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Research Article

Hybrid Procedures. Surgeon and Cardiologist Sharing Suite

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Abstract

Background: Surgeon and cardiologist on their own cannot cope with patients needs, occasionally. Hypoplastic left heart syndrome witnessed the collaboration between them for a palliative, hybrid procedure. As a strategy, hybrid approach has been applied in several, unforeseeable settings. Our initial experience is presented, pointing at indications, shortcomings and mid-term results.

Methods: Fifty-one patients were scheduled for a hybrid procedure along five years. This was defined as close collaboration between surgeon and cardiologist working together in the same room, either cath-lab (26 patients) or theatre (25 patients)

Results: Five groups were arbitrarily defined. A: vascular cut-down in the cath-lab (17 neonates); B: bilateral banding (plus ductal stent) in hypoplastic left heart syndrome or alike (10 children); C: perventricular closure of muscular ventricular septal defect (9 cases); D: Balloon/stenting of pulmonary branches along with major surgical procedure (9 kids); E: surgical implantation of Melody valve (5 patients) and others (1 case). Two complications were recorded: left ventricular free wall puncture and previous conduit tearing. Both drawbacks were successfully sort out under cardiopulmonary by-pass.

Conclusion: Surgeon and cardiologist partnership can succeed where their isolated endeavors are not enough. Hybrid procedures keep on spreading, overcoming initial expectations. As a bridge to biventricular repair or transplant, bilateral banding plus ductal stent sounds interesting. Novel indications can be classified into different groups. Hybrid procedures are not complication-free.

Background

Surgical and percutaneous procedures have experienced striking advances in congenital heart diseases along the past decades. Collaboration between interventional cardiologists and cardiac surgeons has recently paved the way for the so-called "Hybrid procedures". In offering a hand-to-hand intervention, the result becomes less invasive and more efficient, rendering a safer management for the congenital condition.

Partnership in the field of aortic valve replacement in the adult population (either trans-femoral or tans-apically deployed) is an example of hybrid approach. The first report of a hybrid procedure [1] in a neonate with hypoplastic left heart syndrome was launched in 1993. A surgical bilateral pulmonary banding followed by a percutaneous ductal stenting was performed. But it was in 2004 when the first single-room hybrid approach [2] took place, actually. Rather than the milestone itself, the importance relies in the new concept of collaborative approach in complex congenital heart diseases which often require several open heart surgeries throughout their lives well beyond adulthood. Novel hybrid procedures have the goal of reducing the total number of invasive surgeries over a lifetime span and reducing morbidity and mortality of certain interventions.

This holds true not only for the hypoplastic left heart pathway, but for a vast array of cardiac conditions in which surgical nor percutaneous procedures in isolation cannot address the problem. As this field keeps on growing, more sophisticated hybrid rooms will be devised to cope with the increasing needs of both surgeons and cardiologists.

Our group experience along five consecutive years is presented. Provided the sparking use and indications for hybrid procedures, we intend to cluster them into several categories. The rationale for assignment to cath-lab or theatre will be discussed and the complications analyzed.

Methods

From January 2013 until December 2017, 51 patients underwent a hybrid procedure to treat their cardiac condition in our Institution. Data are recorded in a prospective manner. According

to underlying disease and main procedure accomplished, they have been arbitrarily divided into groups (Table 1):

1. Cut-down vascular access (17 patients)
2. Hypoplastic left heart syndrome or alike (10 children)
3. Perventricular ventricular septal defect closure (9 cases)
4. Pulmonary artery branches dilatation/stenting (along with surgical repair; 9 infants)
5. Biological valve (Melody) deployment in open-heart field (5 patients)
6. Others (1 case)

The decision to carry out the hybrid procedure in the cath-lab or in surgical theatre was based upon the likelihood of cardiopulmonary by-pass needs (performed in theatre). Cath-lab and theatre are located in the same level, with a corridor in between both suites. Transition from cath-lab to theatre, or the other way round, is feasible (distinguished as two-stage hybrid procedure).

