Contemporary outcomes of conventional aortic valve replacement in 638 octogenarians: insights from an Italian Regional Cardiac Surgery Registry (RERIC)†

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Abstract

OBJECTIVES: Few data exist on contemporary outcomes after conventional aortic valve replacement (AVR) in the elderly. Accordingly, we evaluated contemporary outcomes and identified predictors of reduced survival in a large series of octogenarians undergoing AVR.

METHODS: The Regione Emilia Romagna Cardiac Surgery registry (RERIC) database (n = 26,938) was queried for clinical features, hospital and mid-term outcomes of octogenarians undergoing AVR between 2003 and 2009. Predictors of hospital and mid-term mortality were identified.

RESULTS: The study population consisted of 638 patients. NYHA class III–IV, congestive heart failure, cerebrovascular disease, extra-cardiac arteriopathy, mostly exacerbated patients’ clinical profile. Mean log-EuroSCORE was 13.0%. Overall hospital mortality and stroke rates were 4.5% and 1.3%, respectively. Other post-operative complications included renal failure (4.9%), intubation time >48 h (3.4%), complete atrio-ventricular block (4.4%). NYHA III–IV (OR = 2.7; CI 95%:1.2–6.7) and CCS III–IV (OR = 3.1; CI 95%:1.1–9.4) emerged as independent predictors of hospital mortality on multivariate analysis. At 6 years, octogenarians’ survival rate was similar to the expected survival of the age- and sex-matched regional population. CCS III–IV (HR = 2.1; CI 95%:1.2–4), preoperative creatinine > 2.1 (HR = 2.8; CI 95%:1.4–5.9), extra-cardiac arteriopathy (HR = 1.5; CI 95%:1.1–2.1) and peripheral neurological dysfunction (HR = 3.8; CI 95%:1.4–10.4) emerged as independent risk factors for decreased 6 years’ survival.

CONCLUSIONS: This study, showing that contemporary outcomes after AVR are excellent, may help to improve treatment decision-making in elderly patients with aortic valve disease.

Keywords: Valve disease • Elderly • Outcome

INTRODUCTION

Aortic stenosis is the most frequent heart valve disease in Western societies and its prevalence increases with age [1]. Thus, with the lengthening of life expectancy, the number of elderly patients with aortic stenosis is continuously increasing, and the decision to select the best definitive management among medical, interventional and conventional surgical therapy in octogenarians with severe aortic valve disease has become a serious daily issue [2–6].

The Euro Heart Survey recently reported that nearly one-third of patients with symptomatic severe aortic valve stenosis and age ≥ 80 was denied standard of care, namely aortic valve replacement (AVR), and main reasons included advanced age and age-related comorbidities [1].

Undoubtedly, considering the potentially higher surgical mortality and morbidity, and the impaired patients’ expectancy and quality of life in the elderly (regardless of valve disease),
patients, families and referring physicians may be reluctant to consider AVR as definitive management [7]. Therefore, decision to operate should be taken according to patients’ expectations and knowledge of up-to-date risk factors for adverse post-operative outcomes.

Although numerous studies assessing short- and mid-term outcome after AVR in the elderly have been conducted, the vast majority are single-institution studies, often older than 10 years or with enrolment periods spanning decades [8–14].

Our study, reporting short- and mid-term outcomes from a regional (Emilia Romagna, Italy) large contemporary (2003–2009) series of octogenarians undergoing primary isolated AVR, may help to improve treatment decision-making in elderly patients with aortic valve disease.

MATERIAL AND METHODS

Data source: the RERIC registry

The rationale and methodology of RERIC have been published previously [15]. Briefly, RERIC Registry (Registro Emilia Romagna degli Interventi Cardiochirurgici) is a prospective regional database collecting pre-, intra- and postoperative data from patients undergoing cardiac surgical procedures in the six regional Cardiac Surgery Departments (Academic Hospitals: n = 2, Private Hospitals: n = 4). Between January 2003 and December 2009, data from n = 26938 cardiac surgical procedures were collected.

