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Original Research

Lithotripsy-Facilitated or Conventional Percutaneous Mitral Balloon Valvuloplasty for Calcific Mitral Valve Disease: A Systematic Review

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ABSTRACT

Background: The efficacy of percutaneous mitral balloon valvuloplasty (PMBV) for mitral stenosis (MS) secondary to mitral annular calcification (MAC) is poorly understood. The purpose of this systematic review was to consolidate existing data on conventional and lithotripsy-facilitated PMBV in patients with calcific mitral valve disease, to better understand procedural outcomes.

Methods: We performed a systematic search of the literature published in PubMed and Scopus databases through May 2024. We included all studies that reported outcomes of conventional PMBV as a standalone therapy or lithotripsy-facilitated mitral intervention for calcific mitral valve disease.

Results: A total of 12 reports met the criteria for inclusion (8 lithotripsy and 4 conventional PMBV), including 4 case series and 8 case reports. Conventional PMBV (n = 44) procedural success in MAC was variable and associated with a limited reduction in mitral gradient in most patients. After conventional PMBV, 4 (9.1%) patients had moderate-to-severe mitral regurgitation (MR) or more, and 6 (13.6%) required mitral re-intervention. On the contrary, lithotripsy-facilitated PMBV for MAC (n = 40) led to hemodynamic improvement in most cases with a mean reduction of 5 to 8 mm Hg in mean mitral gradient. One case (2.5%) developed increased MR from baseline, and 1 (2.5%) required mitral reintervention. Outcomes beyond 3 months were lacking and precluded assessment on whether these improvements are sustained.

Conclusions: This systematic review suggests that lithotripsy-facilitated PMBV for MAC-related MS is feasible and may offer favorable short-term outcomes compared with conventional PMBV alone. These findings highlight the need for larger, multicenter studies with longer follow-up.

Introduction

Mitral stenosis (MS) secondary to mitral annular calcification (MAC) is associated with increased morbidity and mortality and presents an emerging challenge. Currently, there are no effective medical therapies to treat this disease. Surgical mitral valve (MV) replacement has been reported but is associated with poor short-term and long-term outcomes.[1] Owing to the high surgical risk, off-label valve-in-mitral annular calcification (ViMAC) procedures using balloon-expandable valves have been attempted. However, these procedures carry a significant risk, with in-hospital mortality rates of 10% to 20% and 1-year mortality rates reaching up to 50%.[2–4] In addition, a substantial portion of patients with MAC are ineligible for transcatheter mitral valve replacement (TMVR) due to anatomic features that increase the risk of left ventricular outflow tract obstruction or valve embolization.[5] While dedicated transcatheter MVs are currently under evaluation to improve procedural outcomes of ViMAC, there is an urgent need to identify therapies that can improve outcomes and address the limitations of existing surgical and transcatheter valve replacement approaches.

Percutaneous mitral balloon valvuloplasty (PMBV) has been effectively used to treat rheumatic MS; however, its application in MAC has traditionally been discouraged due to concerns about its effectiveness

Abbreviations: MAC, mitral annular calcification; MR, mitral regurgitation; MS, Mitral stenosis; MV, mitral valve; PMBV, percutaneous mitral balloon valvuloplasty; TEER, transcatheter edge-to-edge repair; TMVR, transcatheter mitral valve replacement.

Keywords: mitral annular calcification; mitral stenosis; mitral valve disease; transcatheter mitral valve intervention.

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given the lack of commissural fusion and calcified leaflets.[1,6] To address the potential shortcomings of conventional PMBV for MAC, novel approaches such as lithotripsy-facilitated PMBV are being increasingly used.[7,8] However, data examining the efficacy and safety of conventional and lithotripsy-facilitated PMBV for MAC is limited and restricted to brief reports or case series. Our primary objective in this systematic review was to consolidate existing data on conventional and lithotripsy-facilitated PMBV in MAC to better understand procedural outcomes. Given that mitral lithotripsy is a novel therapy with unproven feasibility regardless of the etiology of MV disease, our secondary objective was to evaluate its outcomes in calcific rheumatic MS.

