Fifteen-year experience with the Tirone David procedure in bicuspid aortic valve: a safe option.

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June 7, 2022

Abstract

Background We evaluated short- and mid-term outcomes with use of aortic valve-sparing root replacement to treat bicuspid aortic valves. Methods From December 2007 to January 2022, all patients with bicuspid aortic valves who underwent aortic root replacement using Tirone's procedure were included. This study based on department database information for retrospective and follow-up data. Results Among 51 adults undergoing aortic root replacement using Tirone's procedure, the mean age was 47.4±12.5 years, and most were men (92.2%). Three presented with a dysmorphic syndrome and one had Marfan's syndrome. All patients were alive at 30 days, and as of January 2022, 45 were alive, two were lost to follow-up, and there were four noncardiac deaths. Two patients had infectious endocarditis and needed a Bentall's procedure. One patient had a double biologic valve replacement in the context of severe mitral insufficiency with moderate aortic stenosis at 4.5 years post-procedure. Echocardiographic follow-up showed a left ventricular ejection fraction of 63±7% (n=36), V_{max} 2±0.6 m/s (n=17), and a mean gradient of 9.4±5.4 mmHg (n=27). No patients had grade 3 or 4 aortic regurgitation, one patient had grade 2, and four had grade 1. Conclusion Tirone's procedure is an option for bicuspid aortic valve surgery, with good safety and outcomes, especially in younger patients.

Introduction

Bicuspid aortic valve (BAV) is one of the most common congenital diseases.(1–3) Some patients will develop an aneurysm or aortic insufficiency and require surgery. The traditional treatment modality for aortic root dilatation, with or without aortic dissection or aortic insufficiency, has been a composite valve-conduit (Bentall). (4) Patients with BAV tend to be younger than other patients undergoing treatment, and Bentall's procedure involves a mechanical prosthesis. (5)

An alternative for such patients is aortic valve-sparing root replacement (AVSRR), which has been used with good results for three decades in patients with tricuspid aortic valves (6,7) but remains debated as an intervention for patients with BAV. (8,9) The aim of this study was to assess short- and mid-term clinical and safety outcomes with AVSRR, specifically Tirone's procedure, in patients with BAV. (10–14)

Material and Methods

For this retrospective analysis, we included data for all patients with BAV who underwent aortic root replacement using Tirone's procedure from December 2007 through January 2022. Patients with acute aortic dissection or age <18 years were excluded. The study was approved by local Ethics Committee (IRB00013412, "CHU de Clermont Ferrand IRB #1", IRB number 2022-CF015) with compliance to the French policy of individual data protection.

In brief, after the chest was opened with a median sternotomy, and application of systemic heparinization, the patient was started on extracorporeal circulation with direct cannulation of the arch or ascending aorta

and right atrial cannulation. Cardiac arrest was achieved by means of infusion of cold blood cardioplegia, first anterograde into the coronary ostia and then retrograde in the majority of cases. Transsection to open the ascending aorta was done above the commissures plane. The aortic root and the valve were carefully inspected by the operating surgeon. The BAV was classified according to Sievers, followed by cutting of the coronary ostia, dissection from the aortic root to the aortic annulus plane, and resection of the sinuses.

After suspension of the commissures, we used a Hegar dilator to measure the aortic annulus. The aortic valve was carefully assessed for configuration and coaptation. When cups presented calcification, decalcification was performed first. In all instances, a Dacron graft was used, initially with a graft 4 mm larger than the measured diameter of the aortic annulus. Then after a few years, a Dacron graft 2 mm larger was usually chosen, although sometimes a graft was used that was the same diameter of the aortic annulus. We routinely use Vascutek Gelweave® (Vascutek Terumo, Glasgow, Scotland). Initially, we performed a proximal subannular fixation of the vascular prosthesis by U-shaped stitches associated with a running suture, but we changed to a technique using a single inflow suture line.

