Risk factors for immediate results and long-term survival following elective open surgery for AAA.

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Statistical analysis of 1111 consecutively-treated patients

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AIM OF THE STUDY: *Perioperative and 10 years follow-up risk factors for 1111 consecutive open AAA repairs were statistically analyzed (χ_2-test and Log-rank test methods for univariate analysis, and logistic regression model and Cox proportional-hazard model for multivariate analysis). Overall operative mortality rate was 2.7%, and significant risk factors were: 1) univariate analysis: Age (>70 years 3.9% vs 1.5% <70 years); CAD (4.3% vs 1.9% without CAD); PAD (4.7% vs 2.0%); III-IV ASA classes (3.8% vs 0% in I-II ASA classes); 2) multivariate analysis: only ASA classes.*

RESULTS: *Long-term survival (42.3 ± 32.6 months) was 93% and 88% at 3 and 5 years respectively, with 0.2% graft-related deaths, and significant risk factors were 1) univariate analysis: Age (92% and 84% at 3 and 5 years in patients aged >70 vs 94% and 91% <70 years); ASA classes (91% and 87% at 3 and 5 years in ASA III-IV vs 98% and 92% in ASA I-II); CAD (92% and dell'85% vs 94% and 90% without CAD); COPD (90% and 80% vs 95% and 92% without COPD); CRF (90% and 82%, vs 94% and 89% without CRF); suprarenal aortic cross-clamping for pararenal aneurysms (91% and 77% in pararenal AAA, vs 94 % and 90% in infrarenal AAA; 2) multivariate analysis: Age; ASA classes; pararenal aneurysms. There was a close relation between number (0-5) of risk factors in each patient and early and late complications. These data are very satisfactory overall, and even in high risk patients who are routinely considered for EVAR.*

PAROLE CHIAVE: Aortic aneurysms, EVAR, Long-term survival, Open surgery, Vascular graft.

Introduction

The recent UKSAT [1] and ADAMS [2] clinical trials, which compared early intervention and ultra-sound imaging for small and medium diameter abdominal aortic aneurysms (AAA), proposed virtually unanimous dimensional criteria on which to base surgical indications in this type of lesion. As highlighted in more recent guidelines [3], preoperatively measurable risk factors in each patient are equally important in predicting immediate outcome and long-term survival. Defining the operation's risk/benefit ratio in relation to this factor [4-9] is considered of primary importance due to the selection of cases for which endovascular aneurysm repair (EVAR) is feasible, being a valid alternative to traditional replacement by laparotomy [10-19]. Provided that the anatomical conditions allow, from a purely technical point of view, application of the aortic prosthesis by open or endovascular surgery, the assumptions for selecting the endovascular method are:

1) reduced surgical trauma and hence lower incidence of complications and death in the oldest and most compromised groups of patients;
2) less weight, in the same patients with reduced life expectancy, of doubts regarding the long-term tightness of the endoprosthesis.

Our statistical analysis of significant factors for mortality, complications and long-term prognosis based on a

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large number of consecutively treated elective open-surgery cases may encourage reflection on the need for further and more thorough analysis of the correspondence of the objective reality of the above assumptions, most of which are clearly accepted when considering the two possible approaches to abdominal aortic aneurysm.

Materials and methods

In order to evaluate only cases with a minimum follow-up of 2 years, of the 1279 patients undergoing elective repair for AAA between January 1992 and December 2004 at the Surgical Clinic of the University of Brescia, only the 1111 patients operated before December 2002 were considered. In 990 patients the aneurysm involved the subrenal aorta, and in 121 it extended to the pararenal aorta (juxtarenal aneurysm in 104 cases and suprarenal in 17). Males numbered 1039 and females 72. The average age was 68.8 years (males: 68.5 years; females 72.9 years): 299 aneurysms had a diameter of between 4 and 5 cm, 367 between 5 and 6 cm, 202 between 6 and 7 cm, and 218 over 7 cm, with a median of 5.4 cm (first interquartile range 4.8-6.5 cm).
In the early years of the trial, US imaging was followed by CT or angiography, multislice angio CT was used as a second level examination.
All the patients underwent standard chest X-ray, electrocardiogram with cardiological assessment by a specialist, spirometry, echocolour Doppler of the supraaortic branches, and standard blood tests (haemochrome, serum protein electrophoresis, clotting test, and liver and kidney function). Further cardiological examinations (echocardiograms and coronarography) were conducted in selected cases on specialist indication.
The following pre-operative data (Table I) were considered for each patient:
- sex;
- age;
- chronic obstructive bronchopneumonia (COPD), of a moderate or severe degree, based on spirometric examination according to GOLD (Global initiative for chronic Obstructive Lung Disease) [20] guidelines;
- ischaemic heart disease (coronary artery disease - CAD), medium to high risk based on ECG and cardiological assessment, taking into account cardiovascular anamnesis, risk factors and any complementary instrumental examinations (echocardiogram and echo-stress, stress test, myocardial scintingraphy, coronarography) [21];
- chronic renal failure (CRF), for creatininemia ≥2.0 mg/dl at admission;
- arterial hypertension, even if undergoing pharmacological treatment;
- stenosis of the internal carotid artery (ICA) >70% or thrombosis or previous carotid endarterectomy;
- peripheral chronic arterial disease of the lower limbs (PAD) with Windsor Index ≤.80;
- supra or infra-renal aortic cross-clamping;
- anaesthesiological risk (defined according to the classification by ASA, the American Society of Anaesthesiologists [22-24]).

