Original Article

Complete Aortic Valve Reconstruction with Autologous Pericardium: Analysis of Mid-Term Results of Single-Center Experience with AVNeo Procedure

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Purpose: Aortic valve neocuspidization (AVNeo) is a relatively recent advancement in surgical AV replacement. Data on its performance beyond the short term are limited. We assessed the mid-term outcomes in patients undergoing AVNeo, focusing on feasibility, perioperative details, and its role in AV pathology treatment.
Methods: Sixty-five consecutive patients underwent AVNeo between December 2016 and February 2018. Clinical data were prospectively collected and retrospectively analyzed. Tricuspid reconstruction with autologous pericardium was performed in all cases. Echocardiographic follow-up was conducted post-discharge, at 6 and 12 months, and annually thereafter.
Results: The mean age was 62.6 ± 18.7 years. AVNeo was feasible in all cases. Concomitant procedures were performed in 43 (66.2%) patients. Mean bypass and cross-clamp times were 119.2 ± 30.3 and 87.1 ± 22.9 minutes, respectively. Postoperative transvalvular hemodynamics was excellent. There was one (1.5%) in-hospital death. Follow-up (mean 66.72 ± 12.77 months) was complete in 58 patients (89.2%). There were no detected valve-related or thromboembolic events. Transvalvular hemodynamic parameters were stable during the observation period: peak pressure gradient at discharge and follow-up was 15.3 ± 4.6 mmHg and 15.01 ± 6.3 mmHg, respectively (ρ = 0.346).
Conclusions: AVNeo demonstrated the feasibility and favorable mid-term outcomes. Studies with longer-term observation are warranted to evaluate its durability.

Keywords: aortic valve neocuspidization, glutaraldehyde-treated pericardium, small aortic root, aortic stenosis, Ozaki procedure

Introduction

Aortic valve (AV) disease, resulting in stenosis, regurgitation, or a combination of both, is the most common surgical pathology of cardiac valves.[1)] Surgical AV replacement (SAVR) remains the gold standard in treating this malformation. The technique of SAVR with mechanical or biological prosthesis is well established, relatively simple, and reproducible. It provides a good immediate hemodynamic resolution of the disease. The most recognized drawbacks of SAVR are complications of long-term anticoagulant therapy in mechanical valves and structural deterioration of biological valves.[1)]

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Postoperative results may be negatively affected by prosthesis–patient mismatch (PPM), paravalvular leaks (PVLs), prosthetic valve endocarditis (PVE), and the need for permanent pacemaker implantation (PPI).[2–5] The prevalence of these complications is significant, and every novel technique should be evaluated against the potential to overcome existing limitations.

AV neocuspidization (AVNeo) is a surgical technique that permits valve reconstruction using autologous pericardial tissue. It is a relatively recent innovation with a limited presentation in the literature. Authors universally report excellent immediate postoperative results. However, a more robust body of data is needed to examine the hemodynamic performance of AVNeo in the longer-term follow-up.[6]

This study aimed to estimate the feasibility of AVNeo operation, analyze immediate and mid-term results, and evaluate this technique's potential to overcome existing drawbacks of SAVR.

Patients and Methods

Sixty-five consecutive patients who underwent the AVNeo procedure between December 2016 and February 2018 were enrolled in this single-center study. Data were collected prospectively, and their retrospective analysis is presented. The Clinical and Research Ethics Committee of the Heart Institute approved the clinical study of this procedure (approval No. 14; approved February 14, 2019). All patients were included in the study after receiving detailed information on existing methods of correcting AV pathology and signing a written informed consent form.

AVNeo was recommended among other surgical options for patients who were candidates for AV replacement (AVR). Additional arguments were small aortic annulus (<21 mm) and the desire of the patient to receive a biological valve made of his tissue, thus preventing the host's immune response. AVNeo was not utilized if the native valve could be repaired or preserved by any of the conventional techniques. Also, we did not recommend this procedure in cases that were candidates for concomitant ascending aortic aneurysm repair. When the quality of the autologous pericardium could be compromised, the procedure was omitted. This included previous cardiac operations, upper body irradiation, and pericarditis of any type. AVNeo was not performed in urgent cases.