The selection of variables (Table 1), shared by the six Cardiac Surgery Departments, is extrapolated from the database of the Italian Society for Cardiac Surgery (SICCH). The Regional Agency for Health and Social Care ensures data quality/completeness control. The identification of patients who died in or out of the hospital was retrieved through record linkage between RERIC and the regional mortality registry.

Patients’ profile

Between January 2003 and December 2009, 3178 patients underwent primary isolated AVR in our region (Emilia Romagna). Of them, 638 (20.1%) patients were older than 80 years and were object of the present study.

The mean age was 82 ± 2.1 years (range: 80–91 years). Aortic valve stenosis (pure or predominant) was the indication for surgery in 94.2% of patients, whereas aortic insufficiency in 5.8%.

New York Heart Association (NYHA) class III–IV (59.2%), urgency of procedure (8.2%), hypertension (77.0%), severe chronic obstructive pulmonary disease (6.9%), diabetes (12.5%) and extra-cardiac vasculopathy (23.5%) mostly exacerbated patients’ clinical profile (Table 2).

By logistic EuroSCORE, the predicted hospital mortality of our study cohort was 13.0 ± 7.9%.

When compared with younger patients, octogenarians were more likely to present with symptoms and pre-operative comorbidities such as that of NYHA III–IV (59.2% vs. 45.9%; P < 0.0001), CCS III–IV (5.2% vs. 3.3%; P = 0.02), congestive heart failure (7.2% vs. 4.4%; P < 0.003), urgent surgery (8.2% vs. 5.5%; P = 0.012), hypertension (77.0% vs. 70.6%; P = 0.002), cerebrovascular disease (3.7% vs. 6.0%; P = 0.01) and previous percutaneous coronary interventions (PCIs; 9.4% vs. 6.8%; P = 0.03).

A higher incidence of active infective endocarditis (3.7% vs. 1.4%; P = 0.008) and body mass index > 30 (18.2% vs. 12.9%; P = 0.001) were observed in patients younger than 80 years.

Preoperative clinical characteristics of patients younger and older than 80 years are reported in Table 2.

A bio-prosthesis was implanted in 96.4% of patients.

Table 1: Pre-operative variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Body mass index</td>
<td>kg (weight)/m²(height)</td>
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<tr>
<td>Hypertension</td>
<td>History of hypertension on medication, diet, physical activity, arterial pressure (AP) &gt; 140/90 mmHg</td>
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<tr>
<td>Diabetes</td>
<td>History of diabetes or medication</td>
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<tr>
<td>Dialysis</td>
<td>Dialysis at admission</td>
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<tr>
<td>Creatinine</td>
<td>mg/dl</td>
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<tr>
<td>Peripheral neurological dysfunction</td>
<td>Disease severely affecting ambulation and day-to-day function</td>
</tr>
<tr>
<td>Central neurological dysfunction</td>
<td>Disease severely affecting ambulation and day-to-day function</td>
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<tr>
<td>Extra-cardiac vasculopathy</td>
<td>Claudication and/or carotid artery stenosis &gt; 50% and/or previous/scheduled procedure on abdominal aorta, carotid artery or limb arteries</td>
</tr>
<tr>
<td>Active infective endocarditis</td>
<td>On antibiotics</td>
</tr>
<tr>
<td>Severe chronic obstructive pulmonary disease</td>
<td>Forced expiratory volume (FEV1) &lt; 50% and/or PO2 &lt; 60 or PCO2 &gt; 50</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>Coma &gt; 24 h</td>
</tr>
<tr>
<td>Active neoplasms</td>
<td>Carotid artery stenosis &gt; 50%</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>Orthopnoea; exertional dyspnoea with diuretics and digital; pulmonary venous congestion at chest X-ray</td>
</tr>
<tr>
<td>CCS</td>
<td>I–II–III–IV</td>
</tr>
<tr>
<td>NYHA</td>
<td>I–II–III–IV</td>
</tr>
<tr>
<td>Haemodynamic instability</td>
<td>AP &gt; 80 mmHg and/or cardiac index &gt; 1.8 L/min/m² with i.v. inotropic support and/or intra aortic balloon pump (IABP)</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>AP&gt;80 mmHg and/or cardiac index &lt; 1.8 L/min/m² despite inotropic and/or IABP support</td>
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<tr>
<td>Cardio-pulmonary reanimation</td>
<td>As estimated by echo and/or angiography</td>
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<tr>
<td>Ejection fraction</td>
<td>Systolic pulmonary artery pressure &gt; 60 mmHg as estimated by preoperative catheterism or Swan–Ganz catheter before surgery</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>Surgery performed during the same hospitalization</td>
</tr>
<tr>
<td>Urgency</td>
<td>Immediate surgery</td>
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Statistical analysis

