Endoscopic mitral valve reconstruction and percutaneous mitral clipping: what is the best solution for our patients?

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Keywords: Mitral valve surgery • Minimally invasive surgery • Percutaneous mitral clip • EVEREST trial

In this historical period for our profession, we are facing complex and challenging experiences. Being a doctor nowadays is probably more difficult than it was ten years ago and performing cardiac surgery requires different skills, compared to when we started our surgical careers.

Firstly, in our daily surgical practice, we are forced to treat an increasingly older population with greater comorbidity.

Secondly, the social environment has changed its attitude towards our specialty, such that we are not just surgeons trying to save lives and give years of life to our patients, but we are sometimes considered the cause of damage to our patients. We practice medicine under pressure from a society that considers illness and death to be not merely a normal component of life but the result of errors or omissions by doctors and that, when an adverse event occurs, someone must be found guilty.

Public healthcare is a major source of expenditure for a country, absorbing an important part of the Gross National Product. The need to limit costs is therefore urgent and, more often than not, contrasts with the vast scale of investment by major medical companies seeking to increase profits through the introduction of new drugs and medical devices. These profits are essential for investment in new research, but sometimes this profit motive can clash with the safety of the patients in terms of technical challenges, reliability and ability to achieve consistent results. On the other hand, patients’ quest for immortality, avoiding illness and death, encourages us to offer our patients surgical procedures and devices that can be recognized as ‘minimally invasive’. However, ‘minimal intrusiveness’ is a very misleading concept that should relate to a more careful consideration of the physiology of body circulation and homeostasis. Practically—and in the majority of cases—it relates only to the extent of the surgical incision. It is a common perception that the relevance and the risk of a surgical procedure is related to the length of the dermal incision or to the number of stitches used to close the skin: the longer the incision, the greater the risk! Some members of the medical community encourage this ‘tribal’ way of approaching the problem, as illustrated by visual displays at meetings, in which a ruler is placed next to a patient’s incision. Except for an aesthetic aspect, no real advantages of minimally invasive procedures over conventional surgery have been demonstrated in large-scale meta-analysis and sometimes the doubt of a suboptimal result can be present [1].

So the definition of ‘small access’ should be preferred to ‘minimally invasive’: a real minimally invasive procedure can be achieved, for example, by optimizing extracorporeal circulation and retaining a ‘physiologic’ haematocrit with low priming, avoiding dangerous haemodilution.

More recently, specific percutaneous approaches to mitral valve pathology have been focused either on the leaflet, with the use of edge-to-edge fixation, or the dilated annulus often present in ischaemic and functional mitral regurgitation.

In April 2011, the results of the EVEREST II trial were reported in the New England Journal of Medicine. The trial was a randomized comparison of percutaneous repair (using the MitraClip device) with conventional surgery for mitral regurgitation, to evaluate the efficacy and safety of the percutaneous approach [2]. In the abstract the conclusions are clear: ‘Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes’. This conclusion should represent the rationale for introducing the device in the clinical practice.

No difference was observed between the two groups in terms of mortality and morbidity: in terms of major adverse events, the only difference was the reduced need for transfusions (8.8 vs. 53.2%, P <0.001) in favour of the percutaneous group.

I think we all have to congratulate the authors of EVEREST II who, for the first time in the history of medicine, have considered a treatment as a complication. Indeed, the rate of bleeding (a complication) is not reported and we can surmise that the rate of transfusion might be different from one centre to another, according to different transfusion strategies. Some centres consider a value of haemoglobin less than 10 g/dL as the lower limit for transfusion; others fix the cut-off at 8 g/dL.

The conclusion that this procedure was associated with ‘superior safety’ is totally misleading and sounds more like an advertisement than a scientific paper.

Furthermore, the cohort of treated patients was exceptionally healthy, with a mean age of 67 years and an EF of 60%; re-do
surgery was present in 21% of the population and was probably the only true risk factor.

At 30 days follow-up, in the percutaneous repair group, 6% of patients died, 20% had surgery for mitral valve dysfunction and a grade 3+ or 4+ mitral regurgitation was observed in 21%. It is very hard to understand how a procedure can be defined as safer when, in 47% of population, the results are really poor.

The results in the surgical repair group were even more disappointing. Mortality was 6% and the recurrence of a grade 3+ or 4+ mitral regurgitation was observed in 20% of patients at 30 days, in spite of 14% who received a mitral replacement.

A common surgeon— as I am— has some difficulty in understanding these results. According to the enrolment criteria, the patients had mitral valves suitable for repair. However, all reports published on surgical mitral repair showed different results [3, 4]. It could be surmised that these data are the results of low surgical standards, against which emerging percutaneous approaches for mitral regurgitation need to be compared.

If the goal is to perform a minimally invasive procedure, then the MitraClip device must also deal with the endoscopic mitral repair that, in all published reports, showed almost the same results as the standard surgical approach and was therefore superior to the results reported from EVEREST II [1].

**WHY SUCH DISAPPOINTING RESULTS SHOULD BE ABANDONED**

Many patients not enrolled in EVEREST II are really at high risk for surgery. For these patients, mitral repair or replacement is not unequivocally beneficial. They present heart failure symptoms with low EF and an enlarged left ventricle, sometimes with moderate mitral regurgitation: for these patients, the best treatment is unclear. The MitraClip could reduce mitral regurgitation and improve quality of life and, hopefully, life expectancy with a lower peri-procedural risk, as compared to surgery. Further studies are needed in this direction. In the meantime, collaboration between the surgeon and cardiologist, functioning as a team, will be the most successful paradigm for the development and eventual practice of percutaneous valve intervention.

Our role as a medical community is firstly to provide guidance, to perform the trials with minimal bias and to work collaboratively as providers of cardiovascular care, in order to perfect the techniques in the best interests of our patients. Furthermore, we need to inform our patients about the variety of options that will ultimately be available. To this end, in accordance with the Hippocratic oath, we need to have the best and most independent information. The most prominent journals and, of course, the scientific societies are notably the sources of this information. In this field, the influence of industry can be very strong for evident reasons and can influence the type of information released to the medical community.

As doctors, we need the correct information and, as a medical community, we have a duty to act because this statement of Marcia Angell former Editor of NEJM will become obsolete in the future: ‘It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine’ [5].

**Conflict of interest:** none declared

**REFERENCES**


