Catheterization and Cardiovascular Interventions 66:254–257 (2005)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Use of a 3 French System for Balloon Aortic Valvuloplasty in Infants

Dennis W. Kim,* MD, PhD, **Anthony A. Raviele,** MD, **and Robert N. Vincent,** MD

For infants with valvar aortic stenosis, balloon aortic valvuloplasty has supplanted surgical valvotomy as the initial treatment of choice at most institutions. Technological innovations have resulted in further miniaturization of balloon dilation catheters, allowing this procedure to be performed through smaller sheath sizes. Currently, the Tyshak-Mini balloon dilation catheter (B. Braun Medical) allows passage of up to an 8 mm dilation balloon catheter through a 3 Fr hemostatic sheath. The efficacy of this system for the treatment of valvar aortic stenosis in infants less than 6 months of age was evaluated in 20 patients undergoing 22 procedures. Mean age at the time of intervention was 26 ± 46 days. Mean transvalvar gradient was 76 ± 22 mm Hg prior to balloon dilation. Following balloon valvuloplasty, residual gradient was 26 ± 12 mm Hg, reflecting a mean change in peak-to-peak gradient of 49 ± 19 mm Hg. Postintervention increase in aortic insufficiency was one grade or less in 19/22 procedures, two grades in 2 procedures, and three grades in 1 procedure. There were no significant vascular complications reported immediately following the procedure. Repeat valvuloplasty was performed in three patients in which the 3 Fr system was used in two patients. The 3 Fr system for balloon aortic valvuloplasty in infants less than 6 months of age is effective and safe.

Key words: aortic stenosis; infants; balloon valvuloplasty

INTRODUCTION

Valvar aortic stenosis remains a source of significant morbidity and mortality. Medical management alone has been reported to result in up to 25% mortality [1,2]. Lababidi [3] initially reported percutaneous balloon aortic valvuloplasty in 1983. This technique was applied in the treatment of neonatal critical aortic stenosis shortly thereafter [4]. Subsequent studies have demonstrated the feasibility, efficacy, and safety of this procedure for critical and severe valvar aortic stenosis in children [5]. Presentation, results, and complications vary, primarily due to the age at which intervention is performed with younger infants less than 3 months old considered a more vulnerable group [6]. A variety of approaches have been described including retrograde, antegrade, transumbilical, and transcarotid methods [7–11].

The results of balloon aortic valvuloplasty have been reported to be comparable to surgical methods both in the short term and in the long term [12–17]. Prospective comparative studies between surgical valvotomy and balloon dilation are lacking, however. Favorable results from balloon valvuloplasty span the age range from the neonatal period to young adulthood [15, 18–23]. Indeed, balloon aortic valvuloplasty is considered to be the initial procedure of choice for significant aortic valve stenosis at most cardiac centers. For those patients with recurrent stenosis and without significant aortic insufficiency, repeat balloon aortic valvuloplasty can be considered with reasonable results reported [24]. Complications of balloon aortic valvuloplasty include the creation of significant aortic insufficiency, ventricular arrhythmias, damage to the mitral valve

Department of Pediatrics, Emory University Medical School, Sibley Heart Center Cardiology, Children's Healthcare of Atlanta, Atlanta, Georgia

*Correspondence to: Dr. Dennis W. Kim, Sibley Heart Center Cardiology, 52 Executive Park South, Suite 5200, Atlanta, GA 30329. E-mail: kimd@kidsheart.com

Received 29 November 2004; Revision accepted 17 March 2005

DOI 10.1002/ccd.20424
Published online 26 August 2005 in Wiley InterScience (www.interscience.wiley.com).

