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Current Advances in Transcatheter Intervention for Children Born with Congenital Heart Defects: A Review of Literature

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Abstract

This review aims to sum up the improvements witnessed in the field of interventional cardiology during recent times. The last decade has witnessed significant technical advances in the field of radiological imaging and also in interventional cardiology which has helped to offer more non-invasive solutions for the management of congenital heart defects. This has resulted from the use of advanced 3-dimensional fusion imaging instead of conventional 2-dimensional angiography, applying interactive real-time enhancement and using computed tomography and Magnetic Resonance Imaging for interventional procedures. Similarly the introduction of next generation devices, have not only improved the final outcome of the procedure but also has helped in reducing the challenges that were faced before and with the initial generation of devices. These advances have helped not only in reducing the radiation exposure, the use of contrast medium dose but also have resulted in improved early survival. The field of neonatal cardiology has advanced at an unprecedented pace. The transcatheter closure of patent ductus arteriosus has evolved over time and now it has been made possible at much lower body weight. Similarly, early use of stents for aortic coarctation has been found effective in some patients, especially when surgical intervention had been denied. The application of the hybrid approach for the management of complex congenital heart defects has also been effectively applied. More recently transcatheter placement of the pulmonary valve has been introduced for severely stenotic and/or regurgitant pulmonary valve in adolescents and adults. It is anticipated that in near future, this procedure would be available for relatively younger patients. In conclusion: last 2 decades have improvised pediatric interventional cardiology to incorporate less invasive solutions for CHD. The current advances in radio-diagnostic imaging, gadgetry and technical expertise have improved significantly and led to manage many of such defects by trans-catheter approach. This has led also, to replace the early surgical intervention with a more subtle hybrid approach, thus reducing not only the major surgical trauma but also been found to be cost-effective due to a shorter hospital stay. But a learning curve for performers is required for optimum results and also such procedures should be performed in a fully developed facility with an optimum surgical backup.

Keywords

Congenital Heart Defects, Interventional Cardiac Catheterization, Pediatric Cardiac Catheterization

1. Introduction

Pediatric cardiac interventions continue to develop fewer invasive solutions for the management of congenital heart defects, thus minimizing the use of open-heart surgery. In the past ten years, there have been significant technical advances in the management of congenital heart defects, especially in the field of diagnostic cardiac imaging and in interventional cardiac catheterization. This is the result of introducing modified and next generation devices, which have helped in improving the final outcome of the procedure and in reducing the challenges that were faced while using the pre-existing first-generation devices. This review aims to explore the major technical and procedural advances made in the field of interventional cardiology and so to sum up the improvements and changes made during the last decade or so.

Successful cardiac management improves the early survival of infants with congenital heart defects and helps them to grow into healthy adult life. Early and optimum cardiac care is required to provide all patients with congenital heart defects with equal opportunities for a healthy life. The innovation in the field of cardiac intervention has helped in better and effective management of such conditions.

Significant progress has been made in radio-diagnostic imaging, which has evolved over time from 2-dimensional angiography to 3-dimensional fusion imaging in the catheterization laboratory. In addition, preparing and conducting procedures using interactive and real-time enhancement has been made possible. The use of computed tomography and MRI for intervention in the catheterization laboratory also has helped in reducing the radiation exposure time and the use of contrast medium dose.

The field of neonatal cardiology has advanced at an unprecedented pace. Many studies have been published regarding innovative transcatheter cardiac interventions for infants and young children. The transcatheter closure of PDA during infancy has evolved over time and now with the development of new and high profile devices, duct occlusion has been made possible in younger children and at much lower body weight. Significant advances have been made in the management of critical stenoses in the same way. Early use of stents for aortic coarctation has been attempted and been found effective in certain patients with neonatal critical coarctation, especially when surgical intervention had been denied because of the critical condition of patients [1]. In this article, Arfi *et al.*, have described a follow-up of up to 15 years after stent angioplasty for critical native aortic coarctation in three newborns who were denied surgical intervention due to the presence of multiple co-morbidity factors. The surgical intervention was not required and they were doing fine till the time of reporting though multiple transcatheter interventions were required. In the same way, use of the hybrid approach for the management of complex congenital heart defects has been effectively applied especially in cases of hypo-plastic left heart syndromes, in percutaneous closure of some cases of ventricular septal defects and also in stent angioplasty of peripheral pulmonary arteries. More recently transcatheter placement of the pulmonary valve has been introduced for severely stenotic and/or regurgitant pulmonary valve in adolescents and adults. The future innovations in technology are promising to cater to the growing patient population and it is anticipated that in near future with improvement in the valve itself and in the introducing sheaths, this procedure would be available for a relatively younger group of patients.

