Cardiology Open Access Open Journal

SOAOJ PUBLISHING

Research

Clinical Results of Trifecta™ GT and Perceval S in the Early Postoperative Period

Marina Potau[1*], Eduard Permanyer[2], Xavier Ruyra[2]

[1]Universitat PompeuFabra – Universitat Autònoma de Barcelona, Barcelona, Spain
[2]Department of Cardiac Surgery -Quironsalud-Teknon Heart Institute. Spain

Correspondence to: Marina Potau, UPF-UAB University, Carrer del Dr. Aiguader 80, 08003 Barcelona, Spain; Tel: +34-636414042; E-mail: marinapotaubermejo@gmail.com

Received: Sep 13th, 2021; **Accepted:** Sep 17th, 2021; **Published:** Sep 22nd, 2021

Citation: Potau M, Permanyer E, Ruyra X. Clinical results of Trifecta™ GT gt and perceval s in the early postoperative period. *Cardio Open A Open J.* 2021; I(1): 8-14

ABSTRACT

Background: Around two-thirds of cardiac surgeries involve aortic valve replacement, being aortic stenosis the most common valvular heart disease. The aim of this study was to compare the clinical results of two bioprosthetic aortic valves: a stented aortic valve (St. Jude Medical Trifecta™ GT) and a sutureless aortic valve (SorinLivaNova Perceval S) in the early postoperative period.

Methods: This study is a prospective, nonrandomized, observational cohort trial. Between July 2019 and December 2020, 143 patients underwent aortic valve replacement with either Trifecta™ GT (n=94) or Perceval S (n=49) aortic bioprostheses at Quironsalud-Teknon Heart Institute. Clinical performances were analysed preoperatively and at the hospital discharge.

Results: Trifecta™ GT presented with younger patients (64.57±2.56 years *vs.* 72.96±2.03 years, respectively; *P=<0.001*), more percentage of men (80.85% *vs.* 61.22%, respectively; *P=0.019*) and more sinus rhythm at discharge (93.62% *vs.* 79.59%, respectively; *P*=0.02). Trifecta™ GT group had lower expected mortality scores regarding EuroSCORE II registry (4.09±1.24 *vs.* 6.31±3.99, respectively; *P*=0.30). Less postoperative complications appeared in Trifecta™ GT patients (31.92% *vs.* 40.82%, respectively; *P=0.38*). Mortality was lower in Trifecta™ GT group (0% *vs.* 2.04%, respectively; *P=0.29*).

Conclusion: Trifecta™ GT patients did not show significantly better results than Perceval S patients. Thus, clinical results in the early postoperative of both bioprosthetic aortic valves are similar. However, further studies are needed to evaluate the long-terms clinical results.

Keywords: *Aortic valve replacement; Bioprostheses; Trifecta™ GT; Perceval S; Propensity score matching.*

INTRODUCTION

Around two-thirds of cardiac surgeries involve aortic valve replacement (AVR).[1] Aortic Stenosis (AS) is the most common valvular heart disease.[2] In addition, it is an important cause of cardiovascular morbidity and mortality.[3]

From a clinical point of view, AS is characterized by a long unremarkable period (usually decades) before symptoms develop. Once symptoms appear, there is a poor prognosis and no medical therapies to modify the disease progression.[4] Life expectancy is shortened to 3 years approximately, unless the obstruction to left ventricular outflow is relieved by AVR,[2] the only available treatment for severe symptomatic AS.[5]

Nowadays, the age of patients undergoing AVR is rising. This fact is increasing the use of bioprosthetic aortic valves.[6] The actual AHA guidelines recommend bioprosthetic valves to patients >65 years old, unless they are taking long-term warfarin for other reasons.[7,8] Nevertheless, the use of bioprosthetic aortic valves is increasing in all age groups, especially in patients <50 years.[9] Bioprosthetic aortic valves can be made of bovine or porcine tissue. Patients with bioprosthesis do not require lifelong anticoagulation, although aspirin is lifelong recommended.[9,10]

Bioprosthetic aortic valves are divided in three different groups: stented, stentless and sutureless.

