vs 2.4% [36 of 1481 patients] in the combined other years; P = .001).

The postoperative complications recorded up to the end of the first month were separated into the three categories indicated in Table II. Of the patients, 377 (24%) had complications recorded: 267 had complications in one category, 99 in two categories, and 11 in three categories. The factors that were associated with systemic complications comprised age more than 65 years, a cardiac risk score of 2 or 3, a consideration of unfit for open surgical AAA repair, any adjuvant procedure being performed, and duration of the operation (Table VI). The duration of the procedure was 160 minutes (IQR, 120 to 220 minutes) in patients with systemic complications and 130 minutes (IQR, 100 to 180 minutes) without complications. Two preoperative variables had a particularly strong effect with ORs of 2 or greater—age and consideration of unfit for open surgery. It appeared in this series that patients of 75 years or older who were considered unfit for an open procedure had a 42% risk of systemic complications, as opposed to only 11% risk in fit patients of 65 years or younger.

Procedure-related and device-related complications included 14 secondary transabdominal interventions (Table II). These operations involved conversion to conventional repair in eight patients, control of bleeding in two patients, arterial recon-

struction in three patients, and a laparotomy for a septic complication in one patient. In this category of complications, the calendar year in which the initial procedure was performed was the only factor that had a positive correlation. This correlation involved a higher risk for patients who underwent operation in 1996 (Table VI).

Access site and lower limb complications were more often observed if adjuvant procedures had been required during the initial operation. Experience of the operating team also had an influence on the risk of complications, with a decrease after the performance of 30 procedures.

Endoleaks. At completion angiography, 250 patients (16%) had a total of 260 endoleaks. One hundred and fourteen (43%) were type I endoleaks, 91 (35%) were type II, 19 (7%) were type III, and 22 (8%) were type IV. In 14 patients (5%), the site of the endoleak was uncertain. The univariate and multivariate analysis results indicated that female gender (P = .02; OR, 1.7; 95% CI, 1.1 to 2.7) and a patient's age of 75 years or older (P = .0009; OR, 1.9; 95% CI, 1.3 to 2.9) were significant risk factors for endoleak. It is of note that the current smokers had a lower incidence rate of endoleak than did the non-smokers, 6.11% versus 10.9%, respectively (P = .02; OR; 0.45; 95% CI, 0.2 to 0.9).

The fate of the endoleaks for the period up to 1 month after operation was studied. The proportion of patients with endoleaks that had resolved at 1 month was 74% (186 of 250), and 25% (63 of 250) had persisting endoleaks (Table VII). On the other hand, during the same period, 86 patients had a new endoleak develop, as shown with CT examination results. With the inclusion of these patients, a total of 149 patients exhibited evidence of endoleak at 1 month. This equates to 10% of the whole cohort of patients. Persisting endoleaks were less frequently observed with type II endoleaks than with other types of endoleaks (15% [13 of 85] vs 30% [50 of 165]; P = .02).

Technical success rates. Death, failure to complete the procedure (including conversions), device (limb) occlusions, secondary transabdominal interventions, extra-anatomic bypass grafting, aneurysm perforation, or endoleaks (excluding type IV) occurred in 437 patients, which resulted in a 72% technical success rate. All the patients were counted in the technical failure category at their first event. Twenty-two patients underwent only a predischarge examination but did not experience any events during their hospital stay. These patients were included in the technical success group.

DISCUSSION

The EUROSTAR Registry was established to gather large amounts of data as quickly as possible for the assessment of the efficacy of treatment of AAAs with endovascular techniques. One advantage of the pooling of data from a large number of departments is that it permits the extensive analysis of subgroups. An additional advantage of a multicenter registry is that the tendency for the selective reporting of good outcomes may be less. It has been observed previously that multi-institutional AAA studies report higher complication rates than do publications on the experiences of single institutions.[18]

A high incidence of early adverse events has a relatively greater negative effect on the well being of the patients and health care resources than do longer term complications. This is because most patients are exposed to the possibility of early complications, but only those who live long enough are subjected to later risks. This very detailed study of operative and early complications associated with endovascular aneurysm repair is, therefore, of considerable relevance to clinical practice.