Methods

In accordance with PRISMA guidelines, we performed a systematic search of the literature published in PubMed/MEDLINE and Scopus databases until May 11, 2024.[9] The search entry was "(lithotripsy AND mitral) OR ([valvuloplasty OR transcatheter mitral valve replacement] AND [mitral annular calcification OR nonrheumatic])." The inclusion criteria for conventional (nonlithotripsy) PMBV studies included reports describing hemodynamic and clinical outcomes of PMBV as a standalone therapy in patients with nonrheumatic MS. Given that conventional PMBV outcomes in patients with rheumatic MS are well established, we excluded studies that included patients with rheumatic MS or if the etiology of MS was not specified. Mitral lithotripsy is a novel therapy with unproven feasibility regardless of the etiology of MV disease, so the inclusion criteria were broader. We included all reports describing the hemodynamic and clinical outcomes of mitral lithotripsy, whether it was used as a standalone therapy or as pretreatment prior to balloon valvuloplasty, TMVR, or transcatheter edge-to-edge repair (TEER) in patients with nonrheumatic or rheumatic MV disease. Given our primary interest was in the MAC population, we focused our main analysis on these studies, reporting rheumatic studies separately. The references of all included studies were screened to identify potential citations not captured in the aforementioned search. If multiple reports were published from the same institution and appeared to include patients from the same period, the study with the smallest sample size was excluded to avoid including duplicates cases. Two authors (B.E. and K.G.) separately performed the search.

Results

A flowchart showing study screening, review, and inclusion is shown in Figure 1. A total of 12 reports met inclusion criteria. This included 8 studies reporting outcomes of lithotripsy-facilitated intervention and 4 with conventional PMBV. Lithotripsy cases from 1 case series and 1 case report were excluded as they were captured in a larger case series from the same center.[8,10,11] One study reporting nationwide outcomes of

