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Early Experience with a New Aortic Clamping System Designed for Port Access Cardiac Surgery: The PortaClamp

Dr. de Cannière

Didier de Cannière, MD, PhD,[1] Mohammad Dindar, MD,[1] Constantin Stefanidis, MD,[1] Olivier Jegaden, MD,[2] Jean-Luc Jansens, MD[1]

[1]Department of Cardiac Surgery Hôpital Erasme, Brussels University, Brussels, Belgium; [2]Hôpital Cardiologique, Lyon, France

ABSTRACT

Background: We report a clinical study to demonstrate the feasibility and safety of a new aortic crossclamping concept for use in port access cardiac surgery. The limited access to the aorta in minimally invasive cardiac surgery mandates specific clamping modalities, which entail specific limitations, drawbacks, and costs. Therefore a new autoguided, extravascular, and atraumatic clamping system (PortaClamp) was developed to facilitate port access surgery while potentially avoiding the complications and costs inherent to endoluminal clamping or "blind" crossclamping.

Methods: Twenty patients underwent various cardiac operations under cardiopulmonary bypass and aortic crossclamping with the PortaClamp between February and September 2003. The method of aortic clamping is described and the operative course and clinical outcome of the patients are reported as surrogates of feasibility and safety.

Results: The average time to position the clamp was 196 ± 75 seconds. Crossclamping through a 10-mm port or incision was achieved successfully, enabling cardiac arrest throughout the procedure in every patient. No patient presented with cardiovascular accident or transient ischemic attack, aortic dissection, or hematoma. Intensive care unit times were 12 ± 3 hours; length of stay was 7.2 ± 1.1 days.

Conclusion: From this early experience we conclude that the PortaClamp system is safe and can effectively be used to crossclamp the aorta inexpensively to facilitate port access cardiac surgery. Further comparative studies with the existing systems are warranted to confirm that the atraumatic design provides further benefit.

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Address correspondence and reprint requests to: D. de Cannière, MD, PhD, Department of Cardiac Surgery, Erasme University Hospital, 808, Route de Lennik, 1070 Brussels, Belgium; 32-2-555-3817; fax: 32-2-555-6652 (e-mail: didier.decanniere@ulb.ac.be).

INTRODUCTION

Despite increasing evidence that port access surgery is a beneficial option in numerous indications [Casselman 2003], its rate of adoption remains low in the surgical community. This situation has multiple causes.

First, most of the operations can be performed with satisfactory results through sternotomies. It is difficult to demonstrate much incremental added value to the existing mature and efficient procedures, such that the benefits of port access are regarded by some surgeons as marginal or insufficient to change their practice in the absence of large-scale randomized studies.

Second, cardiopulmonary bypass and cardiac arrest themselves require experience and carry inherent risks and costs [Wimmer-Greinecker 1999] in the port access environment. Thus the additional investment in time and energy in the development of the skills required by the port access technique itself for a given intervention (eg, mitral repair, atrial-septal defect closure) is regarded by many as a step back. If femoral cannulation can easily be performed, aortic crossclamping and cardioplegia delivery are made awkward by the limited access to the ascending aorta.

These disadvantages have led to the design of purpose-built devices. Aortic clamping is performed either with an endovascular balloon (Endoclamp Cardiovations; Ethicon, Cornelia, GA, USA or Remote Access Perfusion cannula; Estech, Danville, CA, USA) or with the Chitwood clamp (Scanlan International, St. Paul, MN, USA) [Aybeck 2000]. The endovascular balloons necessitate continuous monitoring, may generate specific life-threatening complications, and are associated with a significant increase in operative cost [Wimmer-Greinecker 1999]. The Chitwood clamp represents a cost-effective and readily available alternative but requires a remote and partially blind maneuver to crossclamp the aorta, a procedure that carries the risk of injuring a cardiac structure without direct access to bail out. Because of these drawbacks, an alternative clamping system has been designed to enable safe, easy, and steady extraluminal crossclamping of the aorta with the objective of avoiding the specific difficulties and risks of the existing systems. Here we describe the PortaClamp and report our early clinical experience with this device.

