Effectiveness and Safety of Paediatric Interventional Cardiac Catheterisation in a Subregional Cardiothoracic Unit

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Abstract

Objective: To assess the effectiveness and safety of paediatric interventional cardiac catheterization during the development of the service.
Setting: Sub-regional Paediatric Cardiothoracic Centre.
Patients and Methods: All paediatric admissions for cardiac catheterisation between January, 1985 and December, 1992. Data were collected on all patients in whom interventional cardiac catheterisation was performed excluding babies undergoing balloon atrial septostomy. Results were compared with those reported previously by the larger centres.
Results: One hundred and seventy eight interventional procedures were performed in 158 patients, progressing from pulmonary valvuloplasty (1985) and aortic valvuloplasty (1986) to arterial duct occlusion and coil embolisation of shunts (1991). During the study period there was a rise in the number and variety of conditions for which interventional cardiac catheterisation was performed. In terms of morbidity, mortality and technical success, results compared favourably with those published from larger centres.
Conclusions: Interventional cardiac catheterisation in children can be established effectively and safely in a relatively smaller set up (JPMA 45:29,1995).

Introduction

Interventional cardiac catheterisation was attempted as early as 1950's[1] but the first intervention to alter the clinical management of congenital heart disease was balloon atrial septostomy reported by Raslikind and Miller in 1966[2]. Since then, the application of interventional cardiac catheterisation has expanded significantly[3-10]. These techniques have had a significant impact on the management of congenital heart disease and therefore, have important implications in both clinical and resource management. Groby Road Hospital Leicester, England is a sub-regional cardiothoracic centre serving a population of approximately 3.37 million[11]. There are larger supra-regional centres in U.K. and it is important to establish whetherinterventional cardiac catheterisationcanbe practised safely in a relatively small sub-regional centre. Our results have a special implication in the development of paediatric cardiac services in the developing countries like Pakistan. Currently there are only two established paediatnc cardiac centres in Pakistan, National Institute of Cardiovascular Diseases, Karachi and Military Hospital in Rawalpindi. These centres are obviously unable to meet the needs of a nation with an estimated population of 120 million. Further, paediatric cardiac centres are bound to develop in larger cities like Lahore, Peshawar, Multan and Quetta. These encouraging figures during the development of the service in a relatively small unit would be a guideline and an insentive that such services can be established safely in more centres in Pakistan. We report ourexperience ofinterventional cardiac catheterisationoveraperiod of 8 years andcompare our resultswiththose reported by the larger centres in the world.

Patients and Methods

Paediatric admissions for cardiac catheterisation between January, 1985 and December, 1992 were reviewed. Data were collected on all patients in whom interventional procedure was performed including those in whom the procedure was abandoned or failed for technical reasons. Complications attributable to the procedures were carefully documented, The data were compared with the current literature on interventional catheterisation in children. Paired 't' tests were carried out for statistical analysis.
The population served is approximately 3.37 million", which includes 672 thousand children under the age of 15 years. The service started with one consultant paediatric cardiologist while a second consultantjoinedin 1990. Two out of four cardiothoracic surgeons undertake the paediatric cardiac surgery.

Results

A total of 1,370 cardiac cathetensations were performed over this period of which 178 (13%) were interventional. These figures do not include 63 babies who underwentballoon atrial septostoiny. The proportion of interventional cathetensations increased significantly from 7 of a total of 124(5.6%) in 1985, to 58 out of 228 (25%) in 1992. Interventional techniques started with balloon pulmonary valve angioplasty in 1985 and progressed through balloon aortic valve angioplasty, systemic venous baffle angioplasty, angioplasty for recoarctation of the aorta, balloon angioplasty for branch pulmonary artery stenosis and finally arterial duct occlusion and embolisation. As experience with intervention increased more infants and neonates underwent these procedures. In 1988 only one out of total 20 (5%) who underwent interventional cardiac catheters were infants compared to 13 out of total 58(22%) in 1992.

