Less invasive aortic valve replacement using the trifecta bioprosthesis

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ABSTRACT

Objectives. The safety and effectiveness of the Trifecta GT bioprosthesis (introduced in 2016) in less invasive aortic valve replacement are scarcely investigated. Our aim was to evaluate the immediate and initial follow-up results of this device in the context of less invasive surgery. We discuss patient-specific strategies for the selection of the surgical approach.

Methods. A retrospective review of 133 patients undergoing AVR with the Trifecta GT through three less invasive accesses (UMS, Upper ministernotomy; RMS, Reversed ministernotomy; RAMT, Right anterior minithoracotomy) was performed. In-hospital, follow-up and hemodynamic performance (PPM, Patient-prosthesis mismatch) data were collected.

Results. Among patients, 79% received UMS, 11% RMS and 10% RAMT. Selection of approach was based on preoperative anatomical analysis (CT-scan) and planned concomitant procedures. There was no operative mortality, no valve-related adverse events. There were 36 concomitant procedures. No significant intergroup differences occurred in cardiopulmonary bypass, aortic clamp, mechanical ventilation time, ICU stay and average bleeding. There were two cases of moderate PPM (1.5%) and no instances of severe PPM; there were no significant (>2/4) perivalvular leaks. Average mean gradient at discharge was 8 ± 3 mmHg. At follow-up (average: 2.5 ± 0.9 years, 100% complete, 315 patient years) there was no mortality and no valve-related adverse event. Hemodynamic performance was maintained at follow-up. Conclusions. The optimal device for less invasive AVR needs to be individualized, as well as the selection of the surgical approach. The use of the Trifecta GT bioprosthesis appears to be reproducible whatever less invasive approach is employed, with confirmed excellent hemodynamic performance.

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Introduction

The recent years have seen an expansion of the treatment options for severe aortic valve disease. Transcatheter aortic valve implantation (TAVR) has been characterized by increasing standardization and diffusion [1,2]. On the other hand, the surgical community has developed a growing interest in less invasive surgery of the aortic valve. Several alternative surgical accesses have been proposed, and a large body of research has focused on the optimal valve prosthesis to be employed in such settings. Sutureless valves have been demonstrated to facilitate less invasive aortic valve replacement (AVR), although characterized by specific limitations [3]. In the present paper, we sought to analyze the effectiveness of a third generation sutured aortic pericardial bioprosthesis (Trifecta GT, Abbott Inc., Chicago, IL) (including valve-related events and hemodynamic performance at discharge and follow-up), to address issues associated with safety and effective use, in various minimally invasive surgery settings. The Trifecta GT valve represents the second generation of the Trifecta valve and was introduced in 2016. No previous focused investigations exist to such purpose. Additionally, we address patient-specific strategies for the selection of the optimal less invasive surgical access for AVR.

Materials and methods

Study population, follow-up and management of data

The present investigation included patients operated on from September 2016 until November 2019. Candidates were identified through retrospective review of hospital records; consecutiveness and completeness were ensured by the use of prospectively collected Institutional database of cardiac surgical activity. Patients were included if they received either isolated or non-isolated AVR through any of the following surgical access: upper J ministernotomy
(UMS), reversed J ministernotomy (RMS) or right anterior minithoracotomy (RAMT), and using the Trifecta GT bioprosthesis (Abbott Inc., Chicago, IL). This device has been introduced during recent years as an evolution of its predecessor Trifecta aortic bioprosthesis. Previous cardiac surgery did not constitute an exclusion criterion. Pre-, intra- and immediate postoperative data were retrieved from hospital records and entered in an electronic database by a research assistant, under the surveillance of the surgical team. Baseline comorbidities were defined according to the EuroSCORE II definitions, available online at www.euroscore.org. In the assessment of valve- and non-valve-related events, both immediate and at follow-up, the Akins recommendations were adopted [4] (immediate or early events were defined as occurring within 30 days from surgery or later if during the same hospitalization). For both immediate and follow-up timepoints, valve-related events were categorized as either SVD (structural valve deterioration – any change intrinsic to the valve and leading to dysfunction, evident at echocardiography, reoperation, or autopsy); NSVD (nonstructural valve dysfunction – any abnormality not intrinsic to the valve itself resulting in stenosis, regurgitation, or hemolysis, evident at echocardiography, reoperation, or autopsy) and operated valve infective endocarditis (IE). The database also included immediate postoperative outcomes until hospital discharge. Discharge echocardiography data were collected, including hemodynamic performance. In this perspective, both mean transvalvular gradient (mTVG) and indexed effective orifice area (iEOA) were calculated through the Bernoulli equation and the continuity equation, respectively. Patient-prosthesis mismatch (PPM) was assessed, and defined as either severe ([iEOA, \( \leq 0.65 \text{ cm}^2/\text{m}^2 \)) or moderate ([iEOA \( \leq 0.85 \text{ cm}^2/\text{m}^2 \)) or absent ([iEOA >0.85 cm²/m²]) [5]. Other variables such as left ventricular ejection fraction (LVEF), left ventricular end-diastolic diameter (LVEDD) and peak transvalvular gradient (pTVG), were evaluated and noted. For the performance of follow-up, referring practitioners (cardiologists and family medicine doctors) were contacted telephonically to inquire on the vital status of the patients and on the occurrence of any valve- or non-valve-related adverse event. Last echocardiography at follow-up was also obtained to assess valve function and hemodynamic performance; echocardiography examinations were performed by board-certified cardiologists within referring hospitals or the main study Institution. Whenever complete information could not be obtained, the patients themselves or their families were contacted. The follow-up inquiry was conducted in late 2020.

