

TMVR Technologies Vs Surgical Technologies for Mitral Regurgitation

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Disclosure Statement of Financial Interest

I have no conflict of interest in the context of the subject of this presentation.

I will discuss off-label use of TMVR



Essence

- **To discuss the goals and considerations for intervention on severe mitral regurgitation (focusing on degenerative MR)**

Questions to ask when contemplating MV intervention

1. What is the clinical goal of the mitral valve intervention in this patient?



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 - c) To prolong life expectancy
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Long term effectiveness more relevant

d) To maintain or improve long-term quality of life

2. Will my proposed treatment give the patient a reasonable chance of achieving that goal?

Benefits of Eliminating Severe MR are largely in the Long-term

EDITORIAL VIEWPOINT

Transcatheter Mitral Valve Replacement The Next Revolution?*



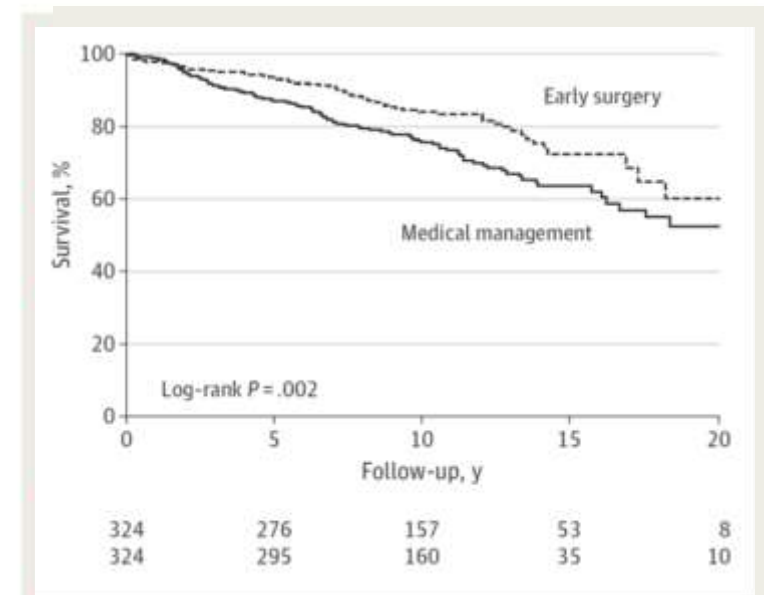
MITRAL VALVE DISEASE IS NOT ASSOCIATED WITH HIGH SHORT-TERM MORTALITY. Mitral valve disease is rarely associated with sudden or rapid progression to death. Although it does shorten life expectancy, this effect is more indolent, occurring over years, as opposed to months.

Anyanwu AC, Adams DH, JACC. 2014;64(17):1820-4

Original Investigation

Association Between Early Surgical Intervention vs Watchful Waiting and Outcomes for Mitral Regurgitation Due to Flail Mitral Valve Leaflets

Rakesh M. Suri, MD, DPH; Jean-Louis Vanoverschelde, MD; Francesco Grigioni, MD, PhD; Hartzell V. Schaff, MD; Christophe Tribouilloy, MD; Jean-Francois Avierinos, MD; Andrea Barbieri, MD; Agnes Pasquet, MD; Marianne Huebner, PhD; Dan Rusinaru, MD; Antonio Russo, MD; Hector I. Michelena, MD; Maurice Enriquez-Sarano, MD



0.9% for medical management, $P=.96$) between treatment strategies at 3 months. In contrast, long-term survival rates were higher for patients with early surgery (86% vs 69% at

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Supplemental content at
jama.com

Suri RM et al. JAMA. 2013;310(6):609-16

Choice of Intervention in Severe MR: Attributes to Consider

Short term outcome more relevant

- Lower procedural risk
- Known or expected short-term effectiveness
- Reasonable to address specific target (MR) alone
- Ideal for investigational procedures

Long term effect more relevant

- Accept trade off between early risk and long-term benefit
- Known or expected durability
- Consider approaches that address entire disease spectrum
- Consider established procedures

Degenerative MR - Catheter or Surgery:

What is the Surgical State of the Art?



Long-Term Results of Mitral Valve Repair for Regurgitation Due to Leaflet Prolapse



Tirone E. David, MD, Carolyn M. David, BA, Wendy Tsang, MD, Myriam Lafreniere-Roula, PhD, Cedric Manlhiot, PhD

ABSTRACT

BACKGROUND Mitral valve (MV) repair has become the standard therapy for mitral regurgitation (MR) due to degenerative diseases, but information on late outcomes is limited.

