

Randomized Comparison of Compression Bandage and TR band for Radial artery Hemostasis in Patients Undergoing Transradial Coronary Interventions

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Abstract

Objective: To compare two different methods (TR band and compression bandage) for radial artery hemostasis in patients undergoing transradial coronary interventions.

Method: This was a randomized control trial carried out at Punjab Institute of Cardiology Lahore for six months. Total 200 indoor patients undergoing elective percutaneous Trans radial interventions were included in the study. Clinical features and investigations were noted in a predesigned proforma after informed consent. Patients were then randomized into TR band or conventional compression in blocks of 4. A resident was dedicated in the ward to remove the sheath immediately after randomization. All puncture sites were independently reviewed and measurements were recorded 24hrs after the procedure.

Results: Frequency of major bleeding was markedly higher in TR group (10) as compared to compression group (02) (p-value=0.017). Frequency of minor bleeding was markedly higher in TR group (23) as compared to compression group (09) i.e. p-value=0.007. In TR group significantly higher number of patients felt discomfort as compared to compression group i.e. TR: 49 vs. Compression: 35, p-value=0.045.

Conclusion: Compression band is more effective than TR band in terms of minimal vascular complications and less patient discomfort.

Keywords: TR band, Compression bandage, Hemostasis, Local vascular complications, Patient discomfort, Radial coronary intervention

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Introduction

There are various arterial access lines and techniques for diagnostic coronary angiography (CAG) and percutaneous coronary intervention (PCI).^{1,2} The most easily accessible arterial line is Radial artery and is widely used for trans radial intervention (TRI).^{3,4} Percutaneous coronary intervention leads to number of vascular complications resulting in morbidity and mortality.⁵

TRI may result in bleeding, hematoma formation, pseudo aneurysm, arteriovenous fistula, limb ischemia, or thromboembolism.³

In order to avoid complications, hemostasis of accessible site following percutaneous cardiac catheterization is a very important. Two compression techniques for achieving hemostasis post TRI common in clinical practice are manual compression with application of pressure bandage and the other is Trans Radial (TR) bandage. The most common technique for achieving local hemostasis is manual compression and pressure bandage application. But its painful and time taking with 35.7% patients reporting it as mild discomfort.^{6,7} This may induce vasovagal reflexes with hypotension and tachycardia and also leads to fatigability of dresser. Local vascular complications are also associated with this

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technique with major bleeding of 0.3% and minor bleeding reported in 2% in literature., i.e., 2-3% local vascular complication.⁸

TR band a newer hemostatic device on the other hand is a quicker, effective, and comfortable technique. It consists of 2 inflatable balloons and a transparent support plate. Among the two balloons, one provides pressure over hemostatic area and other keeps the first balloon in proper place. It is patient friendly and easy to handle with patient discomfort reported only in 16.6%.^{8,9} Few previous studies have shown the hemostatic efficacy of the TR Band with minimal local vascular complications rate with no major bleeding incidence and minor bleed reported in only 2% of cases but Rathore et.al reported 20% minor bleed in TR Band.⁹⁻¹²

Head to head comparison of these two techniques is lacking and there is a need of more conclusive data regarding superiority of these newer devices over conventional methods in achieving hemostasis and tolerability of these techniques in patients. Studies must also be done at national level to validate the use of these newer techniques in our clinical practice for achieving hemostasis and tolerability of these techniques after Trans radial coronary intervention. As variation exist in literature.⁹⁻¹² This study was designed to help us in deciding the technique with little complications and better patient comfort.

Material and Methods

This was a randomized control trial conducted at Angiography Department, Punjab Institute of Cardiology Lahore, Pakistan for a period of 6 months i.e. 1st August 2019 to 31st January 2020. A sample size of 200 (100 in each group) was calculated with 80% power of test, 5% significance level and taking expected percentage of local complications 18.2%⁹ in TR band group vs 2.3%¹¹ in compression band group for achieving hemostasis. Non-probability consecutive sampling was done. Intended Trans radial coronary procedure (Angiography / Angioplasty) in patients with chest pain on exertion during last 1 month. Patient 18-70 years of age of both genders were included. Inability to demonstrate the presence of ulnar collateral circulation (by Allen's test), patients with chronic renal failure diagnosed on Serum Creatinine >2mg/dL or with A-V fistula or patients and previous ipsilateral trans radial procedure or absent Radial pulse were excluded. The clinical features especially Allen's test, anti-platelet therapy and anti-coagu-

