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Mynx Vascular Closure Device Early Ambulation Study

The safety and benefits of 1-hour ambulation with the Mynx 5-F Vascular Closure Device.

BY VIKRANTH R. GONGIDI, DO; AHSAN JAFIR, DO; AND VIJAY VERMA, MD, FACC, FSCAI

Vascular closure devices (VCDs) are increasingly used for femoral access closure in cardiac catheterization, in large part because they allow for early ambulation after the procedure. The benefits of early ambulation include improved hospital throughput and earlier dischargeability, resulting in cost savings. In some cases, this early discharge can convert a potential inpatient procedure to an outpatient case. Early ambulation also can improve patient comfort, especially for those with comorbidities (eg, obesity, back pain, etc.) for whom extended time lying flat can be quite painful.

Early ambulation is of particular value for patients undergoing diagnostic procedures. The risk of vascular complications from diagnostic cardiac catheterization is relatively low, ranging from 0.4% to 3%,[1,2] and diagnostic procedures are less likely to involve heavy use of anticoagulants. Clinicians routinely perform diagnostic procedures entirely with 5-F catheters to minimize trauma to the vessel and reduce the risk of complications. Select VCDs, including the Mynx Vascular Closure Device (AccessClosure, Inc., Santa Clara, CA) (Figure 1), allow closure through an existing 5-F procedural sheath. The aim of the present study was to assess the safety and feasibility of early ambulation in patients undergoing diagnostic procedures utilizing a 5-F introducer sheath and compare outcomes to those in patients undergoing procedures with a 6-F sheath.

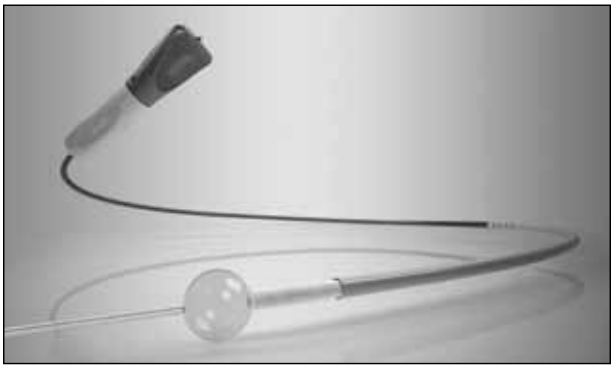

Figure 1. The Mynx Vascular Closure Device.

TECHNOLOGY OVERVIEW

The Mynx VCD is designed to achieve femoral artery hemostasis via delivery of an extravascular, water-soluble synthetic sealant using a balloon catheter in conjunction with the existing procedural sheath. The sealant is made of a polyethylene glycol material that expands upon contact with blood and subcutaneous fluids to seal the arteriotomy (Figure 2). The sealant is resorbed by the body within 30 days.

The Mynx received US Food and Drug Administration approval in May 2007. The original clinical study performed on the Mynx 6/7-F VCD has been described by Scheinert et al.[3] The Mynx VCD is indicated to seal femoral arterial access sites while reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5-, 6-, or 7-F procedural sheath.[4]

Procedures using 5-F sheaths for diagnostic coronary and peripheral catheterization are now common. These smaller sheaths decrease damage to the artery and reduce complications. However, many com-

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mercial VCDs require procedure sheath exchanges and upsizing to enable deployment of the closure implant. The 5-F Mynx (approved in 2009) was designed to eliminate the need for sheath exchange, as it can be deployed through the existing 5-F procedural sheath. This prevents the need to enlarge the arterial hole or traumatize the surrounding tissue.

