Comparison between left distal trans-radial artery approach and right conventional trans-radial artery approach in patients undergoing coronary angiography and / or per-cutaneous coronary intervention

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ABSTRACT

Background: Lately, the left distal radial access approach for coronary artery access either diagnostic or interventional showed to be an optimal alternative.

Objective: This study aimed to compare between the left distal trans-radial and conventional right trans-radial approaches for coronary procedures in terms safety and efficacy.

Methods: This randomized comparative study was conducted in Beni-Suef university hospital in the period from October 2018 to October 2019 on 100 patients. Patients were randomly assigned into the two groups (50 in each arm of the study). The primary clinical outcomes were the incidence of major adverse cardiac events and other complications as vascular access site complications and crossover. The secondary outcomes were, the puncture time, the procedure time, the coronary cannulation time, the fluoroscopy time and the amount of contrast.

Results: there was insignificant lower rate of crossover and complications in the distal left trans- radial approach (ldTRA) than the right trans-radial approach (RTRA). The coronary cannulation time was significantly lower in ldTRA (30±7 seconds) than RTRA (43±11 seconds). Also, there was insignificant lower puncture time, procedure time, fluoroscopy time and amount of contrast in the distal left trans- radial approach (ldTRA) than the right trans-radial approach (RTRA).

Conclusion: the left distal radial artery access technique is feasible and safe for coronary angiography and interventions with a minimal advantage over right radial approach. This approach also leads to preservation of the radial artery which can be used as a conduct in subsequent revascularization procedures as the rate of radial artery occlusion is more with the conventional right radial access.

Key words: Left distal trans-radial, Procedure, Cannulation, crossover.

INTRODUCTION

Trans-radial procedure was first applied for percutaneous coronary intervention (PCI) by Kiemeneij and his colleagues in 1993 **[1].** Despite the easiness of access of femoral artery during the coronary angiography, there are many vessel-related drawbacks and bleeding at the site of puncture increases the morbidity, mortality, and length of hospital stay, especially when antiplatelet and anticoagulation agents are taken **[2-3].**

So, the tans-radial approach became more popular among specialists and patients who are in need to percutaneous coronary diagnostic or revascularization procedures **[4].** Trans-radial approach has many advantages compared to transfemoral approach as less vessel related complications, shorter duration of hospital stays and early mobilization **[5].** Nowadays, trans-radial approach is considered as a conventional approach for PCI **[6]**. However, it has some drawbacks. The most common complication is radial artery occlusion (RAO) which is seen in 2.8%–11.7% of patients even with administration of optimal anticoagulants **[7-8].**

Generally, the right radial access is preferred routinely because of the ease of access of its manipulation for the doctor from the right side of the patient and the new design of the devices of radial compression **[9-10].** On the other hand, in special conditions the doctor needs to cross over to the left radial artery. This may be because of the right radial artery occlusion, high tortuosity, sclerosis, and under-development right radial artery **[11].** Moreover, the puncture of left radial artery is preferred by most of right-handed patients who can't tolerate the diminished utilization of the right hand after PCI **[12].**

In the traditional left radial approach, the left arm is placed in the volar aspect and the doctor has to wrap over the patient, which may lead to prolong the procedure time and expose patient to higher radiation doses. To overcome this issue, Kiemeneij **[11]** hypothesized a novel left distal trans-radial approach (ldTRA) in anatomical snuffbox in 2017.

From this point of view, this study was conducted to compare between the left distal trans-radial and conventional right trans-radial approaches for coronary procedures in terms safety and efficacy.

PATIENTS AND METHODS

This randomized comparative study was conducted in Beni-Suef university hospital in the period from October 2018 to October 2019. The sample size was calculated by G.power 3.1 for windows **[13].** Independent T-test was used to calculate the sample size to assess the difference of two means of procedure time. At an effect size 0.73, power of study 95%, error 0.05 and allocation ratio 1 to 1 in each group. The total sample was 100 in both groups. Patients were randomly allocated into two groups using research randomizer **[14];** 50 patients in left distal trans-radial access group and 50 patients in right trans-radial access group.

Inclusion criteria: patients older than 20 years old either males or females and scheduled for coronary angiography and/or per-cutaneous coronary interventions for different indications were eligible for enrollment in the study. In addition, for the left distal radial artery approach, all patients should have a palpable arterial pulse in their AS area.

Exclusion criteria: patients with non-palpable radial artery, patients with previous trans-radial artery CA / or PCI, chronic renal failure patients with arteriovenous fistula or those patients who have the potential of having arteriovenous fistula and refusal were excluded from the study.