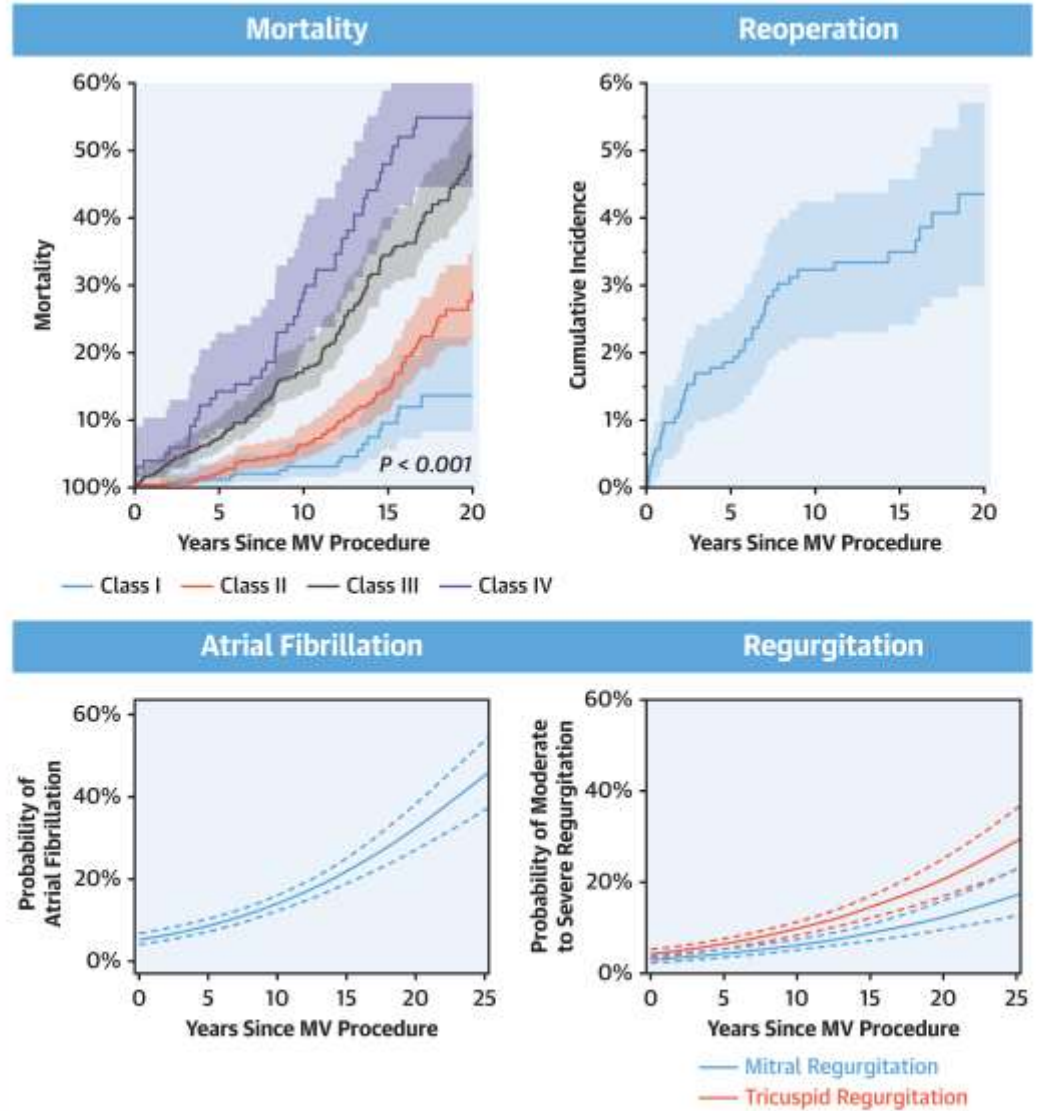
OBJECTIVES The purpose of this study was to examine the late results of MV repair for MR in a large cohort of patients.

METHODS A total of 1,234 consecutive patients (median age 59 years; 70.4% men) had MV repair for MR due to leaflet prolapse and were followed prospectively for a median of 13 years (interquartile range: 8 to 34 years) with periodical echocardiographic studies. There were 163 patients still at risk at 20 years. Cumulative incidences of adverse events and associated factors were examined with death as a competing outcome.

