ORIGINAL ARTICLE

Braz J Cardiovasc Surg 2007; 22(1): 7-14

Procedure-related mortality of endovascular abdominal aortic aneurysm repair using revised reporting standards

Mortalidade relacionada ao tratamento endovascular do aneurisma da aorta abdominal com o uso dos modelos revisados

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RBCCV 44205-863

Abstract

Objective: **The aim of this study was to evaluate the definition of Procedure-related mortality after endovascular aneurysm repair (EVAR) as defined by the Committee for Standardized Reporting Practices in Vascular Surgery.**

Methods: **Data on patients with an AAA were taken from the EUROSTAR database. The patients underwent EVAR between June 1996 and February 2004 and were analyzed retrospectively. Explicit probability of cause of death was recorded. The time interval from operation, hospital discharge or second interventions till death was recorded.**

Results: **A total of 589 out of 5612 patients (10.5%) died after EVAR in total follow up and all causes of death were included. 141 (2.5%) patients died due to aneurysms reported after the EVAR procedure of which 28 (4.8%) were ruptures, 25 (4.2%) graft-infections and 88 (14.9%) patients who died within 30 days after the initial procedure (present definition, also known as short term clinical outcome). In addition 25 patients died after 30 days, but were then (at moment of death) still in the hospital, or were transferred to a nursing home for further re-evaluation, or needed second interventions. Taking into account the duration of hospitalization and mortality immediately after procedure-related second interventions, 49 delayed deaths might also be regarded as being EVAR procedure-related.**

Conclusion: **Delayed deaths are a considerable proportion of procedure-related deaths after EVAR within the revised time frame.**

Descriptors: **Aortic aneurysm, abdominal, mortality. Aortic aneurysm, abdominal, surgery. Stents. Blood vessel prosthesis implantation, mortality.**

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Article received in July, 26th 2006
Article accepted in January, 3rd 2007

Resumo

Objetivo: **O objetivo do estudo foi avaliar a definição da mortalidade relacionada ao procedimento após tratamento endovascular do aneurisma de aorta abdominal (EVAR) como definido pelo *Committee for Standardized Reporting Practices in Vascular Surgery.***

Método: **Dados de pacientes com aneurisma de aorta abdominal foram analisados do banco de dados EUROSTAR. Os pacientes foram submetidos ao EVAR entre junho de 1996 a fevereiro de 2004 e foram estudados retrospectivamente. A probabilidade explicita da causa de morte foi registrada. O intervalo entre a operação, alta hospitalar ou intervenção secundária até a morte foi registrado.**

Resultados: **De um total de 5612 pacientes, 589 (10,5%) faleceram após o EVAR em acompanhamento total e qualquer causa de morte foi inclusa. Cento e quarenta e um pacientes (12,5%) morreram devido a causa relacionada ao aneurisma, sendo que 28 (4,8%) foram rupturas, 25 (4,2%) infecções do implante e 88 (14,9%) foram pacientes que morreram num prazo de 30 dias após o procedimento inicial (definição atualmente utilizada, também conhecido como resultado clínico a curto prazo). Além disso, 25 pacientes faleceram após 30 dias, mas continuavam ainda hospitalizados (ou transferidos a home-care para reavaliação posterior, ou necessitaram intervenção secundária). Levando em conta a duração da admissão ao hospital e a mortalidade imediata após o procedimento relacionada a intervenções secundárias, 49 mortes tardias também podem ser relacionadas ao EVAR.**

Conclusão: **Morte tardia compõe uma proporção considerável da mortalidade relacionada ao EVAR dentro do tempo de análise revisado.**

Descritores: **Aneurisma da aorta abdominal, mortalidade. Aneurisma da aorta abdominal, cirurgia. Contenedores. Implante de prótese vascular, mortalidade.**

INTRODUCTION

Minimal invasive surgery is frequently used nowadays to treat abdominal aortic aneurysms (AAA) because of the many benefits this therapy procures [1-3]. The motivation for aneurysm treatment is to eliminate the risk of rupture and death [4,5]. Therefore, by definition, the primary outcome criteria for endovascular aneurysm repair (EVAR) include the prevention of aneurysm rupture; death from aneurysm rupture and procedure-related death that may result from primary treatment [4]. According to the Committee for Standardized Reporting Practices in Vascular Surgery the present definition of procedure-related death is mortality that occurs within a period of 30 days after the initial procedure, due to rupture, graft infection and mortality related to second interventions [4]. Standardized reporting of deaths and complications is necessary to establish endograft exclusion as safe and effective therapy for AAA-treatment. These standards are necessary to compare endovascular procedures with other minimally invasive techniques and conventional surgery for patients at low or high risk [6].

