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Minimally invasive valve surgery: pushing boundaries over the eighty

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ABSTRACT

BACKGROUND Mean age of patients with valves diseases is significantly increasing, and, in the near future, cardiac surgeons will have to deal with a considerable number of patients aged more than 80 years. The remarkable results gained by the minimally invasive approach have encouraged its application in more complex and fragile patients, such as older people. This study aimed to identify the rate of early mortality and major complications, and independent predictors for mid-term mortality in octogenarians undergoing minimally invasive valve surgery.

METHODS Octogenarian patients undergoing right mini-thoracotomy mitral and/or tricuspid valve surgery between 2006 and 2020 were included. Primary endpoint was to identify independent predictors for mid-term mortality, and secondary endpoints were operative morality, stroke, independent predictors for early composite outcome, and quality of life at follow-up.

RESULTS Analysis was performed on 130 patients. Stroke occurred in one patient (0.8%), while operative mortality was 6% (eight patients). One-year and five-year survival were 86% and 64%, respectively. Logistic regression identified age and creatinine level as independent predictors of mid-term mortality, survival analysis showed that age ≥ 84 years and creatinine level ≥ 1.22 mg/dL were the cut-off points for worst prognosis. Female gender and hypertension were found to be independent predictors of early composite outcome.

CONCLUSIONS Results of the present study show that age alone should not be considered a contraindication for minimally invasive valve surgery. Identifying patients who are most likely to have survival and functional benefits after surgery is decisive to achieve optimal health outcomes and prevent futile procedures.

The expectancy and quality of life (QoL) of the elderly population continue to increase, and patients aged more than 80 years now account for a considerable proportion of all comers requiring valve surgery. Growing clinical experience demonstrates that, despite good early outcome, a significant proportion of old patients die relatively soon after the operation or have little or no improvement in QoL and functional status; therefore, concerns still remain regarding the appropriateness and the effectiveness of the surgical procedure.[1]

Right mini-thoracotomy valve surgery has already proven to be feasible and effective with excellent early and long-term outcomes.[2–4] As a consequence of these remarkable results, interest in minimally invasive surgery applied to patients with higher degree of frailty, such as older people, is growing.[5,6] The rationale is to minimize surgical trauma and accelerate the recovery. During their stay in hospital, older people have a significantly higher risk of experiencing functional decline, delirium and depression, and of developing pressure injuries. Any of these issues can have a significant effect on the ability to maintain a proper level of independence that allows them to return home.

Experience in right mini-thoracotomy valve surgery applied to patients aged more than 80 years still remains limited and, to date, there is no complete agreement on the profile of patient in whom the minimally invasive

approach is likely to be more beneficial. Aims of this study are to identify independent predictors for mid-term mortality, and the rate of operative morality and early major complications in octogenarians undergoing right mini-thoracotomy valve surgery.

METHODS

Study Design

A retrospective analysis was conducted on consecutive octogenarian patients undergoing right mini-thoracotomy valve surgery at the University of Turin, Cardio-thoracic Department, Turin, Italy, between 2006 and 2020.

Inclusion criteria reflected the general indications for mitral valve (MV) and/or tricuspid valve (TV) surgery through right mini-thoracotomy,[7,8] and aged 80 years or more. Exclusion criteria were age lower than 80 years and contraindications to the right mini-thoracotomy approach.

Primary endpoint was to identify independent predictors for mid-term mortality, and secondary endpoints were operative morality, rate of stroke, independent predictors for early composite outcome, and QoL at follow-up. The study protocol was reviewed and approved by the Institutional Ethics Committee (No.00448/2020).

All comers during the study period underwent a preoperative evaluation based upon clinical history and vascular anatomy for the allocation to the most appropriate surgical setting; particularly, patient selection through rigorous vascular screening, with computerized tomography scan and/or aorto-iliac-femoral vessels angiography, became mandatory in our clinical practice since 2009.[9,10]

All demographic and in-hospital data were collected prospectively into a database. Subsequent outcomes and mortality data were obtained through regular post-operative follow-up at the outpatient clinic and from reviews of hospital records, outside records, and telephone surveys. QoL after discharge was investigated through activities of daily living (ADL) and instrumental activities of daily living (IADL) questionnaires administrated during the last follow-up interview. ADL score was used to summarize over-all performance in bathing, dressing, going to toilet, transferring, continence and feeding (0 maximum autonomy – 6 totally dependent); IADL score was used for more complex activities related to independent living in the community (e.g., managing finances and medications) (1 maximum autonomy – 16 totally dependent).[11,12] We chose a threshold > 2 in the ADL score and > 10 in IADL score to indicate dependencies, as used elsewhere.[13] Clinical follow-up was closed on June 30, 2021.