Balloon Pulmonary Valvuloplasty

Pulmonary valvuloplasty was performed on 67 patients (73 procedures). Their ages ranged from 6 weeks to 16 years, with 15 (22%) patients under the age of one year. Fifty-five patients had isolated valvular pulmonary stenosis, eight of them having dysplastic pulmonary valves. The remainder had pulmonary atresia[1], critical pulmonary stenosis[1] and residual narrowing following surgical valvotomy for critical pulmonary stenosis[2] Also included in this category were patients with right ventricular outflow tract obstruction following arterial switch fortransposition of great arteries[6] and after total correction of tet.ralogy of Fallot[2]. In patients with isolated valvular pulmonary stenosis (non-dysplastic) the gradient across the pulmonary valve dropped from 44 (±19.9) to 17.2 mm Hg (±9.0), with 22 of total 47(46.8%) showing a residual gradient of less than 15 mm Hg. The results in other patients were variable (Table I).

Table I. Results of balloon pulmonary valvuloplasties.

Diagnosis (Number of procedures	Mean Gradient (±SEM)	
	Pre (mm Hg)	Post (mm Hg)
Valvular pulmonary stenosis (49)	44 (19.9)	17.2 (9.0)*
Dysplastic pulmonary valve stenosis (8)	54 (11.5)	37 (17.0)**
Post surgical valvotomy (2)	50	23.5
Post Fallot's repair (2)	55	36.5
Post arterial switch (6)	68 (26.7)	55 (33.3)
Critical pulmonary stenosis (1)	108	108
Pulmonary atresia (1)	53	20

*p<0.001, **p<0.002

There were five patients in whom the procedure was unsuccessful on first attempt. They underwent a repeat procedure, one patient had a total of three procedures. Three patients with a previous arterial switch have undergone surgery after failedangioplasty. There were no deaths or major complications. Mild degree of pulmonary regurgitation was seen after balloon dilatation but none had severe regurgitation. Two patients had femoral vein thrombosis following the procedure. Three patients had transient arrhythniias, none of them requiring treatment.

Balloon Aortic Valvuloplasty

Balloon aortic valvuloplasty was performed on 45 patients (55 procedures). Their ages ranged from 2 days to 16 years. There were twelve infants including four neonates (aged less than 4 weeks). Balloon aortic valvuloplasty resulted in a significant fall (a fall in systolic gradient of 50% or more) in the peak to peak systolic gradient in 34 of 45 patients on the first attempt and another 6 on the second attempt. One newborn died during the procedure and there were 2 technical. failures when the balloon could not be advanced across the stenotic valve and no reduction in gradient was achieved in remaining 2 patients despite three attempts each. The last 4 patients required surgical valvotomy. The haemodynamic data is shown in Table II.

Table II. Haemodynamic data from 45 patients (55 procedures), pre and post aortic valvuloplasty.

	Pre	Post
	mm Hg (±SEM)	
Mean left ventricular Systolic pressure	150.5 (36.0)	128.1 (34.1)**
Mean aortic Systolic pressure	86.1 (14.4)	93.9 (18.8)*
Mean systolic gradient left ventricle aorta	65.0 (29.9)	31.7 (26.1)**

*p<0.003, **p<0.001

There wete four deaths. Three occjirred in neonates with critical aortic stenosis. Two died from progresive. left venthcular failure despite adequate relief of aortic stenosis. Both presented within the first week of life and their systemic circulation was ductal dependent. Post mortem examination showed significant leftventricularhypoplasiainone while the other had a dilated left ventricle with secondaiy endocardial fibroelastosis. The third death was due to cardiac tamponade from inadvertent myocardial puncture. The last death occuned in a two year old who developed severe aortic regurgitation and severe pulmonaiy oedema. All neonates and infants were electively heparinized during the procedure and them were no immediate vascular complications. Other complications are listed in Table III.

Table III. Complications of balloon aortic valvuloplasty (55 procedures in 45 patients).

Complications	n	%
Deaths	4	7.3
Aortic regurgitation	9	16
- Mild to moderate	6	
- Severe	3	
Bleeding requiring transfusion	2	3.6
Dysrhythmias	2	3.6
Arterial thrombosis	2	3.6
Balloon rupture	3	5.5

Balloon Aortic Arch Angioplasty

Balloon aortic arch angioplasty was performed on 13 patients(14 procedures) with recurrent or residual obstruction of the aortic arch following coarctation repair (10 patients) or aortic interruption repair (3 patients). Their ages ranged from 4 months to 4 years with the median time interval between initial surgery and angioplasty being 3.4 years (range 3 months to 11 years). Post dilatation peak systolic gradient was less than 10 mm Hg in 6 patients and 10-20 mm Hg in another 6 patients. One patient with a residual gradient of >20 mm Hg needed a repeat angioplasty.

Table IV. Haemodynamic and angiographic data pre and post angioplasty. (Values are mean ±SEM).

