

Current Hospital Mortality of Aortic Valve Replacement in Octogenarians

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Background and aim of the study: The increasing incidence of cardiovascular disease with age, coupled to a constant extension of life expectancy in industrialized countries, is leading to an ever-increasing number of elderly patients being referred for aortic valve replacement (AVR). In light of advances in surgical technology and cardiac protection, the operative mortality and risk factors have been updated in order to specify surgical indications. **Methods:** Between January 2000 and December 2004, a total of 442 patients (203 males, 239 females) aged ≥ 80 years (mean age 82.7 ± 2.3 years) underwent AVR at the authors' institution. Surgery was either isolated ($n = 344$) or associated with coronary revascularization ($n = 86$), mitral valvuloplasty ($n = 5$) or aortic surgery ($n = 7$). Seventeen patients had undergone previous cardiac surgery. The EuroScore was calculated for each patient.

Results: Overall operative mortality was 7.5% ($n = 33$). Independent predictive factors of mortality were:

The increasing incidence of aortic stenosis with age (1), coupled to a constant extension of life expectancy in industrialized countries (2), is today leading to the referral of large numbers of octogenarian patients for aortic valve surgery. Although the surgical risk is known to increase in higher-age groups (3), many authors have reported that aortic valve replacement (AVR) could be realized in advanced-age patients with an acceptable mortality, provided that the stenosis is tight and symptomatic (4-7). Associated diseases such as diabetes mellitus, respiratory or renal insufficiency - the incidences of which increase also with age - may

aortic insufficiency (30%, $p < 0.004$), NYHA class IV (20.5%, $p < 0.001$), left and right heart failure (11.5% and 19.4%, $p < 0.02$), chronic renal insufficiency (18.5%, $p < 0.04$), emergency (37.5%, $p < 0.001$, OR = 4.7), left ventricular ejection fraction (21.1%, $p < 0.004$, OR = 0.9), and redo surgery (35.3%, $p < 0.001$, OR = 6). Mortality was also increased in case of associated coronary revascularization (11.6%), mitral or tricuspid surgery (20%) and ascending aorta procedure (25%).

Conclusion: Patient functional improvement achieved after valve replacement at the cost of a rather low operative mortality justifies considering octogenarians for surgery. However, decisions should be taken on an individual basis. An earlier referral to surgery before the onset of altered cardiac function could lead to further reductions in hospital mortality.

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have a deleterious effect on the operative risk. In the same way, the association of coronary artery lesions and need for revascularization are generally recognized as worsening the postoperative outcome (8).

In light of advances in surgical technology and cardiac protection, the present authors have analyzed their experience of the past five years (2000-2004) in order to update operative mortality and risk factors. The aim was to identify high-risk patients for whom surgery would be highly questionable, and to specify surgical indications.

Clinical material and methods

Patients

Between 1st January 2000 and 31st December 2004, a total of 442 consecutive patients aged ≥ 80 years (mean age 82.7 ± 2.3 years; 62 (14%) aged > 85 years) underwent AVR at the authors' institution, and were included in the present study (Fig. 1). These octogenarians represented 16% of the 2,760 patients operated for AVR

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at the author's center during this five-year period.

Preoperative characteristics

The clinical data are listed in Tables I and II. Nine asymptomatic patients (2%) underwent AVR prior to other major surgery (e.g., hip replacement) because they were considered at high risk due to their tight aortic valve stenosis. Sixteen patients (3.6%) were operated on as emergencies. No patients were excluded from the study. Associated extracardiac diseases were identified in 244 patients (55.2%), including carotid stenosis (n = 66) with cerebrovascular event (n = 15) or neurological deficit (n = 10), peripheral vascular arteriopathy (n = 40), respiratory insufficiency (n = 71), renal insufficiency (clearance <40 ml/min; n = 27) and past history of treated cancer considered as cured (n = 33). A total of 309 patients (70%) had at least one risk factor for atherosclerosis (e.g., systemic arterial hypertension). The prevalence of diabetes among patients (6.3%) was considered normal for the French population of this age group, though a referral bias cannot be excluded as patients with major complications typically do not attain the age of 80 years (which exceeds expectancy) or

Table I: Preoperative clinical data in octogenarians (n = 442).

