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Experience on the Way to Totally Endoscopic Atrial Septal Defect Repair

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ABSTRACT

Background: Remote-access perfusion and robotics have enabled totally endoscopic closure of atrial septal defect (ASD) and patent foramen ovale (PFO). We report on a stepwise approach to a totally endoscopic procedure.

Methods: Seventeen patients (median age, 39 years; range, 21-55 years) underwent limited-access ASD or PFO closure. As a preparative step, the operation was carried out through minithoracotomy in 11 patients. In parallel, experience with robotic surgery was gained with totally endoscopic coronary artery bypass grafting procedures. After performance of ASD closures in dry-laboratory models using the da Vinci telemanipulation system, 6 patients were operated on in a totally endoscopic fashion.

Results: With the endoscopic approach, significant learning curves were noted for cardiopulmonary bypass time $y(\min) = 226 - 41 * \ln(x)$ ($P = .03$) and aortic cross-clamp time $y(\min) = 134 - 42 * \ln(x)$ ($P = .01$) (x = number of procedures). There was no hospital mortality, and no residual shunts were detected at postoperative echocardiography. Median ventilation time was 9 hours (range, 0-18 hours) for the minithoracotomy group and 6 hours (range, 4-19 hours) for the totally endoscopic group. Median intensive care unit stay was 20 hours (range, 18-24 hours) and 18 hours (range, 18-120 hours), respectively.

Conclusions: The implementation of robotic totally endoscopic closure of ASD or PFO in a heart surgery program seems to be safe. An intermediate step of performing the operations through minithoracotomy, adapting to remote access perfusion systems, and gaining experience in other robotic cardiac surgical procedures seems worthwhile. Learning curves are apparent, and adequate defect closure does not seem to be compromised by the totally endoscopic approach.

INTRODUCTION

For more than 4 decades surgical closure in patients with atrial septal defect (ASD) or persistent foramen ovale has been performed through conventional sternotomy with low morbidity, almost 0% mortality and less than 1% residual ASDs [Murphy 1990, Horvath 1992]. However, this standard procedure has been associated with pain and discomfort, a sternotomy scar, and occasionally with deep sternal wound infection. Although more and more ASDs are detected and repaired early in life, and despite the success of catheter-based intervention, a considerable number of older children and young adults, the majority of whom are young female patients, present with an indication for surgical ASD closure. For those patients a short hospital stay, a short rehabilitation phase, and a small surgical scar are matters of importance.

After the introduction of catheter-based intervention, ASD closure became highly attractive to patients [King 1976]. However, not all patients who need ASD closure are appropriate candidates. Position, complexity, and size of the defect limit the method [Hijazi 1999, Rao 2000].

ASD closure via mini-thoracotomy is considered a major step toward development of minimally invasive techniques in the surgical field. The procedure can be performed with excellent results in almost all patients [Doll 2003, Ryan 2003]. Although the cosmetic result has been tremendously improved, pain considerations remain significant, largely owing to division and retraction of intercostal muscles and ribs.

Initial attempts to perform simple cardiac operations endoscopically through small ports have been hindered by the absence of the appropriate accessory technology. Robotic telemanipulation has emerged as a potential facilitator of totally endoscopic surgical procedures [Carpentier 1998]. Robotic systems recently have allowed performance of totally endoscopic operations such as coronary artery bypass grafting on arrested [Dogan 2002] and beating hearts [Boehm 2000], epicardial lead placement for biventricular synchronization [DeRose 2003], and ASD closure.

Totally endoscopic ASD repair (TEASD-R) has so far been reported by only a few groups for small numbers of patients [Toracca 2001, Argenziano 2003, Wimmer-Greinecker 2003]. As with any new technique in surgery, learning curves are involved with new operations, and economical ways to minimize the learning curve effects would be desirable for groups initiating robotic heart surgery programs. It seems likely that several groups will start performing robotically assisted surgery in the near future to provide ASD patients an attractive therapeutic option. Because TEASD-R is a technically and logistically demanding procedure, communication of learning curve experience is a critical issue within the cardiac surgery community.

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Table 1. Patients and Methods*

	All Patients	Minithoracotomy	TEASD-R
Age, median (range), y	38 (21-55)	38 (21-54)	44 (26-55)
Diagnosis, n			
Atrial septal defect	13	8	5
Patent foramen ovale	3	2	1
Atrial septal aneurysm	1	1	0
Closure technique, n			
Direct closure	13	8	5
Patch closure	4	3	1

*TEASD-R indicates totally endoscopic atrial septal defect repair.

