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Original Article

The performance of the supra-annular Top-Hat aortic valves compared to the standard Carbomedics valves

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Abstract

Background: The CarboMedics Top-Hat aortic valve prosthesis was designed to be implanted in a supra-annular position. This study aimed to compare the hemodynamic performance of the Top-Hat aortic prostheses versus the standard CarboMedics aortic valve prostheses.

Methods: The study included 98 patients who had aortic valve replacement and were divided into two groups. Group A included 60 patients who had standard aortic valve prostheses, and Group B included 38 patients who had the Top-Hat aortic prostheses. The study endpoints were hospital outcomes, the effective orifice area, and the pressure gradient during a one-year follow-up.

Results: There was no significant difference in the baseline echocardiographic data and risk factors between the groups. The patients who had Top-Hat aortic prosthesis were younger, with a mean age of 47.5 (44-55) years, and those who had the standard prosthesis were 53.5 (48-56) years old (P= 0.02). The cardiopulmonary bypass time was significantly less in the Top-Hat prosthesis group with an average of 78 min (75- 81) compared to 88 min (84- 95) in the other group (P <0.001). The effective orifice surface area was significantly larger in the group with Top-Hat prosthesis; 0.9 mm/m2 (0.88- 0.92) compared to 0.84 mm/m 2 (0.79- 0.87) for the standard aortic valve prosthesis group (P <0.001). The pressure gradient over the aortic valve decreased significantly postoperatively (coefficient -1.98 (-2.21- -1.75); P<0.001). Patients with Top-Hat valves had significantly lower gradient (coefficient: -4.22 (-6.61- -1.82); P= 0.001), while age had no effect on the pressure gradient (coefficient: 0.1 (-0.07- 0.27); P= 0.25).

Conclusion: The Top-Hat CarboMedics prostheses could be superior to the standard CarboMedics aortic valve prosthesis regarding the effective orifice area and pressure gradient over the valve.

KEYWORDS

Top-Hat; Carbomedics; Aortic valve replacement

Article History

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Introduction

Mechanical aortic valve replacement (AVR) is the standard treatment in young patients with hemodynamically significant aortic valve disease [1, 2]. Small aortic roots increase operative risk, and patients with small roots require particular surgical strategies [3, 4]. Small aortic valve prostheses are an independent risk factor for poor short and long-term outcomes [5]. Implantation of conventional metalic valves in patients with small aortic roots, may mismatch the size of the native aortic valve ring and the sinuses of Valsalva.

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Therefore, the implantation of a mechanical aortic valve with improved hemodynamics parameters in the form of top hat aortic valve could be a good surgical option. The CarboMedics Top-Hat bi-leaflet valve could be inserted in the supra-annular position; therefore, a large valve can be used, decreasing the probability of patient-prosthesis mismatch [6, 7]. The objective of this study was to compare AVR using the standard CarboMedics mechanical valve prostheses to the Top-Hat mechanical valves.

Patients and Methods

Design and patients:

This retrospective study was conducted on 98 patients who underwent aortic valve replacement surgery over 5 years starting from 2015 till 2020. Patients were grouped according to the two CarboMedics aortic valve prostheses; the standard one and the Top-Hat prosthesis. Group (A) involved 60 patients who underwent aortic valve replacement with standard CarboMedics aortic valve prosthesis, and group (B) included 38 patients who underwent aortic valve replacement using Top-Hat aortic valve prostheses.

We included isolated aortic valve surgery with severe symptomatic aortic stenosis either alone or combined with aortic incompetence. All patients had an ejection fraction above 35%. The effective orifice area of the valve was used to fit the patient's body surface area to prevent patient prosthesis mismatch. Diagnostic coronary angiography was done preoperatively for male patients above 40 years and female patients above 45 years. Patients with normal coronaries were included. We excluded those with combined cardiac surgery or heart failure patients with low flow, low gradient aortic stenosis. We excluded patients above 60-year-old and patients with aortic annulus below 19 mm or needing aortic root dilatation. Patients with tissue valve aortic surgery or who needed permanent pacemakers early postoperative were excluded. Patients with minimally invasive access were also not included in our study.

Choice of the prostheses and the surgical procedure were performed according to the surgeons' preferences.

