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Closed chest human aortic valve removal and replacement: Technical feasibility and one year follow-up

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ABSTRACT

Background: Minimally invasive aortic valve replacement has so far required a minithoracotomy or a ministernotomy. We present here the first series of totally endoscopic aortic valve replacement (TEAVR).
Methods: Between June 2013 and April 2015, 14 consecutive patients (12 males, mean age = 76 ± 5.4 years) with a mean EuroSCORE II of 2.72 ± 0.03% underwent TEAVR. A five trocar setting was used in all patients: after ablation of the native valve, a Nitinol stented sutureless 3f Enable Medtronic valve, compressed into the main working trocar, was introduced into the thorax and then expanded in the aortic root.
Results: Among the 14 patients, a thoracoscopic approach was successful in 13 (92.8%) and conversion into an open surgery using the right anterior minithoracotomy was necessary to close the aortotomy in one case. Mean cross-clamping and cardiopulmonary (CPB) times were 112 ± 18 and 161 ± 31 min, respectively. All patients left the surgical unit within 8 days after the operation without any paravalvular leakage. There was no paravalvular regurgitation, conductive block or any major adverse event at a mean follow-up of 10 ± 4 months (range 2–16).
Conclusions: TEAVR is feasible and safe in a selected subset of patients. Closed chest surgery has the potential to become the future approach of the isolated aortic valve replacement in low risk patients but further technical refinement and larger studies are necessary to reduce operative durations and enhance reproducibility.

1. Introduction

The options for the treatment of severe aortic valve stenosis are rapidly evolving. Transcatheter aortic valve implantation (TAVI) has recently been shown to be superior over surgery in high-risk patients [1] and the third generation of transcatheter aortic bioprosthesis allows a significant reduction in the rate of paravalvular leakages that were observed with first generation valves [2,3]. Although surgery is still the technique of reference to treat severe aortic valve stenosis in intermediate risk patients, the extension of TAVI into this population is imminent. However, several points including durability of transcatheter bioprosthesis, further reduction of residual paravalvular leakages, advisability to remove the calcified aortic valvular tissues prior to implantation of a bioprosthesis and impact of bicuspid valves will have to be discussed if one considers to extend the indications of TAVI to lower risk patients.

On the other hand, surgery is also evolving. During the last ten years, surgeons have reported substantial reduction in the iatrogenic wall chest trauma as well as reduction in both morbidity and mortality [4–6]. Partial and ministernotomies have been introduced into the current clinical practice allowing a reduction in blood losses, infections, ventilation time and costs [7]. Replacing the aortic valve throughout the right anterior minithoracotomy represents another successful step toward a less traumatic surgery without sternal fracture [8] but this latter approach still needs to open the chest for a direct view of the operative field and requires to spread the ribs. A turning point in the diffusion of less invasive aortic surgery is the use of aortic sutureless (SU) bioprostheses. The SU prostheses are anchored to the aortic annulus only with the radial force of a stent inside which the valve is mounted without the need of stitches. Transprosthetic gradients appear to be lower with SU bioprostheses than with conventional sutured valves [9–11]. Overall, SU bioprosthesis has been shown to make faster and easier surgery using ministernotomy and minithoracotomy access [12–15]. Finally, some SU models, like Nitinol stent prostheses, can even be compressed and inserted throughout a thoracoscopy trocar enabling a closed chest valvular replacement. In fact exclusive use of thoracoscopy minimizes the iatrogenic thoracic wall chest trauma.

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Recently, we published the achievement of the first-in-man totally endoscopic aortic valve replacement (TEAVR) [16]. In the present work, we report our experience of TEAVR feasibility as well as a one-year clinical follow-up. Limits, developments and perspectives of the technique are discussed.

2. Methods

2.1. Patient selection

Between June 2013 and April 2015, 72 patients were scheduled for an isolated aortic valve replacement with a SU prosthesis. Out of those 14 low risk patients were selected for the total endoscopic implantation of a Medtronic 3f Enable SU valve (Medtronic, Minneapolis, Min), an equine CE approved SU bioprosthesis made up of three pericardial leaflets sewn into a Nitinol compressible stent (Fig. 1A).

Exclusion criteria (Table 1) for the thoracoscopic use of 3f Enable SU bioprosthesis were age < 65 years, left ventricle ejection fraction lower than 30%, active endocarditis, allergy to Nickel alloys, and bicuspid valve type 0 according to the Sievers classification [17] with an annulus larger than 25 mm. Anatomical inclusion criteria (Table 1) were: periaortic working space (distance between the inferior margin of the sternum and the aortic anterior wall >2 cm, Fig. 2, bottom), length of the intrapericardial ascending aorta >5 cm (Fig. 2; top left and right), absence of anomalous orientation of the aortic root (vertical ascending aorta anatomy), and permeability of the femoral and iliac arteries enabling a safe femoro-femoral remote cardiopulmonary bypass. Patients signed up a specific consent approved by the internal ethical Committee.

