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# Primary isolated aortic valve surgery in octogenarians

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**Abstract**

**Objectives:** We reviewed our surgery registry, to identify predictive risk factors for operative results, and to analyse the long-term survival outcome in octogenarians operated for primary isolated aortic valve replacement (AVR). **Methods:** A total of 124 consecutive octogenarians underwent open AVR from January 1990 to December 2005. Combined procedures and redo surgery were excluded. Selected variables were studied as risk factors for hospital mortality and early neurological events. A follow-up (FU; mean FU time: 77 months) was obtained (90% complete), and Kaplan—Meier plots were used to determine survival rates. **Results:** The mean age was 82 ± 2.2 (range: 80—90 years; 63% females). Of the group, four patients (3%) required urgent procedures, 10 (8%) had a previous myocardial infarction, six (5%) had a previous coronary angioplasty and stenting, 13 patients (10%) suffered from angina and 59 (48%) were in the New York Heart Association (NYHA) class III—IV. We identified 114 (92%) degenerative stenosis, six (5%) post-rheumatic stenosis and four (3%) active endocarditis. The predicted mortality calculated by logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was 12.6 ± 5.7%, and the observed hospital mortality was 5.6%. Causes of death included severe cardiac failure (four patients), multi-organ failure (two) and sepsis (one). Complications were transitory neurological events in three patients (2%), short-term haemodialysis in three (2%), atrial fibrillation in 60 (48%) and six patients were re-operated for bleeding. Atrio-ventricular block, myocardial infarction or permanent stroke was not detected. The age at surgery and the postoperative renal failure were predictors for hospital mortality ($p$ value $<0.05$), whereas we did not find predictors for neurological events. The mean FU time was 77 months (6.5 years) and the mean age of surviving patients was 87 ± 4 years (81—95 years). The actuarial survival estimates at 5 and 10 years were 88% and 50%, respectively. **Conclusions:** Our experience shows good short-term results after primary isolated standard AVR in patients more than 80 years of age. The FU suggests that aortic valve surgery in octogenarians guarantees satisfactory long-term survival rates and a good quality of life, free from cardiac re-operations. In the era of catheter-based aortic valve implantation, open-heart surgery for AVR remains the standard of care for healthy octogenarians.


*Keywords:* Aortic valve replacement; Octogenarians; Biological valve prostheses

## 1. Introduction

Over the past 20 years, the life expectancy for men and women has extended continuously in developed countries and it is increasing constantly for people reaching the age of 80, as confirmed by the latest registry reports brought out by Western countries: it is above 7 years and 10 years for men and women, respectively. Because of this rapid ageing population, cardiovascular diseases are one of the most important causes of poor quality of life in the elderly, and a relevant cause of death. Consequently, the number of octogenarians referred to heart surgery has also rapidly increased, and it will probably continue to increase in future. In our demographic population, octogenarians showing signs of degenerative aortic valve stenosis (AS) are increasingly common (disease prevalence of >20%), with consequently a greater amount of increasingly older patients requiring aortic valve replacement (AVR) [1]. This phenomenon seems to be clearly promoted by the ameliorated quality of life, the longest life expectancy and the overall good health conditions of this sub-population. Moreover, previous reports have demonstrated that important results obtained after a standard AVR (low operative mortality/morbidity rate and improved quality of life) are also achievable by this subgroup of very old patients, according to an overall amelioration in early- and late-outcomes after AVR in the elderly [2—7]. This retrospective clinical report aims to discuss our single-centre experience with octogenarians who underwent primary, isolated standard AVR in our cardiovascular surgery unit over a period of 16 years (January 1990—December 2005). Short- and long-term survival outcomes are outlined, and an analysis of risk factors for in-hospital mortality and early neurological events is provided.

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## 2. Materials and methods

We retrospectively analysed our digital surgery registry to identify patients more than 80 years of age, who underwent primary, isolated standard AVR in our cardiovascular surgery unit, between January 1990 and December 2005 (16 years of activity). Patients undergoing redo surgery or AVR combined with coronary artery bypass grafting, or patients who were operated for combined aortic and mitral valve replacement/repair, were excluded from our study. Preoperative and postoperative data taken from the clinical dossiers were collected and retrospectively analysed. Furthermore, a long-term follow-up (FU; mean FU time: 77 months) was obtained contacting the patients themselves (wherever possible), a member of their family or their general practitioner.

