Endoaortic Clamping Does Not Increase the Risk of Stroke in Minimal Access Mitral Valve Surgery: A Multicenter Experience

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Background. Some controversy exists regarding the safety of endoaortic balloon clamping in minimal access isolated mitral valve surgery (MIMVS). The aim of this European multicenter study was to analyze the results in 10 experienced centers and compare the outcomes with published data.

Methods. The most recent 50 consecutive MIMVS cases from 10 European surgeons who had performed at least 100 procedures were prospectively collected and retrospectively analyzed. All procedures were performed through right minithoracotomy with femoral cannulation and endoaortic balloon occlusion. In-hospital and 30-day outcomes were studied. Mortality and stroke rates were compared with published median sternotomy and MIMVS outcomes.

Results. Mean age was 63.2 ± 12.5 years, 289 (57.8%) were male, mean logistic European system for cardiac operative risk evaluation was 6.1 ± 6.2, and 53 (10.6%) procedures had cardiac reoperations. Concomitant procedures were performed in 126 (25.9%) cases. Three patients (0.6%) required conversion to full sternotomy. Ten patients (2.0%) necessitated endoaortic balloon clamping conversion (8 to external clamping), and re-exploration for bleeding was necessary in 24 (4.8%) cases. Mean aortic cross-clamp and cardiopulmonary bypass times were 85.6 ± 30.1 and 129.5 ± 40.2 min, respectively, and were significantly longer for concomitant procedures ($p < 0.001$). There were no aortic dissections and no deep venous thromboses. Operative mortality (none neurologic) and major stroke occurred in 7 (1.4%) and 4 (0.8%) patients, respectively. These rates compared favorably with the published literature on isolated primary mitral valve surgery (MVS) through sternotomy or minithoracotomy (mortality rates 0.2% to 11.6%, stroke rates 0.6% to 4.4%).

Conclusions. Once procedural proficiency is acquired, endoaortic balloon clamping in MIMVS is a safe and effective technique. Despite the fact that this patient cohort also includes combined and redo procedures, the observed mortality and stroke rate compared favorably with the existing literature on primary isolated mitral valve surgery irrespective of the approach.

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D espite excellent operative results in mitral valve surgery using standard sternotomy [1], a gradual interest has emerged to limit the invasiveness of the procedure. As such, minimally invasive mitral valve surgery (MIMVS) was developed in the late 1990s [2].

Since then, several methods have been used to clamp the ascending aorta. Of these, the endoaortic balloon and external aortic clamp are the most frequently used techniques.

Recently, some concerns were raised about inferior outcomes related to the use of the endoaortic balloon in MIMVS [3]. This information was not confirmed by prospective studies but a concern about MIMVS was also raised in a consensus paper by the International Society for Minimally Invasive Cardiac Surgery (ISMICS) where an increased stroke rate was noted [4].

The aim of the current retrospective study was to analyze the perioperative safety and outcomes associated with the use of an endoaortic balloon. In addition, we investigated

the stroke rate associated with MIMVS across Europe, and compared these outcomes with the existing literature.

Material and Methods

Study Population

Ten centers across Europe which perform MIMVS using the endoaortic balloon (Edwards Lifesciences, Irvine, CA) and which were beyond the learning curve (defined as an experience >50 cases) but had performed greater than 100 cases in total (Table 1) were asked to contribute their last 50 consecutive cases (excluding their first 50 cases) to a database to produce a total study population of n = 500. The main reasons for preferring the endoaortic balloon technique were absence of an extra port and direct endoaortic cardioplegia administration, avoiding an extra purse-string suture on the ascending aorta. All data were extracted retrospectively from the various institutional databases. The MIMVS was defined as any mitral repair or replacement; concomitant atrial fibrillation surgery and or tricuspid valve surgery were also included. Reoperative cardiac procedures were not excluded. Patients who had an inadequate iliac access for endoballoon insertion or retrograde arterial perfusion were excluded. Other reasons for exclusion were the following: aortic regurgitation greater than grade 2; an ascending aortic diameter greater than 40 mm; previous right lobectomy; extensive pleural adhesions (discovered perioperatively); and previous aorto-bifemoral or bi-iliac grafting. Usually emergency procedures are excluded although some centers do not take this as an exclusion criterion. Each individual center obtained ethical committee approval for this study but due to the retrospective and anonymous nature of the study, individual patient consent was waived in all centers.

