International Journal of Advanced Multidisciplinary Application | IJAMA
Volume 2 Issue 10 Oct 2025
ISSN No: 3048-9350

Clinical Evaluation of the Vascular Plug System for Arterial and Venous Embolization in Peripheral Vasculature

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***Abstract-** Arterial and venous embolization in peripheral vasculature with vascular plug is a well-established procedure for adults and elderly. The aim of this clinical evaluation is to assess the vascular plug safety and efficacy in treating in peripheral vascular conditions like control bleeding, treat aneurysms and target tumors, traumatic injuries, Arteriovenous malformation, venous malformations, deep vein thrombosis and varicose veins. An analysis of the four cases, in first case patient was diagnosed with portal hypertension with gastric and oesophageal varices. In the second case patient involved with an antiphospholipid syndrome that developed a superficial femoral artery aneurysm. While third and fourth case both patients were diagnosed with Artreiovenous fistula. Medical records follow up imaging and post procedure monitoring were used to evaluate a clinical result. The vascular plug successfully manages this clinical condition in all cases, with minimal complications. No recurrence of vascular plug was observed in all patients. The vascular plug is a safe and effective device for the embolization of arteries and veins. In comparison, traditional methods like medication and coils treatment offers more effective, low complication, less invasive with excellent long term outcome. These results provide acceptance of the vascular plug use as preferred treatment for arterial and venous embolization in peripheral vasculature with potential to improve clinical outcomes and reduce recovery time.*

***Keywords:** Vascular plug, Embolization, Portal hypertension with gastric and oesophageal varices, Antiphospholipid syndrome, Artreiovenous fistula.*

1. Introduction

The Vascular plug system is designed especially for the arterial and venous embolization in peripheral vasculature introduced into a blood vessel to block or reduce blood flow to specific area. The network of blood vessels found outside the heart and brain, such as in the arms, legs, belly, and pelvis, is referred to as the peripheral vasculature. Venous embolization treats venous malformation (abnormalities in vein structure or function), which is used to control or prevent embolization also treats aneurysms, targets tumors, and controls bleeding.

Embolization can reduce symptoms including severe pain; edema, excessive bleeding and hypotension by obstruct blood flow to the diseased or abnormal vessels. [1-4]

According to reports, between 1% and 4% of the general population have venous malformations. Furthermore, studies have revealed that patients with inferior vena cava anomalies have a much greater incidence of deep vein thrombosis 16.2%. [3] (Can we provide approx patients numbers every year across the globe and India to demonstrate the importance of present technique) .

Traditional techniques for treating the arterial and venous embolization in peripheral vasculature such as liquid embolic agents such as cyanocrylate glue or ethylene vinyl alcohol copolymer and dimethyl sulfoxide (DMSO) which are administered as a liquid into the targeted vessel. They solidify or polymerize upon contact with blood, forming a permanent blockage. While metallic coils induce mechanical obstruction to promote clot formation. [5] Recently, vascular plug is extensively employed in the peripheral vasculature for both arterial and venous embolization, aiming to block or reduce blood flow within vessels. Procedures using vascular plugs are substantially faster than coil embolization. Vascular plugs' ability to be repositioned is a significant advantage since it enables interventional radiologists to accurately deploy them and make necessary corrections while the treatment is being performed. This characteristic improves the embolization procedure's accuracy and efficacy, which eventually benefits patients. Unlike coils, this can be less stable, vascular plugs offer improved stability, especially in high-flow or limited locations.

They have minimal risk of migration even in challenging conditions, ensuring reliable embolization and reducing complications. [6,7] The present study designed for the treatment of arterial and venous embolization in peripheral vasculature with vascular plug device, as it is safe minimally invasive procedure as well as cost effective and offer considerable advantages over the previous methods.