All the operations were carried out by the same team of surgeons using the same technique (in 98% of cases with transperitoneal approach to the aorta, with extraperitoneal access only in sporadic cases of severe "hostile abdomen"). Subrenal clamping was possible in 990 patients (89.1%); in 121 (10.9%), juxtarenal extension involved suprarenal clamping, submesenteric in virtually all cases and supraceliac in only 3 cases.
Operative outcome (at 30 days) was analysed, taking mortality and morbidity into account.
In order to verify long-term results, the 1081 patients alive 1 month after surgery were included in a follow-up programme (mean 42.3±32.6 months; median 36 months), which involved echocolour Doppler examination 6 months after surgery for the first year and thenceforth once a year; 71 patients (6.6%) were lost after at least 1 month's follow-up.

Statistical Analysis

All the values are expressed as mean ± standard deviation (SD) or as a percentage. The correlation between the preoperative values considered and perioperative mortality was studied by univariate analysis using the χ^2-test followed by multivariate analysis using a logistic regression model. The association between the variables studied and long-term survival was evaluated by performing a univariate analysis on each variable using the log-rank test. Multivariate analysis was then carried out according to the Cox proportional hazard model (PHM), inserting in the model only factors with P<.05 at univariate analysis. A P-value of <.05 was considered statistically significant.
Lastly, a comparison (χ^2-test) was made of groups of patients based on the number (0-5) of risk factors presents, selected from among ones found to be significant in terms of perioperative mortality and long-term survival, in the univariate statistical analysis of our set of cases and in the main published works, in order to obtain a sort of prognostic score for preoperative use.

Results

Analysis of the preoperative data (Table I)
All the pathologies considered in the preoperative analysis (CAD, CRF, COPD, hypertension, ICA stenosis and PAD) were, as expected, significantly more represented in ASA classes III-IV (P<.001) compared to ASA classes I-II. A comparison of these pathologies by sex and age shows that hypertension and COBP are more frequent in males than in females (P<.01); CAD, CRF and

TABLE I – *Patients' preoperative characteristics*

	Hypertension	CAD	CRF	COPD	Pararenal AAA	ICA stenosis	PAD	Diameter >5 cm	ASA I - II	ASA III-IV	Age	Age	Males	Females
TOTAL 1111 patients	603 (54.3%)	375 (33.8%)	95 (8.6%)	428 (38.5%)	121 (10.9%)	85 (7.7%)	275 (24.8%)	611 (55.0%)	324 (29.2%)	787 (70.8%)	532 (47.9%)	246 (22.1%)	1039 (93.5%)	72 (6.5%)
							ASA CLASSES							
ASA I-II 324 (29.2%)	144 (44.4%)	33 (10.2%)	12 (3.7%)	71 (21.9%)	24 (7.4%)	9 (2.8%)	55 (17.0%)	129 (39.8%)	-----	-----	117 (36.1%)	53 (16.3%)	305 (94.1%)	19 (5.9%)
ASA III-IV 787 (70.8%)	459 (58.3%)	342 (43.5%)	83 (10.5%)	357 (45.3%)	97 (12.3%)	76 (9.6%)	220 (27.9%)	482 (61.2%)	-----	-----	415 (52.7%)	193 (24.5%)	734 (93.3%)	53 (6.7%)
P	<.001	<.001	<.001	<.001	<.025	<.001	<.001	<.001	-----	-----	<.001	<.005	n.s.	n.s.
							SEX							
Males 1039 (93.5%)	553 (53.2%)	357 (34.6%)	87 (8.4%)	411 (39.5%)	112 (10.8%)	81 (7.8%)	264 (25.4%)	574 (55.2%)	305 (29.3%)	734 (70.6%)	482 (46.4%)	214 (20.6%)	-----	-----
Females 72 (6.5%)	50 (8.3%)	18 (25.0%)	8 (11.1%)	17 (23.6%)	9 (12.5%)	4 (5.5%)	11 (15.3%)	37 (51.4%)	19 (26.4%)	53 (73.6%)	50 (69.4%)	32 (44.4%)	-----	-----
P	<.01	n.s.	n.s.	<.01	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	<.001	<.001	-----	-----
							AGE GROUPS							
Age <70 yrs 579 (52,1%)	299 (51.6%)	170 (29.4%)	39 (6.7%)	170 (29.4%)	69 (11.9%)	39 (6.7%)	133 (23.0%)	280 (48.3%)	207 (35.7%)	372 (64.2%)	-----	-----	557 (96.2%)	22 (3.8%)
Age ≥70 yrs 532 (47,9%)	304 (57.1%)	205 (38.5%)	56 (10.5%)	258 (48.5%)	52 (9.8%)	46 (8.6%)	142 (26.7%)	331 (62.2%)	117 (22.0%)	415 (78.0%)	-----	-----	482 (90.6%)	50 (9.4%)
P	n.s	<.005	<.025	<.001	n.s	n.s	n.s	<.001	<.001	<.001	—	—	<.001	<.

CAD, coronary artery disease. CRF, chronic renal failure. COPD, chronic obstructing bronchopneumonia. AAA, abdominal aortic aneurysm. ICA, internal carotid artery. PAD, peripheral arteriopathy. ASA, American Society of Anaesthesiologists.