Upon this rationale, cut-downs and hypoplastic left heart syndrome hybrid approaches (groups 1,2) were mainly performed in the cath-lab, whereas most ventricular septal defect closure, pulmonary branches balloon dilatation and Melody insertion took place in theatre (groups 3,4,5 were scheduled on cardiopulmonary by-pass).

Technique

Vascular access in the cath-lab

Particularly, for neonates and infants below 5 Kg. Requiring aortic valvuloplasty. An incision is performed in the neck by the surgeon. The carotid artery is dissected and looped before purse-string or cut-down cannulation [3]. Should Extra Corporeal Membrane Oxygenation (ECMO) is needed; the jugular vein is easily available. Upon finishing the procedure, the surgeon sutures the vessel and checks its patency [4].

HLHS

For those patients with a hypoplastic left heart syndrome, or alike, and not amenable to Norwood I procedure because a high risk was anticipated, a single-stage hybrid procedure in the cath-lab was offered. Bilateral banding (Doppler velocity around 4 m/sec) plus open cell stent deployment through the entire length of the ductus was performed [5]. Balloon septostomy/stent was deferred as a separate procedure, if requested [6]. In other group of patients, bilateral banding plus ductal stent was applied as a bridge to transplant, or palliation in some complex forms of left heart obstructive lesions, in order to promote chances of biventricular repair [7,8].

Muscular ventricular septal defect

Through mini-sternotomy approach, under echo guidance, the right ventricle free wall is depressed with the tip of the forceps just opposite to the muscular septal defect and a purse-string is secured on a tourniquet. Using Seldinger technique, the free wall is punctured with a needle, followed by a guide wire and a sheath. A device with a waist 2mm larger than the septal defect diastolic diameter is chosen. The left disk is opened, then pulled against the septum to fit the waist in the defect and followed by the right disk deployment [9]. Tricuspid and aortic valves are tested for regurgitation and gross residual shunts are ruled out before device release. Full sternotomy and cardiopulmonary by-pass is chosen when concomitant procedures are requested (debanding, atrial septal defect closure, etc.) For apical muscular defects, patients have a soft guide/balloon inserted in the septal defect via transfemoral access in the cath-lab. Then, they are driven to theatre and, under cardiopulmonary by-pass, a tiny right apical ventriculotomy is performed to identify the guide/balloon. After trimming the trabeculae around the guide, the ventricular septal defect edges are identified and eventually closed.

Balloon dilatation/stenting in pulmonary arteries

Performed with the need for a concomitant surgical procedure [10] such as conduit replacement, pulmonary valve implantation, ventricular septal defect closure, etc. It involves dilatation/stenting under direct vision during open heart surgery, while on cardiopulmonary bypass, in a beating heart. Stents can be manually flared against the wall of the main pulmonary artery to make future access to the vessel easier, and sutures can be placed in the proximal edge of the stent to prevent distal embolization [11].

Melody deployment

In pulmonary position through a sub-xyphoid approach [12]. Inasmuch the Melody valve was initially approved for the pulmonary position only, delivery in mitral [13] location was reported in 2014. The device is flared, so as not to obstruct the left ventricle, and sutured in the mitral annulus. After securing it, the valve is balloon dilated to the target diameter upon direct vision. Further percutaneous dilatations can be scheduled as the child grows.

Table 1: Distribucion of hybrid procedures in clusters. VSD: Ventricular Septal Defect. CPB: Cardiopulmonary By-Pass. 26 procedures were performed in the cath-lab and 25, in theatre. (*): Two patients were first taken to the cath-lab and then, to theatre.

