ORIGINAL ARTICLE

RADIAL ARTERY COMPRESSION COMPARISON FOR HEMOSTASIS WITH AND WITHOUT STERI-STRIPS REINFORCEMENT: RACC RANDOMIZED TRIAL

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Objectives: This study assessed the efficacy of using steri-strips in conjunction with conventional pneumatic trans-radial (TR) bands for achieving radial artery hemostasis after diagnostic coronary angiography (CA). With varying methods aimed at reducing compression duration post-CA via trans-radial access (TRA), our aim was to evaluate time dynamics.

Methodology: We randomly assigned 209 patients in a 1:1 ratio to receive either the TR band with steri-strips (treatment) or conventional TR band alone (control) post-diagnostic CA, and followed them for one month. The primary endpoint was time to achieve adequate hemostasis, defined by the total TR band application duration. Secondary endpoints included radial artery occlusion (RAO) and major bleeding. The treatment group comprised 106 patients with steri-strips alongside the TR band, while the control group had 103 patients with the TR band alone. Median TR band application duration was 60 [IQR: 60-60] min in the treatment group and 250 [IQR: 240-360] min in the control group; p≤0.001.

Results: The incidence of site bleed requiring TR band re-application was 9.4% vs. 4.9%, p=0.364, and hematoma (type I only) was 7.5% vs. 9.7%, p=0.578 in the treatment and control groups, respectively. Radial artery palpability after 24 hours was 95.3% vs. 85.4%; p=0.016, and at one month it was 96.2% vs. 88.3%; p=0.032 in the treatment and control arms, respectively.

Conclusion: Steri-strips significantly reduce TR band compression duration and improve radial artery patency post-diagnostic angiography without causing hematoma or major bleeding complications.

Keywords: Steri-strips; radial artery; pneumatic TR band; coronary angiography; radial artery patency; radial artery occlusion

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INTRODUCTION

Trans-radial access (TRA) is increasingly utilized worldwide as the preferred approach for diagnostic and interventional coronary procedures.[1,2] It has received a class I indication in clinical practice guidelines due to demonstrated survival benefits in certain patient subsets,[3,4] alongside factors such as patient preference, shorter hospital stays, reduced access-site complications, and lower costs compared to standard trans-femoral access.[5-9]

Radial artery occlusion (RAO) represents the most common complication of TRA, with reported frequencies ranging from 0.8% to 30%.[10] Despite often being asymptomatic due to the dual blood supply of the hand, RAO can lead to significant hand ischemia. Symptoms may vary from transient pain and paresthesia to impaired limb function.[11,12] Persistent occlusion renders the artery unsuitable for future procedures or bypass grafting, and RAO also poses a relative contraindication for the ipsilateral trans-ulnar approach.[10,13,14]

Post-procedure hemostasis in TRA is typically achieved through direct mechanical pressure with a trans-radial (TR) band. However, the duration of mechanical compression remains a concern, as it significantly impacts hemostasis attainment and the incidence of complications such as RAO, hematoma formation, or bleeding. Several studies have highlighted the critical role of compression duration after sheath removal in determining future RAO risk. For instance, Pancholy et al. (2012)[15] demonstrated that only 2 hours of compression significantly reduced RAO risk at 24 hours compared to 6 hours of compression. Similarly, Dharma et al. (2015)[16] found that more than 4 hours of compression increased RAO risk compared to compression of less than 4 hours.

This study aims to assess whether the combination of steri-strips with the TR band can effectively reduce the duration of post-procedure radial compression. The primary objective is to investigate whether this approach can decrease the incidence of post-procedure RAO while maintaining radial artery patency and achieving hemostasis. Additionally, the study seeks to evaluate the impact of reduced compression duration on patient discomfort, mobility, and expedited discharge.

