

# A Single-Center Experience of the Sorin Bicarbon Heart Valve Prosthesis: Long-Term Clinical, Hematological and Hemodynamic Results

Donald C. Whitaker, Stuart E. James, Robin K. Walesby

Department of Cardiothoracic Surgery, University College London Hospitals, London, UK

**Background and aim of the study:** The Sorin Bicarbon (SB) bileaflet valve, available since 1990, has a good clinical safety profile. The study aim was to assess the long-term clinical results following implantation, plus hemodynamic and hematological aspects of the valve.

**Methods:** A total of 195 SB prostheses (100 aortic, 67 mitral, 14 double valve replacements) was implanted in 181 patients (108 males, 73 females) since 1991.

**Results:** Mean age at implantation was  $60.5 \pm 10.8$  years. Actuarial analysis at 9.0 years showed an overall survival of  $63.9 \pm 5.5\%$ ; 28.2% of deaths were early ( $n = 11$ ), and 71.8% late ( $n = 28$ ). Freedom from thrombosis was  $99.4 \pm 0.6\%$  (one early event, successfully reoperated on), and from embolic events was  $86.3 \pm 4.7\%$ . Freedom from endocarditis and hemorrhagic complications were respectively  $98.1 \pm 1.1\%$  and  $98.6 \pm 0.9\%$ . No occurrence of hemolysis was reported. Freedom from non-structural valve dysfunction was  $98.7 \pm 0.9\%$ , and from reoperation was  $96.1 \pm 1.6\%$ . Hemodynamic evaluation by echocardiography and hematological testing was performed at  $7.0 \pm 1.3$

years (range 5-9 years) in a subset of 31 patients (20 males, 11 females). Mean valve size was 23.9 mm for aortic prostheses and 29 mm for mitral. Echocardiography showed that aortic valves had a mean effective orifice area (EOA) of  $2.26 \pm 1.28 \text{ cm}^2$ , with peak and mean pressure gradients of  $23.6 \pm 14.6$  and  $12.9 \pm 8.1 \text{ mmHg}$ , respectively. The mean EOA of mitral valve prostheses was  $2.67 \pm 0.66 \text{ cm}^2$ , with peak and mean pressure gradients of  $12.2 \pm 4.5$  and  $3.8 \pm 1.6 \text{ mmHg}$ , respectively. Overall mean hemoglobin was  $13.4 \pm 1.35 \text{ g/dl}$ , and serum lactate dehydrogenase  $630 \pm 13 \text{ IU/l}$ . Serum haptoglobin was detectable in one patient only, and the mean reticulocyte count was  $1.24 \pm 0.51\%$ .

**Conclusion:** In the present authors' experience, the Sorin Bicarbon prosthesis has low complication rates and maintains an excellent hemodynamic function over time. Hemolytic potential is insignificant with this valve.

The Journal of Heart Valve Disease 2004;13:97-102

The Sorin Bicarbon bileaflet prosthetic heart valve has been available in Europe since 1990. This pyrolytic carbon-coated valve has a slim titanium housing which provides a large orifice, as well as improved structural integrity. In contrast to most other bileaflet valves, the Bicarbon valve has curved leaflets that are intended to minimize the pressure drop across the valve and, together with the increased orifice area, improve hemodynamic performance (1).

The hinge mechanism between the leaflets and housing of the Bicarbon is unique in using the engineering

principle of kinematic coupling, which allows the leaflets to roll rather than slide. The purpose of this rolling device is to expose all areas of the valve to blood washing throughout the cardiac cycle and so reduce thrombogenicity.

Although the Bicarbon is one of the more recent bileaflet valves available, several studies have now shown that its use leads to early and mid-term clinical outcome which compares favorably with older valve types (2-5). Notably, the valve's in-vivo hemodynamics have been shown to be superior to those of other bileaflet valves, in both the mitral and aortic positions, at least during the early postoperative period (6-10). As with all bileaflet valves, there remains the enduring potential for thrombosis, hemolysis and tissue overgrowth. There is in-vitro evidence that the Bicarbon valve does cause less hemolysis, having the lowest blood damage index of several bileaflet valves (11).