A total of 133 patients were included; of these operations, 105 (79%) were performed through UMS, 15 (11%) through RMS and 13 (10%) through RAMT. Table 1 displays the baseline characteristics in the entire population.

Since the inclusion in the present investigation did not entail any additional treatment than standard surgical and clinical management, and since the data were collected retrospectively and managed anonymously, written informed consent to enter the study was waived. The local Review Board approved the study protocol.

| Characteristic                              | Value       |
|--------------------------------------------|-------------|
| Age (years)                                | 75 ± 9      |
| BSA (m²)                                   | 2 ± 0.2     |
| BMI (kg/m²)                                | 26 ± 3      |
| Serum creatinine (µmol/L)                  | 96 ± 40     |
| Platelet count (n * 1000/L)                | 211 ± 70    |
| Blood hemoglobin (g/L)                     | 1.3 ± 0.1   |
| Hypertension                               | 112 (84%)   |
| Renal function                             |             |
| • Normal                                   | 111 (83%)   |
| • Moderately impaired                      | 19 (14%)    |
| • Severely impaired                        | 2 (1%)      |
| • Dialysis                                 | 1 (0.8%)    |
| Peripheral vasculopathy                    | 53 (40%)    |
| Neurological dysfunction                   | 2 (1%)      |
| Previous cardiac surgery                   | 3 (2%)      |
| COPD                                       | 31 (23%)    |
| Active endocarditis                        | 1 (0.8%)    |
| Critical preoperative state                | 3 (2%)      |
| Diabetes                                   | 29 (22%)    |
| NYHA class                                 |             |
| • I or II                                  | 63 (47%)    |
| • III or IV                                | 70 (53%)    |
| LVEF                                       |             |
| • Good                                     | 111 (83%)   |
| • Moderately depressed                     | 19 (14%)    |
| • Severely depressed                       | 3 (2%)      |
| Recent AMI                                 | None        |
| Pulmonary hypertension                     |             |
| • Absent                                   | 55 (41%)    |
| • Moderate                                 | 72 (54%)    |
| • Severe                                   | 6 (45%)     |
| Nonelective                                | 3 (2%)      |
| EuroSCORE II (%)                           | 2 ± 2       |
| Aortic valve dysfunction                   |             |
| • Prevalent stenosis                       | 82 (62%)    |
| • Prevalent regurgitation                  | 18 (13%)    |
| • Mixed                                    | 33 (25%)    |
| Mean transvalvular gradient (mmHg)         | 40 ± 13     |
| AVA (cm²)                                  | 0.9 ± 0.5   |
| LVEDD (mm)                                 | 47 ± 6      |

| Characteristic                              | Value       |
|--------------------------------------------|-------------|
| BSA: Body surface area; BMI: body mass index; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; AMI: acute myocardial infarction; AVA: aortic valve area; LVEDD: left ventricular end-diastolic diameter. |

**Surgical methods**

The device evaluated herein (Trifecta GT valve, a third-generation stented bioprosthesis) presents features expected to facilitate its employment in the context of less invasive AVR, compared to the previous generation Trifecta valve. In particular, reference is made to an improved sewing ring (less bulky, with easier suture gliding during valve parachuting into the aortic root) and an improved valve holder. It is also characterized by the addition of a radiopaque basal ring to facilitate an eventual later valve-in-valve procedure. The Trifecta GT device consists in a bovine pericardial sheet mounted outside a titanium stent frame; a bovine- and porcine pericardium concealment of the stent minimizes mechanical attrition with the external pericardial sheet. The anticalcification treatment is ethanol-based (Linx®) [6].

