Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/ihj

Editorial

Balloon aortic valvuloplasty☆

Aortic valve stenosis constitutes of 5–6% of all congenital heart defects. Its prevalence is higher in males than in females. While the pathology of stenosis is variable, it is most commonly a bicuspid valve with fusion of the valve commissures. Unicuspid aortic valves are more common in the neonate with critical obstruction whereas bicuspid valves are common in childhood, adolescence, and adulthood.[1] Truly tricuspid valves are not common. The degree of aortic stenosis increases with increasing age. The management of congenital aortic valve stenosis was by surgical valvotomy in the past, but with the advent of balloon aortic valvuloplasty (BAV),[2,3] it has become the initial option in the treatment of congenital aortic stenosis (AS).[4,5] It should be understood that the natural history, reaction to treatment, and prognosis for congenital aortic valve stenosis are strikingly different from those seen with calcific AS of the elderly.

Following successful adaptation of balloon angioplasty techniques of Dotter,[6] Gruntzig,[7] and their associates to treat aortic coarctation and pulmonary valve stenosis in children, Lababidi and his colleagues[2,3] extended the technique of balloon valvuloplasty to aortic valve stenosis. Subsequently, a number of cardiologists have applied this technique and reported their results, extensively referenced elsewhere.[4,5,8–13] In this issue of the Journal, Awasthy and associates[14] evaluate long-term results of BAV with particular attention to adolescent and adults. They compared the outcomes of this subset with those of children below 1 year of age and those between 1 and 11 years. The need for repeat BAV (10.3–18.1%), presence of aortic regurgitation, grade 3 or more (9–9.6%) and need for surgery (2.4–3.6%) at follow-up were examined and found to be similar ($p > 0.19$) in all three age groups. The authors conclude that long-term outcome in the adults and adolescents is similar to that in infants and children, and BAV is an obvious treatment of choice in adolescent and adults.

This is a well written paper addressing the mid-term (median of 3 years), although the authors call it long-term outcome, of BAV of congenital aortic valve stenosis, particularly pointing out that the outcome in adults is similar to that observed in infants and children. This is particularly timely, given the enthusiasm which many centers are exhibiting for transcatheter aortic valve replacement (TAVR). The TAVR should be reserved for calcific AS of the elderly and the non-calcific AS in adolescents and adults could be addressed adequately by the less invasive balloon valvuloplasty.

An extensive search of the literature (PubMed) of BAV revealed over 500 papers since the Lababidi's publications[2,3] in early 1980s; most of these address calcific AS of the elderly[15,16] or immediate and short-term follow-up after BAV. The long-term results, defined as more than a mean (or median) follow-up of 5 years, are scanty and are listed in Table 1.[10,17–26] Several other investigators[27,28] reported the results of BAV in adolescents and adults, but did not reach the criteria for inclusion in the table. As can be seen by examining the table, a substantial proportion of patients had re-intervention during the follow-up period with actuarial re-intervention-free rates of nearly 50% at 10 years. The re-interventions were for recurrent AS either by repeat BAV or surgery, depending upon the institutional preference. The aortic insufficiency (AI) has been addressed either by surgical repair or replacement of aortic valve, again depending upon the institutional preference. It is prudent to address the causes of AS and AI and examine whether they could be prevented.

1. Aortic valve restenosis

Based on the follow-up results,[8,10] using multivariate stepwise logistic regression analysis, we identified age ≤3 years at the time of valvuloplasty and immediate post-valvuloplasty peak-to-peak aortic valve gradient ≥30 mmHg as predictive factors for restenosis. Several other studies have since made similar observations. The influence of various technical and morphological features on the results of BAV was examined by Sholler and colleagues,[29] but no statistical significance was demonstrated for any factors tested. It is quite possible that the morphology of the aortic valve and the balloon/annulus ratio may play a key role in restenosis at follow-up, but further studies are necessary to establish such a relationship.

It is important to ensure that the balloon is appropriately centered across the aortic valve during BAV since there is a tendency for ejection of the balloon during the balloon

☆ From the Department of Pediatrics, Division of Pediatric Cardiology, UT Health McGovern Medical School, Houston, TX, United States.

Table 1 – Long-term results after balloon aortic valvuloplasty.