Operative Technique

All patients were operated through a right minithoracotomy with peripheral venous and arterial cannulation, and endoaortic balloon occlusion (EndoClamp or Intra-Clude; Edwards Lifesciences, Irvine, CA). Five centers systematically use double (jugular and femoral) venous cannulation, whereas the others use single venous femoral cannulation in isolated mitral valve surgery and double venous cannulation if tricuspid valve surgery is associated. The operative approach for MIMVS performed through a minithoracotomy has been previously described [5]. All centers use intraoperative trans-esophageal echocardiography monitoring. Figure 1 demonstrates the operative setup. Cardiac arrest was obtained using intermittent cold antegrade crystalloid or blood cardioplegia (50.0% vs 49.8%, respectively). Retrograde cardioplegia was not used. The nature of the cardioplegic solution or time intervals of reinfusion was administered according to individual institutional protocols. Both caval veins were occluded if the right atrium was opened.

Six centers performed atrial fibrillation ablation surgery; 4 using cryoablation and 2 using monopolar radiofrequency energy. The lesion set was a full left-sided Cox-Maze lesion set; box lesion with extension to the base of the left atrial appendage and a left isthmus lesion. Two centers closed the left atrial appendage internally in case of ablation.

Data Collection

Using similar templates, demographic data and preoperative assessment were recorded and reviewed for any significant discrepancy. Major clinical outcome measures included cardiopulmonary bypass time (CPB), cross-clamp time, type of surgery, and perioperative events such as full sternotomy conversion. Mortality and major complications (in-hospital and up to 30 days) such as stroke (modified Rankin Scale) [6], reoperation for bleeding, respiratory failure, or severe infection were collected. Echocardiographic data were recorded before, and up to, 30 days after surgery. Definitions of these complications were clear and accepted by all centers, primarily based on The Society of Thoracic Surgeons

Table 1. Centers' Experience With Minimally Invasive Mitral Valve Surgery Prior to Case Inclusion in the Present Study

Center	Institutional Endoballoon Experience Prior to the Study	Institutional % of MIMVS
1	2338	91
2	51	70
3	450	99
4	450	99
5	870	12
6	360	80
7	136	85
8	345	85
9	1000	99
10	529	94

MIMVS = minimally invasive mitral valve surgery (vs total cases of isolated mitral valve surgery in the department).
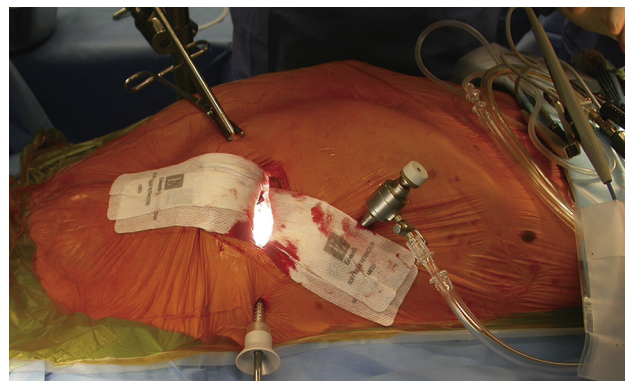

Fig 1. View of the operative setup for minimally invasive mitral valve surgery. Note the working port, the left atrial retractor shaft (top), venting position (right from the working port), and endoscope (under the working port).

score definition. The definition of all outcome variables is available in the Appendix.

Statistical Analysis

Quantitative continuous variables are described with means $\pm$ standard deviation and quantitative discrete variables with absolutes and relatives frequencies. Inference statistics comparing continuous variables are made using the Student t test and the Wilcoxon rank sum test as appropriate. To compare discrete variables, the Pearson χ^2 test was applied. Two-sided tests were utilized and a type I error significance level of 0.05 was considered. Early events ($\leq$ 30 days post-implantation) were calculated as simple percentages (number of complications divided by number of patients). All analyses were performed with the use of R software, version 2.13.1 [7].

Results

All participating centers had experience with MIMVS using the endoballoon technique prior to starting this study. The respective centers' experience is summarized in Table 1.

Study Population

A total of 500 patients equally distributed among the participating centers were included. Baseline patient demographic characteristics are summarized in Table 2. Previous cardiac surgery was reported in 53 patients (10.6%) and consisted of mitral valve surgery in 33 patients (6.6%), coronary artery bypass grafting (CABG) in 18 cases (3.6%), and aortic valve surgery in 13 cases (2.6%). A combined procedure was performed in 126 patients.

