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Evaluation of Safety and Effectiveness of the Floret™ PDA Occluder for Transcatheter Closure of Patent Ductus Arteriosus in Pediatric Patients

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Abstract: ***Background: Transcatherter closure of patent ductus arteriosus with PDA occluder is well-established procedure for the paediatric patients.Surgical closure of patent ductus arteriosus in paediatric patients may be problematic. Transcatheter closure of PDA using the PDA occluder has showed to be safe and effective compared to the previous methods.***
Objective: The purpose of this research is to assess the PDA occluder safety and efficacy in treating PDA in paediatric patient.
Method:An analysis of the three cases of PDA patients treated with the PDA occluder is included in this case 2 females and 1 male with 9-12 years old. The procedure was performed under fluoroscopic guidance; angiography and clinical assessment of the patients were conducted before the procedure. Medical records follow up imaging and post procedure monitoring were used to evaluate a clinical result.
Result:The PDA occluder successfully closed the patent ductus arteriosus in cases, with high success rate and no major complication. No recurrence of PDA was observed in patients. Transcatheter closure of PDA produced improvement of patient's symptoms and signs post closure and also significant reduction in heart rate and respiratory rate.
Conclusion:The PDA occulder is a safe and effective device for the closure of PDA in paediatric patients. In comparison to surgery the treatment offers a less invasive option with excellent long term outcomes. This result provide acceptance to the PDA occluder use as preferred treatment for patent ductus arteriosus, with potential to improve clinical outcomes and reduce recovery time.
Keywords: Transcatherter Closure, Patent ductus arteriosus, PDA occluder, paediatric patients.

I. INTRODUCTION

Patent Ductus Arteriosus is common congenital cardiac defect. This term is referring to a persistent gap between two main blood arteries (Aorta and Pulmonary artery) that emerge from the chambers of heart. This cardiac condition exists from birth. Typically the function of closure usually occurs within 24 to 48 hours of birth in neonates but in this condition ductus arterious does not close within 72 hours after the birth.A blood channel that connects the aorta to the pulmonary artery remains open and causes blood to flow in the incorrect direction. The heart can be strained and the body's ability to get oxygen-rich blood could be complicated by this irregular blood flow. Heart failure and pulmonary hypertension are among the consequences that might arise from patent ductus arteriosus if treatment is not received also raise the possibility of developing chronic lung disease, kidney failure and altered postnatal nutrition and growth are possible consequence of patent ductus arteriosus.(Dice james et al 2007, Cleveland Clinic. 2022,Francis et al., 2010, John Thomson) [1,2,3,4]Overall, the incidence was likely inversely related to increasing gestational age and birth weight. The data suggest that immaturity is the major determinant of the persistent patency of the ductus arteriosus.(Siassi et al., 1976) [5] PDA presents range of symptoms indicative of its presence. These include rapid breathing, dyspnea; Feeding and eating problems are common, often leading to poor weight gain or growth.(Yoo hani et al., 2017, Cleveland Clinic. 2022) [6,2]Traditional methods use for the treatment of patent ductus arteriosus occlusion like medication such as ibuprofen and indomethacin can help close the PDA in newborn by contracting the muscles in the ductus wall.(Van overmeire et al., 1997)[7] However, this type of medication may cause side effects, so not all infants receive them. Alternatively, PDA can close through open heart surgery using PDA ligation. The surgical option carries higher risks and requires a longer recovery time for infants.(Demir et al., 2007) [8]
The present study designed for the treatment of PDA using transcather closure with occulder device, as it is safe, minimally invasive procedure as well as cost effective and offers considerable advantages over the surgical ligation including shorter recovery time and a comparable success rate to surgery.

(Elsheikh et al.,2015, Chen et al.,2009)[9, 10]Meril has innovated the Patent Ductus Arteriosus Occluderfor the closure of normally located patent ductus arteriosus independent of shape or size.Treatment is feasible for the very young pediatric population.(Minocha 2017) [12]

This condition can lead to complications such as pulmonary overcirculation, congestive heart failure, and an increased risk of endocarditis if left untreated.Historically, surgical ligation was the primary treatment modality; however, advancements in interventional cardiology have established transcatheter closure as the preferred approach, particularly in pediatric populations, due to its minimally invasive nature and reduced recovery times. (Thomson 2023)[13]

The Floret™ PDA Occluder, developed by Meril Life Sciences, represents a novel device designed for percutaneous transcatheter closure of PDA. Constructed from braided nitinol wire mesh, the device features cylindrical plug architecture with three integrated polyester fabric inserts. These inserts facilitate occlusion and promote endothelialization, ensuring effective and durable closure of the ductus arteriosus . The device is available in various sizes, accommodating a range of ductal anatomies and patient sizes, including very young pediatric patients.(Meril 2025)[14]

Preclinical evaluation of the Floret™ PDA Occluderwas conducted in 3 male pigs using a porcine carotid artery model to assess its safety and efficacy. In this study, the device demonstrated successful deployment, with no instances of migration or residual flow observed. Histopathological analyses at intervals of 90, 180, and 365 days post-implantation revealed progressive endothelialization over the device surface, indicating favorable integration with the vessel wall.(Kumar Minocha et al., 2024)[15]These findings suggest that the Floret™ PDA Occluder is a promising tool for transcatheter PDA closure in pediatric patients, offering a safe and effective alternative to surgical intervention.(Neeraj et al., 2024)[16]

Ductus arteriosus vessel, which connects the aorta and pulmonary artery, is essential during fetal development as it allows oxygen-rich blood from the mother to bypass the lungs. Typically, it seals off soon after birth, but when it remains open, or “patent,” it can lead to excessive blood flow to the lungs. This abnormal flow increases the workload on the heart and lungs, potentially causing symptoms ranging from mild to severe depending on the size of the duct. (Gillam-Krakauer et al., 2023)[17]