Several studies reported that 10.5% of the patients that underwent EVAR died due to any reason [2,5,7-9], probably due to the high age of the patients and co-morbidity that was pre-existent before EVAR. The current definition of procedure-related mortality according to the Reporting Standards has not been evaluated so far. It is not always obvious whether or not the reason of mortality is EVAR-related. Consequently an arbitrary time frame of 30 days after the initial procedure is used nowadays [4]. Our analyses have shown that after the thirty-day time frame, complications still become obvious and lead to mortality. Therefore, the aim of this study was to assess the proportions of deaths in each category that fall within the current definition of EVAR Procedure-related death.

METHODS

The EUROSTAR (European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair) project was launched in 1996 with the objective of collecting data on the endovascular treatment of aneurysms [10]. Patient enrolment was between June 1996 and February 2004. Excluded were patients with withdrawn devices (Stentor, Vanguard, first generation EVT, patients with AAA < 4 cm in diameter). Preoperative evaluation, operative details and follow-up data were collected. Follow-up protocol requires patient assessment by contrast-enhanced CT scan at 1, 3, 6, 12, 18 and 24 months after the operation and annually thereafter. Surveillance protocol includes clinical examination and an annual plain abdominal X-ray. This information is stored on an "Oracle-based" database (Oracle Corporation, CA, USA.) for periodic analysis (website data entry programming was provided by KIKA medical services, Nancy, France). The registry has no core laboratory or external audit of source data (patient's records and CT scans).

Reminders for overdue follow-up data are regularly sent to the surgeons in the centers who participate in this project. The present cohort consisted of 5612 patients who underwent EVAR between June 1996 and February 2004. From different European countries, there were 153 centers involved in patient treatment and data procurement. Although CT scanning was the standard examination during follow-up, patients had either magnetic resonance angiography or duplex scanning in 6% of the follow-up visits. Data was collected retrospectively and analyzed as well as scored by death cause. The cause of death of patients who underwent a second intervention (SI) to treat the aneurysm was scored after their last procedure. The characteristics of the patients who died after EVAR were analyzed. They were analyzed for the presence of possible precipitating factors.

Variables

The study variables included the clinical characteristics of patients such as ASA-class, diabetes, smoking, hypertension, cardiac and pulmonary co-morbidities. The procedure data included the type of stent graft used and the occurrence of peri-operative complications, as reported by the surgeon. Complications included the occurrence of endoleaks, vascular occlusions or intra-operative death. Other complications that were assessed were myocardial infarction, stroke, graft-infection, AAA-rupture and procedure- or device-related events including (early) conversion to a conventional procedure. Events, seen during follow-up, included endoleaks (type I-IV), endograft thrombosis, second interventions, rupture of the aneurysm and death of the patient.

The causes of death were divided into the following groups; AAA-rupture, graft infection, cancer, cardiovascular, renal, multiple organ failure, pulmonary and other and unknown. According to reporting standards the deaths were divided into procedure-related and non-procedure-related. Deaths within 30 days after EVAR were regarded as procedure-related, those occurring after 30 days as non-procedure-related.

Analysis

Time between date of discharge and date of death was considered. First the Procedure-related death was analyzed according to the current Committee definition. If the number of days between operation and death was ≤ 30 it was regarded as procedure-related mortality. Second interventions (SI) were not regarded. Graft infections and AAA-ruptures were always regarded as procedure-related events. Secondly, the patients with non-procedure-related deaths according to the Reporting Standards were studied further. If the time (in days) between hospital discharge and death or between SI and death did not exceed 30 days these patients were also regarded as having a procedure-related death. Kaplan Meier curves were used to represent survival and freedom from procedure-related mortality. Because of the large number of small centers, we decided to categorize the centers as large (>30 cases), middle (10-30 cases) and small (<10 cases) to make statistical analysis possible. Of the 153 centers, 41 had a team experience of more than 30 cases, 44 operated 10 to 30 patients, and 66 performed less than 10 operations. This distribution of team experience was similar in the patients who did not survive as in those who did.

RESULTS

The EUROSTAR database consisted of 5612 patients, 93% was male; the mean age was 71 years (range: 53-100 years) and the average aneurysm diameter was 55mm (range: 33-145mm). Mean duration of the initial procedure was 137 minutes (range: 25-785 min) with an average hospital stay of 6 days (range: 0-163). Total follow up period of all patients who underwent EVAR was 8960 person-years. The completeness of the follow-up data is 77%. Baseline characteristics of the patients are shown in Table 1.