After aortic valve reimplantation and co-aptation assessment, we used a Schäfers caliper to measure the plicature started by the unfused leaflet at 10/12 mm. Measurement of the other leaflet was impossible because of the symphysis and hypoplastic commissure. We then operated on the second leaflet (symphysis leaflet) to obtain an equal length of the free edges. Additional repair was performed as needed, consisting of fenestration and/or patch repair. According to the operating surgeon's preference, the central plication sutures were performed with 6-0 polypropylene stitches. Reimplantation of the coronary ostia was performed using the button technique.

For follow-up, all patients underwent preoperative transthoracic echocardiography (TTE), intraoperative transesophageal echocardiography, and postoperative TTE before hospital discharge, yearly thereafter for 5 years, and then less frequently. Points of interest included the diameter of the aortic annulus, the mode of aortic valve insufficiency and potential prolapse and sclerosis, the mean systolic gradients, and the left ventricular ejection fraction. Events were defined as such by timing of their initial diagnosis.

Statistical analysis was performed using Stata software (version 15; StataCorp, College Station, Texas, USA). All tests were two-sided, with a Type I error set at 0.05. Categorical variables are expressed as number of patients and associated percentages, and continuous variables as mean±standard deviation or median [25^{th}; 75^{th} percentiles], according to statistical distribution. Censored data (overall survival) were estimated using the Kaplan-Meier method. The 5- and 10-year survival rates are presented with their 95% confidence intervals (CIs).

Results

Patient demographics and perioperative outcomes

A total of 51 adults underwent aortic root replacement using Tirone's procedure, and Table 1 lists their preoperative characteristics. The mean age was 47.4±12.5 years, most were men (92.2%), and 6 (11.8%) had BMI [?]30 kg/m2. Three presented with a dysmorphic syndrome and one had Marfan's syndrome. All operations were performed electively for aortic aneurysm associated or not with aortic regurgitation grade 3 or 4 (n=21, 41.2%). The main cardiovascular risk factors were hypertension (n=20, 39.2%) and smoking (n=13, 25.5%), and none of the patients had undergone previous cardiac surgery or had coronary artery disease. The median Euroscore II was 4 [2; 5].

Table 2 shows the intraoperative data. For extracorporeal oxygenation, cannulation involved the brachiocephalic trunk artery in one patient, and in two, hot blood and non-exclusive retrograde cardioplegia were used. The BAVs were classified according to Sievers and were most often type I (n=31, 60.8%), with only one patient having type II. In most cases (n=29, 56.9%), patients had a fusion of the left and right coronary cusps. The diameter of the basal ring varied from 17 mm to 36 mm (mean 25.7+-4.2 mm, n=41). Cusp plasty was performed in 50 patients (98.0%), via plication stitch in most cases, and 3 (5.9%) underwent commissure repair, one of them associated with patch repair. No additional aortic procedure or concomitant

cardiac procedure was performed. Transesophageal echocardiography was performed for all patients, and mean left ventricular ejection fraction was 63.4+-6.2% (n=46), with no grade III or IV aortic regurgitation, and the mean gradient was 6.9+-1.5 mmHg (n=8). No second aortic cross-clamp was needed to correct residual aortic insufficiency.

Table 2 also shows the early postoperative outcomes. In-hospital mortality was zero, as was rehospitalization at 30 days. Extubation was performed the first postoperative day for 50 patients (98.0%) and the second day for one, and one patient was reintubated for 13 days for pneumopathy. No permanent neurological deficit was reported.

In the intensive care unit, one patient presented with cardiogenic shock requiring extracorporeal life support and received treatment with two stents in the right coronary with good evolution. At 5 years after surgery, this patient is doing well, and TTE findings show no aortic regurgitation or cardiac insufficiency. The principal arrhythmia in this population was atrial fibrillation, identified in eight patients. No patient had a pacemaker or defibrillator implanted during hospitalization.

