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ORIGINAL ARTICLE

An Observational Study on the Efficacy and Safety of Coronary Intervention Via Distal Transradial Access (STRA) in Patients

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ABSTRACT

Objective: The aim of this study was to examine the safety and effectiveness of distal trans-radial access (dTRA), a new coronary intervention procedure, in individuals with low BMI.

Methods: The design of this study was an observational study design. This study was conducted at Pakistan Institute of Medical Sciences (PIMS), Islamabad, and the duration of this study was from December 2020 to December 2022. 67 patients who had a coronary intervention at Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan. The sample was divided into two groups: 38 patients had traditional trans-radial access (cTRA) and 29 patients got direct trans-radial access (dTRA).

Results: The research outcomes indicated that the success rates for puncture procedures in both groups, dTRA and cTRA, were not significantly different. Specifically, the success rate for dTRA was found to be 96.6% while cTRA recorded a success rate of 97.4%. This difference was not considered to be statistically significant as the p-value was 0.846, which means there was an 84.6% chance that the results were due to random chance and not a true difference between the groups. This indicates that both dTRA and cTRA are effective in puncture procedures and can produce similar results in terms of success rate. It is crucial to consider these results alongside the limitations of the research. Despite the overall results indicating a similar success rate between the two groups, there was a disparity in success rates for single-needle puncture procedures. In this aspect, the cTRA group outperformed the dTRA group with a success rate of 81.6% compared to 51.7% for the dTRA group. This difference was statistically significant with a p-value of 0.020, indicating that the results were not due to random chance. However, the dTRA group did have some advantages over the cTRA group. The compression hemostasis time, the time required for the bleeding to stop, was faster for the dTRA group, with a p-value of 0.01. Additionally, the incidence of radial artery occlusion was less frequent in the dTRA group compared to the cTRA group, with a p-value of 0.007 (4% compared to 33.3% in the cTRA group).

Conclusions: In the conclusion of this study, individuals with low BMI, coronary intervention with dTRA is both secure and efficient. This approach offers a less complicated, more effective, and efficient alternative to conventional trans-radial access.

Keywords: Trans-Radial Access, Body Mass Index, Percutaneous Coronary Intervention, Hemostasis, Vascular. Radial Artery Occlusion.

INTRODUCTION

The standard method for diagnosing and treating coronary interventional disease is now conventional trans-radial access (cTRA). It had less death, a decreased likelihood of severe bleeding, a lower frequency of negative cardiovascular events, and a lower rate of vascular problems than the femoral approach [(1)]. But there are certain drawbacks, particularly regarding the prevalence of radial artery blockage. Distal trans-radial access (dTRA), a different access method for vascular treatments, has gained popularity globally in recent years and caught the interest of cardiac intervention specialists [(2)]. There are no discernible differences between dTRA and cTRA in terms of the success rate of puncture catheterization, the risk of hematoma at the access site, or the frequency of radial artery spasm; nevertheless, dTRA has a higher clinical value and a lower frequency of RAO [(3)]. Despite these benefits, distal radial artery coronary catheterization has some drawbacks as well. The distal radial artery, for instance, is narrower and more curved than the proximal radial artery, making puncture more challenging and taking longer [(4)].

Low BMI patients may have a narrower distal radial artery and a reduced puncture with satisfactory results [(5)]. Low BMI has been linked in certain studies to a lower success rate for distal radial artery puncture [(6)], which may be a risk factor in and of itself. There is still little data on the efficacy and safety of employing the distal trans-radial approach (dTRA) for coronary intervention in people with low body mass index, despite the growing usage of the radial artery as a method of reaching the coronary vasculature (BMI). Due to this, our team performed a retrospective cohort research to assess the effectiveness and safety of coronary intervention with dTRA in people with low BMI. By comparing the results of dTRA and the conventional trans-radial approach (cTRA), we aimed to provide valuable insights into the use of dTRA in individuals with low BMI. The study's findings could help improve the quality of care for patients undergoing coronary intervention.

