

Surgical closed pulmonary valvotomy for critical pulmonary stenosis: implications for the balloon valvuloplasty era

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Abstract

Background Closed pulmonary valvotomy for critical pulmonary stenosis has no apparent advantage over the percutaneous balloon technique, though it is used when balloon valvuloplasty fails. Experience of this technique at the Heart Institute, Tel Hashomer, since it was first used in 1973 has been reviewed.

Methods Thirty eight infants up to 1 year old (25 of them neonates—that is, nil to 1 month old) with critical pulmonary stenosis were operated on from 1973 to 1989. All had a trans-ventricular valvotomy, by a modification of the Brock method, and all underwent cardiac catheterisation before surgery.

Results Five of the 25 neonates (20%) died, but none of the other infants, so that the total mortality (five out of 38) was 13%. Three of the 38 required an aortopulmonary shunt. All 38 survivors were followed up—from one month to 14 years (mean 7.5 years). All were symptom free at the last check up. Fifteen of the survivors had required further surgery; this was successful in all cases.

Conclusions For the balloon valvuloplasty era surgical pulmonary valvotomy provides a good back up for failed attempts at percutaneous valvuloplasty. Review of outcome provides data for comparison with balloon valvuloplasty in the future.

Closed pulmonary valvotomy by a modification of the Brock procedure¹ has been the method of choice for treating critical pulmonary stenosis at the Sheba Medical Centre, Israel, since 1973. The early results of the first 14 operations were reported in this journal.²

Percutaneous balloon valvuloplasty is now the preferred method of managing critical pulmonary stenosis, surgical valvuloplasty being used mainly when this fails. Closed valvotomy provides a standard for assessing the results of balloon dilatation, and provides some prediction of long term results for patients receiving this treatment. This report expands our surgical series to 38 cases, and provides long term follow up data on the requirement for and risk of further surgery.

Patients and methods

From July 1973 to September 1989 38 infants were operated on at the Sheba Medical Center for critical pulmonary stenosis. Their ages ranged from 1 day to 1 year (mean age 1.9 months). Twenty six were male and 12 female. The patients' clinical condition, electrocardiograms, and angiographic, echo Doppler (when available), and catheterisation results are presented in table 1.

All the infants were operated on by a modification of the Brock technique that is based on an initial enlargement of the tight passage through the valve with a small mosquito clamp and further dilatation with biliary dilators. The patient is placed supine and a mid sternotomy performed. A purse-string suture is put immediately below the pulmonary valve on the right ventricular wall of the heart. A small incision is made within this suture, and a mosquito clamp is introduced into the heart and through the narrow opening in the valve. Once the valve is opened a distinct tearing is felt. Further dilatation is achieved by passing increasing sizes (5–10 mm) of biliary dilators through the pursestring into the main pulmonary artery.^{1,2}

Since 1980 all neonates have had a prostaglandin E₁ infusion before surgery; this is discontinued gradually a few days after surgery. Systemic artery blood gas tensions are checked, an oxygen tension above 4 kPa being considered adequate. If the value drops below this level an aortopulmonary shunt is added.

Follow up was from 3 months to 14 years (mean 7.5 years). Twenty patients have been observed for more than five years. Surviving patients were divided retrospectively into those who did not require further surgery (group A, n = 19), and those who did (group B, n = 14). Some patients with a good clinical result were followed up by correspondence with their cardiologist; not all patients had a late echo Doppler examination.

Further surgery consisted of a standard open heart procedure in 12 patients and inflow occlusion in two.

