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Research Article

A prospective randomized trial was conducted to evaluate the complication rate and patient comfort using three different vascular closure strategies following coronary angiography

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Abstract

Background: The use of vascular closure devices is now common in clinical practice for femoral artery puncture, although manual compression remains the current gold standard. The development and use of vascular closure devices are aimed at improving patient comfort and avoiding complications such as hematoma, pseudoaneurysm formation, and the need for blood transfusion in the event of significant bleeding or surgical revision at the puncture site.

Aims: The aim of this study is to evaluate the complication rate after femoral arterial puncture using different closure techniques. Furthermore, patient comfort will also be measured.

Material and Methods: In this prospective, two-centre study, 142 patients were randomized into three groups: the Vascular Closure Device (VCD, Cordis), manual compression (MC) and External Compression Device (ECD, Maquet). The primary endpoint is combined with the evaluation of hematoma greater than 5 cm, pseudoaneurysm formation, the need for blood transfusion or relevant bleeding with a hemoglobin drop greater than 2 g/dl, the occurrence of retroperitoneal hematoma, pressure ulcers greater than grade 2, ischemia of the ipsilateral limb, or nerve damage. Follow-up visits are scheduled at 24 hours, 7 days, and 30 days.

Results: The ratio of gender and pre-existing conditions within the randomized groups is almost equal. Medication before coronary angiography is comparable. Significantly more interventions are performed in the VCD group. Correspondingly, the procedure time is longer, and dual antiplatelet therapy is prescribed more often. Compression time and time to first hemostasis were significantly longer in the VCD group. The number of rebleeds after primary hemostasis is significantly higher in the ECD group. None of the enrolled patients suffered major bleeding or required a blood transfusion. No retroperitoneal hematoma was observed. Overall, there is one AV fistula in the MC group, two pseudoaneurysms in the VCD group, and one pseudoaneurysm in the ECD group. Pain was reported at significantly higher rates in the MC group than in either device group. The highest level of pain is reported within 48 hours in the MC group, and voiding dysfunction is significantly more frequent in the MC group. The same results are observed for sleep quality. Patients in the MC group reported significantly fewer hematomas greater than 5 cm at 7 days compared to patients who received a VCD.

Conclusion: Our results show no significant difference in the achievement of the combined primary endpoint of all three groups. However, the rate of rebleeding after primary hemostasis is significantly lower in the VCD group, even with prolonged procedure time. There was no difference in the incidence of MACCE. Patient pain and voiding dysfunction within 24 hours are highest in the MC group. No difference is reported between 7 and 30 days.

Keywords: femoral arterial access; coronarangiography; vascular closure device; external compression device; manual compression; arterial access complication

Introduction

Any cardiac or peripheral catheterization procedure requires vascular access at the start and hemostasis at the finish. A wide range of procedures, such as hemodynamic assessment, coronary and peripheral arterial angiography and intervention, and structural heart disease intervention, are now included in catheter-based diagnosis and therapy [1,2]. The common femoral artery, which is located above the femoral bifurcation and below the hypogastric artery, is the recommended arterial access site for cardiac procedures. Comparing the placement of catheters and introducer sheaths in this region with a more superior arteriotomy or inferior arteriotomy — which raise the risk of hematoma and pseudoaneurysm or reduces the risk of vascular complications [1–3].

Regarding their safety, the use of vascular closure devices in interventional practice has produced conflicting findings. The American Heart Association has recommended this as a class III strategy to lower vascular complications during interventional procedures[2,4,5]. For patients undergoing these operations, vascular access bleeding and complications continue to be a major cause of morbidity[6]. Thus, in the cath lab, enhancing the safety of vascular closure to accomplish hemostasis has taken precedence. According to recent studies, manual compression (MC) is more effective than vascular closure devices for both significant bleeding and minor vascular complications[7–9]. Vascular closure devices are now frequently used in clinical settings, while MC is still the preferred method as of right now.

The goal of developing and utilizing vascular closure devices is to increase patient comfort while preventing problems like hemorrhage, the formation of pseudoaneurysms, and the requirement for blood transfusion in the event of severe bleeding or surgical revision at the puncture site [4,10,11]. During femoral access coronary angiography, patients frequently express dissatisfaction regarding the comfort of manual compression [8–10].

Aim of the Study

The primary objective of the study is to evaluate the complication rate after femoral arterial puncture for coronary angiography and/or coronary intervention and subsequent closure using different closure methods. The secondary objective is to measure patient comfort as a function of the closure system used.

