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Original Article

A comparative assessment of Dorsal radial artery access versus classical radial artery access for percutaneous coronary angiography-a randomized control trial (DORA trial)

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ABSTRACT

Objectives: This is an open-label randomized control trial with a parallel assignment with single masking comparing patients undergoing coronary angiography via dorsal radial and classical radial access.
Methods: Study done at three tertiary cardiac care centers for two years. A total of 970 patients were finally recruited for the study. Patients were randomly selected for dorsal radial artery access Group A (485 patients) and classical radial artery access Group B (485 patients) without any bias for age & sex.
Results: On comparative assessment both techniques are found to be equal in terms of procedural success rate. While dorsal access was superior in terms of fewer incidences of forearm radial artery occlusion, radial artery spasm, less post-procedure persistence of pain, and hand clumsiness. In comparison to this, the number of puncture attempts and time to achieve post-procedure hemostasis is less in classical radial access.
Conclusion: So both techniques have pros and coins and it is the discretion of interventionists to adopt which technique.

1. Introduction

In percutaneous cardiac catheterization both for diagnostic and intervention purposes, the site of vascular access is always a controversial field from the start of this technique. Initially, great scientists like Mason Sones used brachial artery access for cardiac catheterization.[1] Later on, seeing increased cases of upper limb ischemia post-procedure, interventionists started using the femoral artery as a preferred site for vascular access for 2-3 decades. Due to increased incidences of vascular complications in the form of hematoma requiring blood transfusion, retroperitoneal bleed, and formation of arterio-venous fistula, Radner first used radial artery access via the cut-down technique in 1947.[2] The percutaneous radial artery approach for coronary angiography was invented by Lucien Campeau at the Montreal Heart Institute (Canada) in 1986 with the publication of the first 100 cases in 1989. And thereafter, this technique advocated for percutaneous coronary intervention (PCI) by Kiemeneij.[3] A trans-radial approach for coronary angiography has been increasing in comparison to the trans-femoral approach. Several randomized controlled trials and meta-analyses have demonstrated reduced mortality, decreased major bleeding, access site complications, reduced length of the hospital stay, and comparable stroke rate and most important early ambulation by using a trans-radial approach.[4] The findings have been reproduced in non-emergency diagnostic and percutaneous interventional procedures and as well as in urgent settings of ST-segment elevation myocardial infarction. Radial access procedures also enhance patient comfort and reduce post-procedure bed rest.

Abbreviations: PCI, (Percutaneous coronary intervention); RAO, (Radial artery occlusion); TRA, (Trans-radial angiography).

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This has become the standard approach for coronary angiography and percutaneous coronary stent implantation (PCI) (Class I in recent European Guidelines), currently used in the overwhelming majority of procedures. The standard access site of the classical radial artery is located at the distal third of the anterior side of the forearm, where it is situated between the skin and the radius bone which enables easy access and compression. The right radial approach is usually preferred because the left radial approach is less comfortable for the operator (especially if he has a small stature and/or suffers from back problems) and the patient (especially the obese patient).

With age's overtime, classical radial artery access too found be associated with many procedures related complications. Classical trans-radial access complications can be categorized as intra or post-procedural and further categorized as related to bleeding or non-bleeding issues. Major intra and post-procedural complications such as radial artery perforation and compartment syndrome are rare following trans-radial access (TRA). But their occurrence, however, can be associated with morbid consequences, including the requirement for surgical intervention if not identified and treated promptly. Non-bleeding complications such as radial artery spasm and radial artery occlusion are typically less morbid but occur much more frequently. Strategies to prevent TRA complications are essential and include the use of contemporary access techniques that limit arterial injury. A novel technique of accessing the dorsal trans-radial artery in the anatomical snuffbox/dorsal aspect of the palm was described by Kiemeneij.[5,6] The anatomical snuffbox which is also known as the radial fossa, is a triangular-shaped depression on the dorsal aspect of the hand at the level of the carpal bones. It is best to visualize when the thumb is extended. Its floor is formed by carpal bones composed of the scaphoid and trapezium. The medial and lateral borders are formed by tendons of the extensor pollicis longus and the extensor pollicis brevis, respectively. The proximal border is made up of the styloid process of the radius. The puncture of the distal radial artery can be done within the anatomical snuffbox or at some other site on the dorsal aspect depends on palpability and feasibility[Fig. 1]. Dorsal trans-radial access offers an advantage compared to the classical trans-radial access in that the puncture site is distal to the superficial palmar arch bifurcation and preserves the ante-grade flow to minimize the risk of hand ischemia.[7–9] The smaller vessel size beyond the bifurcation has been proposed to offer faster hemostasis.[10–12] However, there is a paucity of data examining the routine use of dorsal trans-radial access (TRA). Despite the frequent use of dorsal radial artery access for percutaneous interventions, there was no head to head trial comparing dorsal radial access with classical radial artery access. This is the first open-label randomized control trial with a parallel assignment with single masking comparing patients undergoing coronary angiography via dorsal radial and classical radial access.

