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The double-orifice technique for mitral valve reconstruction: predictors of postoperative outcome ☆

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Abstract

Objective: The 'double-orifice' (DO) technique has been recently proposed as an additional option in mitral valve repair (MVR). However, little is known regarding the long-term postoperative outcome and the predictors of DO results. Therefore, the aim of this study was to evaluate our clinical series and to identify prognostic factors of DO repair. **Methods**: From 1992, 75 patients underwent DO procedure because of severe mitral regurgitation. The study population consisted of 48 male and 27 female patients with a mean age of 58 ± 13 years (range 16–80 years). The aetiology of mitral incompetence was Barlow disease in 30 cases, rheumatic disease in 18 cases, acute or healed endocarditis in 16 cases and other causes in 11 cases. Carpentier rigid ring was used in 38 patients, whereas autologous pericardium was used in 24 patients. Thirteen patients had no annuloplasty procedure. Statistical analysis included univariate and multivariate Cox proportional models to evaluate the predictors of the DO failure. **Results**: There were four hospital and three late deaths with a survival rate of 92% at 8 years. Mean follow-up was 42 ± 24 months (range 1–93 months). Twelve patients underwent reoperation (five cases of early failure) and had valve replacement, leading to 80% freedom from reoperation at 8 years. At follow-up, 13 patients had no mitral regurgitation, 36 patients had trivial or mild mitral incompetence, whereas eight patients had moderate or severe mitral insufficiency at transthoracic echocardiography. Preoperative low left ventricular ejection faction, pulmonary arterial hypertension and marked left atrial enlargement were predictors ($P < 0.05$) of DO failure at univariate analysis. Pericardial annuloplasty was also a risk factor ($P < 0.05$) for unsuccessful DO repair at long term. Cox proportional multivariate analysis confirmed left atrial dilatation, pulmonary hypertension and pericardial annuloplasty as independent predictors of unfavourable postoperative results. **Conclusions**: This study suggests that preoperative factors, like pulmonary hypertension and severe left atrial dilatation, may predict late DO failure. Our findings also indicate that pericardial annuloplasty may negatively influence mitral valve reconstruction at long term when DO is employed in MVR.

Keywords: Mitral valve repair; Double-orifice mitral valve; Mitral valve repair outcome; Mitral insufficiency

1. Introduction

Mitral valve repair (MVR) is undoubtedly superior to valve replacement to correct mitral valve insufficiency either in terms of patient survival or left ventricular (LV) function at long term [1]. Valve reconstruction, however, may be problematic in peculiar anatomical settings of mitral incompetence with suboptimal early and late functional results. Postoperative unfavourable outcome may be related to demanding, time-consuming and scarcely reproducible surgical procedures, particularly when the anterior leaflet is involved [2–5]. To address these potential drawbacks in the MVR, the 'double-orifice' (DO) technique has been recently proposed as an adjunctive option in MVR and represents a simplified procedure to correct mitral valve insufficiency mainly when anterior leaflet defects are encountered [6]. The apposition of the failing mitral leaflet portion to the opposing edge represents the basic concept of such a technique, which usually leads to fixed central leaflet coaptation and to the creation of a DO valve. The intuitive ease and reproducibility of this procedure has favoured its expanded employment, not only in common pathological conditions, but also in many complex valve lesions with promising results [7–12]. Despite its current applicability in a wide spectrum of mitral valve lesions, some concerns have been raised regarding the DO

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valve function and durability at long term. Indeed, long-term outcome is still poorly defined and no detailed information is available concerning the DO valve dynamics or whether specific preoperative factors may adversely affect such a reconstructive technique. The purpose of this study was to review our clinical experience with DO repair. Analysis of clinical data was carried out to identify potential predictors of postoperative outcome in an attempt to provide some insight on appropriate patient selection and surgical strategy, hoping to shed some light on actual expectations for this peculiar MVR.

2. Methods

Between October 1992 and February 2000, 75 patients with severe mitral regurgitation underwent DO procedure at our institution. Preoperative patient profile is presented in Table 1.