2. Methodology

Inclusion criteria

The criterion for the selection of journals for review was laid as follows:

1) The relevant, credible and peer reviewed research journals with the high impact factor were included for review.

2) The journals available on the scientific database such as Elsevier, Springer, PubMed, and Google Scholars were selected for review.

3) Studies addressing the pediatric cardiac interventional procedures were selected for the review.

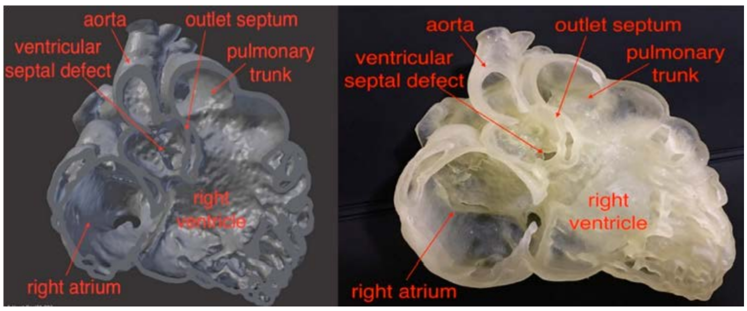
Based on the above criteria about 55 articles were selected for review. Subjective selection reduced the number to about 45. Further shortlisting was done based on the topics of special interest. At the end, about 35 articles were used for reference purposes. All of the articles were gone through thoroughly with special attention given to the methodology, the procedure. The appropriate portions were referenced as required.

3. Literature Review

3.1. Cardiac Imaging

During the past, decade the field of pediatric cardiac disorders has gone through significant advancements, and so the interventional cardiology and catheterization have evolved into major technological achievements. The modalities in cardiac imaging like Intracardiac echocardiography, real-time 3-dimensional vessel navigator, 3-dimentional roadmap, rotational angiography with holography, MRI, Transesophageal Echocardiography (TEE), and 3D printing have evolved over time and, has helped in the management of many types of complex congenital heart defects in the cardiac catheterization laboratory Another mile stone achieved has been the development and application of the Three-Dimensional Rotational Angiography (3DRA) in the cardiac catheterization laboratory. It is one of the most emerging imaging modalities. It helps in real-time attainment of a 3D volume rendering and cross-section imaging, thus aiding in the conception of the complex cardiac anatomy, and in navigation during the interventional procedures. The image attainment is performed by a rotation through an arc of the C-arm of the angiography system. The system is equipped with a flat detector CT (Computed Tomography). The volume set is used in the reconstruction of 3D structures of the point of interest, when the images are overladen onto the live fluoroscopy for road mapping during the interventional procedures. The registered 3D space is also capable of integration with the 3D datasets from the CT or Magnetic Resonance Imaging (MRI) studies [2]. The 3D-printed models thus developed carry a vital role in medical training as well as in the patient education, for cardiac anatomy's spatial conceptualization. The improvements constantly provide for the newer opportunities in the use of 3D-printed models in infants and young children with congenital heart defects (**Figure 1**) [3].

Stenger, Dittrich and Glöckler have evaluated the accuracy and utility of 3DRA during interventions for aortic obstructive lesions [5]. The study was conducted for a period of four years, starting from 2010 to 2014, when 3DRA was used in 77 patients having aortic obstructive lesions. They concluded that the use of 3DRA in patients having aortic obstructive lesions had advantage over the conventional angiography. It helped in more accurate anatomical delineation of the lesions. Three Dimensional (3D) guidances also helped in a simplified and a faster intervention with higher patients' safety and a potential in the reduction of the radiation dose. In the same context, Nguyen *et al.* did a comparative analysis of radiation exposure time with or without the use of 3DRA during trans-catheter placement of Melody valve at the pulmonary position [6]. The study was