COPD are more frequent in patients aged >70 years (P-values <.005, <.025 and <.001, respectively).

Immediate outcome

The following main perioperative complications (Table II) occurred in the 1111 patients undergoing aortic repair due to abdominal aortic aneurysm:

- cardiac events in 25 patients (2.3% of the 1111 AAAs treated), following AMI in 16 cases and acute cardiac failure in 9, lethal in 14 cases (1.3% of operated subjects);
- pulmonary embolism in 7 patients (0.6%), lethal in 3 (0.3% of operated subjects);
- multiorgan failure (MOF - simultaneous decline in the function of one or more organs) in 9 patients, all of whom died (0.8% of operated subjects);
- ischaemic colitis and abdominal apoplexy in 16 patients (1.4%), with patient decease in 2 cases (0.2% of operated subjects);
- pneumonia and acute respiratory failure in 31 patients (2.8%), with 1 death (0.1% of operated subjects);
- 1 suicide (mortality 0.1%) 8 days after surgery with normal postoperative course;
- 2 patients with CRF commencing definitive dialysis following surgery (0.2%);
- 8 cerebro-vascular incidents (0.7%), with 2 cases of non-lethal ictus (0.2%) and 6 TIA;
- 1 paraplegia (0.1%);
- 1 stress-induced duodenal ulcer (0.1%);
- 2 cases of acute pancreatitis (0.2%).

Mortality

The 30 deaths (2.7%) occurring before the 30th day or in clinical-temporal operative continuity underwent univariate and multivariate statistical analysis.

Univariate analysis (TABLE III)

All deaths occurred in male patients with a high anaesthesiological risk (ASA III-IV); in this subgroup therefore, operative mortality was 3.8% (30/787) vs 0% (0/324) for patients in ASA class I-II (P<.005).

As regards the other risk factors, age and the presence of CAD or PAD were statistically significant. The death rate in the group of 579 patients below the age of 70 years was 1.5%, whereas in the 532 patients aged >70 years it was 3.9% (P<.025); in the over-70 group, the death rate for those aged 70-75 years did not differ significantly (4.1%) compared to the over-75s (2.3%). In the presence of CAD (375 cases), 16 patients died (4.3%), vs 1.9% in patients without previous heart disease (P<.025).

Not even the slight increase in mortality found in patients undergoing suprarenal clamping for pararenal aneurysm (4.1%) compared to those undergoing subrenal clamping (2.5%) achieved statistical significance.
In patients with PAD the death rate was 4.7% (13/275) vs 2.0% (17/836) of those not affected by arteriopathy (P<.025).
Only the presence of arteriopathy and belonging to ASA classes III-IV remain significant risk factors when considering just the 990 subrenal AAAs, i.e. excluding the 121 pararenal AAAs.

Number of simultaneous risk factors
a) When considering risk factors found to be significant upon univariate analysis (excluding the purely clinical and highly subjective factor of ASA III-IV classification: advanced age, PAD, CAD), patients with 0 or 1 risk factor have similar perioperative prognoses, and those with 0 or 1 risk factor have a significantly better prognosis than those with 2 or 3 simultaneously present risk factors. The prognosis for patients with 2 or 3 simultaneous risk factors is the same (Table IV).
b) When considering the risk factors identified most frequently in the literature (advanced age, CAD, COPD, CRF), patients with 0, 1, 2 and 3 risk factors have similar perioperative prognoses, whereas patients with 4 risk factors have a much higher operative risk than all the other groups (Table V).

Multivariate analysis (TABLE VI)
An analysis of the correlations between mortality risk factors shows that only the ASA anaesthesiological risk class is an independent prognostic factor (P<.05), patients belonging to the highest ASA classes showing a relative risk of 2.06.
According to same analysis, the data for PAD are borderline (p slightly over 0.05) with a relative risk of 2.05.
The other preoperative parameters considered are not statistically significant.

Morbidity
Of the 1081 remaining patients, the 73 cases (6.7%) with non-lethal major operative complications were analysed in relation to the ASA classes (Table II): there was a total of 9 cases in the group of 324 patients in ASA classes I-II (2.7% incidence) and 64 cases in the group of 757 patients in ASA classes III-IV (8.5% incidence) (P<.001). More specifically:
in the group of 10 ASA I patients, the only event was one case of pneumonia;
in the group of 314 ASA II patients we observed 8 events (2.5%): 1 acute cardiac failure; 2 cases of ischaemic colitis (1 treated with resection according to Hartmann and 1 medical therapy); 4 pneumonias; 1 ictus;
in the group of 652 ASA III patients we observed 54 events (8.3%): 5 myocardial infarctions and 3 cases of acute cardiac failure; 2 cases of CRF (resulting in terminal uremia requiring haemodialysis); 11 cases of ischaemic colitis (4 undergoing medical treatment and the rest surgery); 19 cases of pneumonia and acute respiratory failure; 4 pulmonary embolisms; 1 stress ulcer; 2 cases of acute pancreatitis; 6 TIA; 1 ictus.
In the group of 105 ASA IV patients we observed 10 events (9.5%): 2 cases of AMI; 1 ischaemic colitis (undergoing surgery); 6 cases of pneumonia and acute respiratory failure; 1 case of paraplegia.
Overall, these events of major morbidity are statistically different in the ASA classes; this is true when considering all events and also when considering each morbidity separately.
Lastly, within a month of surgery, we encountered 3 (0.3%) graft-related complications, which did not lead to death and were successfully treated with one retroperitoneal drainage and serum muscular and omental fasting periprosthetic plastic surgery, 1 branch resection and femoro-femoral cross-over, and 1 retroperitoneal debridement and drainage.

