Does Ministernotomy Improve Postoperative Outcome in Aortic Valve Operation? A Prospective Randomized Study

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Background. The aim of this study was to compare the postoperative outcome obtained in patients undergoing elective aortic valve operation, either through ministernotomy or conventional sternotomy.

Methods. Between January 1999 and July 2001, 80 consecutive patients undergoing elective aortic valve replacement were randomly divided into two groups: group I (n = 40 patients) undergoing a ministernotomy approach (reversed-C or reversed-L), and group II (n = 40 patients) undergoing conventional sternotomy.

Results. The length of skin incision was significantly shorter in group I than in group II (8.2 ± 1.3 cm versus 23.7 ± 2.6 cm, $p < 0.001$). No significant differences were found in cardiopulmonary bypass duration, associated procedures, or aortic cross-clamping times. Total operating time was 3.7 ± 0.46 hours in group I compared with 3.4 ± 0.6 hours in group II ($p = 0.014$). A similar incidence of cardiac, neurologic, infective, and renal complications between groups was found. Mean mediastinal drainage and mean blood transfusions (amount of blood transfused) per patient were greater in group II ($p < 0.004$ and $p < 0.001$, respectively). Twenty-five (62.5%) patients in group II and 15 (37.5%) patients in group I required postoperative blood transfusion ($p = 0.04$). Mechanical ventilation time was significantly longer in group II (6.2 ± 1.8 hours versus 4.4 ± 0.9 hours, $p = 0.006$). Five days after the surgical procedure, spirometric data analysis demonstrated a significantly lower total lung capacity and maximum inspiratory and expiratory pressures in group II compared with group I ($p = 0.003$, $p = 0.007$, and $p < 0.001$, respectively).

Conclusions. Our results showed that ministernotomy had not only important cosmetic advantages but also beneficial effects in blood loss and transfusion, postoperative pain, and probably in sternal stability. Ministernotomy also improved recovery of respiratory function and allowed earlier extubation and hospital discharge.

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From the time of the first cardiac surgical procedures, longitudinal median full-length sternotomy has been the approach of choice, offering ample room for cardiac cameras and extensive exposure to the great vessels. In 1996 Cosgrove and Sabik [1] introduced a longitudinal parasternal thoracotomy for aortic and mitral operation: their technique is more aesthetic and reduces thoracic instability, postoperative bleeding, and infections. Recently, different minimal approaches to aortic valve (AV) operation have been reported [2–5], although the advantages and benefits, in addition to cosmetic outcome, were not completely clarified.

Since 1998, reversed-L or reversed-C ministernotomy for mini-invasive AV operation has been used in our department: these techniques make possible a standard cannulation for cardiopulmonary bypass (CPB) without requiring extraperipheral cannulation. In addition, they obviate the need for opening the pleuras, carrying out costal resections, and using video assistance or self-made instruments. Internal mammary arteries (IMAs) are respected and the conversion to "standard sternotomy" is simple and rapid. The skin incision is small, less than 10 cm, and the postoperative advantages for the patients are not limited to esthetic benefits.

The aim of this prospective randomized trial was to compare the operative and postoperative results obtained in patients who underwent elective AV replacement, either through a mini-invasive approach (ministernotomy) or conventional sternotomy.

Material and Methods

Between January 1999 and July 2001, 80 consecutive patients with AV pathology underwent elective AV replacement. They were randomized (by computer-generated randomization) with prior informed consent into two groups: group I, comprising 40 patients who underwent ministernotomy (reversed-C or reversed-L, with a skin incision shorter than 10 cm), and group II, comprising 40 patients who underwent conventional median sternotomy (with a roughly 25-cm incision). Excluded from the study were patients undergoing emergency oper-

