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Access Site Complications Following Cardiac Catheterization Assessed by Duplex Ultrasonography

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ABSTRACT

Access site complications are major source of morbidity following cardiac catheterization. Their incidence varies in the literature because of multiple definitions and methods of determining the presence of particular complication. The aim of this prospective study was to determine the incidence of access site complications following cardiac catheterization using arterial duplex ultrasonography. A total of 319 consecutive patients, who had cardiac catheterization underwent femoral artery duplex study 24 to 48 hours following manual hemostasis. Diagnostic angiogram had 232 (71.8%) while 87 (28.2%) had percutaneous coronary intervention (PCI). Femoral artery duplex ultrasound was normal in 247 (77.4%). Haematoma was found in 48 (15.1%), pseudoaneurysm in 17 (5.3%), AV fistula in 2 (0.6%) and dissection of the femoral artery in 5 (1.6%) patients. Baseline demographic characteristics were similar in group with normal duplex study and group with detected complication. Pseudoaneurysm and AV fistula were more commonly observed in patients following PCI than diagnostic angiogram (9.2% vs. 4.7%, $p < 0.001$). Patients with documented complications more frequently had concomitant administration of antiplatelet and anticoagulant medication compared to the patients without complications ($p = 0.003$). Hemodynamic disturbances (hypotension and bradycardia) during manual compression were more frequent in patients with complication (11% vs. 4.5%, $p = 0.047$). Low threshold for use of duplex ultrasound should be exercised in patients following cardiac catheterization to establish the presence of access site complications. Special attention is needed in the setting of aggressive antiplatelet and anticoagulant therapy, interventional procedures and hemodynamic disturbances during manual hemostasis.

Key words: duplex ultrasonography, access site complications, cardiac catheterization

Introduction

Access site complications regularly occur following cardiac catheterization. Their incidence varies in the literature predominantly because of lack of standardized criteria that characterize them and different modalities that assess for their presence^{1–4}.

Most commonly reported complications include local minor or major haematomas, pseudoaneurysms, arteriovenous fistulas, dissections, acute arterial occlusions, retroperitoneal bleeding, cholesterol emboli and infections with reported incidence of 1.5–9%¹. This wide range of complications reported in the literature is a result

of different inclusion criteria for tested populations and diverse methods of assessment^{1–6}.

Initially, vascular surgeons were predominantly involved in the management of vascular complications, thus most of the original data comes from cohort studies involving patients referred for vascular surgery interventions⁷. Not surprisingly, those data underestimated real incidence of local complications. The patients with silent groin complications who recovered spontaneously or who were treated conservatively were not included in the surgical statistics. Diagnostic strategies and therapeutic fol-

low up have changed in the past 20 years^{8–10}. It was believed that the diagnosis could be made on clinical grounds alone. Some prospective studies selected patients on the basis of local signs, referring them for subsequent Doppler investigation, while excluding those who were asymptomatic^{11,12}. According to different criteria for patient selection various incidences of complications were reported, generating wide and confusing spectrum of data.

The aim of the study was to assess the incidence of access site complications following cardiac catheterization in 319 consecutive patients and to establish differences in risk factors between patients with and without local vascular complications using the arterial duplex imaging.

Patients and Methods

Over a period of two months, a total of 319 consecutive patients who underwent diagnostic or interventional coronary catheterization via femoral artery were prospectively evaluated by duplex ultrasound for presence of access site complications. All of the procedures were performed in one cardiac catheterization laboratory at the University Hospital Centre Zagreb in Zagreb, Croatia. All patients signed informed consent for coronary catheterization and ultrasound duplex scanning of femoral access site. Hospital ethic committee approved the study. Haemostasis was achieved by standard technique of manual compression. It involves use of the first two fingers (index and middle) applied to the groin. Firm direct pressure was applied as the sheath was removed and then intensified to occlude pulsating for about 5 minutes. Pressure was then gradually reduced pressing on the arterial puncture site for next 15 minutes according to the bleeding response. In the case of bleeding, firmer pressure was applied until haemostasis was achieved. After achieving haemostasis at the arterial puncture site a general pressure to the groin was applied by the use of elastic tape and bandage^{13,14}. Bed rest was recommended, in our institution, over the night.