The findings of this study hold significant clinical implications, potentially informing optimal post-procedure compression techniques in TRA. By identifying an effective approach to minimize compression duration without compromising outcomes, clinicians can enhance patient comfort, expedite recovery, and potentially reduce healthcare costs associated with prolonged hospital stays or complications. Ultimately, this study aims to improve patient outcomes and satisfaction following TRA procedures.

METHODOLOGY

Trial Design: This study employed an open-labeled, randomized-controlled trial design, registered with ClinicalTrials.gov under the identifier NCT 04900987. Ethical approval was obtained from the institutional review board of the National Institute of Cardiovascular Disease (NICVD), Karachi, Pakistan, with reference number ERC-29/2021.

Participants: The study included patients aged 18 years and above undergoing diagnostic coronary angiography with a positive Barbeau test (type A to C) at NICVD from April 2021 to February 2022. Patients with negative Barbeau test, bleeding diathesis, oral anticoagulation, recent coronary artery bypass grafting, requiring ad-hoc percutaneous coronary intervention (PCI), or refusal to participate were excluded.

Interventions: Participants were randomized in a 1:1 ratio to either the treatment group receiving clean sterile steri-strips along with pneumatic TR band compression or the control group receiving conventional pneumatic TR band compression alone. Steri-strips were applied after sheath removal and cleaning of the access site with iodinated tincture, followed by pneumatic TR band placement.

Outcomes: The primary outcome was the comparison of compression duration of the TR band between the treatment and control groups. Secondary outcomes included assessment of access site bleeding or hematoma and radial artery patency at 24 hours and one month post-procedure.

Sample Size: A total of 209 patients were enrolled and 578 patients were excluded. A robust sample size was attained, ensuring an adequate representation of patients undergoing diagnostic coronary angiography at the National Institute of Cardiovascular Disease (NICVD) in Karachi, Pakistan, during the specified timeframe.

Randomization: Randomization was achieved using a computed randomization schema generated in Microsoft Excel 2013, ensuring a 1:1 allocation ratio. The schema was accessible only to a dedicated data monitoring team to maintain concealment. Patient allocation was communicated to the recruitment team on a patient-to-patient basis.

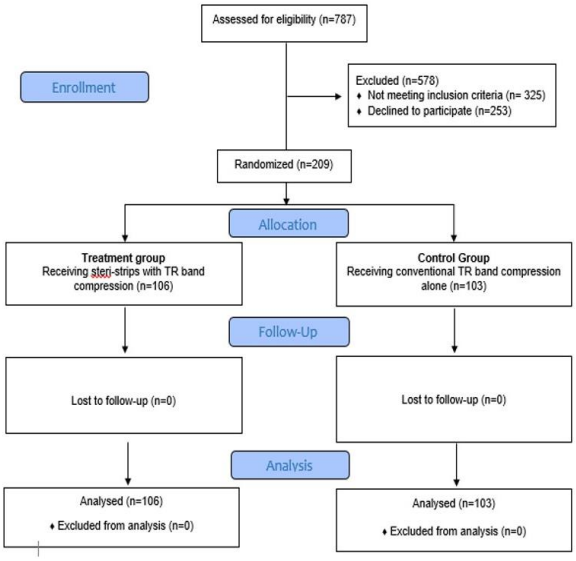
Allocation Implementation: 106 patients were allocated to the treatment group receiving steri-strips with TR band compression, while 103 patients were allocated to the control group receiving conventional TR band compression alone.

Blinding: As this was an open-labeled trial, blinding of participants and healthcare providers was not feasible. However, outcome assessors were blinded to the patient allocation to minimize bias.

Statistical Methods: Data analysis was performed using IBM SPSS version 21. Descriptive statistics were calculated for quantitative and qualitative variables. The Mann-Whitney U test was used to compare compression duration between groups, and

secondary outcomes were compared using appropriate statistical tests such as the Chi-square test or Fisher's exact test. A significance level of $p < 0.05$ was adopted.