Fig. 1. Puncture of distal radial artery at dorsal aspect of palm.

2. Materials and methods

The study was done at three tertiary cardiac care centers for 2 years. A total of 985 patients were recruited for the study, out of which 10 patients were found to be unsuitable for the bilateral radial assess due to weak pulses, and five patients denied for the procedure at last moment due to psychological fear. So a total of 970 patients were finally recruited for the study. Patients were randomly selected for dorsal radial artery access Group A (485 patients) and classical radial artery access Group B (485 patients) assess without any bias for age & sex.

2.1. Aims and objectives of the study

Comparative assessment between dorsal radial and classical radial artery access for percutaneous coronary angiography. The main objectives of the study are to compare both dorsal radial and classical radial artery as vascular access for percutaneous coronary angiography in terms of success rate, a puncture in the single attempt, forearm radial artery occlusion, radial artery spasm, hematoma/swelling at the puncture site, post-procedure hemostasis time, and post-procedure persistence of pain and hand clumsiness.

2.2. Eligibility criteria

2.2.1. Inclusion criteria

Patients of chronic stable angina who require coronary angiography.

2.2.2. Exclusion criteria

A - Patient having forearm AV fistula for haemodialysis.
B - Post-CABG patients who used the radial artery as a graft.
C - Patients who had type III and type IV radial artery.
D - Patients not willing for the procedure.

2.3. Technique

2.3.1. Dorsal radial artery puncture technique

Following distal radial artery palpation, 1 of the 2 possible puncture sites is chosen. Distal TRA in the anatomic snuffbox may appear easier during the learning curve, although puncture in the first inter-metacarpal space may provide the most optimal outcomes of distal radial artery access. The technique has been described in detail by Kiemeneij and Davies and Gilchrist.[13,14] The artery is typically palpable at the intersection of the thumb and first finger over the boney structures of the snuffbox. The patient is positioned with the arm in a neutral position. We usually put a normal saline plastic bottle wrapped with a sterile cloth under the ventral aspect of the wrist and ask the patient to hold a medium size ball of rolled gauge pieces. This serves to keep the dorsal area open for access by separating the thumb and first finger. It also gives the patient something to hold during the procedure, which ultimately increases patient comfort. The hand is thus placed with the snuffbox region facing upwards (anatomical position so less discomfort) rather than the palmar aspect of the wrist (which is the classical approach during radial access). Once the wrist is prepped, access is obtained. The vessel is very superficial. We used to palpate the artery with the tip of the index finger and used to puncture at the site of maximum pulsation. We graded the dorsal radial artery into four types based on findings of palpation:

Type I - Palpable artery without any effort with forceful thrust on tip of the palmer aspect of the index finger which is not suppressible on the minimal force.

Type II - Palpable artery without any effort, with forceful thrust on tip of the palmer aspect of the index finger which is suppressible on the minimal force.

Type III - Palpable artery with effort with weak thrust on the palmer aspect of the index finger.

Type IV - Not palpable.