Primary outcomes were as follows: failure to perform AVNeo with intraoperative conversion to SAVR; 30-day all-cause mortality; and rate of major cardiac and other events during 30-day follow-up. Secondary outcomes were as follows: rate of aortic stenosis or regurgitation, reoperations, and death during follow-up.

Table 1 Patients (n = 65) demographic and preoperative clinical characteristics

Preoperative characteristic	Values
Age (years), mean ± SD	62.6 ± 18.7
Sex, male, n (%)	32 (49.2%)
EuroSCORE II (%), median (IQR)	5.19 (3.22–6.24)
BMI (kg/m^2), mean ± SD	28.8 ± 5.3
BMI greater than 30.0, n (%)	21 (32.3%)
NYHA class	
II, n (%)	5 (7.7%)
III, n (%)	53 (81.5%)
IV, n (%)	7 (10.8%)
AV pathology: stenosis/regurgitation, n (%)	
Stenosis	52 (80%)
Regurgitation	5 (7.7%)
Combination of stenosis and regurgitation	8 (12.3%)
AV morphology, n (%)	
Bicuspid	17 (26.2%)
Tricuspid	48 (73.8%)
Aortic annulus diameter, mm, mean ± SD	21.9 ± 2.3
Small aortic annulus (diameter ≤ 21mm), n (%)	19 (29.2%)
Peak pressure gradient, mm Hg, mean ± SD	88.4 ± 31.5
Mean pressure gradient, mm Hg, mean ± SD	54.8 ± 18.9
Left ventricle ejection fraction, %, mean ± SD	55.3 ± 12.8
Left ventricle ejection fraction ≤40%, n (%)	10 (15.4%)
Left ventricle ejection fraction ≤30%, n (%)	4 (6.1%)

AV: aortic valve; NYHA: New York Heart Association; BMI: body mass index; IQR; interquartile range

Demographic and preoperative clinical characteristics of patients are presented in **Table 1**.

Surgical technique

Surgeries were carried out under general anesthesia through a median sternotomy approach. Glutaraldehyde-treated autologous pericardium (GTAP) was used for reconstruction in all cases. After harvesting, a pericardial flap, 9 × 7 cm in size, was put under slight tension on a plate and cleansed from any adipose and connective tissue remnants. The pericardium was immersed in glutaraldehyde 0.625% in phosphate buffer pH 7.4 solution for 10 minutes. This was followed by triple active rinsing in saline for 6 minutes each time.

After initiation of cardiopulmonary bypass, the aorta was cross-clamped, and transverse aortotomy was made right under the ascending aortic fat body, slightly extending the incision into the non-coronary sinus. The

