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Original Article

Comparison of full and ministernotomy for isolated aortic valve replacement in elderly patients; a prospective randomized study

Dogan Kahraman[1], Cagin Zaim[2]

[1]Gaziantep University, Faculty of Medicine, Department of Cardiovascular Surgery, Gaziantep, Turkey
[2]Burhan Nalbantoglu City Hospital, Clinic of Cardiovascular Surgery, Nichosia, TRNC

Abstract

Aim: To compare the results of isolated aortic valve replacement through ministernotomy and full sternotomy in the elderly.

Material and Methods: This single-center prospective study includes patients over 60 years of age who undergone isolated aortic valve replacement either by upper ministernotomy (22 patients) or full sternotomy (22 patients) during 5 years. Both groups were followed 12 months postoperatively.

Results: All preoperative and operative measures were similar. However, the ministernotomy group had an average of 3 hours less mechanical ventilation time (p<0.001), 200 ml less bleeding (p<0.001), 1.5 days shorter hospital stay (p=0.002), and 4 days less analgesic use (p=0.001). Postoperative wound infection (18.2%), sternal detachment (9.1%) and pericardial effusion (4.1%) were seen only in the full sternotomy group.

Conclusion: The advantages of ministernotomy are more prominent during recovery period in elderly patients.

Keywords: Minimally invasive; aortic valve surgery; ministernotomy; aged; median sternotomy

INTRODUCTION

Minimally invasive aortic valve surgery had been used with an increasing frequency at many centers during the last decades because of attributed advantages (1-3). Also, many studies comparing short-term and long-term results of minimally invasive cardiac surgery and full sternotomy have been conducted (4-10). Minimally invasive techniques were reported to reduce the frequency of infection, blood loss and hospitalization time; improve cosmetic results and patients' comfort during the recovery period (7,9,11). However, some authors have reported several opposite results, such as longer aortic cross-clamp and cardiopulmonary bypass times, which may influence the course of surgery and could be an unfavorable effect for patients of advanced age (11,12). Moreover, elderly patients are more likely to have additional risk factors like osteoporosis, aortic calcification, advanced peripheral arterial disease, and limited mobilization. Therefore, they are expected to experience more postoperative complications with full sternotomy. Both full and ministernotomy are used equally for isolated aortic valve surgery in many centers, but the results of ministernotomy in the elderly are still a debate (13,14). We designed this study to test our hypothesis that the advantages of minimally invasive surgery might be more evident in the elderly patients.

MATERIAL and METHODS

Patient selection and study design

A total of 44 patients who underwent isolated aortic valve surgery for the first time between June 2012 and June 2017 were included after the approval of the institutional ethics committee in Kavaklıdere Umut Hospital, Ankara. All patients signed an informed consent form before inclusion in this study. The inclusion criteria were: ≥ 60 years of age, isolated aortic valve disease and clear indication for surgery, both minimally invasive and conventional median sternotomy incision were alternative treatment options and left ventricle ejection fraction ≥ 45%.

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Corresponding Author: Dogan Kahraman, Gaziantep University, Faculty of Medicine, Department of Cardiovascular Surgery, Gaziantep, Turkey **E-mail:** drdogankahraan@gmail.com

The exclusion criteria were: severe peripheral vascular disease (Rutherford category ≥4); infective endocarditis; presence of severe pulmonary hypertension (≥45mmHg) or preoperative acute pulmonary edema; concomitant congenital heart disease or coronary artery disease that required treatment at the time of the aortic valve surgery; poor general health (such as bed-ridden patients); renal or liver dysfunction; a body mass index (BMI) ≥35 kg/m2; severely calcified ascending aorta; and concomitant other valve pathologies requiring invasive measures.