lant regime were noted on a predesigned proforma. All baselines including coagulation and lipid profile were sent before the procedure.⁵ F arterial sheath was used for transradial coronary procedure; as a routine during the procedure 5000 units of Heparin was administered intra-arterially. Patients were shifted to indoor immediately 30 to 90 minutes after the procedure for removal of the sheath. Patients were assessed for systolic blood pressure. Patients with systolic BP of >160mmHg were given nitroglycerin to lower BP <160 mmHg. Patients were then randomized either to the TR band or conventional compression using computer-generated random digits in sealed envelopes in blocks of 4. Immediately after randomization sheaths were removed by a dedicated experienced resident at the indoor ward. All puncture sites were assessed after the procedure, and outcome measures of patient discomfort and local vascular complications was noted after 24 hours. All endpoints were examined by 2 independent examiners. Data was analyzed by SPSS version 17. The quantitative data like age was presented as Mean \pm SD and qualitative data like vascular complication and Patient discomfort were given as frequencies and percentages (%). Chi-square test was applied to compare outcome in both groups. A p-value < 0.05 was taken as significant. Data units were stratified for age, gender and H/O Hypertension and Major & minor bleeding, BMI to combat effect modifiers. Chi-square test was used after stratification. P-value < 0.05 was taken as significant.

Results

Mean age of patients in TR and compression band groups was 48.09 \pm 13.44 and 48.88 \pm 13.40 years respectively. In TR group there were 51 males and 49 females while in compression group there were 50 male and 50 female. In TR group there were 33 patients whose BMI was normal, 31 patients were obese and 36 were under weight. In compression Group 35 patients BMI was normal, 32 were obese and 33 were underweight. In TR group 58 and in compression group 44 patients were hypertensive. (Table-1)

In TR group 10 patients were observed with major bleeding and in compression group 2 patients were observed with major bleeding. In terms of p-value frequency of major bleeding was significantly higher in TR group as compared to that of compression group. i.e. p-value = 0.017 (Table2)

In TR group 23 patients were observed with minor bleeding and in compression group 9 patients were

observed with minor bleeding. In terms of p-value frequency of minor bleeding was significantly higher in TR group as compared to that of compression group. i.e. p-value=0.007 (Table-3)

Table 1: Descriptive Statistics Of Patients

	Banding	
	TR	Compression
n	100	100
Mean Age	48.09	48.88
SD	13.44	13.40
Minimum Age	26	25
Maximum Age	70	70
Normal BMI	33(33%)	35(35%)
Obese	31(31%)	32(32%)
Underweight	36(36%)	33(33%)
Hypertensive	58(58%)	44(44%)
Normotensive	42(42%)	56(56%)

Table 2: Frequency Distribution For Major Bleeding Disorder

Major Bleeding Disorder	Banding		Total
	TR	Compression	
Yes	10(10%)	2(2%)	12
No	90(90%)	98(98%)	188
Total	100	100	200

Chi-Square Test = 5.67 p-value= 0.017

Table 3: Frequency Distribution For Minor Bleeding Disorder

Minor Bleeding Disorder	Banding		Total
	TR	Compression	
Yes	23(23%)	9(9%)	32
No	77(77%)	91(91%)	168
Total	100	100	200

Chi-Square Test= 7.29 p-value= 0.007

Table 4: Patients Discomfort

Patients Discomfort	Banding		Total
	TR	Compression	
Yes	49(49%)	35(35%)	84
No	51(51%)	65(65%)	116
Total	100	100	200

Chi-Square Test= 4.023 p-value= 0.045

In TR group more patients felt discomfort as compared to the patients in compression group. i.e. TR: 49 vs. Compression: 35, p-value=0.045. (Table-4)