Materiales and Methods

Study design, setting and participants.

The Trail is a prospective, randomized clinical trial intended to evaluate three distinct methods of closure following femoral artery access for the purpose of coronary intervention or diagnostics. We invited 160 patients who met the criteria for coronary angiography to take part in our, randomized trial between June 2011 and July 2014.

The three different techniques of vessel closure are pressure bandaging after manual compression (MC), the Vascular Closure Device (VCD, Cordis) and the External Compression Device (ECD, Maquet).

Inclusion Criteria. The following criteria were met by the patients: a body mass index of less than 30 kg/m2, a femoral access with a 5 or 6 Fr sheath, sinister or dexter puncture of the common femoral artery, age greater than 18 years, and a properly signed informed consent.

Exclusion Criteria. Patients with severe calcification or atheromatosis of the femoral artery, prior femoral or iliac vascular intervention, uncontrolled blood pressure greater than 180 mmHg, or a history of femoral vascular surgery or bypass.

A 24-hour notice was required for informed consent before coronary angiography. Vascular ultrasonography was done both prior to and following the treatment. The patient was randomly assigned to receive the vessel closure technique after the coronary intervention or diagnostic. A physician-assessed questionnaire was completed by the patient within 24 hours following the coronary angiography. Following angiography, a clinical follow-up was conducted on days 7 and 30.

The final protocol was approved by the ethics committee. The study was conducted in accordance with GCP guidelines. All patients gave written, informed consent. The study was registered in the German Clinical Trials Register: *DRKS00000802*.

Study devices.

The method advised by the manufacturer for device placement was followed. The device had to be operated by the user at least fifty times.

Manual Compression (MC). The MC of the puncture site is currently the gold standard for closing a femoral arterial puncture site after cardiac catheterization. Manual compression is applied for a minimum of 20 minutes and is automatically increased until the bleeding stops. After manual compression, a groin pressure bandage is applied. The duration of the pressure bandage depends on the size (diameter) of the puncture set (sheath) and the blood thinning administered during the procedure. The duration of the compression bandage depended on the size of the sheath (5F or 6F) and the use of a GpIIbIIIa inhibitor during the procedure. Thus, the duration of compression bandaging was 6 hours when a 5F sheath was used without GpIIbIIIa and 12 hours with GpIIbIIIa. When a 6F sheath was used, the compression bandage was applied for 12 hours without GpIIbIIIa and 24 hours with GpIIbIIIa. At the end of the resting period, the pressure dressing is removed while the puncture site is checked.

Vascular Closure Device (VCD). The VCD (Cordis) is a bioabsorbable device designed to seal the femoral artery puncture site in patients undergoing diagnostic or interventional procedures using a standard 6F sheath. The device achieves hemostasis through a bioabsorbable polyglycolic acid plug that is released into the femoral artery puncture channel by an optically guided mechanism. The plug, which rests completely extravascularly, then hydrolyzes to CO2 and H2O via the Krebs cycle over a period of 3 months. After direct vascular occlusion, the patient must remain in bed for 2 hours and can then get up under supervision.

External Compression Device (ECD). The ECD (Maquet) is a sterile groin compression system used to occlude the femoral artery after a puncture during cardiac catheterization. The manually assisted closure technique is used in the registry. The location of the maximum pulse, the anatomy, the angle of the puncture, and the direction of blood flow are checked. The introducer sheath is retracted approximately 2-3 cm so that the sheath head is outside of the Safeguard System adhesive area. Clean and dry the patient's skin. The ECD system is applied. The inflation syringe is attached, and the balloon is filled with approximately 40 cc of air. The syringe is removed to maintain pressure on the balloon. The airlock is withdrawn, and manual compression is applied to the balloon for 2-3 minutes or until hemostasis is achieved. The inflation of the balloon is adjusted so that the peripheral pulse is still palpable at the foot and hemostasis is still present in the groin. The Safeguard System remains in place depending on the size (diameter) of the puncture set (sheath) and the blood thinning administered during the procedure. The length of the hospital stay depended on the size of the sheath (5F or 6F) and the use of a GpIIbIIIa inhibitor during the procedure. For example, when a 5F sheath was used without GpIIbIIIa, the length of hospital stay was 6 hours and 12 hours with GpIIbIIIa. When a 6F sheath was used, the length of stay was 12 hours without GpIIbIIIa and 24 hours with GpIIbIIIa. At the end of the infusion period, the balloon is slowly deflated with a syringe while the puncture site is checked, and the dressing is carefully removed.

