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Balloon Aortic Valvuloplasty

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Abstract

Following the description by Lababidi in 1983 of balloon aortic valvuloplasty, it has been adopted by several groups of workers for relief of aortic valve stenosis. The indications for the procedure are peak-to-peak systolic pressure gradients in excess of 50 mmHg with symptoms or ECG changes or a gradient greater than 70 mmHg irrespective of the symptoms or ECG changes. One or more balloon dilatation catheters are placed across the aortic valve percutaneously, over extra-stiff guide wire (s) and the balloon (s) inflated until waist produced by the stenotic valve is abolished. A balloon/annulus ratio is 0.8 to 1.0 is recommended. While trans-femoral arterial route is the most commonly used for balloon aortic valvuloplasty, trans-umbilical arterial or venous or trans-venous routes are preferred in neonate and young infants to avoid femoral arterial injury.

Reduction of peak-to-peak systolic pressure gradient along with a fall in left ventricular peak systolic and end-diastolic pressures is seen after balloon aortic valvuloplasty in the majority of patients. Significant aortic insufficiency, though rare, may develop, particularly in the neonate. At intermediate-term follow-up, peak-to-peak gradients, at repeat cardiac catheterization and noninvasive Doppler gradients remain low for the group as a whole. Nevertheless, restenosis, defined as peak-to-peak gradient ≥ 50 mmHg may develop in nearly one quarter of the patients. Predictors of restenosis are age ≤ 3 years and an immediate post-valvuloplasty aortic valve gradient ≥ 30 mmHg. The restenosis may be addressed by repeat balloon valvuloplasty or surgical valvotomy. Feasibility and effectiveness repeat balloon valvuloplasty in relieving restenosis has been demonstrated. Long-term follow-up data suggest, low Doppler peak instantaneous gradients, minimal additional restenosis beyond what was observed at intermediate-term follow-up and progression of aortic insufficiency in nearly one-quarter of patients. Event-free rates are in mid 70s and low 60s respectively at 5 and 10-years after initial balloon valvuloplasty. A number of complications have been reported, but are rare. Comparison with surgical results is fraught with problems, but overall, the balloon therapy appears to carry less morbidity.

Immediate, intermediate and long-term follow-up data following balloon aortic valvuloplasty suggest reasonably good results, avoiding/postponing the need for surgical intervention. However, late follow-up data indicate that significant aortic insufficiency with left ventricular dilatation may develop, some require surgical intervention and are of concern. Current recommendations favor balloon valvuloplasty as first line therapeutic procedure for relief of aortic valve stenosis.

Introduction

Congenital aortic stenosis makes up 5% to 6% of all congenital heart defects. It occurs four times more frequently in males than females. Although the pathology of stenosis varies, the most common is a bicuspid valve with commissural fusion. Unicuspid aortic valves are more prevalent in neonates with critical stenosis while bicuspid valves are common in childhood. Aortic stenosis is a progressive disorder with worsening severity of obstruction with increasing age. The treatment of choice for congenital aortic valve stenosis has varied from surgical valvotomy in the past to balloon aortic valvuloplasty at the present.

The technique of balloon valvotomy of stenotic pulmonary and tricuspid valves with a modified ureteral catheter was first described by Rubio and Limon-Lason [1] in the early 1950s. Double lumen balloon catheters developed by Gruntzig and their associates [2], based on the concepts of Dotter and Judkins [3], were utilized for dilatation of coarcted aortic segments [4-6] and valvar pulmonary stenosis [7]. Subsequently this technique was extended to the aortic valve by Lababidi and his associates [8] in 1983. Shortly thereafter this technique has been adopted by other workers and reports of immediate, intermediate-term and long-term results of balloon aortic valvuloplasty have been published [9-12]. The purpose of this review is to discuss the technique and results of balloon aortic valvuloplasty.

Assessment of Aortic Valve Severity

Assessment and diagnosis of aortic valvar obstruction is made by clinical examination, roentgenographic, electrocardiographic and echo-Doppler (Figure 1) studies. Once a diagnosis of moderate to severe obstruction is made, cardiac catheterization and cineangiography is performed to confirm the clinical impression and to consider balloon aortic valvuloplasty [9,10]. The most usual method of assessing the severity of obstruction is pressure pullback tracings across the aortic valve (Figure 2) during cardiac catheterization; however, the most accurate method is simultaneous left ventricular and aortic pressure measurement (Figure 3). Since the availability of echo-Doppler studies, this non-invasive method is used for selection of candidates for cardiac catheterization and will be detailed in the next section.

Indications

The indications for balloon aortic valvuloplasty are same as those used for surgical valvotomy. Indications of transcatheter intervention are:

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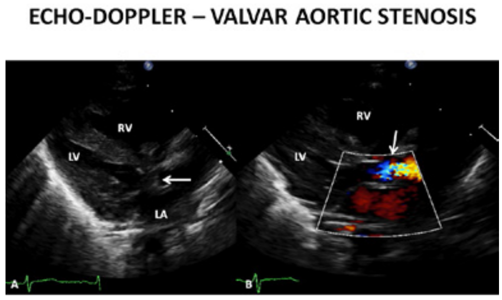

Figure 1: Selected video frames from an echocardiogram of a child with aortic stenosis demonstrating doming (arrow) of the aortic valve (A) and turbulent flow (B) at the aortic valve (arrow) suggesting aortic valve stenosis. However, the degree of obstruction can only be assessed by Doppler-calculated peak instantaneous and mean gradients across the aortic valve (not shown). LA, left atrium; LV, left ventricle; RV, right ventricle.

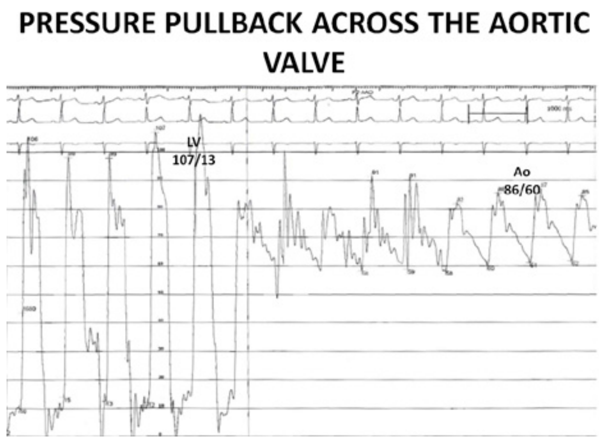

Figure 2: Pressure pullback tracing from the left ventricle (LV) to the aorta (Ao) demonstrating a peak-to-peak gradient of 21 mmHg across the aortic valve; this would suggest that the aortic stenosis is mild, provided the cardiac index is within normal range.

1. A peak-to-peak systolic pressure gradient across the aortic valve more than 70 mmHg, regardless of symptoms or

2. A gradient of more than 50 mmHg with a normal cardiac index and with either symptoms or the presence of electrocardiographic ST-T wave changes indicative of myocardial perfusion abnormality.