Baseline demographic data (age, gender, hypertension, diabetes, body mass index) were collected on all patients. In addition, we have also collected: data on femoral artery wall characteristics, concomitant medications, procedure of cardiac catheterization (introducer sheath size; duration of the sheaths placement in the femoral artery; total duration of the catheterization procedure starting with local anesthesia and ending with coronary catheter removal) and the data related to haemostasis using manual compression (duration; evidence of the patients' perceptions of inguinal pain level during compression; hemodynamic parameters changes). Systolic blood pressure drop of more than 20 mmHg and heart rate of less than 40 beats per minute were noted as hemodynamic changes. Pain perception during manual compression was assessed by use of a pain visual analogue scale.

Duplex ultrasonography

All studies were performed using a 7.5 MHz linear array transducer for B-mode and colour duplex scanning

(General Electrics, GE Vivid 7) 24–48 hours after the completion of manual haemostasis. Measurement of the far common femoral wall was done 1 to 2 cm proximally to the arterial bifurcation. Ultrasound assessment included following vessels wall characteristics: common femoral artery (CFA) diameter, wall thickness of common femoral artery and the ratio of diameter and wall thickness.

The ultrasound recordable haematoma, the dissection of the femoral artery, pseudoaneurysm and AV fistula were all noted as complications.

Haematoma was defined as a localized mass of echogenic fluid outside of the normal vascular space, confined within soft tissue, while the major haematoma was identified as a haematoma with a hematocrit drop of more than 15%. Dissection of femoral artery was defined as an intimal »flap« with arterial blood flowing into the tunica intima or tunica media. Pseudoaneurysm was identified as an extravascular cavity exhibiting flow and communication to the femoral artery through a connecting path, with a characteristic »to and from« Doppler pulsed wave signal, whereas the AV fistula was referred to as an abnormal communication between the femoral artery and vein.

Statistical analysis

Statistical analysis was performed by means of the SAS System for Windows, release 8.02. Nonparametric statistics, Mann-Whitney test and Chi-square test were applied for testing the differences between the testing groups. Multivariate logistic regression analysis was used to determine independent predictors to potential contributors for vascular complications. Spearman correlation was used for correlation evaluation between presumed parameters. A value of $p < 0.05$ was considered statistically significant.

Results

247 (77.4%) patients had normal duplex sonogram while 72 (22.6%) manifested local complications. Minor haematomas, were found in 48 (15.1%), pseudoaneurysm in 17 (5.3%), AV fistula in 2 (0.6%) and arterial dissection in 5 (1.6%) patients. Neither patient had major haematoma which would require transfusion.

Baseline demographic parameters and ultrasound characteristics of common femoral artery were similar among patients with and without access site complications as shown in Tables 1 and 2. According to the multivariate logistic regression analysis conventional risk factors such as gender, age, diabetes, arterial hypertension, femoral artery wall characteristic were not identified as predictors for local vascular complications.

Antiplatelet and anticoagulant drugs were used more often in the group with documented complications (Table 3). More complications were documented in patients receiving PCI compared to the patients who underwent diagnostic procedures (39.4% vs. 24.1%, $p = 0.015$, Table 4). PCI group had longer durations of angiographic pro-

TABLE 1
BASELINE CHARACTERISTIC

Patients	Without complications	With complications	p value
Age	61.3 ± 9.9	60.11 ± 2.8	0.378
Men	165 (66.8)	49 (68.06)	0.887
Hypertension	219 (88.6)	63 (87.5)	0.835
Diabetes mellitus	49 (19.9)	17 (23.6)	0.511
Body mass index (kg/m ²)	27.59 ± 3.8	27.6 ± 3.4	0.692

Results are X ± SD or number (%)

TABLE 2
VESSEL WALL CHARACTERISTIC AND POSTCATHETERIZATION COMPLICATIONS

Vessel's Characteristics	Without complications	With Complications	p value
Diameter			
CFA* (mm)	7.24 ± 1.42	7.39 ± 1.32	0.320
CFA wall thickness (mm)	1.75 ± 0.67	1.70 ± 0.55	0.721
(diameter CFA) : (CFA wall thickness) ratio	4.72 ± 1.98	4.82 ± 1.79	0.438

Results are X ± SD

CFA – Common femoral artery

TABLE 3
INCIDENCE OF APPLIED ANTIPLATELETS AND ANTICOAGULATN THERAPY AND COMPLICATIONS

Medication	Without complications	With complications	p value
Ticlopidin	97 (39.4)	43 (59.7)	0.03
Heparin	76 (38.9)	33 (45.8)	0.024
Tirofiban or Eptifibatide	8 (3.3)	8 (11.1)	0.013
Ticlopidine+Heparin+Tirofibane or Eptifibatide	0.71 ± 0.93	1.1 ± 1.05	0.003