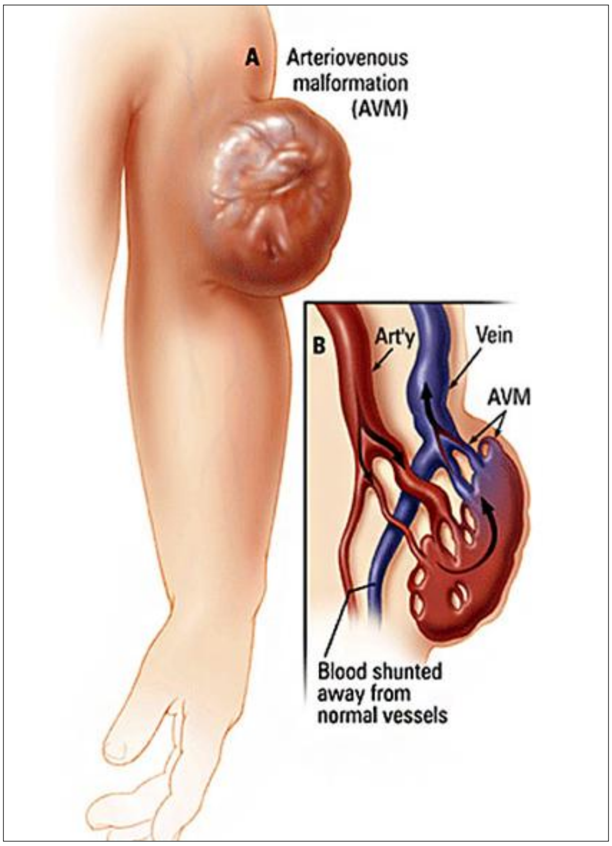

Figure No 1: Abnormal connection between artery and vein (arteriovenous malformation)[8]

2. Materials and Methods:

2.1. Material Required

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

2.2. Diagnosis Methods:

In the peripheral vasculature, arterial and venous embolization is treatment mostly used to treat diseases such as aneurysm, arteriovenous malformation or uncontrolled bleeding or block the abnormal blood flow. Diagnosis methods for this procedure involves various methods, including imaging methods to determine the location and severity of the vascular problem. One of the main diagnostic techniques is angiography, which involves inserting a catheter into the blood vessel and administering contrast dye to make vessels visible on fluoroscopy and x-rays. Doppler ultrasonography, an essential diagnostic technique, is also used to assess blood flow and identify issues. Some forms of angiography, such as arteriogram and venograms, are also utilized for defects in blood vessels, particularly in the case of varicose or venous abnormalities. The aforementioned diagnostics are necessary for determining the location and nature of the peripheral vascular condition, thus facilitating the conduction of the effective embolization procedures.

Device Details:

The vascular plug system is self-expanding implant device is cylindrical shape. It is constructed of nitinol wire mesh. The PET fabric is stitched with polyester suture at the proximal end inside the plug to aid in quick occlusion. This plug is further secured by a primary tube at both ends, encased in a final jacket made of Platinum-Iridium for optimal radiopacity during procedures. Additionally, a stainless-steel micro screw is affixed to the delivery wire, enabling precise engagement and disengagement of the plug.

