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PERIPHERAL VASCULAR EMBOLIZATION VIA AMPLATZER VASCULAR PLUG-4. PRELIMINARY EXPERIENCE

Ahmad Fawad[1], Mohammad Asad Shamsher[2], Saadia Ilyas[3], Bakhtawar Gul Wazir[4], Mian Noshad Kakakhel[5], Asif Malik[6]

[1]Department of Cardiology, Northwest General Hospital Peshawar-Pakistan

[2,4,6]Institute for Kidney Diseases, HMC Peshawar-Pakistan

[3]Department of Paediatric Cardiology, Lady Reading Hospital Peshawar-Pakistan

[5]Department of Urology, Northwest General Hospital Peshawar-Pakistan

Address for Correspondence:

Ahmad Fawad

Department of Cardiology, Northwest General Hospital Peshawar-Pakistan

Emails: cardiogenic73@gmail.com

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Contribution

AF conceived the idea. MAS, SI & MNK planned the study. BGW & AM drafted the manuscript. All the author contributed significantly in manuscript submission.

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ABSTRACT

Objectives: To describe our preliminary experience and feasibility and effectiveness of AMPLATZER Vascular Plug 4 (AVP-4) in peripheral vascular embolization.

Methodology: This cross sectional study consisted of all patients who underwent catheter embolization with Amplatzer vascular plug 4(AVP-4) between March 2012 and January 2018 at two centers (Northwest General Hospital, Peshawar and Institute of Kidneys Diseases, Peshawar). AVP-4 is being presented. The device was chosen 30-50% greater than target vessel. Device was delivered via an appropriate angiographic catheter and was released when satisfactory position achieved. All data was recorded on preformed proforma.

Results: Total 30 patients were recorded. Mean age was 40 $\pm$ 2 years. Predominant indication was Renal cell carcinomawith target vessel main renal artery (60%).Second common indication was post op bleeding with target vessel branch renal artery (23.3%). All cases were successfully embolized.

Conclusions: AVP-4 is safe and effective embolic agent that can be used in peripheral arterial embolization in different clinical settings.

Key Words: AMPLATZER Vascular Plug Transcatheter Embolization Vascular Disease.

INTRODUCTION

Percutaneous embolization has become a treatment of choice for the management of acute bleeding and vascular abnormalities. Several embolic agents are available internationally, including gel foam, polyvinyl alcohol (PVA), microspheres, glue, coils, and occlusion balloons.[1] Among these, coils are the most commonly used devices for peripheral vascular occlusion. However, the number of coils used for complete vessel occlusion depends greatly on the vessel size and blood flow rate. In general, multiple coils are needed to achieve satisfactory embolization.[2,3]

The AMPLATZER Vascular Plug (AVP) is designed to overcome this shortcoming of coils. AVPs are able to occlude a vessel with a single device in most cases.[3,4] Before the introduction of the fourth generation, vascular plugs were deployed through either a sheath or a guiding catheter.[4-8]The recently launched AVP 4 (AGA Medical Corp., Plymouth, MN, USA) is compatible with a 0.038-in. catheter and can be delivered through a diagnostic catheter.[9] We report our preliminary experience with the AVP 4 for the management of peripheral vessels and vascular abnormalities in our patients. Amplatzer vascular plug 4 is newer innovation in field of trans catheter embolization.[9] It is increasingly used as embolic agent for small and medium sized vessels.[3-5]

The AVP 4 is a self-expanding device made of two fine mesh lobes of nitinol wire and is available in diameters of 4-8 mm. Platinum marker bands at both ends of the device make it highly visible under fluoroscopy. The AVP 4 has a microscrew attachment connected to a 155-cm-long PTFE-coated delivery wire. Like other plugs in the AVP family, the device has the ability to be recaptured and repositioned if necessary. Additionally, the AVP-4 can be delivered through a 0.038 in. guidewire compatible diagnostic catheter. Its advantage over previous versions of the plug is that it may be easier to navigate through more tortuous vasculature. It also eliminates the need for sheath or guiding catheter exchange. Once the correct location is confirmed, it can be easily released by turning the delivery wire in a counterclockwise fashion.

It is recommended to select a device approximately 30%-50% larger than the vessel diameter.[9,10] Because the AVP 4 is the latest generation of the plugs, limited experiences have been reported to date in local literature. This study is critical appraisal of feasibility, utility and efficacy of AVP 4 in appropriate clinical settings in local population.