TABLE 4.
PROCEDURAL CHARACTERISTICS IN POPULATION WITH AND WITHOUT COMPLICATIONS

Procedural characteristics	Without complications	With complications	p value
Number of previous catheterizations	1.39 ± 0.74	1.49 ± 0.95	0.951
Number of femoral punctures	1.06 ± 0.34	1.13 ± 0.48	0.154
Duration of total procedure in angio suite (min)	25.48 ± 15	36.38 ± 24.91	<0.001
PCI	59 (24.8)	28 (39,44)	0.015
Size of femoral artery sheath (French)	6.75 ± 0.44	6.83 ± 0.41	0.202
Duration of arterial sheath placement (min)	144.91 ± 147.02	201.62 ± 173.16	0.037

Results are X ± SD or number (%)

PCI – Percutaneous coronary intervention

cedure and femoral artery sheath placement, with a prolonged interval of manual compression (Table 5).

Haemodynamic disorders during manual compression were more frequent among the patients with complications. The level of pain experienced in the group with documented complications was also significantly higher (Table 6 and 7).

Pain perception of moderate to high level during manual compression and after bandage removal as a clinical sign for possible pseudoaneurysm formation has sen-

sitivity of 7.5 % and specificity of 94.3 %. Local hematoma as a clinical sign of pseudoaneurysm has sensitivity 22.7 % and specificity 98.4 % according to our results.

Discussion

Incidence of femoral artery pseudoaneurysm development after coronary catheterization in our study was 5.3 %, which correlates well with what is reported in the literature (1–14%)¹⁵. The observed incidence however, signif-

TABLE 5
CHARACTERISTICS OF THE GROUP SUBMITTED TO DIAGNOSTIC AND THERAPEUTIC CATHETERIZATION (PTCA)

Characteristics	Diagnostic catheterization	PTCA	Significance P value
Duration of vascular sheath placement in femoral artery (minutes)	95.89 ± 100	341 ± 200	0.001
Sheath size (Frenches)	6.72 ± 0.45	6.91 ± 0.36	0.001
Duration of total procedure (minutes)	21.81 ± 13.5	44.55 ± 21.12	0.001
* CFA diameter (mm)	7.29 ± 1.3	7.22 ± 1.51	0.742
* CFA wall thickness (mm)	1.71 ± 0.63	1.81 ± 0.64	0.201
Duration of manual compression (minutes)	19.46 ± 7.86	22.82 ± 8.82	0.002

Results are X±SD

CFA – Common femoral artery

PTCA – Percutaneous coronary angioplasty

TABLE 6
HEMOSTASIS AND COMPLICATIONS

Characteristics related to hemostasis	Without complications	With complications	p value
Duration of manual compression (min)	19.73 ± 7.83	22.52 ± 9.31	0.027
Hemodynamic disorders while achieving hemostasis	11 (4.5)	8 (11)	0.047
Level of pain	1.15 ± 0.41	1.39 ± 0.66	0.010

TABLE 7
CORRELATION OF HEMODYNAMIC DISTURBANCES DURING MANUAL COMPRESSION AND PERIPROCEDURAL DATA

Periprocedural parametar	Measured value	Rho value
Duration of the procedure(min)	27.95 ± 18.86	0.182**
Pain perception (level)	1.2 ± 0.49	0.185**
Duration of the compression (min)	20.35 ± 8.24	0.203**
Serious femoral complications	24 (13.3)	0.176**
Duration of the arterial sheath positioned in the CFA (min)	162.31 ± 173.29	0.165**

CFA – common femoral artery

Correlation is significant at the 0.01 level

icantly exceeds the one of 0.06–0.7%, which is reported in populations assessed with ultrasound, only when a pseudoaneurysm was suspected solely by clinical signs¹⁶. Arteriovenous fistulas in our patients were observed in 2 (0.6%), which was comparable with the data coming from the large prospective trials¹².

Patients' characteristics (age, gender, arterial hypertension, diabetes, body mass index, and femoral wall parameters) at least according to our results had no influence on the vascular integrity or femoral complications following a coronary catheterization. This was comparable to the data published by Schaub¹⁷ who found no significant differences between the patient characteristics in groups with and without a pseudoaneurysm after femoral puncture. We found no increase in incidence of access site complications in patients with repeated catheterization and those with multiple femoral punctures.

Our data demonstrated that prolonged duration of femoral sheath placement has linear correlation with incidence of access site complications. Recent meta-analysis

showed that in spite of shortened duration of hemostasis, use of vascular closure device (VCD) hasn't decreased the number of complications in settings of PCI¹⁸.