Vascular Access (17)	Bi-banding + ductal stent (10)	Muscular VSD (9)	Angio/stent branches (9)	Surgical Melody (5)	Others (1)
Cath-lab: 17	Cath-lab: 8	Cath-lab: none*	Cath-lab: none	Cath-lab: none	Cath-lab: 1
Theatre: none	Theatre: 2	Theatre: 9	Theatre: 9	Theatre: 5	-
Carotid cut-down (15)	Comprehensive (2)	Apical VSD (2)	Pulm prosthesis after Fallot (2)	Mitral (1)	Pulmonary vein stenosis (1)
Yugular cut-down (2)	Biventricular (3)	no CPB (4)	Conduit replacement (3)	Tricuspid (1)	
	Transplant (2)	with CPB (3)	Fontan completion (1)	Off-label pulmonary (2)	
	Waiting list (3)		"second" hybrid (3)	Sub-xyphoid (1)	

Others

Pulmonary vein stenosis. A midline sternotomy is fashioned and a purse-string suture is placed in the right superior pulmonary vein. After introducing a soft wire, a stent is deployed in the opposite left pulmonary veins to relieve their narrowing [14].

Results

Cut-down vascular access

All cases (17) took place in the cath-lab. Carotid artery was approached in 15 neonates for aortic valvuloplasty (12 children), ductal stent (1 Fallot), coarctation angioplasty (1 patient) and coarctation stent (1 case). The yugular vein was used twice: in a 4 month-old Fallot patient on transtoracic ECMO for stenting the right ventricular outflow tract and in a two year-old infant with a previous Melody in the tricuspid position (which happened to be regurgitant) in whom a valve-in-valve procedure was attempted. On completing the procedure, the vessel was repared (either stitching the cut-down or closing the purse-string suture) and the patency checked.

Hypoplastic left heart syndrome or a like (Table 2)

- Eight patients were treated in the cath-lab and two in theatre (after decision change). Six neonates with hypoplastic left heart syndrome were deemed unsuitable for conventional Norwood I technique because low weight (1.8 Kg.), myocardial dysfunction, severe tricuspid regurgitation o ECMO resuscitation.
- The four remaining patients were "bridged" to promote bi-ventricular repair, either as an intention-to-treat (2 cases) or after a decision-making in theatre (2 children, who left the operating-room with a bilateral banding in a "bridge to decision" strategy and had their ductus stented in the cath-lab as a two-stage procedure).
- Three patients underwent subsequent atrial septostomy plus stent deployment. Another child had to be re-banded.
- At follow-up, three patients had a bi-ventricular repair (Ross-Konno, Yasui -Norwood plus Rastelli- and arch repair plus ventricular septal defect closure), four were transplanted [15] and two underwent a comprehensive Norwood plus Glenn repair. One patient died in the transplant waiting list.
- Eventually, four out of the ten patients died, one in each group: arch repair (ventricular arrhythmia), one transplant (pneumoniae), one comprehensive repair (pulmonary hypertension) and the above mentioned in the transplant waiting list.

Muscular ventricular septal defect (9 cases, depicted in Table 3)

- Two patients had their apical muscular septal defect closed by the hybrid two-stage procedure, first in cath-lab (apical septal defect location) and then in theatre (closure under cardiopulmonary by-pass) with good result (trivial residual ventricular septal defect).
- Seven children had their muscular ventricular septal defect closed by a per-ventricular approach.
  - In four cases, provided that it was a single defect, a mini-sternotomy without cardiopulmonary by-pass was scheduled.
  - The three remaining ones were approached through a full-sternotomy and cardiopulmonary by-pass, since other defects had to be addressed: patching of a common atrium, perimembranous ventricular septal defect and debanding, respectively. One of the patients (actually, the first one in our series) was complicated by a puncture in the left ventricle lateral wall (Figure 1A). Because the pump machine was on back-up for the larger perimembranous ventricular septal defect closure, we run the cardiopulmonary by-pass and on

Table 2: Bridge to uni-, bi-ventricular or transplant in pathways HLHS (or alike) with hybrid pulmonary stenting plus bilateral banding.