RESULTS At 20 years, reoperation-free survival was 60.4% (95% confidence interval: 56.2% to 64.2%) and the cumulative incidence of cardiac and valve-related deaths was 12%, noncardiac deaths 21.3%, reoperation on the MV 4.6%, infective endocarditis 1.1%, thromboembolism 10.3%, and bleeding 6.4%. The probability of recurrent moderate or severe MR was 12.5%, persistent or new moderate or severe tricuspid regurgitation (TR) 20.8%, and new atrial fibrillation (AF) 32.4%. Multivariable analysis identified older age, complete heart block, MV repair without annuloplasty ring, and the degree of myxomatous degeneration of the MV to be associated with recurrent MR. The development of AF and TR was unrelated to recurrent MR.

CONCLUSIONS MV reoperation was uncommon after MV repair, but there was an increasing incidence of recurrent MR, TR, and new AF over time. (J Am Coll Cardiol 2019;74:1044-53) © 2019 by the American College of Cardiology Foundation.

CENTRAL ILLUSTRATION Long-Term Outcomes After Mitral Valve Repair for Leaflet Prolapse



David, T.E. et al. J Am Coll Cardiol. 2019;74(8):1044-53.

Mortality according to pre-operative functional class and incidences of reoperation on the mitral valve, development of new atrial fibrillation, and moderate or severe mitral and tricuspid regurgitation over the years.

David et al, J Am Coll Cardiol. 2019; 74(8):1044-1053

Revisiting the Long-Term Goals of Degenerative Mitral Valve Repair*

Beyond Eliminating Mitral Regurgitation

David H. Adams, MD, Anelechi C. Anyanwu, MD



Mitral valve repair is the guideline-recommended therapy for patients with severe mitral valve regurgitation due to degenerative mitral valve disease. A slow, but steady, increase in mitral valve repair procedures has occurred in most surgical programs, although there is still a wide disparity of adoption across centers (1). The durability of mitral valve repair in degenerative patients has been a topic of intense focus over the past decade, and we now know factors associated with early and late recurrence of severe mitral valve regurgitation; this has led to an evolution of repair strategies, the development of valve reference centers, and more targeted referral of complex pathologies (2,3). Surgeons have subsequently focused on strategies to maximize long-term durability of repair including earlier intervention, complete correction of pathological lesions, use of appropriate annuloplasty strategies and nontolerance of residual regurgitation. The contributions of David and colleagues

issue of the *Journal*, they now report the very long-term outcomes of 1,234 patients operated on by Dr. David between 1981 and 2010, with follow-up extending to 34 years (median follow-up of 13 years) (4). Ninety-four percent of survivors had at least 1 echocardiogram between 10 and 20 years—an exemplary standard unmatched by other long-term studies of valve outcomes. Important lessons are always learned from the long-term follow-up of operated patients, and this benchmark analysis has vital implications beyond just the repaired mitral valve.

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A WELL-DONE MITRAL VALVE REPAIR FOR DEGENERATIVE DISEASE IN A REFERENCE CENTER IS DURABLE

In their analysis, David et al. (4) demonstrated exceptional durability of valve repair with a 6.3% recurrence rate of moderate-to-severe mitral regur-