STATISTICAL ANALYSIS

Mortality rates and 95% confidence limits were calculated on the assumption that the number of deaths followed a binomial distribution.³ Fischer's exact probability test was used to test for differences in the percentage of normal

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Table 1 • Details of patients having the Brock procedure

Patient No	Sex	Age	Preoperative RVP (mm Hg)	Dilator size (mm)	Death	Reoperation	Follow up (y)
1	M	1 d	140	6	—	—	0.25
2	M	1 d	100	10	—	—	11
3	M	1 d	110	—	—	+	5
4	M	1 d	110	7	—	+	12
5	M	1 d	150	5	—	+	3.5
6	F	1 d	115	5	—	+	3.5
7	M	2 d	160	—	—	+	3.5
8	M	2 d	Unregistered	5	—	—	4
9	F	2 d	Not taken	6	—	—	1.5
10	M	2 d	—	—	+	—	—
11	M	2 d	140	5	+	—	—
12	M	3 d	140	—	+	—	—
13	M	3 d	160	6	—	—	4
14	F	4 d	—	—	+	—	—
15	M	5 d	120	TD	—	+	14
16	M	6 d	150	8	+	—	—
17	F	10 d	160	8	—	—	12
18	M	10 d	200	6	—	+	10
19	M	13 d	100	7	—	+	8
20	M	14 d	125	5	—	+	3
21	M	21 d	180	5	—	+	4
22	F	30 d	110	7	—	+	10
23	M	30 d	100	9	—	—	11
24	M	30 d	160	10	—	—	10.67
25	F	30 d	160	5	—	—	3.67
26	M	2 m	120	9	—	—	7.5
27	M	2 m	150	8	—	—	8
28	F	2.5 m	190	8	—	+	8
29	F	3.5 m	140	6	—	—	2
30	F	4 m	140	MC	—	—	12.5
31	F	4 m	150	9	—	—	10.67
32	F	5 m	140	8	—	—	2
33	M	5.5 m	120	8	—	—	12
34	F	6 m	120	18 TD	—	—	13.67
35	M	6 m	140	9	—	—	11
36	M	6 m	120	9	—	+	10
37	M	8 m	120	8	—	—	2
38	M	11 m	—	8	—	+	11

RVP—systolic right ventricular pressure; TD—Tubbs dilator; MC—mosquito clamp only.

electrocardiograms between group A and group B. A life table technique was applied to the data according to the product limit method (Kaplan-Meir)³⁻⁵ to estimate the distribution of time to reoperation for patients observed over varying periods. Univariate comparisons of time to reoperation according to age at operation, size of dilator, and presence or absence of diastolic murmur were made by using the Mantel-Cox or Tarone-Ware statistics³⁻⁵ to test the equality of the curves. The relation between all the explanatory variables and the time to reoperation was quantified by using Cox's proportional hazards model.^{4,5}

Results

EARLY RESULTS

Five operative deaths occurred (13%); details are given in table 2. All were neonates under 1 week of age. The operative mortality and 95% confidence limits by age group were: total group 13% (5/38 patients), CL 4.2, 27%; neonates (up to 1 month) 20% (5/25), CL 6.8, 41%; infants (1 month to 1 year) 0% (0/13), CL 0, 22%.

Three of the 38 patients required an aortopulmonary shunt (table 1: patients 9, 11, 37). This was for persistent hypoxaemia in two neonates, one of whom died from septicaemia. The third was admitted with a barely functioning Blalock Taussig shunt.

LATE RESULTS

The remaining 33 patients were available for follow up, of whom 19 had not required further surgery (group A) and 14 had (group B). All patients in group B underwent cardiac catheterisation, and right ventricular systolic pressure ranged from 73 to 200 (mean 130) mm Hg. By five years after the initial operation 22 (67%) had not required further surgery compared with 19 (58%) at eight years. No patient

Table 2 Causes of death

Patient No	Age at surgery (days)	Cause of death
10	2	Technical mistake; intraoperative death
11	2	Technically inadequate valvotomy apparent at necropsy, the perforation being on the floor of one sinus, and a shunt done later thrombosed; death two weeks later from general sepsis
12	3	Emergency operation performed directly from the catheterisation table; unnoticed residual heparin activity led to bleeding and tamponade several hours after seemingly good valvotomy
14	4	Dysplastic pulmonary valve found at necropsy; death from low cardiac output within 24 hours
16	6	Traumatic operation (8 mm dilatation); death within several hours