For our study we selected patients having type I & type II arteries. After subcutaneous injection of 1–5 cc xylocaine, the artery is punctured, preferably with a 21 gauge (G) open needle, under an angle of 30–45° and from lateral to medial. The needle is directed to the point of the strongest pulse. We prefer to access the artery at the dorsum of the hand, distal to the tendon of the extensor pollicis longus muscle, where it is more superficial, rather than at the snuffbox. At the dorsum of the hand, the radial artery is very superficial, less xylocaine is required and the artery will be easily compressed against the base of the 1st or 2nd metacarpal bone. A through-and-through puncture is not recommended, especially if the artery is punctured at the snuffbox since the needle will touch the periosteum of the scaphoid or trapezium bones, which can be painful. After the successful puncture, a flexible, soft, J-shaped 0.21″ metallic wire is inserted. The skin is thicker and harder than at the forearm, therefore, to prevent damage to the tip of the introducer and sheath, which might damage the artery, a small skin incision is usually necessary before introducing the introducer-dilator kit. Routine forearm angiography is not needed, although angiography may be helpful if resistance is encountered. Alternatively, a 0.014 coronary guidewire may be very useful [Figs. 2–4]. After sheath placement, the arm can be located in a neutral position comfortable for the patient and operator. Moving the arm toward the operator no longer requires rotation of the wrist as the elbow is flexed to optimize the position, and the patient remains orthopedically comfortable as the joints are not stressed. Vasodilator cocktails can be given per local norm and patients likewise anticoagulated to prevent radial artery occlusion. The procedure itself should be similar to a standard radial procedure. Hemostasis is different after distal radial access. The common hemostasis bands used for the typical radial hemostasis depend on the relative immobility of the distal wrist. The dorsal part of the hand is more mobile, and rigid hemostasis devices may be loosened by the patient's wrist movements. One solution that has worked is to use the gauze initially given to the patient at the beginning of the case, and roll it up tight to form a plug to place at the arterial entry site. This is then wrapped with a tight elastic bandage to tamponade the artery (initially discovered by our cath lab technician). The patient is positioned with the arm in a neutral position. The recovery area staff then observes for hemostasis.

2.3.2. For classical radial artery puncture

The right or left hand is set in the anatomical position, with the ventral surface of arm face upwards. Afterward, the access site is disinfected, lidocaine injected subcutaneously for local anesthesia. Then the forearm radial artery is palpated to find the point of the strongest pulse. Then at a 45-degree angle, the artery is punctured with a 21-gauge needle and a 0.018 soft, flexible, metallic wire is then inserted in the needle. A cocktail solution containing 200 μg of nitroglycerin and 5000 units of heparin is given via the arterial sheath. A weight-adjusted dose of heparin is further added if PCI is needed. Then, a 0.035" wire is introduced in the sheath with other

Fig. 2. Radiographic (cine film) of punctured site.

Fig. 3. Cine film of radial artery course.

Fig. 4. Cine film of radial artery course in forearm.

required instruments such as the intracoronary device and the catheters. After pulling out the sheath, a compression device, TR band, is used for hemostasis. Since it was a multicenter study (done at three centers), so more than one operator was involved. But we ensured that at each center the same operator who had an experience of at least 1000 successful radial interventions and 5 years of experience in interventional cardiology should perform both the puncture for optimal comparison.

3. Statistical analysis

Statistical quantitative data were analyzed using the Unpaired "t" test/Mann–Whitney *U* test for comparisons of data between the different patient groups. For qualitative variables, the Chi–Square Test/Fischer's Exact Test was applied. $P < 0.05$ was considered significant. Graph pad Instat 3 and medcalc software system was used for statistical analysis.

4. Result

There was no significant difference in age and gender between Group A and Group B. The mean age of the study population in Group A and Group B was 55 ± 6 years and 55 ± 7 years (p-value 0.06). A total number of male subjects in the group A were 290 (60%) and in the group, B was 285 (59%) (p-value of 0.87) while the number of female subjects in the group A was 195 (40%) and in the group, B was 200 (41%) (p-value of 0.86).