Definitions

Post-operative stroke was defined as clinical and radiological evidences of a new post-operative cerebrovascular event. Operative morality was defined as any death prior to discharge or within 30 days of operation. Early composite outcome was defined as the occurrence of operative morality, acute kidney injury, and stroke.

Surgical Technique

All patients underwent operation through a right mini-thoracotomy in the fourth intercostal space and double lumen endotracheal tube to allow single-lung ventilation. A soft tissue retractor was used to expose the surgical port, and an endoscope was inserted in an accessory port created below the working port; the same port is used for carbon dioxide insufflation. An additional sixth intercostal space port is created for pump suction. Intraoperative trans-esophageal echocardiography was used in all the patients to guide cannulas positioning. After full heparinization, peripheral cardiopulmonary bypass was established with the patient cooled to 32 °C. Arterial perfusion strategies and aortic clamping techniques used during the study period were retrograde arterial perfusion (RAP) with endo-aortic clamp (EAC), RAP with trans-thoracic clamp (TTC), antegrade arterial perfusion through the ascending aorta with EAC (EndoDirect system), antegrade arterial perfusion through the axillary artery with TTC, and RAP with beating heart.[9,10,14] The choice of one setting in respect to the others was, in part, patient orientated (anatomy and clinical history), and, in part, dependent on the availability of the different settings in different time spans. Venous return was routinely obtained with a double cannulation (jugular and femoral). Superior and inferior vena cava occlusion was obtained by snaring or, in case of reoperations, by placing endovascular balloons (7 F, 65 cm) (Meditech Boston Scientific Corporation, Natick, MA, USA).[15]

Custodiol® (25 mL/kg) or St. Thomas 1 (1 L induction dose, 500 mL maintenance when repeated) solutions were used for myocardial protection.

Statistical Analysis

For descriptive purposes, categorical data were presented as counts (percentages) and compared using the Pearson's chi-squared test or Fisher's exact probability test where appropriate. Continuous variables were expressed as mean ± SD or medians (interquartile range) and compared using the two-tailed independent Student's *t*-test or the Mann-Whitney *U* test. The primary study analysis consisted in the assessment of factors associated with mid-term mortality. A univariate analysis was initially run and then only those variables which meet a preset cut-off ($P < 0.05$) for significance were included in the multivariable model. A parsimonious Cox regression model was built to identify the best predictors for mid-term mortality. Results are reported as hazard ratio (HR) with 95% CI, and *P*-value. Proportional hazard ratio assumptions were verified graphically and with the Schoenfeld residuals test. Disease-free survival analyses were applied to identify optimal cut-off.[16] The risk models were compared through partial likelihood ratio test. Akaike's information criteria and Bayesian information criteria were reported for both models. Risk factors for early composite outcome were tested using a parsimonious logistic regression model (including variables with $P < 0.05$ at univariate analysis) and reported as odds ratio (OR) with 95% CI. Kaplan-Meier curves for recurrence of mitral regurgitation were created and the curves compared using the log-rank test. An alpha level < 0.05 was considered significant. Statistical analyses were performed with R software (version 4.1.2; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

During the study period, 1740 patients underwent right mini-thoracotomy MV and/or TV surgery at our department. Of these, 130 patients (7.4%) were older than 80 years (Figure 1).

Patients' characteristics are reported in Table 1. Mean age at the date of surgery was 82.1 ± 2.0 years. Seventeen out of 130 patients (13.1%) had undergone previous cardiac surgery.

Intra-operative data and post-operative outcomes are listed in Table 2. Cardiopulmonary bypass was conducted with retrograde perfusion in 120 patients (92.3%). Aortic occlusion was obtained respectively with TTC in 91 cases (70%) and EAC in 34 cases (26.2%). MV surgery was performed in 123 cases (94.6%), 40 of these cases

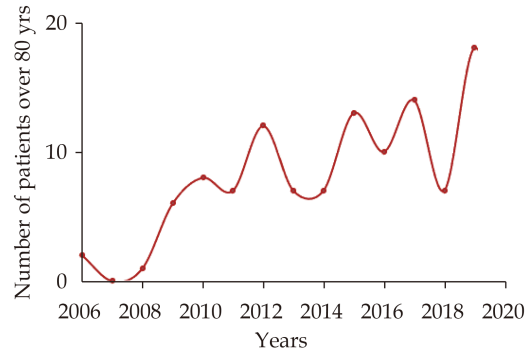

Figure 1 Minimally invasive mitral valve surgery in octogenarians over the study period.

were MV repair (32.5%). Isolated TV surgery was performed in seven cases (5.4%). Stroke occurred in one patient (0.8%), while conversion to sternotomy was required in three cases (4.3%) due to acute aortic dissection in two patients, and to bleeding right ventricle in one patient. Operative mortality was 6% for eight patients and early composite outcome occurred in 26 patients (20%). Mean length of hospital stay was 11.7 days, 98 patients (84.4%) underwent cardiac rehabilitation in a secondary care structure.