Parameter	No. of patients
Age (years)*	82.7 ± 2.3 (80-90.7)
Gender	
Male	203 (46)
Female	239 (54)
Aortic stenosis	386 (87.3)
Aortic insufficiency	10 (2.3)
Aortic stenosis + insufficiency	46 (10.4)
Systemic arterial hypertension	240 (55)
Diabetes	28 (6.3)
Associated diseases	244 (55)
Respiratory insufficiency	71 (16)
Renal insufficiency	27 (6)
Previous myocardial infarction	18 (4)
NYHA class	
I	9 (2)
II	228 (52)
III	156 (35)
IV	49 (11)
Dyspnea (on exertion, at rest)	358-70 (81-15.8)
Angina pectoris (on exertion, at rest)	157-29 (35.5-6.6)
Syncope	61 (13.8)
Left heart failure	122 (27.6)
Right heart failure	31 (7)
Emergency surgery	16 (3.6)
Previous surgical history*	17 (3.8)

Values in parentheses are percentages.

*Values are mean ±SD (range).

†Coronary (n = 8); valvular (n = 9).

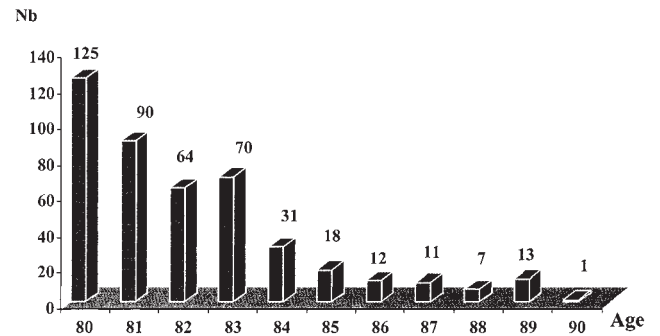


Figure 1: The age distribution of patients (n = 442).

are not considered for open-heart surgery.

Seventeen patients had a past history of cardiac surgery; these included eight coronary revascularizations, one mitral valve replacement, and eight AVRs. The reasons for redo AVR were infective endocarditis (n = 1), major paravalvular leak (n = 1) and structural valve deterioration (n = 6), which occurred at a mean of 14 ± 2 years (range: 12 to 17.5 years) after the first implantation. Coronary arteriography was found to be normal in 333 patients (75.5%), while 109 patients (24.5%) had associated coronary artery disease (CAD), with single-vessel disease in 54 patients, double-vessel disease in 30, and triple-vessel disease in 25.

Surgical data

A bioprosthesis was implanted in all patients but three (who each received a mechanical valve by personal

Table II: Preoperative investigations.

Parameter	No. of patients
Cardiothoracic ratio*	0.54 ± 0.05
ECG sinus rhythm	368 (84)
Atrial fibrillation	52 (12)
Conduction disturbances	15 (3.4)
Pacemaker	17 (3.8)
Echocardiography	
LVEF ejection fraction (%)*	59 ± 12 (24-88)
LVEF <40%	38 (8.5)
Aortic area (cm ²)*	0.59 ± 0.15
Maximum gradient (mmHg)*	81.3 ± 21.8
Mean gradient (mmHg)*	51.1 ± 14.8
Coronary lesions	109 (24.5)
Left main coronary	21
Left anterior descending	87
Marginal branch	29
Distal circumflex	67
Right coronary artery	58

Values in parentheses are percentages.

*Values are mean ±SD (range).

LVEF: Left ventricular ejection fraction.

request). In total, 141 patients (31.9%) received a 21-mm valve and 168 (38%) a 23-mm valve. Cardiopulmonary bypass (CPB) was achieved using moderate hypothermia (nasopharyngeal temperature 32°C). Cold crystalloid cardioplegia was used for myocardial protection in most patients (n = 400; 91%), generally administered via an aortic access and associated with local hypothermia with crushed ice. Cardiac arrest and protection was achieved with warm blood perfusion in 42 patients (9%). The mean CPB time was 66 ± 25 min, and the mean aortic cross-clamp time 50.7 ± 19.6 min.