The overall procedural success rate was 96% (466) in group A and 98% (475) in group B (p-value 0.060). The Puncture in the single attempt was done in 92% (446) in group B while in Group A single attempt puncture was successful only in 78% (378) of the patients (p-value<0.0001). Forearm radial artery occlusion was reported in 2% (10) patients in group A and 13% (63) patients in group B (p-value <0.0001). Radial artery spasm leading to abandoning radial access occurs in 1% (5) patients in group A and 12% (58) patients in group B (p value < 0.0001). In 10% (48) patients radial artery hematoma/swelling at the puncture site reported in group A while in group B it was 8% (38) (p-value 0.27). Time for proper hemostasis at puncture site was 28 min in group A and 24 min in group B (p-value <0.0001). Post-procedure persistence of pain was reported in 1% (5) patients in group A while in group B it was 14% (68) (p-value <0.0001). Post-procedure hand clumsiness was seen in 0.4% (2) patients in group A while in group B it was seen in 9% (44) patients (p-value <0.0001) [Table 1, Figs. 5–7].

5. Discussion

Search for ideal vascular access for percutaneous coronary interventions with minimal vascular complications is always an area of interest for the interventionist. Other than vascular complications, ease of procedure safety, radiation safety for the operator, and post-procedure satisfaction of the patients are the other factors that are too kept in mind. To date classical right radial artery vascular access is scientifically proven superior over femoral artery access in terms of vascular complications and mortality due to it.[15] But with time, it was observed that even classical radial artery access was also not complications proof. Many complications including forearm radial artery occlusion, radial artery spasm, hematoma, compartment syndrome of the forearm, and loss of fine movements of the hand were reported with this access.[16] For the operator, radiation exposure, new back problems, difficulty in repeat procedure from the same access if needed in the future, and lack of radial artery graft if needed during CABG were a concern. So the need for a new access site arises. And a novel technique of accessing the dorsal radial artery was described by Kiemeneij in 2017.[3] Till now, several papers were published with this technique including case reports, case series, and meta-analysis but there was no head to head comparison between the two techniques. Our study is the first randomized control trial comparing dorsal radial artery access with classical radial artery access conducted at 3 tertiary level cardiac care centers. With this technique, the main series are those of the pioneers of the technique, Babunashvili and Dundua,[16] and Kaledin et al.[5] In Babunashvili and Dundua series of 637 patients with distal dorsal radial access, the dorsum of the hand (rather than the snuffbox) was used in 92%, only 11% were PCI procedures and sheath size was 5 F in 91% and 6 F in 9%. The overall success rate was 98%. The forearm radial artery occlusion rate was 0% acutely and 0.2% at late (more than 3 months) follow-up.[16] In our study of 970 patients, 485 patients were undergone dorsal radial access at the dorsum of the hand too, 100% procedures were coronary angiography and sheath size was 5 F inall patients. The overall success rate in our patients was 96% as compared to 98% in classical radial artery access, which was clinically not significant. So we can say in terms of success rate, both access, are the same with no superiority of one over other. Forearm radial artery occlusion was 2% in dorsal radial artery access which is higher than Babunashvili and Dundua series ie 0.2% which may be due to less expertization of our team as compared to pioneers. Forearm radial artery occlusion in dorsal access is clinically less as compared to classical radial artery access (13%) in our study, which is clinically significant. We assess forearm radial artery occlusion after 12 h by assessing the palpability of the forearm radial artery pulse. In those patients whose radial artery pulse was absent we do Doppler ultrasound to confirm. The reason behind less incidence of forearm radial artery occlusion is due to

Table 1
Results of study.

