

Study Protocol

Use of Various Types of Introducers in Conventional Radial Access (TIRE)

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1. Introduction

Today, radial access is preferred for both elective and emergency endovascular interventions [1]. Despite the advantages of this access, there are still some issues that need to be addressed. One of the most frequently discussed topics is the safety of traditional and distal radial accesses [2]. However, the safety of using different types of radial introducers, such as those with hydrophilic coatings or thin-walled manufacturing techniques, remains unexplored.

2. Objective

To compare different types of radial introducers used in conventional radial access by the frequency of complications in routine clinical practice.

3. Materials and methods

A multicenter observational randomized study of the use of different types of radial introducers in traditional radial access in patients who underwent percutaneous coronary intervention was conducted from 2019 inclusive, at the Korolev E.I. Kostroma Regional Clinical Hospital and the Central Clinical Hospital of St. Alexis, Metropolitan of Moscow, of the Moscow Patriarchate of the Russian Orthodox Church. The study included 3307 patients with coronary artery disease. All patients underwent percutaneous coronary angioplasty with stenting of the coronary arteries through the right radial artery. All patients received clopidogrel (75 mg/day) and acetylsalicylic acid (100 mg) as baseline antiplatelet therapy. Patients were enrolled by endovascular specialists with experience of at least 250 radial-access procedures per year.

Inclusion criteria: clear pulsation of the right radial artery, indications for percutaneous coronary intervention.

Exclusion criteria: previous unsuccessful radial artery catheterization; concomitant pathology limiting patient survival; disorders of the blood coagulation system (hemophilia, thrombocytopathy, etc.); previous coronary artery bypass grafting; occlusion of the right radial artery.

Puncture of the right radial artery was performed after local anesthesia with a 2% lidocaine solution. The radial artery was punctured at the typical site using

the puncture needle included in the introducer set, with only the anterior wall being punctured. The type of introducer was selected by randomization using a random-number method, and depending on this assignment the patient was allocated to one of the groups. In the Rad classic group, introducers without a hydrophilic coating were used; in the Rad polymer group, introducers with a hydrophilic coating were used; and in the Rad slender group, thin-walled introducers with a hydrophilic coating were used. The following instruments were used for the intervention: a 0.035-inch hydrophilic diagnostic guidewire, UniQuall (manufacturer Asahi Intecc), a 5 Fr Optitorque diagnostic catheter (manufacturer Terumo) or a 5 Fr Performa diagnostic catheter (manufacturer Merit Medical), a 6 Fr Heartrail II guiding catheter (manufacturer Terumo) or a 6 Fr Launcher guiding catheter (manufacturer Medtronic), coronary guidewires, stents, and balloon catheters.

A total of 5000 IU of heparin in saline was administered into the catheterized artery; calcium channel blockers or nitroglycerin were not administered before introduction of the diagnostic or guiding catheter. All injected solutions, including radiopaque contrast agents, had a temperature of 36.5-36.7°C. Hemostasis was achieved by applying a compression bandage.

The access site was examined within 3 hours after the intervention and then, in the absence of complaints, again at bandage removal. After bandage removal, patients underwent ultrasound examination to confirm radial artery patency.

Complications were recorded within 3 days after the intervention.

4. Outcome Measures

- compare the frequency of occurrence EASY Grade II hematoma between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence acute radial artery occlusion between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence radial artery perforation between groups (Rad classic vs Rad polymer vs Rad slender);

- compare the frequency of occurrence radial artery false aneurysm between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence persistent radial artery spasm between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence total frequency of major complications between groups (Rad classic vs Rad polymer vs Rad slender).

5. Review of Literature

According to research, the total incidence of serious complications associated with radial access is up to 30% [5,6].

The average incidence of Grade II hematomas according to the EASY classification at the access site in all groups according to the literature is (12%) [9,10].

The most severe complication of radial access is acute radial artery occlusion, which occurs at a frequency of 3 to 20% according to the literature [11-14].

According to a meta-analysis, the number of complications associated with radiation access depends on the diameter of the introducers used [15].

6. References

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