	Pre	Post
Peak systolic pressure	118.9 (26.8)	110.8 (19.1)***
Ascending aorta (mm Hg)		
Peak systolic pressure	86.8 (21.0)	100.1 (15.5)**
Descending aorta (mm Hg)		
Gradient across	34.3 (14.0)	12.9 (5.5)*
Recoarctation (mm Hg)		
Coarctation	4.9 (2.6)	8.0 (3.0)*
diameter (mm)		

*p<0.001, **p<0.008, ***p<0.05.

Table IV lists the haemodynamic and angiographic data pre and immediately post angioplasty. There were no deaths related to the procedure. Femoral artery thrombolytic with permanent loss of femoral pulse (but no ischemic changes in the leg) occurred in one patient despite anticoagulation and thrombolytic. Three further patients required heparin for diminished pulses, two of them needing streptokinase infusion. A small initial tear was noted at coarctation site in one patient needing no surgical intervention.

Percutaneous Arterial Duct Occlusion

Thirteen patients have had their arterial ducts successfully occluded with Rashkinds umbrella device. Their ages ranged from 30 months to 16 years. The device was successfully placed in 12 patients. One patient had late embolisation of the device to the left pulmonary artery 24 hours post-implantation. This was retrieved percutaneously and the duct was successfully occluded using the larger device. There were no other complications. Some degree of residual shunting was present in six patients immediately after the procedure but only 1 of the 12 patients had evidence of residual shunting 6 months post-procedure as detected by Doppler echocardiography. There was no residual murmur in this patient.

Miscellaneous Interventions

Angioplasty was also performed for branch pulmonary artery stenosis and superior vena cava obstruction following Mustard's or Senning's procedure, with variable success (Table V).

Table V. Miscellaneous interventions.

Procedure (n)	Age range	Success	Complications
Branch pulmonary artery angioplasty (9)	5 months - 8 years	7/9	Balloon rupture (1)
Superior vena cava baffle obstruction - Post Mustard's (9) - Post Senning's (1)	4 months - 17 years	7/10	Stimulation of pressure receptors leading to intense vasoconstriction (1)
Coil embolisation of shunts (3)	2 - 3 years	2/3	Coil in left lower pulmonary artery (1)
Blade septectomy (1)	12 years	1/1	-

Discussion

Role of interventional cardiac catheterisation is well established in paediatric cardiology, however, to our knowledge there has been no studies looking at the effectiveness and safety of such procedures in relatively small sub-regional centres. We see this even more important as centres developing in the developing countries like Pakistan are more likely to be of the same size and structure as our unit. Although these centres are likely to deal with a much larger population, their resources and structure is not likelyto match the largercentres in the developed world.

In our series balloon pulmonary angioplasty is the most common interventional procedure. In patients with valvular pulmonary stenosis (non-dysplastic valves) the systolic outflow gradient decreased from 44 (±19.9) to 17.2 mm Hg (±9.0) (p12 reported a drop in peak systolic gradientfrom 71 (±32) to 27 mmHg(±20) in737 patients with non-dysplastic valves. Series from Sullivan et al[13] includes two patients with dysplastic valves and another two with residual pulmonary stenosis following surgical valvotomy. They reported a fall in gradient across the pulmonary valve from 76 (±4 1) to 39 mm Hg (±3 1). Our results compare favourably with these major series. As in their reports, we report a very low morbidity associated with balloon pulmonary valvuloplasty. There were no deaths in our patients and there are only two deaths reported in the literature related to this procedure[12]. Intennediate and long term results are now available[14] and it is now considered the treatment of choice for isolated valvular pulmonary stenosis. In dysplastic valves, the obstruction results from thickened, redundant and immobile leaflets rather than commissural fusion. Therefore the results of balloon angioplasty in dysplastic pulmonary valves not unexpectedly are variable[12,15] and the response to angioplasty was less than that of non-dysplastic valves in our series.