PDA is most prevalent among premature infants, with studies indicating that approximately 65% of babies born before 28 weeks’ gestation are affected. It is less frequent in full-term infants and appears to occur more often in females. The exact cause is still not fully understood, though risk factors may include genetic conditions, family history of heart disease, intrauterine infections like rubella, and maternal behaviors such as smoking or medication use during pregnancy. (Mayo Clinic 2018)[18]

The symptoms of PDA vary with the size of the ductus. Small PDAs may be asymptomatic, while larger ones can cause labored breathing, recurring respiratory infections, a noticeable heart murmur, difficulty feeding, and poor growth. Healthcare providers typically detect PDA soon after birth through physical examination and diagnostic tests such as echocardiography or electrocardiograms, which help visualize the heart and assess electrical activity.(Forsey et al., 2009)[19]

Treatment depends on the severity of the condition. In some cases, especially when symptoms are mild, the ductus may close on its own over time. Medications like indomethacin or diuretics may be prescribed to assist closure or manage symptoms. However, persistent or larger PDAs often require intervention. The preferred method is catheter-based closure, a minimally invasive procedure where a small device is inserted through a blood vessel to seal the duct. In more severe cases, particularly those involving large PDAs or when catheterization isn't feasible, open-heart surgery may be necessary.(Kunal Mahajan et al., 2023) [20]

If left untreated, PDA can lead to serious complications such as heart failure, pulmonary hypertension, fluid accumulation in the lungs, or endocarditis, which is an infection of the heart lining. However, with timely and appropriate treatment, most children recover fully and lead normal, active lives. Follow-up care with a cardiologist is essential during childhood and sometimes into adulthood to monitor heart health. In rare instances, additional surgery may be needed if the PDA reopens later in life.(Bloomet al., 2023)[21]

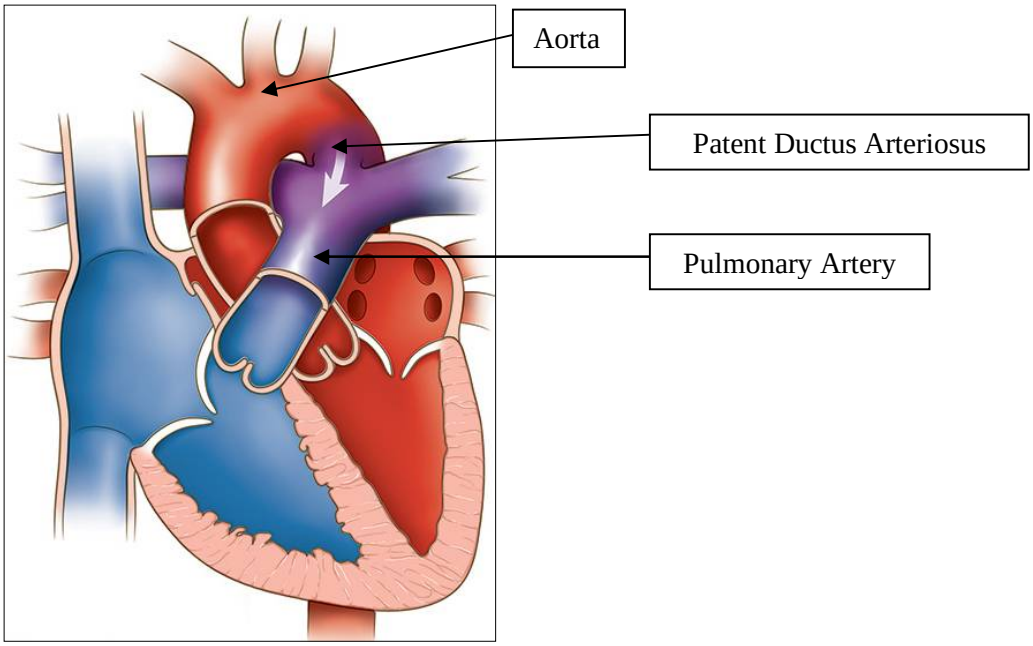

Figure 1: Patent Ductus Arteriosus(Pediatric Echocardiography 2015)[11]

II. LITERATURE REVIEW

Interventional closure of the arterial duct has evolved in 1939 whenGross and Hubbard reported the first case closed by surgical ligationthrough thoracotomy after that various techniques have developeduntil the pioneer of transcatheter occlusion of PDAwho reported the first case using a conical Ivalon plug in 1967 sincethat transcatheter occlusion has become the treatment of choice formost patent ductus in children and adults with the development of techniques and occluder

Percutaneous closure of PDA has been performed for more than 30 years with several generations of devices and is the preferred mode of therapy worldwide, it has largely replaced surgical ligation in different age groups and become the treatment of choice at many institutions, since it is safe as well as cost –effective and offers considerable advantages over surgical ligation.

The Studies conducted by various authors have significant advanced the understanding and application of the Transcatheter Patent Ductus Arteriosus Closure in Children with the development of Transcatheter interventional technique. Transcatheter closure interventional techniques establish as the first line treatment for PDA in Children. The focus on the effectiveness and safety of occluder devices used for Transcatherter PDA closure with long term outcomes.Device achieved excellent occlusion rates with low complication rates(Yıldız et al., 2023).[22]

Closure of patent ductus arteriosus in children, small infants and premature babies with Amplatzer duct occluder, Study shows that closure of medium and small sized PDA by using Amplatzer duct occluder device is effective and safe in children(Metin Sungur et al., 2013).[23]

III. MATERIALS AND METHODS

Materials Required

- Introducer sheath
- 0.035inch guide wire
- Contrast diluted 1:1with normal saline
- Inflation device
- Three-way stopcock
- Guide Wire Introducer

IV. SIMULATION TEST

Acceptance criteria: Patent ductus arteriosus occluder shall be positioned correctly at the intended location, without any damage.

