Feasibility of percutaneous mitral comissurotomy in patients with commissural mitral valve calcification

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Aims

Whether a percutaneous mitral commissurotomy (PMC) should be attempted in patients with mitral stenosis (MS) and valvular calcification, especially located at the commissural level remained debated. We sought to evaluate the impact of the degree and location of mitral valve calcifications on PMC results.

Methods and results

Over a 3-year period, we enrolled 464 consecutive patients who underwent a PMC at our institution. According to the location (within the body valve leaflets’ or at the commissural level) and the degree of calcification, patients were divided into three groups: 261 patients were in Group 1 (no leaflets’ or commissural calcification), 141 in Group 2 (leaflets’ calcification with no significant commissural calcification), and 62 in Group 3 (at least one commissure significantly calcified). Final valve area (1.83 ± 0.26, 1.71 ± 0.25, and 1.60 ± 0.24 cm², \(P \leq 0.00001\)) and the rate of complete opening of at least one commissure (92, 94, and 84%, \(P = 0.05\)) were significantly different. However, the rate of post-PMC mitral regurgitation (MR) of grade \(\geq 3\) (10, 10, and 8%, \(P = 0.90\)) was not different among the groups and if the rate of good immediate result, defined as valve area \(\geq 1.5\) cm² with no MR \(>2/4\) was different among the three groups (88, 78, and 73%, \(P = 0.004\)), an overall procedural success could be achieved in most patients with calcified commissures.

Conclusion

In this large contemporary series of patients with MS, a procedural success was obtained less frequently in patients with calcified commissure but a successful PMC could still be safely achieved in a large proportion of patients. Our results support the use of PMC as a first-line treatment of patients with severe MS even in the presence of significant commissural calcifications with otherwise favourable clinical characteristics.

Keywords

Mitral stenosis • Percutaneous commissurotomy • Calcifications • Echocardiography

Introduction

Since its introduction in 1984 by Inoue, percutaneous mitral commissurotomy (PMC) has become an effective and durable procedure to treat patients with mitral stenosis (MS). Percutaneous mitral commissurotomy safety, and immediate as well as long-term efficacy have been widely demonstrated;1–3 PMC is considered as the first-line treatment for symptomatic patients with favourable anatomy.4,5 Valvular morphology and more specifically the presence of mitral valve calcifications are important predictors of procedural success. However, whether a PMC should be attempted in patients with mitral valve calcifications remains debated due to contradictory results. Some have reported a lower PMC success rate and more frequent post-procedural severe mitral regurgitation (MR) in patients with mitral valve calcifications,6,7 whereas others including our group have previously shown a very acceptable procedural success rate that could postpone surgery in selected patients who have otherwise favourable characteristics.8 Furthermore, the impact of the location of mitral valve calcifications has been rarely evaluated and commissural calcifications are often considered as a contra-
indication, at least relative to PMC. This is of particular importance since in Western countries, patients with MS often present nowadays with calcified mitral valve and with growing experience, indications for PMC have progressively widened to include patients with less favourable conditions and more challenging anatomy.7 Thus, we aimed to evaluate the impact of the degree and location of mitral valve calcification on PMC results in a large and consecutive contemporary series of patients referred to our institution for PMC.

**Methods**

**Study population**

All consecutive patients who underwent a PMC at Bichat Hospital for symptomatic MS during the last 3-year period were enrolled in the present study. All patients underwent a comprehensive two-dimensional transthoracic echocardiography before and after PMC. The decision to proceed to PMC was based on clinical evaluation and on mitral valve anatomy. Exclusion criteria for PMC were severe bilateral commissural calcifications, more than mild MR and left atrial thrombus.4

