"Evaluation of pseudoaneurysm management post multiple injections in drug abuser using endovascular approach by covered stent"

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Abstract

**Background:** Femoral pseudoaneurysm considered the common complication of repeated femoral puncture during drug addiction by self-trials injections. Pseudoaneurysms form at the different sites arterial entrance (femoral, brachial, radial…) if not sealed, leaking of blood and result in a well-formed pulsatile hematoma. This is a very crucial problem by the exponential growth of drug addiction.

**Methods:** A prospective clinical trial study over a period of 20 months, 22 patients were attended complaining of a local pulsatile swelling at different site of recurrent drug injection and involved in this study. Antegrade or retrograde approach used depending on the site of the pseudoaneurysm and feeding neck. Excluded from study any patient presented with signs of infection or bleeding or treated by other method.

**Results:** 22 patients, 20 were males and 2 were females. Age was 31.2 + 9.2 in years. The incidence of traumatic pseudo aneurysm between 15 - 25 years old (45.5% of our cases). The most common site forming pseudoaneurysm the groin (femoral artery), the antecubital region (brachial artery) and carotid artery (11) 44%, (8) 32% and 3 (12%) respectively. Management by endovascular covered stent may with different complications post intervention like 4.5% (one patient) thrombosis on brachial artery, endo-leak of the femoral artery (one patient) and all managed with no residual complication and all patients passed well.

**Conclusion:** Endovascular intervention using covered stent to close the feeding neck, with less controllable complications and less hospitalization time.

**Key words:** endovascular, pseudoaneurysm, covered stent and endo-leak.
Introduction:

Arterial injuries after penetrating trauma by multiple drug site injections can result in transection, pseudo-aneurysm, arterio-venous fistula, dissection, occlusion or aneurysm formation.

Pseudoaneurysm may cause significant complications, as skin ischaemia with resulting in necrosis, pain, infection, compression on other structures, as blood vessels and nerves, distal embolism, and rupture resulting in life-threatening bleeding (Tsetis D. 2010).

The most common complication of recurrent arterial punctures is the formation of Pseudoaneurysm, with increasing the chance of occurrence by parenteral drug addiction (Sharma NK. et al, 2001). The trauma of multiple drug injections in the femoral artery of addict patients and iatrogenic puncture result in Pseudoaneurysm formation (Levi MND. et al, 1995). Patients mostly presented with bleeding or aching pain at the groin region (Righini M. et a1, 2004).

The diagnosis of Pseudoaneurysm is easily reached, but incorrect diagnosis as an abscess resulting in a tremendous bleeding by drainage. The best choice of assessment is duplex ultrasound. In case of non-infected pseudo-aneurysms that discovered as early as possible because of local swelling in the groin area post multiple arterial trial injections. Endovascular treatment for this type of pseudoaneurysm is considered the best choice of treatment with less invasive maneuver that help the patient to set out of hospital as rapid as possible (Bukhtiari AM. et al, 1998).

Patient and methods:

This study is a prospective clinical trial study that conducted at surgical department, Suez Canal University Hospital, Ismailia, Essalam hospital in Port-Said Angio suite and two central hospitals in Port Said, Egypt, over a period of 25 months since November 2018, 22 patients were involved in this study, and all patients were informed about different ways of management and role of endovascular intervention with all risks and benefits using an informed consent from patients. All the patients were addict for different durations, with different types of drugs and different route of administrations (by injections, oral and inhalation). The patients attend complaining of a local pulsatile swelling at the site of recurrent drug injection with normal skin overlying (healthy skin). Cases with marked local inflammation or infected aneurysms were excluded from this study.

In the study, the patients mentioned that, they discovered a swelling in the groin resulting of multiple punctures to get the vessel for injection of drug. And feeling of pain by recurrent trauma to the wall of the vessel, with increasing pulsatile swelling
could be detected in all patients with dual-phase (systolic and diastolic) vascular bruit, was detected in each patient.

The best way to confirm the right diagnosis of pseudoaneurysm is duplex ultrasound. By revealing of extravasation of blood flow through a false lumen connected to the native arterial flow at the multiple entrance site.

Duplex ultrasound facilitate detection of two different way of the blood flow (pansystolic pathway from the native lumen of the artery to the neck of the false lumen, and pandiastolic back flow). So, using the color duplex ultrasound technique to identify the specific site of neck of the pseudoaneurysm by detecting the abnormal flow.