Methods:

All patients were subjected to the following:

- A medical history was taken, as well as a clinical examination.

- ECG before and after the procedure.
- Routine laboratory tests, including INR and haemoglobin, prior to the procedure.
- Evaluation of cardiac enzymes after the procedure in individuals who had chest pain or severe ECG abnormalities.
- Hemoglobin testing after a procedure in patients who have had post-procedural bleeding.
- The Allen test was used to examine the function of the palmar arch circulation between the radial and ulnar arteries in all patients.
- A pulse oximetry test is performed prior to the procedure.
- Duplex examination of the radial artery after the procedure.1-A thorough medical history is taken, as well as a clinical examination.

Vascular access site hemostasis:

The artery access sheath was withdrawn immediately after the trans-radial procedure, and early hemostasis was achieved by compressing the access site with the assistant's thumb for around 15 minutes, followed by a minimally compressive bandage with gauze for full hemostasis for 3 hours.

The primary clinical outcomes of interest:

1- The incidence of major adverse cardiac events (MACEs) in one month was observed: MACEs are defined as death, recurrent myocardial infarction and stroke.

2- *Vascular access site complications:*

a) Major bleeding defined as fatal bleeding, intracranial hemorrhage, or bleeding associated with ≥3 g/dL hemoglobin drop or requiring transfusion or requiring surgery.

b) Minor bleeding: any bleeding does not meet the definition of major bleeding.

c) Pseudo-aneurysm.

d) Radial artery occlusion with or without ischemia.

e) Pain: An unpleasant sensation that can range from mild, localized discomfort to agony. Although it is not an objective scale, the visual analog scale score was used.

3- Access site crossover; any procedural failure (inability to puncture the entry site artery, failure to cannulate the coronary artery, inability to conduct the planned PTCA or stenting of the coronary artery) or a significant access site complication result in the requirement to puncture a second arterial access site.

Secondary procedural outcomes:

1- Puncture time (in minutes): The time from local anesthesia to sheath insertion.

2- Coronary cannulation time (in seconds): The time from sheath insertion to first cineangiography recording.

3- Procedural time (in minutes): It ranges from the arterial access time (time required to access the artery) to the end of the procedure while sheath removal time was not included.

4- Fluoroscopy time (in minutes): It is the time of cineangiography used during the procedure including all views taken.

5- Amount of contrast used during the procedure.

The procedural techniques:

1-Conventioal right trans-radial access:

A vital component of patient position was an arm board extending from the side of the catheterization table, and preferably hinged to allow lateral motion toward and away from the table. The patient was placed on the catheterization table in the usual fashion with the right arm extended on the arm board, palm upward, the wrist was extended by placing a roll of gauze underneath it.

The radial artery was punctured with a 21gauge open needle to obtain a pulsatile blood flow 2–3 cm, above the styloid process, where the artery is best palpable. The subsequent punctures in a patient who had a prior unsuccessful access attempt was at 1 cm proximal to the initial site **[15].**

2-Left distal trans-radial access:

In their anatomical snuffbox (AS) location, all patients had a detectable arterial pulse. The patient left hand was bending toward their right groin. Then, with the thumb underneath the remaining four fingers, their left hand was gently abducted, highlighting the fossa radialis. The operator was on the right side of the patient, preparing to puncture the left distal radial artery. A 21-gauge open needle was used to get access to the left distal radial artery after 2 mL of 2% Xylocaine was applied to the AS. Following successful puncture in both groups, a 0.018-inch straight guide wire with a soft, flexible proximal part and a hard distal part was inserted. A 6 French radial hydrophilic sheath (Prelude Ease, Merit Medical) was then inserted into the radial artery, and all patients were given a cocktail of 2500 units of unfractionated heparin, 200 mcg of nitroglycerin, 2.5 mg verapamil, and normal saline 0.9 percent to prevent radial spasm. In the event of interventions, the heparin dose was appropriately modified. The operator on the patient's right side (groin) would start the trans-radial coronary angiography or intervention after flushing the radial sheath **[16].**

Statistical analysis:

Analysis of data was performed using SPSS version 25.0. Description of quantitative variables was in the form of mean ±standard deviation (SD). Description of qualitative variables was in the form of numbers (No.) and percent’s (%). T-test was used to compare between two groups regarding the normally distributed scale variable and Mann-Whitney test was used to compare groups regarding the non-normally distributed variables. Chi-Squared test/ Fisher exact was used to compare the two groups regarding categorical variables. The significance of the results was assessed in the form of P-value that was differentiated into non-significant when P-value > 0.05 and significant when P-value ≤ 0.05.

