

MISE AU POINT / IN-DEPTH REVIEW

THE RADIAL APPROACH IN THE CARDIAC CATHETERIZATION LABORATORY Is It Meant To Become The Gold Standard ?

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Azzi N. The radial approach in the cardiac catheterization laboratory: Is it meant to become the gold standard ? J Med Liban 2011 ; 59 (4) : 227-232.

ABSTRACT : The transradial approach in interventional cardiology was born twenty years ago. Since then, many studies and meta-analyses have compared it with the former approaches, the transfemoral in particular. The most recent data is reviewed in this article through a double perspective : an anatomical and technical viewpoint in terms of a practical and successful vascular access ; and a clinical and economical viewpoint with actual data concerning access site bleeding, access site complications, with a particular emphasis on the radial approach. Its impact on major adverse events, cost-effectiveness and patient comfort are also discussed. New advances and techniques are emerging with the radial approach which is gaining more and more magnitude in the world of interventional cardiology. However, can we actually affirm that this approach is meant to become the gold standard?

INTRODUCTION

The radial or transradial (TR) approach for coronary angiography was first described by Campeau in 1989 [1], and the technique was extended to percutaneous transluminal coronary angioplasty (PTCA) and stenting by Kiemeneij and Laarman since 1993 [2].

Many studies and meta-analyses have compared the TR approach with the former approaches, specially the transfemoral (TF). The most recent data will be reviewed through a double perspective: first, the anatomical and technical aspects in terms of a practical and successful vascular access. Second, and more important, is the clinical and economical aspect of the vascular approach which will expose actual data concerning access site bleeding, access site complications, with a review of the problems attributed to the radial approach. It will end with the impact on major adverse events with a look on comfort and cost-effectiveness issue. Finally the article will report new advances, techniques and guidance about the TR approach, which is gaining more and more magnitude

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Azzi N. L'approche radiale va-t-elle devenir la voie d'accès standard dans les laboratoires de cardiologie interventionnelle ? J Med Liban 2011 ; 59 (4) : 227-232.

RÉSUMÉ : L'approche transradiale en cardiologie interventionnelle a vu le jour il y a vingt ans. Depuis lors, plusieurs études et méta-analyses l'ont comparée aux autres voies, notamment fémorale. Les données les plus récentes sont discutées dans cet article selon une double perspective : un point de vue anatomique et technique en termes de facilité d'accès et de réussite ; et un point de vue clinique et économique basé sur les données actuelles portant sur le saignement et les complications de la voie d'accès, en mettant l'accent sur la voie radiale. Son impact sur les événements cliniques majeurs, le coût-efficacité et le confort du patient sont aussi discutés. De nouveaux progrès et techniques sont en train d'émerger avec la voie radiale qui gagne de plus en plus d'importance dans le monde de la cardiologie interventionnelle. Cependant, peut-on affirmer actuellement que cette approche va devenir la voie d'accès standard ?

even in the countries and centers naturally reluctant to that technique.

The objective of the recent evidence that will follow is to explain why that revolution is taking place in the world of interventional cardiology since the beginning of this millennium. Hence the rational question: Is the radial approach meant to become the gold standard?

ANATOMICAL AND TECHNICAL ASPECT OF THE RADIAL APPROACH

Safer and more practical vascular access

From an anatomical standpoint, it's important to know that no major veins or nerves are located near the radial artery at the wrist, reducing the chance of neurological or vascular injury. Hemostasis is easily achieved because of the superficial course of the radial artery. Thrombotic or traumatic radial arterial occlusion does not jeopardize the viability of the hand if an adequate collateral blood supply from the ulnar artery is present [3].

Regarding the femoral artery, the situation is more complex with a higher risk on the adjacent structures, and also regarding hemostasis which is somewhat more difficult. Also there is a high risk on the concerned limb if the artery was occluded by accident [3].

Another practical issue is that the left radial approach has numerous advantages compared with the conventional

TF approach: a lower rate of vascular complications and an easier vascular access to the left internal mammary artery graft. The distance from the access site to the origin of the artery is shorter and involves fewer angulations than the TF approach [4].

Also, graft angiography via the right radial access can be performed reliably in most patients that lack severe subclavian tortuosity. This procedure could be used as one of the alternative approaches for angiography in patients who underwent coronary bypass surgery and in whom a TF approach is difficult or impossible despite the necessity of invasive angiography or for those in whom the left radial artery must be preserved [5].