Hemodynamic recovery was excellent (requiring no inotropic support in either the operating room or during the postoperative course) in 376 patients (85%), but was moderate or poor in 66 (15%), requiring inotropic support before weaning from CPB or subsequent intensive care unit stay (Table III).

Among patients, aortic stenosis was the main indication for surgery (n = 432), associated with a significant insufficiency in 46 cases (10.4%). Degenerative aortic stenosis was the most prominent lesion (n = 400; 91%), bicuspid valve was found in 16 patients (3.6%) and rheumatic sequelae in seven (1.6%). Surgical indication was isolated aortic insufficiency in only 10 patients (2.3%), due mainly to infective endocarditis (n = 5) as well as aortic dilatation (n = 1) or post-traumatic (n = 1). Concomitant surgery was performed in 98 patients (22%) (Table III). A total of 86 patients (19.4%) underwent associated coronary artery bypass grafting (CABG) (63 patients received one graft, 20 received two grafts, and three received three grafts).

Table III: Surgical data.

Parameter	No. of patients
CPB time (min)*	66 ± 25 (26-197)
Aortic cross-clamp time (min)*	50.7 ± 19.6 (21-129)
Defibrillation	
Spontaneous	167 (38)
One shock	200 (45)
Several shocks	75 (17)
Hemodynamic recovery	
Excellent	362 (85)
Average or poor	65 (15)
Associated surgery	98 (22)
Coronary revascularization	86
Left ventricular myotomy	2
Mitral valvuloplasty	4
Ascending aorta	7
Tricuspid valvuloplasty	1

Values in parentheses are percentages.

*Values are mean ±SD (range).

CPB: Cardiopulmonary bypass

Data analysis

Clinical data and all investigation reports (hemodynamic, radiological and echocardiographic studies, surgical and postoperative records) were entered prospectively into a computerized database and regularly updated according to a prospective protocol. Causes of death were established by chart review; autopsies were not performed routinely due to legal regulations. Data analyses were conducted using SPSS 12.5 software. Qualitative variables were expressed as a percentage and compared using the chi-square test and Fisher's Exact test. Continuous data were expressed as mean ± SD and compared using ANOVA or a non-parametric Kruskal-Wallis test. All variables were first tested individually by univariate analysis and evaluated as statistically significant when the p-value was <0.05. To evaluate independent factors of predictive mortality, all variables with p <0.1 in univariate analysis were submitted to multivariate analysis and entered in a step-by-step ascending and descending logistic regression analysis (Wald's test). The goodness of-fit was determined with the Hosmer-Lemeshow test. Confirmation was also sought that there was no interaction between parameters. The additive EuroScore and the Logistic EuroScore were calculated for each patient (9).

Results

The overall hospital mortality (<30 days) was 7.5% (n = 33). Causes of death are detailed in Table IV. Cardiac causes were predominant (n = 17; 51.5%) including peroperative myocardial damage with or without myocardial infarction (n = 12), low cardiac output (n = 2), tamponades (n = 2) and ventricular dysrhythmia (n

Table IV: Surgical mortality of patients (n = 33; 7.5%).

Cause of death	No. of patients
Cardiac	17 (51.5)
Myocardial damage ± MI	12 (36)
Low cardiac output	2 (6)
Tamponade	2 (6)
Ventricular arrhythmias	1 (3)
Valve-related	1 (3)
Hemorrhage: surgical technique	1 (3)
Miscellaneous	15 (45.5)
Mesenteric infarction	7 (21)
Infection	3 (9)
Multi-organ failure	3 (9)
Renal insufficiency	1 (3)
Anaphylactic shock	1 (3)

Values in parentheses are percentages.

MI: Myocardial infarction.

= 1). Mesenteric infarction was the second leading cause of death (n = 7; 21%). Four of these patients had an associated coronary disease and one a peripheral vascular disease, but none displayed chronic mesenteric ischemic symptoms. Only two of these patients presented postoperatively with a low cardiac output requiring the use of inotropic drugs (i.e., dobutamine (5-20 µg/kg/min) and norepinephrine (100-500 µg/min)), that may have reduced mesenteric blood flow and unbalanced a mesenteric arteritis that had until then remained quiescent. One patient died from rupture of an aortic annulus; repair of this was unsuccessful despite repeated attempts, due mainly to typical tissue fragility associated with elderly patients.