TABLE I. Baseline Demographics

Sex	
Male	15
Female	5
Diagnosis	
Critical aortic stenosis	10
Severe aortic stenosis	12
Age, mean (days)	26 ± 46 (range, 1–164)
Weight, kg (mean)	3.6 ± 1.1 (range, 2.2–7.5)
Approach	
Right femoral artery	15
Left femoral artery	7

TABLE II. Procedural Data

Annulus size (mean, mm)	7.5 ± 1.1
Final balloon size (mean, mm)	6.4 ± 1.2
Annulus:balloon ratio	0.86 ± 0.10
Pregradient (mm Hg)	76 ± 22
Postgradient (mm Hg)	26 ± 12
Change in gradient (mm Hg)	49 ± 19
Procedural time (mean, min)	48 ± 19

apparatus, and vascular complications related to the access site. Significant vascular complications have been reported to occur in almost 50% of procedures, with those patients less than 3 years old being particularly vulnerable, though admittedly these data were published when much larger bore size dilation catheters were routinely used in infants [25,26]. As balloon dilation catheters have become smaller in profile, this complication rate is likely to be lower, though published data are lacking. We reviewed our recent experience with balloon aortic valvuloplasty in infants using the combination of a 3 Fr hemostatic sheath and the Tyshak-Mini dilation catheter.

MATERIALS AND METHODS

The institutional review board at Children's Healthcare of Atlanta approved this study. The cardiac catheterization database at Sibley Heart Center Cardiology was reviewed from 1 January 2001 to 31 December 2003 for patients with the diagnosis of critical or severe aortic stenosis who underwent balloon aortic valvuloplasty in the first year of life. Only those patients in whom a 3 Fr hemostatic sheath (Check-Flo Performer, Cook, Bloomington, IN) and a 3 Fr dilation catheter were used were included. The use of heparin varied among the physicians performing the procedure. In 12 procedures, no heparin was given while in 10 procedures 50–100 units/kg were administered before catheter entry. Aortic angiography was performed prior to and after balloon valvuloplasty using a 3 Fr pigtail catheter in the anterior-posterior and straight lateral projections. Tyshak-Mini balloon dilation catheters (NuMED/B. Braun Medical, Hopkinton, NY) were used ranging from 4 to 8 mm. All dilation balloons were 2 cm in length. If initial dilation did not result in adequate relief of stenosis, larger balloons were used in 1 mm diameter increments. Balloon dilation was performed by hand using saline-diluted contrast. Aortic root angiography was performed following each progressive dilation to assess for aortic insufficiency. Charts were reviewed for the type of vascular access used, dilation balloon sizes, pre- and postvalvuloplasty gradients, amount of pre- and postdilation aortic valve insufficiency, and procedural/postprocedural complications including arrhythmias requiring treatment, inability to dilate successfully, immediate vascular complications, and deaths.

RESULTS

Twenty-eight patients undergoing 30 procedures were identified in which a 3 Fr dilation catheter was used. Twenty patients undergoing 22 procedures were identified in which balloon aortic valvuloplasty was performed along with using a 3 Fr arterial sheath and 3 Fr Mini-Tyshak balloon dilation catheters. Baseline demographics are shown in Table I. Critical aortic stenosis was defined as valvar stenosis resulting in diminished left ventricular systolic function or requiring continuous prostaglandin infusion to maintain systemic output. Eight patients had balloon valvuloplasty performed using a 3 Fr balloon dilation catheter, but using a larger sheath. These patients were excluded from further analyses. These patients generally represented those procedures that were performed before the availability of the 3 Fr sheath in mid-2001. One patient required the use of a Tyshak II dilation catheter and larger sheath due to repeated ejection of the Mini-Tyshak catheter from the valve. In all 22 cases using the 3 Fr sheath, valvuloplasty was performed retrograde from the femoral artery. Mean age was 26 days. As shown in Table II, mean initial peak-to-peak gradient was 76 ± 22 mm Hg. After balloon valvuloplasty, mean residual gradient was reduced to 26 ± 12 mm Hg. Mean reduction of gradient was 49 ± 19 mm Hg. Pre- and postangiographic assessment of aortic insufficiency was graded as none (0), mild (1), moderate (2), and severe (3). Following valvuloplasty, change in aortic insufficiency of one grade or less was seen in 19 procedures, two grades in 2 procedures, and 3 grades in 1 procedure. Procedure time was defined as the time from arterial access to sheath withdrawal. There were no procedural or immediate vascular complications reported. Three patients underwent repeat aortic valvuloplasty, in which the 3 Fr system again was used in two patients (3 weeks old, 4.5 months old).