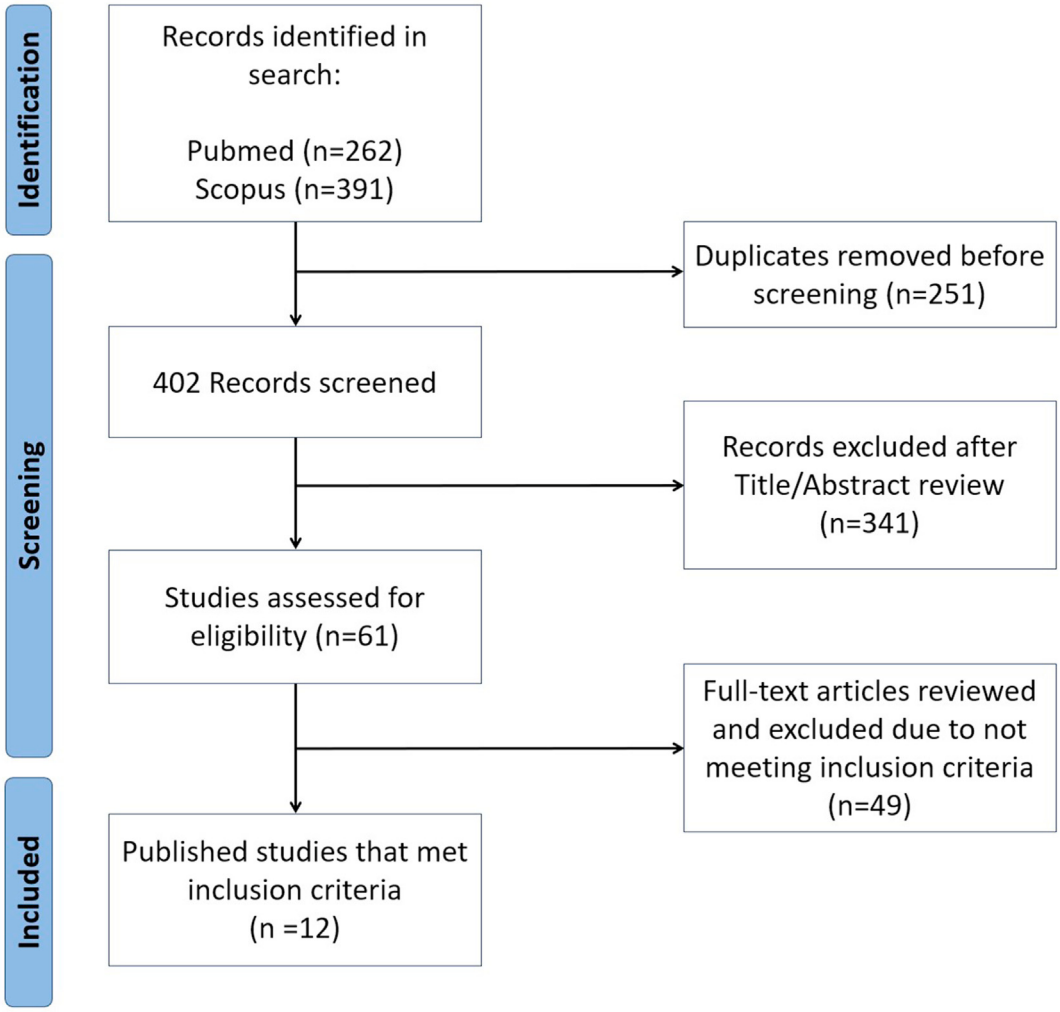


Figure 1.
Flowchart showing study screening, review, and inclusion.

PMBV in nonrheumatic MS was excluded for not reporting hemodynamic or procedural results.[12]

Conventional PMBV in MAC

Of the 4 reports of conventional PMBV for MAC, 2 were case series and 2 were case reports. These reports totaled to 44 patients. Baseline and procedural characteristics are shown in Table 1.[10,13–15] All had PMBV for symptomatic severe MS with mild-to-moderate MR or less at baseline. One patient had PMBV via transapical access and the remainder of patients were transfemoral (n = 31) or not specified (n = 12). Use of cerebral protection was not described in these reports. Procedural success was variable and partially dependent on definition used. The largest series (n = 30) reported procedural success in 47% using a definition of mean mitral gradient reduction of ≥50% from baseline or mitral valve area of >1.5 cm^2.[10] Another series (n = 12) with lower mean mitral gradients at baseline (8.3 ± 1.6 mm Hg) reported a mean improvement of 2.7 ± 1.6 mm Hg.[15] Both case reports reported >50% reductions in mean mitral gradient immediately after PMBV from baseline.[13,14] Four patients (9.1%) had moderate-to-severe MR or greater after PMBV. Procedural complications included 2 (4.5%) patients with Valve Academic Research Consortium ≥3 bleeding. Six (13.6%) patients required mitral reintervention during follow-up. One (2.3%) death was reported at 1 month in a patient receiving hospice care.[13] Follow-up was limited to 1 month in 1 series[15] and extended to a median of 0.3 (0.1-1) years in the other series.[10]

Lithotripsy-facilitated intervention in MAC

Of the 4 studies describing lithotripsy-facilitated intervention for MAC, there were 2 case series and 2 case reports, encompassing 41 patients. This included 40 treated for indication of MS and 1 treated for mixed MV disease with severe MR. Baseline and procedural characteristics are shown in Table 2.[11,16–22] Mitral lithotripsy for MS was performed prior to PMBV in 37 patients and was a standalone therapy in 3 patients. Transfemoral access was used in all cases where access was specified. Lithotripsy was performed using 1 to 3 balloons between 7 and 12 mm in size. Use of cerebral protection was reported in 29 cases.

Among studies involving lithotripsy-facilitated intervention for the treatment of MS, only 1 case series (n = 15) reported the mean mitral gradient before and after lithotripsy but prior to PMBV. This series observed a reduction in invasive mean mitral gradient from 14.0 to 12.0 mm Hg ($P < .05$) with lithotripsy alone.[18] Final result after PMBV included a mean reduction in mitral gradient by 8 mm Hg, with 53% achieving a >50% from baseline.[18] The largest case series of mitral lithotripsy-facilitated PMBV (n = 24) reported a mean reduction of 5.4 mm Hg and 70.8% with a final mean gradient of ≤5.0 mm Hg.[11] Among cases of lithotripsy-facilitated PMBV for MAC across all included studies, 1 (2.5%) developed increased MR from baseline. The severity of the MR in this case was not specified and no cases of moderate-severe or greater MR were reported. Complications included 1 stroke where cerebral protection was not used, 1 right ventricular perforation suspected to be induced by a wire and unrelated to valvuloplasty, and 1 late pericardial effusion. Echocardiographic data between 1 and 3 months postprocedure were reported in 14 patients from a single series that showed no significant change at follow-up when compared with the immediate postprocedural gradient (8.4 ± 2.9 mm Hg at follow-up vs 7.7 ± 2.0 mm Hg immediately postprocedure).[18] Echocardiographic or clinical data after 3 months were limited. One series reported 1-year outcomes in 4 patients, including 1 patient with radiation induced calcific MS who required a repeat mitral lithotripsy valvuloplasty for recurrent MS.[18]