Another method practiced by some cardiologists is the calculation of the aortic valve area to evaluate the degree of aortic valve obstruction as opposed to pressure gradient. Sullivan et al. [13] opined that direct pressure gradient measurements are advantageous over calculated aortic valve area in children. However, it is necessary to measure cardiac index to ensure its normalcy prior to using valve gradients as indicators of severity of aortic valve obstruction.

As mentioned above, non-invasive Doppler studies are currently used for selection of candidates for cardiac catheterization and for consideration of balloon aortic valvuloplasty. Initially it was thought that peak instantaneous and/or mean [14] Doppler gradients reflect the peak-to-peak catheter gradients, but because of pressure recovery phenomenon [15,16], the Doppler gradients are not as accurate as one would like. We generally use an average of peak instantaneous and mean Doppler aortic valve gradients in excess of the above values to recommend balloon aortic valvuloplasty.

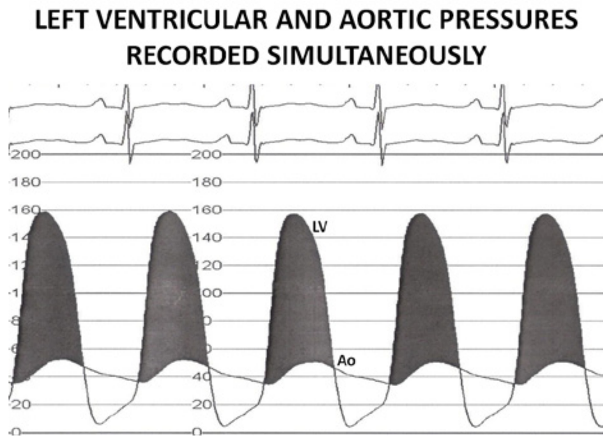

Figure 3: Simultaneous pressure recordings from the left ventricle (LV) and the aorta (Ao) demonstrating a peak-to-peak gradient of 110 mmHg across the aortic valve suggesting that the aortic stenosis is very severe.

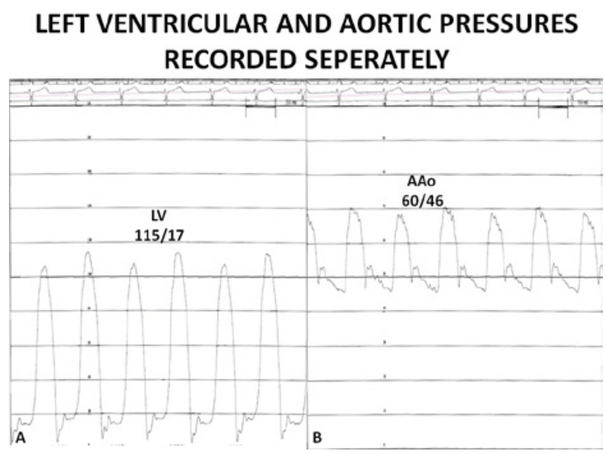

Figure 4: Left ventricular (LV) and ascending aortic (AAo) pressures recorded separately showing a peak to peak gradient of 55 mmHg across the aortic valve. Pressure pullback was not recorded because of the difficulty in crossing the aortic valve initially.

Neonates with very severe aortic valve stenosis with high gradient across the aortic valve, congestive heart failure or ductal–dependent circulation, characterized as critical obstruction, will require administration of PGE1 initially followed by transcatheter intervention, which is an acceptable alternative to surgery.

The presence of significant aortic insufficiency is considered a contraindication for balloon intervention for fear of further worsening of aortic valve insufficiency. However, previous surgical aortic valvotomy is not considered a contraindication for balloon dilatation [17-19].

Sub-aortic stenosis caused by thin membrane is amenable to balloon dilatation [20-22], whereas the presence of fibromuscular and tunnel sub-aortic obstruction and hypertrophic cardiomyopathy with dynamic sub-aortic obstruction are not responsive to balloon therapy. These entities are not the subject of this review.

Technique

After obtaining informed consent, cardiac catheterization and selective cineangiography are performed to confirm the clinical and echocardiographic findings. Sedation may be obtained with a mixture of meperidine, promethazine and chlorpromazine, ketamine or general anesthesia; this is usually institutional dependent. We recommend general anesthesia with elective endotracheal intubation and controlled ventilation for infants less than three months of age. Once the venous and arterial access is achieved, 50-100 units/kg of heparin (maximum 3,000 units) are administered intravenously and ACTs (activated clotting times) monitored and maintained above 200 sec. Several routes have been used to accomplish balloon aortic valvuloplasty; percutaneous femoral arterial approach is the most commonly used approach.

Retrograde femoral arterial approach

In the retrograde femoral arterial approach a #4- or #5-F sheath is placed percutaneously in the femoral artery and a 4- or 5-F multipurpose or right coronary artery catheter is advanced into the ascending aorta. With the help of a floppy-tipped coronary guide wire (in infants), a 0.035-inch straight Benston guide wire (Cook) or similar wires, the catheter is advanced into the left ventricle across the stenotic aortic valve. Other types of catheters and guide wires may be used if there is difficulty in crossing the aortic valve. Peak to peak systolic pressure gradient is determined by pressure pullback across the aortic valve (Figure 2) and cardiac output measurements performed. However, if there is marked difficulty in crossing the aortic valve, no pressure pullback is performed; instead, previously recorded aortic pressure is used to determine the peak to peak systolic pressure gradient across the aortic valve (Figure 4). Cineaortography and left ventriculography are performed and a final diagnosis is made. Cine projections should be chosen to best highlight the aortic valve stenosis and any additional subvalvar and supravalvar anomalies.

A J-tipped extra-stiff Amplatz guide wire (Cook, Bloomington, IN) {or an apex guide wire (Cook) in the older child} is positioned in the left ventricular apex, through the catheter already in place. The chosen balloon should have a diameter 80% to 100% of the aortic valve annulus and should not exceed the aortic annulus. The aortic valve annulus is measured both in the echocardiogram performed prior to catheterization and from the left ventricular angiography during the procedure. The balloon length varies depending on the size of the patient: neonates and young infants – 2 cm; older infants and young children – 3 cm; older children and adolescents – 4 to 5.5 cm. There is a tendency for ejection of the balloon during balloon inflation and therefore, we prefer to use longer balloons. Others use Adenosine induced transient cardiac standstill [23] or rapid right ventricular pacing [24] to achieve stable position of the balloon during valvuloplasty. Using stiff guide wires and long balloons were found adequate in the majority of our patients [9,10,12,17,25] with rare need for rapid right ventricular pacing.

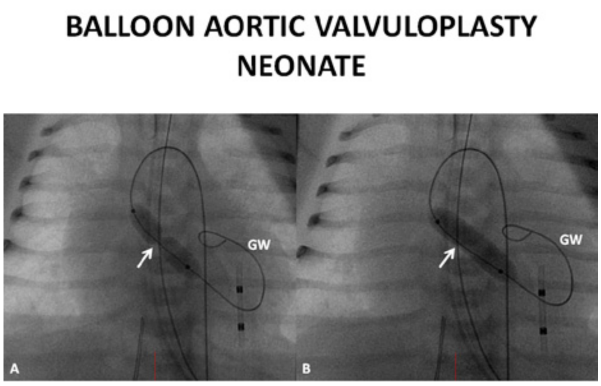

Figure 5: Selected cineradiographic frames showing a balloon positioned across the aortic valve in a neonate for balloon valvuloplasty. Note waisting (arrow) of the balloon (A) which was almost completely abolished (B) on further inflation of the balloon. GW, guide wire.

