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Distal Versus Traditional Radial Approach for Coronary Angiography

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ABSTRACT

Purpose: The aim of this study was to evaluate the efficacy and safety of distal radial (DR) versus traditional radial (TR) approach during coronary angiography.
Methods: Two hundred patients scheduled to undergo transradial coronary angiography were randomized between the two approaches. Primary endpoint of the study was switching to another access site due to inability of successful target artery cannulation. Secondary endpoints were time to cannulation, total procedure duration, number of attempts, number of skin punctures and duration of manual hemostasis. Secondary safety endpoints were the rate of moderate or severe spasm, arm hematoma EASY class III or more and radial artery occlusion at discharge. Quality of life endpoint was the patient's preference of cannulation method at 30 days.
Results: The primary endpoint was met in 30 patients (30%) from the DR group and 2 patients (2%) from the TR group ($p < 0.001$). The time of cannulation was longer in the DR group compared to the TR group (269 ± 251 s vs 140 ± 161 s, $p < 0.001$), but this did not affect the total procedural duration (925 ± 896 s vs 831 ± 424 s, $p = 0.494$). The number of attempts and the number of skin punctures were more in the DR group compared to the TR group (6.8 ± 6.2 vs 3.4 ± 4.5, $p < 0.001$ and 2.4 ± 1.7 vs 1.6 ± 1.2, $p < 0.001$, respectively). However, DR treated patients had faster manual hemostasis time compared to TR treated patients (568 ± 462 s vs 841 ± 574 s, $p = 0.002$). There were no differences recorded in the safety endpoints of moderate or severe spasm, EASY grade III or more radial hematomas or the incidence of radial artery occlusion after the procedure. Patients' preference to the randomized puncture sites was the same (79% vs 85%, $p = 0.358$).
Conclusion: Distal radial approach is associated with lower successful cannulation rates and shorter manual hemostasis time compared to the traditional radial approach.

1. Introduction

Transradial approach for cardiac catheterization is an expanding technique. The rate of patients treated transradially is growing, since radial approach is associated with less access site bleeding complications [1], increased patient comfort [2], faster mobilization [3] and lower mortality in high risk populations, like patients with ST elevation myocardial infarction [4].

The radial puncture is traditionally performed 2 to 3 cm proximal to the radial styloid process of the hand. However, recently a new site of radial artery puncture, distally to the traditional puncture site, in the anatomical snuffbox was introduced by Kiemenej [5]. Case reports and case series have been reported evaluating the new radial artery puncture site [6–8], but the two methods were never compared in a randomized manner so far.

The aim of this randomized study is to evaluate the distal radial (DR) and the traditional radial (TR) artery puncture sites in terms of efficacy and safety.

2. Methods

Two hundred patients scheduled to undergo transradial coronary angiography in two different Greek hospitals were enrolled in this study. Inclusion was performed between April and June 2018. Randomization was performed with closed envelopes. Patients with palpable DR and TR were evaluated. Patients with previous surgical cardiac revascularization, on oral anticoagulation treatment, those with GFR <30 ml/min/m^2, those with previous cannulation of both radial arteries and those with planned PCI after angiography were excluded from the study. In patients with prior cannulation of one radial artery, the contralateral arm was used for the study. Both DR and TR puncture sites were sterilized in all patients in order to have the advantage of immediate access site switch in case of initial site cannulation failure. The

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cannula over needle technique was used for radial artery puncture and a 6Fr Engage™ radial, 12 cm long sheath (St Jude Medical, Minnesota, USA) was introduced after successful stainless steel 0.025 wire insertion. The detailed protocol of sheath insertion was previously described [9]. All operators participating in the study were high volume operators (more than 200 procedures per year for the last five years), highly experienced in forearm approach (>80% of their procedures were performed through the forearm) and experienced in both ways of puncture, with an experience of more than 50 DR procedures before participating in the study. The study was approved by the Ethics Boards of both hospitals and informed consent was obtained from all patients before participating in the study.

Barbeaux's test was not performed in any patient before catheterization, since it is not used in the routine of our laboratories [10].

Successful cannulation was confirmed by arterial waveform and arterial blood back flow from the radial sheath side arm.