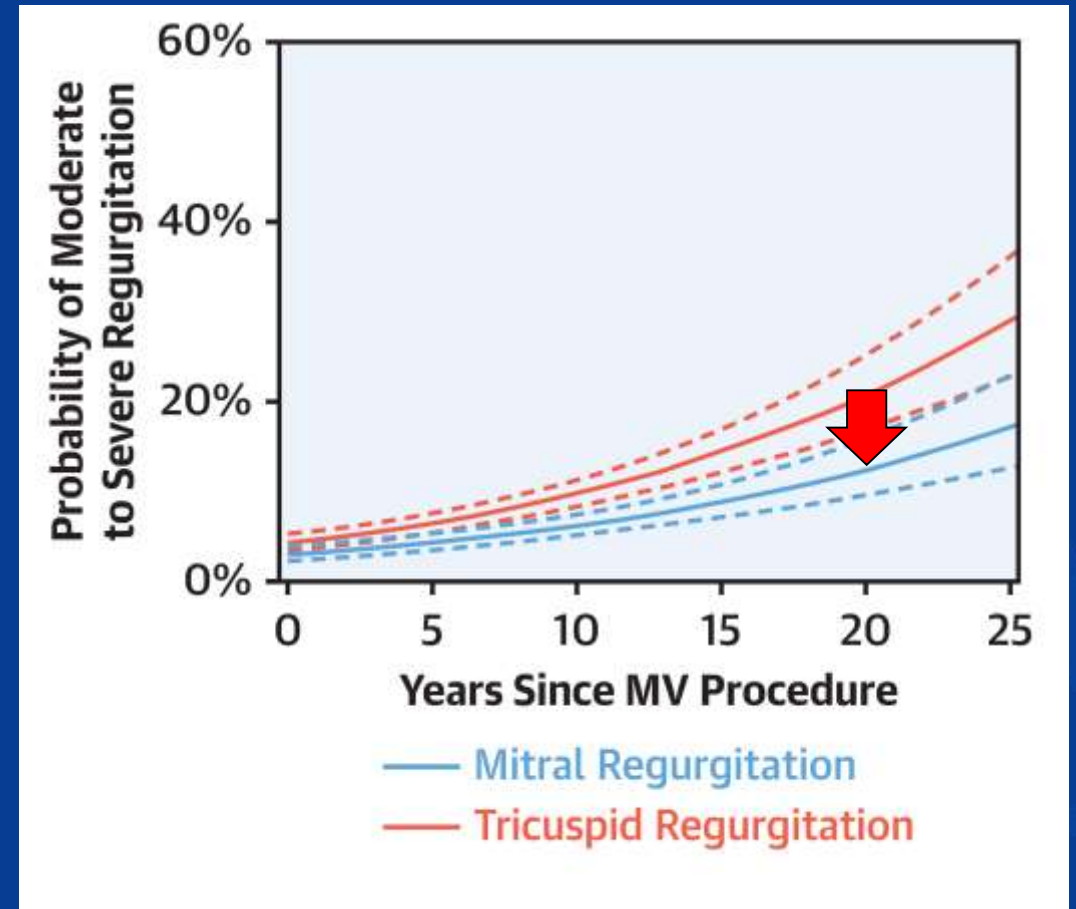
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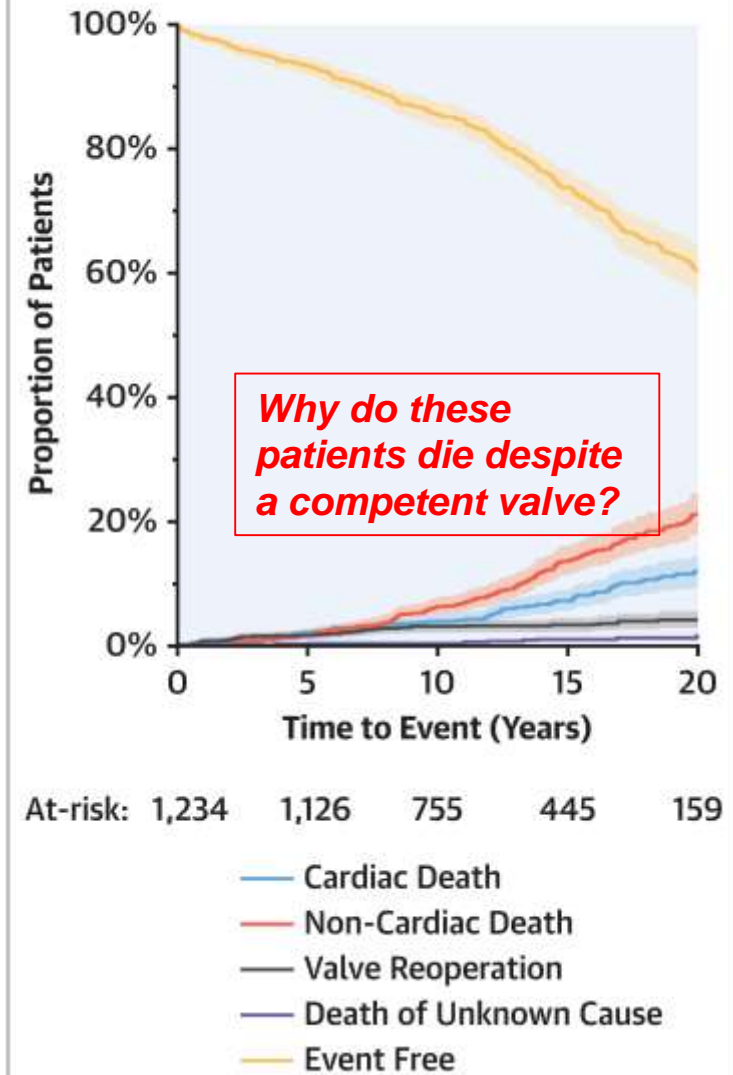
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DESPITE ELIMINATION OF MITRAL REGURGITATION, CARDIOVASCULAR EVENTS OCCUR AFTER MITRAL VALVE REPAIR