DISCUSSION

Miniaturization of the tools used in the pediatric catheterization laboratory has resulted in the ability to perform interventional procedures in smaller children with less vascular trauma at the entry site. Of course, the ultimate goal of interventional catheterization is to achieve a therapeutic goal, in this case, reduction of gradient across the aortic valve. The combination of the 3 Fr Tyshak-Mini dilation catheter as well as a 3 Fr introducer sheath allows balloon aortic valvuloplasty to be performed successfully.

During the course of this study period, several technical issues unique to this system have been identified. Retrograde passage of a wire and catheter across the aortic valve was performed by first truncating a 3 Fr pigtail catheter such that a slight angle resembling the contour of a Judkins right coronary catheter was made. This allows for improved steerability of the catheter and wire across the aortic valve. The wires used to cross the aortic valve were either floppy-tipped 0.014″ wires (e.g., Hi-Per Flex, Medtronic AVE) or 0.018″ angled glidewires along with the truncated 3 Fr pigtail catheter. After wire and catheter passage across the aortic valve, the access wire was exchanged for a stiffer 0.014″ wire (Iron Man, Guidant). Though balloon dilation generally occurs easily, balloon deflation can be slow due to the small shaft size of the catheter and viscosity of the inflation solution. As the fully inflated balloon obstructs the left ventricular outflow tract, cardiac output and coronary perfusion can be compromised during the slow deflation period. In order to shorten the deflation period, the amount of contrast used during balloon dilation was minimized. With larger amounts of contrast, the increased viscosity of the solution makes deflation more difficult. In general, less than 20% contrast agent (and often less than 10%) was used for balloon inflation. Only enough contrast to allow fluoroscopic visualization of balloon shape and position is necessary. If secure wire position is established, the balloon can be withdrawn into the ascending aorta during balloon deflation. As the ascending aorta usually displays poststenotic dilation, withdrawal of the partially deflated balloon into the ascending aorta while maintaining wire position in the left ventricle allows for continuing deflation while allowing cardiac output as well as unobstructed coronary perfusion during deflation.

Hand inflation was generally preferred to using an inflation device. Rated burst pressure is 6 atm for the 4 mm balloon and 4 atm for the 8 mm balloon. Balloon bursting was not a recurring problem as the stenotic valves tended to dilate relatively easily. This may be due to the fact that the aortic valve is generally thinner in this age group. It was felt that hand inflation allowed for more tactile control of the inflation process.

There was difficulty in maintaining balloon position in one patient. This patient then underwent dilation using a Tyshak II dilation catheter through a 4 Fr arterial sheath. Adenosine-induced AV block or rapid right ventricular pacing was not used in this patient. The dilation catheter is quite flexible and transvalvar balloon positioning may be difficult during inflation. In general, a stiff 0.014″ guidewire with a short floppy tip (e.g., Iron Man, Guidant) was used to position the dilation catheter. This type of wire generally allows enough backbone to permit successful valvuloplasty in most patients while providing an atraumatic floppy tip section. Balloon ejection tends to occur with older infants and using the larger dilation catheters. Methods to improve catheter position during inflation include the use of intravenous adenosine to promote transient AV block and rapid right ventricular pacing during balloon inflation. Rapid right ventricular pacing with simultaneous balloon inflation has been successful using the 3 Fr system.

Finally, though a truncated pigtail catheter allows for easier retrograde passage of the wire/catheter complex, the use of the truncated pigtail catheter for angiography is not recommended, particularly for the postvalvuloplasty angiogram. After the pigtail is truncated, the angled tip is directed toward the aortic valve. Power injection through this catheter can result in contrast being directed directly toward the valve apparatus, resulting in overestimation of the degree of aortic insufficiency. A significant difference in the angiographic appearance of aortic insufficiency between a truncated and nonaltered pigtail catheter can be seen, as the latter promotes a more diffuse filling of the aortic root. While 3 Fr end-hole catheters such as the Cobra exist, they generally have a much more angled tip section than the truncated pigtail catheter. The truncated pigtail catheter allows for the slight change in tip angle to allow for easier retrograde passage across the aortic valve while maintaining more reliable pressure measurements due to the presence of the additional side holes.