heart was arrested by infusion of Custodiol HTK Solution (Custodiol; Koehler Chemi, Alsbach-Haenlien, Germany) directly into the coronary ostia. The diseased valve was excised, and meticulous decalcification of the annulus was achieved. The intercommissural distance of each cusp was measured, and the corresponding leaflet was trimmed using sizers and a template developed by Ozaki (AVNeo Sizer Kit, JOMDD, Tokyo, Japan).[6] Care was taken to ensure that the smooth pericardial surface of the leaflets should face toward the left ventricle. Each leaflet was fixed to the corresponding annulus using running 4.0 polypropylene sutures (Ethicon Inc., Johnson & Johnson; Somerville, New Jersey, USA) in the following sequence: left, right, and non-coronary cusp. Suturing starts at the nadir of the sinus and travels toward the top of the commissure. New leaflets are larger than native ones; therefore, significant plication should be performed. Bigger bites are taken on the patch with a ratio of 3:1 while suturing near the nadirs. More equal bites (2:1 and 1:1) are taken while approaching the commissures. At the top of commissures, sutures are brought outside the aorta and fixed on the Teflon patch. In the case of the bicuspid AV, reconstruction with three cusps was always performed, using raphe as a landmark to create a new commissure. We accept the 2-size difference between the leaflets and never needed to develop a neocommissure for symmetric tricuspidization of bicuspid AV. We did not use additional polypropylene stitches to reinforce the commissures. The final alignment of leaflets was achieved by applying small vertical U-shaped 5.0 polypropylene sutures at the top of the commissures. In a patient with an enlarged non-coronary sinus, it was repaired by vertical plication with two U-shaped pledgeted stitches. Non-coronary intercommissural distance did not change after this maneuver. Another patient with a local ascending aortic aneurysm insisted on receiving an AVNeo procedure. In operation, his aortic root was not enlarged. The aneurysm was limited to the ascending aorta and was located above the sinotubular junction. It was repaired by standard ascending aorta replacement with a vascular prosthesis. AVNeo was performed in a standard fashion in this case.

Upon completion of valve implantation, negative pressure was put on the left ventricular vent to control the new valve for competence and symmetry (**Fig. 1**). After weaning from the bypass, transesophageal echocardiography (TEE) was performed as the final evaluation.

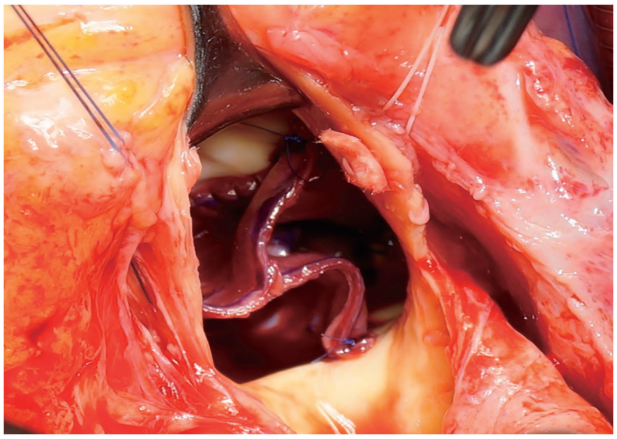

Fig. 1 AVNeo valve. Final evaluation for competence and symmetry before completion of the procedure. AVNeo: aortic valve neocuspidization

Statistical analysis

Data are presented as mean ± SD for continuous variables and number (%) for categorical variables. The survival rate and cumulative incidence of aortic regurgitation (AR) were calculated using Kaplan–Meier methods. Comparisons between groups were performed using a Student's t-test, with independent samples t-tests applied for comparing one variable between two separate sets of samples, and paired samples t-tests used for matched pairs or repeated measures. The data were tested for normality using the Shapiro–Wilk test. The median interquartile range (IQR) was used for variables that deviated from normal distribution. ρ-values were two-sided and subject to a significance level of .05. Data analysis and statistical testing were conducted using the R programming language. The packages used included survival, survminer, dplyr, and the base R function t-test.

Results

AVNeo was feasible in all cases. An isolated procedure was performed in 22 (33.8%) cases; the rest received concomitant procedures. Intraoperative data are presented in **Table 2**.

All operations were performed by three independent surgeons. The learning curve was flat. The operative, cross-clamp, and bypass times were rather dependent on the anatomical situation (size and exposure of the aortic annulus, rotation of the heart, and concomitant procedure) than on the number of AVNeo procedures performed by the operating surgeon.