The in vitro heart Simulation was conducted using a mimic realistic heart model physiological and mechanical situation to analyze device performance, safety and efficacy before use in the clinical study. The PDA occluder used to Transcatheter device designed for percutaneous closure of Patent Ductus Arteriosus. In vitro heart Simulation test performance to ensure PDA occluder shall be positioned correctly at the intended location, without any damage.In this test a total thirty sterile samples of size were taken for visual inspection and Dimensional verification.The PDA occluder was successfully positioned at the target location within the heart model while the device demonstrated stable fixation without migration or displacement during and after deployment with no evidence of mechanical damage.

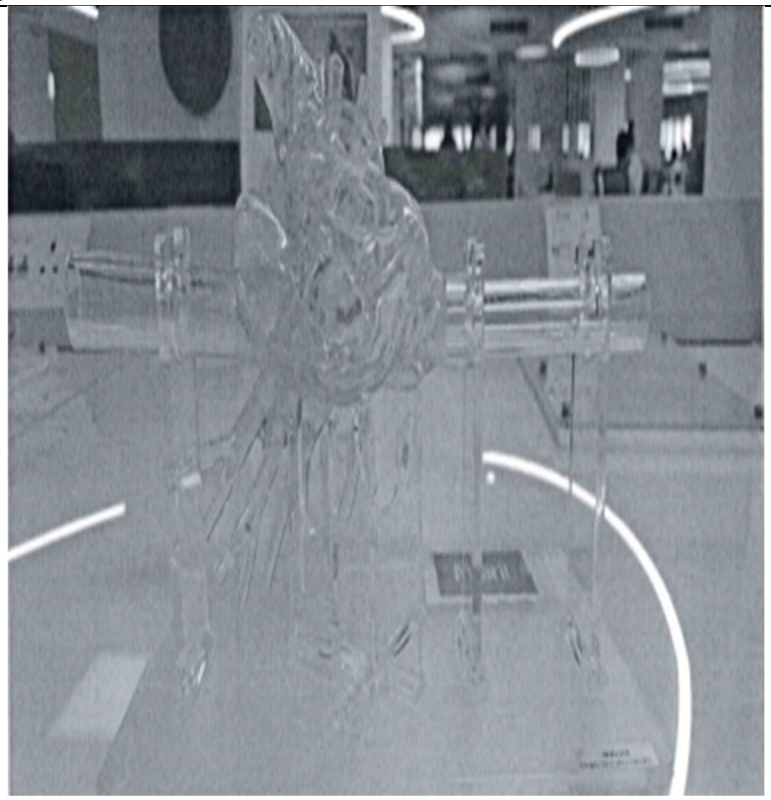

Figure 2: Photograph showing the test set up Simulation Model

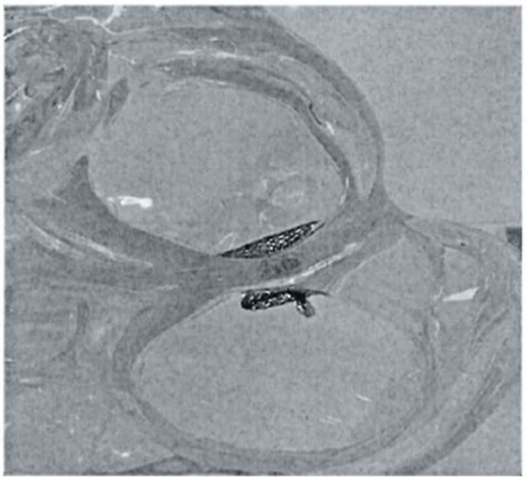

Figure 3: Photograph with insertion of Patent Ductus arteriosus Occluder (4mm x 6mm x 6F) into Simulation Model

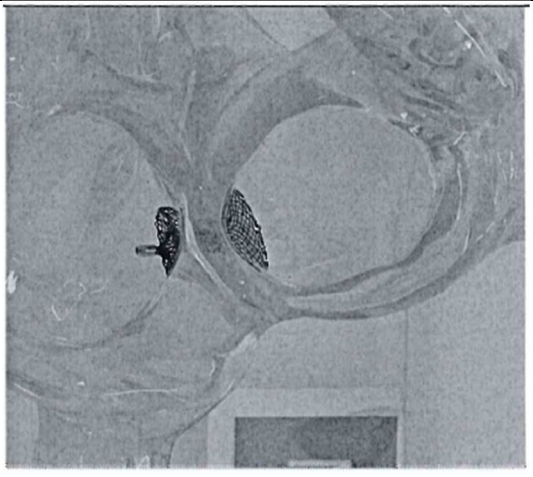

Figure 4: Photograph with insertion of Patent Ductus arteriosus Occluder (8mm x 10mm x 7F) into Simulation Model

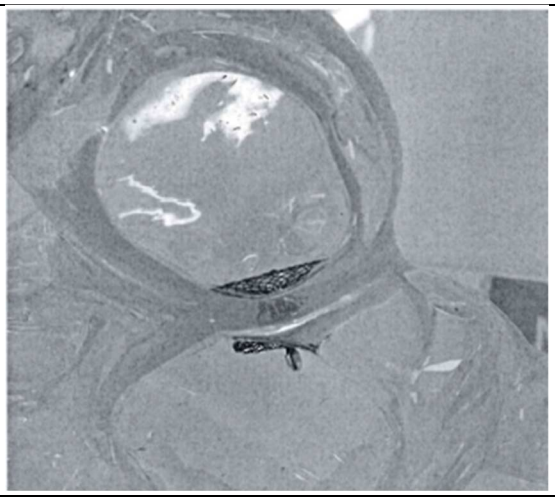

Figure 5: Photograph with insertion of Patent Ductus arteriosus Occluder (14mm x 16mm x 8F) into Simulation Model