The aim of this study was to describe the development of our own program toward reproducible performance of TEASD-R and to evaluate the major learning curves during a stepwise approach.

MATERIALS AND METHODS

Patients

Between January 2001 and January 2004, 17 consecutive minimally invasive ASD closure operations were performed. The first 11 patients were operated on via right minithoracotomy, and the last 6 procedures were performed in a totally endoscopic fashion with the da Vinci telemanipulation system (Intuitive Surgical, Sunnyvale, CA, USA). Patient demographics and indications for the procedure are shown in Table 1. The indication was defect closure in patients with a secundum type ASD with a Qp/Qs ratio >1.5 or patent foramen ovale with a documented neurologic event. Patients were excluded if they were expected not to tolerate single-lung ventilation or peripheral cardiopulmonary bypass (CPB) or were otherwise considered poor candidates for a thoracoscopic approach. Signed informed consent was obtained from all patients. The telemanipulation system was purchased and used as an interdisciplinary device shared with the departments of urology, general surgery, and gynecology.

Anesthesia

After induction of general anesthesia, a double-lumen endotracheal tube was positioned to allow single-lung ventilation and right lung collapse. Transesophageal echocardiography and bilateral radial arterial pressure monitoring were performed in all patients to monitor remote access perfusion and endoaortic balloon positioning. Percutaneous defibrillator patches were also used in all cases.

The following stepwise approach was undertaken toward performance of totally endoscopic ASD closure. The procedures performed during development of the program are listed in Figure 1.

Step 1: ASD Closure via Mini–Right Thoracotomy

During induction of anesthesia, a guide wire was placed in the superior vena cava through the right internal jugular vein to allow later cannulation of the superior vena cava. The patient was positioned in a 30-degree left lateral decubitus position with the right arm tucked at the side and the pelvis relatively flat to facilitate femoral cannulation. After sterile preparation and draping, the patient was systemically heparinized and a 17F cannula (Biomedicus; Medtronic, Eden Prairie, MN, USA) was percutaneously inserted into the superior vena cava under echocardiographic guidance. In parallel, the femoral vessels were accessed through an oblique incision along the inguinal crease. The inferior vena cava was cannulated with a 23F or 25F venous return cannula (96370 Biomedicus; Medtronic), which was inserted through the right femoral vein. The bypass circuit was completed by cannulating the common femoral artery with a 17F or 21F remote access perfusion (RAP) cannula with endoaortic balloon (Estech, Danville, CA, USA). The distal tip of the arterial cannula was passed under echocardiographic guidance into the ascending aorta, approximately 1 cm from the aortic valve. In 1 minithoracotomy case it was impossible to insert

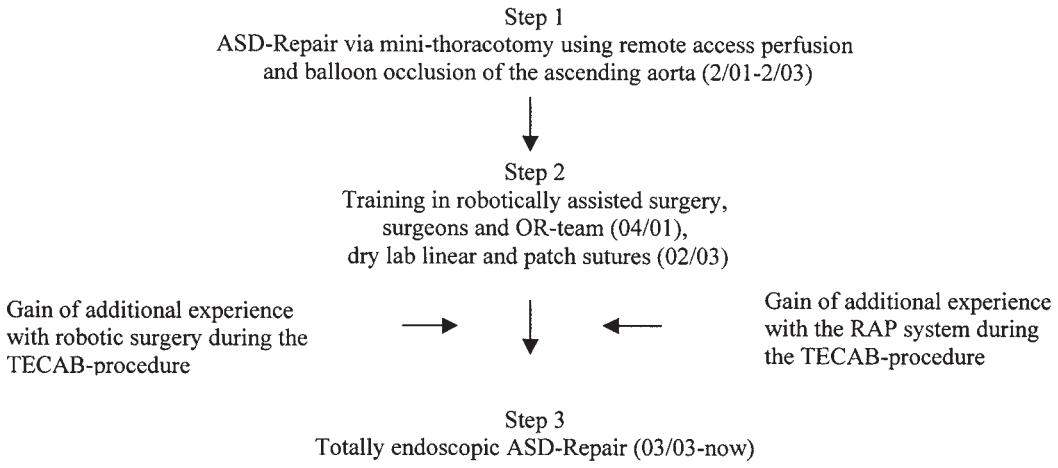

Figure 1. Stepwise approach to totally endoscopic atrial septal defect (ASD) repair. OR indicates operating room; TECAB, totally endoscopic coronary artery bypass; RAP, remote access perfusion.