**Echocardiography**

Echocardiography was performed the day before and 24–48 h after the procedure by experienced operators using high-quality commercial ultrasound systems (IE33, Philips, Andover, MA, USA; or Vivid7, General Electric, Fairfield, CT, USA). Mitral valve area (MVA) was measured by 2-dimensional echocardiography in parasternal short-axis view (planimetry). Mean transmitral gradient was assessed by continuous wave Doppler. Measurement of the systolic pulmonary artery pressure was based on the maximal velocity of the tricuspid regurgitation. Mitral regurgitation was semi-quantitatively graded from 0 to 4.10 After PMC, the ‘degree of commissural opening’ was semi-quantitatively evaluated as none, partial (up from only several millimetres from the valve orifice), or complete (up to the level of the mitral annulus) in parasternal short-axis view. Mitral valve calcification was defined using transthoracic echocardiography as bright areas with acoustic shadowing. Location of valvular calcifications—leaflets’ or commissural’—was evaluated in parasternal short-axis view. The degree of calcification was independently and semi-quantitatively scored for each commissure from 0 to 3 (0 = absent, 1 = mild, 2 = moderate, 3 = severe; Figure 1). Patients were then divided into three groups according to the location and degree of mitral valve calcifications: Group 1 patients with no mitral valve calcification, Group 2 patients with body leaflets but no significant commissural calcification (absent or mild) and Group 3 patients at least one commissure significantly calcified (moderate or severe commissural calcifications). All echocardiographic measurements, including the assessment of the degree of commissural opening, were performed prospectively except the assessment of the degree and location of calcifications which was performed retrospectively but blinded of PMC results.
Percutaneous mitral commissurotomy

Percutaneous mitral commissurotomy was performed by anterograde transvenous approach using the Inoue balloon with stepwise inflation under echocardiographic guidance. In brief, balloon size was chosen according to the patient’s height and the balloon was inflated in steps of 1–2 mm. Valve area (planimetry), mean transmitral gradient, commissural splitting, and the degree of MR were assessed by transthoracic echocardiography after each inflation. Our criteria for stopping the procedure were complete opening of at least one commissure with a valve area $>1.5$ cm$^2$ or the occurrence or increase of regurgitation $>2/4$. A good immediate result was defined as a good valve opening (final valve area $>1.5$ cm$^2$) with no regurgitation $>2/4$.

Statistics

Quantitative variables were expressed as mean ± standard deviation. Group comparisons were performed using ANOVA, $\chi^2$ test or $t$-test as appropriate. Comparison before and after PMC were performed using the paired Student $t$-tests and Pearson’s correlation. Inter- and intra-observer agreement of the assessment of the degree of commissural calcifications was evaluated in 30 randomized patients and intra-observer agreement of the assessment of the degree of commissural calcifications was $0.90$ and the lower rate of good immediate results between the three groups (88, 78, and 73%, respectively, $P = 0.004$) was only related to significant differences in final MVA. Only 28 and 30 mm balloons were used in the present cohort and nominal (30 mm for 80% of patients in Group 1, 82% for patients in Group 2, and 84% in Group 3, $P = 0.77$) and effective balloon sizes (28 ± 2 in the 3 groups, $P = 0.22$) were not different among the three groups.

Compared with patients in Group 2, patients in Group 3 had smaller baseline and final MVA ($P = 0.004$ and $P = 0.006$, respectively) but similar MVA increase ($P = 0.92$) and rate of good immediate results ($P = 0.40$) (Figure 2).

Table 1  Baseline clinical and echocardiographic characteristics of the population, overall and according to subgroups

