Can the edge-to-edge technique provide durable results when used to rescue patients with suboptimal conventional mitral repair?†

Michele De Bonis*, Elisabetta Lapenna, Nicola Buzzatti, Maurizio Taramasso, Maria Chiara Calabrese, Teodora Nisi, Federico Pappalardo and Ottavio Alfieri

Department of Cardiac Surgery, San Raffaele Scientific Institute, Milan, Italy

* Corresponding author. Department of Cardiac Surgery, San Raffaele Scientific Institute, Via Olgettina 60, 20132 Milano, Italy. Tel: +39-02-26437102; fax: +39-02-26437125; e-mail: michele.debonis@hsr.it (M. De Bonis).

Received 14 September 2012; received in revised form 25 December 2012; accepted 28 December 2012

Abstract

OBJECTIVES: The ‘edge-to-edge’ technique (EE) can be used as a bailout procedure in case of a suboptimal result of conventional mitral valve (MV) repair. The aim of this study was to assess the long-term outcomes of this technique used as a rescue procedure.

METHODS: From 1998 to 2011, of 3861 patients submitted to conventional MV repair for pure mitral regurgitation (MR), 43 (1.1%) underwent a rescue edge-to-edge repair for significant residual MR at the intraoperative hydrodynamic test or at the intraoperative transoesophageal echocardiography. Residual MR was due to residual prolapse in 30 (69.7%) patients, systolic anterior motion in 12 (27.9%) and post-endocarditis leaflet erosion in 1 (2.3%). According to the location of the regurgitant jet, the edge-to-edge suture was performed centrally (60.5%) or in correspondence with the anterior or posterior commissure (39.5%). The original repair was left in place.

RESULTS: There were no hospital deaths. Additional cross-clamp time was 15.2 ± 5.6 min. At hospital discharge, all patients showed no or mild MR and no mitral stenosis. Clinical and echocardiographic follow-up was 97.6% complete (median length 5.7 years, up to 14.6 years). At 10 years, actuarial survival was 89 ± 7.4% and freedom from cardiac death 100%. Freedom from reoperation and freedom from MR ≥2+ at 10 years were both 96.9 ± 2.9%. At the last echocardiogram, MR was absent or mild in 37 patients (88%), moderate in 4 (9.5%) and severe in 1 (2.4%). No predictors for recurrence of MR ≥2+ were identified. The mean MV area and gradient were 2.8 ± 0.6 cm² and 2.7 ± 0.9 mmHg. NYHA I–II was documented in all cases.

CONCLUSIONS: A ‘rescue’ EE can be a rapid and effective option in case of suboptimal result of ‘conventional’ MV repair. Long-term durability of the repair is not compromised.

Keywords: Mitral regurgitation • Mitral valve repair • Edge-to-edge technique

INTRODUCTION

In centres with large expertise in the field, mitral valve (MV) repair can nowadays be performed in >95% of patients affected by degenerative valve disease [1]. The absence of residual mitral regurgitation (MR) immediately after the procedure is extremely important for the long-term durability of the repair [2–4]. Therefore, at the end of every reconstructive procedure, the competence of the MV is carefully checked by forceful saline injection into the left ventricle (water testing) and by transoesophageal echo Doppler, which is routinely performed immediately after weaning from cardiopulmonary bypass (CPB). The goal of the repair is to achieve both a perfect intraoperative ‘water testing’ and no or mild residual MR at the transoesophageal echocardiography (TEE) examination. Moreover, a good length of coaptation between the two leaflets should be obtained, together with a sufficient valve area and no systolic anterior motion (SAM) of the anterior leaflet into the left ventricular outflow tract (LVOT). In the presence of significant residual regurgitation and/or SAM refractory to conservative management, surgical revision of the MV is necessary and further repair or mitral replacement is required during the same operation. Sometimes the mechanism of the initial suboptimal result is clearly identified and easy to correct as it typically occurs in case of residual clefts, suture dehiscence, partial annulusplasty ring detachment and so on. In other circumstances, however, the cause of the residual regurgitant jet is unclear or it would require a complex and time-consuming procedure to correct, often with an uncertain result. In those more complex cases of suboptimal conventional mitral repair, we have been using the ‘edge-to-edge’ technique (EE) as a bailout procedure as already reported by Gatti et al. [5]. The aim of this study was to assess the early and long-term outcomes of this technique used to rescue patients with suboptimal conventional mitral reconstruction.

