Is surgery the fair competitor for MitraClip?

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Abstract

In the last decades, the overlapping areas of intervention between cardiac surgeons and interventional cardiologists are rocketing, especially in the field of treatment of heart valve disease. But, while for the aortic valve the competition, even for non-high risk patients, has become tightened, in the context of mitral regurgitation, the surgery seems to not have competitors .In fact looking the results of studies published so far, a question arises: Is surgery the fair competitor for the Mitraclip? The meta-analysis by Abdul Khader et al summarized few evidences present in this field, only 11 observational studies and 1 randomized trial, providing an awesome response: "NO". Is therefore not a case if recently two trials, MITRA-FR and COAPT, chose to use as competitor for MitraClip, more rightly, medical therapy instead of surgery. In conclusions, in case of mitral regurgitation, surgery is still largely the gold standard treatment and so MitraClip cannot be mention at all as competitor of surgery. It can be the right choice of case of primary MR where patients showed high risk for surgery. In case of secondary MR, especially with large and poor left ventricle we should wait for a clear answer on its role, yet.

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Abstract

In the last decades, the overlapping areas of intervention between cardiac surgeons and interventional cardiologists are rocketing, especially in the field of treatment of heart valve disease. But, while for the aortic valve the competition, even for non-high risk patients, has become tightened, in the context of mitral regurgitation, the surgery seems to not have competitors .In fact looking the results of studies published so far, a question arises: Is surgery the fair competitor for the Mitraclip?

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In the last decades, the overlapping areas of intervention between cardiac surgeons and interventional cardiologists are rocketing, especially in the field of treatment of heart valve disease [1,2]. But, while for the aortic valve the competition, even for non-high risk patients, has become tightened [3], in the context of mitral regurgitation, the surgery seems to not have competitors [4] In fact looking the results of studies published so far, a question arises: Is surgery the fair competitor for the Mitraclip?.

The meta-analysis by Abdul Khader et al [4] summarized few evidences present in this field, only 11 observational studies and 1 randomized trial, providing an awesome response: "NO".

The authors, indeed, compared 1210 patients receiving MitraClip with 3009 patients undergoing surgery. Although, the length of hospital stay was unsurprisingly shorter for Mitraclip group, the rate of failure significantly lower when surgery was performed. So, even this meta-analysis confirmed the overwhelming superiority of surgery over Mitraclip.

The only trial published, the EVEREST II trial [5] showed several limitations, firstly excluding high-risk patients, that later became instead the class of reference for this treatment, then only 27% of patients had secondary MR, where surgery is the gold standard, yet.

There are some pathophysiological reasons supporting the concept that percutaneous edge-to-edge and surgery cannot be played off against each other. MitraClip was developed starting from the Alfieri stitch procedure which did not acted on the annulus but only fixing the two leaflets each other so to solve the mitral regurgitation transforming the valve in a double orifice structure [6]

Alfieri himself wrote "*The absence of annuloplasty definitely leads to accelerated failure of mitral valve repair. As a matter of fact, the surgical experience reveals that freedom from reoperation is remarkably lower when annuloplasty is, for some reasons, omitted* " [6,7]

This is particularly true in the setting of secondary MR with dilated cardiomyopathy where annular dilatation play a key-role in the pathophysiology of the regurgitation [8-10]. Moreover, we recently discovered as in this subset of patients, especially the ischemic ones, the valve structure undergoes changes in terms of leaflets and chords [11-13] which alongside with papillary muscle displacement make MitraClip unsuitable as treatment, since even surgery deserves to adopt a new paradigm [13]. In fact, the reasons why the results of isolated

mitral annuloplasty are still flaws, has to be search in the need to surgically address not only the annulus but also the subvalvular apparatus [14,15]. Hence, the question is how can an interventional procedure, which per se act only on a part of the valve, solve a more complex problem?.

If we give a glance wot European and North American guidelines [16,17], the place for MitraClip is very limited and the level of evidence (LOE) is low.

For ESC/EACTS guidelines [16], Mitraclip is indicated in patients with either primary or secondary severe mitral regurgitation (MR), with low ejection fraction, refractory to medical therapy or cardiac resynchronization therapy (CRT), with high comorbidity, where a durable surgical valve repair is not feasible or surgical revascularization is not need (Class IIb; LOE C). Moreover, an heart team discussion should precede the procedure and feasibility criteria have to be met.

The North American Guidelines [17] provides similar indications for Mitraclip, that are in case of severely symptomatic patients with chronic severe primary MR, with favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal medical therapy or CRT for heart failure (HF) (Class IIB, LOE B). In the latter guidelines, Mitraclip is not cited in the range of treatments.

Is therefore not a case if recently two trials, MITRA-FR [18] and COAPT [19], chose to use as competitor for MitraClip, more rightly, medical therapy instead of surgery.

In the MITRA-FR and COAPT trials, patients with moderate to severe and severe secondary MR with reduced left ventricular function received either medical treatment or MitraClip implantation. However, the results were conflicting, with the COAPT trial showing better clinical outcomes in the device group, while MITRA-FR failed to evidence any superiority.

This different conclusions can be due to some difference between the two trials. Firstly, COAPT trial double sized respect to MITRA-FR, then typology of enrolled patients seems not to be similar, since the definition of MR was different and so patients with worse MR were enrolled in the COAPT trial. Conversely, patients enrolled in the MITRA-FR showed wider ventricular damage.

From these divergences is possible to conclude that patients with too severe LV dilatation or dysfunction may not benefit from the MitraClip procedure [20]

In conclusions, in case of mitral regurgitation, surgery is still largely the gold standard treatment and so MitraClip cannot be mention at all as competitor of surgery. It can be the right choice of case of primary MR where patients showed high risk for surgery. In case of secondary MR, especially with large and poor left ventricle we should wait for a clear answer on its role, yet.

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