Limitations of this study include limited follow-up for vascular access problems. The majority of patients who underwent balloon aortic valvuloplasty during the reviewed time period did not have repeat catheterization procedures performed at our institution. Only three patients required recatheterization directed toward the aortic valve. We did not observe any immediate postprocedural arterial vascular complications. However, monitoring for vascular access problems was limited to the duration of the hospital admission after valvuloplasty. No clinical evidence of postprocedure arterial occlusion was reported following hospital discharge. Follow-up for femoral arterial damage was limited to those patients in whom an additional catheterization was performed after the initial valvuloplasty. One patient was documented to have right femoral artery occlusion during a procedure performed 8 months after the initial valvuloplasty. This patient was found to have coarctation of the aorta after discontinuation of prostaglandin infusion, which required surgical coarctation repair. In addition to an extended intensive care unit stay requiring femoral arterial access, three additional catheterization procedures were performed directed at postsurgical aortic recoarctation, though right femoral artery patency was documented 4 months after the initial valvuloplasty procedure. One patient ultimately underwent single-ventricle palliation. During diagnostic catheterization at 22 months of age, femoral arterial patency in this patient was documented. These results cannot, however, be generalized to the rest of the study cohort.

Whether the 3 Fr system would be useful in the setting of alternative forms of vascular access was not studied. As the introduction of a 4 Fr sheath for antegrade femoral venous access in infants is currently not thought to be excessive, the 3 Fr system may play a limited role from this approach. It has been the preference at our institution to perform balloon aortic valvuloplasty using a retrograde approach, though other methods are certainly feasible. Balloon aortic valvuloplasty from an umbilical arterial approach theoretically could be performed using the 3 Fr system. However, as direct puncture of the femoral artery would not be required in an umbilical arterial approach, any difference in iliac arterial trauma due to a 3 Fr sheath in comparison to a 4 Fr sheath using this approach may be negligible. This system may be useful if a carotid arterial approach is used, though we have not used it in this setting.