The selection of the optimal surgical access to the aortic valve was performed case-by-case on the basis of anatomical features evaluated through preoperative non-contrast-enhanced CT scan. Briefly, a J-shaped UMS (with the J incision performed at either the third or the fourth right intercostal space) was selected whether the aortic valve
specifically, the hinge point of the left coronary leaflet) was not caudal to the level of the fourth intercostal space on transverse CT-scan views (Figure 1A), and more than half of the diameter of the ascending aorta was located medial to the right parasternal line on the same views. A J-shaped RMS was privileged when the aortic valve was observed to be located caudal to the level of the fourth intercostal space (Figure 1B), and the exposure for the aortic cannulation site was judged to be sufficient at the level of the second intercostal space. Right-sided J incision was performed in case of isolated AVR, while a left-sided J incision was preferred whenever associated revascularization of the left anterior descending artery was required. An RAMT was decided when more than half of the diameter of the ascending aorta (at the level of the pulmonary trunk bifurcation) was located rightwards the right parasternal line on transverse CT scan views (Figure 1C). When concomitant ascending aortic replacement was indicated, an UMS was performed; similarly, an RMS was employed in case of concomitant coronary bypass. Additional parameters involved in the planning of the less invasive surgical procedure were: the distance between the aortic annulus and the skin on transverse CT scan views; the presence and extension of calcifications of the aortic root and ascending aorta; the quality of iliofemoral vessels and abdominal/descending aorta (in case of planned RAMT). Cardio-pulmonary bypass (CPB) was established through central cannulation in UMS and RMS cases, and through peripheral cannulation at the common femoral vessels in case of RAMT. Myocardial protection was obtained through cold crystalloid cardioplegia delivered antegradely.

Interrupted, U-shaped, noneverting pledgetted sutures were employed for valve implantation. For the use of the Trifecta GT device, careful intra- and supra-annular sizing must be performed, in order to prevent upper stent deformation by narrow sinotubular junction anatomies. Facilitated suture gliding through the sewing ring allows early separation from the valve holder, and the parachuting of the valve can be completed with the aid of surgical forceps. Care must be paid to manipulate only the suture ring and avoid touching the leaflets (Video 1). This maneuver facilitates parachuting in narrow spaces. Knot tying was performed either manually or using a knot pusher in conditions of unfeasible or difficult manual knotting. For RAMT cases, a soft tissue retractor and a rib spreader were used; video assistance was employed to facilitate visualization of the aortic annulus, native valve excision, suture placement and tying.

Statistical analysis

Continuous and categorical data are presented as mean± standard deviation and as percentages, respectively. Multiple-group comparison was conducted through one-way ANOVA (Analysis of Variance) for continuous variables. The two-tailed Student’s t test for paired variables was employed for mean comparison among two subgroups. All continuous data were normally distributed. The alpha level was 0.05. Statistical analysis was performed through SPSS ver. 20.0 for Windows (SPSS, Chicago, IL).

Results

Early results

In the study population, the intended operative procedure could be performed in all cases, without instances of conversion to full sternotomy. During the study period, there were no cases of intraoperative decision to implant another bioprosthesis in a case where the use of a Trifecta GT had been foreseen. Average CPB and aortic clamp times were 102 ± 19 min and 77 ± 17 min, respectively. The distribution of the sizes of the implanted bioprostheses is as follows: 19 mm in 6%, 21 mm in 32%, 23 mm in 36%, 25 mm in
Follow-up results

During the follow-up (average: 2.5 ± 0.9 years, 100% complete, 315 patient years), there were no cases of valve-related complications (either SVD, NSVD or IE). All patients were alive at the end of the follow-up. At the latest available echocardiography, average mTVG was 7 ± 2 mmHg, average LVEF was 60% ± 4 (% < .001 vs. discharge echocardiography) and average LVEDD was 45 ± 6 mm. Average iEOA was 1 ± 0.2. There were no new cases of PPM.

Table 3. Early postoperative results in the entire population (N = 133).