†Presented at the 26th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Barcelona, Spain, 27–31 October 2012.
PATIENTS AND METHODS

Patients

From 1998 to 2011, of 3861 patients submitted to conventional mitral repair for pure MR, 43 (1.1%) underwent a rescue edge-to-edge repair to improve a suboptimal result of the initial MV reconstruction. Preoperative, intraoperative and postoperative data were retrospectively reviewed through a hospital database and controlled on patients’ records. The Institutional Ethical Committee approved the study and waived the informed consent for this retrospective analysis.

Preoperative clinical data are reported in Table 1. There were 36 (83.7%) male and 7 (16.3%) female patients, with a mean age of 57 ± 11.9 years. At admission, 35 (81.3%) patients were in New York Heart Association (NYHA) class I or II, whereas 8 (18.6%) were in class III. The majority of patients (38 of 43, 88.3%) were in sinus rhythm. Mean ejection fraction was 59 ± 7.1. The aetiology of MR was degenerative in 40 patients (93%), post-endocarditis in 2 (4.6%) and post-traumatic in 1 (2.3%).

Echocardiographic study

All patients underwent preoperative transoesophageal Doppler echocardiography. The degree of MR was measured semi-quantitatively by Doppler colour-flow imaging and defined as mild (1+/4+) if the percentage of the left atrial area subtended by the MR jet was 1–15%, moderate (2+/4+) if it was 16–35%, moderate-to-severe (3+/4+) if between 36 and 55% and severe (4+/4+) if ≥ 0.5, 4+ [7]. In case of discordance of the two methods, the clinical decision was made quantitatively by Doppler colour-flow imaging and defined as mild (1+/4+) if ≤ 0.3, 1–2+; between 0.3 and 0.5, 3+ and ≥ 0.5, 4+ [8].

The mechanism of regurgitation was a Type 2 lesion in all patients. In Table 2, the mechanisms responsible for severe MR are described by the preoperative TEE are listed. The most common mechanism of MR was prolapse or flail of the posterior leaflet. Anterior leaflet and bileaflet prolapse were present in 1 (2.3%) and 6 (13.9%) patients, respectively. In 7 patients (16.2%) more than one segmental lesion was present. Transoesophageal echocardiography was repeated intraoperatively after induction of general anaesthesia and immediately after weaning from CPB once the haemodynamic conditions were stabilized.

Surgical technique of the initial mitral repair

All operations were performed through a conventional midline sternotomy. Bicaval cannulation and CPB with moderate hypothermia were employed. Intermittent antegrade cold blood cardioplegia or, more recently, a single-dose Bretschneider HTK-cardioplegia was used. The MV was approached through the left atrium with the incision done in the interatrial groove. The MV was carefully inspected and the initial mitral repair technique was chosen according to the preoperative TEE results and the intraoperative findings, which were occasionally different from the baseline echocardiographic diagnosis. The vast majority of the patients (39 of 43, 90.6%) underwent posterior leaflet quadrangular or triangular resection. In 6 of them (6 of 39, 15.3%), another concomitant repair procedure was carried out including cleft obliteration, neochordae implantation and triangular resection of the anterior leaflet. Particularly, in the first period of the study time frame, a simple annular plication was usually performed after the resection of the posterior leaflet. Only in 12 cases (12 of 39, 30.7%), a sliding/folding plasty was used to decrease more effectively the height of the posterior leaflet. When the extension of the posterior leaflet prolapse or flail was considered too large for a resection technique, implantation of artificial chordae was preferred (Table 3). All patients included in this series had a concomitant ring annuloplasty. The annuloplasty ring system used was a semi-rigid ring (St Jude Medical Seguin) in 18 patients (18 of 43, 41.8%) or a flexible one (St Jude Medical Tailor) in 25 cases (58.1%). The size of the ring was chosen according to the inter-trigonal distance and the

Table 1: Baseline characteristics of the patients

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>43</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>57 ± 11.9 (27–73)</td>
</tr>
<tr>
<td>Male sex (n, %)</td>
<td>36 (83.7)</td>
</tr>
<tr>
<td>NYHA class (n, %)</td>
<td>21 (48.8), 14 (32.5), 8 (18.6)</td>
</tr>
<tr>
<td>AF at presentation (n, %)</td>
<td>5 (11.6)</td>
</tr>
<tr>
<td>Aetiology of MR (n, %)</td>
<td>Degenerative 40 (93%), Healed infective endocarditis 2 (4.6%), Post-traumatic 1 (2.3%)</td>
</tr>
<tr>
<td>LVEF, mean ± SD (%)</td>
<td>59.2 ± 6.35</td>
</tr>
<tr>
<td>LVEDD, mean ± SD (mm)</td>
<td>59 ± 7.1</td>
</tr>
<tr>
<td>LVEDV, mean ± SD (mm)</td>
<td>34.4 ± 7.20</td>
</tr>
<tr>
<td>SPAP, mean ± SD (mmHg)</td>
<td>37.5 ± 9.53</td>
</tr>
<tr>
<td>AF: atrial fibrillation; MR: mitral regurgitation; LVEF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; LVEDV: left ventricular end-systolic diameter; SPAP: systolic pulmonary artery pressure.</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Mechanisms of MR as diagnosed by preoperative transoesophageal echocardiography