Authors/ref.	Number of subjects	Age at valvuloplasty (mean ± SD)	Duration of follow-up (mean ± SD)	Country	Long-term results
Hawkins et al.[17]	60	7.3 ± 6 years	1–110 months	USA	38% required surgery at 44 ± 37 months after BAV (AI in 13 and AS in 10). Actuarial freedom from surgical intervention was 70% ± 6% at 5 years and 51% ± 12% at 9 years.
Kuhn et al.[18]	22		61 ± 23 months.	USA	45% required re-intervention after BAV (AI in 3 and AS in 7). Freedom from re-intervention was 75% at 100 months.
Galal et al.[10]	26	6 weeks to 20 years	3–9 years (median 6 years)	Saudi Arabia and USA	23% had restenosis and underwent surgical (4 patients) or repeat BAV (2 patients). Actuarial intervention-free rates at 5 and 9 years were 76% and 76% respectively.
Demkow et al.[19]	55	3.5–23 years (11.7 ± 4.5)	62 ± 30 months	Poland	33.3% re-intervention 51 ± 24 months after BAV (AI in 6 and AS in 5). Actuarial freedom from re-intervention at 6 and 8 years was 61% and 56% respectively.
Jindal et al.[20]	74	1–20 years	5.5 ± 2.9 years	India	14% had re-intervention. Actuarial intervention-free rates at 5, 7 and 12 years were 92.9%, 84.4% and 60%, respectively.
Reich et al.[21]	269	0–23 years (median 8 months)	Median 5.3 years	Czech Republic	20.1% needed surgery. Valvuloplasty failure occurred in 41.6%. Probability of surgery-free survival was 50% at 14.4 years after BAV
Fratz et al.[22]	120	5.8 ± 5.9 years[a]	Up to 17.5 years	Germany	12% had repeat BAV for recurrent AS and 23% had surgery for AI. Freedom from aortic valve surgery at 10 years was 59%.
Brown et al.[23]	509	Median = 2.4 years (1 day to 40.5 years)	Median 9.3 years	USA	23% had repeat BAV, 13% had aortic valve repair and 23% had aortic valve replacement. Freedom from aortic valve replacement was 90% at 5 years, 79% at 10 years, and 53% at 20 years.
Maskatia et al.[24]	272	1 day to 30.5 years	5.8 ± 6.7 years	USA	15% had repeat valvuloplasty (balloon or surgical); 15% had aortic valve replacement; 9% had heart transplantation or death.
Rossi et al.[25]	31	2–92 days	Mean 81 months	Brazil	24% patients required surgery during follow-up. Survival free from aortic valve surgery was 66% at 63 months and 50% at 80 months.
Soulatges et al.[26]	93	Mean 2.4 years (1 day to 18 years)	11.4 ± 7 years	Belgium	Freedom from surgery at 5, 10, and 20 years was 82%, 72%, and 66%, respectively.

AI, aortic insufficiency; AS, aortic stenosis; BAV, balloon aortic valvuloplasty; SD, standard deviation.
[a] Babies <1 month were excluded from the table.

procedure. Use of stiff guide wires and long balloons were considered adequate in the most of our patients.[4,5,8–10] Use of adenosine-induced transient cardiac standstill[30] or rapid right ventricular pacing[31] to achieve stable position of the balloon during BAV may become necessary in some patients to ensure appropriate positioning of the balloon.

2. Aortic insufficiency

AI was noted as a significant long-term complication after BAV and requires surgical repair of the valve or valve replacement. The majority of the studies show a trend toward increase in the degree of AI with time; the longer the follow-up, the greater is the AI. The reasons for progression of AI are not well understood. The hypotheses put forward include greater relief of gradient immediately following BAV,[32] Doppler-quantified AI both prior to and immediately following BAV,[10] unicommissural aortic valves,[29] aortic valve prolapse,[33] poor valve morphology,[10] and large balloon/annulus ratio.[29,34] Our studies[10] indicate that balloon/annulus ratio may not be related to AI (Fig. 1A), but the degree of AI immediately after BAV (Fig. 1B) is predictive of development of significant late AI. Further studies to explore these and other causes for development of late AI and device methods to prevent AI are in order.