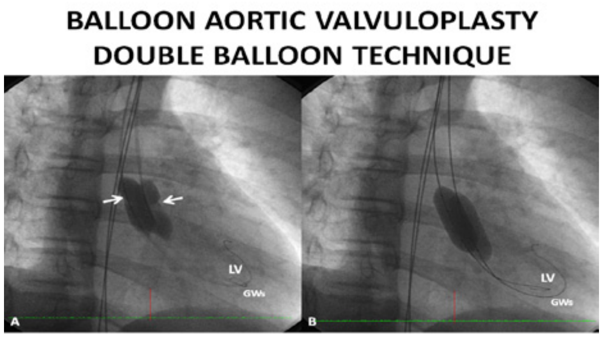

Figure 6: Right anterior oblique views of selected cineradiograms demonstrating two balloons placed across the aortic valve. The balloons were positioned retrogradely via both femoral arteries. Balloon waisting (arrows) during the initial phases of balloon inflation (A) was completely abolished on further inflation of balloon (B). GWs, guide wires; LV, left ventricle.

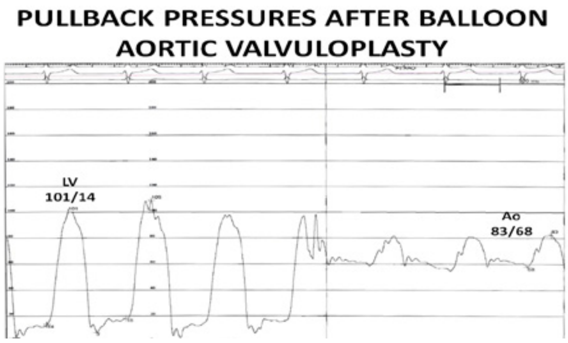

Figure 7: Pressure pullback tracing across the aortic valve following balloon aortic valvuloplasty, demonstrating a residual peak-to-peak gradient of 18 mmHg, indicating good result of the procedure. LV, left ventricle; Ao, aorta.

The selected balloon is placed across the aortic valve over the guide wire already in place using landmarks on the scout film and keeping with the same camera angulations. The balloon is inflated (Figure 5) with diluted contrast solution (1 in 4) to a pressure not exceeding the catheter manufacturer stated burst pressure. The recommendation is to perform two to four balloon inflations for duration of five seconds each, five minutes apart. In the case of an aortic valve annulus that is too large to dilate with a commercially available single balloon or when the balloon catheter size is too large that there is high probability of femoral arterial damage, a double-balloon technique in which two balloons are simultaneously inflated across the aortic valve (Figure 6) is used. Effective balloon diameter may be calculated by the following formula [26], which again, should not exceed the aortic valve annulus diameter:

$$\frac{D_1 + D_2 + \pi\left(\frac{D_1}{2} + \frac{D_2}{2}\right)}{\pi}$$

Where D_1 and D_2 are diameters of the balloon used. This formula

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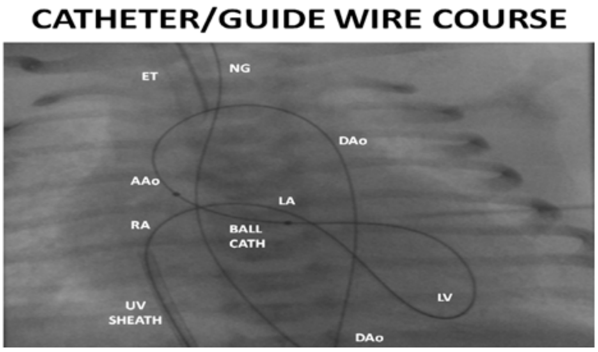

Figure 8: The course of the balloon catheter (BALL CATH) in a neonate with aortic stenosis is shown; the catheter traversed from the umbilical venous (UV) sheath to the right (RA) and left (LA) atrium, left ventricle (LV), ascending aorta (AAo) and descending aorta (DAo) – see the text for details. The endotracheal (ET) and nasogastric (NG) tubes are marked.

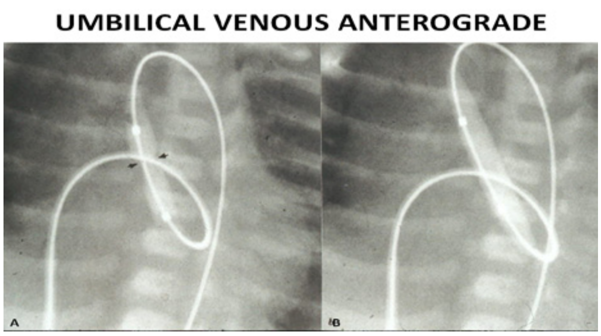

Figure 9: Selected cineradiographic frames showing a balloon positioned across the aortic valve in a manner demonstrated in figure 8. Note waisting (arrows) of the balloon (A) which was abolished on further inflation of the balloon.

was simplified [27]: Effective balloon diameter = 0.82 ($D_1 + D_2$). Post intervention pressure pullback tracings across the aortic valve (Figure 7), cardiac output measurements and left ventricular and/or aortic root angiography are performed fifteen minutes following the valvuloplasty.

Balloon aortic valvuloplasty in the neonates [28-31] may also be performed in a similar manner but, due to concerns for femoral artery injury in the neonatal period, alternative arterial routes such as carotid [32], axillary [33], umbilical arterial [34], subscapular [35], anterograde femoral venous [36,37] and umbilical venous [38,39] approaches have been attempted.

Balloon aortic valvuloplasty via carotid artery

Right carotid artery cut down and isolation is performed by either the pediatric cardiologist or the pediatric cardiovascular surgical colleague depending on institutional practices. A 4-F sheath is placed with a purse string suture. The remainder of the procedure is performed using the above described femoral arterial access method. Due to the straight catheter course, it is easier to position the catheter/guide wire across the aortic valve into the left ventricle [32]. At the end of the procedure, the catheters and sheaths are removed, the purse string suture is tightened and the skin incision sutured.

Transumbilical arterial balloon aortic valvuloplasty [34]

A 4-French multi-A2 catheter (Cordis) is used to replace the previously existing umbilical arterial catheter and advanced in a retrograde fashion into the ascending aorta. With the help of a floppy-tipped coronary guide wire or a similar soft-tipped guide wire, the catheter is advanced into the left ventricle across the stenotic aortic valve. If there is difficulty in crossing aortic valve other catheters and wires may be used. At this juncture, a left ventricular angiography is performed and balloon dilatation is performed using the previously described femoral arterial access method.

