

## Letters

### TO THE EDITOR

## A Remedy to the Paradoxical Increase of Femoral Access Complications

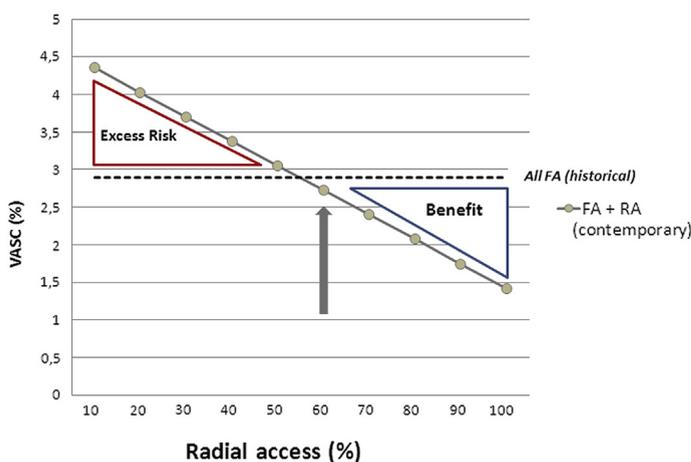
### A Full Switch to the Radial Route for Cardiac Catheterization

In the past decade, many centers have switched to radial access (RA) to perform cardiac catheterization on the grounds that it would reduce local vascular access site complications (VASC) and favor fast track patient management. However, its use remains highly variable. The study by Azzalini et al. (1) raises an unforeseen drawback of RA, which is a paradoxical increase in VASC risk with the femoral access (FA) when it is still used; this questions the net benefit of the RA over the classic FA approach. In their carefully designed study, they addressed several potential



confounders of the FA paradox such as the severity of illness of the patients in whom the FA has been used, the progressive loss of skills when the physician changes from the FA to the RA, and new anticoagulant therapies. Yet, 1 crucial point is omitted in estimating the real benefit of switching to the RA in the cath lab, which is the rate of RA use. In their report, their contemporary cohort encompasses a rate of RA of only 46%, which is much lower than the rate of a center accustomed to using, by default, the RA (2). Based on the VASC risk reported by Azzalini et al. (1) (i.e., 2.9% for the historical FA cohort, 4.7% for the contemporary FA cohort, and 1.4% for the RA cohort), RA use >60% will overcome the paradoxical increased VASC related to FA use ( $2.9\% > 4.7\% \times 0.4 + 1.4\% \times 0.6$ ) (Figure 1). Thus, albeit, we do not intend to question the reality of this paradoxical increase in VASC with the FA, we would like to emphasize the need to switch more widely to the RA approach when this route is used in the cath lab. This condition is probably the best way to minimize VASC in the modern era. Indeed, even if the risk of complications increased with the residual use of FA, having very little FA will translate into low overall VASC because of the lower risk associated with changing to the RA. In a way, the simplest and almost trivial message of the paper by Azzalini et al. (1), rather than questioning its advantage, is to favor the RA in most cases, which is currently largely feasible.

**FIGURE 1** Vascular Access Site Complications According to Percentage of Radial Access Use



Vascular access site complications (VASC) when using the radial access (RA) and femoral access (FA) expressed as a function of RA use; VASC estimation is based on a VASC rate of 4.7% for FA and 1.4% for RA; for comparison, the VASC of an exclusive FA cohort of 2.9% is indicated (dotted line); the arrow indicates RA required for the contemporary approach to lead to fewer VASC than the historical one. Excess risk and benefit shown are for the combined FA/RA approach.

\*Brahim Harbaoui, MD, MS  
Nicolas Girerd, MD, PhD  
Pierre-Yves Courand, MD, PhD  
Pierre Lantelme, MD, PhD

\*Cardiology Department  
Hôpital de la Croix-Rousse  
103 Grande Rue de la Croix-Rousse  
69004 Lyon  
France

E-mail: [bharbaoui@gmail.com](mailto:bharbaoui@gmail.com)

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### REFERENCES

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2. Johnman C, Pell JP, Mackay DF, et al. Clinical outcomes following radial versus femoral artery access in primary or rescue percutaneous coronary intervention in Scotland: retrospective cohort study of 4534 patients. *Heart* 2012;98:552-7.