This study was conducted to asses the role of Amplatzer vascular plug 4 for catheterembolization and critically appraise its feasibility and efficacy in management of different vascular abnormalities necessitating catheter embolization.

METHODOLOGY

In this cross sectional study all patients underwent catheter embolization with Amplatzer vascular plug 4(AVP-4) between March 2012 and January 2018 at two centers (Northwest General Hospital, Peshawar and Institute of Kidneys Diseases, Peshawar). Patients were identified from the hospital coding system and from a prospective hospital and cardiac cath lab database using procedural codes. The hospital audit and ethical committee approved this study. All procedures were performed either on an emergency basis or on an elective list by experienced interventional cardiologist. Data was extracted on pre-designed data extraction sheets.

The diameter of the AVP4 was chosen according to clinical situation and approximately 30% to 50% greater than target blood vessel. All patients had an angiographic confirmation of the occlusion after deployment of the devices.

Different clinical and procedural variables were recorded for each patient on pre-designed proforma. The success of procedure was defined as complete occlusion of blood flow on post-embolization fluoroscopic contrast imaging of vascular bed.

RESULTS

Total 30 patients were included from 2012 to 2018. Males were 21(70%) while females were 79 (30%). Mean age was 40 $\pm$ 2 years. Immediate technical success was achieved in all patients (100%).

Main indication was Renal cell Carcinoma (60%) followed by post Pyelolithotomy bleeding / hemorrhage (23.3%) leading to multiple blood transfusions. Among Renal Cell Ca group, 61% of patients (n=11) indication for embolization was disseminated tumor in inoperable stage. Rest of the patients (n=7) were referred for embolization as adjunct therapy pre operatively for tumor shrinkage.

Table1: Clinical Indications and Vascular Territory Embolized (n=30)

Clinical Condition	Vascular Territory	Total No (n)	Percentage (%)
Renal Cell Carcinoma	Main renal artery	18	60
Post Op bleeding / Gross hematuria	Branch of renal artery (Segmental)	7	23.3
Bladder Ca (Post Op gross hematuria)	Internal Iliac artery (anterior division)	2	6.6
Renal AVM with hematuruia	Branch of renal artery (segmental)	2	6.6
Trauma / FRI with hematoma / bleeding	Profunda femoris artery branch	1	3.3

Two cases (6.6%) were referred for internal iliac artery embolization. These patients hadBladder Ca and were operated and received chemotherapy. Post operatively they had recurrent gross hematuria leading to sever anemia and multiple blood transfusions. Anterior division was super selectively embolized on either side of internal iliac arteries to avoid buttock claudication.

Two patients (both females) hadcongenital renal AVM leading to recurrent hematuria. Culprit feeding branch was selectively embolized with cessation of clinical symptoms on follow up.

One patient had history of recent fire-arm injury to right thigh with hematoma and bleeding post operatively. Right Profunda Femoris artery was severed extensively and was successfully embolized.

Judkin Right (JR) was the most common catheter used (83.3%) followed by Cobra catheter (16.6%). All cases were performed using right femoral route (100%). Mean Flouro time was 25 minutes. Mean contrast volume was 70 ml.

Table 2: Procedural Characteristics of Study Population (n=30)

S.No	Parameters		Number (n)	Percentage (%)	Mean
1	Age (Years)				40 ± 2
2	Gender	Males	21	70	
		Females	9	30	
3	Catheter used	Judkins Right	25	83.3	
		Cobra	5	16.6	
4	Access site	Femoral	30	100	
5	Contrast Volume			100	70 ml
6	Flouro time				25 min
7	Additional embolic agent		0		
8	Success		30		

DISCUSSION

Therapeutic embolization has been in practice for the past 30 years. There is continuous refinement of technique and material used for embolization.[1,2] Different embolic materials have been used over the last few decades including gel foams, coils and vascular plugs. People have tried autologus blood clots infusion and silk suture materials to embolize arteries with different success rates.[1,3]

Among different agents used and tried in the past for selective and non selective embolization, Amplatzer vascular plugs have been more effective and feasible.[4]Among different generations of vascular plugs, AVP- 4 is a newer device with claims of excellent maneuverability and effectiveness.[8-10] It is a disc made of braided nitinol meshwork, attached to PFTE coated 155 cm long delivery wire with stainless micro screw, which allow the operator to release the plug by just rotating the cable in counter clock wise direction once proper position is achieved .[9,10]

Minimal invasive Trans catheter procedures have changed the paradigm of surgical practice by reducing large access surgical incision, maximizing tissues preservation, shortening of hospital stay, lowering need for narcotics and reducing time to full recovery.