Discussion

Radial artery as access site has shown lesser number of complications. Patient can be early mobilized and hence early discharge from the hospital thereby reducing staff workload and overall procedure cost.¹³⁻²¹ Early hemostasis can be achieved by immediate removal of arterial sheath after the procedure with mechanical compression.^{12,23} Among the commonly used compressive devices used to achieve hemostasis are the Radistop (RADI, Uppsala, Sweden), and the TR Band (Terumo, Japan). Both these devices are safe and effective and allow application of controlled pressure with sustained arterial flow and venous return.¹⁰

In this study it was seen that major bleeding in TR group and in compression group was seen in 10(10%) and 2(2%) patients only. However minor bleeding in TR and in compression group was seen in 23 and 9 patients respectively. Bleeding was markedly higher in TR compression banding group. (p - value = 0.017 & 0.007). Patients discomfort was also high in TR banding compression group. i.e. TR Banding: 49% vs. Compression banding: 35%, p-value= 0.045.

Major bleeding was not significantly associated in any of the age groups of patients. But frequency of major bleeding was high in TR banding compression group. Same trend was seen for minor bleeding but minor bleeding was markedly higher in patients in age group >55 years. Among female major as well as minor bleeding was also markedly higher in TR banding group however among male patients no statistically significant association was seen for major as well as for minor bleeding. Among hypertensive and non-hypertensive patients major and minor bleeding did not differ significantly except among non-hypertensive patients minor bleeding was markedly raised in TR banding group. Both major and minor bleeding was markedly higher in TR banding group among obese patients only. Chatelain and his colleagues worked on the efficacy of Radistop in 159 patients and concluded that device was painful in 18% and vascular complications were seen in 19.4%.²² Ochiai et al. in their study of 199 patients worked on the efficacy of Adapty (Medikit, Tokyo) compressive hemostatic device and found it successful in 99.5% with no significant vascular problems.¹ Pancholy et al. evaluated hemostasis using conventional pressure by applying tourniquet with the TR band. None of 436 patients in this randomized study developed a bleeding complication.²⁴ Sudhir Rathore in his study compared the effects of Radistop and TR band. They studied

patient discomfort, time taken for hemostasis, and local vascular problems. In his findings they reported that there were large number of patients with no discomfort in the TR band(77%) as compared to the Radistop (61%) group (p-value= 0.0001). Radistop group reported more pain severity and three patients were shifted to TR band because of severe pain. Local vascular complications were similar in both groups. Minor vascular problems were seen in about 16% and major in 5.4%.¹⁰

Mai Miao in his study compared the effect of different hemostasis methods after the radial artery puncture and discuss its nursing methods and effect. In his results he reported that the proportion of patients without the swelling, pain and numbness in group B (the inflatable radial artery hemostasis device) was slightly lower than group A (compression elastic bandage) (P<0.05).⁷ In order to reduce complications of TRA care should be taken in case selection. Those patients with absence of palmar collateralization TRA should be avoided. Vascular complications are more effectively reduced using TRA.²¹ In patients with low BMI, use of lower profile access reduces the risk of most of the major complications.

Heparinization, makes the local environment less thrombotic and aids in recanalization after an occlusive hold. After the procedure, hemostasis is the most potent variable to lower the incidence of radial artery occlusion. Immediately after sheath removal it maintains patency, easy to use, and is not limited by other co-morbid. On the contrary this also does not cause systemic risks associated with anticoagulation and does not affect the overall procedure.²⁴

Even with all these benefits there are certain complications associated with radial access, such as occlusion, perforation, local hematomas, spasm and pseudo-aneurysm. The risk factors for complications are prolonged occlusion,, repeated attempts, higher anticoagulation, diabetes mellitus, and low artery to sheath diameter ratio.³ Many scholars concluded that degree of compression determines artery occlusion.^{6,25}

Conclusion

Compression band is more effective than TR band in terms of minimal vascular complications and less patient discomfort.

Conflict of Interest

None

Funding Source

None

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Authors Contribution

MNA, SI: Conceptualization of Project

SUM, : Data Collection

SUM: Literature Search

MNA, SI, SUM: Statistical Analysis

NHM: Drafting, Revision

SI, SUM, SH: Writing of Manuscript