



Porcine pulmonary prosthesis to repair the dysfunctional right ventricle outflow tract.

Does it work the same in children than in adults?

A call for caution.

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Introduction & Objectives:

The pulmonary valve replacement for dysfunctional right ventricle outflow tract (RVOT) is increasing in childhood to prevent the dysfunction of the right ventricle (RV). The question is: ¿are the results the same in children and in adults?

Our goal is to compare the results of the stented porcine prosthesis (PPP) in people older and younger than 18 years, to analyze the risk factors of mortality and prosthetic dysfunction, as well as the effects of the valve on the functional status of patients and their RV functionality.

Methods:

All patients who received a PPP between 1999-2015 for repairing the sequela after primary surgery on the RVOT. Prosthetic dysfunction criteria: surgical/percutaneous reintervention, prosthetic gradient > 50 mmHg or severe prosthetic regurgitation. Statistical analysis with SPSS 20.0.

Results:

102 PPP/101 patients (81/81 in > 18 years cohort; 21/20 under 18). 60% male. Fallot, most common primary disease in both groups.

From 24 preoperative variables studied, statistically significant differences occur in 4: last surgery mean age before PPP, $p < 0.001$; NYHA status, $p = 0.005$; QRS interval, $p = 0.007$ all of them greater in adults. Surgical indication (pulmonary regurgitation/pulmonary stenosis/double pulmonary lesion), $p = 0.036$, with more pulmonary stenosis in group <18 years.

Overall **hospital mortality**: 2.9% (3.7% adults vs 0% children, $p < 0.001$). If PPP is a single procedure mortality is 0%. From 14 perioperative variables, 7 were statistically significant, highlighting: cardiopulmonary by-pass (CPB) with peripheral access, $p < 0.001$; associated surgical procedure, $p = 0.02$; CPB time $p = 0.01$; aortic cross-clamp need, $p = 0.043$; intubation time, $p < 0.001$, all variables greater in adult group.

Risk factors for mortality: CPB time ($p = 0.01$) and implantation over 18 years ($p < 0.001$)

Associated surgical procedure in 72,5%, most often a residual shunt closure

Complications in 32% of cases, most often tachyarrhythmia. No significant differences.

Mean **follow-up time** 4 ± 3.7 years (4.4 adults versus 2.4 children, $p = 0.017$). Only 1 late dead, in over 18 years group.

Bioprosthesis size	Global	Adults	Under 18 years
19	1 %	0 %	4,8 %
21	0 %	0 %	0 %
23	2 %	0 %	9,5 %
25	24,4 %	14,8 %	61,9 %
27	42,2 %	46,9 %	23,8 %
29	30,4 %	38,3 %	0 %

From 16 postoperative variables, 6 had statistically significant differences, highlighting: systolic/diastolic RV volumes, $p < 0.001$, greater in adults. The need for surgical/percutaneous reintervention, $p = 0.029$ and reoperation for prosthesis dysfunction ($p = 0.001$), in contrast, are higher in < 18.

Prosthetic dysfunction: 6.1% (1.3% adults versus 23.8% children, $p < 0.001$).

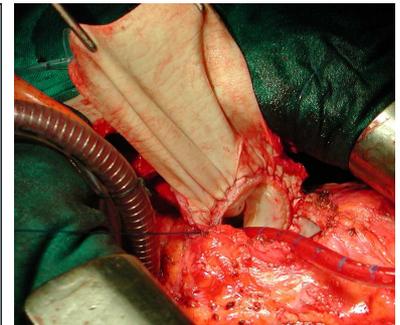
Risk factors for prosthetic dysfunction in **univariate analysis** ($p < 0.05$): previous conduit/prosthesis in RVOT, pulmonary stenosis indication surgery, bioprosthesis implantation under 18 years, low weight and low body surface.

In **multivariate analysis** remained pulmonary stenosis indication surgery and low body surface.

Multivariate model for the association of prosthetic dysfunction with surgical risk factors			
	OR	(IC 95 %)	p
Prosthesis implant indication (reference:PR)			
DPL	2,62	(0,33 - 20,83)	0,363
PS	10,1	(1,06 - 95,52)	0,044
Body surface (m ²)	0,1	(0,01 - 0,95)	0,044

CI, confidence interval

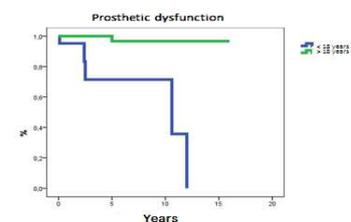
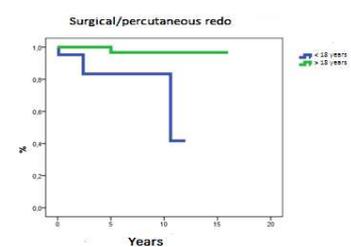
After surgery the patients improved their functional NYHA class and right ventricular volumes returned to normal ($p < 0.05$). If RV ejection fraction was already depressed, it would not recover.



Associated surgical procedures with PPP implant*

Procedure	n
Residual shunt closure	36
Tricuspid valvuloplasty	27
Tricuspid prosthesis implant	6
Aortic prosthesis implant	12
Central pulmonary branch arterioplasty	7
Arrhythmia surgery	4
Aortic ascending aneurism repair	3
Discrete subaortic stenosis repair	2
Mitral prosthesis implant	2
Dislocated stent removal	2
Partial anomalous pulmonary venous return repaired	2
Disfunctional PPP removal	1
By-pass LIMA- ADA	1
Sinus of Valsalva aneurism repair	1
Pacemaker implant	1

*The same patient may have been several associated procedures



Conclusions:

- The implant of a PPP leads to low in-hospital and follow-up mortality, recovering normal RV volumes, but not its function if it was already depressed.
- The patients' functional class improve.
- PPP dysfunction is greater and earlier in children than in adults, so the implant of the PPP should be reserved for the RV function is at risk, the tricuspid regurgitation associated is severe, or when functional class is advanced.