Ethical consideration:

All data were anonymous and confidential. The study was conducted according to the declaration of Helsinki. The study protocol was approved by the research ethics committee of Faculty of medicine in Beni-Suef University. An informed consent was obtained from all participants before enrollment in the study.

RESULTS

Both groups were well matched regarding their baseline characteristics with no statistically significant differences between both approaches. Regarding their age, the mean age was 54.2 ± 9.5 years in ldTRA group and 55.3±9.4 years in RTR group. The sex distribution was almost the same in both approaches; male (78%) in ldTRA group and (74%) in RTR group. Concerning the co-morbidities, diabetes was 34% for ldTRA group and 34% for RTR group, hypertension was 36% for ldTRA group and 40% for RTR group & smoking was 62% for ldTRA group and 58% for RTR group with no statistically significant difference between both groups. There were 44 (88%) of ldTRA group indicated for elective procedure versus 40(80%) in the RTR group and only 6(12%) of ldTRA were in need to urgent procedure versus 10(20%) among the RTR group (P-value>0.05). As regard the type of intervention, it was distributed equally in both group (30)60% CA and 20(40%) PCI in both groups (p>0.05). Of the PCI, 5 of those who were subjected to ldTRA were categorized under primary PCI compared to 8 subjects in RTR. The two groups spend nearly the same puncture time. The ldTRA was associated with significantly lower coronary cannulation time compared with the RRA. Although the procedure time, fluoroscopy time & contrast amount were less in ldTRA group, they were not significantly different between the two groups. The mean puncture time was (2.1 ± 0.5 min) in ldTRA group and (2.3 ± 0.7 min) in RTR group (P-value = 0.103). The mean coronary cannulation time was (30 ± 7 sec) in ldTRA group and (43 ± 11 sec) in RTR group with statistically significant difference between both groups. Concerning the mean procedure time, it was (23 ± 8.1 min) in ldTRA group and (26.6 ± 13.2 min) in RTR group with no significant difference between both procedures. Regarding the mean fluoroscopy time, it was (5.9 ± 2.1 min) in ldTRA group and (6.1 ± 2.9 min) in RTR group (P-value = 0.745). The mean contrast amount used in each group was (65.7 ± 24.9 mL) in ldTRA group and (75.6 ± 33.2 min) in RTR group (P-value = 0.097) (Table 1).

Table (1) Puncture time, coronary cannulation time, procedure time, fluoroscopy time and the amount of contrast in both groups:

Items (Mean±SD)	**ldTRA n=50 (%)**	**RTR n=50(%)**	**P-value**
Puncture time (min)	2.1±0.5	2.3±0.7	0.103
Coronary cannulation time(sec)	30±7	43±11	<0.001*
Procedure time (min)	23±8.1	26.6±13.2	0.107
Fluoroscopy time (min)	5.9±2.1	6.1±2.9	0.745
Amount of contrast (mL)	65.7±24.9	75.6±33.2	0.097

*P-value is significant ldTRA= left distal trans-radial artery RTR=right trans-radial
Min=minutes, mL= milliliter, sec=seconds

For subgroup analysis, the mean procedure time was (18.7 ± 4.9 min) in CA of ldTRA group versus (20.6 ± 4.1) in CA of RTR and it was (29 ± 7.8 min) in PCI of ldTRA versus (35.6 ± 16.7) in PCI of RTR group with no statistically significant difference between them. In addition, the mean fluoroscopy time and contrast time didn't differ significantly between CA of both procedures and PCI of both procedures (P-value>0.05) (Table 2).

Table (2) Procedure time, fluoroscopy time and the amount of contrast in each procedure in both groups:

Items (Mean±SD)	**ldTRA n=50 (%)**		**RTR n=50(%)**		**P-value**
	CA1	**PCI1**	**CA2**	**PCI2**	
Procedure time	18.7±4.9	29±7.8	20.6±4.1	35.6±16.7	CA1 vs CA2=0.118 PC1 vs PCI2=0.111
Fluoroscopy time	4.7±1.2	7.5±2.2	4.9±0.9	8.1±3.7	CA1 vs CA2=0.875 PC1 vs PCI2=0.514
Amount of contrast (mL)	54.6±18.6	81±24.8	60.2±15.6	98.7±39.2	CA1 vs CA2=0.220 PC1 vs PCI2=0.092

*P-value is significant ldTRA= left distal trans-radial artery RTR=right trans-radial
Min=minutes, mL= milliliter, sec=seconds, CA= Coronary angiography, PCI=percutaneous coronary intervention

Crossover occurred in 3 patients (6%) in the RTR group compared to 1 patient (2%) in the ldTRA group (p-value=0.222). In this study, there were neither deaths, myocardial infarction nor need for emergency revascularization by either PCI or coronary artery bypass graft had occurred (Table 3).