MATERIAL AND METHODS

This study was conducted at Pakistan Institute of Medical Sciences (PIMS), Islamabad, and the duration of this study was from December 2020 to December 2022. The design of this study was an observational study design. The participant of this study were 67 low-BMI individuals who received cardiac surgery. The median age of the participants was 74 (68-78), and 36 of them were men (53.7%). The decision to puncture was made at our center based on operator experience. A team of five experienced cardiologists, each having performed over 1,000 radial artery punctures, ran the cTRA group. Meanwhile, the dTRA group was handled by a group of three cardiologists, all of whom were well-versed in both traditional radial artery punctures and dTRA punctures with more than 100 instances under their belts. The study consisted of two groups of patients, the dTRA group with 29 patients and the cTRA group with 38 patients, who were selected based on their preferred interventional approach. Throughout the follow-up, the patient's progress was monitored and the final effective interventional and catheterization procedures were recorded. To assess the incidence of radial artery occlusion, ultrasonography was used.

There were records of general information, information about the procedure, and information on the follow-up. General information comprised gender, weight, height, age, smoking history, drinking, diabetes mellitus (DM), high Bp, stroke, coronary artery disease (CAD), and hyperlipidemia, as well as information from cardiac ultrasound procedures and postoperative vital signs. Rate of success of puncture, time of puncture, operational time, operational technique, operational category, contrast dose, radiation time of exposure, compression hemostasis duration, and consequences including hematoma, bleeding,

numbness, hematoma, hand swelling, and level of discomfort were among the procedure-related data. Follow-up information includes RAO and follow-up time.

Figure 1: (a) Anatomic snuffbox area in one patient with low body mass index. (b) Ultrasound follow-up operation.

In our prior investigation [7], the surgical techniques and procedures of catheterization and puncture were presented. To put it plainly, the anatomical snuffbox was the access site in the dTRA group. To expose the anatomic snuffbox area, the patient was told to hold their forearm in a natural vertical posture with their thumb tucked beneath their four fingers for the cTRA group. The transverse line of the wrist was about three cm from the access site. The wrist was stretched over 90° and the arm was 70° abducted, totally exposing the radial artery. Following standard cleaning, 2% lidocaine was used to induce local anesthesia. The anatomic snuffbox and the wrist were then punctured using Seldinger's method. A 20 G puncture needle was used together with a 0.025″ guidewire to accomplish the puncture. A successful puncture was followed by the insertion of an arterial sheath. Successful cannulation was followed by the injection of 200 g of nitroglycerin and 3000 U of unfractionated heparin via the sheath. The dTRA group was given an elastic bandage for hemostasis after catheterization, while the cTRA group was given a compression device or bandage.

The patient was seated and put their hand in the form of a wine cup with their wrist vertically positioned on the examination table. In several locations along the anatomical snuffbox, the examiner applied the high-frequency probe to the skin vertically while coating it with a coupling agent. To prevent applying pressure to the blood vessels, the probe was just gently placed against the skin. An organized strategy was used to scan the radial artery. (Figure 1).

According to this research, a successful puncture was one in which the guidewire's radial sheath was successfully inserted and the puncture needle returned blood. Patients experiencing compression hemostasis had their discomfort rated using a visual analog scale (VAS). A score of 0 meant there was no pain, 1-3 meant the pain was light and manageable, and 4-6 meant the pain was severe enough to interfere with sleep. An intensity score of 7 to 10 indicated excruciating discomfort that interfered with sleep and appetite. The BARC criteria were used to classify bleeding, and the EASY categorization method was used to assess blood loss. Ultrasound proved the full blockage by demonstrating the growth of a thrombus and the absence of blood flow in the arteries. Contrarily, functional occlusion was identified as the steady and slow reduction in blood flow in the radial artery as seen by ultrasonography in the absence of continuous flow. [8]

The SPSS version 26.0 program was used to analyze the data. Statistical techniques were used to examine the data, such as the normal distribution for numerical data, which is represented by the mean (x) and standard deviation (s). For comparisons between the groups, the independent sample t-test was employed, and the Wilcoxon test was used to non-normally distributed data provided as the median (M) with quartiles (Q1, Q3). For intergroup comparisons, the Pearson chi-square test was used, and qualitative data was given as frequency with a percentage. A result was considered statistically significant if the P-value was 0.05 or below.