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior leaflet prolapse/flail</td>
<td>32 (74.4)</td>
</tr>
<tr>
<td>P2 scallop</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P2 scallop + post-endocarditis A2 and P2 free margins’ erosion</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P2 and P3 scallops</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P3 scallop</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>Anterior leaflet prolapse</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>A2 scallop + posterior leaflet hypoplasia</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Bileaflet prolapse</td>
<td>3 (6.9)</td>
</tr>
<tr>
<td>P2 and A2 scallops</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>P2 and A3 scallops</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P2-P3 and A3 scallops</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P1 and A1 scallops + post-endocarditis A2 free margin erosion</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>P2 and A1–A2 scallops</td>
<td>1 (2.3)</td>
</tr>
</tbody>
</table>
was not SAM related, a second pump run was immediately
unavoidable. On the other hand, whenever a residual MR
pump run for surgical revision of the MV was considered
In case of unresponsiveness to those manoeuvres, a second
repair procedure. A rescue edge-to-edge suture was performed in
eliminate the LVOT pressure gradient and the secondary MR [9].

The mean length of clinical follow-up was 5.7 ± 4.59 years
(range 1 month to 14.6 years) with a median (interquartile range,
IQR) of 4.8 years (1.4–10.4) whereas the last echocardiographic
examination was performed at a mean of 5.2 ± 4.58 years after
surgery with a median (IQR) of 4 years (0.7–10.1). Thirteen
patients (30.9%) had >10 years follow-up (up to 14.6 years).

Statistical analysis

Calculations were performed using SPSS version 11.5 (SPSS, Inc.,
Chicago, IL, USA) for Windows (Microsoft Corp., Redmond, WA,
USA) software package. Data were expressed as mean ± SD or as
median and IQR. Comparison of continuous data was performed
with the Student’s t-test for (un)paired samples as indicated.
Comparison of categorical variables was performed using $\chi^2$ and

| Table 3: Surgical techniques used for the initial repair on the base of preoperative TEE and intraoperative findings |
|-------------------|------------------|---------|
| Resection of the posterior leaflet ± sliding/folding plasty | n (%) |
| Without other procedures | 33 (76.7) |
| Combined with | |
| P1–P2 cleft closure | 1 (2.3) |
| A2 artificial chordae implantation | 3 (6.9) |
| A3 artificial chordae implantation | 1 (2.3) |
| Triangular resection of the anterior leaflet | 1 (2.3) |
| Artificial chordae implantation | |
| Anterior leaflet | 1 (2.3) |
| Posterior leaflet | 3 (6.9) |

surface area of the anterior leaflet (mean size 34.4 ± 2 mm, median
35 mm). A number of associated procedures were carried out con-
comitantly with valve repair, including coronary artery revascular-
ization (2 patients), radiofrequency ablation of atrial fibrillation (2
patients), atrial septal defect closure (2 patients), tricuspid annulo-
plasty (1 patient) and aortic valve replacement (1 patient).

Evaluation of valve repair

**Water testing.** At the end of the mitral repair procedure the
competence of the reconstructed MV was systematically checked
with forceful saline injection into the left ventricle (water testing).
Water testing was classified as normal if no leak at all could be
detected. In the presence of residual regurgitation, this was
judged by the operating surgeon as mild or greater than mild
(evident leak). A water testing showing a grade of residual MR
greater than mild (evident leak) was considered not acceptable
and the MV was immediately revised.

**Intraoperative transoesophageal echocardiography.** Patients
with a satisfactory water test (no or trivial residual regurgitation)
were weaned from CPB. As soon as a good haemodynamic state
was achieved, a TEE control was performed. If SAM was
detected, a conservative management consisting of intravenous
volume expansion, discontinuation of inotropic drugs and
administration of β-blockers was first attempted in order to
eliminate the LVOT pressure gradient and the secondary MR [9].
In case of unresponsiveness to those manoeuvres, a second
pump run for surgical revision of the MV was considered
unavoidable. On the other hand, whenever a residual MR ≥1+ was
not SAM related, a second pump run was immediately
started in order to reassess the MV.

