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Totally Thoracoscopic Versus Open Surgery for Closure of Atrial Septal Defect: Propensity-Score Matched Comparison

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ABSTRACT

The purpose of this study is to compare early clinical outcomes of surgical repair for isolated atrial septal defect (ASD) with a totally thoracoscopic approach without robotic assistance versus a conventional open procedure.

Between September 2010 and June 2012, 254 consecutive patients with isolated ASD underwent totally thoracoscopic surgery without robotic assistance in seven institutions participating in the nationwide multi-centered registry in China. During the same period, these patients were matched using propensity score methodology with 254 patients who had accepted conventional open surgery through a median sternotomy. The early in-hospital results between the two groups were analyzed and compared.

The patient age was 26.8 ± 14.0 years and weight was 52.9 ± 16.9 kg in the totally thoracoscopic group. The totally thoracoscopic surgery required longer aortic clamp time (32.1 ± 17.3 minutes versus 28.3 ± 16.7 minutes, $P = .01$); shorter length of stay in the intensive care unit (25.3 ± 12.2 hours versus 34.8 ± 24.4 hours, $P = .001$); shorter length of stay in hospital (6.5 ± 6.3 days versus 7.9 ± 6.4 days, $P = .008$); and shorter mechanical ventilation time (8.3 ± 5.0 hours versus 11.4 ± 14.8 hours, $P = .04$). The cardiopulmonary bypass (CPB) time (62.7 ± 29.3 minutes versus 61.5 ± 28.0 minutes, $P = .64$) showed no significant difference between the two groups. The totally thoracoscopic group had significantly less postoperative chest tube drainage (322.1 ± 213.7 mL versus 462.8 ± 398.4 mL, $P = .001$). The intraoperative (35.4% versus 38.6%, $P = .46$) and postoperative blood products usage (20.9% versus 21.3%, $P = .91$) showed no significant difference between the two groups. There also was no significant difference in mortality and major in-hospital complications between the two groups.

The early outcomes for treatment of isolated ASD were similar between the totally thoracoscopic group conventional open operation performed through median sternotomy, despite a longer aortic clamp time in the totally thoracoscopic group.

INTRODUCTION

Over the last decade, minimally invasive cardiac surgery (MICS) has undergone numerous technical innovations, from small incision procedure to thoracoscopic approaches to robotic manipulation. Totally thoracoscopic technique is acknowledged as an essential component of MICS. In some countries, the widespread use of totally thoracoscopic surgery is mainly assisted by a robotic surgical system [Modi 2009; Modi 2008; Argenziano 2003]. However, considering the high costs and technical challenges of the robotic system, robotic-assisted cardiac surgery is not suitable for routine care in China. Previously, a few studies on the repair of ASD by totally thoracoscopic surgery without robotic assistance have been reported, and the pertinent results were favorable and encouraging [Casselman 2005]. Nevertheless, these single-institution and small-sample studies do not represent the reality of totally thoracoscopic surgery for ASD in China [Wang 2011; Ma 2011; Ma 2011]. Therefore, using a nationwide multi-centered registry, we aim to compare early in-hospital

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outcomes of ASD repair with totally thoracoscopic repair without robotic assistance and conventional open surgery.

MATERIALS AND METHODS

In 2004, the Chinese Cardiovascular Surgery Registry (CCSR) was initiated to promote cardiovascular surgery quality improvement efforts, reduce disparities in cardiovascular surgical care, and improve clinical outcomes through increased adherence to guideline recommendations. CCSR data is recorded from 45 hospitals nationwide. Standard and minimally invasive procedures both are included in the registry. The minimally invasive procedures comprise small-incision approaches, totally thoracoscopic procedures without robotic assistance, robotic operations, and hybrid procedures. Collectively, more than 70,000 admissions have been captured in these registries.

Between September 2010 and June 2012, 254 consecutive patients undergoing totally thoracoscopic repair of ASD without robotic assistance were enrolled from the CCSR database involving seven institutions. Using propensity score matching (PSM), a control group of 254 patients nationwide who accepted a conventional open procedure through median sternotomy also was selected from the database during the same period.

