

Safety and Efficacy of Percutaneous Femoral Artery Access Followed by Mynx Closure in Cerebral Neurovascular Procedures: a Single-Center Analysis

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Introduction

The majority of diagnostic and interventional neuroendovascular procedures utilize percutaneous puncture of the femoral artery. Vascular closure devices (VCD) have become an increasingly popular method of access site management. VCD complications include hematoma, pseudoaneurysm, retroperitoneal hemorrhage, and limb ischemia. The Mynx VCD delivers an extravascular, dissolvable, polyethylene glycol (PEG) sealant and is used for 80% of procedures at UPMC Presbyterian Hospital.

Methods

Prospective study of all patients who underwent diagnostic cerebral angiograms and neurointerventions with arteriotomy closure using the Mynx device at UPMC Presbyterian from July 2009 to May 2010. Retrospective chart review to screen for delayed complications at 6 months. Primary outcome: Device failure and development of complication. Complications that were considered: Major: Surgical intervention for pseudoaneurysm or dissection, hematoma requiring blood transfusion. Minor: Hematoma, pain, infection, nonoperative vessel injury. Potential predictors: age, weight,

antithrombotic use, history of angiography, and procedural details, such as indication, side, and sheath size. Analysis: Wilcoxon rank sum and Fisher exact tests to compare groups. Multivariable logistic regression to assess prognostic factors for device failure and complication.

| Acounts and a second seco | |
|--|--|
| Subject Demograph | nics |
| Age (years), Median (range) | 57 (16-89) |
| Gender (% Female) | 59 |
| BMI (kg/m ²), Median (range) | 27.8 (10.3-71) |
| Antithrombotic Medications, Count (%) Aspirin Clopidogrel Heparin or Warfarin Low Molecular Weight Heparin | 388 (41) 120 (13) 160 (17) 72 (7.7) |
| Eptifibatide | 23 (2.5) |
| INR, Median (range) | 2 (0.2) 1.1 (0.2-4) |
| Procedures 24 | 4 Excluded |
| 218 | other VCD, |
| 937 Mynx VCDs | nanual compression |
| 84% 16% Diagnostic Interventional | |
| Figure 1 | igure 1: .eft) Femoral seudoaneurysm Ilowing Mynx CD. |

Doculto

(Right) Femoral artery occlusion following Mynx VCD.

Acknowledgements

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| Procedure Characteristics | | | |
|---|-------------------------------|--|--|
| | Count (%) | | |
| Sheath Size (French) 5 6 7 | 708 (75) 221 (24) 8 (1) | | |
| Side (% Right) | 899 (96) | | |
| History of Angiography Last 2 Weeks | 356 (38) 91 (10) | | |
| Prior Closure Method Manual Compression Mynx AngioSeal | 28 (8) 275 (77) 53 (15) | | |
| Primary Outcomes | 6 | | |
| | Count (%) | | |
| Device Failure | 75 (8) | | |
| Overall Complication | 23 (2.45) | | |
| Major Complication Operative Intervention Hematoma with Transfusion | 13 (1.39) 7 6 | | |
| Minor Complication Hematoma Infection Pain Dissection | 10 (1.07) 5 3 1 1 | | |
| 1 A | ×A A | | |

Learning Objectives

1. Education of femoral artery closure devices after invasive transfemoral procedures. 2. Education of risks associate with this procedure. 3. Identification of higher risk patients for potential device complication.

| Predicto | rs of Complication* | | | |
|---|--------------------------------------|-------------------------|--|--|
| | Odds Ratio (95% CI) | P-Value | | |
| Age (years) | 1.02 (0.98-1.06) | 0.275 | | |
| Gender (Female) | 2.43 (0.89-6.6) | 0.082 | | |
| BMI | 0.917 (0.848-0.993) | 0.032 | | |
| Side (Right) | 0.240 (0.060-0.952) | 0.042 | | |
| History of Angiography | 0.204 (0.055-0.756) | 0.017 | | |
| INR | 4.37 (1.09-17.5) | 0.037 | | |
| Number of Antithrombotics 1 vs. 0 2+ vs. 0 | 4.38 (1.34-14.4) 3.63 (0.98-13.4) | 0.041 0.015 0.053 | | |
| Device Failure | 5.24 (1.68-16.4) | 0.004 | | |
| Predictors of Device Failure* | | | | |
| | Odds Ratio (95% CI) | P-Value | | |
| Age (years) | 1.00 (0.98-1.02) | 0.975 | | |
| Gender (Female) | 1.23 (0.74-2.06) | 0.423 | | |
| | | | | |

| BMI | 0.948 (0.910-0.988) | 0.011 |
|-----------------------------------|--------------------------------------|-------------------------|
| Side (Right) | 0.796 (0.255-2.49) | 0.695 |
| History of Angiography | 0.556 (0.312-0.990) | 0.046 |
| Sheath Size 6 vs. 5 7 vs. 5 | 2.83 (1.44-5.55) 7.37 (1.21-44.7) | 0.004 0.003 0.030 |
| Diagnostic vs. Intervention | 1.22 (0.57-2.61) | 0.607 |

*Using multivariable logistic regression

Limitations

Limitations of this study include: Selection bias in patient population seen by particular physicians. Potential confounders regarding patient comorbidities. Bias in potentially subjective physician choice of closure device.

Conclusions

The Mynx device is safe and effective for cerebral neurovascular procedures; however, specific patient populations may warrant particular attention and thorough consideration of risks and benefits prior to employing the device.