Original Article

Initial Analysis of the Use of the L-D-Hydro (Eato L-D-Hydro) Organic Tubular Graft for Performing the Modified Blalock-Taussig Procedure in Congenital Heart Diseases with Decreased Pulmonary Blood Flow

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Objective

To analyze the initial results of the use of an organic tubular graft for systemic-pulmonary anastomoses.

Methods

From March 2002 to April 2003, 10 patients underwent systemic-pulmonary shunt of the modified Blalock-Taussig type, using a new type of biological graft originating from the bovine mesenteric artery treated with polyglycol, the so-called L-D-Hydro. The patients' ages ranged from 3 days to 7 years, and 60% of them were of the male sex. The diagnoses of heart disease were determined on echocardiography. All patients had clinical signs of severe hypoxia (cyanosis). The heart diseases were as follows: tetralogy of Fallot (40%), tricuspid atresia (50%), and atrioventricular septal defect (10%).

Results

One patient died due to sepsis and 9 had an immediate improvement in O_2 saturation on pulse oximetry and in the partial oxygen pressure on arterial blood gas analysis. The intensive care unit length of stay ranged from 2 to 6 days. No patient had obstruction of the shunt on the immediate postoperative period or any other complication. All patients had a patent shunt on the echocardiographic studies performed in the immediate postoperative period and later, in the third postoperative month. No bleeding occurred during surgery or in the postoperative period.

Conclusion

The tubular L-D-Hydro graft proved to be promising for performing systemic-pulmonary shunt as an alternative for the inorganic products available in the market, however, we need a greater number of implantations and late follow-up for definitive assessment.

Key words

systemic-pulmonary anastomosis, modified Blalock-Taussig

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The systemic-pulmonary shunt using blood flow from the subclavian artery to the ipsilateral pulmonary artery was clinically introduced by Blalock and Taussig [1]. Potts et al [2] have reported the performance of a shunt between the descending aorta and the pulmonary artery, Waterston [3] has created a shunt between the ascending aorta and the pulmonary artery, and Redo and Ecker [4] have introduced the use of a prosthesis for performing a systemic-pulmonary shunt.

We present the initial analysis of the results with 10 patients undergoing systemic-pulmonary shunt with a new type of organic graft (L-D-Hydro) originating from the bovine mesenteric artery treated with polyglycol.

Methods

From March 2002 to April 2003, 10 patients underwent systemic-pulmonary shunt of the modified Blalock-Taussig type, using a new type of biological graft originating from the bovine mesenteric artery treated with polyglycol, the so-called L-D-Hydro. The patients' ages ranged from 3 days to 7 years, and 60% of them were of the male sex.

The inclusion criterion was children of any age with congenital heart disease and decreased pulmonary blood flow, who required systemic-pulmonary shunt. The diagnosis of the heart diseases regarding pulmonary blood flow was determined through echocardiographic study as follows: 6 patients had pulmonary atresia and 4 patients had severe stenosis of the right ventricular outflow tract. All patients had clinical signs of severe hypoxia (cyanosis) confirmed on pulse oximetry and arterial blood gas analysis. The heart diseases were as follows: tetralogy of Fallot (40%); tricuspid atresia (50%); and atrioventricular septal defect (10%). All patients were followed up after the surgical procedure by the clinical team with clinical and echocardiographic assessments (tab. I).

The L-Hydro treatment was developed aiming at reducing the reaction of the receptor against implanted grafts. The process consists of 3 different stages. The first stage combines the extraction of antigens (without using detergents, surfactants, or digestive enzymes) with masking of the remaining antigens with polyglycol, under controlled chemical oxidation and performed under specific physical conditions that protect the extracellular components, such as collagen and elastin. The second stage consists of a process of incorpo-

Table I - Distribution of patients according to age, sex, diagnosis, surgery, and graft size.