Figure 1: CONSORT diagram describing the flow of participants throughout the study



Cath=catheterization laboratory, CABG=coronary artery bypass grafting, PCI=percutaneous coronary intervention

RESULTS

Baseline Data: The baseline characteristics between the treatment (TR Band with Steri-strip) and control (TR Band Alone) groups were comparable, demonstrating no significant differences in gender distribution, age, height, weight, blood pressure, prevalence of hypertension, diabetes, smoking, family history of premature coronary artery disease (CAD), prior CAD, dyslipidemia, prior catheterization (Cath), use of aspirin or clopidogrel, and sheath size.

Numbers Analyzed: A total of 209 patients (106 in the treatment group and 103 in the control group) were included in the analysis. The median duration until hemostasis was significantly shorter in the treatment group compared to the control group (60 [IQR: 60-60] vs. 250 [IQR: 240-360] min, $p \leq 0.001$), Table 1.

Outcomes and Estimation: Immediately after TR band removal, there were no significant differences in systolic and diastolic blood pressure between the treatment and control groups. The frequency of hematoma, minor bleeding, and major bleeding was comparable between the two groups ($p = 0.578$ and $p = 0.794$, respectively). At 24 hours post-procedure, the radial artery was palpable in a significantly higher proportion of patients in the treatment group compared to the control group (95.3% vs. 85.4%, $p = 0.016$). Additionally, positive reverse Barbeau (type A) was more prevalent in the treatment group compared to the control group (88.7% vs. 69.9%, $p = 0.003$). At one month, palpable radial artery and positive reverse Barbeau (type A) remained significantly higher in the treatment group compared to the control group ($p = 0.032$ and $p = 0.003$, respectively).

Table 1: Comparisons of baseline demographic and clinical characteristics between treatment (TR Band with Steri-strip) and control (TR Band Alone) group

Characteristics and Demographics	Compression Technique	
	TR Band with Steri-strip (Treatment)	TR Band Alone (Control)
Total (N)	**106**	**103**
Gender		
Male	83 (80.6%)	80 (75.5%)
Female	20 (19.4%)	26 (24.5%)
Age (years)	57.58 ± 9.11	56.38 ± 9.57
Height (cm)	169.75 ± 5.56	168.38 ± 5.98
Weight (kg)	72.19 ± 11.18	69.79 ± 8.76
Systolic BP (mmHg)	127.62 ± 16.82	128.77 ± 20.34
Diastolic BP (mmHg)	77.09 ± 12.5	75.65 ± 10.97
Hypertension	71 (68.9%)	71 (67%)
Diabetes	43 (41.7%)	40 (37.7%)
Smoking	16 (15.5%)	12 (11.3%)
Family history of premature CAD	27 (26.2%)	21 (19.8%)
Prior CAD	31 (30.1%)	23 (21.7%)
Dyslipidemia	28 (27.2%)	19 (17.9%)
Prior Cath	22 (21.4%)	16 (15.1%)
Prior CABG	0 (0%)	0 (0%)
Use of Aspirin last 1 week	73 (70.9%)	83 (78.3%)
Use of Clopidogrel last 1 week	39 (37.9%)	36 (34%)
Use of GpIIbIIIa inhibitor in last 24 hours	0 (0%)	0 (0%)
Heparin dose (IU)	5000 ± 0	5000 ± 0
Sheath Size		
5 F	51 (49.5%)	59 (55.7%)
6 F	52 (50.5%)	47 (44.3%)

CAD=coronary artery disease, CABG=coronary artery bypass grafting

Ancillary Analyses: The relative risk (RR) of radial artery occlusion (RAO) at 24 hours was significantly lower in the treatment group compared to the control group (RR = 0.290, 95% CI: 0.101-0.831, $p = 0.021$). At 30 days, although the RR of RAO was lower in the treatment group compared to the control group, it did not reach statistical significance (RR = 0.415, 95% CI: 0.162-1.064, $p = 0.067$).