On the one hand, stented bioprosthetic valves are the oldest of the biological prostheses. Furthermore, they are the most studied and tested, with good clinical and hemodynamic results. For this reason, they are considered the gold standard, which means that the rest of valves have to be compared to this one. The structure is made of a metal stented framework with three valve leaflets mounted on the stent. This design makes the valve look like the native tri-leaflet valve, which leads in similar hemodynamic.[11] Among all the types of stented bioprosthetic valves, in this comparative study the Trifecta™ GT (St. Jude Medical Abbot, Minneapolis, MN, USA) is used. This valve is designed for a supra-annular implant with non-everting sutures, which allows the valve to be used in both conventional and minimally invasive procedures.[12-14] Among the multiples advantages that the Trifecta™ GT has, the following ones are the most significant: excellent hemodynamic output, maintenance of structural integrity and excellent durability.[6,15] Previous clinical trials show no valve-related perioperative complications and low perioperative mortality.[6,12]

On the other hand, sutureless valves are bioprostheses that allow a rapid deployment of the valve due to the self-anchoring mechanism and the lack of sutures.[16,17] Nevertheless, previous resection of the aortic valve and decalcification of the annulusis needed in order to deploy the aortic ring under direct vision.[16] There are two sutureless valves available: the Perceval S (LivaNova, Saluggia, Italia) and the Intuity Elite (Edwards Lifesciences, Irvine, CA). At present, Perceval S (LivaNova, Saluggia, Italia) is the only true 100% sutureless valve available for AVR, since the Intuity requires 3 sutures to fix the valve to the annulus.[16,17,18] The sutureless design allows a fast implantation and an excellent hemodynamic due to the maximized effective orifice area.[19,20] This design also makes the valve suitable for both surgical approaches, traditional and minimally invasive replacement.[18,20,21] Fast implantation of the valve results in lower Aortic Cross-Clamp (ACC) and Cardiopulmonary Bypass (CPB) times compared to conventional AVR. This fact decreases the perioperative mortality.[18,20-22] Several clinical trials show no valve thrombosis, valve migrations, structural valve degeneration or thromboembolic stroke.[16,18,21] However, more studies are needed to know the long-term durability and hemodynamic data for the Perceval S valve.[18,20-22]

Previous comparative studies between different types of aortic valve prostheses are reflected in the scientific literature, but the two used in this study have never been compared as far as we know. We used these two valves because they are the ones which have the best hemodynamic within the stented and sutureless subtypes, respectively. For this reason, these two valves are habitually used in the hospital where the study is carried out. The increase in the durability of biological prostheses and the aging of the population have decreased the use of mechanical valves.[23] That is why this study will be focused on the biological ones.[24] For this reason, the study will compare a stented and a sutureless bioprosthetic valve.

The initial hypothesis is that clinical results in the early postoperative period are similar between the two types of aortic valves. This hypothesis is based on the experience of other trials that have already compared biological aortic valves from other commercial brands than those used in this study. The aim of this study is to compare the clinical results of a stented aortic valve (St. Jude Medical Trifecta™ GT) and a sutureless aortic valve (SorinLivaNova Perceval S).

MATERIALS AND METHODS

Patient Selection and Study Design

This study is a prospective, nonrandomized, observational cohort trial. The aim of this study is to know if the results observed are similar between the two types of aortic valves and, therefore, to validate what clinical experience indicates. In this way, no type of causal relationship will be established.

The exact sample size was not calculated because in this type of study, N>30 in each group is enough for the results to be reliable. Having a size in each group greater than 30 individuals ensures that all the asymptotic regularity properties (central limit theorem) are fulfilled and, therefore, that the estimated mean in a group is normally distributed.