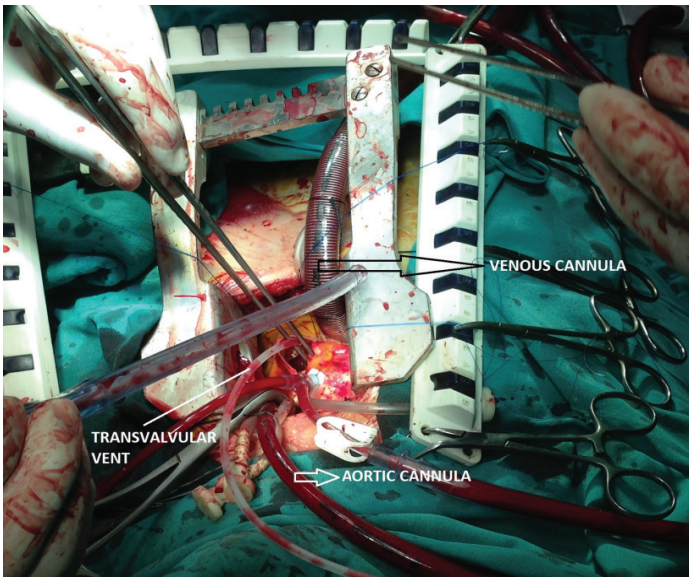
Forty-four consecutive patients with eligibility criteria were divided into 2 groups in one-by-one fashion for randomization; the upper ministernotomy group (MS group, n=22), and the full sternotomy group (FS group, n=22). Preoperative demographic parameters (Age; gender; diabetes mellitus [DM], using oral antidiabetics and/or insulin; BMI; hypertension, taking oral antihypertensive medicine; functional status, New York Heart Association functional classification [NYHA]; chronic obstructive pulmonary disease [COPD], history of using inhaler or tablets upon diagnosis; and the aortic pathology) were recorded to a distinct follow-up chart. Perioperative data were collected from hospital records of anesthesia, perfusion, and intensive care unit (ICU) charts before the discharge of the patient. All patients were followed by the same physician and if a patient missed the scheduled visit the missing data was gathered by phone call.

Anesthesia and details of operations

All operations were performed under general anesthesia with mild hypothermic cardiopulmonary bypass by two physicians with adequate expertise. Mechanical ventilation was maintained in CMV mode with the initial parameters set as 8 ml/kg tidal volume; 14-16 breaths/min respiratory frequency; 60% fraction of inspired oxygen; and 5 cmH2O positive end-expiratory pressures. After successful anesthesia, a 7F central venous catheter via the right internal jugular vein, a 22G radial artery catheter to the left forearm was inserted. The transesophageal echocardiography probe (TEE) was used to evaluate cardiac functions before and after valve surgery in every case.

The whole anterior chest and the groin were prepared and draped accordingly. A straight skin incision of approximately 5 to 7 cm in the midline over the sternum was made starting from the level of the head of the first rib and extended to the level of the head of the fourth rib. The skin and subcutaneous tissue were separated by using electrocautery until sternum. A pendular saw was used to cut the upper sternum from the middle of the jugular notch down to the level of the third intercostal space. The saw was removed and placed through the right 3rd intercostal space and the tail incision was made until the tip of midline incision to complete the j- sternotomy. The right internal thoracic artery is usually 1 cm away from the sternal edge and can be protected by this technique.

A retractor with 5 cm blade length was placed and the mediastinal tissues were dissected providing access to the upper anterior pericardium. Then the pericardium was opened from the innominate vein to beneath the caudal border of the intact sternum. We put multiple silk sutures on the pericardium to expose the aorta and right atrium into good view. The aorta was then cannulated just proximal to the innominate artery in a conventional manner and a two-stage venous cannula inserted into the right atrial appendage. For enhanced exposure of the aortic root, we passed the venous cannula under the connection bar of the retractor and pulled caudally Figur 1.



The appearance of the aortic root from the surgeon's view. Passing the venous cannula under the connection bar of the retractor and pushing it caudally creates extra space (black arrow)

Figure 1. Operative settings for aortic valve replacement with ministernotomy

The mode of the cardioplegic arrest depended on the surgeon's preference. After placing a standard angled aortic cross-clamp on the distal ascending aorta, antegrade delivery of cold blood cardioplegia was used unless the patient had severe aortic insufficiency requiring coronary osteal cardioplegia. From this point, the aortic procedure does not deviate from normal until the de-airing stages. We preferred the standard oblique incision extending down to the annulus in the non-coronary sinus and exposure of the aortic valve was provided by stay sutures on commissures. Valve replacement and posterior annular dilatation, if required, was accomplished through this incision. A bloodless surgical field was achieved by a trans-valvular suction vent. The valve with an appropriate size was implanted by using 12-15 ethibond sutures after excising the leaflets. An ideal de-airing process must be achieved through the highest point of the aorta. To achieve this, the operation table was positioned in the Trendelenburg position and the lungs were inflated rhythmically to expel air into the left ventricular outflow tract. An aortic root cannula with suction vent on the highest point of the aorta helps to evacuate air bubbles. If the heart started to fibrillate

spontaneously then paediatric sized paddles were applied to the epicardium for defibrillation. TEE was used to check the remaining air and the ventricular functions. After placing right ventricular pacing wire and successful weaning off cardiopulmonary bypass the cannulas were removed. The potential sites were checked for bleeding, and then a chest tube was inserted through the right third intercostal space without opening the pleura. The sternal edges were accurately opposed using two sternal wires in figure of 8 fashions to ensure sternal stability.