FIGURE 1 Patient Survival and Competing Risk for Mortality and Mitral Valve Reoperation



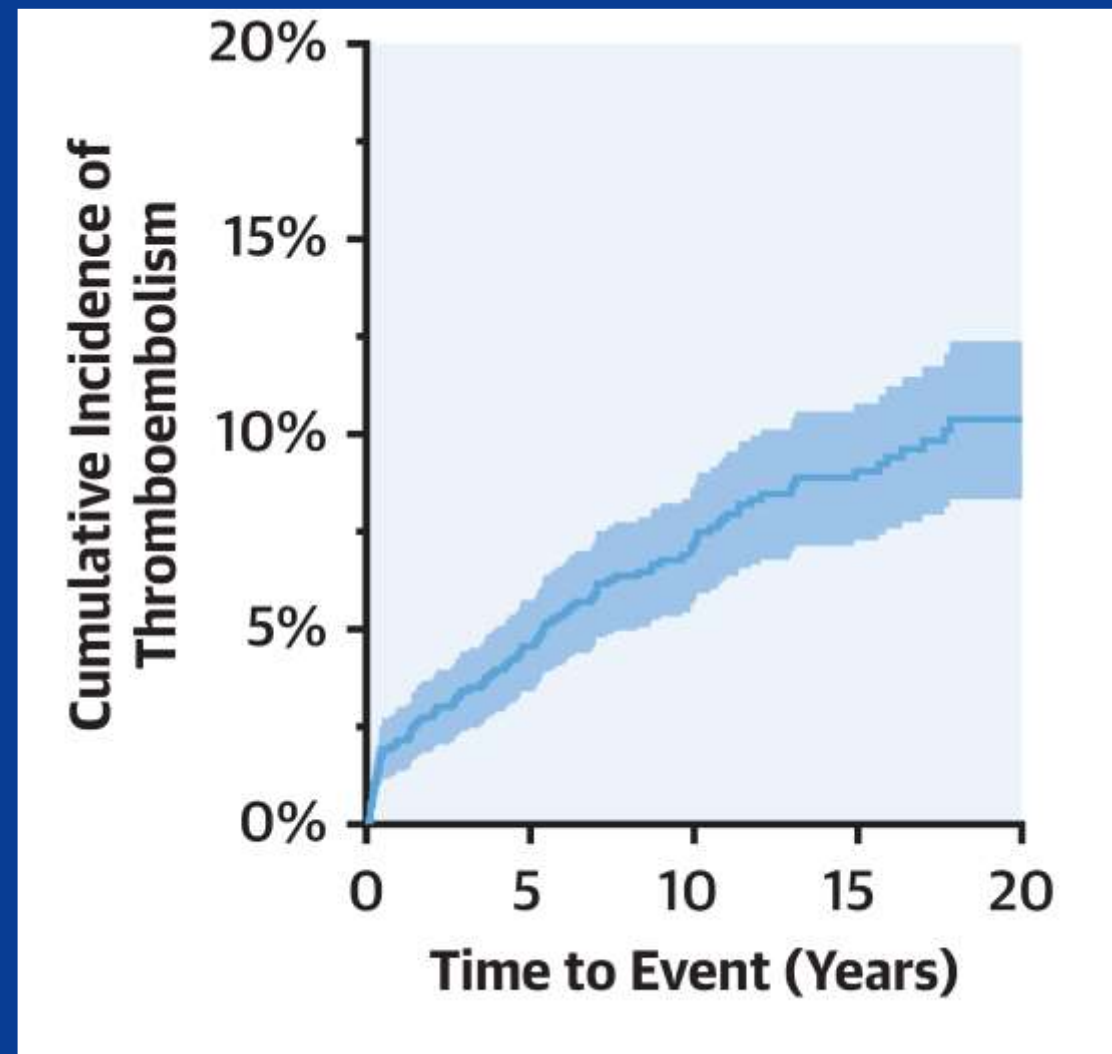
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DESPITE ELIMINATION OF MITRAL REGURGITATION, CARDIOVASCULAR EVENTS OCCUR AFTER MITRAL VALVE REPAIR