Patient	Age	Sex	Diagnosis	Surgery	Graft size (mm)
1	2 months	M	AVSD + RVOT stenosis	MBT to the L	4
2	8 days	F	T4F + Pulmonary atresia	MBT to the R	4
3	3 days	F	Pulmonary and tricuspid atresia	MBT to the L	4
4	2 months	F	Pulmonary and tricuspid atresia	MBT to the L	4
5	3 months	M	Tricuspid atresia + TGA + PVS	MBT to the L	4
6	4 days	F	Pulmonary and tricuspid atresia	MBT to the R	4
7	7 years	M	Pulmonary and tricuspid atresia + Coronary cavitary fistula RC-RV	MBT to the L	5
8	12 days	M	T4F + Pulmonary atresia	MBT to the L	4
9	10 months	M	T4F	MBT to the L	4
10	10 months	M	T4F	MBT to the L	4

M- male; F- female; AVSD- atrioventricular septal defect; RVOT- right ventricular outflow tract; TGA- transposition of the great arteries; PVS- pulmonary valve stenosis; T4F- tetralogy of Fallot; RC- right coronary; RV- right ventricle; MBT- modified Blalock-Taussig; R- right; L- left; mm- millimeter.

ration of a nonsteroidal anti-inflammatory agent and an antithrombotic agent to the tissue. The third stage consists of sterilization of the tissue in the aqueous phase of hydrogen peroxide. The fourth stage is the D-Hydro process, which consists of lyophilization and replacement of the water molecules in the matrix and extracellular space by glycerol, a flexible polymer that replaces water.

The surgical technique was as follows: 8 patients were placed in the right lateral decubitus position; they underwent left lateral thoracotomy according to the anatomic location of the aortic arch; opening was performed in the third or fourth intercostal space; anastomosis of the graft to the subclavian artery and the pulmonary artery was performed with Prolene 7-0 thread, taking care not to clamp the graft, according to the recommendation of the manufacturer (fig. 1). The other 2 patients underwent right thoracotomy, and the shunt was performed with the right subclavian artery and the right pulmonary artery, due to the location of the aortic arch. In all patients, the anastomoses were preceded by heparinization at the dosage of 1 mg/kg, and no patient required heparin reversion (fig. 2).

In the postoperative period, the immediate follow-up protocol was similar to that of the procedure used for patients undergoing the Blalock-Taussig shunt with expanded polytetrafluoroethylene (PTFE) graft, which is as follows: all patients were heparinized with 400 to 600 U/kg/day of sodium heparin in continuous infusion beginning 2 hours after admission at the ICU; their APTT was maintained 1.5 to 2.5 times the normal value, and heparin was kept for 24 hours, being then replaced by acetylsalicylic acid, at the dosage of 5 mg/kg/day, for 3 months.

In late follow-up, our protocol included clinical, echocardiographic, and arteriographic assessments in all patients on the occasion of indicating definitive correction (fig. 3).

Results

Of the 10 patients studied, one died due to sepsis on the third postoperative day. The 9 remaining patients had an immediate

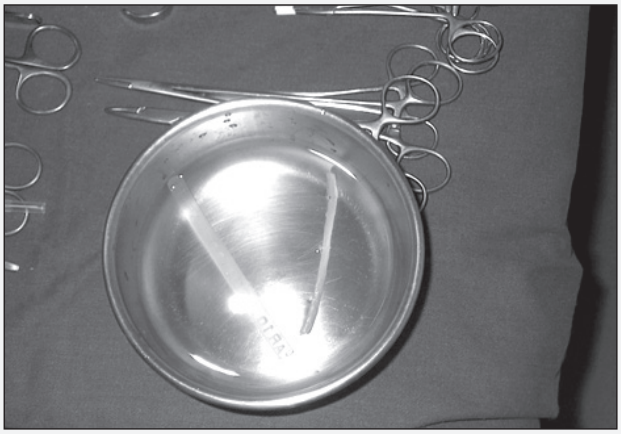

Fig. 1 - Re-hydration of the D-hydro graft in saline solution and heparin at the time of implantation.

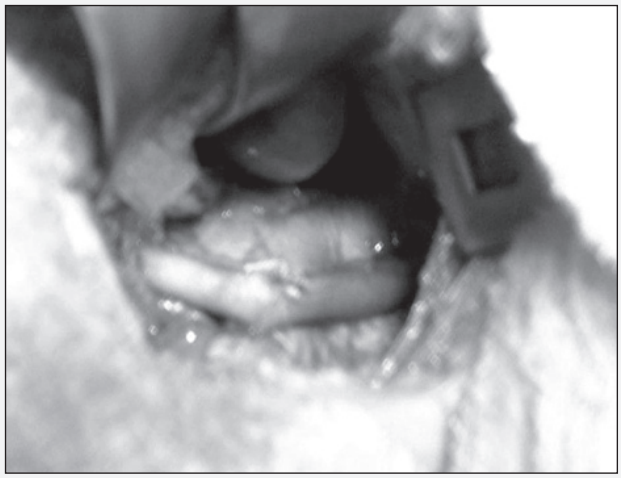

Fig. 2 - Final aspect of the anstomosis.