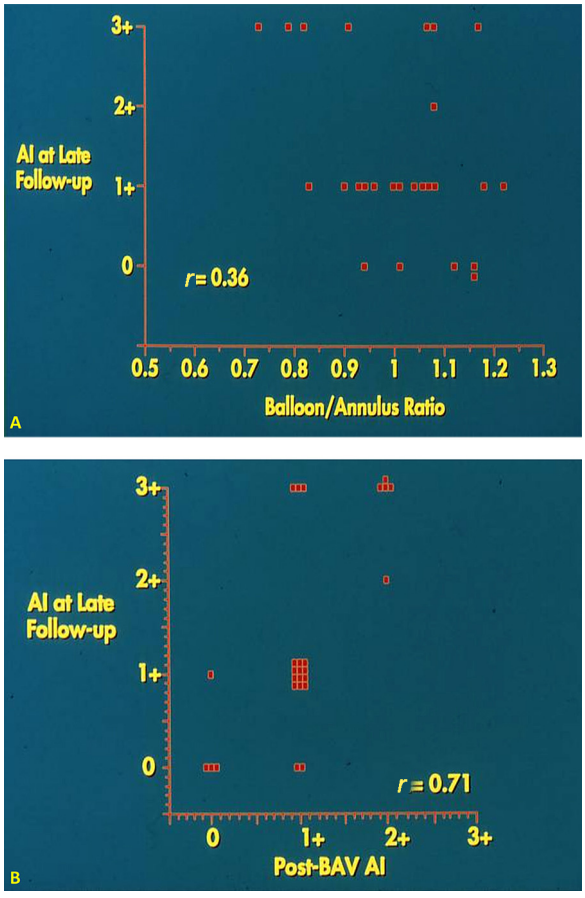

Fig. 1 – (A) Relationship between the balloon/annulus ratio and degree of aortic insufficiency (AI) at late follow-up. Note that there is no correlation with an *r* value of 0.36. (B) Relationship between the degree of aortic insufficiency (AI) immediately following balloon aortic valvuloplasty with AI at late follow-up. Note that there is a significant correlation with an *r* value of 0.71.

3. Summary and conclusions

In summary, the paper by Awasthy is an excellent contribution to our knowledge of BAV and clearly points out the BAV is as good a treatment option for adolescents and adults with congenital aortic valve stenosis as for neonates, infants and children. This is particularly timely given the enthusiasm for TAVR and help us to consider BAV for treatment of congenital aortic valve stenosis in adolescents and adults and reserve TAVR for calcific AS of the elderly. Recurrence of AS at follow-up can usually be treated with repeat BAV. The predictors of recurrence are young age (≤3 years) and high residual gradients (≥30–40 mmHg) immediately following BAV. AI seems to be problematic at late follow-up and requires surgical intervention. The degree of immediate post-valvuloplasty AI grade may be predictive of late AI. Because of late development of AI, requiring surgical intervention, it is prudent to strictly adhere to indications for BAV and not to perform balloon valvuloplasty for milder or borderline gradients.

Conflicts of interest

The author has none to declare.

REFERENCES

1. Singh GK, Rao PS. Left heart outflow obstructions. In: Crawford MH, DiMarco JP, Paulus WJ, eds. In: *Cardiology* third ed. Edinburgh, UK: Mosby Elsevier; 2010, ISBN: :978-0-7234-3485-61507–1518.
2. Lababidi Z. Aortic balloon valvuloplasty. *Am Heart J.* 1983;106:751–752.
3. Lababidi Z, Wu J, Walls JT. Percutaneous balloon aortic valvuloplasty: results in 23 patients. *Am J Cardiol.* 1984;54:194–197.
4. Rao PS. Balloon aortic valvuloplasty in children: a review. *Clin Cardiol.* 1990;13:458–466.
5. Rao PS. Balloon aortic valvuloplasty. *J Interv Cardiol.* 1998;11:319–329.
6. Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction: description of a new technique and a preliminary report of its application. *Circulation.* 1964;30:654–670.
7. Gruntzig AR, Senning A, Siegothaler WE. Non-operative dilatation of coronary artery stenosis: percutaneous transluminal coronary angioplasty. *N Engl J Med.* 1979;301:61–68.
8. Rao PS, Thapar MK, Wilson AD, Levy JM, Chopra PS. Intermediate-term follow-up results of balloon aortic valvuloplasty in infants and children with special reference to cause of restenosis. *Am J Cardiol.* 1989;64:1356–1360.
9. Rao PS. Balloon valvuloplasty for aortic stenosis. In: Rao PS, ed. In: *Transcatheter Therapy in Pediatric Cardiology*. New York, NY: Wiley-Liss; 1993:105–127.
10. Galal O, Rao PS, Al-Fadley F, Wilson AD. Follow-up results of balloon aortic valvuloplasty in children with special reference to causes of late aortic insufficiency. *Am Heart J.* 1997;133:418–427.
11. Chopra PS, Rao PS. Balloon aortic valvuloplasty in children (editorial). *J Invasive Cardiol.* 1999;11:277–279.
12. Rao PS. Long-term follow-up results after balloon dilatation of pulmonic stenosis, aortic stenosis and coarctation of the aorta: a review. *Progr Cardiovasc Dis.* 1999;42:59–74.
13. Agu NC, Rao PS. Balloon aortic valvuloplasty. *Pediatr Ther.* 2012;S5:004. http://dx.doi.org/10.4172/2161-0665.S5-004.
14. Awasthy N, Garg R, Radhakrishnan S, Shrivastava S. Long term results of percutaneous balloon valvuloplasty of congenital aortic stenosis in adolescents and young adults. *Indian Heart J.* 2016. http://dx.doi.org/10.1016/j.ihj.2016.03.001.
15. McKay RG, Safian RD, Lock JE, et al. Balloon dilatation of calcific aortic stenosis in elderly patients: postmortem, intraoperative, and percutaneous valvuloplasty studies. *Circulation.* 1986;74:119–125.
16. Cribier A, Savin T, Saoudi N, et al. Percutaneous transluminal aortic valvuloplasty using a balloon catheter. A new therapeutic option in aortic stenosis in the elderly. *Arch Mal Coeur Vaiss.* 1986;79:1678–1686 [in French].
17. Hawkins JA, Minich LL, Shaddy RE, et al. Aortic valve repair and replacement after balloon aortic valvuloplasty in children. *Ann Thorac Surg.* 1996;61:1355–1358.
18. Kuhn MA, Latson LA, Cheatham JP, Fletcher SE, Foreman C. Management of pediatric patients with isolated valvar aortic stenosis by balloon aortic valvuloplasty. *Catheter Cardiovasc Diagn.* 1996;39:55–61.

