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Successful Reduction of Surgeries Secondary to Arterial Access Site Complications: A Retrospective Review at a Single Center with an Extravascular Closure Device

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Abstract

Background: Access site complications requiring emergent surgery following femoral catheterization expose patients to additional morbidities and mortality. We observed a significant decrease in such surgeries after the Mynx device was introduced. **Methods:** A retrospective review of surgeries performed as a complication of 6F & 7F femoral cardiac and peripheral catheterization was done. Rates of surgeries among 3 closure methods were compared during the study period July 2006 to July 2008 (Mynx, AngioSeal, and manual/mechanical compression). **Results:** Of 11 006 6F &7F transfemoral catheterization procedures, 26 (0.24%) surgeries secondary to access complications resulted. Surgeries were done in 14 (0.61%) AngioSeal patients, 10 (0.19%) manual/mechanical compression, and 2 (0.06%) Mynx patients ($P < .0001$ vs AngioSeal, $P = .14$ vs compression). **Conclusions:** Significant reduction in surgeries was seen in the Mynx vs Angioseal patients, no difference was noted in compression subset. Further analysis is warranted to prospectively evaluate these findings.

Keywords

catheterization, vascular closure, complications, vascular surgery

Vascular access site complications following transfemoral catheterization procedures are infrequent, yet they are potentially serious, and they can cause significant adverse events, in this subset of moderate-to-high risk patients. Such complications typically necessitate additional treatment (ie, compression, transfusion, increased intensive care unit (ICU) stays, imaging studies, and surgical intervention), thus exposing patients to additional risks as well as further discomfort and longer hospital stays.[1,2] Furthermore, bleeding complications, including but not limited to access site-related bleeding, have been identified as important predictors of increased 30-day mortality post percutaneous coronary intervention (PCI).[2-10] Concern regarding bleeding risk postprocedure has led to debate regarding antiplatelet and anticoagulation strategies as well as access site management.

From an access-site management standpoint, vascular closure devices (VCDs) were introduced in the mid-1990s in an effort to improve procedural outcomes, expedite hemostasis and ambulation, and improve patient comfort after catheterization. Although VCDs have proven advantageous with regard to earlier sheath removal, hemostasis, ambulation, and discharge,[11,12] concerns linger regarding the potential for rare but serious access-site complications related to their intravascular components (ie, anchors, plugs, sutures, or clips).[13] Published research on complication rates associated with VCDs has been inconclusive, partly owing to patient and procedural factors that affect outcomes. Although some studies indicate complication rates with VCDs are no greater than rates with manual compression,[14-20] others indicate higher complication rates with VCDs,[21,22] and still others suggest lower complication rates for VCDs.[23-25] Two recent meta-analyses, 1 of randomized controlled trials only[11] and 1 of both randomized controlled trials and observational studies[12] found no reduction in complications associated with VCDs relative to manual compression. Perhaps more importantly, small studies and case reports have suggested that complications reported with intravascular closure devices tend to be more serious (ie, ischemic or embolic events, infection) than those associated with manual compression (ie, hematoma, pseudoaneurysm, re-bleed).[19,22,26-29]

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In recent years, VCDs designed to minimize vessel trauma and alteration by leaving no foreign material behind in the vessel have been introduced in an effort to reduce the risk of more serious complications. One such device with growing adoption in our institution is the Mynx 6F&7F VCD (AccessClosure, Inc, Mountain View, California), which received FDA approval in May 2007. The Mynx device uses an extravascular polyethylene glycol (PEG) sealant deployed through the existing procedural sheath in conjunction with an intravascular balloon at the arteriotomy site to provide durable hemostasis in femoral arteriotomies. With no permanent intravascular components and a sealant that is resorbed within 30 days, this novel extravascular sealant offers potential advantages in terms of reducing the risk of vascular access site complications. In its clinical trial (N = 190), procedure success was obtained in greater than 99% of catheterizations, both diagnostic and interventional, achieving hemostasis in a median 0.5 minutes and ambulation in a median 2.0 hours, with 1 (0.5%) major complication (an access-site related bleed requiring transfusion).[30]

More than 5000 transfemoral cardiac catheterizations and 750 vascular surgical procedures are performed each year at Buffalo General Hospital. Prior to Mynx adoption, manual or mechanical compression was the primary closure method, with only 33% of transfemoral catheterization cases closed with VCD. After the Mynx was introduced, the majority (60%) of cases are closed with VCD, with Mynx closing approximately 88% of cases in which a VCD is used. The vascular surgery service manages all vascular complications secondary to femoral arteriotomy closure at Buffalo General Hospital. Anecdotally, we observed a noticeable decrease in such procedures after the Mynx device was introduced at our institution. To explore a possible effect of the Mynx device on the need for surgical repair of vascular closure complications, we conducted a retrospective evaluation of our surgical procedures secondary to vascular closure complications.

