Clinical Case Study on Assessing the Safety and Efficacy of the Atrial Pressure Controller Device in Symptom Management for Patients with Pulmonary Arterial Hypertension and Heart Failure

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Abstract:- Objectives: To assess in retrospect the safety and effectiveness of atrial pressure controller device for symptom management in patients with pulmonary arterial hypertension and heart failure.

Methods: The study involved 14 patients (4 males, 10 females) with a mean age of 65 years (range 50-80 years old). All had a history of chronic heart failure (NYHA class III-IV). Baseline atrial pressure ranged from 18 to 25 mmHg (mean 21 mmHg). Co-morbidities included hypertension (10 patients), diabetes (7 patients), and previous myocardial infarction (4 patients), were treated with AFR with fenestration diameters of 8 and 10 mm, with device diameter is 21 or 23 mm and the distance between the LA and RA discs being 5 and 10 mm, respectively. Device requires a delivery system of 12 and 14 Fr.

Results: Study included 14 patients (4 male, 10 Females) with a mean age of 65 years (range 50–80 years), all with heart failure (NYHA class III–IV). Baseline atrial pressure ranged from 18 to 25 mmHg (mean 21 mmHg). Hypertension, diabetes, and a history of previous myocardial infarction were common. The mean study time was 45 minutes. Mean atrial pressure decreased from 21 mmHg to a maximum of 14 mmHg, after transplantation ($p<0.01$). Twelve patients reported a 30% reduction in symptoms and a 30% improvement in quality of life (QOL). The device-maintained target pressure (12–16 mmHg) in 13 patients. Minor complications included cardiac arrhythmias, which resolved without complications in three patients. There were no signs of infection or migration. After 6 months, 13 patients had improved stress management and decreased symptoms. In one patient, symptoms recurred after 4 months and he was treated with medication. There were no deaths.

Conclusion: The implantation of the ThoroughFare™ Atrial Pressure Controller is important in patients with severe idiopathic pulmonary hypertension and requires collaboration between pulmonologists and cardiologists due to its complexity. A good cardiac assessment suggests surgery in conjunction with other methods to resolve problems such as paddle advancement and septal puncture. Post-implantation evaluation using imaging and hemodynamic testing ensures that the device is functioning, and the patient is stable. Follow-up studies have shown that the device is effective, reduces cardiac chamber load, improves hemodynamics and reduces symptoms. The device is safe for all ages and genders, meets the needs of the treatment and permanently improves the management of the treatment.

Keywords: Pulmonary Artery Hypertension, Idiopathic Pulmonary Artery Hypertension, Interatrial Shunt, Atrial Flow Regulator.

INTRODUCTION

Pulmonary arterial hypertension (PAH):

Pulmonary hypertension (PH) is a disease in which blood pressure rises in the pulmonary arteries and the right side of the heart. In pulmonary arterial hypertension (PAH), the arteries in the lungs narrow, become blocked, or widen, causing low blood pressure and high blood pressure. Over time, this condition weakens the heart, leading to muscle weakness and potential failure; this can become life-threatening as the disease progresses. There is currently no cure for pulmonary hypertension, but the goal of treatment is to control symptoms, improve quality of life, and prolong life. Symptoms of PH gradually worsen over time and include shortness of breath during exercise and later at rest, yellow or gray skin due to low oxygen, pain on pressure, dizziness, weakness, and rapid pulse, weakness, swelling in the ankles, legs, and stomach. Diagnosis involves identifying risk factors that may include genetic

factors, heart and lung disease, blood clots, and certain medications or illegal drugs. Complications of PH include enlargement and failure of the right side of the heart, increased risk of blood clots in the lungs, abnormal heart rhythms, bleeding in the lungs, and serious problems during pregnancy [1-2].

Risk factors for developing lung disease include age, family history, obesity, smoking, and exposure to asbestos, certain heart conditions, or living at high altitude. Ongoing care and support are critical to improving outcomes and quality of life for people with pulmonary hypertension [1-2].

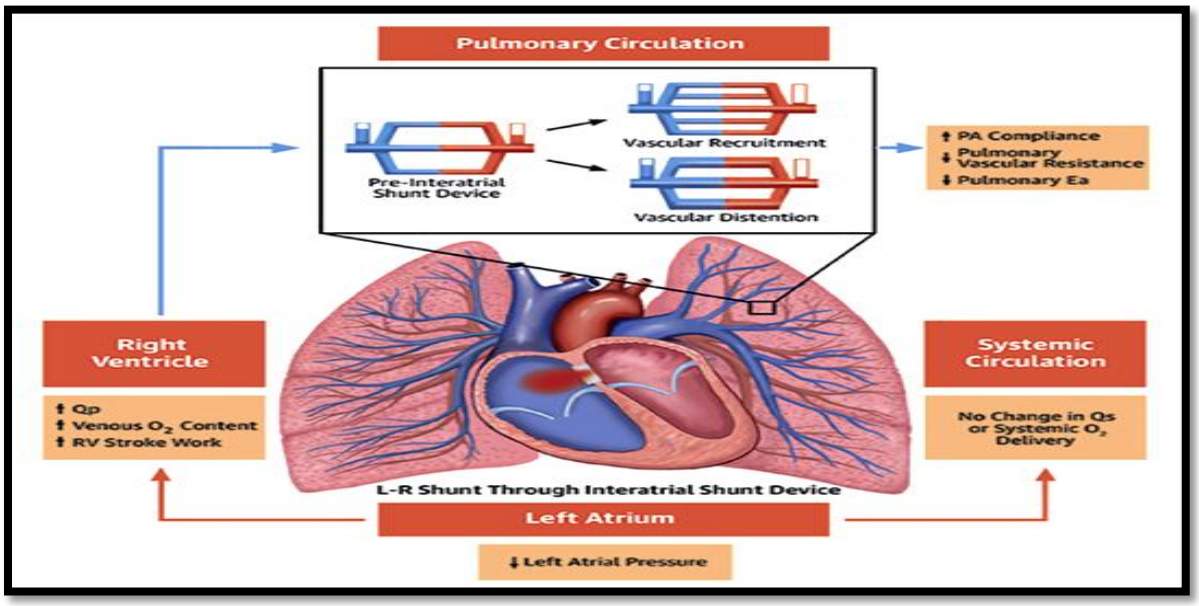


Figure 1: *Illustration of the effects of the Interarterial Shunt Device on pulmonary vascular function and systemic blood flow in heart failure with preserved ejection fraction* [22].

Heart failure (HF) is a clinical condition characterized by dyspnea, fatigue, decreased blood pressure, body edema, and signs of fluid retention such as increased jugular venous pressure (JVP), pulmonary congestion, and peripheral edema. These symptoms occur because myocardial function is impaired and cannot maintain cardiac output in response to metabolic demands. Worldwide, heart failure affects approximately 1% to 3% of the population. In the US this figure is estimated at 2.5%, and in the UK it is estimated at 1.6%. However, the actual incidence rate may be higher due to unidentified factors. Heart failure can occur in two main types: heart failure with preserved ejection fraction (HFpEF) and heart failure with reduced ejection fraction (HFrEF). HFpEF affects approximately 50% of heart failure patients and is associated with increased left ventricular pressure and diastolic dysfunction. Prevalence is expected to increase with age, particularly affecting people over 60 years of age, and is estimated at 4.9%. Non-cardiovascular diseases such as atrial fibrillation and obesity and obstructive pulmonary disease. Women are more likely than men to develop HFpEF, with a sex ratio of approximately 2:1[10].

Despite advances in treatment, heart failure is still associated with high mortality, reaching 50–75% within 5 years. The mortality rate in HFpEF is similar to HFrEF, highlighting the importance of early intervention to reduce mortality, morbidity, and adverse patient outcomes. Non-cardiovascular diseases are associated with mortality in patients with HFpEF. Clinical evidence suggests that HFpEF is associated with better survival compared to HFrEF, but clinical studies have shown that the differences in length of hospital stay, duration and impact on quality of life are incredible. Since patients are often hospitalized on average once a year after diagnosis, treatment strategies such as stress management, symptom control, and the use of diuretics to shorten the hospitalization period are necessary. Doctors must have a good understanding of HFpEF to properly diagnose and treat it [10].

Ejection fraction (EF) in diagnosis:

1. Preserved ejection fraction (HFpEF), also known as diastolic heart failure: In this condition, the heart muscle contracts normally, but the ventricles do not relax adequately during ventricular filling [10].

2. Reduced ejection fraction (HFrEF), also known as systolic heart failure: Here, the heart muscle does not contract effectively, resulting in less oxygen-rich blood being pumped out to the body [10].

This article mainly focuses on the PAH and Heart Failure related cases done by the physician by using the Atrial Pressure Controller Device which also has the intended use as:

1. Heart Failure patients with reduced ejection fraction (HFrEF).
2. Heart Failure patients with preserved ejection fraction (HFpEF).
3. Idiopathic Severe PAH.

Sr. No	Condition	Description	Ejection Fraction (EF)	Heart Muscle Status
1	Normal Heart	The heart pumps blood effectively and relaxes properly to fill with blood.	50%–70%	Healthy and functional.
2	HFrEF (Systolic HF)	Weakened heart muscle leads to difficulty in pumping blood out of the heart. - Eccentric (dilated) LV remodeling. - Low LV mass-to-volume ratio.	≤40%	Weak and unable to pump efficiently.
3	HFpEF (Diastolic HF)	Stiffened heart muscle results in difficulty filling the heart with blood. Concentric (thickened) LV remodeling. - High LV mass-to-volume ratio. - Borderline EF: 41%–49% - Improved EF: >40% (but still impaired filling).	≥50% (normal EF but impaired filling)	Stiff and unable to relax properly.