---

Presented at the 51st meeting of the European Society for Cardiovascular Surgery, June 2002, Helsinki, Finland

Address for correspondence:  
Mr. Donald Whitaker, Department of Cardiothoracic Surgery, Guy's Hospital, St. Thomas Street, London, UK  
e-mail: donaldc@doctors.org.uk

Moreover, recent in-vitro studies have shown a shorter spatial extension of the turbulent zone in the forward flow phase associated with curved leaflets (12). These experimental observations have been supported by clinical evidence, at least during the short-term period (12).

The study aim was to investigate the longer-term clinical performance, hemodynamic profile and hemolytic effects of the Sorin Bicarbon valve. Hence, only those patients who had been implanted with the Bicarbon prosthesis for five years or more were evaluated with a detailed echocardiographic examination and hematological tests. To the present authors' knowledge, this is the first such detailed long-term report.

## Clinical material and methods

### Patients

Between January 1991 and January 1996, the Sorin Bicarbon (SB) prosthesis was implanted in 181 patients by a single surgeon (R.K.W.). The mean age of the overall patient population (108 males, 73 females) was  $60.5 \pm 10.8$  years (range: 16 to 82 years). The follow up period ranged from six to 11 years.

### Surgical approach

Aortic valve replacement (AVR) was carried out in 100 patients, mitral valve replacement (MVR) in 67, and double valve replacement (DVR) in 14. Concomitant procedures were carried out in 48 patients, and in 43 of those (23.8%) coronary artery bypass was performed. Rheumatic disease was the most common cause of operation (101 cases), followed by degenerative (calcific) aortic stenosis (Table I). All prostheses were inserted using semi-continuous, non-absorbable sutures following systemic cooling to 32°C and cold crystalloid cardioplegic arrest.

### Postoperative care and follow up

Postoperatively, all patients were maintained on life-

long anticoagulation with a targeted International Normalized Ratio (INR) of 2.5-3.5.

Follow up information was obtained by direct contact with patients, family physicians, consultants, hospital health records, and official death registries. When this was not possible, telephone communication or mailed questionnaires were substituted. The occurrence and classification of postoperative events were assessed according to guidelines for reporting mortality and morbidity in prosthetic valve recipients (14).

### Data analysis

Survival and freedom from valve-related complications were evaluated using the Kaplan-Meier method. Linearized complication rates were calculated as the number of events per 100 patient-years (pt-yr), or % per pt-yr.

### Hemodynamic/hematological investigations

Hemodynamic and hematological assessments were performed on a subset of patients. Those in whom a concomitant procedure or a different second type of valve had been used were excluded, as were any patients with major non-cardiac disease such as diabetes. Consequently, 31 patients (21 after AVR, 10 after MVR) were accepted and provided their informed consent to participate.

Echocardiography was performed using transthoracic color flow echo-Doppler. The examinations were conducted by two senior technicians who had been specifically trained in the techniques required for this study, using a single machine (Hewlett Packard Model No. 2500). Pictures were recorded onto videotape for subsequent analysis. All measurements were made from an average of three beats in patients with sinus rhythm, and of five beats in those patients in atrial fibrillation.

Red cell count, white cell count, hematocrit, hemoglobin, serum lactate dehydrogenase (LDH), serum haptoglobin and reticulocyte count were measured. The method of Skoularigis et al. (15) was used to assess

Table I: Etiology of valve disease.

Condition	Overall	AVR	MVR	DVR
Rheumatic	101 (55.8)	57 (57.0)	34 (50.7)	10 (71.5)
Degenerative (calcific)	21 (11.6)	21 (21.0)	0	0
Congenital	2 (1.1)	1 (1.0)	1 (1.5)	0
Myxomatous	2 (1.1)	0	2 (3.0)	0
Non-rheumatic endocarditis	6 (3.3)	3 (3.0)	3 (4.5)	0
Prosthetic valve dysfunction	20 (11.1)	9 (9.0)	10 (14.9)	1 (7.1)
Other/Unknown	29 (16.0)	9 (9.0)	17 (25.4)	3 (21.4)

Numbers in parentheses are percentages.