For the assessment of shape, origin and connection of pseudoaneurysm with the true lumen of the vessel, multidetector computed tomographic (MDCT) angiography was done using an iodinated contrast agent (70—100 ml Ultravist 370) at 3 ml/sec. all the patients were assessed from the abdominal aorta till the arch of the foot.

The target was to maintain patency of the artery, with all significant branches.

**Table (1)**

There are different sites for drug injection used by addicts to reach to blood circulation; the most common site forming pseudoaneurysm in the femoral region (femoral artery) and the elbow region (brachial artery) 36.4% and less by saphenous vein 4%. In addition, three patient (12%) used the carotid artery for injection, and patients could use different sites after difficult reach the old one.

<table>
<thead>
<tr>
<th>Site of injection</th>
<th>Brachial a</th>
<th>Femoral a</th>
<th>Carotid a</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patient</td>
<td>8</td>
<td>11</td>
<td>3</td>
<td>22</td>
</tr>
<tr>
<td>Percent %</td>
<td>36.4%</td>
<td>50%</td>
<td>13.6%</td>
<td>100%</td>
</tr>
</tbody>
</table>

There are other patients presented with radial artery ( 2 patients) and saphenous vein ( one patient) are excluded from the study as the different maneuver done to these patients by ligation of the vessel and excision of the aneurysms.

**Table (2)**

Most age group of incidence of traumatic pseudo aneurysm between 15 – 25 years old and 25 to 35 years old (45.5% & 27% respectively), and less above 55 years old (4.5%).

<table>
<thead>
<tr>
<th>Age in year</th>
<th>15-25</th>
<th>25-35</th>
<th>35-45</th>
<th>45-55</th>
<th>&gt;55</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>10</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>22</td>
</tr>
<tr>
<td>%</td>
<td>45.5%</td>
<td>27%</td>
<td>13.5%</td>
<td>9%</td>
<td>4.5%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Selection of patients in the study:

Inclusion criteria:
All addict patients presented with femoral, brachial and carotid arteries pseudoaneurysm post multiple site drug injection.

Exclusion criteria:

1- Patients known to be can’t tolerate the contrast as pre-renal disease or hypersensitivity to contrast.
2- Patients presented with radial artery or saphenous vein aneurysm, as managed by different procedure (ligation and excision).
3- Patients refused participation in the study or difficult to follow up.
4- Patients with inflamed aneurysm

Procedure
The interventions were performed in a dedicated endovascular suite. Initiated by the injection of 10 mL of 1% lignocaine as a local anesthesia at the entrance site. After puncture of the artery, an 8-Fr introducer (entrance) sheath (William Cook Europe, Bjnverskov, Denmark) was inserted, by reaching the artery, and flushed with 3000 IU unfractionated heparin.

The entrance point for assessment of site and size of pseudoaneurysm in distal superficial femoral artery through antegrade approach by ipsilateral common femoral artery. But, if the pseudoaneurysm in the inguinal region, it’s better to be contralateral retrograde approach, (72.7%) 8 patients through contralateral retrograde femoral access). The brachial artery reached by axillary artery ipsilateral antegrade approach. Or through retrograde RT. Femoral access if not accessible, (12.5%) one patient through retrograde femoral access). The carotid could be reached through the retrograde brachial artery or femoral access, (33.3%) one patient through femoral access).

For assessment of the site and dimension of the pseudoaneurysm, a 10 ml of contrast (ULTRAVIST 300; Bayer Inc., Canada) was injected to get images of all data about the swelling. Endovascular evaluation was done by selective angiography and the entrance sheath was inserted away of origin of the aneurysm to facilitate identification the location and dimension of the aneurysm. Moreover, the target of angiography is detection of inflow and outflow of the swelling.

Using the roadmap guidance, by the needle, entrance sheath and the guidewire inserted into the target affected artery, then replaced the wire with a 0.035-in
hydrophilic wire (Terumo Corporation, Tokyo, Japan) using an angiographic catheter.

Finally, after confirmation of diagnosis of pseudoaneurysm by selective catheters and angiograms, using a stiff guidewire, an 8 Fr. Entrance sheath was inserted over it. Insertion of a self-expandable stent graft of an appropriate diameter and length over the guidewire and deployed ideally at the exact point origin of the pseudoaneurysm using roadmap guidance.