Between July 2019 and December 2020, all patients with severe AS who underwent AVR in a single centre (Quironsalud-Teknon Heart Institute) were included in this study. Patients were divided into two groups based on the aortic valve type chosen (Group A: stented aortic valve (St. Jude Medical TrifectaTM GT); Group B: sutureless aortic valve (SorinLivaNova Perceval S)). The prosthetic valve chosen was based on surgeon's preference and it was also made in deliberation with the patient. All patients undergoing AVR, with or without concomitant procedures, were included for this study and analysis. This study complies with the guidelines indicated by Good Clinical Research Practices and with the Declaration of Helsinki and successive revisions (updated version at the 64th General Assembly, Fortaleza, Brazil, October 2013). Furthermore, the confidentiality of patient data is respected, in compliance with the European Data Protection Regulation (EU) 2016/679 and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of the digital rights. Finally, the participants in this study are not benefited or harmed at any time since it is an observational study. For these reasons, the ethics committee of the medical centre approved this study (Internal Code: 2020/151-CAR-CMT). Thus, in this study was not needed prior informed consent from all participants since all the items studied are routinely asked preoperatively and at discharge. In addition, all data was recorded in an anonymous database of the Cardiac Surgery Service (SICCS) and then retrospectively analysed between January 2021 and March 2021.

Follow-up

Clinical performances were analysed preoperatively (Table 1) and at the hospital discharge (Table 2). Baseline patients' characteristics (gender, age, body mass index, preoperative New York Heart Association, EuroSCORE II and comorbidities), operative details (valve type and valve size), and in-hospital complications (complications, mortality during hospitalization, days in intensive care unit, hospitalization days, electrocardiogram on discharge, reason for discharge and postoperative New York Heart Association) were also collected.

Statistical Analysis

All these data variables were prospectively recorded in a database program named SICCS (Biomenco Inc., Madrid, Spain) and then retrospectively listed in Microsoft Excel (Microsoft Corporation, Redmond, WA). Statistical analysis was performed using the R Foundation for Statistical Computing (R) software for Mac OS (Version 4.0.3, Vienna, Austria).

Table 1. Baseline and after PSM baseline patients' characteristics (before AVR) [a].

Variables	Baseline			After PSM [b]		
	Trifecta™ GT	Perceval S	P-value	Trifecta™ GT	Perceval S	P-value
	(n=94)	(n=49)		(n=44)	(n=44)	
Gender						
Male, n (%)	76 (80.85)	30 (61.22)	0.019	30 (68.18)	27 (61.36)	0.65
Female, n (%)	18 (19.15)	19 (38.78)		14 (31.82)	17 (38.64)	
Age, years	64.57 ± 2.56	72.96 ± 2.03	<0.001	71.68 ± 2.34	72.14 ± 2.09	0.77
BMI, Kg/m2	26.39 ± 0.88	26.49 ± 1.12	0.89	27.00 ± 1.28	26.79 ± 1.18	0.81
Preop NYHA functional class						
NYHA I, n (%)	14 (14.89)	4 (8.16)	0.48	1 (2.27)	4 (9.09)	0.22
NYHA II, n (%)	43 (45.75)	27 (55.10)		22 (50.00)	24 (54.54)	
NYHA III, n (%)	32 (34.04)	14 (28.57)		20 (45.46)	13 (29.55)	
NYHA IV, n (%)	5 (5.32)	4 (8.17)		1 (2.27)	3 (6.82)	
EuroSCORE II	4.09 ± 1.24	6.31 ± 3.99	0.3	4.35 ± 1.69	6.59 ± 4.44	0.36
Comorbidities Smoking						
Former smoker, n (%)	25 (26.60)	19 (38.78)	0.32	16 (36.36)	18 (40.91)	0.17
No, n (%)	58 (61.70)	25 (51.02)		27 (61.37)	21 (47.73)	
Yes, n (%)	11 (11.70)	5 (10.20)		1 (2.27)	5 (11.36)	
Diabetes mellitus						
No	79 (84.04)	36 (73.47)	0.23	36 (81.82)	31 (70.45)	0.52
Diet	0 (0)	1 (2.04)		0 (0)	1 (2.27)	
OAD	14 (14.90)	10 (20.41)		7 (15.91)	10 (22.73)	
Insulin	1 (1.06)	2 (4.08)		1 (2.27)	2 (4.55)	
AHT	53 (56.38)	35 (71.43)	0.11	31 (70.45)	31 (70.45)	1
Hypercholesterolemia	54 (57.45)	31 (63.27)	0.62	30 (68.18)	28 (63.64)	1
COPD	7 (7.45)	4 (8.16)	1	3 (6.82)	4 (9.09)	1
Asthma	0 (0)	2 (4.08)	0.22	2 (4.55)	0 (0)	0.47
Liver disease	0 (0)	1 (2.04)	0.74	0 (0)	0 (0)	-
CVA	1 (1.06)	1 (2.04)	1	1 (2.27)	1 (2.27)	1
Nephrourological diseases	10 (10.64)	7 (14.29)	0.71	7 (15.91)	6 (13.64)	1
Endocarditis	4 (4.25)	5 (10.20)	0.3	1 (2.27)	5 (11.36)	0.2
Cancer	5 (5.32)	1 (2.04)	0.62	3 (6.82)	1 (2.27)	0.61

