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PRELIMINARY RESULTS FROM A NATIONAL ENQUIRY OF INFECTION IN ABDOMINAL AORTIC ENDOVASCULAR REPAIR (R.I.-EVAR)

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Abstract

Objective: to preliminary report on epidemiology, risk factors, diagnosis, treatments and outcomes in a multicenter series of patients treated for EVAR infection and detected by a Italian National enquiry

Methods: From June 2012 twenty-six cases of abdominal aortic endograft infection were collected by a National Enquiry and recorded in the Italian National Registry of Infection in EVAR (R.I.-EVAR). Cases collected were available for patients submitted to EVAR implantation from January 2004 to June 2013.

Results: Mean time from EVAR treatment to infection diagnosis was 20.5±20.3 months (range 1-72). In 6 cases (23.1%) an aorto-enteric fistula (AEF) was detected. Positive microbiological cultures were found in 20 patients (76.9%). More than 1 infectious agent was found in 6 cases (19.2%). EVAR infection treatment was conservative in 4 cases, endovascular in 2. Endograft excision was performed in 10 cases by conventional treatment (aortic stump+extra-anatomic bypass) and in 10 cases by in situ reconstruction (cryopreserved allograft or rifampin-soaked silver Dacron graft). 30-day mortality was 38.4% (10/26 cases), 3 patients died from 2 to 24 months after infection treatment, accounting for a mean time from infection treatment to death of 1.25±0.62 months. Mortality rates were 50% in all treatment groups. In those survived (13/26 cases) recurrence-free follow-up after infection treatment was 27.9±22.4 months (range 2-74). Four patients with AEF died in the first month following treatment (66.6%). Suprarenal endografts required supraceliac aortic cross-clamping for removal. Supraceliac cross-clamping was burdened by higher mortality rates than infrarenal cross-clamping (71.4% vs 30.7%).

Conclusions: EVAR infection diagnosis is burdened by extremely high mortality rates. Prospective registries could help monitoring outcomes in EVAR infection patients and, possibly, developing new surveillance protocols in patients at high risk of recurrence.

Key words: endovascular abdominal aneurysm repair, EVAR infection, EVAR complications, aorto-enteric fistula

Introduction

The increase of EVAR procedures in recent years has given rise to a parallel increase in late open surgical removal of abdominal aortic stentgraft, in those cases when complications can't be fixed by a new endovascular procedure. Among them, endograft infection can be considered one of the most serious and devastating one, with mortality rates following diagnosis ranging from 16% in surgically-treated patients[1] to 100% in conservatively-treated patients[2]. Risk factors for such an occurrence are usually considered an urgent setting, the employment of a radiology suite instead of the operating theatre, a redo operation, and a too short prophylactic antibiotic therapy before any invasive procedures performed in a patient previously submitted to EVAR[1]. The incidence of abdominal endograft infection is reported between 0.25%[3] and 1%[4], even if its exact magnitude is difficult to estimate because many of those cases are underreported.

In 2002 our Vascular Division performed an international enquiry with the aim of estimating the incidence and registering the treatment of endograft infection[1]. Ten years after that first enquiry a second questionnaire has been sent to all Italian Vascular Centers performing EVAR.

The aim of the present study is to report on incidence, risk factors, diagnosis, treatment options and results on a series of patients previously treated by EVAR and with an infection diagnosed from 1 to 72 months after endograft implantation and collected by the Italian Registry of Infection in EVAR (R.I.-EVAR).

Materials and Methods

In June 2012 a comprehensive questionnaire was sent to all Vascular Centers in Italy with the aim of collecting retrospective cases of abdominal aortic aneurysm (AAA) endograft infections. A prospective registry (Registry of Infection in EVAR – R.I.EVAR) was also started[5]. By the end of

October 2013 twenty-six cases were collected. Patients in the case-series had been submitted to EVAR implantation from January 2004 to June 2013 in 13 Tertiary Hospitals (see Appendix).