Table 2 Intraoperative characteristics

Characteristics	Value
Mean bypass time, hours	
General cohort (N = 65)	119.2 ± 30.3
Isolated AVNeo (N = 22)	99.7 ± 24.6
AVNeo with concomitant procedures (N = 43)	135.3 ± 28.1
Mean cross-clamp time, hours	
General cohort (N = 65)	87.1 ± 22.9
Isolated AVNeo (N = 22)	75.2 ± 17.4
AVNeo with concomitant procedures (N = 43)	96.0 ± 21.2
Patients with concomitant procedures	43 (66.2%)
CABG	24 (36.9%)
Mitral valve repair	9 (13.8%)
CABG + mitral valve repair	6 (9.2%)
CABG + left ventricle aneurysm resection	1 (1.5%)
Ascending aortic aneurysm + tricuspid valve repair	1 (1.5%)
Non-coronary sinus repair	1 (1.5%)
Renal neoplasm resection	1 (1.5%)
The mean ventilation time, hours	10.2 ± 3.8
The mean ICU stay, days	2.5 ± 1.0
The mean postoperative hospital stay, days	8.2 ± 1.7

AVNeo: aortic valve neocuspidization; CABG: coronary artery bypass grafting; ICU: intensive care unit

Between the patients who received concomitant procedures and the isolated AVNeo Group, there was a significant statistical difference in mean bypass time ($p = 0.003$) and mean cross-clamp time ($p = 0.002$).

Intraoperative TEE demonstrated good function of the new valve in all cases. There was no need for repeat cross-clamp to correct neovalve dysfunction or perform conversion to SAVR with a bioprosthesis.

There was one in-hospital death: a 79-year-old male patient with multiple comorbidities (EuroSCORE II 6.2%). He received right internal carotid artery stenting 5 days prior to his AVNeo + coronary artery bypass grafting procedure. Postoperatively, the patient developed encephalopathy, acute renal insufficiency, requiring dialysis, thrombocytopenia, and pulmonary hemorrhage. Repeated echocardiography (EchoCG) demonstrated good neovalve function. The patient died on postoperative day 22 due to multiorgan failure. In-hospital mortality constituted 1.5%.

Intensive care course was significant for thrombocytopenia (less than 5×10^9/L), which occurred in 5 (7.6%) patients. In otherwise uncomplicated cases, it remained without clinical consequences. Being associated with other complications, thrombocytopenia led to increased hemorrhage from serous surfaces and around venous catheters. All patients who developed thrombocytopenia were operated in the very beginning of our experience. We associate this phenomenon with the fact that the rough surface of the pericardium could have been placed facing the left ventricle, causing destruction and consumption of thrombocytes. Having performed this analysis, the rule of placing the smooth visceral surface of the pericardium toward the left ventricle was meticulously followed. Later in the series, clinically significant isolated thrombocytopenia was not observed.

In other means, the postoperative course was not different from that of patients who underwent SAVR or AV repair. The mean ventilation time was 10.2 ± 3.8 hours. The mean intensive care unit (ICU) stay was 2.5 ± 1.0 days. The mean postoperative hospital stay was 8.2 ± 1.7 days.

Data of EchoCG control at discharge from the hospital are presented in **Table 3**. There was no statistically significant difference in peak pressure gradient between subgroups of patients with small (diameter ≤ 21 mm) and normal aortic annulus ($\rho = 0.369$).

There was no need for PPI in any case.

All patients were discharged home on warfarin for 1 month unless their pathology dictated a different strategy. After that, they were prescribed low-dose aspirin for 6 months.

Follow-up

Patients received clinical and instrumental (EchoCG, electrocardiography) follow-up monitoring at the outpatient Department of the Heart Institute or local referral hospital. This was done 6 and 12 months after discharge and annually thereafter.

The mean time of follow-up was 66.72 ± 12.77 months. Three patients were lost for control due to emigration. There were four deaths during follow-up: two—because of cancer and two—due to complications of COVID-19. Echocardiographic follow-up was complete in 89.2% of cases. Echocardiographic follow-up data of the remaining 58 patients under control are presented in **Table 3**. The results between subgroups of patients with small and normal aortic annulus were also not significantly different at this stage ($\rho = 0.831$).