Continuous variables were expressed as the mean ± SD and categorical variables as percentage. All preoperative and intra-operative variables were first analysed using univariate analysis (Mann–Whitney U test for continuous variables, χ² test or Fisher’s exact test when appropriate, for categorical variables) to determine whether any single factor influenced...
hospital mortality. Variables that achieved a P-value less than 0.05 in the univariate analysis were examined using multivariate analysis by forward stepwise logistic regression to evaluate independent risk factors for hospital mortality. Survival curves (taking into account perioperative deaths) were estimated at 6 years using Kaplan–Meier method and compared using log-rank test only for regional patients. The potential difference of risk for in-hospital mortality between regional inhabitants and extra-regional inhabitants was assessed including regional residence as a dummy variable in the multivariate logistic regression model.

The estimated 6 year survival of our patient’s cohort was compared with the expected survival of the general regional population, matched on gender and age, according to the most recent regional life tables provided in 2006 by the Italian Statistical Office (ISTAT). To estimate the expected survival rate, patients’ withdrawal or death were assessed at different times, by matching the reference cohort on age and gender at each year of follow-up [16]. Thus, the one-sample log-rank test [17] was used to compare our patients’ survival with the expected survival of the age- and sex-matched regional population.

Independent predictors of 6-year survival were estimated using Cox proportional hazards model and the proportional hazard assumption was assessed using Schoenfeld residuals test. All statistical analysis was performed using SAS 9.1.

**RESULTS**

**Early mortality**

Hospital mortality of patients aged more than 80 years was 4.5% (n = 26/582), and was higher than that observed (n = 52/2540; 2.0%) in the younger ones (P = 0.0003).

On univariate analysis, congestive heart failure (P = 0.032), cardiogenic shock (P = 0.048), NYHA III–IV (P = 0.048), CCS III–IV (P = 0.031), central neurological dysfunction (P < 0.001) and peripheral neurological dysfunction (P < 0.001) emerged as risk factors for hospital mortality.

Multivariate analysis revealed NYHA III–IV (OR = 2.7; P = 0.034) and CCS III–IV (OR = 3.1; P = 0.044) to be independent predictors of hospital mortality.

Postoperative complications are reported in Table 3. When compared with younger patients, octogenarians were more likely to be complicated by stroke (1.3% vs. 0.6%; P = 0.056), renal insufficiency (3.6% vs. 1.8%; P = 0.004), atrial fibrillation (33.9% vs. 25.4%; P < 0.001) and third-degree atrio-ventricular block (4.4% vs. 2.2%; P = 0.002), which resulted in longer lengths of hospital stay (16.6 ± 0.5 vs. 14.2 ± 0.2; P < 0.0001).

**Follow-up**

Survival data at follow-up were obtained for all patients resident in the region (86.4%). Median time of follow-up was 1130 days (range: 69–2613 days).

