

DCB was associated with an increased risk of TLR (11.4% vs 5.6%; risk ratio [RR] 1.83, 95% CI 1.07 to 3.13, $p=0.03$, $I^2=14\%$) at a mean of 27 months. This effect was noted on the analysis limited to DES-ISR only (RR 1.88, 95% CI 1.08 to 3.20, $p=0.02$, $I^2=4\%$). There was no difference between both strategies in terms of the secondary clinical outcomes (Figure 1).

In this updated meta-analysis of 7 randomized trials with 1,363 patients with any ISR (i.e., bare metal stent or DES), we demonstrated that DCB was associated with a higher incidence of TLR at 27 months. This observation was noted even when the analysis was limited to DES-ISR only. The increased incidence of TLR with DCB could be related to the lower in-segment MLD and higher DS at a mean 8.2 months. These findings suggest that optimal late angiographic and clinical outcomes are achieved with second-generation DES. It is reassuring that there were no differences between both strategies on the incidence of MACE, TVR, myocardial infarction, stent thrombosis, and all-cause mortality. Thus, future studies should focus on identifying lesions that might obtain excellent angiographic and clinical outcomes with DCB. This meta-analysis represents the largest meta-analysis of randomized trials to date comparing both strategies, although this analysis might be limited by the methodological heterogeneity due to the different types of paclitaxel-eluting balloons, we noted minimal statistical heterogeneity for TLR.

This meta-analysis of randomized trials demonstrated that second-generation DES is associated with improved late TLR and angiographic outcomes compared with DCB for any ISR. This effect is noted when limited to DES-ISR. Further studies are needed to elucidate on the role of DCB for the management of ISR.

Disclosure

All the authors have no conflicts of interest to disclose.

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Trends in Utilization of Surgical and Transcatheter Mitral Valve Repair in the United States*



Mitral regurgitation (MR) is the most frequent valve disease in the United States (US). Nearly 1 in 10 people aged ≥ 75 years are estimated to have moderate or severe MR.¹ Surgery with either mitral valve repair (MVR) or replacement is generally recommended for patients with severe MR to improve symptoms and survival.² However, $\approx 50\%$ of patients with severe MR requiring surgery are turned down due to increased perioperative risk owing to advanced age, frailty, left ventricular dysfunction, and comorbidities.³ Due

to this unmet need, there has been a dramatic growth in the development of novel transcatheter mitral valve repair (TMVr) technologies. The Mitra-Clip transcatheter edge-to-edge repair (TMVr) system was approved for commercial use by the FDA in October 2013 in the US for use in patients with symptomatic severe degenerative MR who were considered at prohibitive risk for surgery based on safety and efficacy data from the Endovascular Valve Edge-to-Edge Repair II clinical trial.^{4,5} Although TMVr utilization in clinical practice has increased dramatically, there are limited data on the relative utilization of TMVr and isolated surgical MVR (SMVr) in the U.S. Although hospitals are required to report TMVr data to the Society of Thoracic Surgeons/American College of Cardiology (ACC) Transcatheter Valve Therapy Registry by the Centers for Medicare and Medicaid services national coverage determination, data entry is voluntary making it subject to selective reporting and there is potential underreporting of non-Medicare patients since follow-up data are linked to Medicare databases.⁶ Lastly, data on SMVr utilization are not available. Therefore, in this study, we utilized the publicly available National Inpatient Sample database to examine the national practice patterns in parallel utilization of TMVr and isolated SMVr following FDA approval of TMVr in October 2013.⁷

We queried the NIS databases from October 2013 to September 2015 to identify all patients aged ≥ 65 years undergoing TMVr (ICD-9-CM code 35.97) or SMVr (ICD-9-CM code 35.97). In the SMVr group, those undergoing concomitant coronary bypass grafting or other valvular surgery were excluded to identify those undergoing isolated SMVr. Survey specific techniques accounting for the multilevel nature of the data were used for weighting to obtain national estimates.⁸ For trend analyses, the study period was divided into quarterly (Q) time intervals. Poisson regression analyses were used to examine the changes in the number of MVR procedures over time in the overall study population and in prespecified age subgroups (65 to 74 years, 75 to 84 years, and ≥ 85 years). Statistical analysis was conducted using SPSS version 23.0 (IBM Corp., Armonk, New York). All p

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values are 2-sided with a significance threshold of <0.05.