Management of bleeding patient dictates multi disciplinary approach. Once the bleeding sources are identified, treatment varies between surgical resection of bleeding organ, reconstruction of bleeding vessel/organ and angiographic embolization.[11] Embolization has advantage of minimal invasiveness with ability of super selectivity of blood vessel for occlusion.[10, 11]

Therapeutic catheter-embolization has been used successfully for managing a variety of benign and malignant urological conditions for the past 30 years.[12,13] People have documented use of pre op renal artery embolization in Renal cell carcinoma as an adjunct therapy to surgery. It is well reported that such pre op embolization reduces bleeding risk and decreased tumor size owing to shrinkage. Medical nephrectomy can be effectively achieved in those patients who are deemed unsuitable for surgery due to disseminated nature of renal cancer and other co morbid conditions.

Use of catheter embolization for controlling massive bleeding in urological / surgical injuries and condition can be life saving. Renal artery or injury to its branches during percutaneous nephrolithotomy can be accurately diagnosed and treated with embolization, minimizing unavoidable nephrectomies and preserving maximum nephron.[13]

Phadke et al successfully treated reno vascular injuries in 27 post PCNL hematuria patient, with super selective embolization of culprit vessel[14]. We successfully treated such post PCNL patients by selectively embolizing such lesion with excellent post-operative results. Kessaris et al performed more than two thousand percutaneous nephrolithotomies where only 0.7% requiring angiography and embolization for significant bleeding[15].

Spontaneous perirenal-haemorrhage is acute emergency and accurate diagnosis and timely treatment save many

avoidable nephrectomies. Takebayashi et all reported good outcome of trans arterial angio-embolization in patient s with AV fistula and hematuria[16]. They reported salvage of maximum function of renal unit in long term. Our patients with AV fistula were symptom free clinically once they were selectively embolized with AVP4. Nabi et al reported successful palliation of intractable hematuriain patient with bladder tumor with angioembolization of internal iliac arteries[17]. In our study 2 patient have underwent angioembolization of bilateral internal iliac arteriesarteries with excellent results on table. No patient required additional embolic agent then AVP 4 and were symptom free in immediate post operative period.

Bakal reported 93 consecutive cases of renal cell carcinoma where they did pre operative embolization of renal artery and found that preoperative embolized patient had lesser per operative blood loss as compared to nonembolized patient[18].

AVP 4 is an attractive device for peripheral embolization, especially in the emergent setting, because it can be delivered through a diagnostic catheter, which is already inplace for diagnostic purposes. Quick occlusion can be achieved with this effective device and with fewer deployment steps. The manufacturer recommends choosing 20%-30% larger plug to increase thrombogenicity and prevent distal migration.[5-9,19,20]

Our preliminary experience indicates that the AVP 4 has many advantages over coils and other generations of vascular plugs: (1) the device can be placed through a diagnostic catheter as small as 4 Fr which is flexible enough to negotiate tortuous vessels or acute angles for peripheral embolization; (2) we found that the device was easy to handle, allowing for precise deployment; (3) a test injection of contrast medium is possible through the delivery catheter for verification of device position before release; (4) the device can be easily repositioned if the initial deployment position is not desirable; (6) theoretically there is minimal risk of distal embolization; and it is an effective, single-device solution for vascular embolization in patients with normal coagulation. Like previous versions of the vascular plugs, the AVP 4 can be used either alone for vascular occlusion or combined with other embolic agents serving as both a scaffold and an occluder[2-7]. There may be two potential disadvantages of the AVP-4: first, the existing sizes may limit its application to vessels with large diameter vessels, provided the requirement for at least 30% oversizing; and second, the 7 and 8mm devices are in some cases a little difficult to advance through a catheter when angulated shapes are encountered. However, we found that continuous injection of normal saline through the catheter can ease the advancement of the device by reducing the friction of the device against the catheter wall. Selection of AVP-4 limits its use due non availability of large diameter devices and in such situations earlier generation plugs like AVP-2 can be considered.

Although this study is critical appraisal of feasibility and effectiveness of AVP-4in different clinical settings, there are some limitation to this studying in terms of cost of device and lack of awareness among different surgical colleagues regarding availability of such procedural facility.

CONCLUSION

AVP- 4 is a safe and effective vascular closure device that can be used for peripheral embolization. The use of the device not only simplifies the embolization procedure but also reduces radiation exposure of both patients and radiologists. Only limitation remains cost of device in our setup.

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