Methods

Study Design

This study was a physician-initiated, single-center, retrospective analysis of consecutive patients who underwent surgical procedures secondary to 6F/7F vascular closure complications in our practice between July 2006 and July 2008. This period represents the 1-year period prior to Mynx introduction at our institution and the 1-year period after Mynx introduction. The number and type of catheterization procedures and closure methods was collected from hospital records. Hospital patient records and operating room records were analyzed to identify surgical procedures secondary to femoral arteriotomy closure complications. The rates of such surgeries among the 3 closure methods in use at our institution during the study period—Mynx, AngioSeal (St Jude Medical, Minnetonka, Minnesota), and manual/mechanical compression—were compared.

The protocol for this study was approved by the Buffalo General Hospital Institutional Review Board, and a waiver of authorization was granted due to the retrospective nature of the data collection.

Patients and Assessments

This analysis included all surgeries to repair 6F/7F femoral access site complications during the study period. As such, there were no patient inclusion or exclusion criteria.

Major access site complications were defined as any event requiring vascular surgical intervention in patients undergoing 6F/7F transfemoral catheterization and treated with Mynx, AngioSeal or direct manual or mechanical compression. Minor complications not requiring surgical intervention were not included in this study. For each patient identified as undergoing surgery to repair an access site complication, the catheterization report, operative report, and discharge summary were reviewed to determine the method of arteriotomy closure, as well as patient demographics and procedural characteristics.

Device Description

The Mynx 6F/7F device is composed of an intravascular balloon catheter introduced through the 6F/7F procedural sheath to provide temporary hemostasis at the arteriotomy site of the vessel. Proximal to the balloon, on the catheter shaft, is a freeze-dried PEG hydrogel sealant used for extravascular sealing of the puncture. This novel arteriotomy closure device leaves behind no intra-arterial components and requires no suturing or stapling of the artery. The hydrogel sealant is delivered extravascularly above the arteriotomy site coaxially over the shaft of the balloon catheter using a delivery cartridge and an advancer tube. The advancer tube is used to place the hydrogel sealant into apposition with the puncture site. After deployment, the hydrogel sealant establishes rapid hemostasis by swelling as it absorbs local fluids. The sealant is then resorbed by the body through hydrolysis within 30 days.

Statistical Analysis

No formal study hypotheses were tested in this exploratory study. Data are presented using descriptive summary statistics, that is, frequency and percentage for binary variables. *P* values for comparison of surgical repair rates among closure methods were calculated using Fisher exact test of equality of proportions. A *P* value of $<.05$ was considered statistically significant.

Results

During the study period, 11 006 diagnostic and interventional transfemoral cardiac and peripheral 6F/7Fcatheterization arteriotomies were closed with manual compression, Angio-Seal, or Mynx. Of the 11 006 procedures performed, 5332 arteriotomies were closed with manual/mechanical compression, 2290 with Angio-Seal, and 3384 with Mynx.

A total of 26 (0.24%) patients required surgical procedures secondary to femoral access site complications, following their catheterization procedures at our institution. The majority of

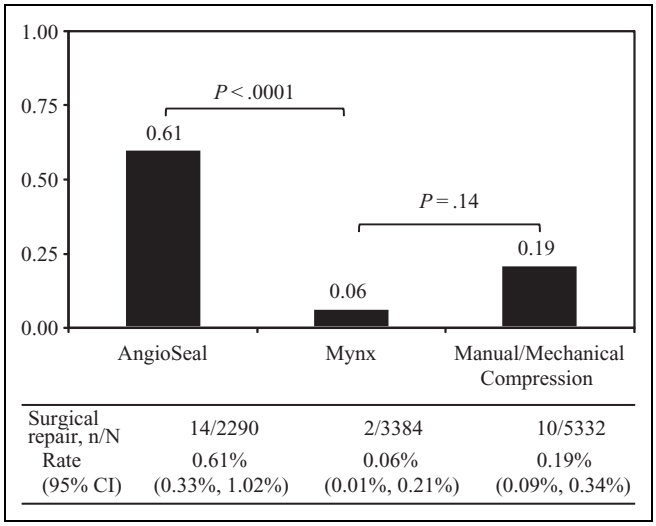

Figure 1. Rates of surgical repair following arteriotomy closure with AngioSeal, Mynx, and manual/mechanical compression.
Abbreviation: CI, confidence interval. P value derived from Fisher exact test of equality of proportions. P value displayed for descriptive purposes only. Formal hypothesis testing was not performed.

these patients were female (62%) with a mean age of 69 years, and an average body mass index of 26.6 kg/m^2. Sixty-five percent (17 of 26) of the complications occurred after an interventional catheterization. Among patients with a complication following VCD use, device failure or failure to achieve hemostasis resulted in conversion to manual/mechanical compression in 9 (56%)of 16 cases.

