DIStal versus COnventional RADIAL access for coronary angiography and intervention: a randomized multicenter trial

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The objective of this study is to demonstrate the superiority of Distal Transradial Access (DTRA) to Conventional Transradial Access (CTRA) regarding forearm radial artery occlusion (RAO) using the 6Fr Glidesheath Slender (GSS).

Ethical review	Approved WMO
Status	Completed
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49666

Source
ToetsingOnline

Brief title
DISCO RADIAL

Condition

- Coronary artery disorders
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
narrowed or blocked heart blood vessel / ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Terumo
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: Conventional Transradial Access, Coronary Angiography, Distal Transradial Access

Outcome measures

Primary outcome

Forearm radial artery occlusion (RAO) rate before discharge.

Following the procedure, the patient will be treated in accordance with

hospital standard of care and data will be collected until discharge.

Assessment for Radial Artery Occlusion (RAO):

The diagnosis of RAO (Radial Artery Occlusion) is made by an independent

investigator (not the operator) assessing the presence or absence of a 2D

Doppler Ultrasound flow signal at distal to the original entry site between 8

and 48 hours after the procedure.

If the patient is randomized to distal transradial access group, both forearm

and distal radial patency must be checked.

Local bleeding:

The diagnosis of puncture site bleeding is made before discharge and using the

EASY (visual assessment) and BARC criteria*s.

Activated Clotting Time (ACT):

ACT should be performed before removal of the sheath.

Pain Assessment by VAS (Visual Assessment Score):

The procedural pain intensity is measured by the Visual Assessment Scale (VAS), a numeric rating scale. VAS is a 10 cm line with anchor statements on the left (no pain = 0) and on the right (worst possible pain = 10). The patient is asked to mark their current pain level on the line. The examiner scores the VAS by measuring the distance in centimeters (0 to 10) from the *no pain* anchor point.

The pain score need to be taken immediately after sheath removal on the bed.

It takes into account from the puncture and cannulation until sheath removal.

Secondary outcome

- Rate of successful sheath insertion.
- Rate of access site crossover (See definition given in point 6.7)
- Total procedural time.
- Sheath insertion time.
- Puncture site bleeding according to EASY criteria. (See definition in Appendix B).
- Overall bleeding according to BARC criteria. (See definition in Appendix B).
- Vascular access-site complication. (See definition in Appendix B).
- Rate of radial artery spasm. (See definition in Appendix B).
- Rate of distal radial artery occlusion (dRAO).

- Patent hemostasis was achieved or not (CTRA) by reverse Barbeau test. (See

point 6.4 for more information).

- Time required to reach hemostasis.

- Pain associated with the procedure.

Study description

Background summary

On September 16th, 1977, Dr Andreas Gruentzig performed the first successful angioplasty treatment in a patient with angina on exertion in Zurich, Switzerland, which was the first case of percutaneous coronary intervention (PCI). Since then, PCI had established a definite role in the treatment of ischemic heart disease. In order to perform PCI, it is necessary to make an access to the peripheral arteries by an arterial puncture or cut down, which can be performed in several ways.

Percutaneous transfemoral approach is the first adopted access approach and has been used widely. In 1992, Dr Ferdinand Kiemeneij performed the first transradial percutaneous coronary balloon angioplasty and coronary stenting in Amsterdam (1). In the last decades, the transradial approach has emerged as the preferred vascular access for angiography and PCI, due to its advantages over femoral approach including effective hemostasis due to the easy compressibility of the radial artery, reduction of vascular complications and immediate ambulation after the examination. These features of radial access have a positive impact on the reduction of hospital stay and hospitalization costs. The radial approach for PCI has been validated in numerous trials and meta-analyses showing a reduction in bleeding complications. In patients presenting with an acute coronary syndrome (ACS), radial access, compared to femoral access reduces not only major bleeding complications but also all-cause mortality. Based on the clinical evidence available, radial access has been recommended in the 2018 ESC guidelines as standard approach, unless there are overriding procedural considerations with evidence level Class I A (2).

