

The utility of duplex ultrasound scanning in reporting the vascular complications after heart catheterization performed from new arterial approaches – radial or femoral artery access with StarClose usage – a substudy of the RADIAMI II trial

Rola badania dopplerowskiego w ocenie powikłań naczyniowych po cewnikowaniu serca z dostępu promieniowego lub udowego z użyciem StarClose – badanie w ramach RADIAMI II

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Abstract

Background: RADIAMI II – Radial versus Femoral Approach for Percutaneous Intervention with StarClose Device Using in Patients with Acute Myocardial Infarction was a single center, randomized prospective trial. A substudy of this trial was to evaluate the utility of duplex ultrasound scanning (DUS) in the patency assessment of the radial or femoral arteries as well as the to evaluate the occurrence of local iatrogenic complications.

Aim: To choose the safest method of arterial access in primary coronary angioplasty in ST elevation myocardial infarction (STEMI) by the comparison of both studied groups.

Material and methods: The 108 consecutive patients hospitalized from September 2006 to March 2008 with STEMI and qualified to percutaneous coronary intervention (PCI) were randomly assigned to transradial (group I, $n = 49$) or transfemoral (group II, $n = 59$) approaches. The DUS protocol was devised and implemented by vascular ultrasound core laboratory with extensive experience in vascular device trials in 5 days after PCI. DUS inguinal region from 6 cm proximal to 6 cm distal to the arteriotomy puncture was performed. A qualitative examination was performed to determine the presence StarClose localization and iatrogenic vascular injuries: major haematoma ≥ 5 cm, pseudoaneurysm (PSA), arteriovenous fistula (AVF), and arterial thrombosis or stenosis, using 2-dimensional gray scale, color and focused Doppler images.

Results: Duplex ultrasonography of 108 subjects randomized to either group I ($n = 49$) or group II ($n = 59$) were performed and evaluated. In both groups there were no evidence of PSA, AVF, stenosis or arterial thrombosis. The hematoma ≥ 5 cm was observed in 4 patients of group I whereas in group II such a complication was affirmed in 10 patients (8.16% vs. 16.95%, $p = 0.287$). Pseudoaneurysm was observed only in patient from the group II (1.69%, $p = 0.926$). Both groups maintained vessel patency without stenosis, thrombosis, pseudoaneurysm, or AV fistula in follow-up.

Conclusions: Duplex ultrasonography is a reliable, safe and accurate method for the assessment the vascular access site complications after invasively treated patients with STEMI. The study showed that both radial and femoral access followed by StarClose implantation are safe methods of arterial access during PCI.

Key words: duplex ultrasound scanning, pseudoaneurysm, arteriovenous fistula, thrombosis, hematoma

Streszczenie

Wstęp: RADIAMI II (*Radial versus Femoral Approach for Percutaneous Intervention with Star Close Device Using in Patients with Acute Myocardial Infarction*) to jednośrodkowe, prospektywne badanie z randomizacją, polegające na porównaniu efektów leczenia

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inwazyjnego pacjentów z zawałem serca z uniesieniem odcinka ST (STEMI) z dostępu promieniowego lub udowego z zastosowaniem systemu StarClose. W ramach badania oceniano powikłania miejscowe przy użyciu metody DUS (*duplex ultrasound scanning*).

Cel: Określenie najbezpieczniejszej metody oraz miejsca nakłucia przy użyciu badania DUS na podstawie rodzaju powikłań miejscowych po nakłuciu tętnicy promieniowej i udowej.

Materiał i metody: Grupę 108 chorych hospitalizowanych od września 2006 r. do marca 2008 r. ze STEMI podzielono na dwie grupy: grupa I ($n = 49$) interwencja z nakłucia promieniowego oraz grupa II ($n = 59$) – z nakłucia udowego z zastosowaniem systemu StarClose. W 5. dobie po angioplastyce wieńcowej wykonywano DUS, oceniając okolicę miejsca wkłucia w promieniu 6 cm. Jako powikłanie po nakłuciu brano pod uwagę: krwiak ≥ 5 cm, tętniak rzekomy, przetokę tętniczo-żylną, zakrzepicę lub zwężenie tętnicy.

Wyniki: W obydwu grupach u badanych nie stwierdzono obecności przetoki tętniczo-żylną, przewężenia ani zakrzepicy w miejscu nakłucia tętnicy promieniowej lub udowej. Krwiak ≥ 5 cm wystąpił u 4 pacjentów z grupy I i u 10 pacjentów z grupy II (8,16% vs 16,95%, $p = 0,287$). Tętniak rzekomy uwidocznił się jedynie u jednego pacjenta z grupy II (1,69%, $p = 0,926$).