Data on time from EVAR intervention to infection diagnosis, diagnostic symptoms, signs and tools, infectious agent, infection degree, type of treatment (conservative or invasive by in situ or extra-anatomical reconstruction), type of endograft, antibiotic therapy employed, additional risk factors for development of infection after EVAR, presence of aorto-enteric fistula (AEF), survival, mortality and complications rates were collected and recorded in a dedicated database.

Comparative mortality rates analysis was performed respect to type of infection treatment, presence of aorto-enteric fistula, site of aortic cross-clamping for endograft removal, presence of risk factors for infection. Data were expressed as numbers, percentages, mean and standard deviation, and were compared using the chi-square test and logistic regression test. Significance was set at $p<0.05$.

Results

By the end of October 2013 twenty-six cases were collected from 13 centers. Those patients had been treated by EVAR from January 2004 to June 2012. Twenty-four out of 26 had been treated for endograft infection from 2006 to 2012. In that same period 31420 endograft implantations for abdominal aortic aneurysm repair were performed in Italy (**Table I**).

Endografts implanted were Excluder (W. L. Gore, Flagstaff, Ariz, USA) in 11 cases, Zenith (Cook Inc, Bloomington, Ind, USA) in 3 cases, Talent (Medtronic, Minneapolis, Minn, USA) in 4 cases, Anaconda (Vascutek Ltd., Inchinnan, Scotland, UK) in 2 cases, non-reported in 6 cases.

Mean time from EVAR treatment to infection diagnosis was 20.5±20.3 months (range 1-72 months).

In 6 cases (23.1%) an aorto-enteric fistula (AEF) was detected and 1 patient out of 6 has had previous aortic surgery thus suggesting a secondary fistula. Infection clinical presentation was fever in 21 patients (80.7%), weight loss in 23 (88.4%), weakness in 24 (92.3%), pulsating mass in 5 (19.2%), melena in 5 (19.2%), and hemathemesis in 1 (3.8%). Infection was detected in emergency in 3 cases out of 26 (11.5%). In all cases contrast-enhanced Computed Tomography (CT) scan was employed for infection diagnosis, with adjunct Tagged Leukocyte scan localizing to the endograft in 8 cases (30.7%), Positron Emission Tomography (PET) in 2 (7.7%), Ultrasound (US) in 2 (7.7%), Gastrointestinal Endoscopy in 3 (11.5%) and Magnetic Resonance Imaging (MRI) in 1 (3.8%).

Of the considered risk factors for infection[1] urgent procedure was detected in 8 cases (30.8%) with adjunct preoperative fever (more than 37 °C) in 3 (11.5%), EVAR deployment in radiology suite in 4 (15.4%), and one or more adjunct procedures following EVAR in 9 (34.6%;percutaneous correction of endoleak in 3 cases, adjunct endograft implantation in 2 cases, femoral pseudoaneurysm resection in 1 case, appendicular abscess drainage and appendectomy in 1 case, psoas abscess drainage in 1 case, and non-specified abdominal surgery in 1 case; **Fig. 1**).

Positive cultures (prosthetic/periaortic material or blood, or both) were found in 20 patients (76.9%). More than 1 infectious agent was found in 5 cases (19.2%). *Staphylococcus aureus* and *Escherichia Coli* were isolated in 5 (19.2%) and 6 (23.1%) cultures respectively, *Candida albicans* in 4 (15.4%), *Enterococcus* and *Staphylococcus epidermidis* in 2 (7.7%), *Klebsiella, Pseudomonas aeruginosa, Staphylococcus lugdunensis, Bacteroides fragilis, Fusobacterium mortiferens, and Haemophylus aphrophilus* in 1 each (3.8%).