EchoCG revealed no signs of increasing thickness, rigidity, or growing calcium deposits on AVNeo cusps. All patients were in New York Heart Association class I or II. We obtained no data on thromboembolic events, major bleeding complications, or newly identified rhythm disturbances requiring PPI.

Table 3 Echocardiographic control at discharge compared to mid-term follow-up

Characteristic	Immediate postoperative results (N = 65)	Mid-term results (N = 58)	ρ-value
Aortic regurgitation			
None/trivial	57 (87.7%)	51 (87.9%)	0.999
Mild	7 (10.7%)	6 (10.3%)	
Moderate	1 (1.5%)	1 (1.7%)	
Severe	0	0	
Average peak pressure gradient			
General cohort, mmHg	15.3 ± 4.6	15.01 ± 6.3	0.346
Cohort with normal aortic annulus, mmHg	14.1 ± 4.5	14.9 ± 6.1	0.717
Cohort with a small aortic annulus*, mmHg	16.3 ± 5.3	15.4 ± 7.3	0.611

*For adults, a small aortic annulus is considered to be less than 21 mm in diameter.

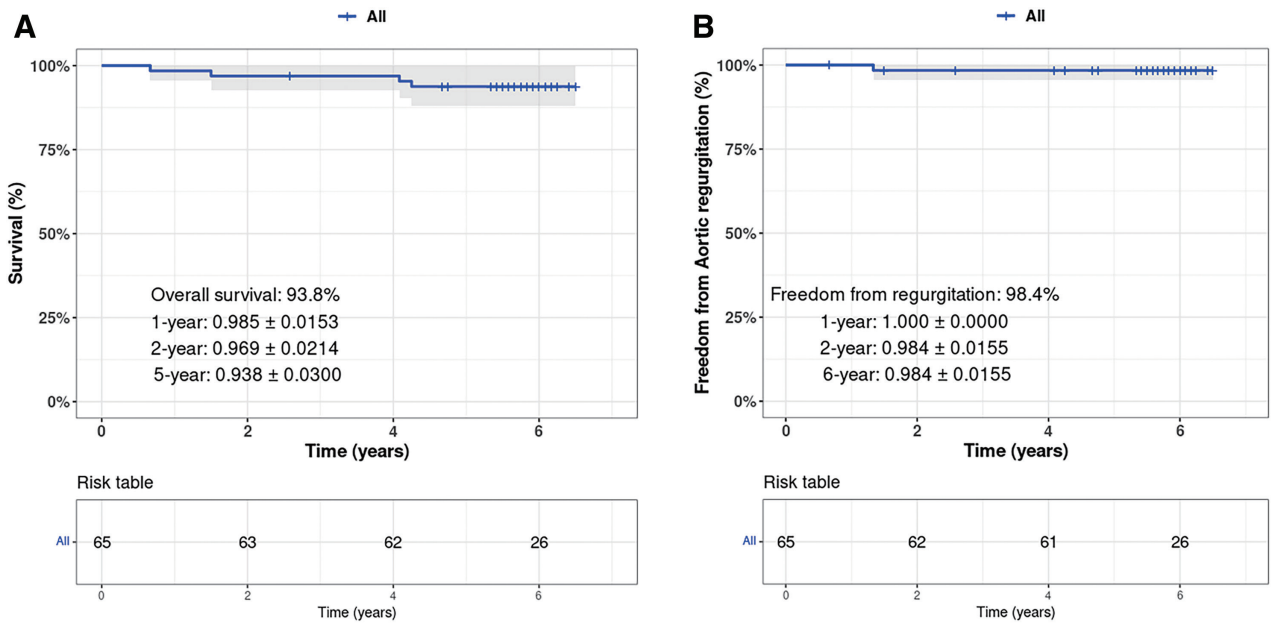

Fig. 2 (**A**) Survival and all-cause mortality. (**B**) Freedom from greater than mild aortic regurgitation

During follow-up, overall survival and freedom from greater than mild AR were 93.8% and 98.4%, respectively (**Fig. 2**).