Figure 2: *Illustrates the main distinctions between Normal Heart Ejection Fraction, HFrEF and HFpEF. HF denotes heart failure, with HFpEF referring to heart failure characterized by preserved ejection fraction, and HFrEF indicating heart failure with reduced ejection fraction. LV stands for left ventricle [23,34,35].*

Pathphysiology:

1. Pulmonary arterial hypertension (PAH) is a serious disease that causes increased right ventricular (RV) pressure, right ventricular failure (HF), and death. Despite the continuous development of medical technology in recent years, the condition of many patients continues to deteriorate despite receiving good treatment, leading to problems such as shortening life expectancy, high hospitalization rates and increasing medical costs. Therefore, new treatments and interventions are needed to improve long-term outcomes. Increasing ventricular output through atrial fenestration to provide right-to-left shunting may improve oxygen quality and delivery despite the decrease in arterial oxygen saturation. Percutaneous stent implantation and balloon dilatation of the atrial septum (IAS) are well-established procedures to create or expand atrial communications to improve cardiac output in various areas. However, complications that occur when this technique is used include premature closure of the perforation, excessive desaturation, stent occlusion or migration, and difficulty in determining the size of the shunt to achieve full hemodynamic effect[23]. We have further describe the successful use of the atrial flow regulator (Atrial Pressure Controller Device , Meril Life Science Pvt Ltd, Vapi, India), an implantable device with a central hole, in patients aged 5–70 years with severe PAH.

2. HFpEF's pathophysiology is complex and relies on changes caused by comorbidities that affect myocardial function. Various mechanisms, including left ventricular diastolic dysfunction, contribute to the pathogenesis of HFpEF. Recently, a new paradigm suggests a cascade of systemic proinflammatory states caused by comorbidities underlying HFpEF pathology. HFpEF results from a variety of underlying diseases and leads to diversity. Future therapies focus on an individualized approach using appropriate assessment, treatment, and prevention strategies. Myocardial abnormalities in HFpEF include functional and structural abnormalities. Concomitant disease causes a proinflammatory state that causes inflammation of the coronary microvascular endothelium. This inflammation causes molecular changes that

promote cardiomyocyte hypertrophy and interstitial fibrosis, leading to left ventricular diastolic stiffness and discomfort. As left ventricular diastolic filling pressure increases, cardiac output decreases, leading to symptoms of heart failure. Other findings include directional changes in the myocardium, impaired energy, and microcirculatory dysregulation. In contrast to HFrEF, remodeling in HFpEF is often associated with cardiomyocyte loss [23].

Treatments Available prior to Atrial Pressure Controller Device:

Balloon atrial septostomy has been proposed as a palliative measure or a bridge to Transplant procedures in patients with PAH and severe heart failure (HFrEF & HFpEF), resistant ascites, and recurrent syncope despite maximal medical therapy [24].Balloon atrial septostomy performed out-of-hours produced higher adverse outcome rates as opposed to balloon atrial septostomy performed in routine hours. This may be due to the fact that these patients were considered ill enough to do the procedure as an emergency intervention. Nonetheless, in view of our findings, it seems important to review the patients carefully, so that only essential cases are undertaken in the night time while all other cases should be deferred to the daytime to limit unnecessary adverse complications.

The effective use of the ThoroughFare™ Atrial Pressure Controller Device has not only met the immediate clinical requirements of patients but has also laid the groundwork for continued therapeutic management and patient-centered care in the treatment of severe pulmonary hypertension and associated conditions. In summary, the ThoroughFare™ Atrial Pressure Controller Device is safe and practical for patients of different ages and genders in critical care environments. It successfully reduces the load on both the right and left cardiac chambers, resulting in notable hemodynamic improvements and alleviation of symptoms.

MATERIALS AND METHOD

Materials Required for Implantation:

The following materials and accessories are necessary for the implantation of the Developed Atrial Pressure Controller Device:

- Required Accessories (not included in the Atrial Pressure Controller Device Set)
- Atrial Pressure Controller Device Delivery Set
- Guidewire
- Appropriate Accessories to manage potential adverse events

Diagnostic Methods and Material for PAH, HFrEF, and HFpEF:

Diagnostic tests for pulmonary hypertension are critical for assessing pulmonary artery pressure. The primary diagnostic methods include:

- Cardiac Catheterization: Used to measure the pressure directly in the pulmonary arteries. Normal pulmonary artery pressure ranges from 11 to 20 mm Hg. Elevated pressure, indicating pulmonary hypertension, is diagnosed with readings of 25 mm Hg or higher.
- Echocardiography: Non-invasive method to estimate pulmonary artery pressure. Elevated pressure is indicated by readings of 35 to 40 mm Hg or higher.

Additional diagnostic tests include:

- Blood Tests: To detect blood clots, heart stress, or anemia.
- Heart Imaging Tests: Such as cardiac MRI for detailed images of heart structure and function.
- Lung Imaging Tests: Such as chest X-ray to assess the size and shape of the heart and pulmonary arteries.
- Electrocardiogram (ECG or EKG): To monitor heart electrical activity and identify any damage or strain.
- Transesophageal Echocardiography (TEE), Transthoracic Echocardiography (TTE), or Intracardiac Echocardiography (ICE).
- Fluoroscopy Equipment: To guide and visualize the procedure.

Device Details:

The Atrial Pressure Controller Device is a self-expandable, double-disc wire mesh device constructed from nitinol, with fenestration diameters of 8 and 10 mm. The total device diameter is 21 or 23 mm, with the distance between the LA and RA discs being 5 and 10 mm, respectively. The device requires a delivery system of 12 and 14 Fr.

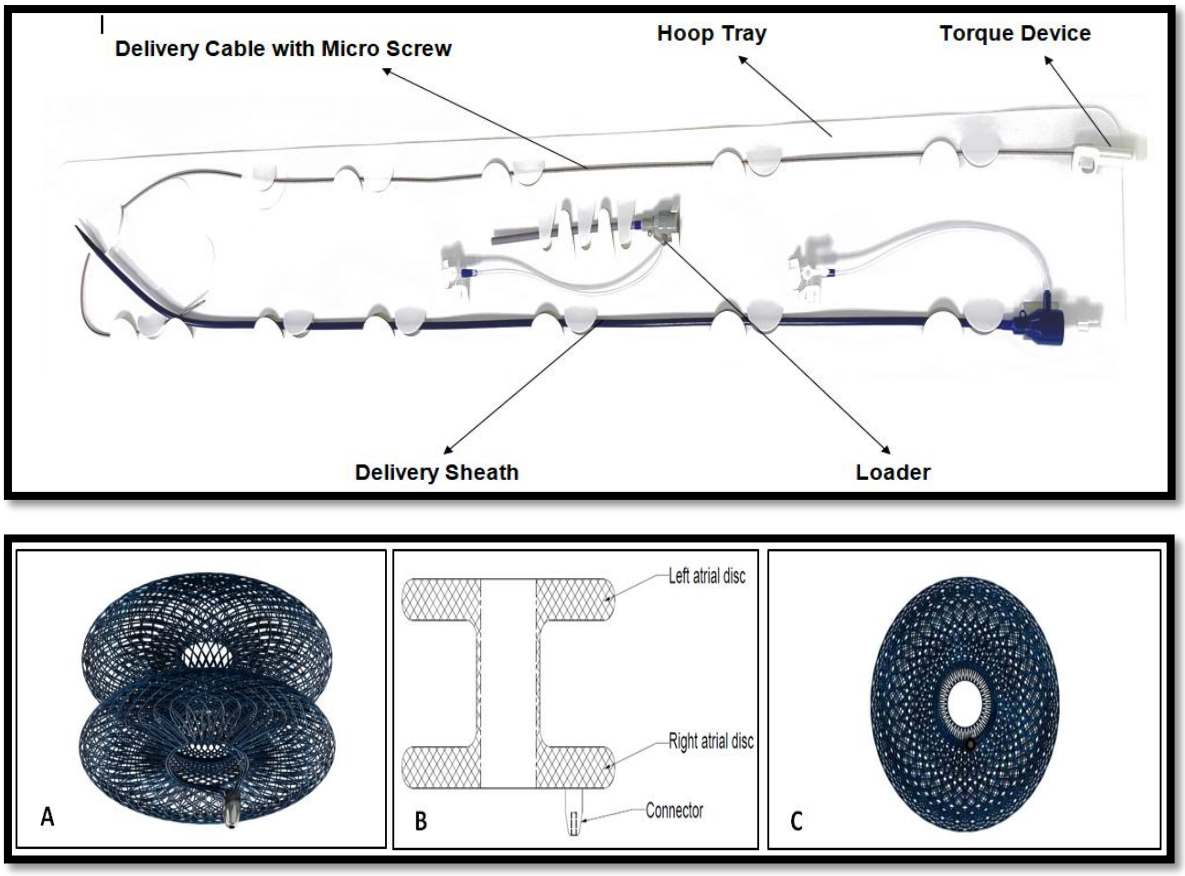


Figure 3: Atrial Pressure Controller Device. (A) Device with Left atrial disc and Right atrial disc. (B) Technical drawing of the Left atrial disc and Right atrial disc with connector. (C) Device with fenestration at center.