Rates of surgical repair for each closure method are shown in Figure 1. Complications requiring surgical repair occurred in 14 (0.61%) patients who received AngioSeal. These included 3 patients with thrombectomy or embolectomy and 11 patients with vascular repair secondary to pseudoaneurysm (PSA), arteriovenous fistula (AVF), abscess and/or hematoma evacuation. Surgical repair of the 10 complications (0.19%) occurring among patients who underwent manual/mechanical compression included 2 hematoma evacuations and 8 vascular repairs secondary to PSA, AVF, and/or retroperitoneal hematoma. Two patients (0.06%) who received the Mynx device required surgical repair, 1 was a hematoma evacuation and 1 an incision and drainage for an abscess which was isolated to the tissue above the PEG sealant.

Discussion

Although very infrequent, 6F/7F femoral access site complications requiring surgical intervention expose patients to increased risks postcatheterization. Contemporary literature shows mixed results with regard to access site complications with closure devices compared to manual or mechanical compression.[11,12,14-25] In this single-center retrospective evaluation, the rate of surgical procedures secondary to closure complications in patients receiving Mynx was statistically comparable to that of patients receiving manual or mechanical compression and significantly lower than patients receiving AngioSeal. Importantly, the 2 complications in the patients receiving the Mynx device did not involve embolism or artery damage, worsening PVD state or necessitate device removal.

Possible explanations for the lower incidence of serious complications observed with the Mynx device in this study may include its atraumatic design, bioinert sealant, and lack of intravascular components left behind in the artery. Such characteristics could potentially be beneficial in terms of minimizing the risk of serious infection involving the femoral artery, embolic/ischemic complications, and vessel scarring, as well as facilitating re-puncture and use in bifurcation anatomy and some calcified vessels.

Consistent with other closure device studies, rates of vascular complications requiring surgery in this study were quite low for all 3 closure methods. Although manual compression is a closure option typically associated with less-serious complications than closure devices,[22] the current trend toward greater use of antiplatelet agents may ultimately foster more reliance on vascular closure technologies. Ultimately, closure devices get patients ambulating and discharged faster than compression.[11,12] Furthermore, it is always optimal to avoid added morbidity associated with an operation in the groin, vessel repair, and potential use of general anesthesia, especially in high-risk populations with multiple morbidities.

Our understanding of access site complications following femoral catheterization has improved in recent years. In addition to seeing a decrease in vascular complications over time with use of both VCDs and manual/mechanical compression,[1,2] patient and procedural factors have been identified, which influence the risk of vascular complications. Several studies have documented increased risk of vascular complications associated with female gender,[1,15,19,23,31,32] interventional procedures,[19,23,32] lower body surface area,[1,31] older age,[1,19,23,31] history of renal failure,[19,32] and peripheral vascular disease.[19] Procedural factors associated with increased risk of vascular complications include VCD failure, heparin use (greater duration and intensity), and larger sheath size.[1,2,18] Indeed, successful use of VCD, higher body surface, and smaller sheath size were shown to be strong predictors of fewer vascular complications.[1] The importance of successful closure device deployment is illustrated by the increased risk of any complication from 9% after successful deployment to 80% and 83% after failure to achieve hemostasis by means of Perclose and AngioSeal devices, respectively, in a study of patients receiving periprocedural glycoprotein IIb/IIa inhibitors.[21] We observed consistent outcomes in the surgical repair patients of our study, where 56% of closure device failures with conversion to manual compression, resulted in a complication requiring surgical repair. Although patient factors are not modifiable, substantial evidence suggests that modifying those practice patterns associated with vascular complications can improve safety of both diagnostic and interventional catheterization procedures.[1,19,32] At Buffalo General, moving to an extravascular closure device made sense, and the lower rate of surgical repairs in the Mynx group supports the reasoning behind that decision.

This study is subject to the limitations of uncontrolled, retrospective studies. Thus, it does not allow for randomized, blinded comparison of vascular repair rates associated with each closure method. Complete patient and procedural data were reviewed for the 26 patients who underwent surgical repair for closure complications, and pertinent records were reviewed of the 11 006 patients undergoing 6F/7F femoral access catheterization, using manual/mechanical compression, Angio-Seal, or Mynx, during the study period. This limitation precludes the analysis of patients with and without access site complications not requiring surgical repair. Finally, the low total number of complications in this study precludes definitive conclusions regarding the nature and risk of surgical complications with the various closure methods.

Two long-term studies spanning 1994-2005 and 1998-2007 point to a decrease in vascular complications after catheterization in recent years.[1,2] These investigators also identified procedural factors (ie, successful closure device use, reduced heparin duration/intensity, and smaller sheath size) that could be responsible for the observed reductions. Our study suggests that the use of an extravascular closure device may be an additional procedural factor to further reduce the occurrence of access site complications that necessitate surgical repair. With an ever-increasing population undergoing endovascular procedures requiring large hole arteriotomy closure, a closure device that can rapidly achieve durable hemostasis and bring the rate of surgical repair procedures closer to 0 would be quite valuable. Further evidence-based analysis is warranted to prospectively evaluate this novel extravascular arteriotomy closure device.

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Declaration of Conflicting Interests

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