Using covered stents is considered the established therapeutic option for the management of recurrent traumatic pseudoaneurysm in addict patients. By covering and preventing the supply to the aneurysm by the circulation. By evaluation of various types of stents, discovered that, the covered stents lined by expanded polytetrafluoroethylene can overcome the process of remodeling of the vessel by mechanically scaffolding its wall that occur later on. This happen by preparing a barrier against neo-intimal hyperplasia. So, providing increasing of stent patency (Virmani R. et al, 1999).

In some instances, minimal extravasation of stain proximal or distal to the inserted stent by control angiograms. Subsequently, the balloon catheter of the same diameter used to expand the stent. By the end of the intervention, no filling of lumen of the pseudoaneurysm and the inserted stent was patent; then, removing of the sheath and the wire later on.

A 70 IU/kg heparin was given to the patients during the procedure as a medical treatment. Next day to the intervention, discharge of the patients to home and recommended to keep on 100 mg aspirin and 75 mg Clopidogrel per oral once a day for one month for sure of patency of the stent.

At 1, 3, 9 and 12 months post- intervention, were the follow up of the patients. Including clinical assessment and measurement of ankle brachial index (ABI) and investigation by duplex ultrasound (Lammer J. et al, 2013).

**Result:**

In the study, we deal with non-complicated aneurysms after drug injection. As must be non-infected and evaluated by laboratory investigations for WBCs and with duplex ultrasound to evaluate the condition of the aneurysm and the wall and possibility for endovascular intervention.

Immediate technical evaluation of the procedure. Using covered stent for the vessel of the patient to cover and close the pseudoaneurysm. Then, by the end of the
procedure conventional to confirm exclusion of any para-anastomotic aneurysm in all patients.

Among the 22 patients, 20 were males and 2 were females. 5 patients (22.8%) were diabetics, 3 patients (13.7%) were hypertensive, and 6 (27.3%) patients have hyperlipidemia, 4 (18%) patients have ischemic heart disease, 4(18%) patients have liver disease.

**Table (3):** Demographic data about participating patients in study:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>31.2 ± 9.2</td>
</tr>
<tr>
<td>male</td>
<td>20 (90.9%)</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>24.5 ± 8</td>
</tr>
<tr>
<td>HPT</td>
<td>3 (13.7%)</td>
</tr>
<tr>
<td>D.</td>
<td>5 (22.8%)</td>
</tr>
<tr>
<td>IHD</td>
<td>4 (18.2%)</td>
</tr>
<tr>
<td>hyperlipidemia</td>
<td>6 (27.3%)</td>
</tr>
<tr>
<td>smoking</td>
<td>20 (90.9%)</td>
</tr>
<tr>
<td>HBV</td>
<td>3 (13.7%)</td>
</tr>
<tr>
<td>HCV</td>
<td>4 (18.2%)</td>
</tr>
<tr>
<td>HIV</td>
<td>1 (4.5%)</td>
</tr>
</tbody>
</table>

BMI (body mass index), HPT (hypertension), D (diabetes), IHD (ischemic heart disease), HBV (hepatitis B virus), HCV (hepatitis B virus) and HIV (human immunodeficiency virus).

**Table (4):** Pre intervention assessment:

<table>
<thead>
<tr>
<th>Radiological finding</th>
<th>Femoral</th>
<th>Brachial</th>
<th>Carotid</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombus in pseudoaneurysm</td>
<td>2 (9.1)</td>
<td>6 (27.3%)</td>
<td>-</td>
<td>8 (36.36%)</td>
</tr>
<tr>
<td>Arterio-venous fistula</td>
<td>1 (4.54%)</td>
<td>-</td>
<td>-</td>
<td>1 (4.54%)</td>
</tr>
<tr>
<td>Length of Pseudoaneurysm (cm)</td>
<td>9.4 ± 1.18</td>
<td>6.5 ± 0.79</td>
<td>3.9 ± 0.4</td>
<td>9.1 ± 0.8</td>
</tr>
<tr>
<td>Width of Pseudoaneurysm (cm)</td>
<td>7.2 ± 1.2</td>
<td>5.3 ± 0.62</td>
<td>3.5 ± 0.31</td>
<td>5.8 ± 1.7</td>
</tr>
<tr>
<td>Size feeding defect (mm)</td>
<td>4.2 ± 1.4</td>
<td>3.9 ± 0.41</td>
<td>3.7 ± 0.4</td>
<td>3.1 ± 1.3</td>
</tr>
<tr>
<td>Stenosis of the artery because of compression</td>
<td>10 (45.5%)</td>
<td>7 (31.8%)</td>
<td>3 (13.6%)</td>
<td>20 (90.9%)</td>
</tr>
</tbody>
</table>
Table (5): Complications post procedure:

After endovascular intervention, and insertion of the covered stent, different complications were faced after finishing the procedure, was 4.5% (one patient) thrombosis of the artery, thrombectomy was done and follow up of the patient conservatively with best medical treatment. Only one patient presented with endo-leak (type 1A) and managed the condition by conservative and follow up the complication, and no bleeding occurred for any patient.

<table>
<thead>
<tr>
<th>complications</th>
<th>Thrombosis</th>
<th>Endo-leak</th>
<th>Bleeding</th>
<th>Non</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patient</td>
<td>1 (brachial a.)</td>
<td>1 (femoral a)</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>%</td>
<td>4.5%</td>
<td>4.5%</td>
<td>0%</td>
<td>90.9%</td>
</tr>
</tbody>
</table>

Table (6): Post intervention assessment:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>success of procedure</td>
<td>22 (100%)</td>
</tr>
<tr>
<td>Normal peripheral pulse</td>
<td>22 (100%)</td>
</tr>
<tr>
<td>Active hemorrhage</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Additional treatment</td>
<td>2 (9%)</td>
</tr>
</tbody>
</table>

Table (7): measurements of ABPI along the study.

<table>
<thead>
<tr>
<th>Time of assessment</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
<td>0.65 ± 0.11</td>
</tr>
<tr>
<td>Post intervention</td>
<td></td>
</tr>
<tr>
<td>immediate</td>
<td>0.85 ± 0.07</td>
</tr>
<tr>
<td>3 month</td>
<td>0.85 ± 0.06</td>
</tr>
<tr>
<td>9 month</td>
<td>0.86 ± 0.05</td>
</tr>
<tr>
<td>12 month</td>
<td>0.87 ± 0.05</td>
</tr>
</tbody>
</table>

Noticed improved in ABPI preoperative to postoperative (0.65 ± 0.11) to (0.87 ± 0.05) respectively.

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**Figure (1):**

Angiography for assessment showed RT SFA pseudoaneurysm.

**Figure (2):**

Post angioplasty showed normal intervention using covered stent.

**Figure (3):** angiogram showed RT CFA Pseudoaneurysm post injections

**Figure (4):** post intervention using covered stent with normal flow.
Figure 7: color duplex for femoral pseudoaneurysm.

Figure 8: color duplex of brachial pseudoaneurysm.

Figure 9: Angiogram showed distal superficial femoral artery pseudoaneurysm.

Figure (5): Angiogram showed LT brachial a. Pseudoaneurysm post injections

Figure (6): post intervention with covered stent with normal blood flow
Discussion:

Multiple complications can be occurred as the result of recurrent drug injections. Including local inflammation at site of injection, venous thrombosis, insufficiency and infective endocarditis. Femoral pseudoaneurysm considered as a consequence of recurrent groin injection in drug addict patients by intra-arterial or peri-arterial injection of illicit drug (Huebl, H.C. & Read, R.C. 1996).

It is vital to reach the right diagnosis, by detection a pulsatile swelling at the site of recurrent drug injections. Because of the delaying of attendance of addict patients to the hospital, and taking medications to overcome the problem. Therefore, this explain the delay of detection of signs and symptoms of infection. The diagnosis of pseudoaneurysm can be obvious and easily made by clinical assessment. The misdiagnosis of the condition inadvertently with massive bleeding if drained as an abscess (Reddy, D.J. et al, 1986).

The main choice of diagnosis is duplex scanning, with pulsed and color Doppler flow mapping. The criteria of assurance of diagnosis of pseudoaneurysm include: Detection of color flow passing through a mass separated from the main artery, and color flow through a tract from the artery to lumen of mass consistent with pseudoaneurysm neck, and a typical “to and fro” ultrasound waveform in the neck of pseudoaneurysm (Eisenberg L. et al, 1999).

