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Evolution of Micro-invasive Strategy

The importance of developing devices with lower entry and crossing profiles for use in transfemoral and transradial access.

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It is well documented that as French size of larger introducers or guide catheters is increased to accommodate devices of varying diameters, the risk of complications, especially vascular access site complications (VASCs), significantly increases. Compared with 6-F guides, percutaneous coronary interventions (PCIs) performed with 7-F and 8-F guides were associated with more renal complications, bleeding, VASCs, in-hospital major adverse cardiac events, and mortality. These data suggest that selection of **smaller guide catheters may result in improved clinical outcomes** in patients undergoing PCI.[1] Complication rates range from 3% to 20% depending on the criteria used for analysis.[2-4] Complications add significant risk to patients, cost to procedures, and increase hospital time.

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VASCs ASSOCIATED WITH PCI

VASCs make up the majority of complications associated with both traditional femoral and transradial access procedures and are historically defined as vascular complications such as pseudoaneurysm; arteriovenous fistula; femoral neuropathy; retroperitoneal hematoma; any complication requiring surgical repair; and hematoma requiring transfusion, prolonged hospital stay, or causing a decrease in hemoglobin of more than 3 g/dL. Studies have demonstrated the increased costs and risks of procedure-related complications.[5-8] Bleeding-related VASCs more than double the cost of PCI procedures as compared with uncomplicated PCIs.[9] VASCs are more common with larger access devices, regardless if closure devices are utilized, and lead to a significant increase in cost, postprocedure morbidity, as well as other socioeconomic-related costs.[10]

Transfemoral arterial access is the most common method of vascular access for coronary angiography and percutaneous interventions globally, but it is also the most frequent cause of complications during these interventions.[11] Although manual compression is still the most commonly used technique to achieve hemostasis after removal of a femoral sheath, closure devices are becoming more commonly used to reduce the time required for postprocedure ambulation and accelerated hospital discharge time.[11] Studies have shown ambulation as early as 1 hour after diagnostic catheterization.[12,13] Although attempts have been made to reduce complication rates by utilizing femoral closure devices, overall complication rates have not been impacted; however, ambulation has been improved.[14]

TRANSRADIAL APPROACH IN PCI

With the advent of the transradial approach to PCI, complication rates can be reduced. However, transradial access is underutilized, even though it has been shown to reduce complications such as major bleeding by as much as 73% as compared with femoral access.[15] Currently, transradial access is used in only 10% to 20% of cases globally and even less in proposed leading markets such as the United States.[15,16] There is a considerable variation in use of transradial access across Europe and Asia/Australia; however, these regions have the highest rates of uptake at 30% and 40%, respectively. In Norway, Bulgaria, and Malaysia, transradial access is used in as many as 70% to 80% of cases.[16]

The transradial approach offers some significant benefits over traditional femoral access in the treatment of patients with coronary disease, such as in procedures for diagnostics, PCI, primary PCI (including kissing technique for bifurcated lesions), and vein graft angiography. These benefits extend to patients with peripheral vascular disease, including

internal carotid, vertebral, and basal lesions and procedures involving the subclavian and innominate, renal, iliac, celiac, mesenteric, and superficial femoral arteries. The trend toward increased use is clear, as the clinical community continues to consider the transradial approach due to its inherent benefits, including lower morbidity and mortality, a reduced rate of access site complications, and a reduced length of hospital stay.[17,18] In some cases, studies suggest that the transradial approach can virtually eliminate VASCs while permitting a wide range of diagnostic and therapeutic interventions.[19]

As is the case with the transfemoral approach, "smaller is better" for the transradial approach as well. Transradial access for coronary procedures has demonstrated success in reducing major bleeding and other VASCs compared to femoral access. In addition, 6-F sheaths produced VASCs with rates of 32.6% versus 15% for 5-F sheaths (Figure 1). When evaluating the frequency of VASCs after using 5-F or 6-F sheaths in transradial cases, the rate of radial artery occlusion detected by prospective vascular ultrasound examination was higher than expected. As in transfemoral cases, use of a 5-F sheath significantly reduces the rate of radial artery occlusion and complications in general.[20]

Barriers to Adoption

The transradial approach offers the potential for significant advantages; however, it is not free from complications. Despite the reduction of VASCs in the transradial approach versus the femoral approach, with and without the use of vascular closure devices (VCDs), the transradial approach has not become widely accepted primarily due to the higher failure rate of lesion crossing and the lack of technology needed to perform both coronary and peripheral vascular procedures transradially.[14]

Training and technology continue to impede accelerated adoption and limit the use of the transradial approach to specific indications. In fact, technical challenges of adoption were highlighted in a meta-analysis, which found an average conversion rate of 1 in 14 or higher, depending on the skills and experience of the operator.[19]

Even when proper training and skills are acquired, there remains a limitation in the technology that can support accelerated adoption of the transradial approach. To see a significantly improved rate of adoption outside of traditional diagnostic approaches, it is necessary to improve the technology available to perform transradial coronary and peripheral interventions. It is clear that future, more advanced applications associated with venous access are possible, but a next-generation technology is required to facilitate its growth.

DISCUSSION

As a more "micro-invasive" approach for both transradial and transfemoral PCI becomes adopted globally, the focus becomes more critical on developing technology that can assist the interventionist with downsizing port site entry while increasing treatment opportunities. It is well known that larger access site size correlates with increased potential for complications associated with VASCs, regardless of whether traditional manual compression or VCDs are used.[4,14] There is a significant surface area differential depending on the French size of the devices used and its associated material wall thickness. The device's internal lumen (French size) plus its wall thickness (multiplied by 2) determines the puncture site diameter (PSD) and provides the ability to calculate the puncture site surface area (PSSA).