Surgical Procedure

Perioperative details are presented in Tables 3 and 4. Concomitant procedures (atrial fibrillation surgery or tricuspid valve) were performed in 126 patients (140 procedures) (25.4%). The IntraClude device was used in 70.2% of cases. The CPB and cross-clamp times were prolonged in this group versus patients without concomitant procedures; CPB time 153.8 $\pm$ 43.7 versus 120.8 $\pm$ 34.8 min ($p < 0.001$), and cross-clamp time 98.1 $\pm$

Table 2. Baseline Characteristics

Characteristic	MIMVS (500 Patients)
Age (years, mean $\pm$ SD)	63.2 $\pm$ 12.5
Male sex (%)	289 (57.8%)
Body mass index (kg/m^2, mean $\pm$ SD)	25.9 $\pm$ 4.3
Preoperative atrial fibrillation	32.4%
Logistic EuroSCORE 1 (mean $\pm$ SD)	6.1% $\pm$ 6.2%
Previous cardiac operation	10.6%
NYHA $\geq$ III or IV	263/499 (52.7%)

EuroSCORE = European system for cardiac operative risk evaluation; MIMVS = minimally invasive mitral valve surgery; NYHA = New York Heart Association functional class.

Table 3. Surgical Procedure

Surgical Procedure	MIMVS (500 Patients)
Replacement	131 (26.2%)
Bioprosthesis	32/131 (24.4%)
Mechanical	99/131 (75.6%)
Repair	369 (73.8%)
Commissurotomy	10/369 (2.7%)
Ring annuloplasty	363/369 (98.4%)
Chordae surgery	20/369 (5.4%)
Concomitant procedures	
Tricuspid valve surgery	70/500 (14.0%)
Atrial fibrillation ablation	70/500 (14.0%)
Antegrade cardioplegia	
Blood	249/500 (49.8%)
Crystalloid	250/500 (50.0%)

MIMVS = minimally invasive mitral valve surgery.

32.7 versus 81.1 $\pm$ 27.6 min ($p < 0.001$). Clamping conversion was observed in 2.0% (10 patients; 8 patients required a direct aortic clamping and 2 patients were further operated on fibrillating heart) (Table 4). Surgical conversion to full sternotomy was reported in 3 patients (0.6%): 1 patient underwent a mitral valve repair with unsatisfactory result and underwent a conversion to sternotomy for valve replacement; another patient underwent also an unsatisfactory mitral valve repair followed by valve replacement during the same clamping time but with ischemia during CPB weaning. This patient underwent a conversion to sternotomy for additional CABG. This patient ultimately died of severe multiple organ failure postoperatively. The reason for the third conversion was unclear from the retrospective analysis.

Clinical Outcomes

Thirty-day or in-hospital outcomes are summarized in Table 5. The observed mortality rate was 1.4% (n = 7). No aortic dissection occurred and the incidence of postoperative hemorrhage requiring re-exploration was 4.8% (n = 24 patients). Major stroke (defined as modified

Table 4. Intraoperative Variables

Variable	MIMVS (500 Patients)
Endoaortic occlusion	500 patients
IntraClude	351/500 (70.2%)
Endoclamp	149/500 (29.8%)
Cross-clamp time (minutes, mean $\pm$ SD)	85.6 $\pm$ 30.1
CPB time (minutes, mean $\pm$ SD)	129.5 $\pm$ 40.2
Operation time (minutes, mean $\pm$ SD)	218.9 $\pm$ 72.2
Clamping conversion	10/500 (2.0%)
Direct aortic clamping	8/10 (80.0%)
Surgical conversion to full sternotomy	3/500 (0.6%)

CPB = cardiopulmonary bypass; MIMVS = minimally invasive mitral valve surgery.

Table 5. Major Postoperative Outcome

30-Day Outcomes	MIMVS (500 Patients)
Mortality	7/500 (1.4%)
Morbidity	
Aortic dissection	0
Reoperation for bleeding	24/500 (4.8%)
Transfusion postoperative	159/500 (31.8%)
Deep venous thrombosis	0
TIA	3/500 (0.6%)
Permanent stroke	4/500 (0.8%)
Renal failure	13/500 (2.6%)
Groin lymphocele	7/500 (1.4%)
Myocardial infarction	5/500 (1%)

MIMVS = minimally invasive mitral valve surgery;   TIA = transitory ischemic attack.

Rankin Score MRS ≥2) was observed in 4 patients (0.8%). Transitory ischemic attack occurred in 3 patients (0.6%) resulting in a total neurologic event rate of 1.4%. Renal failure was observed in 2.6%. The incidence of a new myocardial infarction was 1.0% (5 patients).

