

EDITORIAL COMMENT

Can Transcatheter Edge-to-Edge Mitral Repair Be Considered as Efficient as Surgical Mitral Valve Repair?*



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Despite tremendous technical progress in technology of devices and in imaging to address severe mitral valve regurgitation (MR), particularly in elderly patients,¹ there are still some unresolved issues, leading to current severe undertreatment of the condition despite its high prevalence.² Every time the industry launches a “new device,” it seems that it will fit all pathologies and will be the answer to previous device failures. But we, as physicians, should mitigate our enthusiasm, and not be technology driven but patient driven.

The concept of percutaneous mitral valve (MV) repair is derived from the Alfieri technique (or edge-to-edge technique),³ which has emphasized the role of an annuloplasty in conjunction with the edge-to-edge technique.⁴ Any transcatheter technique will be weakened by failing to address annular dilatation, which is a major pathophysiological component in chronic MR. From some enthusiastic reports about the use of MitraClip (whatever type, from original to NT, NTR, XTR, G4, or Pascal [Abbott Cardiovascular]), there is an impression left that MR is addressed, that residual/recurrent MR is not a real issue, and even

that surgery nowadays is indicated only for patients not suitable for a Clip!

This report⁵ is the first one to analyze mitral transcatheter edge-to-edge repair (TEER) failures requiring MV surgery mostly in relation to residual/recurrent MR, and including >300 patients according to 3 scenarios: aborted TEER, acute MV surgery, or delayed MV surgery. Primary MR (PMR) (n = 155, 47%) was analyzed separately from secondary MR (SMR) allowing to identify specific risk factors inherent to the etiology. There will always remain criticisms regarding registries’ methodological approach, but technology and results have improved over the years, and these, as a snapshot, reflect reality bringing unknown data.

Not surprisingly, SMR patients were sicker, with more comorbidities. Patients’ inclusion was not noteworthy: mean age was 73 years, 42% were female, mean STS score was at 4%, 48% were deemed high surgical risk, 26% had undergone previous cardiac surgery, and 84% were in NYHA functional class III and IV. From these data, it is possible to say that neither the mean age nor the STS score was very high, and that the heart team estimated that 48% were high or extremely high risk for surgery. Knowing that a failed TEER may lead to urgent or emergent cardiac surgery, the heart team’s decision at first instance should also take into consideration that “a high-risk patient” may become a surgical candidate in the worst environment after failed TEER. Such parameter is difficult to quantify but should be included in the heart team decision, as surgeons have been exposed in the past decades, in operating on unstable patients considered initially inoperable after a failed noninvasive procedure. It is to be outlined that this issue is never addressed, as mortality after cardiac surgery is not accountable to the initial failed percutaneous

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procedure but only to surgery: it is not arguable, but it is a bias that we should bear in mind.

The major messages are quite clear and very informative. In pre-mitral TEER procedures, more than 2+ tricuspid regurgitation (TR) was present in 55% of the patients, and 22% had some degree of right ventricular dysfunction. In the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation) trial, more than 2+ TR was an independent predictor of mortality or heart failure hospitalization at 2 years. In this report, whether for PMR or SMR, TR severity was an independent predictor of 1-year mortality especially in SMR. Patients showing more than moderate TR after failed TEER underwent combined mitral and tricuspid surgery, with no increased mortality at 30 days and at 1-year follow up. Some interventional cardiologists are convinced that addressing both valves during the same procedure is beneficial to patients, but not all of them, and the current practice should include both valves more liberally, especially regarding TR considerable independent impact on PMR⁶ or SMR outcome.⁷

As far as residual/recurrent MR is concerned, after failed mitral TEER, the median time interval from TEER procedure to MV surgery was only 3.5 months, and there was no difference according to etiology as 70% of PMR and 60% of SMR underwent surgery for residual/recurrent MR. The subsequent message is very clear, the index TEER should aim for residual MR $\leq 1+$.⁸ Anatomical selection and improved technology may reach such goals. Some studies, such as EXPAND G4 (MitraClip EXPAND G4 Study), or the EXPAND (The MitraClip® EXPAND Study of the Next Generation of MitraClip® Devices) show promising results that would lead to less residual MR and decrease the need for secondary surgery. It seems obvious that all studies should separate “curative” procedures from “palliative” ones, as a 90-year-old frail patient with chronic renal failure is usually only considered for the TEER option and this, whatever the result. The intention to treat should be clearly stated because secondary MV surgery incidence could be artificially decreased by including a group of patients that in any case could become surgical candidates after failed TEER.

Causes for MR surgery after failed TEER were not different either for PMR or for SMR as 30% showed residual MR and 30% recurrent MR, except for mitral stenosis, which seems to be an issue in SMR. This fate of mitral stenosis was not reported in the COAPT trial and should be investigated further. A total of 97% underwent MV replacement and 42% concomitant

tricuspid surgery. After a failed TEER in a high-risk patient, MV replacement seems the best option. It is not really an issue for SMR patients but could be considered as a loss of the chance of having a good surgical MV repair at 73 years old for PMR. Overall, in-hospital and 30-day mortality was at 15.2% and 16.7%, respectively. However, SMR reached a higher mortality at 20.4% as opposed to 12.7% for PMR. It would be interesting to know how these figures compare with expected mortality in such cases. This cohort also shows that SMR patients present with significant mitral stenosis, ranging from 19% to 37% in contemporary studies despite the use of new devices. It also shows that TR at the time of indexed TEER is an independent predictor of mortality at 1 year.

Of great interest to be included in patients' selection for mitral TEER, are the different risk factors identified in a multivariate analysis predicting mortality at 1 year. For PMR: kidney disease, preoperative MR grade, emergent surgery, were found to be significant. For SMR, male, cirrhosis, pre-TEER TR grade, and cardiopulmonary bypass time were found to be significant.

Despite limitations, this cohort shows patients with failed TEER, even if considered extremely high risk for surgery at first instance, are operable, but in much worse conditions than if they had been assigned to surgical MV repair or replacement initially. However, it brings up the concept of percutaneous MV replacement, which still has many limitations but might represent a better option than a bad “repair,” which is also true for surgery. This report also emphasizes the risks of residual MR, which is well known in surgery, as a successful surgical MV repair is one with no or trivial MR at intraoperative echo control. Therefore, TEER has similar constraints as surgery if it wants to be an alternative therapy to surgery in some selected cases.

TEER is part of the therapeutic armamentarium to address both PMR and SMR, but patients' selection can be refined. Surgical MV repair is a true repair with its inherent risks, but once performed, results on residual/recurrent MR are well known and stable throughout time. Percutaneous therapy's main advantage over surgery is that it is truly mini-invasive, mainly due to the absence of cardiopulmonary bypass and inflammatory response, but both surgery and TEER have advantages and drawbacks with specific risks according to the etiology. All such considerations should be well known and openly discussed by the heart team before deciding on one or the other option, keeping in mind the patient-expected survival and benefits.

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