Patients were excluded for the following: They were inappropriate for transcatheter device closure of atrial septal defects; 4 years of age or older with a body weight of 14 kg or more; no severe peripheral vascular disease; no previous history of operation for a right hemothorax; no history of pleural infection or severe pleural adhesions; no severe deformity of trachea and bronchus; no mental retardation, or no severe coagulopathy.

This study was approved by the Fuwai Hospital Institutional Review Board and Ethics Committee as well as the other six participating institutions.

The procedure of totally thoracoscopic repair of ASD without robotic assistance has been introduced in detail by Wang and Ma [Ma 2011; Ma 2011]. After systemic heparinization, the right femoral artery and vein were accessed through an oblique incision along the inguinal crease. A 24F/29F Carpentier double-lumen catheter (Medtronic Inc., Minneapolis, Minnesota) was inserted through the right femoral vein into the inferior and superior vena cava. The bypass circuit was completed by positioning a 17F or 21F catheter (Medtronic Inc.) in the abdominal aorta through the right femoral artery. There were three ways to set up the ports. In the first way, the first port was located between forth intercostals space in anterior midaxillary line. The second port was located between third intercostals space in midaxillary line.The third port was located between fifth intercostals space in midaxillary line. In the second way, the first port was located between third intercostals space in midaxillary line. The second port was located between third intercostals space in anterior midaxillary line.The third port was located between sixth intercostals space in midaxillary line. In the third way, the first port was located between third intercostals space parasternal. The second port was located between fifth intercostals space in anterior midaxillary line. The third port was located between third intercostals space in midaxillary line. Once the three ports were secured, a pericardiotomy was performed. Caval snares were placed in the superior and inferior vena cava to install total CPB. After CPB initiation and cooling to 32°C, the thoracoscopy was placed through the second port to visualize the root of the aorta. An aortic cross-clamp was positioned on the ascending aorta. A needle was inserted through the third port to the aortic root for the delivery of cold cardioplegic solution to achieve cardiac arrest. The thoracoscopy was repositioned through third port to visualize the right atrium. Tissue forceps and scissors entered through the first and second ports, respectively. After snaring the superior and inferior vena cava, the right atrium was opened from a site parallel to the atrioventricular annulus, and four stay sutures were placed on the incision to expose the intra-atrial structure. The ASD was closed with direct 4–0 Prolene sutures (Ethicon Inc., Somerville, New Jersey; Fig. 4). A dacron or pericardium patch was used to repair larger ASDs with running Prolene sutures. After ASD closure, the aortic cross-clamp was released. The patient was rewarmed and weaned from CPB. The integrity of the ASD closure was confirmed by means of transesophageal echocardiography. Protamine sulfate (1:1) was administered. After adequate hemostasis was achieved, all instruments were removed from the chest [Ma 2011].

STUDY ENDPOINTS

The primary endpoints of this study were in-hospital mortality and reoperation. The secondary endpoints included CPB time, aortic clamp time, mechanical ventilation time, length of stay in the intensive care unit, postoperative chest tube drainage, intraoperative and postoperative blood products usages, length of hospital stay, and major in-hospital complications including stroke, multi-organ failure, reintubation, and renal failure.

STATISTICAL AND PROPENSITY-MATCHED ANALYSIS

Quantitative variables are expressed as a mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Continuous variables with normal distribution were compared between the two groups by paired-test and continuous variables without normal distribution by the Wilcoxon Rank-Sum Test. Categorical variables were compared between the groups by using the McNemar's test. All P values of less than 0.05 were considered significant. All data was prospectively analyzed using the SPSS Statistics for Windows, version 19 (IBM, Chicago, Illinois).

