

Use of the Multilayer Flow Modulator for the Treatment of Complex Iliac Artery Aneurysms

Kompleks İliak Arter Anevrizmalarında Çok Katmanlı Akış Modülatörü Kullanımı

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Abstract: We are presenting early- and mid-term results of iliac artery aneurysms treated with the Multilayer Flow Modulator (MFM). The MFM was used to treat 14 aneurysms involving the internal and external iliac arteries (complex iliac artery aneurysm). The procedure was performed under local anesthesia implemented through femoral artery under local anesthesia. The effective implantation of MFM within the aneurysmal area without complications was defined as a successful intervention. The patients were followed for the development of clinical events during 12 months. A total of 8 out of 14 aneurysms were presented with complex iliac artery aneurysm and they were successfully treated using MFM. While iliac artery aneurysm was bilateral in six patients, it was unilateral in two patients. In addition, 6 patients were male and two patients were female with average age of 64 years ranging from 56 to 72 years. Type 1 endoleak occurred in one patient. Endovascular re-intervention ballooning was performed (ballooning) and the endoleak was successfully treated. The creatinine level increased to 2.1 mg/dl on the 2nd post-operative day in one of the patients but the patient did not need any dialysis and his kidney functions returned to normal on the 7th day after the operation. Moreover, right iliac artery occlusion occurred in one of the patients on the 30th day after the operation and the occlusion was treated with thrombectomy followed by ballooning and stenting. No other complications developed either during or after the procedure. MFM stents appeared to be effective and safe in the treatment of complex iliac artery aneurysms. Our results need to be supported by larger and longer-term follow-up studies.

Key Words: Iliac artery aneurysms, multilayer flow modulator, endovascular treatment

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Özet: Multilayer Flow Modulator (MFM) ile tedavi edilen iliak arter anevrizmalarına ait erken ve orta dönem sonuçları sunmak. İnternal ve eksternal iliak arter tutulumlu 14 anevrizmanın (Kompleks iliak arter anevrizması) tedavisinde Cardiatis MFM stentler kullanıldı. İşlem lokal anestezi altında femoral arter yoluyla yapıldı. MFM stentin komplikasyon olmaksızın anevrizmalı bölgeye yerleştirilmesi başarılı girişim olarak tanımlandı. Klinik olay gelişimi açısından hastalar 12 ay boyunca takip edildi. Toplam 8 hastada 14 kompleks iliak arter anevrizması mevcuttu ve MFM stentler ile başarılı bir şekilde tedavi edildi. 6 hastada iliak arter anevrizması bilateral iken, 2 hastada tek taraflı idi. Hastaların 6'sı erkek, 2'si ise bayan idi ve ortalama yaş 64 idi (56 - 72). Bir hastada tip 1 kaçak oluştu. Aynı seansta endovasküler ek girişimler ile (balon) endoleak başarılı bir şekilde tedavi edildi. Bir hastada işlem sonrası 2.gün kreatinin seviyesinde (2,1mg/dl) yükselme oldu. Diyaliz ihtiyacı olmadı ve böbrek fonksiyonları 7. gün tamamen normale döndü. Başka bir hastada 30. gün sağ iliak arterde MFM' nin distal tarafında trombotik oklüzyon gelişti. Trombektomi yapılarak kobalt kaplı balon ekspandable stent yerleştirildi ve akım sağlandı. Bunlardan başka işlem esnasında yada sonrasında komplikasyon gelişmedi. Hiçbir hastada mortalite olmadı.MFM stentler, eksternal ve internal iliak arter tutulumlu anevrizmaların tedavisinde etkili ve güvenli bir alternatif olarak görülmektedir. Bizim sonuçlarımızın daha büyük sayılı ve daha uzun süreli takipli çalışmalarla desteklenmesi gereklidir.

Anahtar Kelimeler: multilayer flow modulator, iliak arter anevrizması, endovasküler tedavi

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1. Introduction

Iliac artery aneurysms (IAA) are an uncommon pathology, with an estimated incidence of 0.03 – 0.4% in the general population. IAA are often associated with abdominal aorta aneurysms (AAA). Isolated IAA are considerably rare and account for about 2-7% of all abdominal aneurysms (1-4). Although they are often asymptomatic and show a subtle progress, they carry a high risk of rupture as they reach a bigger size. IAA rupture being a serious morbidity and mortality reason, early diagnosis and patient management is of utmost importance (5,6).