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Table 2. Clinical Outcome*

	Minithoracotomy	TEASD-R
Total operating time, median (range), min	295 (210-405)	342 (292-590)
Bypass time, median (range), min	132 (86-234)	185 (128-239)
Cross-clamp time, median (range), min	58 (35-103)	93 (46-133)
ICU stay, median (range), h	20 (15-24)	19 (15-120)
Intubation time, median (range), h	9 (0-18)	6 (5-19)
Hospital-stay, median (range), d	7 (5-12)	8 (6-14)
30-day mortality, n	0	0
Conversions, n	0	0
Revisions for bleeding, n	0	0
Perioperative neurologic events, n	0	0
Residual ASD (repaired on table), n	1	0

*TEASD-R indicates totally endoscopic atrial septal defect (ASD) repair; ICU, intensive care unit.

both arterial pressure monitoring lines in both radial arteries. In this case a Chitwood transthoracic aortic clamp was used to clamp the ascending aorta, and cardioplegic solution was injected by needle into the aortic root.

Thoracic surgical access was gained using a right minithoracotomy through the fourth intercostal space. Exposure was acquired with a soft-tissue retractor and 2 or 3 pericardial stay sutures. Standard endoscopic instruments, snares, and carbon dioxide flushing were used to optimize surgical accessibility.

Step 2: Dry-Laboratory Training

As a second step toward totally endoscopic ASD closure, we used the da Vinci telemanipulator system in dry-laboratory training. The console surgeon (J.B.) performed 10 linear and 5 patch sutures on holes created in a plastic surface using 4/0 Gore-Tex suture (W. L. Gore, Flagstaff, AR, USA). During these procedures the patient-side surgeons practiced dry-laboratory endoscopic assistance using long surgical instruments.

Step 3: Totally Endoscopic ASD Closure

Preoperative preparation, anesthesia management, and establishment of CPB were carried out as described above. After establishment of selective left lung ventilation, a port incision was made in the fourth intercostal space in the midclavicular line, and a 12-mm endoscopic trocar was placed into the right pleural space. The endoscopic camera was inserted, and the pleural space was insufflated with carbon dioxide to a maximum pressure of 8 mm Hg. Two additional 8-mm port incisions were made in the third and sixth intercostal spaces in the anterior axillary line. The robotic telemanipulator surgical cart was positioned at the left side of the operating table, and the robotic instruments were inserted into the pleural space. For transthoracic assistance and suction, a fourth (9 mm) and in 3 cases a fifth (7 mm) port incision were made in the fifth and the fourth intercostal spaces in the posterior axillary line.

The console surgeon began the intrathoracic part of the operation by controlling the robotic camera and surgical instrument arms. After pericardiotomy and placement of pericardial stay sutures, caval snares were placed with a special long Endoflex clamp for placing loops around the superior and inferior venae cavae (Video 1 online). After initiation of CPB and cooling to 32°C, the endoaortic balloon was insufflated under echocardiographic control, and cardiac arrest was achieved by delivery of an initial dose of adenosine (3 mg/20 mL saline) and cold cardioplegic solution. After the superior and inferior venae cavae were snared, the right atrium was opened (Video 2 online), and the margins of the incision were sutured to the pericardium for proper exposure of the defect in the interatrial septum (Video 3 online). Cardiotomy suction was passed through the posterior assistance port by the patient-side surgeon. Anatomic landmarks, including the fossa ovalis, coronary sinus ostium, and eustachian valve, were identified. According to the size of the defect, either a double-layer 4/0 Gore-Tex running suture (Video 4 online) or a Dacron patch (Video 5 online) was used. The endoaortic balloon was deflated, and the patient was rewarmed. The atriotomy was closed with 2 layers of running 4/0 Gore-Tex suture (Video 6 online), and the patient was weaned from CPB. The integrity of the atrial septal closure was confirmed by transesophageal echocardiography, and protamine was administered. After adequate hemostasis was achieved, the robotic arms were removed from the chest, and a 24F chest tube was inserted in the right pleura.

Postoperative Management

All patients were transported to the intensive care unit and after extubation were transferred to the intermediate care unit. Chest drains were removed when drainage was less than 100 mL/24 hours. Anticoagulants were administered only to patients with specific indications, such as atrial fibrillation. Postoperative control transesophageal echocardiography was performed in all patients before discharge.