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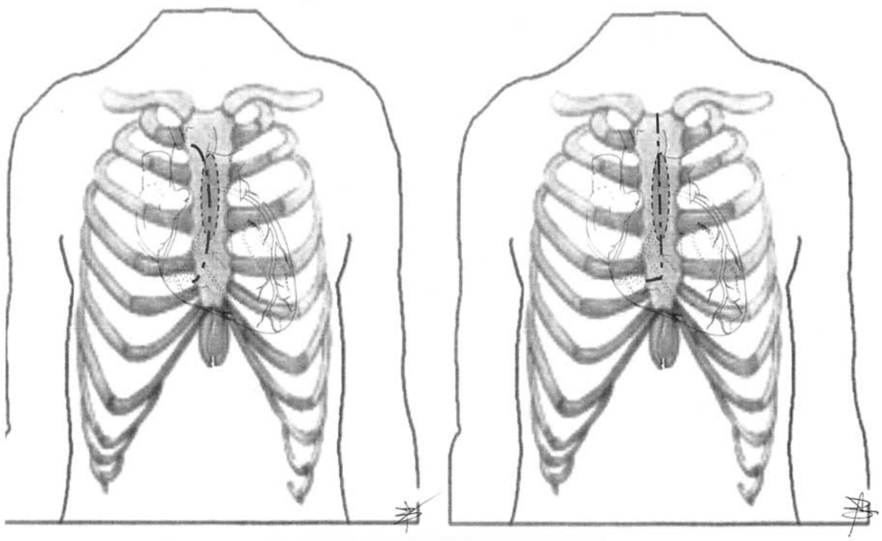

Fig 1. Reversed-C (left) and reversed-L (right) ministernotomy. The interrupted line indicates sternal opening, the gray area the skin incision.

ations or concomitant coronary revascularization, patients with depressed left ventricular function (left ventricular ejection fraction less than 0.25), and patients with a heavily calcified ascending aorta.

Patient Characteristics

The groups were similar in terms of age and New York Heart Association functional class: mean age in group I was 62.6 ± 9.5 years compared with 64 ± 12.4 years in group II (p = 0.57); mean New York Heart Association functional class in group I was 2.7 ± 0.9 compared with 2.5 ± 0.7 in group II (p = 0.27). There were no significant differences between groups in terms of demographic data, cardiac status, associated pathologies, body mass index, and hemocoagulative and blood gas analysis data. Pulmonary functional status was assessed by spirometry. The forced vital capacity, forced expiratory volume in 1 second (FEV_1), total lung capacity (TLC), residual volume (RV), maximum inspiratory pressure (MIP), and maximum expiratory pressure (MEP) were calculated for each patient. No differences were found between groups for pulmonary functional status. Eight patients in group I presented with AV insufficiency compared with 7 patients in group II (p = 1.0); 12 patients in group I had AV stenosis compared with 10 in group II (p = 0.8). The remaining patients in both groups presented with AV insufficiency and stenosis. Mean left ventricular ejection fraction was 0.57 ± 0.12 in group I versus 0.56 ± 0.13 in group II (p = 0.73).

Anesthesia and Cardiopulmonary Bypass

All patients received the same anesthetic regimen and monitoring. External defibrillator pads were placed on the patient's back and anterior left chest. Normothermic CPB and standard aortic cross-clamping were used. The aorta was cannulated just proximal to the innominate vein. A two-stage cannula placed in the right atrium was used for the venous return. A retrograde cardioplegia cannula was placed just below the right atrial appendage. The left ventricle was vented through a cannula placed in the right superior pulmonary vein. Myocardial protection was achieved by perfusing cold blood cardioplegia into the coronary ostia and, retrogradely, into coronary sinus.

Surgical Techniques

Standard instruments, cannulas, and the heart-lung machine used during the surgical procedures were the same for both groups. With the exception of the surgical approach, the operation was performed using the same technique in all patients.

MINISTERNOTOMY (GROUP I). In group I we used two techniques: reversed-C [4] in 15 patients and reversed-L [2] in 25 patients (Fig 1). The reversed-C approach is the technique of choice, but the decision about which technique to use was based on the thoracic radiogram: in cases with discrepancies of the ascending aorta length, aortic root ectasia, or calcifications, the L technique was used.

A 6-cm to 10-cm midline skin incision was made starting 2 cm apart from the angle of Louis until 4 to 6 cm from the xiphoid base. The subcutaneous tissue flap was raised and the sternum divided, by a sagittal saw, starting at the right border of the fourth-to-fifth intercostal spaces and extending, along the sternum's midline, until the first-to-second intercostal spaces (reversed-C), or from the fourth right intercostal space to the sternal notch (reversed-L). The right IMA is usually 1 to 2 cm from the sternal edge, untouched by the saw. The right pleural cavity remained intact in all patients. A standard Finocchietto retractor was used to separate the sternum edges, exposing the superior mediastinum. Thymic remnants were dissected and excised to improve access to the upper anterior pericardium. The pericardium was opened only in its superior portion (T shape), in the midline, from the innominate vein to the lower intact sternal table. The ascending aorta and the right atrial appendage were clearly exposed with properly placed traction sutures from the pericardial edge to the skin.