METHODS

Between February and September 2003, 20 patients underwent various cardiac procedures on cardiopulmonary bypass with aortic crossclamping and cardioplegia (Table). We report the surgical procedure, operative times, and patient outcomes. All patients provided written informed consent in concordance with a protocol approved by the ethics committee of Erasme Hospital at Brussels University.

Surgical Procedures

With the patient under general anesthesia with transesophageal echocardiography (TEE) monitoring, a sternotomy (n = 4), ministernotomy (n = 3), or right anterolateral minithoracotomy (n = 13) is performed and cardiopulmonary bypass instituted either centrally or peripherally. A 5-mm port (Thoracoport, US Surgical, Norwalk, CT, USA) is positioned in the 2nd or 3rd intercostal space laterally behind the anterior axillary line. The PortaClamp guidewire is inserted through this port in the transverse sinus through a small (2-3 cm) pericardial incision between the aorta and the superior vena cava (SVC) (unless the pericardium had been widely opened in the case of central cannulation). The guidewire is pushed into the sinus (eventually with the help of a forceps in the vicinity of the SVC) perpendicularly to the axis of the aorta, until it pops up along the anterior aspect of the pulmonary artery (PA) and aorta (Figure 1). The proximal end of the guidewire is retrieved and pulled back through the same port with a shafted forceps while the distal end is pushed forward. At this point in time the guidewire encircles the aorta and pulmonary artery and the Thoracoport is eventually withdrawn (Figure 1). After cardiopulmonary bypass is instituted, 2 clamping jaws are inserted sequentially in front of and behind the aorta. Those clamping jaws follow the guidewire as they present with an axial lumen in which the 2 free ends of the guidewire are threaded (Figure 2). The clamping jaws are

Procedures and Demographics

Procedure	
Coronary artery bypass graft/sternotomy	3
Aortic valve replacement/sternotomy	1
Aortic valve replacement/ministernotomy	3
Mitral valve repair/right minithoracotomy	9
Atrial-septal defect/right minithoracotomy	2
Myxoma/right minithoracotomy	1
Demographics	
Sex, M/F	13/7
Age	71.2 ± 8.6 y
Peripheral atheroma	6
Diabetes	5
Hypertension	7
Renal failure	3
Crossclamp time	65 ± 28 min
Cardiopulmonary bypass time	82 ± 35 min
Intensive care unit time	16.8 ± 12 h
Length of stay	7.2 ± 2.1 d

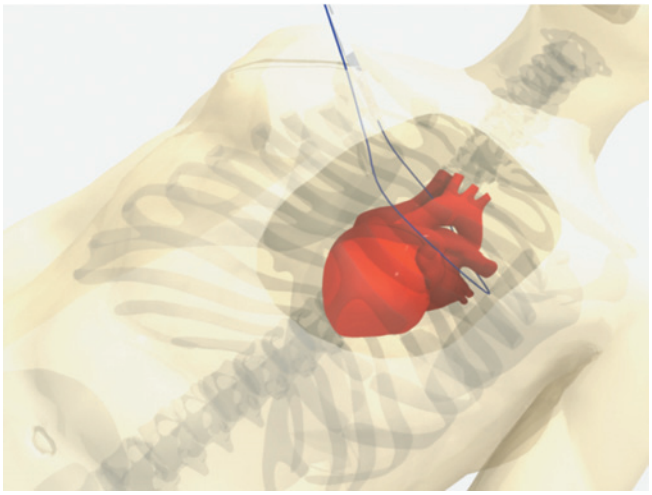

Figure 1. Procedural step 1: guidewire positioned around aorta and pulmonary artery.

pushed freely around the aorta, and eventually also around a part of the PA without risk of damaging any cardiovascular structure. A marking shows the surgeon that the clamping position has been reached. A cylindrical squeezing tube (Figure 3) is placed around the 2 clamping jaws and gently slid toward the aorta until it reaches a stop, to crossclamp the vessel (Figures 4 and 5). The guidewire does not play any role in the clamping mechanism and is left loose to avoid a strangulation effect of the PA. The unclamping is performed by gently withdrawing the squeezing tube. The jaws have been designed to ensure a homogenous clamping force and pressure along the clamping area and to avoid the "crab forceps effect," which is encountered with the Chitwood clamp and other external clamps. A broader and smoother clamping surface enables the delivery of a smaller clamping pressure to the aortic wall for any given clamping force.