Table 3 Results for the 19 patients in group A (no reoperation)*

Patient No	Age at surgery	Dilator size (mm)	Follow up (y)	Postoperative results		
				DM	ECG	Pressure gradient (Doppler† (mm Hg))
1	1 d	6	0.25	1/6	—	40
2	1 d	10	11	2/6	IRBBB	30
8	2 d	5	4	—	RVH	40
9	2 d	6	1.5	—	—	50
13	3 d	6	4	—	Normal	—
17	10 d	8	12	1/6	RVH	—
23	30 d	9	11	1/6	IRBBB	—
24	30 d	10	10.67	2/6	IRBBB	—
25	1 m	5	3.67	—	Normal	—
26	2 m	9	7.5	2/6	Mild RVH	—
27	2 m	8	8	2/6	IRBBB	—
29	3.5 m	6	2	1/6	RVH	60
30	4 m	MC	12.5	—	RVH	—
31	4 m	9	10.67	1/6	IRBBB	20
32	5 m	8	2	—	—	—
33	5.5 m	8	12	1/6	Normal	—
34	6 m	9 TD	13.67	2/6	IRBBB	0
35	6 m	9	11	—	IRBBB, RVH	—
37	8 m	8	2	2/6	—	—

*All symptom free at follow up.

MC—mosquito clamp only; TD—Tubbs dilator; DM—diastolic murmur; ECG—electrocardiogram; RVH—right ventricular hypertrophy; IRBBB—incomplete right bundle branch block.

†The Doppler method was introduced later in the series and some patients therefore did not have it.

required further surgery after that time. Univariate comparison of the time interval before the initial operation and further surgery showed that the interval was shorter in younger patients ($p = 0.07$, fig 1), with the smaller dilators ($p = 0.06$, fig 2), and in those without a diastolic murmur ($p = 0.02$, fig 3). Multivariate analysis using these three variables showed a borderline effect for diastolic murmur and dilator size on the risk of requiring a further operation.

When this analysis was applied to the neonates only the effect of dilator size showed a stronger relation to need for further surgery. Neonates had a 3.5 fold higher risk of reoperation if the dilator size was 5 mm or less compared with neonates with a dilator size of 6 mm or more, after the presence or absence of a diastolic murmur had been controlled for. No such analysis could be used for infants (age 30 days and over) because the group was too small ($n = 13$).

The morphology of the pulmonary valve in the patients who underwent open pulmonary surgery was analysed for angiographic-pathological correlation. Angiography had

been performed for all 14 patients requiring a second operation. The pulmonary valves in eight were judged to be dome shaped, of which six proved to be classically dome shaped at surgery; two had some dysplastic features. Four valves were judged to be dysplastic from angiography; three proved classically dysplastic and one was only partially so (defined as thickened leaflets and enlarged sinuses with no commissural fusion). Two patients had distorted valves that appeared thick on the angiograms, but were not described as dysplastic. At surgery one appeared to be dysplastic; the other was a distorted dome shaped valve. The pulmonary valve showed widely varying morphological abnormalities.⁶ There was a correlation between angiographic diagnosis of dysplastic valve and the findings at surgery ($\kappa = 0.62$, $p < 0.05$).

The 19 patients who did not require further surgery (group A, table 3) were all symptom free when last seen, though 12 had a pulmonary diastolic murmur.⁷ Most had a normal electrocardiogram, in contrast to patients in group B, who had signs of right ventricular hypertrophy ($p < 0.01$).