Octogenarians’ survival estimated at 1, 3 and 6 years was 91.3%, 80.6% and 67.5%, respectively; and age ≥80 years adversely impacted mid-term survival (log-rank P < 0.0001; Fig. 1). Six years survival of octogenarian patients was comparable with the expectancy of life of the age- and sex-matched 2006 regional population (log-rank P = 0.35; Fig. 2).

CCS III–IV (HR = 2.1; P = 0.0162), preoperative creatinine > 2.1 (HR = 2.8; P = 0.005), extra-cardiac arteriopathy (HR = 1.5; P = 0.047) and peripheral neurological dysfunction (HR = 3.8; P = 0.009) emerged as independent risk factors for decreased 6-years’ survival.
In our study, we ought to respond to the continuing need for the up-to-date post-operative outcomes of octogenarian patients undergoing AVR that are, due to relevant epidemiological variations, observed in the last decade, and to the development of alternative trans-catheter aortic valve procedures of unique and contemporary interest.
Our prospective, contemporary and regional enrolment allowed us to depict an interesting sample of 638 octogenarian patients currently referred to AVR.

Pre-operative characteristics of our patients strongly confirm that calcific aortic valve stenosis is a disease of the elderly (only 5% of patients underwent AVR due to pure aortic regurgitation) and that comorbidities are more frequent in octogenarians when compared with the younger ones. In particular, pre-operative clinical profile of elderly patients was burdened by a more advanced clinical status, as demonstrated by the higher prevalence of NYHA III–IV, CCS III–IV, congestive heart failure and urgency, and by a higher frequency of comorbidities related to atherosclerosis such as cerebrovascular disease, extra-cardiac arteriopathy and previous PCI, which can be explained by the numerous risk factors shared by aortic stenosis and atherosclerosis [18].

Surgical timing is a critical issue when dealing with elderly patients: symptoms are often difficult to interpret and, besides that, it can be understood that clinicians would be reluctant to recommend AVR in asymptomatic or pauci-symptomatic patients (NYHA I–II; CCS I–II) [7]. However, it should be kept in mind that the window for optimal surgical timing is very narrow in this setting since end-stage disease, as expressed by advanced NYHA functional class, congestive heart failure, impaired left ventricular function and urgency, is indicated as the strongest risk factor for adverse outcome after surgery [3, 4, 8, 9, 13, 14, 19], and is the only one on which clinicians can act by avoiding a too late decision for surgery. In our series, hospital mortality of octogenarians was twice higher than that observed in the younger counterpart, but on multivariate analysis, not advanced age or associated comorbidities, but rather NYHA III–IV and CCS III–IV have had an impact on hospital mortality. This finding stresses the importance of close patient’s clinical surveillance to avoid late referral and disappointing postoperative results.

Hospital mortality of our octogenarian group was 4.5%, which favourably compares with the ones reported in single-institution studies with prolonged time spans for enrolment (which range from 4.3% and 13.7%) [2–6], and is consistent with the ones from studies analysing contemporary larger patients’ populations [19].

Once more, our study confirmed the inadequateness of Logistic EuroSCORE in predicting hospital mortality in the context of elderly patients undergoing AVR [15, 20].

Undoubtedly, a bias in patient referral and selection is present in our study and may influence our results and implications. Nevertheless, despite all potential limitations and bias inherent to registry studies, our data from a community shared database system may provide a fair picture of how elderly patients undergoing AVR are currently managed. It is likely that current clinical and surgical management can play an important role in the achievement of seemingly improved results, which should be considered when contraindicating elderly patients to aortic valve surgery.

We reported a stroke rate of only 1.3%. Regrettfully, our database did not allow to collect data about surgical tools and methods employed for brain protection (epi-aortic scan, soft aortic clamps, temperatures, etc.) and clearly, the exclusion from our analysis of patients with a more severe atherosclerotic disease, namely those requiring coronary artery bypass grafting, could partially explain the very low rate of neurological complications.