Procedural success with the radial approach

There could be several reasons that interfere with procedural success in TR approach: First, there may be failure to successfully puncture and cannulate the radial artery, because of the small vessel size, tortuosity, or spasm vascular anomalies. Second, there may be failure to reach the ascending aorta, or to cannulate the coronary ostia due to difficulty in rotating and manipulating the catheters. Third, the procedure may fail because of inadequate guide catheter support [3, 6].

Hamon et al. found that the advantages gained with the radial approach were at the expense of a higher rate of procedural failure in comparison to femoral access (7.2% vs 2.4% of 1,373 subjects) [3].

However, these problems can be overcome in the majority of cases with recent advances and availability of equipment dedicated to the TR approach. In fact there is an observed equalization of the rate of procedural success over the years, which is also due to increased operator experience [3].

It's important to remind that the procedural duration and radiation exposure are higher using the TR access [7]. Hence, optimized individual radiation protection devices for operators are mandatory when procedures are performed by radial approach [8].

Learning curve

Louvard et al. reported a 10% failure rate for the first 50 cases and less than 1% after 1000 cases [9-10]. With skilled angiographers, a level of simplicity can be achieved with less than 500 cases. Hildick-Smith published data showing increased procedure success of more than 95% with a significant decrease in procedural time with greater than 100 cases [11].

In a meta-analysis published in 2004, Agostini et al. suggested that studies conducted after 1999 have lower failure rate indicating a faster learning curve. Trials after 1999 showed no significant difference in terms of procedural failure between radial and femoral access, compared to trials prior 1999 [12].

Finally, there are two ways to learn the TR approach: a systematic attempt in all kind of patients when working with a mentor; or patient selection when beginning the technique alone in order to get a high and stable success

rate from the beginning. The systematic radial approach for coronary angiography is a must in order to learn the technique [10].

CLINICAL AND ECONOMICAL ASPECTS OF THE RADIAL APPROACH

The complications usually found with the femoral approach are: hematomas, arteriovenous fistulae, arterial pseudoaneurysms, and retroperitoneal hemorrhage, which are influenced by anatomic variations, obesity, and puncture technique [6]. Moreover, the need for blood transfusion or surgical arterial repair occurs in 2-8% of cases [4]. Vascular closure devices have not been found to reduce the rate of hemorrhagic or vascular complications with the femoral approach in meta-analyses of randomized trials [13]. These factors altogether affect patient satisfaction, morbidity and length of hospital stay [6].

Access site bleeding

The data from the Organization for the Assessment of Strategies for Ischemic Syndromes 5 (OASIS 5) and the Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trials [14-15] suggest that pharmacologic and technologic advances have now reduced ischemic complications to the point that reduction in bleeding events should become the primary target for further improvement in PCI outcomes.

A recent meta-analysis of the impact of bleeding on outcomes in patients with ACS reported an 11% increase in the absolute risk of death associated with major bleeding [16].

Transfusion is the strongest predictor of the length of in-hospital stay after percutaneous coronary intervention (PCI) and is associated with increased mortality in patients with underlying coronary artery disease. Bleeding and anemia may also lead to the discontinuation of aspirin, thienopyridines, or both [6].

The TR approach has been found to be safe and feasible in a large spectrum of clinical practice and in the setting of aggressive pharmacologic treatments such as glycoprotein IIb/IIIa inhibitors and oral anticoagulants [3, 17].

In a recent registry, 531 patients undergoing urgent TR PCI under glycoprotein inhibitor treatment were prospectively enrolled. The TR approach dramatically reduced access site bleedings, including TIMI major and minor bleedings, and transfusion rate, while preserving procedural success and clinical outcome. On the opposite, the TF approach was the strongest predictor of TIMI major/minor bleedings (odds ratio 6.67) [18]. In OASIS 5 [14], as in the earlier ACCESS study [19] there were also a significant reduction in major bleeding with the TR approach.

Access site complications and need for vascular repair

There is evidence of reduced incidence of access site complications with the radial approach [3].

A recent meta-analysis published by Hamon et al. considered 12 randomized trials published between 1989 and 2003, including a total of 3224 patients, comparing TR and TF approaches for coronary procedures. The radial access was associated with a significantly lower rate of entry site complications (0.3% vs 2.8%, $p \leq 0.0001$) [20].