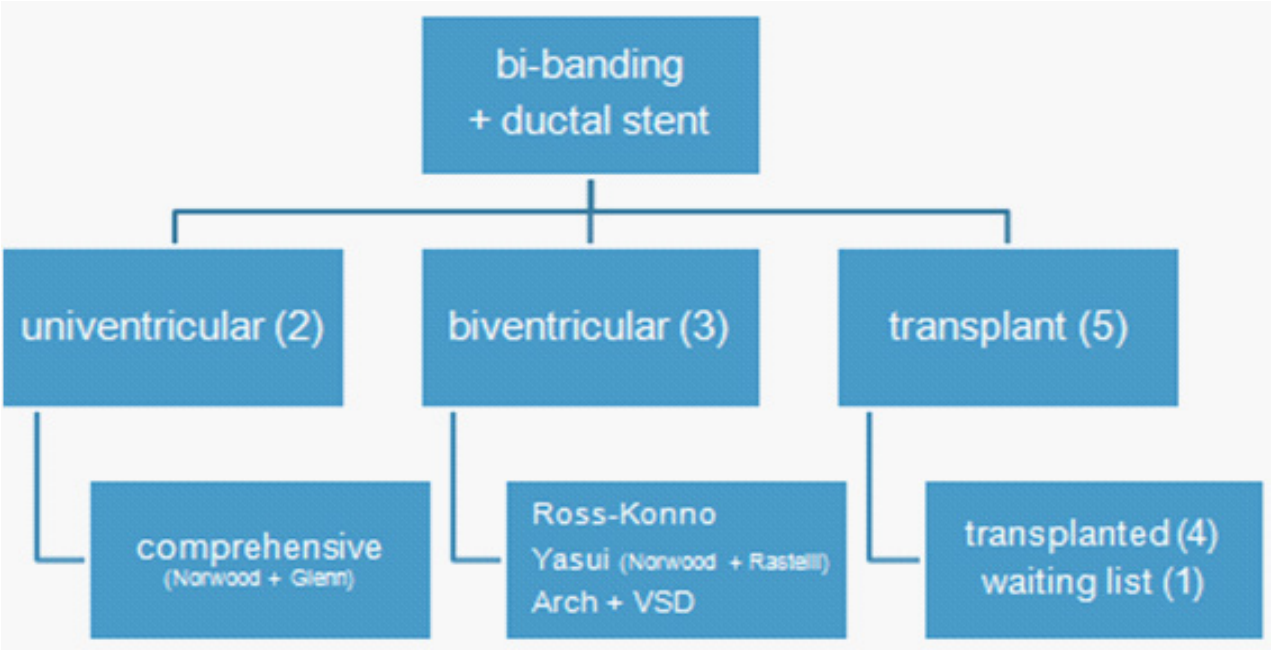