AVR: Aortic valve replacement; DVR: Double valve replacement; MVR: Mitral valve replacement.

subclinical intravascular hemolysis. The normal range of LDH in the present authors' laboratory was 211 to 423 U/L. Subclinical intravascular hemolysis is present when LDH is >460 U/l, together with at least two of the following: decreased haptoglobin, decreased hemoglobin; and increased reticulocyte count.

All results were recorded onto, and analyzed using, the SPSS database (Version 10).

## Results

Early mortality within 30 days was 6.1% (11 patients), mainly due to non-cardiac causes (Table II). Complete follow up information was available for 161 patients; the remaining nine were lost to follow up. The cumulative follow up was 722 pt-yr.

An additional 28 patients died during the follow up period, mostly from either progressive heart failure or non-cardiac causes (Table II). Seven late deaths were valve-related; hence the event-free rate was  $90.7 \pm 4\%$ . At nine years after surgery, survival - including early deaths - was  $63.9 \pm 5.5\%$ . Patients who received an aortic valve had a better prognosis (Fig. 1). At the end of follow up, 63% of patients were in NYHA functional classes I and II.

Valve thrombosis occurred in one AVR patient (INR = 1.1) at day 3 after surgery. This patient presented with dyspnea and was successfully reoperated on. (The normal policy was to commence intravenous heparin if warfarin was not therapeutic by day 3.) The overall freedom from valve thrombosis was  $99.4 \pm 0.6\%$  at nine years ( $0.14\%/pt\text{-yr}$ ). Nine embolic events were observed (eight after AVR, one after DVR). Five major events were fatal (four late cerebral infarctions,

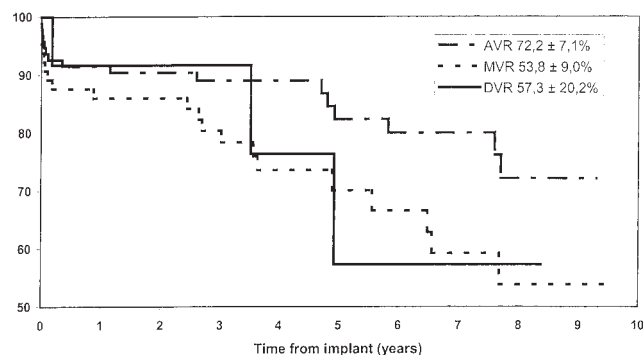


Figure 1: Survival to nine years according to valve site. AVR: Aortic valve replacement; DVR: Double valve replacement; MVR: Mitral valve replacement.

one early peripheral vascular embolism), two cerebral emboli resulted in permanent neurological defect, and two patients had minor events without any lasting disability. The overall freedom from emboli was  $86.3 \pm 4.7\%$  at nine years ( $1.25\%/pt\text{-yr}$ ), while that for the AVR subset was  $80.3 \pm 7.0\%$  ( $1.98\%/pt\text{-yr}$ ). Anticoagulant-related bleeding was observed in two patients ( $0.28\%/pt\text{-yr}$ ).

Paravalvular leakage occurred in two patients ( $0.28\%/pt\text{-yr}$ ), and endocarditis in three ( $0.42\%/pt\text{-yr}$ ). A total of six patients was reoperated on (three AVR, three MVR). One AVR patient underwent re-do surgery for thrombotic obstruction, three (two MVR, one AVR) because of persistent endocarditis, and two because of perivalvular leakage (one MVR, one AVR). The overall freedom from reoperation was  $96.1 \pm 1.6\%$  at nine years ( $0.83\%/pt\text{-yr}$ ).

Table II. Causes of death.