<table>
<thead>
<tr>
<th></th>
<th>Overall (n = 464)</th>
<th>Group 1 (n = 261)</th>
<th>Group 2 (n = 141)</th>
<th>Group 3 (n = 62)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>54 ± 15</td>
<td>49 ± 15</td>
<td>61 ± 13</td>
<td>58 ± 14</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Female gender</td>
<td>360 (78)</td>
<td>211 (81)</td>
<td>108 (77)</td>
<td>41 (66)</td>
<td>0.04</td>
</tr>
<tr>
<td>Previous commissurotomy</td>
<td>92 (20)</td>
<td>54 (21)</td>
<td>26 (18)</td>
<td>12 (19)</td>
<td>0.77</td>
</tr>
<tr>
<td>NYHA functional class III–IV</td>
<td>357 (77)</td>
<td>196 (75)</td>
<td>112 (79)</td>
<td>49 (79)</td>
<td>0.56</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>143 (31)</td>
<td>61 (23)</td>
<td>56 (40)</td>
<td>26 (42)</td>
<td>0.0004</td>
</tr>
<tr>
<td>Normal left ventricular ejection fraction, %</td>
<td>423 (91)</td>
<td>242 (93)</td>
<td>126 (89)</td>
<td>55 (89)</td>
<td>0.40</td>
</tr>
<tr>
<td>Mitral valve area, cm$^2$</td>
<td>1.06 ± 0.22</td>
<td>1.09 ± 0.22</td>
<td>1.05 ± 0.20</td>
<td>0.95 ± 0.24</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Mean gradient, mmHg</td>
<td>10 ± 5</td>
<td>10 ± 6</td>
<td>10 ± 4</td>
<td>11 ± 5</td>
<td>0.16</td>
</tr>
<tr>
<td>Systolic pulmonary artery pressure, mmHg</td>
<td>46 ± 13</td>
<td>44 ± 12</td>
<td>48 ± 14</td>
<td>50 ± 15</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Group 1 are patients with no mitral valve calcifications, Group 2 patients with leaflets but no significant commissural calcifications, and Group 3 patients at least one significantly calcified commissure

Data presented are number of patients (percent) or mean ± SD.

Percutaneous mitral commissurotomy results

After PMC, mean MVA increased from $1.06 ± 0.22$ to $1.76 ± 0.27$ cm$^2$ and mean transmitral gradient decreased from $10 ± 5$ to $5 ± 2$ mmHg (both $P < 0.0001$). There was no procedural death, a tamponade occurred in one patient and a stroke in another one. An MR grade $\geq 3$ was observed in 45 patients (10%), and 11 patients (2%) underwent a mitral valve replacement during the same hospital stay. A good immediate result was achieved in 384 patients (83%).

Results are summarized in Table 2 (left part).

Mitr al valve area increased significantly after the procedure in the three groups (all $P < 0.0001$) but there was a significant difference between the three groups as regard to final MVA ($1.83 ± 0.26$ cm$^2$ in Group 1, $1.71 ± 0.25$ cm$^2$ in Group 2, and $1.60 ± 0.24$ cm$^2$ in Group 3, $P < 0.00001$), the rate of patients with final MVA $\geq 1.5$ cm$^2$ (93, 85, and 77%, respectively, $P = 0.007$) and MVA increase ($+0.74 ± 0.27$, $+0.66 ± 0.26$, and $+0.66 ± 0.31$ cm$^2$, respectively, $P = 0.01$) (Table 2 left part and Figure 2B and C). However, the complication rate, in particular the rate of MR grade $\geq 3$, was not different between the three groups (10, 10, and 8%, respectively, $P = 0.90$), and the lower rate of good immediate results between the three groups (88, 78, and 73%, respectively, $P = 0.004$) was only related to significant differences in final MVA.

Only 28 and 30 mm balloons were used in the present cohort and nominal (30 mm for 80% of patients in Group 1, 82% for patients in Group 2, and 84% in Group 3, $P = 0.77$) and effective balloon sizes (28 ± 2 in the 3 groups, $P = 0.22$) were not different among the three groups.

Compared with patients in Group 2, patients in Group 3 had smaller baseline and final MVA ($P = 0.004$ and $P = 0.006$, respectively) but similar MVA increase ($P = 0.92$) and rate of good immediate results ($P = 0.40$) (Figure 2).
Commissural opening

One commissure was completely split in 424 patients (91%), and a complete bilateral commissural opening was achieved in 139 patients (30%). The rate of complete opening of at least one commissure was significantly different between the three groups (92% in Group 1, 94% in Group 2, and 84% in Group 3, \( P = 0.05 \)). In contrast, the rate of bilateral complete commissural opening was similar (31% in Group 1, 33% in Group 2, and 21% in Group 3, \( P = 0.23 \)). Interestingly, the rate of at least one complete commissural opening was significantly lower in Group 3 than in Group 2 (\( P = 0.02 \)), and the rate of bilateral complete commissural opening was of borderline statistical significance (\( P = 0.09 \)). In contrast, the rate of unilateral (\( P = 0.68 \)) and bilateral (\( P = 0.32 \)) commissural opening was not different between patients in Groups 1 and 2.