### 2.1. Statistical analysis

The statistical analysis was performed using the SPSS 15.0 statistical software package for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables are summarised as mean $\pm$ 1 standard deviation (SD). Categorical variables are presented as numbers and proportions (%). Selected categorical and continuous preoperative and postoperative variables were analysed as risk factors for hospital mortality (defined as any death occurring within 30 days of the operation or death during the same hospital admission) or early neurological complications, using the Fisher's exact test or the Wilcoxon signed-rank test. A *p*-value less than 0.05 was considered to be statistically significant. The estimate survival curves were computed with the Kaplan—Meier method (a log-rank test was also performed to compare the men's and the women's survival curves).

Authors had full access to data and they take responsibility for their integrity.

### 2.2. Surgical procedures

All patients underwent AVR for following our standard surgical protocol (open-heart surgery). A preoperative Doppler evaluation of the carotid arteries was introduced routinely since 2000: in case of presence of a severe left carotid artery disease, a surgical thrombo-endarterectomy under local anaesthesia was scheduled separately, before the AVR. A preoperative computed tomography (CT) scan to evaluate the quality of the ascending aorta has never been performed routinely in our institution. The anaesthesiological management for these patients underwent few modifications during this period of time. Through a median sternotomy, a standard cannulation was performed in the routine fashion, and, since 2005, we routinely employed the Embol-X$^{TM}$ arterial cannula (Edwards Lifesciences, Irvine, CA, USA) to prevent calcium migration. After having clamped the aorta and arrested the heart with antegrade/retrograde cold blood cardioplegia or cold crystalloid cardioplegia solution (St. Thomas) added to topical cooling, the ascending aorta was opened and the aortic valve was replaced with a bioprosthesis (only biological prosthesis were used because of patients' mean age) fixed to the aortic annulus (intra-annular or supra-annular) using either six 2/0 polypropylene running sutures [8] or multiple 2/0 U-fashion single stitches reinforced with pledgets. An intra-operative two-dimensional trans-oesophageal echocardiogram (TEE) was performed routinely. The postoperative full anticoagulation therapy included 3 months of warfarin or Coumadin (international normalised ratio (INR) of 2.5—3.5%), in the absence of permanent atrial fibrillation or other concomitant co-morbidities requiring long-lasting anticoagulation.

## 3. Results

Between January 1990 and December 2005, 124 consecutive octogenarians underwent open AVR in our hospital (Fig. 1). Four cases (3%) required an urgent procedure (endocarditis). The mean age was 82 $\pm$ 2.2 (range: 80—90 years) and 63% were female. Regarding the risk factors and previous cardiac events, 71 patients (57%) suffered from hypertension, 27 (22%) showed signs of chronic renal insufficiency (serum creatinine level above 150 $\mu$g dl$^{-1}$), 29 (23%) were affected by hypercholesterolaemia and 13 by diabetes (three patients (2%) by diabetes type I and 10 (8%) by diabetes type II). Thirteen patients (10%) were suffering from stable angina and 20 (16%) had a positive anamnesis of coronary artery disease: in particular, 10 patients (8%) had previously had an acute myocardial infarction, and, of these, six (5%) were treated by coronary angioplasty (PTCA) and coronary stent positioning. Seven patients (6%) were already equipped with a pacemaker. Among the 124 octogenarians, 59 (48%) were chronically symptomatic for severe dyspnoea (the New York Heart Association (NYHA) functional class III and IV). Preoperative details are listed in Table 1.

The preoperative transthoracic echocardiogram (TTE) showed 60% of patients had good left ventricular function (left ventricle ejection fraction (LVEF): above 50%), 32% with moderate left ventricular function (LVEF: between 30% and 50%) and 8% with poor left ventricular function (LVEF: below 30%). As far as the aetiology of valve disease and haemodynamic parameters are concerned, the age-related degenerative AS was the most common disease, with 114 out of 124 patients (92%) affected (old sub-population). Less frequently, patients were affected by post-rheumatic aortic valve degeneration (5%), and acute or sub-acute aortic valve