Surgery remains the gold standard in the treatment of IAA. However, with recent developments in stent-graft technology, endovascular aneurysm repair (EVAR) has emerged as a solid alternative since the 90s. Due to the necessity of spending less time in intensive care and patients presenting with other -and often numerous- comorbidities, the use of EVAR has increased and has also led to minimized blood loss during procedure, has limited the need for transfusion and diminished mortality and morbidity (7-9).

Conventional stent grafts are often used when major branches are involved in the aneurysmal area. If conventional endovascular stent grafts are not compatible with patient anatomy, other techniques have been developed and they are in use for complex aneurysms involving major branches. The most described are the chimney stent graft, the fenestrated stent grafts and Multilayer Flow Modulator (MFM). In the chimney and fenestrated technique, the aneurysm is isolated and the flow to major branches is respectively continued with the use of parallel grafts and fenestrations. Those procedures are reported to be complex and do not present satisfying clinical results (10,11). The MFM constitutes an appealing off-the-shelf alternative since it does not require any customization, is readily available in a wide range of lengths and diameters and has already demonstrated very good mid-term clinical results (10,12,13).

The MFM has been developed for the treatment of peripheral arterial aneurysms (CE-Marked in 2009) and aortic aneurysms (CE-Marked in 2011). This device is an uncovered, self-expanding wire 3D-mesh with

high radial force and flexibility. It is designed to modulate blood-flow dynamics by relieving local peak wall shear stress (PWSS), achieving stabilization of aneurysm-sac or false lumen pressure and preserving branches patency. Aneurysm rupture is prevented while flow lamination allows for both aneurysm thrombosis and branch perfusion (14,15).

The present study offers early- and mid-term results on 8 patients with complex iliac artery aneurysms treated with MFM.

2. Materials and Methods

Eight patients were treated with MFM between January 2015 and July 2016. Inclusion criteria were determined as presenting with aneurysms of at least 35 mm diameter and having internal or external iliac artery involvement in the aneurysmal area. Technical success was defined as MFM, successfully deployed without any complications. Mean age of the patients was 64 years (56-72). Six patients were male and two patients were female. Seven out of 8 patients were presented with concomitant fusiform AAA along with IAAs. The last patient developed a traumatic isolated IAA due to a lumbar disc hernia-related surgical intervention (Figure 1). Three patients were asymptomatic while both others suffered from stomach and back pain. Regarding the comorbidities, 6 out of 8 patients had high blood pressure, 3 had diabetes mellitus, 2 patients had coronary artery disease, 4 patients possessed hyperlipidemia and 2 had obstructive lung disease. Patients' characteristics are summarized in Table 1. Aneurysmal configuration and the presence/involvement of major branches were evaluated in detail before the procedure by performing CT angiography in all 8 patients. Artery diameter, wall calcifications, presence of thrombus in artery lumens, required MFM length and artery angulations were calculated. Examination of access femoral arteries was performed and consideration regarding compatibility of the delivery system size and access artery diameter was made. MFM were oversized over the diameter of the target artery.

Iliac aneurysm was also accompanied by AAAs in 7 patients. MFM was used in 5 of these patients because they had critical sub-branches inside the sac of the aorta aneurysm (superior mesenteric artery (SMA), coeliac trunk (CT) and renal arteries (RA)). Other two patients were implanted with an Endologix AFX (Endologix, USA, CA, Irvine). In those 7 patients with AAA, complex IAAs were treated with the MFM (Figure 2). Notably, both the internal and external iliac arteries were involved in the aneurysmal area and covered by the device in all 7 patients. In the remaining patient, the

IAA due to lumbar disk hernia surgical intervention was located on the bifurcation level of the right iliac artery and was treated with the MFM. All patients were properly informed about the procedure and a signed consent form was obtained. Procedures that were completed under sedation and local anesthesia were performed as per the requirements of an angiography unit. The patients were discharged on a prescription of 100 mg/day aspirin/day and 75 mg/day clopidogrel/day. They were followed up on the 1st, 3rd, 6th and 12th months.