Harms: There were no significant differences in the incidence of hematoma, minor bleeding, or major bleeding between the treatment and control groups,

indicating the safety of both compression techniques. However, the treatment group demonstrated significantly improved radial artery patency and reverse Barbeau test outcomes at both 24 hours and one month post-procedure, suggesting the potential clinical benefits of the addition of steri-strips to TR band compression.

Table 2: Comparisons of outcomes immediately after removal, after 24 hours and after one month of TR band between treatment (TR Band with Steri-strip) and control (TR Band Alone) group

Characteristics	Compression Technique		P-value
	TR Band with Steri-strip (Treatment)	TR Band Alone (Control)	
Total (N)	**106**	**103**	-
Median duration until hemostasis (min)	60 [60-60]	250 [240-360]	<0.001
Immediate after TR band removal			
Systolic blood pressure (mmHg)	125.04 ± 16.21	126.66 ± 13.61	0.434
Diastolic blood pressure (mmHg)	73.51 ± 11.38	75.06 ± 8.47	0.265
Hematoma	8 (7.5%)	10 (9.7%)	0.578
^Type I	8 (100%)	10 (100%)	-
^Type II	0 (0%)	0 (0%)	
^Type III	0 (0%)	0 (0%)	
^Type IV	0 (0%)	0 (0%)	
Bleeding	20 (18.9%)	18 (17.5%)	0.794
~Minor	10 (50%)	13 (72.2%)	0.162
~Major	10 (50%)	5 (27.8%)	
At 24 hours			
Radial Artery Palpable	88 (85.4%)	101 (95.3%)	0.016
Doppler US waveform	94 (91.3%)	103 (97.2%)	0.066
Reverse Barbeau Test			
Type A (positive)	72 (69.9%)	94 (88.7%)	0.003
Type B (positive)	5 (4.9%)	4 (3.8%)	
Type C (positive after 2 min of compression)	11 (10.7%)	5 (4.7%)	
Type D (negative)	15 (14.6%)	3 (2.8%)	
At 1-month			
Radial Artery Palpable	91 (88.3%)	102 (96.2%)	0.032
Doppler US waveform	93 (90.3%)	101 (95.3%)	0.162
Reverse Barbeau Test			
Type A (positive)	74 (71.8%)	96 (90.6%)	0.003
Type B (positive)	6 (5.8%)	2 (1.9%)	
Type C (positive after 2 min of compression)	8 (7.8%)	1 (0.9%)	
Type D (negative)	15 (14.6%)	7 (6.6%)	

^based on patients who developed hematoma
~based on patients who developed bleeding complication

DISCUSSION

The radial artery has emerged as the preferred access site for percutaneous interventional procedures, with various techniques utilized to achieve optimal hemostasis while minimizing compression duration. Maintenance of distal flow during hemostasis is crucial for preserving radial artery patency, and different compression methods have been investigated to achieve this goal. A multicenter study from Brazil highlighted the efficacy of pneumatic bands in reducing bleeding incidence compared to simple compressive dressings,[17] although no significant difference in radial artery occlusion rates was observed.[18] Previous research has established the duration of compression as a key predictor of radial artery occlusion, with studies demonstrating a significant reduction in occlusion incidence by minimizing compression duration from 6 hours to as low as 2 hours.[19] Our study introduces a novel approach to further reduce compression duration by incorporating steri-strips into the conventional compression technique.

Faravash et al. (2016)[20] demonstrated the efficacy of steri-strips in reducing ecchymosis post-rhinoplasty, suggesting its potential application in minimizing post-procedure compression duration. While previous studies have utilized advanced radial devices to achieve compression durations as low as 1 hour, our study targets a similar duration using readily available materials, such as steri-strips, making it more feasible in clinical practice.[21] The incorporation of steri-strips led to a significant reduction in compression duration, with notable improvements in radial artery patency observed at both 24 hours and one month post-procedure. Consequently, the risk of radial artery occlusion was significantly reduced, highlighting the clinical significance of our findings in enhancing post-procedure outcomes.

