Percutaneous balloon valvuloplasty validity for congenital aortic stenosis. Experience since the beginning of the tequnique☆

Vigencia de la valvuloplastia con balón en la estenosis aórtica congénita. Experiencia desde los inicios de la técnica

Dear Editor:

Percutaneous balloon valvuloplasty is a technique used since the late 1980s to treat congenital aortic stenosis.[1] Published studies, either on this technique alone or comparing it to surgical valvotomy, have identified predictors of unfavourable outcomes, such as severe thickening of the valve, unicuspid morphology, neonatal critical aortic stenosis or a balloon-to-annulus ratio greater than 1. There have been no statistically significant differences in survival, residual regurgitation or the need of valve replacement between the 2 techniques. The only aspect that may favour the use of the open surgery is the need of reintervention. Due to the reduced invasiveness and comparable outcomes of percutaneous balloon valvuloplasty, this technique is currently considered the first-line treatment for congenital aortic stenosis.[2,3]

We present a retrospective analysis of all the patients with congenital aortic stenosis that have undergone percutaneous balloon valvuloplasty in our hospital since 1990. The sample included 45 patients with a mean age of 4.1 ± 5.7 years, with a predominance of the male sex (57.8%); 28 patients (62.2%) were aged less than 1 year and 9 less than 1 month. The valvular morphology was bicuspid in most cases (80%). Six of the patients (13.3%) had previously undergone surgical valvotomy, as they were initially not considered good candidates for the percutaneous approach because their aortic valves were severely dysplastic.

The procedure was considered indicated for patients who were symptomatic or with a peak gradient greater than 50 mm Hg. The intervention was elective in most patients, but out of 8 who had critical stenosis, 2 developed cardiogenic shock and require urgent intervention.

All the interventions were performed under general anaesthesia with a femoral arterial approach with a 4 to 8 F catheter. Catheters were chosen to achieve a ratio of approximately 1:1 (0.90–1.1) relative to the annulus (measured by both ultrasound and angiography). We considered the intervention effective if it achieved a reduction of the peak gradient to less than 35 mm Hg with residual regurgitation grade 1 or less, which was accomplished in 84.1% of cases (Table 1).

Rapid ventricular pacing was used in 70.4% of the patients (in the left ventricle with a 0.014 Biotronik Vision Wire guidewire in neonates and infants and in the right ventricle with an electrode catheter in all other patients) to improve balloon stability during inflations, which results in a statistically significant increase in the effectiveness of the procedure and reduced damage to the valve and, therefore, a lesser degree of residual regurgitation after the procedure.

The salient complications were 2 cases of femoral artery thrombosis, both in neonates, that resolved with administration of heparin, and there were no other severe complications or any deaths related to the procedure.

All patients remained in follow-up with clinical and echocardiographic assessments for a mean of 11 ± 9.8 years, and 12 of them (26.7%) required reintervention (another valvuloplasty or valve replacement). Eight patients (17.8%) required a new valvuloplasty, percutaneous in 3 cases (after a mean of 259 days) and surgical in 5 (after a mean of 2.6 years); 2 of the patients that required reintervention with surgical valvulotomy underwent yet another percutaneous balloon valvuloplasty during the follow-up.

Eight patients (18.2% of the total) required aortic valve replacement surgery during the follow-up a mean of 15.25 ± 7.8 years after the initial valvuloplasty, and 4 of them had required a second valvuloplasty in between. The survival free of aortic valve replacement was 94% at 10 years, 82% at 15 years and 58% at 20 years.

Table 2 presents the variables that were associated with effective valvuloplasty, the need of reintervention or increase grades of residual aortic regurgitation.

Six patients (13.3%) died during follow-up, corresponding to a mortality of 2% at 1 month and 6.6% at 1 year post valvuloplasty. Fifty percent of the deaths occurred in the postoperative period following surgical repair of complex heart defects (atrioventricular septal defect with aortic arch hypoplasia and coarctation of the aorta, Shone complex treated with dilatation of the aortic arch and surgical repair of the coarctation and aortic valve and supravalvular stenosis treated with the Ross-Konno procedure).

