

# MITRAL VALVE REPAIR: REGULATORY OR ETHICAL PROBLEM?

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## Abstract

The long-term outcome of patients undergoing mitral valve repair (MVR) is based on what happens during the more or less 60 minutes of aortic cross clamping necessary to transform a leaking valve in a well-functioning one. As a consequence, the experience of the surgeon performing the procedure is the only determinant of the success rate that deserves to be taken into account. It is clear from the literature that the number of cases/year is inversely related to the number of early and late deaths, of repair failures and of reoperations. However, there is no agreement on the minimum caseload/year that represents the threshold to identify surgeons that can perform or not MVR. This problem then cannot be regulated by specific guidelines of by Scientific Societies, but only by the ethical perception we have of our profession.

## MITRAL VALVE REPAIR: REGULATORY OR ETHICAL PROBLEM?

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## ABSTRACT

The long-term outcome of patients undergoing mitral valve repair (MVR) is based on what happens during the more or less 60 minutes of aortic cross clamping necessary to transform a leaking valve in a well-functioning one. As a consequence, the experience of the surgeon performing the procedure is the only determinant of the success rate that deserves to be taken into account. It is clear from the literature that the number of cases/year is inversely related to the number of early and late deaths, of repair failures and of reoperations.

However, there is no agreement on the minimum caseload/year that represents the threshold to identify surgeons that can perform or not MVr. This problem then cannot be regulated by specific guidelines of by Scientific Societies, but only by the ethical perception we have of our profession.

Mitral valve repair (MVr) for mitral regurgitation (MR) is one of the most intriguing valvular procedures. Most surgeons are following general rules, but there is always room for some personalization of the techniques, an aspect that allows to reach the best results in the hands of that particular surgeon.

On the other side, as surgeons are always reporting the results in patients undergoing MVr, the general vision is lost. We often do not know exactly how many patients have MV replacement (MVR) as a first strategy, or mechanical complications (eg, mitral stenosis after repair)<sup>1</sup>, being the outcome focused on MR return or, more often, on MV reoperations. Moreover, the advent of minimally invasive mitral surgery (MIMS) through a right small thoracotomy pushed many surgeons to start a program in the hope to attract patients in an era when the number of referrals is reducing.

All these aspects, together with the necessity to guarantee a reasonable result to the patient, led to a discussion on some specific points. Is MVr a procedure for all surgeons? Can all the surgeons perform MVr using any approach? Is it necessary to limit MVr to selected Centers?

The European<sup>2</sup> and American<sup>3</sup> guidelines recommend, in general, repair when results are expected to be durable. However, in symptomatic and asymptomatic (with triggers) patients, they recommend only MV surgery, not the type of intervention. Only in asymptomatic patients without triggers MV repair is formally recommended and both guidelines suggest that it has to be performed in a Heart Valve Center<sup>2</sup> or in a Center where the possibility of repair are >95% and the operative mortality is <1%<sup>3</sup>.

The first question is then: who has to be the surgeon for an asymptomatic patient? A recent survey by Gammie et al<sup>4</sup> found that asymptomatic patients without triggers were only the 8.5% of 31,475 patients operated on between 2011 and 2016 in US and the repair rate was 92% with an overall early mortality of 0.8%. It is very likely that asymptomatic patients were already directed toward high-volume centers (>23 cases/year). In this report only 48 Centers out of 1020 (4.7%) were high-volume centers, but their case volume was 40.5% with a repair rate of 92% (versus 75.9% in the remaining centers).

These observations, while show that asymptomatic patients are often addressed to high-volume centers, on the other side rise another problem: are the results of MVr depending on the volume of cases and then on the experience of the single surgeon?

