True Femoral Arterial Puncture Site vs Perceived Arterial Puncture Site
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ABSTRACT: Introduction: Angiography is often performed following femoral arterial access for catheter-based procedures typically with the sheath angled away medially to determine the arterial puncture site location. This information is factored into decisions regarding deployment of a closure device. We hypothesized that determining the puncture site using the above technique may be inaccurate. Methods: We retrospectively analyzed 200 baseline femoral sheath angiograms (FSA) in a 35-degree ipsilateral oblique view with sheath angled medially away from the common femoral artery (CFA). The standard of care at our facility is to perform imaging using fluoroscopic subtraction angiography (“roadmapping”) capturing a contrast-filled Mynx balloon (MB; AccessClosure, Inc.) as it is withdrawn to the true arterial puncture site (TAPS) during closure device deployment. Three independent operators, blinded to MB images, were asked to mark the perceived arterial puncture site (PAPS) on baseline angiograms. The PAPS was then compared with TAPS (the center of the MB margin abutting the vessel wall), and the distance between the two points was measured. Results: TAPS was >3 mm caudad to PAPS in >80% of patients. Incidentally TAPS determined in this fashion correlates to the site where the angled sheath silhouette crosses the CFA silhouette. Conclusion: Commonly used techniques for isolating TAPS are often imprecise. When making decisions regarding closure devices, operators must be mindful of the fact that TAPS is often significantly lower than PAPS. Incidentally, a useful indicator of TAPS is the point where the angled sheath silhouette crosses the CFA silhouette in a 35-degree ipsilateral oblique view FSA.

Key words: angioplasty, catheterization, interventional cardiology, vascular intervention, access site management

Percutaneous catheterization, for the performance of catheter-based vascular procedures, has long been achieved via access in the femoral artery.1 Within the past decade, alternative access sites such as the radial artery have increased in popularity. Nevertheless, the majority of invasive catheterization operators in the United States still access the femoral artery because of relative ease of use, range of sheath sizes, and personal familiarity. However, in spite of decades of experience with femoral artery access, vascular access site complications, especially bleeding, continue to occur.2,3
The standard of care at our facility is a novel technique that employs the fully withdrawn contrast filled Mynx balloon (MB; AccessClosure, Inc.), to identify the location of the puncture site.4 Using this technique, we tested the hypothesis that the true arterial puncture site (TAPS) is not in the same location as the PAPS, as determined by the traditional method described above.

METHODS

We use the Mynx device as our “workhorse” vascular closure device (VCD). It is our standard practice that at the end of the procedure a baseline FSA at 17˝ magnification and right anterior oblique of 30 degrees is performed with the sheath angled medially, as far away as is possible without losing arterial access (Figure 1). Immediately following this angiogram, the Mynx device is placed in the vessel through the sheath and the contrast-filled balloon is inflated and visualized under fluoroscopy in exactly the same view and magnification. Because motion artifact is always a potential source of error when using roadmapping, once we are satisfied that there is no patient, table, or image intensifier movement, the roadmap mode is quickly activated and the vessel is opacified with contrast injected through the sheath sidearm, thus obtaining a roadmap FSA. The inflated radio-opaque MB is clearly visible at this time at the tip of the unw withdrawn sheath. The MB is then swiftly withdrawn as per manufacturer deployment instructions to the arteriotomy site and abutment against TAPS is confirmed by documenting lack of bleed back from the side arm. This roadmap FSA is then “saved” (Figure 2). This modified Mynx deployment technique of filling the MB with contrast has been previously described by our group in a large case series, capturing the MB under fluoroscopy as it was withdrawn to the TAPS during MB deployment.5,6 The closure device deployment is then completed by tamping down the extravascular polyethylene glycol sealant as per manufacturer instructions. For initial CFA access, ultrasound guidance was not used in our patients, nor was it customary in cardiology labs for routine CFA access at the time of this study.

After obtaining institutional review board approval, we retrospectively analyzed 200 consecutive studies and made a set of three hard copies (HC 1A, 1B, 1C) of the baseline FSA (Figure 1), which were printed and distributed to three independent observers to pinpoint with a sharp ball point pen the PAPS. A second
hard copy (HC2) of the saved roadmap FSA with the MB withdrawn to TAPS was also printed (Figure 2). TAPS was pinpointed with a pen on HC2. The TAPS was depicted by a point on the horizontal line traversing the center of the MB where the line crossed the medial border of the CFA silhouette. The three PAPS hard copies (HC 1A, 1B, and 1C) were then sequentially placed on top of the TAPS hard copy (HC2) in a successive fashion, and each time the PAPS was projected from HC 1A, 1B, and 1C onto HC2 with a pen. These 3 PAPS were labelled A, B, and C on HC2 (hard copy of the TAPS). If PAPS marked by two different independent observers were within .5 mm of each other they were considered to be one PAPS. Additional horizontal lines were then drawn through PAPS A, B, and C on HC2, which already had the horizontal line depicting TAPS on it. The vertical distance between each horizontal line depicting PAPS A, B, and C and the horizontal line depicting TAPS in the same patient, was then measured and carefully catalogued for final calculations.

**PATIENT POPULATION**

Inclusion criterion for this study was any patient 18 years of age or older having undergone diagnostic or interventional coronary or peripheral endovascular procedure via a CFA access, in whom a Mynx VCD had been used.