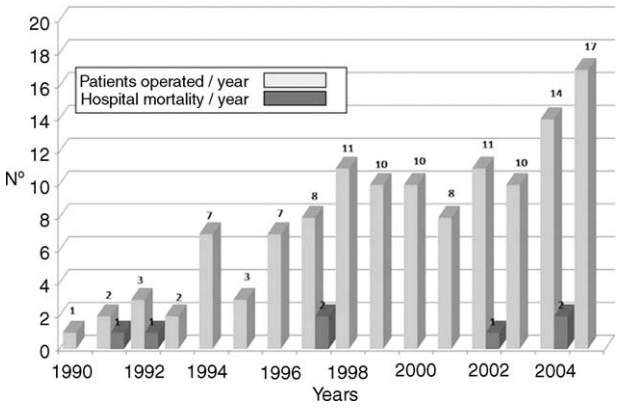


Fig. 1. The graphic shows the distribution, annually, of octogenarians operated in our institution for primary, isolated aortic valve replacement during a period of sixteen years (January 1990—December 2005), and the related hospital mortality.

Table 1
Demographics, symptoms, and risk factors.

| | *N* (%) | *p* for hospital mortality |
|---|---|---|
| No. of patients | 124 | – |
| Age (years) | 82 ± 2.2 (range 80–90) | 0.043 |
| Women | 78 (63%) | NS |
| Mean logistic EuroSCORE (%) | 12.6 ± 5.7 | – |
| Dyspnoea (NYHA functional class): | | |
| I | 10 | NS |
| II | 55 (44%) | |
| III | 38 (31%) | |
| IV | 21 (17%) | |
| Angina | 13 (10%) | NS |
| Associate coronary disease | 20 (16%) | 0.083 |
| Previous myocardial infarction | 10 (8%) | NS |
| Previous PTCA/coronary stenting | 6 (5%) | NS |
| Hypertension | 71 (57%) | NS |
| Renal insufficiency | 27 (22%) | NS |
| Diabetes type 1 | 3 (2%) | NS |
| Diabetes type 2 | 10 (8%) | 0.099 |
| Hypercholesterolemia | 29 (23%) | NS |

Data are presented as mean ± SD or *N* (%). NYHA: New York Heart Association; PTCA: percutaneous coronary angioplasty.

endocarditis (3%). Regarding the valve haemodynamic, 107 (86%) were pure stenosis, six patients (5%) carried a pure regurgitation and 11 (9%) had a combination of stenosis and regurgitation (Table 2).

The predicted hospital mortality calculated by logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE; www.euroscore.org) was 12.6 ± 5.7%.

All 124 patients were successfully operated for AVR and 18 procedures (14%) also required a combined sub-valvular septal myectomy. The implanted valves were all biological prosthesis (100%), according to the patients' mean age: the mean valve size was 23 ± 2 mm, and the different types of implanted bioprosthesis are listed in Table 3. Mean cardiopulmonary bypass time and aortic cross-clamp time were 80 ± 18 min and 58 ± 14 min, respectively, and the mean operative time was 138 ± 28 min. The observed hospital mortality was 5.6% (seven patients). Among the seven patients who died during postoperative recovery in the intensive care unit (ICU), four died of severe postoperative cardiac failure, two died of multi-organ failure (MOF) and one patient of sepsis.

Concerning early postoperative complications (listed in Table 4), the intra-aortic balloon pump (IABP) was used three times intra-operatively (2%), a re-thoracotomy for bleeding was necessary six times (5%) and a transitory acute renal failure occurred 14 times (12%). Eleven patients with postoperative renal insufficiency required a conservative medical treatment, while a short treatment with continuous dialysis was necessary for three patients (2%). Of the entire group, three patients (2%) showed signs of transitory neurological events: one right hemiplegia regressing after 5 h, one visual trouble (amaurosis) and a one Wernike's aphasia. All these neurological complications regressed spontaneously without medical treatments during the post-operative recovery, and all 117 patients who survived surgery were discharged from our hospital without signs of stroke. The mean hospital and ICU stay were 15 ± 6 and 4 ± 2 days,

Table 2
Preoperative 2D echocardiogram assessment and valve disease.

| | *N* (%) | *p* for hospital mortality |
|---|---|---|
| Left ventricle ejection fraction – LVEF (%) | | |
| >50% | 60% | NS |
| 30–50% | 32% | NS |
| <30% | 8% | 0.066 |
| Mean aortic valve area ($cm^2$) (stenosis) | 0.6 ± 0.1 | – |
| Mean trans-valvular peak gradient (mmHg) (stenosis) | 76.6 ± 21.2 | – |
| Pure aortic valve stenosis | 107 (86%) | – |
| Pure aortic valve regurgitation | 6 (5%) | – |
| Combined valve stenosis and regurgitation | 11 (9%) | – |
| Degenerative aortic valve disease | 114 (92%) | – |
| Post rheumatic aortic valve disease | 6 (5%) | – |
| Endocarditis (acute/sub-acute) | 4 (3%) | – |

Data are presented as mean ± SD or *N* (%).