In the ACCESS study, 900 (47.4%) of 1899 patients who had angioplasty in a 20-month period were randomized to the radial, brachial, or femoral approach. Major entry site complications (hemoglobin loss ≥ 2 g/dl or need for blood transfusion or vascular repair) occurred in significantly fewer patients in the radial group (0%, 2.3% and 2.0%, respectively; $p = 0.035$) [4, 19].

Problems attributed to the radial approach and their relevance

■ **Radial artery occlusion**

Incidence of RA occlusion is underestimated due to the often asymptomatic clinical course. The consequences of radial artery occlusion are usually benign. This has traditionally been evaluated using Allen's test, but ultrasound, Doppler, and plethysmography prior to the procedure are more accurate [21].

Several variables influence the incidence:

- Adequate anticoagulation is extremely important (heparin)
- Catheter size has also been shown to be a predictor of radial artery occlusion. The ratio between the diameter of the radial artery and the radial sheath has an impact on the rate of radial artery occlusion [22].
- Concerning the length of the introducer sheaths and the different hemostatic compression devices available (Radistop, TR band, tourniquet, etc.), their impact on clinical outcomes and radial artery injury has not been tested in a randomized trial.
- Finally, treatment of symptomatic RA occlusion with low-molecular-weight heparins was shown to significantly increase patency rates after 4 weeks [23].

■ **Nonocclusive radial artery injury**

It may occur following TR intervention in some patients. The mean radial artery internal diameter as measured by ultrasound was smaller in patients undergoing repeat TR interventional procedures as compared to the first-time procedure.

Nagai et al. found that late after the procedure, segmental stenosis was seen in 1%, diffuse stenosis in 22%, and no flow in 5% of patients [24]. This progressive narrowing is due to intimal hyperplasia.

Although luminal cross-sectional diameter and area were significantly smaller than a control group, vasoreactivity was maintained.

This fact is important not only in patients undergoing repeat interventional procedures, but also in patients in whom the radial artery may be used as a conduit for coronary artery bypass surgery or for the creation of arteriovenous fistulae for hemodialysis [3].

■ **Radial artery spasm**

The radial artery is a muscular artery with a prominent medial layer that is largely dominated by α -1 adreno-receptor function [25]. Much of the discomfort and difficulty of the TR procedure is related to vasospasm induced by the introduction of a sheath or catheter into the radial artery. Therefore, local anesthesia and adequate sedation to control anxiety during catheter insertion may be important preventative measures.

Incidence of radial artery spasm has been reported to be around 10-20%, and in about 2-5% of patients it prevents the successful completion of the procedure by the TR route [3, 26].

Clinically important radial artery spasm was seen in 8% of patients receiving a spasmolytic cocktail compared to 22% in the control group ($p = 0.029$).

The size (both diameter and length) of the radial artery sheath may have an impact on radial artery spasm and also a hydrophilic coating might reduce the incidence of radial artery spasm by reducing friction and irritation of the endothelium.

■ **Local access site bleeding**

The most important benefit of TR procedures is the elimination of access site bleeding complications [27].

It is of paramount importance to understand that the radial artery should be compressed both proximally and distally to puncture site, to prevent retrograde flow from palmar arch collaterals.

■ **Forearm hematoma**

Bleeding may occur from the radial artery remote from the access site. This may be due to perforation of a small side branch by the guide wire in patients receiving aggressive antiplatelet agents, or due to avulsion of small branches. This can rarely lead to compartment syndrome and can lead to pressure-induced occlusion of radial and ulnar artery [28].

■ **Aberrancies of the radial artery**

A radial loop is the most common congenital anomaly and may be a cause of access failure [29].

At angiography, anatomic variations are noted in 22.8% patients and include tortuous configuration (3.8%), stenoses (1.7%), hypoplasias (7.7%), radioulnar loop (0.8%), abnormal origin of radial artery (8.3%), and lusoria subclavian artery (0.45%). Clinicians need to be aware of these anatomic variations and in most cases (usually > 90%) the procedure could be completed via radial route [29].

■ **Rare complications**

- *Radial artery avulsion* which is actually very rare [28].
- *Mediastinal hematoma* has been reported and should be considered as differential diagnosis of chest pain following TR cardiac catheterization. A thoracotomy might be needed in this case [3].

■ **Late complications**

Sterile abscess formation was reported in about 2-3% of patients in whom a sheath with hydrophilic coating was used. It occurred 2-3 weeks after the procedure. No infec-

tious agent could be implicated and all patients had good long-term outcomes with conservative [30].