## REPLY: A Remedy to the Paradoxical Increase of Femoral Access Complications



A Full Switch to the Radial Route for Cardiac Catheterization

In their recent editorial, Rao and Nolan (1) decided to ignore the well-known relationship among experience, volume, and medical outcomes and played the dangerous game of rejecting an important hazard signal that, if tackled properly, could better the outcomes of patients undergoing heart catheterization. Our data demonstrated an increase in the rate of femoral vascular access-site complications (VASCs) after the widespread adoption of radial access (RA) that persisted after multivariate adjustment. This increase in femoral access (FA)-related VASCs was numerically so relevant that it offset the benefit of RA at the overall population level. We concluded that approximately one-half of VASCs occurring in patients undergoing FA are attributable to the adoption of RA (2). However, Rao and Nolan went so far as to ascribe a causality dimension to attributable fractions (“by using the term *attributable*, the authors imply causation—that the radial approach caused femoral complications” [1]). Their statistical *faux pas* translates a defective understanding of the concept of population attributable fraction (PAF), which is defined as the proportional reduction in average disease risk over a specified time interval that would be achieved by eliminating the exposure(s) of interest from the population, but does not address the probability of causation for a specific disease or event (3). A clear and extensive dissertation on the concept, use, and misuse of PAF is provided by Rockhill et al. (3). The widespread adoption of RA in the clinical arena has coincided with other important changes (such as the increase in procedural complexity and patient risk profile) that have all contributed to increase the risk for femoral VASCs in patients undergoing cardiac catheterization. Our observation that the VASC rate in patients undergoing FA has increased, in comparison with the “pre-radial era,” had also been hinted at by an analysis of a large (1.4 million patients) cohort of the National Cardiovascular Data Registry: the risk for FA site bleeding increased as a function of the relative increase in RA adoption over a 3-year period: from 6.3% in the very low adoption group (<2% of RA percutaneous coronary interventions) to 7.4% in the high-adoption group (~45% of RA

percutaneous coronary interventions) ( $p < 0.001$ ) (4). Although stating that a causative relationship exists between the introduction of RA and the VASC rate increase in FA patients is not supported by the available evidence, these findings nevertheless warrant reconsideration of the indications of FA and improvement of FA technique in the contemporary practice.

The overwhelming benefits of RA are not to be discussed. The radial artery is and must remain the default approach in most patients undergoing cardiac catheterization. The question now becomes how to achieve safer FA when it is needed. As appropriately pointed out by Dr. Harbaoui and colleagues, reducing the number of FA procedures will translate into a low overall VASC rate because of the lower risk associated with the use of RA. However, we are uncertain if the linear relationship proposed by Harbaoui and colleagues can reliably estimate of the exact figures of VASC rates in a real-world population, as one could expect an exponential increase of the VASC rate in FA patients as FA volume goes down. Additionally, our contemporary cohort is meant to represent the transition from FA to RA that, at our institution, took place almost a decade ago. Nowadays, patient clinical profile and procedural factors might be markedly different. Therefore, a scientifically sound estimation of the actual contemporary VASC rates with FA and RA might be provided only by replicating our study with data from a current cohort.

In the current radial era, we think that the focus of the scientific community should be on the improvement of FA techniques among trainees and the maintenance of adequate FA volume among established interventional cardiologists, while, as appropriately recommended by Dr. Harbaoui and colleagues, striving for the extension of RA indications. In this ideal scenario, the safer RA would be used in the overwhelming majority of cases, and the potentially more dangerous FA would be performed by skilled operators in a very small proportion of patients.

There are several important lessons to be learned from this ongoing discussion. First is that causation cannot be assumed from observational data, not even when used in the context of an attributable fraction. Second is the importance of backing up opinions with objective data, not expertise alone. Third, and perhaps most important, is to diligently consider safety signals and explore how these signals can be addressed to improve the quality of care.

Lorenzo Azzalini, MD, PhD, MSc

\*E. Marc Jolicœur, MD, MSc, MHS