Transumbilical venous balloon aortic valvuloplasty [38]

The existing umbilical venous catheter is replaced with a 5-French sheath and the tip of the sheath positioned in the low right atrium. The usual catheterization and left ventricular cineangiography are performed and the diameter of the aortic annulus is obtained. This will be an adjunct to the aortic valve annulus measurement made from the pre-intervention echocardiogram. A 4-F multi-A2 catheter (Cordis) with a slightly curved tip (special order) is introduced through the umbilical venous sheath and advanced into the left atrium across the patent foramen ovale and into the left ventricle through the mitral valve. Using a soft tipped straight Benston guide wire (Cook) and/or J-tipped 0.035-in, core-movable Amplatz guide wire, the catheter is advanced into the aorta and the catheter tip is positioned in the descending aorta. The guide wire is then exchanged for a 0.025-in J-tipped Amplatz extra stiff wire (Cook). At this juncture, a balloon dilatation catheter (Tyshak -II {Braun} or Ultrathin {Meditech}) based on the annulus size not to exceed 80-100% of the aortic valve annulus is selected, advanced over the guide wire and positioned across the aortic valve. The course of

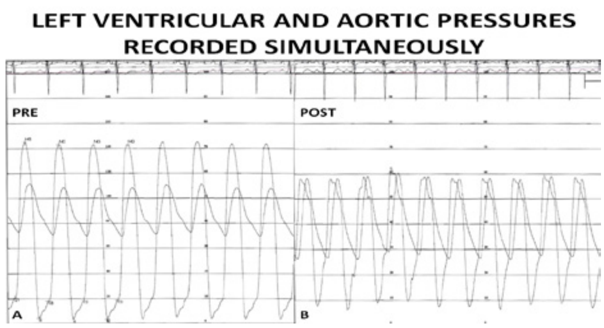

Figure 10: Simultaneous pressure recordings from the left ventricle and aorta prior to (PRE - A) and immediately after (POST - B) balloon aortic valvuloplasty demonstrating no residual gradient. There is a slight decrease in aortic diastolic pressure (B) suggesting aortic insufficiency.

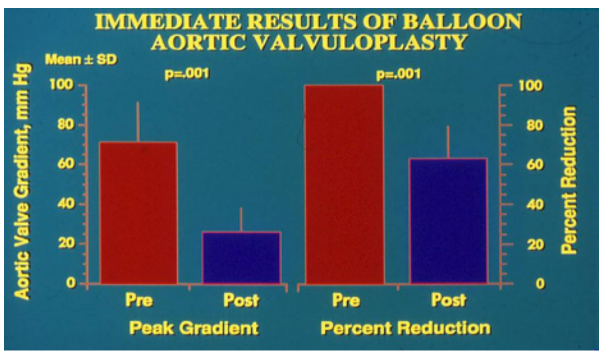

Figure 11: Bar graph showing immediate results after balloon valvuloplasty of aortic valve stenosis. Note significant (p = 0.001) decrease in peak-to-peak systolic pressure gradients (left panel) and percent reduction (right panel).

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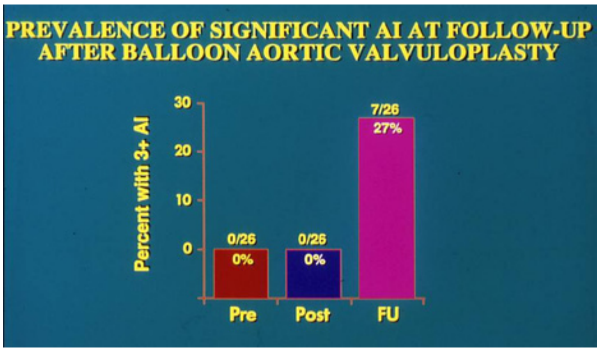

Figure 12: Bar graph showing the prevalence of grade III aortic insufficiency prior to (Pre), immediately following (Post) and at late follow-up (LFU). Note significant increase at late follow-up.

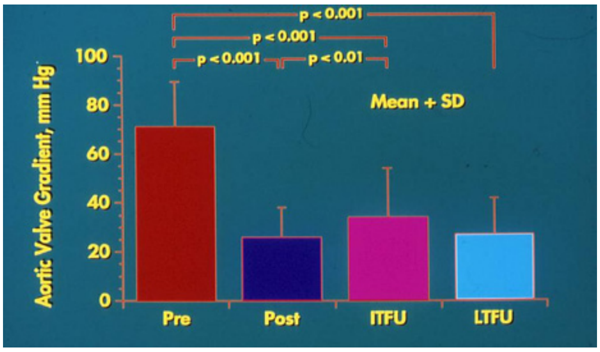

Figure 13: Bar graph depicting maximum peak instantaneous Doppler gradients prior to (Pre) and one day after (Post) balloon aortic valvuloplasty and at intermediate-term (ITFU) and late (LTFU) follow-up. There was significant reduction (p< 0.001) after valvuloplasty which remained essentially unchanged (p > 0.1) at ITFU (12 ± 5 mo) and LTFU (3 to 9 years [mean 6 years]). Doppler-derived maximum peak instantaneous gradients at follow-up continue to be lower (p < 0.001) than pre-valvuloplasty gradients. SD, standard deviation.

the balloon catheter in a neonate with severe aortic stenosis is shown in Figure 8. Balloon inflation is performed (Figure 9) with diluted contrast solution up to or less than the burst pressure specified by the manufacturer of the selected balloon catheter. Afterwards, the balloon catheter is replaced with the 4-F multi-A2 catheter (Cordis) with the tip positioned in the aorta and an aortic root angiography is performed as well as pull back measurements across the aortic valve. A repeat left ventricular angiography may be performed. Antibiotic prophylaxis is given because of extensive umbilical area manipulation.

If there is difficulty in maneuvering the guide wire into the descending aorta, a gooseneck micro-snare (Microvena, White Bear Lake, MN) can be used. The snare is advanced in a retrograde fashion through a 4-F multi-A2 catheter (Cordis) via the umbilical artery to the descending aorta and used to snare the antegradely placed 0.025-in J-tipped Amplatz extra stiff wire (Cook) into the descending aorta where it is held in place. This establishes an umbilical venous to umbilical arterial wire rail and with gentle traction the balloon catheter can be eased into place and the usual dilatation performed. Once the dilatation is completed, the guide wire is released from the snare and withdrawn.

Antegrade femoral venous balloon aortic valvuloplasty [33,34]

A 5-F sheath is used to achieve femoral venous access. The rest of the procedure is performed using the previously described umbilical venous access method.

Comparison of antegrade and retrograde techniques by Magee and associates [40] suggests similar results in terms of feasibility and gradient reduction. However, the retrograde methods had higher mortality, more severe aortic insufficiency and greater incidence of arterial complications compared to the antegrade approach.

Immediate Results

There is an acute reduction in the peak to peak systolic pressures across the aortic valve (Figure 7, 10 and 11) along with a reduction in the left ventricular peak systolic and end diastolic pressures without significant change in cardiac index. There is approximately 60% reduction in the gradient compared to the pre-valvuloplasty gradients (Figure 11). The degree of aortic insufficiency does not worsen as a general rule (Figure 12); there is improvement seen in some patients suggesting better coaptation of the aortic valve leaflets after balloon dilatation. With the exception of neonates, most patients are discharged home within 24 hours of the procedure.

