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Long-Term Follow-Up of Minimally Invasive Cardiac Surgery Using an Endoaortic Occlusion System

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ABSTRACT

Objectives: We reviewed the initial patient series (n=116) of our institution performing minimally invasive coronary artery bypass grafting (CABG) (n=79), mitral valve surgery (n=1), or atrial septal closure (ASD) procedures (n=26) using an endoaortic occlusion system. With this technique relevant intra-aortic pressures are exerted on the aortic wall during the clamping time. This might lead to late aortic degeneration and aneurysm formation. Our study sought to evaluate postoperative aortic complications and the quality of life (modified SF-12).

Methods: One hundred sixteen patients (56% male; 54 years ± 14.5; range 19 years to 77 years) underwent a cardiac procedure using an endoaortic clamp. The endoaortic balloon clamp catheter was used to occlude the ascending aorta at pressures >300 mmHg. Patients were rescheduled for echocardiographic examination after a mean follow-up period of 8.8 years.

Results: The analysis performed among 78 patients showed no incidence of any structural damage to the ascending aorta at the intraoperative position of the endoaortic balloon. The physical and mental summary scores are equal to those of comparable patient groups.

Conclusions: The endoaortic occlusion system causes no damage to the aortic wall. If the system causes any problems, they occur immediately during surgery. Patients treated with this minimally invasive technique exhibited the same quality of life as those undergoing conventional surgery.

INTRODUCTION

Since being introduced in the late 1990s, minimally invasive cardiac surgery now covers a wide range of surgical therapy [Schachner 2004]. It offers the advantages of less surgical trauma, shorter inpatient stays, reduced pain, and better cosmetic results [Schachner 2004; Yozu 2002]. When these new surgical techniques were first implemented, new instruments and products played a primary role by ensuring that surgical safety and quality were on par with that of conventional heart surgery. One of these methods and techniques is the Heartport Port Access System (Edwards Lifesciences Corporation, Irvine, Calif., USA), the name of which has changed as a reflection of multiple corporate takeovers [Viganó 2000]. This technology makes CABG, mitral valve interventions, or ASD closures possible as surgical procedures [Loforte 2010; Vistarini 2010; Dogan 2002]. A cardiopulmonary bypass can be established through femoral cannulation and the use of an intra-aortic balloon clamp [Chan 2012]. The heart is arrested by using an endoaortic clamp and antegrade cardioplegia administration [Fann 1997]. However, several authors have pointed out several pitfalls of this system [Hesselvik 1999; Krapf 2013; Wimmer-Greinecker 1999]. The most deleterious complication, which led to a serious adverse outcome, was a retrograde ascending dissection [Krapf 2013; Wimmer-Greinecker 1999]. Moreover, myocardial protection may be suboptimal due to balloon dislocation or rupture. The placement of the balloon is complex and expensive, requiring transesophageal echocardiography and entailing a lengthy learning curve [Schachner 2005]. The procedure can be performed only on select patients not exhibiting dilatation of the ascending aorta, peripheral vascular disease, moderate/severe aortic regurgitation, or arteriosclerosis [Ius 2009; Zingone 2006]. Between 1999 and 2005, this procedure was used at the University Hospital Frankfurt in Germany, before being abandoned due to a high rate of intraoperative complications. This study seeks to ascertain whether the use of an endoaortic occlusion system causes long-term damage to the ascending aorta in addition to intraoperative complications.

METHODS

From 1999 to 2005, cardiopulmonary bypass via port access system was performed on 116 patients. (55±14 years, 58% male). The surgical procedures performed included total endoscopic coronary artery bypass grafting (n=79), total endoscopic atrial septal defect closure (n=26), and minimally invasive mitral valve surgery (n=1). Surgeries were accomplished in most cases via port access using the Da Vinci telemanipulator (Intuitive Surgical, Sunnyvale, Calif., USA).