Wnioski: Badanie DUS jest tanią i łatwo dostępną metodą oceny powikłań miejscowych po nakłuciu tętnicy udowej lub promieniowej. Badanie to powinno być wykonane obligatoryjnie u wszystkich chorych poddanych koronarografii. U chorych ze STEMI metody z dostępu promieniowego lub udowego są jednakowo bezpieczne.

Słowa kluczowe: badanie dopplerowskie, tętniak rzekomy, przetoka tętniczo-żylna, zakrzepica, krwiak

Introduction

Although the introduction of angioplasty to the treatment of patients with acute myocardial infarction became enormously advantageous for survival and prognosis, the vascular access is still a major concern. In most cases coronary angiography is performed from femoral access and the closure of artery is than achieved by the manual compression. Such a protocol has many disadvantages. It requires to control the clotting time before the removal of arterial sheath, necessitates the prolonged stay in bed and thus delays the rehabilitation and discharge from hospital. Therefore, the alternative methods of vascular access and/or arterial closure are appearing. Nowadays the vascular closure devices (VCDs) play an increasing role in the care of patients, who undergo transfemoral arterial puncture for invasive endovascular therapies [1-3]. While VCDs are generally regarded as providing some advantages over manual compression (such as shorter time to hemostasis, more rapid patient ambulation and the potential for cost effectiveness) [2], the risk of periprocedural complications remain a concern.

The StarClose Vascular Closure device (Abbott Vascular Devices, Redwood City, CA) features a nitinol (nickel titanium) clip that is designed to provide mechanical closure without impinging upon the vessel lumen by effecting the closure of the arteriotomy from an extravascular approach [4]. The clip is delivered in a sterile fashion through the sheath and grasps tissue in a circumferential fashion to provide arteriotomy closure. Some small randomized and unrandomized trials have demonstrated that radial access reduces access site complications, such as: death (MORTAL study – mortality after one year post radial access 2.5% vs. 3.4% femoral access), ischemic events and major bleeding compared to femoral access both in stable and in unstable coronary disease with the special regard of the advantage for older persons [5-8]. The catheterization from the radial access essentially shortens the duration of hospitalization [5].

The aim of this study was to compare the frequency of vascular complications assessed by ultrasonography of the two newly introduced methods: radial puncture and femoral puncture followed by the StarClose insertion in patient percutaneous angioplasty for acute myocardial infarction.

Material and methods

Study group

The patients participating in the RADIAMI II (RADial vs. femoral approach with using StarClose for PCI for patients with Acute Myocardial Infarction) – a prospective, randomized, single-center clinical trial – represented a study group. The main aim of RADIAMI II was to compare the efficacy and safety of the two mentioned above methods of arterial closure approach. Hundred eight consecutive patients who have signed an informed consent participated in the study. Fifty nine patients were randomized to the femoral access followed by the StarClose Vascular Closure System usage (group II), whereas the remaining 49 patients were randomized to radial access (group I). Patients included in the RADIAMI II study fulfilled the following criteria: age between 18 and 75 years; presence of STEMI (ST segment elevation myocardial infarction) defined as retrosternal pain lasting longer than 20 min, but not longer than 12 h, resistant to nitroglycerin, and accompanied by ECG changes: ST elevation of at least 1 mV in two neighboring leads or new left bundle branch block.

The criteria for exclusion were as follows: age over 75 years, Killip class III or IV, necessity of an intra-aortic contrapulsation balloon placement and/or an endocavitary stimulating electrode placement before the coronary angiography, height < 150 cm, history of aortocoronary bypass grafting, in case of infarction caused by occlusion venous or arterial by-pass graft.

Randomization was conducted at the admission room based on the year of birth: group I included individuals with an even year of birth and group II those with an uneven year of birth. In group I the radial artery access was



Fig. 1. StarClose
Ryc. 1. System StarClose

achieved by: right radial artery $n = 48$; and left radial artery $n = 1$. In group II the right femoral artery was chosen in 55 patients; and left femoral artery in 4 patients.

Procedure (protocol) description in group I

In group I an adequate collateral blood flow from the ulnar artery was confirmed by a pulse oximeter. In case of an abnormal test's result for the right upper limb, it was repeated on the left one. If the result was normal, than the coronary angiography was performed using the left radial access. When the result was abnormal on both upper limbs, than the procedure was performed with the femoral approach. Vascular sheaths size 6 F were used for coronary angiography and angioplasty. After puncturing the radial artery and introducing the sheath, verapamil was administered in the dose of 5 mg diluted in 5 ml of 0,9% NaCl. The dose was repeated if spasm was present, until reaching a total dose of 15 mg. Analgesia during the procedure was achieved by administering morphine in 2 mg doses, depending on the intensity of chest pain. Activated clotting time (ACT) was checked in all patients from both groups after introducing the vascular sheath. Depending on ACT results, additional doses of heparin (70 U/kg) were administered. Fibrinolytic drugs and platelet glycoprotein IIb/IIIa receptor blockers were administered during the intervention according to the operator's decision. In patients from group I the vascular sheath was removed immediately after the procedure, and the radial artery was secured with a Terumo Band. Heparin administration was continued after the intervention only in the presence of clinical indications.