Table 3
Implanted biological prosthesis (*N*: 124 patients).

| | |
|---|---|
| Edwards Lifesciences Perimount™, Magna™, Magna Ease™ | 88 (71%) |
| St. Jude Biocor™ | 12 (10%) |
| Shellhigh stentless bioprosthesis | 11 (9%) |
| Sorin Group Mitroflow™ | 9 (7%) |
| Medtronic Freestyle™ | 4 (3%) |
| Mean valve size (mm) | 23 ± 2 |
| Size distribution: | |
| 19 mm | 3 (2%) |
| 21 mm | 39 (32%) |
| 23 mm | 44 (36%) |
| 25 mm | 29 (23%) |
| 27 mm | 7 (6%) |
| 29 mm | 2 (1%) |

Data are presented as mean ± SD or *N* (%).

Table 4
Operative results (*N*: 124 patients).

| | *N* (%) | *p* for hospital mortality |
|---|---|---|
| Hospital mortality | 7 (6%) | – |
| Causes of death: | | |
| Severe cardiac failure | 4 | |
| MOF | 2 | |
| Sepsis | 1 | |
| Atrial fibrillation | 60 (48%) | NS |
| Acute renal failure | 14 (11%) | 0.001 |
| Dialysis (transitory) | 3 (2%) | |
| Surgical bleeding requiring re-thoracotomy | 6 (5%) | NS |
| Pneumonia | 11 (9%) | NS |
| Cardiac dysfunction: | 7 (6%) | NS |
| Severe | 4 | |
| Mild | 3 | |
| Intra-operative IABP | 3 (2%) | NS |
| Mediastinitis | 1 (1%) | NS |
| Sepsis | 1 (1%) | NS |
| Transitory neurological events | 3 (2%) | NS |

Data are presented as mean ± SD or *N* (%). MOF: multi-organ failure; IABP: intra-aortic balloon pump.

Table 5
Follow-up (117 patients survived at surgery; N:105 patients contacted successfully at FU).

| | |
|---|---|
| Mean FU time (months) | 77 (6.5 years) |
| FU completeness | 105/117 patients (90%) |
| Missing patients at FU | 12/117 (10%) |
| Patients alive at FU | 67/105 (64%) |
| Mean age of surviving patients (years) | 87.1 ± 3.7 (range 81–95) |
| Mortality during the FU | 38/105 (32%) |
| Estimated prosthesis dysfunctions | 0 |
| Valve-related cardiac re-operations | 0 |
| Dyspnoea (NYHA class): | |
| I | 59 |
| II | 8 |
| III | 0 |
| IV | 0 |
| Causes of death: | |
| Cardiac | 7 |
| Stroke | 5 |
| Cancer | 5 |
| Renal failure | 2 |
| Traumas | 3 |
| Unknown | 16 |

Data are presented as mean ± SD or *N* (%). FU: follow-up.

respectively, and three patients required a prolonged hospital stay (>20 days).

Data from the long FU were systematically analysed and listed in Table 5. The mean FU time was 77 months and the mean age of people still alive at FU was 87 ± 4 years (67/105 patients, range: 81–95 years). Despite difficulties in collecting information regarding octogenarians operated during the 90 s, for 90% of patients (105/117), complete FU has been obtained. Nevertheless, data coming from this survey are interesting: the Kaplan–Meier curves (Figs. 2 and 3) show that the actuarial survival estimates for our selected cohort of patients are 88% at 5 years and 50% at 10 years. Thirty-eight patients died during the FU: among the causes of death, a cardiac cause was counted seven times (which were mostly ischaemic events), a stroke five times and in 16 cases the cause of death was not identified. However, we could not prove any valve-related death and any valve-related complication (bleeding or endocarditis), or prosthesis dysfunction, and there were no cardiac re-operations. Patients answering at FU (67) were doing well and, in the course of the interview, they confirmed a fulfilling quality of life comparable to the standard quality of life of non-operated octogenarians. With regard to the presence of cardiac symptoms, no patient described angina, 59 were in NYHA functional class I, and eight were in NYHA functional class II.