BMI: Body mass index; Preop NYHA: Preoperative New York Heart Association Functional Classification; OAD: Oral antidiabetics drugs; AHT: Arterial hypertension; COPD: chronic obstructive pulmonary disease; CVA: Cerebrovascular accident.
[a] Plus-minus values are means ± SD.

Table 2. Baseline and after PSM operative details and in-hospital complications (after AVR) [a].

Variables	Baseline			After PSM [b]		
	Trifecta™ GT	Perceval S	P-value	Trifecta™ GT	Perceval S	P-value
	(n=94)	(n=49)		(n=44)	(n=44)	
Valve prothesis size						
19 mm, n (%)	7 (7.45)	10 (20.41)	0.09	4 (9.09)	10 (22.73)	0.32
21 mm, n (%)	29 (30.85)	17 (34.69)		19 (43.18)	15 (34.09)	
23 mm, n (%)	37 (39.36)	13 (26.53)		14 (31.82)	11 (25.00)	
25 mm, n (%)	21 (22.34)	9 (18.37)		7 (15.91)	8 (18.18)	
Postop complications	30 (31.92)	20 (40.82)	0.38	17 (38.64)	18 (40.91)	1
Surgical, n (%)	2 (2.13)	1 (2.04)	1	1 (2.27)	1 (2.27)	1
Cardiac, n (%)	2 (2.13)	2 (4.08)	0.89	1 (2.27)	2 (4.55)	1
Arrythmia, n (%)	22 (23.40)	15 (30.61)	0.46	14 (31.82)	14 (31.82)	1
Respiratory, n (%)	3 (3.19)	4 (8.16)	0.36	1 (2.27)	4 (9.09)	0.36
Kidney, n (%)	4 (4.25)	4 (8.16)	0.56	2 (4.55)	3 (6.82)	1

Digestive, n (%)	1 (1.06)	1 (2.04)	0.77	0 (0)	1 (2.27)	1
Days in ICU	2.99 ± 1.00	3.14 ± 1.25	0.85	2.52 ± 0.31	3.16 ± 1.38	0.38
Hospitalization Days	9.94 ± 1.82	11.29 ± 2.98	0.45	8.39 ± 1.14	11.59 ± 3.31	0.08
EKG on discharge						
Sinus rhythm	88 (93.62)	39 (79.59)	0.02	41 (93.18)	34 (77.27)	0.05
Pacemaker	3 (3.19)	8 (16.33)		1 (2.27)	8 (18.18)	
Atrial fibrillation	3 (3.19)	2 (4.08)		2 (4.55)	2 (4.55)	
Reason for discharge						
Routine discharge	93 (98.94)	48 (97.96)	0.29	43 (97.73)	43 (97.73)	0.37
Transfer	1 (1.06)	0 (0)		1 (2.27)	0 (0)	
Death	0 (0)	1 (2.04)		0 (0)	1 (2.27)	
Postop NYHA functional class						
NYHA I, n (%)	59 (62.77)	28 (57.14)	0.77	24 (54.55)	26 (60.46)	0.47
NYHA II, n (%)	32 (34.04)	19 (38.78)		20 (45.45)	16 (37.21)	
NYHA III, n (%)	3 (3.19)	1 (2.04)		0 (0)	1 (2.33)	
NYHA IV, n (%)	0 (0)	0 (0)		0 (0)	0 (0)	

ICU: Intensive care unit; EKG: Electrocardiogram; Postop NYHA: Postoperative New York Heart Association Functional Classification.
[a] Plus-minus values are means ± SD.

