Impact of Preprocedural Stress Ball Use on Radial Artery Outcomes in Elective Coronary Angiography: A Randomized Controlled Trial

NCT Number: Pending

Date: July 18, 2025

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Study Protocol and Statistical Analysis Plan

1. Background and Rationale

Radial artery occlusion (RAO) is a common complication following transradial coronary angiography. Pre-procedural hand exercises, such as stress ball use, may improve arterial compliance and reduce the risk of RAO. This randomized controlled trial (RCT) investigates whether scheduled stress ball use in the days prior to elective radial angiography reduces the incidence of RAO at 7 days.

2. Objectives

Primary Objective:

To assess the effect of preprocedural stress ball use on the rate of radial artery occlusion at day 7 post-procedure, confirmed by Doppler ultrasonography.

Secondary Objectives:

- To evaluate the incidence of intra-procedural radial artery spasm
- To compare procedure-related pain scores (VAS)
- To assess time to successful radial artery cannulation
- To record the number of puncture attempts

3. Study Design

- **Type:** Interventional (Clinical Trial)
- **Design:** Prospective, Randomized, Double-Blind, Parallel Assignment
- Number of Arms: 2
- **Masking:** Double-blind (Participant and Interventional Cardiologist)
- Primary Purpose: Prevention
- Planned Sample Size: 400 participants

4. Eligibility Criteria

Inclusion Criteria:

-Age between 18 and 85 years
-Elective radial coronary angiography planned
-Written informed consent provided
-Ability to understand and comply with the stress ball exercise protocol (3×5 minutes/day for 3 days prior to procedure)
-Palpable radial pulse on the planned access site

Exclusion Criteria:

-Emergent or urgent coronary procedures
-Known radial artery occlusion or non-palpable radial pulse on the intended access side
-Prior arteriovenous fistula or vascular surgery in the ipsilateral arm
-History of Raynaud's disease, severe peripheral artery disease, or Buerger's disease
-Neurological or musculoskeletal disorders affecting hand grip (e.g., stroke, advanced arthritis, peripheral neuropathy)
-Cognitive impairment or psychiatric condition preventing protocol adherence
-Inability to use hand muscles effectively (e.g., recent hand trauma, paralysis)
-Unwillingness or inability to perform the stress ball exercises as instructed
-Pregnancy or breastfeeding

5. Intervention

Arm A: Stress Ball Group

- Participants will squeeze a soft stress ball for 5 minutes, three times daily, for 3 days before the procedure.

Arm B: Standard Care Group

- No preprocedural exercise; standard preparation.

6. Outcome Measures

Primary Outcome:

- Radial Artery Occlusion at Day 7: Confirmed via Doppler USG

Secondary Outcomes:

- **Radial artery spasm rate** during procedure (operator reported)
- Pain score (VAS) during procedure
- Time to successful cannulation (in seconds)
- Number of puncture attempts

7. Randomization and Blinding

Patients will be randomized 1:1. Allocation will be concealed. Outcome assessors and operating interventional cardiologists will be blinded to group assignment.

8. Statistical Analysis Plan

- Descriptive statistics for baseline data
- Chi-square test for primary endpoint
- Independent t-test or Mann-Whitney U for continuous secondary outcomes
- Statistical significance set at $p < 0.05$
- Analysis will be performed using SPSS version XX

9. Ethics and Registration

The study protocol has been reviewed and approved by the Sakarya University Faculty of Medicine Scientific Research Ethics Committee.

10. Dissemination Plan

The results of the study will be submitted for publication in peer-reviewed journals and presented at national/international cardiology conferences.