Still Doing Femorals?

It's a brave new radial world.

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Historically, the initial route for coronary angiography was via brachial cut-down. Subsequently, there was a shift toward the transfemoral approach due to its ease of use.[1] However, in the last decade, there has been a trend of increasing international and national[2] awareness and interest in learning and performing the transradial approach.[3-5] This change in approach is propelled by increasing clinical literature documenting the "superiority" of the transradial approach to the transfemoral approach[6,7] with regard to patient satisfaction[8] and same-day discharge.[9]

The clear and significant advantages of the radial approach also include shorter ambulation times and a decrease in the incidence of access site bleeding, even with an aggressive concomitant antithrombotic therapy regimen.[10] Recently, studies have suggested a mortality benefit in patients presenting with ST-elevation myocardial infarction (STEMI).[11-13] The question that naturally arises is whether the average interventional cardiologist in the United States is ready or able to adopt a more radial-first strategy or whether there are logical exceptions to this strategy.

VASCULAR ANATOMY AND ARTERIAL ACCESS

It is essentially the combination of anatomy and bleeding risk that differentiate radial and femoral access. The radial artery approach has significant advantages in that it is readily accessible due to its superficial anatomy, regardless of patient body mass index, and its close proximity to the radial bone, which makes hemostasis easier. By comparison, the femoral artery is larger and not prone to vasospasm; however, it is anatomically deeper, and its retroperitoneal course makes it vital that its access point be over the femoral head.[14,15]

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For the novice, radial access is hampered by its propensity for vasospasm and its anatomical variants and brachial loops. It also has occlusion rates ranging from 13.7% (in 5-F sheaths) to as high as 30.5% (in 6-F sheaths), depending on the procedural technique, duration, and intensity of occlusive hemostasis.[16] These complications, although asymptomatic for the patient, also reduce the possibility of reaccess; they also exclude the subsequent use of the radial artery for arterial conduit for coronary artery bypass surgery[17] and arteriovenous fistula for hemodialysis. However, the issues of occlusion can be mastered and overcome, with significant decreases in the morbidity and mortality of bleeding.[18-20]

There have been attempts to minimize bleeding from the femoral route with the use of anatomical landmarks using fluoroscopy[14,15,21] along with ultrasound-guided access[22] and the use of micropuncture[23] to optimize femoral access. However, despite these improvements of meticulous technique, the unique anatomy of the femorals still predisposes it to a higher risk of bleeding, especially in the milieu of aggressive anticoagulation.

TABLE 1. COMPARISON OF RADIAL VERSUS FEMORAL ROUTE		
	Radial	**Femoral**
Anatomy	Mostly superficial	Retroperitoneal course
Bleeding site	Generally remote	Access site and remote
Sheath sizes	Up to 7 F or sheathless guides	Up to 10 F and above including 24 F for TAVR
Reuse	Higher occlusion rates	Minimal occlusion rates
Ease of adoption	Greater operator learning curve and practice volume dependent	Less operator learning curve and practice volume dependent
Ambulation times and patient satisfaction	Shorter and greater	Longer and less
Cost	Mostly cheaper	Mostly more expensive
Radiation exposure	Higher	Lower
Complex interventions	Higher crossover rates	Preferred route for cardiogenic shock

BLEEDING

A recent analysis (NCDR Cath PCI Registry) of population percutaneous coronary intervention (PCI) studies showed that there has been an approximate 20% decline in the incidence of PCI bleeding in the United States, despite the preponderance of the transfemoral approach, with the maximum decline seen with the concomitant increase in the use of bivalirudin and a concomitant decline in glycoprotein IIb/IIIa use.[24] The role of the access location was less powerful, although the study reported a very low incidence of radial usage.

There is also a difference in the type of bleeding based on the patient population studied. In the outpatient elective PCI population, bleeding is most often access site related, whereas in the NSTEMI/STEMI population, the bleeding is predominantly nonaccess site related (most commonly gastrointestinal related) and has more to do with the type and intensity of the anticoagulation regimen than with the access site utilized.[25] It would have been interesting to perform vascular access subgroup analysis of bleeding according to the type of anticoagulation used and the postprocedure access site management used.

In the RIVAL trial, the use of bivalirudin was small versus glycoprotein IIb/IIIa usage, and as such, it is unclear if the higher utilization of bivalirudin would have negated the reduction in bleeding rates seen in radial versus femoral access. In the ACUITY trial, there was a significant decline in access site bleeding when there was a combination of bivalirudin and vascular closure device use;[26] within the femoral group, vascular closure devices were utilized in only a minority (26%) of patients.