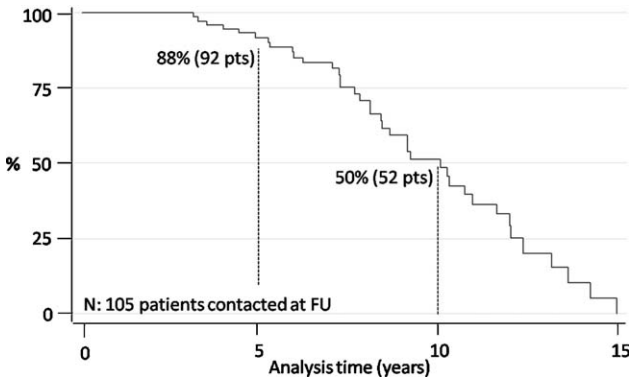


Fig. 2. Cumulative Kaplan–Meier survival curves.

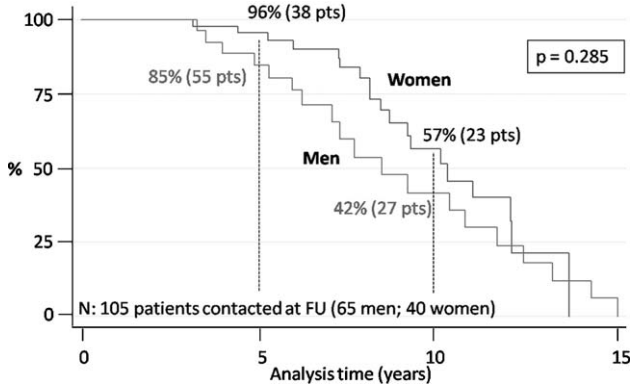


Fig. 3. Cumulative Kaplan–Meier survival curves, for males/females separately.

## 4. Discussion

In the era of catheter-based stent-valve implantation (transfemoral and trans-apical procedures), open-heart surgery remains the gold standard for primary, isolated AVR. Nevertheless, cardiologists and cardiac surgeons in developed countries are increasingly faced with having to treat a population aged 80 years or more, suffering from severe and symptomatic AS, and requiring medical or surgical treatment. The natural prognosis of severe AS becoming symptomatic is well known: 90% of patients die within 3 years of the onset of symptoms (typically angina, syncope and dyspnoea) and, if heart failure is present, death occurs within 2 years [9–11]. Unfortunately, the advancing age of these patients together with their concomitant co-morbidities, are perceived by the general practitioner and/or cardiologists as important risk factors for poor outcomes once surgical AVR and clinicians are encouraged to investigate non-surgical options. However, the non-surgical options are affected by a very poor outcome: solely medical management is associated with high mortality within 3 years, and balloon valvuloplasty is associated with short-term re-stenosis and a high necessity for re-intervention [12,13].

Therefore, non-traditional techniques should be compared with modern short- and long-term outcomes of standard open AVR in octogenarians. Our report confirms that primary, isolated standard AVR can be performed safely in this subgroup of patients, with acceptable morbidity and hospital mortality. In our series, the 30-day mortality (5.6%) and the incidence of major postoperative complications compare favourably to data present in literature and data reported in other series [2–6]. Despite earlier reports (early to mid-1990s) of isolated AVR in the elderly, which showed higher operative mortality (from 6% to 20%), recent articles have shown a lower mortality rate ranging around 3–10%: Thourani et al. [6], for example, described 88 octogenarians operated for isolated AVR with a hospital mortality of 5.7%; Kolh et al. [5] reported a 30-day mortality of 8.5% in a series

of isolated primary AVR, and similar results have been reported by Chiappini et al. [14] who described a mortality rate of 8.5% in a group of octogenarians requiring isolated and combined AVR, and by Collart et al. [15] who described a short-term mortality of 8.8% in a cohort of 215 elderly patients requiring valve replacements. The reason for such a decline in hospital mortality is probably multifactorial. Nevertheless, the ameliorations in surgical techniques, cardiac anaesthesia and intensive care postoperative management certainly play a key role in decreasing the operative mortality risk and the onset of postoperative complications.