RESULTS

The general features are shown in Table 1. The average age of the 29 participants in the dTRA group was 75 years. Out of these patients, 15 were males, making up 51.7% of the total number of participants in this group. The median age of the cTRA group was 73.5 years, with 21 men (55.3%) making up the group. Neither the gender nor the age of the two groups differed significantly. Additionally, when compared to the cTRA group, there were no appreciable variations in BMI, health records, or postoperative heart rate.

Table 1: Evaluation of The Two Groups' Baseline Features

Characteristics	cTRA				dTRA				P-value
	n/x	%	Range	S. D	n/x	%	Range	S. D	
Male (n (%))	21	55.3			15	51.7			0.773
Age (Y)	73.5		69.0, 78.3		75		67.0, 78.5		0.82
EF	60.5		46.5, 66.5		62		57.0, 67.0		0.244
LVSD	32		28.0, 35.0		29.5		26.8, 31.3		0.044
LVEDD	46		42.5, 50.0		44.5		42.5, 46.0		0.039
Postprocedural heart rate	74		65.5, 86.0		72		68.0, 81.0		0.746
Postprocedural diastolic pressure	76.4			11.5	74.6			11	0.503
Postprocedural systolic pressure	131.7			22.8	132.7			24.3	0.861
Several procedures*	4	10.5			6	20.7			0.247
Hyperlipidaemia	0	0			1	3.4			0.249
Cerebral infarction	0	0			2	6.9			0.1
CAD	8	21.1			10	34.5			0.219
DM	6	15.8			5	17.2			0.874
Hypertension	13	34.2			14	48.3			0.245
Drinkers	1	2.6			2	6.9			0.403
Smokers	9	23.7			9	31			0.501
BMI	17.4		16.7, 18.0		17.6		16.5, 18.2		0.621

Table 2: Examination of The Two Groups' Effectiveness

	Characteristic	cTRA			dTRA			p-value
		n	%	Range	n	%	Range	
	Procedural time	30		15, 50	45		20, 70	0.043
procedural category (n (%))	Routine	30	76.90%		22	78.60%		0.873
	Emergency	9	23.10%		6	21.40%		
Procedural method (n (%))	PCI	14	35.90%		13	46.40%		0.386
	CAG	25	64.10%		15	53.60%		
	Compression hemostasis time	6		6, 10	4		3, 6	<0.001
	Radiation exposure time	3.3		1.7, 11.9	9.5		3.1, 15.1	0.181
	Contrast dosage	60		50, 100	100		50, 150	0.113

Table 3: Evaluation of The Two Groups' Levels of Safety

Characteristics	dTRA		cTRA		P
	n	%/Range	n	%/Range	
VAS	2	2, 3	3	3, 4.5	<0.001
Hand swelling	0	0	1	2.6	0.393
Numbness	0	0	2	5.1	0.224
Haematoma (EASY I)	1	3.6	0	0	0.24
Bleeding (BARC II)	3	10.7	7	17.9	0.388

This study indicates that both dTRA and cTRA techniques were effective in radial artery puncture procedures. The success rates for dTRA and cTRA were 96.6% and 97.4%, respectively, with no statistically significant difference between the two groups. Even in patients receiving the percutaneous coronary intervention, this consistency in success rate was seen in both groups (PCI). It was shown that the success rate of a single needle puncture in the dTRA group was significantly lower than that of the cTRA group, with a success rate in the dTRA group of 51.7% and a success rate in the cTRA group of 81.6%. A P-value of 0.020 indicated that there was a statistically significant difference between the two groups. Another noticeable difference between the two groups was the puncture time, with the dTRA group having a longer puncture time of 72 seconds (range 60 to 90) compared to the cTRA group's puncture time of 60 seconds (range 60 to 63.5) (P-value = 0.003). This difference between the two groups is illustrated in Figure 2.