In the first series of 23 consecutive patients with valvar aortic stenosis, reported by Lababidi et al. [11], the peak to peak systolic gradient across the aortic valve decreased from 113 +/- 48 mmHg to 32 +/- 15 mmHg (p<0.001) after balloon valvuloplasty. Very mild aortic regurgitation was noted in 10 (43%) patients after balloon dilatation and two patients required surgery. Acute results following balloon aortic valvuloplasty reported during the decade (1983 to 1992) following its description were tabulated elsewhere [10] and the interested reader is referred to this book chapter.

Equally impressive reduction in gradients was noted in the neonates and the results from the first seven neonatal series [28-32,34,41] is tabulated elsewhere [10]; however, high complication rate including deaths and need for surgical intervention because of development of severe aortic insufficiency were reported in this age group [10,41].

Intermediate-Term Follow-Up Results

During intermediate-term follow up (defined as ≤ 2 years), peak-to-peak gradients across the aortic valve at repeat cardiac catheterization and Doppler peak instantaneous gradients either remain unchanged or increased slightly compared to immediate post-intervention values (Figure 13) but continued to be significantly lower than pre-valvuloplasty values [12]. However, with careful examination of the

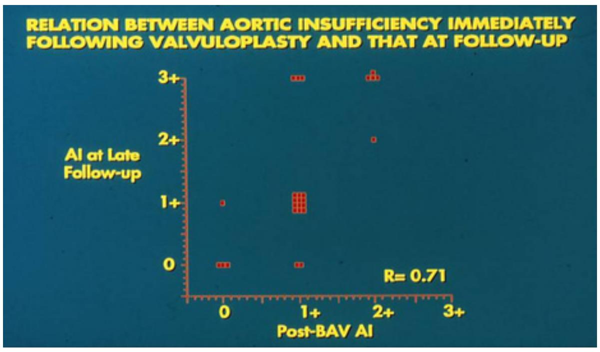

Figure 14: Relationship of immediate post-valvuloplasty Doppler-derived aortic insufficiency (AI) with AI at late follow-up. Note good correlation (r=0.71).

results, restenosis defined as a peak to peak gradient of greater than or equal to 50 mmHg, was found in 23% of children, some requiring surgical valvotomy or repeat balloon valvuloplasty. The degree of aortic insufficiency remains stable during intermediate-term follow-up [12]. Again, intermediate-term follow up during the decade after first description of balloon valvuloplasty were tabulated elsewhere [10] for the interested reader.

Predictors of Restenosis

Based on the intermediate-term follow up results [12,17] we subdivided our patients into two groups: group 1 with residual aortic valvar gradients <50 mmHg and group 2 with residual gradients ≥ 50 mmHg. Using multivariate stepwise logistic regression analysis, age ≤ 3 years at the time of valvuloplasty and immediate post-valvuloplasty peak to peak aortic valve gradient ≥ 30 mmHg were identified as predictive factors for restenosis. Sholler et al. [41] investigated the influence of various technical and morphological features on the immediate results of balloon aortic valvuloplasty but no statistical significance was demonstrated on any factors tested. The morphology of the aortic valve and the balloon/annulus ratio may play an important role in restenosis at follow up evaluation, however further studies are required to establish this.

Long-term Follow-up Results

Although there are several reports on immediate and intermediate-term results of balloon aortic valvuloplasty for the relief of congenital aortic valve stenosis in infants and children [8-13,17-19,41-54], reports of long-term results are few. Galal et al. [12] reported 26 children followed for 3 to 10 years after balloon aortic valvuloplasty and found stable gradients (Figure 13), but there was a significant increase in the left ventricular end-diastolic dimension even after normalizing to the square root of the body surface area. However, the left ventricular shortening fraction and posterior wall thickness in diastole did not change. Eight (31%) children (including six at intermediate follow-up) developed restenosis and most were successfully treated with transcatheter balloon therapy. One child required a left ventricular apex-to-descending aortic valve conduit for severe left ventricular mid cavitary obstruction. Seven (27%) children developed severe aortic insufficiency at long-term follow-up (Figure 12) and two children required the Ross procedure. Event-free rates suggested 80%, 76%, 76% and 60% probability of freedom from re-intervention at 1-, 2-, 5- and 10- year follow-up respectively. Kuhn et al. [54] reported on 22 children followed for 61 ± 23 months; during follow up, six (27%) underwent repeat balloon valvuloplasty and three (14%) children required aortic valve replacement for progressive aortic insufficiency. The overall probability of survival without surgical intervention was 75% at 100 months. Similar results were reported by Corzani et al. [55] in 37 patients.

More recently, Brown [56], Ewert [57], Maskatia [58] and their associates reported longer term follow-up in larger cohorts of patients. Brown et al. [56] followed 509 patients for a median time period of 9.3 years. During the follow up 225 (44%) of the 509 patients underwent 338 interventions on the aortic valve. A total of 115 (23%) patients required 149 repeat balloon aortic valve dilations; 49 (10% of total) of these were second repeat balloon dilations before aortic valve surgery. Surgical intervention was performed in 159 (31%) patients, aortic valve repair in 65 and replacement in 116 patients. Aortic valve re-intervention-free rates were 89%, 72%, 54% and 27% at 1-, 5-, 10-, and 20-year follow-up intervals, respectively. Multivariate regression analysis suggested lower post-dilatation gradient and lower post-dilation aortic insufficiency grade were associated with longer freedom from aortic valve replacement. Ewert et al. [57] analyzed follow-up results of 1004 patients who had balloon aortic valvuloplasty in three European centers and found decreased pressure gradients across the aortic valve, higher complication rates in the neonates (15%) than in infants (11%) and older children (6%) and freedom from surgery 10 years after intervention in 50% of all patients. They conclude balloon aortic valvuloplasty postpones the need for surgery in infants, children and adolescents. Maskatia et al. [58] followed 272 patients for 5.8 ± 6.7 years. Aortic insufficiency was found in 83 patients (31%), repeat valvuloplasty (balloon or surgical) was required in 37 (15%) patients, aortic valve replacement was needed in 42 (15%) patients and transplantation or death occurred in 24 (9%) patients. Adverse outcomes are associated with neonatal interventions, high residual post-valvuloplasty gradients and depressed baseline left ventricular function.

In conclusion, the long term results suggest maintenance of gradient relief for most with evidence of restenosis in a third of the patients, need for repeat balloon valvuloplasty, progression of aortic insufficiency, some requiring aortic valve replacement, left ventricular enlargement and relatively high re-intervention rates.