Table 1. Main characteristic features pertaining to the patients

	(n)
Sex	
• Male	6
• Female	2
Age (years)	64 (range: 56-72)
Iliac anerysm	
• Bilateral	6
• Unilateral	2
Presence of concomitant abdominal aortic aneurysms	7
Symptoms	
• Stomachache / backpain	5
• Asymptomatic	3
High blood pressure	6
Diabetes Mellitus	3
Coronary artery disease	2
Hyperlipidemia	4
Chronic obstructive respiratory disease	2

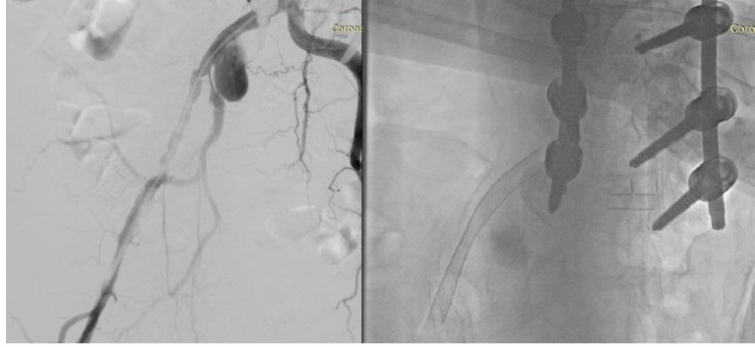


Figure 1. Pre/post-operative images of traumatic isolated right iliac artery aneurysm consequent to lumbar disc hernia surgery



Figure 2. Pre/post-operative images of iliac artery aneurysm

3. Results

Procedure was successfully performed in all 8 patients and technical success was thus 100.0%. Average procedure duration in patients presenting with concomitant AAA was 65 minutes and the average hospitalization stay was 6.5 days. In the other patient, procedure duration was 25 minutes and the hospitalization stay was 4 days. All patients were monitored for about 12 months (range of 6-18 months) with regards to the development of clinical events. (Table 2). Type 1 endoleak occurred in one patient. It

consisted of a small leak on the distal side of the MFM inserted in the iliac artery. Endovascular reintervention ballooning was performed and the endoleak was successfully treated.

One patient presented with increased creatinine level to 2.1 mg/dl on the 2nd day after the operation. The patient did not require dialysis and on the 7th day, functionality of the kidneys was restored. One thrombotic occlusion occurred in the right iliac artery in one patient, the MFM distal side

occluded on the 30th day (Figure 3). Cobalt covered balloon expandable stent was successfully implanted and the flow was restored with thrombectomy. No other complications have been recorded and no mortality was documented (Table 2).

Table 2. Results

The number of patients that have been implanted with MFM®	(n)
• Bilateral implantation	6
• Unilateral implantation	2
• Overall application	14
Intervention success (n,%)	14 (100%)
Procedure-related Adverse Events	
• Endoleak	1
• Femoral hematoma	0
• Stent migration	0
• Aneurysm rupture	0
• Other	0
Other Adverse Events	
• Acute Kidney Injury	1
• MFM® occlusion	1
• Other	0
Anesthesia type	
• Local	8
• General	0
Procedure duration (minutes)	
• Presence of concomitant abdominal aortic aneurysms	65±12
• No concomitant abdominal aortic aneurysms	25
Hospital stay (days)	
• Presence of concomitant abdominal aortic aneurysms	6,5
• No concomitant abdominal aortic aneurysms	4
12 months Mortality (n,%)	0 (0%)

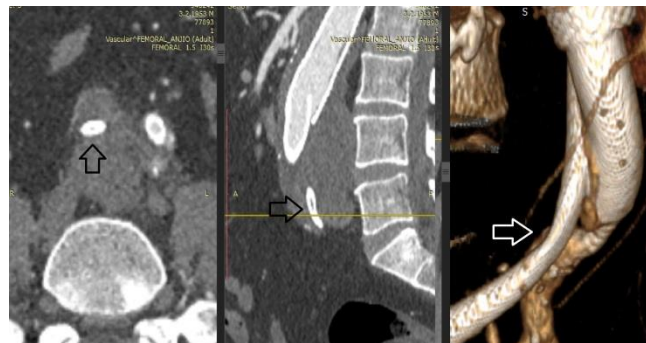


Figure 3. Thrombotic MFM occlusion of MFM in the right iliac artery (arrows)

4. Discussion

The MFM is a new, unique device which is used for the treatment of complex aneurysms. Its usage has increased with time and is being more frequently reported in the literature (12-15). In this study, we presented our early- and mid-term results on 8 patients treated with the MFM for IAA.