Of 11,615 patients undergoing isolated MVr during the study period, 8,395 (72.3%; age 72.9 ± 59 years, 43.9% women) underwent isolated SMVr and 3,220 (27.7%; age 80.1 ± 7.0 years; 44.4% women) underwent TMVr. The total number of MVr increased linearly from 1,180 in 2013 Q3 to 1,795 in 2015 Q3 (OR 1.07 [1.06 1.07]; +52%; p trend < 0.001). This was largely driven by a dramatic increase in the number of TMVr (from 90 to 690; +666%; OR 1.25 [1.23 to 1.27]; p trend < 0.001), whereas the number of isolated SMVr procedures remained unchanged (from 1,090 to 1,105; OR 1.00 [0.99 to 1.01]; p trend = 0.36). Of all patients undergoing isolated MVr, the proportion of TMVr increased with increasing age groups: 12.1%, 34.5%, and 75.4% in those aged ≥65 to 74, 75 to 84, and ≥85 years, respectively. The number of TMVr increased in all age categories (p trend < 0.001 for all), whereas the

number of isolated SMVr increased modestly in patients aged 65 to 74 years (from 710 to 755; OR 1.02 [1.01 to 1.03]; +6.3%; p trend = 0.005) and remained unchanged in those aged 75 to 84 and ≥85 years (Figure 1).

These observations highlight a previously undertreated or untreated population of MR patients that were not suitable candidates for surgery and are now being treated with TMVr. Our results also underscore that the adoption of the MitraClip technology has complemented and not supplanted SMVr. Recently, the landmark COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional MR) trial established the efficacy of MitraClip in patients with severe functional MR.⁹ With the advent of newer transcatheter treatments targeting annular reduction and subvalvular apparatus, percutaneous MVr therapies are poised to grow further in the coming years.¹⁰

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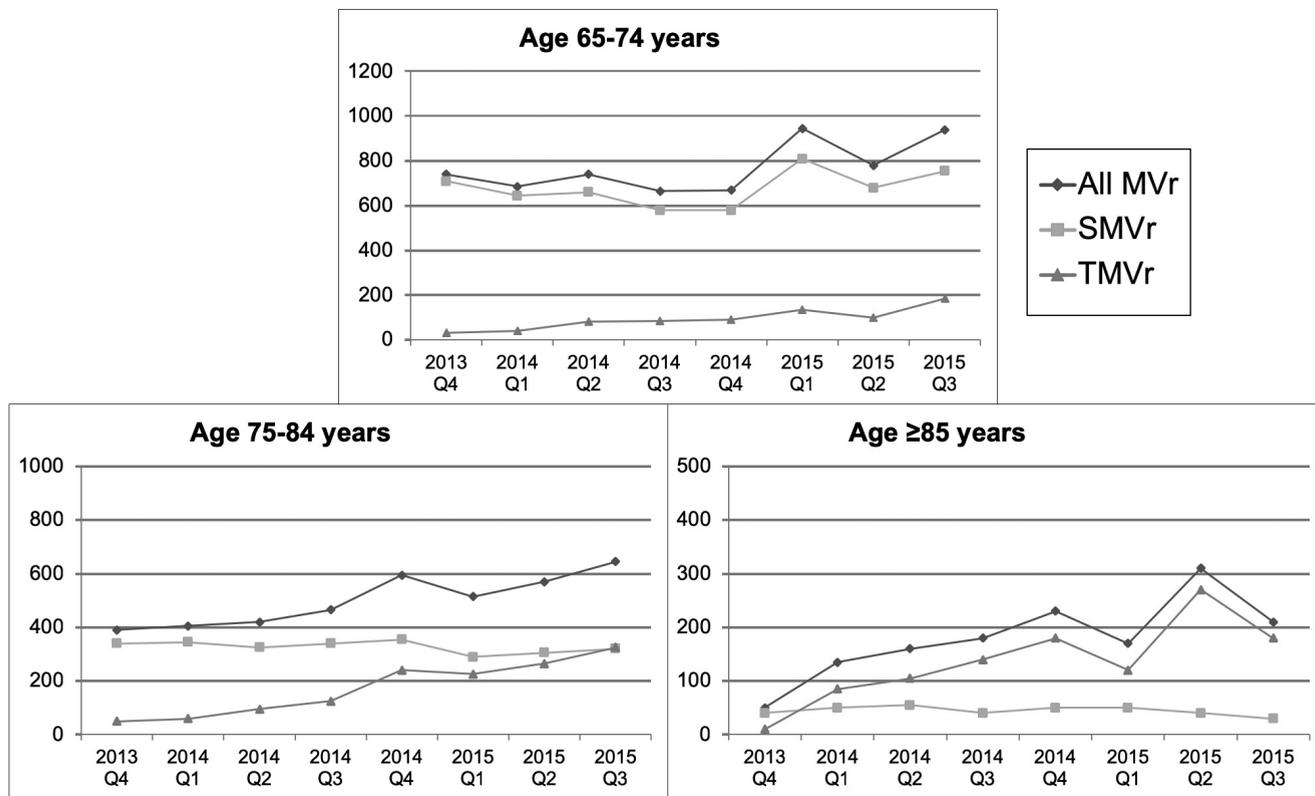