One patient required re-exploration for bleeding. Ten (19.6%) patients needed one or more red blood cell infusions, four (7.8%) needed one or more platelet treatments, and four (7.8%) had needed one or more transfusions of fresh-frozen plasma. The median hospital stay was 9 days [8; 12], two of which were in the intensive care unit, and more than half of the population was discharged home after surgery. All patients had TTE before discharge, with a mean ejection fraction of 59.4+-9.9%, no grade III or IV aortic regurgitation, and a mean gradient of 8.7+-4 mmHg (n=43).

Follow-up results

Table 3 lists the follow-up data. The median follow-up time was 5.6 years [2.0; 9.1], and 45 (88.2%) patients having follow-up TTE data within the last 2 years. Two patients were considered lost to follow-up because they have had no medical consultation for more than 10 years.

The 5-year overall survival was 90.9% (95% CI, 74.3%–97.0%), and the 10-year overall survival was 84.9% (95% CI, 62.4%–94.4%). Four (7.8%) patients died during the follow-up period, three following stroke and one from drowning. The strokes, one of them hemorrhagic and the other two of unknown etiology, occurred more than 3 years after the surgery (3.5, 3.9 and 8.9 years after, respectively), and the mean age at death was 58.8+-4.5 years. Rehospitalization was reported for 18 patients, 7 of them (13.7%) for cardiac events: two with endocarditis necessitating Bentall's procedure with mechanical prosthesis at 15 months and 93 months, respectively, and one with mitral insufficiency at 4.5 years after the Tirone procedure. For this last patient, echocardiography showed a modified aortic valve associated with stenosis, so reoperation consisted of a double biological replacement valve. Two patients had been treated for atrial fibrillation, and two others had a pacemaker implanted well after the surgery. There were no deaths with reinterventions.

Regarding medical outcomes, 45 patients had not had discomfort since surgery and three had New York Heart Association (NYHA) II dyspnea. Three others patients (5.9%) needed an anticoagulant drug, while six (11.8%) were without medication. The reports were all from recent follow-up, with less than one year since Canadian Cardiovascular Society and NYHA classification, and less than 2 years for transesophageal echography TEE-related data and events since surgery. The follow-up TEE data showed ejection fraction at 62.6+-6.7% (n=36) and a V_{max} 2.0+-0.6 m/s (n=17), a mean gradient of 9.4+-5.4 mmHg (n=27), and no grade III or IV aortic regurgitation (Table 3).

Discussion

Our results support that AVSRR for BAV is a safe option, with low mortality and low morbidity, good valve stability, and good quality of life many years after surgery.

The characteristics of our patient population were similar to those reported in other studies.(8, 11, 15) Patients were in a good state of health, which can be explained by the relatively young age of 47.4+-12.5

years and the preserved left ventricular ejection fraction. Most of our patients had mild symptoms, with 3.9% having NYHA functional class III or IV, and 96.1% with Canadian Cardiovascular Society class I.

BAV is the most common congenital cardiac malformation (1–3), which can represent a health burden because some patients develop valvular and/or aortic complications. Severe aortic stenosis is typically managed with valve replacement, whereas patients with aortic regurgitation are candidates for valve repair. The reference treatment involves a composite replacement of the valve and aorta, i.e., the procedure of Bentall.(4) Generally, the population with BAV associated with aortic or valvular disease is young (3, 16), and with valve replacement, the use of a mechanical prosthesis with anticoagulation medication requires an altered lifestyle in some cases.(5, 17) Moreover, mechanical prosthesis may predispose patients to higher rates of thromboembolic events.(3) For these reasons, AVSRR techniques have been developed.