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SURGICAL TECHNIQUES

Anesthesia was induced with etomidate, sufentanil, and pancuronium and maintained with propofol and sufentanil. One-lung ventilation was used for the minimally invasive procedure. Surgeons used the surgical port access CABG technique described by Dogan et al [Dogan 2002], using the Heartport Port Access System for this procedure: "All patients underwent Doppler ultrasound of the femoral vessels before randomization to rule out relevant calcification of the femoral artery cannulation site. Duplex sonography was employed to detect potential stenoses of peripheral arteries. Transthoracic echocardiography was performed to evaluate the ascending aorta. Only after relevant peripheral and central vascular disease had been excluded, were patients then randomized for the study. Intraoperatively, the femoral artery and the thoracic aorta were reassessed by palpitation and transesophageal echocardiography (TEE), respectively. Prior to skin incision, a pulmonary vent and a coronary sinus catheter were introduced through the jugular vein and advanced into their proper position under echocardiographic guidance. With the patient under one-lung ventilation, the left internal thoracic artery (ITA) was dissected following a minithoracotomy approach in the fourth intercostal space. Meanwhile, the vein grafts were harvested. After dissection of the left groin, the femoral vessels were cannulated. A long venous drainage cannula was advanced into the right atrium. For the intra-arterial return, the left femoral artery was cannulated using open technique and a guide wire was advanced into the descending aorta. The distal femoral artery was occluded during CPB. After onset of CPB, the endoaortic balloon clamp was guided into the ascending aorta. All intravascular maneuvers were performed under echocardiographic control. Proximal anastomoses were performed first through the minithoracotomy incision on the beating but decompressed heart after partial clamping of the aorta [Aybek 2000; Grossi 2012]. The intra-aortic balloon was then insufflated, and antegrade as well as retrograde cold blood cardioplegia was administered. Distal anastomoses were performed on the arrested heart by exposing the target anastomotic site with sponges. After weaning from CPB, the femoral cannulas were removed and the thoracotomy was closed. Before transfer to the intensive care unit (ICU), the ventilation tube was changed. Heparin (300 U/kg) was administered for systemic anticoagulation. CPB was instituted with a Jostra Quadrox capillary membrane oxygenator and tubing set (Jostra Medizintechnik AG, Hirrlingen, Germany). All patients were cooled to a rectal temperature of 32°C. For mitral valve surgery, an inverted T pericardiotomy just ventral to the right phrenic nerve and a left atriotomy was performed in the interatrial groove to expose the mitral valve. Core temperature was lowered to between 28°C and 30°C. De-airing was performed using a left atrial vent during the left atrial closure under increased pulmonary pressure and through the aortic root. This was continued during reperfusion and weaning. Carbon dioxide was insufflated into the chest cavity using a Veress needle at a rate of 2 L/min."

Post Operative Follow-Up

Follow-up was conducted in stages by letter, phone interview (medical history and quality of life (SF12), examination, and echocardiography (GE Vivid 7, USA). The mean duration of the follow up was 8.8±2.4 years. with interviews being completed for 68% of patients.

The SF-12 is an efficient, abbreviated version of the SF-36 Health Survey that uses 12 items from the complete survey selected based on experience with the SF-36. The SF-36 is a generic tool for measuring a patient's health-related quality of life. It was designed to assess the success of therapy by eliciting a subjective estimate of health-related quality of life by patient groups and facilitates comparisons to healthy populations.

STATISTICS

All numeric values are provided as mean ± standard deviation of means. All categorical values are presented in absolute numbers and percentages. Death and event-free survival were calculated using the Kaplan-Meier method (SPSS 21.0 IBM, USA). An interim analysis of 105 patients was presented during the ISMICS meeting in 2012.

RESULTS

The primary end point of post-operative damage to the ascending aorta resulting from the use of an endoaortic occlusion system was not detected in any patients. The follow-up transthoracic echocardiograms showed normal values for both the aortic trunk and ascending aorta (mean 3.1±0.33 cm, min 2.48 cm, max 4.31 cm). In the structured survey, none of the patients indicated that they had been hospitalized for new cases of aneurysm or had to undergo surgical intervention on the aorta.

After undergoing surgery with the endoaortic occlusion system, 9.6% of patients died within a mean observation period of 8.8 years. Each of the deceased patients had an underlying coronary disease. All of the patients who underwent surgery for an aortic septal defect survived (Figure 1).

The patients' quality of life was measured with the SF-12. The answers to the individual questions are summarized in the table. The physical summary scores show only a minimal impairment compared with the average healthy western population (Figure 2). Greater differences are seen in the mental summary scores. These differences are also expressed in the NYHA classification, with 85% of patients indicating NYHA class I and 15% NYHA class II.

Wound-healing complications following primary inpatient treatment appeared in the inguinal regions of two patients.

DISCUSSION

This large series involving patients with endoaortic occlusion system demonstrated the postoperative safety of the system. While there is no comparable data available, the use of this system must continue to be classified as critical. The majority of complications associated with this medical product did not occur in the postoperative period or in long-term follow up, but rather during surgery [Krapf 2013]. Some of

SF-12 questions with patients expressing frequency in terms of percentage after undergoing surgery with an endoaortic occlusion system

How much of the time during the past 4 weeks have you felt calm and peaceful?					
All of the time	Most of the time	A good bit	Some of the time	A little of the time	None of
1%	36%	15%	27%	15%	6%
How much of the time during the past 4 weeks did you have a lot of energy?					
All of the time	Most of the time	A good bit	Some of the time	A little of the time	None of
3%	43%	13%	24%	12%	5%
In general, health is:					
Excellent	Very good	Good	Fair	Poor	
3%	15%	57%	22%	3%	
How much of the time has your physical health or emotional problems interfered with your social activities?					
All of the time	Most of the time	Some of the time	A little of the time	None	
4%	5%	16%	22%	53%	
Does the pain interfere with your normal work (including both work outside the home and housework)?					
Not at all	A little bit	Moderately	Quite a bit	Extremely	
43%	12%	33%	0%	12%	
Does your health now limit you in these activities: Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? If so, how much?					
Yes, limited a lot	Yes, limited a little	No, not limited			
7%	31%	62%			
Does your health now limit you in these activities: Climbing several flights of stairs?					
Yes, limited a lot	Yes, limited a little	No, not limited			
19%	43%	37%			
Do you experience problems with your work or other regular daily activities as a result of your physical health?					
Yes	No				
25%	75%				
Were you limited in the kind of work or other activities?					
Yes	No				
26%	74%				
Problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?					
Yes	No				
16%	83%				
Did work or other activities less carefully than usual?					
Yes	No				
19%	81%				