REFERENCES

1. Campbell M. The natural history of congenital aortic stenosis. Br Heart J 1968;30:514–526.
2. Wagner HR, Ellison RC, Keane JF, Humphries OJ, Nadas AS. Clinical course in aortic stenosis. Circulation 1977;56(Suppl 1):I47–I56.
3. Lababidi Z. Aortic balloon valvuloplasty. Am Heart J 1983;106 (4 Pt 1):751–752.
4. Lababidi Z, Weinhaus L. Successful balloon valvuloplasty for neonatal critical aortic stenosis. Am Heart J 1986;112:913–916.
5. Rocchini AP, Beekman RH, Ben Shachar G, Benson L, Schwartz D, Kan JS. Balloon aortic valvuloplasty: results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. Am J Cardiol 1990;65:784–789.
6. McCrindle BW. Independent predictors of immediate results of percutaneous balloon aortic valvotomy in children: Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) registry investigators. Am J Cardiol 1996;77:286–293.
7. Magee AG, Nykanen D, McCrindle BW, Wax D, Freedom RM, Benson LN. Balloon dilation of severe aortic stenosis in the neonate: comparison of anterograde and retrograde catheter approaches. J Am Coll Cardiol 1997;30:1061–1066.
8. Peuster M, Fink C, Schoof S, Von Schnakenburg C, Hausdorf G. Anterograde balloon valvuloplasty for the treatment of neonatal critical valvar aortic stenosis. Catheter Cardiovasc Interv 2002;56:516–520.
9. Rao PS, Jureidini SB. Transumbilical venous, anterograde, snare-assisted balloon aortic valvuloplasty in a neonate with critical aortic stenosis. Cathet Cardiovasc Diagn 1998;45:144–148.
10. Maeno Y, Akagi T, Hashino K, Ishii M, Sugimura T, Takagi J, Suzuki K, Kato H. Carotid artery approach to balloon aortic valvuloplasty in infants with critical aortic valve stenosis. Pediatr Cardiol 1997;18:288–291.
11. Borghi A, Agnoletti G, Poggiani C. Surgical cutdown of the right carotid artery for aortic balloon valvuloplasty in infancy: midterm follow-up. Pediatr Cardiol 2001;22:194–197.
12. Gatzoulis MA, Rigby ML, Shinebourne EA, Redington AN. Contemporary results of balloon valvuloplasty and surgical valvotomy for congenital aortic stenosis. Arch Dis Child 1995;73:66–69.
13. Justo RN, McCrindle BW, Benson LN, Williams WG, Freedom RM, Smallhorn JF. Aortic valve regurgitation after surgical versus percutaneous balloon valvotomy for congenital aortic valve stenosis. Am J Cardiol 1996;77:1332–1338.
14. Zeevi B, Keane JF, Castaneda AR, Perry SB, Lock JE. Neonatal critical valvar aortic stenosis: a comparison of surgical and balloon dilation therapy. Circulation 1989;80:831–839.
15. Jindal RC, Saxena A, Juneja R, Kothari SS, Shrivastava S. Long-term results of balloon aortic valvulotomy for congenital aortic stenosis in children and adolescents. J Heart Valve Dis 2000;9:623–628.
16. McCrindle BW, Blackstone EH, Williams WG, Sittiwangkul R, Spray TL, Azakie A, Jonas RA. Are outcomes of surgical versus transcatheter balloon valvotomy equivalent in neonatal critical aortic stenosis? Circulation 2001;104(12 Suppl 1):I152–I158.
17. Cowley CG, Dietrich M, Mosca RS, Bove EL, Rocchini AP, Lloyd TR. Balloon valvuloplasty versus transventricular dilation for neonatal critical aortic stenosis. Am J Cardiol 2001;87:1125–1127.
18. Latiff HA, Sholler GF, Cooper S. Balloon dilatation of aortic stenosis in infants younger than 6 months of age: intermediate outcome. Pediatr Cardiol 2003;24:17–26.
19. Moore P, Egito E, Mowrey H, Perry SB, Lock JE, Keane JF. Midterm results of balloon dilation of congenital aortic stenosis: predictors of success. J Am Coll Cardiol 1996;27:1257–1263.
20. Egito ES, Moore P, O'Sullivan J, Colan S, Perry SB, Lock JE, Keane JF. Transvascular balloon dilation for neonatal critical aortic stenosis: early and midterm results. J Am Coll Cardiol 1997;29:442–447.
21. Reich O, Tax P, Marek J, Razek V, Gilik J, Tomek V, Chaloupecky V, Bartakova H, Skovranek J. Long term results of percutaneous balloon valvoplasty of congenital aortic stenosis: independent predictors of outcome. Heart 2004;90:70–76.
22. Sandhu SK, Lloyd TR, Crowley DC, Beekman RH. Effectiveness of balloon valvuloplasty in the young adult with congenital aortic stenosis. Cathet Cardiovasc Diagn 1995;36:122–127.
23. Rosenfeld HM, Landzberg MJ, Perry SB, Colan SD, Keane JF, Lock JE. Balloon aortic valvuloplasty in the young adult with congenital aortic stenosis. Am J Cardiol 1994;73:1112–1117.
24. Satou GM, Perry SB, Lock JE, Piercey GE, Keane JF. Repeat balloon dilation of congenital valvar aortic stenosis: immediate results and midterm outcome. Catheter Cardiovasc Interv 1999;47:47–51.
25. Burrows PE, Benson LN, Williams WG, Trusler GA, Coles J, Smallhorn JF, Freedom RM. Iliofemoral arterial complications of balloon angioplasty for systemic obstructions in infants and children. Circulation 1990;82:1697–1704.
26. Vogel M, Benson LN, Burrows P, Smallhorn JF, Freedom RM. Balloon dilatation of congenital aortic valve stenosis in infants and children: short term and intermediate results. Br Heart J 1989;62:148–153.