Preoperative confirmation of diagnosis of the swelling and delineate the anatomical site and the feeding of the aneurysm using digital subtraction angiography (DSA). The accuracy and reliability of DSA for confirmation of diagnosis of pseudoaneurysm in drug addicts was later confirmed (Shetty, P.C. et al, 1995). But, recently the color duplex ultrasound scanning has become the best choice for assessment, and details of the anatomy given by angiography is considered non-indicated (Paulson, EK. et al 2003).

In this study, 22 drug addict patients complaining of different sites pseudoaneurysm and were successfully treated using covered stents, associated with follow-up of patients for a time.

We consider the endovascular intervention is the best way for management of PVD. Many trials done for achieving a high rate of success in this modality of treatment in all peripheral vascular problems. In addition, efforts spent for development of the instruments that facilitate the ease of the procedure and increasing rate of success.
Therefore, using of endovascular intervention in management of traumatic pseudo aneurysm post multiple drug injections considered a new and better way to deal with the problem, to avoid different type of obstacles and complications that can be faced during the surgical maneuver.

Whereas Some investigators who over a long time, deal with most of traumatic pseudo aneurysm post drug addiction by different site injections through open surgical intervention by direct attacking the aneurysm that detected by examination and diagnostic radiology, as Open surgery still invokes a relatively high bleeding risk and possibility of thrombosis (Tisi, H. et al, 2013).

Other investigators report that endovascular intervention using a covered stent is an alternative to open surgery, which has revealed an improvement over only percutaneous transluminal angioplasty for the management of aorto-iliac and femoral occlusive disease since 1969 (Blum U. et al, 1993). In comparison with angioplasty, insertion of stent gives similar rate of complications; however, the rate of technical success by stenting is often higher and reduction of the risk of long-term failure (Ferreira J. et al, 2010) (Puech-Leão P. et al, 2011).

By management of the patients with endovascular stenting which considered as a non-invasive procedure, resulted in decreasing of time of operation and hospital stay in comparing with open surgical intervention (Devecigolu M. et al, 2014). Furthermore, such type of minimal invasive approach, could prevent the outcomes of surgical repair and its related risks, especially in specific patients as cachectic, immune-compromised patients with low nutritional, social and general health status (Antoniou GA. et al, 2014).

The measurements of ABI were mildly increased in the follow-up. As the result of lack chances of restenosis and restoration of steady blood flow in the artery. Although, in a previous study, after 9 months of surgical operation, ABI values were stable, with no significant differences were mentioned in comparing with normal legs (Duda SH. et al, 2002).

Non of our cases suffered haemorrhage While surgical management, the complication of hemorrhage resulting from open surgical intervention and traditional treatment may result in increasing the chance of mortality (up to 7.5% within 1 year) (Dzijan-Horn M. et al, 2014). Furthermore, surgical treatment for pseudoaneurysm is not recommended in patients with ischemia of surrounding tissues, resulted from vascular affection, deep venous thrombosis, nerve compression or infected pseudoaneurysm. Although, the efficacy of ultrasound-guided compression is very high. But, it’s applicable only for narrowed neck pseudoaneurysm, as it grows slowly and keeps small size, location and relations (Latic A. et al, 2011). So, in our study, endovascular approach of repair by a covered stent was considered the best

To reduce the possibility of stent fracture and thrombotic formation, we should care about the length of the used covered stent to be relatively short. However, the problem of intravascular leakage can result from too short stent. By adding our clinical knowledge with the data of previous studies, the decision taken for the covered stents in the study, was slightly larger in diameter than the target artery (10–20% larger). And the length of the stent should be longer than the injured part of the artery, but the edges were no more than 1cm proximal and distal to the injured part of the artery in the health artery (Li Z. et al, 2014).

It is vital to reach the right diagnosis, by detection a pulsatile swelling at the site of recurrent drug injections. Because of the delaying of attendance of addict patients to the hospital, and taking medications to overcome the problem. Therefore, this explain the delay of detection of signs and symptoms of infection. The diagnosis of pseudoaneurysm can be obvious and easily made by clinical assessment. The misdiagnosis of the condition inadvertently with massive bleeding if drained as an abscess (Reddy, D.J. et al, 1986).

Conclusion:
The using of endovascular angioplasty by covered stent considered the best way for management of pseudoaneurysm post multiple injections for drug abuse. Saving time and less postoperative hospitalization stay, and less in mortality and blood loss.

Conflict of Interest/Funding:
None.
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