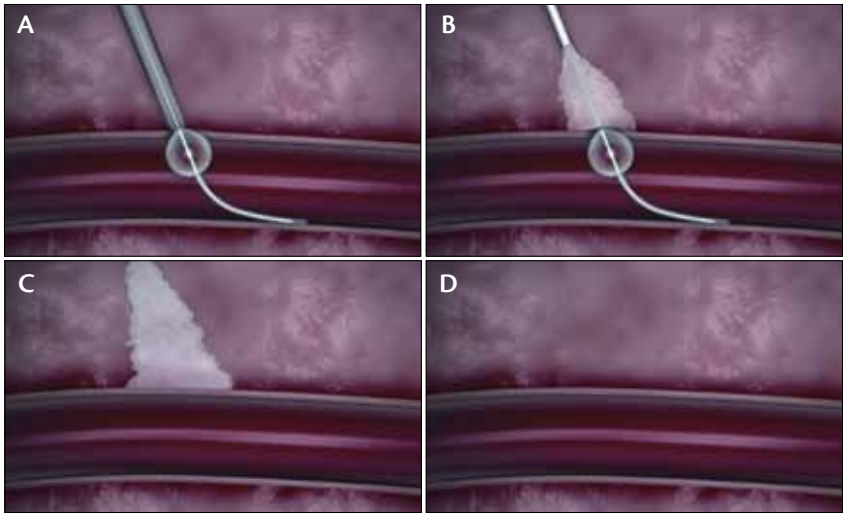

Figure 2. Insertion of balloon (A). Delivery of polyethylene glycol (B). Expansion of polyethylene glycol upon contact with blood (C). Resorption of polyethylene glycol (D).

THE MYNX EARLY AMBULATION STUDY

At the New Jersey Heart Institute, Our Lady of Lourdes Medical Center, we examined clinical outcomes of patients receiving the 5-F Mynx VCD in a single-center, postmarket setting, and ambulating at 1 hour after VCD deployment.

This single-center, prospective study enrolled patients undergoing percutaneous diagnostic procedures using a 5-F procedural sheath in the common femoral artery and arteriotomy closure with a 5-F Mynx VCD. The study was approved by the Institutional Review Board, and written informed consent was obtained from patients before enrollment. Primary and secondary endpoints included the number of major complications at 30 ± 7 days, device success, time to ambulation, time to discharge, and minor complications.

This study was intended to demonstrate noninferiority of the 5-F Mynx VCD when ambulating patients at 1 hour to the historical safety of the 6/7-F Mynx VCD as reported by Scheinert et al[3] and in the regulatory filing of the Mynx VCD.[4] A sample size of 160 patients was required (alpha = 0.05, 90% power) to test the study hypothesis (nQuery Advisor, version 7.0; Statistical Solutions, Saugus, MA). Two hundred patients were enrolled in the study to account for any patients that were withdrawn or lost to follow-up. All statistical analyses were performed with statistical analysis software (version 9.2 SAS Institute, Cary, NC).

METHODS

All patients underwent diagnostic angiography according to standard practice. At the end of the procedure, angiography of the access site was performed. If the puncture site was deemed appropriate based on the iliofemoral angiogram, the Mynx VCD was deployed per the manufacturer's instructions. After closure, the access site was assessed for hemostasis. Device success was defined as successful deployment of the Mynx device and hemostasis achieved with no more than 10 minutes of manual compression. Patients were ambulated 1 hour after Mynx deployment, and the time to ambulation and dischargeability were recorded. Patients were assessed for complications postprocedure, at ambulation, and at discharge and were contacted via telephone at 30 ± 7 days to assess any late complications. Any patients seeking medical attention after the procedure for access site– or procedure-related concerns received ultrasound evaluation of the access site. All adverse events had independent adjudication of complication classification.

RESULTS

Two hundred patients were enrolled in the study from April 2010 to March 2011. All deployments (100%) were successful, and there were no device failures. One major (0.5%) complication (requiring an endovascular procedure) occurred within 30 days. No minor complications occurred. The average time to ambulation after deployment was 1.03 hours. The average time to dischargeability was 1.9 hours (Table 1).

TABLE 1. EFFECTIVENESS DATA

Device success	100% (200/200)
Time to ambulation after deployment	1.03 ± 0.16 h
Time to dischargeability	1.9 ± 3.5 h

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TABLE 2. PATIENT CHARACTERISTICS (N = 200)		
Age	59.4 y ± 12	
Men:women	50%	100:100
BMI	30.2 ± 5.2	
Previous ipsilateral femoral access or closure device	29.5%	59/200
Recent tobacco use (< 6 months)	78.5%	157/200
Hypertension	74.5%	149/200
Hypercholesterolemia	74.5%	149/200
Diabetes mellitus	23.5%	47/200
Cerebrovascular accident/ transient ischemic attack	5.5%	11/200
History of congestive heart failure	1.5%	3/200
Chronic renal insufficiency	7%	14/200
Bleeding disorder	1.5%	3/200
Peripheral vascular disease	3.5%	7/200

