Distal vs. Forearm Radial Artery Access

The Distal Radial Access (DRA) to the coronaries has emerged recently. It's done via the distal radial artery in the radial fossa, which is known as the snuff-box. The rationale of conducting this research is to assess this new access advantages and disadvantages, in comparison with the standard conventional forearm radial access and examine if it's worthy to be a future alternative method for coronary angiography. It aims to randomly compare between the new distal radial access via the snuffbox and the conventional forearm radial access for percutaneous coronary angiography and angioplasty procedures. The objectives of comparing both procedures are to analyze the frequency of complications in terms of occlusion, arterial spasm, hematoma, and to weigh accesses effectiveness in terms of time and attempts to puncture, crossover rate, procedure duration, hemostasis time, and convenience of the patients and operators. Candidates for coronary angiography are being randomized into the interventional group to undergo the angiography through the distal radial artery as the access site, or the control group accessing through the radial artery in the forearm. Procedural and post procedural outcomes and complications are being reported while patients are in hospital. All patients undergo doppler ultrasonography within 24 hours after the procedure.

Condition or Disease:
- Coronary Artery Disease
- Angina, Unstable
- Angina, Stable
- Non STEMI
- Non ST Segment Elevation Myocardial Infarction
- Acute Coronary Syndrome
- Atherosclerosis, Coronary
- Atherosclerotic Heart Disease With Ischemic Chest Pain
- Chest Pain
- Myocardial Infarction
- Myocardial Ischemia
- ST-segment Elevation Myocardial Infarction (STEMI)

Intervention/treatment:
- Procedure: distal radial artery access in coronary angiography and angioplasty
- Procedure: Forearm radial artery access in coronary angiography and angioplasty

Phase: Not Applicable

DETAILED DESCRIPTION

N/A

STUDY DESIGN

| Study Type: | Interventional |
| Estimated Enrollment: | 212 participants |
| Intervention Model: | Parallel Assignment |
| Masking: | Single (Outcomes Assessor) |
| Primary Purpose: | Treatment |
| Official Title: | Distal vs. Forearm Radial Artery Access |

Actual Study Start Date: December 2019
Actual Primary Completion Date: December 2020
Actual Study Completion Date: December 2020

ARMS AND INTERVENTIONS

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tbody>
<tr>
<td>Experimental: Distal Radial</td>
<td>Procedure: distal radial artery access in coronary angiography and angioplasty  The patient grasps his thumb towards the palm to bring the radial artery up to the surface. The left hand is set on the right side of the groin toward the operator, who stands on the right side, with the dorsal surface of hand upwards. Afterward, the access site is disinfected, lidocaine HCL is SC injected for local anesthesia. Subsequently, the distal radial artery is palpated to find the point of the strongest pulse. Later, at a 45-degree angle, the artery is punctured with a 21-gauge needle and a 0.018 soft, flexible, metallic wire is then inserted in the needle. Through the sheath, 200 micrograms of Nitroglycerin is given. A 5000 unit of unfractionated heparin is administered through the IV line. A weight-adjusted dose of heparin is further added if PCI is needed. Then, a 0.035 wire is introduced in the sheath with other required instruments such as the intracoronary device and the catheters. After pulling out the sheath, a compression device, Safe Guard, is used for hemostasis.</td>
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Patients who undergo coronary catheterization by accessing the distal radial artery in the snuff-box of the hand. |
Active Comparator: Forearm Radial
Patients who undergo conventional coronary catheterization by accessing the forearm radial artery.

Procedure: Forearm radial artery access in coronary angiography and angioplasty
The right hand is set in the anatomical position, with the anterior surface of arm face upwards. Afterward, the access site is disinfected, lidocaine HCL is SC injected for local anesthesia. Subsequently, the forearm radial artery is palpated to find the point of the strongest pulse. Later, at a 45-degree angle, the artery is punctured with a 21-gauge needle and a 0.018 soft, flexible, metallic wire is then inserted in the needle. Through the sheath, 200 micrograms of Nitroglycerin is given. A 5000 unit of unfractionated heparin is administered through the IV line. A weight-adjusted dose of heparin is further added if PCI is needed. Then, a 0.035 wire is introduced in the sheath with other required instruments such as the intracoronary device and the catheters. After pulling out the sheath, a compression device, TR band, is used for hemostasis.

