### **Original Research Article**

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### Percutaneous transcatheter intervention in a cyanotic congenital heart disease at tertiary care hospital in Western Rajasthan: a single centre experience

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#### ABSTRACT

**Background:** Treatment of congenital heart disease (CHD) is either surgical or interventional. Medical management is mainly symptomatic or palliative. Although surgery is the main mode of treatment but in the recent past non-surgical interventional method is replacing it because of its multiple advantages over surgical procedures. In this article, we report the success rate of the percutaneous transcatheter device closure procedures in our tertiary care hospital.

**Methods:** The aim of this study is to review the short-term outcome of the non-surgical interventional treatment of congenital heart diseases. We included percutaneous transcatheter device closure of atrial septal defect (ASD), ventricular septal defect (VSD), patent ductus arteriosus (PDA) and ruptured sinus of valsalva aneurysm (SVA) performed at our hospital between September 2014 and November 2016.

**Results:** We performed total 28 cases of ASD device, 3 cases of VSD device, 12 cases of PDA device, 2 cases of ruptured SVA device closures. Almost all our intervention procedures were successful except two cases of failure of ASD closure. There was no mortality and major complication related to procedures. All patients of successful interventional treatment are enjoying new life without any morbidity.

**Conclusions:** Percutaneous transcatheter device closure for suitably selected cases of a cyanotic CHDs including ASD, VSD, PDA and ruptured SVA may be an alternative, lucrative, safe and effective option with least morbidity and mortality.

Keywords: CHD, Percutaneous transcatheter intervention

#### **INTRODUCTION**

Surgical method of treatment of congenital heart disease (CHD) is an established method. But non-surgical device closure is an alternative mode replacing the surgical method.<sup>1</sup> Surgical method has more morbidity and mortality than the device closure. Surgery is subjected to complications of cardio pulmonary by pass (CPB) which not infrequently leads to perfusion injury to brain and other vital organs.<sup>2</sup> Moreover, the hazards of blood

transfusion, prolonged anaesthesia, prolonged hospital stay, psychological trauma to the patients and parents, finally the ugly scar on chest preclude the final outcome of surgical closure.<sup>3</sup> Device closure is a new mode of treatment of shunt anomalies particularly patent ductus arteriosus (PDA), ostium secundum atrial septal defect (ASD), ventricular septal defect (VSD) and ruptured sinus of Valsalva aneurysm (SVA). The era of intervention in pediatric cardiology started in 1966 by Rashkind et al with the advent of balloon atrial septostomy and by Portsman et al in 1967 with nonsurgical PDA closure by Ivalon plug.<sup>4-5</sup> Since then lot of innovations and bioengineering modifications of different devices with animal studies were done to ensure the safety and efficacy of devices for human use until 2001, when FDA has approved this method of treatment.<sup>6</sup>

ASDs constitute 22% to 30% of the cases of CHD in adults and are more prevalent among women. Closure is indicated in ostium secundum type of ASD, which show dilatation of the right chambers without irreversible pulmonary hypertension. Ostium primum, coronary sinus, and sinus venosus type ASD defects should be repaired surgically. The most widely used device in the world is the amplatzer septal occluder (St. Jude Medical). They offer the advantage of lesser incidence of erosion, a rare complication that has been observed in less than 0.05% to 0.3% of amplatzer devices and appears to be related to an oversized device or defects directly related to the aorta or left atrium. The overall success rate with complete closure of the defect is over 95%.

# Indications for percutaneous closure of atrial septal defects

According to the 2008 guidelines of the American college of cardiology/American heart association. Indications for percutaneous closure of ASDs

- Class I: Right atrial and ventricular dilatation with or without related symptoms
- Class IIa: Paradoxical embolism or platypneaorthodeoxia syndrome
- Class IIb: Presence of net left-to-right shunt with pulmonary artery pressure less than two thirds of the systemic pressure or pulmonary vascular resistances less than two thirds of the systemic vascular resistances and positive response to pulmonary vasodilators or to test occlusion of the defect.

#### Criteria for percutaneous closure

ASD with a minimum diameter >5 mm and <40 mm on echocardiographic study.

Adequate rims (>5 mm) from the defect toward adjacent structures, including superior and inferior venae cava, coronary sinus, atrioventricular valves, and pulmonary veins.

Patent ductus arteriosus is a common form of CHD. It has been estimated to occur in 1 in 2500-5000 live births. As an isolated lesion, it represents 9-12% of all CHDs.<sup>1</sup> The presence of volume overload of the left atrium and left ventricle is an indication for closure of the defect. Closure eliminates left to right shunt, volume overload of the left-sided circulation, the risk of pulmonary hypertension and the risk of infective endocarditis. Gross et al began the era of congenital heart surgery when they reported the first successful ligation of a PDA.<sup>7</sup> Masura et al had reported the use of the new amplatzer duct occluder (ADO) in humans to close the PDA by the transcatheter approach.<sup>8</sup>

## Indications for transcatheter intervention for patent ductus arteriosus

According to the 2008 guidelines of the American college of cardiology/ American heart association

- Class I: When left chambers are dilated, presence of pulmonary hypertension, net left-to-right shunt, previous endocarditis
- Class IIa: It is reasonable to consider closure of small asymptomatic ductus with transcatheter devices.

