The Journal of
Thoracic and Cardiovascular Surgery

A randomized comparison of the MCRI On-X and CarboMedics Top Hat bileaflet mechanical replacement aortic valves: Early postoperative hemodynamic function and clinical events

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J Thorac Cardiovasc Surg 2005;130:759-764

A randomized comparison of the MCRI On-X and CarboMedics Top Hat bileaflet mechanical replacement aortic valves: Early postoperative hemodynamic function and clinical events

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Objective: This study compared hemodynamic function and clinical events in consecutive patients randomly assigned to receive a wholly supra-annular replacement valve or a valve with an intra-annular component.

Methods: Fifty-two patients with an average age of 62 years (range 40-74 years) were sized for both a CarboMedics Top Hat valve (CarboMedics Inc, Austin, Tex) and an MCRI On-X valve (Medical Carbon Research Institute, LLC, Austin, Tex) before random assignment to receive either valve type. Echocardiographic and clinical assessments were performed in the immediate postoperative period and at 1 year.

Results: The mean effective orifice areas were 1.41 ± 0.42 cm^2 for the Top Hat and 2.17 ± 0.78 cm^2 for the On-X ($P < .0001$). The mean pressure differences were 12.2 ± 4.4 mm Hg and 6.9 ± 3.6 mm Hg, respectively ($P < .0001$). New York Heart Association functional class was better with the On-X than the Top Hat valves, but there were no differences in clinical events, regression of left ventricular mass, or measures of hemolysis.

Conclusion: The partially intra-annular MCRI On-X valve was hemodynamically superior to the wholly supra-annular CarboMedics Top Hat valve. However, there were no differences in early clinical outcomes between the two valve types.

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Funded by Research Echocardiography with an unrestricted grant from MCRI (Medical Carbon Research Institute). The Valve Study group has also received grants from Medtronic, St Jude Medical, CarboMedics, and Cryolife. The study was wholly designed, analyzed, and written by the authors, who retain all academic rights to the data.

Some of the data in this article were presented at the Second Biennial Meeting of the Society of Heart Valve Disease (2003) and the Annual Meeting of the Society of CardioThoracic Surgeons of Great Britain (2004).

Received for publication Nov 6, 2004; revisions received Feb 10, 2005; accepted for publication Feb 25, 2005.

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J Thorac Cardiovasc Surg 2005;130:759-64

0022-5223/$30.00

doi:10.1016/j.jtcvs.2005.02.057

Most surgeons try to obtain the best possible hemodynamic result after aortic valve replacement surgery in the belief that this optimizes functional recovery and survival.[1,2] Bileaflet valves are the least obstructive mechanical design[3] but may still cause clinically significant resistance in the small sizes because the sewing ring reduces the area available for flow.[4,5] Manufacturers have therefore developed enhanced-performance intra-annular valves by reducing the bulk of the sewing ring. Another solution is to raise the cuff above the tissue annulus while at the same time retaining an intra-annular component (Figure 1, *A*) as in the MCRI On-X (Medical Carbon Research Institute, LLC, Austin, Tex) valve and AP-ATS valve. Finally, the whole of the valve can be placed in a supra-annular position so that the tissue annulus contains no valve parts and the orifice of the valve

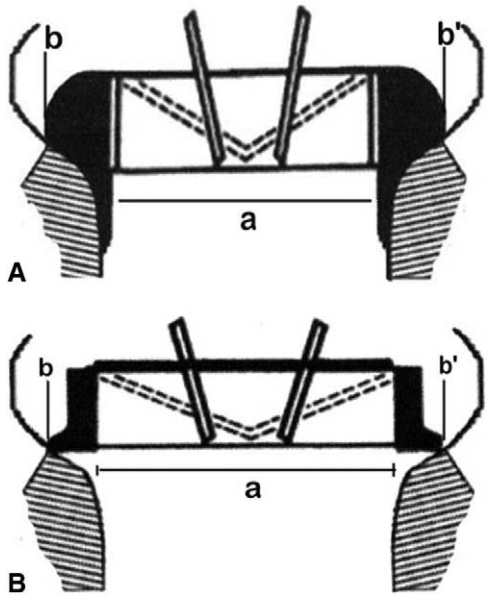

Figure 1. Diagram of different implantation positions for supra-annular valves. A, Partially intra-annular valve such as On-X. Sewing ring is supra-annular, but part of housing is implanted within annulus. B, Wholly supra-annular valve such as Top Hat. Diameter *(a)* represents internal diameter of orifice, and diameter between points *b* and *b′* represents maximum diameter of supra-annular portion of valve. Patient tissue annulus diameter is diameter of annulus after débridement. For On-X, this is equivalent to outer diameter of intra-annular portion of housing. For Top Hat, it can be equivalent to inner diameter *(a)*, provided that maximum supra-annular diameter (*b* to *b′*) is then able to fit within aortic root.