**STATISTICS**

Frequencies are presented as the mean ± the standard deviation. To discern the mean distance from PAPS to TAPS, the distance was measured and rounded off to the nearest 1mm. The Student t test was used to explore if this difference was other than zero. The Analysis of Variance (ANOVA) technique was used to obtain the necessary variance components to calculate the reliability coefficient for this continuous outcome. To test the rater’s ability to distinguish caudad from cephalad, such as for dichotomous responses, multirater kappa (k) statistics, or the chance adjusted measure of agreement, were used to evaluate the intraobserver reliability among the 3 reviewers using a SAS macro called “magree.sas.” The range for k is from -1 (complete discordance among reviewers) to 0.0 (random chance) to +1 (perfect concordance among reviewers). All data were analyzed using SAS system software (SAS Institute Inc.).
RESULTS

Femoral artery angiograms of 200 consecutive patients with Mynx VCD usage were analyzed in this study. Patient demographics are tabulated in Table 1. One hundred and eleven patients (56%) were male, and the mean weight was 83.8 kg. The mean distance for the entire cohort of TAPS being caudad to PAPS was 4.4 mm ± 1.7 mm. Only 18.8% of patients demonstrated a TAPS to PAPS caudad difference of <3 mm, while 81.2% demonstrated the TAPS to PAPS caudad distance to be >3 mm. In 30.4% of patients, the TAPS was as far as 5 mm or more caudad to the PAPS (Table 2). Incidentally, in 97% of patients, TAPS is exactly the point where the angled sheath silhouette crosses the CFA silhouette in a 35-degree ipsilateral oblique view FSA. In spite of TAPS almost always being caudad to PAPS, there were no significant clinical adverse events noted in the first 30 days of follow-up, which may be attributable to the fact that the Mynx VCD used in all cases in this study is totally extravascular and is known not to negatively impact low CFA bifurcation sticks. In 15% of cases the operators identified a “low stick;” or perceived to be below the CFA bifurcation, and in the remaining 85% of cases, operators perceived the sticks to be above the bifurcation. Among these 85%, we did not routinely analyze the position of TAPS in relation to the CFA bifurcation to obtain an exact percent of patients in whom PAPS was felt to be “safe,” or above the bifurcation, but TAPS was in fact below.

DISCUSSION

Complications from percutaneous, invasive cardiovascular procedures via femoral access range from minor bleeding, hematoma, fistula formation, and pseudoaneurysm to, less commonly, catastrophic retroperitoneal hemorrhage. The likelihood of these complications occurring as well as the morbidity associated with them is clearly affected by the location of the arterial puncture; whether into, below, or above the CFA, and/or inguinal ligament. This study challenges confidence in identifying the puncture site from the FSA, which most operators in the angiography suite take for granted. Using 3 different interventionalists to review baseline images depicting PAPS on FSA and comparing them to FSA images with a contrast-filled MB abutting the true arteriotomy site depicting TAPS, we demonstrated...
that in the overwhelming majority of cases, there was a difference as to where the operator perceived the arteriotomy site (PAPS) to be and where the arteriotomy site actually was (TAPS).

The practical, salient connotation of our observations is that TAPS is almost always caudal to PAPS. In more than 80% of cases by an average of 4.4 mm, TAPS is more caudally located than PAPS. An arterial puncture site that most operators would currently interpret as borderline high, above the inguinal ligament (as determined by using the inferior epigastric artery as a surrogate for the inguinal ligament), and therefore possibly intrapelvic and not suitable for most closure devices, may actually in 80% of patients be at least 3 mm or more lower than perceived. In this scenario, knowledge of the TAPS, as opposed to PAPS, would allow for a safe deployment of a closure device, without major risk for retroperitoneal hemorrhage. Alternatively, an arterial puncture site that in the minds of most operators appears to be just clearing the CFA bifurcation on FSA and therefore perceived suitable for any type of VCD may actually be in or below the CFA bifurcation. In those cases, the use of certain VCDs could result in device malfunction, causing vessel occlusion, hematoma, or pseudoaneurysm. This would be especially true for closure devices like Angioseal (St. Jude Medical) and Perclose (Abbott Vascular). Although some may consider an absolute difference of 3 mm to 5 mm not very significant, this difference may precipitate a change in management of the arterial puncture site.

The optimal access point in the CFA has been a matter of considerable research and debate and studies by Yaganti et al\textsuperscript{10} and Pitta et al\textsuperscript{11} have demonstrated that factors such as age, gender, body mass index, and anatomy of the pelvis may impact the optimal arteriotomy site. Thus the meaningful role of vascular ultrasound as a standard practice during vascular access cannot be overlooked.\textsuperscript{12-15}

**STUDY LIMITATIONS**

Although our study was a nonrandomized retrospective analysis, readers were blinded during image analysis. Also, interobserver variability may be a potential problem.

**CONCLUSIONS**

In almost all cases, TAPS is caudal to PAPS. What appears to the operator to be a borderline high arterial puncture site posing a risk for retroperitoneal hemorrhage, obviating safe use of an arteriotomy closure device, may actually be a relatively benign stick amenable to closure. Conversely, what appears to be a borderline low arteriotomy, that just clears the CFA bifurcation and therefore in the mind of the operator suitable for any closure device may actually be fraught with the hazard of complications with certain types of VCDs like Angioseal and Perclose, which are not entirely extravascular and traditionally contraindicated in this situation.

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REFERENCES