STANDARD STERNOTOMY (GROUP II). A midline skin incision, 20 cm to 25 cm long, was made from the sternal notch to the xiphoid appendage. A full-length median sternotomy (involving manubrium, body, and xiphoid appendage) was carried out by sagittal saw. The thoracic retractor was inserted and the pericardium was incised in an "I" shape.

In the ministernotomy approach, the aortic sinuses were exposed by a gentle traction of the venous cannula using a transcutaneous stitch around the cannula. The suspension of the aortic edges for exposure improvement was applied in all patients; moreover, a suture placed above each commissure and clamped to the surrounding drapes under tension, lifted up the aortic root into the operative field and improved access to the AV plane.

Having achieved almost identical preoperative conditions, we operated on the two groups in the usual way for their specific AV replacement. In particular, for stentless valves we preferred a transverse aortic incision located 1 cm above the right coronary ostium. For mechanical valve and stented bioprostheses we used an oblique incision extending down 0.5 cm from the aortic annulus in the noncoronary sinus.

After closing the aortotomy and filling the heart, the surgeon put the patient in the Trendelenburg position and the lungs were inflated for expelling air into the left ventricular outflow tract. A suction vent for evacuating bubbles was placed in the highest point of the closed aorta. After insertion of temporary pacing wires, internal small-sized paddles were used, when needed.

Transesophageal echocardiography was used each time to check for the removal of air and to evaluate the valve and the ventricular performance. The procedure was also used to assess the correct position in coronary sinus of the cardioplegic catheter.

In the ministernotomy group only one chest tube was placed in the pericardium left of the aorta, exiting through the right chest. Closure of the sternum was accomplished with three sternal wires: two wires were in a simple fashion, and the central as a figure-of-eight. Two chest tubes (one in the pericardium and the other in the retrosternal space) were positioned in patients undergoing standard sternotomy; closure of the sternum was accomplished with four alternate (figure-of-eight and simple) wires. The pleural cavities were not opened in all cases.

Postoperative Ventilation

In the intensive care unit (ICU) the patient management protocol included supplementary intermittent mandatory ventilation at 12 to 14 breaths per minute; tidal volume of 10 mL/kg; pressure support of 10 to 20 cmH_2O; positive end expiratory pressure of 3 to 5 cmH_2O; and an inspiratory-expiratory ratio of 1:2. Arterial blood gases analysis data at 1 and 4 hours, before and after extubation, were taken. Chest roentgenograms were taken daily, including during the stay in the ICU and on the day of discharge.

Pain was evaluated routinely by self-reporting scores, using a scale of 1 to 5 as follows: 1 = no pain; 2 = mild pain; 3 = moderate pain; 4 = severe pain; and 5 = extremely severe pain. The measurements were taken by nurses who did not know to which group the patients belonged. Patients whose chest pain score reached 3 or more (moderate pain or worse) were treated with morphine and nonsteroidal antiinflammatory drugs (ketorolac-tromentamina). The postoperative spirometry evaluation was performed on the fifth postoperative day and at 1 and 3 months of follow-up (Table 1).

Statistical Analysis

Group statistics are expressed as mean ± SD. The data of pulmonary function are expressed as a percentage of normal value. For statistical analysis, generalized Wilcoxon test between the two groups and Fisher's exact test for the evaluation of noncontinuous variables were performed. The relationship between preoperative and postoperative variables within the same group was assessed by the McNemar test. Data differences were considered significant when p was less than 0.05.

Results

The length of skin incision was 8.2 ± 1.3 cm in group I patients, significantly shorter than that in group II, 23.7 ± 2.6 cm ($p < 0.001$). No significant differences were found in CPB duration; associated procedures (aortoplasty: 4 in I versus 5 in group II; carotid thromboendarterectomy: 2 in group I versus 1 in group II); prosthesis type (mechanical bileaflets: 25 in group I versus 27 in group II; biological pericardial: 10 in group I versus 7 in group II; biological stentless: 5 in group I versus 6 in group II); and aortic cross-clamp time (51.7 ± 12.2 minutes in group I versus 52.4 ± 9.8 minutes in group II). The only difference was found in total operating time (3.7 ± 0.46 hours in group I compared with 3.4 ± 0.6 hours in group II, $p = 0.014$). All patients, except one for each group, were successfully weaned from CPB without the need of mechanical circulatory support. Only one ministernotomy approach was converted to a full sternotomy, for better exposure of the left ventricle, because the recovery of spontaneous cardiac activity had been difficult. This patient died from massive perioperative myocardial infarction probably as a result of poor myocardial protection. Two patients in group II died: 1 patient had severe aortic stenosis, left ventricular hypertrophy, the circumflex artery arising from the right coronary artery, and subsequently multiorgan failure; the second patient had ascending aortic rupture (Table 1).