Echocardiographic Data

Table 6 summarizes the 30-day echocardiographic findings. The cardiac function was preserved and mitral and tricuspid valve function restored.

Literature Comparison

We compared the results to the currently available literature on isolated mitral valve surgery either minimally invasively or through full sternotomy [1, 2, 4, 8–19]. Mortality rates reported were anywhere between 0.2 for elective mitral valve repair [19] to 11.6% for valve replacement [9] versus an observed mortality rate of 1.4% in the current analysis including valve replacement, combined and reoperative cases. The reported major stroke rates in elective mitral valve repair were between 0.6% [19] and 4.4% [11] versus an observed major stroke rate of 0.8% in our study population including valve replacement, combined and reoperative procedures.

Comment

Despite the fact that MIMVS has now been around for 20 years [2, 20], its penetration or adoption rate remains

Table 6. Echocardiographic Data

Echocardiographic Findings	Baseline	30 Days
MR (moderate to severe – 3 or severe -4)	445/500 (89.0%)	3/396 (0.8%)
TR (moderate to severe – 3 or severe -4)	57/499 (11.4%)	8/396 (2.0%)
Ejection fraction	0.569 ± 0.112	0.541 ± 0.094

MR = mitral valve regurgitation;   TR = tricuspid valve regurgitation.

relatively low. Indeed, a report from The STS database indicated that MIMVS was performed in only 20.1% of isolated mitral valve surgery in 2008 [21]. Various reasons may account for this. First, the transition to MIMVS requires additional training, even for established practices of mitral valve surgery. In addition, the need for different perfusion cannulas, video-assistance, and surgical instruments require an investment from teams wishing to start a MIMVS program. These factors may create a hurdle for teams evaluating an eventual start of a MIMVS program.

In addition, the ISMICS consensus paper of 2011 [4] indicated longer operative times with higher incidences of stroke, aortic dissection, phrenic nerve palsy, and groin infection rates in order to reach a reduction in intensive care unit and hospital stay, transfusion rate, incidence of postoperative atrial fibrillation, and ventilation time. No wonder that teams evaluating a potential transition to MIMVS express reluctance to do so.

The present analysis challenges the existing literature and studies the outcome across Europe of real world practices in teams performing MIMVS on a regular basis. Because adopting any new technique requires a learning curve, we excluded these individual curves from the present analysis. In line with the recently suggested length of the learning curve between 35 and 75 cases [22, 23], we defined the learning curve at 50 cases. All co-authors estimated this to be a reasonable number, although some subjectiveness is certainly not excluded. We also included combined and reoperative cases.

Applying these criteria, we found very favorable outcome data. The 30-day mortality rate was 1.4%, which is at the lower end of reported rates for primary isolated mitral valve surgery (0.2 to 11.6%). In addition, the major stroke rate (modified Ranking Score ≥2) was only 0.8% (compared with 0.6% to 4.4% reported so far) and no aortic dissections occurred. These findings are in sharp contrast with the ISMICS consensus findings [4].

While we can speculate why the results reported here are better than results reported so far, some factors may play a role. First, all centers participating in this analysis made at some point a definite decision to go for MIMVS. They were all fully experienced with mitral valve surgery as such and made a consistent change to MIMVS. This means that they were really dedicated to do so and performed MIMVS on a regular basis, albeit introducing some case selection in the transition period to MIMVS as their standard technique for mitral valve surgery. We believe it is crucially important to perform MIMVS regularly during the learning phase in order to reach reproducible results.

Next, the current analysis excludes the learning curve of the various centers involved. This may have influenced the outcome data in a favorable way. While it is not always clear in reported manuscripts if a total patient population (including the learning curve) is considered, one may assume so if it is not explicitly mentioned that the learning phase is excluded. To account for this potential bias, we considered "real daily life" data by also including combined (with tricuspid or atrial fibrillation

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surgery) and reoperative cases. Even doing so, the outcome data reported are excellent in comparison with the existing literature.

Another potential influencing factor may be the type of endo-balloon used. While most reports on MIMVS using the endo-aortic balloon technique used the Endoclamp, the current series used a mixture of Endoclamp and IntraClude devices. The IntraClude has some different features to enhance manipulation, but above all also has a precurved zone in order to facilitate aortic arch passage and limit balloon movement once inflated above the sinotubular junction. It is speculated that these features may enhance the clinical behavior of this type of endo-balloon. However, this is unproven to date and is currently the topic of further research.