In case of initial failure of radial artery cannulation, the new access site was on operating physician discretion.

After successful sheath insertion unfractionated heparin (50 IU/kg) and verapamil (5 mg) were administered intrasheath in order to reduce the rate of spasm and postprocedural radial artery occlusion.

After the end of the procedure the radial sheath was immediately removed and manual hemostasis was applied in all patients [11]. We choose not to use radial artery closure devices, since they are designed especially for TR puncture and their performance in patients treated through the DR approach is not confirmed yet.

After the end of hemostasis, the patency of the radial artery at the site of puncture was evaluated using the color dublex ultrasound evaluation.

After hemostasis, a light bandage was applied in all patients and they remained in the hospital for an hour after hemostasis, before they were discharged, unless it was clinically contraindicated.

Telephone contact was performed at 30 ± 3 days in order to evaluate clinical outcomes and patients' willingness to undergo cardiac catheterization from the allocated access site, in case there is such an indication in the future.

2.1. Endpoints

Primary endpoint of the study was the failure rate of radial artery cannulation. Failure of procedure completion and access site switch after successful radial artery cannulation was recorded, but it was not incorporated in the primary endpoint. Secondary efficacy endpoints of the study were duration of cannulation, total procedure time, number of cannulation attempts, number of skin punctures, as well as duration of manual hemostasis. Safety endpoints were the incidence of moderate or severe spasm, hematomas EASY class III or more and the incidence of radial artery occlusion at discharge, documented with color duplex ultrasonography. Quality of life endpoint was the willingness of the patient to undergo a future cardiac catheterization through the allocated access site 30 days after the procedure.

2.2. Statistical analysis

Continuous parameters are reported as mean ± standard deviation or as median (interquartile range) and compared using one-way ANOVA, student *t*-test or *U* test as appropriate. Categorical variables were reported as percentages and compared using the chi-square test or the Fisher's exact test, as appropriate. All statistical analyses were performed using SPSS 20.0 (IBM, Armonk, New York) and Prism 6.0 (GraphPad Software, La Jolla, California). A p value <0.05 was considered statistically significant.

Sample size calculation was not performed since this is a pilot study and no data of cannulation failure rates with DR approach were available at the time of study schedule.

Table 1
Demographic characteristics of study population. BMI: body mass index, PCI: Percutaneous coronary intervention, MI: Myocardial infarction.

	Distal Radial group (n = 100)	Traditional Radial group (n = 100)	*p* value
Age (years)	63.8 ± 10.9	62.8 ± 11.0	0.499
BMI (kg/m^2)	28.6 ± 4.7	29.0 ± 5.3	0.342
Male gender	74	77	0.743
Current smoker	35	28	0.361
Diabetes	27	28	1.000
Hypertension	73	63	0.172
Hyperlipidemia	71	59	0.103
Prior PCI	28	23	0.517
Prior MI	25	17	0.224

Data analysis was performed following the intention to treat principal.

3. Results

Two hundred patients were totally randomized between DR (100 patients) and TR (100 patients) puncture. Demographic characteristics of patients participated in the study are presented in Table 1. There were no significant differences between the two study groups. Multivariate analysis did not identify any possible predictors of access site failure in patients treated through DR approach (See Table 2).

The indications for the procedure were similar between the two groups, with non-specific chest pain [61 patients (30.5%)], positive non-invasive stress test [42 patients (21%)] and heart failure [25 patients (12.5%)] being the most common. The catheterization was performed from the right arm in 152 patients (76%), without differences between DR and TR (74 patients vs 78 patients, $p = 0.620$). Seventy eight patients (39%) had underwent a prior cardiac catheterization and in 64 (32%) of them the transradial approach was used. In these patients the contralateral arm was used, in order to use a radial artery that was not catheterized in the past.

3.1. Outcomes

The primary endpoint of the study was met in 2 patients from TR group and 30 patients in the DR group ($p < 0.001$). Alternative access sites used after initial study access site failure in the TR group were ipsilateral ulnar (1 patient) and contralateral radial (1 patient) arteries. After cannulation failure in the DR group, the alternative access site was in all 30 patients ipsilateral radial artery. No access site switch was performed due to spasm, perforation or tortuosity after successful artery cannulation. However, balloon assisted tracking was performed in 2 patients (one from each group) in order to overcome radial artery perforation and visualize both coronary arteries.