Antegrade cardioplegia was delivered through a regular cardioplegic needle (DLP standard aortic root cannula;

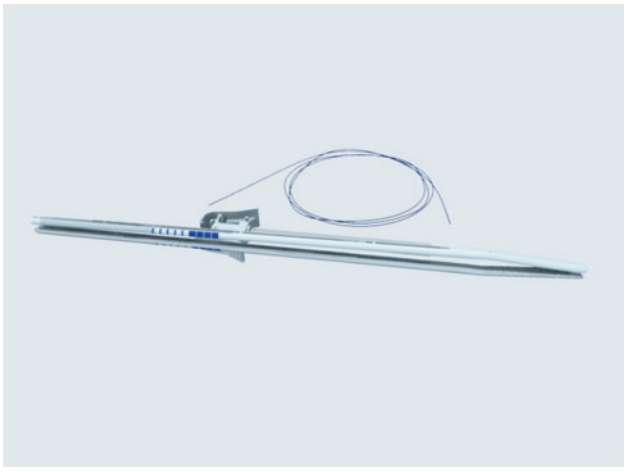

Figure 2. Clamping jaws with the axial lumen in which the 2 ends of the guidewire are threaded.

Figure 3. Clamping ("squeezing") tube with locking handle.

Medtronic, Tolochenaz, Switzerland) that was eventually inserted through the working incision: small anterolateral thoracotomy or sternotomy. The needle was secured by a purse string pledgetted suture and a tourniquet. No bleeding occurred at the puncture site.

RESULTS

Four cases were performed with sternotomy in order to verify the adequacy of the clamping function with the ability to convert the procedure in the event of a device malfunction or complication such as aortic hematoma or dissection. The next 16 cases were performed through right minithoracotomies (n = 13) or ministernotomies (n = 3). The time to position the clamp, including the port placement, pericardial incision, guidewire, and jaws insertion and clamping decreased steeply from 370 to 127 seconds with increasing experience (mean 196 ± 75 seconds). Satisfactory crossclamping, as demonstrated by a complete heart arrest throughout the entire clamping period, was achieved in every single case without need for repositioning. In only 1 case a recurrence of some electrical activity during crossclamp occurred and mandated reiteration of antegrade cardioplegia. The completeness of occlusion was further verified by direct vision in cases of proximal aortotomy (4 aortic valve replacement and 3 coronary artery bypass grafts necessitating proximal venous anastomosis performed on the crossclamped aorta). TEE and visual inspection of the aortic clamping site at the end of operation showed no lesion or even marking of the aortic wall at the site of clamping. All the patients recovered uneventfully. No complications occurred in this group, namely no patient experienced transient ischemic attack or stroke. Mean intensive care unit stay was 0.7 ± 0.5 days, mean length of hospital stay was 7.2 ± 2.1 days.