| Characteristic                | Discharge | Follow-up | p Value |
|------------------------------|-----------|-----------|---------|
| Operative mortality          | None      | None      | .01     |
| Stroke                       | 1 (0.8%)  | 1 (0.8%)  | .1      |
| Acute kidney injury (AKI)    | 90 (68%)  | 72 (54%)  | .001    |
| None                         | 4 (3%)    | 2 (1%)    | .1      |
| AKI 1                        | 4 (3%)    | 2 (1%)    | .1      |
| AKI 2                        | 4 (3%)    | 2 (1%)    | .1      |
| AKI 3                        | 4 (3%)    | 2 (1%)    | .1      |
| Atrial fibrillation          | 31 (23%)  | 4 (3%)    | .001    |
| Surgical wound infection/disunion | None       | None      | .01    |
| Permanent pacemaker          | None      | None      | .01    |
| Blood products transfusion   | 26 (19%)  | 7 (6%)    | .01    |
| Pulmonary complications      | None      | None      | .01    |
| None                         | 125 (94%) | 112 (85%) | .01    |
| Pneumothorax                 | 3 (2%)    | 2 (1%)    | .1      |
| Atelectasis                  | 1 (0.8%)  | 1 (0.8%)  | .1      |
| Other                        | 4 (3%)    | 2 (1%)    | .1      |

Table 4. Hemodynamic performance of the bioprostheses at discharge and at follow-up (overall population) (N = 133).

| Characteristic              | Discharge | Follow-up | p Value |
|-----------------------------|-----------|-----------|---------|
| mTVG (mmHg)                 | 8 ± 3     | 7 ± 2     | < .001  |
| pTVG (mmHg)                 | 16 ± 5    | 13 ± 3    | < .001  |
| EOA (cm²)                   | 2 ± 0.3   | 2 ± 0.3   | .09     |
| iEOA (cm²/m²)               | 1 ± 0.2   | 1 ± 0.2   | .01     |
| No PPM                      | 131 (98%) | 131 (98%) | .99     |
| Moderate PPM                | 2 (1%)    | 2 (1%)    | .99     |
| Severe PPM                  | None      | None      | –       |

Discussion

The treatment paradigms for severe aortic stenosis are evolving. The main features of such evolution include the expansion of the indications to TAVR (and the increasing standardization of both transfemoral and non-transfemoral access routes), as well as the growing adoption of less invasive techniques for surgical AVR. Rather than a reaction to the success of TAVR, this trend testifies the intention to provide patients with the benefits of an effective and reproducible treatment for aortic stenosis, and those of minimal surgical aggressiveness. Less invasive AVR has been associated with reduced ICU and overall hospital stay, shorter mechanical ventilation time, lower rate of transfusion and reduced postoperative pain vs. full sternotomy [7], despite longer average CPB and cross-clamp times. No previous investigations have specifically addressed the feasibility and safety of the Trifecta GT valve in various less invasive surgery settings. In fact, these settings entail peculiar technical conditions for valve implantation, including valve parachuting into position and knot tying. These aspects are significant to maintain the integrity and durability of this valve device. Trifecta GT is the second-generation Trifecta valve, it was introduced in 2016 and features several evolutions in design with respect to the first-generation device.

Procedure planning is a pivotal step. Preoperative CT scan helps in the selection among alternative surgical accesses through anatomical evaluation, in order to achieve a customized surgical procedure (Figure 1). UMS and RAMT are established in the literature; we suggest the...
effectiveness of RMS in selected cases where the aortic valve annulus presents a lower position within the chest. RMS allows concomitant coronary revascularization; it might further minimize chest instability compared to UMS through preservation of the continuity of the sternal manubrium and sternoclavicular articulations. Such hypothesis should be tested in dedicated biomechanics investigations. Studies reporting direct comparison between alternative approaches for less invasive AVR are limited. It has been suggested that RAMT might offer greater benefit in terms of hospital stay than UMS, at the price of the risk of groin complications. A cost-benefit analysis has indicated that AVR through RAMT is associated with greater economic costs than AVR through either UMS or full sternotomy [8]; this can be ascribed to the frequent employment of sutureless prostheses in RAMT.

The average CPB and cross-clamp times reported herein are adequate, and the rate of associated procedures needs to be considered. We failed to identify significant differences in CPB and clamp times among subgroups by surgical approach (Table 2), likely due to the 13% rate of associated ascending aortic replacement in the UMS group. It appears, that less important difference exists under this profile among UMS and RMS patients. We identified no significant intergroup difference in terms of mechanical ventilation time and ICU stay, which suggests a general effectiveness of the three approaches. Of note, a recent meta-analysis suggested that no increased incidence of CPB-related adverse effects is observed in minimally invasive approaches vs. conventional sternotomy [9].