TABLE 1. Demographic data

	Top Hat (n = 25)	On-X (n = 27)
Age (y, mean and range)	61 (50-72)	62 (40-74)
Male/female ratio	14:11	17:10
Body surface area (m^2, mean ± SD)	1.82 ± 0.21	1.87 ± 0.31
Left ventricular outflow diameter (cm, mean ± SD)	2.05 (0.26)	2.10 (0.22)
Associated mitral replacement (No.)	2 (8%)	2 (7%)
Associated coronary artery bypass grafting (No.)	6 (24%)	5 (19%)
Preoperative NYHA class (No.)		
Class I	5 (20%)	3 (11%)
Class II	10 (40%)	12 (44%)
Class III	9 (36%)	10 (37%)
Class IV	1 (4%)	2 (8%)
Preoperative aortic stenosis (No.)	18 (72%)	19 (70%)
Aortic regurgitation (No.)	6 (24%)	5 (19%)
Mixed aortic valve disease (No.)	1 (4%)	3 (11%)
Left ventricular hypertrophy (No.)	15 (60%)	13 (48%)
Left ventricular ejection fraction <40% (No.)	2 (8%)	1 (4%)

NYHA, New York Heart Association.

can theoretically be the same size as the annulus (Figure 1, *B*). An examples of this valve type is the CarboMedics Top Hat valve (CarboMedics Inc, Austin, Tex).

We confirmed[6] that a larger geometric orifice is possible in vitro with the wholly supra-annular CarboMedics Top Hat valve than with the MCRI On-X valve. However, the extended housing of the intra-annular component of the On-X valve is designed to reduce the pressure drop across the orifice. It is possible that this design feature might compensate for any tendency toward higher pressure differences as a result of the smaller geometric orifice. The purpose of this study was to compare early hemodynamic function and clinical events in patients randomly assigned to receive either the MCRI On-X or CarboMedics Top Hat valve.

Methods

Patients

A total of 52 consecutive patients scheduled to undergo aortic valve replacement with a mechanical valve were randomly assigned to receive either the On-X valve (n = 27) or the CarboMedics supra-annular Top Hat valve (n = 25). The mean age was 62 years (range 40-74 years), and 31 (60%) were male. The disease requiring surgery was dominant stenosis in 36 patients, dominant regurgitation in 11, and mixed disease in 5. No patient had preoperative endocarditis or a coexistent condition with significant mortality. Two patients were discharged early, and 3 patients died within 1 year. Predischarge echocardiograms were therefore available for 50 patients, and echocardiograms at 1 year were available for 49 patients. Demographic data in the On-X and Top Hat groups were similar, except that there were more men in the On-X group (Table 1). The study was approved by the local committee on ethical practice, and all patients gave written, informed consent.

Surgery

There were 11 associated coronary artery bypass grafting procedures and 4 mitral replacements, divided evenly between the two groups. No patient required aortoplasty. Before the randomization envelope was opened, the patients were sized for both designs of valve with the sizers provided by the manufacturers. Both sets of sizers incorporate models of the valve to be implanted, and these vary according to the label size of the valve (Table 2). Table 2 displays label size versus the theoretic tissue annulus diameter modeled in vitro with machined polypropylene blocks,[6] the geometric orifice area,[6] and the maximum diameter of the supra-annular portion of the valve measured with a previously validated[6] vernier caliper (Mitutoya RS 548-710; Mitutoya, Japan). There is no sizer for the 27/29 On-X. In each case, the surgeon selected a label size determined by the largest sizer that could be accommodated in the aortic root after excision of the diseased valve and full débridement of calcium. The limiting factor in sizing both types of

TABLE 2. Valve measurements

	In vitro tissue annulus diameter (mm)*		Maximum external diameter of sizer (mm)†		Geometric orifice area (mm^2)*	
Label size	Top Hat	On-X	Top Hat	On-X	Top Hat	On-X
19	17	20	22.9	22.0	160	222
21	18	22.5	25.2	24.0	208	280
23	19.5	24.5	27.5	26.0	256	343
25	21.5	26.5	30.6	28.0	316	405
27	24	26.5	32.7	—	384	405

*These measures taken from Chambers and colleagues.[6] The geometric orifice area and the internal diameter (a in Figure 1) are measured from the orifice omitting the leaflets. †Measured from point b to b′ in Figure 1, *A* and *B*.