Mechanisms of mitral incompetence consisted of defects involving the anterior leaflet in 39 patients (54%), the posterior leaflet in 16 patients (19%) and both leaflets in 20 patients (27%), frequently with complex patterns of valvular regurgitation and difficult anatomical features associated (extensive annular calcification, leaflet erosion and so forth).

2.1. Surgical technique

All patients underwent the DO approach according to the technique previously described [6]. Modification of the original technique along the study course consisted of the application of a short 5-0 prolene running suture at the apposition point to create the DO instead of single or double 5-0 prolene mattress stitches, reinforced with autologous pericardial patches in case of thin mitral leaflets or frank fibroelastic deficiency. In the presence of Barlow disease, ample approximation of the prolapsing portion of the mitral leaflets was often required, sometimes leading to complete fusion of the central posterior scallop to the opposing leaflet edge. Annular remodelling was initially not considered a standard part of the reconstructive technique in this clinical series. Indeed, if marked annular dilatation was not present or if the postrepair hydraulic test to assess valve competence was completely satisfactory, annular support was generally not included in the initial phase of this clinical series. Due to worldwide [2,3] and personal evidences [6] showing that annular fixation could have favoured long-term results after MVR, annular support was subsequently always performed, unless severe annular calcification or small mitral annuli were encountered.

Prosthetic rigid ring (Carpentier classic ring, Edwards Lifescience, Englewood, CO, USA) was used in 38 patients (ring no. 36 in eight patients, no. 34 in 18 and no. 32 in 12 patients, respectively), whereas glutaraldehyde pretreated autologous pericardium was used in 24 patients as posterior support of the mural leaflet. Thirteen patients had no annuloplasty procedure. Associated surgery is summarized in Table 2. Three patients were operated on urgent basis.

2.2. Echocardiographic assessment and follow-up

Preoperative echocardiographic patient data are shown in Table 3. The majority of patients received preoperative and intraoperative transoesophageal echocardiography to precisely define the mechanism of mitral incompetence and to evaluate the surgical result, respectively. Transthoracic echocardiography was carried out prior to hospital discharge to confirm the effects of MVR. During follow-up, transthoracic echocardiography was performed at constant interval postoperatively (every 6 months during the first year and yearly thereafter). In case of reintervention performed at other institutions, details regarding the cause of reoperation were obtained directly from the patient with

Table 1
Patient profile[a]

Number of patients	75
Gender	
Male	48 (64%)
Female	27 (36%)
Age (years)	58 ± 13 (range 16–79)
NYHA class	
I–II	32 (42%)
III–IV	43 (58%)
Cardiac rhythm	
Sinus rhythm	52 (69%)
Atrial fibrillation	23 (31%)
Aetiology	
Degenerative	
Barlow disease	30 (40%)
Fibro-elastic deficiency	7 (9%)
Rheumatic	18 (24%)
Bacterial endocarditis	
Acute	7 (9%)
Healed	9 (12%)
Ischaemic	2 (3%)
Congenital	2 (3%)
Mechanism of regurgitation	
Anterior leaflet prolapse	39 (52%)
Bileaflet prolapse	20 (26%)
Posterior leaflet prolapse	16 (22%)

[a] NYHA, New York Heart Association.

Table 2
Associated surgical procedures[a]

Procedures	Patients
PQR	5 (6%)
Paracommissural E–E	5 (6%)
Paracommissural Kay	3 (4%)
Annuloplasty	62 (82%)
Carpentier classic ring	38 (61%)
Autologous pericardium	24 (39%)
AVR	10 (13%)
CABG	7 (9%)

[a] PQR, posterior quadrangular resection; E-E, edge-to-edge repair; AVR, aortic valve replacement; CABG, coronary artery bypass grafting.

Table 3
Postoperative mortality after DO repair[a]

Causes	Patients
Early	
LCOS	2
Sepsis	1
Acute cardiac tamponade (aortic rupture)	1
Late	
Sudden death	1
Ascending aortic aneurysm rupture	1
Chronic heart failure	1

[a] LCOS, low cardiac output syndrome.

telephone interview and from the operating reports. Any event that led to death within 30 min from the beginning of acute symptoms was considered as sudden death.

