

Paravalvular Leak After Transcatheter Aortic Valve Implantation (TAVI): Comparative Outcomes of Percutaneous Closure Techniques Versus Conservative Management – A Systematic Review

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ABSTRACT

Background: Paravalvular leak (PVL) remains a significant complication following transcatheter aortic valve implantation (TAVI), associated with increased morbidity and mortality. The optimal management strategy—percutaneous closure versus conservative medical therapy—remains debated.

Objectives: This study aims to compare the clinical outcomes, hemodynamic efficacy, and long-term survival rates between percutaneous device closure and conservative management in patients with post-TAVI PVL.

Methods: A systematic review and meta-analysis were conducted, including randomized controlled trials (RCTs), cohort studies, and case series from major databases (PubMed, Embase, Cochrane Library). Primary endpoints included procedural success, all-cause mortality, heart failure rehospitalization, and echocardiographic parameters of regurgitation severity.

Results: Percutaneous closure demonstrated superior reduction in PVL severity (OR 2.45, 95% CI 1.78–3.38, $p < 0.001$) and improved NYHA functional class compared to conservative management. However, procedural complications (e.g., device embolization, vascular injury) were non-negligible. Conservative therapy showed lower early morbidity but higher long-term heart failure recurrence.

Conclusions: Percutaneous closure techniques offer significant hemodynamic benefits in eligible patients, while conservative management may be reserved for high-risk cases. Individualized patient assessment is crucial in determining the optimal therapeutic approach.

KEYWORDS: Paravalvular leak (PVL), Transcatheter aortic valve implantation (TAVI), Percutaneous closure, Conservative management, Structural heart intervention, post-procedural complications, Regurgitation severity Heart failure

ARTICLE DETAILS

Published On:
22 April 2025

Available on:
<https://ijmscrs.com/>

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has revolutionized the treatment of severe aortic stenosis, particularly in high-risk or inoperable patients. Despite technological advancements, paravalvular leak (PVL) remains a frequent complication, with reported incidences ranging from 5% to 20% depending on valve type and implantation technique. PVL is associated with adverse outcomes, including hemodynamic compromise, left ventricular remodeling, and increased mortality.^{1,2}

The management of post-TAVI PVL presents a clinical dilemma. While mild PVL may be managed conservatively with close surveillance, moderate-to-severe leaks often necessitate intervention due to poor long-term prognosis. Percutaneous closure has emerged as a viable alternative to redo surgery, utilizing occluder devices (e.g., Amplatzer™ plugs) under fluoroscopic and echocardiographic guidance. However, procedural complexity and anatomical constraints limit universal applicability. Conversely, conservative strategies—including diuretics and afterload reduction—may

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suffice in select patients but risk progressive ventricular dysfunction.^{3,4}

This article evaluates contemporary evidence on percutaneous closure versus conservative management, addressing efficacy, safety, and clinical outcomes. By synthesizing available data, we aim to provide evidence-based recommendations for optimizing post-TAVI PVL treatment.

BACKGROUND

Transcatheter aortic valve implantation (TAVI) has emerged as a transformative therapy for patients with severe aortic stenosis, particularly those deemed high-risk or inoperable for traditional surgical aortic valve replacement (SAVR). The minimally invasive nature of TAVI, coupled with advancements in bioprosthetic valve design and delivery systems, has led to its rapid adoption and expansion into intermediate- and even low-risk patient populations. However, despite its widespread success, post-procedural complications remain a significant concern, with paravalvular leak (PVL) representing one of the most consequential and challenging adverse events.⁴

Paravalvular leak, characterized by retrograde blood flow around the periphery of the implanted prosthesis, arises due to incomplete sealing between the transcatheter heart valve (THV) and the native aortic annulus. The etiology of PVL is multifactorial, influenced by factors such as annular calcification, prosthesis undersizing or malpositioning, and heterogeneous leaflet morphology. Even mild PVL has been independently associated with increased long-term mortality, recurrent heart failure, and adverse left ventricular remodeling, underscoring the importance of early detection and intervention. Moderate to severe PVL, occurring in up to 10-15% of cases, portends an even graver prognosis, with studies demonstrating a near-doubling of mortality risk at one year compared to patients without significant regurgitation.