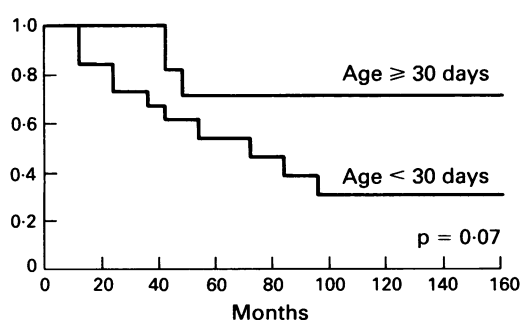


Figure 1 Cumulative proportion of patients surviving without reoperation according to whether at first operation they were neonates (younger than 30 days) or infants (30 days to one year), showing a borderline advantage to surgery in infants ($p < 0.07$).

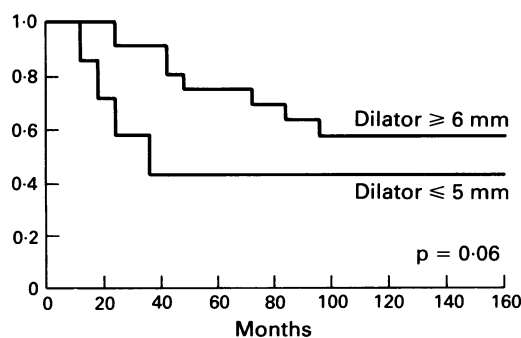
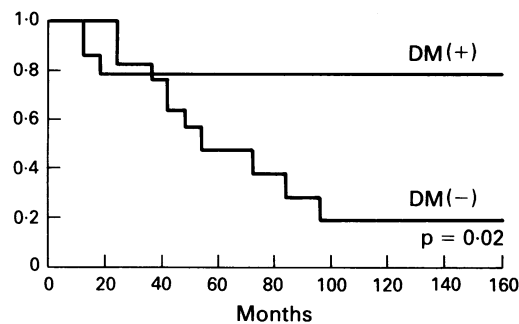


Figure 2 Cumulative proportion of patients surviving without reoperation according to whether the dilator size was 5 mm or less (mosquito clamp only) or 6 mm or more, showing better results with the larger dilators ($p < 0.06$).

Figure 3 Cumulative proportion of patients surviving without reoperation according to whether they had a diastolic murmur, showing that patients with no diastolic murmur are at significant risk of reoperation and that those with a diastolic murmur will probably not require reoperation ($p < 0.02$).



Discussion

This study of 38 patients is one of the larger series of neonates and infants undergoing closed pulmonary valvotomy by a modification of the Brock procedure. There were no operative deaths in patients over 1 week of age.

As we are now in the balloon dilatation era the old debate on which surgical procedure should be used (closed valvotomy, inflow occlusion,⁷⁻⁹ or open heart technique¹⁰⁻¹²) seems outdated, and the discussion is limited to the results of closed valvotomy.

Closed transventricular valvotomy, as proposed by Brock in 1948,¹ is regarded as a simple and atraumatic method of treating critical pulmonary stenosis, especially in neonates and infants.^{1, 2, 8, 13-17} It relieves the pulmonary valve stenosis without allowing direct inspection of the valve. Many authors discarded this technique because of the high proportion of patients requiring reoperation.^{13, 16} The average mortality is reported to be about 28% in neonates and 14% in infants.^{2, 8, 14, 16-19}

Although we had no deaths,² haemorrhage and cardiac arrest sometimes occurred during the valvotomies until 1980, often when larger sized dilators were used. In our technique the full diameter of the dilator passes through the right ventricular wall, which may then be more difficult to close. Since 1980 we have not insisted on large dilators—5–7 mm are considered sufficient. We have assumed that the primary tear by the mosquito clamp causes most of the dilatation. Smaller dilators were significantly related to a shorter interval before reoperation, however, in keeping with the commonsense expectation that the larger the dilator the better. Our main object was the safety of the operation; surgical or balloon valvuloplasty may be used safely at a later stage. As the size of dilator, however, was the most important factor predicting freedom from reoperation in neonates, we would now recommend a larger dilator when possible. Thus when we are confronted nowadays with a patient (usually after failure of attempts at balloon dilatation) we may use an 8 mm balloon intraoperatively instead of a metal dilator. When it is deflated the catheter will enter the right ventricle through a 2–3 cm hole, and only when the catheter is in position in the orifice of the pulmonary valve, its tip palpable in the main pulmonary artery, will the balloon be inflated to a diameter of 8 mm. This maintains the small diameter of the entry hole in the wall

of the right ventricle while still providing a large dilatation.