"Valve-sparing root replacement" is a collective name for multiple kinds of procedures, (7) but in general, two principal techniques are used: remodeling or reimplantation. For three decades, both approaches have yielded good results, including good long-term outcomes in the case of tricuspid aortic valves. (8,11,15) However, our center has preferred the Tirone procedure because it provides a complete stabilization of the root, including the annulus. After Modine et al. described a modified technique using a single inflow suture line, we adopted that, as well. (18) In cases of regurgitant BAV associated with aortic dilation, preservation or repair seems to be an attractive alternative to replacement. If a patient does not want a mechanical prosthesis, a bioprosthesis also is an option, but the limited durability does not make it ideal for younger individuals, and bioprostheses may increase risk of endocarditis and reintervention. (5,19,20)

Most of our cases were Sievers type I (60.8%), which reflects the natural distribution of BAV type.(21) We did, however, find a relatively frequent occurrence of type 0 (29.4%) compared to rates that Sievers et al. reported (7%). (21) Regarding intra- and post-operative outcomes, our data are in line with reports from other groups and confirm that AVSRR, such as the Tirone procedure, can be performed in patients with BAV with very low perioperative risks for morbidity and mortality (0%–2.5%) (8,11–13,16). Most of our patients had elective surgery for the Tirone procedure without other associated surgery to exclude confounding from other procedures. Holmgren and colleagues, however, still reported that even combined surgery was not associated with higher observed or relative mortality.(9)

We needed to use a graft size [?]26 mm for three women with lower heights (146, 155 and 157 cm, respectively), in whose cases the rings were measured as <20 mm at the TEE, <26 mm on computed tomography, and [?]24 mm with the Hegar sizer. This choice has not constituted a problem for the post-operative evolution, and during a follow-up of more than 5 years, we have noted no aortic regurgitation, their mean gradients were respectively 3, 9 and 11 mmHg, and their left ventricular ejection fraction measures were 60%, 60% and 65%. For patients who had an aortic root <45 mm, we offered the Tirone procedure because they had a severe aortic insufficiency. The aim is to stabilize the root for the lifetime.

There were no in-hospital deaths or deaths at 30 days, emphasizing that this operation can be performed extremely safely in experienced hands. There also were no perioperative strokes, and only one patient (2.0%) had acute coronary syndrome that presented as cardiogenic shock at 4 postoperative days. This case was particular because extracorporeal life support was needed for 5 days, two stents were placed in the right coronary artery, and dialysis was temporarily required. At the time of this writing, more than 4 years after the surgery, the patient was in good health, and TEE show a left ventricular ejection fraction of 65%, no remodeling of the aortic valve, and no aortic regurgitation. One patient (2.0%) needed reintervention for bleeding, indicating that in an experienced center, this procedure can be performed with low mortality rates.(11,16)

With our experience now extending back 15 years, we have seen stable aortic valve function in most cases. Here, we have presented outcomes at 5 years and 10 years. Although we have complete follow-up for the first case 15 years ago, a patient who is alive and doing quite well with no complications, we had only 17 patients with 10–15 years of follow-up. This early paucity can be explained by the fact that this technique was progressively integrated into the surgical options on offer and was used with increasing frequency after

the first 5 years following its introduction.

As observed previously, three patients needed a reintervention after some lengthy period following the first surgery, an outcome that is better than that seen with bioprostheses in this age group. (20) When reoperation is necessary, the surgery is straightforward and consists of excising the native valve and implanting a prosthesis, as we did for the patient who had mitral insufficiency associated with moderate stenosis at 4.5 years following their Tirone procedure. Theirs is the only case in which we reoperated for reasons related to aortic stenosis, so in our 15 years of experience, the probability of developing relevant aortic stenosis has been very low. (5,16) As Schneider and colleagues also found, the incidence of endocarditis was low, with two patients in 15 years needing reoperation with Bentall's mechanical procedure. (12)

We also can indirectly assess quality of life based on medication needs. During follow-up, we noted that only three patients needed anticoagulants, including the two patients reoperated with Bentall's procedure, and that six patients are taking no medications at all. For us, this information provides another argument supporting valve-sparing procedures especially in the young population.

Conclusion

The current findings show that AVSRR using the Tirone procedure can be applied to patients with BAV with excellent short-term and mid-term results. Furthermore, the data from this study demonstrate low perioperative risks and a good quality of life for most patients after surgery. Longer term follow-up is needed to confirm the durability of reimplanted BAV.