Operative complications. Technical mishaps that precluded the completion of the procedure were caused by arterial injury and inability to gain access or to deploy the device at the planned site. Procedural failure resulted in conversion to open repair in 27 patients (1.7%). This rate is in the same range as the 2% reported by Stelter et al[7] and slightly lower than the 3% and 4% reported recently by other investigators.[19,20] In the published series that included the early experience with endovascular AAA treatment, the conversion rate was considerably higher, ranging from 7% to 18%.[4,21,22] The low conversion rate in this registry population may reflect the large proportion of patients who underwent treatment in more recent years and the benefits of effective supervision and instruction during the learning curve by an increasing number of available experienced physicians. Our observation, that conversion is associated with a perioperative mortality rate as high as 22%, is in agreement with the 11% to 22% reported in previous studies.[20,23,24] Technical complications that precluded the completion of the procedure were associated with advanced age, large aneurysm diameter, and the need for adjuvant procedures, all factors that may reflect the complex anatomy of the aneurysms. EVT and Talent prostheses were associated with a higher risk of procedural complications than were other makes of device. It should be emphasized that some aspects that influenced device performance were not included in this analysis. For

example, a higher proportion of straight tube grafts in the EVT group might have been responsible for the relatively high incidence of problems encountered. However, an additional multivariate comparison failed to showed device configuration to be a significant predictor of procedural failure. May et al[25] also found that straight tube grafts did not correlate with a greater risk of primary conversions, although they were associated with more endoleaks and secondary conversions. It should be noted that many EVT devices in this registry were implanted between 1994 and 1996 (ie, they constituted a relatively high proportion of the early experience). The latest modification of the EVT devices makes them easier to use than the earlier models, and low complication rates have recently been reported by other investigators.[26] It is known that the Talent endografts are used frequently in larger sizes that are not offered by other manufacturers. This indicates that they are used more often in patients with wide and short infrarenal necks. With the availability of aortic extension cuffs, the problems of migration during the procedure can now be resolved. Thus, there are factors that can be identified that relate to the use of both the EVT and the Talent devices that may explain the relatively high rate of associated complications. It would be unreasonable to conclude that they are any less efficient than are any other currently available devices on the basis of these data alone.

Device-related or procedure-related complications and arterial complications during the operation were most clearly related to the need for adjuvant interventions and to the experience of the physicians. The former is likely to be a reflection of adverse anatomy. At first sight, it seems curious that the second phase of the learning period (from the 10th to the 30th procedure) was associated with the greatest risk of complications rather than the first phase. Perhaps during the first series of procedures, proctoring helped to prevent serious problems, but during the second phase, the team experienced its actual learning curve. Alternatively or additionally, increased confidence may lead to widening indications and the inclusion of less ideal patients. In contrast, arterial complications occurred significantly more often in the initial 30 patients of an institution's experience. It may well be that during this period more attention was paid to the endovascular procedure than to the details regarding arterial access.

First month mortality and morbidity. The overall mortality rate of 2.6% was approximately in the middle of the range of the 0 to 6.6% rate that was reported in recent studies on endovascular AAA repair.[7,10,11] The few studies that compared patients who underwent treatment with endografts with a contemporary group of controls who underwent treatment with open surgery showed no difference in mortality rate.[27-29] However, these series were too small for a meaningful comparison of the incidence of death between the two treatments. The observed mortality rate in this registry compares favorably with the rates that were obtained from the pooled data of multicenter studies of the results of open AAA repair (8.2% and 7.4% in prospective and retrospective studies, respectively), and they are comparable with the outcome in the hospital-based studies (3.8%).[18] Although the patient numbers in this study are large, a different distribution of risk factors as compared with the risk factors of other series cannot be ruled out. The issue of selection bias can only be resolved in a large-scale randomized study.

The positive correlation of ASA classifications III and IV as indicators of the general medical status with the increased risk of mortality is not surprising. However, there was no correlation between specific cardiac risk factors and death. This is in contrast to the usual findings in studies on open AAA surgery.[30-32] The proportion of cardiac deaths as opposed to deaths from other causes (12 of 40; 30%) in this patient series was low in comparison with the 60% normally associated with conventional operations.[30,33,34]

Systemic complications in this series occurred in 18% of the cases, which is comparable with the 11% to 20% reported in other series of patients who underwent treatment with endovascular technique.[5,28,35] The prevalence of systemic complications as found in this study has been compared with that reported in prospective multicenter studies of open AAA repair.[18] Most types of complication occurred less frequently in patients who underwent treatment with endovascular repair. For example, the rate of cardiac complications was 5% versus 11%, the rate of pulmonary complications was 3% versus 5.3%, and the rate of renal complications was 3% versus 7%. In the case of endovascular repair, the risk factors for all systemic complications together were similar to those for cardiac events in studies on open aortic surgery. These factors were an impaired preoperative cardiac risk score and poor general medical condition. Additional factors, such as prolonged duration of the operation and advanced age, were also found to apply in studies on open aneurysm surgery.[32]

The 9% incidence rate of complications related to access site and lower limb was lower than those rates in earlier series, which approximate to 20%,[11,29] but

similar to the 5% to 8% reported in more recent series.[7,10,27] Chuter et al[4] experienced a 40% incidence rate of local and arterial complications in the first 20 patients as opposed to 0% in the second 20 patients in their study group. Increasing experience with endovascular AAA treatment had a beneficial effect on this type of complication in this series also. The approach to training in endovascular AAA treatment has recently attracted considerable interest. Sophisticated flow models for practicing are now available,[36] and the interest in hands-on training sessions is considerable. It is likely that the increased access to well-structured training facilities will make the learning curve shorter and smoother.

