Will the use of percutaneous aortic valves remain compassionate?

The mid 1990s saw the emergence of percutaneous dilatation of the calcified aortic valve (also known as aortic balloon valvuloplasty). The procedure was initially touted [1] as a gentle and minimally invasive approach that will eventually replace surgery. However, it soon became evident that in contrast to mitral balloon dilatation, the benefits of ballooning the calcified aortic valve were minimal if any and short-lasting [2]. For these reasons it was recommended that the procedure should be applied only on a compassionate basis, i.e. in patients who had unacceptably high risk for a surgical intervention. Unfortunately, this pretense was more often than not disregarded and ossified aortic valves were dilated by the thousands, including those in patients having well acceptable surgical risks. Only after several years when the overwhelming number of short-term failures became undeniable did the technique fall in disrepute, and nowadays it is utilized only as a last resort for short-term palliation. It is notable, however, that whenever the procedure acutely failed and there was a need for immediate surgical intervention, most of these inoperable patients came through surgery unscathed. Also, nobody expressed any remorse or accepted responsibility for the aortic balloon valvuloplasty fiasco.

Now, we are about to witness a similar sequence with the introduction of percutaneous aortic valve replacement by some of the same individuals who gave us aortic balloon valvuloplasty [3]. At the present, a powerful alliance of innovative cardiac specialists and device manufacturers are conducting clinical trials of percutaneously inserted aortic valve prostheses. Because of the undeniable fact that even the best of these devices are expected to significantly underperform surgically implanted aortic valves, the justification for their use has been designated as compassionate (where have we heard this word?), i.e. to be applied only if the patient is regarded by cardiological and surgical expertise as the most significant or as having an unacceptably high risk for open heart surgery.

We are obliged to raise the question: can we really trust the same parties involved to use this new and powerful clinical, and no doubt also, marketing tool, with restraint and wisdom? To provide an answer, one must consider the clinical as well as the economical background. While the issue of investment capital moved significantly up on the ladder of priorities, short-term profits still remain a primary interest to manufacturers. In lack of expected short-term profit, they remain reluctant to spend funds on research and development. From where will this profit expect to materialize?

In their recent study, Gaudino et al. [4] examined the surgical risks of 1695 patients who in their practice were in need of aortic valve replacement. Using EuroScore ≥9 as a watershed, they found that only a limited number of patients (6% in 2003 and 2.2% in 2006) were in need of aortic valve intervention fulfilled the criteria for compassionate percutaneous aortic valve insertion. Translating these findings as they may relate to the respective patient population in the U.S. and in Europe, the EACTS database [5] reports 10,927 patients who underwent isolated aortic valve replacement in the years of 2004 and 2005 in Europe, while the STS database lists 16,849 patients (added) who underwent the same procedure in 2006 in the United States [6]. Adjusting the EACTS data to one year, the combined volume totals 22,315 isolated aortic valve replacements yearly. Applying the data of Gaudino et al. [4] only 491 patients, or 2.2%, would fall into the compassionate category. The two registries also list 20,430 patients who underwent aortic valve replacement combined with either coronary bypass grafting and/or mitral valve replacement. While it is unlikely that many of these patients who are already undergoing conventional cardiac surgery would undergo simultaneous percutaneous aortic valve insertions as well, taking them into consideration, we still have only 950 patients who meet the compassionate criteria. To be fair, we may add another estimated 1600 patients whom, because of their grave condition, surgery may not have even been offered. This still leaves only about 1500—2500 patients to be considered for compassionate percutaneous aortic valve intervention in Europe and the United States!

At present more than 20 companies are involved in the development of percutaneous aortic valve substitutes [6]. The device manufacturers have already spent and continue to spend large amounts of money to engineer, manufacture and study delivery systems. Such a modest volume of patients is hardly expected to cover the past and future of such tremendous costs. For the industry, having the device turn out to be a niche treatment for only a select subset of patients would be a disaster. Also, the surgeons can offer both conventional and percutaneous intervention to their...
patients; however, the scope of interventional cardiologists is limited to percutaneous insertion.

The conclusion is inevitable: though present publications and clinical trials express the intent that percutaneous aortic valve replacement will be limited to compassionate use, in reality the entities involved in the issue of developing and disseminating the device expect a wider use, including a large segment of the patient population with low-risk for conventional aortic valve surgery. This is readily evident in the report of the Cardiovascular Roundtable [7] that predicts 13,000 yearly percutaneous aortic valve implantations in the United States within 7 years. Based on logic and presently already available data, long-term results will be significantly inferior to conventional aortic valve replacements.

If not prevent, but at least mitigate this, our profession is obliged to: (A) redefine the concept of compassionate as it relates to aortic valve surgery, (B) monitor the indication and volume of percutaneous aortic valve insertions in respective institutions, (C) assure that not only short- but also long-term outcomes are documented, (D) encourage prospective randomized trials evaluating high-risk cases treated by percutaneous versus conventional approaches and, (E) last, but not least, assure by obtaining an informed consent, the patient is aware not only of the procedural mortality, but also of the short- and long-term outcomes.

We should not repeat the mistakes of the past.

References

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