The analysis by David et al. (4) surprisingly revealed a high incidence of other cardiovascular problems in the long term after mitral valve repair for degenerative disease



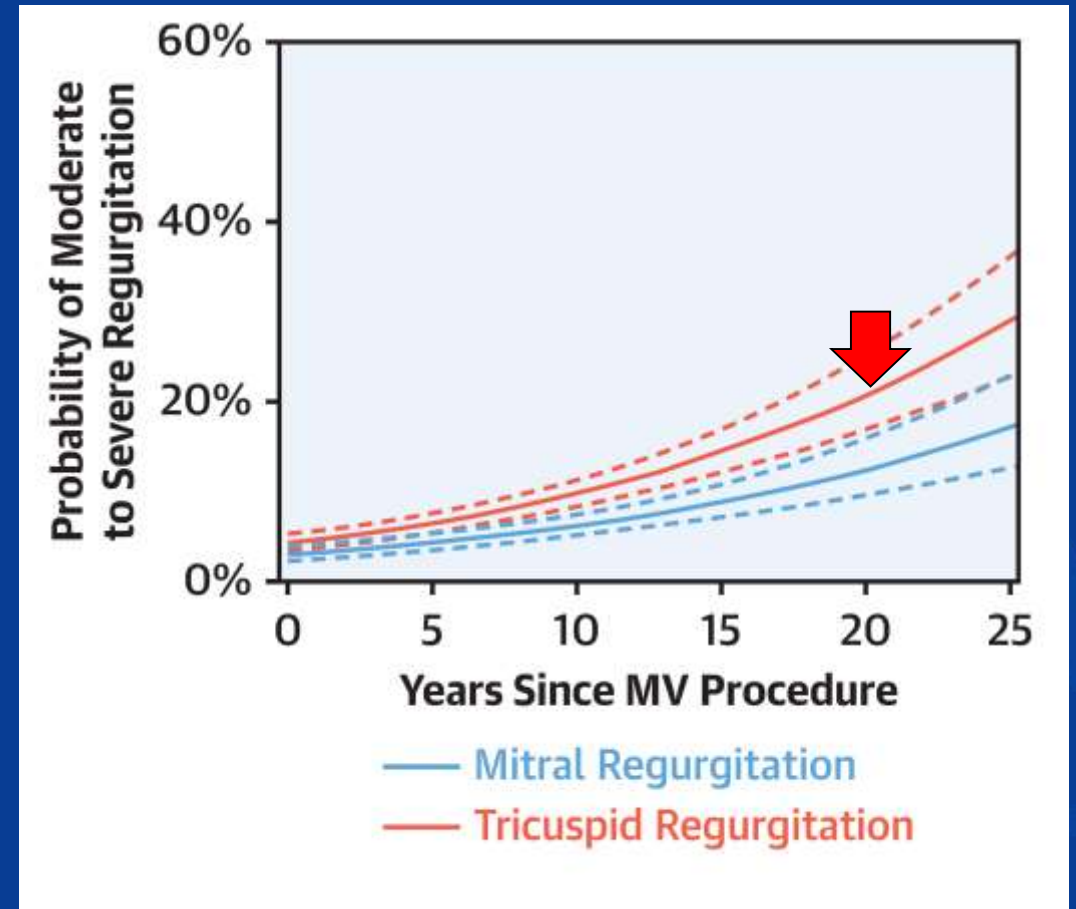
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LATE TRICUSPID REGURGITATION IS NOT INFREQUENT FOLLOWING ISOLATED MITRAL VALVE REPAIR

The observation of significant tricuspid regurgitation in one-fifth of patients at 20 years in David et al.'s series (4) is concerning because tricuspid regurgitation is unequivocally associated with worse long-term outcomes, as shown in multiple clinical settings.



