Tyumen Cardiology Research Center, Tomsk National Research Medical Center, Russian Academy of Science, Tomsk, Russia

Effect of introducer length on the rate of radial artery occlusion during endovascular coronary procedures: a pilot randomized clinical trial (146)

Study Protocol

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Annually, the number of endovascular diagnostic and therapeutic procedures, such as coronary angiography (CAG) and percutaneous coronary intervention (PCI), has increased in our country.

Concurrently, the rate of radial artery access (RAA) has increased. According to the 2016 data, in the Russian Federation more than 75% of CAG and more than 74% of PCI were performed using RAA . RAA was first used for endovascular intervention in 1989. The method has become widespread in clinical practice, as it has several advantages. Compared to the femoral, RAA allows the number of puncture site complications to be reduced significantly . Due to the radial artery surface location, there is possibility of effective hemostasis, even with anticoagulants and inhibitors of glycoprotein IIb / IIIa platelet receptors . A very low rate of hemorrhagic complications (<1/1000) is determined in patients after RAA. In accordance with European Guidelines on myocardial revascularization, use of RAA is recommended in all cases of CAG and PCI (recommendation class I, level of evidence: A).

Despite all advantages, radial artery occlusion (RAO) is determined in patients in 1-10% of cases after transradial puncture. RAO often has asymptomatic clinical course. However, the presence of RAO does not allow using of transradial artery access technique for subsequent interventions. Among the main mechanisms of RAO development, endothelial damage is distinguished, as well as decrease or complete stop of blood flow through the artery after introducer placement. This leads to thrombosis and is a predisposing factor for RAO development. Considering the above-mentioned mechanisms, it might be assumed that the use of increased length introducer will exclude the possibility of radial artery endothelial damage during endovascular procedures and replacement of catheters and thereby reduce RAO imcidence.

Planned work is a prospective pilot simple blind randomized study

Inclusion criterion:

- Signed informed consent form;
- Age ≥ 18 years;

- RAA technical capability

The exclusion criteria.

- RAA technical failure

Patients will be randomized into two groups, depending on the length of introducer by generating random numbers on a remote site just before the procedure. The main study group will be consisted of patients who underwent transradial CAG and / or PCI using a long introducer. The comparison group will be consisted of patients who underwent transradial endovascular procedures using a short introducer. In the main group of patients, 25 cm length with 6 Fr diameter and equipped with an internal metal needle with a 20 G plastic cannula and a hydrophilic conductor Radifocus Introducer II (Terumo, Japan) will be used. Moreover, in the comparison group of patients, 10 cm length, equipped with a 21 G needle and steel conductor Radifocus Introducer II (Terumo, Japan) will be used.

The primary endpoint of the study is RAO rate according to DU findings in the next closest hospital period (from 1 to 10 days). Secondary endpoints are: postpuncture hematomas, radial artery perforation/dissection, neuritis of the median nerve, puncture site bleeding, the rate of needle type conversion, puncture time, procedure from the introduction of the introducer to its extraction, time of fluoroscopy, total air kerma rate (mGy).

Local hematomas are classified according to the following scale: I - diameter not more than 5 cm, II - not more than 10 cm, III - not more than 10 cm, but not higher than the elbow, IV - above the elbow, V - with the threat of hand ischemia. All endovascular interventions will be performed by 5 experienced endovascular surgeons. CAG and PCI procedures will be performed on an Allura Clarity angiographic complex (Phillips, Netherlands). After the introducer placement, 10

mcg nitroglycerin solution will injected, as well as heparin 5,000 units after CAG, and heparin 7,500 units after PCI.

Then, catheterization and contrasting of the left and right coronary arteries will be consecutively performed with 6 Fr diagnostic catheters, or, catheterization and contrasting will be performed using 6 Fr. guiding catheters during PCI. After removing the introducer, a standard pressure bandage will be applied for 6 hours. The control DU will be performed on an iE 33 apparatus (Phillips, Netherlands) no earlier than 24 hours after the procedure.