In the subset of patients with neonatal critical aortic stenosis, we found a higher peak gradient measured by echocardiography before the procedure compared to the rest of the series (91.7 ± 18.4 vs 79.4 ± 14.4; $P = 0.06$), with similar gradients post valvuloplasty (40 ± 2 vs 38.6 ± 7; $P = 0.08$). The overall reintervention-free survival was 93% at 1 year, 78.8% at 5 years and 71% at 10 years, compared to 78% at 1, 5 and 10 years in the neonatal subset, differences that were not statistically significant and were particularly biased by first-year outcomes in neonatal patients on account of the greater complexity of disease and associated defects.

Despite the limitations of our study due to the small sample size and its retrospective design, we conclude that balloon valvuloplasty is a safe and effective procedure for treatment of congenital aortic stenosis with good outcomes in the short and medium terms, although less so in the long term on account of the need for reintervention. The main goal of the intervention is to facilitate growth and development and postpone surgical valve replacement for as long as possible, an intervention that is necessary within 20 years in nearly 40% of the patients.[3–5]

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Table 1 Demographic characteristics of the sample and outcomes of the procedure.

Sample characteristics		Valvuloplasty outcomes	
Total patients	45	Balloon/annulus ratio	0.97 ± 0.1
Male	26 (57.8%)	Number of inflations:	
		1	4 (8.9%)
		2	29 (64.4%)
		3	7 (15.6%)
		4	5 (11.1%)
Age	Mean 4.1 ± 5.7 years	Combined procedure	3 (6.8%)
	Median 148 days	Angioplasty for coarctation	2
		Pulmonary valvuloplasty	1
Age groups:		Systolic peak-peak gradient (catheterization)	
<1 month	9 (20.0%)	Baseline	61.6 ± 18.8
1–12 months	19 (42.2%)	After valvuloplasty	19.5 ± 14.7
1–10 years	11 (24.4%)		
10–18 years	7 (15.6%)		
Weight	Mean 17.4 ± 20.1 kg	Peak gradient (echocardiogram)	
	Median 6 kg	Baseline	91.7 ± 18.4
		After valvuloplasty	37.9 ± 14.2
Associated congenital heart defects		Pre-existent aortic valve regurgitation	
Coarctation of aorta/hypoplastic arch	11 (24.4%)	0	37 (82.2%)
Ventricular septal defect	2 (4.4%)	1	7 (15.6%)
Pulmonary stenosis	2 (4.4%)	2	1 (2.2%)
Shone complex	1 (2.2%)		
AV septal defect	1 (2.2%)		
Combined defects	3 (6.6%)		
Valve morphology:		Aortic insufficiency after valvuloplasty	
Unicuspid	3 (6.7%)	0	27 (60.0%)
Bicuspid	35 (77.8%)	1	10 (22.2%)
Tricuspid	7 (15.6%)	2	8 (17.8%)
Critical stenosis	8 (17.8%)	Need of new valvuloplasty	8 (17.8%)
		Percutaneous	3
		Surgical	5
Previous surgical valvuloplasty	6 (13.3%)	Aortic valve replacement	8 (17.8%)
Left ventricular dysfunction	1 (2.2%)		

Table 2 Variables associated with effective valvulopathy, reintervention and residual aortic regurgitation.