Ultrasound Study

The right and left inguinal arteries' angiological results are recorded before cardiac catheterization. This comprises measuring the diameter of the vessel, calculating the degree of stenosis, and evaluating atheromatous and calcified lesions. 48 hours after cardiac catheterization, the punctured inguinal vessel

is monitored with duplex sonographic technology. This includes assessing the presence of new vascular lesions, aneurysms, hematomas, and AV fistulas.

Patient Comfort Analysis

Prior to and following cardiac catheterization, patient comfort was evaluated. Patients evaluate their pain level right now, mobility, and urination. The quality of sleep is evaluated last. Following the heart catheterization process, patients are also questioned regarding how secure they feel utilizing the closure system.

Data analyses.

A non-inferiority test was used for the primary endpoint. The primary endpoint was defined as a composite of hematoma greater than 5 cm, pseudoaneurysm formation, need for blood transfusion or relevant bleeding with a drop of more than 2 mg/dl of hemoglobin, occurrence of retroperitoneal bleeding, pressure ulcer greater than stage 2, ischemia of the ipsilateral limb, or nerve injury within 24 hours. To estimate the number of patients per group based on 1:1:1 randomization, we tested whether the odds ratio was close to 1.00. The hypotheses are represented in the odds ratio model as follows: H0: $\ln(OR) \geq \delta$; H1: $\ln(OR) < \delta$. Assuming an incidence of 5% for the primary endpoint and a delta of 1.30, the calculated number of patients was 43 in each group to achieve 80% power. This power margin was selected based on clinical judgment and expertise. Categorical variables were compared using ANOVA. All continuous variables are expressed as the mean ± SD. Differences between proportions and t-tests were calculated using the StataIC statistical program.

Results

Following coronary angiography, 142 patients were randomly assigned to one of three groups. 46 patients (32%), 49 patients (34.9%), and 47 patients (32.9%) used closure devices, manual compression, and compression devices. Within the randomized groups, the relationship between gender and pre-existing conditions is nearly equal. Prescription drugs prior to coronary angiography are similar as well. Tables 1 and 2 provide information on the patient's history and medication taken both before and after the procedure.

	VCD	MC	ECD	P
N	46	49	47	
Age (y)	64 ± 12	66 ± 13	63 ± 11	NS
BMI	25,9 ± 3,8	25,2 ± 2,8	25,9 ± 2,8	NS
Gender (male)	30 (65%)	24 (49%)	31 (66%)	NS
Diabetes Mellitus	4 (8,7%)	7 (14.3%)	5 (10.6%)	NS
Renal Failure	5 (10.9%)	6 (12.2%)	3 (6.4%)	NS
Previous PCI	17 (37.0%)	18 (36.7%)	15 (32.0%)	NS
Bypass graft	4 (8.7%)	2 (4.1%)	2 (4.3%)	NS
Periphere vascular intervention or surgery	0 (0%)	1 (2%)	0 (0%)	NS
pAVK	1 (2%)	1 (2%)	1 (2%)	NS
Hyperlipidemia	18 (39%)	17 (35%)	16 (34%)	NS
Hypertension	28 (61%)	33 (67%)	31 (66%)	NS
Smoking	19 (41%)	16 (33%)	22 (47%)	NS
Previous art. Puncture at same side	19 (41%)	21 (43%)	15 (32%)	NS

Table 1. Patient history

	VCD	MC	ECD	P
N	46	49	47	
PRE				
ASS	35 (76%)	34 (69%)	35 (74%)	NS
Clopidogrel	21 (46%)	20 (41%)	23 (49%)	NS
Prasugrel	2 (4%)	1 (2%)	2 (4%)	NS
Ticagrelor	0 (0%)	0 (0%)	2 (4%)	NS
Marmuar or NOAK	2 (4%)	1 (1%)	1 (1%)	NS
DURING				
ASS	3 (6%)	0 (0%)	1 (2%)	NS
Clopidogrel	3 (6%)	3 (6%)	1 (2%)	NS
Prasugrel	1 (2%)	0 (0%)	2 (4%)	NS
Ticagrelor	1 (2%)	0 (0%)	0 (0%)	NS
Heparin	29 (63%)	33 (67%)	34 (72%)	NS
Bivalirudin	0 (0%)	1 (2%)	0 (0%)	NS
GpIIIB/IIA	0 (0%)	0 (0%)	0 (0%)	NS
Protamin	4 (9%)	15 (31%)	13 (27%)	NS

Table 2. Medication before and after Procedure

Interventions during coronary angiography were performed in 23.1% (35 total) of all patients. There were significantly more interventions in the VCD group. Accordingly, the duration of the procedure was longer in this group (Table 3).

