Retrograde Nontransseptal Balloon Mitral Valvuloplasty
Immediate Results and Long-term Follow-up

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Background. Percutaneous retrograde nontransseptal balloon mitral valvuloplasty is a new technique developed in our institution for opening a stenotic mitral valve. This technique is based on a new, externally steerable cardiac catheter that enters the left atrium retrogradely via the left ventricle.

Methods and Results. The technique was used in 86 consecutive patients (18 men and 68 women; mean age, 51 ± 11 years). Dilatation of the stenotic mitral valve was achieved in 85 of the 86 patients. After the procedure, mitral valve area increased from 0.92 ± 0.22 to 2.14 ± 0.54 cm² and transmirtal gradient decreased from 16 ± 6 to 5 ± 2 mm Hg. Major complications, such as cardiac perforation, embolic events, or death, were not encountered. Severe mitral regurgitation (>2+) developed in three patients (3.5%). In two patients (2.4%), there was major injury of the femoral artery. The maintenance of the initial improvement was similar to that found in studies that used transseptal techniques. The restenosis rate during the 2-year follow-up was 15.4%.

Conclusions. The immediate and long-term findings of this study indicate that retrograde percutaneous nontransseptal balloon mitral valvuloplasty is an effective and safe procedure with an acceptable major complication rate. Moreover, this new technique has the advantage that it does not involve puncture and dilatation of the interatrial septum, although it may occasionally lead to arterial damage. Further studies will show whether it may really be considered as an alternative method or method of choice for percutaneous balloon mitral valvuloplasty. (Circulation 1992;85:1760–1767)

KEY WORDS • valves • valvuloplasty

Percutaneous balloon mitral valvuloplasty has been performed increasingly often for the treatment of isolated mitral stenosis.1–7 However, the procedure involves puncture with1,2,8–11 or without12 dilatation of the interatrial septum. Although this technique poses no practical problem if reasonable care is taken, it is associated with serious, albeit rare, complications.3–5,13–18 In an effort to avoid transeptal catheterization, attempts using a purely arterial retrograde route have been reported but have met with limited use,19,20 probably because of the technical difficulties encountered during retrograde left atrial catheterization when conventional19 or preshaped20 catheters are used. To overcome these difficulties, we have designed and developed a steerable catheter that easily and consistently enters the left atrium retrogradely via the left ventricle.21

The encouraging preliminary results of retrograde nontransseptal balloon mitral valvuloplasty (RNBMV) with this steerable left atrial catheter have been reported previously.22,23 In the present study, the immediate and long-term results in 86 patients who underwent the procedure between April 1988 and July 1991 are presented.

Methods

Study Population

The new technique was attempted in 86 consecutive patients with symptomatic mitral stenosis (18 men and 68 women aged 51 ± 11 years; range, 25–70 years). Three patients had previously undergone closed mitral commissurotomy. Two patients had suffered an embolic episode more than 8 months before their evaluation, but there was no evidence of left atrial thrombi. Fifty-five patients were in atrial fibrillation, and the remainder were in sinus rhythm. All patients in atrial fibrillation were anticoagulated for at least 2 months before valvuloplasty. Informed consent was obtained from all the patients before the procedure. Cardiac surgery standby was available in every instance.

The steerable left atrial catheter (Figure 1), developed in our center,21–23 is a modification of standard guiding catheters (right Judkins or Ablatz) and accessories for coronary angioplasty (Advanced Cardiovascular Systems, Inc., Mountain View, Calif.; C.R. Bard, Ireland; Schneider-Shiley AG, European Division, Zurich, Switzerland). Modifications were made by our own technical staff. The external diameter of the guiding...
catheter is 8F or 9F, its usable length is 110 cm, and the configuration of its tip may be altered by the external manipulation of a steering arm. This arm consists of a Teflon-coated stainless-steel wire 0.014 in. in diameter that passes along the lumen of the catheter and emerges a short distance from the catheter tip. The wire is attached to the exterior of the catheter close to the tip. The proximal end of the catheter is connected to a system of two hemostatic valves: the steering arm passes through one of these and the other may be used for the insertion of a guide wire into the catheter lumen.

