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EDITORIAL

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# Seeking the truth about femoral artery pseudoaneurysm

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### Introduction

Despite the use of smaller caliber angiographic and interventional catheters and the advent of new closure techniques, adverse events related to the arterial access site remain the most common noncoronary complication following diagnostic and interventional cardiac catheterization. While typically not life threatening, arterial access site complications can be associated with significant patient discomfort, lengthened hospitalization, and increased economic costs.

#### Incidence and risk factors

Among potential vascular complications related to femoral artery puncture, arterial pseudoaneurysm is the most frequent with a reported incidence ranging from < 0.5% to 6.3% [1]. Other access related events include femoral arteriovenous fistula formation, noted in 0.2 to 2.1% of procedures, and the less common but potentially more dangerous occurrence of retroperitoneal hemorrhage following 0.1 to 0.5% of catheterization procedures [1]. An arterial pseudoaneurysm occurs as the result of incomplete closure of the femoral vessel following removal of the vascular sheath. An extravascular hematoma develops adjacent to the incompletely sealed arteriotomy site, and persistent hemorrha-

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601 Elmwood Ave, Box 679, Rochester, NY 14642, USA Tel: 585 275 1669, fax: 585 271 7667 e-mail: craig\_narins@urmc.rochester.edu ge from the artery with continued expansion of the hematoma can occur.

Previous studies have identified a variety of patient and operator related factors that may predispose to pseudoaneurysm formation. Among patient-specific features, female gender, the presence of diabetes mellitus (both of which may be associated with smaller femoral artery size) and obesity (which can render direct manual pressure of the artery more difficult) have been identified as predictors of pseudoaneurysm development. From a technical standpoint, failure to puncture and insert the arterial sheath in the common femoral artery proper, above its bifurcation into the superficial femoral artery and profunda femoris, has been shown to increase the risk of pseudoaneurysm formation. The presence or absence of a relationship between arterial sheath size and pseudoaneurysm development has been inconsistent among studies [2]. Interestingly, in a recent analysis at one institution, pseudoaneurysms were noted to occur more frequently on days that a greater number of cases were performed, presumably because less time and attention were given to groin compression on busier days [3].

#### How to remove an arterial sheath?

Despite the fact that well over one million angiographic procedures are performed worldwide on an annual basis, no standardized approach for achieving access site hemostasis exists among hospitals, or at times even amongst physicians within the same institution. Variations exist with respect to virtually all aspects of the process, including method of groin compression (digital pressure versus use of a C-clamp or elastic band-type device), the amount of time that compression is maintained, the level of anticoagulation at which the sheath is removed (usually measured by the activated clotting time following coronary interventional procedures), and the amount of bed rest required after hemostasis is achieved before.

In addition, over the past decade, a variety of "vascular closure" devices have been introduced that allow immediate removal of the arterial sheath with rapid hemostasis at the termination of a diagnostic or interventional procedure. As with the other parameters mentioned above, there is substantial variability among physicians in the use of these devices. With closure devices, hemostasis is typically achieved via the percutaneous delivery of a suture, clip, or procoagulant material to the arteriotomy site, and the devices can be used even if the patient remains fully anticoagulated. While expensive, these devices have demonstrated the ability to increase patient comfort by reducing bedrest times, and despite their up-front financial cost may reduce overall hospital expenses by permitting earlier ambulation and hospital discharge.

The major potential drawback of vascular closure devices relates to the retained foreign material (suture or other material, depending on device type) left behind at the puncture site, which may render early re-puncture of the same artery problematic, and can predispose to rare but potentially devastating infectious complications [4]. Despite the practical advantages of these devices, they do not appear to be associated with a reduction in the incidence of arterial complications following catheterization. One meta-analysis examined 30 trials that compared various closure devices to manual compression. No significant differences were noted in the incidence of major or minor access related complications based on closure technique; However when the analysis was restricted to include only studies that employed the most rigorous design and analysis techniques, the use of vascular closure devices was associated with a significant excess risk of femoral pseudoaneurysm formation (odds ratio 5.4, 95% confidence interval 1.21-24.5) [5]. A second meta-analysis that included trials involving a total of 37,066 patients showed a slight increase in access-site related complications among patients treated with a closure device rather than manual compression (odds ratio 1.01, 95% confidence interval 1.01-1.79) [6].

