Conventional surgery results in patients originally referred for transcatheter aortic valve implantation
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Aims Transcatheter aortic valve implantation (TAVI) is increasingly considered as a viable alternative to conventional aortic valve replacement (AVR) in high-risk patients. Long-term results, however, are still scarce and the medical community hesitates in enlarging indications to lower-risk patients. Moreover, available devices are expensive and a strict potential candidate selection is necessary.

Methods From April 2008 to August 2012, a total of 212 patients, originally referred for percutaneous treatment, were thoroughly evaluated by the aortic team of our department in order to choose the optimal procedure. Of them, 55 patients (35 women; 20 men) were considered as still acceptable candidates for conventional AVR.

Results Mean age was 80.7 ± 4.7 years; mean additive and logistic Euroscore I were 9.7 ± 1.8 and 17.8 ± 9.5%, respectively. Mean Euroscore II was 7.9 ± 5.5%. Mean New York Heart Association class was 2.9 ± 0.5. The majority of patients (87.2%) presented a geriatric frailty score of 0–1. Four patients showed a heavily calcified ascending aorta, and five patients (9%) underwent reoperations. Hospital mortality was 10.9% (six patients). Mean follow-up was 535.9 ± 407.4 days (range: 6–1365 days). Six other patients died during this period for a mean survival of 74.4 ± 6.9% at 2 years. Mean New York Heart Association class at 1 year was 1.25 ± 0.5 (P < 0.01 vs. preoperative value).

Conclusion AVR should be indicated with caution in high-risk patients originally referred for TAVI. Despite medium-term results being good, with excellent functional status, hospital mortality is not negligible.

Keywords: aortic valve, geriatric, heart valve, percutaneous, replacement

Introduction Degenerative aortic valve stenosis represents a frequent clinical scenario. In fact, population aging conveys an increasing number of individuals affected by this condition. Aortic valve replacement (AVR) is the treatment of choice when a symptomatic and severe aortic valve stenosis develops.

A few years ago, however, a large survey has showed that more than 30% of these patients were not operated upon because they were considered poor surgical candidates because of their advanced age or comorbidities. In order to offer another therapeutic option to these patients, in the last decade transcatheter aortic valve implantation (TAVI) devices have been introduced in the clinical practice with excellent early results.

Therefore, an increasing number of patients are referred for TAVI procedures. But the cost of the commercially available devices remains high. Therefore, their availability is limited and not all potential candidates can be treated. Some of them are inevitably turned back to conventional AVR.

The aim of this study is to present the results of those patients who, originally referred for a TAVI procedure, underwent instead a conventional AVR.

Patients and Methods Preimplant triage The present study was notified to the ethical committee of our hospital, and patient consent was waived. Because of financial reason, hospital administrators have allowed a limited number of devices per year, varying from 25 to 30. Therefore, a strict preimplant triage was necessary in order to avoid TAVI in patients who were still operable conventionally with an acceptable risk.

For this purpose in early 2008 a multidisciplinary aortic team was created. This aortic team is composed of two cardiac surgeons, two interventional cardiologists, two clinical cardiologists, an anesthesiologist and a research nurse. Their assessment included a thorough clinical...
evaluation, transthoracic echocardiogram, coronary angiogram, contrast-medium computed tomography (CT) scan, respiratory function tests and geriatric frailty status assessment according to Rockwood et al.9

In general, patients with a high-risk profile or nonconventional risk factors (porcelain aorta, high frailty) were discussed. Our institution is a regional referral center for TAVI. From February 2008 to September 2012, a total of 212 patients were considered for TAVI, which was carried out in 80 (37.7%) of them. Seventy-seven patients (36.3%) were considered unsuitable for either TAVI or AVR, mostly because of very poor clinical conditions. Some of them were treated with balloon aortic valvuloplasty (BAV). Fifty-five patients (25.9%), 35 women (63.6%) and 20 men (36.4%), were considered still adequate candidates for conventional surgery, and they represent the object of this study.

Surgical technique
All patients were operated through limited or full median sternotomy. Cardiopulmonary bypass with moderate hypothermia (32–34°C) and cardioplegic arrest was used. Aortic valves were replaced with bioprosthesis in all patients. Heterologous blood products were usually administered when blood hemoglobin level fell below 8 g/100 ml unless clinical condition prompted otherwise. The majority of the patients were transferred to rehabilitation after discharge.

Data collection and follow-up
Hospitalization data were collected prospectively on an electronic database.

During follow-up all patients were regularly contacted by telephone in order to assess their clinical status. Any available echocardiogram was retrieved and analyzed.