In Group 3, the medial commissure was calcified in 28 patients and could be completely split in 7 patients (25%); the lateral commissure was calcified in 36 patients and completely split in 14 patients (39%). Overall, a calcified commissure could have been completely split in 33%. Our results also remained unchanged after exclusion of the 92 patients with previous commissurotomy.

Discussion

In this large consecutive and contemporary series of patients with severe MS referred for PMC, we evaluated the impact of the degree and location of mitral valve calcifications on a procedural success rate. The presence of significant commissural calcifications was associated with a lower procedural success rate than in the absence of leaflet or commissural calcification, but a good immediate result could still be achieved in almost three-fourth of patients and not the expense of an increased complication rate. Our results clearly demonstrate that PMC can be safely attempted despite the presence of commissural calcification with a very acceptable procedural success rate.

Mitral valve anatomy is a strong independent predictor of procedural success. Transthoracic echocardiography is the most commonly used method to assess the valve morphology and provides important screening information for PMC. Valve morphology is usually semi-quantitatively assessed using the Wilkins echocardiographic score,\(^1,2\), which relies on 4 valve characteristics, leaflet thickening, extent of subvalvular disease, leaflet mobility, and valve calcifications. In our institution, we routinely use the Cormier score,\(^1\) based on the extent of subvalvular disease and mitral calcification, which is easier.

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**Figure 2** Comparison between groups overall and group by group. (A) Baseline mitral valve area, (B) final mitral valve area, (C) mitral valve area increase after the procedure, and (D) rate of immediate good results (defined as a final mitral valve area of \( \geq 1.5 \text{ cm}^2 \) with no mitral regurgitation \( > 2/4 \)). Group 1 patients with no mitral valve calcification, Group 2 patients with body leaflets but no significant commissural calcification (absent or mild) and Group 3 patients at least one commissure significantly calcified (moderate or severe commissural calcifications).
and more reproducible. A high Wilkins score (≥8) or a Cormier grade 3 (presence of any mitral valve calcification) are associated with a lower MVA increase and a lower PMC success rate. However, if commissural splitting is the main mechanism by which the valve area increases during PMC and if achievement of a complete and bicommissural opening is a major goal during PMC, none of these scores include an assessment of the commissural morphology. Pioneering studies have shown that calcifications localized at the commissure level were associated with a lower procedural success rate, a higher occurrence of MR, and a lower mid-term survival, and that the prognostic value of commissural calcification superseded the one of the Wilkins score. More recently, in 311 patients referred for PMC during a 10-year period (1986–96), presence of significant commissural calcification was associated with a lower procedural success rate (40 vs. 64% in the absence of commissural calcification) and with a lower functional improvement. Based on these results, the authors advocated that the presence of commissural calcification, which was associated with a <50% procedural success rate, should lead to consider surgery as the first-line therapy. Our conclusions—and clinical implications—are markedly different. Our group has previously reported a 76% procedural success rate in patients with calcified MS but calcifications’ location was not analysed. In the present study, we confirm and extent these findings to commissural calcification. Presence of commissural calcification was associated with a lower procedural success rate but a good immediate result could still be achieved in most patients. Interestingly, if the procedural success rate was not significantly different between patients with commissural calcifications and patients with body leaflet calcifications, the rate of unilateral and bilateral commissural opening was significantly lower. However, the calcified commissure could have been split in approximately one-third of patients. These results demonstrate that the splitability of one commissure remains largely unpredictable. In contrast, in the absence of commissural calcification, the rate of commissural opening was not different between patients with and without body leaflet calcification. Reasons explaining the differences between our results and those of the literature may be multiple. Expertise of interventional cardiologists cannot be excluded and, indeed, we could achieve an 83% good immediate result rate in the overall population compared with only 58% in the above-mentioned study. The stepwise echocardiographic technique may offer a safer and more efficient procedure. On the other side, patients with MS represent a heterogeneous group, and procedural success rate depends not only on valve anatomy, but also on clinical characteristics. It is worth noting that in Sutaria et al.’s paper, patients were slightly older than our population and 30% were judged unsuitable for surgery. Importantly, in our series, the overall good procedural success rate observed in patients with commissural calcification was not achieved at the expense of an increased complication rate. Previous studies suggested that commissural calcification resulted in an increased post-procedural MR rate which was not the case in our series, and post-procedural MR rate grade ≥3 was not different among the three groups. Of note, neither the nominal nor the effective balloon size was different among the three groups.