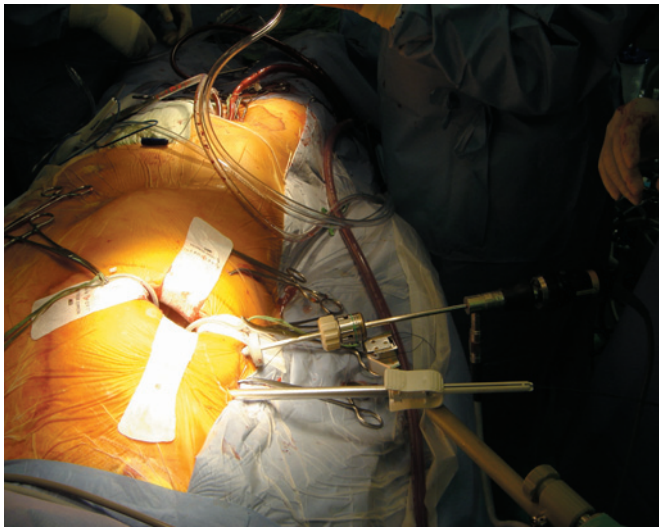

Figure 4. PortaClamp in place during mitral valve surgery.

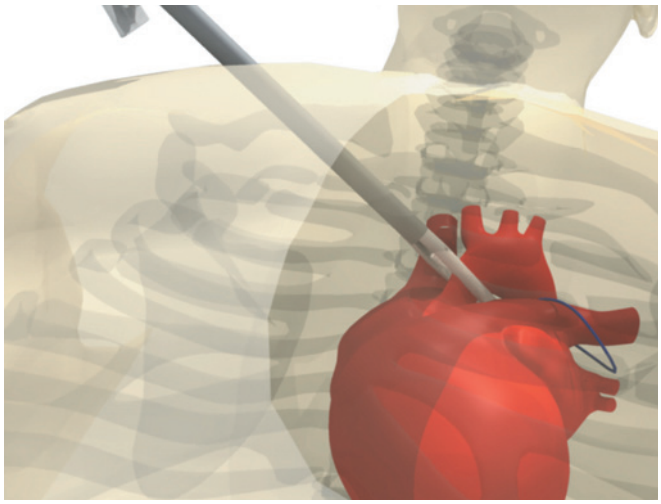

Figure 5. Schematic representation of the clamping mechanism in place.

COMMENT

The present pilot study shows that port access aortic crossclamping is feasible, stable, and reproducible with the new dedicated PortaClamp system. This procedure does not generate undue morbidity.

The clamping maneuver is safe, fast, and easy and does not require a long learning process. To the best of our knowledge it has been reported only once in the literature as a technology enabling a new minimally invasive approach to aortic valve replacement [Gersak 2003].

The limited access to the aorta in port access cardiac surgery has mandated the design of new clamping modalities because the insertion of a "classical" clamp was impossible. New technologies developed include endoluminal clamping systems and the Chitwood clamp. Those systems have demonstrated their usefulness and validity as platforms enabling port access cardiac surgery [Casselman 2003], but they carry specific complications and drawbacks.

The endoaortic clamping mode entails specific risks for the benefit of exerting its action without necessitating a direct intrathoracic introduction. Those specific risks are rupture of the dedicated aortic cannula (Heartport), endoclamp balloon rupture, balloon migration toward the left ventricle or toward the brachiocephalic trunk, and aortic dissection. Besides those specific risks, which are due to the catheterization technique, there is a risk of particulate embolism into the systemic circulation as in any clamping modality [Barbut 1994].

Balloon rupture is an event that is reported in almost every Heartport series [Hesselvik 1999]. The consequence of a bal-

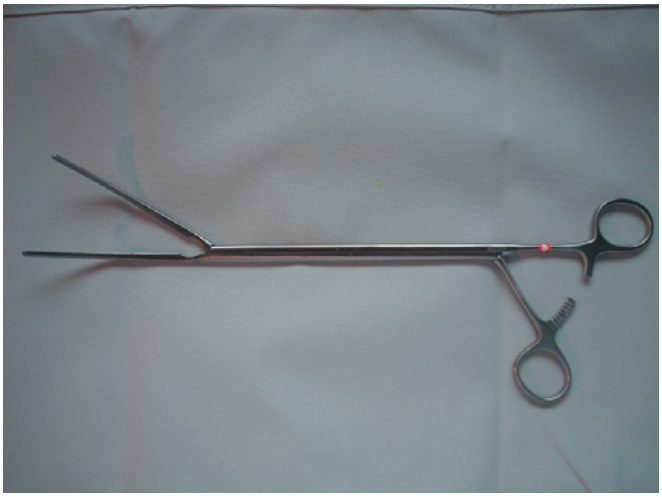

Figure 6. Crab forceps effect of articulated clamp.