Table (3) incidence of cross over and complication in both groups:

Items	**DLR n=50 (%)**	**RTR n=50(%)**	**P-value**
Cross over	1 (2)	3 (6)	0.307
Complications			
No complications	48 (96)	40 (80)	0.258
RAS	1 (2)	3 (6)	
RAO	1 (2)	4 (8)	
Subclavian artery tortuosity & dissection	0 (0)	1 (2)	
TIA/stroke	0 (0)	1 (2)	
Perforation of radial artery	0 (0)	1 (2)	
MI	0 (0)	0 (0)	

ldTRA= left distal trans-radial artery, RTR=right trans-radial

DISCUSSION

Despite the high incidence of tortuosity and loops of the right radial artery and subclavian that lead to higher manipulation by the catheter, the right traditional radial procedure is widely preferred by most of operators may be due to the convenience of catheter manipulation the right side of the patient with more physical comfort of the operator **[17]**. In addition to the higher risk of embolism during the catheter passage from the innominate

artery to the ascending aorta where the right carotid artery comes off **[18]**. While the left traditional radial approach has a resemble approach to the femoral procedure. This makes it easier to handle the catheter, reduce the procedure time, the fluoroscopic time, amount of contrast, and exposure to radiation **[19-20]**.

Regarding the coronary cannulation time, there was a significant longer time among the right trans-radial approach than the left distal trans-radial approach. This result disagreed with the TALENT study in which both groups had the same average cannulation time **[17]**. Also, **Koutouzis et al. [21]** concluded in his randomized trial that ldTRA was associated longer cannulation time and increased the number of trials and skin punctures. However, this did not affect the total procedural time, which was similar between ldTRA and TRA. This also was explained by the increased tortuosity and angulations at the distal puncture site would be the reason of high failure rate.

Concerning the overall fluoroscopy time and the amount of contrast regardless the type of intervention, there was insignificant difference between the right trans-radial approach (6.1±2.9 minutes) and the left distal trans-radial approach (5.9±2.1 minutes). This result was supported by a previous study was conducted to compare between both procedures for experienced operators **[17]**. On contrary to **Pacchioni et al. [22]** study who found that the left distal trans-radial approach had significantly lower fluoroscopy time and radiation dose, but this may be explained by the lower experience among the operators as showed in **Sciahbasi et al. [17].** Moreover, in a meta-analysis conducted by **Shah et al. [9]** who reported that the overall mean fluoroscopy time and amount of contrast was significantly higher in the right trans-radial approach than the left trans-radial approach. In this study, the fluoroscopy time and the amount of contrast showed insignificant longer time either in the coronary angiography or percutaneous coronary intervention between both approaches as showed in many previous studies **[17, 23-25].** Another study showed a significant longer time of fluoroscopy and amount of contrast also in diagnostic procedure **[22]**.

As regard the overall procedure time, there was no significant difference between both approaches. This insignificant result was mentioned in a recent randomized study done by **Cázares-Díazleal et al. [26]** in addition to the meta-analysis conducted by **Shah et al. [9]**. Also, both diagnostic and interventional procedures in both groups didn't differ significantly regarding the procedural. This finding was supported by previous studies **[27-28].**

This study confirmed that the two groups consumed nearly the same puncture time. The ldTRA was associated with significantly lower coronary cannulation time compared with the RRA. Although the procedure time, fluoroscopy time & contrast amount were less in ldTRA group, they were not significantly different between the two groups. This can be explained by; the right subclavian artery has significantly higher incidence of tortuosity in comparison to the left subclavian artery **[29]**. In addition, the catheter manipulations with the left radial approach are considered very similar to the femoral approach with use of Judkins catheters while in right radial approach procedures, the catheters must be rotated to adapt to the S-shaped geometry of the subclavian-innominate-aorta axis, which can increase procedural complexity **[17]**. Moreover, in the right trans-radial access we need the patient to take a deep breath to bring the catheter into the ascending aorta or even to cannulate the coronary ostia.