2.3. Statistical analysis

Values are presented as mean ± standard deviation. Statistical analysis included univariate and multivariate Cox proportional models to evaluate predictors of the DO failure. Variables included in univariate and multivariate analysis were gender, age, marked (>50 mm) left atrial dilation, LV dysfunction (EF < 50%), pulmonary hypertension, aetiology of mitral insufficiency (MI), associated mitral valve posterior quadrangular resection, annuloplasty type, annuloplasty absence, bileaflet pathology, timing of intervention, surgeon, presence of associated surgery, presence of coronary artery disease and preoperative cardiac rhythm. These variables were confronted in terms of risk factors for reoperation. *P* values less than 0.05 were considered significant.

3. Results

Operative data confirmed the expeditious application of the DO technique (mean aortic cross-clamp time of 55 ± 20 min and mean extracorporeal circulation time of 82 ± 30 min), particularly in patients submitted to DO repair alone (aortic cross-clamp time of 48 ± 18 min and extracorporeal circulation time of 70 ± 22 min, respectively). Perioperative complications consisted of transient low cardiac output syndrome in six patients (requiring only inotropes), stroke in one patient (septic emboli in acute endocarditis), pericardial tamponade in one patient, revision for haemorrhage in one patient and pacemaker implantation in two patients. Late complications included stroke in one patient (cerebral haemorrhage on anticoagulant therapy), pacemaker implantation in one patient and congestive heart failure in one patient. All patients in atrial fibrillation had permanent anticoagulation therapy after surgery, whereas patients submitted to MVR with prosthetic ring received anticoagulation for 3 months postoperatively if sinus rhythm was present. No late thromboembolic events were observed in this series.

There were four hospital and three late deaths, leading to a survival rate of 92% at 8 years (Fig. 1). The causes of postoperative mortality are summarized in Table 4. Follow-up was 100% complete and the mean follow-up was 42 ± 24 months (range 1–93 months). Twelve patients underwent reoperation (five cases of early failure) and had valve replacement, leading to a freedom from reoperation of 80% at 8 years (Fig. 2). Causes of reintervention and mechanisms related to reoccurrence of mitral incompetence are listed in Table 4. Recurrence of MI occurred for variable factors.

3.1. Early DO failures

The cases of early MVR dysfunction occurred in one case for inappropriate DO indication (extensive mitral valve abnormality secondary to rheumatic disease), whereas technical pitfall (incomplete approximation of the prolapsing leaflets) determined the recurrence of MI in one patient. In two cases, acute endocarditis induced complete or partial rupture of the central stitches. In one patient, acute myocardial ischaemia related to a small and ungraftable coronary vessel during the original surgical procedure deteriorated the tethering effect on the posterior leaflet and leaflet malapposition at different levels.

3.2. Late DO failures

In Barlow disease, there were a few cases of recurrent valve regurgitation mainly at the paracommissural level (lateral or central ones), due to leaflet malapposition or partial prolapse. The lack of the paracommissural obliteration at the time of surgery was the probable cause of recurrent MI in two cases. Pericardial ring dehiscence and limited central fusion of the valve leaflets induced massive mitral incompetence and haemolysis. Chordal rupture occurred only in cases related to the endocarditis process (acute in

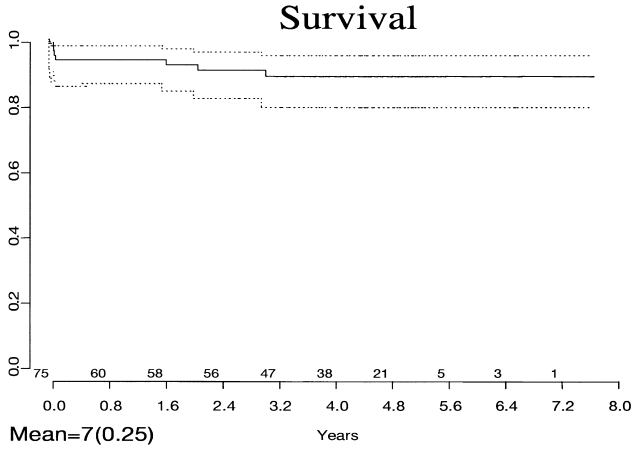

Fig. 1. Actuarial survival after DO repair. The numbers at the bottom indicate, at each timing, the number of patients at risk.