A similar incidence of cardiac, neurologic, infective, and renal complications between the groups was found. Two patients in group II, who underwent rethoracotomy for bleeding, developed deep sternal wound infection that required debridement and drainage. Two other patients had sternal instability, which needed external contention 3 weeks postoperatively (Table 1).

The mean mediastinal drainage and the mean blood transfusions per patient were higher in group II ($p <$

Table 1. Early Postoperative Data and Pulmonary Functional Status

Variable	Group I	Group II	p
In-hospital death	1	2	1.0
Reexploration for bleeding	0	3	0.24
Mean mediastinal drainage (mL/m^2)	183 ± 89	280 ± 189	0.004
Bleeding > 800 mL	0	7	0.012
Mean blood transfused (mL/m^2)	157 ± 98	293 ± 172	< 0.001
Complications			
Atrial fibrillation	4	3	1.0
Atelectasis during ICU	2	3	1.0
Respiratory insufficiency	1	2	1.0
Sternal wound infection	0	2	0.49
Sternal instability	0	2	0.49
Mechanical ventilation time (hours)	4.4 ± 0.9	5.3 ± 1.8	0.006
FiO_2 % (PaO_2 > 100 mm Hg and $PaCO_2$ < 35 mm Hg)			
At 4 hours before extubation	56 ± 5.7	55 ± 7.5	0.51
At 1 hour before extubation	50 ± 2.2	51.6 ± 5.4	0.087
At 1 hour after extubation	38.6 ± 4.3	40 ± 4.7	0.17
At 4 hours after extubation	28.8 ± 5.2	32.4 ± 6.7	0.01
Pain score (at 1 and 12 hours)	2.7 ± .4/3 ± .5	3.1 ± .8/3.5 ± .8	0.006/0.001
NSAID during first 72 hours (mg)	83 ± 12	104 ± 34	0.003
Morphine during first 12 hours (mg)	7.8 ± 1.8	9 ± 2.7	0.024
Prolonged ventilation (> 24 hours)	0	2	0.24
ICU stay (day)	1.1 ± 0.4	1.4 ± 0.8	0.04
Hospital stay (day)	7.2 ± 1.6	8.2 ± 2.3	0.029
Postoperative spirometric data at 5 days (% expected)			
TLC	65.9 ± 10[a]	59.6 ± 8.3[a]	0.003
FEV_1	80.8 ± 18.6	81.7 ± 21.5	0.84
MIP	54 ± 12[a]	46.6 ± 17.7[a]	0.007
MEP	62 ± 11.4[a]	53 ± 10.5[a]	< 0.001
RV	84 ± 16.3	85 ± 17.4	0.6
Postoperative spirometric data at 1–2 months (% expected)			
TLC	92 ± 13[b]	88.6 ± 19[b]	0.35
FEV_1	80.5 ± 22	79.6 ± 20	0.93
MIP	72 ± 25[b]	67 ± 21[b]	0.34
MEP	68.8 ± 14.7[b]	64.7 ± 10.6[b]	0.155
RV	91 ± 25.5	86 ± 18.4	0.32

[a] $p < 0.05$ versus preoperative data. [b] $p < 0.05$ versus fifth postoperative day data.

FEV_1 = forced expiration volume at first second; ICU = intensive care unit; MEP = maximum expiratory pressure; MI = myocardial infarction; MIP = maximum inspiratory pressure; NSAID = nonsteroid antiinflammatory drugs; RV = residual volume; TLC = total lung capacity.

0.004 and 0.001, respectively). The incidence of bleeding more than 800 mL was significantly higher in group II ($p = 0.012$) (Table 1). Twenty-five (62.5%) patients in II versus 15 (37.5%) patients in group I required postoperative blood transfusion ($p = 0.04$).

Pulmonary complications and respiratory functional status were analyzed in both groups. Mechanical ventilation time was significantly longer in group II, 6.2 ± 1.8 hours compared with 4.4 ± 0.9 hours in group I ($p = 0.006$). The incidence of pleural effusion, pneumothorax, thoracentesis, and atelectasis during the hospital stay was similar in both groups. In all measurements, during mechanical ventilation and 1 hour after extubation, all patients independently of the group, necessitated a similar FiO_2 level for having acceptable PaO_2 and $PaCO_2$ arterial levels. At 4 hours after extubation the FiO_2 requirement was significantly greater in group II ($p = 0.01$).