In our group of patients, the predictive hospital mortality calculated by logistic EuroSCORE was 12.6%, a value almost twice the observed mortality rate (5.6%). Following the latest trend of using the EuroSCORE system to identify high-risk AVR patients to be addressed for trans-catheter therapies (EuroSCORE >20%), our data confirm that the logistic EuroSCORE remains a useful tool, despite the fact that the predicted operative mortality is overestimated and needs to be halved, in general, to coincide with the real score [16].

Another aspect that must be underlined is the incidence of postoperative complications. In general, one of the most important aspects after an AVR procedure is the patient's quality of life and the absence of irreversible complications: in particular, as far as octogenarians are concerned, the onset of major neurological complications can determine a total change in their quality of life, with serious changes in physical well-being and mental state [7,17,18]. Neurological complications can lead to severe handicaps with loss of independence and physical autonomy. In our cohort, we experienced three cases (2%) of transitory neurological events before the advent of the Embol-X™ arterial cannula (in 2005): symptoms regressed spontaneously within few hours, with no patients leaving our institution with signs of stroke. This result is in line with rates reported in other series: Thourani et al. [6] showed 3.4% of neurological events in his cohort of elderly patients, whereas Kolh et al. [5] reported a stroke rate of 2.8%. Nevertheless, despite the evidence of a decreasing trend in stroke after AVRs, the risk of calcium migration from the valve itself, from the cannulation site or from the aortic cross-clamping site remains relevant, and all efforts should be undertaken to decrease this risk constantly (new-generation arterial cannulas, routine epi-aortic ultrasound and preoperative CT-scan imaging).

Regarding the operative morbidity, the incidence of renal insufficiency, re-operation for bleeding, pneumonia and atrial fibrillation is compatible with other recent reports [3–7].

We also tried to define risk factors for early death and early neurological events: the age at surgery and the income of postoperative renal failure were the only preoperative risk factors statistically associated with higher operative mortality ($p$ value $<0.05$). Risk factors for early neurological events were not identified, whereas the presence of concomitant coronary disease, an impaired left ventricular function and type II diabetes were also associated with higher hospital mortality despite a lower statistical significance.

With regard to the long-term outcome and quality of life, our survival estimates at 5 and 10 years were 88% and 50%, respectively, showing good long-term results despite the advanced age. The 5-year survival estimate, in particular, appears higher than the one expected in AVR in octogenarians, which is around 50–70% [19], and it appears also higher than the 5-year rates of 55% [20], 69.4% [14], 56% [4] and 61% [6], recently published in comparable series. On the other hand, the survival estimates for our sub-population are lower than in younger patients, but they compare favourably with the life expectancy of a general population of octogenarians; and a 10-year survival rate of 50% appears extremely favourable. Moreover, these patients do not only have a longer expectancy of life, but they also enjoy an improved quality of life. Patients alive at FU were doing surprisingly well, with a high percentage of people still living at home or with their families. Concerning valve-related complications, no thrombo-embolic events, bleedings, endocarditis, structural failure or re-operations were clearly identified at FU. Nevertheless, valve-related complications cannot be totally excluded from the following series because in many cases the cause of death was unclear: 16 patients died for unknown reasons, seven patients died during FU from the evolution of their undefined heart disease (probably ischaemic, arrhythmic or valvular) and in five cases there were occurrences of stroke.

The current study has some important limits as its single-centre retrospective nature and the possibility of bias present in the selection criteria. It is not inadmissible that patients 'too sick for surgery' were excluded following personal selection criteria of the individual cardiologist or surgeon, and such criteria probably changed continuously over a period of 16 years. However, the study confirms the reliability of standard open AVR in very old patients during a lapse of time of 16 years.

In conclusion, conventional primary, isolated AVR can be safely performed in octogenarians with acceptable mortality, good long-term survival and good quality of life. Patients of 80 years of age or older carrying a mid- or low-operative risk should not be denied the benefit of standard surgery that remains, so far, the standard of care for isolated AVR. As an alternative, elderly high-risk patients should become candidates for trans-catheter AVR therapies, and it is plausible that, in a near future, percutaneous procedures may provide evident benefits in terms of postoperative mortality and morbidity.

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