Matching criteria included demographics (gender, age, weight), comorbidities known to be risk factors for surgical procedure (left ventricular ejection fraction, blood creatinine, hypertension, smoking status, history of congestive heart failure). Age, weight, left ventricular ejection fraction, and blood creatinine were variables included as continuous variables. Gender, hypertension, smoking status, and history of congestive heart failure were variables included as categorical variables. We first used logistic regression to develop a propensity

Table 1. Patient Baseline Characteristics Before Matching

Characteristics	Totally thoracoscopic (N = 254) No.(%) or Mean ± SD	Conventional open (N = 598) No.(%) or Mean ± SD	*P*
Male	122(48.0%)	168(28.1%)	<.01
Age (years)	26.8 ± 14.0	32.7 ± 13.6	<.01
Weight (kg)	52.9 ± 16.9	56.1 ± 12.8	<.01
Left Ventricular Ejection Fraction (%)	64.6 ± 6.7	61.6 ± 7.8	.01
Blood Creatinine (μmol/L)	69.1 ± 18.4	62.0 ± 17.1	<.01
Pulmonary Hypertension	0(0%)	0(%)	NA
Congestive Heart Failure	2(0.8%)	9(1.5%)	.27
Current Smoke	18(7.1%)	42(7.0%)	.78
Diabetes	1(0.4%)	4(0.7%)	.95
Hypertension	2(0.8%)	14(2.3%)	.06
Hypercholesterolaemia	1(0.4%)	7(1.2%)	.05
Neurological Dysfunction	0(0%)	1(0.2%)	1.00
Peripheral Vascular Disease	0(0%)	1(0.2%)	1.00

Table 2. Patient Baseline Characteristics After Matching

Characteristics	Totally thoracoscopic (N = 254) No.(%) or Mean ± SD	Conventional open (N = 254) No.(%) or Mean ± SD	*P*
Male	122(48.0%)	121(47.6%)	.93
Age (years)	26.8 ± 14.0	27.3 ± 14.2	.74
Weight (kg)	52.9 ± 16.9	51.9 ± 10.8	.47
Left Ventricular Ejection Fraction (%)	64.6 ± 6.7	64.0 ± 8.0	.37
Blood Creatinine (μmol/L)	69.1 ± 18.4	68.8 ± 17.3	.64
Pulmonary Hypertension	0(0%)	0(0%)	NA
Congestive Heart Failure	2(0.8%)	6(2.4%)	.18
Current Smoke	18(7.1%)	22(8.7%)	.51
Diabetes	1(0.4%)	1(0.4%)	.99
Hypertension	2(0.8%)	8(3.1%)	.11
Hypercholesterolaemia	1(0.4%)	3(1.2%)	.37
Neurological Dysfunction	0(0%)	1(0.4%)	1.00
Peripheral Vascular Disease	0(0%)	0(0%)	NA

score that reflects the probability of receiving the totally thoracoscopic procedure, conditional on the same covariates. We then matched each patient in the conventional open group with those in the totally thoracoscopic group with an estimated logit within 0.2 SDs of the selected patient undergoing conventional open operation (one-to-one nearest neighbor matching).

RESULTS

Two hundred fifty-four patients with isolated ASD who underwent totally thoracoscopic surgery were enrolled and matched with a group of 254 patients undergoing conventional open surgery. Table 1 demonstrates the unbalanced baseline characteristics of the two different groups of patients with isolated ASD, before PSM. Table 2 demonstrates the similar baseline characteristics of the two different groups of patients with isolated ASD after matching. The gender (male 48.0% versus 47.6%), age (26.8 ± 14.0 years versus 27.3 ± 14.2 years), and weight (52.9 ± 16.9 kg versus 51.9 ± 10.8 kg) of patients showed no significant difference between the two groups. Comorbidities, including left ventricular ejection fraction (64.6 ± 6.7% versus 64.0 ± 8.0%), blood creatinine (69.1 ± 18.4 μmol/L versus 68.8 ± 17.3 μmol/L), hypertension (0.8% versus 3.1%), smoking status (7.1% versus 8.7%), and hypercholesterolaemia (0.4% versus 1.2%) also were similar between the two groups.