EVAR infection treatment was conservative in 4 cases, and endovascular in 2 cases. Those patients were considered too fragile to be submitted to an open repair. Conservative treatment was achieved by wide-spectrum intravenous (i.v.) antibiotic therapy administration (Meropenem 1g three times daily) in 1 patient and percutaneous drainage combined to culture-specific antibiotic therapy in 3 cases. Two patients treated conservatively died within one month since infection diagnosis and the remaining were alive at 6 and 10 months following diagnosis, respectively. Urgent endovascular treatment for aneurysm rupture was performed in 1 case by a Jotec endograft (JOTEC, Hechingen, Germany) implantation followed by culture-specific antibiotic therapy for 2 months and no recurrent infection at 18-month follow-up. One patient with AEF treated by a new endograft implantation died perioperatively.

Twenty Endograft total excisions were performed by conventional treatment (extra-anatomic bypass - EAB + simultaneous aortic stump ligation) in 10 cases and in situ reconstruction (cryopreserved allograft or rifampin-soaked silver Dacron graft implantation) in 10 cases **(Fig. 2).** All patients submitted to endograft excision were under initial empiric, wide-spectrum, i.v. antibiotic therapy at first, then subsided by culture-specific i.v. antibiotic administration for 2-to-6 weeks postoperatively. After that period, prolonged (6 or 12 months) oral antibiotic therapy was prescribed in those survived. In 2 patients extra-anatomical reconstruction was performed by an ePTFE graft implantation, in 2 patients by Dacron graft, in 3 patients by cryopreserved allograft and in 3 patients the graft employed was not reported. In patients treated by in situ reconstruction silver Dacron was employed in 1 case, cryopreserved allograft in 1 case, and rifampin-soaked silver Dacron in 8 cases. In 7 patients with suprarenal EVAR fixation graft removal was performed in 5, conservative treatment in 1 , and endovascular treatment in 1. Four out of 5 patients submitted to suprarenal endograft explants were treated by EAB, and 1 by in situ reconstruction. Graft explantation was achieved by supraceliac aortic cross-clamping in all patients with suprarenal endograft fixation.

Perioperative (30-day) mortality was 38.4% (10 out of 26 cases). One patient died 2 months after treatment of multiple organ dysfunction syndrome (MODS) and 1 patient after 3 months of sepsis. One patient died of acute myocardial infarction (AMI) 24 months after treatment. Four patients with AEF died in the first month following treatment (66.6%). Mean time from infection treatment to infection-related death was 1.25±0.62 months**.**

Mortality rates were 50% in all treatment groups: 2 patients treated conservatively died of MODS, 1 submitted to endovascular treatment died of bleeding, together with 5 patients treated by extra-anatomic bypass reconstruction (2 died of MODS, 1 of sepsis, 1 of respiratory failure, 1 of AMI), and 5 by in situ reconstruction (2 died of MODS, 1 of sepsis, 1 of bleeding, 1 of AMI) . In those survived (13/26 cases) recurrence-free follow-up after infection treatment was 27.9±22.4 months (range 2-74). No reinfection was reported in those survived. Four patients with AEF died in the first month following treatment (66.6%). Life table analysis is presented in Figure 3.

Respect to the type of endograft mortality rates were 27.3% in patients with Excluder endograft, 50% in patients with Anaconda, 66.6% in patients with Zenith, and 75% in patients with Talent. Suprarenal endografts required a supraceliac aortic cross-clamping for removal and were burdened by higher mortality rates than infrarenal endografts (71.4% vs 30.7%; p=0.01). No significant difference was encountered in 30-day and overall mortality respect to presence of risk factors and presence of AEF.