	VCD	MC	ECD	P
N	46	49	47	
Duration (min)	50 ± 10	38 ± 7	36 ± 7	0.02
Intervention	17 (38%)	7 (14%)	9 (19%)	0.02
Puncture Problems	2 (4%)	1 (2%)	1 (2%)	NS
How to Puncture				
Easy	33 (71%)	38 (78%)	38 (81%)	NS
Moderate	9 (20%)	7 (14%)	8 (17%)	NS
Difficult	4 (9%)	4 (8%)	1 (2%)	NS
Assessment Puncture Side				
Smooth	38 (83%)	42 (86%)	43 (91%)	NS
Scarred	1 (2%)	2 (4%)	0 (0%)	NS
Calcified	5 (11%)	1 (2%)	1 (2%)	NS
Fibrotic	2 (4%)	4 (8%)	3 (6%)	NS
Sheath				
5F	26 (57%)	36 (73%)	35 (74%)	NS
6F	20 (43%)	13 (27%)	12 (26%)	NS
ACT after Procedure (sek)	212 ± 14	200 ± 16	206 ± 19	NS
Time of Compression (min)	3:59 ± 0:36	14:55 ± 1:51	10:24 ± 3:00	< 0.01
Time until first Hemostesis (min)	3:23 ± 0:48	10:43 ± 1:38	7:08 ± 2:05	< 0.01
Re-Bleeding after primary hemostasis	2 (4%)	1 (2%)	7 (15%)	0.03
Duration of immobilisation (H:min)	4:21 ± 1:12	9:59 ± 2:18	10:24 ± 1:58	< 0.01

Table 3: Procedere related data

Time of compression and time to first hemostasis were significantly longer in the MC group, with 12:43 +/- 1:38 minutes versus 7:08 +/- 2:05 minutes in the ECD group and 3:23 +/- 0:48 minutes in the VCD group. The number of rebleeds after primary hemostasis was significantly higher in the ECD group, with 15% (7 in total) versus 4% (2 in total) in the VCD group and 2% (1 in total) in the MC group (Tabel 3).

Not one of the enrolled patients needed a blood transfusion or experienced significant bleeding. There was no retroperitoneal hemorrhage. Overall, the MC group had one AV fistula, the VCD group had two aneurysm spuriums, and the ECD group had one aneurysm spurium. These were all insignificant occurrences. The 24-hour pre-intervention ultrasound, the exclusion criteria involving prior femoral vessel surgery or bypass, and prior femoral or iliac vessel intervention may have contributed to the lack of device failures documented in our trial. There was no infection reported.

Table 4 displays the findings of the femoral artery ultrasound examination both before and after the puncture and occlusion.

	VCD	MC	ECD	P
N	46	49	47	
PRE Procedure				
AFC right (mm)	9.5 ± 0,4	9.9 ± 0.6	9.6 ± 0.6	NS
Calcification				
None	10 (24%)	8 (15%)	17 (40%)	NS
Focal	18 (44%)	14 (34%)	21 (49%)	NS
Diffuse	12 (29%)	13 (32%)	2 (5%)	NS
Circumferential	1 (2%)	6 (15%)	3 (7%)	NS
Atheromatosis				
None	13 (32%)	9 (21%)	22 (51%)	NS
Mild	23 (56%)	26 (63%)	20 (47%)	NS
Moderate	4 (10%)	6 (15%)	1 (2%)	NS
severe	1 (2%)	0 (0%)	0 (0%)	NS
POST Procedure				
Puncture side right	46 (100%)	49 (100%)	47 (100%)	NS
AFC	21 (46%)	22 (45%)	21 (46%)	NS
Vessel Stenosis	1 (2%)	0 (0%)	0 (0%)	NS
AV Fistula	0 (0%)	1 (2%)	0 (0%)	NS
Aneurysma spurium	2 (4%)	0 (0%)	1 (2%)	NS

Table 4: Duplex Sonografie Evaluation

Results of Patients comfort

The pre-intervention assessment of patient comfort showed a balanced randomization of problems with mobility, pain, and quality of night sleep. An observed difference in micturition problems is not significant (Table 5).