Long-term results
When excluding the 30 operative deaths and the 71 patients lost during follow-up, in the remaining 1010 patients we found 9 cases (0.9%) of graft-related complications: 4 aorto-prosthetic infections (diagnosed and treated at 2, 6, 26 and 44 months, respectively) and 5 non-septic pseudoaneurysms (at 84, 90, 97, 105 and 120 months). Two of these 9 patients died, so long-term graft-related mortality was 2/1010 patients, equal to 0.2%.
In these 1010 patients, we observed a total of 100 long-term deaths (9.9%), occurring after an average survival of 31.1±29.9 months, range 2-108 months (median 33 months). The current duration of mean follow-up of the 910 alive patients is 43.7±31.6 months, range 12-131 months (median 36 months).
Survival calculated according to Kaplan and Meier was 93% at 3 years and 88% at 5 years; in particular, 94% at 3 years and 91% at 5 years for patients aged >70 years, and 92% at 3 years and 84% at 5 years for the over-70s.
Univariate statistical analysis showed that sex, arterial hypertension, obliterating arteriopathy and carotid pathology were not significant risk factors for long-term survival, whereas the rate of survival was significantly lower in patients with high anaesthesiological risk (3- and 5- year survival 91% and 87%, respectively, for ASA classes III-IV vs 98% and 92% for ASA classes I-II) (P<.05), advanced age (3- and 5-year survival 92% and 84%, respectively, for the over-70s vs 94% and 91% in the under-70s) (P<.01), and pararenal lesion (3- and 5-year survival 91% and 77%, respectively, vs 94% and 90% in patients with subrenal aneurysm) (P<.005). COPD (3- and 5-year survival 90% and 80%, respectively, vs 95% and 92%) (P<.001), CAD (3- and 5-year survival 92% and 85%, respectively, vs 94% and 90%)

(P<.05) and CRF (3- and 5-year survival 94% and 89%, respectively, vs 90% and 82%) (P<.05) also determined a significant reduction in long-term survival (Table VII).

Number of simultaneous risk factors

a) When considering risk factors found to be significant upon univariate analysis (excluding the purely clinical and highly subjective factor of ASA III-IV classification: advanced age, CAD, CFR, COPD and pararenal site), patients with 0 and 1, with 1 and 2, and with 3 and 4 risk factors have similar long-term survivals, whereas long-term prognosis is significantly different for all the other comparisons (the result of comparisons with the small group with 5 risk factors is unreliable) (Table VIII).

b) When considering the risk factors identified most frequently in the literature (advanced age, CAD, COPD, CRF), comparisons between the groups with 0 and 1 risk factor, the groups with 2 and 3 risk factors, the groups with 2 and 4 risk factors, and the groups with 3 and 4 risk factors showed similar long-term survival, whereas all the other survival comparisons were statistically different (Table IX).

Multivariate analysis (TABLE X)

Of the parameters positive at univariate analysis, only advanced age, positive anamnesis for COPD and suprarenal clamping are the independent variables that have a significant influence on long-term survival.

Discussion

Indication for elective surgery for abdominal aortic aneurysms derives from an evaluation of the ratio of risks resulting from persistence of the lesion to those associated with surgery. When an aneurysm is judged to be at imminent risk of rupture, the problem is easier to solve [1-3], but a more careful and more critical assessment is required when the lesion is apparently stable.

When performed electively and at a clinical centre with specific experience, AAA laparotomy has an overall mortality of less than 5% [25-34]. The reasoning behind surgical indication should therefore be based on factors that characterise categories of patients at greater or lesser specific risk for this type of intervention. Due to the low number of deaths, it is difficult to make an objective assessment of such risk factors. Univocal opinions do not emerge from the literature since different factors prevail in each experience. Some authors attribute to coronaropathy, chronic obstructive bronchopneumonia and chronic renal failure independent predictive significance [29,30,35-37], others attribute this role to coronaropathy alone [8,38], or chronic renal failure alone [39] or chronic obstructive bronchopneumonia alone [40,41], and it can be deduced from other studies that the results are not influenced not so much by preoperative risk factors as by the quality of care and patient monitoring in the perioperative period [42]. Even more discordant is the assessment of age as a risk factor [26,27,29,36,43-49].

These considerations are only partly confirmed by an analysis of the data concerning the 1111 patients we operated on consecutively in the last 10 years. In our experience, when assessed individually, many of the operative risk factors considered – sex (although no female patient died within 30 days of surgery), COPD, hypertension, CRF, obstructive carotid pathology, suprarenal clamping, diameter of the aneurysm – do not determine operative mortality. Univariate analysis also highlights the significance of the parameters of age, intended both as a continuous variable and as a class of advanced age (3.9% mortality >70 years vs 1.5% <70 years), ischaemic cardiopathy (4.3% mortality vs 1.9% in patients without CAD), peripheral arteriopathy (4.7% vs 2.0%) and belonging to ASA classes III-IV (3.8% mortality vs 0% in patients in ASA classes I-II). Only the last factor continues to be significant when subjected to rigorous multivariate analysis, the relative risk being 2.06. Returning to univariate analysis, it is interesting to note that only the presence of peripheral arteriopathy and advanced ASA class remains significant when considering only the 990 AAAs treated with subrenal clamping. Therefore, when comparing these findings with other published results, our experience only partially confirms that greater specific risk is associated with advanced age, CAD and peripheral arteriopathy, whereas the absence of operative mortality among the 72 female patients is in contrast with several authors' observations of a specific operative risk associated with female sex [50]. Nor can we confirm most authors' findings regarding the significance of the risk factors CRF, COPD and obstructive carotid pathology. Overall, therefore, our data show that the only factor of a definite significance in influencing operative mortality is belonging to ASA classes III-IV (3.8% vs 0% in ASA classes I-II); this is the parameter most commonly quoted by the other authors as well [43-48].