19. Demkow M, Ruzyllo W, Ksiezycka E, et al. Long-term follow-up results of balloon valvuloplasty for congenital aortic stenosis: predictors of late outcome. *J Invasive Cardiol.* 1999;11:220–226.
20. 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.
21. Reich O, Tax P, Marek J, et al. Long term results of percutaneous balloon valvoplasty of congenital aortic stenosis: independent predictors of outcome. *Heart.* 2004;90:70–76.
22. Fratz S, Gildein HP, Balling G, et al. Aortic valvuloplasty in pediatric patients substantially postpones the need for aortic valve surgery: a single-center experience of 188 patients after up to 17.5 years of follow-up. *Circulation.* 2008;117:1201–1206.
23. Brown DW, Dipilato AE, Chong EC, Lock JE, McElhinney DB. Aortic valve reinterventions after balloon aortic valvuloplasty for congenital aortic stenosis intermediate and late follow-up. *J Am Coll Cardiol.* 2010;56:1740–1749.
24. Maskatia SA, Ing FF, Justino H, et al. Twenty-five year experience with balloon aortic valvuloplasty for congenital aortic stenosis. *Am J Cardiol.* 2011;108:1024–1028.
25. Rossi RI, Manica JL, Petraco R, et al. Balloon aortic valvuloplasty for congenital aortic stenosis using the femoral and the carotid artery approach: a 16-year experience from a single center. *Catheter Cardiovasc Interv.* 2011;78:84–90.
26. Soulatges C, Momeni M, Zarrouk N, et al. Long-term results of balloon valvuloplasty as primary treatment for congenital aortic valve stenosis: a 20-year review. *Pediatr Cardiol.* 2015;36:1145–1152.
27. Rosenfeld HM, Landzberg MJ, Perry SB, et al. Balloon aortic valvuloplasty in the young adult with congenital aortic stenosis. *Am J Cardiol.* 1994;73:1112–1117.
28. Sandhu SK, Lloyd TR, Crowley DC, Beekman RH. Effectiveness of balloon valvuloplasty in the young adult with congenital aortic stenosis. *Catheter Cardiovasc Diagn.* 1995;36:122–127.
29. Sholler GF, Keane JF, Perry SB, Sanders SP, Lock JE. Balloon dilatation of congenital aortic valve stenosis: results and influence of technical and morphological features on outcome. *Circulation.* 1988;12:480–485.
30. De Giovanni JV, Edgar RA, Cranston A. Adenosine induced transient cardiac standstill in catheter interventional procedures for congenital heart disease. *Heart.* 1998;80:330–333.
31. Daehnert I, Rotzsch C, Wiener M, Schneider P. Rapid right ventricular pacing is an alternative to adenosine in catheter interventional procedures for congenital heart disease. *Heart.* 2004;90:1047–1050.
32. Helgason H, Keane JF, Fellows KE, Kulik TJ, Lock JE. Balloon dilatation of aortic valve: studies in normal lambs and in children with aortic stenosis. *J Am Coll Cardiol.* 1987;9:816–822.
33. Shaddy RE, Boucek MM, Sturtevant JE, Ruttenberg HD, Orsmond GS. Gradient reduction, aortic valve regurgitation and prolapse after balloon aortic valvuloplasty in 32 consecutive patients with congenital aortic stenosis. *J Am Coll Cardiol.* 1990;16:451–456.
34. Rocchini AP, Beekman RH, Shachar GB, et al. Balloon aortic valvuloplasty: results of the valvuloplasty and angioplasty of congenital anomalies registry. *Am J Cardiol.* 1990;65:784–789.

P. Syamasundar Rao MD, DCH, FAAP, FACC, FSCAI
Professor of Pediatrics and Medicine, Emeritus Chief of Pediatric Cardiology, UT Health McGovern Medical School, Children's Memorial Hermann Hospital, Houston, TX, United States
E-mail address: P.Syamasundar.Rao@uth.tmc.edu

Available online 4 April 2016

http://dx.doi.org/10.1016/j.ihj.2016.03.018
0019-4832/