■ *Radial artery as a graft after transradial procedures*

The authors concluded that use of the radial artery as a bypass conduit after TR catheterization should be undertaken cautiously, particularly when multiple previous procedures have been performed [29].

Effect on major adverse events

Hamon et al. found that the risk of major adverse cardiac events was similar for the radial vs the femoral approach [3].

However, the Registry on Intra-Venous Anticoagulation in the Elective and Primary Real World of Angioplasty (RIVIERA), a large prospective international registry, reported that, by limiting bleeding risk and transfusion requirement, the use of radial access is associated with a reduction in PCI-related mortality [31].

In OASIS 5 [14], in addition to the reduction in major bleeding when patients underwent PCI by the radial approach, there was a trend toward a reduction in death at 6 months.

In a meta-analysis involving twelve studies with 3324 patients presented with ST-segment elevation myocardial infarction (STEMI), TR PCI reduced the risk of periprocedural major bleeding and the composite of death, myocardial infarction, or stroke compared to TF PCI [32]. A newer study showed a fourfold reduction in major bleeding and a significant reduction in major adverse cardiac events at 12 months [33].

Patients presenting with STEMI can undergo successful PCI via radial artery approach without compromise in door-to-balloon times as compared to TF approach. There was even a small but statistical difference among the 240 patients randomized to either approach (radial PCI 76.4 min vs femoral PCI 86.5 min, $p = 0.008$) [33-34].

Finally, in a large database of current practice coronary catheterization and PCI, the incidence of chronic kidney disease (CKD) onset within 6 months of the procedure was 0.9%. The transradial access site was associated with less CKD than the femoral approach [35].

Comfort and cost-effectiveness

The radial approach is not only safe but has proven benefits in improving patient comfort and cost reduction [4, 6].

Any decrease in postprocedural complications can potentially result in reduction in healthcare expenses. Reduction in bleeding complications which are the most common postprocedural complications can directly reduce the total cost of hospitalization for the procedure. In a series of 210 consecutive patients randomized to femoral versus right or left radial approach by experienced operators Louvard et al. showed also that the radial technique permits earlier ambulation and discharge, improves patient comfort, and reduces the cost [36].

A new cost-effectiveness study compared coronary catheterization via the radial and femoral techniques with

or without the use of a closure device. When including the overall cost of the artery access, catheters, contrast medium, closure device and of the recovery, the radial approach showed small significant reduction in costs (between \$ 77.40 and \$ 183.90 per patient) [37]. The cost savings would be expected to be even higher if PCIs are integrated, mainly by the decrease in bleeding complications and subsequently the need for transfusion. It is also expected that there will be a decrease in hospital stay and a higher cost savings than in a simple coronary angiogram. However, large scale prospective trials analyzing the cost-effectiveness of this technique are still lacking.

NEW ADVANCES AND TECHNIQUES WITH THE TRANSRADIAL APPROACH

The safety of TR access with devices requiring catheters with a larger internal diameter (7F or greater) need to be evaluated in large trials. Initial results are encouraging in selected patients by experienced operators [3, 38].

Simultaneous kissing stenting technique requires a guiding catheter 7 Fr or larger and is therefore difficult to perform via TR approach. A hydrophilic SheathLess guiding catheter that possesses approximately the same size outer diameter as a 6 Fr sheath and an internal diameter of a 7.5 Fr catheter has been used successfully in a recent study [39].

There are arising possibilities for peripheral interventions using the radial approach as in that recent study by Tchetché et al. Subclavian, renal, carotid and femoral arteries are the most concerned in that case [40].

CONCLUSION

The available evidence base as described in this review supports a switch to radial access for most diagnostic and specially PCI procedures.

The TR approach virtually abolishes vascular entry site complications and allows us to perform a wide range of diagnostic and therapeutic interventions. Short recovery time, less bleeding complications, and improved patient satisfaction made the TR approach a favored route to perform cardiac catheterization and PCIs in an increasing number of countries. As operators become more comfortable with this approach, they are using it to perform more and more complex procedures such as rotational atherectomy and opening chronic total occlusions.

At this point it would be appropriate to declare that the radial approach is meant to become the gold standard in interventional cardiology... However, further research into methods of reducing the incidence of radial artery spasm and minimizing anatomical and physiological changes in the radial artery following TR procedure are needed.

Radial access is only one facet of improving patient outcomes in interventional cardiology. A further advance would be to implement safer drug strategies that maintain antithrombotic efficacy but limit bleeding risk.

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