Cause	Overall	AVR	MVR	DVR
Embolism	1	1	-	-
Cardiac arrest	2	-	2	-
Myocardial infarction	1	-	1	-
Other non-cardiac	7	4	3	-
Total early deaths	11	5	6	-
Valve-related				
Embolism	4	3	-	1
Bleeding	2	1	1	-
Unknown	1	-	-	1
Non-valve-related				
Cardiac arrest	8	2	5	1
Myocardial infarction	2	1	1	-
Other non-cardiac	11	3	7	1
Total late deaths	28	10	14	4

Table III: Hemodynamic data for aortic and mitral prostheses.

Parameter	Aortic	Mitral
Peak gradient (mmHg)	23.6 ± 14.6	12.2 ± 4.5
Mean gradient (mmHg)	12.9 ± 8.1	3.8 ± 1.6
EOA (cm <sup>2</sup> )	2.26 ± 1.28	2.67 ± 0.66
Peak transvalvular flow velocity (m/s)	2.27 ± 0.74	-
Mean ejection fraction (%)	64.8 ± 15.2	69.6 ± 15.4

### Hemodynamic and hematological profile

Among the 21 AVR patients studied, the prosthesis size ranged from 19 to 29 mm, with the majority being either 21 or 23 mm (mean 23.9 mm). Among MVR patients studied (n = 10), the prosthesis size ranged from 25 to 33 mm (mean 29 mm). Both groups had completed at least a five-year follow up (mean 7.0 ± 1.3 years).

Transvalvular gradients, effective orifice area (EOA), peak transvalvular flow velocities and ejection fraction are summarized in Tables III and IV.

In defining aortic regurgitation (AR) qualitatively for all aortic prostheses, 12 of the 21 patients (57%) had none, five (24%) had trivial (AR jet limited to outflow tract), and four (19%) had mild (AR jet extends to the left ventricular body).

The mean length of the flow jets detected was 1.68 ± 1.49 cm (range: 0.15 to 4.0 cm), while the mean width was 0.62 ± 0.57 cm (range: 0.05 to 2.0 cm). Among the 10 mitral valve patients, two (20%) had mild regurgitation and eight (80%) had none.

Hematological data are summarized in Table V. Serum LDH was raised in all but one patient, but serum haptoglobin was detectable in only one patient. Red cell counts and hemoglobin levels were within the normal range in all patients - that is, there was no decompensated anemia. Six out of 31 (19%) patients - all of whom had undergone AVR - were identified as having subclinical hemolysis according to the method of Skoularis et al. (15).

### Discussion

To the authors' knowledge, the present study was

the first to evaluate the long-term clinical performance of the Sorin Bicarbon valve together with a detailed assessment of valve hemodynamics and hemolytic potential.

The results confirmed that the Bicarbon valve has an excellent performance. The hospital mortality and long-term patient survival was good, and freedom from valve-related mortality was well over 90%, and similar to values reported in other series (2-5). The overall rate of thromboembolism was low among the present patients, and included one valve thrombosis (0.14%/pt-yr) in an under-coagulated patient, as well as seven major and two minor embolisms (1.25%/pt-yr). All of these events were restricted to AVR patients. The thromboembolism rate is generally higher in MVR patients, although in some reports the incidence among AVR patients exceeded that in the MVR group (3,16-18).

Anticoagulant-related bleeding events (0.28%/pt-yr) occurred much less frequently than embolic events, which suggested that the actual INR levels may have been lower than the targeted values, at least in some patients. However, the thromboembolism occurrence in the present study was low and certainly comparable with that reported by others (3-5,16-18). This suggested a reduced thrombogenicity potential associated with the Bicarbon prosthesis.

In terms of hemodynamic function, the results of the present study provided evidence that Bicarbon hemodynamics are good at seven years after implantation. The peak and mean gradients and EOA for aortic prostheses in the present study were similar to those found by Badano et al. (6) during the early postoperative period. The overall mean gradient was 12.9 mmHg in

Table IV: Peak and mean gradients and effective orifice area (EOA) for aortic prostheses.