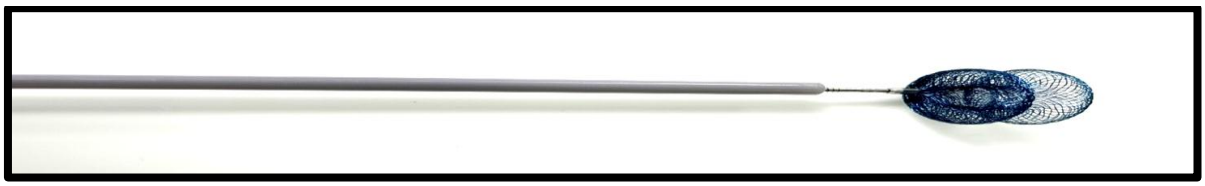


Figure 4: Delivery system

Implantation Procedure:

The implantation procedure is performed under general anesthesia. The steps include:

1. Venous Access: The venous circulation is accessed via the femoral or jugular vein to introduce the guidewire and transseptal sheath.

2. Atrial Septal Puncture: Conducted under fluoroscopy/TEE/TTE guidance, followed by balloon atrial septostomy (BAS).

3. Device Selection: The appropriate Atrial Pressure Controller Device is selected based on the fenestration diameter and atrial septal wall thickness. The fenestration diameter (D1) should match or be 1-2 mm smaller than the atrial septal communication created by balloon dilatation.

4. Device Preparation: The device is removed from sterile packaging, immersed in sterile physiological NaCl solution, and loaded into the delivery system. The balloon catheter is removed while retaining the exchange guidewire.

5. Device Deployment: The left atrial disc and connecting waist are deployed first, followed by the right atrial disc, ensuring proper positioning under fluoroscopic and echocardiographic guidance.

6. Position Confirmation: The device's position is confirmed with ultrasonography, and if satisfactory, the device is released. A plastic vise is secured to the delivery cable, and in rare cases where detachment

proves challenging, the sheath is advanced against the right atrial disc to facilitate detachment.

Throughout the procedure, the patient's hemodynamics remain stable, with no arrhythmias or other complications noted.

Procedural Precautions:

- Prophylactic Antibiotic Therapy: Post-implantation to prevent infection.
- Antiplatelet Drug Therapy: Short-term therapy for approximately six months, with long-term assessment based on individual needs.
- Avoidance of Strenuous Activity: For at least two weeks post-implantation.
- Monitoring for Allergic Reactions: Especially for patients allergic to nickel or titanium.
- Echocardiography Assessments: Before discharge and at 1, 3, and 12 months post-implantation to ensure device stability and patency.

Handling Precautions:

Before use, it was ensured that the device reverted to its original shape when immersed in physiological NaCl solution. A visual inspection was conducted to confirm the correct shape and attachment to the delivery cable

The user also confirmed that:
- Atrial Pressure Controller Device was firmly attached to the delivery cable by gently pulling the device a few times.
- Atrial Pressure Controller Device could be released from its delivery cable by rotating the delivery cable in an anti-clockwise direction 4-5 times.
- In case of any inconsistency, the user selected another device.

Case Reports:

Total 14 Patients of varying ages and genders, ranging from 5 to 70 years old, presented with a constellation of severe idiopathic pulmonary hypertension, right ventricular failure, mild pericardial effusion, and a spectrum of debilitating symptoms including recurrent syncope, headache, subsequent memory loss, unstable standing, rapid sweating, and vomiting. Due to the significant deterioration in their clinical condition, a multidisciplinary team comprising pulmonologists and congenital cardiologists recommended implantation of an atrial pressure controller device as the most suitable therapeutic intervention. Emphasis was placed on strict adherence to procedural precautions and handling techniques during the implantation procedure.

Upon admission, each patient underwent a comprehensive cardiac evaluation, including electrocardiography (ECG) to assess the electrical activity of the heart, transthoracic echocardiography (TTE) to visualize cardiac structure and function, and a battery of blood tests. These blood tests encompassed assessments of blood pressure, kidney and liver function, electrolyte levels, and cardiac enzyme concentrations to provide a thorough baseline assessment of each patient's cardiovascular health. All patients were classified as NYHA class III or IV.

Under strict sterile conditions, access to the right femoral vein (RFV) and left femoral vein (LFV) was achieved using a 6 Fr and a 20 gauge needle, respectively. Arterial pressure monitoring was established via the left radial artery to continuously monitor blood pressure throughout the procedure.

The puncture procedure began with the replacement of the RFV groin sheath with an 8 Fr sheath. An 18 gauge needle was guided through this sheath for atrial septal puncture under the guidance of transesophageal echocardiography (TEE) and fluoroscopy. Despite attempts, the sheath could not be advanced into the left atrium (LA). Consequently, a coronary wire was passed through the atrial septal defect (ASD) puncture and into the LA. Following this, the RFV sheath was exchanged for a 6 Fr sheath, and an anticoagulant dose of 5000 IU of heparin was administered to prevent clotting during the procedure.

Initial attempts at dilation using a 3x15 mm balloon were unsuccessful in negotiating the guiding catheter. Therefore, a catheter equipped with a 0.035 wire combination was utilized instead. After exchanging the coronary wire for a stiffer 0.035 wire, a 5x20 mm balloon was advanced across the ASD puncture and inflated under TEE and fluoroscopic guidance to 15 atmospheres of pressure.
Upon achieving adequate dilation of the atrial puncture site, an 8 Fr short sheath was introduced through the RFV groin. A 10x40 mm balloon was then inflated across the septum to 11 atmospheres of

pressure, facilitating the successful advancement of a larger 12 Fr sheath across the septum.

Subsequently, a 12 Fr delivery system was passed over an extra-stiff wire, with the tip positioned in the left upper pulmonary vein (LUPV). An 8mm fenestrated atrial pressure control device was carefully delivered through the sheath under continuous TEE and fluoroscopic guidance to ensure accurate placement.

Following the deployment of the atrial pressure control device, echocardiography confirmed its proper positioning with observed left-to-right shunting through the fenestration. Once confirmed, the device was released into its intended position. To address mild restriction observed on the left atrial side, the device was subsequently dilated using a 10x40 mm balloon at 11 atmospheres of pressure.

Post-deployment, pressures within the right ventricle (RV), left atrium (LA), and pulmonary artery (PA) were measured using a 5 Fr pigtail catheter and wire. Transthoracic echocardiography (TTE) performed after the procedure verified the correct positioning of the device with ongoing left-to-right shunting through the fenestration. Throughout the entirety of the procedure, each patient remained hemodynamically stable.

Special Case Scenario:

One of the notable case out of 14 patents involved a 70-year-old female patient with a significant medical history of multiple cardiac conditions, including atrial septal defect (ASD) with subsequent severe pulmonary arterial hypertension (PAH) and chronic atrial fibrillation (AF), along with moderate to severe right ventricular (RV) dysfunction. The patient experienced complications such as arrhythmias, pneumothorax, cardiac tamponade, and aortic dissections.

In 2017, the patient underwent ASD device closure to mitigate the effects of the septal defect. Despite treatment, ongoing symptomatic presentation required regular follow-ups. In 2023, the patient presented with acute chest pain and breathing difficulties lasting two days. Diagnostic investigations, including AF monitoring and echocardiography, revealed severe idiopathic PAH.

Given the severity of her condition, the patient required ventilator support and was assessed for treatment options. The medical team recommended the atrial pressure controller device to manage and stabilize pulmonary pressures in patients with severe PAH. This intervention was chosen based on its potential to optimize cardiac function and improve symptoms.

The patient's management plan involved close monitoring of PAH progression, evaluation of cardiac function, and ongoing adjustment of therapeutic interventions as needed. Regular follow-ups assessed treatment efficacy and overall patient well-being, focusing on optimizing quality of life while managing the complexities associated with her cardiac history and current presentation.

Upon completion of the procedure, the sheath used for implantation was carefully removed, achieving hemostasis at the site of entry. All patients were subsequently transferred to the catheterization laboratory recovery area in stable condition. All patients underwent scheduled follow-up transthoracic echocardiography 24 to 48 hours post-implantation, with additional assessments scheduled as needed based on clinical progression and response to treatment. None of the patients died as a result of the surgery, and all procedures were completed successfully.

Recommended Medication during Implantation Procedure:

- Endocarditis Prophylactic Therapy: Administered during the procedure.
- Heparinization: Throughout the procedure to maintain an activated clotting time (ACT) of >250 seconds after septal access.

Fluoroscopy Presentation:
Detailed fluoroscopic images and case presentations are provided for each patient to illustrate the procedural steps and device deployment.

Recommended Medications During and After the Implantation Procedure:

- Antiplatelet Agents: Aspirin: Administer 3-5 mg/kg/day, either the day before or immediately after the procedure, and continue as prescribed.
- Additional Medications: Macitentan: 5 mg, twice daily (BD), Tadalafil: 20 mg, twice daily (BD).