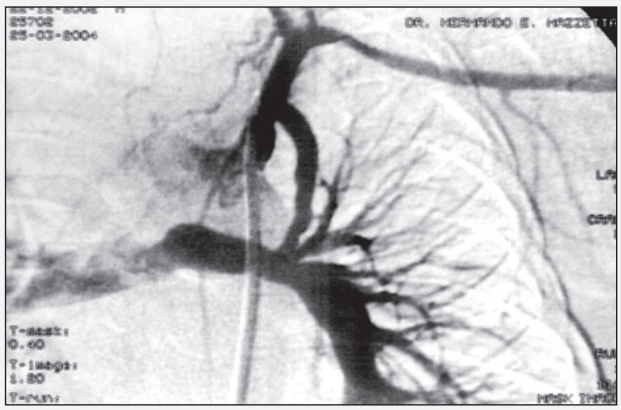

Fig. 3 - Arteriography showing a patent Blalock Taussig shunt to the left, with a well-developed pulmonary tree.

improvement in oxygen saturation on pulse oximetry and arterial blood gas analysis. The mean initial arterial oxygen saturation was 69.4% ± 1.17%, with a significant increase to 90.1% ± 1.85% immediately after the procedure. The length of stay in the intensive care unit ranged from 2 to 6 days.

No patient had obstruction of the shunt in the immediate postoperative period or any other complication, although the classical modified Blalock-Taussig murmur could not be heard with its usual intensity, which can be explained by the elasticity of the graft. All patients showed, on the echocardiographic study, a patent shunt with turbulent flow (fig. 4). In the immediate postoperative period, the diameter of the graft ranged from 4.3 to 5.4 mm (4.68±0.29), and, in the third month, from 4.2 to 5.2 mm (4.48±0.29) (tab. II).

No bleeding was observed during surgery or in the postoperative period.

Discussion

Usually, the indications for the use of the systemic-pulmonary shunt varied among the institutions as follows: cyanogenic complex defects; hypoplasia of the pulmonary arteries; hypoplasia of the pulmonary ring, which required a transannular flap for complete repair; abnormality of the pulmonary arteries; neonates with tetralogy of Fallot and pulmonary atresia; and young low-weight neonates. In addition, the systemic-pulmonary shunt is used when the mortality of the total correction is greater than that of the 2-stage repair [5-12].

Currently, the most used shunt in most services is the modified Blalock-Taussig, which has a mortality rate lower than 1% [12]. De Leval and Stark [5], McKay et al [6], and other authors reported excellent results with the modified Blalock Taussig. The shunt has adequate patency, a low index of surgical complications, low mortality, and allows the growth of the pulmonary tree, without the risks of the secondary repair [13-21]. In our study, no patient died in the immediate postoperative period; all patients had an immediate improvement in oxygen saturation on pulse oximetry and arterial blood gas analysis (from 69.4% ± 1.17% to 90.1% ± 1.85%). The diameter and characteristic of the flow, shown on echocardiography, confirmed the efficacy of the shunt.

Berger [19] and other authors [22-26] have reported high postoperative morbidity and mortality in the procedures of Potts et al [2] and Waterston [3]. Kirklin et al [10] have identified age (below 3 months) as a risk factor for postoperative mortality, mainly when other risk factors coexisted. Arciniegas et al [29] have also identified age as a risk factor for postoperative mortality as follows: 6% for one month, 4% for 3 months, 3% for 6 months, and 2.5% for 12 months [6,28]. Alkhulaifi et al [30] have identified low weight and preoperative ventilation as risk factors for mortality. Khalid et al [31] have related low weight (below 3 kg) to the early failure of the shunt, and identified the use of intra- and postoperative heparin as a protective