Table 1: Size matrix of the Vascular Plug System

Sr. No	Plug Diameter(mm)	Plug Length(mm)
1.	8	7
2.	10	7
3.	12	8
4.	14	8
5.	16	8

Table 2: Technical specification of the Vascular Plug System

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

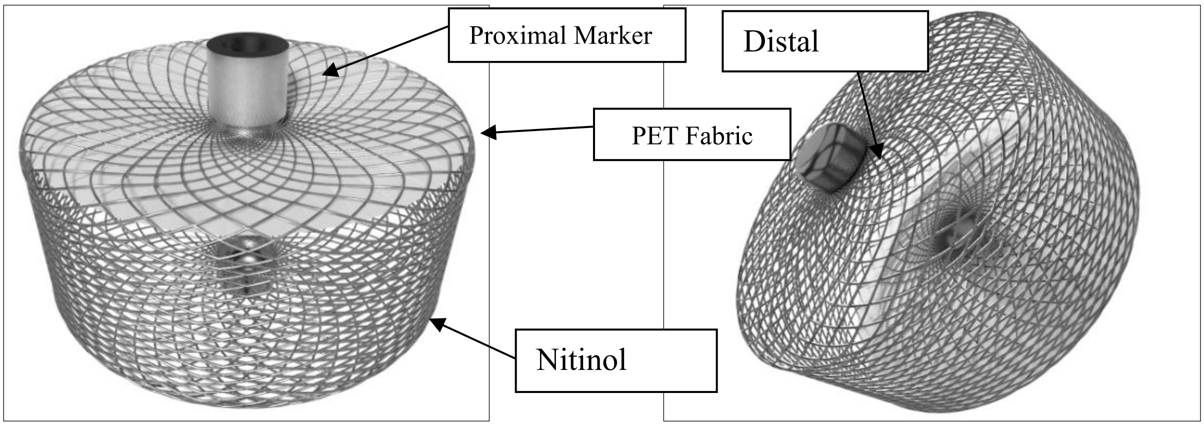

Figure No 2: Vascular Plug

3. Implantation Procedure:

Firstly, the hemodynamic evaluation was done. The procedure was done under the general anaesthesia; the implantation procedure of vascular plug was carried out by accessing the arterial circulation i.e femoral artery. After that an angiography was performed to demonstrate the anatomy of artery and measured the occlusion site, according to the measurement select the vascular plug with diameter approximately 30% -50% bigger than the vessel diameter at the occlusion site. Further 0.035 guide wire was passed under direct vision into the peripherally seen aneurysm. A compatible 6F delivery catheter was introduced over the wire into the occlusion site, once the catheter is placed the guide wire was removed then inserted preloaded loader and is attached to a 135 cm long PTFE coated delivery wire through the homeostasis valve or Y-connector. After that push the delivery wire to advance the device into the delivery catheter and remove the loader from the wire. Hold the delivery wire in place and slowly retract the delivery catheter to deploy the vascular plug at the target area. When the position was satisfactory rotate the delivery wire clockwise until is separates from plug and then remove the delivery catheter and wire together from the patient. This action was confirmed by fluoroscopy.

Table No 3: Patients Details

4. Case Report:

Sr. No	Age (Yr)	Sex	Disease Name
1	52	Female	Portal Hypertension with Gastric and Esophageal Varices
2	60	Male	Antiphospholipid Syndrome (APLA) cause Superficial femoral artery aneurysm (SFA)
3	21	Male	Arteriovenous (AV) Fistula
4	56	Male	Arteriovenous (AV) Fistula

There are four patients consider in the vascular plug system

Case 1: Portal Hypertension with Gastric and Esophageal Varices

In the first case, the female patient who is around 52 years old who has the medical history that was Type 2 DM along with hypertension. Portal hypertension was the diagnosis for patients having gastric and esophageal varices. Stomach and esophagus varices (veins that are not normally expanded) are most commonly caused by portal hypertension, which is characterized by high pressure in the portal venous system. These varices lead to risk of bleeding and other complications. Under aseptic precaution, patient's right jugular vein was punctured, and 7 FR sheath was inserted, using terumo guide wire and C1& MPA catheter combination inferior vena cava was accessed and IVC graphs was done which revealed normal opacification of patient inferior vena cava. The catheter and wire combination were further advanced & left renal vain access. Angiogram was done which revealed a dilated left gastro renal shunt and 12 mm vascular plug was deployed in the gastro renal shunt. Post deployment venogram revealed adequate flow across left renal vein and no flow across the plug into the shunt. Procedure was uneventful. Sheath removed and bandaging done. This procedure conduct under the fluoroscopy. Patient shifted to post operative care unit for further care and monitoring. The patient was following up after the procedure, showed a significant improvement of patient.