The first assessment of patient comfort within 48 hours showed a significant difference in pain during arterial occlusion. In the MC group, the pain level was reported as 1.5±0.6 vs. 0.7±0.4 with the occlusion VCD device and 0.8±0.6 with the ECD device. The pain level within 48 hours was not significantly different between the three closure methods. However, the highest level of pain was still reported in the MC group, with 1.3±0.8 vs. 1.1±0.6 for the ECD device and 0.5±0.4 for the VCD device (Table 5). Patients were asked about mobility limitations within 48 hours after coronary angiography. With a p-value of 0.06 there is no significance, but overall, the pain level was highest in the MC group with 3.6±1.0 vs. 2.3±0.9 in the VCD Device group and 2.7±0.9 in the ECD group. The difference in voiding problems was highly significant. In the MC group, this problem was rated at 3.0±1.1 vs. 1.5±0.8 in the VCD group and 0.9±0.5 in the MC group. Disturbance of sleep quality was significantly lower in the VCD group, with 2.6±0.3 vs. 3.6±0.4 in the MC group and 3.3±0.4 in the ECD group (Table 5).

	CVD	MC	ECD	P
N	46	49	47	
PRE Procedure				
Mobility	1.4 ± 0.8	1.5 ± 0.7	1.2 ± 0.5	NS
Miction	1.4 ± 0.8	1.3 ± 0.6	0.5 ± 0.4	NS
Pain	1.1 ± 0.6	0.9 ± 0.5	1.8 ± 0.8	NS
Quality of Night Sleep	3.1 ± 0.3	3.4 ± 0.3	3.2 ± 0.2	NS
POST Procedure within 48h				
Pain during Closure	0.7 ± 0.4*	1.5 ± 0.6*	0.8 ± 0.6	0.05
Savety	0.9 ± 0.5	0.7 ± 0.4	0.9 ± 0.6	NS
Mobility	2.3 ± 0.9*	3.6 ± 1.0*	2.7 ± 0.9	0.06
Miction	1.5 ± 0.8	3.0 ± 1.1	0.9 ± 0.5	<0.01
Pain within 48h	0.5 ± 0.4*	1.3 ± 0.8*	1.1 ± 0.6	0.07
Quality of Night Sleep	2.6 ± 0.3	3.6 ± 0.4	3.3 ± 0.4	<0.01

Table 5: Patient Comfort Analysis

The incidence of hematoma >5 cm and decubitus ulcers showed no significant difference between the three methods tested.

Follow up 7 and 30 days

Follow-up was conducted by telephone 7 and 30 days after coronary angiography. At the 7-day evaluation, no significant differences were found in mobility, feeling of safety, micturition problems, quality of sleep at night, or pain level. However, there is a significant difference in the incidence of hematoma > 5 cm. The MC group reported hematoma > 5 cm in 6% (total 3 patients), whereas patients in the occlusion VCD group reported hematoma > 5 cm in 24% (11 patients) and 21% (10 patients) in the ECD group (Table 6).

At 30 days, there were no significant differences in the appearance of the hematoma (Table 6).

	VCD	MC	ECD	P
N	46	49	47	
1° EP	16 (35%)	12 (24%)	17 (36%)	NS
In-Hospital Evaluation within 48h				
Hematoma > 5cm	14 (30%)	11 (22%)	16 (34%)	NS
Pressure Ulcera	0 (0%)	0 (0%)	1 (2%)	NS
7d Follow up				
Hematoma >5cm	11 (24%)	3 (6%)	10 (21%)	0.04
Mobility	1.1 ± 0.8	0.7 ± 0.7	1.5 ± 0.9	NS
Safety	0.6 ± 0.6	0.8 ± 0.7	1.3 ± 0.8	NS
Miction	0.5 ± 0.6	0.3 ± 0.4	0.7 ± 0.6	NS
Pain	0.9 ± 0.6	0.6 ± 0.4	1.2 ± 0.8	NS
Quality of Night Sleep	2.5 ± 0.3	2.6 ± 0.3	2.7 ± 0.3	NS
30d Follow up				
Hematoma >5cm	0 (0%)	0 (0%)	1 (2%)	NS
Mobility	0.3 ± 0.5	0.1 ± 0.1	0.6 ± 0.5	NS
Safety	0.6 ± 0.7	0.4 ± 0.4	0.5 ± 0.4	NS
Miction	0.4 ± 0.6	0.1 ± 0.3	0.3 ± 0.4	NS
Pain	0.1 ± 0.2	0.1 ± 0.1	0.6 ± 0.5	NS
Quality of Night Sleep	2.3 ± 0.4	2.3 ± 0.3	2.7 ± 0.3	NS