TABLE 3. Valves implanted at each labeled size

Label size	Top Hat	On-X	Proportion of total
19	2	3	9.6%
21	5	4	17.3%
23	10	7	32.7%
25	6	10	30.8%
27	2	3	9.6%

TABLE 4. Predischarge hemodynamic results

Label size	Top Hat	On-X	*P* value
Peak velocity (m/s)	2.39 ± 0.39	1.94 ± 0.44	<.0001
Peak pressure drop (mm Hg)	22.55 ± 7.51	14.91 ± 6.75	<.0001
Mean pressure drop (mm Hg)	12.18 ± 4.37	6.88 ± 3.58	<.0001
Effective orifice area (cm^2)	1.41 ± 0.42	2.17 ± 0.78	<.0001

Values are mean ± SD.

valve was the diameter of the immediate supra-annular portion of the recipient aortic root, as determined by the rigid valve sizer. For those receiving a Top Hat valve, the mean (±SD) label size was 23.4 ± 2.2, which was not statistically significantly different from the mean size (23.0 ± 2.5) had the On-X had been implanted instead. For those receiving an On-X valve, the mean size was 23.7 ± 2.1, whereas it would have been 23.7 ± 2.2 had the Top Hat been chosen instead (difference not significant). The difference between the sizes of Top Hat and On-X valves actually implanted was not statistically significant.

Echocardiography

Studies were performed preoperatively, immediately before hospital discharge, and at 1 year (11-14 months). An ATL HDI 3000 (ATL Ultrasound, Bothell, Wash) was used with a 3-2 20-mm duplex probe and 1.9-MHz continuous-wave stand-alone probe. Effective orifice area was calculated with the classic form of the continuity equation incorporating the ratio of subaortic to transaortic systolic velocity time integral. The mean transprosthetic pressure difference was calculated from the long form of the modified Bernoulli equation. Left ventricular mass was calculated from a standard formula,[7] and sex-related criteria for left ventricular hypertrophy[8] were applied.

Clinical Follow-up

Clinical data were recorded preoperatively, before discharge, and at 1 year. Clinical events were defined by standard criteria[9] according to occurrence before 30 days and between 30 days and one year. Blood was drawn preoperatively and at 12 months to measure lactate dehydrogenase (LDH), haptoglobin, bilirubin, and hemoglobin levels and the reticulocyte count.

Analysis

Mean and SD values were calculated. Continuous variables were compared with unpaired *t* tests, and discrete variables were compared with the Fisher exact test. The 27/29 MCRI On-X was treated as a 27 valve for comparison with the labeled size of the CarboMedics Top Hat valve. We also recorded the proportion of patients in whom the LDH level was above the normal range (286-580 U/L), the haptoglobin level was below the normal range (30-200 mg/dL), and the reticulocyte count was above the normal range (40-130 × 10^9 cells/L).

Results

Hemodynamic Function

The frequencies of labeled sizes are given in Table 3. The CarboMedics Top Hat group was relatively more obstructive than the MCRI On-X group (Table 4), with a mean pressure drop of 12.2 mm Hg versus 6.9 mm Hg ($P < .0001$) and an effective orifice area of 1.41 cm^2 versus 2.17 cm^2 ($P < .0001$). Results by labeled size are given in Tables 5A through 5C. Preoperative left ventricular mass indices were 143.5 ± 61.2 g/m^2 for the Top Hat and 139.8 ± 51.6 g/m^2 for the On-X. At 1 year, left ventricular mass indices had fallen to 101.9 ± 53.5 g/m^2 in the Top Hat group and 95.9 ± 44.1 g/m^2 in the On-X group. The falls were 41.6 g/m^2 for the Top Hat and 43.9 g/m^2 for the On-X (difference not significant).

Clinical Follow-up

Clinical events. There were no differences in the frequency of clinical events (Table 6). There was 1 death before 30 days in each group (total early mortality 3.8%) and 1 death in the Top Hat group between 30 days and 1 year. There were no strokes before 30 days in either group and 1 between 30 days and 1 year in the Top Hat group. There were no transient ischemic attacks in the Top Hat group and 2 in the On-X group, 1 before 30 days and 1 between 30 days and 1 year. There were no instances of myocardial infarction, endocarditis, valve thrombosis, or valve failure.