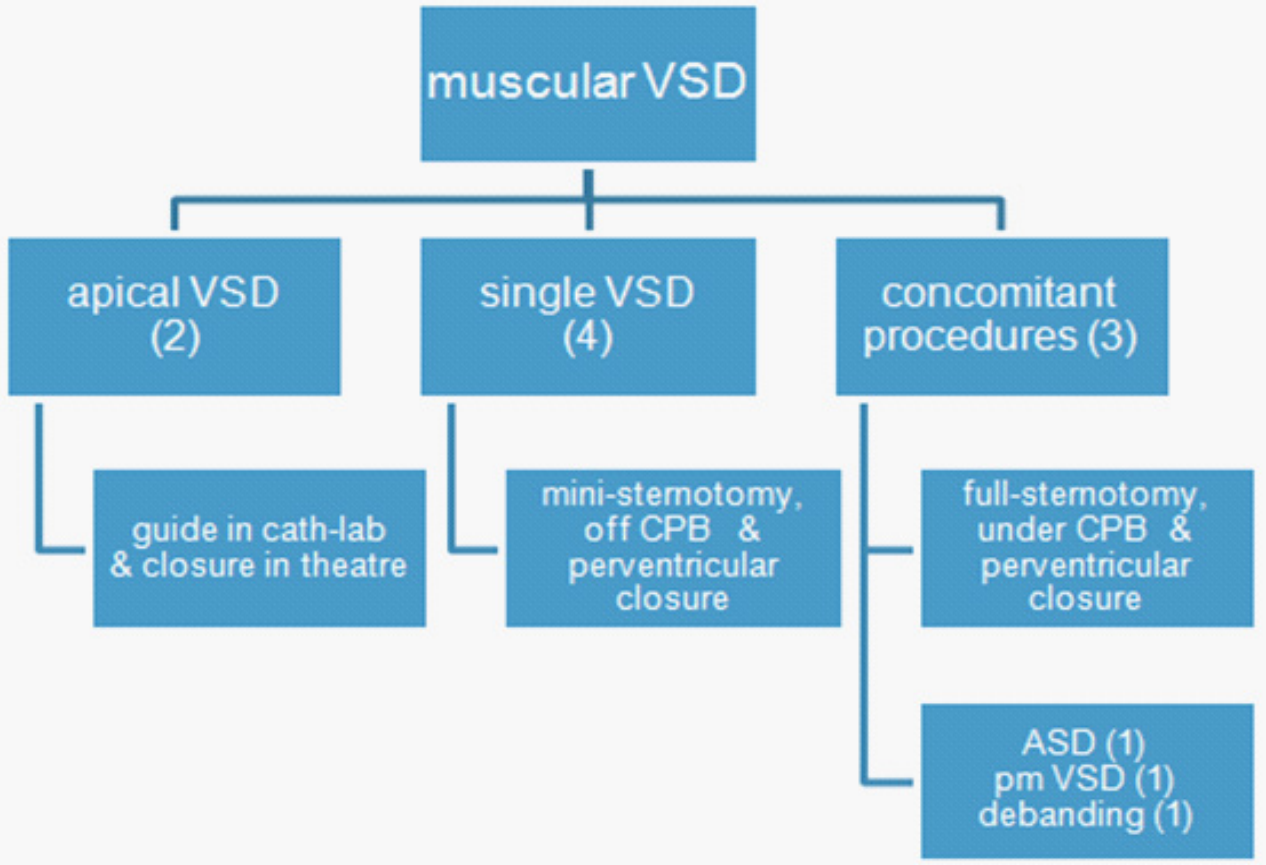