Some authors^{17, 20} claim that a small right ventricle poses an additional risk in critical pulmonary stenosis, whereas others¹⁸ do not. In our series most patients had a normal sized right ventricle, as in Weldon's series.²¹ In only one angiogram from the 14 patients who returned for a repeat assessment before further surgery could the right ventricle be defined as hypoplastic, and this patient had a favourable outcome in the long term.

During the time that most of our patients had their initial surgery balloon dilatation was not available, so they were referred for closed transventricular valvotomy, regardless of right ventricular size or presence of tricuspid insufficiency. Some recent reports on the success of balloon dilatation seem to show a correlation between unfavourable outcome and small size of right ventricle, whereas others dispute the correlation.²²⁻²⁴ A small right ventricle was not a major risk factor in our patients who died.

The need for an elective shunt in neonates under 1 week of age is still debated. Of the neonates less than 1 week old in our series, two received a shunt (one survived, one died). Coles *et al*¹⁸ claim that adding a shunt should improve survival in neonates, as their mortality for patients with pulmonary atresia (shunt in all cases) is lower than in patients with pulmonary stenosis (who do not usually receive a shunt electively), though the latter is considered a lesser lesion than atresia. Our policy is not to add an aortopulmonary shunt electively in every neonate, as this is an additional surgical procedure with added risk, and the condition can usually be managed with a prostaglandin drip for a few days. Only rarely, when oxygen tension falls below 4 kPa, will a patient undergo further surgery and an aortopulmonary shunt be added (two patients out of 38 in our series).

A favourable five year follow up does not exclude the possibility that some of these children will require further surgery later.¹⁸ Two of our patients developed signs of right ventricular hypertrophy after the initial improvement on the electrocardiogram. Long term follow up after puberty is important for determining whether a late pressure gradient develops.

When the different surgical approaches, with their surgical mortality, are being evaluated the need for further surgery must be considered. The necessity of reoperation is reported in conjunction with all the methods.^{16, 18, 25-27} Coles *et al*¹⁸ reported a 28% five year and a 58% 10 year reoperation rate, irrespective of operative technique. Restenosis will usually be treated nowadays by repeated balloon dilatation.

The optimal approach for patients with a dysplastic pulmonary valve and its precise recognition²⁸ are debated. Several authors object to the use of the Brock procedure in patients with dysplastic valves^{6, 11, 12, 25, 29-32} as mortality has been 38–66%.^{1, 33-35} Valvectomy and transannular patch are recommended, usually with an open heart procedure.^{12, 26} There is no commissural fusion in these

infants, and no commissures to tear open, so they do not benefit from balloon dilatation.³¹ Most patients with dysplastic valves are not neonates, however,¹⁶ as we confirmed. We would also choose valvectomy with inflow occlusion if faced with a clearcut preoperative diagnosis of dysplastic anatomy.

Surgical closed pulmonary valvotomy is very similar to balloon valvuloplasty in that both use blind, forceful methods to break open and dilate the valve. We see no reason therefore to recommend surgical dilatation unless the percutaneous method is unavailable or has failed. The failure rate of balloon dilatation is likely to decrease as experience increases and equipment improves, even in more difficult patients with non-dilated ventricles.²²⁻²⁴ Acceptable long term results (58% of patients not needing reoperation) for one good dilatation may be predicted even when the procedure is performed in neonates.

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