Statistical Analysis

Statistical calculations were performed with SPSS 11.0 statistical software (SPSS, Chicago, IL, USA). Continuous variables are given as median and range; categorical variables are given as absolute values. For calculation of learning curves, regression models with logarithmic curve fit were applied. Statistical significance was anticipated at $P < .05$.

RESULTS

We experienced no major technical failures attributed to the telemanipulator. There was no mortality and no serious surgical complication in the series of patients included in the study. Total operative time, CPB time, and aortic cross-clamp time were in an acceptable range. Durations of aortic occlusion, CPB perfusion, and total operation time were higher in the TEASD-R group (Table 2). We observed no statistically significant reduction in operative times in patients operated on via minithoracotomy (Figure 2). However, statistically significant learning curves were found in patients in the endoscopic group with regard to CPB time and aortic occlusion time (Figure 3).

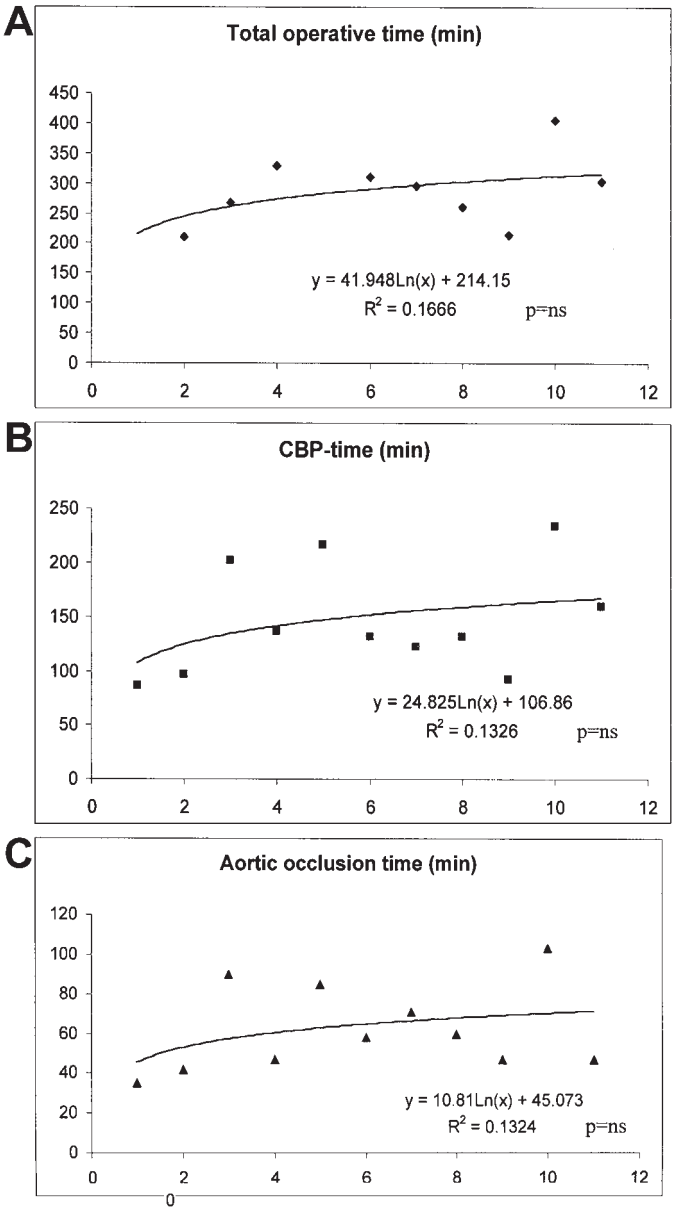

Figure 2. Operating times for the atrial septal defect repair procedure via minithoracotomy. A, Total operative time. B, Cardiopulmonary bypass (CPB) time. C, Aortic occlusion time. NS indicates not significant.

In 1 patient in the minithoracotomy group, a residual ASD was detected with intraoperative transesophageal echocardiography, and this defect was closed with an additional suture. In another case the primary incision was enlarged for surgical repair of the bleeding source at the superior vena cava. In the TEASD-R group, there was no need for conversion to enlarged thoracotomy or median sternotomy, and all procedures were completed endoscopically. No surgical revisions for bleeding or residual ASD were performed. The postoperative course was uneventful in all patients except for a 45-year-old woman with history of obstructive lung disease, who developed respiratory failure after extubation. This patient needed prolonged respiratory therapy with continuous positive airway pressure but did not need reintubation. All other patients returned to the general ward on the first postoperative day. They were discharged home approximately 1 week after the operation.