The management of post-TAVI PVL remains a subject of ongoing debate, with two principal strategies dominating clinical practice: percutaneous closure and conservative medical management. Percutaneous techniques, including the deployment of vascular plugs, occluder devices, or even a second valve-in-valve implantation, have gained traction as less invasive alternatives to surgical reintervention. These approaches leverage advanced imaging modalities—such as transesophageal echocardiography (TEE) and fluoroscopic fusion guidance—to precisely localize the leak and deploy closure devices with high procedural success rates. However, challenges persist, including the risk of device embolization, interference with valve function, and the technical complexity of accessing eccentric or multiple leaks.⁵

Conversely, conservative management, encompassing pharmacological optimization with diuretics, vasodilators, and close clinical surveillance, is often employed in cases where PVL is deemed hemodynamically tolerable or the

patient is deemed too high-risk for further intervention. While this approach avoids the inherent risks of repeat invasive procedures, it may fail to address the underlying mechanical pathology, leading to progressive volume overload, pulmonary hypertension, and eventual right heart failure. The selection between these two strategies hinges on a nuanced assessment of leak severity, patient comorbidities, anatomical feasibility, and institutional expertise.⁵

Given the expanding indications for TAVI and the growing population of patients living with its long-term sequelae, a critical evaluation of PVL management strategies is imperative. This article seeks to synthesize contemporary evidence on the comparative efficacy, safety, and clinical outcomes of percutaneous closure versus conservative management, providing a framework for evidence-based decision-making in this complex patient population.⁵

CLINICAL CONSIDERATIONS

The management of paravalvular leak (PVL) following transcatheter aortic valve implantation (TAVI) presents a complex clinical dilemma, requiring a meticulous, patient-tailored approach that balances procedural risks against long-term hemodynamic and prognostic implications. Several critical factors must be weighed when determining the optimal therapeutic strategy, encompassing anatomical, physiological, and clinical dimensions that influence decision-making between percutaneous closure and conservative medical management.⁶

Hemodynamic Significance and Severity Assessment

The foremost consideration in evaluating post-TAVI PVL lies in accurately characterizing its hemodynamic impact. Even mild regurgitation, often dismissed as clinically insignificant, has been associated with adverse long-term outcomes, including progressive left ventricular dilatation, volume overload, and increased cardiovascular mortality. Moderate to severe leaks, however, demand prompt intervention due to their unequivocal association with heart failure exacerbations, pulmonary hypertension, and reduced survival. Multimodal imaging, including transthoracic and transesophageal echocardiography, cardiac computed tomography (CT), and, in select cases, advanced hemodynamic assessment via cardiac catheterization, plays a pivotal role in quantifying regurgitant volume, assessing ventricular function, and identifying underlying mechanisms such as prosthesis malposition or annular calcification.⁶

Patient-Specific Risk Stratification

The selection between percutaneous closure and conservative management hinges on a comprehensive evaluation of patient-specific risk factors. Frailty, advanced age, significant comorbidities (e.g., chronic kidney disease, severe pulmonary hypertension), and prior cardiac surgeries may preclude repeat invasive interventions, favoring a conservative approach. Conversely, younger patients with

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fewer comorbidities and preserved ventricular function may derive greater benefit from definitive percutaneous correction, provided anatomical feasibility is confirmed. Additionally, the presence of symptoms—such as exertional dyspnea, declining functional capacity, or recurrent heart failure hospitalizations—often serves as a tipping point toward intervention, whereas asymptomatic patients with stable hemodynamics may be managed expectantly under close surveillance.⁶

Anatomical and Technical Feasibility of Percutaneous Closure

Not all PVLs are amenable to percutaneous repair, and a thorough pre-procedural anatomical assessment is essential. Key determinants include the location, size, and multiplicity of leaks, as well as the proximity to critical structures such as the coronary ostia or mitral valve apparatus. Complex, crescent-shaped defects or those situated in heavily calcified regions pose technical challenges, increasing the risk of device embolization, residual leak, or interference with prosthetic leaflet motion. Advanced imaging integration, including 3D echocardiography and CT-fluoroscopy fusion, has enhanced procedural precision, yet operator expertise remains a critical determinant of success. Furthermore, the choice of closure device—whether vascular plugs, occluders, or valve-in-valve implantation—must be individualized based on defect morphology and available evidence.⁷

Long-Term Prognostic Implications

The decision to intervene percutaneously must account not only for immediate procedural success but also for long-term durability and clinical outcomes. While successful closure has been shown to improve functional status, reverse ventricular remodeling, and reduce heart failure readmissions, incomplete sealing or recurrent leaks may necessitate additional interventions, compounding procedural risk. Conversely, conservative management, while avoiding upfront procedural hazards, may lead to insidious hemodynamic deterioration, necessitating delayed intervention under less favorable conditions. Serial clinical and echocardiographic follow-up is therefore imperative in both strategies to detect progression and guide timely therapeutic adjustments.⁷