The choice of valve for less invasive AVR is a matter of debate. Sutureless valves are currently part of the clinical practice; their effectiveness in reducing average CPB and aortic clamp times has been proven in such context [10], and they are also a powerful tool to manage complex anatomical situations. Yet, they have also been associated with specific limitations, such an increased rate of permanent pacemaker implantation (up to 11.9% and 11.6% in published series [11]). The rate of significant (moderate or severe) periprosthetic regurgitation has been reported to approach 1.6% and 1%, with early valve explant in some instances [11]. Both values tend to be higher than those observed in historical AVR series using conventional sutured bioprostheses [12]. These factors are also of importance in the comparison vs. transcatheter valves [13]. In the domain of TAVR, technological evolution and clinical experience have been the determinants of improving results. An in-depth analysis of the national French TAVR database noted a statistically significant decrease in the rate of moderate/severe postprocedural perivalvular leak during recent years, although such rate still reaches 10.2% in current practice [2]. In the same database, the rate of permanent pacemaker implantation remained as high as 17.5% in the most recent part of the experience. Hence, we believe that the choice of valve device in less invasive AVR should be tailored on the type of surgical approach and on the anatomical characteristics of the patient (i.e. ease of suture passing and knotting), and that the employment of a less invasive approach should not systematically lead to the use of a sutureless valve. As such, the existence of risk factors for postoperative conduction disturbance (i.e. left bundle branch block) might be considered in decision-making.

Our data indicate that the investigated device can be safely employed in various less invasive AVR settings, including three surgical approaches (UMS, RMS and even RAMT) and several associated procedures (ascending aortic replacement, coronary revascularization), which suggests its versatility and adaptability. No patient in our series presented significant periprosthetic regurgitation or permanent pacemaker implantation, which is coherent with the low rates of these complications in major published experiences (0.5% and 1.9%, respectively in a series of 824 implants [14]; 5.7% rate of permanent pacemaker in a series of 918 implants [15]; 0.3% rate of major perivalvular leak in a series of 1,014 implants [16]). Under the technical profile, facilitated parachuting through suture gliding and confident manipulation of the valve play a role in such sense. Automatic knot fastener devices may also be employed. On the other hand, careful sizing and suture knotting without interference with the valve stent are required in order to prevent any dysfunction. Oversizing needs to be avoided, since too narrow sinotubular junction anatomy may induce deformation of the upper valve stent and intraprosthesis regurgitation. Optimal hemodynamic characteristics are an essential requirement of modern bioprostheses, as testified by randomized investigations [17]. We observed a very low rate of moderate PPM (1%) and no cases of severe PPM, which confirms previous literature from conventional surgery [18]. The hemodynamic performance of the Trifecta valve is maintained at mid-term follow-up [19] and on effort [20]. We have limited follow-up duration, as the Trifecta GT valve has been recently introduced. Yet, follow-up echocardiography data in our study confirm stability of hemodynamic properties and absence of adverse events. It has been suggested that the Trifecta valve and stentless valves share similar hemodynamic properties, similar to stentless valves and TAVR devices. The investigated stented valve device might couple versatility and implantability in less invasive AVR and excellent hemodynamic properties, which seem to favorably compare with transcatheter valves [21].

Reports have been made about early SVD of Trifecta bioprostheses under the form of significant intraprosthetic regurgitation [14,22]. These reports all concern the first-generation Trifecta valve; the behavior under such perspective of the more recent Trifecta GT model with its evolved design remains to be ascertained. The present study is insufficient in sample size and follow-up duration to definitely address durability as an endpoint; on the other hand, the introduction of Trifecta GT is relatively recent, and herein we feature amongst the longest possible follow-up (our inclusion period starting in the same year the device was introduced). We conversely focus on early safety and hemodynamic performance in the exclusive context of less invasive surgery.

**Limitations**

The present investigation is limited by its retrospective nature and by its sample size; nonetheless, the inclusion of
only less invasive access recipients allowed to focus on features and safeguards for the use of a unique AVR device in this context. We cannot conclude about bioprosthesis durability, given the limited follow-up time. Nonetheless, our purposes consisted in the assessment of in-hospital and initial follow-up valve-related adverse events potentially associated with use of less invasive approaches. Finally, imbalanced distribution of patients among types of less invasive approach significantly limits the possibilities to perform intergroup comparison of clinical outcomes.

Conclusion

The evolving spectrum of management options for aortic valve disease includes transcatheter therapy, several minimally invasive surgical accesses and various sutured and sutureless devices. The current research challenge lies in the definition of the respective place of these strategies. The selection of the less invasive surgical access should be customized case-by-case in order to ensure patients’ safety and maximize the benefits. Our data suggest the effectiveness and reproducibility of the Trifecta GT valve device in less invasive surgery settings, including RAMT. The relatively limited number of patients included herein do not allow definitive evaluation of safety in this specific context; nonetheless, we provide supportive data of good security. The choice of the optimal valve for less invasive AVR needs to be individualized and should consider multiple factors such as reproducibility and safety, rate of valve-related events (i.e., permanent pacemaker implantation), hemodynamic performance, and social costs.

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