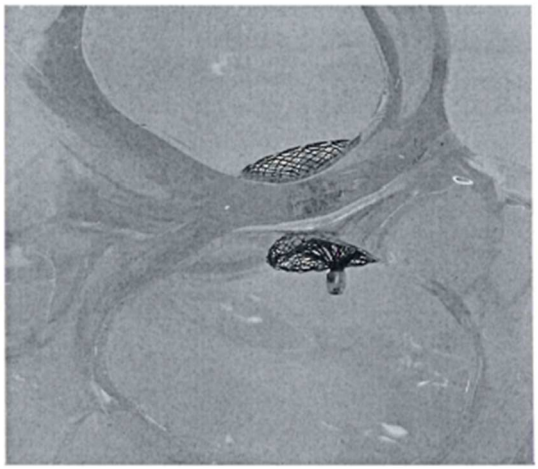

Figure 6: Photograph with insertion of Patent Ductus arteriosus Occluder (16mm x 18mm x 9F) into Simulation Model

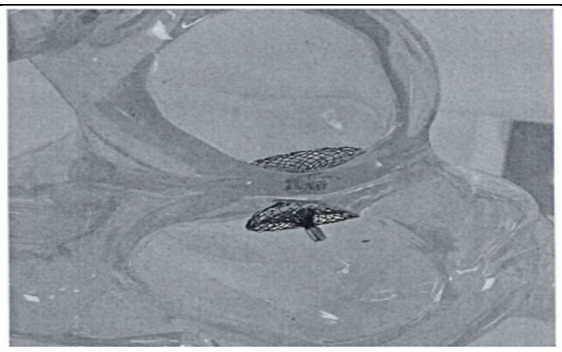

Figure 7: Photograph with insertion of Patent Ductus arteriosus Occluder (18mm x 20mm x 10F) into Simulation Model

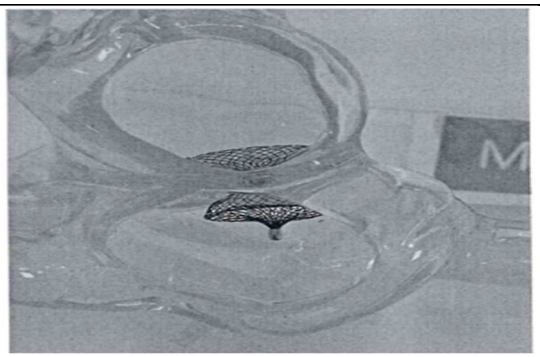

Figure 8: Photograph with insertion of Patent Ductus arteriosus Occluder (22mm x 24mm x 12F) into Simulation Model

V. DIAGNOSIS METHODS

Diagnosing a Patent Ductus Arteriosus (PDA) involves employing various diagnosis tests including Chest X-ray, Echocardiogram (heart ultrasound) and Electrocardiogram (ECG). These tests help healthcare professional assess the presence and severity of the condition. During the implantation procedure, angiography is used to detect the measurement of the duct and demonstrate the anatomy, while fluoroscopy is used throughout the procedure to ensure visibility of the device such as placement of device, ensuring accurate positioning and no residual shunting.

VI. DESCRIPTION OF PATENT DUCTUS ARTERIOUS OCCLUDER

The Patent Ductus Arteriosus (PDA) Occluder is a self-expanding implant made of Nitinol wire mesh which has super-elastic and flexible properties. It has a mushroom shape, with a broad disk on one end and a narrower stem on the other. The device features a primary jacket to hold the wire, a secondary jacket for system attachment/detachment, PET fabric to enhance closing ability, and polyester sutures to secure the fabric to the occluder frame.

Table 1: Technical specification of the Patent Ductus Arteriosus Occluder

Occluder structure	Nickel Titanium Alloy which is design with braiding technology
Mechanical Properties	Super-elastic and flexible
Deployment Method	Self-expanding via manual deployment