Table 3: hybrid approach for muscular VSD (Ventricular Septal Defect). ASD: Atrial Septal Defect. CPB: Cardiopulmonary By-Pass. Pm: perimembranous (VSD).



the empty beating heart a glued-patch was gently applied (Figure 1B) before proceeding with a routinely trans-tricuspideal both perimembranous and muscular septal defects closure.

Surgical dilatation of pulmonary branches

Concomitant surgical repair and pulmonary arteries dilatation was accomplished in nine children.

- Two former Fallot patients had their left pulmonary branch balloon-dilated and then a biological pulmonary valve implanted on a beating-heart basis.
- Three children who underwent right ventricle to pulmonary artery conduit replacement (2 Rastelli, 1 Ross-Konno) had their left pulmonary branch balloon-dilated (2) or stented (1) in the same fashion.
- One patient had a plug delivered in the pulmonary trunk by a perventricular puncture along with Fontan completion.
- Three patients with a previous "hybrid bilateral banding" had their pulmonary arteries revisited: a 3.4 Kg. transplant who suffered a tear in the right pulmonary artery and had a covered stent deployed and two patients (arch repair and Yasui) who were electively scheduled for branches dilatation at the time of band removal plus bi-ventricular repair.

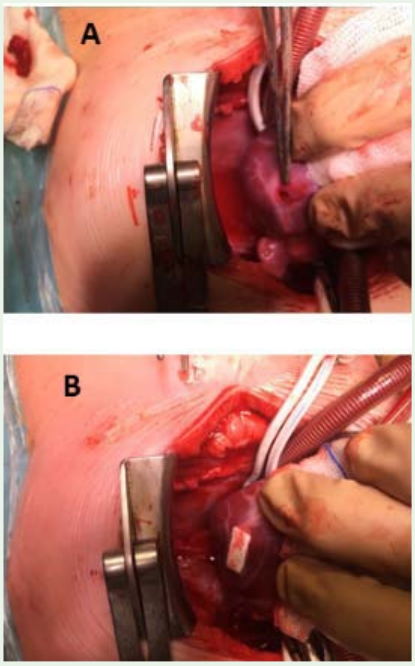


Figure 1: Perventricular closure of muscular ventricular septal defect. A: Accidental puncture in lateral wall of the left ventricle, close to a marginal coronary artery. B: Glued-patch repair of fee-wall puncture.

Melody deployment in theatre (5 cases)

- Mitral regurgitation after a switch procedure in a neonate was unsuccessfully addressed by artifitial chordal insertion and eventually treated with a Melody under cardiopulmonary by-pass and cardioplegic arrest. Unfortunately, the child died on septicemia several days later, with a well functioning valve.
- A neonate with pulmonary atresia and intact ventricular septum plus severe tricuspid regurgitation had a Melody implanted in tricuspid position, after a failed attempt of valve repair (plus conduit insertion between right ventricle and pulmonary artery).
- Two former Fallot patients presenting with residual VSD and pulmonary regurgitation had the ventricular septal defect addressed, plus a transannular Melody valve implanted (as a biological valve insertion) and balloon dilated in the pulmonary position (Figure 2).
- An infant with a right ventricle to pulmonary conduit in place was scheduled for a perventricular conduit deployment by sub-xyphoideal approach. One purse-string was stitched in the diaphragmatic right ventricle wall. The stiff wire happened to dissect the previous conduit and emergent re-sternotomy plus cardiopulmonary by-pass was instituted, ending up in a surgical conduit replacement.

Pulmonary vein stenosis

A five month-old infant with congenital left pulmonary vein stenosis was attempted to treat percutaneously twice. Transeptal approach proved unsuccessful. In the cath-lab, by midline sternotomy, a purse-string suture was fashioned in the right superior pulmonary vein (as for a regular "vent" sucker in theatre) and a sheath advanced through it. Then, a BUS absorb stent was deployed in the opposite left superior pulmonary vein under fluoroscopy.

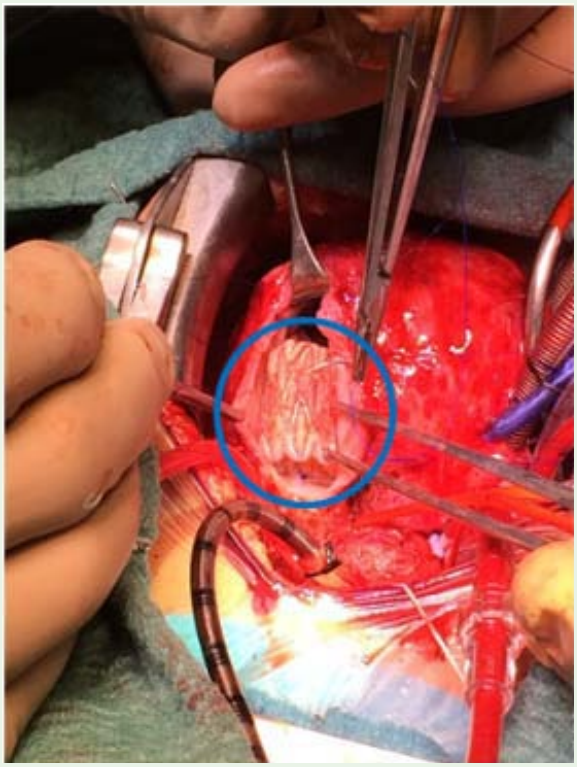


Figure 2: Surgical insertion of melody valve (blue encircled) in an arrested heart on cardiopulmonary bypass.