TABLE 3. PROCEDURE CHARACTERISTICS (N = 200)		
Medication use during the procedure		
ASA	0%	0/200
Heparin	1%	2/200
Glycoprotein IIb/IIIa inhibitors (Integrilin/ReoPro)	0%	0/200
Warfarin	0%	0/200
Lovenox	0%	0/200
Bivalirudin	0%	0/200
Clopidogrel	0%	0/200
Dypridamole	0%	0/200
International normalized ratio	1 ± 0.11	
Outpatient (ie, discharged same day)	98.5%	197/200
Systolic blood pressure (mm Hg)	133 ± 18 (range, 93–195)	
Diastolic blood pressure (mm Hg)	78 ± 11 (range, 52–112)	

Comparison to Historical Data

In the original Mynx clinical study by Scheinert et al,[3] the 6/7-F Mynx VCD was studied in both diagnostic (n = 95) and interventional (n = 95) patients, and detailed clinical data are available in the Mynx device Instructions for Use document.[4] The time to ambulation was similar for both arms (mean, 2.5 ± 2.1 vs 2.8 ± 3 h).[4] This was a significant improvement over both manual compression control arms, for which the time to ambulation was 5.4 ± 2.7 hours for diagnostic patients (n = 82) and 9.4 ± 5.6 hours (n = 78) for interventional patients.[4] Safety and efficacy endpoints with the Mynx VCD were similar for both patient populations as well: major complications were observed in 0% of diagnostic patients and 1.1% of interventional patients, whereas minor complications were observed in 3.2% and 4.2%, respectively.[4]

This study evaluated the 5-F Mynx device in diagnostic patients with the goal of comparing these results to the diagnostic arm of the original Mynx study. Per protocol, ambulation was required at 1 hour, and as a result, the mean time to ambulation in our study was less than half of that in the original Mynx study (1.03 ± 0.16 vs 2.5 ± 2.1 h).[4] The major complication rate was comparable (0.5% vs 0%) to the diagnostic arm in the original Mynx study[4] and remained within the acceptable complication rate of < 1% for low-risk diagnostic angiographic procedures as recommended by the American Heart Association scientific statement on arteriotomy closure devices.[5] The minor complication rate improved from 3.2% in the diagnostic arm of the original study[3] to 0% in our study.

Patient Characteristics

The baseline patient characteristics are described in Table 2. The average age was 59 years, sexes were evenly divided at 50%, and the average body mass index was 30.2. There were 59/200 patients (29.5%) with a history of ipsilateral femoral access or closure device. A majority of the patients had hypertension (74.5%) and hypercholesterolemia (74.5%). There were a small number of patients with a history of diabetes mellitus (23.5%), cerebrovascular accident or transient ischemic attack (5.5%), and peripheral vascular disease (3.5%). A majority of the patients were outpatient (98.5%). See the *Inclusion and Exclusion Criteria* sidebar for an overview of how these factors applied in this study.

Procedural Characteristics

Table 3 summarizes the procedural characteristics. International normalized ratios were available in 79 patients (39.5%) and averaged 1 ± 0.11. During the procedure, aspirin was used in one patient (0.5%, N = 1/200), and heparin was used in two patients (1%, N = 2/200). No patients received warfarin, enoxaparin, bivalirudin, clopidogrel, or dypridamole during the procedure. The average blood pressure was 133 ± 18 mm Hg systolic

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TABLE 4. SAFETY DATA (N = 200)		
Major complications Access site–related surgical/vascular repair (eg, pseudoaneurysm repair)	0.5%	1/200
Minor complications	0%	0/200

(range, 93–195 mm Hg) and 78 ± 11 mm Hg diastolic (range, 52–112 mm Hg).

Complications

See the *Definitions of Major and Minor Complications* sidebar for an overview of how these were defined in this study. Postprocedure, 15 patients sought medical attention for access site– or procedure-related concerns, of which only one patient met the criteria for major or minor complications. One major complication was noted in one patient (0.5%), who presented at another institution with groin pain. The ultrasound could not rule out thrombus in the femoral artery, and the patient underwent thrombectomy with infusion of lytics. No minor complications occurred (Table 4).

DISCUSSION

This study shows that the Mynx 5-F VCD is a safe choice for patients undergoing diagnostic procedures and demonstrates that early ambulation at approximately 1 hour after deployment is feasible and safe for this low-risk patient population.