Feasibility of Repeat Balloon Valvuloplasty

Successful relief of obstruction following balloon dilatation of congenital stenotic lesions of the heart, including aortic valve stenosis has been demonstrated. However, varying incidence of residual obstruction or recurrence, referred to as restenosis, has been observed at follow-up. We [12,59] were among the first to show that repeat balloon valvuloplasty is feasible and effective in relieving residual aortic valvar obstruction; four of the six patients that developed restenosis underwent repeat balloon valvuloplasty with resultant immediate reduction in the gradient which was maintained during further follow-up period. In a recently published study quoted in the preceding section [56], 115 (23%) of the 509 patient cohort underwent repeat balloon valvuloplasty with relief of obstruction and an additional 49 (10% of total) had second repeat balloon dilations, again with relief of obstruction. Consequently, we conclude that repeat balloon dilatation is feasible and effective in relieving restenosis after initial balloon valvuloplasty and repeat balloon should be the first option in the management of these patients.

Aortic Insufficiency

Aortic insufficiency remains a significant long-term complication of balloon aortic valvuloplasty; however, this is not too dissimilar to that following surgical valvotomy. Galal et al. [12] reported seven (28%) of 26 children with 3+ aortic insufficiency at late follow-up (Figure 12) with two (8%) children undergoing the Ross procedure. Left ventricular end diastolic dimensions were at or greater than 90th percentile for body surface area. Several factors predict significant aortic insufficiency namely Doppler quantified aortic insufficiency both prior to and immediately after balloon aortic valvuloplasty [12]. Most studies reviewed demonstrate a general trend toward increase in the degree of aortic insufficiency at follow-up; this increase appears to become more significant with longer follow up times. The reasons for progression of aortic insufficiency are not well understood. There are some hypotheses which suggest that greater relief of gradient immediately following balloon valvuloplasty [44], unicommisural aortic valves, aortic valve prolapse [49], poor valve morphology [12] and larger balloon/annulus ratio [41,48] are associated with a higher grade of aortic insufficiency at follow-up. Our data [12] suggest that degree of aortic insufficiency immediately after balloon aortic valvuloplasty is predictive of development significant late aortic insufficiency (Figure 14).

Comparison With Surgery

Comparison of follow-up results of surgical with transcatheter balloon therapy is plagued with problems consisting of a smaller number of transcatheter patients available for follow up compared to surgical patients, shorter follow up time, and potential inaccuracies in comparing older surgical studies with current balloon therapies. Ten papers reporting long-term follow-up results of surgical valvotomy were reviewed [10] and showed operative mortality ranging from 0% to 4% (1.2% mortality rate in the natural history study [60]). Restenosis was reported in 10% to 78%, aortic insufficiency in 6% to 65% and surgical intervention in 16% to 39%. Gatzoulis et al. [61] found no significant difference in mortality, morbidity or need for re-intervention within 12 months of the procedure between the surgical and balloon groups. McCrindle and associates [62], comparing surgical and balloon groups in neonates found that the two modes of therapy have similar rates of freedom from re-intervention at five years following the procedure. Consequently, significant prevalence of early and late mortality and the need for re-operation associated with surgical valvotomy would make balloon aortic valvuloplasty an attractive alternative to surgical approach.

Complications

Immediate complications include transient bradycardia, premature beats and a fall in systemic pressure during balloon inflation; these return to baseline following balloon deflation, thus reiterating the previously suggested balloon inflation time of ≤ 5 seconds. Other reported complications are blood loss requiring transfusions; femoral artery thrombosis requiring heparin, streptokinase or thrombectomy [63]; other rhythm disorders including transient left bundle branch block [10], right bundle branch block, transient prolongation of QTc interval [64], temporary atrioventriuclar block, supraventricular and ventricular dysrhythmias [10,57]; cardiac arrest [65]; transmural tears with vessel or ventricular wall perforation [63,66]; balloon rupture [11,67]; balloon dislodgement [48]; aortic insufficiency or mitral valve tears [48,68]; myocardial perforation; occlusion of the right coronary artery; transient myocardial ischemia [57]; cerebrovascular accidents [69]; and development of subvalvar obstructions [70] although rare. Aortic valve tears have been seen with animal models with large balloon sizes, 1.2 to 1.5 times the valve annulus [71] and therefore, large balloons should not be used. Death associated with balloon dilatation has also been reported [41,44,68,72,73]; these are associated with aortic rupture, occlusion of extreme critical obstruction, perforation or avulsion of aortic valve cusp, exsanguination from torn iliac/femoral vessels, and ventricular fibrillation. Sudden unexplained death is also recorded, but is extremely rare [73]. Complications at follow up were femoral artery occlusion [9,74], aortic valve insufficiency and recurrence of obstruction; the latter two were discussed in the preceding section.

Conclusions

Balloon aortic valvuloplasty provides an excellent alternative to surgical intervention and has become the preferred intervention for initial palliation for aortic stenosis in neonates, infants, children and adolescents. With the exception of neonates, most patients can be discharged within 24-hours of the procedure. Although there is definitive evidence for gradient relief immediately after as well as at follow-up and postponement of surgical intervention following balloon aortic valvuloplasty, the progression of aortic insufficiency at late follow up remain a major concern. In the neonatal population, severe aortic insufficiency may develop requiring surgical intervention. Despite these limitations, balloon aortic valvuloplasty is currently considered as therapeutic procedure of choice in the management of congenital aortic stenosis in the pediatric population. Careful follow-up to detect recurrence of stenosis and development of significant aortic insufficiency is recommended.