Three different sizes of catheter may be used, according to the size of the left ventricle in individual patients. The curvable part of the catheter tip is 1.7 cm long in the small, 2.2 cm in the medium, and 3 cm in the large catheters. The large model was used in the first 20 cases, the medium model was used in 61, and the small model in five. The medium and small models have the advantage that they may be more easily curved and manipulated within the left ventricle.

Procedure

Right and left cardiac catheterization and left ventriculography were performed before and immediately after RNBMV; grading of mitral regurgitation and measurements of cardiac output were performed as previously described. Coronary arteriography was also performed in patients over 40 years old.

Two arterial sheaths were placed: a 9F in the right and a 6F in the left femoral artery for the continuous monitoring of arterial pressure. A pacing catheter was always placed in the right ventricle. After biplane left ventriculography in the right anterior oblique 45° and left anterior oblique 45° projections, the steerable left atrial catheter was advanced over a guide wire to the left ventricle via the right femoral artery. The tip of the guide wire was then withdrawn slightly into the catheter lumen, and the steering arm was retracted, causing the catheter tip to form a curve close to the apex of the left ventricle. The angle of curvature depends on the position of the mitral valve as determined from the frozen ventriculographic projections. The curve was fixed by tightening of the hemostatic valve through which the steering arm passes. At the same time, heparin (100 units/kg) was administered in all cases. Counterclockwise rotation of the catheter caused the plane of the curve to rotate until the catheter tip pointed toward the mitral valve (Figure 2A). The catheter was then retracted until its tip reached a point immediately below the anterior mitral valve leaflet. The correct position of
the catheter may be confirmed either by the recording of left atrial pressures through the catheter or by the unobstructed movement of a J wire through the catheter lumen into the left atrial cavity (Figure 2B).

Difficulties may be encountered when the catheter tip is misplaced toward either the outflow tract of the ventricle or the free ventricular wall. In the former case, the catheter is advanced a short distance toward the apex and rotated slightly clockwise, and the curve is opened. In the latter, the catheter is rotated counterclockwise, and the curve is slightly tightened. Should these maneuvers meet with no success, the curve of the catheter tip is completely released, the catheter is moved toward the apex, and the procedure is repeated from the beginning. (In the latter case, the time needed to readjust the catheter tip is less than 2 minutes.) The steering was successful at the first attempt in approximately one quarter of the procedures and at the second or the third in most of the remainder; rarely were more than three attempts made. All the above manipulations were performed under fluoroscopy with the same predetermined projections as in the left ventriculography.

Once the catheter was in place, a 0.038-in. J guide wire 260 cm long was inserted into the left atrium and was stabilized either by forming spirals within the atrial cavity (Figure 2C) or by being introduced into a proximal branch of the pulmonary vein. The atrial catheter was then removed, and a pigtail catheter was introduced over the guide wire into the atrium. Atrial pressures were recorded, and a stiffer guide wire (0.038 in., 260 cm, J tip, heavy duty) was inserted into the atrium via the pigtail catheter and stabilized as above. The pigtail catheter was then removed.

As a final check on the route of the guide wire, a flow-directed catheter was introduced over this wire to the left ventricle. The balloon was inflated in the outflow region of the ventricle with carbon dioxide or with a dilute dye solution and advanced toward the mitral valve (Figures 3A and 3B). If this movement was unobstructed, it proved that the guide wire had passed correctly through the inflow tract of the ventricle and had not become involved with the subvalvular apparatus.

When the double balloon technique was used, the same maneuvers were repeated through the left femoral artery. The second left atrial catheterization was easier and faster than the first, because the fluoroscopic image of the first guide wire could be used as an aid in positioning the second steering system.