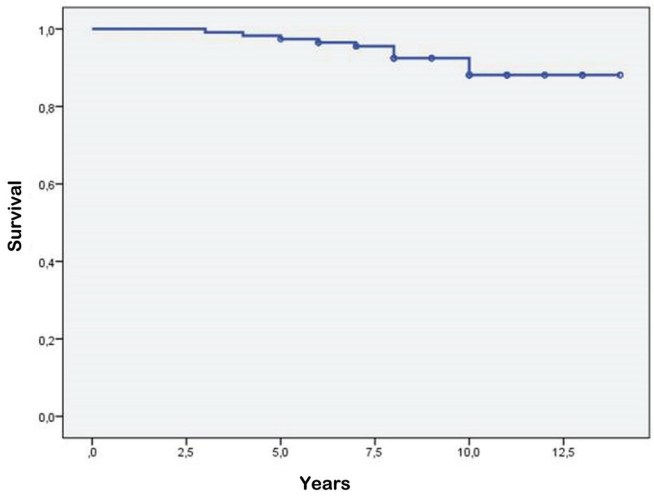

Figure 1. Kaplan-Meier survival curve of patients after minimal invasive cardiac procedure (TECAB, ASD) and the use of an endoaortic occlusion system.

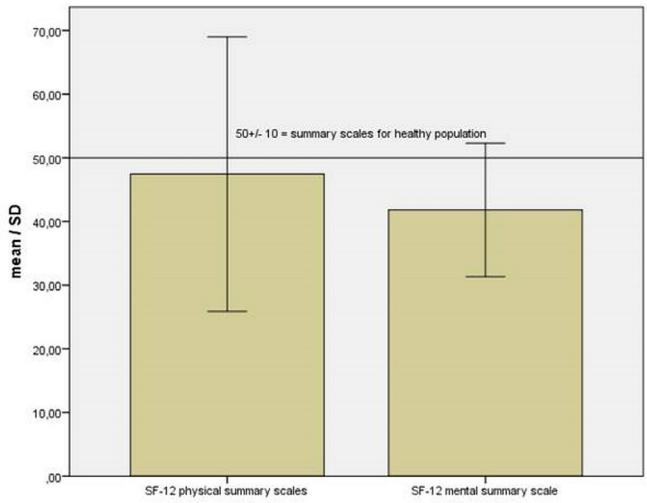

Figure 2. Mental and physical health summary scores for Quality of Life questionnaire SF12. Normal values for healthy populations are 50±10.

these complications were highly frequent or life-threatening. Wimmer-Greinecker et al reported complications, some of which were life-threatening, in a total of 50% of patients (n=39/78) [Wimmer-Greinecker 1999]. Given their fatal outcome, the incidence of intraoperative aortic dissections is among the most feared scenarios. A dissection can be caused either by retrograde arterial flow or a mechanical intima lesion. However, this would occur following balloon migration which is by far the most frequent complication when using an endoaortic occlusion system (30%) [Krapf 2013; Wimmer-Greinecker 1999]. We believe that this manipulation of the aortic wall is the most likely cause for mural damage to the aortic wall [Wimmer-Greinecker 1999]. A dissection is also described by Krapf, who conducted a series with n=307 patients focusing on the migration of the balloon during the perfusion [Krapf 2013]. In clinical practice, the endoaortic balloon catheter appears to have lost its significance. At many hospitals aortic clamping by means of external, flexible clamps has become standard procedure for mitral valve interventions [Aybek 2000; Grossi 2012]. Robot-assisted coronary revascularization is still available only at a handful of centers and is performed primarily on beating hearts [Bonatti 2012].

The data gathered from the SF-12 surveys is comparable to that of other studies with similar patient cohorts. Both the physical and mental summary scores are below those of the healthy normal population. Nevertheless, similar and comparable measured values are observed for patients following heart surgery or patients diagnosed with coronary artery disease [Sen 2012; Failde 2010].

The study has several limitations that put the conclusions thereof into perspective. The relatively low number of patients reached must be viewed critically. Despite intensive efforts, 32% of patients were not prepared to complete the survey or undergo an echocardiogram. The causes of death are unknown. In these cases, dissections may have occurred without our being notified.

Another point of criticism is the retrospective design of the study. At the time of their use, endoaortic occlusion catheters and cannula techniques were not subject to any standardized procedure and were performed by various surgeons. The manner of use had to be gathered from actual surgery reports.

SUMMARY

The endoaortic occlusion system causes no bilateral damage to the aortic wall. If the system causes any problems, they occur immediately during surgery. Patients treated with this minimally invasive technique exhibited the same quality of life as those undergoing conventional surgery.

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