OUTCOME MEASURES

Primary Outcome Measures:
1. Radial artery occlusion [ Time Frame: Within 24 hours after the procedure. ]
   Doppler Ultrasonography of the radial artery for occlusions along its course, in both groups.
2. Puncture Time [ Time Frame: During the procedure ]
   Which is time from first attempt to puncture to the successful one in seconds
3. Puncture Attempts [ Time Frame: During the procedure ]
   Which is the number of puncture attempts from first one until the successful one (maximum 6)
4. Procedure Duration [ Time Frame: During the procedure ]
   In minutes from the insertion of the sheath to its exertion.
5. Radiology Dose [ Time Frame: During the procedure ]
   Which is measured by the radiological device in mGy.
6. Compression "hemostasis" time [ Time Frame: Up to 240 minutes after band placement. ]
   The time from the placement of the compression band until its removal (when there's no blood oozing after deflation), measured by minutes.
7. Arterial spasm [ Time Frame: During the procedure ]
   Which is assessed by the operator if present or absent in terms of the difficulty in inserting the wire at the time of the procedures. of the procedure.
8. Hematoma and bleeding complications [ Time Frame: Within 24 hours after the procedure ]
   It is defined by EASY hematoma scale.
9. Ischemic changes to the hand [ Time Frame: Within 24 hours after the procedure ]
   It is noted by clinical features of pallor, absence of pulse, pain, cold, paresthesia or paralysis.
10. Crossover (failure to puncture) [ Time Frame: During the procedure ]
    It is transforming from the selected access to another after 6 failed attempts to puncture the first selected access
11. Procedural pain [ Time Frame: During the procedure ]
    Assessed by numerical rating scale (NRS) for pain, which is an 11 point subjective scale (0-10) where 0 refers for no pain, 1-3 for mild pain, 4-6 for moderate pain and 7-10 for severe pain.
12. Post-procedural pain [ Time Frame: Within 24 hours after the procedure ]
    Assessed by numerical rating scale (NRS) for pain, which is an 11 point subjective scale (0-10) where 0 refers for no pain, 1-3 for mild pain, 4-6 for moderate pain and 7-10 for severe pain.
13. Rare complications [ Time Frame: Within 24 hours after the procedure ]
    Pseudo-aneurysm, AV fistula formation, radial artery dissection, which are assessed by Doppler US. In addition to radial artery erosion or perforation.
14. Radial Artery Occlusion on follow up [ Time Frame: After 2 weeks of the procedure. ]
   Follow up Doppler Ultrasonography for patients with occluded radial artery within 24 hours.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Criteria
Inclusion Criteria:
Patients who agree to participate in the study and sign the consent form. Patients with an indication for coronary catheterization Clinically stable patients Patients with palpable pulses on both access sites of the radial artery.
Exclusion Criteria:
Patients with STEMI Patients with radial AV shunt for hemodialysis Patients with previous CABG using radial artery Patients with previous CABG using LIMA, RIMA or both. Patients with Reynaud phenomenon or lymphedema

CONTACTS AND LOCATIONS

Contacts

Locations
Palestinian Territory, occupied An-Najah National University Hospital Nablus

Sponsors and Collaborators
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Investigator
Principal Investigator: Yunis Daralammouri, asst. prof. An-Najah National University
MORE INFORMATION

Responsible Party: An-Najah National University

ClinicalTrials.gov Identifier: NCT04125992

Other Study ID Numbers: DRAvsFRA

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Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by An-Najah National University:
- cardiac catheterization
- coronary angiography
- coronary angioplasty
- snuff-box
- snuff box
- radial fossa
- distal radial artery
- radial artery
- safeguard
- distal radial access
- distal radial angiography
- radial access
- angiography
- distal radial radial
- coronary arteries
- randomized controlled trial
- left distal radial artery
- Percutaneous Coronary Intervention
- radial artery occlusion
- forearm radial access
- forearm radial artery
- coronary catheterization
- catheterization
- left distal radial
- angioplasty
- coronary artery disease
- radial vs distal

Additional relevant MeSH terms:
- Coronary Artery Disease
- Myocardial Ischemia
- Coronary Disease
- Myocardial Infarction
- Heart Diseases
- Acute Coronary Syndrome
- Atherosclerosis
- Angina Pectoris
- ST Elevation Myocardial Infarction
- Angina, Unstable
- Angina, Stable
- Infarction
- Chest Pain
- Ischemia
- Pathologic Processes
- Necrosis
- Cardiovascular Diseases
- Arteriosclerosis
- Arterial Occlusive Diseases
- Vascular Diseases
- Pain
- Neurologic Manifestations