(a) (b)

Figure 1. Comparison of virtual 3D reconstruction model (a) and 3D printed heart model (b) (Sun Z. *et al.*, 2019) [4].

conducted to test the hypothesis that 3DRA does not cause excess radiation exposure during TPV placement. They concluded that there was no statistically significant difference of radiation exposure time between 3DRA and non-3DRA assisted procedure. Major success rate has been achieved by use of 3DRA in the treatment of the obstructive lesion, including obstructive surgical conduits, acute postoperative stenoses, which had previously been resistant to the conventional interventional therapies [7].

3.2. Duct Occlusion

Trans-catheter duct occlusion has evolved over time significantly. The first-generation devices for PDA occlusion were suitable only for selected types of ducti and in certain age groups only. Subsequently more innovations were introduced in the device profiles. So many different types of devices were introduced, the delivery systems were miniaturized (**Figure 2**). This has resulted in the use of trans-catheter approach for duct occlusion in younger and younger patients. There is no sufficient data on the efficacy of Nit-occluder devices for PDA occlusion. Duct occlusion by using ADO (Amplatzer Ductal Occluder) was found to be associated with the risk of aortic obstruction. Same way transcatheter closure of PDA had been found risky in patients who had developed significant pulmonary arterial hypertension. It has been recommended suitably only for those patients who had pulmonary to systemic flow ratio of 2:1 or more [8]. Suitability for PDA closure in high risk group could also be determined by recording a significant drop in pulmonary artery pressure upon transient test occlusion in catheterization laboratory. This test occlusion has helped in selecting some more cases for trans-catheter occlusion, which initially were labeled as high risk and/or inoperable.

3.3. Hybrid Procedures

More recently, hybrid approach has been developed and now being in practice for managing some complex Congenital Heart Diseases (CHD) in children. A hybrid approach combines the traditional surgical and interventional catheterization into a single strategy. The execution of a successful hybrid procedure necessitates a dynamic and close working relationship between the surgeon and the interventional cardiologist that begins not only before but also continues throughout and even after the hybrid procedures [9]. A hybrid approach has specifically been applied for managing the patients having Hypo-plastic Left Heart Syndrome (HLHS). It is an alternative to the standard surgical procedure called Norwood palliation and involves atrial septostomy, ductus arteriosus stenting, and bilateral pulmonary artery banding [10] [11]. The Hybrid Norwood procedure, now known as hybrid Stage 1 palliation has gone through quite modifications over time (**Figure 3**), however, the three main objectives of the procedure have been same as the standard surgical approach: creation of unobstructed atrial communication, unobstructed systemic arterial blood flow, and restricting the pulmonary blood flow [12].

Figure 2. Defferent devices used for PDA closure. 1. Gianturco coils; 2. Amplatzer duct occuluder 1; 3. Amplatzer duct occuluder 2; 4. Amplatzer duct occuluder Additional Size (AS); 5. Amplatzer vascular plug II.

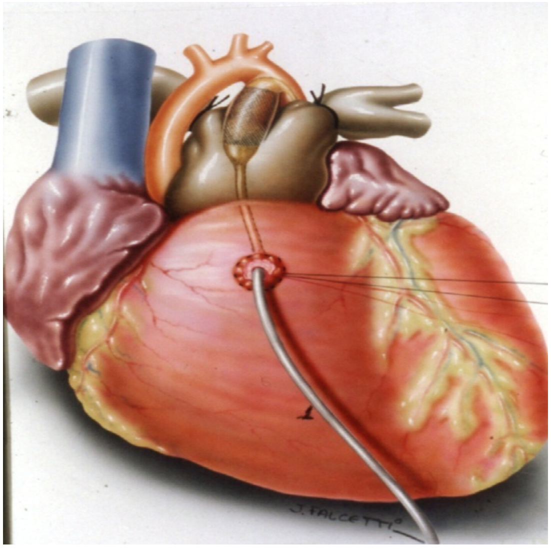


Figure 3. Hybrid Stage 1 palliation procedure surgical diagram: On the main PA, a purse-string suture is set, and a 6-Fr sheath is installed. Under fluoroscopic guidance, the ductal catheter is inserted via the scabbard, resulting in stage I palliation (Maluf Miguel: 2014) [17].