POSSIBLE LIMITATIONS TO INCREASED RADIAL USE

It is important to acknowledge that patients in cardiogenic shock were excluded from the RIVAL trial. It stands to reason that this subgroup requires large-caliber catheters and concomitant mechanical hemodynamic support, which has a direct and significant impact on bleeding. There are also significant limitations to the radial approach when complex bifurcation or trifurcational lesions are tackled, when there is a need for rotational artherectomy requiring larger-sized burrs in heavily calcified vessels, or when there is a need for extra backup and support from large-caliber catheters for tackling chronic total occlusions. Although there are reports of all of these limitations being possible via the radial approach, the studies are small and are of highly selected cases.[27]

The benefits of the radial approach are seen most clearly in the elderly, the same population that has the highest incidence of tortuous anatomy, which may be the most difficult hurdle for the novice operator.[28] The radial approach may also be the most important limiting factor in achieving the required door-to-balloon times in an acute coronary syndrome situation,[29] although some experienced operators have actually demonstrated improved door-to-balloon times using the radial approach.[11,30] More interestingly, from the RIVAL trial, there was no discernible benefit in obese patients (body mass index > 25 kg/m^2).

LEARNING CURVE AND OPERATOR VOLUME

The radial approach is clearly a more technically challenging route with a steep learning curve and a high crossover rate of approximately 3% to 7%, even with experienced operators. Numerous studies have tried to quantify the minimum number of transradial cases for an operator to achieve basic competence,[31] and although this is a personal feeling that is hard to

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quantify, it would appear that at the very minimum, 50 cases are required to get on the first plateau of a steep learning curve. Even then, there is substantial room for improvement seen thereafter, often requiring more than 150 to 300 cases before the crossover rates plateau again. It is clear that practice makes (almost) perfect, and although this number may easily be achieved with a high-volume center/operator, it is a challenge when the total caseload for the operator is low.

To overcome this learning curve, it has been advised that the left radial site be utilized,[32] but there still remains a unique set of anatomical complexities and hurdles, along with procedural techniques and complications pertinent and unique to the transradial approach, that need to learned and mastered. In cases of increasing technical complexity, a particular understanding of specialized transradial guide catheters and careful foresight and judgment are required.

In the RIVAL trial, the maximum mortality benefits in the STEMI population from the transradial approach were noted in the highest center volume tertile (> 147 PCIs/year) of operators. In a field in which the median center volume was 300 PCIs/year, there was no real benefit noted in the middle or lower tertile groups. Given that the average number of PCIs for the average community hospital in the United States may be less, there may be a substantial volume gap that may need to be bridged. Several studies have also indicated a small increase in door-to-balloon times in the radial group, but that seems to be balanced by improved mortality. Although the radial approach is associated with an increase in catheter failure, as compared to the transfemoral approach, and a higher procedure time, the reduction of access site complications and bleeding compared with transfemoral procedures results in a substantial cumulative cost savings per case.[33] However, these benefits may only be seen in high-volume centers.

PROCEDURE TIMES AND RADIATION EXPOSURE

Procedural times are generally higher with early adoption of the transradial technique and then gradually decrease with increasing experience. The small increase in procedural times is matched by the improvement in mortality in STEMI patients. Left radial access has also been shown in small studies to match the procedural times of the femoral approach. Radial artery access cardiac catheterization is also associated with a slight increase in radiation exposure to the patient and the operator when compared with femoral access.

The combination of operator inexperience with the technique, the operator being closer to the radiation source, and the increased times required to cannulate the coronary arteries in general increase the overall radiation exposure.[34-37] In a recent study, there was still an increased degree of radiation exposure to the operator, even with the use of a specialized patient pelvic shield to reduce operator exposure.[38] In some early studies, the operator dose was doubled for diagnostic procedures and was 50% higher for interventions performed via radial access.

VASCULAR CLOSURE DEVICES: DO THEY MAKE A DIFFERENCE?

One question that has been raised is whether the choice of exit strategy (closure devices vs manual compression) can make a significant impact on cost and clinical bleeding from the femoral approach.[39] In a recent real-world retrospective analysis, arterial closure devices were associated with reduced major bleeding by 70% in highest-risk patients, with a reduction in entry site bleeding and pseudoaneurysm and a trend seen toward reduced in-hospital mortality.[40]

There is also a question as to which type of device is best. Although there seems to be an advantage of both the collagen-based plug and suture-mediated devices over others, when compared, the suture-mediated Perclose (Abbott Vascular, Santa Clara, CA) and the intravascularly anchored collagen Angio-Seal (St. Jude Medical, Inc., St. Paul, MN) devices were found to be more effective than the externally placed VasoSeal device (St. Jude Medical, Inc.), which is no longer in clinical use.[41-46] It has also been shown in the ACUITY trial that it is perhaps the combination of bivalirudin along with the closure device that may provide the greatest decrease in bleeding complications.[25]

CONCLUSION

In the end, the two routes may be mutually complimentary (Table 1). With the advent of structural heart disease procedures, there is still a need for meticulous femoral access technique to be taught. The growth of fellowship training in the radial approach offers an avenue to acquire life-long radial skills that will be

propagated in clinical practice. It should be mentioned that for those practitioners wishing to adopt the radial approach, the acquisition of skills in workshops or seminars along with initial careful patient selection and a significant volume to acquire and continue to maintain those skills is necessary, as opposed to only resorting to the radial approach only for "difficult" cases that cannot be performed transfemorally. It may turn out that for low-volume operators in low-volume institutions, more meticulous attention to perfecting the femoral technique with ultrasound guidance and more operator expertise with one to two different complementary types of vascular closure devices will be more effective in decreasing bleeding complications than only occasional use of transradial access. ■

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