Endoleaks. The presence of endoleaks may be associated with the subsequent expansion of the aneurysm and possible rupture.[37-39] The 16% incidence rate of early endoleaks that was found in this registry is in the middle of the reported range, which varies from 12% to 44%.[1,7,10,11,21] Two factors independently favored an increased incidence of endoleak: advanced age and female gender. Increasing age may be associated with more complex anatomy, although none of the anatomic variables investigated were found to be predictive of endoleakage. The higher incidence of endoleaks associated with female gender may be related to as yet undetermined factors, intrinsic to the aneurysm, to the vessel wall, or to the blood. In addition, the coagulation profile, on which we have no information in this study, may be a significant factor, especially with respect to type II endoleaks.[40] It was surprising to find that current smokers had a smaller risk of endoleaks than did nonsmokers. The mechanical properties of the vessel wall or the patterns of distribution of the thrombus within the aneurysm sac may have some influence, but the reason for this association is unknown.[41]

Most (71%) of the endoleaks that we observed at the completion angiogram had disappeared within the first month. Other investigators have found a comparable decrease.[9,27] A useful classification of endoleaks has been proposed by White et al.[15] These authors distinguished four types of endoleaks. We observed a lower incidence of persisting endoleaks in type II endoleaks than in other types of endoleaks. This finding is different from the findings of Matsumura and Moore,[42] perhaps because of the greater numbers of patients in this series. There is concern that thrombus sealing of an endoleak may still be able to transmit pressure to the aneurysm sac. Therefore, patients with self-sealed endoleaks require continued careful follow-up examination. Further expansion of the aneurysm is a clear indication that it is still pressurized.

Technical success. The overall technical success rate, as defined by the Ad Hoc Committee of the SVS / ISCVS,[12] was 72%, which is in the same range as the 77% obtained in a recently reported controlled study.[27] This outcome measure includes successful access and deployment in addition to absence of endoleak and patency of the graft. For technical success, the result must be maintained for a minimum period of 1 month without death or the need for open aortic reconstruction. The assessment of outcome must be made on an intent-to-treat basis. The EUROSTAR Registry adheres to these principles. The pretreatment registration of the intended procedure is mandatory. Nevertheless, the operative data of 43 enrolled patients (2.7%) were not retrieved and, in a worst case scenario, with the assumption of an adverse event in all these patients, the technical success rate would have been 69%. Of 22 additional patients, the 1-month results were not known. However, an uneventful procedure and admission period was recorded in all of these patients and it has been assumed that no problems occurred within the first month.

Technical success according to the previous definition was not used in most previous institutional multicenter reports, and this precludes comparison with this series. The use of this outcome parameter in future reports is recommended because it represents the 1-month procedural results on the basis of a combination of events that all can be assessed objectively. Nevertheless, it provides a rather technique-oriented parameter, and the chance of success as viewed by the patient may be rather different. After all, a technically failed procedure, followed by the successful management of endoleak or graft limb occlusion, still renders endovascular repair preferable to open surgery.[43]

CONCLUSION

Despite the minimal invasive nature of endovascular aneurysm repair, a variety of complications do occur with considerable frequency. The probability of technical complications that preclude the completion of the procedure is increased in large aneurysms and by the need for adjuvant procedures. The patient's age and cardiac and general medical status have an important influence on the risk of systemic complications. The experience of the operating team is an important factor influencing the risk of device-related or procedure-related adverse events. These findings underline the importance of adequate training and may help to guide the selection of patients and devices for endovascular AAA repair in the future.

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Submitted Jun 8, 1999; accepted Sep 16, 1999.

DISCUSSION

Dr Juan C. Parodi (Buenos Aires, Argentina). After briefly reviewing the manuscript, I believe that Dr Buth and his colleagues should be commended for obtaining reasonable conclusions from a complex database.

The aim of this study was to identify the risk factors for adverse events and to assess the early success rate in 1554 patients with abdominal aortic aneurysms who underwent treatment with endovascular technique. The EUROSTAR Registry database has multiple variables, most of them related to each other. The database, as it is, has an obvious potential value representing the reality of the clinical practice. I am not sure that the conclusions that can be raised on the basis of this database are very valuable.