References

1. Rubio A, Limon Lason R (1954) Treatment of pulmonary valvular stenosis and of tricuspid valve stenosis using a modified catheter. Second World Congress on Cardiology, Washington DC, Program Abstract 11: 205
2. Grüntzig AR, Senning A, Siegenthaler WE (1979) Nonoperative dilatation of coronary-artery stenosis: percutaneous transluminal coronary angioplasty. N Engl J Med 301: 61-68.
3. Dotter CT, Judkins MP (1964) Transluminal treatment of arteriosclerotic obstruction: Description of a new technique and a preliminary report of its application. Circulation 30: 654-670.
4. Sos T, Sniderman KW, Rettek-Sos B, Strupp A, Alonso DR (1979) Percutaneous transluminal dilatation of coarctation of thoracic aorta post mortem. Lancet 2: 970-971.
5. Singer MI, Rowen M, Dorsey TJ (1982) Transluminal aortic balloon angioplasty for coarctation of the aorta in the newborn. Am Heart J 103: 131-132.
6. Sperling DR, Dorsey TJ, Rowen M, Gazzaniga AB (1983) Percutaneous transluminal angioplasty of congenital coarctation of the aorta. Am J Cardiol 51: 562-564.
7. Kan JS, White RI Jr, Mitchell SE, Gardner TJ (1982) Percutaneous balloon valvuloplasty: a new method for treating congenital pulmonary-valve stenosis. N Engl J Med 307: 540-542.
8. Lababidi Z (1983) Aortic balloon valvuloplasty. Am Heart J 106: 751-752.
9. Rao PS (1990) Balloon aortic valvuloplasty in children. Clin Cardiol 13: 458-466.
10. Rao PS (1993) Balloon valvuloplasty for aortic stenosis. In Transcatheter Therapy in Pediatric Cardiology, Rao PS (ed), Wiley-Liss, New York, NY, pp. 105-127.
11. Lababidi Z, Wu JR, Walls JT (1984) Percutaneous balloon aortic valvuloplasty: results in 23 patients. Am J Cardiol 53: 194-197.
12. Galal O, Rao PS, Al-Fadley F, Wilson AD (1997) Follow-up results of balloon aortic valvuloplasty in children with special reference to causes of late aortic insufficiency. Am Heart J 133: 418-427.
13. Sullivan ID, Wren C, Bain H, Hunter S, Rees PG, et al. (1989) Balloon dilatation of the aortic valve for congenital aortic stenosis in childhood. Br Heart J 61: 186-191.
14. Bengur AR, Snider AR, Serwer GA, Peters J, Rosenthal A (1989) Usefulness of the Doppler mean gradient in evaluation of children with aortic valve stenosis and comparison to gradient at catheterization. Am J Cardiol 64: 756-761.
15. Singh GK, Balfour IC, Chen S, Ferdman B, Rao PS (2003) Lesion specific pressure recovery phenomenon in pediatric patients: A simultaneous Doppler and catheter correlative study. J Am Coll Cardiol 41: 493A.
16. Singh GK, Rao PS (2010) Left heart outflow obstructions. In: Cardiology, Third Edition, Crawford MH., DiMarco JP, Paulus WJ. (Eds), Mosby Elsevier, ISBN 978-0-7234-3485-6, Edinburgh, UK, pp. 1507-1518.
17. Rao PS, Thapar MK, Wilson AD, Levy JM, Chopra PS (1989) Intermediate-term follow-up results of balloon aortic valvuloplasty in infants and children with special reference to causes of restenosis. Am J Cardiol 64: 1356-1360.
18. Meliones JN, Beekman RH, Rocchini AP, Lacina SJ (1989) Balloon valvuloplasty for recurrent aortic stenosis after surgical valvotomy in childhood: immediate and follow-up studies. J Am Coll Cardiol 13: 1106-1110.
19. Sreeram N, Kitchiner D, Williams D, Jackson M (1994) Balloon dilatation of the

aortic valve after previous surgical valvotomy: immediate and follow up results. Br Heart J 71: 558-560.

20. Suárez de Lezo J, Pan M, Sancho M, Herrera N, Arizon J, et al. (1986) Percutaneous transluminal balloon dilatation for discrete subaortic stenosis. Am J Cardiol 58: 619-621.
21. Rao PS, Wilson AD, Chopra PS (1990) Balloon dilatation for discrete subaortic stenosis: immediate and intermediate-term results. J Invasive Cardiol 2: 65-71.
22. Shrivastava S, Dev V, Bahl VK, Saxena A (1991) Echocardiographic determinants of outcome after percutaneous transluminal balloon dilatation of discrete subaortic stenosis. Am Heart J 122: 1323-1326.
23. De Giovanni JV, Edgar RA, Cranston A (1998) Adenosine induced transient cardiac standstill in catheter interventional procedures for congenital heart disease. Heart 80: 330-333.
24. Daehnert I, Rotzsch C, Wiener M, Schneider P (2004) Rapid right ventricular pacing is an alternative to adenosine in catheter interventional procedures for congenital heart disease. Heart 90: 1047-1050.
25. Rao PS (1998) Balloon Aortic Valvuloplasty. J Intervent Cardiol 11: 319-329.
26. Rao PS (1987) Influence of balloon size on short-term and long-term results of balloon pulmonary valvuloplasty. Tex Heart Inst J 14: 57-61.
27. Narang R, Das G, Dev V, Goswami K, Saxena A, et al. (1997) Effect of the balloon-anulus ratio on the intermediate and follow-up results of pulmonary balloon valvuloplasty. Cardiology 88: 271-276.
28. Lababidi Z, Weinhaus L (1986) Successful balloon valvuloplasty for neonatal critical aortic stenosis. Am Heart J 112: 913-916.
29. Wren C, Sullivan I, Bull C, Deanfield J (1987) Percutaneous balloon dilatation of aortic valve stenosis in neonates and infants. Br Heart J 58: 608-612.
30. Kasten-Sportes CH, Piechaud JF, Sidi D, Kachaner J (1989) Percutaneous balloon valvuloplasty in neonates with critical aortic stenosis. J Am Coll Cardiol 13: 1101-1105.
31. Zeevi B, Keane JF, Castaneda AR, Perry SB, Lock JE (1989) Neonatal critical valvar aortic stenosis. A comparison of surgical and balloon dilation therapy. Circulation 80: 831-839.
32. Fischer DR, Ettedgui JA, Park SC, Siewers RD, del Nido PJ (1990) Carotid artery approach for balloon dilation of aortic valve stenosis in the neonate: a preliminary report. J Am Coll Cardiol 15: 1633-1636.
33. Austoni P, Figini A, Vignati G, Donatelli F (1990) Emergency aortic balloon valvotomy in critical aortic stenosis of the neonate. Pediatr Cardiol 11: 59-60.
34. Beekman RH, Rocchini AP, Andes A (1991) Balloon valvuloplasty for critical aortic stenosis in the newborn: influence of new catheter technology. J Am Coll Cardiol 17: 1172-1176.
35. Alekyan BG, Petrosyan YS, Coulson JD, Danilov YY, Vinokurov AV (1995) Right subscapular artery catheterization for balloon valvuloplasty of critical aortic stenosis in infants. Am J Cardiol 76: 1049-1052.
36. Hausdorf G, Schneider M, Schrimer KR, Schulze-Neick I, Lange PE (1993) Anterograde balloon valvuloplasty of aortic stenosis in children. Am J Cardiol 71: 460-462.
37. O'Laughlin MP, Slack MC, Grifka R, Mullins CE (1993) Prograde double balloon dilation of congenital aortic valve stenosis: a case report. Cathet Cardiovasc Diagn 28: 134-136.
38. Rao PS, Jureidini SB (1998) Transumbilical venous, anterograde, snare-assisted balloon aortic valvuloplasty in a neonate with critical aortic stenosis. Cathet Cardiovasc Diagn 45: 144-148.
39. Rao PS (2003) Anterograde balloon aortic valvuloplasty in the neonate via the umbilical vein. Catheter Cardiovasc Interv 59: 291.
40. Magee AG, Nykanen D, McCrindle BW, Wax D, Freedom RM, et al. (1997) Balloon dilation of severe aortic stenosis in the neonate: comparison of anterograde and retrograde catheter approaches. J Am Coll Cardiol 30: 1061-1066.
41. Sholler GF, Keane JF, Perry SB, Sanders SP, Lock JE (1988) Balloon dilation of congenital aortic valve stenosis. Results and influence of technical and morphological features on outcome. Circulation 78: 351-360.
42. Gatzoulis MA, Rigby ML, Shinebourne EA, Redington AN (1995) Contemporary results of balloon valvuloplasty and surgical valvotomy for congenital aortic stenosis. Arch Dis Child 73: 66-69.
43. Choy M, Beekman RH, Rocchini AP, Crowley DC, Snider AR, et al. (1987) Percutaneous balloon valvuloplasty for valvar aortic stenosis in infants and children. Am J Cardiol 59: 1010-1013.
44. Helgason H, Keane JF, Fellows KE, Kulik TJ, Lock JE (1987) Balloon dilation of the aortic valve: studies in normal lambs and in children with aortic stenosis. J Am Coll Cardiol 9: 816-822.
45. Wren C, Sullivan I, Bull C, Deanfield J (1987) Percutaneous balloon dilatation of aortic valve stenosis in neonates and infants. Br Heart J 58: 608-612.
46. Vogel M, Benson LN, Burrows P, Smallhorn JF, Freedom RM (1989) Balloon dilatation of congenital aortic valve stenosis in infants and children: short term and intermediate results. Br Heart J 62: 148-153.
47. Shrivastava S, Das GS, Dev V, Sharma S, Rajani M (1990) Follow-up after percutaneous balloon valvoplasty for noncalcific aortic stenosis. Am J Cardiol 65: 250-252.
48. Rocchini AP, Beekman RH, Ben Shachar G, Benson L, Schwartz D, et al. (1990) Balloon aortic valvuloplasty: results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. Am J Cardiol 65: 784-789.
49. Shaddy RE, Boucek MM, Sturtevant JE, Ruttenberg HD, Orsmond GS (1990) Gradient reduction, aortic valve regurgitation and prolapse after balloon aortic valvuloplasty in 32 consecutive patients with congenital aortic stenosis. J Am Coll Cardiol 16: 451-456.
50. O'Connor BK, Beekman RH, Rocchini AP, Rosenthal A (1991) Intermediate-term effectiveness of balloon valvuloplasty for congenital aortic stenosis. A prospective follow-up study. Circulation 84: 732-738.
51. Saiki K, Kato H, Suzuki K, Inoue O, Toyoda O, et al. (1992) Balloon valvuloplasty for congenital aortic valve stenosis in an infant and children. Acta Paediatr Jpn 34: 433-440.
52. Witsenburg M, Cromme-Dijkhuis AH, Frohn-Mulder IM, Hess J (1992) Short- and midterm results of balloon valvuloplasty for valvular aortic stenosis in children. Am J Cardiol 69: 945-950.
53. Moore P, Egito E, Mowrey H, Perry SB, Lock JE, et al. (1996) Midterm results of balloon dilation of congenital aortic stenosis: predictors of success. J Am Coll Cardiol 27: 1257-1263.
54. Kuhn MA, Latson LA, Cheatham JP, Fletcher SE, Foreman C (1996) Management of pediatric patients with isolated valvar aortic stenosis by balloon aortic valvuloplasty. Cathet Cardiovasc Diagn 39: 55-61.
55. Corzani A, Donti A, Gesuete V, Formigari R, Testa G, et al. (2010) [Percutaneous aortic valvuloplasty in congenital aortic valve stenosis performed in patients older than one month: a good alternative to surgery]. G Ital Cardiol (Rome) 11: 674-679.
56. Brown DW, Dipilato AE, Chong EC, Lock JE, McElhinney DB (2010) Aortic valve reinterventions after balloon aortic valvuloplasty for congenital aortic stenosis intermediate and late follow-up. J Am Coll Cardiol 56: 1740-1749.
57. Ewert P, Bertram H, Breuer J, Dähnert I, Dittrich S, et al. (2011) Balloon valvuloplasty in the treatment of congenital aortic valve stenosis--a retrospective multicenter survey of more than 1000 patients. Int J Cardiol 149: 182-185.
58. Maskatia SA, Ing FF, Justino H, Crystal MA, Mullins CE, et al. (2011) Twenty-five year experience with balloon aortic valvuloplasty for congenital aortic stenosis. Am J Cardiol 108: 1024-1028.
59. Rao PS, Galal O, Wilson AD (1996) Feasibility and effectiveness of repeated balloon dilatation of restenosed congenital obstructions after previous balloon valvuloplasty/angioplasty. Am Heart J 132: 403-407.
60. Wagner HR, Ellison RC, Keane JF, Humphries OJ, Nadas AS (1977) Clinical course in aortic stenosis. Circulation 56: I47-56.
61. Gatzoulis MA, Rigby ML, Shinebourne EA, Redington AN (1995) Contemporary results of balloon valvuloplasty and surgical valvotomy for congenital aortic stenosis. Arch Dis Child 73: 66-69.
62. McCrindle BW, Blackstone EH, Williams WG, Sittiwangkul R, Spray TL, et al. (2001) Are outcomes of surgical versus transcatheter balloon valvotomy equivalent in neonatal critical aortic stenosis? Circulation 104: I152-158.
63. Wessel DL, Keane JF, Fellows KE, Robichaud H, Lock JE (1986) Fibrinolytic therapy for femoral arterial thrombosis after cardiac catheterization in infants and children. Am J Cardiol 58: 347-351.