Factors determining surgical mortality

Although 30 preoperative, peroperative and postoperative parameters were considered for statistical analysis, only 10 were found to be significant, though increasing surgical mortality might be observed with regard to some variables, including chronic obstructive pulmonary disease (11.3%). Those variables found to be significant either in univariate or in multivariate analysis are listed in Table V. Age has been identified previously as highly significant (6), with surgical mortality increasing from 2.2% to 12.4% depending on the age subgroup. In the present series mean age appeared to be significantly higher (p <0.05) in the group of deceased patients (83.4 ± 2.3 versus 82.7 ± 2.3 years). No difference was found according to gender. Univariate analysis confirmed the role of NYHA functional class IV (p <0.001), left heart failure (p <0.05),

right heart failure (p <0.02), cardiothoracic ratio (p <0.04) and renal insufficiency (p <0.04). Regurgitation associated with the stenosis has a pejorative impact on mortality (15.8%, p <0.005) which reached 30% in case of isolated aortic insufficiency (n = 10). The requirements for emergency and redo surgery were found to be significant both by univariate and multivariate analysis, with odds ratios (OR) respectively of 4.7 and 6. The left ventricular ejection fraction (LVEF) was a highly significant factor both in univariate and multivariate analyses (p <0.0008), with an OR of 0.9 (i.e., for each added unit of ejection fraction, the risk of mortality was multiplied by 0.9). The LVEF was 52.2 ± 14.2% among non-survivors, compared to 59.4 ± 11.6% among operative survivors. Operative mortality was 42.9% when the LVEF was <30%, 14.5% when LVEF was 30-50%, and 5.6% when LVEF was >50%.

An associated coronary disease was not found to be a prognostic factor (p <0.2), though surgical mortality increased according to the number of vessels involved: mortality was 6.6% among those with no lesion (n = 333), 9.3% in those with single-vessel disease (n = 54), 10% in those with double-vessel disease (n = 30), and 12% in those with triple-vessel disease (n = 25). Likewise, associated CABG was not statistically significant, though operative mortality was increased to 11.6% versus 6.5% in isolated valve replacement.

Associated mitral valve or ascending aorta surgery was responsible for a large increase in operative mortality (to 20% and 25%, respectively), but this was not statistically significant, mainly due to the small numbers of patients involved.

Table V: Surgical risk factors.

Parameter	Mortality (%)	Univariate p-value	Multivariate p-value; OR
Age	-	<0.05	-
Gender	-	NS	-
NYHA class IV	20.5	<0.001	-
Left heart failure	11.5	<0.05	-
Right heart failure	19.4	<0.02	-
Cardiothoracic ratio	-	<0.04	-
Atrial fibrillation	11.5	NS	-
Ejection fraction	-	<0.004	<0.003; 0.9
Respiratory insufficiency	11.3	NS	-
Renal insufficiency	18.5	<0.04	-
Emergency	37.5	<0.001	<0.017; 4.7
Aortic insufficiency	15.2 and 30	<0.004	-
Associated coronaropathy	10	<0.2	-
Associated coronary bypass	11.6	<0.1	-
Mitral or tricuspid valve surgery	20	NS	-
Ascending aorta surgery	25	NS	-
Redo surgery	35.3	<0.001	<0.002; 6.0

NS: Not significant; OR: Odds ratio.

Discussion

During the 20th century, life expectancy increased steadily throughout Western Europe and other industrialized countries (Fig. 2). For example, in France today men and women who reach the age of 80 years would expect to live for a further 7.65 and 9.67 years, respectively. At the age of 85 years, these expectancies would be 5.46 and 6.75 years, while at the age of 90 years they would still be 3.85 and 4.57 years (2). Among the French population of 2004 there were 3,341,600 octogenarians, representing 5.5% of the total (2), while in the United States the total number of octogenarians is expected to be 12 million in 2010 (4.3% of the population) (10-12). Moreover, the incidence of cardiovascular disease is enhanced with age (1,12,13), with aortic valve stenosis being the most frequently identified lesion.