‘Rescue’ edge to edge. All 43 patients had either an
unsatisfactory water test or a suboptimal result at the TEE control
(SAM/residual MR ≥1+) and underwent surgical revision of the MV
repair procedure. A rescue edge-to-edge suture was performed in
all cases without undoing the primary repair.

In patients with refractory SAM, the procedure was exclusively
echo-guided: if the echocardiographic examination demonstrated
that the portion of the valve responsible for LVOT obstruction was
the middle one, a central edge-to-edge was performed. On the
other hand, if the commissural region of the MV was mainly
involved in determining the SAM, the edge-to-edge suture was
realized in correspondence with the commissure.

In patients with residual MR (at water test or TEE) but without
SAM, the MV was inspected once again looking for the residual
anatomical defect.

The EE was used to restore MV competence whenever, in the
opinion of the surgeon, a more conventional re-repair would
have been not suitable or too time consuming or at high risk of
an unsatisfactory result. From a technical point of view, a 4–0
polypropylene continuous suture without pledgets was used for
leaflet approximation. A central or commissural rescue EE was
performed according to the regurgitant jet location identified at
the water test or at the TEE. As the overall MV area had already
been reduced by the initial repair and ring annuloplasty, care
was taken to keep the EE suture as short as possible to avoid
mitral stenosis. In patients with SAM or with a very localized
regurgitant jet, even a single 4.0 polypropylene stitch was con-
sidered to be enough. The distance of the suture bites from the
free edges was variable according to the redundancy of the leaf-
lets. Typically in patients with postoperative SAM it was around
1 cm or more to prevent the motion of the myxomatous leaflets
into the LV outflow tract. Whenever the non-coapting zone of
the mitral leaflets was not exactly in the middle of the MV, the
position of the EE had to be somewhat asymmetric. In this case,
the sizes of the two orifices were different, one being larger than
the other. A second water testing was always performed at the
end of the rescue procedure to be sure that no distortion of the
valve anatomy had been caused by the EE suture. The final valve
area was assessed by direct inspection and, in case of doubts,
by the introduction of Hegar dilators. A global valve area of 2.5 cm²
was considered satisfactory for normal-sized patients. Lower
values of the mitral valve area (between 2 and 2.4 cm²) were con-
sidered acceptable in a minority of patients with a BSA ≤1.6 m².
Finally, TEE was repeated after weaning from CPB to assess the
competence of the valve and measure the valve area, usually by a
planimetric method using the trans-gastric short-axis view.

**Follow-up.** Follow-up data were obtained by means of outpatient
visits, including a TTE examination performed in our institution or
by means of telephone interview with the patients and the
referring cardiologists. Clinical and echocardiographic follow-up
information was available for 42 patients (97.6% complete). One
patient was lost to follow-up. All 42 patients had at least one
Doppler echocardiographic examination performed within the
previous 6 months in our centre or in their referral hospitals.
For those patients who died or underwent reoperation, clinical
and Doppler echocardiographic data refer to the latest findings
available before the event.

The mean length of clinical follow-up was 5.7 ± 4.59 years
(range 1 month to 14.6 years) with a median (interquartile range,
IQR) of 4.8 years (1.4–10.4) whereas the last echocardiographic
examination was performed at a mean of 5.2 ± 4.58 years after
surgery with a median (IQR) of 4 years (0.7–10.1). Thirteen
patients (30.9%) had >10 years follow-up (up to 14.6 years).

| Table 3: Surgical techniques used for the initial repair on the base of preoperative TEE and intraoperative findings |
|-------------------|------------------|---------|
| Resection of the posterior leaflet ± sliding/folding plasty | n (%) |
| Without other procedures | 33 (76.7) |
| Combined with | |
| P1–P2 cleft closure | 1 (2.3) |
| A2 artificial chordae implantation | 3 (6.9) |
| A3 artificial chordae implantation | 1 (2.3) |
| Triangular resection of the anterior leaflet | 1 (2.3) |
| Artificial chordae implantation | |
| Anterior leaflet | 1 (2.3) |
| Posterior leaflet | 3 (6.9) |

Statistical analysis

Calculations were performed using SPSS version 11.5 (SPSS, Inc.,
Chicago, IL, USA) for Windows (Microsoft Corp., Redmond, WA,
USA) software package. Data were expressed as mean ± SD or as
median and IQR. Comparison of continuous data was performed
with the Student’s t-test for (un)paired samples as indicated.
Comparison of categorical variables was performed using $\chi^2$ and
Fisher’s tests. NYHA functional class and grade of MR were treated as ordinal variables and compared with the Wilcoxon signed-rank test (related samples) or with the Mann-Whitney U-test (independent samples). Survival and freedom from events (reoperation and recurrence of MR ≥3+) were analysed with actuarial methods. For actuarial estimates, data are presented as mean ± standard error. Univariate analysis of predictors of recurrence of MR ≥2+ was performed with Cox proportional hazards regression.