S No	Parameters	Dorsal radial artery (n = 485) (Group A)	Classical radial artery (n = 485) (Group B)	P value
1	Success rate	466 (96%)	475 (98%)	0.06
2	Puncture in single attempt	378 (78%)	446 (92%)	<0.0001
3	Radial artery occlusion	10 (2%)	63 (13%)	<0.0001
4	Radial artery spasm	5 (1%)	58 (12%)	<0.0001
5	Radial artery hematoma/swelling at puncture site	48 (10%)	38 (8%)	0.27
6	Post procedure hemostasis time	28 min	24 min	<0.0001
	Post procedure persistence of pain	5 (1%)	68 (14%)	<0.0001
7-	Post procedure hand clumsiness	2 (0.4%)	44 (9%)	<0.0001

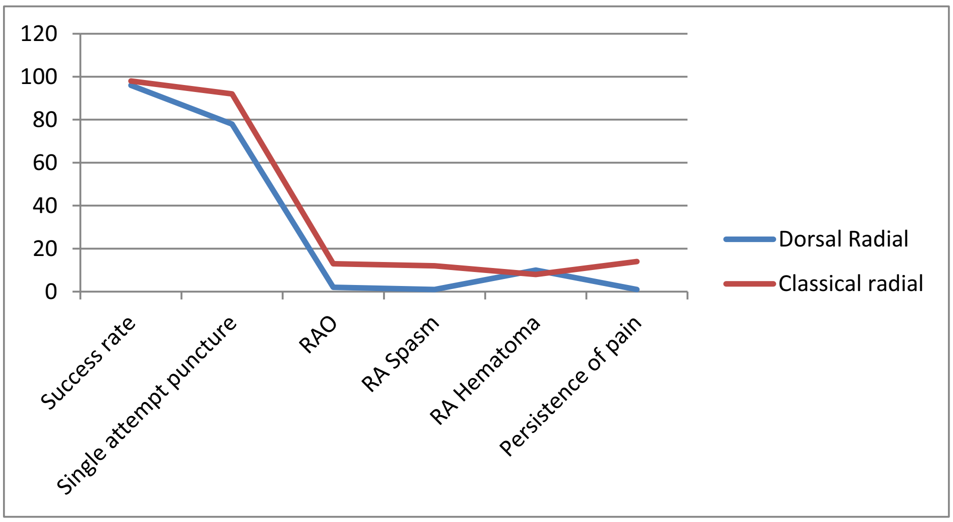

Fig. 5. Line diagram showing different parameters of comparison between dorsal (Group A) and classical radial (Group B) access.

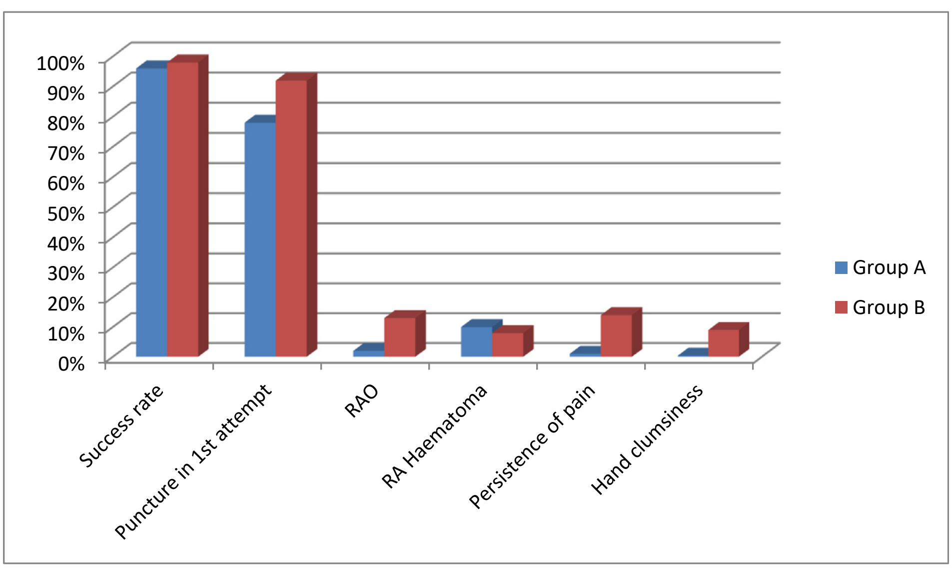

Fig. 6. Different parameters in both arms. (Group A-Dorsal radial artery, Group B-Classical radial artery).