## Contraindications for interventional procedures in patent ductus arteriosus

Surgical management is preferred in cases of large ductus or with distorted anatomy that cannot be treated by means of device closure. Closure is not indicated in patients with pulmonary hypertension and right-to-left shunt.

Ventricular septal defect is the most common CHD. Muscular defects, whether congenital or acquired (caused by trauma or infarction), and postoperative and peri membranous (PM) VSD are treatable with percutaneous closure.

Transcatheter closure is an attractive option for patients with CHD who have undergone multiple surgical interventions and have a VSD or a residual VSD. Closure is indicated in patients with significant hemodynamic overload, without irreversible pulmonary hypertension and in those who have developed endocarditis.

#### Criteria for percutaneous closure

Only type IV VSD or muscular defects are subject to percutaneous closure (IIb), although there is extensive experience with type II or peri membranous VSD.

VSD following infarction for which surgery has been ruled out or in cases of postoperative residual shunt. Adequate rims (>4 mm) from the defect toward the adjacent structures, including the aortic, pulmonary, mitral, and tricuspid valves.

Rupture sinus of Valsalva aneurysm (SVA) is an uncommon condition with a wide spectrum of presentation, ranging from an asymptomatic murmur to cardiogenic shock or even sudden cardiac death.<sup>9</sup>

Although the first report of ruptured SVA was published in 1839 by James Hope it was not until 1957 that Lillehei et al reported the first successful surgical repair.<sup>10-11</sup> And since then surgical correction has become the treatment of choice. However, lately isolated ruptured SVAs have been successfully closed percutaneously using transcatheter devices.<sup>12</sup>

#### **METHODS**

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This study was carried out at department of cardiology, MDM hospital, Dr. S. N. Medical College Jodhpur, Rajasthan, India. Patients with acyanotic CHDs including ASD, VSD, PDA and ruptured SVA of both inpatient and department outpatient were scrutinized with echocardiography to find out the suitable candidate for interventional treatment. The study was carried out between September 2014 and November 2016. Since then, we performed 12 cases of PDA device closure, 28 cases of ASD device closure including one case of Lutembacher syndrome, 3 cases of VSD, and 2 cases of ruptured SVA device closures.

Cases for device closure of PDA were selected based on size and morphology of PDA determined with echocardiography and aortic angiography. More than 2.5 mm sizes were selected for device closure with amplatzer duct occluder (ADO) or Cera PDA occluder (life tech) device. For selection of size of PDA device, we added 2-3 mm more to the diameter of the pulmonary end of the PDA.

For ASD device closure, cases were selected with transthoracic and transesophageal echocardiographic assessment (TEE) of different rims of ASD for suitability of device closure as well as sizing of the defect. ASD size was measured with TEE along with colour flow mapping (CFM) and then 2-4 mm more was added for appropriate size selection of ASD. Amplazer septal occluder and Cera ASD (life tech) device occluder were used for device closure. In Lutembacher syndrome first we did balloon mitral commissurotomy (BMV) then ASD device closure.

For VSD device closure, cases were selected with transthoracic and transesophageal echocardiographic assessment with adequate rim. For PM VSD cases Cera duct occluders (life tech) were used of size12x14 mm and 14x16 mm, one muscular VSD of size 6x8 mm was closed with ADOII.

Two cases of ruptured SVAs were closed by transcatheter technique. Among them in one case right coronary sinus was ruptured in right ventricle and was closed with Cera PDA (life tech) device occluder and in other case noncoronary sinus was ruptured in right atrium and was closed by ADO. All cases were kept in hospital at least for two days following procedure for assessment of any immediate complications.

#### RESULTS

In September 2014, we performed the first device closure of PDA. Since then, till November 2016, we have performed 12 cases of PDA device closure, 28 cases of ASD device closure, 3 cases of VSD device closure and 2 cases of ruptured SVA device closure.

All PDA device closure patients have undergone successful closure of shunt without any immediate complications. None of the patient had residual shunt and significant gradient in descending thoracic aorta across device on follow up.

Table 1: Results of PDA device closure.						
o. of patients	Age (year)	Size of PDA	Size of device	Successful cases	Failed cases	Major complications

6x8-12x14mm 12 (100%)

In ASD cases, age of our patients was between 5-55 years. The size of ASD was between 12-34 mm. One case was of size 40mm. Out of 28 cases of ASD device closure including one case of Lutembacher syndrome, 26

cases (92.8%) had successful device closure without any

morbidity. Two cases were unsuccessful, one due to

4-10mm

4-37

generous size (40mm) and other due to inadequate inferior vena caval (IVC) rim. All patients were observed for two days in hospital for any immediate complication. Out of these, 26 cases were discharged after 2 days without any complications. Two failed cases were referred for surgical closure. On follow up, no patient has any residual lesion.

nil

Nil

#### Table 2: Results of ASD device closure.

No. of patients	Age (year)	Size of ASD	Size of device	Successful cases	Failed cases	Major complications
28	5-55	12-34mm	16-36mm	26 (92.8%)	2 (7.2%)	nil

We attempted device closure of two PM VSD cases and one muscular VSD case. All underwent successful closure of defect without any immediate complication. We attempted device closure of two patients of ruptured SVA. Both underwent successful closure of defect without any immediate complication.