The present study deserves several comments. First, assessment of mitral valve calcification—presence and degree—was performed using echocardiography. Echocardiography has a modest tissue characterization capability and cannot accurately differentiate calcification from dense fibrosis. However, if computed tomography and fluoroscopy are more specific to affirm the presence of calcification, computed tomography is not routinely performed in MS and fluoroscopy is performed during the procedure and not as a screening test.

Table 2

<table>
<thead>
<tr>
<th>Overall (n = 464)</th>
<th>Group 1 (n = 261)</th>
<th>Group 2 (n = 141)</th>
<th>Group 3 (n = 62)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral valve area, cm²</td>
<td>1.76 ± 0.27</td>
<td>1.83 ± 0.26</td>
<td>1.71 ± 0.25</td>
<td>1.60 ± 0.24</td>
</tr>
<tr>
<td>Mitral valve area ≥1.5 cm², in cm²</td>
<td>411 (89)</td>
<td>243 (93)</td>
<td>120 (85)</td>
<td>48 (77)</td>
</tr>
<tr>
<td>Mitral valve area increase, cm²</td>
<td>0.70 ± 0.28</td>
<td>0.74 ± 0.27</td>
<td>0.66 ± 0.26</td>
<td>0.66 ± 0.31</td>
</tr>
<tr>
<td>Mean gradient, mmHg</td>
<td>5 ± 2</td>
<td>4 ± 2</td>
<td>5 ± 2</td>
<td>5 ± 2</td>
</tr>
<tr>
<td>Systolic pulmonary artery pressure, mmHg</td>
<td>38 ± 10</td>
<td>37 ± 10</td>
<td>39 ± 11</td>
<td>40 ± 12</td>
</tr>
<tr>
<td>Medial commissure completely open</td>
<td>268 (58)</td>
<td>155 (59)</td>
<td>83 (59)</td>
<td>30 (48)</td>
</tr>
<tr>
<td>Lateral commissure completely open</td>
<td>295 (64)</td>
<td>164 (63)</td>
<td>96 (68)</td>
<td>35 (56)</td>
</tr>
<tr>
<td>At least one commissure completely open</td>
<td>424 (91)</td>
<td>239 (92)</td>
<td>133 (94)</td>
<td>52 (84)</td>
</tr>
<tr>
<td>Bilateral complete commissural opening</td>
<td>139 (30)</td>
<td>80 (31)</td>
<td>46 (33)</td>
<td>13 (21)</td>
</tr>
<tr>
<td><strong>In-hospital complications</strong></td>
<td><strong>Mitrval regurgitation grade ≥3</strong></td>
<td><strong>Mitrval regurgitation grade ≥3</strong></td>
<td><strong>Mitrval regurgitation grade ≥3</strong></td>
<td><strong>Mitrval regurgitation grade ≥3</strong></td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Tamponade</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Embolism</td>
<td>1 (0.2)</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Mitral regurgitation grade ≥3</td>
<td>45 (10)</td>
<td>26 (10)</td>
<td>14 (10)</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Mitral valve replacement*</td>
<td>11 (2)</td>
<td>7 (3)</td>
<td>3 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Good immediate results</td>
<td>384 (83)</td>
<td>229 (88)</td>
<td>110 (78)</td>
<td>45 (73)</td>
</tr>
</tbody>
</table>
In addition, fluoroscopy cannot differentiate commissural from leaflet calcifications. In most centres, the decision to perform or not a PMC is mainly based on echocardiographic findings and thus our approach reflects current practice further reinforcing the clinical implications of the present paper. It is also worth noting that the assessment of the degree and location of mitral valve calcification was retrospectively performed but blinded of PMC results and intra- and inter-observer agreement was excellent. Second, the degree of commissural opening was assessed using two-dimensional echocardiography. We have previously shown that three-dimensional echocardiography may provide a more accurate assessment of the degree of commissural opening but it was performed in a minority of patients due to logistic reasons. However, two-dimensional echocardiography tends to underestimate the degree of commissural opening which further reinforces our conclusion. Third, the rate of MR grade \( \geq 3 \) in the present study seems higher than previously reported. In our opinion, this higher rate is more likely due to modifications in MR grading with the distinction of moderate to severe (grade 3) and severe (grade 4) than to a real increase in the post-procedural MR rate which has been stable for years. Fourth, severe bilateral commissural calcification is considered as a contra-indication for PMC, and such patients were excluded from the present study. Finally, we do not have any outcome data. However, all studies are concordant showing that immediate result is a major predictor of the mid- and long-term outcomes.\(^2^{,22} \) In addition, a 5- to 10-year follow-up would have implied a less contemporary series.