Patient preparation, anesthesia, and cardiopulmonary bypass measures were the same for conventional aortic surgery. After preparation step the surgery was continued through midline full sternotomy, central (aorta-unicaval) cannulation, antegrade cold cardioplegia, oblique aortotomy, and transaortic venting. A chest tube and pacing wire were inserted subxiphoidaly and sternum was closed with 4 steel wire fashioned in figure of 8. Subcutaneous tissue and skin were sewn continuous manner using vicryl sutures.

Chest tubes were removed from clinically stable patients if last 12-hour drainage was less than 200 ml. The MS patients were allowed to lie on their side after ICU period while FS group was advised to lie supine for 6 weeks to avoid possible detachment of sternal halves.

Statistical Analysis

The dichotomous variables were evaluated using the Fisher exact test and the data are presented as percentages and number of cases. Categorical data were analyzed using the chi-square test. Continuously variables with normal distribution were evaluated using the Student t-test and presented as the mean standard deviation. The Shapiro–Wilk test was applied to check the normality of distribution of our data. Comparison of nonparametric variables between groups were done using Mann-Whitney U test. One-year survival was calculated by Kaplan–Meier analysis and compared statistically using the log rank test. Statistical analysis were performed using the Statistical Package for Social Sciences, version 21.0 (SPSS, Chicago, IL, USA), and a p value < 0.05 was considered statistically significant.

RESULTS

Patients (27 male and 17 female) with a mean age of 67.45±3.98 were included in this study. The COPD was more frequent in patients with ministernotomy access (22.7% vs. 9.1%, p=0.412). Male gender and hypertension were slightly higher in the FS group but considering all preoperative characteristics there was not any significant difference (Table 1).

Table 2 shows the intraoperative and postoperative variables of both groups. In the overall cohort, operation time (180.41±23.33 min vs. 188.36±24.60 min, p=0.277), cardiopulmonary bypass time (83.09±13.28 min vs. 89.18±15.73 min, p=0.173), and cross-clamp times (48.54±12.35 min vs. 54.63±14.08 min, p=0.118) were similar during both surgical procedures.

Table 1. Preoperative characteristics of patients

Patients' Demographics	MS group (n=22)	FS group (n=22)	p
Age,y	67.31±3.72	67.59±4.30	0.823
Gender (m/f), n	12/10	15/7	0.357
BMI (kg/m²)	25.96±2.45	25.40±3.22	0.514
Functional Class, n(%)			0.361
NYHA Class II	11(50%)	14(63.6%)	
NYHA Class III	11(50%)	8(36.4%)	
Diabetes, n(%)	8(36.4%)	5(22.7%)	0.322
Hypertension, n(%)	5(22.7%)	9(40.6%)	0.195
Atrial fibrillation,n(%)	2(9.1%)	1(4.5%)	1
COPD, n(%)	5(22.7%)	2(9.1%)	0.412
Aortic valve pathology, n(%)			
Stenosis	14(63.6%)	17(77.3%)	0.322
Insufficiency	5(22.7%)	4(18.2%)	1
Stenosis+insufficiency	3(13.6%)	1(4.5%)	0.607

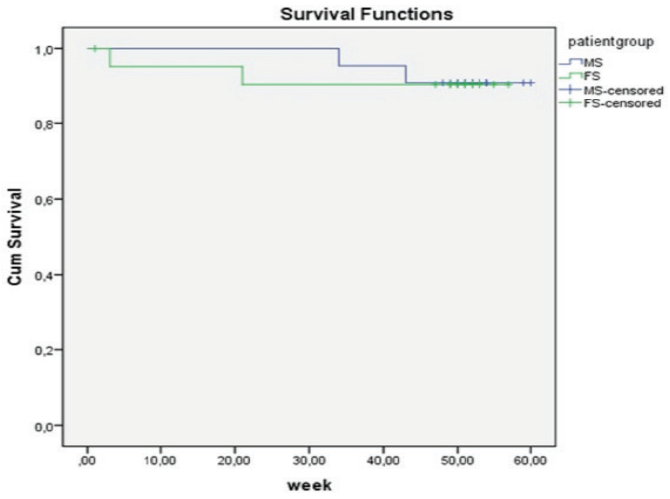
Abbreviations: BMI; body mass index, NYHA; New York Heart Association functional classification, COPD; chronic obstructive pulmonary disease

