Percutaneous aortic valve implantation. The demise of classical aortic valve replacement?

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This editorial refers to ‘Contemporary surgical or percutaneous management of severe aortic stenosis in the elderly† by F. Descoutures et al., on page 1410

The Paris group of Descoutures et al. describe their recent experience with percutaneous aortic valve implantation (PAVI). During a 7-month period they were referred 66 elderly patients (>70 years; mean 83 years) for treatment of severe aortic stenosis (AS). Thirty-nine of these (59%) were judged inoperable or ‘high risk’ for surgery. From this subgroup, 12 (31%) were submitted to PAVI and the remaining 27, who were deemed unsuitable for this procedure, were either treated medically (16 patients) or had a catheter balloon dilatation (inappropriately termed valvuloplasty by the authors—seven patients). Perhaps ironically, the last four of these patients, initially deemed inoperable or high-risk, were later submitted to classical aortic valve replacement (AVR), because the surgical risk was considered ‘high but not prohibitive’. Two of them also had severe coronary heart disease and underwent combined myocardial revascularization (CABG). The remaining 27 of the initial 66 patients were primarily sent for AVR.

This group’s results throw light on the problems still facing these procedures. Valve implantation was primarily not successful in two patients (17%) and there were three peri-procedural deaths (25%), for a global failure rate of 33.3%, while among the 27 originally sent for AVR only one patient died early (3%) and there were no further deaths up to 6 months. In contrast, 10% (6/60) of the non-surgical group survivors had died after this short follow-up: two after valvuloplasty and four after medical treatment. Furthermore, none of the four patients who were later redirected towards AVR died, and all had an uneventful recovery.

Percutaneous valve implantation was initially directed at the pulmonary valve, first applied by Bonhoeffer in 2000, and has been very successful in many hundreds of patients, especially for the treatment of degenerated homografts used for treatment of congenital anomalies with right ventricular outflow tract obstruction. Extension to the aortic valve followed naturally, and the first human implantation was performed in 2002 by Cribier; however, the results could not immediately match those of the pulmonary valve because this valve is far more forgiving. Effectively, access to the right heart is technically less demanding, and mild to moderate degrees of regurgitation are usually very well tolerated.

In these early days, PAVI was plagued by several types of complications. Vascular injury at the access site, usually femoral or iliac arteries, may be serious and was the primary cause of the death of one of the patients in the series of Descoutures et al. The incidence of significant peri-prosthetic regurgitation was initially ~25% and, although it was reduced after the introduction of larger prostheses, still occurs in at least 10% of the cases. A high incidence of A-V block has necessitated pacemaker implantation in up to a quarter of the cases. Last, but not least, incorrect implantation of the prosthesis occurs in a significant number of cases, as happened in two patients in the current series.

An alternative approach, the transapical implantation, was developed to overcome these shortcomings. Larger and shorter catheters can be used which theoretically permit a better controlled and more accurate positioning of the prostheses, and this approach does not have vascular problems. Some proponents of this method, mainly surgeons, claim better results than for the transvascular approach, but the number of procedures performed is still too low to permit conclusions. Interestingly, these two apparently competitive procedures have had the virtue of approximating the cardiological and surgical groups, as the collaboration of a surgeon in a typical cardiological field and of a cardiologist in a typical surgeon’s field is judged essential by almost everybody involved.

These new technologies have attracted an unprecedented interest and enthusiasm, especially amongst young cardiologists and surgeons, some of whom would be ready to do their ‘first’ tomorrow. This may become one of its most dangerous aspects. The current report originates from a group which is famous for their experience with catheter-based valve interventions, especially of the mitral valve, and we ought to congratulate the authors for their pioneering efforts. However, these procedures are far from being standardized and are not easily reproducible. Therefore,
and at least for the near future, they must rest in the hands of very specialized teams of cardiologists and surgeons working, in association, in high-volume units, operating in specially adapted environments, preferably in hybrid (cath lab and operating) suites. This is exactly what the companies producing these devices are currently demanding from prospective users.

In the absence of published guidelines, the selection of cases must be multidisciplinary. In a joint position statement published a few years ago, the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI) cautioned against the widespread use of these technologies without proper evaluation. Although much has happened since then, these cautions are still warranted, and the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) are currently preparing a joint position statement, soon to be published in this journal, which aims at counselling both cardiological and surgical fraternities until evidence-based guidelines can be produced.

Another important point to consider is the uncertainty about the durability of the prostheses currently available. The need to reduce the volume of the prosthesis to conform to the size of the implantation catheters, currently 18–24 French, has obliged the manufacturers of catheter-based prostheses to compromise on some of the features previously considered essential in those used in AVR. The impact of these changes on the wear of the prostheses is largely unknown. This obviously limits the use to elderly patients and excludes younger patients whose life expectancy exceeds the predictable durability of the prostheses. So far, PAVI has been limited to the so-called compassionate cases, i.e. elderly patients with severe aortic stenosis who have a very limited life expectancy and who are judged to be at unacceptably high risk for surgery. However, this classification is very subjective. Risk models, such as the EuroScore and the STS score, are not specifically designed for aortic stenosis and tend to overestimate the risk. Also, they are not widely applicable, as it is now well accepted that the risk is also related to the particular surgical team.

One argument most often used by the enthusiasts of these novel technologies is that many patients with aortic stenosis are never referred to surgery because they are ‘assumed’ to be high-risk candidates. The investigators in the EuroHeart Survey found that 33% of patients with severe valve disease and severe symptoms were not referred to surgery. However, I, personally, do not recognize this ‘reality’. In my 30-year surgical experience, I have not denied surgery to anything like as many patients as appear to be ‘inoperable’ today. Perhaps the physicians responsible for these patients either did not have a close relationship with surgeons or did not talk to them. More than ever, this close relationship is essential for adequate management of the most difficult cases.

It is ironic that all four patients initially considered inoperable or very high risk in the series of Descoutures et al. and secondarily sent for AVR survived both the hospital admission and the 6-month follow-up period. Presumably, the same could have happened to some or many of those submitted to PAVI or to medical therapy, had they been subjected to AVR. This is an important limitation of studies such as that under discussion. One will never know what would have happened if... Naturally, the only way to resolve this issue would be a large multicentre randomized study comparing the ‘old’ and the ‘new’ techniques, but this is probably not feasible, although some relatively limited such trials are currently under way.

Finally, the procedure is also not applicable to cases other than calcific aortic stenosis. Use in aortic regurgitation is unlikely in the foreseeable future, as is the use in other pathologies, such as complex infective endocarditis.

Surgical AVR is a time-honoured technique which has produced excellent results in probably more than 1 million patients over the last four decades. Its mortality and morbidity rates have been extensively investigated and discussed. Most experienced surgeons can perform it today with single-digit mortality, close to values of other common cardiac surgeries, even in septuagenarians and octogenarians, and beyond. At this stage, and probably for quite some time, its safety cannot be matched by PAVI. Hence the application of this procedure should remain limited to a minority niche of patients who are truly not operable with an acceptable risk. Yet, it is currently being advocated for patients with an STS risk score >10%, far lower than its current margin of safety, which means that it is already extending its own limits.

Therefore, it appears obvious that AVR is going to be around for a long time. The number of patients with aortic valve stenosis is increasing exponentially and most will still require conventional valve replacement. At least from this point of view, cardiac surgeons need not be afraid. Nobody is (certainly I am not) against progress; but progress often starts slowly and painfully, and it cannot be pursued at any cost, especially not at that of the patients. It has to be constructed on solid foundations, a secure step at a time. There is no longer a place for the blind adventures of the first pioneers. They did not have alternatives; we do!

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References


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