Procedure (protocol) description in group II

StarClose Vascular Closure System is comprised of an introducer sheath, dilator, guidewire, and a clip applicator. The "vessel locator button", when depressed, deploys four small flexible wings, which form the vessel locator [3]. An implantable nitinol clip is housed within the clip applicator.

When released from the clip applicator into the tissue, tines on the clip grasp the edges of the arteriotomy and draw them together, much like a purse-string suture. The clip is 0.170 inches (4 mm) in diameter and assumes a low profile in the tissue (fig. 1). The sheath is a 6 F sheath with a sidearm that is introduced into the target vessel and then used as a passageway for the insertion of diagnostic, guide, or other interventional catheters [9-11]. The angiography of femoral arteries was not executed before the implantation of the StarClose clip.

Vascular ultrasonography

Duplex ultrasound scanning (DUS) of femoral and radial arteries was performed in all patients from both groups 5 days after intervention. All examinations were performed on GE VIVID 3 machine equipped with linear transducer. All studies included 2-dimensional gray scale, color enhanced and focused Doppler images. We analyzed the diameter, velocity and presence of atherotic plaques. Especially the attention was paid to visualize the presence of any of the following vascular iatrogenic complications: haematoma, pseudoaneurysm (PSA), arteriovenous fistula (AVF), arterial and venous thrombosis or stenosis.

In all patients from the group II a gray scale Doppler imaging demonstrated localization, tissue reaction and blood flow around the StarClose device. A qualitative examination was performed to determine the absence or presence of iatrogenic vascular injury: hematoma, PSA, AVF, haematoma, arterial thrombosis or stenosis. The core protocol required that each examination begin with B-mode gray scale images in transverse and longitudinal planes of both the common femoral artery (CFA) and the proximal superficial femoral artery (SFA). Images of any extravascular masses (pseudoaneurysm, haematoma) were also evaluated in two plains. The scan was repeated with the addition of color for observation of the artery in transverse and longitudinal planes. Color scale was optimized to minimize color overwrite and flash artifact outside of the vessel wall. Pulsed Doppler evaluation was performed using a small sample volume with the wall filter set low. The Doppler sample volume was then walked throughout the course of both the artery and vein. Doppler signals were obtained in the proximal, mid and distal CFA, proximal SFA.

The radial artery we examined from the bifurcation of the brachial artery, most commonly just distal to the ante-cubital fossa, and then traverses distally along the radial side of the volar forearm under the brachioradial muscle and the radial flexor muscle of the wrist (flexor carpi radialis). Of note, the brachial artery may bifurcate more proximally in the arm and give off anomalous branches. The radial artery gives off multiple fasciocutaneous perforators until it reaches the wrist, where it courses over the dorsum of the first web space and forms the deep palmar arch. The radial artery

contributes to the principal artery of the thumb and the radial artery of the index finger. In addition, the radial artery often anastomoses with the deep branch of the ulnar artery system. At the wrist, the radial artery gives off a volar carpal branch that joins the ulnar artery. Often, a distal branch in the volar aspect of the wrist forms part of the superficial palmar arch, and it also contributes to the blood supply of the skin over the thenar region. The superficial arch is complete in about 80% of patients, and the predominant blood supply is thought to be from the ulnar artery, although the results of a recent study suggest otherwise. The contributing blood supply of the arch has several variations, including ones in which the superficial arch is incomplete.

The absence or presence of PSA, haematoma, arteriovenous communication, and vessel stenosis, or thrombosis was evaluated. In the case of suspected PSA, a specific Doppler signal was obtained in the “neck”, and diagnosis of PSA was made if the classic “to and fro” Doppler waveform was obtained, in association with the finding of an extravascular mass with chaotic arterial flow (the “sac”). Arteriovenous communications were to be evaluated by documenting low resistance Doppler spectral waveform with increased diastolic flow through communication as well as a native arterial Doppler signal proximal and distal to the communication or a native venous Doppler signal proximal and distal to the communication. Vessel thrombosis was defined as a documented absence of arterial blood flow within the vessel along with a preocclusive “thump” within the artery. Stenosis was defined as a local increase in peak systolic velocity (PSV) within the stenosis of at least 100% increase in PSV, when compared to the proximal normal segment. The mean, standard deviation, minimum, maximum, and sample size for each of the continuous variables PSV of the CFA, PSV of the SFA, and hematoma size were examined and statistically analysed.