The chest pain score was significantly higher in group II than in group I at 1 to 12 hours after awakening ($p = 0.006$ and $p < 0.001$, respectively), but the difference was not significant after 72 hours (1.2 ± 0.3 versus 1.5 ± 0.7, p = NS). Significant differences were also found in the postoperative analgesia requirements: mean morphine (first 12 hours) and nonsteroidal antiinflammatory drug (first 72 hours) quantities were greater in group II than in group I ($p = 0.003$ and 0.024, respectively).

Intensive care unit and hospital stay were significantly longer in group II ($p = 0.04$ and 0.029, respectively). Five days after the surgical procedure, pulmonary function measurements dropped significantly in both groups in comparison with preoperative data. However, spirometric data analysis demonstrated a significantly lower TLC, MIP, and MEP in group II versus I ($p = 0.003$, $p = 0.007$, and $p < 0.001$, respectively). The other spirometric measurements were almost similar between groups (Table 1).

Thereafter, pulmonary functional measurements improved until the first postoperative month and, particularly in group I, reached the preoperative values: at this time a significant difference persisted between groups. The recovery of group II patients reached the preoperative values only at 3 months' follow-up. Follow-up (9.7 ± 5.7 months) was completed in all postoperative 77 survivors. There were no late deaths. All patients were found to be in New York Heart Association class I or II. Echocardiographic examination showed good functional status of the prostheses.

Comment

Over the past few years, several studies have reported excellent postoperative outcome in patients undergoing different mini-invasive approaches for cardiac surgical procedures. Cosgrove and Sabik [1] introduced a right parasternal approach that included the excision of the second and third costal cartilages, right IMA division, and femoro-femoral CPB. Since then, five other mini-invasive approaches have been developed such as transverse sternotomy [3], superior hemisternotomy [3], inverted-T [6], reversed-L [2], parasternal [1] and reversed-C [2]. Recently, Chang and coworkers [7] introduced an "I" shape ministernotomy for AV replacement. Despite an increasing number of authors reporting their experience with mini-invasive approaches, few data have been published from randomization studies that compared the postoperative outcome between mini-invasive and conventional operation [8].

Since 1998, reversed-L [2] and more recently reversed-C [4] sternotomy for mini-invasive AV operation have been used in our institution. Additional advantages of these approaches are the comfort factor of sternotomy over thoracotomy and the integrity of IMAs and pleural cavities. Ministernotomy prevents complications of overdistension at the costovertebral joint or brachial plexus traction at the thoracic inlet. Moreover, cannulation of the ascending aorta and right atrium is easier, and access to the coronary sinus for retrograde cardioplegia is more feasible. Besides, ministernotomy guarantees effective sternum stability (mainly for reversed-C) and allows for a rapid conversion to full sternotomy. Reversed-C is our technique of choice because the upper and the lower parts of the sternum remain intact and the thoracic cage is more stable: this technique was used in 15 patients in this series. The other 25 of group I underwent reversed-L [2] ministernotomy (sternal manubrium totally transected): Variables considered for the use of the reversed-L procedure were the topographic relationships of the anatomic structures as assessed by chest roentgenogram, echocardiography, and catheterization (length and diameter of ascending aorta, AV position, presence of extensive calcification in the aortic root) and possible difficulties in cannulation. The slight differences between the reversed-C and reversed-L techniques did not seem to affect overall postoperative outcome [8].

We have had an excellent exposure of the heart's base in patients undergoing these ministernotomy approaches. Usual cannulation was adopted using ascending aorta, right atrial appendage for venous return, right atrium for retrograde cardioplegia, and the right superior pulmonary vein for left ventricular vent. In all patients we used intrapericardiac defibrillation with common defibrillator paddles (diameter about 4 cm): transcutaneous adhesive paddles have been placed preventively but have never been engaged.

The operation time was significantly longer in patients undergoing ministernotomy approaches, probably resulting for surgeon in a greater discomfort and more demanding dexterity (not dextrixity NdA) in preparing the surgical field.

The main drawback of ministernotomy is the amount of cardiac manipulation and the need to displace the cardiac apex to remove air at the end of the operation, although it appeared that suction from the aortic root and the patient's position were sufficient to achieve good air removal from the left ventricle. The absence of bubbles was assessed by means of transesophageal echocardiography.