In 1 patient with mixed calcific MV disease with severe MR, mitral lithotripsy was performed prior to TEER. Lithotripsy led to improved

Table 1. Reports of conventional percutaneous mitral balloon valvuloplasty for nonrheumatic calcific mitral stenosis.

Reference, year	Total (N)	Baseline characteristics				Procedural characteristics			Outcome		
		Age, y	MG, mm Hg	MVA, cm^2	MR severity	Access	Embolic protection	Balloon type and size	Procedural results	Complication	Follow-up
Knapper et al,[13] 2014	1	89	18-22	0.7-0.9	—	Transfemoral	—	26.0-mm Inoue	MG: 9 mm Hg; no MR increase	No	1 mo: Died in hospice care
Kar et al,[14] 2013	1	64	11	—	Mild-to-moderate	Transapical	—	27.0-mm Inoue	MG: 2.1 mm Hg; MR not reported	No	—
Donatelle et al,[15] 2022	12	69 ± 10[a]	8.3 ± 1.6[a]	—	≤Mild-to-moderate	—	—	—	MG: 5.5 ± 1.6[a] mm Hg; 1 (8%) with moderate MR	No	1 mo: no deaths
Gelovani et al,[10] 2022	30	76 (68-82)[b]	11 (8-14)[b]	—	—	Transfemoral	—	—	MG: 7 (4-9)[b] mm Hg; 4 (13%) with moderate-to-severe MR	2 (7%) VARC3 bleeding	0.3 (0.1-1)[b] years: 6 (20%) mitral reintervention

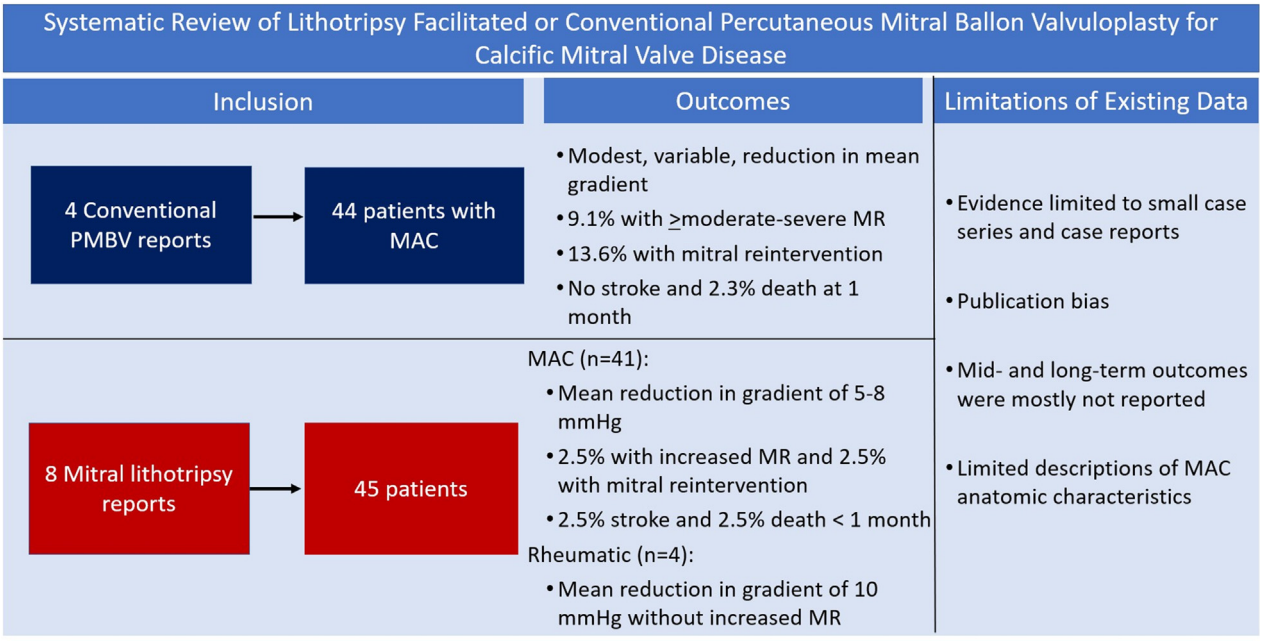
MG, mean gradient; MR, mitral regurgitation; MVA, mitral valve area; PMBV, percutaneous mitral balloon valvuloplasty; VARC, Valve Academic Research Consortium.
[a] Values are mean ± SD. [b] Values are median (IQR).