In the United States, 40% of the population aged over 80 years has symptomatic cardiovascular disease, and this is a leading cause of death in this age group (10-12). The rewarding results of cardiac surgery (14,15) in the elderly, combined with ageing of the population, has led to increasing numbers of octogenarians and nonagenarians being referred to the surgeon to treat symptomatic valve disease (16-19). Moreover, there is no reason to question the decision to perform valve replacement if the aortic stenosis is tight and symptomatic.

In the present study the overall operative mortality (<30 days) was 7.5%, which compared well with values reported elsewhere, of 4% to 29% (4,5,7,17-28). When comparing these results, at least two points should be taken into account which may have a drastic influence. First, the small number of patients enrolled due to tight selection criteria may have created a bias and artificially improved the results. Second, the long time interval over which surgery was performed was associated with advances in surgical technology and cardiac protection that led to reductions in both hospital mortality and morbidity (29). If the present data were compared to those reported previously (29) for 771 patients, aged >80 years, operated on between 1978 and 2003 for an aortic stenosis, then mortality was decreased from 10.1% to 7.5%. This observation confirms the need for risk factors to be updated regularly in order to specify surgical indications and to select from the growing number of patients referred on an every-day basis.

In a previous report (3) by the present authors with 2,871 patients operated on for aortic stenosis, age had a clear influence on mortality. The risk was low (2.2-2.9%) for patients aged <60 years, increased between 60-70 years (6.2%), and then leveled off after age 70 (11.2%). In the present series, age was a significant risk

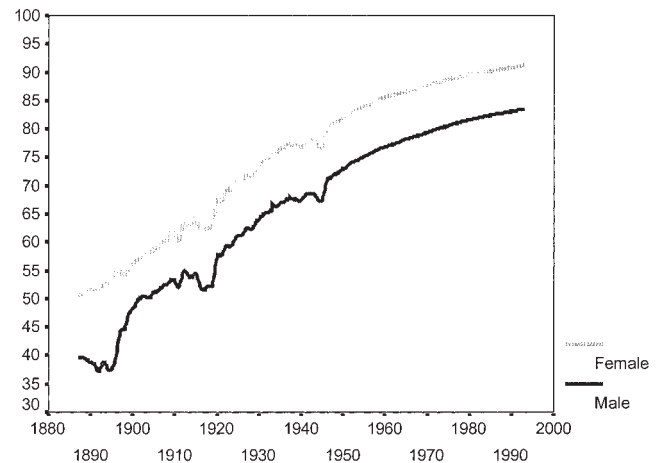


Figure 2: Life expectancy has increased during the 20th century.

factor ($p < 0.05$), while left and right heart failure, NYHA class IV and renal insufficiency were found to be predictive factors in univariate analysis. The need for emergency surgery, low LVEF and redo surgery are independent factors of mortality in multivariate analysis. The LVEF, when tested as a mean value, was significantly lower ($p < 0.001$) among deceased patients ($52.2 \pm 14.2\%$ versus $59.9 \pm 11.6\%$). When these three parameters were associated (Fig. 3), the risk exceeded 70% and prompted the question of whether surgery should remain reasonable under such circumstances. Chronic obstructive pulmonary disease, concomitant mitral valve surgery and ascending aorta are responsible for two-, three- or four-fold increases in patient mortality (to 11.3%, 20%, and 25%, respectively). Even if the analysis failed to reveal any statistical significance (most likely due to very low patient numbers), these parameters should be also considered for indication. Aortic insufficiency may influence outcome, whether associated with the stenosis or isolated ($p < 0.004$). Pure aortic regurgitation was very rare in the present series (only 10 cases identified), but raised a serious problem with 30% mortality. Because today cardiologists do not

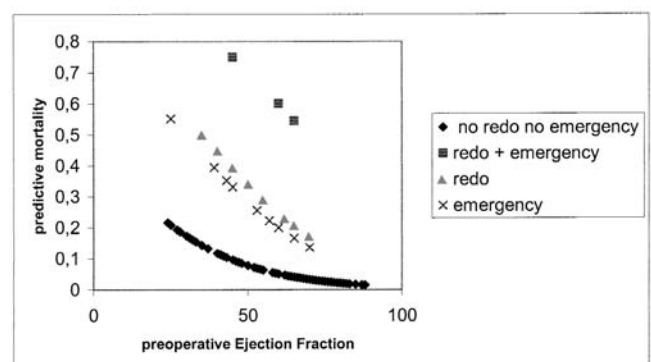


Figure 3: Representation of the logistic regression analysis.