Data and endpoints:

Preoperative data included age, gender, comorbidities, baseline echocardiographic data, including (pressure gradient across the aortic valve, presence of aortic incompetence, regurgitant volume, and ejection fraction). Procedural details included the valve size, ischemic and cardiopulmonary bypass times. Postoperative data included blood loss, re-exploration for bleeding, ICU hospital stay, renal failure, wound infection, and postoperative echocardiographic findings (effective orifice area and pressure gradient across the valve) 6 and 12 months postoperatively.

Study endpoints were hospital outcomes and the change in the pressure gradient across the aortic valve during follow-up

Ethical considerations:

The Local Ethical Committee approved the study, and the need for patients' consent was waived.

Statistical analysis:

We tested the distribution of continuous variables with histograms and the Shapiro Wilk test. Data were described as mean and standard deviation if normally distributed or median and inter-quartile range if non-normal. Binary data were expressed as frequencies and percentages. When appropriate, continuous data were compared with the Student t-test or Wilcoxon test and binary data with the Chi-square or Fisher exact test. A random linear effect model was used to evaluate factors affecting the change in pressure gradient on the aortic valve. All statistical analyses were done using Stata 16 (Stata Corp- College Station- TX- USA), and a P-value of less than 0.05 was considered significant.

Results

Preoperative and operative data:

The patients who had Top-Hat aortic valves were younger, and there were no differences in other preoperative parameters between both groups. Cardiopulmonary bypass time was shorter in the Top-Hat patients, with no significant difference in ischemic time and valve size between both groups. (Table 1)

Table 1: Comparison of the preoperative and operative data between groups. Continuous data were presented as mean and SD or median (25th- 75th percentiles) and binary data as frequencies and percentages

	Standard AVR (n= 60)	Top Hat AVR (n= 38)	P
Age (years)	53.5 (48- 56)	47.5 (44- 55)	0.02
Male	35 (58.33%)	22 (57.89%)	>0.99
Aortic valve lesion			
Aortic stenosis	51 (85%)	32 (84.21%)	>0.99
Aortic regurgitation and stenosis	9 (14.75%)	6 (15.79%)	
Aortic annulus (mm)	20.48± 1.17	20.52±1.20	0.86
Aortic valve pressure mean gradient (mmHg)	50 (45- 52)	50.5 (45- 54)	0.42
Ejection fraction (%)	47.68± 6.17	47.39± 6.21	0.82
Regurgitation volume (ml)	69.56± 4.30	68.17± 1.83	0.47
Hypertension	5 (8.33%)	4 (10.53%)	0.73
Diabetes mellitus	34 (56.67%)	23 (60.53%)	0.83
Ischemic time (min)	52 (46- 57)	50 (46- 52)	0.27
Cardiopulmonary bypass time (min)	88 (84- 95)	78 (75- 81)	<0.001
Valve size (mm)	20± 1.01	19.68± 0.96	0.13

Postoperative data:

There were no differences in postoperative outcomes between groups. Effective orifice area was higher in patients with Top-Hat. (Table 2)

Change in the pressure gradient:

Pressure gradient over the aortic valve decreased significantly postoperatively (coefficient -1.98 (-2.21- -1.75); P<0.001). Patients with Top Hat valve had significantly lower gradient (coefficient: -4.22 (-6.61- -1.82); P= 0.001), while age had no effect on the pressure gradient (coefficient: 0.1 (-0.07- 0.27); P= 0.25). (Figure 1)