Radial artery puncture and sheath insertion can induce acute injuries and chronic thickening of the radial artery intima, which may subsequently result in radial artery occlusion with or without thrombus formation (3,4). Although radial artery occlusion (RAO) rarely induces hand ischemia under normal bi-directional circulation between radial and ulnar arteries through the carpal network (5), the repeated catheterization through the radial approach from the same side becomes impossible (6). The incidence of a RAO after catheterization

is generally reported to be 1% to 10% and is influenced by many factors such as the relative diameter of the sheath introducer versus the inner lumen of the radial artery (7), the duration of hemostatic compression (8), maintenance of radial artery patency during hemostasis (9), the use of hydrophilic-coated introducer sheath (10), female gender, the presence of peripheral arterial occlusive disease, younger age (11), and so on. Although transient compression of the ulnar artery on the same side may facilitate the recanalization of the occluded radial artery (12), its prevention is desirable.

Among the different factors that can contribute to the occurrence of RAO, the size of the introducer sheath compared to the radial artery size is one of the major determinants. The use of a 5Fr sheath can reduce the incidence of RAO compared to the use of a 6Fr sheath (11). TERUMO corporation has developed a 6Fr sheath (Glidesheath slender: GSS), which is characterized by having an inner lumen diameter like other contemporary 6Fr sheath as well as having an outer diameter similar like a contemporary 5Fr sheath. The introduction of this sheath into transradial access might help to reduce RAO compared to the use of contemporary standard 6Fr sheath. Recent study by Dr Adel Aminian reported that the Glidesheath Slender 6Fr showed a safe and feasible profile with a high rate of procedural success and a low rate of RAO (13). Based on these experiences, we finished the international RAP and BEAT clinical trial for 1,900+ case, which revealed various important findings on RAO. The result was already published (14).

Study objective

The objective of this study is to demonstrate the superiority of Distal Transradial Access (DTRA) to Conventional Transradial Access (CTRA) regarding forearm radial artery occlusion (RAO) using the 6Fr Glidesheath Slender (GSS).

Study design

DISCO RADIAL is a prospective, global, open label, multicenter randomized controlled trial with plan to include approximately 1300 patients on who transradial coronary angiography and/or intervention is performed. The patients will be randomized in 1:1 ratio to either Distal Transradial Artery Access (DTRA) or the Conventional Transradial Access (CTRA) arm. In both arms 6Fr Glidesheath Slender * (GSS) will be used as access sheath.

Study burden and risks

Risks/complications related to transradial catheterization
These include, but are not limited to the following:
• Bleeding
• Radial artery spasm
• Radial artery occlusion

• Pain
• hematoma of the wrist and/or forearm
• Transitory finger numbness
• Radial artery dissection
• AV fistula
• Pseudoaneurysm

Risk associated with Angiography, Cardiac Catheterization, Stenting and Percutaneous Transcatheter Coronary Angioplasty
The amount of radiation you will be exposed to with angiography is small. Such doses of radiation may be possibly harmful, but the risks are so small that they are hard to measure.
During the angiography the doctor will use a liquid that will help to see the blood vessels in the area to be treated. This liquid is called contrast medium and it can cause problems in patients with kidney disease. Contrast medium can raise or lower blood pressure, cause abnormal heart rhythms, trigger allergic reactions or cause nausea and vomiting.
Coronary angioplasty, catheterization and stenting procedure have established the definite role in the treatment of ischemia heart disease. There is extensive clinical experience worldwide. The benefits of this procedure outweighs the potentials risks, and it is expected that the procedural risks will not be significantly different in this clinical trial.

Risks Associated with Blood Draws
Drawing blood may cause temporary discomfort from the needle stick, bruising or infection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patient is at least 18 years of age.
- Patient has provided written informed consent.
- Patient is undergoing diagnostic coronary angiography and/or PCI.
- Patient is willing to comply with all protocol-required evaluations during the hospitalization.
- Patient is suitable for both DTRA and CTRA using 6Fr GSS.

Exclusion criteria

- Patient has a medical condition that may cause non-compliance with the protocol and/or confound the data interpretation.
- Patient is on chronic hemodialysis.
- Patient is presenting with ST-elevated myocardial infarction (STEMI).
- Patient has chronic total occlusion (CTO) lesions in coronary artery.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-12-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	05-10-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04171570
CCMO	NL74158.075.20