Parameter	Valve size (mm)					
	19	21	23	25	27	29
No. of valves	1	6	6	1	4	3
Peak gradient (mmHg)	43.9	38.9	19.1	16.0	14.0	10.2
Mean gradient (mmHg)	24.4	21.4	10.7	7.0	7.3	6.2
EOA (cm <sup>2</sup> )	0.7	1.4±0.7	1.3±0.1	3.2	3.9±0.4	3.0±2.4

Table V: Overall hematological data.\*

Parameter (normal value)	AVR (n = 21)	MVR (n = 9)
Hemoglobin (M: 13-18; F: 11.5-16.5 g/dl)	13.38 ± 1.44	13.71 ± 0.97
Serum LDH (240-480 U/l)	625 ± 123	668 ± 160
Serum haptoglobin (0.5-2.0 g/l)	0.27 ± 0.27	0.06 ± 0.00 <sup>+</sup>
Red cell count [4.5-6.5×10 <sup>12</sup> /l]	4.62 ± 0.48	4.69 ± 0.39
White cell count [4.0-11.0×10 <sup>9</sup> /l]	7.07 ± 1.82	7.27 ± 1.16
Hematocrit (40-54%)	39.44 ± 4.11	40.38 ± 2.59

\*Values are mean ± SD.

<sup>+</sup>p <0.01, aortic versus mitral prosthesis (Mann-Whitney test).

AVR: Aortic valve replacement; LDH: Lactate dehydrogenase; MVR: Mitral valve replacement.

the present series, compared with 11 mmHg in Badano et al.'s series. Moderately high gradients were seen in the smaller aortic prostheses, but this is a known finding with mechanical valves. It should be noted that, in the present study, the patients had all received the original Bicarbon design, and more recent models designed specifically for small aortic annuli should reduce the gradient further.

When using the peak flow velocity as derived directly from Doppler data, a mean value of 2.27 m/s was found for aortic prostheses. Autschbach et al. (19) reported six-month values of 2.4, 2.4 and 2.3 m/s for St. Jude, CarboMedics and ATS aortic valves, respectively, with the mean size of these implanted prostheses being very similar (24, 23.7 and 23.6 mm) to those of the present study.

Regurgitation through a closed valve is a common design feature of all bileaflet valves. Previously, Badano et al. (6) described the regurgitation pattern of normally functioning Bicarbon valves. Accordingly, in the present series trivial and mild regurgitation was seen in aortic prostheses, without evidence of paravalvular leaks. It is not possible to comment on the regurgitant jets detected in two mitral prostheses, as transthoracic echocardiography is less sensitive than transesophageal echocardiography in detecting such jets.

In the present series there was no occurrence of clinically significant hemolysis, and the overall incidence of intravascular hemolysis was 19% using the Skoularis criteria. This value was similar to that of 22% reported by Mecozzi et al. (13) at one-year follow up, the values being much lower than those associated with other bileaflet valves (13,15). It was interesting to note that, in the present series, the presence of hemolysis was restricted to AVR patients, though patient numbers were too low to draw statistical inferences about the effect of valve size on hemolysis.

### Study limitations

Among limitations of the study, the first was its single-center design; this provided consistency, but meant that the results might not be applicable to other patient populations. The single-center design also limited the number of patients that could be recruited. Although the clinical follow up was 95% complete, only 31 patients were willing to attend for echocardiography and blood testing. This number was adequate to draw conclusions, but it should be noted that these patients might not be representative of the entire population of Bicarbon recipients.

*In summary* - and within the limitations described above - the Sorin Bicarbon valve demonstrated good hemodynamic function and minimal subclinical hemolysis seven years after implantation, in keeping with previous short-term results. There was no echocardiographic evidence of deterioration of the valve over time, and the nine-year survival and complication rates compared favorably with those of other bileaflet designs.