The low complication rate observed with the Mynx VCD may be attributed to several factors. Procedural factors, such as the use of small sheaths (5 F) and the lack of anticoagulation, may have contributed to the safe nature of the closure procedure. Device factors favorably affecting outcomes include the compatibility of the Mynx VCD with existing procedure sheath (ie, nonrequirement of sheath exchanges and associated arteriotomy manipulations). Although the only complication observed in this study resulted in a requirement for intervention, this type of complication has been shown to occur significantly less often with Mynx (0.06%) versus other closure devices (0.61% in Angio-Seal [St. Jude Medical, Inc., St. Paul, MN]; $P < .0001$), or manual compression (0.19%; P = NS).[6]

In addition to reductions in discomfort associated with early ambulation, the Mynx VCD has been shown to provide improved patient comfort and is particularly valuable to patients undergoing diagnostic procedures, which often require minimal sedation. Fargen et al reported significantly reduced pain at closure with the Mynx device as compared to Angio-Seal ($P = .009$) in a blinded, randomized controlled study.[7]

Study Limitations

The current study compares closure outcomes in diagnostic procedures utilizing 5-F introducer sheaths to historical data available from diagnostic procedures utilizing 6/7-F sheaths. The impact of sheath size has been shown to be a direct predictor of closure outcomes.[8] The relatively small sheath size in the present study may have offset the complication risk arising from early (1-h) ambulation and could explain the difference in minor complications seen in the present study (0%) versus historical data (3.2%).

CONCLUSION

In this single-center study investigating the use of the Mynx VCD in patients undergoing diagnostic procedures, early (1-h) ambulation was feasible. Only one major complication and no minor complication events were observed. This was comparable to historical safety data available on the Mynx device. ■

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DEFINITION OF MAJOR AND MINOR COMPLICATIONS

Major complications were defined as any of the following: permanent access site–related nerve injury; access site–related surgical/vascular repair (eg, pseudoaneurysm repair); amputation related to access closure complication; access site–related bleeding/hematoma requiring transfusion; any new ipsilateral lower extremity ischemia assessed by physical exam, Doppler, or angiogram requiring nonsurgical intervention; and local access site–related infection (fever, elevated white blood cell count, sepsis, and positive blood cultures) requiring treatment with intravenous antibiotics and/or surgical intervention.

Minor complications were defined as arteriovenous fistula documented by ultrasound not requiring treatment, pseudoaneurysm not requiring treatment, pseudoaneurysm treated with thrombin injection, access site hematoma ≥ 6 cm, access site–related bleeding requiring > 30 minutes manual compression to re-achieve hemostasis, late access site–related bleeding (ie, pre- or posthospital discharge), ipsilateral deep vein thrombosis, transient access site–related nerve injury, and/or local access–site related infection (fever, elevated white cell count, positive wound cultures) requiring treatment with oral antibiotics or intravenous antibiotics for < 2 days.

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INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

- Age ≥ 18 years
- Percutaneous diagnostic procedure utilizing a 5-F procedural sheath via the common femoral artery
- Ability to ambulate (routinely walk 6 meters or 20 feet without assistance for any reason)

Exclusion Criteria

- Previous surgical procedure, percutaneous transluminal angioplasty, stent placement, or vascular graft in the common femoral artery
- Bleeding disorder, such as thrombocytopenia (platelet count < 100,000/mm^3), hemophilia, von Willebrand's disease, or anemia (Hgb < 10 g/dL, Hct <30%); uncontrolled hypertension (systolic BP >180 mm Hg)
- Morbid obesity (body mass index > 40 kg/m^2)
- Pregnant or lactating women
- Documented international normalized ratio > 1.5 or patients currently receiving glycoprotein IIb/IIIa platelet inhibitor
- Known severe allergy to contrast medium; known allergy to polyethylene glycol
- Unable to ambulate at 1 hour secondary to a comorbid condition
- Known to require an extended hospitalization or rehospitalization (eg, patient is undergoing coronary artery bypass graft surgery) or scheduled to have coronary artery bypass graft surgery ≤ 30 days after the procedure
- Common femoral artery < 5 mm in diameter; clinically significant peripheral vascular disease in the vicinity of the puncture
- Puncture site is located above the most inferior border of the inferior epigastric artery and/or above the inguinal ligament based upon bony landmarks
- Posterior puncture or multiple punctures in an attempt to gain access
- Ipsilateral venous sheath
- Intraprocedural findings or complications that in the opinion of the investigator preclude participation (eg, difficulty inserting the procedural sheath, requiring a sheath size other than 5 F or overall sheath lengths > 15.7 cm, or patient requires coronary or peripheral intervention)
- Pre-existing arterial bleed/extravasation identified on preprocedure femoral arteriogram, brisk oozing, hematoma, pseudoaneurysm, or arteriovenous fistula present before sheath removal

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