#### **Treatment options**

When a femoral artery pseudoaneurysm does occur, several treatment options exist. The least invasive approach consists of reapplication of external pressure over the incompletely sealed arteriotomy site, which is often continued for several hours using an elastic-type compression device. Because a large painful hematoma invariably lies between the skin and the leaking femoral artery, prolonged external compression can be quite uncomfortable for the patient. Furthermore, the presence of the hematoma overlying the arteriotomy site may diffuse the external pressure away from the area of leakage, resulting in failure to achieve hemostasis. A second technique, designed to overcome these issues, involves the use of duplex ultrasound to precisely localize the site of arterial leakage. The ultrasound probe itself can then be used to apply focused pressure over the specific site of the arterial leak. This focused technique typically requires pressure to be applied for a much shorter duration, which can improve patient comfort, and is typically associated with successful closure in 60-90% of cases [7, 8]. When these approaches fail, ultrasound can be used to guide the percutaneous injection of thrombin directly into the pseudoaneurysm cavity, a technique that is associated with a high degree of safety and efficacy [9, 10].

### **Current study**

The study of Kaźmierski and colleagues that appears in this issue of "Folia Cardiologica" provides a detailed overview of the incidence and management femoral artery pseudoaneurysm in a large population of patients undergoing diagnostic and interventional cardiac catheterization procedures at a single center, and serves to expand upon previous findings. Among the 8,279 patients analyzed, the overall incidence of pseudoaneurysm was quite low, at 0.7%. As is standard in clinical practice, ultrasonography to screen for pseudoaneurysm was only performed when a symptom (typically groin pain or hematoma) or sign (femoral bruit) suggestive of an arterial complication was present. Interestingly, no other arterial access complications aside from pseudoaneurysm (such as arteriovenous fistula and retroperitoneal bleeding) were noted in this series of patients. Unlike most previous reports, no associations between various clinical features and pseudoaneurysm formation were noted, including female gender, hypertension, diabetes mellitus or peripheral arteriosclerosis. There was likewise no relationship between arterial sheath size and pseudoaneurysm development. The authors do not comment on whether or not body weight served as a predictor of pseudoaneurysm. One important omission in this report is the lack of a description by the authors of the protocol by which arterial sheaths are removed at their institution, including details such as the

frequency of vascular closure device use, the length of time manual compression is typically applied following sheath removal at their institution, the activated clotting time threshold used to permit sheath removal, and the typical length of bedrest after hemostasis is achieved. It is also not mentioned whether other procedurally related factors were associated with groin complications, including procedural duration, procedural activated clotting time, and procedural success.

The authors provide a description of the algorithm used at their center for the treatment of pseudoaneurysm, which follows the logical progression from repeat compression for 8 hours, followed by ultrasound-guided compression, and finally to thrombin injection if the prior techniques fail. This sequential approach ultimately provided obliteration of the pseudoaneurysm in all patients studied. Remarkably, only one individual out of the over 8,000 patients studied required an open surgical vascular repair. Given the safety and efficacy of both ultrasound-directed compression and collagen injection, one might question whether, for the sake of expediency and patient comfort, it would be reasonable to forego the initial attempt at prolonged repeat compression and proceed directly to one of these other less painful and highly effective techniques.

# Prevention: should we abandon the groin?

One increasingly popular approach aimed at reducing vascular access complications and providing improved patient comfort is the use of the radial artery for performing diagnostic and therapeutic catheterization. One meta-analysis of several studies comparing radial to femoral artery access for diagnostic or interventional coronary procedures documented a 5-fold reduction in entry site complications among individuals who received radial artery access [11]. The incidence of major adverse cardiac events was not affected by route of access, however radial artery access was associated with a significantly increased rate of "procedure failure", necessitating crossover to the femoral approach.

Other potential drawbacks of the radial approach include its steep learning curve and the greater technical demands this approach places on the operator. Even for experts, compared to the femoral approach, radial artery access is associated with greater procedural times and radiation exposure [12]. Nevertheless, with improvements in operator experience and equipment, selective use of the radial artery can serve as a useful alternative to femoral access, especially for patients in whom obtaining femoral artery access may be difficult or potentially associated with a heightened risk of complications, such as individuals with obesity or peripheral arterial disease. Even so, the very low rate of access site complications and exceptionally rare need for open vascular repair following femoral artery catheterization observed by Kaźmierski and colleagues provides reassurance that the femoral approach remains a safe means of achieving vascular access that will certainly and deservedly continue to endure.

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