At first glance, a mitral valve repair rate of 73.8% may seem low to readers. However, one needs to consider that more than 10% of the cases were reoperations and that the patient population included both rheumatic and degenerative valve pathology. Four of the participating centers are located in southern Europe where the prevalence of rheumatic heart disease is still substantial. While occasional attempts for valve repair are made, most of these valves are replaced.

Limitations

The current manuscript aims to report the "real world experience" in MIMVS using a right minithoracotomy and endo-aortic balloon occlusion. We did not include centers which perform robotic MIMVS using the endo-aortic balloon. However, since the principles of patient selection in robotic MIMVS and endo-aortic balloon occlusion are similar to the population studied, we do not anticipate any major outcome changes with the current results.

Our patient follow-up is limited to 30 days or in-hospital time, whichever comes last. We recognize this may seem short but the scope of the current study was mainly to study outcomes related to the usage of the endo-aortic balloon. We therefore believe the study period should suffice to detect any adverse outcomes related to this technique.

The current manuscript reports on the usage of the endo-aortic balloon technique. Both the Endoclamp and IntraClude were used for aortic occlusion. The IntraClude has incorporated some design changes (easier manipulation, precurved for easier arch passage, etc) which may have influenced the outcomes in a positive way. The current analysis, however, was unable to account for this.

Although the aim of the study was also to compare the current outcome data with other techniques of mitral valve surgery, we compared our outcomes with the existing literature rather than to set up a comparative or controlled trial. This may influence the results somewhat as study populations may not be fully comparable. Nevertheless, the current study population is by no means a selected low-risk first time population undergoing MIMVS; combined and redo procedures were included making this a real world report on MIMVS. The fact that we compared the current outcomes with

published data on primary isolated mitral valve surgery does certainly warrant against a lower risk population studied in this paper. In fact, the opposite should be true.

Conclusions

Once procedural proficiency is acquired, endoaortic balloon clamping in MIMVS is a safe and effective technique. Despite the fact that this patient cohort also includes combined and redo procedures, the observed mortality (1.4%) and major stroke rate (0.8%) compared very favorably to the existing literature on primary isolated mitral valve surgery irrespective of the approach. We believe these data strengthen the arguments to establish and expand a MIMVS program.

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Appendix

All complications, including death, were monitored within 30 days after the operation

1. Postoperative blood transfusion:
   Packed cells transfused after the operation were recorded
2. Reoperation for bleeding
   Any surgical reexploration (minithoracotomy or full sternotomy) required for suspected bleeding during the postoperative period [7].
3. TIA [transitory ischemic attack]
   As proposed by the STS [Society of Thoracic Surgeons] database, TIA is defined as a loss of neurologic function that was abrupt in onset but with complete return of function within 24 hours.
4. Stroke
   As proposed by the STS database, a postoperative stroke is defined as any confirmed neurologic deficit of abrupt onset caused by a disturbance in blood supply to the brain, that did not resolve within 24 hours.
   Stroke is separated into 2 groups:
   Minor: Modified Rankin score <2 at 30 days
   Major: Modified Rankin score ≥2 at 30 days
5. Respiratory failure - Pneumonia
   Severe respiratory failure is defined as intubation >24 hours or the patient requires reintubation for severe respiratory failure
6. Acute severe renal failure
   An increase in creatinine to twice the preoperative value or the patient receives renal replacement therapy.
7. Myocardial infarction (MI)
   Acute MI is present if ≤7 days from the last documented MI or evolving, if, at the time of surgery, Q-waves or ST changes were present along with a CK-MB >5% of total CPK [7]. If patient received concomitant atrial fibrillation ablation, cardiac biomarkers were not used. Only clinical signs and electrocardiogram changes will be analyzed.
8. Peripheral ischemic event–Major vascular complication
   Major vascular complications include:
   - Any aortic dissection.
   - Aortic rupture.
   - Annulus rupture.
   - Left ventricle perforation.
   - New apical aneurysm/pseudoaneurysm.
   - Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life-threatening or major bleeding, visceral ischemia or neurologic impairment.
   - Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.
   - The use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia, or neurologic impairment.
   - Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, or decreased or absent blood flow on lower extremity angiogram.
   - Surgery for access site-related nerve injury OR permanent access site-related nerve injury [8].
   Aortic dissection will be recorded separately in the database.
9. Surgical site infection
   Any severe sterna infection requiring site reexploration (resternotomy if conversion occurred).

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