Results
Preoperative characteristics are summarized in Table 1. As expected, they reflect an extreme population. Briefly, mean age was 80.7 ± 4.6 years. Mean Euroscores (I additive, I logistic and II) were high in accordance with the risk profile of these patients. Figure 1 shows patient distribution among the frailty score classes; the majority of the patients were in classes 0 and 1, demonstrating a relatively low frailty. Many patients presented with peripheral or cerebral vascular disease. Mean prosthesis dimension was 20.7 ± 1.5 mm. In 12 patients (21.8%) an associated coronary revascularization was performed. In two patients a mitral annuloplasty ring was implanted. Six patients (10.9%) died in the hospital or during the first month after the operation. Six patients (10.9%) were re-explored for excessive postoperative bleeding. Fifty-four patients (98.1%) required one or more heterologous blood units. Mean length of stay was 11.2 ± 4.4 days. Major complications are summarized in Table 2. Follow-up was 100% complete. Mean follow-up was 535.9 ± 407.4 days (range: 6–1365 days). Six other patients died during this period for a mean survival of 74.4 ± 6.9% at 2 years (Fig. 2). New York Heart Association (NYHA) class at 1 year was significantly improved with respect to preoperative value (1.25 ± 0.5; \( P < 0.01 \)). Figure 3 shows NYHA class distribution differences between preoperative and 1-year follow-up assessments.

Discussion
Large clinical trials and registries carried out so far have demonstrated that TAVI is more effective than medical
therapy in high-risk patients with severe aortic valve stenosis. There is also increasing evidence that high-risk, but still operable, patients may also be treated with TAVI with early results comparable, if not better, to those of conventional AVR. Nevertheless, many aspects have not been elucidated yet: the long-term freedom from structural valve deterioration is not known; the residual aortic insufficiency, quite common after TAVI, is also poorly predictable and may probably jeopardize the benefit of the pressure overload reduction. The current economic global crisis has profound effects on national health services worldwide. New hospital policies pay great attention to expense optimization. Moreover, current clinical guidelines for valvular heart diseases clearly state that rigorous selection is needed for TAVI screening. This resulted in the exclusion of a group of patients whose clinical profile was not considered too severe to contraindicate conventional surgery. Nevertheless, mean Euroscores were high, mean age was over 80 years and several comorbidities were present. One factor that certainly played a role in preferring conventional surgery to TAVI was the low geriatric frailty score. These AVR patients were often independent for daily activities and showed good mobility. A significant number of them, however, would have undergone a TAVI if its availability were wider.

A recent study considered a similar population of patients, reporting a very low hospital mortality (1.3%). The authors concluded that the indication to TAVI should be considered with care because conventional AVR still remains the gold standard even when surgical risk profile is probably elevated. Their patient series, however, presented a lower risk level with respect to ours, reflecting the current wider indication to TAVI among German centers.

We recently presented the results of 10 years of isolated AVR performed at our department. Mean hospital mortality was similar to that of other large series. Therefore, we were disappointed by finding that, in these high-risk AVR patients, mortality was even worse than that predicted by Euroscore II. Four out of the six expired patients were re-explored for bleeding. This may have been the trigger event that eventually caused a negative outcome. These critical patients may not tolerate any
remarkable complication and deserve a meticulous surgical attitude. A recent analysis of high-risk patient outcome discussed by a large-volume aortic team demonstrated a similar high hospital mortality among AVR patients, superior to that expected according to the STS score evaluation. These data may support the concept that wider availability of TAVI devices would avoid forceful referral of suboptimal candidates to conventional AVR, reducing 30-day mortality. The predictive value of Euroscore and STS score have been questioned in current AVR series. Many authors have shown that these scores usually overestimate the surgical risk in those patients with recognized indication to conventional AVR especially if at high risk. Instead, it seems that they underestimate it in patients initially considered for TAVI. As a matter of fact, the patients of this AVR series cannot be considered as standard surgical population; they may represent a different typology of patients, thus requiring a different scoring approach. We believe that even the more recent Euroscore II is probably inappropriate to categorize TAVI candidates. A recent validation of Euroscore II in a series of 3800 surgical patients even demonstrated its poor calibration, with underestimated risk.

On the other hand, in these AVR patients, despite a high hospital mortality, we noticed a relatively low incidence of other perioperative complications; permanent pacemaker implantation was relatively low (3.6%), whereas there were no major cerebral complications, despite the average age.

Follow-up results may also be considered satisfactory. Our 2-year survival is in accordance with other series and similar to that found in lower-risk AVR patients. It is well demonstrated that conventional AVR has excellent medium-term and long-term survival rates. As in other studies, we may suggest that, once the higher operative burden is overcome, the AVR patients may benefit from a durable and effective therapeutic solution of severe aortic valve stenosis. From a functional standpoint, NYHA class at 1 year of follow-up was significantly improved in comparison to preoperative data. The majority of patients were asymptomatic, and medical treatment was significantly reduced.

The limitation of this study relates to the small series of patients; therefore, definite conclusions may not be drawn. One may argue that a direct comparison with contemporary TAVI patients treated at our department may add further insights. We believe that patient risk profiles were different as we used our limited TAVI resources for ‘true’ nonsurgical candidates. It may be interesting to know the real functional capacity at follow-up by more accurate assessment (i.e. 6-min walk test).

We may conclude that conventional AVR should be indicated with caution in very critical patients, potential TAVI candidates. Despite midterm results being satisfactory, 30-day mortality may be high.

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