#### Table 3: Results of VSD device closure.

No. of patients	Type of VSD	Size of VSD	Size of device	Successful cases	Failed cases	Major complications
2	PM	10mm and 12mm	12x14and 14x16	2 (100%)	nil	nil
1	Muscular	4mm	6x8mm	1 (100%)	nil	nil

#### Table 4: Results of ruptured SVA device closure.

No. of patients	Size of ruptured SVA	Size of device	Successful cases	Failed cases	Major complications
2	6-8mm	10-12mm	2 (100%)	nil	nil

#### DISCUSSION

Surgery was the only gold standard method for treating CHDs. But the recent advancements in interventional methods of treating such lesions have remarkably changed the scenario. There are a lot of advantages of interventional method over the surgical procedure particularly avoidance of cardiopulmonary bypass (CPB), prolonged anaesthesia, thoracotomy, ugly scar and psychosocial trauma to the patients and parents.

The era of intervention in pediatric cardiac patients started with balloon atrial septostomy in a patient of complete transposition of great arteries with intact ventricular septum by Rashkind et al, transcatheter closure of congenital cardiac shunt defect started with PDA closure by Portsmann et al, by Ivalon plug in 1967 followed by Rashkind et al, by Umbrella type device in 1979, Cambier et al, in 1992 started use of coils for smaller size PDA.<sup>4,5,13,14</sup> For moderate to large PDA closure, subsequently newer safer devices and easy techniques of transcatheter closure started with the advent of amplatzer duct occluder (ADO), with least morbidity. Pass et al in a multicenter study demonstrated the safety and efficacy of transcatheter closure of PDA with ADO.15 In their series of 439 attempted patients, 435 were successfully implanted ADO, 78% cases had immediate closure, which increased up to 98% after one year. They had one periprocedural death. The major events occurred in 2.3% cases, including 2 cases of embolization and 2 cases of bleeding requiring blood transfusion.

In the series of 12 cases of PDA patients, we had no death and no other complication like device embolization, intravascular haemolysis with haemoglobinuria, no obvious residual shunts and significant gradient in descending thoracic aorta across the device in echo-doppler study.

First ASD device closure was done by King et al.<sup>16</sup> Since then a lot of research and modification of design of different devices have been done. Du ZD et al published the results of multi-center nonrandomized trial on amplatzer septal occlueder (ASO) indicating the safety and efficacy of percutaneous ASD closure with respect to surgical closure.<sup>17</sup> Recently Abaci et al reported multicenter meta-analysis of 28, 142 patients who underwent ASD percutaneous device closure in 203 centers.<sup>18</sup> Peri-procedural major complications found in 1.6% cases and most common were device embolization requiring surgery. The reported significant complications of ASD device closure include cardiac perforation, device malposition, embolization, residual shunts, vascular trauma, thrombus formation with embolic events, AV valve or aortic valve regurgitation, atrial arrhythmias, infective endocarditis and sudden death.<sup>19</sup>

In our series, out of 28 patients attempted for ASD device closure including one case of Lutembacher syndrome, 26 were successful, 2 patients were unsuccessful- one due to unsuitable IVC rim and second due to generous size. We had no mortality and other major events. On short term and intermediate follow up all patients are having healthy life.

Device closure of VSD was started by Lock et al.<sup>20</sup> There are two types of amplatzer VSD devices, one for muscular defects and other for PM VSDs having unequal LV/RV disc to avoid injury to aortic valve. In both conventional methods arterio-venous loop is produced and ante grade approach via venous side is used for deployment of the device. In this method of PM VSD closure, reported incidence of complete heart block (CHB) is 1% to 5%.<sup>21</sup> But recently non-conventional use of ADO II in retrograde way for closure of PM VSD showed more promising result with no or very infrequent incidence of CHB.<sup>22</sup> We performed two cases of PM VSD and one case of muscular VSD closure with ADO II with excellent outcome.

The transcatheter technique for ruptured SVA closure was first reported by Cullen et al with a Rashkind umbrella device in 1994.<sup>23</sup> Since then, Gianturco coils, Amplatzer duct occluders, and Amplatzer septal occluders have been used for device closures of ruptured SVA.<sup>24</sup> We performed transcatheter closure of two cases of ruptured SVA by Cera PDA (Life tech) device occluder and ADO with excellent outcome.

#### CONCLUSION

Thus, in conclusion percutaneous transcatheter device closure for suitably selected cases of acyanotic CHDs including ASD, VSD, PDA and ruptured SVA may be an alternative, lucrative, safe and effective option with least morbidity and mortality.

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