Figure 1. Age-stratified trends in number of transcatheter mitral valve repair (TMVr), isolated surgical mitral valve repair (SMVr), and all isolated mitral valve repair (MVr) procedures after FDA approval of TMVr. Time intervals (in quarterly intervals) on x axis and number of procedures on y axis; age group 65 to 74 years: p trend < 0.001 for all MVr, p trend = 0.005 for SMVr, and p trend < 0.001 for TMVr; age group 75 to 84 years: p trend < 0.001 for all MVr, p trend = 0.07 for SMVr, and p trend < 0.001 for TMVr; age group ≥ 85 years: p trend < 0.001 for all MVr, p trend = 0.15 for SMVr, and p trend < 0.001 for TMVr.

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Angiographic and Midterm Thrombosis of Bioresorbable Vascular Scaffold for Coronary Bifurcation Narrowings



We have read with interest the important paper published in the *American Journal of Cardiology*¹ concerning the angiographic and midterm thrombosis of bioresorbable vascular scaffold for coronary bifurcation lesions. The authors admitted that the 3.9% scaffold/stent thrombosis rate at 1 year was apparently higher than reported with second-generation drug eluting stents. They attributed, this higher rate, to device-specific and/or procedure-related factors, flow disturbance and high/shear stress, extensive vessel preparation that induces higher response to platelet adhesion, acute side-branch occlusion, strut thickness, location of bifurcation, and the presence of ostial stenosis.

However they did not elaborate on the bioresorbable scaffold components that can induce such milieu intérieur pathophysiologic disturbances that can lead to scaffold thrombosis.

Indeed, the embedded bioresorbable poly (L-lactide) coated by bioresorbable poly (D,L-lactide) polymers are eventually degraded into lactic acid and finally into carbon dioxide and water, through metabolism in the Krebs cycle that can induce: enhancement of local acidosis by the carbon dioxide which can cause thrombosis as has been seen in open thorax surgery,² diminishing of activated partial thromboplastin time facilitating thrombosis,³ and decrease of clot lysis that maintains thrombus formation.⁴ Furthermore, the decreased pH of the surrounding intima, media, and adventitia, by accumulation of lactic acid, stimulates lactic acid sensors on sensory neurons innervating the heart⁵ and induces the same pain as in angina and myocardial infarction.

Bioresorbable scaffolds bear 4 platinum marker beads, 2 embedded at both the proximal and distal ends for fluoroscopic visualization that have been