Discussion

The Italian National enquiry performed in 2012-13 has presented to the authors with a conflicting scenario. For once, EVAR infection seems quite rare, since 24 cases were reported in a period (2006-2012) in which about 30000 EVAR implantations have been performed in Italy[6]. Moreover, 26 cases were treated in 13 Centers, thus confirming that this very complex disease has to be treated

in dedicated and high-volume Vascular Centers. It is also likely that the problem is highly underreported, with many of the cases not diagnosed or not adequately treated in dedicated Vascular Centers, so that the real incidence is difficult to estimate and the need for a prospective registry establishment has arisen. On the other hand, mortality rates recorded in the present enquiry are the highest reported (50% for every kind of treatment), thus probably reflecting the contemporaneous experience. The majority of patients died in the first month after infection diagnosis or treatment of infection-related causes (MODS, sepsis, bleeding or respiratory failure following invasive treatment). Those data emphasize the complexity of postoperative management in those patients, whose infectious involvement is often difficult to eradicate.

Despite the progress of science, the refinements of techniques, the improvement of devices, and the availability of new techniques, no specific or preventive treatment has been developed to face this rare but devastating condition. Further, no dedicated surveillance protocol has been approved for early detection of infection in EVAR patients and, probably, not enough effort is nowadays spent to warn EVAR patients and their treating physicians on the potential risk of infection carried by any following invasive moneuvres (not only vascular) in those submitted to EVAR implantation[7].

Etiology of infections has been changing over time. Since the first enquiry performed in 2002 by our Vascular Surgery Division[1], more and aggressive bacteria, often in combination with multiple microorganisms, seem responsible for EVAR contamination. In that first enquiry[1] *staphylococcus epidermidis* was responsible for endograft infection in 50% of cases. In the present series a multibacterial etiology could be identified in 19% of cases, with bacteria that usually contaminate the skin, such as *staphylococcus epidermidis* and *staphylococcus aureus* in 7.7% and 19% of cases respectively, and those that usually contaminate the gastrointestinal tract in about 30% of cases (*Escherichia Coli* and *Enterococcus faecalis* in 23% and 7.7% respectively). Unusual and multiple bacterial culture growth was identified in 5 patients, thus posing serious treatment concerns.

Risk factors for infection are commonly recognized as urgent procedure, radiology suite endograft implantation[1], presence of fever before EVAR, and adjunct invasive procedures following EVAR. Even if no consensus exists on the classification of those features as risk factors for infection, nonetheless a higher mortality is reported in patients operated in an urgency setting in major series[8,9]. Despite preoperative antibiotic prophylaxis is nowadays routinely performed everywhere, redo operation after EVAR is considered a risk factor for infection, thus strengthening the necessity of informing EVAR patients, as well as all patients carrying a vascular prosthesis and their treating physicians, on the possible risk of infection during any kind of invasive procedure and of recommending them prolonged antibiotic therapy since the prosthesis is biocompatible but biologically inert. As expected in strictly followed-up patients, EVAR patients may require a reintervention during their post-implantation screening, so new surgical open or endovascular procedures can be suggested as possible sources of bacterial seeding[10]. Since pseudointima formation in newly-implanted vascular grafts starts from the edges of the graft and proceed inwardly, the first weeks after implantation are critical for possible infectious graft contamination by haematogenous seeding, as reported by Murphy et al.[7] that found most of the infections occurring within 3 months. However, it is probable that very long grafts may possibly never be fully incorporated, as indirectly proven by late detection of infection, up to 72 months in the present series.

The diagnosis of an endograft infection is usually based on a combination of clinical symptoms, imaging studies and microbial cultures whenever possible. If CT scan is almost employed in 100% of infection diagnosis, as reported in the present series, cultures of blood or samples collected from the infected field can sometimes be negative as reported by Cernohorsky et al.[11] and in our series in 33 % of cases.

In the present series no significant increase in mortality was detected in those presenting an adjunct risk factor for infection but this is likely due to the small number of cases collected. In our study

mortality rates are among the highest reported in literature for every kind of treatment strategy (50% in all treatment groups). It may possibly reflect not only the tough challenge that EVAR infection represents, but also what really happens in the real-world setting once you begin to count all your "dead and injured". So it could be useful to establish prospective registries for rare and very challenging diseases since they could help to depict the magnitude and severity of the problem at hand.