Table 4
Causes of reoperation[a]

Timing of reoperation	Patients	Aetiology at reoperation	Mechanism	Primary aetiology	Original surgery	Ring type
Early	5					
7 days	1	Bacterial endocarditis	Central stitch rupture	Bacterial endocarditis	DO + E-E	P
11 days	1	Bacterial endocarditis	Massive haemolysis	Bacterial endocarditis	DO	C 32
17 days	1	–	Massive haemolysis	Barlow	DO + CABG	C 30
21 days	1	–	MI from antero-lateral orifice	Rheumatic	DO + AVR + TVR	P
25 days	1	Ischaemic	MI with multiple jets and periprosthetic leak	Rheumatic	DO + CABG	C 30
Late	7					
2 months	1	–	MI from leaflet malapposition and haemolysis	Barlow	DO + E-E	–
6 months	1	–	Pericardial ring detachment	Barlow	DO	P
9 months	1	–	MI from both orifices	Healed bacterial endocarditis	DO	P
3 years	1	–	Paracommissural leak	Barlow	DO	C 36
3 years	1	Bacterial endocarditis	Chordal rupture	Rheumatic	DO + PQR	C 36
4 years	1	Bacterial endocarditis	Chordal rupture	Ischaemic	DO + CABG	C 32
4 years	1	–	Chordal rupture	Bacterial endocarditis	DO	P

[a] MI, mitral insufficiency; DO, double-orifice; E–E, edge-to-edge repair; P, pericardial ring; C, Carpentier rigid ring; PQR, posterior quadrangular resection; TVR, tricuspid valve repair.

two cases and chronic in one, respectively). However, preoperative aetiology did not prove to be significantly correlated with postoperative repair prognosis.

In terms of predicting postoperative reoperation after DO repair, univariate analysis showed that left atrial dilatation, pulmonary hypertension and LV dysfunction were potential indicators of postoperative DO failure (Table 5). The use of autologous pericardium also represented a negative determinant of repair durability. The application of Cox models showed that preoperative pulmonary arterial hypertension, marked left atrial enlargement and pericardial annuloplasty were independent risk factors for the failure of DO repair at long term (Table 5).

In terms of repaired valve function, at the time of follow-up, 13 patients had no mitral regurgitation, 36 patients had trivial or mild mitral incompetence, whereas eight patients had moderate or severe MI (four moderate and three severe, respectively) at resting transthoracic echocardiography. Unexpectedly, patients who had MVR and DO procedure without annular remodelling showed excellent valve function with no trace or trivial residual mitral incompetence. Satisfactory long-term findings were also observed in patients with DO repair and prosthetic annular support. In contrast, some patients who received biological support for annular fixation had suboptimal postoperative result with haemodynamically significant recurrence of MI (Fig. 3), a situation confirmed by the higher rate of reintervention in this patient subgroup.

Postoperative echocardiographic evaluation also showed significant reduction in the left atrial dimension and left ventricular end-systolic volume (LSESV). A decrease in the left ventricular ejection fraction (LVEF) was also documented (Table 6), although global LV contractile performance was still within normal ranges. At resting conditions, transthoracic echocardiographic assessment did not show significant mitral stenosis, whereas moderate pulmonary hypertension was detected in 29 patients.