Functional class. The New York Heart Association (NYHA) functional classes before surgery were similar between the groups (Table 1). At 1 year after surgery, 16 of 23 patients in the Top Hat group (70%) were in class I, and

ACD

TABLE 5A. Peak velocities in Top Hat and On-X valves by labeled size

Label size	Top Hat	On-X
19	2.85	2.20
21	2.45 ± 0.44	2.37
23	2.34 ± 0.51	2.23 ± 0.31
25	2.32 ± 0.16	1.62 ± 0.35
27	2.20	1.70

Values are mean ± SD.

TABLE 5B. Mean pressure differences in Top Hat and On-X valves by labeled size

Label size	Top Hat	On-X
19	18.3	9.70
21	13.38 ± 4.64	10.13
23	11.76 ± 5.18	8.81 ± 3.56
25	10.36 ± 2.47	4.47 ± 2.67
27	9.87	4.70

Values are mean ± SD.

TABLE 5C. Effective orifice areas in Top Hat and On-X valves by labeled size

Label size	Top Hat	On-X
19	1.05	1.22
21	1.17 ± 0.23	1.90
23	1.37 ± 0.34	1.78 ± 0.34
25	1.61 ± 0.32	2.37 ± 0.37
27	1.94	2.55

Values are mean ± SD.

7 (30%) were in class II. By comparison, 24 of 26 in the On-X group (92%) were in class I, and 2 (8%) were in class II. The difference between the valve types was statistically significant ($P = .039$; Table 7).

Blood Results

The LDH level increased by a mean of 169 U/L (range −37 to 559 U/L) for the On-X valves and 261 U/L (range −14 to 544 U/L) for the Top Hat valves ($P = .069$). In the Top Hat group, there was a low haptoglobin level before surgery in 10%, compared with 68% after surgery; in the On-X group, there was a low haptoglobin level in 29% before surgery, compared with 72% after surgery. In the Top Hat group, the LDH level was high in 19% before and 85% after surgery; in the On-X group, these proportions were 30% before and 64% after.

At 1 year after surgery, there were 9 patients in the Top Hat group and 8 in the On-X group with a combination of a raised LDH level, low haptoglobin level, and normal reticulocyte count. There were 2 patients, both with Top Hat valves, with a high LDH level and a raised reticulocyte count, 1 with a normal haptoglobin level and the other with a low haptoglobin level. However, no patient in either group had a low hemoglobin level or a significantly raised bilirubin level.

TABLE 6. Clinical events

	Top Hat	On-X
Death, <30 d	1	1
Death, 30 d to 12 mo	1	0
Stroke, <30 d	0	0
Stroke, 30 d to 12 mo	1	0
Transient ischemic attack, <30 d	0	1
Transient ischemic attack, 30 d to 12 mo	0	1
Hemorrhage, <30 d	1	0
Hemorrhage, 30 d to 12 mo	0	1

Discussion

The orifice of the CarboMedics supra-annular Top Hat valve is expected to approximate that of the patient tissue annulus (Figure 1, *B*). In contrast, the On-X valve housing is partially intra-annular, so that its internal orifice must be smaller than the patient tissue annulus (Figure 1, *A*). The main aim of this study was to see whether the flared inlet and elongated housing could offset this potential hemodynamic disadvantage. In fact, the On-X proved hemodynamically superior to the Top Hat valve.

The expectation when two types of valve are compared is that sizing will be based on the patient tissue annulus. In an in vitro study,[6] in which the annulus was modeled by a machined polypropylene block, a CarboMedics Top Hat valve corresponded to an On-X valve two sizes smaller. However, the in vitro model did not incorporate an aortic root, and the results of this study show that the label sizes of both valves were limited by the size of the supra-annular portions of both valves, rather than by the tissue annulus. Table 2 shows that for a given in vitro annulus diameter, a Top Hat approximately two sizes larger than an On-X could be implanted. For example, the 23 Top Hat fits a 19.5 mm annulus, and the 19 On-X fits a 20 mm annulus. However the supra-annular diameter, as shown by the sizer, is 27.5 mm for the 23 Top Hat and only 22.0 mm for the 19 On-X. In fact, for a given label size, the supra-annular diameter of the Top Hat is between 0.9 and 2.6 mm larger than that of the On-X valve. We believe this explains why we found similar label sizes when each patient was sized for both valve types. Because of differences in sizing convention, the orifice area is larger for the On-X than the Top Hat for a given label size. In this study, the mean geometric orifice area for the Top Hat valves actually implanted was 2.63 ± 0.59 cm^2, versus 3.50 ± 0.65 cm^2 ($P < .0001$) for the On-X. In clinical practice, factors other than aortic root size may determine label size. A heavily calcified annulus may limit