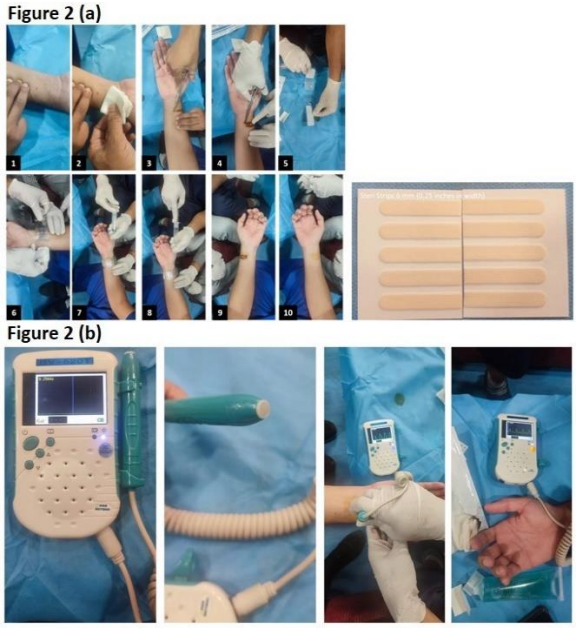


Figure 2 (a): Stepwise method for application (1-7) and removal (8-10) of steri-strips and TR band. (b): Ultrasound pulse wave Doppler

This study represents the first open-labeled randomized clinical trial investigating the safety and efficacy of steri-strips in achieving hemostasis, with none of the previous studies comparing steri-strip use with conventional pneumatic band compression alone. By providing evidence of the effectiveness of this simple intervention in reducing compression duration and improving radial artery patency, our study contributes valuable insights to optimize post-procedure management in TRA. Further research exploring the long-term outcomes and cost-effectiveness of incorporating steri-strips into routine practice is warranted to validate its broader applicability and clinical utility.

LIMITATIONS

This trial was conducted at a single center and focused exclusively on patients undergoing diagnostic coronary angiography. Generalizing these findings to patients undergoing percutaneous coronary intervention (PCI) may necessitate further investigation. Additionally, the limited sample size of the study represents a potential constraint on the generalizability and robustness of the results.

CONCLUSION

The incorporation of steri-strips alongside standard TR band compression significantly reduces the time required to achieve adequate hemostasis following radial access procedures. Furthermore, this approach is associated with improved radial artery patency without a notable increase in hematoma formation or major bleeding complications at the radial access site.

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AUTHORS' CONTRIBUTION

KAK and AH: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. AA, KIB, JAS, JAS, BAS, GA, TS, DK, AAK, ASA, FF, DQ, FM, FAS, AK, and SK: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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REFERENCES

1. Bertrand OF, Rao SV, Pancholy S, Jolly SS, Rodés-Cabau J, Larose E, et al. Transradial approach for coronary angiography and interventions: results of the first international transradial practice survey. JACC Cardiovasc Interv. 2010;3(10):1022-31.
2. Schussler JM. Effectiveness and safety of transradial artery access for cardiac catheterization. Proc (Bayl Univ Med Cent). 2011;24(3):205-9.
3. Feldman DN, Swaminathan RV, Kaltenbach LA, Baklanov DV, Kim LK, Wong SC, et al. Adoption of radial access and comparison of outcomes to femoral access in percutaneous coronary intervention: an updated report from the national cardiovascular data registry (2007-2012). Circulation. 2013;127(23):2295-306.
4. Andò G, Capodanno D. Radial Access Reduces Mortality in Patients With Acute Coronary Syndromes: Results From an Updated Trial Sequential Analysis of Randomized Trials. JACC Cardiovasc Interv. 2016;9(7):660-70.
5. Bertrand OF, Bélisle P, Joyal D, Costerousse O, Rao SV, Jolly SS, et al. Comparison of transradial and femoral approaches for percutaneous coronary interventions: a systematic review and hierarchical Bayesian meta-analysis. Am Heart J. 2012;163(4):632-48.