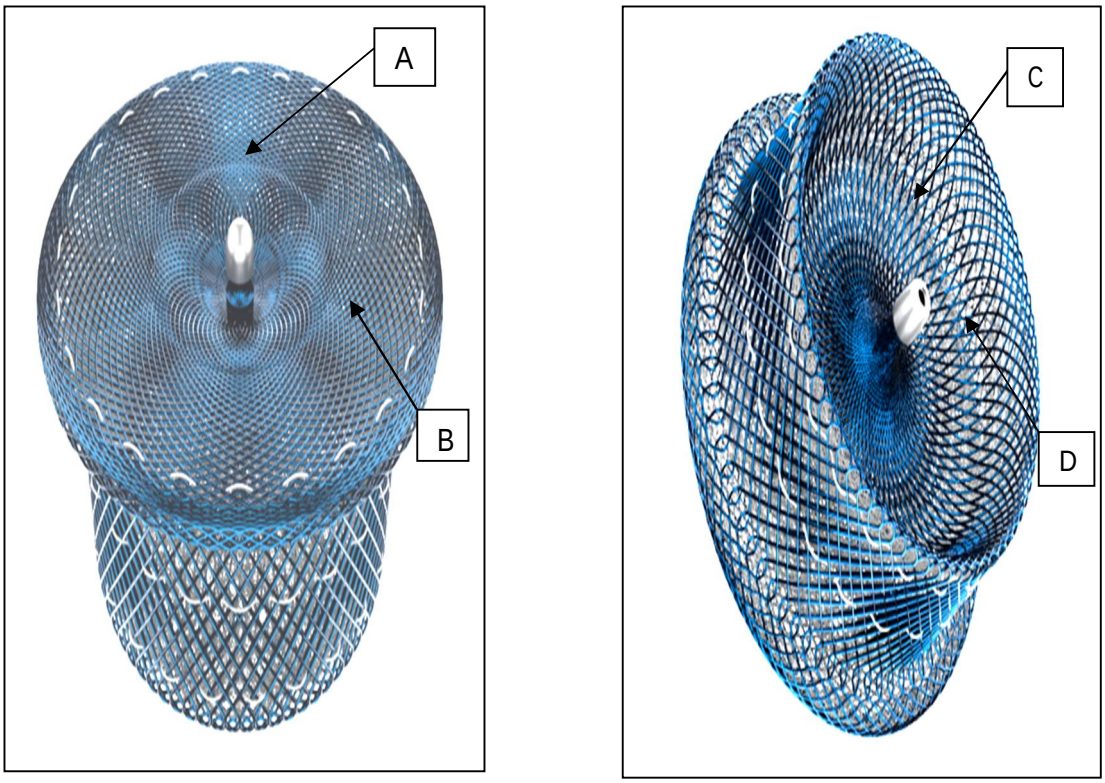

Figure 9: Patent Ductus Arteriosus Occluder

Illustrated the key component of the PDA Occluder A is Primary Jacket, B: Polyster Suture
C: Secondary Jacket, D: Nitinol Wire

VII. IMPLANTATION PROCEDURE

Firstly the hemodynamic evaluation was done. Under the general anaesthesia, the implantation procedure of PDA occluder was carried out by accessing the arterial circulation i.e. femoral artery was using seldinger technique. Heparin/kg was administered after gaining artial access. After that, an angiogram was performed to demonstrate the morphology and size of PDA. Select a device at least 2mm larger than ductus. Then began the procedure catheter was passed through the patent ductus arteriosus and introduce an exchange 0.035inch guidewire was pass through the catheter. Then catheter removed and 856mm of delivery sheath with the inner diameter of 2.16- 4.83 mm were placed over the guide wire. In addition to this, passed the delivery cable through 135mm of loader with an inner diameter of 2.05-4.7mm and placed the occluder at the tip of delivery cable. The loader and device were passed through the saline solution before the device was pulled into the loader. Introduce loader into delivery sheath and PDA occlude was deployed at targeted site; this action was confirmed by fluoroscopy.

VIII. CASE REPORT

1) Case 1

In this case, 9 year old male patient whose was diagnosed with Patent Ductus Arteriosus (PDA) had undergone treatment for the gap between the aorta and pulmonary artery. The patient has developed symptoms such as rapid breathing, dyspnea which is shortness of breath, irregular blood flow and pulmonary hypertension. To select the size of patent ductus arteriosus, angiography was performed, enabling precise measurement of the ductus. Based on this measurement an appropriate size of occluder was selected for intervention, with the chosen device being 2mm lager than the diameter of the PDA to ensure effective closure. For this patient 6-8mm occluder was selected for the procedure. The patient was follow up after the procedure, showed a significant improvement of patient.