Discussion

Last decades have witnessed the evolution of surgical and percutaneous procedures. Hybrid approaches offer the advantages of both disciplines together [16], where neither of them achieves the desired results on their own. A minimally invasive approach can bring substantial benefits on closing a muscular ventricular septal defect in an infant, avoiding cardiopulmonary by-pass and potential vascular complications. This is an example of how to fix a simple defect expeditiously. On the other hand, for those complex cardiac conditions requiring staged surgical and percutaneous procedures, hybrid strategies can spare some of them on addressing surgeon and cardiologist the issue in a collaborative step. The partnership between surgeons and cardiologists will grow as long as the technology develops to catch the new challenges our patient's pose [17].

An ideal hybrid program would require investment in infrastructure, cross-training of surgeons, cardiologists and scrub-nurses, and reliability in each other for decision-making process. This holds particularly true when a real hybrid room is lacking, which is our case, because criteria for attempting the procedure in the cath-lab or theatre should be clear in advance.

Since its inception for the palliation of hypoplastic left heart syndrome (1), the concept of hybrid has spread even beyond the univentricular pathway. The potential applications have their boundaries in the collaborative imagination of surgeon and cardiologist, as is shown by the growing number of techniques which are depicted in recent papers [16,17]. Whether to carry out a hybrid procedure in theatre or cath-lab can be easily defined (carotid cut-down *vs* conduit replacement, e.g.) but, occasionally, the decision process is far from easy. We arbitrarily agreed to rely on X-ray or cardiopulmonary by-pass needs in order to choose the room. Interestingly, 26 patients in our cohort were hybrid-treated in the cath-lab and the remaining 25 ones were hybrid-operated in theatre. Fortunately, the two major complications happened in theatre, with a stand-by pump machine to sort them out.

First collaboration in cath-lab between cardiologists and surgeons were aimed to surgical support for vascular access. Neonates with aortic stenosis became the main target (4), for whom hybrid valvuloplasty is a straightforward procedure nowadays. The advantages of a transcarotid over a femoral artery approach has proved to shorten the length of the procedure, making it easier to cross the aortic valve. In our expierence, it achieves also better balloon stabilization during valve dilatation. Finally it preserves the femoral arteries for future transcatheter interventions, preventing vascular complications. Cumulative experience prompted us to expand the indications towards ductal stent and coarctation in neonates, as well as other custom-made approaches above mentioned.

The hybrid procedure is used in neonates with hypoplastic left heart syndrome as an alternative to the conventional Norwood when the risk is considered too high due to prematurity/low weight or other comorbidities, as in our 10 patients. Any comparison between

Norwood and hybrid palliation is skewed, since the latter group gathers patients not amenable to Norwood and, hence, at a higher risk [18]. Like in other studies [2,6,18] around 20-30% (three out of ten of our patients) needed a second (or more) visit to the cath-lab for inter-atrial or ductal stenting. Beyond an alternative to Norwood I as a first stage of univentricular repair, the hybrid procedure is emerging as a palliation for other forms of complex left heart lesions so as to increase the chances of a biventricular repair [7,8] or even a transplant (Table 2). This is the case in our short series, where three of four patients ended up in biventricular physiology (Ross-Konno, Yasui and arch surgey) and only one in a comprehensive repair (Shone plus mitral stenosis). On the other hand, five patients were included in the transplant list: four were successfully transplanted [15] (at one,two,four and five months of life, respectively) and one patient died awaiting a graft (necrotizing enterocolitis, at five months). The remaining patient, weighting 1.8 Kg. at hybrid procedure, underwent a comprehensive repair at four months and 3.4 Kg (he died of pulmonary hypertension, thereafter).