The wire insertion was successful with the first attempt in 41 patients from the TR group and 27 from the DR group ($p = 0.052$).

Table 2
Multivariate analysis of possible predictors of cannulation failure in patients randomized to distal radial approach. PCI: Percutaneous coronary intervention, MI: Myocardial infarction.

	Odds ratio	Confidence interval	*p* value
Gender	0.529	0.165–1.695	0.284
Age	1.003	0.961–1.047	0.876
Diabetes	1.001	0.294–3.412	0.999
Smoking	1.524	0.809–2.870	0.192
Hypertension	0.929	0.305–2.827	0.896
Hyperlipidemia	0.400	0.129–1.236	0.111
Previous PCI	0.746	0.233–3.942	0.623
Previous MI	0.524	0.324–4.126	0.528

The time of cannulation was longer in the DR group compared to the TR group (269 ± 251 s vs 140 ± 161 s, $p < 0.001$), but this did not affect the total procedural duration (925 ± 896 s vs 831 ± 424 s, $p = 0.494$). The number of attempts and the number of skin punctures were more in the DR group compared to the TR group (6.8 ± 6.2 vs 3.4 ± 4.5, $p < 0.001$ and 2.4 ± 1.7 vs 1.6 ± 1.2, $p < 0.001$, respectively).

Fluoroscopy duration, radiation Dose Area Product (DAP) and consumed contrast media did not differ between the DR and the TR groups [252 ± 131 s vs 235 ± 149 s ($p = 0.398$), 2034 ± 1478 cG/cm^2 vs 1850 ± 1140 cGy/cm^2 ($p = 0.339$) and 89 ± 39 ml vs 82 ± 36 ml ($p = 0.198$)].

Duration of hemostasis was significantly shorter in the DR compared to the TR group (568 ± 462 s vs 841 ± 574 s, $p = 0.002$).

There were no differences in any of the safety endpoints, since the rate of moderate or severe spasm [3 patients in the DR and 4 patients in the TR group ($p = 1.000$)], hematomas EASY class ≥III [1 patient in each group, $p = 1.000$)] and postprocedural radial artery occlusion [5 patients in the DR vs 9 patients in the TR group ($p = 0.407$)] were similar between the two groups.

The quality of life endpoint that we used also did not differ between the two groups, since 79 patients of the DR group and 85 patients from the TR group were positive in using again the access site they were randomized to in case of a future catheterization. When we excluded patients that an access site switch was performed, the rates of patient' satisfaction were even higher [62 patients (89%) in DR group vs 85 patients (87%) in the TR group, $p = 0.815$].

4. Discussion

This is the first study to evaluate DR and TR access in a randomized way. We demonstrated that DR site of puncture is associated with increased rate of cannulation failure compared to the TR site of puncture. Additionally, DR approach is associated with prolonged duration of cannulation, increased number of attempts and number of skin punctures. However, this did not affect the total procedural time, which was similar between the two groups. The only benefit of DR approach seems to be the shorter duration of hemostasis, at least when this is performed manually, as it was the protocol in our study.

The increased rate of failure to cannulate the DR artery is possibly due to the increased tortuosity and angulations at the site DR puncture, while on the other hand the TR site of puncture is performed in a more straight artery segment. In many DR patients we observed an inability to insert the wire even when the flow from the cannula indicated that we were in the right lumen of the vessel. This finding must be evaluated in the future with different wires (for example coated wires) and cannulation methods (for example needle puncture).

The fact that in this study DR access was found inferior to the TR access site does not mean that the doctors should not be familiar with it. We previously demonstrated that when evaluating both left and right radial and ulnar arteries, the rate of switching to femoral access may be extremely low [12]. The fact that with DR access we have two more forearm access to evaluate (left and right DR access) may help further in reducing the need of femoral puncture.