Variable	Effective valvulopathy	Repeat valvulopathy	Aortic insufficiency
Rapid ventricular pacing	HR, 11.7 (95% CI, 1.5–93.8; $P = 0.02$)	–	HR, 0.7 (95% CI, 0.07–0.6; $P = 0.02$)
Previous surgical valvulotomy	HR, 0.7 (95% CI, 0.1–5.8; $P = 0.6$)	HR, 0.7 (95% CI, 0.14–7; $P = 0.2$)	HR, 19.6 (95% CI, 1.1–339.1; $P = 0.04$)
Transvalvular gradient before valvuloplasty > 60	HR, 1.8 (95% CI, 1.1–3; $P = 0.06$)	HR, 1.5 (95% CI, 1.1–1.9; $P = 0.05$)	–
Post-valvuloplasty gradient > 40	–	HR, 8.7 95% CI, 1·1–71.6; $P = 0.04$	–
Balloon-to-annulus ratio >1	HR, 1.1 (95% CI, 0.08–15.5; $P = 0.9$)	–	HR, 7 (95% CI, 0.66–71.7; $P = 0.1$)
More than 2 inflations	HR, 0.9 (95% CI, 0.12–7.3; $P = 0.9$)	–	HR, 2.1 (95% CI, 0.3-14.1; $P = 0.4$)
Ao morphology not bicuspid	HR, 1.3 (IC 1.1–1.6; $P = 0.09$)	HR, 1.2 IC 95%1.05–1.5; $P = 0.03$)	HR, 0.8 (0.2–3.1; $P = 0.5$)

Ao, aorta; CI, confidence interval; HR, hazard ratio.

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Desing of a risk map in a paediatric emergency department☆

Diseño de un mapa de riesgos en un servicio de urgencias pediátrico

Dear Editor:

Patient safety is a perspective from which to understand health care without which the latter would be meaningless.[1]

In paediatric emergency departments (PEDs), the risk of adverse effects is high due to the particular characteristics of their patients.[2] The clinical information paediatricians obtain from parents and medication dosages are individualised, which involves calculations that provide opportunities for error.

Traditionally, patient safety refers to event investigation and analysis, which is difficult to translate to learning and prevention of repeated errors. In Spain, several studies have been developed with this approach (ENEAS, APEAS, EARCAS, SYREC and EVADUR). They contribute to the detection of errors once they have already happened, so other, proactive tools need to be implemented, such as risk maps, to promote awareness of probable or demonstrated risks and harm in care delivery.[3] The aim of our study was to describe our experience with the design and development of a risk map for our own care setting.

We developed the risk map using the Failure Modes and Effects Analysis (FMEA) approach.[4] We started by defining the emergency care processes and subprocesses from arrival of the patient to the desk to discharge from the PED. We identified risks in a brainstorming process that involved a multidisciplinary team (paediatricians, nurses and security, laboratory, radiology, administrative and pharmacy staff) based on staff statements concerning 719 events (2012–2018) and the review of complaints and suggestions filed by families (635 in the period under study). We collected the data in a FMEA template, including the specific care process and subprocesses, the defined failure mode or risk, its causes, the type of effect and possible measures for control or improvement. We estimated the severity (S), probability of occurrence (O) and probability of detection (D) of the events (Table 1), rating each on a scale from 1 to 5. The ratings were established by consensus by all participating professionals. We stratified risk based on the risk priority number (RPN): $RPN = S \times O \times D$. The resulting numbers could range from 1 to 125, with higher values indicating greater priority. We developed the risk map prioritising the causes that corresponded to the highest RPNs for the purpose of developing improvement strategies (essential risk map).

In the initial round, we identified 7 urgent care processes (admission, triage, initial nursing care, medical care, diagnostic testing, treatment and discharge destination), 17 subprocesses, 60 potential failures or risks with 92 effects and 199 causes. The essential risk map ended up comprising 15 subprocesses with 19 effects with a RPN greater than 30 (Table 2).

The proposed risk map reviews every care process in emergency care and allows their proactive analysis. To develop it, we used brainstorming and reactive analytics. We used brainstorming repeatedly in the FMEA[4] as a proactive safety measure. Incident analysis is weaker for this purpose.[5] An aspect worth highlighting was the incorporation of the information and feedback provided by families, given the importance of the experience

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