The prevalence of repair on patients with degenerative MR goes from 67% to 81%<sup>5-7</sup>. Repair rate is lower in the elderly, in women and in patients with comorbidities<sup>6</sup>. The number of cases performed yearly by a surgeon or by a Hospital has a huge influence not only on the repair rate, but as well on early and late mortality<sup>5,8-10</sup> and reoperation rate<sup>5</sup>. A recent report from the New York State showed that high-volume hospital increased their caseload and improved the outcome in valve surgeries<sup>11</sup>, reinforcing the concept that high volumes will improve results that will increase more the caseload. In South Korea, analyzing 6,041 patients undergoing MVr, 1-year mortality was higher in low- (<20 cases/year) and medium-(20-40 cases/year) volume centers if compared with high-volume (>40 cases/year) centers (10.1%, 8.7% and 4.7%). The reoperation rate was as well higher in low-volume (HR 1.86, 1.16-2.98, p=0.010) and in medium-volume (HR 1.91, 1.30-2.82, p=0.001) compared with high-volume centers<sup>8</sup>. Better results in high-volume centers were confirmed by other Authors<sup>9,12</sup>. Badhwar et al<sup>10</sup> reported, in patients with primary degenerative MR, a repair rate of 80.8%, increasing from the lowest (63.8%) to the highest volume quartile (84.5%). The median hospital median repair volume was 11 cases (5-25) and the median surgeon repair volume was 5 (2-11). Rate of successful MVr were lower in the lowest quartile as well as 1-year mortality rate, but not reoperation rate, both for hospital and surgeon volumes. An inverse correlation was found between composite endpoint of morbidity and mortality and volume quartile, with the results changed when the hospital volumes reached 75 cases/year and surgeon volume 35 cases/year.

In a recent report<sup>13</sup> analyzing the outcome of 4,420 patients operated on in Australia and New Zealand for

degenerative MR from 2008 to 2017, Wayne et al. confirmed that repair rate was depending from caseload: 62.6% to 79.5% for lowest to highest volume surgeons and 54.6% to 77.5% from lowest to highest volume hospitals. Surgeons performing >10 cases per year were more likely to repair the valve, in particular if the caseload was >20/year. Hospitals performing >10 cases/year were more likely to repair the valve, without any benefit over this threshold. Interestingly, low-volume surgeons ([?]25 cases/year) obtained better repair rate if they worked in Hospitals where there was at least a high-volume surgeon (>50 cases/year)<sup>4</sup>.

If there is general agreement that the caseload is crucial to achieve optimal results, it is not clear from the literature which is the cut point either for the surgeon or for the Hospital, being as low as >10 cases/year for Hospitals<sup>13</sup> or as high as >50 cases/year for surgeons. Then even if many surgeons are in favor of establishing MVr as a subspecialty<sup>14,15</sup>, it is not a solution that can be regulated in the short time.

Other surgical approaches were developed to repair a regurgitant MV. MIMS has become widely used as patients feel that the cosmetic result confers an added value to the procedure. Optimal results have been published, but data from the real world have not been extensively reported. A recent Nationwide survey<sup>16</sup> analyzed the outcome in 2,501 patients who underwent MVr between 2013 and 2018 through different approaches. In propensity score matched groups (718 each) the Authors found that patients undergoing MVr through a right mini-thoracotomy had a lower rate of repair (76.3% versus 80.9%,  $p=0.04$ ). At 5-year follow-up, survival was similar but freedom from reintervention was lower in patients who underwent MIMS (95.8% vs 97.4%,  $p=0.003$ ). This data could be the mirror of the acceptance of a suboptimal result at the end of the procedure.

A new technique in the field of prolapsing MV, transapical implantation of neochords gained attention from the surgical world. However, even in dedicated hands, this technique did not entail satisfying results. In a propensity matched study<sup>17</sup>, in patients with a mean age of 63 years, freedom from 5-year moderate or more MR was 57.6% in the neochord group versus 84.6% in the conventional group ( $p<0.001$ ) and freedom from reoperation was, respectively, 78.9% versus 92% ( $p=0.022$ ). The same team analyzed 100 consecutive cases operated on from 2013 to 2016<sup>18</sup>. 5-year freedom from severe MR was 14% in patients with favorable anatomy and 63% when anatomy was unfavorable ( $p<0.001$ ), with a reoperation rate of 14.7% versus 43.4% ( $p<0.001$ ).

MVr represents an ethical more than a regulatory problem, that every surgeon has to solve personally. It is evident that the experience of the single surgeon or of the Hospital is the main determinant of the success of the repair, of a lower early mortality and of a lower reoperation rate. As a consequence, MVr has to be considered a subspecialty. However, this is not practically possible. There is no agreement on the minimum caseload for surgeons or for Hospitals and is difficult to identify any procedure able to identify who has to do what. We, as surgeons, have to think that, anything we do, will influence the length and the quality of life of our patients. Adopting new techniques or new approaches has to be performed having in mind the patient's safety and the durability of the repair. Accepting a low-grade result in the name of a lesser invasiveness is against the interests of the patient and has to be rejected. Only an ethical vision of the profession can guide our decisions.

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