Balloon aortic valvuloplasty was successful in 34 out of 45 patients on first attempt and in another 6 on second attempt. Including the unsuccessful attempts, the peak systolic gradient across the aortic valve decreased from 65 (±29) to 31 mm Hg (±26). Rochini et al[16] inthe VACARegistiy, reportedafall from 77 (±28) to 30 mmHg(±14) in 192 of 224 patients where valvuloplasty was successful. Witensburg et al[17] reported 21 patients with isolated valvular aortic stenosis including ten patients who had earlier undergone surgical valvotomy. They reported a fall in peak systolic gradient from 71 (±23) to 22 mm Hg (±11). In our series, there was one death in the age group above the age of one month, who

developed severe aortic regurgitation and died. Significant aoitic regurgitation occurred in 16% of the patients, a figure comparable to reported by others[16,17]. Femoral artery thrombosis occurred in only 3.6% of the children, a figure less than reported by others[16-18]. We used a balloon/annulus ratio of 0.8 to 1.0 and this probably was the main reason for a low incidence of these two complications. The results were poorer in neonates in whom angioplasty was performed in the first month of life compared to the group as a whole. However, the results of therapeutic intervention are poor in this age group whatever mode of treatment is used[16,18,19]. In patients with critical aortic stenosis, the aortic valve is markedly deformed with thickening and poor mobility. The valve is often "unicuspid" with hypoplasia of the "annulus". Secondary fibroelastosis involving the left ventricle with severe left ventricular dysfunction are usually associated[20]. Three out of four neonates with critical aortic stenosis died in our series. One deathwas directly related to the procedure while other two died from progressive myocardial failure despite adequate relief of gradient across the aortic valve. The high mortality in patients with critical aortic stenosis is due to progressive left ventricular myocardial dysfunction and ability to reduce the left ventricular outflow tract obstruction does not seem to be the crucial factor in determining survival. Balloon dilatation of 'native' coarctation is achieved at the expense of damage to the arterial wall with late appearance of aneurysms and outcome is still unpredictable[21]. Lock et al had addressed this with a provocative paper entitled "We can dilate - should we?" [22]. We have upto now not performed balloon angioplasty for native coarctation in our centre. However, balloon angioplasty for recurrent or residual coarctation after surgical repair was perfonned successfully even in infants. Inadequate anastomotic growth and/or inadequate resection of ductal tissue are the two main factors related to high incidence of recoarctation especially among patients who have undergone surgery in infancy. Although the numbers are small, a good (residual gradient of 10 to 20 mm Hg) to excellent (residual gradient of less than 10 mm Hg) relief of residual or recurrent aortic obstruction was achieved in 12 out of 13 patients. Hellenbrand et al[23] in their large series of 190 patients reported the residual gradient of 13.3 (±12.1) mm Hg across the recoarctation site which is comparable to the residual gradient of 12.9 (±5) mm Hg in our patients. All patients were electively heparinised before the procedure. Femoral artery complications known to be frequent following the procedure 24/1 occurred in four patients. Three of these resolved with heparin and/or streptokinase but there was permanent loss of femoral pulse in only one patient with no ischemic changes. No aneurysmal dilatation or neurological complications were seen. Arterial duct occlusion by Rashkind's "double umbrella" device was done successfully in 13 patients. The number of patients are limited in this study reflecting only our initial experience. The size of the duct was carefully assessed by echocardiogram before the procedure and occlusion was not attempted in babies of less than 10 kg in weight. Embolisation of the device into the pulmonary arteries is a well recognized complication[24,25] and occurred in one patient in our series. There were no other complications. A complete occlusion has been achieved by using a single device in 11 out of 12 patients at six months follow-up. The results of the European Registry[24] have shownthat even when the technique is done by a wide range of operators, transcatheter occlusion of the arterial duct is safe. Our initial results certainly support this conclusion. The results of angioplasty for branch pulmonaiy artery stenosis and superior vena cava obstruction following Mustard's or Senning's procedure are promising as well but the numbers are too small to assess their efficacy adequately. Intravascular stents for narrowed vascular channels[26], transcatheter occlusion of atrial and ventricular septal defects[10] and percutaneous laser- assisted valve dilatation for valvular atresia[27] are being applied in the young with promising short-term results. Once established, these procedures will also be applied by the paediatric cardiologists worldwide. This study has shown the short-term results and early complications of the common paediatnc interventional procedures and success is judged on the basis of reduction in systolic pressure drop across the obstruction or narrowing at the time of angioplasty. These immediate results are comparable with those reported in the larger

series. Intermediate and long term follow- up is important and our results will be reported in due course. As new techniques continue to be developed in the larger centres in the developed world, we have shown that paediatric cardiac catheterisationcanbe developed effectively and safely ma relatively small sub-regional centre. There is no reason to believe that further services of this standard cannot be developed in the developing countries like Pakistan.

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