Limitations

This study has several limitations, including that it is single center and retrospective. The design also entails a selection bias because the surgeon made the final decision about whether to proceed with the Bentall or Tirone procedure. Another limitation is the missing conversion rate to classical Bentall after a failed Tirone attempt.

Abbreviations

AVSRR: Aortic valve-sparing root replacement

BAV: Bicuspid aortic valve

CI: Confidence interval

TEE: Transesophageal echography

TTE: Transthoracic echography

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TABLES

Table 1. Patient characteristics

Patient characteristics	**N=51**
Age (years), mean±SD	47.4±12.5
Male, n (%)	47 (92.2)

BMI (kg/m^2), mean±SD	25.9±3.7
Body surface area (m^2), mean±SD	1.99±0.23
Arterial hypertension, n (%)	20 (39.2)
Dyslipidemia, n (%)	9 (17.6)
Diabetes mellitus, n (%)	2 (3.9)
Smoking, n (%)	13 (25.5)
Serum creatinine (n=50), mean±SD	87.7±12.8
Clearance (n=50), mean±SD	93.8±23.4
NYHA functional classification, n (%)	
I	32 (62.8)
II	17 (33.3)
III	2 (3.9)
IV	0 (0.0)
CCS classification, n (%)	
I	49 (96.1)
II	2 (3.9)
III	0 (0.0)
IV	0 (0.0)
Echocardiography	
Left ventricular ejection fraction (%), mean±SD	62.9±8.6
No/trivial aortic insufficiency, n (%)	19 (37.3)
Mild aortic insufficiency, n (%)	11 (21.6)
Moderate aortic insufficiency, n (%)	9 (17.6)
Severe aortic insufficiency, n (%)	12 (23.5)
Ring (mm) (n=41), mean±SD	25.7±4.2
Ascending aorta (mm), mean±SD	52.2±5.3

BMI: Body Mass Index; CCS: Canadian Cardiovascular Society; n: number of patients; NYHA: New York Health Association; SD: Standard Deviation.

Table 2. Intraoperative data and post-operative outcomes

Intraoperative data	**Intraoperative data**
Cardiopulmonary bypass time (min), mean±SD	182.7±18.7
Aortic cross-clamp time (min), mean±SD	153.8±16.5
Cannulation	
Ascending aorta, n (%)	8 (15.7)
Arch, n (%)	42 (82.3)
Brachiocephalic artery, n (%)	1 (2.0)
Right atrial, n (%)	51 (100.0)
Antegrade cardioplegia alone, n (%)	9 (17.7)
Antegrade and retrograde cardioplegia, n (%)	42 (82.3)
Sievers classification of aortic valve, n (%)	
Type 0	15 (29.4)
Type I	31 (60.8)
Type II	1 (2.0)
Unclassified	4 (7.8)
Type of fusion, n (%)	
Fusion of left and right coronary cusps	29 (56.9)
Fusion of non- and right coronary cusps	4 (7.8)