While data on antibiotic prophylaxis is standardized for patients undergoing EVAR and subsequent invasive manoeuvres following the index operation in Italy, data on antibiotic therapy following EVAR infection diagnosis in the present series were extremely variable and non comparable. They reflect the lack of consensus on type, dosage, administration route, and duration in those very fragile patients.

As much expected, mortality rates were higher in patients requiring supraceliac aortic cross-clamping, even if conflicting data on perioperative mortality in patients submitted to endograft explants are reported in literature. In their series published in 2011 Laser et al.[8] reported nine endograft explants with a perioperative death in 2 cases (22%). Furthermore, perioperative death rate was reported between 0 and 5.5% in surgically treated patients by Fatima et al.[12] in their recent publication. On the contrary, Lyons et al.[13] reported a 30% mortality in surgically treated patients and a 100% mortality in conservatively treated patients. In those patients in which the endograft can't be completely removed it is likely that the portion left in place can give rise to a re-infection, since it is commonly agreed that total endograft explant is mandatory in order to eradicate infection. However, it has to be acknowledged that complete graft removal is not always easy to achieve. It has to be balanced with general and specific anatomic conditions in every single patient so that nowadays no guideline is available, no direction could be outlined, and infection treatment always requires a case-by-case evaluation, since those very fragile patients will often not tolerate adjunct procedures. In their literature review on endograft infection reports Moulakakis et al.[14]

found a 44.8% mortality rate in conservatively treated patients. However, data from literature report not comparable infection-related mortality rates in conservative-treated patients, as summarized in **Table II**[8,12-14]. Similarly, in surgically-treated patients reinfection is a cause of major concern with reinfection rates expecially high in patients presenting with AEFs after open surgery, reported to be up to 41% at 2 years[15].

In past years the recognition and treatment of vascular graft infections has led to the development of high resistance-to-infection prosthesis, as for silver Dacron grafts[16-18]. Recently, Escobar et al.[19] reported two cases of infected aortic aneurysms treated by rifampin-soaked endograft, thus demonstrating that to apply the principles that led to the production of high-resistance-to-infection vascular grafts to EVAR is possible. Even if there is no evidence for such employment, nevertheless a higher-resistance-to-infection endograft might be developed and used in patients at high risk for infection such as patients with fever at the time of EVAR, urgency setting, bridging therapy for AEFs, suspected mycotic aneurysms, iatrogenic or infectious immunosuppression, etc.

Limitations

The present study represents what happens in a real-world setting, but its multicenter and retrospective nature can possibly affect results since different hospitals and different surgeons could apply no uniform treatment strategies. Even if unbiased by selection criteria and representative of multicenter experiences that are mainly self-reported, our series is small in size so that risk factors analysis is underpowered and robust conclusions on treatment and outcome are not allowed.

Conclusions

Unfiltered results of EVAR infection therapy from the present registry show alarmingly high mortality rates for every kind of treatment employed. Patients deemed unsuitable for major surgery experience the same mortality rates, and so apparently, the same chances of survival than patients submitted to endograft explant. Prospective registries might help to monitor outcomes in EVAR

infection patients and, possibly, to develop new infection-dedicated surveillance and treatment strategies.

Conflict of interest statement

No competing interest declared.

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Table I. Abdominal endograft implantations in Italy from 2006 to 2012 (Code ICD9-CM 39.71)

Discharge year	Index procedure	Adjunct procedure	Total
2006	2414	227	2641
2007	3077	247	3324
2008	3706	327	4033
2009	4226	396	4622
2010	4754	440	5194
2011	5272	480	5752
2012	5482	372	5854
Total	28931	2489	31420

National Archives SDO (hospital discharge data sheet), Ministry of Health, Department of Planning and Organization of the National Health Service, Directorate General for Health Planning, 6th Office