The right femoral arterial sheath was then replaced with either a 14F sheath or an adjustable introducer (Medina-Schneider). Through this, the balloon catheter was introduced along the guide wire under fluoroscopy and positioned across the mitral valve. The balloon was then inflated by hand (Figure 4) according to the standard steps.1,2,9-12 Because the guide wire remains stabilized within the left atrium throughout the procedure, it is difficult for the balloon to slip from the mitral orifice during dilatation. In this event, however, the balloon tends to move along the guide wire into the atrium rather than back into the left ventricle.
were neglected. A small balloon (23 or 25 mm) was used initially, and if the immediate result was assessed as suboptimal, redilatation was performed with a larger balloon (up to 30 mm). In four patients in whom a larger-diameter balloon was considered to be necessary, the bifemoral technique was used. Twin balloons were used when they became available to us. For patients later in the series, the choice of the twin balloon was based on criteria reported previously.

The patients were kept in the coronary care unit, the sheaths were removed, and hemostasis was performed by compression. Most patients were discharged 24 hours after the procedure. If there were any arterial or other complications, the patients remained under observation; most were discharged 1 day later.

**Echocardiographic Examination**

M-mode, two-dimensional, and Doppler echocardiography were performed before and 1 or 2 days after valvuloplasty in all patients and were repeated over the follow-up period. Transesophageal echocardiography was also performed in the last 42 patients.

Echocardiographic studies were focused particularly on 1) the presence of thrombi in the left atrium, 2) the determination of mitral valve area, 27, 28 3) the degree of mitral regurgitation, and 4) assessment of the morphological characteristics of the mitral valve and subvalvular structures by use of an echocardiographic score.

**Evaluation of Functional Capacity**

Evaluation of functional capacity was based on the criteria of the New York Heart Association (NYHA) and on exercise duration and maximal oxygen consumption during cardiopulmonary exercise stress testing (Weber protocol).

**Follow-up**

The patients were routinely examined in the third, sixth, and 12th month after valvuloplasty and annually thereafter for functional capacity evaluation as above and the determination of mitral valve area by both Doppler and two-dimensional echocardiography. All patients who had been treated by valvuloplasty alone were examined in July 1991 for overall evaluation of their condition.

**Statistical Analysis**

Data are presented as mean±1 SD. For comparisons between continuous variables before and after valvuloplasty, Student’s paired t test and ANOVA for repeated measurements were used. The relation between hemodynamic and echocardiographic parameters was examined with linear regression analysis. To identify predictive factors for an increase in mitral regurgitation or in mitral valve area after RNBVM, stepwise regression analysis was performed on the following parameters: sex, age, NYHA class, cardiac rhythm, valve rigidity, valve thickening, valve calcification, subvalvular fibrosis, total echocardiographic score, cardiac output, mean pulmonary arterial pressure, mean left atrial pressure, mitral valve area, transmirtal pressure gradient, effective balloon dilating area (EBDA), and the EBDA normalized to body surface area (EBDA/BSA). A value of p<0.05 was accepted as statistically significant.

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**Table 1. Types of Balloon Catheter (Mansfield) Used for Valvuloplasty**

<table>
<thead>
<tr>
<th>Balloon type</th>
<th>Diameter (mm)</th>
<th>Patients (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td>Single</td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>Single</td>
<td>30</td>
<td>4</td>
</tr>
<tr>
<td>Twin</td>
<td>15, 15</td>
<td>7</td>
</tr>
<tr>
<td>Twin</td>
<td>15, 18</td>
<td>21</td>
</tr>
<tr>
<td>Twin</td>
<td>18, 18</td>
<td>24</td>
</tr>
<tr>
<td>Twin</td>
<td>18, 20</td>
<td>5</td>
</tr>
<tr>
<td>Twin</td>
<td>20, 20</td>
<td>2</td>
</tr>
<tr>
<td>Two single*</td>
<td>15, 20</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>18, 20</td>
<td>2</td>
</tr>
</tbody>
</table>

*Using both femoral arteries.
Results

Baseline Characteristics

The study group consisted of 86 patients: 20 in NYHA functional class II, 54 in class III, and 12 in class IV. The total echocardiographic score was 8.9±2.1 (range, 5–14). Mild mitral regurgitation was found in 14 patients. Mild aortic regurgitation was found in 17 patients and moderate in two. Coronary arteries were normal in all except one patient with significant (80%) right coronary artery stenosis. The left ventricular ejection fraction was 0.58±0.12 (range, 0.33–0.75). The baseline hemodynamic and echocardiographic measurements were similar to those shown in Table 2.