Table 1. Characteristics of AAA patients, who died after EVAR

Character		Number of patients
Total		589
ASA class	1	22 (3.8)
	2	154 (26.9)
	3	301 (52.5)
	4	96 (16.8)
Diabetes	Yes	78 (14.5)
	No	461 (85.5)
Smoking	Yes	298 (55.0)
	No	244 (45.0)
Hypertension	Yes	328 (60.5)
	No	214 (39.5)
Cardiac problems	Yes	368 (68.1)
	No	172 (31.9)
Cardiac signs	Yes	114 (21.5)
	No	416 (78.5)

Overall procedure-related mortality of the 5612 patients who underwent the EVAR procedure was 2.5% (141 patients) and 589 patients died due to *any* reason (10.5%). The 8-year survival of patients who underwent EVAR is 70%. Causes of death included rupture (4.8%), cancer (15.5%), cardiovascular problems (37.4%), pulmonary problems (7.7%), graft infections (4.2%), and other or unknown reasons (23.6%). The 589 patients who died after EVAR had a mean age of 74 years (range: 52-94 years). Their mean duration of the procedure was 164 minutes (range: 30-785 min) and the mean hospital stay was 8.9 days (range: 0-163 days). Patients who died after EVAR, often experienced co-morbidity or showed precipitating risk factors.

Table 2. Procedure related mortality according to Reporting Standards definition and the definition including the period after discharge and SI

Mortality	Number of patients*
AAA – rupture	
Graft infection	28 (4.8)
Mortality within 30 days	25 (4.2)
after procedure	88 (14.9)
Total of procedure related	
deaths	141 (23.9)
Mortality within 30 days	
after discharge	25 (4.2)
Mortality within 30 days	
after SI	24 (4.1)
Total deaths according	
definition including period	190 (32.3)

**Overall calculation of the 589 patients who died*

The procedure-related mortality based on the Standard Reports definition was 16 per 1000 treated patients per year (1.6%). Overall, 141 out of the 589 deaths (24%) died because of the procedure. Eighty-eight patients (14.9%) died within 30 days after the initial EVAR procedure (Table 2), 28 patients (4.8%) died due to AAA-rupture and 25 died due to graft-infection (4.2%). The majority of the patients died because of cardiovascular complications (29.8%) and multi-organ failure (MOF) (10.6%) (Table 3). The mean duration of the initial EVAR procedure of patients with procedure-related death was 206 minutes (range: 30-785 min). The mean age of these 141 patients was 76 years (range: 52-94 years).

A total of 83 patients had a prolonged hospital stay of more than 30 days after primary intervention. Of these 83 patients, 25 patients (4.2%) died within 30 days after hospital discharge. The mean duration of hospital admission of these 25 patients was 47 days (range: 0-163 days). Furthermore, 669 (17%) of the 3928 patients still under follow up were submitted to a SI after hospital discharge. A total of 32 patients died after SI, of which 24 (3.6%) died within 30 days (Table 4).

Table 3. Comparision: procedure related deaths according to the Reporting Standards definition vs. the definition including the period of discharge and SI

	Reporting Standards definition		Definition including period	
Cause of death (N=589)	Procedure related mortality nº (%)	Non-procedure related mortality nº (%)	Procedure related mortality nº (%)	Non-procedure related mortality nº (%)
Overall	141 (23.9)	448 (76.1)	190 (32.2)	399 (67.7)
Cancer	1 (0.7)	117 (26.1)	13 (6.8)	94 (23.6)
Cardiovascular	42 (29.8)	159 (35.5)	76 (35.3)	149 (37.3)
Graft-infection	25 (17.7)	0 (0.0)	25 (13.2)	0 (0.0)
MOF	15 (10.6)	8 (1.8)	16 (8.4)	0 (0.0)
Pulmonary	11 (7.8)	38 (8.5)	17 (8.9)	32 (8.0)
Renal	3 (2.1)	9 (2.0)	11 (5.8)	1 (0.3)
AAA-rupture	28 (19.9)	0 (0.0)	28 (14.7)	0 (0.0)
Unknown	7 (5.0)	63 (14.1)	2 (1.1)	66 (16.5)
Others	9 (6.4)	54 (12.1)	11 (5.8)	57 (14.3)