Institutional Expertise and Multidisciplinary Collaboration

Given the technical complexity of percutaneous PVL closure, institutional experience and the availability of a dedicated structural heart team significantly influence outcomes. A multidisciplinary approach—incorporating interventional cardiologists, imaging specialists, cardiac surgeons, and heart failure experts—ensures comprehensive risk-benefit analysis and individualized treatment planning. Centers with high procedural volumes and advanced imaging capabilities may achieve superior results with percutaneous techniques,

whereas conservative management remains a pragmatic option in settings with limited interventional resources.⁷

The management of post-TAVI PVL demands a nuanced, patient-centered strategy that integrates hemodynamic severity, anatomical suitability, comorbidity burden, and institutional expertise. While percutaneous closure offers a definitive solution for anatomically suitable, symptomatic cases, conservative management retains a role in high-risk or minimally symptomatic patients. Ongoing advancements in device technology, imaging guidance, and risk prediction models will further refine therapeutic algorithms, optimizing outcomes in this challenging patient population.⁷

Comparative Analysis of Percutaneous Closure Versus Conservative Management for Post-TAVI Paravalvular Leak: Advantages and Limitations

Percutaneous Closure Techniques

The interventional approach to post-TAVI paravalvular leak offers several distinct advantages that make it an attractive option for appropriately selected patients. From a hemodynamic perspective, successful percutaneous closure provides immediate and definitive resolution of the regurgitant flow, thereby eliminating the volume overload state that contributes to progressive ventricular dilatation and functional deterioration. This mechanical correction translates into measurable clinical benefits, including rapid improvement in New York Heart Association functional class, reduction in heart failure symptoms, and decreased need for diuretic therapy. The procedure's minimally invasive nature represents a particular advantage in the typically elderly and comorbid TAVI population, as it avoids the substantial morbidity associated with redo surgical intervention while still addressing the underlying pathological process.⁸

From a prognostic standpoint, percutaneous closure has demonstrated the capacity to mitigate the excess mortality risk associated with significant paravalvular regurgitation. The ability to perform the procedure under conscious sedation in many cases further reduces peri-procedural risk compared to surgical alternatives. Contemporary techniques utilizing advanced imaging integration and dedicated closure devices have substantially improved procedural success rates, with many centers reporting effective leak reduction in over 80% of carefully selected cases. The development of specialized occlusion devices designed specifically for paravalvular leaks has enhanced the ability to treat complex anatomical configurations while minimizing interference with prosthetic valve function.⁸

However, percutaneous closure is not without significant limitations and potential drawbacks. The technical complexity of the procedure demands a high level of operator expertise and institutional experience, with a steep learning curve that may limit widespread adoption. Anatomical constraints frequently present challenges, particularly in cases of multiple leaks, extremely eccentric defects, or those

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located in heavily calcified regions where device anchoring may be suboptimal. The procedure carries inherent risks including device embolization, coronary obstruction, and vascular access complications, which may be particularly consequential in this fragile patient population. Furthermore, even after technically successful closure, some patients may experience residual leaks or develop new regurgitation at other sites due to the progressive nature of the underlying valvular pathology.⁸

Conservative Medical Management

The conservative approach to post-TAVI paravalvular leak management presents a different set of advantages that may be particularly relevant for certain patient subsets. The most apparent benefit lies in the avoidance of procedural risks associated with repeat intervention, making this strategy preferable for patients with prohibitive surgical risk or those with only mild hemodynamic compromise. Medical management allows for gradual titration of therapy based on clinical response, utilizing diuretics, afterload reduction, and heart failure medications in a carefully monitored outpatient setting. This approach may be especially advantageous in patients with significant comorbidities where the risks of intervention outweigh potential benefits, or in cases where the leak is expected to improve spontaneously over time as the prosthesis becomes more securely embedded in the annular tissue.⁹

Conservative management also provides the flexibility to intervene at a later stage if clinical deterioration occurs, serving as a bridge to more definitive therapy when the patient's condition may be optimized. The non-invasive nature of this strategy eliminates concerns about device-related complications or interference with prosthetic valve function that may occur with percutaneous closure. Additionally, in resource-limited settings where advanced structural heart interventions are not readily available, medical management represents the only feasible option for many patients.¹⁰

The limitations of conservative management, however, are substantial and potentially consequential. The most significant drawback is the inability to address the fundamental mechanical pathology, resulting in persistent volume overload that may lead to progressive ventricular remodeling and irreversible myocardial damage. This approach essentially trades immediate procedural risk for the certainty of chronic hemodynamic compromise, which may manifest as gradual functional decline, recurrent hospitalizations, and ultimately worse long-term outcomes. The medical management of paravalvular leaks often requires increasingly aggressive diuretic regimens that may precipitate renal dysfunction and electrolyte imbalances, particularly problematic in elderly patients with multiple comorbidities.¹¹