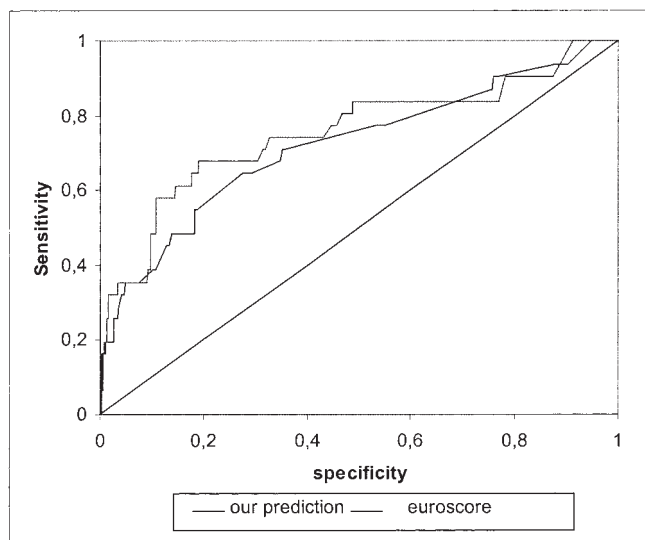


Figure 4: Receiver Operating Characteristics (ROC) curve comparison of EuroScore probability of mortality and calculated probability with the observed mortality.

hesitate in referring elderly patients (aged >80 years) with acute endocarditis for surgery, aortic insufficiencies are frequently complicated by an impaired LVEF or are operated on in an emergency. Thus, great care must be taken not to extrapolate the enthusiastic results of AVR for stenosis to aortic regurgitation when considering these patients for valve replacement.

Many studies have been published (6,17,30-33) comparing the operative risk of isolated valve replacement versus combined surgery with coronary revascularization. Most of these have reported an increased risk when the procedure includes coronary surgery (6,17,30,31). However, although operative mortality occurred twice as often in all age groups (8,34,35) in several recently published large series (6,17,30,31), concomitant CABG was found not to influence mortality in other studies (7,20,36), and hence this point remains controversial. In the present series coronary disease was associated with an increase in hospital mortality (6.5% versus 11.6%), though the difference was not statistically significant. Coronary angiography is used routinely in all patients (even the elderly) to detect high-risk lesions (left main coronary, three-vessel or proximal left anterior descending stenosis) for which revascularization is absolutely mandatory; otherwise, postoperative myocardial infarction is more likely to occur. For more trivial lesions (isolated stenosis of a marginal branch or a diagonal, involving a limited territory or with a poor run-off), the benefit of additional bypass is less evident and, as proposed by several groups, its use should be discussed (6,11,18). It has been shown previously (29) that operative risk increases with the number of narrowed vessels and the number of grafts; this raises the

question of whether a combined strategy should be adopted which associates preoperative coronary angioplasty and surgery in order to improve the preoperative coronary status and ventricular function, changes in which might have a major impact on mortality.

The EuroScore has been considered by some authors to overestimate operative risk in elderly patients (28,37). By using a receiver operating characteristics (ROC) curve, the present authors analyzed the EuroScore probability of mortality and the probability of mortality that was calculated from the logistic regression (Fig. 4). However, comparison of the areas under the two curves for the EuroScore 0.75 [0.65, 0.86] and the authors' prediction (0.72 [0.61, 0.83]) suggested that the specificity and sensitivity of these two tests was similar and that the EuroScore was not more discriminating than logistic regression. Cardiac-related complications represent the leading cause of operative mortality (51.5%), underlining not only the importance but also the limits of myocardial protection, especially in case of preoperative ventricular dysfunction or ischemic heart disease. This is also in favor of earlier referral for surgery, before the onset of cardiac insufficiency and myocardial changes. On the basis of the older age of patients, no mechanical support has been implanted to maintain therapy within reasonable limits. Among the present patients, mesenteric infarction was the second leading cause of death ($n = 7$). Low cardiac output, inotropic drugs and hypothermia can each reduce blood flow in the mesenteric area and contribute to the generation or aggravation of mesenteric ischemia; this is important given the fact that patients may have asymptomatic atheroma lesions of the mesenteric vessels. Hence, today moderate hypothermia at 32°C or warm blood cardioplegia with normothermia is preferred to the 28°C used during the early years of this study. Other causes of death (i.e., renal insufficiency, multiorgan failure) underline the importance of a preoperative patient check-up and preparation (respiratory training), and the need for a perfect surgical technique. Aortic annulus decalcification must be performed with great caution in order to avoid hemorrhages, dissections and hematomas which are not only poorly tolerated (3) but also very difficult to repair due to tissue fragility in octogenarians.

