Safety and Feasibility of a Novel Vascular Closure Device in Neurointerventional Procedures

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Summary

This retrospective study evaluated the safety and feasibility of a new arterial femoral access closure device in neurointerventional procedures.

The study includes all consecutive adult patients who underwent femoral arteriotomy closure with the MynxGrip™ closure device after Neurointerventional procedures performed between June and December 2012. All patients had a follow-up color Doppler ultrasound (US) within 48 hours after the procedure, which was independently interpreted by two experienced radiologists to evaluate for access site complications. Device success/failure, sheath size, ambulation time, and periprocedural complications were recorded.

Fifty-five closure devices were deployed in 53 patients. There were 23 (43%) males and 30 (57%) females; age ranged from 22 to 84 years (mean: 52.1 years). Thirty of the 55 procedures (55%) were therapeutic and 25 were diagnostic interventions (45%). Sheath sizes used were 5F in 35 procedures (64 %) and 6F in 20 procedures (36%). The right femoral artery was accessed in 51 procedures (93 %) and the left in four procedures (7%). There was only one (1.8 %) minor periprocedural complication (small hematoma). Hemostasis was successful in 51 of the 55 procedures (93 %) with subsequent early ambulation. No device-induced complications associated with serious clinical sequelae were reported.

In our small series, the MynxGrip™ femoral access closure device provided a safe and feasible way of closing the femoral artery puncture site after neurointerventional procedures with low minor complication rates and no major

complications. Further large prospective randomized trials are necessary to evaluate the efficacy of the device.

Introduction

Femoral access closure devices have been reported to reduce time to ambulation, increase patient comfort, and accelerate time to discharge compared with manual compression¹⁻⁴. A percutaneous collagen femoral closure device has been shown to reduce the puncture site hemostasis time and time to ambulation without significantly increasing peripheral vascular complications⁵. Yet widespread use of these devices has not occurred due to acute complications related to placement and to the intravascular components required for vascular closure. In addition, there are longer-term clinical limitations related to residual metallic or animal-based implanted components. Questions also persist regarding the ability to re-access the artery or reuse femoral access closure devices in the same arterial regions after periprocedural complications. For example, severe vascular complications have resulted from the use of some vascular closure devices that require surgical intervention for retrieval of intra-arterial components, thrombolytic therapy, and, in worst case situations, limb loss^{6,7}. Furthermore, these complications are likely to result in prolonged hospitalization and added cost.

The pursuit of an ideal closure device would avoid use of permanent intravascular implants, minimize trauma to the arteriotomy site, have a minimal effect on platelet activation, be non-

inflammatory, and rapidly absorbed, allow repeat access at the same site, be simple to use and result in predictable outcomes regardless of operator skill level and the degree of anticoagulation or platelet inhibition. This study aimed to evaluate the safety and feasibility of the second generation of the extra-vascular, water-soluble femoral arteriotomy closure device (MynxGrip™) in neurointerventional procedures.

Materials and Methods

Institutional review board approval for this HIPAA-compliant study was obtained, with waiver of informed consent. From our radiology archive, we identified all consecutive patients at our tertiary care center that underwent MynxGrip™ closure of a femoral artery puncture after a diagnostic or therapeutic neurointerventional procedure from June to December 2012. All consecutive patients at our institution who had arteriotomy closure with the MynxGrip™ closure device underwent gray-scale/color Doppler ultrasonography (US) examination of the femoral artery performed within 48 hours following the procedure. The indication for the US was to rule out complications with the use of a new device before discharge and was performed without cost for the patient and considered part of the angiographic procedure.

A single neurointerventionalist with eight years of experience performed all procedures, in the angiography suite. Femoral artery cannulation was achieved with 21-gauge entry needles using a micropuncture technique. Iliofemoral angiography was performed using 5F or 6F systems. If the patient was receiving heparin, it was not reversed following the procedure. Periprocedural antibiotics were not used. We recorded patient age, sex, side of arterial access, hemostasis success/failure, sheath size, the indication for angiography, whether anticoagulant and/or antiplatelet therapy was in use, patient's ambulation time, and periprocedural complications.