flow perseverance in dorsal radial access. The absence of blood flow during the hemostasis process significantly increased the risk for radial artery occlusion, interruption of flow at the time of hemostasis is one of the significant predictors of radial artery occlusion.[17] So interventions directed to maintain flow in the radial artery after sheath removal, such as patent hemostasis,[18] nitroglycerin administration through the sheath before its removal,[19] and ipsilateral ulnar artery compression during radial artery hemostasis,[20] have been shown to reduce the rate of post-catheterization radial artery occlusion. On this background, distal TRA could maintain forearm radial artery patency during hemostatic compression or in case of occlusion at the puncture site. Thrombus formation due to endothelial injury is another important factor responsible for RAO. Flow preservation in distal radial access due to the collateralization of

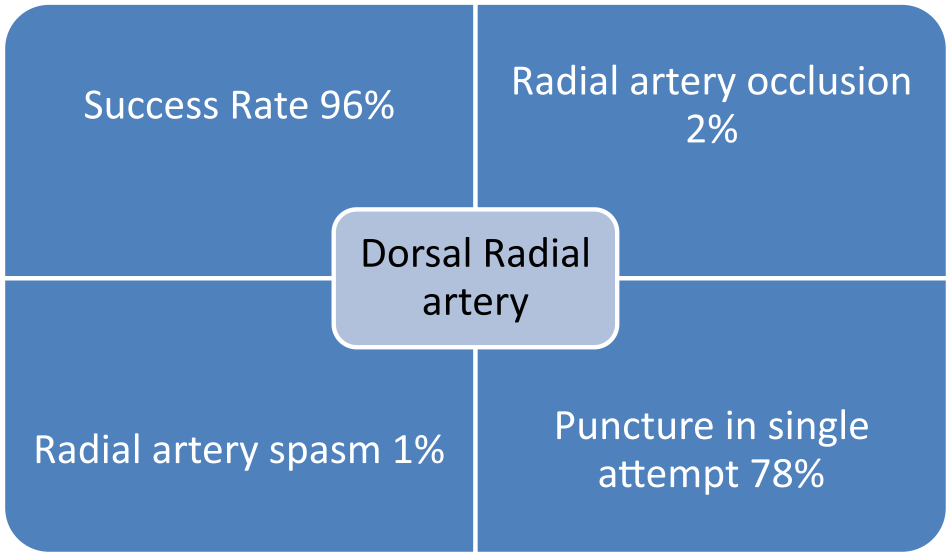

Fig. 7. Dorsal radial artery access parameters.

blood vessels is of paramount importance to avoid proximal thrombus growth and maintain forearm radial artery patency after TRA. So in terms of forearm radial artery occlusion, dorsal radial artery access is superior to classical radial artery access. Dorsal radial access is also statistically and clinically superior to classical access in terms of radial artery spasm, post-procedure persistence of pain, and hand clumsiness. The reason behind the superiority of distal dorsal radial artery over classical radial artery despite small vessel caliber of distal radial artery concerning radial artery spasm, post-procedure persistence of pain, and hand clumsiness is due to perseverance of flow as branches arising from the radial artery before its entry in the anatomic snuffbox make significant anastomotic connections in the wrist and hand region, hence allowing optimal distal blood flow[18] Classical radial artery access is statistically and clinically superior to dorsal access in terms of a puncture in single attempt and post-procedure hemostasis time. Puncturing dorsal radial artery is demanding and required a learning curve of at least 50 puncture even in those who are experts in classical radial artery puncture. Puncture at snuff box or other sites on the dorsal surface hardly carries clinical importance. More post-procedural time in the distal dorsal radial artery despite small-caliber vessel is due to the less established occlusive device and unfamiliarity with the technique. This point needs to be elaborated in future studies. While both procedures are statistically equal in terms of success rate, radial artery hematoma/swelling at puncture site without any clinical superiority of one technique over other.