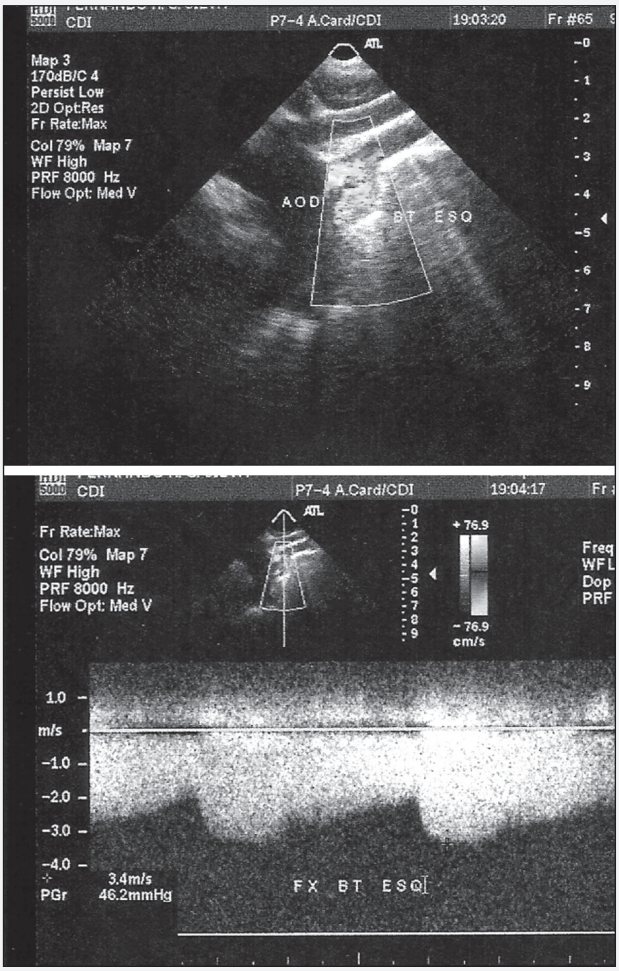

Fig. 4 - Echocardiographic image during late postoperative period on continuous color Doppler, flow by the Blalock Taussig.

Table II - Postoperative assessment through Doppler echocardiography in patients undergoing systemic-pulmonary anastomosis with the L-D Hydro graft

Patient	Diagnosis	Graft diameter		Type of flow	
		Immediate (mm)	3 months (mm)	Immediate	3 months
1	AVSD + RVOT stenosis	4.6	4.5	Turbulent	Turbulent
2	T4F + Pulmonary atresia	4.5	4.3	Turbulent	Turbulent
3	Pulmonary and tricuspid atresia	4.8	-	Turbulent	-
4	Pulmonary and tricuspid atresia	4.3	4.2	Turbulent	Turbulent
5	Tricuspid atresia + TGA + PVS	4.6	4.4	Turbulent	Turbulent
6	Pulmonary and tricuspid atresia	4.8	4.5	Turbulent	Turbulent
7	Pulmonary and tricuspid atresia + Coronary cavitary fistula RC-RV	5.4	5.2	Turbulent	Turbulent
8	T4F + Pulmonary atresia	4.7	4.5	Turbulent	Turbulent
9	T4F	4.5	4.3	Turbulent	Turbulent
10	T4F	4.6	4.2	Turbulent	Turbulent

AVSD- atrioventricular septal defect; RVOT- right ventricular outflow tract; TGA- transposition of the great arteries; PVS- pulmonary valve stenosis; T4F- tetralogy of Fallot; RC- right coronary; RV- right ventricle; mm- millimeter.

factor for reducing shunt failure and early obstruction in 1.6% of the modified Blalock Taussig. They have also reported that patients with shunts with a greater caliber and those who received no heparin had a greater incidence of occlusion. In our study, no obstruction was observed in the period assessed, and permeability of the shunt was shown on Doppler echocardiographic study.

In our case series, one patient died due to sepsis on the third postoperative day, and, therefore, a cause not directly related to the graft.

Berger et al [32], using the PTFE graft, reported 12% of serum collection around the graft in patients receiving heparin in the postoperative period, a complication that was not observed in our case series, although some cases may have remained undetected.

On clinical assessment, we observed that the intensity of the murmur was lower than usual, which may be explained by the elasticity of the graft.

In conclusion, the L-D-Hydro graft proved to be effective for replacing inorganic grafts in systemic-pulmonary shunts, because of its excellent performance with no bleeding during surgery and in the postoperative period, graft patency in all patients, easy technical management, technical reproducibility, in addition to being of organic material and low cost.

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