For patients with isolated ASD, the totally thoracoscopic surgery required longer aortic clamp time (32.1 ± 17.3 minutes versus 28.3 ± 16.7 minutes, $P = .01$); shorter length of stay in the intensive care unit (25.3 ± 12.2 hours versus 34.8 ± 24.4 hours, $P = .001$); shorter hospital stay (16.5 ± 6.3 days versus 17.9 ± 6.4 days, $P = .008$); and shorter mechanical ventilation time (8.3 ± 5.0 hours versus 11.4 ± 14.8 hours, $P = .04$). CPB time (62.7 ± 29.3 minutes versus 61.5 ± 28.0 minutes) showed no significant difference between the two groups. The totally thoracoscopic group had statistically significant less chest tube drainage (322.1 ± 213.7 mL versus 462.8 ± 398.4 mL, $P = .001$). The intraoperative (35.4% versus 38.6%) and postoperative blood products usages (20.9% versus 21.3%) showed no significant difference between the groups (Table 3).

The results of the major in-hospital complication indicated there was no significant difference between the two groups on mortality (0% versus 0%, NA), reoperation (0.4% versus 0.4%, NA), stroke (0% versus 0%, P = NA), multi-organ failure (0% versus 0%, NA), reintubation (0% versus 0.8%, $P = .499$), and renal failure (0% versus 0.8%, $P = .499$) (Table 4).

DISCUSSION

ASD is one of the most common congenital heart diseases worldwide, with an incidence rate of 6%-10% [Murphy 1990]. Conventional surgical approach for ASD repair has proven to be an excellent option with a low morbidity and mortality since the 1950s. However, surgical trauma and unaesthetic incision brought psychological and physiological suffering to patients undergoing conventional median sternotomy [Hongxin 2007]. Since the development of minimally invasive techniques, transcatheter closure of ASDs gradually has become an effective alternative to surgical treatment [Vistarini 2010; Du 2002]. Unfortunately, the

Table 3. In-Hospital Outcomes

Outcome	Totally thoracoscopic (N = 254) No.(%) or Mean ± SD	Conventional open (N = 254) No.(%) or Mean ± SD	*P*
Bypass time (minutes)	62.7 ± 29.3	61.5 ± 28.0	.636
Aortic-clamp time (minutes)	32.1 ± 17.3	28.3 ± 16.7	.009
Length of ICU Stay (hours)	25.3 ± 12.2	34.8 ± 24.4	.001
Length of Hospital Stay (days)	6.5 ± 6.3	7.9 ± 6.4	.008
Mechanical Ventilation Time (hours)	8.3 ± 5.0	11.4 ± 14.8	.037
Intraoperative Blood Product Usage	90(35.4%)	98(38.6%)	.458
Postoperative Blood Product Usage	53(20.9%)	54(21.3%)	.908
Postoperative Drainage(mL)	322.1 ± 213.7	462.8 ± 398.4	.001

Table 4. In-Hospital Complications

Complication	Totally thoracoscopic (N = 254) No. (%)	Conventional open (N = 254) No.(%)	*P*
Mortality	0(0)	0(0)	NA
Reoperation	1(0.4%)	1(0.4%)	NA
Stroke	0(0)	0(0)	NA
Multi-Organ Failure	0(0)	0(0)	NA
Reintubation	0(0)	2(0.8%)	.499
Renal failure	0(0)	2(0.8%)	.499