The occurrence of other post-operative complications was encouraging with a need for mechanical ventilation longer then 2 days in 3.1%, and for dialysis in 1.3%. As expected, when compared with younger patients, octogenarians experienced more strokes, renal failure, atrial fibrillations and complete atrio-ventricular blocks which, however, led to only a slightly longer period of hospital stay with a similar ICU length of stay.

Kaplan–Meier estimates of survival were also very encouraging with 1, 3 and 6 years survival of 91.3%, 80.6% and 67.5%, respectively. Importantly, our data confirm the findings reported by other recent studies showing similar mid-term survival rates between elderly patients receiving AVR and the corresponding age- and gender-matched general population [3, 4]. The lower cumulative incidence of tissue valve-related complications in elderly patients with limited life spans, the higher incidence of cardiac events in people with severe aortic valve stenosis not receiving AVR, and the exclusion of patients at clear higher risk from our analysis, such as those undergoing redo procedures or receiving associated myocardial revascularization may represent a potential explanation for such a finding. However, a reduced mid-term survival rate can be expected in patients with preoperative creatinine > 2.1 mg/dl, extra-cardiac arteriopathy and peripheral neurological dysfunction, which, at Cox analysis, adversely influenced mid-term survival of our elderly group.

It has to be mentioned that our mid-term analysis and relative implications were limited by follow-up survival data obtained only on regional inhabitants (86.4%). Nevertheless, it is plausible that our mid-term analysis remains meaningful considering that (i) extra-regional inhabitants had a 100% follow-up completed; (ii) regional and extra-regional inhabitants presented with similar pre-operative risk profiles; and (iii) surgery in extra-regional inhabitants was not associated with an increased risk of hospital mortality on multivariate analysis (data not shown).

Post-operative quality of life and cost-effectiveness of AVR are serious concerns in elderly patients, and object of ongoing research at our Institutions. In several studies, estimates of quality of life, as measured by NYHA functional class improvement, autonomy or satisfaction after receiving surgery, or by more sophisticated functional scores (also in comparison with the general population) have shown excellent functional recovery after AVR in patients aged > 80 years [21–24], and Wu et al. [25], in a recent study, determining the economic value of the additional life given to patients undergoing AVR, concluded that AVR is cost-effective for all ages, and is still worth in octogenarian and nonagenarian patients.

CONCLUSIONS

Although our study presents all limitations inherent to registry data analysis, we observed that, when compared with younger patients, octogenarians were burdened by a more advanced clinical status and by a higher number of atherosclerosis-related comorbidities. Despite that, conventional AVR resulted in very encouraging short- and mid-term outcomes.

In our opinion, AVR still represents the standard of care for elderly patients with aortic valve stenosis, and our results may act as reference for alternative aortic valve procedures if the latter will ever be indicated in patients with a lower risk profile.

A close clinical patient’s surveillance is essential for a timely indication as advanced symptoms (NYHA III–IV and CCS III–IV) appear to adversely impact hospital mortality.

We believe octogenarians who are judged to be physiologically and mentally able to oppose the stress of surgery should benefit
of surgery. A decreased mid-term survival can be expected in those with pre-operative renal insufficiency, peripheral neuro-
logical dysfunction and extra-cardiac vasculopathy.

It is hoped that our study may be of aid to improve treatment
decision-making in elderly patients with aortic valve disease.

Confict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr M. Shrestha (Hannover, Germany): Just a question. In this patient collective,
did you try to find out whether the length of the cross-clamp times and the
CPB had any role or connection with the renal dysfunction or not?

Dr Di Eusanio: No. In our analysis we did not look at the impact that
intraoperative variables had on postoperative outcomes.

Dr G. Gerosa (Padova, Italy): This is a very interesting paper, because it
provides contemporary data on risk profile and outcomes of elderly patients
undergoing AVR, and we need such data in order to improve our treatment
decision-making algorithm. So I have three questions for you.