**Clinical implications**

Percutaneous mitral commissurotomy is the first-line therapy of patients with severe symptomatic MS and favourable anatomy. In contrast, decision-making in patients with unfavourable anatomy must take into account the multifactorial nature of predicting the results of PMC.\(^2 \) Current ESC/EACTS recommendations stated PMC should be considered as initial treatment in symptomatic first-line therapy also in this subset of patients. Not be considered as a contra-indication to PMC, and our results support the use of PMC as a first-line treatment of patients with severe MS and (unilateral) calcified commissures otherwise with favourable clinical characteristics and further reinforce current guidelines.

**Conclusions**

In this large contemporary and consecutive series of patients with severe symptomatic MS, we showed that if good immediate PMC results are obtained less frequently in patients with commissural calcification than in patients free of any calcification or of body leaflets calcification, a procedural success could still be achieved in most patients and not at the expense of an excess procedural complication rate. Our results support the use of PMC as a first-line treatment of patients with severe MS and (unilateral) calcified commissures otherwise with favourable clinical characteristics and further reinforce current guidelines.

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**Conflict of interest:** All authors have contributed to the concept, design, data acquisition, analysis, or to the drafting of the manuscript. All authors have read and approved the manuscript.

**References**

Cleft posterior mitral leaflet resembling a tri-leaflet mitral valve: a novel phenotypic association with hypertrophic cardiomyopathy

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1 H.J. and S.L.D. contributed equally to this work.

Three patients with hypertrophic cardiomyopathy (HCM) and progressive dyspnoea presented for surgical evaluation. In all three, trans-thoracic echocardiography showed asymmetric septal hypertrophy, dynamic left ventricular outflow tract obstruction, systolic anterior motion of the mitral apparatus, and mitral regurgitation ranging from moderate to severe.

All the patients underwent surgical septal myectomy and were found to have deep posterior mitral valve leaflet clefts (CPML) clearly demonstrated on intra-operative three-dimensional transoesophageal echocardiography (3DTEE) [Panels 1A (ventricular view), 2A (atrial view), 3A (atrial view), and Supplementary material online, Videos S1–S6] in addition to complex multi-directional mitral regurgitation jets (Panels 1B and C, 2B and C, 3B and C, and Supplementary material online, Video S7) on 2D Doppler colour flow evaluation.

Mitral regurgitation resolved in all patients after septal myectomy with no need for further mitral repair, highlighting the importance of immediate post-bypass mitral regurgitation assessment after septal myectomy, before considering further mitral interventions, even with pre-bypass multi-directional significant leakage jets.

A cleft mitral valve presents an exceedingly rare finding in isolation, particularly when involving the posterior mitral leaflet. The patients presented herein likely represent a novel phenotype of previously unrecognized mitral valve abnormalities associated with HCM. The clinical significance of these findings is yet unknown. Increasing utilization of intra-operative 3DTEE played a pivotal role in the identification of the observed mitral valve abnormalities.

Supplementary material is available at European Heart Journal online.

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