Measurements of Mitral Valve Area

There were no significant differences among the three methods used for estimation of the mitral valve area. The valve area measured by hemodynamics correlated well with the two-dimensional echocardiography and Doppler results both before (r=0.77, SEE=0.136 and r=0.77, SEE=0.132, respectively) and after (r=0.89, SEE=0.217 and r=0.88, SEE=0.247, respectively). Likewise, there was a good correlation between the two echocardiographic methods (before: r=0.86, SEE=0.109; after: r=0.89, SEE=0.248).

Table 2. Initial Hemodynamic Results of Retrograde Nontransseptal Balloon Mitral Valvuloplasty in 85 Completed Procedures

<table>
<thead>
<tr>
<th></th>
<th>Before valvuloplasty</th>
<th>After valvuloplasty</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (beats per minute)</td>
<td>82±12</td>
<td>85±12</td>
<td>NS</td>
</tr>
<tr>
<td>Mean left atrial pressure (mm Hg)</td>
<td>25±6</td>
<td>15±4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean transmitial gradient (mm Hg)</td>
<td>16±6</td>
<td>5±2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mitral valve area (cm²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gorlin formula*</td>
<td>0.92±0.22</td>
<td>2.14±0.54</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Two-dimensional echocardiography</td>
<td>0.95±0.21</td>
<td>2.15±0.51</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Doppler echocardiography</td>
<td>0.95±0.21</td>
<td>2.17±0.55</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cardiac output (l/min)</td>
<td>3.9±0.5</td>
<td>4.6±0.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean pulmonary artery pressure (mm Hg)</td>
<td>37±10</td>
<td>29±8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pulmonary arterial resistance (dyne · sec · cm⁻²)</td>
<td>260±139</td>
<td>253±126</td>
<td>NS</td>
</tr>
</tbody>
</table>

Values are mean±SD.

*Estimated in 82 patients; patients with severe mitral regurgitation were excluded.

Evaluation after the valvuloplasty, even in the more complex procedures.

Valvular thickening (r=−0.475, F=11.488, p<0.001) and subvalvular fibrosis (r=−0.42, F=17.151, p<0.001) were the only significant predictors for mitral valve area immediately after the procedure.

Complications

See Table 3. Major complications such as cardiac perforation, cardiac tamponade, embolic events, or death were not encountered in our study population.

Mitral regurgitation. The degree of mitral regurgitation was unchanged or improved in 58 patients (68%) and increased by one grade in 21 patients (25%), by two grades in five patients (6%), and by three grades in one patient (1%). However, only three patients had mitral regurgitation of >2+ at the end of the procedure. The first of these underwent valve replacement immediately and the second 4 months later. The third did well under medical treatment.

The EBDA/BSA ratio (r=0.666, F=20.69, p<0.001), mitral valve leaflet rigidity (r=0.58, F=20.011, p<0.001), and mitral valve regurgitation before the procedure (r=0.458, F=21.255, p<0.001) were the most significant predictors for an increase in mitral regurgitation immediately after the procedure.

Bleeding and vascular complications. Bleeding requiring blood transfusion occurred in two patients (2.4%). Three patients (3.5%) showed hematoma in the region of the right femoral artery, which disappeared without any sequelae.

In two patients (2.4%), there was significant weakening of the arterial pulse in the leg. The first was successfully treated with balloon angioplasty of the right femoral artery, whereas the second, who had no functional problems, required no special treatment.