Mean follow-up time was 45 months (interquartile range: 1–181 months), and was 93% of patients completed. Twenty-one mid-term deaths were recorded; of these, nine deaths were cardiac related. One-year and five-year survival were respectively 86% (95% CI: 80–92.4), and 64% (95% CI: 55.1–74.8). Eleven late hospital re-admissions were recorded for the following reasons: congestive heart failure (five cases), pneumonia (two cases), and arrhythmia (four cases). Five patients presented recurrence of moderate to severe mitral regurgitation at follow-up. At five years, 98.1% of patients (95% CI: 95.6–100) were free from recurrence of more than mild mitral regurgitation.

As shown in Table 3, logistic regression identified age (HR = 1.31, 95% CI: 1.01–1.26, $P = 0.03$) and creatinine level (HR = 2.59, 95% CI: 1.34–5.02, $P = 0.0005$) as independent predictors of mid-term mortality, survival analysis showed that age ≥ 84 years (HR = 2.15, 95% CI: 1.21–3.84, $P = 0.01$) and creatinine level ≥ 1.22 mg/dL (HR = 2.06, 95% CI: 1.19–3.59, $P = 0.01$) were cut-off points for worst prognosis (Figures 2 & 3). Female gender (OR = 2.91, 95% CI: 1.04–9.25, $P = 0.05$) and hypertension (OR = 4.79, 95% CI: 1.21–32.8, $P = 0.05$) were found to be independent predictors of early composite outcome.

ADL and IADL questionnaires were administrated in 91 patients (74.6%) after at least six months from surgery.

Table 1 Patients' characteristics (n = 130).

Variables	
Age, yrs	82.1 ± 2.0
Female	74 (56.9%)
Body mass index, kg/m^2	23.8 ± 3.7
NYHA class 3 or 4	88 (67.7%)
Hypertension	97 (74.6%)
Diabetes mellitus	16 (12.3%)
Previous myocardial infarction	4 (3.1%)
Peripheral vascular disease	26 (20%)
Chronic obstructive pulmonary disease	18 (13.8%)
Pre-operative creatinine, mg/dL	1.2 ± 0.3
Pre-operative neurological impairment	9 (6.9%)
Atrial fibrillation	78 (60%)
Previous cardiac surgery	17 (13.1%)
Log EuroScore I, %	15.8 ± 13.5
MV regurgitation	119 (91.5%)
MV stenosis	8 (6.2%)
Degenerative MV disease	66 (53.6%)
Ischemic MV disease	6 (4.6%)
Rheumatic MV disease	12 (9.2%)
Endocarditis	3 (2.3%)
Prosthesis dysfunction	9 (6.9%)
Ejection fraction, %	59.8 ± 9.1
Systolic pulmonary artery pressure, mmHg	50.1 ± 15.2

Data are presented as means ± SD or n (%). MV: mitral valve; NYHA: New York Heart Association.

In 73 patients (80.2%), ADL score was ≤ 3; and in 71 patients (78.1%), IADL score was ≥ 9; showing a good QoL in about 80% of patients.

DISCUSSION

Mean age of patients referred for valve surgery has significantly increased, and it is clear that, in the future, cardiac surgeons will have to deal with an even larger number of patients aged 80 years or over than today.[17–19] These patients have a significantly higher risk profile with more comorbidities and fragility when compare to general population;[6] moreover, the rate of proportionate MV disease with different degree of involvement of the left ventricle in the elderly population is significantly higher, such as the probability to be at their second, third or even more cardiac procedure.[20]

The excellent results reported by the minimally invasive cardiac surgery have shifted the surgical indications towards more complex cohorts of patients, such as octogenarians, and evidences of safety and effectiveness have already been reported.[21–23] However, the decision for surgery is complex, and reviewing outcomes of minimally invasive valve surgery in this high-risk group of patients is of great importance to guide clinical practice.

Aims of this study were to identify the profile of patients with increased perioperative risk and to detect patients in whom the surgical procedure is likely to be futile.