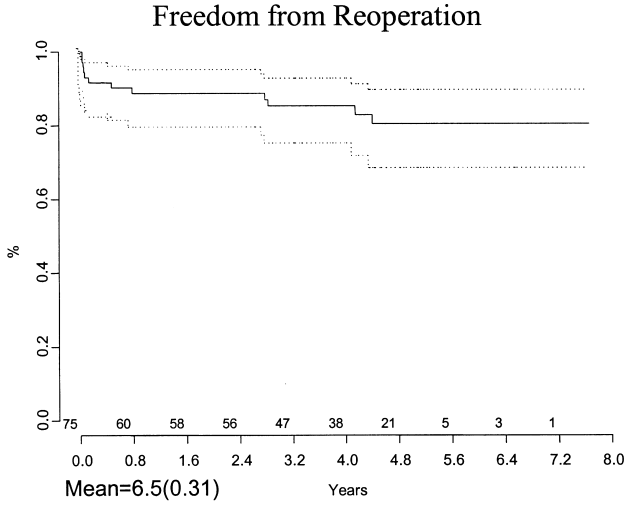

Fig. 2. Freedom from reoperation after DO repair is shown. The numbers at the bottom indicate, at each timing, the number of patients at risk.

Table 5
Statistical analysis for predictors of reoperation after DO repair[a]

Variables	Univariate	Multivariate		
	P	*P*	Odds ratio	95% CI
Pericardial annuloplasty	0.005	0.009	4.94	1.48–16.41
Left atrial dilatation	0.02	0.04	4.30	1.05–17.5
Pulmonary hypertension	0.01	0.03	3.74	1.12–12.4
LV dysfunction	0.04	0.1	0.21	0.04–1.9

[a] CI, confidence interval.

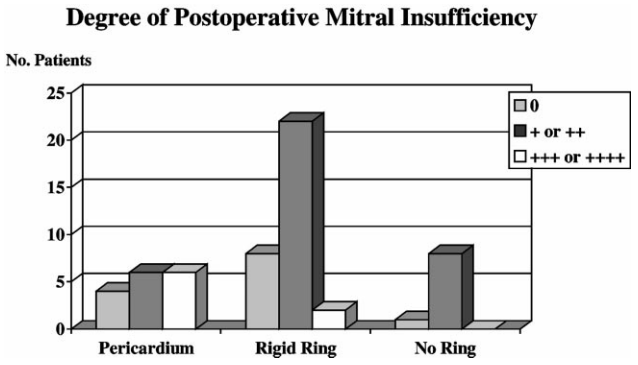

Fig. 3. Degree of MI at follow-up as measured by transthoracic echocardiography at rest according to the presence and type of annuloplasty. Excellent valve function was observed in patients who underwent DO repair without annular remodelling, whereas less favourable results were related to biological annular support.

4. Discussion

MVR is unanimously recognized as the gold standard for treating mitral valve insufficiency. Nonetheless, addressing the mechanisms of valve incompetence implies marked variability in terms of surgical approach and postoperative outcome. Mitral incompetence due to posterior leaflet defects is widely considered the most favourable valve dysfunction to be corrected [2,3,13]. In contrast, involvement of the anterior leaflet, alone or in combination with the mural leaflet, is frequently associated with demanding reconstruction, less effective restoration of mitral valve function and less favourable long-term durability of MVR [2–5]. Physiological and anatomical constraints exert marked limitations to surgical reconstruction when directed to anterior leaflet defects, often requiring a great deal of dexterity and experience to correct usually complex valvular lesions with consequent poor technical reproducibility. These premises prompted some surgeons to look for simplified technical manoeuvres to be used routinely or in specific subsets of mitral valve incompetence. In this light, the DO repair was introduced by Alfieri at our institution in 1992, particularly to address the MI secondary to anterior leaflet dysfunction [6,7,10–12]. The creation of a DO valve was designed to appose the involved leaflet segment (either prolapsing, flailing or injured leaflet portion) to the opposing leaflet edge [6]. This artificially induced and fixed leaflet apposition, besides creating a DO valve, invariably leads to reduced excursion of the sutured leaflets and reduced mitral valve area. The DO procedure was originally designed to simplify the MVR specifically in the presence of anterior leaflet abnormalities. This target was undoubtedly reached by the DO procedure, as shown by our operative data, having provided an expeditious, easy and largely reproducible technique for MVR also when difficult patterns of MI are encountered. Repair durability, however, remains another important aspect of DO repair to be conclusively determined. Early failure after DO repair was observed in our experience. The learning curve, either in terms of procedural technique or in terms of patient selection, may have accounted for less favourable results in the initial phase. Recent modifications of the DO technique (deeper bites, suture reinforcement with pericardial pledgets, particularly in the presence of acute endocarditis, wide 'fusion line' on the prolapsing portion and more frequent adjunct of commissural obliteration also in the presence of minimal leak, particularly in Barlow disease) reduced the rate of perioperative failure. Patient selection may be responsible for an additional quote of early or late failures. Rheumatic-related valve anomalies have been suggested to represent a risk factor for late MVR dysfunction, whereas myxomatous valve degeneration has been shown to favour long-term durability of the DO repair [12]. However, the limited number of patients included in this study, either globally or evaluated at late follow-up, could not corroborate this hypothesis. Recurrence or onset of acute bacterial endocarditis was relatively frequent in our study population either at short or long term. The increase in resistance or alteration of blood flow represents well-established predisposing factors to bacterial colonization of the leaflet endocardium. Furthermore, due to increased tension on the newly formed central commissures, the valve tissue, previously weakened by the infective process, may be prone to late rupture. In this setting, a more stable MVR (i.e. deeper and pledget-supported valvular bites and complete prosthetic ring) may prevent late valve dysfunction. However, by multivariate analysis, we could not show any conclusive correlation between the aetiology of MI and failure of DO repair, although this potential relationship warrants further investigations.