Not surprisingly, pseudoaneurysms were more common in patients that underwent PCI. That group of patients received aggressive anticoagulant and antiplatelet therapy during and after the PCI and had a bigger introducer sheath placed in the femoral artery. Development of the VCD was enthusiastically welcomed in interventional community because of their ability to decrease time to hemostasis, period to ambulation and theoretically achieve hemostasis in the cath-lab. However, two recent meta-analyses have failed to demonstrate an advantage of the VCD in reducing access site complications in comparison to manual compression in diverse groups of diagnostic and interventional patients^{19–21}.

According to our data, pseudoaneurysm formation in patients in whom hemostasis were achieved with manual compression could probably be reduced with an earlier sheath removal, and rational anticoagulation.

Level of pain (determined by visual analogue scale), hemodynamic changes (blood pressure drop or bradycardia) during hemostasis and the duration of manual compression had positive correlation with appearance of local complications. Those findings should prompt higher alertness for early use of duplex sonography in order to detect and treat pseudoaneurysms and AV fistulas, especially due to the low sensitivity of clinical signs (local hematoma and local tenderness on the femoral puncture site).

Study limitations

Further research with higher numbers of patients is required because of relatively low incidence of pseudoaneurysms and AV fistula. Newer anticoagulant medications used during PCI have been associated with lower incidences of bleeding (bivalirudin). However these medications were unavailable during our analysis²². Future

studies should evaluate correlation between bivalirudin and access site complications assessed by duplex sonography.

Conclusion

Access site complications occur frequently during cardiac catheterization. Bed-side diagnosis of the pseudoaneurysm, as the most important complication of femoral puncture could not be achieved on the clinical ground only, because of very low sensitivity of local physical findings. Clinical symptoms and signs could be subtle, therefore high awareness and low threshold for the use of duplex ultrasound should be utilized in the patient population. Special attention is needed in the setting of aggressive anticoagulant therapy, interventional procedures and hemodynamic disturbances during manual hemostasis.

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LOKALNE VASKULARNE KOMPLIKACIJE NAKON KATETERIZACIJE SRCA

SAŽETAK

Najčešći uzroci periproceduralnog morbiditeta nakon kateterizacije srca su lokalne vaskularne komplikacije na mjestu arterijske punkcije. Incidencija komplikacija prema podacima iz literature je varijabilna obzirom na načine i metode kojima su komplikacije definirane i dijagnosticirane. Cilj ove prospektivne studije je utvrditi incidenciju lokalnih komplikacija punkcijskog mjesta pomoću duplex ultrazvučne pretrage pristupne arterije. U studiju je uključeno ukupno 319 kateteriziranih bolesnika kojima je u periodu od 24 do 48 sati nakon kateterizacije i manualne kompresije učinjen duplex arterije na mjestu punkcije. Dijagnostičku koronarografiju imalo je ukupno 232 (71,8%) bolesnika, dok je 87 (28,2%) imalo perkutanu koronarnu intervenciju. Uredan nalaz kolor Dopplera punkcijog mjesta imalo je 247 (77,4%) bolesnika. Hematom je dijagnosticiran u 48 (15,1%), pseudoaneurizma u 17 (5,3%) AV fistula u 2 (0,6%) a disekcija femoralne arterije u 5 (1,6%) bolesnika. Demografske osobitosti skupina bolesnika sa i bez femoralnih komplikacija nisu se bitno razlikovale. Komplikacije kao što su pseudoaneurizme i AV fistule češće su se pojavljivale u bolesnika u kojih je učinjena

perkutana koronarna intervencija (9,2% vs. 4,7% $p < 0,001$), u bolesnika kod kojih je bila primjenjivana antikoagulantna i antiagregacijska terapija ($p = 0,003$) te kod bolesnika koji su za vrijeme manualne kompresije imali hemodinamske poremećaje kao što su hipotenzija i bradikardija (11% vs. 4,5%, $p = 0,047$). Primjena duplexa arterija kod kliničke sumnje na postojanje lokalnih vaskularnih komplikacija nakon kateterizacije srca bi trebala biti pristupačnija i češće primjenjiva metoda. Posebnu pozornost zaslužuju bolesnici nakon perkutane koronarne intervencije, kod kojih je primjenjeno antitrombocitno i antikoagulantno liječenje ili su imali hemodinamske poremećaje tijekom hemostaze postignute manualnom kompresijom.