Table 4. Free from death

Interval start time (months)	Number entering this interval	Number of deaths, cumulative	Proportion surviving
0	5612	107	0,981
1	5505	110	0,980
3	4830	148	0,972
6	4575	277	0,943
12	4175	347	0,923
18	3262	392	0,907
24	2527	453	0,881
36	2064	519	0,839
48	1317	561	0,792
60	703	580	0,749
72	331	586	0,718
84	139	588	0,694
96	57	589	0,694

Ten SIs were transfemoral procedures. 10 patients underwent a conversion of which five were because of AAA-rupture, one because of stent-graft migration and four because of unknown reasons. Finally, four patients underwent an extra-anatomical intervention. If mortality because of SI and the mortality in the 30-day period after hospital discharge are taken into account, 49 more deaths should be regarded as procedure-related. These additional 49 patients died mainly (42%) due to cardiovascular complications such as myocardial infarction, emboli and strokes. The overall procedure-related mortality after EVAR showed an increase from 16 to 24 per 1000 treated patients per year in this study.

DISCUSSION

Endovascular aneurysm repair (EVAR) is, besides the conventional procedure and "watchful-waiting" strategy, a relatively new manner to manage AAA-patients [3,11]. Recently the Committee for Standardized Reporting Practices in Vascular Surgery published definitions of outcome measures in endovascular surgery. This study was designed to evaluate the current definition of procedure-related mortality of patients after EVAR, one of the most important outcome measures for treatment evaluation available. Although the overall mortality after EVAR is low (7-10%) the results from our study showed a considerable additional number of delayed deaths that seemed to be procedure-related [11-13]. According to the Standard Reports definition 2.5% of the patients died because of the procedure. However the Standard Reports definition does not consider mortality within a time frame of 30 days after SIs or after hospital discharge. Taking into account mortality in the 30-day period immediately after hospital discharge and after SI, an additional 49 patients' deaths were procedure-related.

Again, the importance of using hard clinical outcomes is necessary to evaluate EVAR in AAA patients [14]. Risk factors such as co-morbidity and medication are becoming more important. The recent published conclusion of the DREAM Trial informed our colleagues that "the initial survival advantage over open aneurysm repair, however, is not sustained after the first postoperative year" [18]. The mortality rate of 2.5% in the present study population is comparable to those of the EVAR-1 and the DREAM trials. In these studies mortality rates of 2.7% and 3% were recorded for elective EVAR [18,20].

The main cause of late postoperative death in both trials was cardiovascular, confirming the impact of co-morbidity in EVAR patients. The EVAR-2 study was conducted in patients unfit for open aneurysm repair. It showed that EVAR is not a safe procedure in such high-risk patients [19]. It also raised concern about the medical treatment of these patients, fuelling the attention for co-morbidity and pharmacological interventions.

Risks on developing complications after EVAR are high, supporting the cautious use of EVAR [14]. Both patient characteristics and procedural variables are independent risk factors for complications and mortality.

According to the current definition of The Reporting Standards 141 patients deaths were related to the procedure. Taking into account the time between delayed discharge and death and the time after SI and death, an additional 49 patients should be regarded as having aneurysm-related deaths. Other studies, such as the ones by Chaikof et al. (2002) and Dias et al. (2002) reported lower aneurysm-related mortality percentages (respectively 6.5% and 2.6%) [6,9]. The incidence of procedure related mortality after EVAR (2.5%) in the EUROSTAR-cohort is comparable with the previously reported institutional series.

The EUROSTAR population has a thorough follow up protocol. It requires contrast-enhanced CT scans at 1, 3, 6, 12, 18 and 24 post-operative months and annually thereafter. The possible development of a new or persisting endoleak can be noticed.

While endovascular AAA repair has several advantages over open surgical repair in the short-term, there is still concern regarding its durability [15]. The advantages of EVAR are reasonably exciting. In fact there is no need for a laparatomy and the anesthesia period can be much shorter

and lighter. Therefore endovascular surgery is a good option for patients with poor medical conditions (ASA-class 3 or 4) and therefore unfit for open procedures [2]. This group of patients typically demonstrates a high prevalence of co-morbidity, such as peripheral arteriosclerosis, coronary heart diseases, (renal-vascular) hypertension, diabetes mellitus or other medical disorders [13,16]. Procedure-related mortality in patients unfit for a conventional procedure is higher than in those with good conditions [10]. Considering the outcomes of this study and in particular the causes of mortality, EVAR may cause an increased risk of procedure-related complications and death for patients suffering from disorders such as cancer, cardiovascular problems or pulmonary disease.