2.2. Operative technique

We first evaluated the operative trocar setting during several sessions in cadavers in order to obtain an endoscopic frontal view of the aortic root valve without conflicts between the camera and the endoscopic surgical instruments. As well, the possibility of compression of all sizes of the 3f Enable prosthesis into existing thoracoscopic trocars has been previously validated in our anatomy lab. After this first stage, the endoscopic setting was then transferred into a clinical scenario.

Table 1
Contraindications and anatomical inclusion criteria.

Contraindications
• Age lower than 65
• Left ventricle ejection fraction < than 30%
• Allergy to nickel alloys
• Active endocarditis
• Type 0 Sievers bicuspid with annulus sized larger than 25 mm
• Redo cardiac surgery
• Other concomitant cardiac procedure, included ascending aorta replacement
Anatomical inclusion criteria
• Distance between the aorta and the sternum >2 cm
• The absence of anomalous orientation of the aortic root (vertical aorta without the physiologic curvature, pectus excavatum) producing a significant misalignment between the aortic root central axis and the operative axis of the second and third space ports
• Length of the central line of the ascending aorta > 5 cm
• Permeability of the common femoral and iliac arteries (femoro-femoral CPB)

The senior surgeon selected to carry out the endoscopic procedures had previously mastered a learning curve in the 3f Enable valve implantation with more than 100 cases, inclusive of more than 50 minimally invasive procedures (ministernotomy and right anterior minithoracotomy). The delivery and positioning technique of the valve into the aortic root by a video assistance had been developed in a consecutive minithoracotomy cohort [18]. In the cadaver, the surgeon had also been trained to convert within 5 min from the closed chest setting to open right anterior minithoracotomy, by connecting the incisions of the main trocar and the optics in the second space, and inserting a rib retractor enabling a direct visual control of the aortic root. This recovery maneuver was acquired in order to safely shorten procedural duration in case of complications not manageable in a closed chest setting, like annular lesion of the mitro aortic continuity or difficult closure of the ascending aorta.

A preoperative CT scan was performed in all patients in order to check the permeability of the iliac and femoral arteries in view of a femoro-femoral cardiopulmonary bypass (CPB) and with respect the aforementioned anatomical criteria. A 3D reconstruction of the costal grill (Fig. 3) and of the torso was performed in each patient in order to plan the ideal site of penetration into the thorax of surgical trocars (Fig. 4). The intervention was performed under general anesthesia with selective lung ventilation. Two working trocars (Flaxipath, Ethicon,

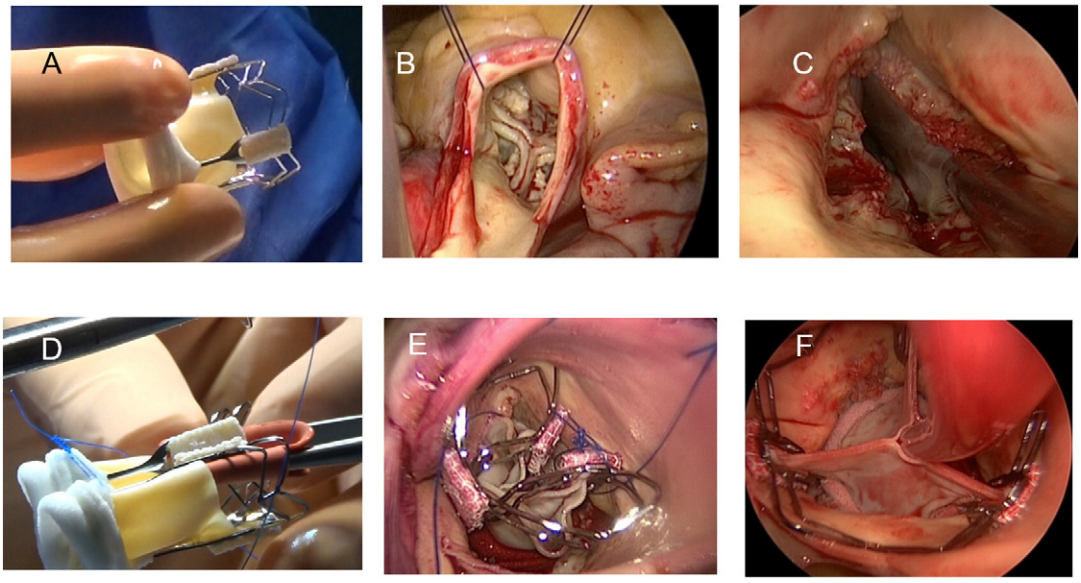

Fig. 1. A: The 3f Enable valve before compression and insertion throughout the main working trocar. B: After the aortotomy, frontal view of a tricuspid sclerotic aortic valve. C: The aortic valvular calcified tissues have been ablated and the aortic annulus decalcified. D: The 3F Enable valve is kept folded by a 4/prolene stitch. E: The compressed 3f Enable valve has been inserted into the aortic root. F: The 3f Enable valve has been expanded into the aortic root. Correct leaflet coaptation inducing the wide into the left ventricle with a suction cannula throughout the biosprosthetic leaflets.