Continuous data were expressed as mean ± SD and qualitative variables were expressed as percentages. Pre- and postoperative categorical variables of the two different groups were analysed using the Chi-squared test, whereas continuous data were analysed using the Student's t-test. In continuous data, in order to have reliable results, it is required normality (using the Shapiro-Wilks test) and homoscedasticity (using the Levene test) which are shown in Table 3. Then, a propensity score matching (PSM) was used to reduce the bias caused by differences between the two groups. It was estimated using a logistic regression model. Variables included in the PSM were age and gender.95% Confidence Intervals (CI) were used in this study. A P-value<0.05 was needed to consider the results statistically significant.

Table 3. Normality (Shapiro-Wilks test) and homoscedasticity (Levene test) tests.

Variables	Shapiro-Wilks test		Levene test
	Trifecta™ GT (n=94)	Perceval S (n=49)	P-value
Age, years	<0.001	0.02	<0.001
BMI, Kg/m2	0.13	0.17	0.74
EuroSCORE II	<0.001	<0.001	0.18
Days in ICU	<0.001	<0.001	0.84
Hospitalization Days	<0.001	<0.001	0.41

RESULTS

A total number of 143 patients underwent AVR with either Trifecta™ GT or Perceval S aortic bioprostheses, of which 94 patients received a Trifecta™ GT prosthesis (size 19 to 25 mm) and 49 a Perceval S prosthesis (size 19 to 25 mm).

As shown in Table 1, Trifecta™ GT presented with younger patients (64.57 ± 2.56 years *vs.* 72.96 ± 2.03 years, respectively; *P*=<0.001), more percentage of men (80.85% *vs.* 61.22%, respectively; *P*=0.019) and more sinus rhythm at discharge (93.62% *vs.* 79.59%, respectively; *P*=0.02).

The proportion of preoperative NYHA II and IV was lower in Trifecta™ GT (45.75% *vs.* 55.10%, respectively; *P*=0.48 and 5.32% *vs.* 8.17%, respectively; *P*=0.48), while NYHA I and III were greater in this group (14.89% *vs.* 8.16%, respectively; *P*=0.48 and 34.04% *vs.* 28.57%, respectively; *P*=0.48).Body mass index and smoking were similar in both groups (26.39 ± 0.88 *vs.* 26.49±1.12, respectively; *P*=0.89 and 11.70% *vs.* 10.20%, respectively; *P*=0.32).

The rest of comorbidities registered in the study [Diabetes mellitus (15.96% *vs.* 26.53%, respectively; *P*=0.23), arterial hypertension (56.38% *vs.* 71.43%, respectively; *P*=0.11), hypercholesterolemia (57.45% *vs.* 63.27%, respectively; *P*=0.62), chronic obstructive pulmonary disease (7.45% *vs.* 8.16%, respectively; *P*=1), asthma (0% *vs.* 4.08%, respectively; *P*=0.22), liver disease (0% *vs.* 2.04%, respectively; *P*=0.74), cerebrovascular accident (1.06% *vs.* 2.04%, respectively; *P*=1), nephrourological diseases (10.64% *vs.* 14.29%, respectively; *P*=0.71) and endocarditis (4.25% *vs.* 10.20%, respectively; *P*=0.30)] except cancer (5.32% *vs.* 2.04%, respectively; *P*=0.62), were more common in Trifecta™ GT group. With respect to the operative data, the Trifecta™ GT group had lower expected mortality scores regarding EuroSCORE II registry (4.09±1.24 *vs.* 6.31±3.99, respectively; *P*=0.30).