Table 6. Follow up

Discussion

The purpose of the clinical trial was to evaluate the complication rates as well as the comfort of patients with three distinct arterial occlusion techniques. In terms of safety, there was just one noteworthy distinction. The ECD group experienced a notably elevated incidence of rebleeding following primary hemostasis, with 15% of cases in contrast to 2% in the MC group and 4% in the VCD group. This was noted even though the VCD group's coronary angiography took noticeably longer and had a noticeably higher intervention rate. Following initial hemostasis, these rebleeds did not cause significant bleeding, blood transfusions, or a decrease in hemoglobin levels. Furthermore, compared to the other two devices, patients in the MC group reported a noticeably higher incidence of micturition issues within 48 hours. Additionally, there was a significant improvement in the VCD group's quality of sleep at night.

A comparative study of the efficacy of the ExoSeal extrafemoral vessel closure device with the well-validated AngioSeal plug-anchor system for vessel closure after coronary angiography and PCI showed that the use of ExoSeal was no worse than treatment with AngioSeal in terms of bleeding, hematoma, false aneurysms, and device failure. The use of ExoSeal was associated with a higher, although not significant, rate of device failure and significantly less pain as measured by the Borg scaleccone[12].

The occurrence of vascular complications is an independent predictor of non-fatal myocardial infarction or death within one year of surgery and has been associated with a significant increase in mortality[13,14].

Data from several studies have shown an association between a lower risk of bleeding with the use of a vascular closure device compared to manual compression[2,3,8,15–18]. In the observational study ACUITY[19], which was conducted in patients with NSTEMI, the authors reported that a VCD was used in 37.1% of patients who underwent transfemoral PCI. In the comparator arm of the study, VCD was found to reduce the size of a puncture site bleed by 22% compared to manual compression.

In more than 1.5 million US patients who underwent PCI and were included in the National Cardiovascular Data Registry, the use of a VCD was associated with a significant 23% reduction in bleeding after the procedure. Patients with a higher risk profile benefited in particular[6]. In this study, the lowest rate of periprocedural bleeding occurred in patients who received VCDs for femoral access site closure and who were also treated with bivalirudin rather than unfractionated heparin[6,19].

However, meta-analyses of 30 randomized trials found no significant benefit of a VCD compared to manual compression in terms of the incidence of inguinal hematoma, inguinal hemorrhage, AV fistula or pseudoaneurysm. The various vascular devices used to close femoral accesses were not superior to manual compression in reducing complications, but they did offer a shorter time to hemostasis(20). A further meta-analysis of 40 randomized studies with a total of 16,868 patients also found no significant difference in the use of a VCD compared to manual compression(17).

This did not include the results of the ISAR-CLOSURE study, which compared intravascular, extravascular VCD and manual compression in 4,524 patients undergoing diagnostic coronary angiography using a 6F sheath [9]. The study demonstrated the non-inferiority of VCDs compared to manual compression. The use of VCDs resulted in less hematoma and a shorter time to haemostasis. The intravascular VCDs showed a lower rate of device failure than the extravascular VCDs[9].

Conclusion

Our results show no significant difference in the achievement of the combined primary endpoint between all three groups. However, primary hemostasis is achieved more rapidly with the use of VCD than with MC or ECD. Similarly, the rate of rebleeding after primary hemostasis is achieved is lower with the use of VCD or MC, regardless of the duration of the procedure. No difference in MACCE was observed between the different closure strategies. However, patients with MC reported more pain and voiding dysfunction in the first 24 hours. This difference was not observed

at 7 and 30 days. Finally, we conclude that there is no decisive advantage to the use of any closure system in daily clinical practice.

Limitations

There had been plans for 600 patients in total. The spike in the number of coronary angiographies conducted using radial access was the cause of the enrollment pause. As a result, there are much fewer patients included, which reduces the power. Furthermore, based on their medical histories, the enrolled patients were randomized into three highly homogeneous groups. However, the patients that are included do not accurately depict the typical day-to-day activities of a clinical setting.

The telephone was used for the 7- and 30-day follow-up. Therefore, the size and occurrence of the hematoma that was reported during the 7-day follow-up are not verified by trained personnel.

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