6. Jolly SS, Yusuf S, Cairns J, Niemelä K, Xavier D, Widimsky P, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. Lancet. 2011;377(9775):1409-20.
7. Valgimigli M, Gagnor A, Calabró P, Frigoli E, Leonardi S, Zaro T, et al. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial. Lancet. 2015;385(9986):2465-76.
8. Amin AP, House JA, Safley DM, Chhatriwalla AK, Giersiefen H, Bremer A, et al. Costs of transradial percutaneous coronary intervention. JACC Cardiovasc Interv. 2013;6(8):827-34.
9. Cooper CJ, El-Shiekh RA, Cohen DJ, Blaesing L, Burket MW, Basu A, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: A randomized comparison. Am Heart J. 1999;138(3 Pt 1):430-6.
10. Greenwood MJ, Della-Siega AJ, Fretz EB, Kinloch D, Klinke P, Mildenberger R, et al. Vascular communications of the hand in patients being considered for transradial coronary angiography: is the Allen's test accurate? J Am Coll Cardiol. 2005;46(11):2013-7.
11. Avdikos G, Karatasakis A, Tsoumeleas A, Lazaris E, Ziakas A, Koutouzis M. Radial artery occlusion after transradial coronary catheterization. Cardiovasc Diagn Ther. 2017;7(3):305-16.
12. Kotowycz MA, Dzavík V. Radial artery patency after transradial catheterization. Circ Cardiovasc Interv. 2012;5(1):127-33.
13. Rhyne D, Mann T. Hand ischemia resulting from a transradial intervention: successful management with radial artery angioplasty. Catheter Cardiovasc Interv. 2010;76(3):383-6.
14. Ruzsa Z, Pintér L, Kolvenbach R. Anterograde recanalisation of the radial artery followed by transradial angioplasty. Cardiovasc Revasc Med. 2010;11(4):266-e1.
15. Pancholy SB, Patel TM. Effect of duration of hemostatic compression on radial artery occlusion after transradial access. Catheter Cardiovasc Interv. 2012;79:78-81.
16. Dharma S, Kedev S, Patel T, Kiemeneij F, Gilchrist IC. A novel approach to reduce radial artery occlusion after transradial catheterization: postprocedural/prehemostasis intra-arterial nitroglycerin. Catheter Cardiovasc Interv. 2015;85(5):818-25.
17. Cong X, Huang Z, Wu J, Wang J, Wen F, Fang L, et al. Randomized Comparison of 3 Hemostasis Techniques After Transradial Coronary Intervention. J Cardiovasc Nurs. 2016;31(5):445-51.
18. Neto SA, de Freitas Jr JO, Berti SL, Costa Jr JR, Zbeid JA. Comparison of compressive dressing vs. hemostatic bracelet after radial catheterization. Braz J Cardiovasc Surg. 2015;23(4):271-5.
19. Dharma S, Kedev S, Patel T, Kiemeneij F, Gilchrist IC. A novel approach to reduce radial artery occlusion after transradial catheterization: Postprocedural/prehemostasis intra-arterial nitroglycerin. Catheter Cardiovasc Interv. 2015;85(5):818-25.
20. Farahvash MR, Khorasani G, Mahdiani Y, Taheri AR. The Effect of Steri-Strip Dressing on Patients' Satisfaction and Reduction of Ecchymosis in Lower Eyelid, Malar and Cheek Following Rhinoplasty. World J Plast Surg. 2016;5(1):51-7.
21. Lavi S, Cheema A, Yadegari A, Israeli Z, Levi Y, Wall S, et al. Randomized Trial of Compression Duration After Transradial Cardiac Catheterization and Intervention. J Am Heart Assoc. 2017;6(2):e005029.

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