The contemporary presence of several preoperative risk factors appears to have a negative effect on operative mortality, the highest risk being associated with at least 3 of those shown by our univariate analysis or in the literature to be the most significant (Tables IV and V).

As far as morbidity is concerned, which we only assessed in connection with major non-lethal operative complications, published opinions are discordant; in particular, several authors [50,51] report that the parameters that influence morbidity more significantly are ischaemic cardiopathy, chronic obstructive bronchopneumonia and chronic renal failure, as well as advanced age and cigarette smoking. Our findings are in disagreement with this – none of the major non-lethal operative complications considered (CRF, myocardial infarction, ischaemic colitis, pneumonia, pulmonary embolism) were observed with a statistically higher incidence in patients presenting these preoperative risk factors.

As regards long-term results, in our experience graft-relat-

TABLE II – *Total perioperative complications (within 30 days) according to ASA classes.*

	TOTAL (Morbidity + Mortality) 103/1111 (9.3%)	DEATHS 30/1111 (2.7%)	ASA III 27/679 (3,9%)	ASA IV 3/108 (2,7%)	MORBIDITY 73/1081 (6.7%)	ASA I-II 9/324 (2.8%)	ASA III-IV 64/757 (8.5%)
Myocardial infarction and cardiac failure	5 (2.3%)	14 (1.3%)	12	2	11 (1.0%)	1	10
Pulmonary embolism	7 (0.6%)	3 (0.3%)	3	0	4 (0.4%)	0	4
MOF	9 (0.8%)	9 (0.8%)	8	1	0	0	0
Ischaemic colitis and bowel infarction	16 (1.4%)	2 (0.2%)	2	0	14 (1.3%)	2	12
Pneumonia and Respiratory failure	31 (2.8%)	1 (0.1%)	1	0	30 (2.7%)	5	25
Suicide	1 (0.1%)	1 (0.1%)	1	0	/	/	/
Definitive dialysis	2 (0.2%)	0	0	0	2 (0.2%)	0	2
TIA	6 (0.5%)	0	0	0	6 (0.5%)	0	6
Ictus	2 (0.2%)	0	0	0	2 (0.2%)	1	1
Paraplegia	1 (0.1%)	0	0	0	1 (0.1%)	0	1
Perforated peptic ulcer	1 (0.1%)	0	0	0	1 (0.1%)	0	1
Acute pancreatitis	2 (0.2%)	0	0	0	2 (0.2%)	0	2

MOF, multi-organ failure. TIA, transient ischaemic attack. ASA, American Society of Anesthesiologist

ed deaths (0.2%) were highly sporadic, confirming the reliability of the prosthesis and the method of open repair of the subrenal aorta, while not ignoring the possible bias, as in all retrospective trials, of the number of patients lost to follow-up, equal in our case to 71/1081 patients alive at 30 days (6.6%).

The other findings of our study are in line with those of the majority of published works [51-52]: following the operative stage, the chances of long-term survival are high both overall (93% and 88% at 3 and 5 years) and in patients of advanced age (92% at 3 years and 84% at 5 years for age >70 years).

It would therefore appear correct to conclude that the life expectancy of patients successfully undergoing aortic repair is virtually the same as for the general population (in Italy, according to the latest ISTAT figures for 2002[53], a person aged sixty-five years can expect to live a further 16.8 years if male and 20.8 years if female). Despite the different life expectancy for the two sexes in the general population, the long-term findings for our operated patients do not present statistically significant differences, survival being 93% and 88% at 3 and 5 years for males, and 95% and 91% at 3 and 5 years for females.

Our study shows that, besides advanced age, ASA classes III-IV, COPD, CAD, CRF and pararenal site of the aortic lesion (Table VII) are variables negatively influencing long-term survival, but multivariate analysis shows that age, COPD and site of the lesion (Table X) are the only independent factors of significance. Since the upper limit of EVAR is still uncertain as to the duration of the endoprosthesis, which can therefore be considered a more rational indication in the class of patients with shorter life expectancy [23,28], it would be particularly interesting to identify suitable parameters for dividing patients with aortic aneurysms into classes with different durations of life expectancy. It should be pointed out that patients in the less favourable classes from this point of view still survive for many years after surgery, and hence the concept of "shorter life expectancy" must be considered critically. Lastly, it should not be forgotten that the periodic instrumental examinations (angio-TC or NMR) required after EVAR to identify the 10-25% of endoprostheses requiring endovascular or open repair call for patient compliance that is often lacking, particularly in the elderly, particularly when affected by comorbidities.