Hemostasis failure was defined as an inability to achieve hemostasis immediately after deployment. Time to ambulation was defined as the time from device deployment until recovery room personnel noted that the patients had been removed from bed rest and allowed to ambulate or assume their baseline level of activity. A minor complication was defined as a small hematoma (≤ 3 cm in diameter). A major complication was defined as: pseudoaneurysm, arte-

rial dissection, occlusion, arteriovenous fistula, luminal filling defect, large hematoma (>3 cm), or groin infection. In addition, two radiologists with at least five years of experience independently reviewed the follow-up gray-scale/color Doppler US studies and documented whether minor or major complications had developed. When no clinical follow-up was available, the patient was contacted and asked if there had been any bleeding or swelling at the puncture site since discharge.

Results

Patient data are summarized in Table 1. We identified 53 patients who received MynxGrip™ devices; two patients underwent two procedures with MynxGrip™, for a total of 55 cases in which MynxGrip™ was used.

Among these 53 patients, there were 23 (43%) males and 30 (57%) females; their mean age was 52.1 years (SD=12.4 years). Thirty of the 55 procedures (55%) were therapeutic and 25 (45%) were diagnostic interventions. In 52 procedures (95%), the patient received between 3000 and 9000 IU heparin intravenously (mean 4268, SD 1761), while 15 (27 %) were taking antiplatelet agents, mainly ASA and clopidogrel; one patient was taking prasugrel. In 35 of 55 procedures (64%) we used a 5F sheath while a 6F sheath was used in 20 procedures (36%). One of 55 cases (1.8%) had a minor periproce-

Table 1 Clinical Characteristic.

	n= 55
Age	51.1 ± 12.4
Male gender	23 (43%)
Type of procedure:	
– Therapeutic	30 (55%)
– Diagnostic	25 (45%)
Patients who received IV heparin	52 (95%)
Heparin dose, IU	4268 ± 1761
Patients who received antiplatelet agents	15 (27%)
5 Fr sheath	35 (64%)
6 Fr sheath	20 (36%)
Minor complications	1 (1.8%)
Major complications	0 (0%)
Successful hemostasis	51 (93%)

Figure 1 The Mynx with Grip Technology vascular closure device.

dural complication (small hematoma). Hemostasis was successful in 51 out of the 55 procedures (93%; 95%CI 82-98%). Twenty minutes of manual compression were required to achieve hemostasis on four cases where hemostasis was unsuccessful. The ambulation time was two hours in all cases with immediate successful hemostasis. No device-precipitated complications associated with serious clinical sequelae were reported.

Discussion

The Mynx™ (a first generation extra-vascular, water-soluble closure device) consists of a delivery catheter with an intravascular balloon component and a coaxial delivered cartridge loaded with polyethylene glycol (PEG) sealant. It is designed to produce femoral artery hemostasis via extra-vascular delivery of a conformable, water-soluble sealant over the arteriotomy site. When deployed, the sealant is 5% polyethylene glycol (PEG) and 95% blood and tissue tract fluids. The porous structure of the PEG allows it to absorb blood and subcutaneous fluids, expanding three to four times its original size and filling the tissue tract. The PEG is a commonly used bio-inert, polymer material used for a range of medicinal applications with an established safety profile^{8,9}. The biocompatible nature of PEG allows the sealant to reside in the body without initiating platelet activation or an abnormal inflammatory response, or generating fibrous scar tissue. After hemostasis is achieved, the sealant begins a steady process of hydrolysis, dissipating within 30 days. The by-products of this reaction are PEG monomers that are small

enough to undergo renal clearance, quickly and consistently removing all traces of the sealant from the body.

The MynxGrip™ (Figure 1), the newer generation device, has the addition of a different type of PEG in the distal segment that adheres to the extra-vascular arteriotomy site. In the distal segment, the PEG components are combined, but are not reacted or cross-linked, triggering them to react and cross-link when exposed to the pH level and temperature inside the body^{8,10}. This cross-linking causes the PEG to soften and interlock with the contours of the vessel wall. Hemostasis is achieved through the combination of sealant expansion and active adherence to the artery wall.