Most of the present patients reported a substantial functional improvement, and many associated publications have emphasized the excellent quality of life obtained with valve replacement (15,19,33). Previously, long-term survival after surgery was shown to be similar in an equivalent age- and gender-matched group of the French population (19).

In conclusion, as the world's elderly population continues to expand and acquired heart disease is recognized as a leading cause of death, aortic stenosis has become the most common cardiovascular disease among older

people. Published data emphasize the fact that valve replacement is the only effective treatment with an acceptable operative risk, functional improvement and good long-term outcome that must be compared to the very poor prognosis of spontaneous evolution. Surgical decisions should be taken on an individual basis, taking into account cerebral function, general status, associated comorbidities and myocardial evaluation. Moreover, statistical analyses suggest that an earlier referral to surgery before the onset of altered cardiac function might lead to further reductions in hospital mortality. Finally, it must be emphasized that one of the most important factors for surgical success is the patient's demand for an improved quality of life, coupled to their fighting spirit during the postoperative period.

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Meeting discussion

DR. JOHN PEPPER (London, UK): Could I ask you about the risk factors? You used univariate and multivariate analyses, but they are only as good as the data you have. There seemed to be some items missing - neither body mass index nor diabetes was included. Also, what did you mean by renal insufficiency? Could you elaborate on that?

DR. THIERRY LANGANAY (Rennes, France): We do

not use body mass index routinely in our unit.

DR. PEPPER: But it's very much involved in the EuroScore.

DR. LANGANAY: We did not use the EuroScore here, but we have compared our analyses with EuroScore and both give the same results.

DR. PEPPER: Then what did you mean by renal insufficiency?

DR. LANGANAY: We chose a renal clearance less than 40 mm/min.

DR. PEPPER: What about the serum creatinine?

DR. LANGANAY: We don't use that.

DR. AD BOGERS (Rotterdam, The Netherlands): You did not mention the patients you refused for surgery, and there was no information about the patients who were not presented at all to you. Can you comment on that, and about your referral region?

DR. LANGANAY: We have a long-term interest in aortic stenosis, and many cardiologists in western France refer their aortic stenosis patients to us. A few patients are not referred because they are beyond the possibility of surgery, and some are not considered or are refused based on the factors I mentioned. The multivariate analysis shows that if a patient has an association of an ejection fraction less than 40%, redo surgery and/or a need for emergency surgery, then the operative risk reaches 70% and they are not considered for surgery. We do not refuse to treat many patients because we are convinced that those who are highly symptomatic have no other chance of surviving the problem. Our goal is to give them a longer life and a good quality of life, and to restore the autonomy that some have lost due to the aortic stenosis. Aortic insufficiency concerned only 10 of the patients, but that's another problem. It is possible to operate on such patients, but the operative risk is much higher.

DR. NEAL KON (Winston-Salem, North Carolina, USA): When we are operating on older people the 'kiss of death' is postoperative renal failure. Do you have a protocol on how to conduct your operation in terms of how you maintain perfusion pressure and what alternative or additional drugs you might use to help prevent this awful complication in older people?

DR. LANGANAY: These patients are operated in the classical way, under cardiopulmonary bypass, and we try to maintain a perfusion pressure over 80 mmHg to ensure good cerebral and renal perfusion. Among our patients none was receiving dialysis before surgery, and none has received dialysis after surgery. Nevertheless, renal insufficiency is a major risk factor. If a patient receiving artificial renal treatment is referred to us for surgery, we will discuss the situation fully with the cardiologists and anesthesiologists before attempting surgery.