It has been demonstrated that implantation of a foreign body in the circulation may cause a systemic response such as inflammation and platelet activation [9,12]. Inflammation and platelet activation may cause additional complications, such as graft-infection, thrombosis and embolic processes in lungs, brain or gastric-intestinal system [2,17]. These complications can be lethal and will not always be identified as procedure-related mortality for patients who underwent EVAR because of the very fact that these complications can occur in the short-term as well as in the long term [4]. The complications caused by EVAR are procedure-related by definition. The definition of the Committee on Reporting Standards specifies that a patient, who died after 30 postoperative days, is non-procedure-related. The thirty-day postoperative timeframe was also arbitrarily chosen in our study but several patients stayed in the hospital for longer than 30 days. These were included in the definition of procedure-related death. Variations in the severity of complications and the effect of SI remain uncertain factors for measuring hard clinical outcomes.

In our study few patients died immediately after SI. The type of SI was not of significance. Because of the fact that several patients will need SI after EVAR, mortality and morbidity will be of significance.

In this study, 12% of the study population underwent SI, 4.1% of these patients died within thirty days after this SI. These results are comparable with other studies such as Zarins et al. (2000). They concluded that 15 late deaths (10%) occurred after SI [3]. An analysis of the causes of death of patients who underwent SI showed that more than 20% of the patients who underwent a SI for rupture died within 30 postoperative days.

CONCLUSION

In conclusion, delayed deaths make up for a considerable proportion of procedure-related mortality after EVAR within this revised time frame.

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COMMENTARY

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Endovascular aortic aneurysm repair (EVAR) is a recent procedure that is less invasive compared to conventional surgery. A comparison with the conventional procedure is fundamental and should be achieved in two ways: with clinical trials and with registers. Two clinical trials (EVAR 1 and DREAM) demonstrated lower mortality rates using the endovascular procedure when compared to conventional surgery in the first 30 days after treatment for abdominal aortic aneurysms (AAA).

In the medium-term analysis of these studies (1 to 4 years) there was a loss of the initial benefit over time with a tendency of evening out, mainly in respect to higher mortality rates in the EVAR Group, with this being considered 'not related' to the procedure.

Initiated in 1996, EUROSTAR (European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair), the main register accompanying the used of endoprostheses for AAAs, includes a large number of patients (more than 5000) and has a rigid follow-up protocol and is therefore closer to the real life scenario than clinical trials.

The Koning et al. study in this edition of the journal raises an important aspect in the evaluation of results after the endovascular repair of abdominal aortic aneurysms. The definition of procedure-related mortality rate should be more comprehensive than that restricted to 30 days following the procedure. The additional late deaths identified by the authors as being related to the aneurysm and/or procedure in the EUROSTAR register only reinforce the importance of the necessity of careful follow-ups of patients using imaging methods with the aim of identifying and treating potential complications and to identify late deaths related to the aneurysm. Long-term results are necessary for the true role of this procedure to be established.

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The possibility of endovascular treatment of abdominal aorta aneurysms (AAAs) has occupied a significant place in present-day cardiovascular scenery. Aggregating the theoretical advantages of the less invasive nature of the technique with the reduced risks in comparison to the conventional approach, endovascular aneurysm repair (EVAR) has been proposed not only as an alternative for high operative risk patients, but as a potential substitute to open chest surgery.

Recently, analysis of the EVAR-1 studies demonstrated that, even though there is a reduction of around 2/3 of early deaths in the endovascular arm of the trial, this benefit is

not sustained over a 4-year follow-up period, due to the high complication rates and late re-interventions. Additionally, the DREAM trial demonstrated that the equivalent survival curve at 2 years was justified for the EVAR group, only because of the "advantage" obtained in the in-hospital period.

In this edition of the BJCVS, Koning et al. bring a new and interesting ingredient into the discussion, EVAR versus conventional surgery: the importance of redefining the notion of death related to the procedure based on data from the real world. Supported by the data in the EUROSTAR register, the authors propose that late mortality related to EVAR can be significantly higher than that initially recognized if data of subsequent interventions are taken into account. Other data, brought to our attention, are in respect to the high late cardiovascular mortality rate even in a group under such rigorous clinical control, reinforcing the necessity of aggressive treatment of atherosclerosis, independent of the technique used for AAA repair.

Finally, the Koning et al. study contributed greatly to the real world; if on one hand it does not have the evidence level of clinical trials, on the other it is closer to the day-to-day practice and contributes to clinical judgment.

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