RESULTS

Mechanisms of residual regurgitation after the initial repair

After the initial MV repair, 16 patients (16 of 43, 37.2%) had an abnormal intraoperative water testing with residual prolapsing lesions and underwent immediate re-inspection of the MV

The remaining 27 patients (27 of 43, 62.7%) had a satisfactory water test (no or trivial residual regurgitation) but a residual moderate (2+/4+) MR was present at the intraoperative TEE (only 1 patient showed a moderate-to-severe MR). Persistent MR was due to residual prolapse in 14 patients (14 of 27, 51.8%), malcoaptation secondary to post-endocarditis leaflet erosion in 1 (3.7%) and SAM in the other 12 (12 of 27, 44.4%). When residual MR was not SAM related, a second pump run was immediately started in order to reassess the MV. On the other hand, in the 12 patients with SAM, a conservative management was first attempted without success. Therefore, a second pump run for surgical revision of the MV was started, and the echocardiographic findings were used to guide the rescue procedure. Table 4 summarizes the residual defects identified either during the water test or at the intraoperative TEE responsible for the suboptimal result of the initial mitral repair. Considering the entire study population, a residual prolapse was observed in 30 patients (30 of 43, 69.7%), SAM in 12 (12 of 43, 27.9%) and malcoaptation due to post-endocarditis leaflet erosion in 1 (1 of 43, 2.3%).

Table 4: Residual defects responsible for the suboptimal result of the initial mitral repair as assessed by water testing or intraoperative TEE

<table>
<thead>
<tr>
<th>Description</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAM (systolic anterior motion of the anterior mitral leaflet)</td>
<td>12 (27.9)</td>
</tr>
<tr>
<td>Residual prolapse*</td>
<td>30 (69.7)</td>
</tr>
<tr>
<td>Posterior leaflet</td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>6</td>
</tr>
<tr>
<td>P2</td>
<td>3</td>
</tr>
<tr>
<td>P1</td>
<td>1</td>
</tr>
<tr>
<td>Anterior leaflet</td>
<td></td>
</tr>
<tr>
<td>A2</td>
<td>11</td>
</tr>
<tr>
<td>A1</td>
<td>3</td>
</tr>
<tr>
<td>A3</td>
<td>1</td>
</tr>
<tr>
<td>Bileaflet</td>
<td></td>
</tr>
<tr>
<td>A2-P2</td>
<td>3</td>
</tr>
<tr>
<td>A3-P3</td>
<td>2</td>
</tr>
<tr>
<td>Malcoaptation due to post-endocarditis margin erosion</td>
<td>1 (2.3)</td>
</tr>
</tbody>
</table>

*In 2 patients, a persistent annular dilatation (too large annuloplasty ring) was concomitantly present.

In most cases, by revising the mitral anatomy, a new unexpected prolapse was present in correspondence with one of the commissural regions or in a segment of the valve that was not supposed to be diseased according to the preoperative TEE and the initial intraoperative MV assessment. In some patients, a residual prolapse was still present at the level of the resection, usually performed on the posterior leaflet. In one patient, the lack of coaptation was due to the post-endocarditis erosion of the free margins of the leaflets.

Rescue edge to edge

According to the regurgitant jet location identified at the water test or at the TEE, 26 (26 of 43, 60.5%) patients received a central edge-to-edge repair and 17 (17 of 43, 39.5%) a commissural one (anterior commissure in 4 patients and posterior commissure in 13). Second, CPB and aortic cross-clamping times were 25 ± 8.9 and 15 ± 5.6 min, respectively.

None of the 43 patients required early reoperation for residual MR or mitral stenosis. The TEE performed after the rescue edge-to-edge showed no SAM and no (32 of 43, 74.4%) or mild (11 of 43, 25.5%) MR in all patients. Transthoracic Doppler echocardiography was repeated before discharge and showed similar results.

Clinical outcome

There were no hospital deaths. Postoperative complications included low-output syndrome in 2 patients (4.6%), re-exploration for bleeding in 2 cases (4.6%) and implantation of permanent pacemaker in another 2 (AV block in 1 patient and slow rate atrial fibrillation in another 1). In addition, 2 patients (4.6%) developed postoperative acute renal failure.