Results

In both groups there were no evidence of PSA, AVF, stenosis or arterial thrombosis. In group I the hematoma ≥ 5 cm was observed in 8 patients, whereas in group II the major haematoma was affirmed in 12 patients (16.32% vs. 20.33%, $p = 0.087$). Pseudoaneurysm was observed in 1 patient from group II (1.69%, $p = 0.926$) and reduced after dressing compression. In all patients, the radial and femoral arteries after puncture of the day 5th were patent.

No ischaemic incidents within limbs were detected. StarClose was visualized in 31 of 59 patients (52.54%). The distance of clip from the wall of the femoral artery averaged 1.2 (± 0.84) mm. Remaining results of such parameters, like: flow velocity in the artery, arteries diameter, presence of arteriosclerosis in radial or femoral arteries and the continuity of the hand arch are presented in the table 1.

Discussion

This substudy confirms the reliability and utility of duplex ultrasonography performed in a controlled manner as an appropriate measure of access site patency and freedom from iatrogenic vascular injury in prospective multicenter studies. The results of the clinical study of this new technology demonstrated that the StarClose device achieved hemostasis without evidence of vascular abnormality at day 5 based on independent DUS analysis. Direct visualisation of the clip, while not a part of the protocol nor a focus of the examination, was noted in many of the examinations, typically represented as a bright echogenic image superficial of the lumen of the common femoral artery.

This visualisation of the clip was previously reported in a single center study from Italy suggesting that the clip is typically imaged when seen at 2 mm from the lumen [13]. The DUS data reported here confirms that flow is not interrupted by successful StarClose closure, as arterial scar

Table 1. Results

Tabela 1. Wyniki

	Right radial artery (n = 108)	Left radial artery (n = 108)	Right femoral artery (n = 108)	Left femoral artery (n = 108)
Artery diameter [mm]	2.93 \pm 1.48	2.41 \pm 0.48	7.39 \pm 1.86	7.41 \pm 1.08
Flow speed [m/s]	0.59 \pm 0.30	0.45 \pm 0.21	0.74 \pm 0.39	0.80 \pm 0.29
Arteriosclerosis < 50% [%] (n)	0.0 (0)	0.0 (0)	2.77 (3)	0.96 (1)
Arteriosclerosis > 50% [%] (n)	0.0 (0)	0.0 (0)	4.63 (5)	0.96 (1)
Clip's demonstrating [%] (n)	0.0 (0)	0.0 (0)	52.72 (29/55)	50.0 (2/4)
Demonstrating on the place of the clip implantation [%] (n)	0.0 (0)	0.0 (0)	21.8 (12/55)	0.0 (0/4)
The continuity of the hand bow – open [%] (n)	70.73 (29/41)	63.4 (26/41)	0.0 (0)	0.0 (0)
The continuity of the hand bow – close [%] (n)	29.26 (12/41)	36.58 (15/41)	0.0 (0)	0.0 (0)

formation at 5 days is minimal, and preserves luminal patency. Gray scale Doppler imaging demonstrates no soft tissue reaction to the nitinol clip device. Some researchers [3] confirmed the safety of implantation of StarClose without iatrogenic complications with very good flow of blood in the place its implantation .

Similarly our study showed no evidence of arteriovenous fistula, stenosis, or thrombosis in cohort of 59 subjects in whom ultrasound evaluation post StarClose was completed. Transradial approach for coronary angiography has become popular in many countries in recent years. The transradial approach for coronary catheterization permits a better comfort for the patient, a faster mobilization and less movement restraint within the bed; patient care and access site control are easier. This is of special importance for elderly, obese or suffering from back pain patients. Many explorers bring about the safety of transradial access during catheterization.

Vefali estimated by DUS 487 patients and observed only in 5.4% of them the presence of haematoma > 5 cm no other local, iatrogenic complications [14]. Our substudy showed no statistical differences regarding the iatrogenic local complication between both groups.

Conclusions

Duplex ultrasound scanning is a reliable, safe and accurate method of assessing vascular access site complications after invasive treatment patients with STEMI. Duplex ultrasound scanning is a safe and reliable method for determining the safety and efficacy of access site closure device.

There are no statistical differences regarding local complications between radial and femoral access.

Choice of arterial access (radial or femoral with StarClose implantation) does not influence the frequency of vessel occlusion, stenosis, thrombosis, pseudoaneurysm formation, or AV fistula occurrence.

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