In the current study, the conventional right radial approach was associated with higher crossover rate than ldTRA approach but without statistically significant difference. There were 3 cases had failed out of 50 cases (6%) compared to 1 case in ldTRA group (2%). The reason for crossover in the right trans-radial approach to the transfemoral approach despite success in arterial puncture were because of persistent radial artery spasm despite using nitroglycerin and verapamil before the procedure, another case developed radial artery perforation due to marked tortuosity with extravasation of dye and the last case had marked right subclavian artery tortuosity resulting in subclavian artery dissection during manipulation of diagnostic catheter. While in the ldTRA group the reason for crossover to trans-femoral approach in one case was due to persistent radial artery spasm in post-CABG patient after coronary angiography of the left system & LIMA despite using nitroglycerin & verapamil injection. This is agreed with **Soydan and Akın [16]** study in which 54 patients assigned to ldTRA, brachial artery spasm was encountered in two patients (3.7%), and both had a tortuosity in the brachial artery silhouette identified thanks to the shape of the guidewire. This made advancing the catheters impossible, and the procedure was continued with the right femoral artery approach as the patient anxiety increased.

In addition to **Lo and Rao [30]** study that showed that access crossover rate was 1.7%. The results of the study are an unsurprising yet important steppingstone to further determining the appropriateness of selected ldTRA use in clinical practice. **Andrade et al. [31]** confirmed the findings from Kiemeneij's initial 70 patient case series of ldTRA, which showed 1.5% access-site related complications and 11% access crossover rate.

Regarding the incidence of complications, most of cases had no complications in both groups. There was no significant difference between both groups regarding the absence of complications (96% versus 80%) in distal left trans-radial group versus the right trans-radial group. In the study of **Kiemeniej [11] and Soydan and Akın [16]** out of 70 and 54 patients respectively who underwent coronary intervention through distal trans radial access none of them had complications like hematoma, numbness which was very much similar to our study.

The reported complications in this study were radial artery spasm (2% vs 6%), radial artery occlusion (2% vs 8%), subclavian artery tortuosity & dissection (0% vs 1%), stroke (0% vs 2%), and perforation of radial artery (0% vs 2%) in distal left trans-radial and right trans-radial, respectively with no significant difference between both approaches. In this study the radial artery spasm had occurred in three cases among the conventional right radial group, two of which were transient and relieved after injection of nitroglycerin, and one was persistent leading to crossover from right radial access to right femoral access. While in the ldTRA group, only one case developed persistent radial artery spasm after angiography of the left system & LIMA graft due to excessive manipulation leading to crossover to right femoral access for RCA angiography. As radial artery is thinner and is mainly controlled by α1 adrenergic nerve, it is prone to spasm.

The reported radial artery perforation in this study was in one case of the conventional right radial access group during advancing the wire due to marked radial artery tortuosity leading to extravasation of dye with risk of developing compartmental syndrome & crossover was done from radial to femoral approach. Arterial duplex was done within one week revealing

normal blood flow inside radial artery without any signs of forearm or arm complications. In ldTRA, arterial entry is beyond compartments of forearm reducing risk of compartment syndrome. Also, the subclavian artery dissection was occurred in one case during manipulations to access the right radial-aortic route due to excessive right subclavian artery tortuosity leading to crossover to ipsilateral femoral artery.

Regard the major cardiovascular events, it hadn't occurred in this study even with primary PCI cases except one case in the conventional right radial group. This case had inferior STEMI & received thrombolytic therapy 1 month before presentation to have an elective CA. During the procedure through right radial access the patient developed aphasia and left sided weakness lasting for half an hour then returned to his previous normal state and the patient had normal CT Brain denoting the occurrence of TIA. This finding was explained in **Pacchioni et al. [22]** study that showed a higher rate of cerebral micro-embolization during right trans-radial procedures in comparison to left trans-radial procedures due to the increased number of catheter exchanges.

CONCLUSION

In conclusion, left distal radial artery access technique is feasible and safe for coronary angiography and interventions with a minimal advantage over right radial approach in terms of association with significantly lower coronary cannulation time. It is also associated with less procedure time, fluoroscopy time & contrast amount despite being statistically non-significant. This approach also leads to preservation of the radial artery which can be used as a conduct in subsequent revascularization procedures as the rate of radial artery occlusion is more with the conventional right radial access.

LIMITATIONS

This study has some limitations as it has relatively small sample size and it is single center study. In addition, the left distal radial artery is the arterial segment that is a continuation of the forearm radial artery. Its puncture can be challenging as its diameter is smaller than the radial artery. Its access requires a learning curve, especially when the pulse in AS is weak or not felt at all.

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