Two patients died 5 and 9 years after MV repair. The causes of death were liver and prostatic cancer, respectively. Both of them had undergone a TTE examination a few months before death showing mild MR in the first patient and moderate valve regurgitation (2+/4+) in the second.

Overall actuarial survival at 10 years was 89 ± 7.4% (Fig. 1) and freedom from cardiac death, 100%. One patient required reoperation after about 1 year. He had undergone quadrangular resection of the posterior leaflet and flexible ring annuloplasty for severe MR due to fibroelastic deficiency followed by rescue edge-to-edge at the posterior commissure for residual moderate MR at the intraoperative TEE. MV replacement was performed in another institution and the cause of the repair failure remained unknown. Overall freedom from reoperation at 10 years was 96.9 ± 2.9%.

Doppler echocardiographic assessment and late results

The last follow-up TTE (available in 42 patients) demonstrated that MR was absent or mild in 37 patients (88%), moderate in 4 (9.5%) and severe in 1 (2.3%) (this patient was reoperated). Actuarial freedom from MR ≥3+ at 10 years was 96.9 ± 2.9%. The mean MV area and the mean transmural pressure gradient were 2.8 ± 0.6 cm² and 2.7 ± 0.9 mmHg, respectively. In 8
patients with a small BSA (≤1.6 m²), the area of the MV at the TEE examination was between 2 and 2.4 cm² with a mean pressure gradient of 3.3 ± 0.5 mmHg (median 3.8 mmHg). Those patients had received, as part of their initial mitral repair, a ring annuloplasty with a mean size of 33.2 ± 2.3 mm (median 32.5 mm, range 31–38 mm). They had no pulmonary hypertension at a median follow-up of 5.4 years and NYHA class I was present in all of them.

As only 1 patient had MR ≥3+ whereas MR ≥2+ was present in 5 cases, we looked for predictors of recurrence of MR ≥2+. None of the tested variables was identified as a risk factor for this event. In particular, age, LV function, the presence of more complex mechanisms of MR (anterior and bileaflet vs posterior leaflet prolapse) and the site of the rescue edge-to-edge suture (commissure vs middle of the valve) were not associated with recurrence of regurgitation, moderate or greater. Similarly, the degree of MR at discharge and the final MV area showed no correlation with this event (Table 5).

Data on heart rhythm at follow-up were available in 42 patients, with 37 (88%) being in sinus rhythm, 3 (7.1%) in persistent/permanent atrial fibrillation and 2 having a pace-maker induced rhythm. A significant clinical improvement was also documented because all patients were in NYHA functional class I (88%) or II (11.9%) at follow-up, while before surgery, 22 patients (51.1%) were in NYHA class II or III (P < 0.0001).

**DISCUSSION**

The most important finding of this study is that a ‘rescue’ edge-to-edge can be a rapid and effective option to restore valve competence in patients with suboptimal result of ‘conventional’ mitral repair. The long-term durability of those ‘rescued’ MVs is very satisfactory and is not compromised by the ‘bailout’ EE procedure.

The immediate result of any mitral valve reconstruction depends on a large number of variables including the aetiology of MR, the complexity of the lesions, the quality of the preoperative echocardiographic diagnosis, the technique of repair and the surgical expertise.

The absence of residual MR immediately after the procedure is extremely important for the long-term durability of the repair [2–4]. Therefore, intraoperative water test and TEE after weaning from CPB are used to confirm the competence of the MV after surgical correction. The goal of the repair is to achieve both a perfect intraoperative ‘water testing’ and no or mild residual MR at the TEE examination (and no SAM).

The role of the water test in predicting the success of a mitral reconstruction is controversial. In some studies, a very good correlation between the result of this manoeuvre and the final outcome of the repair has been reported [10]. In others, significant residual MR has been detected by intraoperative TEE in patients with an apparently satisfactory saline testing [11, 12]. In our series, 15 patients with a satisfactory water testing had a residual regurgitation that was moderate or greater at the TEE examination, which emphasizes once more the fundamental role played by intraoperative TEE in the final assessment of the result of the repair [12–15]. In the literature, the rate and mechanisms of immediate MV repair failures are not clearly established because the patients are often unselected in terms of MR etiologies, and because there is no consensus on the criteria used to define a ‘suboptimal’ MV reconstruction. Despite those limitations, the incidence of immediate residual MR requiring further repair or replacement during the same operation has been reported to be 7.7–10% [2, 5, 11, 12, 16, 17]. In our institution, the rate of suboptimal result after mitral repair, requiring further surgical manoeuvres either immediately (after water testing and before unclamping the aorta) or after the TEE control (during a second pump run) was initially about 10%. Over the years, this rate has decreased to about 4%. Overall, we have been using the EE as a rescue procedure in about 30% of those cases. In the remaining patients, the initial suboptimal result was improved with other procedures including cleft closure, ring adjustment, repair of suture dehiscence and so on.