Figure 5: Case 01 Fluoroscopy Description of Patient 01:

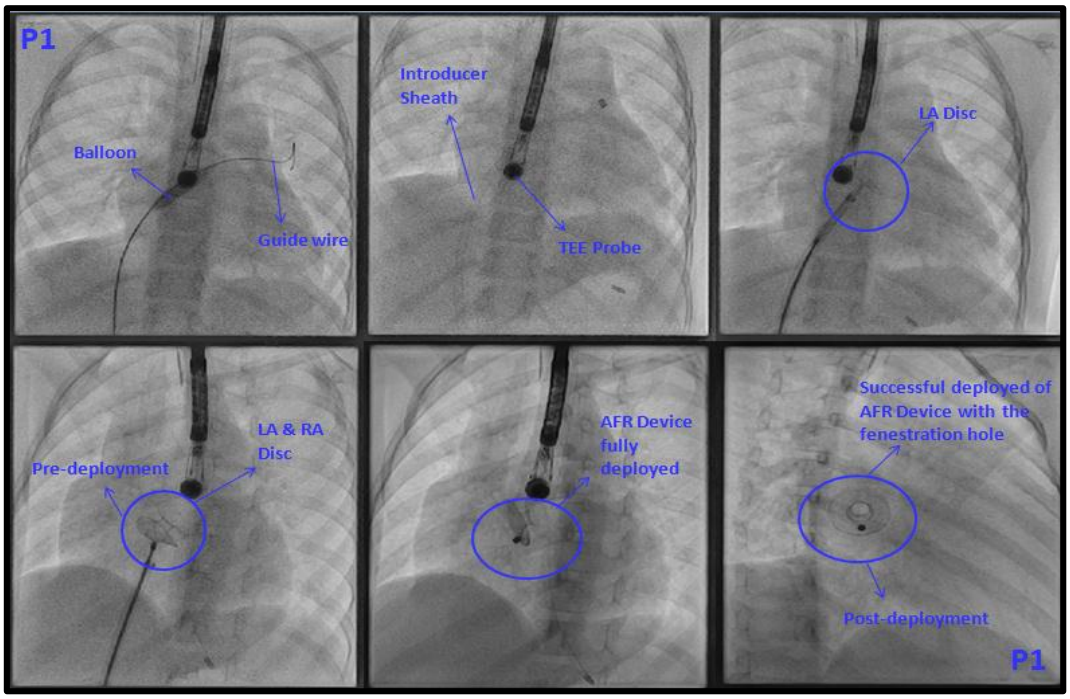


Figure 6: Case 02 Fluoroscopy Description of Patient 02

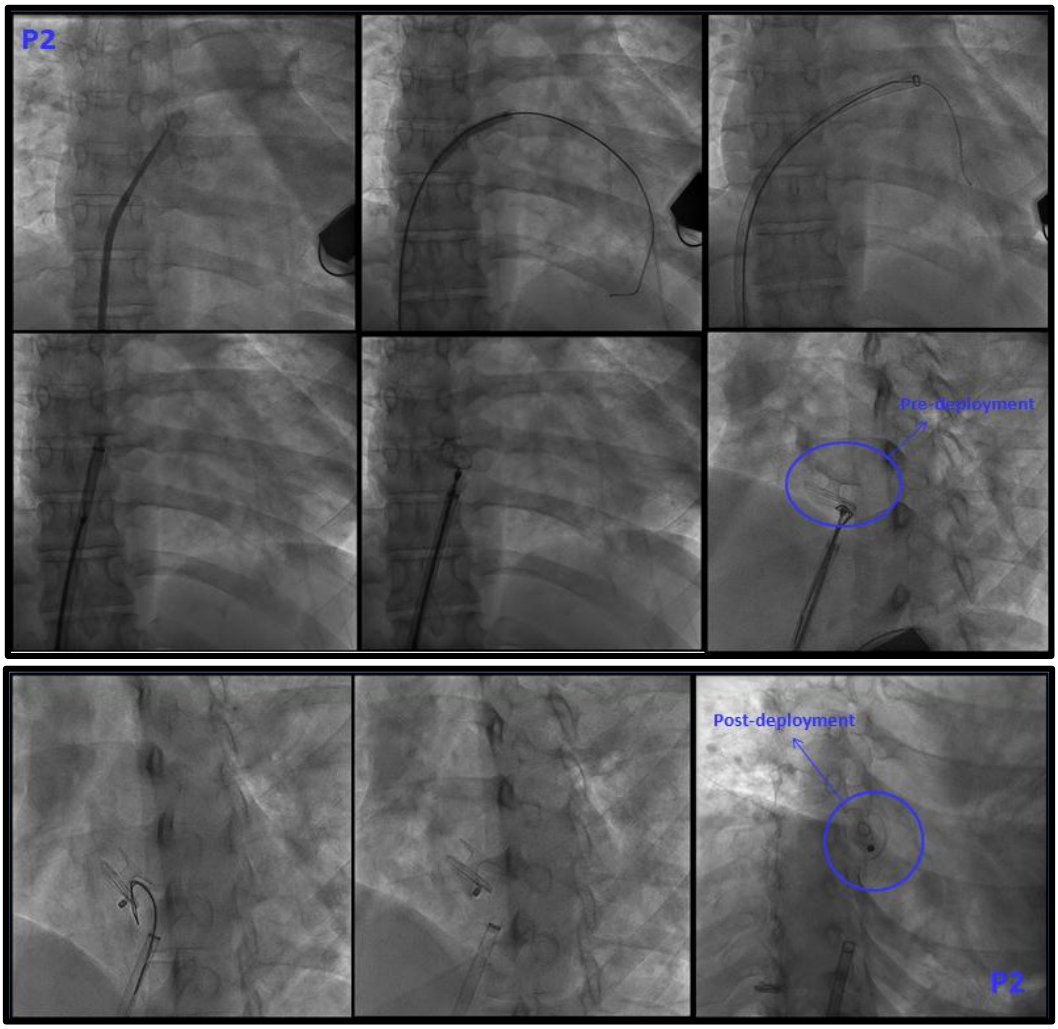


Figure 7: Case 03 Fluoroscopy Description of Patient 03

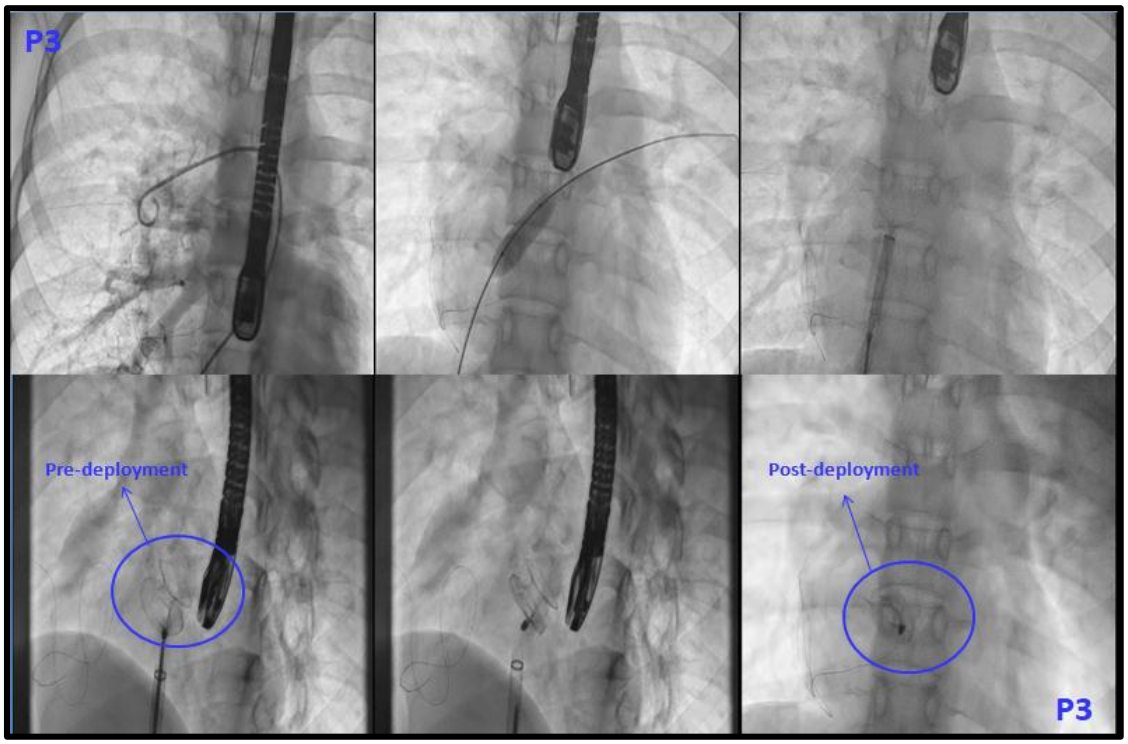


Figure 8: Case 04 Fluoroscopy Description of Patient 04

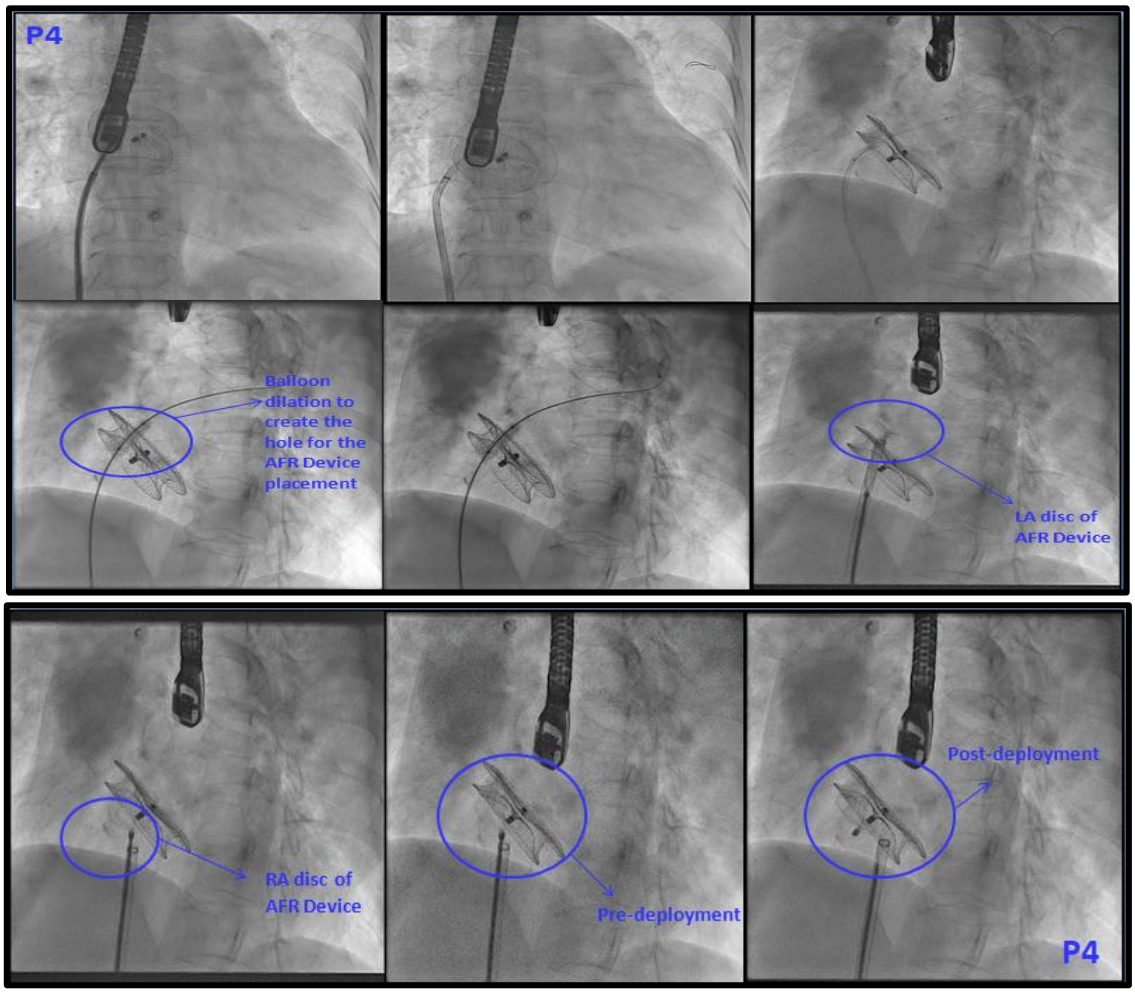


Figure 9: Case 05 Fluoroscopy Description of Patient 05

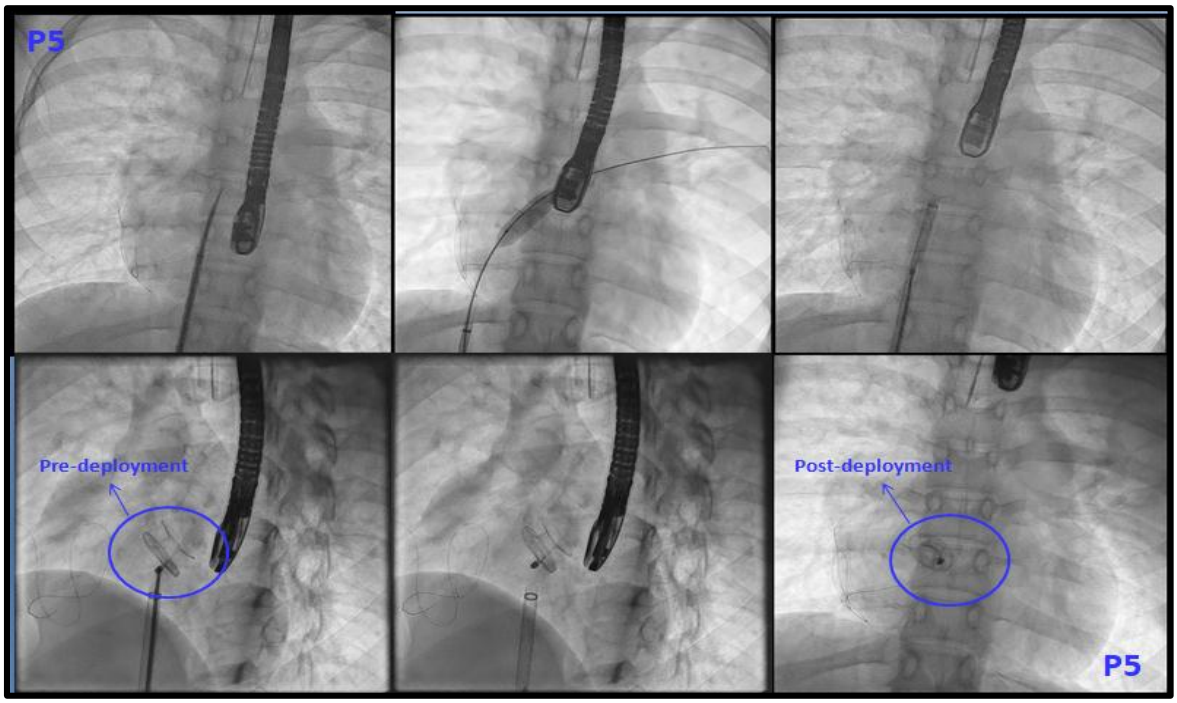


Figure 10: Case 06 Fluoroscopy Description of Patient 06

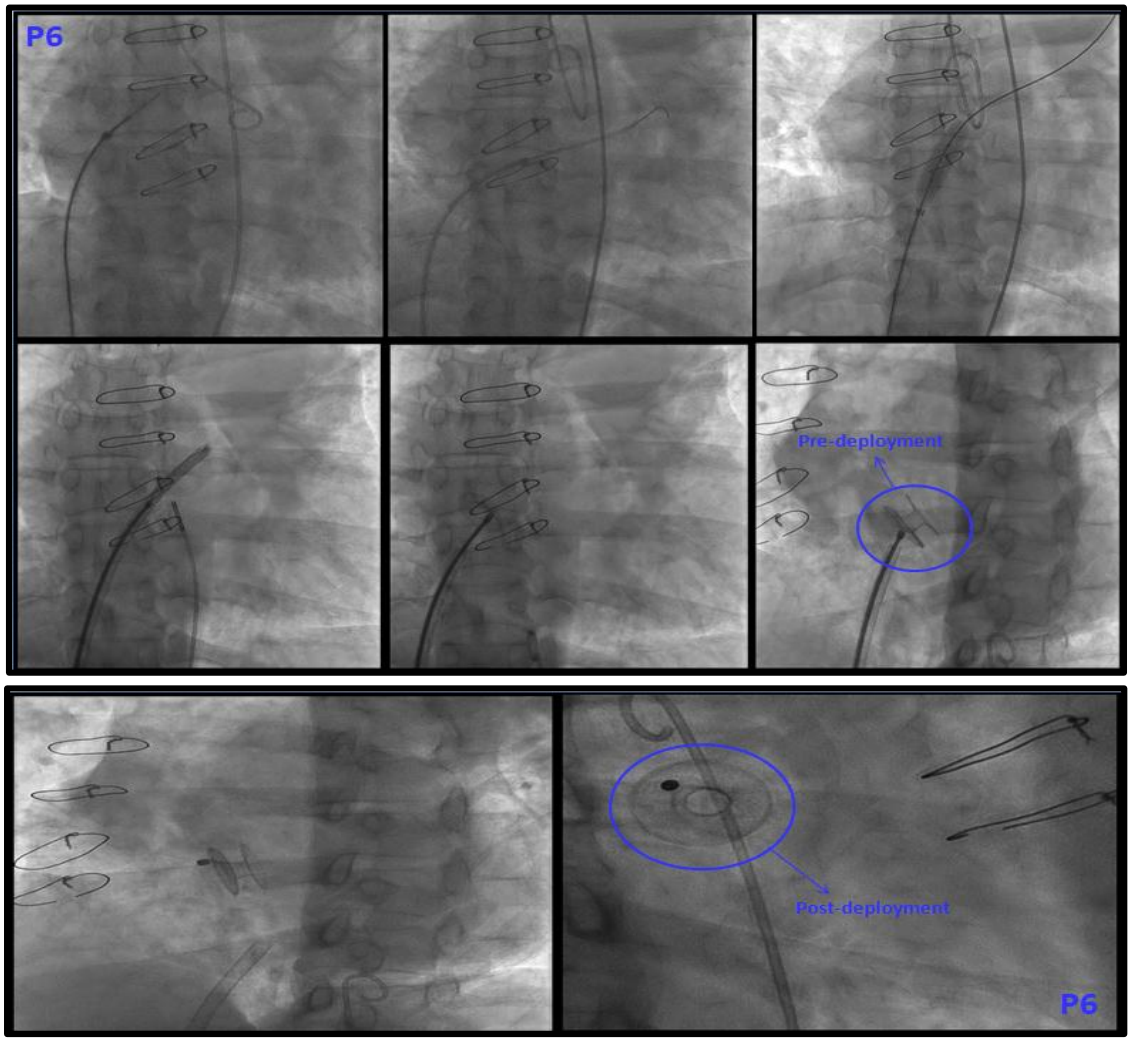


Figure 11: Case 07 Fluoroscopy Description of Patient 07

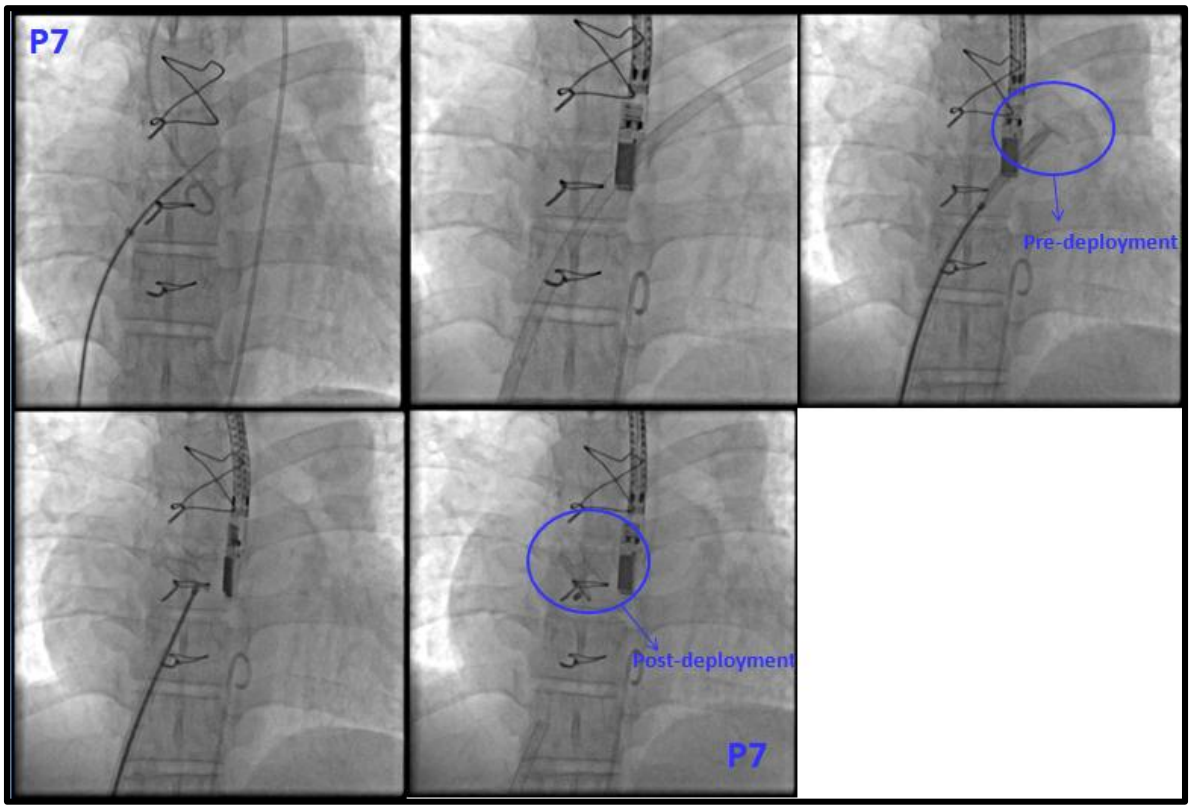


Figure 12: Case 08 Fluoroscopy Description of Patient 08

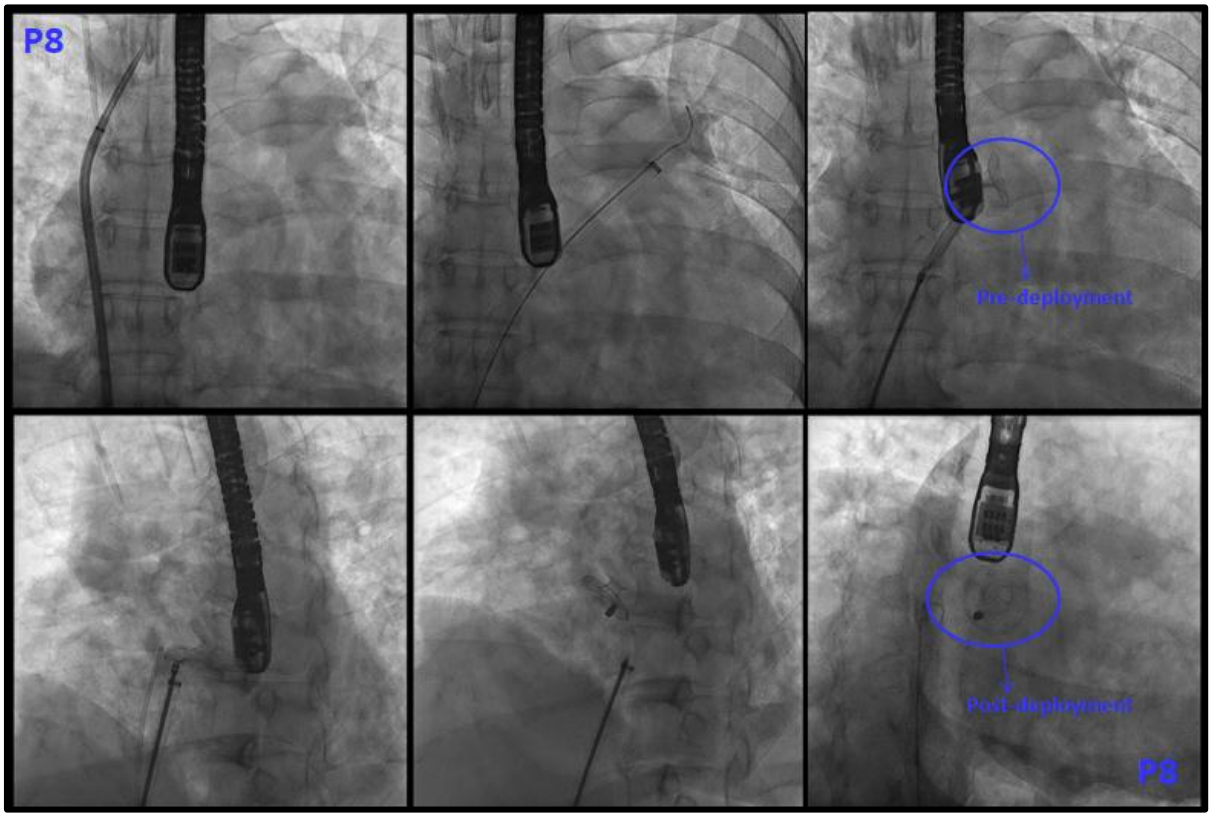


Figure 13: Case 09 Fluoroscopy Description of Patient 09

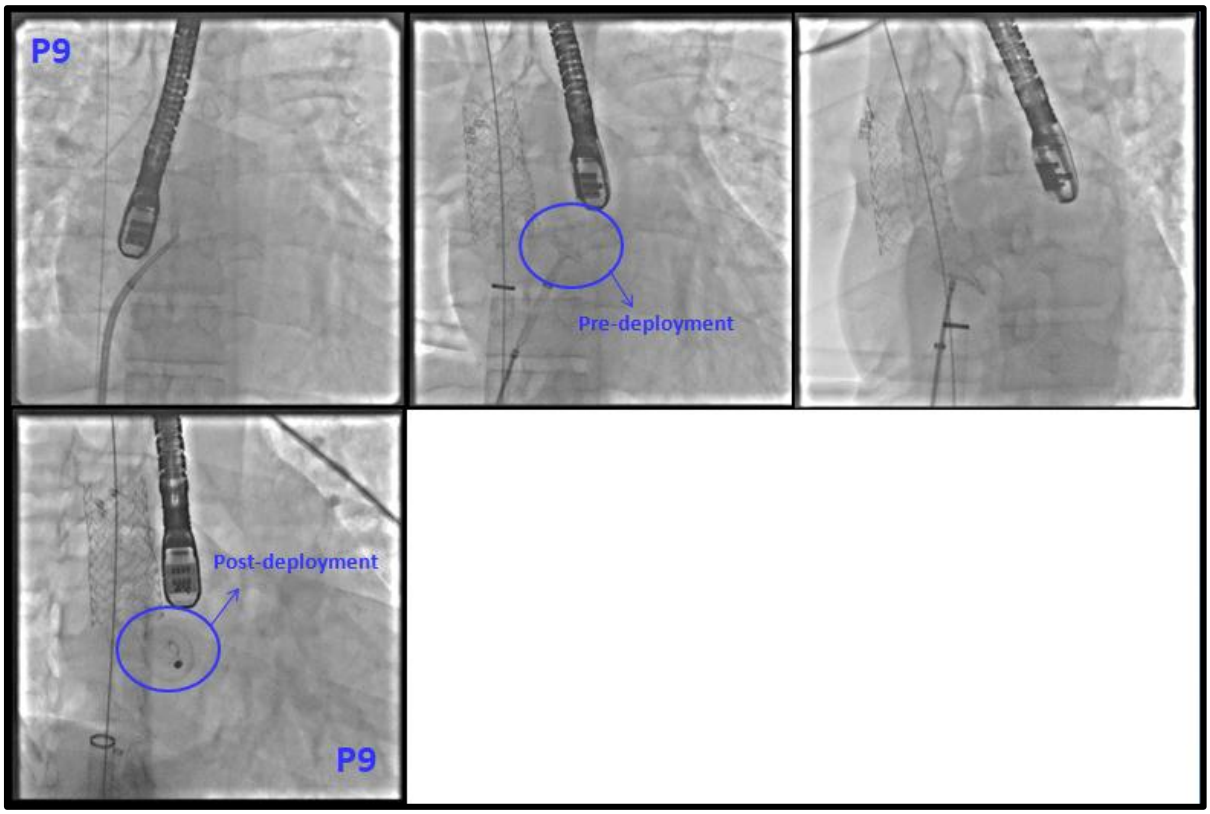


Figure 14: Case 10 Fluoroscopy Description of Patient 10

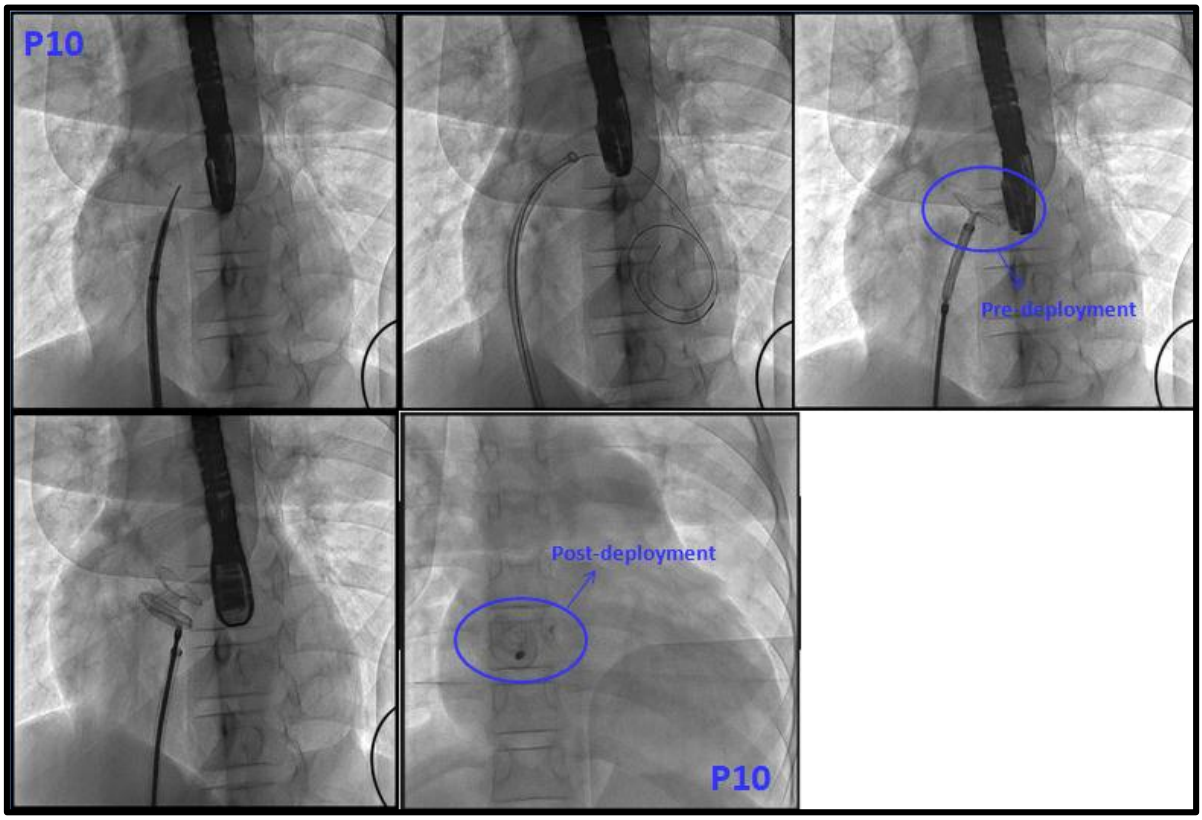


Figure 15: Case 11 Fluoroscopy Description of Patient 11

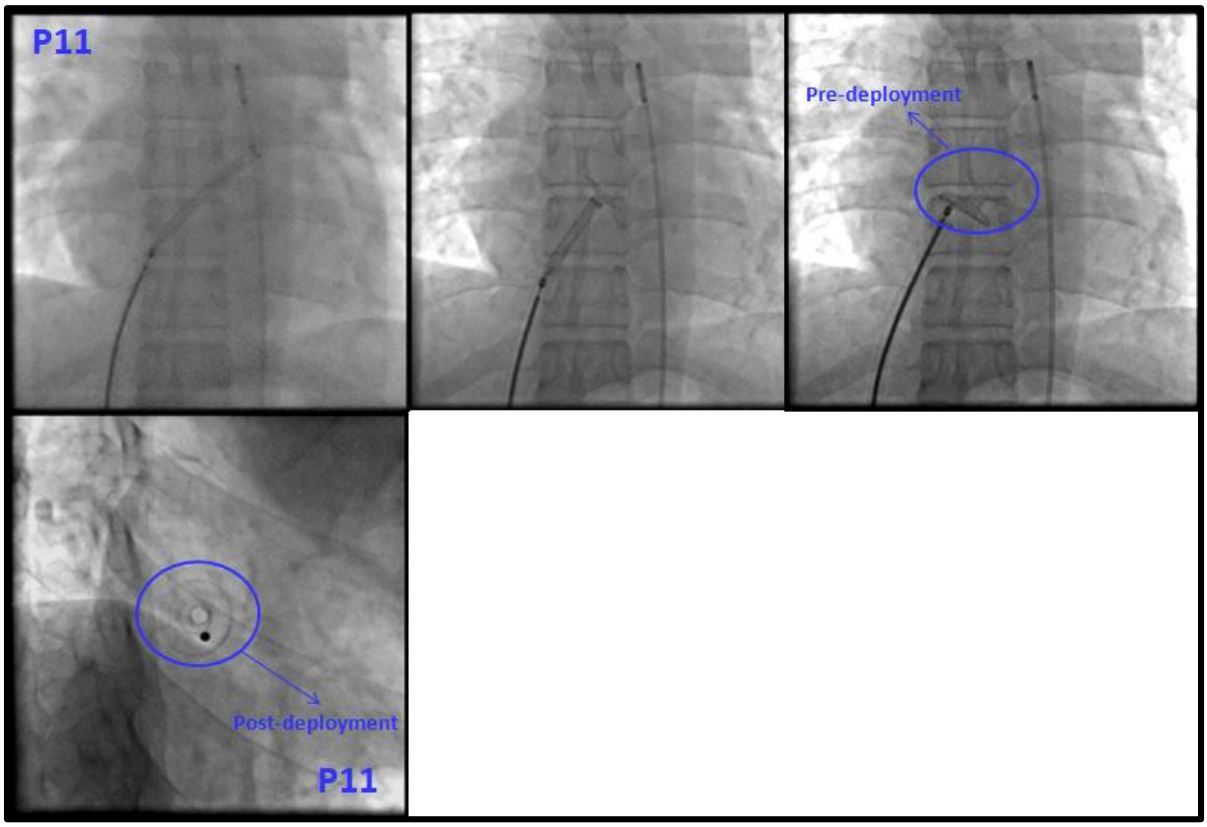


Figure 16: Case 12 Fluoroscopy Description of Patient 12

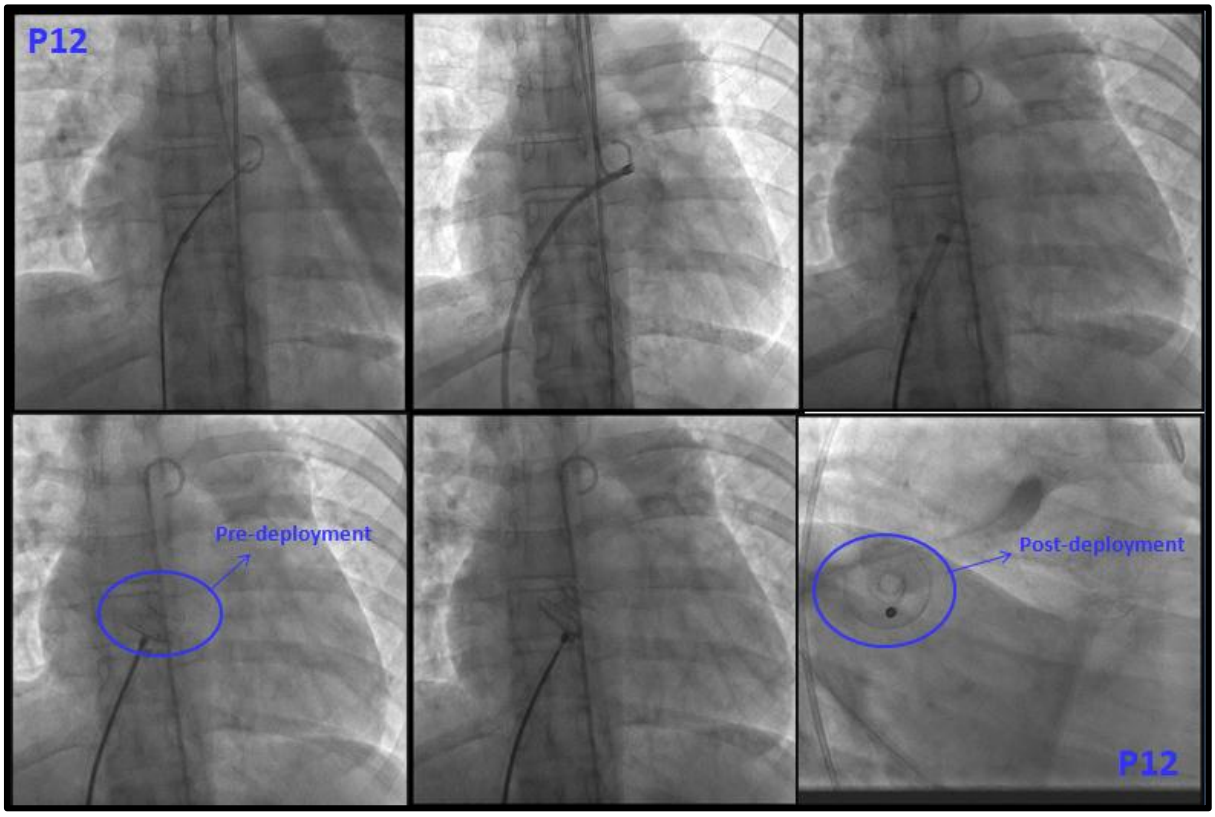


Figure 17: Case 13 Fluoroscopy Description of Patient 13

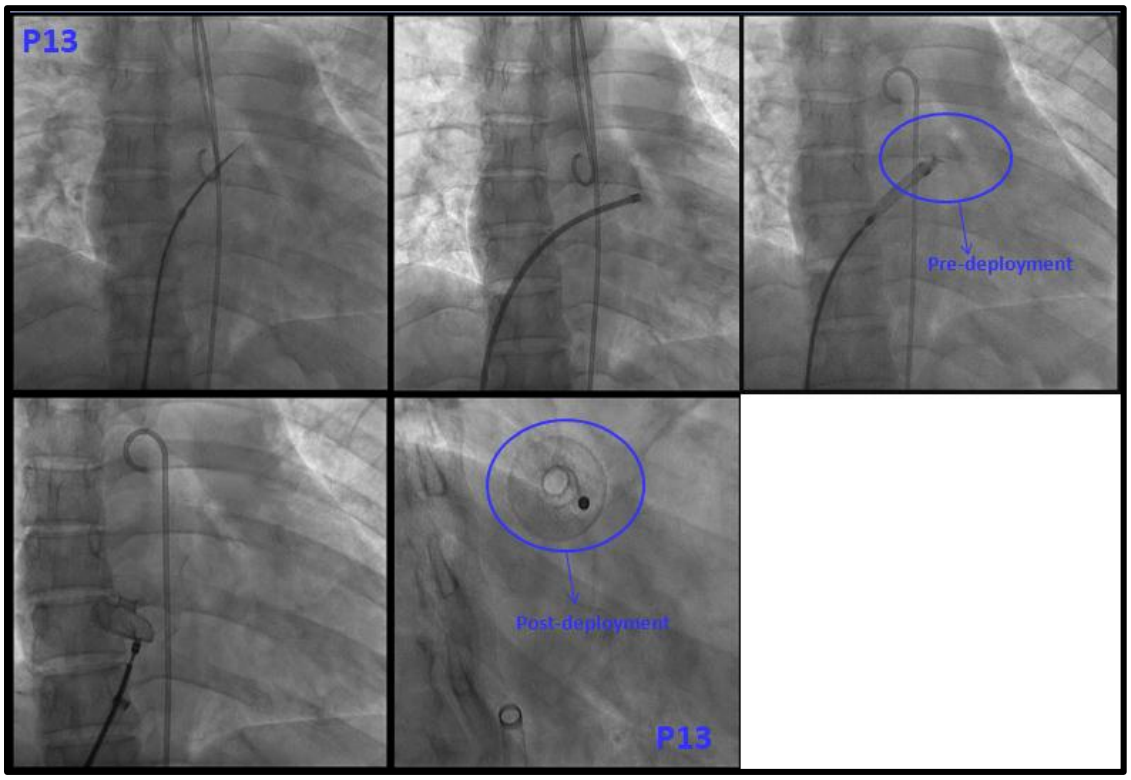
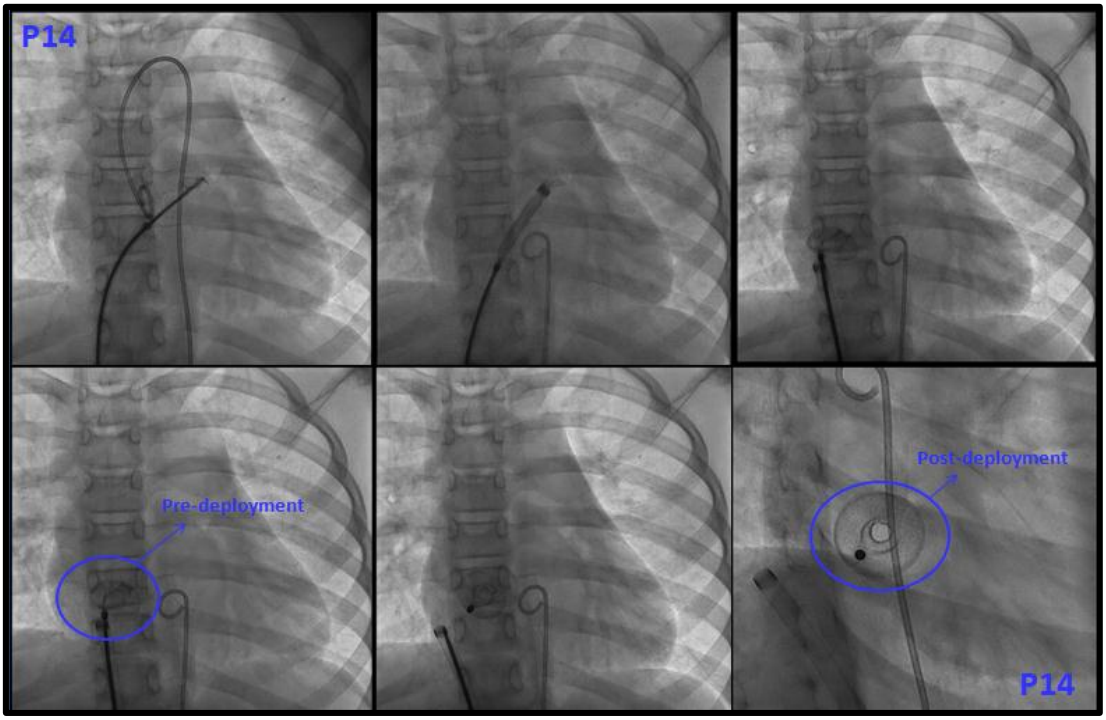


Figure 18: Case 14 Fluoroscopy Description of Patient 14



RESULTS

Patient Demographics and Baseline Characteristics:

- The study included 14 patients (4 males, 10 females) with a mean age of 65 years (range 50-80 years).
- All patients had a history of chronic heart failure (NYHA class III-IV).
- Baseline atrial pressure ranged from 18 to 25 mmHg with a mean of 21 mmHg.
- Comorbidities included hypertension (10 patients), diabetes (7 patients), and previous myocardial infarction (4 patients).

Procedural Details:

- Device implantation was successful in all 14 patients.
- The mean duration of the procedure was 45 minutes (range 35-60 minutes).
- No intraoperative complications were reported.
- Immediate post-operative observations indicated stable hemodynamics in all patients.

Clinical Outcomes:

- Mean atrial pressure decreased significantly from 21 mmHg pre-implantation to 14 mmHg post-implantation ($p < 0.01$).
- 12 out of 14 patients reported significant reduction in symptoms, including decreased dyspnea and fatigue.
- Quality of life scores improved by an average of 30% as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ).

Device Performance:

- The device successfully maintained target atrial pressures within the desired range (12-16 mmHg) in 13 out of 14 patients.
- One device required recalibration due to initial over-correction of atrial pressure.

Safety and Complications:

- No major adverse events were reported during the study period.
- Minor complications included transient atrial arrhythmias in 3 patients, which resolved without intervention.
- There were no device-related infections or dislodgements.

Follow-Up Data:

- At the 6-month follow-up, 13 patients continued to show improved atrial pressure control and symptom relief.
- One patient experienced a recurrence of symptoms at 4 months, which was managed with medical therapy.
- No device failures were reported during the follow-up period.

DISCUSSION

Summary of Key Findings:

- The atrial pressure controller device demonstrated significant efficacy in reducing atrial pressure and improving symptoms in patients with chronic heart failure.
- Procedural success was high, and the device performance was reliable in the majority of patients.

Comparison with Existing Literature:

- These findings are consistent with previous studies on similar devices, which have shown improvements in hemodynamics and clinical outcomes.
- Our study adds to the growing body of evidence supporting the use of atrial pressure control devices in heart failure management.

Mechanisms and Interpretation:

- The reduction in atrial pressure likely alleviated congestion and improved cardiac output, leading to symptomatic relief.
- The observed improvements in quality of life further support the physiological benefits of targeted atrial pressure management.

Clinical Implications:

- This device could be a valuable tool in the management of advanced heart failure, particularly in patients who remain symptomatic despite optimal medical therapy.
- The high procedural success rate and low complication rate suggest that the device can be safely implemented in clinical practice.

Limitations:

- The small sample size and short follow-up duration are limitations of this study.
- Further studies with larger cohorts and longer follow-up are necessary to confirm these findings and assess long-term outcomes.

Future Directions:

- Future research should focus on refining patient selection criteria and optimizing device calibration protocols.
- Long-term studies are needed to evaluate the durability of device performance and sustained clinical benefits.

CONCLUSION

The implantation of the Meril Atrial Pressure Controller Device has proven to be a vital intervention for patients suffering from severe idiopathic pulmonary hypertension and its associated complications. The ThoroughFare™ Atrial Pressure Controller Device is a self-expanding, double-disc wire mesh device made from nitinol. It features fenestration diameters of 8 mm and 10 mm. The overall diameter of the device is available in sizes of 21 mm or 23 mm, with a spacing of 5 mm or 10 mm between the left atrial (LA) and right atrial (RA) discs. The device is delivered using a 12 Fr or 14 Fr delivery system. This procedure, performed with a multidisciplinary team of pulmonologists and congenital cardiologists, highlights the complexity and severity of these cases, necessitating detailed procedural planning and strict adherence to safety protocols. Comprehensive cardiac evaluations prior to implantation were essential in gaining a thorough understanding of each patient's cardiovascular status, guiding the decision-making process and ensuring precise procedural steps. Challenges encountered during the procedure, such as difficulties in advancing sheaths and navigating septal punctures, were skillfully managed through the team's resilience, adaptability, and use of alternative approaches and equipment modifications. Post-implantation assessments, supported by imaging techniques and hemodynamic measurements, confirmed the successful deployment and functionality of the devices. The immediate post-procedural period was marked by vigilant monitoring and management, reflecting the team's commitment to patient stability and recovery. The continuity of care was further emphasized through scheduled follow-up evaluations, aimed at monitoring device efficacy and patient progress. These follow-ups underscore the dedication to optimizing outcomes in these complex cases. The successful implementation of the Atrial Pressure Controller Device not only addressed the acute clinical needs of these patients but also established a foundation for ongoing therapeutic management and patient-centered care in the treatment of severe pulmonary hypertension and related conditions. In conclusion, the ThoroughFare™ Atrial Pressure Controller Device is both safe and feasible for patients of varying ages and genders in critical settings. It effectively unloads the right and left cardiac cavities, leading to significant hemodynamic improvement and symptom relief.

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