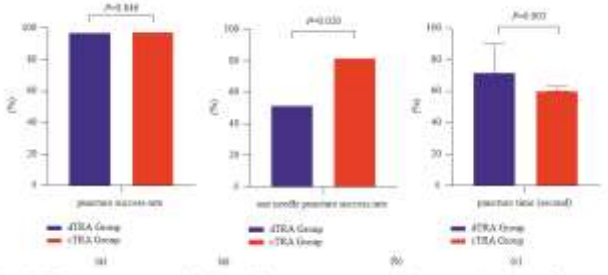

Figure 2: (a) The puncture success rate, (b) the one-needle puncture success rate, and (c) the puncture time between the two groups.

67 patients underwent coronary intervention. 38 in the cTRA group, and 29 in the dTRA group. 1 patient moved from cTRA to the left radial artery and 1 from dTRA to cTRA. The final groups were 39 cTRA & 28 dTRA, with no differences in procedure, contrast dose, or radiation exposure. 27 patients had PCI, 15 with stents, 4 from cTRA, and 5 from dTRA. 6 patients received 2+ stents, 2 from cTRA and 4 from dTRA. No significant difference in the number of PCI implants between groups (P-value=0.228). However, the procedure took significantly longer in the dTRA group (45 minutes, range 20 to 70) compared to the cTRA group (30 minutes, range 15 to 50) (P-value = 0.043). Additionally, the compression hemostasis time was shorter in the dTRA group (4 hours, range 3 to 6) compared to the cTRA group (6 hours, range 6 to 10) (P-value = 0.001). This information can be found in Table 2.

Both the dTRA and cTRA groups experienced bleeding classified as BARC type II and hematomas classified as EASY type I. The occurrence of postoperative bleeding, hematoma, numbness, or hand edema was similar in both groups. However, patients in the dTRA group reported a significantly lower pain level according to the VAS score (2 vs. 3, P-value = 0.001) compared to the cTRA group. Thirteen patients experienced myocardial infarctions with ST-segment elevation, but neither group reported any swelling in the hands. The study found no significant difference between the two groups (cTRA and dTRA) in terms of bleeding, hematoma, numbness, and VAS (Visual Analogue Scale) score. No unfavorable effects were observed in either group, with non-ST-segment elevation myocardial infarction occurring in seven patients. The study also found no difference in the VAS scores between the two groups. The results indicate that there were no negative outcomes related to the interventional procedure and no differences in terms of patient discomfort or post-procedural symptoms between the two groups. (Table 2)

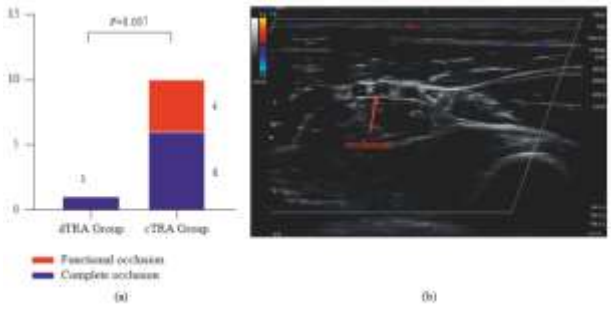

Figure 3: (a) Results of ultrasound follow-up. (b) Ultrasound image of complete radial artery occlusion.

Participants in the research presented a conflicting image when it came to follow-up. Sadly, 12 patients could not be located—6 were unaccounted for, 3 in the cTRA group declined follow-up, and the remaining 3 were out of reach. For the remaining patients, the follow-up time was, nevertheless, well recorded. Ultrasonography follow-up for the cTRA group covered the period from 31 days to 27 months, whereas for the dTRA group, it covered the period from 8.8 to 5.4 months, spanning the period from 31 days to 17 months. Unfortunately, 6 patients in the cTRA group had entire obstructions of the radial arteries, and another 4 had partial blockages; luckily, just 1 patient in the dTRA group had a full blockage, much to the researchers' satisfaction. The findings demonstrated that there was a considerably decreased incidence of radial artery occlusion in the dTRA group (4.0% vs. 33.3% in the cTRA group; P-value = 0.007). This was an amazing and unexpected discovery.