All patients underwent postoperative control transesophageal echocardiography before discharge in addition to the study performed intraoperatively. In all patients an excellent postoperative result was observed without residual ASD.

The postoperative cosmetic result was judged excellent by all patients (Figure 4).

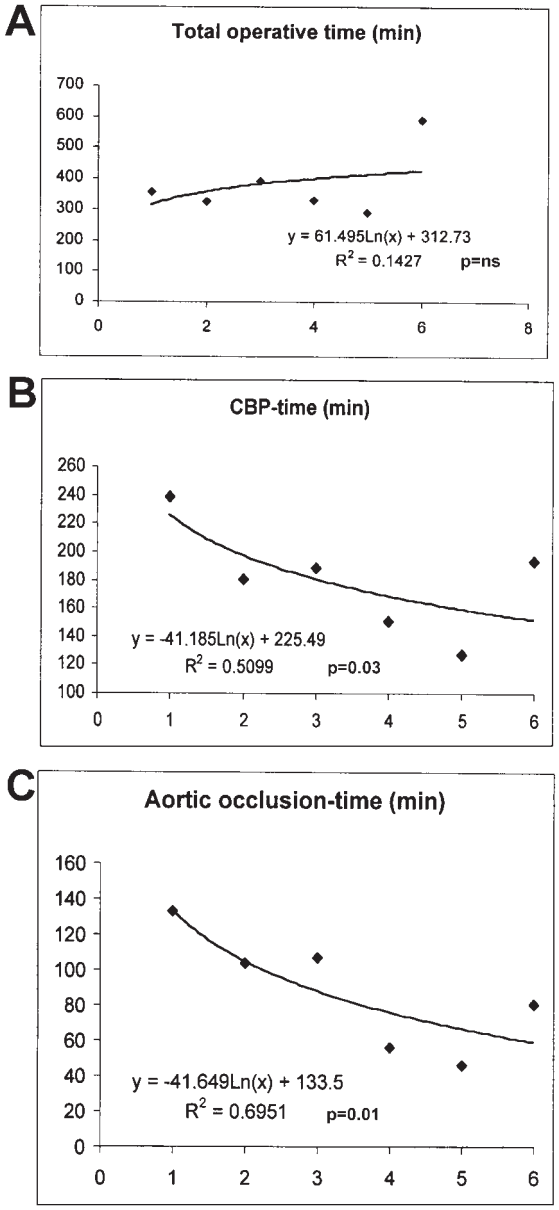

Figure 3. Operating times for the totally endoscopic atrial septal defect repair. A, Total operative time. B, Cardiopulmonary bypass (CPB) time. C, Aortic occlusion time. NS indicates not significant.

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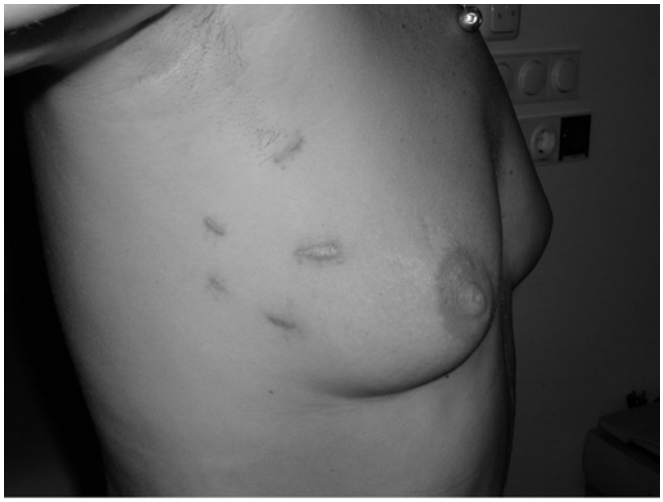

Figure 4. Cosmetic postoperative result 3 months after totally endoscopic atrial septal defect repair.

DISCUSSION

Various minimal access incisions have been described for ASD closure. These incisions allow the surgeon to use familiar exposures, cannulas, and instruments. Whether parasternal upper partial sternotomy, lower partial sternotomy, or midsternotomy is performed, these incisions all leave obvious scars, which may have a negative influence on the psychology and quality of life of young adult patients. Furthermore, none of these approaches has demonstrated striking advantage over conventional sternotomy in regard to pain management, pulmonary physiology, or hospital stay [Bichell 2000].