Fluoroscopy image: Fluoroscopic check was performed to verify the detachment and deployment of the vascular plug. The fluoroscopic images are shown in figure no 3.

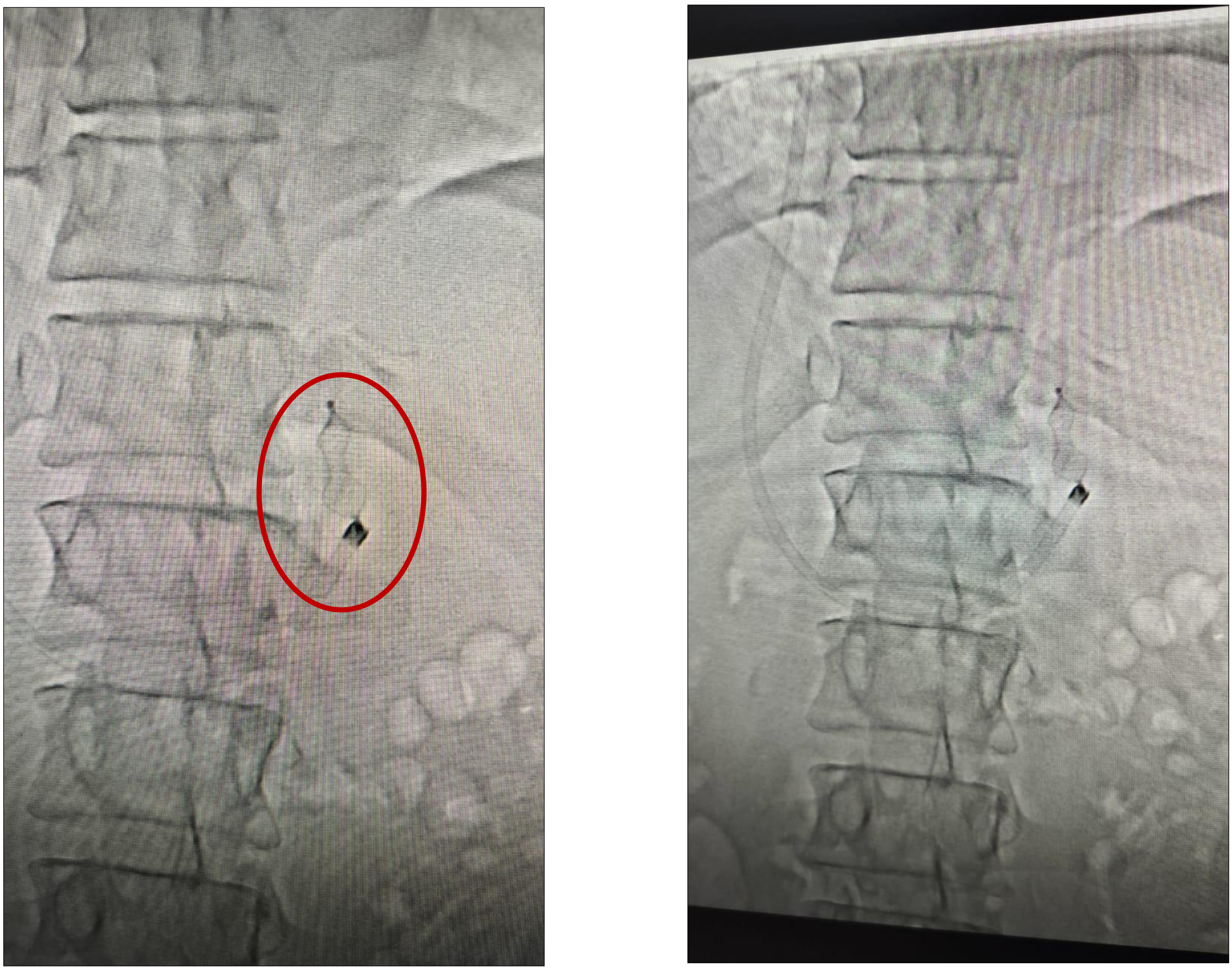

Figure No 3: Successful Deployment of Vascular Plug in Target Area

Case 2: Superficial Femoral Artery Aneurysm

In the second instance, the male patient, aged approximately 60 years, was found to have been affected by the Antiphospholipid syndrome (APLA), which is an autoimmune disorder where the immune system wrongly produces antibodies that attack the body's own tissues. The antibodies can induce arterial and venous disorders leading to aneurysms. In this particular case, a Superficial Femoral Artery Aneurysm, which is a very rare condition noticed in connection with Antiphospholipid syndrome, formed in the patient. The superficial femoral artery is a principal blood vessel responsible for blood delivery to the lower limb. As part of the procedure, the anatomy of the artery and the size of the aneurysm were both evaluated using angiography. According to the imaging report, a 16x8 mm plug was selected for the superficial femoral artery occlusion. The plug was used to occlusion the superficial femoral artery in the area of the aneurysm, effectively sealing off the weakened part of the vessel to prevent further complications, such as rupture or colt formation. Estimate intra-procedural blood loss was minimal across in case with an average loss of less than 50 mL, no patients required blood transfusion and there was no access-site hematomas or major bleeding complication. Patients shifted to post-operative care units for further care and monitoring. The patient was following up after the procedure, showed a significant improvement of patient. A fluoroscopic examination was conducted to confirm the detachment and deployment of the vascular plug. The images are shown in figure no 4 and 5.

Fluoroscopy image