Akintuerk *et al.* in 2002 published their initial experience of the arterial duct stenting followed by the pulmonary arteries banding in cases of Hypoplastic Left Heart Syndrome (HLHS) [11]. It was the first clinical trial that showed its efficacy-in the newborns who were born with HLHS. This allowed for a combination of surgical neo-aortic reconstruction and stenting of ductus, as part of the first-stage palliation. It helped in-achieving a reduction in the distal PA pressure (< 50%) of the systemic pressure and in the systemic oxygen saturation of 80%. The study showed a survival rate of 82% through to the Stage 2 palliation of placement of bidirectional glen shunt. A modification of this method was introduced by Galantowicz and Cheatham in 2005 by performing PA banding and arterial duct stenting, thus increasing the survival to be 83% through to the Stage

3 palliation [13] [14].

Lie *et al.* has published their experience of five years of the Intraoperative Hybrid Procedure (IHP) in neonates and children having CHD [15]. The study was conducted for a period starting from 2003 to 2009 and included 152 children-younger than two years of age. It was concluded that a hybrid procedure could avoid the application of the cardiopulmonary bypass and help in the reduction of surgical trauma in young children having CHD. Haponiuk *et al.* also had published their experience of 5 years (from 2008 to 2013) of using hybrid approach. 80 children who underwent a hybrid procedure for congenital heart defects were included in the review. They concluded that application of hybrid procedures reduce the initial mortality rate as compared to open-heart surgery procedures alone [16].

3.4. Trans-Catheter Valve Implantation

The transcatheter valve implantation is one of the fastest growing innovative procedures in the field of cardiothoracic medicine in older children and adolescents. The use of currently developed devices has helped in the treatment of a large number of patients that formerly required repeated surgical intervention. The first of its prototype, The Melody® TPV (Medtronic, Inc., Minneapolis, MN, USA) was developed for percutaneous implantation at pulmonary position and was based on Philipp Bonhoeffer's prototype of a stent-mounted biological valve (**Figure 4**). Butera *et al.* studied the implications of Melody® pulmonary valve implantation from the registry of pediatric cardiology. The implantation success rates were quite acceptable. However, no definitive conclusions were drawn from the study [18]. Even though the delivery system of Melody valve was explicitly designed for use at the pulmonary position, but the Edwards Sapien valve was developed for transcatheter placement at the aortic valve position but later on its use was extended at the pulmonary valve position [19]. FDA approval in 2016 was awarded to the next-generation device, the Edwards Sapien XT Valve, for its use in the dysfunctional pulmonary artery to right ventricle conduits. A newer version of the Sapien valve by the name S3 valve has also been successfully implanted in the non-pulmonary position [20] [21]. More recently, a meta-analysis of the transcatheter pulmonary valves implantation, including both the Sapien and Melody valves, has confirmed a very high success rate of 96.2% amongst 1044 patients [22].

4. Discussion

The current advances in imaging modalities have led to better understanding of complex cardiac anatomy. Three Dimensional (3D) echocardiography, 3D printing and 3D reconstruction of MR images has played a major role in better and spatial understanding of complex cardiac anatomy not only for attending physicians but for the patients also. Same way 3DRA has also been found to have major diagnostic advantage in profiling the complexities of cardiac anatomy

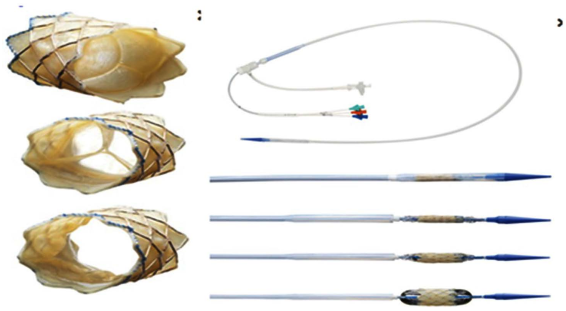


Figure 4. Showing the melody valve, the implants can be twisted down to 6 mm, placed on a BIB balloon, and re-expanded up to 18, 20, and 22 mm. A modified bovine giugular vein with valve segment sutured on Numed Platinum Iridium stent; the stent can be crimped down to 6 mm, mounted on a BiB balloon, and re-expanded up to 18, 20, and 22 mm.