The most frequent causes of immediate MV repair failure are LVOT obstruction due to SAM, incomplete repair (residual prolapse, inadequate annuloplasty, clefts) and suture dehiscence [2].

In our patients, the most common reasons for the failure of initial conventional MV reconstruction were SAM and incomplete/suboptimal repair leading to residual prolapse.

Postoperative SAM was significantly more common in the early phase of the study period when surgical techniques aiming at decreasing more effectively the height of the posterior leaflet (sliding, folding, butterfly, posterior leaflet plication) were not extensively adopted.

**Table 5:** Predictors of recurrence of MR ≥2+ at follow-up

<table>
<thead>
<tr>
<th>Predictor</th>
<th>HR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.0</td>
<td>0.9–1</td>
<td>0.5</td>
</tr>
<tr>
<td>Preoperative LVEF</td>
<td>1.0</td>
<td>0.9–1</td>
<td>0.8</td>
</tr>
<tr>
<td>Anterior or bileaflet prolapse</td>
<td>2.1</td>
<td>0.3–15.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Commissural vs central rescue EE</td>
<td>0.9</td>
<td>0.8–1.1</td>
<td>0.8</td>
</tr>
<tr>
<td>MR at discharge</td>
<td>1.0</td>
<td>0.1–10.2</td>
<td>0.9</td>
</tr>
<tr>
<td>MV area post-EE</td>
<td>4.0</td>
<td>0.5–28.4</td>
<td>0.1</td>
</tr>
</tbody>
</table>

LVEF: left ventricular ejection fraction; EE: edge-to-edge.
Residual prolapse was usually the result of both misdiagnosis/interpretation of the mechanisms of MR and wrong surgical decision making. In the majority of cases, the prolapsing lesion was found in correspondence with one of the commissural regions or in a segment of the valve that was not supposed to be diseased according to the preoperative TEE and the initial intraoperative MV assessment. In some patients, a residual prolapse was still present at the level of the posterior leaflet resection. Occasionally, the mechanism responsible for residual MR was not clearly identified due to the combination of more than one factor. In 2 patients, for instance, a moderate residual prolapse was combined with a too large annuloplasty, which was contributing to the persistence of regurgitation. In another patient, the lack of coaptation was due to the post-endocarditis erosion of the free margins of the leaflets.

Owing to the heterogeneity of the patients included in this study, it is rather difficult to understand all the possible causes of those residual defects. However, failure to correct anterior mitral leaflet prolapse (due to preoperative/intraoperative misjudgement), insufficient leaflet resection, imperfect sizing of the ring and concomitant complex lesions (like hypoplasia of the posterior leaflet) have certainly played an important role in most cases.

In all those 43 patients, a ‘rescue’ edge-to-edge was added to the initial repair to improve the competence of the valve as previously described by Gatti et al. [5]. This technical solution was adopted whenever, in the opinion of the surgeon, a more conventional re-repair would have been unsuitable or too time consuming or at high risk of an unsatisfactory result. Indeed, the EE is not necessary when the mechanism responsible for persistent regurgitation is clearly identified and easy to correct (residual clefts, suture dehiscence). However, it can be extremely useful when the mechanism of residual MR is difficult to address (undefined diagnosis) or when its correction would require time-consuming conventional re-repair attempts (neochordae, further leaflet resection) with uncertain final results.

In our experience, the EE was able to immediately restore valve competence in all patients. The long-term durability of this approach was very satisfactory. During the follow-up period, only 1 patient developed severe MR (treated with mitral replacement) and 4 had moderate (2+ to 4+) MR, confirming a substantial stability of the repair. The presence of more complex mechanisms of MR (anterior and bileaflet prolapse), the site of the residual regurgitation, the degree of MR and the final MV area at discharge showed no correlation with the recurrence of MR ≥2+ at follow-up.