Table 6
Transthoracic echocardiographic data at rest[a]

Parameter	Preoperative	Postoperative	*P*
LAD	54 ± 10	43 ± 12	< 0.001
LVEDD	65 ± 13	54 ± 7	< 0.001
LVESD	40 ± 9	37 ± 8	NS
LVEF	61 ± 10	55 ± 13	0.02

[a] LAD, left atrial diameter; LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; LVESV, left ventricular end-systolic volume; LVEF, left ventricular ejection fraction.

Preoperative factors, namely atrial dilatation and pulmonary hypertension, were related to unfavourable functional results of the MVR in our study. Although these factors are not at first glance ascribable to postoperative results, they may be directly linked to weakness of valve components because of long-lasting mitral valve disease. This condition might predispose to suboptimal tissue response to modified haemodynamic and mechanical stresses induced by the reconstructed and modified valve configuration, and, hence, favour MVR dysfunction.

Preoperative LV impairment, usually associated with the LV chamber dilation, did not represent, in our study, an independent predictor of postoperative DO failure. The

use of the DO repair to specifically correct mitral incompetence due to dilated left ventricle has been recently reported [9,13], and some cases of early failure have been observed [9], but no specific factors have been associated to repair dysfunction, also due to the limited clinical series. Long-term results on the application of such MVR technique in severely impaired and dilated ventricles are lacking, and the effects of the DO repair in this setting deserve further investigation.

Annular remodelling is currently highly recommended during MVR [2,3,6], although several investigators still consider annular support questionable or useless for effective long-term results to be achieved [14]. Gillinov et al. [2] showed that repair of the anterior leaflet defects has higher failure rate at long term if annuloplasty is not performed. Cohn et al. [3] also indicated annular remodelling as a crucial determinant of MVR durability. Our data suggest that the performance and the type of annular fixation may also play a role in the DO repair although with contradictory findings. Because of the peculiar valve configuration and complex pathophysiology related to an artificially induced DO valve, the impact of and type of annuloplasty in such a repair setting can be more complicated to elucidate as compared to conventional MVR. In our study, pericardial annuloplasty, unlike the beneficial effects demonstrated in case of posterior leaflet correction [15], appeared to negatively affect the DO repair at long term. The presence of biological ring, although effective in terms of mitral dynamism enhancement, might provide a less reliable tool for repair stabilization at long term in the presence of a DO valve configuration if annular dilatation is originally encountered. In contrast, the long-term results in the patient subgroup of the DO repair where no annular remodelling was performed were excellent. Umana et al. [16] showed that the DO repair without annular remodelling acutely preserves annular dynamics in a sheep model of the MI and, therefore, enhances MVR efficacy and related LV function. These experimental findings were confirmed by the same author also in a limited clinical series where patients with ischaemic MI received a DO repair without annular fixation [8]. Nonetheless, the authors endorsed the use of annular remodelling particularly because of the worse MVR durability if no annuloplasty is performed. Our data suggest that in peculiar patient subgroup (without annular dilatation) the DO repair without annuloplasty may provide satisfactory long-term results. Conversely, in case of annular dilatation, DO repair would be in jeopardy if an annular fixation is not performed or carried out with pliable material. In this case, excessive tension on the central stitch and on the surrounding valvular tissue might be exerted during the diastolic phase, playing a potential complementary role, together with the inherent valve pathology, to the recurrence of the MI. A flexible prosthetic ring, if annular remodelling is necessary, would provide a better DO valve stabilization by reducing more efficiently the inevitable tethering effect on the newly formed commissures situated laterally to the central stitch, and would partially maintain the physiological annular dynamics.