TABLE III – *Perioperative mortality: univariate analysis.*

	Alive N = 1081	Deaths N = 30	Total N = 1111	Test Statistic	
Age	64.00 **69.00** 74.00 (68.77±7.40)	68.00 **72.50** 75.00 (71.50±7.03)	64.00 69.00 74.00 (68.84±7.40)	$F_{1,1109}$ = 4.61, P = .032[1]	SIGNIFICANT
CAD				= 5.29, P = .0215[2]	
NO	67% (722)	47% (14)	66% (736)		
YES	33% (359)	53% (16)	44% (375)		
PAD				χ^2 = 5.72, P = .0168[2]	
NO	76% (819)	57% (17)	75% (836)		
YES	24% (262)	43% (13)	25% (275)		
ASA				χ^2 = 13.2, P = .00422[2]	
1	1% (10)	0% (0)	1% (10)		
2	29% (314)	0% (0)	28% (314)		
3	60% (652)	90% (27)	61% (679)		
4	10% (105)	10% (3)	10% (108)		
Diameter of the lesion	4.70 **5.40** 6.30 (5.70 ± 1.46)	5.00 **5.55** 7.00 (5.76 ± 1.24)	4.70 **5.40** 6.40 (5.70 ± 1.46)	$F_{1,1109}$ = 4.61, P = .032[1]	
Sex				χ^2 = 2.14, P = .144[2]	NOT SIGNIFICANT
F	7% (72)	0% (0)	6% (72)		
M	93% (1009)	100% (30)	94% (1039)		
COPD				χ^2 = 0.86, P = .353[2]	
NO	62% (667)	53% (16)	61% (683)		
YES	38% (414)	47% (14)	39% (428)		
CRF				χ^2 = 2.6, P = .107[2]	
NO	92% (991)	83% (25)	91% (1016)		
YES	8% (90)	17% (5)	9% (95)		
Hypertension				χ^2 = 0.23, P = .634[2]	
NO	46% (493)	50% (15)	46% (508)		
YES	54% (588)	50% (15)	54% (603)		
Dyslipidemia				χ^2 = 0.21, P = .644[2]	
NO	87% (942)	90% (27)	87% (969)		
YES	13% (139)	10% (3)	13% (142)		
ICA				χ^2 = 0.81, P = .367[2]	
NO	92% (997)	97% (29)	92% (1026)		
YES	8% (84)	3% (1)	8% (85)		
Site of the lesion				χ^2 = 1.29, P = .525[2]	
juxtarenal	9% (100)	13% (4)	9% (104)		
subrenal	89% (965)	83% (24)	89% (990)		
suprarenal	1% (16)	3% (1)	2% (17)		

Legend: COPD, chronic obstructive bronchopneumonia; CAD coronary artery disease; CRF, chronic renal failure; PAD, peripheral arteriopathy; ICA, Internal carotid artery; ASA, American Society of Anaesthesiologists; χ^2, chi-square; Tests used: 1 Wilcoxon test, 2 Pearson test; F, Fischer-Snedecor's variable.

Conclusions

1) Elective laparotomy for AAA is characterised by a low incidence of operative complications and low mortality rate in the short term, and by longer life expectancy.
2) Sex, diameter of the lesion, CRF, COPD, arterial hypertension, obstructive carotid pathology, and supra or subrenal clamping are not specific risk factors for operative mortality; only at univariate analysis and only when considering together aneurysms treated with subrenal and suprarenal clamping, advanced age, CAD and peripheral arteriopathy are significant risk factors; at multivariate analysis, only belonging to ASA classes III-IV is significant.
3) Long-term survival calculated on the whole group of operated patients is virtually the same as in the general population; age, COPD and pararenal extension of the aneurysm have a significant influence on life expectan-

TABLE IV – *Statistical significance of the presence of a different number of risk factors (selected from those significant at univariate analysis, but excluding the ASA parameter) in each patient for OPERATIVE MORTALITY.*

1111 AAA divided into no. of perioperative risk factors significant at univariate analysis (excluding ASA classification)		
Age, PAD, CAD		
	No.	Deaths
0 factors	314	4
1 factor	472	8
2 factors	265	12
3 factors	60	6

Statistical comparison		
No. of risk factors	**%**	**P**
0 vs 1	1.3 vs 1.7	ns
0 vs 2	1.3 vs 4.5	<.025
0 vs 3	1.3 vs 10.0	<.001
1 vs 2	1.7 vs 4.5	<.025
1 vs 3	1.7 vs 10.0	<.001
2 vs 3	4.5 vs 10.0	ns
0 vs 1+2+3	1.3 vs 3.3	ns
0+1 vs 2+3	1.5 vs 5.5	<.001
0+1+2 vs 3	2.3 vs 10.0	<.001

Legend: ASA: American Society of Anaesthesiologists; CAD, coronary artery disease. PAD, peripheral arteriopathy.