Arrhythmias and intraventricular conduction disturbances. Ventricular extrasystoles or salvos of nonsustained ventricular tachycardia were recorded in all patients during the procedure, and transient disturbances of atrioventricular conduction were noted in four. In no case was special treatment necessary. ECG disturbances of intraventricular conduction persisting for more than 24 hours were observed in five patients (2 days in two, 1 week in two, and 3 months in one patient).
Follow-up

Overall evaluation of the followed patients. The follow-up group consisted of 84 patients. Three of these required surgery 4–14 months after valvuloplasty, one because of severe mitral regurgitation and two because of insufficient hemodynamic improvement. Four of the 81 patients have been determined by telephone interview to be in NYHA class I. The remaining 77 patients were followed for a period of 13.2±9.8 months (range, 1–40 months). Of these, 76 were in NYHA classes I and II, and only one was in class III. The mitral valve area was 0.94±0.21 cm² before valvuloplasty, increased to 2.17±0.55 cm² immediately after valvuloplasty, and remained unchanged (2.15±0.58 cm²) thereafter. Six patients with a mean overall echocardiographic score of 11.7±1.6 had valve restenosis (loss of >50% of the initial gain in valve area).

In 46 patients, the cardiopulmonary exercise stress test was repeated at least 3 months after the valvuloplasty (11.2±7.5 months; range, 3–30 months). No exercise stress test was carried out on the first eight patients of our series. Exclusion criteria of the remainder included poor functional status, inability to cooperate, and patient refusal. The durations of the stress tests before and 3 months after valvuloplasty and at final follow-up were 5.6±1.8, 9.9±2.6, and 12.8±2.4 minutes, respectively, and the maximum oxygen consumption increased from 9.1±2.2 to 14.1±3 and 17.1±2.6 ml/kg/min, respectively. The increases in these two parameters were significant both over the first 3 months and after the third month.

Two-year follow-up. All of the first 26 consecutive patients who had undergone valvuloplasty 2 or more years before were reevaluated 3, 6, 12, and 24 months after the procedure.

The mitral valve area was 0.93±0.22 cm² before valvuloplasty, increased to 2.06±0.4 cm² immediately after, and remained unchanged during the 2-year follow-up period (third month, 2.14±0.47; sixth month, 2.15±0.51; first year, 2.01±0.47; second year, 1.99±0.48 cm²; Figure 5). Four patients (15.4%) had restenosis, three with recurrence of symptoms.

In all 16 patients who had undergone cardiopulmonary exercise stress testing before the procedure, including three of the four with restenosis, the test was repeated at each follow-up during the 2-year period. The durations of the stress tests before valvuloplasty and at the 3, 6, 12, and 24-month follow-up were 5.3±1.8, 10.1±2.4, 12.7±1.9, 13.9±2, and 13.7±2.6 minutes, respectively (Figure 6). The trend of maximal oxygen consumption was similar (8.8±2.2, 14.3±2.6, 17.1±2.2, 18.4±2.1, and 18.3±3.1 ml/kg/min, respectively, Figure 7). The main improvement in both these parameters occurred during the first and, to a lesser degree, the second trimesters.

Discussion

The findings of this study indicate that RNBMV is an effective and safe procedure with an acceptable complication rate and immediate and long-term results that compare favorably with those of surgical commissurotomy32,33 and percutaneous mitral valvuloplasty using the transseptal route.3–5,13,34–37

Effectiveness

The immediate and long-term results of the two techniques are similar. Our 2-year restenosis rate was 15.4%; this was comparable to the results of studies using the transseptal technique.13,36,37 It should be noted that the interatrial communication created by the transseptal technique may occasionally lead to overestimation of the mitral valve area after dilatation,38 so determination of the valve area might be more accurate with the retrograde technique.