Discussion

The era of SAVR began in 1960 with Dwight Harken's implantation of a "double-caged ball" valve in the AV position. Since then, significant progress has been made, but complications like PVL, PPM, elevated pressure gradients, postoperative rhythm disturbances, PPI, PVE, and postoperative thrombocytopenia (PTP) still persist.[2–5,7] In addition, long-term issues with mechanical SAVR's antithrombotic therapy and biological valves' structural deterioration remain problematic, prompting ongoing research to improve AVR techniques and materials.[1]

Early attempts at AV reconstruction with autologous tissues faced issues like degeneration and retraction of the leaflets. The introduction of 0.625% GTAP significantly improved outcomes.[8] GTAP's tensile strength is four times higher than native AV tissue, and it produces no immune reaction, potentially avoiding accelerated valve calcification.[9,10] Analysis of reoperated patients showed no calcification or degeneration of cusp tissue.[11,12] During follow-up, we obtained no instrumental data indicating GTAP degeneration in our patients.

Among methods of AV reconstruction with pericardial tissue, AVNeo is the most popular due to its standardization and reproducibility.[6,11,13,14] First reported in 2011, AVNeo shows excellent immediate postoperative results, with good hemodynamic performance attributed to the preserved natural mobility of the left ventricular outflow

tract (LVOT).[15,16] This preservation allows for optimal leaflet opening and closing with minimal stress.[17] The high coaptation zone of the AVNeo valve prevents AR even with some tissue retraction. Altogether, these factors result in the excellent and stable hemodynamic performance of the AVNeo valves in the follow-up.[6,18] Ozaki et al. reported an analysis of the mid-term results of 850 consecutive patients who had undergone AVNeo. The authors demonstrate an average peak pressure gradient of 15.2 ± 6.3 mmHg 8 years after surgery with a cumulative incidence of reoperation and recurrent moderate AR of 4.2% and 7.3%, respectively.[6] Among our patients, an average peak pressure gradient of 15.01 ± 6.3 mm was preserved along the mean follow-up of 66.72 ± 12.77 months. Freedom from greater than mild AR constituted 98.4%.

AVNeo's preservation of natural LVOT mobility helps prevent PPM, a complication occurring in 20%–70% of SAVR cases. New valve designs are reducing PPM, but severe cases still occur in up to 11% of SAVR. Severe PPM is linked with excessive pressure gradients, slower clinical improvement, increased adverse cardiac events, and worse survival rates.[2] Aortic root enlargement (ARE) procedures (Nicks, Manouguian, or Y-incision) have demonstrated their effectiveness in preventing severe PPM.[19,20] However, some authors report the association of ARE with increased morbidity and mortality.[21] AVNeo's direct annulus suturing ensures minimal obstruction to blood flow, preventing elevated pressure gradients. Among our patients, even in the Small Aortic Annulus Group, follow-up EchoCG demonstrated excellent transvalvular hemodynamics with an average peak pressure gradient of 15.4 ± 7.3 mm Hg. It was not different from the Normal Aortic Annulus Group (14.9 ± 6.1 mm Hg). We had no cases with an elevated pressure gradient across the valve, indicating PPM. These data are supported by reports from other centers.[6,22]

The high versatility of the neocuspidization permits adaptation of the neovalve to the individual anatomical features of the patient's aortic root. This is the advantage of AVNeo over the majority of existing SAVR techniques. They require the reshaping of the crown-like aortic annulus into the round structure, exerting tissue to excessive tension and resulting in tears and PVLs. PVL is among the serious complications of SAVR. The incidence may vary from 2% to 17.7%.[3] In a series of 850 patients, Ozaki et al. reported only one reoperation due to AVNeo valve incompetence caused by the break of the thread.[6] We had not observed any suture line dehiscence, resulting in PVLs among our patients. Other authors have reported similar data.[22]