### References

1. Vallana F, Rinaldi S, Galletti PM, Nguyen A, Piwnica A. Pivotal design in bileaflet valves. *Am Soc Artif Intern Organs Trans* 1992;38:M600-M601
2. Casselman F, Herijgers P, Meyns B, Flameng W, Daenen W. The Bicarbon heart valve prosthesis: Short term results. *J Heart Valve Dis* 1997;6:410-415
3. Goldsmith I, Lip GYH, Patel RL. Evaluation of the Sorin Bicarbon bileaflet valve in 488 patients (519 prostheses). *Am J Cardiol* 1999;83:1069-1074
4. Borman JB, Brands WGB, Camilleri L, et al. Bicarbon valve - European multicenter clinical evaluation. *Eur J Cardiothorac Surg* 1998;13:685-693
5. Bortolotti U, Milano A, D'Alfonso A, et al. Evaluation of valve related complications in

- patients with Sorin Bicarbon prosthesis. A 7-year experience. *J Heart Valve Dis* 2001;10:795-801
6. Badano L, Mocchegiani R, Bertoli D, et al. Normal echocardiographic characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions. *J Am Soc Echocardiogr* 1997;10:632-643
  7. Reisner SA, Harpaz D, Skulski R, Borenstein D, Milo S, Meltzer RS. Hemodynamic performance of four mechanical bileaflet prosthetic valves in the mitral position: An echocardiographic study. *Eur J Ultrasound* 1998;8:193-200
  8. Flameng W, Vandeplas A, Narine K, Daenen W, Herijgers P, Herregods MC. Postoperative hemodynamics of two bileaflet heart valves in the aortic position. *J Heart Valve Dis* 1997;6:269-273
  9. Noera G, Pensa P, Lamarra M, Mascagni R, Cremonesi A, Balestra G. Hemodynamic evaluation of the CarboMedics R, St. Jude Medical HP and Sorin-Bicarbon valve in patients with small aortic annulus. *Eur J Cardiothorac Surg* 1997;11:473-475
  10. Kadir I, Wan I, Walsh C, Wilde P, Bryan A, Angelini G. Hemodynamic performance of the 21-mm Sorin Bicarbon mechanical aortic prostheses using dobutamine Doppler echocardiography. *Ann Thorac Surg* 2001;72:49-53
  11. Steegers A, Paul R, Reul H, Rau G. Leakage flow at mechanical heart valve prostheses: Improved washout or increased blood damage? *J Heart Valve Dis* 1999;8:312-323
  12. Grigioni M, Daniele C, D'Avenio G, Barbaro V. The influence of the leaflets' curvature on the flow field in two bileaflet prosthetic heart valves. *J Biomech* 2001;34:613-621
  13. Mecozzi G, Milano A, De Carlo M, et al. Intravascular hemolysis in patients with new generation prosthetic heart valves: A prospective study. *J Thorac Cardiovasc Surg* 2002;123:550-556
  14. Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. *Ann Thorac Surg* 1996;62:932-935
  15. Skoularigis J, Mohammed RE, Skudicky D, Middlemost SJ, Sareli P. Frequency and severity of intravascular haemolysis after left sided cardiac valve replacement with Medtronic Hall and St. Jude Medical prostheses, and influence of prosthetic type position size and number. *Am J Cardiol* 1993;71:587-591
  16. Duncan JM, Cooley DA, Reul GJ, et al. Durability and low thrombogenicity of the St. Jude Medical valve at 5-year follow-up. *Ann Thorac Surg* 1986;42:500-505
  17. Czer LSC, Chaux A, Matloff JM, et al. Ten-year experience with the St. Jude Medical valve for primary valve replacement. *J Thorac Cardiovasc Surg* 1990;100:44-55
  18. Soga Y, Okabayashi H, Nishina T, et al. Up to 8-year follow up of valve replacement with CarboMedics valve. *Ann Thorac Surg* 2002;73:474-479
  19. Autschbach R, Walther T, Falk V, et al. Prospectively randomised comparison of different mechanical valves. *Circulation* 2000;102(suppl.III): III-1-111-4