Figure No 4: Successful Deployment of Vascular Plug in Target Area

Case 3: Artreiovenous (AV) Fistula Closer

For the second case, the young male patient, approximately 21 years old, presented with a diagnosis of Artreiovenous (AV) Fistula, which is characterized by an abnormal communication between an artery and a vein. The symptoms included swelling, pain, and a pulsatile mass in the hand. Angiography was done to illustrate the artery's anatomy and to measure the AV fistula. According to imaging report, two plugs with size 16x8 mm were selected for the Arteriovenous (AV) Fistula Closer. A fluoroscopic examination was conducted to confirm the detachment and deployment of the vascular plug. The images are shown in figure no 6 and 7.

Fluoroscopy image

Figure No 6: Vascular plug deployment under fluoroscopy

Figure No 7: Successful Deployment of Vascular Plug in Target Area

Case 4: Arteriovenous (AV) Fistula Closer

In the third case, 56 year old male patient was diagnosed with Arteriovenous (AV) Fistula with symptoms of swelling, pulsatile mass and pain. Angiography was performed to assess the anatomy of artery and measure the AV fistula. Based on this measurement an appropriate size of vascular plug was selected for intervention. For this patient 12x8 mm vascular plug was selected for procedure. The patient was follow up after the procedure, showed a significant improvement of patient. Estimate intra-procedural blood loss was minimal across in case with an average loss of less than 50 mL, no patients required blood transfusion and there was no access-site hematomas or major bleeding complication. Patients shifted to post-operative care units for further care and monitoring. The patient was following up after the procedure, showed a significant improvement of patient. A fluoroscopic examination was conducted to confirm the detachment and deployment of the vascular plug. The images are shown in figure no 4 and 5.