PVE is a life-threatening complication after AVR. It occurs at 0.3%–1.2% per patient-year for SAVR and 0.6%–3.4% for transcatheter aortic valve replacement (TAVR).[23] Some studies report PVE as a major reoperation cause after AVNeo.[22] In the Ozaki et al. series, 0.3% of patients per year needed reoperation due to PVE. In all these cases, the material used for leaflet reconstruction was treated equine (n = 1) or bovine (n = 12) pericardium.[6] Other authors report comparable incidences of PVE after AVNeo and SAVR.[15,16] Also, none of our patients demonstrated signs of PVE during follow-up. In our series, only GTAP was used for leaflet reconstruction. We assume that cases of PVE after AVNeo reported in the literature may largely be attributed not to the technique but to the material used for the valve reconstruction. GTAP has a higher resistance to infection than xenogenic pericardium.[15,16] Our experience using the Ozaki technique for the surgical treatment of pulmonary valve endocarditis further supports this fact. Pulmonary valve neocuspidization (PVNeo) was used in three adult patients. In two of them (intravenous drug abusers), the tricuspid valve was simultaneously replaced with a biological prosthesis. In two cases, follow-up results are excellent. One patient was readmitted 9 months postoperatively because of repeat endocarditis associated with continuous drug abuse. TEE revealed vegetations on the bioprosthesis, while the PVNeo valve was completely intact and demonstrated perfect hemodynamic performance.[24,25] Nevertheless, we assume that aggressive prophylaxis of PVE should be warranted for AVNeo patients in the postoperative period, no matter what material was used for reconstruction.

PPI occurs in 2%–7% of standard SAVR cases, up to 9% in rapid deployment valve implantation, and 6%–34% in TAVR patients.[5,26,27] PPI is linked with longer hospital stays, higher morbidity, treatment costs, and worse long-term survival. Unlike in SAVR, AVNeo avoids the placement of U-shaped pledgeted stitches and pressure of the tissue against the rigid sewing cuff of the prosthesis. This results in lower trauma to the conductive tissue and potentially reduces PPI rates. Literature reports a very low incidence of rhythm disturbances leading to PPI after AVNeo.[6,22] We did not observe this complication in our series.

PTP is common after AVR with biological prostheses, particularly stentless and sutureless valves or TAVR. The incidence of PTP is poorly defined and can be influenced by the characteristics of the biological

material of the valve.[7] Our experience revealed that severe PTP did occur after the AVNeo procedure and was observed in 7.6% of our patients. Modifying surgical technique with the obvious placement of the smooth visceral surface of GTAP toward LVOT helped to solve a problem of clinically significant isolated PTP in AVNeo patients.

Our results have demonstrated the feasibility of performing AVNeo operation in all 65 consecutive patients enrolled in this study. The patient group constituted typical candidates for SAVR, including severely compromised patients (median [IQR] EuroSCORE II was 5.19% [3.22–6.24]). Forty-three (64.2%) of patients have received concomitant procedures. Other authors also report a large proportion (43.9% to 65.4%) of combined procedures among their AVNeo patients.[6,22] A relatively large number of patients in our cohort underwent combined procedures due to two main factors. First, we serve a vast rural area with limited access to specialized cardiologic care. Consequently, patients are often referred to us after developing concomitant cardiac complications. Second, we ensure that our patients are informed about all available options for correcting their AV pathology. Some candidates with isolated AV pathology opt for a biological AVR via minimally invasive approaches, such as upper J-sternotomy or small right anterior thoracotomy, instead of AVNeo, which requires a full median sternotomy.