The deployment technique followed was to insert the device into the existing procedural sheath with the same angulation used for the puncture. It was advanced until the white marker in the device was reached. At this point the compliant balloon was inflated inside the vessel. The Mynx-Sheath complex with the balloon inflated was then gently pulled back until resistance was encountered. This means the balloon is at the distal sheath site. Then the gentle pulling continued until resistance was encountered again indicating that the balloon was opposing the arteriotomy site. Tension was released in the device and confirmation of the position noted when there was back bleeding through the vascular sheath site port that stopped when tension was reapplied. This was performed twice to expose the sealant to blood. At this point the sealant was delivered gently and slowly. The delivering position was maintained for 30 seconds. Tension was then released in the system and after another 60 seconds the balloon was deflated

← Figure 2 A) The MynxGrip sealant technology. B) Grip tip technology (white) interlocking with vessel wall tissues (red).

Figure 3 Color Doppler of the right common femoral → artery showing a patent vessel without complicating features.

and the entire system withdrawn from the patient. Gentle manual pressure was then applied for two minutes.

Published results with MynxTM have varied; some report that it is safe and effective¹¹⁻¹³, while others reported significant complication rates with the first generation device^{14,15}. In our study, one minor complication was reported (1.8%) which is at the lower range of reported results using manual compression (1.5% to 9%,^{16,17}), slightly higher than those of AngioSealTM (0.13 to 1.4)¹⁸, and almost equal to StarClose (1.9%)¹⁹. No major complication was reported with MynxGrip. We have 51 cases (93%) of successful hemostasis which is slightly lower than AngioSealTM (99.7) and slightly higher than StarClose (91.2%). Time to ambulation was two hours in our study in all patients with successful deployment, the standard time adopted by most institutions when using closure devices. There are emerging reports of early ambulation, including one hour with AngioSealTM²⁰ and two to three hours after manual compression²¹) and even immediate ambulation with AngioSealTM²² and StarClose¹⁹.

However, one disadvantage of using AngioSeal is the intravascular deposition of one of the components of the device. Major complications such as pseudoaneurysm, vessel occlusion/stenosis and retroperitoneal hematoma have been reported with the use of AngioSeal¹⁸. Anecdotally we have encountered fibrosis at the AngioSeal closure site that causes difficulty when there is a need to access the femoral artery again. This difficulty was not encountered using the MynxGrip. In addition, with StarClose there is the disadvantage of a metallic foreign body left behind in the surface of the vessel. With early ambulation after manual compression there is still a small risk of major complications

such as pseudoaneurysms and large hematomas requiring surgical evacuation²¹.

The cost of the Mynx device at our institution is 195 US dollars (US\$) compared to US\$230 and US\$235 for AngioSeal and StarClose respectively. In our institution the charge for the first hour in a recovery bed is US\$1092. There is a charge of US\$364 for any additional half hour in recovery. The approximate cost for a two hour recovery period after successful MynxGrip deployment is approximately US\$2035 vs US\$4640 for a six hour recovery period after manual compression.

The four cases of unsuccessful hemostasis occurred during the first month of our experience with the device that probably relates to the learning curve associated with the use of any new device. Also the four cases were therapeutic interventions where a 6 F sheath was used. This was also the case for the small hematoma encountered in our series. We speculate that the use of a larger sheath size for therapeutic procedures played a role in the unsuccessful hemostasis and minor complication encountered at the beginning of our series. Experience is required to gain the skills of applying the right amount of tension when pulling back the balloon against the arteriotomy site (not too tight, just enough to achieve hemostasis) and also delivering the sealant gently and slowly, not forcefully since this will increase the risk of forcing the sealant into the vascular lumen with subsequent deployment failure and vascular complications.

Conclusion

In our small series the MynxGripTM femoral access closure device provided a safe and feasible way of closing the femoral artery punc-

ture site after neurointerventional procedures with low minor complication rates and no major complications.

Further large prospective randomized trials are necessary to evaluate the efficacy of the device.

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