Figure 1 clearly illustrates the growing proportion of octogenarians referred for MV and/or TV surgery through our 15-year experience in minimally invasive cardiac surgery. This is in part due to the increased life expectancy of the elderly population and to the increased number of elderly people referred for surgery; in part, it reflects the growing confidence and experience of a center dedicate to a minimally invasive program that allow to move toward more complex and fragile patients with

Table 2 Intra-operative data and post-operative outcomes (n = 130).

Variables	
Mitral valve surgery	123 (94.6%)
Mitral valve repair	40 (32.5%)
Tricuspid valve surgery	27 (20.8%)
Atrial fibrillation ablation	6 (4.6%)
Cardiopulmonary by-pass, min	125.5 ± 37.6
Aortic clamping, min	83.4 ± 29.1
RAP with endoaortic clamp	28 (21.5%)
RAP with trans-thoracic clamp	91 (70%)
Antegrade arterial perfusion with EndoDirect system	5 (3.8%)
Antegrade arterial perfusion with trans-thoracic clamp	5 (3.8%)
RAP without clamping	6 (4.7%)
Conversion to sternotomy	3 (2.3%)
Aortic dissection	2 (1.5%)
Major neurological events	1 (0.8%)
Myocardial infarction	–
Acute kidney injury	8 (6.1%)
Re-exploration for bleeding	8 (6.1%)
Atrial fibrillation	35 (2.7%)
Definitive pace-maker	9 (6.9%)
Multiorgan failure	3 (2.3%)
Intensive care unit stay, days	3.1 ± 6.9
Mechanical ventilation, h	28.6 ± 83.1
Hospital stay, days	11.7 ± 9.9
Early composite outcome	26 (20%)
30-day mortality	8 (6.1%)

Data are presented as means ± SD or n (%). RAP: retrograde arterial perfusion.

Table 3 Logistic regression and survival analysis for age and creatinine level.

	HR (95% CI)	*P*-value
Logistic regression		
Age	1.31 (1.01–1.26)	0.03
Creatinine level	2.59 (1.34–5.02)	0.0005
Survival analysis		
Age ≥ 84 yrs	2.15 (1.21–3.84)	0.01
Creatinine level ≥ 1.22 mg/dL	2.06 (1.19–3.59)	0.01

the aim to address the benefits of the minimally invasive approach also to these subgroups of patients.

The present study shows that being octogenarians does not necessarily implicate prohibitively surgical risk. Thirty-day mortality was 6.1%, despite a predictive mortality of nearly 16%; a high proportion of patients (86%) survived for one year, and more than 60% of patients survived for five years after the procedure.

Our data are in contrast with the meta-analysis provided by Biancari, *et al.*,[24] where the overall operative mortality in MV patients older than 80 years was rather high (15%) and long-term survival lower when compared with octogenarians undergoing aortic valve surgery; however, the large heterogeneity of patient characterist-

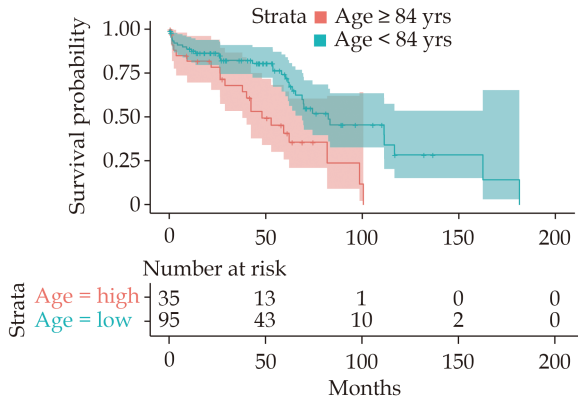

Figure 2 Proportional hazard ratio for age.

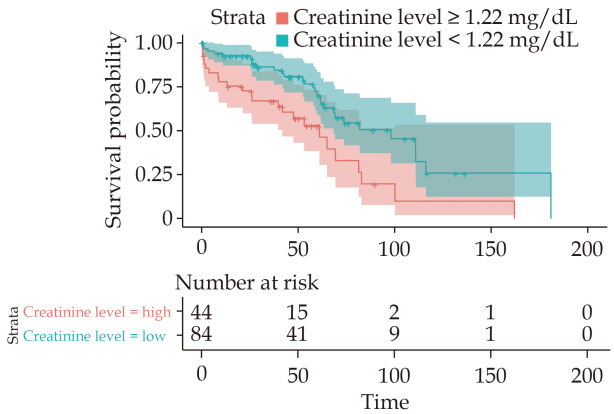

Figure 3 Proportional hazard ratio for creatinine level.