Table 2. Reports using percutaneous mitral lithotripsy for calcific mitral valve disease.

Reference, year	Total (N)	Baseline characteristics				Procedural characteristics					Outcome		
		Age, y	MG, mm Hg	MVA, cm^2	MR severity	Embolic protection	No. and size of lithotripsy balloon used	Post-PML MG, mm Hg	Post-PML MR	Post-PML procedure	Procedural result	Complication	Follow-up
Nonrheumatic MV disease studies													
Kassar et al,[16] 2023	1	84	8	0.6	Mild	Yes	2 × 8 mm	—	—	PMBV	MVA 1.5 cm^2; MG 4 mm Hg; mild-to-moderate MR	No	—
Fam et al,[17] 2022	1	71	5	2.2	Severe	Yes	2 × 7 mm	4	Severe	PMBV, TEER	MG 4 mm Hg; mild MR	No	1 mo: MG 5 mm Hg; mild MR
Giustino et al,[11] 2023	24	77.8 ± 9.0[a]	10.2 ± 3.6[a]	797.8 ± 184.1[a,b]	Mild: 10 (41.7%); Moderate: 4 (16.7%)	17 (70.8%)	1 (4%) with 1 balloon, 5 (21%) with 2, and 18 (75%) with 3; 14 (58%) with 7 mm, 7 (29%) with 8 mm, and 3 (13%) with 12 mm	—	—	PMBV in 21 (87.5%)	MG 4.8 ± 2.5 mm Hg[a]; 1 had increased MR from baseline	1 stroke, 1 right ventricular perforation, 1 pericardial effusion	—
Alnasser et al,[18] 2024	15	74 ± 9[a]	13.0 ± 1.4[a]	1.0 ± 0.25[a]	<Moderate	10 (66.7%)	14 (93%) with 1 balloon and 1 (7%) with 2; 14 (93%) with 7 mm and 1 with 8 mm (7%)	12[a]	—	PMBV	MG 6 mm Hg[a]; MVA 1.7 cm^2[a]; none with ≥moderate MR	None	Median, 90 d (IQR, 58-115 d): 1 nonprocedural death, 1 mitral reintervention; MG 8.4 ± 2.9 mm Hg[a]
Rheumatic MV disease studies													
Sanz-Ruiz et al,[19] 2021	1	79	17	0.9	Mild	—	3 × 7 mm	—	—	PMBV	MVA 1.5 cm^2; MG 4; mild MR	No	3 mo: No adverse events
Sharma et al,[20] 2022	1	86	14	0.6	None	Yes	3 × 7 mm	7	—	PMBV	MG 4 mm Hg; no MR	No	1 mo: MG, 4-6 mm Hg
Seshiah et al,[21] 2023	1	83	10	0.9	Moderate-to-severe	Yes	2 × 8 mm	7	—	PMBV, TMVR	MG 4 mm Hg; moderate MR	No	1 mo: MG 4 mm Hg; mild MR
Chaddha et al,[22] 2021	1	69	11	0.9	Mild-to-moderate	Yes	2 × 7 mm	6	Mild-to-moderate	PMBV	MG 3 mm Hg; mild MR	No	1 mo: MG 8 mm Hg; MVA 1.7 cm^2

MG, mitral gradient; MR, mitral regurgitation; MV, mitral valve; MVA, mitral valve area; PMBV, percutaneous mitral balloon valvuloplasty; PML, percutaneous mitral lithotripsy; TEER, transcatheter edge-to-edge repair; TMVR, transcatheter mitral valve replacement.