DISCUSSION

To examines the efficiency and safety of dTRA in low BMI individuals for coronary intervention. The conventional trans-radial access (cTRA) and direct trans-radial access (dTRA) groups did not show any differences in puncture success rates, according to the research. The dTRA group was able to stop the bleeding with one needle, however, it required a little more work to reach the appropriate area. The study also made a fascinating finding: among those with lower BMIs, the radial artery blockage rate was much lower in the dTRA group compared to the cTRA group. The benefits of dTRA in the coronary intervention are due to its unique anatomical structure. It can reduce compression time and ease patient comfort while also reducing the workload for medical professionals. [9,10] However, accessing the distal radial artery can prove challenging and requires a great deal of skill. Research on the success rate of dTRA in comparison to cTRA has produced conflicting findings. According to certain research, the success rate for dTRA is lower than that of cTRA, at 85% as opposed to 100%. [11,12] With an OR of 1.94 and a 95% confidence interval, a new meta-analysis reveals that there is no discernible difference between the two methods (0.97, 3.86). [13]

According to research, the dTRA group had a lower rate of RAO than the cTRA group. The RAO rate was 0.7% in the dTRA group at 24 hours and 30 days after surgery, but it was considerably higher in the cTRA group (OR 12.8, 95% CI: (1.6, 100.0), P-value = 0.002; OR 8.2, 95% CI: (1.0, 67.2), P-value = 0.019). The potential benefits of dTRA over cTRA in terms of lowering the risk of RAO and enhancing patient outcomes are highlighted by this. [14]

The association between radial artery diameter and BMI remains unclear and controversial. Some studies have found no link between traditional radial artery diameter and BMI, while others have reported a significant correlation. [15,16,17] A

retrospective study found no connection between BMI and distal radial artery diameter via multivariate analysis. The surface area of the distal radial artery was found to significantly correlate with body weight and BMI in another study, though. [18] According to recent studies, people with low BMI may have a smaller distal radial artery diameter, which could make puncture more challenging. [19] Low BMI individuals typically have less subcutaneous tissue and closer blood vessels to the bone plane, making puncture failure more likely. The connection between BMI and the diameter of the distal radial artery is still up for debate. [20]

The study examines the first-time use of dTRA in low BMI people and looks at efficacy and safety. With a success rate of 96.6% in the dTRA group and a success rate of 97.4% in the control group (cTRA), the puncture success rate was found to be comparable between the two groups (P-value = 0.846). The success rate was lower in the dTRA group compared to the cTRA group, and it took them longer to penetrate the skin with a single needle. The two groups' puncture-related side effects, such as bleeding and hematoma, were not significantly different from one another. Even though the dTRA group's patients reported more comfort, the dTRA group's compression hemostasis time and Visual Analog Scale (VAS) ratings were lower.

The study had several limitations including being a single-center retrospective cohort with limited sample size, potentially introducing errors. Additionally, not all patients underwent pre-surgery ultrasounds, so prior radial artery lesions couldn't be confirmed. The success rate of dTRA punctures in low BMI individuals might also be higher due to experienced medical staff who have completed the learning process.

CONCLUSION

In conclusion, the findings of this research show that patients with low body mass index may safely and successfully undergo coronary intervention utilizing the dorsalis pedis trans-radial technique. In comparison to the conventional trans-radial technique, patients reported greater procedural comfort and a much-reduced incidence of radial artery blockage. Additionally, the time required for compression hemostasis after the procedure was short. These findings suggest that the dorsal pedis trans-radial approach could be a promising alternative for patients with low BMI undergoing coronary intervention.

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