ics and associated procedures found in the meta-analysis prevent an adequate interpretation of the results (a large number of patients enrolled underwent concomitant coronary or aortic valve surgery), and most of the studies considered were made of mid date series of patients. The effect of mid date studies is of particular interest as the staged decrease in operative mortality in recent studies seemed to provide evidence of a marked improvements in perioperative care of these fragile and high-risk group of patients. More recent series are in line with our outcomes and reflect the misperception that MV surgery in the elderly is associated with excessively high mortality.[25,26]

In the era of micro-invasive procedures, transcatheter valve repair or replacement should be definitely be considered an alternative to traditional or minimally invasive cardiac surgery in fragile and high-risk patients such as octogenarians.[27] However, it is well-known that micro-invasive procedures have strict parameters of selection, particularly regarding the anatomy of the MV or TV; therefore, a not negligible proportion of patients are excluded from the benefits of these options. Moreover, when looking at micro-invasive options for MV replacement, suboptimal outcomes in terms of in-hospital mortality and weaknesses of the procedure, such as iatrogenic left ventricular outflow tract obstruction and MV stenosis, are still reported and represent a restraint in the broader adoption of these techniques.[28–30] Data from the VIVID (Valve-In-Valve International Data) Registry, on more than 1000 patients from 90 centers undergoing valve-in-valve or valve-in-ring, show a 30-day mortality of 7% and a consistent rate of residual stenosis (immediate postprocedural mean gradient ≥ 5 mmHg in 61% of cases and ≥ 10 mmHg in 9% of cases).[31]

Our study shows that age over than 80 years should not be considered an absolute contraindication for surgery, however, it is of paramount importance to identify the profile of patient with prohibitive perioperative risks and low chance of mid-term survival. Logistic regression analysis of the present study highlights that age over than 84 years and creatinine level higher than 1.22 mg/dL are associated to a worst prognosis in term of mid-term mortality, while female gender and hypertension were found to be independent predictors of early composite outcome; surgical indication in patients with these characteristics should be properly evaluated by a dedicated heart team.

When looking at the subgroup of octogenarian patients, where the rate of comorbidities is definitely higher than those reported in the general population, a rigorous pre-operative vascular screening becomes of paramount importance with the aim of identify unknown peripheral vascular disease and allocate the patient to the safest approach.[9,10] In our experience, from 2009, the pre-operative vascular screening with computerized tomography scan and/or aorto-iliac-femoral vessels angiography become mandatory; moreover, all the modes of arterial perfusion and aortic clamping available (RAP with EAC, RAP with TTC, direct ascending aorta cannulation with EAC, or axillary artery cannulation with TTC) were taken into consideration and tailored to the patient's characteristics. Our team has already analyzed results reported after the adoption of this decision-making process on the overall population of patients undergoing minimally invasive MV surgery, and has shown a trend toward a progressive decrease in the rate of surgical related complications and a significant protective effect of the tailored approach on the occurrence of major neurological complications.[10,14] In the subgroup of octogenarians, stroke was reported only in one patient

(0.8%, before 2009), while acute aortic dissection was reported in two cases (1.5%, both cases before 2009).

Other point of controversy in the literature concerns the optimal management of elderly patients with degenerative MV disease. MV repair was initially considered to be an unnecessary procedure in the elderly because of frailty, poor quality of tissues, calcified annuli, and prolonged clamping and bypass times when complex repairs are attempted.[32] However, the repair rate, especially in high-volume centers, has nevertheless continued to grow and an increasingly number of papers has reported better results of the repair technique compared with the replacement also in the elderly population.[33,34] The present study reports a repair rate of 32.5% in patients with diagnosis of degenerative MV disease, and this is in line with data in the literature.

The elderly population faces with a limited remaining lifetime, therefore, along with results in terms of early mortality and major complications, preservation or even improvement of QoL is of key importance. In the present report, we used ADL and IADL scores to summarize over-all performance in daily activities. However, quantification of life and performance status following surgery is difficult and inherently subjective; moreover, as part of limitations, no pre-operative evaluation of ADL and IADL scores was performed. On the other hand, in our clinical practice, patients not autonomous or with a poor QoL, are generally deferred from surgery and re-directed to palliative care.

CONCLUSIONS

In current time, age alone should not be considered an absolute contraindication for minimally invasive valve surgery; however, identifying patients who are most likely to have survival and functional benefits after minimally invasive valve surgery is decisive to achieve optimal health outcomes and prevent futile procedures. Minimally invasive surgery should be considered the benchmark for comparisons with new hybrid catheter-based technologies especially in this cohort of patients.

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