When evaluating the differences between an 8-F and 5-F outer lumen device in terms of changes in PSD and PSSA, both the diameter and surface area change significantly (Figure 2). It is well documented that lower PSD and PSSA measurements are associated with a decreased potential for VASCs in both transfemoral and transradial indications.[21] The understanding of PSD and PSSA and the impact on reducing VASCs are critical to realizing the potential limitations for developing new technologies with lower entry and crossing profiles but with the same mechanical integrities associated with the current state-of-the-art devices. The key for the future will be to allow for the use of standard instruments through smaller access and guide sheaths that

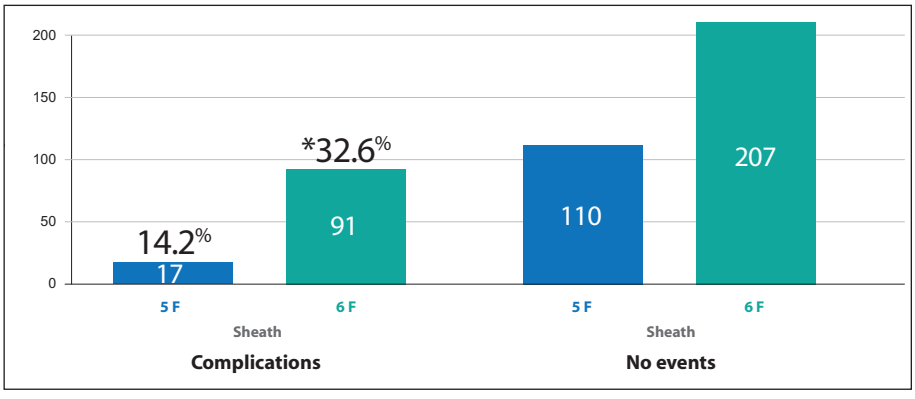

Figure 1. In a prospective study of 425 patients, the rate of VASCs was 32.6% with 6-F sheaths versus 15% for 5-F sheaths. Data from Uhlemann M, Gielen S, Schuler GC. Routine vascular ultrasound after radial artery catheterization detects clinically silent access site complications: prospective registry of 425 consecutive patients. Available at: http://spo.escardio.org/eslides/view.aspx?eevtid=40&fp=129. Accessed July 6, 2015.

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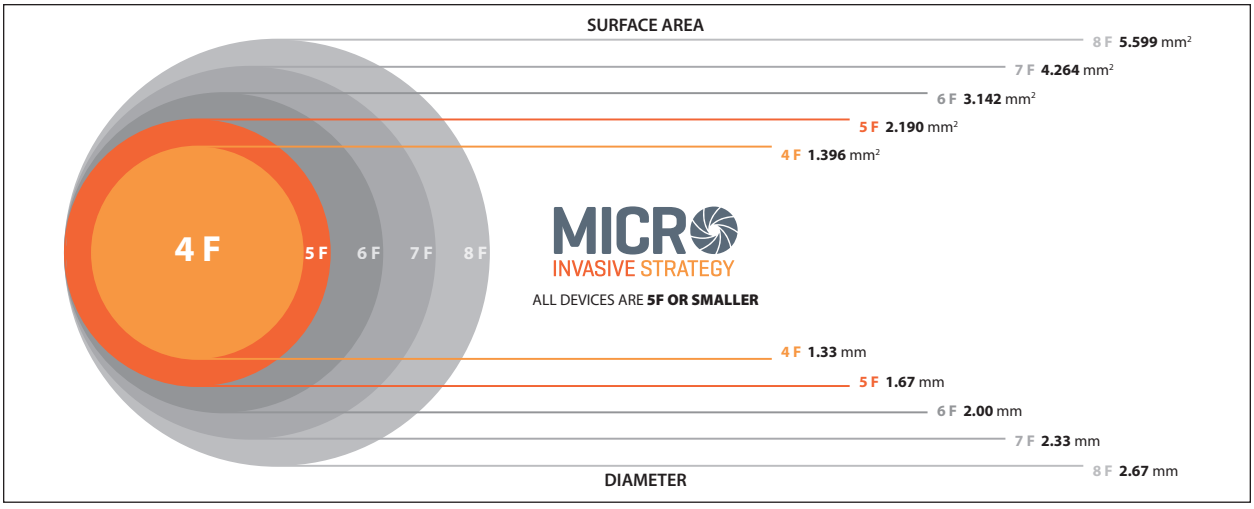

Figure 2. Puncture site diameter (PSD) and puncture site surface area (PSSA) measurements.

can achieve rapid hemostasis.[21] The literature suggests that a significant reduction in VASCs for both transradial and transfemoral approaches will be seen if technology can be developed in a sheath compatibility of 5 F or less that allows for the same functionality as devices of 6 F or greater while also allowing for adequate contrast delivery. As this is achieved, significant reductions in hospital costs and patient risk and morbidity related to nonischemic procedures may be observed.

CONCLUSION

As demand for "micro-invasive" products for use in transfemoral and transradial applications increase, so too will the demand for technology with lower entry and crossing profiles ≤ 5 F with the same mechanical integrity and adequate contrast flow used in traditional interventional approaches. Technologic advances that result in reduced PSD and PSSA offer the potential for early ambulation and reduced VASCs, hospital costs, and patient morbidity, and the reduction in the use of VCDs will have a significant advantage.

With training, clinical technique, and technologic advances, including the advent of dilating tip introducers and guide catheters, and if historical adoption holds true, accelerating incremental gains should be seen in the coming years in terms of adoption of the transradial approach, as well as a reduced need for VCDs when traditional femoral access is utilized. A company that can provide technology used in micro-invasive approaches, including use in tibiopedal access, will have a significant competitive advantage. ■

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