Table II. EVAR infection-related mortality in recently published series

Author/year of publication	Type of treatment of EVAR infection	Infection-related death/number of treated cases	Time from infection diagnosis to infection-related death
Laser/2011	EAB	1/5	<30 days
Laser/2011	In situ	1/4	<30 days
Fatima/2013	EAB	0/3	--
Fatima/2013	In situ	1/18	44 days
Lyons/2013	EAB	3/10	<30 days
Lyons/2013	Conservative	3/3	0-5 months
Moulakakis/2014	Conservative	13/29	0-10 months
Present series-R.I.EVAR/2014	Conservative	2/4	<30 days
Present series-R.I.EVAR/2014	EAB	4/10	0-3 months
Present series-R.I.EVAR/2014	In situ	5/10	<30 days

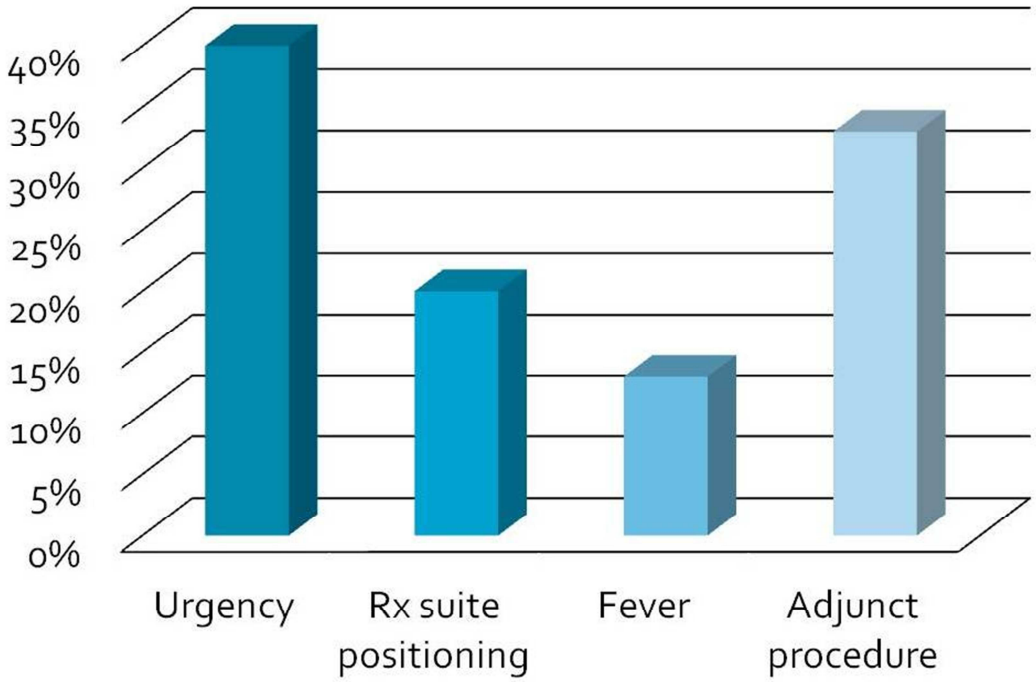
EAB: extra-anatomical bypass reconstruction