transcatheter approach is not suitable for all types of defects and has resulted in increased reoperation and postoperative complications for patients with complex defects [Casselman 2005]. The complication rate varies from 0.1% to 4% for various closure devices [Hongxin 2007], a rate which may be higher in China. Meanwhile, the costs of the catheter-based closure are much higher than surgery in third world nations [Hongxin 2007]. Therefore, the potential number of patients unable to receive a transcatheter approach is substantially large in China. The thoracoscopic technique offers a reliable and safe supplement for transcatheter approach and is appropriate for multiple types of ASD. Previous studies have demonstrated the feasibility and effectiveness of thoracoscopic ASD closure when percutaneous ASD closure is impossible or has failed [Hongxin 2007]. Compared with conventional median sternotomy or small incision surgery, this thoracoscopic technique exhibits similar results, but with an improved cosmetic appearance, shorter rehabilitation period, less pain, and decreased hospital cost [Argenziano 2003; Casselman 2005]. Modi and colleagues compared totally thoracoscopic surgery with the conventional open approach for mitral valve treatment. Some previous single-center and limited-sample studies indicated that totally thoracoscopic surgery, without a robotically assisted surgical system, was a technically attainable, safe and reliable therapeutic option for treatment of ASDs [Wang 2011; Ma 2011]. Ma reported 40 patients with isolated ASD who underwent totally thoracoscopic operation without robotic assistance. The reports indicated that after a short-duration learning curve, the procedure could be handled proficiently and the results were encouraging compared with conventional open approach [Ma 2011]. Wang reported 28 small children with ASD who underwent totally thoracoscopic surgery. The reported cases were the youngest patients undergoing totally thoracoscopic ASD closure in China [Wang 2011]. However, though many studies have indicated totally thoracoscopic operation for ASD closure is safe and feasible, whether this method was superior to the conventional open way remains to be determined. Few studies have compared conventional open surgery and thoracoscopic operation for treatment of ASD. This study reports on the largest amount of cases of totally thoracoscopic surgery without robotic assistance for isolated ASD closure based on a national multi-centered data set and compared with conventional median sternotomy surgery through PSM to date.

In this study, the totally thoracoscopic approach for ASD treatment required longer aortic clamp time, but there was no significant difference in CPB time between the two groups. In addition, the length of hospital stay, cumulative intensive care unit stays, and postoperative mechanical ventilation time decreased significantly in the totally thoracoscopic group. Also, the patients in the totally thoracoscopic group recovered faster postoperatively than their open group counterparts. Similarly, the total volume of the postoperative chest tube drainage was less in the totally thoracoscopic group than the open group. Our study indicated the intraoperative and postoperative blood products usage showed no significant difference between the groups. Additionally, we found no statistically significant difference in mortality, reoperation, stroke, renal failure, or reintubation between the totally thoracoscopic group and open group during the study period. However, midterm and long-term follow-up time, and larger sample sizes are warranted for validation of these findings.

Robotic devices have been regarded as an essential element of the totally thoracoscopic approach for ASD repair, due to the ability to assist complex manipulation. The robotic system is purported to enhance surgical flexibility and accuracy, an idea that has led to the application of this approach for totally thoracoscopic procedures in some countries. However, given the high cost and intensive training demand of robotic manipulation, totally thoracoscopic techniques with a robotic system were not suitable for a developing country like China. Compared with robotic technology, totally thoracoscopic cardiac surgery without robotic assistance provides the advantage of minimal trauma and lightens the heavy burden of the high medical costs for patients. For surgeons, it shortens the duration of the learning curve and lessens the manipulation difficulty. For the hospital, it reduces the large initial capital investment for the device and its accessories.

LIMITATIONS

This study was not a randomized clinical trial, so there was an element of patient selection bias. To minimize this, we closely matched patients' baseline characteristics between those undergoing totally thoracoscopic ASD repair with those undergoing conventional open surgery for ASD, during the same period. Also, we compared only the early in-hospital outcome between the two groups. However, midterm and long-term follow-up outcomes were unreported. Thus, follow-up outcomes should be further investigated to ensure the safety and effectiveness of this procedure.

CONCLUSION

This study indicates the early outcomes in totally thoracoscopic procedure without robotic assistance for treatment of isolated ASD are similar to the conventional open operation performed through median sternotomy. However, mid- and long-term follow-up is necessary, and randomized studies comparing the totally thoracoscopic technique with conventional open approaches are still warranted.

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