In Kaledin et al[5] series of 2884 patients undergoing endovascular interventions, the snuffbox (rather than the dorsum of the hand) was used in 96% of patients, 93.5% of interventions were PCI procedures, with sheath size of 6 F in 98% and 7 F in 1%. The success rate was 97%. At follow-up, radial artery occlusion rate at the access site with preserved blood flow of the forearm radial artery was observed in 2% of cases. Other access site complications were similar to those observed with the forearm approach: hematoma (0.2%), pulsatile hematoma (<0.1%), infection (0.1%), dissection (0.1%), arteriovenous fistula (<0.1%). This is in contrast with the 4.2% radial artery occlusion rate observed by the same authors using the traditional forearm radial approach. In our study, the radial occlusion rate is higher in both technique as compared to this study but forearm radial occlusion significantly less in dorsal access as compared to classical access.

Out of 118 consecutive patients assigned to Kiemeneij's operation program, 70 patients were considered suitable for left distal radial access. There were eight procedural failures, requiring crossover to traditional right radial or left radial approach. All other procedures were successful (89%), without major discomfort for the patient and operator. No radial artery occlusions at the site of the forearm were encountered. In our study, the right distal TRA is currently chosen in the majority of the cases, mainly because of the working position of the operator. In limited patients left side is chosen. In these patients, the patient's arm hyper adduction is not limited by the need to keep it in a supine position, and consequently, the operator does not have to bend over the patient. Thus, distal radial artery access offers the possibility to have the left hand close to the right groin in such a way that it is comfortable for both the patient and the operator. Moreover, distal radial artery access offers the opportunity to increase the rate of left TRA. This, in turn, would be very welcome by the vast majority of patients who are right-handed and who would no longer experience a restriction of the use of their dominant upper limb during the hemostatic compression following sheath removal. Though our study was not designed to assess a difference between left and right dorsal radial

Table 2
Advantage and disadvantage of dorsal radial puncture as compared to classical radial puncture.

Advantage	Disadvantage
Anatomical position of the forearm & palm, so the patient is in a more comfortable position.	The needed learning curve to puncture. (At least 50 successful puncture needed)
Proximal radial artery access is preserved for future interventions and as graft material for future CABG if required.	In patients of long height (above 6 feet), long length catheters (110 or 120 cm length) are required.
Post procedure complications in the form of hand clumsiness, persistent pain are less as compared to classical radial artery access.	Proper hemostasis device needed to be discovered.
Advantageous in terms of patient comfort.	
Fewer incidences of forearm radial artery occlusion and access site arterial spasm.	

access and it is only a practical thought. We will include this parameter in our future studies in this field.

In Kim et al.[14] series of 150 selected patients who had coronary angiography or PCI with 6 French catheters via the left snuffbox approach, the success rate was 88%. The main reasons for failure were failed puncture. In our study too it is found after data analysis that classical radial artery access is statistically and clinically superior to dorsal radial access in terms of a puncture in a single attempt. Puncturing dorsal radial artery is demanding and required a learning curve of at least 50 puncture even in those who are experts in classical radial artery puncture.

6. Conclusion

First time on a comparative assessment of dorsal versus classical radial artery vascular access it was found equal in terms of procedural success rate and complication in the form of incidences of radial artery hematoma. While dorsal access was superior in terms of fewer incidences of forearm radial artery occlusion, access site radial artery spasm. Post-procedure persistence of pain and hand clumsiness was also less in dorsal radial artery access. In comparison to this, several puncture attempts and time to achieve post-procedure hemostasis was less in classical radial access [Table 2]. So both techniques had pros and coins and it is the discretion of interventionists to adopt which technique.

Conflicts of interest

All authors have none to declare.

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What is known

Classical radial artery access is a commonly used vascular access site for percutaneous coronary interventions and preferred over femoral access. Though in recent years interventionists also used dorsal radial artery access in few cases. However, there is a paucity of data examining the routine use of dorsal trans-radial access (TRA).

What is new

Despite the frequent use of dorsal radial artery access for percutaneous interventions, there was no head to head trial comparing dorsal radial access with classical radial artery access. This is the first open-label randomized control trial with a parallel assignment with single masking comparing patients undergoing coronary angiography via dorsal radial and classical radial access.