loon rupture is a sudden restart of the heart leading to either an immediate replacement of the balloon, which is risky and technically challenging and performed only by several experienced teams in the world, or an urgent conversion to sternotomy in order to crossclamp the aorta and readminister cardioplegia. In the Estech system, the balloon is part of the cannula, and its rupture leads to an untreatable situation because the cannula cannot be removed and the heart, eventually opened, cannot be rearrested. In this case urgent conversion is the only option. There are no clear-cut figures to determine the exact incidence of these complications with either endoballoon system (Heartport or Estech).

Because of the compliance of the aortic wall and/or a pressure decrease in the endoclamp, the endoaortic balloon can migrate and occlude the brachiocephalic trunk [Grocott 1998, Schneider 1998]; the monitoring of this complication, which may provoke ischemia to one hemisphere of the brain, requires specific invasive insertion of a intraarterial catheter in the radial artery in every single patient.

Aortic dissection may be the Achilles heel of endovascular clamping; the incidence of this rare but catastrophic complication of endovascular clamping has been part of the driving force to develop an alternative such as the PortaClamp. The endoarterial maneuvers such as sequential guidewires and retrograde introductions coupled with the retrograde blood flow are prone to tear apart the fragile monocellular intimal layer or atheromatous plaques and trigger aortic dissection.

A higher incidence of aortic dissection is classically reported when endoclamp is used. It has been reported to be as high as 3.9% in early series by Mohr and colleagues [Mohr 1998]. More recently Vanermen et al [2000] reported 2 aortic dissections (1 lethal) in a series of 121 patients who underwent minimally invasive mitral valve repair (1.65 % compared to an expected 0.1 % [Hagl 2000]).

The Chitwood thoracoscopic clamping mode also entails specific risks, which balance the benefit of enabling a minimally invasive, eventually endoscopic, intervention. Those risks are inherent to the difficulty of adequately positioning the forceps without visualization of the entire aortic and pulmonary artery structures and the crab forceps effect (Figure 6). If the clamp is positioned too deeply, there is a risk of hurting the PA; if the clamp is not positioned deeply enough, the aorta is insufficiently crossclamped, making it impossible to perform the operation or leading to insufficient heart protection during the operation.

Felger et al [2001], presenting their experience of minimally invasive mitral valve repair with the Chitwood clamp, reported the occurrence of 1 stroke in a series of 124 patients (0.8%). This figure corresponds to the expected incidence of stroke reported in the STS (Society of Thoracic Surgeons) database. Specific complications have been recorded only as case reports.

The above-mentioned risks, coupled with a significant cost increase and the need for the entire surgical team to undergo a complex learning processes, have contributed to a relatively low adoption of port access techniques. We therefore felt there was a need to develop an alternative clamping method that would be fast, safe, reliable, and cost-effective. The guided feature of the PortaClamp avoids the risk of damaging the vascular structures adjacent to the clamping zone of the aorta (ie, the SVC, main PA, and right PA), which is not the case with the currently available technologies for aortic occlusion. The PortaClamp brings the surgeon back to the well known paradigm of extraluminal crossclamping, obviating the need for invasive monitoring of the right radial artery pressure and the necessity of continuous monitoring and specific attention paid to the clamping throughout the operation. The results of the present study using the PortaClamp show that clamping is feasible, reproducible, and does not generate undue mortality or morbidity. We believe that it greatly facilitates port access cardiac surgery by enabling the surgeon to focus on the objective of the intracardiac maneuver. Only redo cases in which adhesions preclude the passage of the guidewire cannot be dealt with by the method. Further data is required to demonstrate that the atraumatic design providing a more homogenous clamping force and a broader clamping area throughout the clamping zone leads to a lower incidence of injury to the aortic wall.

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