The valve size more commonly chosen for Trifecta™ GT group was 23 mm (39.36% *vs.* 26.53%, respectively; *P*=0.09), while in Perceval S was 21 mm (34.69% *vs.* 30.85%, respectively; *P*=0.09). Less postoperative complications appeared in Trifecta™ GT patients (31.92% *vs.* 40.82%, respectively; *P*=0.38). Patients of Trifecta™ GT group were less days in intensive care unit and hospitalized than Perceval S patients (2.99±1.00 *vs.* 3.14±1.25, respectively; *P*=0.85 and 9.94±1.82 *vs.* 11.29±2.98, respectively; *P*=0.45). Routine discharge as a reason for discharge was similar in both groups (98.94% *vs.* 97.96%, respectively; *P*=0.29). Postoperative NYHA functional class showed slightly better results in Trifecta™ GT group being that more patients move to NYHA I (62.77% *vs.* 57.14%, respectively; *P*=0.77). Mortality was lower in Trifecta™ GT group (0% *vs.* 2.04%, respectively; *P*=0.29).

Nevertheless, all those results with a P-value>0.05 in the quantitative variables do not reject the equality of means of the variables between the two groups and, in all those results with a P-value>0.05 in the qualitative variables, the independence of the variable considered

and the aggrupation variable, type of valve, is not rejected.

However, as seen in Table 1 and Table 2, after applying a PSM, baseline patients' characteristics, operative details and in-hospital complications were well balanced across both bioprosthetic valve type groups. Thus, regarding sex, age, EuroSCORE II, diabetes mellitus, arterial hypertension, hypercholesterolemia, asthma, nephrourological diseases, valve size, postoperative complications, cardiac postoperative complications, arrythmia, kidney postoperative complications, digestive postoperative complications, electrocardiogram on discharge and reason for discharge the P-value obtained were greater than the one before PSM.

All patients except one from Perceval S group, who died, completed the whole follow-up.

In order to have reliable results in continuous data, extra tests are needed. For this reason, it is required normality (using the Shapiro-Wilks test) and homoscedasticity (using the Levene test). The results are shown in Table 3. All variables tested with Shapiro-Wilks test have P<0.05 except body mass index (Trifecta™ GT *P*= 0.13 and Perceval S *P*=0.17). The Shapiro-Wilks test has rejected normality in Trifecta™ GT and Perceval S groups for the variables, but since sample sizes in both groups are greater than 30 and the P-value is not around 5%, this rejection does not have practical effects. All variables tested with Levene test have P>0.05 except age (P<0.001). The Levene test has rejected the homogeneity of variances in age, but since sample sizes in both groups are greater than 30 and the P-value is not around 5%, this rejection has no practical effects. The inhomogeneity of variances is considered in the contrasts of differences of means using the Welch correction. 95% CI were used in this study. A P-value<0.05 was needed to consider the results statistically significant.

DISCUSSION

Although previous studies have compared different types of aortic valve prostheses,[22,24] Trifecta™ GT and Perceval S have never been compared as far as we know. Based on the experience of other trials that have already compared other biological aortic valves, clinical results in the early postoperative period are supposed to be similar between the two types of aortic valves compared.

Patients from the Perceval S group were older than Trifecta™ GT patients (72.96±2.03 years *vs.* 64.57±2.56 years) and had smaller aortic annulus size (55.10% *vs.* 38.30%, respectively in 19-21mm valve protheses size). Shestha et al. indicated the advantages of sutureless valves for patients with small aortic roots.[25] Perceval S design allows the implantation of a bigger prosthesis size in small aortic annulus than stented valves. As the word says, sutureless valves do not have sutures. This leads in shorter ACC and CPB times and better results compared to conventional AVR with stented valves. In our study, this fact was translated into a decrease of general postoperative complications (40.82% *vs.* 31.92%, respectively although not statistically significant). However, in Mujtaba et al. study, the shorter ACC and CPB times of sutureless bioprostheses did not involve a reduction of postoperative complications.[26]

Perceval S group had a higher EuroSCORE II (6.31±.99 *vs.* 4.09±1.24, respectively; *P*=0.30). Patients with Perceval S had more comorbidities and this was reflected in the EuroSCORE II, which reflects a higher risk of mortality. However, in our study there was no higher mortality in Perceval S group, as the difference was not statistically significant (2.04% *vs.* 0%, respectively; *P*=0.29). In Forcillo et al. study same results are obtained and explained by a shorter ACC time which buffered the higher comorbidity.[27]

Moreover, a healthcare quality parameter of a service is the risk-adjusted mortality. In our study, this ratio is 0.16 in the Perceval S group and 0 in the TrifectaTM GT group. As both results are <1, we can conclude that the service quality standard is adequate.