First of all, looking at the data included in the RERIC database, there are
patients coming from outside of your region. Now, you included those
patients in in-hospital death analysis but excluded them from the
Kaplan–Meier survival curve. Can you elaborate on this discrepancy and its
impact on the statistical analysis?

Second, you included only patients undergoing primary AVR. Can you
provide data in terms of hospital mortality and post-discharge outcomes for
redo patients included in the registry?

And third, as far as patients’ risk profile is concerned, the mean EuroSCORE
in this series is 13%. It is actually slightly lower than other series; in Padua we have
18%. So probably in the most recent years and in the most recent part of your
series, higher risk patients have been diverted to TAVI. So how many patients in
the registry have been assigned to the TAVI option and excluded from surgery?

Dr Di Eusanio: I would like to start from the last question. It is correct that
in the last two years of our study period TAVI became an available treatment
option. However, since in our region TAVI procedures are indicated in
patients considered as inoperable due to their prohibitive risk profile, I am
not sure that the introduction of TAVI would have modified the mean logistic
EuroSCORE of our patients. Probably it is possible to imagine the opposite.

With the introduction of TAVI, we have certainly observed an increased refer-
ral of high-risk patients that were not previously sent to us, and we have
operated on many of them, surgically I mean. So my answer to your question,
strictly speaking, would be “I don’t know; we should look at that.” But I am
not sure that the introduction of TAVI has resulted in any modification of the
risk profile of our patients.

Turning to the second question, which was about redos, in our study we
excluded patients requiring reoperative surgery. We aimed to have a very
pure population. I think that redo AVR may mean a lot of things: a repeat
AVR, an aortic valve replacement in the context of patent grafts or after previ-
ous aortic surgery, may involve very different degrees of risk. So I think this is
a very particular subgroup of patients that should be analysed separately.

Redo patients were excluded from our study, and I don’t have the figures
and the numbers of these patients.

And the first question was about follow-up and intra- and extra-regional patients. About 20% of patients were extra-regional. We have,
of course, included these patients in the analysis of our hospital results. But as
you know, in Italy we do not have a national registry of mortality, so for our re-
gional agency of social and health care it was impossible to retrieve survival
data for these extra-regional patients. So we missed these patients.

But I would like to say that preoperative comorbidities and hospital out-
comes were similar in extra- and intra-regional patients. On multivariate
Conventional aortic valve replacement: still a feasible option in the transcatheter aortic valve implantations era?

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To evaluate the perspectives of potential and success of transcatheter aortic valve implantations (TAVIs), a fundamental analysis of conventional cardio-surgical aortic valve implantation is absolutely necessary guiding the procedural decision-making and patient stratification. Even though several single-centre observations on the outcome of octogenarians with aortic valve surgery have been published [1, 2], a more global and representative information is still missing.

Di Eusanio et al. [3] have to be congratulated to present in this issue the substantial data out of a regional Italian cardiac surgery registry. Compared with the available single-centre analysis, the patient population has a much larger size and is very actual including patients between 2003 and 2009.

In particular, the mentioned logistic EuroSCORE of 13% in their patients indicates that this is not a highly selected group of superior octogenarians in top condition but a representative average also including individuals with high-risk constellations.

The obtained hospital mortality of 4.5% in these patients is remarkable and clearly demonstrates that conventional aortic valve implantation is a routine procedure in this group of patients.

Aiming at the question what should be done best for an octogenarian with aortic stenosis either conventional heart surgery or a TAVI procedure, some additional information would be interesting, especially data on paravalvular leakage and remaining aortic insufficiency [4]. The number of pacemaker implantation which corresponds to the incidence of complete atrial ventricular block appears to be comparably low and is also basically different from pacemaker implantations in TAVI procedures, especially when dealing with the CoreValve® system [5]. Beyond the perioperative situation, the long-term outcome of these patients is also quite impressing with an estimated 6-year survival rate of 67.5%.

These data strongly emphasize the necessity for complete registry analyses combining the periprocedural outcome with a