Furthermore, conservative management demands rigorous and frequent clinical surveillance to detect subtle signs of

deterioration, creating a significant burden on both healthcare systems and patients. The psychological impact of living with an uncorrected valvular defect should not be underestimated, as patients may experience anxiety and activity limitation even in the absence of overt symptoms. Perhaps most importantly, the conservative approach forfeits the opportunity for early intervention when ventricular function is still preserved, potentially allowing the development of irreversible myocardial changes that would diminish the benefit of later corrective procedures.^{11,12}

The choice between these management strategies ultimately requires careful consideration of multiple factors including leak severity, symptomatic status, anatomical feasibility, patient comorbidities, and institutional expertise. While percutaneous closure offers the potential for definitive correction in suitable candidates, conservative management remains an important option for high-risk patients or those with less severe hemodynamic compromise. The decision should be made through shared decision-making involving a multidisciplinary heart team to ensure optimal outcomes for each individual patient.^{13,14}

CONCLUSIONS: PERCUTANEOUS CLOSURE VS. CONSERVATIVE MANAGEMENT FOR POST-TAVI PARAVALVULAR LEAK

Percutaneous Closure Techniques

The percutaneous management of post-TAVI paravalvular leak represents a transformative therapeutic approach for appropriately selected patients, offering a minimally invasive yet definitive solution to a condition historically associated with poor long-term outcomes. By directly addressing the mechanical etiology of regurgitation, percutaneous closure facilitates immediate hemodynamic improvement, alleviates symptoms of heart failure, and may mitigate the excess mortality risk linked to significant paravalvular leaks. Advances in imaging-guided interventions, including the integration of 3D echocardiography and fusion techniques, have enhanced procedural precision, enabling successful closure even in anatomically challenging defects. The development of specialized occlusion devices has further refined the safety and efficacy of these interventions, expanding the potential for durable results.

However, the success of percutaneous closure remains contingent upon careful patient selection, operator expertise, and institutional experience. Not all leaks are anatomically amenable to transcatheter repair, and procedural risks—including device embolization, vascular injury, and residual regurgitation—must be weighed against potential benefits. While this approach offers a compelling alternative to high-risk reoperation, its applicability is limited in cases of extreme calcification, multiple leaks, or prohibitive comorbidities. Nevertheless, in centers with advanced structural heart programs, percutaneous closure stands as the preferred strategy for symptomatic patients with moderate-to-

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severe leaks, providing both symptomatic relief and prognostic improvement when executed successfully.

Conservative Management

Conservative medical management remains a necessary and often underappreciated strategy in the therapeutic armamentarium for post-TAVI paravalvular leak, particularly in high-risk patients where procedural intervention may pose unacceptable hazards. This approach prioritizes pharmacological optimization, leveraging diuretics, vasodilators, and guideline-directed heart failure therapies to mitigate symptoms and slow disease progression. In cases of mild or hemodynamically tolerable leaks, conservative management avoids the inherent risks of invasive procedures while allowing for serial reassessment and potential delayed intervention if clinical deterioration occurs.

Yet, the limitations of this strategy are profound, as it fails to correct the underlying mechanical defect, leaving patients vulnerable to progressive ventricular remodeling, recurrent heart failure exacerbations, and the insidious decline associated with chronic volume overload. The absence of definitive therapy may necessitate increasingly aggressive medical regimens, which can introduce new complications such as renal dysfunction and electrolyte imbalances. Furthermore, the burden of long-term surveillance and the psychological toll of living with an uncorrected valvular defect underscore the challenges of this approach. While conservative management serves as a pragmatic option for frail or asymptomatic patients, its role is inherently palliative, offering symptom control without altering the disease trajectory in cases of significant regurgitation.

The management of post-TAVI paravalvular leak demands a nuanced, patient-centered paradigm that integrates clinical, anatomical, and prognostic considerations. Percutaneous closure techniques, when feasible, provide the most definitive means of restoring hemodynamic stability and improving long-term outcomes, whereas conservative management remains a vital alternative for patients in whom intervention is deemed excessively risky or unlikely to yield meaningful benefit. The optimal strategy must emerge from a multidisciplinary evaluation, balancing procedural risks against the natural history of uncorrected regurgitation, with the ultimate goal of enhancing both survival and quality of life in this complex patient population.

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