from the multiple projections that enhance the appreciation of spatial vascular relationships. Many studies have reported added advantages of using 3DRA in understanding of the mechanism of pulmonary artery stenosis and in identification of additional discrete lesions. Besides, it also helps in the assessment of airways and their compression caused by vascular anomalies which are quite frequently encountered and have significant implications in clinical management [23] [24] [25]. More advances are anticipated in the image-fusion technology when ultrasonically and magnetically acquired imaging could be fused for a clearer profiling of spatial anatomy of complex lesions.

The hybrid closure of Ventricular Septal Defect (VSD) had been attempted in animal studies since late 1990s and then later on, was successfully applied in clinical practice. A puncture in the right ventricular free wall was performed via a mini sternotomy without putting the patient on cardiopulmonary bypass machine and the device was introduced and placed across the defect under fluoroscopic visualization. In ideal conditions, the hybrid interventions in patients with HLHS must be carried out in a specially made hybrid suite, with the surgeon banding both the pulmonary arteries via a median sternotomy, whereas, the interventional cardiologist would stent arterial duct via a purse-string in the main pulmonary artery. In the cases of restrictive atrial septal communication, atrial-septostomy could be performed, or a stent would be placed across the restrictive defect in the septum. Even though the hybrid approach has been known to reduce the initial mortality, however, it predictably leads to increased inter-stage mortality and a more complex second-stage palliation [12] [26] [27].

The children who are born with semilunar valve atresia present a life threatening situation and patency of the ductus is a key to maintain their life [28]. Patency of ductus needs to be maintained for a period till the patients are brought in for phased cardiac surgical repair. Aortic and pulmonary atresia are common duct-dependent cardiac lesions that present early in life and in emergency. It is critical to recognize and treat these as soon as possible in order to save their life [28].

In both children and adults, transcatheter closure of PDA has been the cornerstone of care [29]. In their study which was published in 2010, Fortescue *et al.* presented a retrospective case series of 1808 patients who underwent transcatheter closure of PDA [30]. The overall closure rate was 94 percent-nonetheless, procedure-related concerns were also reported in patients of various ages, but particularly were common in infants [31] [32] [33]. Fischer *et al.* has recommended, Amplatzer Duct Occluder (ADO) as an alternative to surgical ligation for small babies with persistently patent ductus arteriosus [31]. Further improvements in the devices and miniaturization of introducing sheaths helped in further limiting the surgical referral to very few premature newborns. Same way, coils, gel foams, septal and ductal occluders have all made a significant progress in transcatheter occlusion of various irregular vascular communications [34]. Amplatzer Vascular Plugs (AVPs) are great alternatives to other current embolization systems for medium-to-large vascular communications [35]. The majority of the current research on AVPs is based on their use in peripheral vascular anomalies. Because of their low profile, simplicity, control of distribution, and low risk of embolization, their use in various venous malformation is increasing. The use of AVPs to close PDAs is also in practice [36] [37]. Delaney, J. W. and Fletcher, S. E. evaluted the safety and efficacy of AVP II for PDA closure in 43 infants less than 4.3 kg and have 89% successful closure in labs and 100% closure in post procedural echocardiogram [38]. AVPs prove to be a more cost-effective for PDA occlusion as compared to the ADO, particularly in tubular type of PDA that had been considered to be more difficult to occlude with other duct occluder devices [38].

5. Conclusion

During the last decade or 2, pediatric interventional cardiology was able to incorporate less invasive solutions for CHD. The current advances in gadgetry and techniques used for transcatheter intervention for simple and complex congenital heart defects had improved significantly over time and had led to manage many of such defects by trans-catheter approach. The application of advanced and improved imaging modalities has led to replacing the early surgical intervention with a more subtle hybrid approach, thus reducing not only the major surgical trauma to the patient but also been found cost-effective due to a shorter hospital stay. Such procedures should be performed by expert hands and in a fully developed facility. All these have helped to increase the early life expectancy and so the chances of patients to grow to adulthood.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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