One of the main advantages of the rescue EE is that it can be carried out in a short period of time, as demonstrated by the duration of second CPB and aortic cross-clamping times in our series. This is particularly important in patients who had already had a long operation during the initial repair and in those with poor preoperative conditions or advanced LV dysfunction. In addition, the ‘functional’ rather than ‘anatomical’ approach provided by the EE allows the elimination of the residual regurgitant jet, regardless of the mechanism responsible for it. Of course, there are some potential drawbacks that have to be taken into consideration when performing this procedure. In particular, the risk of inducing mitral stenosis has to be kept in mind, particularly when the rescue EE is used to correct a previous resection. Under those circumstances, the EE suture should be as short as possible (few millimetres) and should probably be avoided in valves that already have a border-line residual area after the initial repair. Significant mitral stenosis was never detected in our patients either during the hospital stay or during the follow-up, as shown by the low transvalvular gradients recorded. Most of the patients had a residual MV area ≥2.5 cm². Lower values (between 2 and 2.4 cm²) were considered acceptable in 8 patients with a small BSA (≤1.6 m²). An exercise echocardiography to exclude functional mitral stenosis in those specific patients was not performed. However, at a median follow-up of 5.4 years, the low mean transmitral gradient registered, the absence of pulmonary hypertension and the lack of symptoms during exercise (NYHA class I) make the possibility of functional mitral stenosis rather unlikely. In addition, Agricola et al. have previously demonstrated that patients with a MV area between 2 and 2.5 cm² after double orifice EE repair combined with ring annuloplasty do not have any important degree of MV obstruction either at baseline or during physical exercise. Interestingly, the double orifice MVs with a smaller area at rest demonstrate a higher capacity to increase their baseline area during exercise compared with MVs with larger residual area [18].

In conclusion, the EE can be an effective and durable option to restore valve competence after a failed conventional repair. MVs initially repaired with a suboptimal result and then rescued with the adjunct of an edge-to-edge suture remain competent at long term.

LIMITATIONS

Data were retrospectively collected with all possible limitations related to this model of analysis. The number of patients is small, and the reported results have to be confirmed by a larger number of cases. Finally, the high heterogeneity of the study group might have been a source of biases and confounding factors.

Conflict of interest: none declared.

REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr F. Jatene (São Paulo, Brazil): Based on the guidelines of the European Society, I observed that the indication for surgery was done in your cohort at a relatively early phase of the mitral disease, 80% of the patients in functional class I and II, with a mean ejection fraction of 59%, with diastolic diameter less than 45, mean 34, on average, and with no or low pulmonary hypertension. The failure of mitral valve repair and the need for a valve replacement in those patients represents a clear undesirable occurrence. So the main point of discussion is that sometimes your echocardiographer will tell you that there is a 2+ regurgitant jet. Then you go back, you look at the valve, you try to understand what is going on. You can probably redress and re-repair the valve, but sometimes the mechanism is not clear or what you need to do is to redo it again, maybe you need a more extensive resection and so on. In those circumstances this was a very quick and effective solution.

Dr De Bonis: In patients with low ejection fraction, functional MR and so on, that is another story. Then you have to decide from the beginning to repair the valve or to replace it, but you cannot rely on a rescue edge-to-edge, I believe, to make the valve competent. You can do that, but I don’t trust the long-term results in that setting. The decision there is to replace the valve or to repair it with an undersized ring or even with an undersized ring plus edge-to-edge, but electively, not as a rescue procedure.

Dr Jatene: The second question is, do you believe that any one variable is more important than another in terms of predicting recurrent mitral regurgitation? For example, annuloplasty was performed in all patients, 42% with rigid rings and 58% with semi-rigid ones. Do you believe that the ring model is the most important? For example, annuloplasty was performed in all patients, 42% with rigid rings and 58% with semi-rigid ones. Do you believe that the ring model or another variable has some kind of influence on the late outcome?

Dr De Bonis: Well, again, as you have seen, the events in terms of recurrence of mitral regurgitation were really few in this series; just one patient had severe MR. Therefore we looked for predictors of MR 2+ or greater. And I don’t believe the ring really plays a major role. We had been using a semi-rigid complete ring in the past, then switched to a posterior flexible band. I don’t think that really changed the results in our practice. So to answer your question, no, I don’t believe there is one variable which might play a more important role, particularly in terms of type of ring.

Dr P. Ortu (Cagliari, Italy): My question is, what is the percentage of a second pump run in your population? This is to understand whether you are suggesting this technique at the outset, as a first attempt, do you suggest solving the problem in a conventional way if it is possible?

Dr De Bonis: At the very beginning of our experience, the rate of suboptimal results was about 10%, either during water testing or at the transesophageal echocardiography. Now it is down to about 4%. Two-thirds of these cases are rescued, I would say, or optimized with a conventional technique, and between a quarter to one-third with a rescue edge-to-edge.