Complication Rate

The transseptal methods1,2,8–12 pose no particular practical problems provided that reasonable precautions are taken, but the puncturing of the interatrial septum has inherent complications39 and, especially when the septum is dilated, may occasionally lead to a hemodynamically significant left-to-right shunt.3–5,13–18 Although most patients with this complication have a stable course, its natural history has not been clarified. In the retrograde transseptal technique,12 there is no distension of the interatrial septum, but the potential complications of the transseptal catheterization remain, and the septum may be torn by excessive traction applied to the guide wire.15

With RNBMV, one might expect complications related to the cannulation of the femoral artery with large introductory sheaths. The incidence of major injury to the femoral artery was extremely low in the present study, however, and significantly lower than in aortic

<table>
<thead>
<tr>
<th>Complication</th>
<th>Patients (n)</th>
<th>%</th>
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<tbody>
<tr>
<td>Mitral regurgitation ≥ Seller's grade 3+</td>
<td>3</td>
<td>3.5</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Embolic events</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding requiring blood transfusion</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td>Femoral artery occlusive damage</td>
<td>2</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Figure 5. Graph of mitral valve area assessed by Doppler echocardiography in 26 patients before and after valvuloplasty and during 24-month (M) follow-up.
valvuloplasty. This is probably because of the relatively young age of our patients and the removal of the arterial sheaths immediately after the completion of the procedure.

The second, and probably more important, reservation is related to the possibility of damage to the subvalvular apparatus by the dilating balloon. Such an event was not encountered in our patients, however, and it is highly unlikely for the following reasons: 1) the use of the steerable left atrial guiding catheter, whose maneuverable tip ensures an unhindered course through the subvalvular apparatus; 2) the characteristic thickening and fusion of the chordae tendineae in mitral stenosis; 3) the "subvalvular channel" formed in the beating heart by the papillary muscles and chordae tendineae, which prevents any displacement of the catheter or guide wire and protects against valvular damage (the routine use of a metal dilator retrogradely during closed surgical mitral commissurotomy with a relatively low risk supports this hypothesis); and 4) the introduction of a Swan-Ganz catheter to test for the free movement of the inflated balloon along the guide wire (this test was performed in the last 24 patients of this study, in whom a twin balloon was used for mitral valve dilatation, and there was no involvement of the guide wire with the chordae tendineae in any case). As a result, the incidence of mitral regurgitation >2+ was relatively low in our series of patients (3.5%) compared with mitral valvuloplasty by the transseptal route and was exclusively related to torn mitral valve leaflets.

The position of the guide wire within the left ventricle rules out the possibility of damage to the ventricular apex during insertion of the balloon catheter, because the catheter tip, constrained by the guide wire, never approaches this part of the heart at all closely.

**Technical Skills**

Mitral valvuloplasty is a procedure that demands ability and experience on the part of the operator, with the incidence of serious complications diminishing as the operator's experience grows. The learning curve for RNBMV seems to be no different from that of the transseptal technique and may be even shorter. This assumption is supported by the fact that, despite its continuous refinement, the technique is performed by four different operators in our institution.

**Financial Aspects**

The cost of a mitral valvuloplasty procedure is determined by the cost of the materials, the duration of the procedure, and the hospital stay of the patient. Because the hospital stay is approximately the same with the RNBMV and transseptal techniques (most of our patients were discharged after 24 hours and almost all of the rest 1 day later), the first two factors are the most important. The time required for the retrograde procedure is shorter than for the transseptal technique. Furthermore, with RNBMV there is no need for a system to puncture and dilate the interatrial septum. The cost of the guiding catheter used in the retrograde technique has not yet been determined but is likely to be comparable to the cost of the system used to puncture the interatrial septum. Thus, the overall cost of the retrograde technique would seem to be less than the cost of the transseptal procedure.

**Retrograde or Transseptal?**

RNBMV compares favorably with the transseptal technique in terms of effectiveness, safety, and cost. Furthermore, it seems to be less technically demanding and has the advantage that it does not involve puncture of the interatrial septum. However, it does have the drawback of occasionally leading to arterial injury.

Further studies will show whether it may really be considered as an alternative method or method of choice for opening a stenotic mitral valve.

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