The same numbers of biological and mechanical valves were used in the ministernotomy and full sternotomy procedures.Posterior annular dilatation (Manougian procedure) was needed for one patient in each patient cohort. Mean duration of ventilatory support (p<0.001), ICU time (p<0.001), and hospital stay (p=0.002) were significantly shorter in MS group (Figure 2). The MS group had comparably less drainage (410.54±141.24 mL and 627.27±183.53 mL respectively, p<0.001), and also, needed less blood transfusion (502.27±194.23 ml and 781.82±277.12 ml respectively, p<0.001) than the FS group. Although reoperation (18.2%; 1 for postoperative bleeding, 1 for postoperative tamponade and 2 for sternal dehiscence) and sternal wound infection (both superficial and deep) were seen only after full sternotomy, they do not have statistical significance. The mean duration of analgesic use was significantly shorter in ministernotomy patients than conventional sternotomy (10.36±3.87 day and 14.45±3.91 day respectively, p=0.001). The Kaplan-Meier test showed that expected 1-year survival rates were similar comparing MS (58.05±1.35 week) and FS procedures (52.71±2.95 week, p=0.923) (Figure 2).

Table 2. Comparative results of the isolated aortic valve surgeries

Perioperative and Follow-up Variables	MS group (n=22)	FS group (n=22)	p
Operation time, min	180.41±23.33	188.36±24.60	0.277
CBP time, min	83.09±13.28	89,18±15.73	0.173
Cross-clamp time, min	48.54±12,35	54.63±14.08	0.118
Bioporsthetic valve, n(%)	6(27.3%)	6(27.3%)	1
Annular dilatation procedure, n(%)	1(4,5%)	1(4.5%)	1
Extubation time, hr	7.24±2.03	10.77±2.61	<0.001
ICU stay, hr	28.23±7.60	38.18±7.13	<0.001
Hospital stay, d	7.72±112	9.14±1.62	0.002
Reoperation, n(%)	0	4(18.2%)	0.108
Blood transfusion, ml	502.27±194.23	781.82±277.12	<0.001
Stroke, n(%)	0	0	
Drainage, ml	410.54±141,24	627.27±183.53	<0.001
Atrial fibrillation, n(%)	6(27.3%)	3(13.6%)	0.457
Superficial infection, n(%)	0	2(9,1%)	0.488
Deep sternal infection, n(%)	0	2(9.1%)	0.488
Readmission, n(%)	0	4(18.2%)	0.108
Analgesic use, d	10.36±3.87	14.45±3.91	0.001
Follow-up time, w	52(34-60)	51.5(1-57)	0,441
1-year mortality, n(%)	2(9.1%)	2(9.1%)	1

Abbreviations: CPB time; cardiopulmonary bypass time, ICU stay; intensive care unit time



Abbreviations: FS; full sternotomy group, MS; ministernotomy group

Figure 2. Kaplan-Meier analysis presenting one year survival

DISCUSSION

The evaluation of the results of the ministernotomy and the full sternotomy for isolated aortic valve replacement in the elderly revealed that the duration of surgery and critically important intraoperative objectives were similar in this study. These results are consistent with novel finding achieved in young patients (15). Nonetheless, there are still arguments on variabilities in intraoperative parameters. Murtuza et al. pointed to longer cross-clamp times and cardiopulmonary bypass with minimally invasive procedures, which is generally thought to predict worse outcomes in cardiac surgery (16). Some authors also reviewed a series of minimally invasive aortic surgeries and concluded that aortic valve replacement via a ministernotomy can be performed safely but with longer cardiac ischemia time (5,10,17-19). Long ischemia time could be thought to worsen the results of the operation as a whole especially for elderly patients with comorbidities like limited functional capacity, disseminated calcification of aorta and COPD. However, consistent with the result