TABLE 7. Postoperative NYHA functional class

	Top Hat			On-X		
	30 d	6 mo	1 y	30 d	6 mo	1 y
Class I	21 (88%)	19 (83%)	16 (70%)	24 (92%)	25 (96%)	24 (92%)
Class II	2 (8%)	4 (17%)	7 (30%)	2 (8%)	1 (4%)	2 (8%)
Class III	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Class IV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

NYHA, New York Heart Association.

the labeled size of an On-X valve because of its flared housing, or a low left coronary ostium may limit the size of Top Hat valve.

This is the first randomized comparison of the Top Hat and On-X valves. However, examination of previous clinical studies[10,11] shows evidence that the apparent label size advantage of the Top Hat is not fully realized. Those studies[10,11] reporting a size advantage for the Top Hat relative to the standard CarboMedics valve do in fact show downsizing of the Top Hat by 3 to 4 mm in comparison with in vitro data.[6] In one study,[10] the mean labeled size for the Top Hat was 20.8, versus 18.9 for the standard valve. However, a standard size 19 valve fits a patient tissue annulus about 21.5 mm in diameter,[6] which according to in vitro data[6] would be expected to take a Top Hat size 25 rather than only 20.8. Such size comparisons are more in keeping with the results of this study than with expectations from in vitro work.

Other evidence suggests that our sizing was appropriate. We implanted substantially larger Top Hat valves than in a study of 693 patients from five centers in the United States[12] and another of 127 patients from Spain.[10] The proportion of larger valves (size 25 and 27), was 40% in our study, versus only 15% and 0% in the other studies.[10,12] In contrast, the proportion of smaller valves (size 19 and 21) was only 28% in our study, versus 52% and 77%.[10,12] Although body surface area was not given for these other two studies, it is unlikely that the patients were significantly smaller than ours.

Clinical Results

The incidence of clinical events was low, with an early mortality of 2.8% and no myocardial infarction, endocarditis, valve thrombosis, or valve failure. This is consistent with previous reports of both the On-X[13,14] and Top Hat,[10,12,15] although no other randomized comparisons exist. We showed no significant differences between the groups. This study was small, however, and not powered to detect small differences in clinical events.

There was no difference in the degree of regression of left ventricular mass, despite the statistically significant difference in hemodynamic function. Other studies also show a lack of congruence between hemodynamic function and left ventricular mass.[16,17] This could be related to the poor repeatability of unidimensional echocardiography relative to magnetic resonance imaging,[18] so that small difference in left ventricular mass could have been missed. It may also have been caused by the presence of other determinants of left ventricular mass.[19]

Previous studies have commented on a low incidence of hemolysis for the On-X relative to other valves[13,20] according to historical data.[21,22] However, there have been no previous randomized comparisons. In fact, although there was a smaller increase in LDH from before surgery to 1 year in the On-X group than in the Top Hat group, there were no statistically significant differences between the groups. No patient in either group had anemia or a raised bilirubin level.

Functional class was significant better with the On-X valves than with the Top Hat valves. No patient was in NYHA functional class III or IV, but 30% with a Top Hat valve as opposed to only 8% with an On-X valve were in NYHA functional class II, and 70% and 92%, respectively were in NYHA functional class I. It is possible that this reflects the difference in hemodynamic function, but it is more likely to be a statistical variant.

Limitations

The population sizes were small, and the follow-up was only for 1 year. Concomitant procedures might ideally have been excluded, but the small number of patients with concomitant mitral surgery and those with coronary bypass grafting were evenly divided between the two groups. Furthermore, there were no statistically significant differences in demographic characteristics at baseline. Nevertheless, our power to comment on clinical events, NYHA functional class, and regression of left ventricular mass is inevitably limited. However, the population size is not expected to affect our general conclusions about valve size and hemodynamic performance.

Conclusion

In a randomized comparison, the MCRI On-X valve with a partially intra-annular housing had a better hemodynamic performance than the wholly supra-annular CarboMedics

Top Hat valve. We suggest that the label size of the valves implanted was limited by the diameter of the sizer within the aortic root, which was larger for the Top Hat than for the On-X. There were no statistically significant differences in clinical event rate, hemolysis, or regression of left ventricular hypertrophy at 1 year.

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