Effect on hand function of distal transradial access for angiography and angioplasty

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The objective is to make an inventory of hand function before and after dTRA. In addition secondary endpoints are measured like success rates and complications of distal radial access for coronary angiography and interventions.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46418

Source
ToetsingOnline

Brief title
Hand function after distal transradial access

Condition

- Procedural related injuries and complications NEC

Synonym
"neuropathy" "nerve injury"

Research involving
Human

Sponsors and support

Primary sponsor: IJsselmeerziekenhuizen
Source(s) of monetary or material Support: eigen geld/tijd.

Intervention

Keyword: distal, Function, Hand, radial

Outcome measures

Primary outcome

The main study endpoints are: hand function, feasibility, safety and

operational aspects (such as fluoroscopy time, radiation doses).

Secondary outcome

- Success of distal arterial access (defined as accessing the artery with

needle and wire)

- Success of wire introduction (defined as succeeding in introducing the wire

through the needle enough length to introduce the sheath).

- Success of coronary cannulation (defined as succeeding in sheath insertion)

- Distal radial artery diameter as measured on doppler (if available).

- Vascular access complications (other than occlusion and bleeding)

- Radial artery occlusion

Distal (at the level of snuffbox and distally)

Proximal (proximally to the level of the anatomical snuffbox)

- Procedural success

- Procedural time

- Fluoroscopy time

- Contrast use

- Hemostasis duration

- Hemostasis success

- Major adverse cardiac events (MACE)

- Cerebrovascular accident (CVA)

- Local bleeding. The diagnosis of puncture site bleeding is made by visual assessment before discharge Bleeding is graded according to the BARC classification (20)

Study description

Background summary

Distal radial access (dTRA) in the anatomical snuffbox to retrogradely open occluded radial arteries has first been described by Dr. Babunashvili in 2011 (1). Later, Dr. Kaledin reported distal radial access as default technique for coronary access (2). During the 3rd Isfahan Transradial Course, Dr. Roghani, interventional cardiologist Isfahan University of Medical Sciences in Iran, demonstrated advantages of alternative distal access sites at the volar and the palmar sides of the hand. Based on this information Kiemeneij modified the technique to left distal transradial access (ldTRA) as a default procedure in right handed patients (3). Not even a year later, predominantly due to the influence of social media platforms as Twitter, the ldTRA is pioneered in 4 countries. The rapid and progressive acceptance of this new technique is explained by the many advantages for patients and doctors, such as the availability of 2 new entry sites in the arms, patient comfort, operator comfort and an expected lower rate of radial artery occlusions. However, not much is known yet about the effect of dTRA on hand function. Theoretically, pinch grip cannot be affected since the thenar muscles and the finger muscles all get their nervous innervation and blood supply from nerves and vessels at the palmar side of the hand, not related to the anatomy of the anatomical snuffbox. However, frequent mis-puncture and/or hematoma formation and prolonged total hemostatic compression in the anatomical snuffbox may have the risk of sensory nerve damage and distal embolization, resulting in sensory loss and ischemia of the dorsal of the radial three fingers, thenar ischemia and scaphoid hypoperfusion. Sensory function of part of the dorsal side of the hand can become affected by potential damage of the superficial branch of the radial artery which runs through the snuffbox. Occlusion of the distal radial artery may result in ischemia of the dorsal sides of thumb, index-and middle fingers. Although none of these complications have been reported, it is justified to perform a systematic follow-up of hand function before and after dRA. Information on these important endpoints will also contribute to refine the current technique, in order to obtain the best possible outcomes.

Study objective

The objective is to make an inventory of hand function before and after dTRA. In addition secondary endpoints are measured like success rates and complications of distal radial access for coronary angiography and interventions.

Study design

The study design is a prospective non-randomized multicentre inventory of outcome of distal transradial coronary angiography and/or intervention. Hand function tests (Levine Katz and DASH questionnaires, VAS score, pinch grip test and sensory test with Semmes Weinstein filaments) will be performed at baseline and at one month.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: On the same day of a previously planned coronary angiography and on the outpatient follow-up appointment, patients will undergo assessment using questionnaires and other hand function tests. The burden will be very mild as all tests are non-invasive and will take but short time to perform. No change will occur on the intended therapy for the patients. Coronary angiogram and/or angioplasty will be performed as indicated on discretion of the physician in charge of treating the patient. The puncture site, also referred to as access site, will be according to this protocol the distal part of radial artery at the anatomical snuff-box. The standard technique of gaining arterial access will be exercised. In case arterial access is not obtained in the distal radial region, the performing operator will be able to shift to the a more proximal access site on the radial artery. All tests and procedures involved in this protocol are already part of standard patient care which are regularly performed by other disciplines such as neurologists and physiotherapists and are considered safe. Possible benefits include establishing more insight about the effect on hand function of a rather new access site for performing angiography and/or angioplasty. This access site is more distal (distal radial approach). This access site inevitably imply less burden for the vascular system. In addition, in case the distal (radial) access site occludes, the forearm radial artery will remain patent because distal flow is guaranteed by the presence of the superficial palmar branch. We consider it very important to gain more knowledge about this rather new technique (distal access site) as it bears a lot of potential benefits for patients and doctors. Such benefits include less risk of bleeding, the possibility of undergoing angiography via the left hand, ergonomically comfortably for the operator. Possible risks are sensibility loss of part of the hand if the cutaneous nerve running in the anatomical snuffbox becomes damaged. Furthermore, distal embolization can result in digital ischemia. Occlusion of the branch supplying the scaphoid bone can result in bone necrosis. Based on reported data, these serious complications have not been

described. Thus is this research project undertaken.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients ondergoing coronary angiography via the distal radial approach als part of their treatment

Exclusion criteria

A prior complication, such as radial artery occlusion, due to angiography procedure

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	15-08-2018
Application type:	Amendment
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
CCMO	NL65183.048.18