The larger the diameter of aneurysms is, the higher the tension on the aneurysm wall. Also, recirculating flow inside the aneurysm sac is one of the main factors causing the aneurysm to expand and to rupture. Surgical treatment is the gold standard in treatment of iliac artery aneurysm. Despite all the improvements in the field, mortality rates can reach up to 11% and 50% in elective facts and ruptured aneurysms respectively (16,17). Endovascular approach has become increasingly relevant, especially in old patients with other comorbidities. Its use has been boosted in the recent years; EVAR being the first choice for most health centers, causing much less morbidity and mortality rates compared to Open Surgical Repair EVAR mortality rates falls within the range of 0 to 3.6% for IAA treatment (7,17,18). Notably, no mortality was documented in all 8 patients treated with the MFM.

In the event IAA stretches out to Internal Iliac Artery (IIA), a treatment solution is using conventional stent grafts. However, IIA occlusion is often necessary to avoid endoleak. (4). Pelvic ischemia resulting in complications such as gluteal claudication, erectile dysfunction, colonic and spinal ischemia can occur in case of atresia or tightness in contralateral IIA due to IIA's occlusion (19). General complication rate after the occlusion of IIA is not negligible and comprised between 12 to 20% (20,21). IIA bypass operation, chimney grafts, fenestrated stent grafts and the MFM are the most used methods to prevent this. When the aneurysm is isolated, chimney and fenestrated stent grafts can mechanically ensure the flow to major branches. However, applying these stents is technically challenging, complication rates are high and clinical results are not satisfying (10,11). Importantly, the MFM is becoming an relevant treatment alternative, its advantages lying in its ease of use and its off-

the-shelf availability with early- and mid-term good clinical results. Several studies about the use of the MFM for the treatment of visceral and peripheral artery aneurysms such as hepatic artery, renal artery, subclavian artery as well as thoracoabdominal aneurysms have been published, documenting good clinical outcomes (10,12,13). In the present study, the patients were elected for MFM implantation due to the complexity of IAA; their treatment with conventional stent grafts would have led to occlusion of IAA and consequent complications.

In the study of Ruffino et al., 54 patients who suffered from peripheral and visceral aneurysms were treated with the MFM and were followed during 12 months. Branches patency at a rate of 97.9% has been reported (22). In the STRATO study by Vaislic et al., 23 patients were treated with MFM and at the 12-month follow up, the branches patency rate was 96% (13). In the 8 patients treated with the MFM and reported here, patency of all major branches was achieved after implantation. However, one patient out of 8 patients came on the 30th day because of acute occlusion in the lower right extremity. CT angiography allowed for the detection of a collapse of the distal end of the MFM and the presence of an atheromatous plaque at this location. It collapsed in because of the plaque in distal end of the iliac MFM device. The external iliac artery (EIA) occluded as a result of thrombus formation. The patient was successfully re-intervened upon and by making an intervention from the right femoral artery, thrombectomy has been applied with thrombectomy catheter on the distal side of the MFM device that has a collapse, and a flow has been achieved by placing a balloon expendable stent covered with cobalt. Apart from this event, no occlusion of the covered branches occurred during the 12-month follow-up. In the literature, it was shown that besides an insufficient anticoagulant treatment, there were the filaments in the outcome areas of the stent thrombogenic and this might result in-stent occlusion compliance to anticoagulation treatment is of utmost importance for preventing in-stent thrombosis and occlusion. Within a year,

Ruffino et al., identified 11% of stent occlusions probably due to improper anticoagulation medication compliance and as a result of this and emphasized on the significance of providing an effective habitation with balloon dilatation of the proximal and distal ends of the stent (22). We think that the collapse of the distal end of the MFM was due to the progression of the atherosclerotic plaque and not the thrombogenicity of the struts at the distal end of the MFM.

The study presented here has some limitations of being retrospective, with a short follow-up period is short and low number of patients. Two factors affecting the number of patients are very low incidence of the pathology and the high cost of MFM in our country, not

being subjected to re-imburement at the present day. Although the MFM can be virtually used to treat almost all aneurysms, we decided to treat aneurysms involving major branches only. As for the other aneurysms, we preferred either to use conventional stent grafts or surgical repair.

5. Conclusion

MFM for the treatment of iliac artery aneurysm involving major branches can be assumed reliable and competent based on the present results; however, present results need to be strengthened with larger samples and longer follow-ups.

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