This study failed to show any differences at safety endpoint such as the rate or moderate or severe spasm, hematomas class III or more and radial artery occlusion, but it was not powered enough to focus on these endpoints.

5. Conclusions

Distal radial artery cannulation in the anatomical snuffbox is associated with increased rate of cannulation failure, but with shorter duration of manual hemostasis, compared to the TR access site. Further studies are needed in order to provide a more detailed evaluation of this new radial artery puncture site.

5.1. Limitations

This randomized study has many limitations. There were only two centers participating in the study (Red Cross General Hospital of Athens and University Hospital of Thessaloniki). The experience of all participating doctors in DR punctures, although significant (more than 50 procedures each), is very limited compared to their long experience in TR access. The fact that we used a specific introducer with a 0.025 stainless steel wire, does not exclude that the results of the study could be different, if other introducer or coated wire were used. Ultrasound guidance was not used in any patient in this study since it is not used in our laboratory routine. It is possible that the use of ultrasound by experienced operators may alter the results of a future similar study.

References

[1] Agostoni P, Biondi-Zoccai GG, de Benedictis ML, et al. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures; systematic overview and meta-analysis of randomized trials. J Am Coll Cardiol Jul 21 2004;44(2):349–56.
[2] Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. Am Heart J Sep 1999;138:430–6.
[3] Koutouzis M, Karatasakis A, Brilakis ES, Agelaki M, Maniotis C, Dimitriou P, et al. Feasibility and safety of same-day discharge after complex percutaneous coronary intervention using forearm approach. Cardiovasc Revasc Med 2017 Jun;18(4):245–9.
[4] Romagnoli E, Biondi-Zoccai G, Sciahbasi A, Politi L, Rigattieri S, Pendenza G, et al. Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome: the RIFLE-STEACS (Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome) study. J Am Coll Cardiol 2012 Dec 18;60(24):2481–9.
[5] Kiemeneij F. Left distal transradial access in the anatomical snuffbox for coronary angiography (ldTRA) and interventions (ldTRI). EuroIntervention 2017 Sep 20;13(7):851–7.
[6] Schulte-Hermes M, Klein-Wiele O, Vorpahl M, Seyfarth M. Feasibility of transradial access for coronary interventions via percutaneous angioplasty of the radial artery in cases of functional radial occlusion. J Invasive Cardiol 2018 Aug 15 pii: JIC2018815-3, Epub ahead of print.
[7] Koutouzis M, Kontopodis E, Tassopoulos A, Tsiafoutis I, Lazaris E. Hand hematoma after cardiac catheterization via distal radial artery. J Invasive Cardiol 2018 Jun 19 pii: JIC2018619-1, Epub ahead of print.
[8] Valsecchi O, Vassileva A, Cereda AF, Canova P, Satogami K, Fiocca L, et al. Early clinical experience with right and left distal transradial access in the anatomical snuffbox in 52 consecutive patients. J Invasive Cardiol 2018 Jun;30(6):218–23.
[9] Koutouzis M, Kaoukis A, Hamilos M, Tsigkas G, Tsiafoutis I, Maniotis C, et al. Needle versus cannula over needle for radial artery cannulation during transradial coronary angiography and interventions. Cardiovasc Revasc Med 2017 Sep;18(6):436–9.
[10] Maniotis C, Koutouzis M, Andreou C, Lazaris E, Tsiafoutis I, Zografos T, et al. Transradial approach for cardiac catheterization in patients with negative Allen's test. J Invasive Cardiol 2015 Sep;27(9):416–20.
[11] Petroglou D, Didagelos M, Chalikias G, Tziakas D, Tsigkas G, Hahalis G, et al. Manual versus mechanical compression of the radial artery after transradial coronary angiography: the MEMORY multicenter randomized trial. JACC Cardiovasc Interv 2018 Jun 11;11(11):1050–8.
[12] Rigatou A, Kontopodis E, Tassopoulos A, Kintis K, Nikitas G, Patsilinakos S, et al. Strategies to increase the use of forearm approach during coronary angiography and interventions. Cardiovasc Revasc Med 2018 Jul 5. https://doi.org/10.1016/j.carrev.2018.07.002 pii: S1553-8389(18)30277-X.