However, randomized studies comparing the DO repair with and without annular remodelling would be advisable and extremely helpful for a more appropriate patient selection and surgical management.

4.1. Study limitation

This study population represents the global experience of DO repair at a single institution. Patients were not randomly assigned to any specific subgroups (like for annular remodelling or for the type of annular support); therefore, selection bias should be taken into account for the interpretation of late functional results. Because of the novel application of DO repair at our institution, factors associated with the learning curve may have influenced the initial experience, although statistical analysis did not show any correlation between the postoperative results and the timing of operation. Reoperation after the DO procedure was defined as the indicator of repair durability. Recurrence of MI was not considered as repair failure for statistical analysis. Eventually, the limited number of enrolled patients might have influenced the power of any statistical analysis and data interpretation.

In conclusion, the DO repair was shown to provide safe, effective and durable mitral valve reconstruction at long term in selected patients with complex lesions of the mitral valve. Although anatomical or haemodynamic factors appeared to predispose to late failure of the DO approach, larger clinical series will be needed to shed some light in this respect. Operative technique and procedural details certainly play a critical role in DO repair durability, but these aspects still remain controversial. Annular remodelling, an essential component of conventional MVR, was shown to be not essential in some patients, particularly in the absence of annular dilatation. Therefore, additional investigations in this respect are also warranted. However, if annular support is planned, a prosthetic ring seems to be advisable since biological material proved to be poorly durable at long term. Furthermore, additional studies are mandatory to improve our understanding of novel functional and anatomical dynamics secondary to the new valve configuration, particularly during exercise conditions, to additionally enhance surgical strategy.

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Appendix A. Conference discussion

Dr O. Alfieri (*Milan, Italy*): I noticed that you have a rather high reoperation rate. This is in contrast with our experience and it is probably due to the wrong selection of the patients. Many patients with rheumatic disease are not candidates for any kind of repair.

My other observation is on the statistical analysis. I have a lot of respect for complex statistical analysis, but I need all my imagination to understand how pulmonary hypertension can determine a failure of the double orifice repair. How do you interpret this finding which is apparently a nonsense?

Dr Lorusso: I don't think it is a nonsense, because there was a perfect linear correlation between the left atrial dilatation and pulmonary hypertension. So this means that two factors were consistently associated with the outcome, and this can explain partially. I mean, of course we have to speculate, but I believe that these factors confirm that when you have a long-lasting mitral valve disease with a very enlarged left atrium and enlarged annulus, then probably you have even leaflets which are thin like in fibroelastic deficiency. So you have a mitral valve which has been affected by a long time. This tissue probably, I say probably, can be suboptimal for the double orifice repair; and we all know that putting the stitch in the center part of the valve, if you have very thin leaflets, can be troublesome, and that is the reason why we think that this makes sense, because left atrial dilatation and pulmonary hypertension were strictly correlated. So there was a linear correlation between the two, not with the left ventricular dysfunction.

So it was not due to left ventricular dysfunction and atrial dilatation but probably to a long-lasting disease, and this can affect the valve, and we know the durability of the repair is certainly related in this procedure to the consistency of the tissue, to the thickness of the tissue. I think this makes sense.