TABLE V – *Statistical significance of the presence of a different number of risk factors (selected from among those most frequently identified in the literature) in each patient for OPERATIVE MORTALITY in our set of cases.*

1111 AAA divided into no. of perioperative risk factors most frequent in the literature		
Age, CAD, COPD, CRF		
	No.	Deaths
0 factors	274	5
1 factor	400	6
2 factors	301	11
3 factors	116	4
4 factors	20	4

Statistical comparison		
No. of risk factors	**%**	**P**
0 vs 1	1.8 vs 1.5	ns
0 vs 2	1.8 vs 3.7	ns
0 vs 3	1.8 vs 3.5	ns
0 vs 4	1.8 vs 20.0	<.001
1 vs 2	1.5 vs 3.7	ns
1 vs 3	1.5 vs 3.5	ns
1 vs 4	1.5 vs 20.0	<.001
2 vs 3	3.7 vs 3.5	ns
2 vs 4	3.7 vs 20.0	<.001
3 vs 4	3.5 vs 20.0	<.005
0 vs 1+2+3+4	1.8 vs 3.0	ns
0+1 vs 2+3+4	1.6 vs 4.3	<.01
0+1+2 vs 3+4	2.3 vs 5.9	<.025
0+1+2+3 vs 4	2.4 vs 20.0	<.001

Legend: CAD, coronary artery disease; COPD, chronic obstructive bronchopneumonia; CRF, chronic renal failure.

TABLE VI – *Perioperative mortality: multivariate analysis*

	Estimate	**Std. Error**	**Z value**	**Pr(> | z |)**
(Intercept)	–8.9551	2.1063	–4.25	.0000212
PAD	0.7164	0.3807	1.88	.0598705
ASA	0.7244	0.3245	2.23	.0256103
AGE	0.0427	0.0275	1.55	.1205978

Legend: ASA: American Society if Anaesthesiologists; PAD: peripheral arteriopathy

TABLE VII – *Long-term survival: univariate analysis.*

	Survival at 3 yrs	Survival at 5 yrs	Log Rank (Mantel Cox) Chi-Square	P
ASA				
I-II	98.1%	91.8%	6.057	.014
III-IV	91.3%	86.6%		
AGE				
< 70 yrs	94.1%	91.4%	7.369	.006
≥ 70 yrs	92.1%	83.5%		
SITE OF LESION				
Subrenal	93.6%	89.5%	11.178	.001
Pararenal	90.8%	77.0%		
COPD				
YES	90.1%	80.5%	18.167	.000
NO	94.9%	92.3%		
CAD				
YES	91.7%	84.7%	4.406	.036
NO	94.1%	89.7%		
CRF				
YES	90.6%	81.4%	4.236	.040
NO	93.5%	88.9%		
SEX				
M	93.1%	88.0%	0.082	.775
F	95.2%	90.9%		
HYPERTENSION				
YES	93.9%	89.7%	2.566	.109
NO	92.5%	86.4%		
DYSLIPIDEMIA				
YES	96.3%	93.2%	2.162	.141
NO	92.8%	87.3%		
ICA STENOSIS				
YES	88.2%	85.3%	1.023	.312
NO	93.7%	88.4%		
PAD				
YES	93.2%	88.1%	0.053	.817
NO	93.3%	88.2%		

Legend: COPD, chronic obstructive bronchopneumonia. CAD coronary artery disease. CRF, chronic renal failure. PAD, peripheral arteriopathy. ICA, internal carotid artery. ASA, American Society of Anaesthesiologists.

cy; ASA, CAD and CRF are only significant at univariate analysis.

4) Late graft-related complications are very rare.

5) The association of 3 or more risk factors from among those found to be significant in our study or in the literature negatively influences short- and long-term prognosis.

Our findings show that in patients undergoing open aortic repair operative mortality is low and post-operative survival is long term, even in the presence of risk factors significantly affecting the results. These factors can be used to identify categories of patients in which it is correct to consider alternative therapies that have shown or are expected to show even better results for the patients concerned.

TABLE VIII – *Statistical significance of the presence of a different number of risk factors (already significant at univariate analysis, but excluding the ASA parameter), simultaneously present in each patient: LONG-TERM SURVIVAL, excluding the 30 perioperative deaths and the 71 lost to follow-up.*

1010 AAA divided into no. of risk factors significant at univariate analysis for long-term survival (excluding ASA classification)

Age, Site, COPD, CAD, CRF (univariate analysis without ASA)

No. of risk factors	at 3 yrs	at 5 yrs	P
0 vs 1	96% vs 96%	94% vs 93%	Ns
0 vs 2	96% vs 89%	94% vs 83%	<.005
0 vs 3	96% vs 89%	94% vs 76%	<.001
0 vs 4	96% vs 84%	94% vs 58%	<.001
0 vs 5	96% vs 100%	94% vs 100%	ns
1 vs 2	96% vs 89%	93% vs 83%	<.01
1 vs 3	96% vs 89%	93% vs 76%	<.001
1 vs 4	96% vs 84%	93% vs 58%	<.001
1 vs 5	96% vs 100%	93% vs 100%	ns
2 vs 3	89% vs 89%	83% vs 76%	ns
2 vs 4	89% vs 84%	83% vs 58%	<.025
2 vs 5	89% vs 100%	83% vs 100%	ns
3 vs 4	89% vs 84%	76% vs 58%	ns
3 vs 5	89% vs 100%	76% vs 100%	ns
4 vs 5	84% vs 100%	58% vs 100%	ns
0 vs 1+2+3+4+5	96% vs 92%	94% vs 86%	<.005
0+1 vs 2+3+4+5	96% vs 89%	94% vs 80%	<.001
0+1+2 vs 3+4+5	94% vs 90%	90% vs 73%	<.001
0+1+2+3 vs 4+5	93% vs 85%	89% vs 62%	<.001
0+1+2+3+4 vs 5	93% vs 100%	88% vs 100%	ns

Legend: ASA, American Society of Anaesthesiologists;
COPD, chronic obstructive bronchopneumonia;
CAD, coronary artery disease. CRF, chronic renal failure.