Revisiting the Long-Term Goals of Degenerative Mitral Valve Repair*

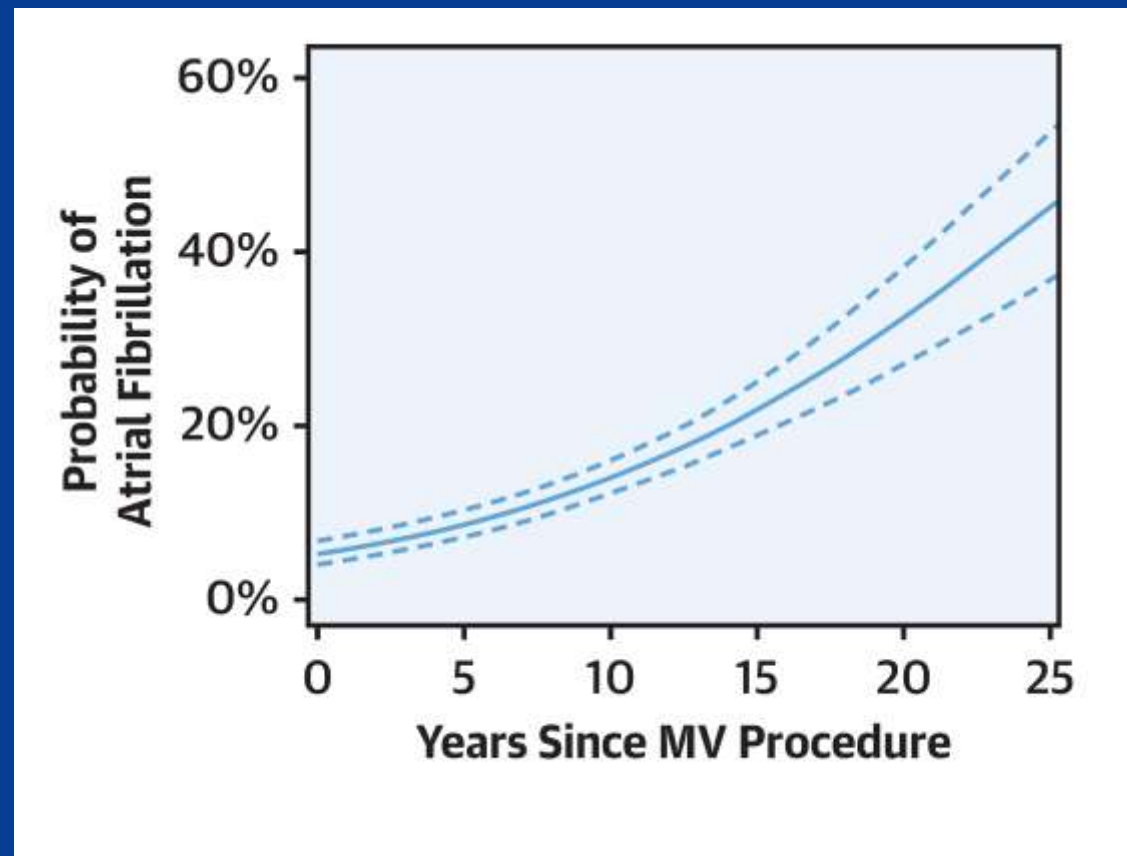
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PATIENTS ARE AT SIGNIFICANT RISK TO DEVELOP ATRIAL FIBRILLATION AFTER MITRAL VALVE REPAIR

The presence of new-onset atrial fibrillation in about one-third of survivors at 20-year follow-up was an important and surprising finding in their analysis.