Fusion of non- and left coronary cusps	1 (2.0)
No data available	17 (33.3)
Graft size (mm), n (%)	
24	1 (2.0)
26	2 (3.9)
28	12 (23.5)
30	23 (45.1)
32	13 (25.5)
Additional aortic valve-related procedure, n (%)	
Cusp plasty	50 (98.0)
Commissure repair	3 (5.9)
Decalcification	8 (15.7)
Patch repair	1 (2.0)
Window closure	1 (2.0)
Transesophageal echography	
Left ventricular ejection fraction (%) (n=46), mean±SD	63.4±6.2
Aortic ring (mm) (n=22), mean±SD	22.4±2.3
No/trivial aortic insuffiency, n (%)	47/48 (97.9)
Mild aortic insuffiency, n (%)	1/48 (2.1)
Moderate aortic insuffiency, n (%)	0/48 (0.0)
Severe aortic insuffiency, n (%)	0/48 (0.0)
Mean gradient (mmHg) (n=8), mean±SD	6.9±1.5
Effective height (mm) (n=31), mean±SD	9.8±1.8
Apposition height (mm) (n=22), mean±SD	8.6±2.4
Hospitalization/postoperative data	**Hospitalization/postoperative data**
Intensive care unit stay (days), median [p25; p75]	2 [2; 5]
Hospital stay (days), median [p25; p75]	9 [8; 12]
Cardiac complications	
Acute coronary syndrome	1 (2.0)
Arrhythmias	9 (17.7)
Extracorporeal life support	1 (2.0)
Pulmonary complications	
Extubation <24 hours, n (%)	50 (98.0)
Reintubation, n (%)	3 (5.9)
Mechanical ventilation time >3 days, n (%)	2 (3.9)
Tracheostomy, n (%)	0 (0.0)
Infectious, n (%)	5 (9.8)
Neurological complications	
Temporary or permanent neurological deficit, n (%)	0 (0.0)
Other neurological events	
Amnesic stroke	1 (2.0)
Delirium tremens	1 (2.0)
Other complications	
Reintervention for bleeding, n (%)	1 (2.0)
Dialysis, n (%)	1 (2.0)
Echocardiography at discharge	
Left ventricular ejection fraction (%), mean±SD	59.4±9.9
Aortic ring (mm) (n=35), mean±SD	21.5±2.1
V_{max} (m/s) (n=32), mean±SD	1.8±0.5
Aortic insufficiency grade, n (%)	

0	44 (86.3)
1	6 (11.7)
2	1 (2.0)
3	0 (0.0)
4	0 (0.0)
Mean gradient (mmHg) (n=43), mean±SD	8.7±3.9
Ascending aorta (mm) (n=32), mean±SD	32.3±3.4

n: number of patients; p25: 25th percentile; p75: 75th percentile; SD: Standard Deviation.

Table 3. Follow-up data

Finding	**N=51**
Death during follow-up, n (%)	4 (7.8)
Cardiac-related death, n (%)	0 (0.0)
Lost to follow-up, n (%)	2 (3.9)
Rehospitalization for cardiac event, n (%)	7 (13.7)
Rehospitalization for non-cardiac event, n (%)	11 (21.6)
Aortic valve-related reintervention, n (%)	3 (5.9)
By indication	
Aortic valve insufficiency, n (%)	0 (0.0)
Aortic valve stenosis, n (%)	1 (2.0)
Endocarditis, n (%)	2 (3.9)
By type of reintervention	
Mechanical aortic valve replacement, n (%)	1 (2.0)
Biological aortic valve replacement, n (%)	0 (0.0)
Bentall procedure with biological prosthesis, n (%)	0 (0.0)
Bentall procedure with mechanical prosthesis, n (%)	2 (3.9)
Ross procedure, n (%)	0 (0.0)
Transcatheter aortic valve implantation, n (%)	0 (0.0)
Mortality at reintervention, n (%)	0 (0.0)
Concerning the medical treatment	45 (88.2)
Cardiologic medication, n (%)	34 (66.7)
Anticoagulant, n (%)	3 (5.8)
Others, n (%)	2 (3.9)
None, n (%)	6 (11.8)
Echocardiography with last 2 years	37 (72.5)
Left ventricular ejection fraction (%) (n=36), mean±SD	62.6±6.7
Aortic ring (mm) (n=7), mean±SD	22.7±4.1
V_{max} (m/s) (n=17), mean±SD	2.0±0.6
Aortic insufficiency, n (%)	
0	31/37 (83.8)
1	5/37 (13.5)
2	1/37 (2.7)
3	0/37 (0.0)
4	0/37 (0.0)
Mean gradient (mmHg) (n=27), mean±SD	9.4±5.4
Ascending aorta (mm) (n=22), mean±SD	34.7±5.4

n: number of patients; SD: Standard Deviation.