In terms of the use of this data for analysis, let us briefly analyze the following weaknesses of the EUROSTAR Registry: (1) the lack of independent audit, (2) the mixture of retrospective and prospective data, (3) the inclusion of 56 centers with quite different experiences in the field and different technical capabilities, (4) the inclusion of patients of quite different categories in relation with risk factors, (5) the inclusion of homemade and commercially available devices, (6) the inclusion of five different commercially available devices, and (7) the use of different ways of evaluation with different imaging methods.

In any event, the results were acceptable. The conversion rate was 1.7%, the mortality rate was 2.6%, the systemic complications were 18%, and the device-related and procedure-related complications were 10%. The authors reported endoleaks in 16% of the patients, with 43% type I, and in 9% after 1 month. We believe that the subsequent evolution of the patient with type I endoleak, even sealed, represents a failure of the procedure. This assumption invalidates the evaluation of success in this series.

In conclusion, I believe that we can take these data as a general idea of what the problems are and accept the limitations of the analysis.

I have only one question, which is, what controls do you use in terms of imaging quality?

Thank you.

Dr Jacob Buth. Thank you very much, Dr Parodi. Thank you especially for your willingness to review this on such short notice.

We think that the EUROSTAR Registry does reflect the reality of the practice of endovascular AAA treatment in several countries. We consider that most of the arguments that you put forward just reflect the reality that one likes to see. Our study shows that there are considerable differences in experience between institutions and that these differences matter for the procedural outcome. Also, there are differences in risk factors of patients who undergo treatment and there are differences in imaging methods between one or another hospital. This also belongs to the real practice, and we have to take these factors into account. In our opinion, knowledge of healthcare is more served by studying the actual practice patterns than the outcome of a single center of excellence.

With regard to a number of other flaws that you indicated, it is correct that there was no audit of patient data. It would simply be beyond practical possibilities to have available the large number of monitors required for a study of this size. Although the study includes a number of patient groups that have been monitored, in essence this is a non-audited study. We think that this may be compensated by the large study group and by good feedback between the individual participants and the data registry center.

In this study, we have not discriminated between the group of 360 patients who were enrolled retrospectively and the 1200 patients from whom the data had been collected prospectively. In an earlier study, which was reported in a poster at the Society for Vascular Surgery / International Society for Cardiovascular Surgery, North American Chapter, meeting, no significant differences with regard to most endpoints were observed between the prospective and the retrospective part. The rate of procedural complications was slightly higher in the prospective cohort. This was reassuring because this indicated that the occurrence of complications was no reason that the initial nine centers, from which the retrospective data were retrieved, had provided incomplete information.

With regard to the different device types, homemade devices were not included in this study. Five types of commercially available devices had been used in this patient material. Again, this illustrated the present day practice of endovascular abdominal aortic aneurysm treatment.

Your final question was on the imaging techniques used. The preoperative assessment was not strictly uniform between the different participating institutions. For the preoperative workup, usually a combination of DSA and computed tomographic scanning was used, whereas for follow-up examination, a regular computed tomographic examination was part of the routine schedule. Thank you.

APPENDIX. EUROSTAR COLLABORATIVE CENTERS

Amsterdam, The Netherlands; Arnhem, The Netherlands; Athens, Greece; Barcelona, Spain; Bonheiden-Dendermonde, Belgium; Bonn, Germany; Bournemouth, United Kingdom; Bristol, United Kingdom; Creteil, France; Draguignan, France; Dublin, Ireland; Düsseldorf, Germany; Eindhoven, The Netherlands; Enschede, The Netherlands; Frankfurt, Germany; Freiburg, Germany; Gilly, Belgium; Glasgow, United Kingdom; Groningen-University Hospital, The Netherlands; Groningen-Martini Hospital, The Netherlands; Hannover, Germany; Heidelberg, Germany; Hull, United Kingdom; Leuven, Belgium; Lille, France; Liverpool, United Kingdom; London, United Kingdom; Lublin, Poland; Lund, Sweden; Luxembourg, Luxembourg; Lyon, France; Madrid-Hospital La Paz, Spain; Madrid-Hospital Gregorio Maranon, Spain; Manchester, United Kingdom; Modena, Italy; Munich, Germany; Nancy, France; Newcastle-upon-Tyne, United Kingdom; Nieuwegein, The Netherlands; Oslo-Aker Hospital, Norway; Oslo-Ulleval Hospital, Norway; Paris, France; Regensburg, Germany; Rotterdam, The Netherlands; San Sebastian, Spain; Stockholm, Sweden; Tilburg-Elisabeth Hospital, The Netherlands; Tilburg-Tweesteden Hospital, The Netherlands; Toulouse, France; St Truiden, Belgium; Trondheim, Norway; Ulm, Germany; Utrecht, The Netherlands; Veldhoven, The Netherlands; Vienna, Austria; Zürich, Switzerland.