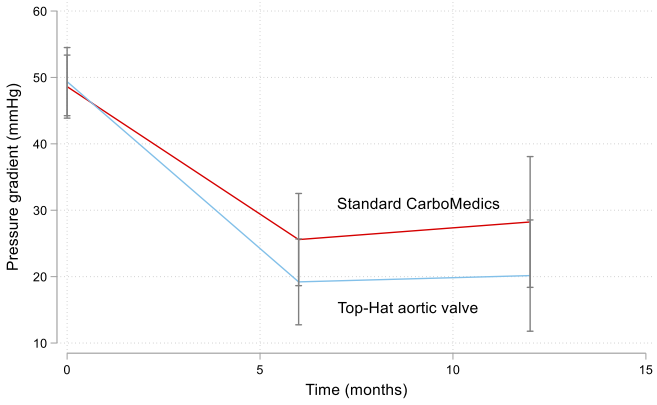

Figure 1: Changes of the mean aortic valve pressure gradient between groups

Discussion

The CarboMedics heart valves were first used worldwide in 1986. They were superior to other valves in the rotatability of the valve after implantation, and their outcomes were generally favorable compared to those reported from St. Jude prosthesis [8-13]. In 1993 CarboMedics Top-Hat valve was introduced to be inserted in supra-valvular position allowing larger effective orifice area postoperative and less incidence of patient prosthesis mismatch [14-16].

In this study, we compared the patients who did aortic valve replacement using Top-Hat CarboMedics prosthesis with those who underwent aortic valve replacement using standard CarboMedics prosthesis. We found that the patients with Top-Hat prostheses were younger than those with traditional prostheses by a significant value. This difference could be attributed to our preference to insert the Top-Hat valve in young patients to achieve a higher effective orifice area.

There was a significant decrease in cardiopulmonary bypass time in patients who had Top-Hat prosthesis with an average time of 78 minutes compared to those with standard CarboMedics prosthesis with an average of 88 minutes. This finding is similar to that reported by Roedler and colleagues, which was done on 316 patients where 56 patients had Top-Hat, and the other 260 patients had the standard CarboMedics prosthesis. They found that cardiopulmonary bypass time was less in the Top-Hat prosthesis with less postoperative hospital stay [17]. Several

Table 2: Comparison of postoperative outcomes between the groups. Continuous data were presented as mean and SD or median (25th- 75th percentiles) and binary data as frequencies and percentages

	Standard AVR (n= 60)	Top Hat AVR (n= 38)	P
Blood loss (ml)	535 (480- 580)	530 (490- 570)	0.89
Re-exploration for bleeding	4 (6.67%)	2 (5.26%)	>0.99
ICU stay (days)	5 (4- 6)	5 (4- 5)	0.14
Effective orifice surface area (mm/m2)	0.84 (0.79- 0.87)	0.9 (0.88- 0.92)	<0.001
Renal failure	1 (1.67%)	1 (2.63%)	>0.99
Wound infection	6 (10%)	4 (10.53%)	>0.99

factors could contribute to the shorter bypass time, including the surgeons' experience and the supra-annular position of the valve. On the other hand, we did not report a significant difference in ischemic time between groups; however, it was lower in the Top-Hat group. This finding may be due to the small sample size in our study. Bernla and colleagues found a significant decrease in myocardial ischemic time with the Top-Hat patients, which could have impacted the short and long-term outcomes.

The effective orifice area was larger with the Top-Hat prostheses compared to the standard CarboMedics prostheses. This result is concordant with Bernla and colleagues' study, which found that the Top-Hat CarboMedics supra-annular prosthesis had a relatively large effective orifice area and allowed implantation of a larger prosthesis without increasing valve-related complications [18]. This observation is related to the valve position since the supra-annular implantation facilitates the use of larger valves. Therefore, Top-Hat valves could be an option in patients with small aortic roots.

Aagaard and colleagues performed a study on 52 patients who had Top Hat supra-annular prosthesis and were compared with CarboMedics intra-annular valves. They noted that patients with supra-annular Top-Hat prosthesis had better hemodynamic parameters and an effective orifice area and mean pressure gradient across the aortic valve. They found that using supra-annular prosthesis allowed the use of a larger prosthesis with less valve-related complications and less patient prosthesis mismatch [19].

Study limitations

There are several limitations to the current study. First, the study is retrospective in nature with its inherent biases. Patient selection could be confounded by indication, and there could be several factors that affected the outcomes and were not measured in our study. Second, the study is limited by the small sample size in both groups. Lastly, this is a single-center experience, and generalization of the results could be an issue.

Conclusion

The Top-Hat CarboMedics prostheses could be superior to the standard CarboMedics aortic valve prostheses regarding the pressure gradient and the effective orifice area, especially in patients with small aortic annulus with decreased patient prosthesis mismatch.

Conflict of interest: Authors declare no conflict of interest.

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