TABLE X – *Long-term survival: multivariate analysis.*

	coeff	exp (coeff)	se (coeff)	Z	P
COPD	0.457	1.579	0.185	2.47	.014
CAD	0.293	1.341	0.189	1.56	.120
CRF	0.387	1.472	0.257	1.50	.130
Infrarenal lesion	-0.523	0.593	0.261	-2.01	.045
Age	0.032	1.032	0.013	2.41	.016
ASA	0.220	1.246	0.163	1.35	.180

Legend: COPD, chronic obstructive bronchopneumonia;
CAD, coronary artery disease;
CRF, chronic renal failure;
ASA, American Society of Anaesthesiologists.

TABLE IX – *Statistical significance of the presence of a different number of risk factors (considering the risk factors most frequently identified in the literature) simultaneously present in each patient: LONG-TERM SURVIVAL, excluding the 30 perioperative deaths and the 71 lost to follow-up.*

1010 AAA divided into no. of risk factors most frequently identified in the literature (excluding ASA classification)

Age, CAD, COPD, CRF (literature factors)

No. of risk factors	at 3 yrs	at 5 yrs	P
0 vs 1	96% vs 95%	94% vs 91%	ns
0 vs 2	96% vs 89%	94% vs 84%	<.001
0 vs 3	96% vs 89%	94% vs 76%	<.001
0 vs 4	96% vs 89%	94% vs 65%	<.005
1 vs 2	95% vs 89%	91% vs 84%	<.01
1 vs 3	95% vs 89%	91% vs 76%	<.005
1 vs 4	95% vs 89%	91% vs 65%	<.01
2 vs 3	89% vs 89%	84% vs 76%	ns
2 vs 4	89% vs 89%	84% vs 65%	ns
3 vs 4	89% vs 89%	76% vs 65%	ns
0 vs 1+2+3+4	96% vs 92%	94% vs 86%	<.005
0+1 vs 2+3+4	95% vs 89%	92% vs 81%	<.001
0+1+2 vs 3+4	94% vs 90%	90% vs 73%	<.005
0+1+2+3 vs 4	93% vs 89%	89% vs 65%	<.05

Legend: ASA, American Society of Anaesthesiologists;
COPD, chronic obstructive bronchopneumonia;
CRF, chronic renal failure.

Riassunto

La casistica relativa a 1111 aneurismi dell'aorta addominale, trattati consecutivamente mediante tecnica chirurgica open in elezione e seguiti con follow-up sistematico per oltre un decennio, è stata analizzata con metodica statistica univariata (χ^2 -test e Log-rank test) e multivariata (Modello di regressione logistica e Cox proportional-hazard model), allo scopo di identificare i fattori di rischio che incidono sui risultati operatori e sulla sopravvivenza a medio ed a lungo termine.
Relativamente alla mortalità operatoria, pari al 2.7%, questi sono i risultati:
– Analisi univariata: *significatività* per età, intesa sia come variabile continuativa, sia come classe d'età avanzata (≥70 aa mortalità del 3,9% vs. 1.5% in pazienti di età <70aa.), CAD (mortalità del 4.3% vs. 1.9% in pazienti senza CAD), presenza di arteriopatia periferica (4,7% vs 2,0%), classi di rischio ASA III-IV (mortalità del 3.8% vs. 0% in pazienti di classi ASA 1-11); *non significatività* per sesso, BPCO, ipertensione, IRC, patologia ostruttiva carotidea, clampaggio sovrarenale, diametro della lesione aortica;

– Analisi multivariata: *significatività* per le classi ASA 111-1V, valori di significatività borderline per l'arteriopatia periferica.
Ad un follow-up medio di 42.3 ± 32.6 mesi la sopravvivenza a lungo termine secondo Kaplan-Meier è risultata complessivamente pari al 93% a 3 anni e all'88% a 5 anni. 1 decessi graft-related sono stati 2 (0.2%).
Secondo l'analisi univariata i fattori condizionanti la sopravvivenza sono stati:
– l'età avanzata (sopravvivenza a 3 e 5 anni del 92% e 84% per i pazienti di età ≥70 anni, vs. 94% ed 91% in pazienti di età <70 anni);
– il rischio anestesiologico elevato (sopravvivenza a 3 e 5 anni rispettivamente del 91 % e 87% in ASA III-IV, vs. 98% e 92% in ASA I-II);
– la presenza di CAD (sopravvivenza a 3 e 5 anni rispettivamente del 92% e dell'85% vs. 94% e 90%), di BPCO (sopravvivenza a 3 e 5 anni rispettivamente del 90% e dell'80%, vs. 95% e 92%), di IRC (sopravvivenza a 3 e 5 anni rispettivamente del 90% e dell'82%, vs. 94% e 89%);
– il clampaggio aortico sovrarenale (sopravvivenza a 3 e 5 anni rispettivamente del 91% e 77%, vs. 94% e dell'90% se il clampaggio era sottorenale).
All'analisi multivariata solo l'età, l'ASA e la sede della lesione hanno inciso sulla sopravvivenza a distanza. Si è riscontrata una stretta correlazione tra il numero (da 0 a 5) dei fattori di rischio presenti in ogni paziente e le complicanze precoci ed a distanza.
Questi dati risultano complessivamente molto soddisfacenti, anche nei pazienti ad alto rischio che sono di routine considerati per l'EVAR.

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