Fluoroscopy Image

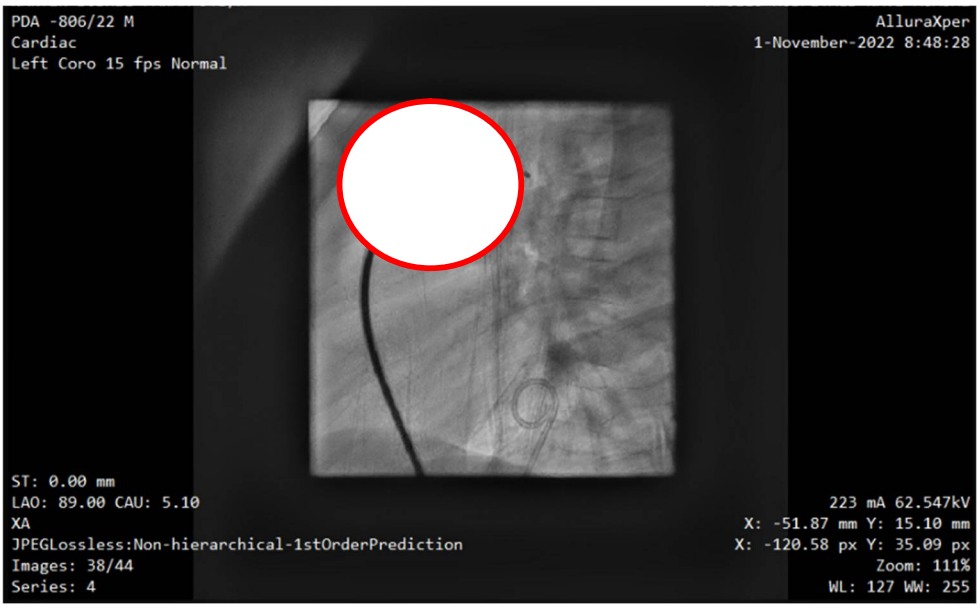

Figure 10: Deployment of Patent Ductus Arteriosus Occluder

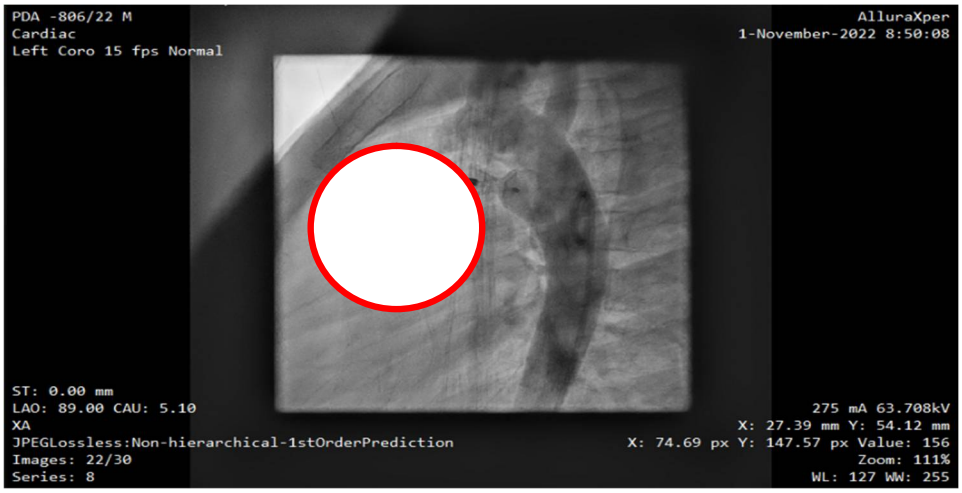

Figure 11: Regulate blood flow after the deployment of PDA occluder

2) Case 2

In the second case, the female patient, who is around 9 years old, was diagnosed with Patent Ductus Arteriosus. The patient present with symptoms such as dyspnea,irregular blood flow, and rapid breathing. Angiography was conducted to accurately measure the size of patent ductus arteriosus. Using this measurement, an occluder 2mm lager than the PDA diameter was chosen to ensure effective closure. For this patient, a 4-6mm occluder was selected. Post-procedure follow-up showed significant improvement in the patient condition.

Fluoroscopy Image:

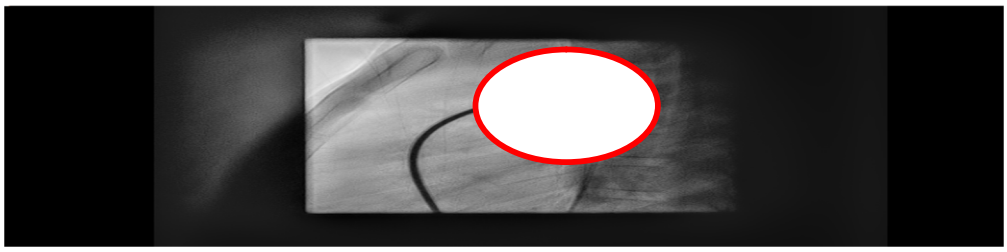

Figure 12: Deployment of Patent Ductus Arteriosus Occluder

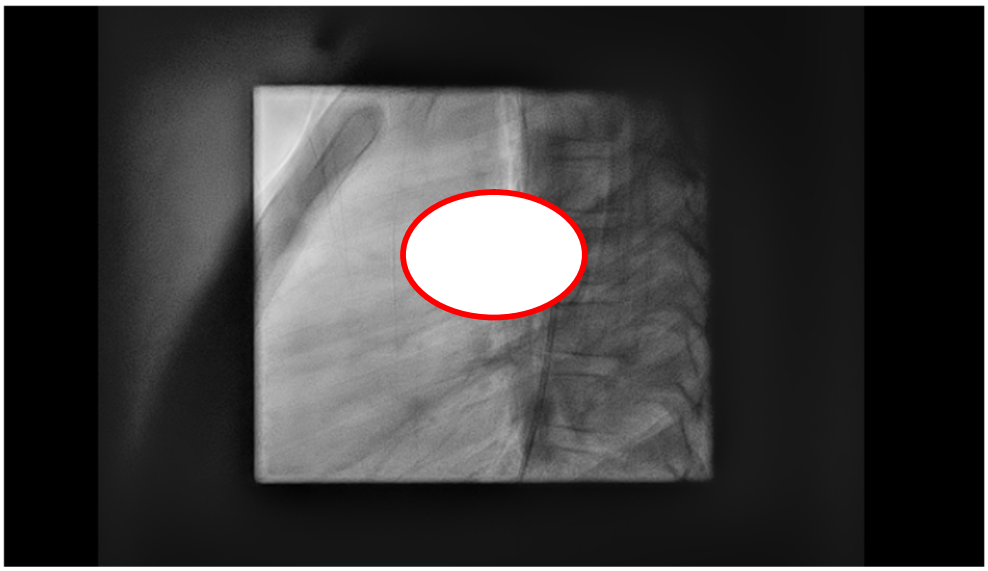

Figure 13: Successful Deployment of Patent Ductus Arteriosus Occluder in Targeted Area

3) Case 3

In the third case, 12 year old female patient was diagnosed with patent ductus arteriosus with symptoms of irregular heartbeats, shortness of breath, sweating while feeding, and pulmonary hypertension. Angiography was performed to assess the anatomy of a heart and measurement the size of patent ductus arteriosus. Based on this measurement an appropriate size of PDA occluder was selected for the intervention. For this patient 8-10mm PDA occluder was selected for procedure. The patient was follow up after the procedure, showed a significant improvement of patient.

Fluoroscopy Image:

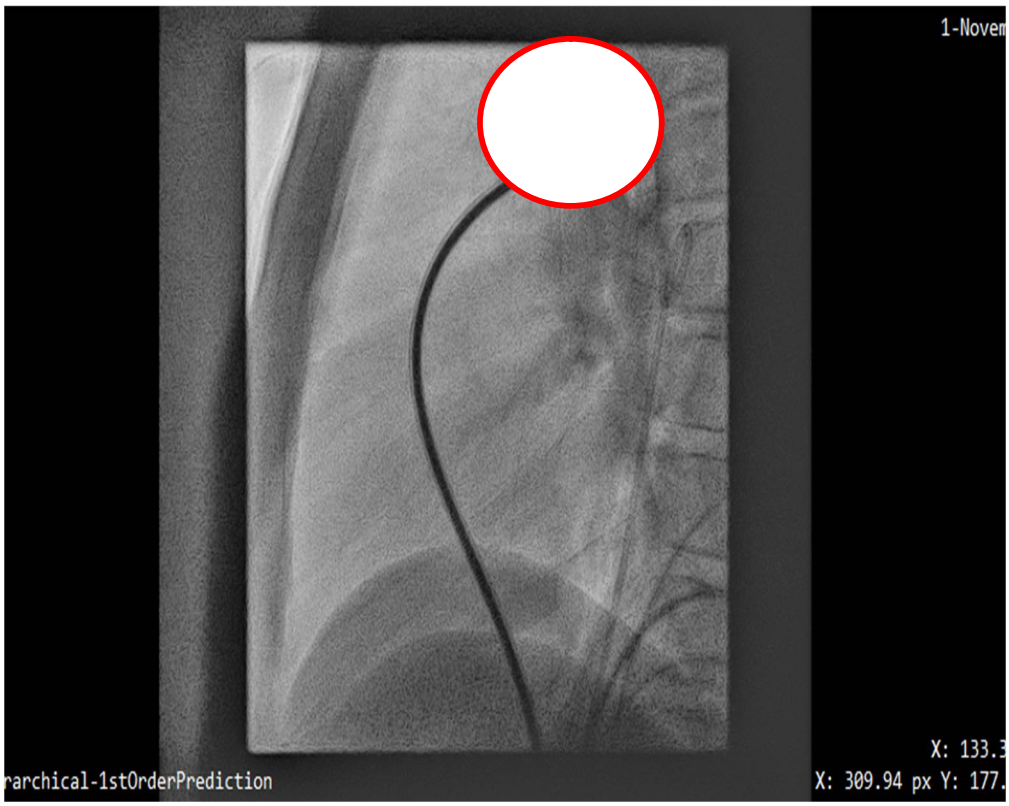

Figure 14: Deployment of Patent ductus arteriosus Occluder

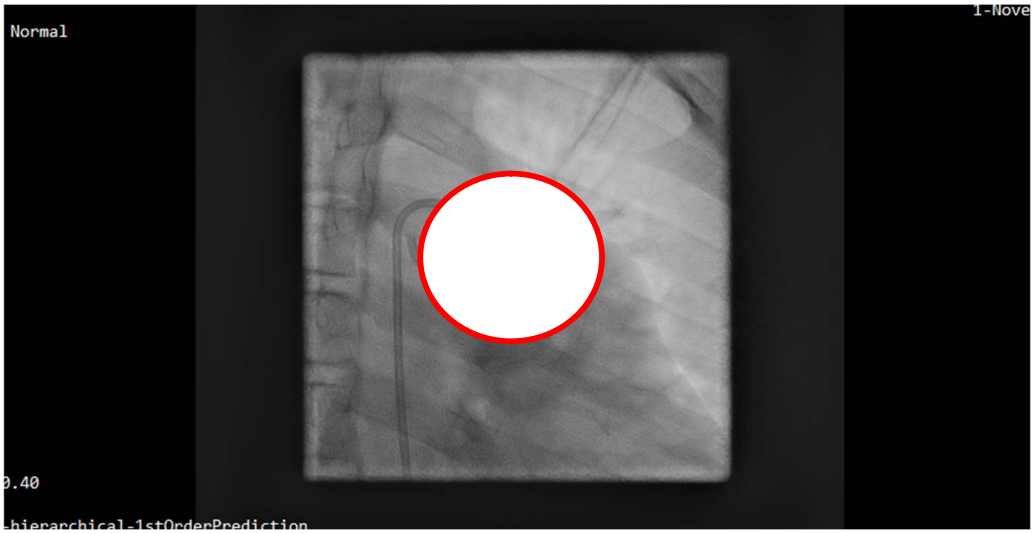

Figure 15: Successful Deployment of Patent ductus arteriosus Occluder in Targeted Area

IX.OUTCOMES

Treatment of Patnet ductus arteriosus(PDA) using a PDA occluder device has shown excellent outcomes both clinically and procedurally. The transcather closure with PDA occluder approach produced more successful closure of patent ductus arteriosus with high success rate and no major complication. This was minimally invasive and effective alternative to surgical closure for the treatment of Patent Ductus Arteriosus (PDA). While the Transcatheter closure of PDA has been proven to be effective and safe, no several complications occurred such as embolization, narrowing of the LPA, aortic obstruction, hemolysis and infective endocarditis after the procedure. In general, the complication rate of Transcatheter closure of PDA is low.

X. RESULT

The PDA occluder successfully closed the patent ductus arteriosus in cases, with high success rate and no major complication. The In vitro test the Patent ductus artreiosus occluder meets the acceptance criteria of the simulation test. Thus patent ductus arteriosus occluder passes the simulation test additionally an Angiography at the end of the procedure showed complete occlusion in 3 patients. Before and immediately after release of the PDA occluder an aortogram was performed to evaluate the position of the device, residual shunt and aortic obstruction and No recurrence of PDA was observed in patients.

Transcatheter closure of PDA produced improvement of patient's symptoms and signs post closure and also significant reduction in heart rate and respiratory rate. All the patients have complete transthoracic echocardiographic evaluations prior to discharge. The evaluations were performed at 1 month, 6 months and 12 months after the procedure. Overall the PDA occlusion rate in our study was as high as 98.1% after the short-term, mid-term and long term follow-ups.

XI.DISCUSSION

Transcatherter closure of patent ductus arteriosus with PDA occluder is well-established procedure for the paediatric patients. Surgical closure of patent ductus arteriosus in paediatric patients may be problematic. Transcatheter closure of PDA using the PDA occluder has showed to be safe and effective compared to the previous methods.

The condition of Patent Ductus Arteriosus (PDA) has evolved since 1938, when Robert Gross first reported successfully closing a PDA via surgical ligation. While pharmacological therapy with indomethacin or ibuprofen is frequently used to encourage ductal constriction and close the PDA in neonates, the use of these medications is limited in some newborns due to potential side effects such as gastrointestinal problems and renal failure. In cases where pharmacological treatment is inappropriate or ineffective, PDA ligation may be employed as a surgical option. Although this procedure, which requires a thoracotomy to access the heart, is generally successful, it carries risks including infection and extended recovery, with infants typically requiring intensive care and prolonged hospitalization.