[a] Values are mean ± SD. [b] Unit reported is mm^2.



Central Illustration.
Systematic review of lithotripsy-facilitated or conventional percutaneous mitral balloon valvuloplasty for calcific mitral valve disease. MAC, mitral annular calcification; PMBV, percutaneous mitral balloon valvuloplasty.

leaflet grasping for TEER without complication.[17] This patient had residual mild MS and mild MR on follow-up echocardiography at 1 month.

Lithotripsy-facilitated intervention in calcific rheumatic disease

A total of 4 case reports described outcomes of mitral lithotripsy in calcific rheumatic MV disease, including 3 cases with lithotripsy-facilitated PMBV for severe MS and 1 case pre-TMVR for mixed MV disease. All cases used 2 to 3 lithotripsy balloons sized 7 to 8 mm delivered via transfemoral access. Three reported use of embolic protection devices. Three cases reported mitral gradients before and after mitral lithotripsy but prior to PMBV or TMVR. They observed a mean reduction of 5 mm Hg (range, 3-7 mm Hg) after lithotripsy alone. Final results after lithotripsy-facilitated PMBV demonstrated an immediate mean reduction in mitral gradient of 10 mm Hg (range, 8-13 mm Hg) with no significant increase in MR. There were no major complications. Two cases reported echocardiography results at 1 month, including 1 case that had sustained improvement in mitral gradient[20] and 1 case that had a modest increase in gradient (3-8 mm Hg).[22]

In the only published case of mitral lithotripsy prior to planned TMVR, it led to improved transcatheter heart valve expansion, with mild residual MR and no significant MS on 1 month echocardiography.[21]

Discussion

In this systematic review of outcomes following conventional and lithotripsy-facilitated PMBV of calcific MV disease, we made the following observations: (1) conventional PMBV in MAC was associated with variable reduction in mitral gradients and 14% required reintervention during short-term follow-up; (2) lithotripsy-facilitated PMBV was feasible and successful at reducing the mean gradient by 5 to 8 mm Hg in most cases with MAC without increasing MR; and (3) outcomes beyond 3 months were lacking and whether these improvements were sustained is unknown (Central Illustration). Overall, these findings suggest that lithotripsy-facilitated PMBV may provide favorable short-term outcomes compared with conventional PMBV in patients with MAC-related MS. However, given the limitations of existing data, these observations should be interpreted cautiously and underscore the need for larger, multicenter studies with longer follow-up.

Conventional PMBV in MAC

Extrapolating data from studies evaluating conventional PMBV in rheumatic MS to valvular disease from MAC is problematic due to considerable differences in the 2 patient profiles. This review highlighted the limited nature of existing data, with only 4 reports covering 44 patients who underwent PMBV for MAC. The observed relief of MS was variable and inconsistent with this approach. Additionally, PMBV for MAC was not without risk. Approximately 9% of patients developed moderate-severe MR or greater after PMBV and 14% required reintervention during follow-up. There were no reported strokes. Furthermore, existing evidence is limited to reports with short-term follow-up (1-3 months), and the sustainability of the modest improvement in MV gradient observed in some patients with PMBV for MAC is unknown. It is possible with longer-term follow-up that mitral reintervention rates would be higher, and studies with longer follow-up are needed.

Despite reservations regarding routine PMBV in MAC, there remains some potential for PMBV as a standalone treatment in highly symptomatic patients who are ineligible for transcatheter or surgical replacement and exhibit anatomic features that may indicate a more favorable outcome (eg, symmetric annular involvement, nonbulky calcification, and minimal MR). Additionally, PMBV may be useful as a bridging intervention in patients with MS who are in shock to facilitate definitive therapy at a later time.[23] The complexity and heterogenous nature of MAC necessitates additional data to better delineate the role and potential benefits of PMBV in these nuanced settings.

Lithotripsy-facilitated PMBV

Mitral lithotripsy has emerged as a potential solution to address the limitations of traditional PMBV in treating MAC. MAC presents unique anatomic challenges, including high burden of subvalvular and annular

calcification, calcified leaflets, and the absence of commissural fusion. Additionally, the calcium in MAC is often asymmetric and bulky, further complicating intervention. In such cases, uncontrolled dilation with balloon-based techniques carries the risk of unintended tears or ruptures in the calcific leaflet tissue, which can result in severe acute MR and necessitate emergency surgery. Accordingly, calcium modification with mitral lithotripsy prior to PMBV has been proposed as a strategy to improve leaflet flexibility and optimize safety and efficacy.