Outcome analysis in this series of patients proved that the upper ministernotomy approaches did not compromise the quality of the operation and that these procedures are safe and effective for AV replacement. However, different opinions have been expressed regarding the advantages of these approaches and considerable skepticism still remains [9–11]; the smaller incision limits heart exposure and makes dealing with any operative complications difficult.

In this series we found a lower hospital mortality (2.5%) in patients undergoing mini-invasive approaches, although these data did not reach statistical significance. The CPB and aortic cross-clamping times were not related to the mini-invasive procedures. The operation time, however, appeared to be affected by the use of mini-invasive techniques, because of the extra time spent on mini-access construction and cannulation, and the greater difficulty working through a smaller incision. Postoperative complications proved to be similar between patients undergoing mini-invasive or conventional approaches. The skin incision is shorter in mini-invasive incision, enhancing a better aesthetic result because of the limited extension of the scar, but this advantage was not the fundamental point. We found significantly less bleeding and mean blood transfusion in patients undergoing ministernotomy, probably because the conventional procedure requires dissection of more surrounding tissue. All patients with postoperative sternal wound infection and sternal instability had been treated by the conventional approach. Although the difference between groups in such outcomes was not statistically significant, probably because of the small number of patients in our study, we do believe that complete sternotomy induces a higher risk of infections and sternal instability. Postoperative atrial fibrillation remains a problem even when mini-invasive operation [12] is considered. In the present trial we did not find a high incidence of postoperative atrial fibrillation in the ministernotomy group, but the atria should be manipulated carefully to avoid postoperative arrhythmias.

Patients undergoing ministernotomy had improved postoperative respiratory rescue, mostly preserving the chest wall integrity and reducing postoperative pain, as evidenced by a shorter mechanical ventilation time, better postextubation blood gases analyses and pain scores, and lower analgesic requirements. The increased stability of the thoracic cage and integrity of pleural cavities allow patients to move early and cough more effectively [5]. Aris and colleagues [8] compared the pulmonary function in patients undergoing mini-invasive versus conventional AV replacement, but they did not report definitive and complete data of spirometry: the study group included only 20 patients and lung functional tests (only vital capacity and FEV_1) were conducted only before hospital discharge.

We evaluated the postoperative thoracic-lung functional status with complete pulmonary function tests, performed after 5 days and at follow-up 1 to 3 months postoperatively. A severe restrictive disturbance of lung function and a decreased muscle-related inspiratory impulse (MIP and MAP) was present in all patients 5 days postoperatively. This "restrictive syndrome" has been described in patients undergoing sternotomy [8, 13, 14] and is related to the extent of surgical trauma, pleural lesions, CPB, and postoperative pain. The mini-invasive procedures showed great advantages over the standard sternotomy in terms of postoperative pulmonary function and the time needed to make a full recovery of pulmonary status: the spirometric data (TLC, MIP, MEP) at 1-month follow-up were similar to the preoperative values. Such an outcome was not found in patients undergoing conventional full-length standard sternotomy: they recovered to baseline levels only after 3 months, as is widely known from other cardiac operations [15, 16]. Thus, the significant reduction of postoperative lung function is influenced not only by the use of CPB but also by the length of the sternal incision.

The mini-invasive technique seems suitable mainly for the beneficial effects on pulmonary status and for patients with previous pulmonary disease, chronic obstructive pulmonary disease, or a smoking history. Such patients are at a higher risk of developing pulmonary complications and altered gases exchange compared with other patients undergoing cardiac operation.

In conclusion, the mini-invasive approaches (reversed-C or -L) for AV operation are safe and effective, allowing implantation of all types of prostheses and combining of surgical procedures in the ascending aorta with the same high degree of effectiveness as the conventional procedure. The advantages, without sacrificing safety, were the reduction of surgical trauma and wound pain, enhanced recovery particularly of lung functional status, decreased blood loss, and shortened ICU and hospital stays, resulting in cost savings and good cosmetic healing.

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INVITED COMMENTARY

In contrast with coronary artery bypass surgery, cardiopulmonary bypass surgery can not be obviated in valve operations. Thus, minimally invasive aortic valve surgery relates only to the extension of the incision. After an initial experience with transverse and parasternal incisions, surgeons have elected to split the sternum in several degrees of length, with lateral extensions at different intercostal levels [1]. These incisions, named

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