64. Weesner KM (1990) Ventricular arrhythmias after balloon aortic valvuloplasty. Am J Cardiol 66: 1534-1535.

65. Shrivastava S, Das GS, Dev V, Sharma S, Rajani M (1990) Follow-up after percutaneous balloon valvoplasty for noncalcific aortic stenosis. Am J Cardiol 65: 250-252.

66. Waller BF, Girod DA, Dillon JC (1984) Transverse aortic wall tears in infants after balloon angioplasty for aortic valve stenosis: relation of aortic wall damage to diameter of inflated angioplasty balloon and aortic lumen in seven necropsy cases. J Am Coll Cardiol 4: 1235-1241.

67. Loya Y, Sharma S (1991) Balloon tear during valvuloplasty. Am Heart J 121: 1840-1841.

68. Fellows KE, Radtke W, Keane JF, Lock JE (1987) Acute complications of catheter therapy for congenital heart disease. Am J Cardiol 60: 679-683.

69. Treacy EP, Duncan WJ, Tyrrell MJ, Lowry NJ (1991) Neurological complications of balloon angioplasty in children. Pediatr Cardiol 12: 98-101.

70. Ludomirsky A, O'Laughlin MP, Nihill MR, Mullins CE (1991) Left ventricular mid-cavitary obstruction after balloon dilation in isolated aortic valve stenosis in children. Cathet Cardiovasc Diagn 22: 89-92.

71. Phillips RR, Gerlis LM, Wilson N, Walker DR (1987) Aortic valve damage caused by operative balloon dilatation of critical aortic valve stenosis. Br Heart J 57: 168-170.

72. Booth P, Redington AN, Shinebourne EA, Rigby ML (1991) Early complications of interventional balloon catheterisation in infants and children. Br Heart J 65: 109-112.

73. Brown DW, Dipilato AE, Chong EC, Gauvreau K, McElhinney DB, et al. (2010) Sudden unexpected death after balloon valvuloplasty for congenital aortic stenosis. J Am Coll Cardiol 56: 1939-1946.

74. Lee HY, Reddy SC, Rao PS (1997) Evaluation of superficial femoral artery compromise and limb growth retardation after transfemoral artery balloon dilatations. Circulation 95: 974-980.

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