Regarding surgical management of ductal stent at second stage (either comprehensive, biventricular repair -whatsoever- or transplant), several groups have reported their experience in handling the stented ductus/arch [5,19,20] including deep hypothermia for thorough tissue removal and complete arch replacement along with heart transplant [15]. The prevalence of pulmonary branches intervention at the site of the previous banding is high [5,6]. Whether it is related to the span of time until next stage is accomplished remains to be elucidated, inasmuch prompt comprehensive repair is recommended when intended. We routinely balloon-dilate both pulmonary arteries after band removal since our latest three cases (Yasui, 8 month-old; and arch repair, 3month-old and transplant, five month-old).

Hybrid muscular ventricular septal defect closure in patients under 5 Kg. not amenable to percutaneous approach or needing concomitant surgical corrections has become a valid option. Albeit figures are still low, it has proved successful. Avoidance of X-ray is an advantage, because the whole procedure can be eco-guided only. For those two patients needing guide insertion in the cath-lab and then surgical repair in theatre (two-stage hybrid procedure), that option was chosen instead of moving the X-ray and the staff to theatre. That was early in our experience.

According to pulmonary arteries dilatation/stenting along with major surgical repair, our team has gained experience and confidence. Those patients can spare a visit to the cath-lab for branch ballooning/stenting either before or after surgery [10]. Interestingly, three children underwent two hybrid procedures at different stages: first, ductal stent plus bilateral banding in the cath-lab and then, angioplasty/stent of their pulmonary arteries after band removal in theatre (transplant, arch repair, Yasui).

Our experience with Melody device is scarce. Just one neonate in the mitral position, and another one in the tricuspid valve, following Boston´s report [13]. The former patient died shortly after, with a proper function of the prosthesis. The latter underwent a second hybrid approach two years later for a valve-in-valve procedure (the Melody regurgitation was likely produced by adherence between one leaflet and the cage) Off-label, we implanted a Melody in pulmonary position concomitant with residual ventricular septal defect repair in two Fallot re-do procedures (Figure 2). The rationale is to provide competence and growth potential in the pulmonary valve. One year later, both prostheses behave nicely, with no need of dilatation yet.

The hybrid procedure is not complication-free. Learning curve and range of techniques should be born in mind. Two major drawbacks have been recorded. An accidental puncture (Figure 1) in a perventricular approach [9] had no consequences because the use of cardiopulmonary by-pass was scheduled beforehand. The conduit dissection in the sub-xiphoideal approach [12] prompted us to rush and initiate cardiopulmonary by-pass, which was not intended to be used. Fortunately, both unexpected events happened in theatre, with a stand-by pump machine and ended up successfully.

Study Limitations

The present paper gathers a vast array of congenital conditions and hybrid procedures. Despite arbitrarily clustering the patients in categories alike, the authors are well aware of the difficulties in drawing any early conclusions provided the sacrcity of data in every column (Table 1).

Conclusion

Hybrid procedures can change the fate of congenital heart diseases. As a strategy, surgeon and cardiologist collaboration can reach targets unavoidable on isolation. The decision whether to perform the approach in the cath-lab or theatre depends on patient´s needs and staff reliability, until true hybrid rooms become available. Cross-training of surgeons and interventionists is advisable until fulfilling their learning curves, since all teams are considered complementary to each other.

The expectations of the hybrid methods, devised for hypoplastic left heart syndrome, have been overcome by the increasing number of indications which have been successfully applied. Bridging children to biventricular repair or transplant with the hybrid bilateral banding plus ductal stenting is becoming particularly appealing. Patients´ challenges and team imagination set the boundaries for this strategy. Equipment, training and ideas are the basis for innovation, fostering the future of cardiovascular medicine.

As a word of caution, hybrid approaches are not complication-free, Inasmuch when some procedures are custom-made and tailored to any given patient needs.

Disclosures

The authors specify that there is no financial, property or intellectual aid from any commercial source. The authors state that they had full control of the design of the study, methods used, outcome parameters, analysis of data and production of the written report.

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