Because of a higher number of patients with comorbidities in Perceval S group, in our study, these patients had longer intensive care unit stay and hospitalization stay, but this difference was not statistically significant, as it is seen in Forcillo et al. study.[27] Nevertheless, after balancing the samples with PSM, although the results were still not statistically significant, both P-value decreased in intensive care unit days and in hospitalization days from 0.85 to 0.38 and from 0.45 to 0.08, respectively. In Gilmanov et al. study, both stays were lower in the sutureless group.[28]

The incidence of postoperative pacemaker implantation was significantly higher in the Perceval S group (16.33% *vs.* 3.19%, respectively). Sutureless valves design effectuates higher radial strain in the aortic annulus. This fact can affect the cardiac conduction system. In other studies such as in Meco et al., this finding was algo obtained.[20]

Perceval S bioprosthetic valve was most frequently implanted in women (38.78% *vs.* 19.15%, respectively). This is because the aortic valve orifice is anatomically smaller in women than in men. As explained before, small valve protheses sizes (19-21mm) are more suitable in Perceval S group.

Our study allows drawing important conclusions. Both prostheses are safe and effective for AVR. However, their different design establish accurate indications for each of them. The TrifectaTM GT is a stented biological prosthesis that could be considered the gold standard for most AVRs. Nevertheless, Perceval S group had results comparable to those obtained in the TrifectaTM GT, even in patients with more comorbidities. For this reason, the implantation of Perceval S could be the first choice in patients with higher comorbidities and, thus, with a higher EuroSCORE II. Moreover, Perceval S could also be first choice in patients with small annulus. Apart from what is indicated above, the literature favours the Perceval S in cases of minimally invasive surgery, as its design allows an easier implantation through small accesses. In cases of endocarditis with aortic annulus destroyed, Perceval S is also indicated. Perceval S is also suitable in calcified aortic root without the possibility of suture.

Limitations

The present study has some limitations. Firstly, it enrolled a relatively small sample size. Due to SARS-CoV-2 the total number of operations has been reduced, which has forced the elimination of one of the groups initially planned to be added to the present study (Group C: TAVI (St. Jude Abbot Portico)). Secondly, the lack of randomization in the design. It is mandatory carrying out a prospective randomized controlled trial comparing both bioprostheses to confirm the findings from the current study. Thirdly, as it is a retrospective study, it has not been possible to study the hemodynamic results, since these data are not routinely saved in the database used, the SICCS. What is more, postoperative hemodynamic profiles that are routinely evaluated through transthoracic echocardiography are performed in the patient's referral centre and it is not always the Quironsalud-Teknon Heart Institute. That is why it would be necessary to add these outcomes in future studies to confirm

that the different clinical results obtained resemble to the hemodynamic performances. Finally, the follow-up time is another limitation of the present study since both bioprostheses need also long-term follow-up data to confirm their promising clinical results. Clinical results only at discharge are not enough to have complete information about the durability and global complications of Trifecta™ GT prosthesis compared to Perceval S prosthesis.

CONCLUSION

In conclusion, although Perceval S group included older patients, more women, more comorbidities and higher EuroSCORE II, short-term results did not show any statistical significant differences between stented and sutureless valves. However, further studies are needed to evaluate the clinical results in mid and long-term, confirming the early documented favourable data.

ACKNOWLEDGMENTS

We gratefully acknowledge Dr. Xavier Ruyra, head of the Department of Cardiac Surgery at Quironsalud-Teknon Heart Institute, for giving us the opportunity to carry out this study in his department; the cardiac surgeons of the Department of Cardiac Surgery at Quironsalud-Teknon Heart Institute who performed the heart surgeries and all of the Hospital/Heart Institute collaborators. We would also acknowledge Matías-Gámez for his assistance on the statistical analysis, teaching us how to use the software programme; and Isabel García for contacting us and facilitating the search for statistical help.

CONFLICTS OF INTEREST

None.

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