The inception of mitral lithotripsy dates back 3 decades, involving ex vivo procedures on 12 explanted calcified rheumatic MVs.[24] Despite its initial abandonment due to poor efficacy and embolic risk of calcium, technological advancements have led to an increasing use of intravascular shockwave systems (Shockwave Medical). Additionally, cerebral protection devices are now commonly used to mitigate stroke risk in high-risk transcatheter valvular interventions and may increase the safety of intravascular lithotripsy for MV disease. Eng et al[8] reported the first documented case of lithotripsy-facilitated PMBV in 2019. In this instance, a patient with severe degenerative MS underwent treatment with 3 peripheral lithotripsy balloons before undergoing PMBV. This successfully reduced the mean gradient from 11 to 2 mm Hg without inducing significant MR. Since then, a growing body of mitral lithotripsy experiences has been published at other medical centers.

In this review, we identified 8 published reports of mitral lithotripsy (6 case reports and 2 case series) that totaled 45 patients (41 with MAC and 4 with rheumatic disease). Most cases were performed prior to PMBV. While these findings are limited by potential publication bias due to the inclusion of case reports, most cases reported significant improvements in the mean mitral gradient and no increase in MR. There was 1 reported stroke in a case that did not use cerebral protection.[11] Only 1 observational study has compared outcomes of consecutive mitral lithotripsy-facilitated PMBV with those of conventional PMBV and found significant improvements in procedural success with the addition of lithotripsy.[10] Indirect comparisons of available observational evidence for PMBV in MAC in this review further suggests that lithotripsy-facilitated PMBV may lead to favorable short-term outcomes when compared with conventional PMBV.

When viewed alongside previous investigations on ViMAC, the potential benefits of lithotripsy-facilitated PMBV may become more apparent. In previous studies of ViMAC, primarily using transcatheter aortic valves, outcomes have been largely discouraging with 30-day mortality of ~20% and 1-year mortality of ~40%.[2,4] Similar 1-year mortality has been observed in early studies using dedicated transcatheter mitral valves (eg, Tendyne).[25,26] In contrast, there was only 1 death (2.5%) in the first 30 days after lithotripsy-facilitated PMBV for MAC in this review. Further, approximately two-thirds of patients are screen failures for ViMAC studies, predominantly due to the risk of left ventricular outflow tract obstruction association with ViMAC.[27] This unmet clinical need combined with the totality of evidence highlighted in this review demonstrates an urgent need for multicenter, larger studies with longer follow-up to better understand outcomes of this treatment strategy in patients with calcific MS. If effective, the development of dedicated mitral lithotripsy devices could simplify this technique and improve outcomes further.

Limitations

These findings must be considered in the context of several limitations. First, systematic reviews based on small case series and case reports are sensitive to publication bias. As such, reported positive outcomes may be inflated. Second, follow-up was limited in included studies, and these findings suggest only early results. Third, the technical approaches to mitral lithotripsy, including type and size of valvuloplasty balloon, varied across experiences and might have influenced outcomes. Given these issues, combined with small sample size, ability to make meaningful comparisons between conventional PMBV and lithotripsy-facilitated PMBV was limited. Despite these challenges, this is the first systematic review to consolidate existing reports of conventional PMBV or lithotripsy-facilitated PMBV for calcific mitral valve disease and provides insight to guide future research in this space.

Conclusions

This systematic review suggests that lithotripsy-facilitated PMBV is feasible and safe and may lead to short-term reduction of mitral gradient in patients with MAC-related MS. Indirect comparison suggests that this may be better than PMBV alone. However, given the limitations of existing data, future studies are required to confirm these findings and assess long-term outcomes after PMBV with or without lithotripsy in MAC-related MV disease.

Declaration of competing interest

Kashish Goel is a proctor and consultant for Edwards Lifesciences. All other authors reported no financial interests.

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Ethics statement and patient consent

Institutional review board oversight was not required for this systematic review.

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