Fluoroscopy image

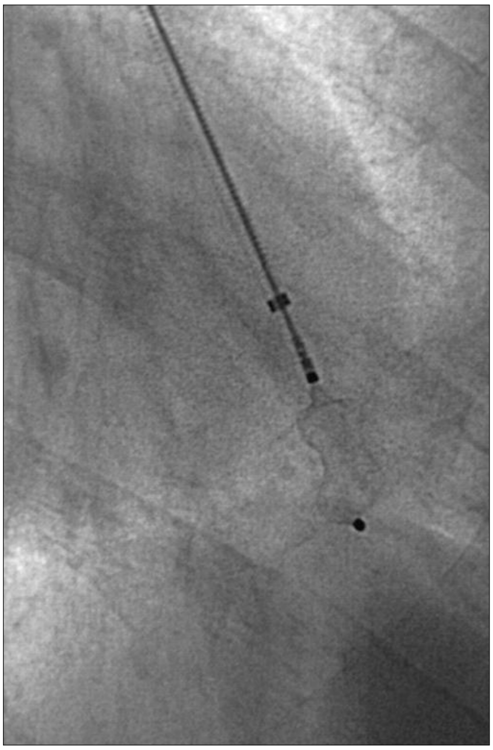

Figure No 8: Successful Deployment of Vascular Plug in Target Area

5. **Result**

Technical success was achieved in all patients with complete occlusion of the targeted vessels. Post-procedural care included assessment of the insertion site for signs of infection, verification of patient adherence to prescribed anticoagulant or antiplatelet regimens, and scheduling of follow-up imaging to evaluate the position and efficacy of the vascular plugs. No major complications were observed. Imaging performed at the conclusion of the procedure demonstrated complete embolization in all assessed cases. Angiography conducted immediately before and after deployment of the vascular plug confirmed correct device positioning, with no migration or residual shunt detected. The majority of the participants demonstrated a marked relief of the clinical symptoms. Several post-procedure time points served for the follow-up evaluations, and these evaluations were helpful to verifying the device's long-term effectiveness and the patients' rehabilitation. There was, in fact, a minimal blood loss in all instances and no case of transfusion was needed. Pain measured by the Visual Analog Scale (VAS) was significantly lowered from pre-procedure levels and stayed low during the follow-up period. To sum up, vascular plug embolization was very effective in the long run, which was proven by short-term, mid-term, and long-term follow-ups, thus, a high degree of safety and efficacy in the procedure was indicated.

Discussion

The self-expanding lattice of the nitinol mesh vascular plug penetrates the vessel and secures the device, while the PET fabric introduces resistance to blood flow and encourages fast platelet-fibrin deposition. All the mentioned factors result in fast thrombus formation, stable occlusion, and low migration. Failure occurrences are rare, though they can still arise from wrong dimensions, very high-flow shunts, or complex anatomy, thus bringing out the cruciality of careful sizing, complete pre-procedural evaluation, and catheter backing. In all instances, technical success was accomplished with no major complications, which matches the multicenter reports of high occlusion rates and almost no migration. Lesser devices, less fluoroscopy time, and lower procedural costs are the requirements while comparing plugs to coils, whereas liquid embolic might get to the same occlusion but with the risk of higher non-target embolization and longer procedural demands. Among the limitations are small sample size, heterogeneous pathologies, and a single-center design which could possibly overestimate success and restrict generalizability. Late recanalization, device fatigue, and comparisons with coils or liquid embolic will be evaluated in future studies. The combination of computational modeling, 4D flow MRI, and bioactive plug materials could potentially lead to better results. Health economic analyses will be the ones to inform about the cost-effectiveness, quality-of-life improvements, and the eventual widespread adoption.

6. Conclusion

The introduction of minimally invasive embolization options with a vascular plug as one of the key options is directed towards meeting a pressing clinical requirement: to secure the occlusion of the blood vessel in a durable way and to do it with the least possible morbid effects. Successful first-pass occlusion with negligible migration or recanalization not only shortens procedural time and hospital stays but also reduces the cumulative radiation and contrast exposure that patients—and interventional teams—face. Plug-based embolization that is dependable in the wider public health context can, therefore, result in fewer repeat procedures and lower costs, hence allowing the reallocation of medical resources to other complicated cases. In addition, the acceptance of plug-mediated closure as a safe method in both arterial and venous beds has made it a tool with multiple applications for such problems as blood loss, Artreiovenous malformations, and pre-surgical revascularization. This, in turn, results in patient's quality of life and long-term outcomes being improved in the case of various vascular diseases.

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