of the present study, in a retrospective analysis of a large patient cohort (936 ministernotomy and 1167 full sternotomy), Shehada et al. (20) reported that the time of aortic clamping and 30-day mortality were not statistically different between the full sternotomy and ministernotomy. They also noted that the ministernotomy is an effective and safe procedure with a low mortality rate and good long-term survival rates. It is reasonable to expect an improvement in the quality of isolated aortic valve replacement with ministernotomy due to feasibility without special instruments, affords the surgeon a familiar view, increasing number of eligible patients in the aging population and the increased expertise of physicians in time. Like our aortic root enlargement procedure, diverse operation types involving aortic root and ascending aorta had been increasingly reported through mini-incisions, such as total aortic root replacement and ascending aortic aneurysm excision (20-25). Historically, we observe that the time gap in favor of the ministernotomy has been equalized in parallel with the increase in experience over time and even complex aortic surgery could be performed (8,26,27). Besides, we could suggest that additional comorbidities in elderly patients equally affect intraoperative outcomes of those with full sternotomy as seen in this study.

When considering postoperative indices, we found that the ventilation time, ICU stay and hospitalization time with ministernotomy were significantly shorter than that of the full sternotomy. Indeed, the sternal pain is a source of discomfort even in a young patient, and older people are more vulnerable to the pain. Using a less invasive approach involves only a short segment of sternal bone. Limited trauma to the sternum causes less pain and therefore less need for postoperative sedation, early weaning from anesthesia, and quick recovery of pulmonary function. The duration of analgesic use, which is indicative of patient comfort in the postoperative period, was significantly shorter in the elderly with ministernotomy. Ambulatory improvement and consequent early discharge from hospital were also seen as positive outcomes in elderly patients possibly due to reduced pain. Moreover, we noted a smaller amount of bleeding after surgery through the chest tube drainage in the ministernotomy group. Exposure of only a short segment of sternal bone marrow and limited mediastinal dissection resulted in less bleeding and ultimately improved sternal healing. The reduction of blood volume loss not only could contribute to a more rapid patient recovery but also has a significant economic implication. It is well known that effusion due to the postpericardiotomy syndrome is an inflammatory response triggered by pericardial damage (28). Therefore it is important to limit the pericardiotomy in the prevention of tamponade physiology, which constituted one-third of the reoperations after full sternotomy. Although statistically insignificant, early postoperative complications like sternal dehiscence, superficial and deep sternal wound infection, and readmission related to mainly those were only seen in the FS group. Therefore we propose that the main advantage of AVR with ministernotomy becomes apparent in short term postoperatively.

According to the results obtained in our study from the 1-year follow-up, the differences between the groups were no longer statistically significant, which was confirmed by the Kaplan–Meier analysis. Minimally invasive aortic valve surgery with upper ministernotomy should not be expected to make a difference in elderly surpassing recovery period which lasts about 6 weeks. Similar results, even in mid- and long term, were obtained by previous studies and they also noted no significant differences between patients in the mini-invasive and those in full access groups (7,29,30). Moreover, Merk et al. (29) reported to observe higher 5-year survival in patients treated with minimal access surgeries than those with conventional methods. But they also noted that this finding may be due to the high expertise of the surgeons in the institution that the study was conducted.

We started to conduct this study after experiencing more than 50 patients for each surgeon. Even though there is a risk of conversion to full sternotomy, we did not experience any. Although there are surgical difficulties of working in a narrow area, mini sternotomy can be performed with the same maneuvers that most surgeons are familiar with during standard surgery in properly selected patients. We also suggest that stented bioprosthetic valve implantation with right anterior mini-thoracotomy should be an alternative to decrease the cross-clamp time in patients with various comorbidities that limit the life expectancy less than 10 years.

This study has some limitations; the limited age only to the elderly and the single-center experience resulted in a limited number of study patients. But preoperative characteristics are unexpectedly matched well between groups. We have to point out the fact that preoperative matching between the two groups, assessed with a larger population, may help to conclude more obvious outcomes with significance, especially in the short term.

CONCLUSION

Based on our findings, aortic valve replacement with the ministernotomy in the elderly is sufficiently safe and effective. Aortic valve surgery with this approach reduces surgical trauma, blood loss, ventilation time, ICU stay, hospitalization time, readmission rate, and improves rehabilitation as much as in younger patients. The main advantages of AVR with MS potentially appear during the recovery period in elderly patients.

Competing interests: The authors declare that they have no competing interest.

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Ethical approval: The institutional ethics committee approved the study at May 3, 2012.

Dogan Kahraman ORCID: 0000-0002-5367-2340
Cagin Zaim ORCID: 0000-0001-8258-8773

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