Revisiting the Long-Term Goals of Degenerative Mitral Valve Repair*

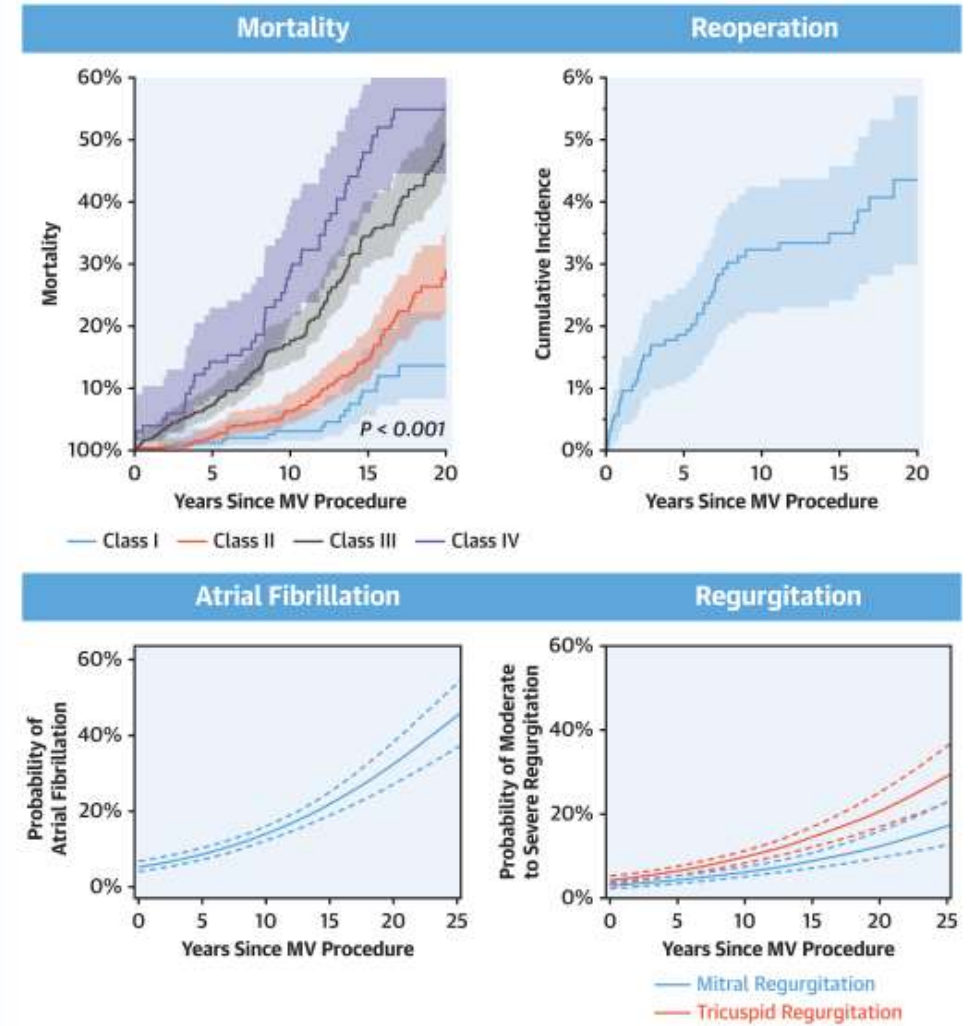
Beyond Eliminating Mitral Regurgitation

CLINICAL IMPLICATIONS

The data presented by David et al. (4) put renewed emphasis on performing a “complete operation” at the time of degenerative mitral valve repair, ideally before the onset of symptoms or left ventricular dysfunction, with an eye toward, not only achieving a durable repair with minimal residual mitral regurgitation, but also considering additional adjunct procedures that may decrease long-term morbidity and mortality in selected patients (Figure 1).



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Adams DH, Anyanwu AC, J Am Coll Cardiol. 2019;74:1054-1056

FIGURE 1 Long-Term Goals of Degenerative Mitral Valve Repair

Minimize Recurrent MR	<ul style="list-style-type: none"> • Utilize reference surgeons • Adopt techniques with proven durability • Zero tolerance for residual MR
Minimize Thromboembolism	<ul style="list-style-type: none"> • Low threshold for closing left atrial appendage • Tailor anticoagulation strategies
Minimize Late AF	<ul style="list-style-type: none"> • Consider pre-operative event monitoring • Low threshold for left atrial maze • Explore role for prophylactic maze and antiarrhythmic drug therapy
Minimize Late TR	<ul style="list-style-type: none"> • Identify patients at high risk for TR progression • Increase use of prophylactic annuloplasty

AF = atrial fibrillation; MR = mitral regurgitation; TR = tricuspid regurgitation

FMR – Is there still a role for surgery?

- Paucity of data showing benefit of surgery over medical therapy
- COAPT suggesting benefit of clip over medical therapy
- Lack of robust head to head comparison of surgery vs clip
- Ongoing TMVR trials focus largely on FMR patients
- **Surgery lost its opportunity to provide data on utility in FMR**
- **Surgery for FMR is rapidly being superseded by catheter therapy so its true effectiveness may never be known**

Summary – *Management of MR for early 2020s*

1. What is the **clinical** goal of the mitral valve intervention in this patient?

- | | | |
|----|--|--|
| a) | To provide relief from acute illness | <i>Catheter therapy or Surgery (if safe)</i> |
| b) | To provide limited palliation | <i>Catheter therapy</i> |
| c) | To prolong life expectancy | <i>Surgery</i> |
| d) | To maintain or improve long-term quality of life | <i>Surgery</i> |

2. Therapy should focus on durable repair of MR, prophylaxis against TR, and minimization of potential for AF and thromboembolism

Thank You