The Percutaneous close of a PDA is a well established technique that has low incidence of complication. In the cases 9 year old male patient with patent ductus arteriosus was subjected to transcartheter closer of the duct with PDA Occulder.

Complete history, clinical examination and echocardiography data was obtained before and after closure. The procedure was carefully carried out through the femoral artery using the seldinger technique to reach the targeted site. This careful approach allowed for the reducing the risk complication.

The Patient with PDA who was underwent percutaneous closure of duct showed significant improvement of clinical status and asymptomatic during follow up periods. The successful outcome of this case highlights the effectiveness and safety of using PDA occluder for the percutaneous occlusion of patent ductus arteriosus. Transcatheter closure has become the main approach for most PDA closures as it has lower complications and shorter hospital stay when compared to the surgical approach.

This method offers a less invasive compared to the surgical method, resulting in less pain, faster recovery and low complication. The ability to select the specific size of occluder for the duct is also improves the success and long term results of the procedure.

However, treating patent ductus arteriosus with a PDA occlude, it is important to consider factor such as the size, of ductus as well as the patient overall health, to ensure the significant outcome. Additionally, post –procedure monitoring and follow up imaging are crucial to confirm that the occluder has successfully closed the ductus and to detect any potential complications or recurrence of the condition.

XII.CONCLUSION

Percutaneous Transcatherter PDA occlusion in preterm infants is feasible and showed positive short –term and long-term effects, the transcatheter closure of patent ductus arteriosus results in marked improvement of clinical and hemodynamic status of the patient. Percutaneous closure of PDA show is safe and effective procedure achieving high occlusion rate in younger population with small to moderate size of patent ductus arteriosus with no complications. The findings from our study showed that Transcatheter closure of PDA with PDA occluder was very efficient and safe when used inPediatric patients with excellent and satisfied short-term, mid-term and long term results. The minimal incidence of complications and residual shunts makes this device ideal for the Transcatheter closure of patent ductus arteriosus in pediatric patients..

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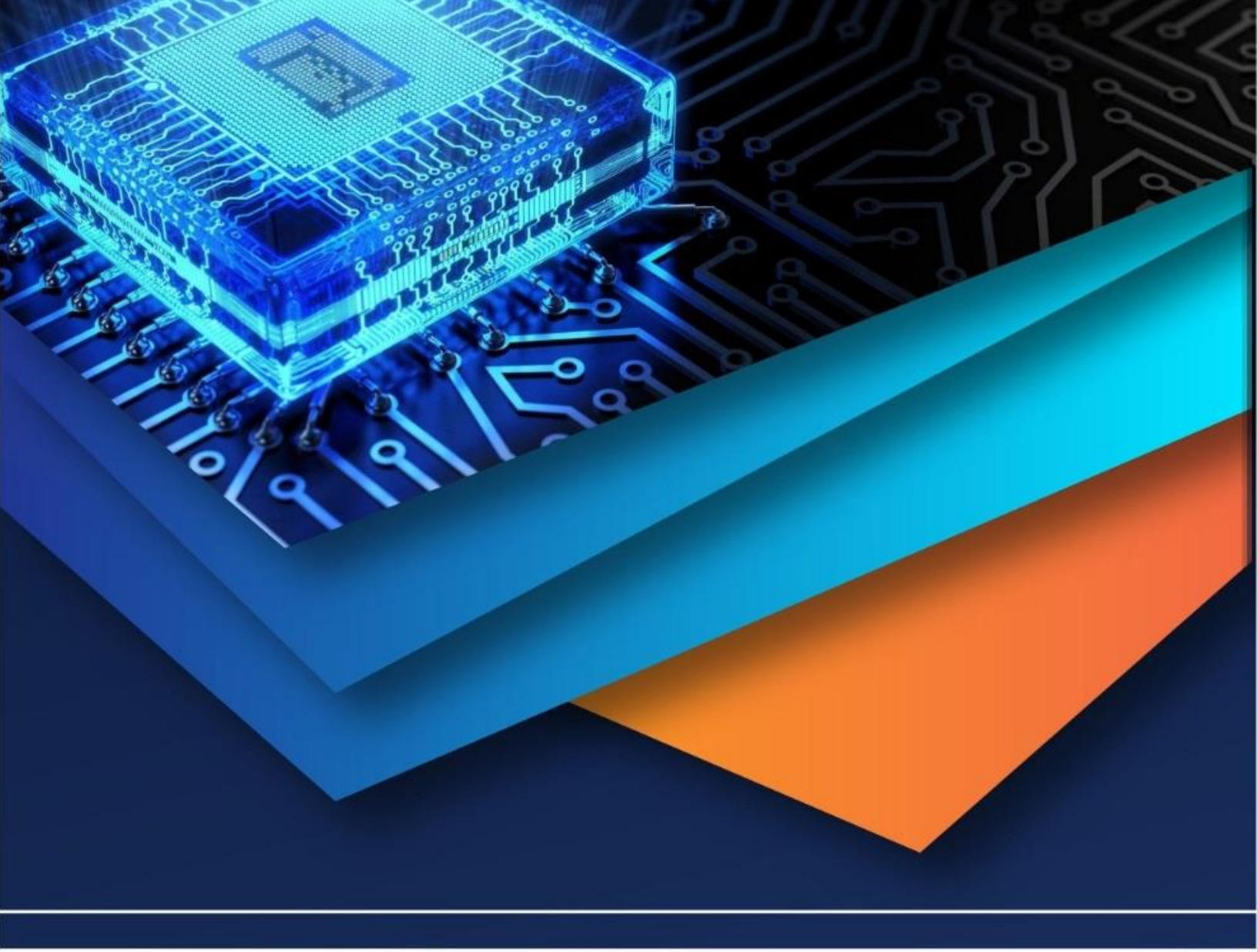

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