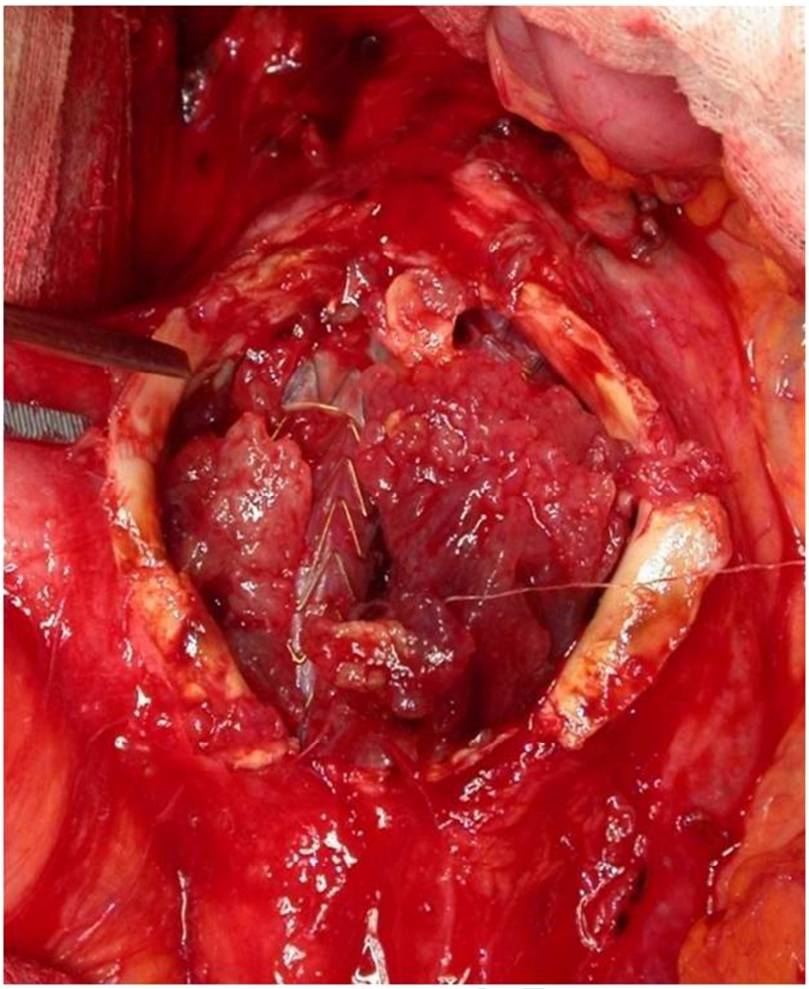
FIGURE LEGENDS

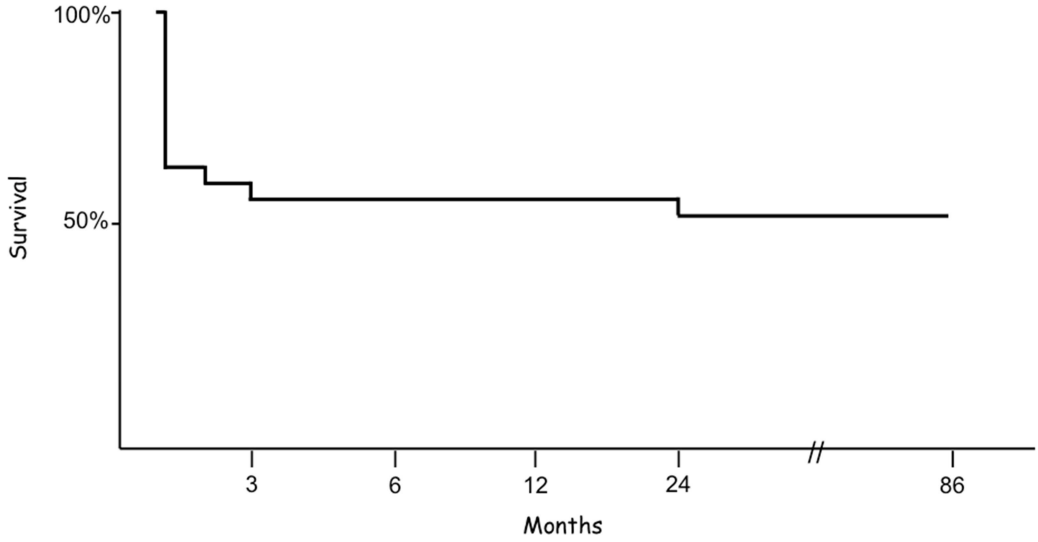
Figure 1. Frequency of risk factors for EVAR infection detected in 26 patients

Figure 2. Endograft infection explant. Intraoperative findings

Figure 3. Kaplan-Meier life table analysis of patients in the present series







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