The introduction of robotic technology and refined remote access CPB has enabled a totally endoscopic approach to ASD repair via small thoracic holes. Because of the small number of TEASD-R operations reported worldwide, we should be cautious in drawing conclusions with regard to the efficacy of the method. However, on the basis of the attractiveness of the technique for surgeons and referring cardiologists and because young adult patients appreciate an endoscopic procedure, we believe that installation of a TEASD-R program is worthwhile.

It has been emphasized that introduction of innovative methods should be guided by strict patient selection, especially in cases in which learning curves are inevitable [Novick 1999]. As demonstrated by the demographic data, we chose low-risk patients with few comorbid conditions to keep reserves should unexpected intraoperative problems occur. Transesophageal contrast echocardiography was routinely performed on all patients prior to the operation for evaluation of the size and position of the defect and to exclude accompanying congenital defects. Patients with sinus venosus defects or superior vena caval anomalies were not eligible for TEASD-R. However, unlike Argenziano et al [2003] and Toracca et al [2001], we did not decline including patients with large or multiple ASDs necessitating patch closure.

The use of RAP requires additional patient selection modalities because of its complexity and the extent of potential complications. For those reasons all patients underwent preoperative computer tomography. With the scans, the following parameters were determined: size of the ascending aorta for adequate positioning of the endoaortic occlusion balloon, size of the femoral arteries for adequate match of the arterial RAP cannula, and presence of atherosclerotic changes or other arterial pathology in the aorta and the iliofemoral arteries.

Because of the complexity of the procedure, we decided to use a stepwise approach to TEASD-R whereby we split the procedure into several modules. We started with ASD closure via minithoracotomy to gain experience with remote-access CPB and thoracoscopic cardiac procedures. In parallel we organized and successfully used a similar stepwise approach to totally endoscopic coronary artery bypass surgery on the arrested heart [Bonatti 2004] to familiarize ourselves with the use of telemanipulation and robotically assisted surgery. The last step was to combine the experience gathered from both procedures and to perform TEASD-R after extensive dry-laboratory training. That no significant learning curve was observed for the minithoracotomy group can probably be explained by the fact that our group has accumulated surgical experience with endoscopic manipulations during other limited-access procedures.

In the robotic totally endoscopic procedures, we found statistically significant learning curves with regard to CPB time and aortic occlusion time. Both learning curves were steep because only the technique of direct or patch ASD closure was practiced during the dry-laboratory training, whereas establishment of total CPB, robotically assisted ASD exposure, and atrial closure were performed for the first time in the clinical operating room setting. The learning curves can be explained in part by the fact that in the first two patients the atriotomy was closed during cardioplegic arrest, whereas it was closed on the beating heart after aortic endoocclusion balloon deflation in the other patients.

No significant reduction of the overall duration of the procedure was noted. After our implementation phase we can state that minithoracotomy ASD repair can be performed in approximately 5 hours and that the totally endoscopic approach takes approximately 45 additional minutes. Our operative times were comparable in part with those described by other groups with regard to CPB and aortic occlusion time. In the hands of the Milan group the procedure was performed with 102 minutes of CPB time and 63 minutes of aortic endoocclusion time, but no patch closure was used [Toracca 2001]. Wimmer-Greinecker et al [2003] reported a total operating time of 262 minutes, CPB time of 161 minutes, and aortic endoocclusion time of 67 minutes in 7 patients who underwent direct TEASD-R and 1 patient who underwent patch TEASD-R. Argenziano et al [2003] reported significantly shorter operating times with a median CPB time of 122 minutes and an aortic endoocclusion time of 32 minutes. As of this writing Argenziano et al have the most extensive experience with this procedure.

Because a conventional ASD repair operation can be performed with almost zero mortality and morbidity, we must offer candidates for TEASD-R a surgical treatment that combines the advantages of endoscopic treatment with the safety

and success of conventional procedures. Despite learning curves [Chitwood 2001], we believe that our stepwise approach to TEASD-R allowed us to perform a complex procedure under development without major complications. Several cases of suture tear or insufficiency after minimally invasive procedures have been reported in the literature, one of them after TEASD-R [Argenziano 2003]. For this reason, to exclude postsurgical residual ASD in all our patients, we performed contrast echocardiography examination in addition to the study performed intraoperatively.

CONCLUSIONS

Our preliminary and learning curve experience with totally endoscopic ASD closure suggests that this procedure can be introduced with adequate safety if a stepwise approach is taken. Experience with other robotic totally endoscopic procedures, such as totally endoscopic coronary artery bypass, may enhance the implementation process. Long operative times do not seem to translate into significant clinical problems, and proper ASD closure is not compromised by the totally endoscopic approach.

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