AVNeo is associated with longer bypass and cross-clamp time than SAVR. However, it did not translate into clinical consequences in our patients: mortality and morbidity completely fall into standard SAVR frames. Benedetto et al. performed a meta-analytic comparison of AVNeo with modern biological AV prostheses. The authors conclude that AVNeo is on par with most AV substitutes in terms of structural valve deterioration, endocarditis, and reintervention rate.[15] At the same time, a unique characteristic of AVNeo in preserving LVOT natural mobility makes this technique preferable over SAVR in preventing PPM, especially in patients with a small aortic root or increased body mass index.

Echocardiographic follow-up of our patients in the immediate and mid-term postoperative periods demonstrated low transvalvular pressure gradients, with no cases of severe AR. The incidence of moderate AR was 1.5% and 1.7%, respectively. The rate of mild AR was 10.7% immediately after surgery and 10.3% at follow-up.

When comparing our results to the available literature, it appears that the occurrence of hemodynamically significant (moderate or severe) forms of AR in our patients is comparable to those reported for SAVR with biological prostheses.[28] However, the incidence of mild AR is relatively higher in our cohort.[29,30] Similar findings are reported by other authors.[14]

The elevated rate of mild AR in our patients may be attributed to the specific characteristics of the AVNeo procedure: a high coaptation zone, tissue excess, and the fan-like shape of the valve. These factors likely contribute to echocardiographic phenomena resembling type IIa AR (flail cusp with excessive leaflet motion) at the coaptation zone. We acknowledge that this observation warrants further investigation. Importantly, our echocardiographic data indicate that postoperative results were stable, with no increase in the incidence or severity of AR during follow-up.

A significant advantage of AVNeo over commercially available biological AV prostheses is its economical effectiveness. Considering the similarities to other AVR methods' clinical results, neocuspidization may be an excellent choice, especially in countries with limited healthcare resources.

Our learning curve was flat in terms of surgical timing and hemodynamic performance of the AVNeo valves. We attribute this fact to the characteristics of the technique originally described by Ozaki, whereas all stages of the operation are highly standardized and reproducible.[6]

We did not have any reoperations or valve-related adverse events during postoperative observation. EchoCG did not detect any signs of calcification or retraction of GTAP. Excellent postoperative hemodynamic performance of the AVNeo valve is preserved through 6.5 years of median follow-up period.

Limitations

First, the number of patients involved in the study is relatively small. Thus, the feasibility, safety, and effectiveness of the procedure may not have been evaluated with sufficient power. Second, this is a single-center study. Therefore, another clinical environment may affect the results in different ways. Third, the duration of follow-up permits the drawing of conclusions from the AVNeo procedure only up to the mid-term period. Fourth, our analysis did not include case-matching with standard AVR (mechanical or biological). Such a study is warranted to understand the advantages and disadvantages of AVNeo in comparison to standard AVR.

Conclusion

AVNeo was feasible to perform in all patients with various forms of AV pathology. It provided excellent immediate hemodynamic resolution of the disease. Our data demonstrate the stability of this result in the mid-term period of follow-up. AVNeo patients require close EchoCG monitoring in the follow-up with special attention to the AR grade. Active prophylaxis of PVE should be warranted in the postoperative period. AVNeo may be considered a valid technique for treating patients who need AVR and wish to remain warfarin-free, especially those with a higher risk of developing PPM. Data from larger, multicenter, randomized-controlled long-term studies are warranted to determine the appropriate place of AVNeo in the surgical armamentarium for treating patients with AV pathology.

Declarations

Ethics approval and consent to participate

There is no ethical problem presented. The Clinical and Research Ethics Committee of the Heart Institute approved the clinical study of this procedure (approval No. 14; approved February 14, 2019).

All patients were included in the study after receiving detailed information on existing methods of correcting AV pathology and signing a written informed consent form.

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Data availability statement

Not applicable.

Author contributions

All authors contributed significantly to the article's content and have read and approved the manuscript's submission.

Disclosure statement

The authors have no conflicts of interest to declare.

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