Determinants of iatrogenic femoral pseudoaneurysm after cardiac catheterization or percutaneous coronary intervention via the femoral artery

Femoral yol ile yapılan kalp kateterizasyonu veya perkütan koroner girişimler sonrası gelişen iyatrojenik femoral psödoanevrizma komplikasyonunun belirteçleri

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ABSTRACT

Objective: This study aimed to define the prevalence and predictors for pseudoaneurysm after coronary angiography, cardiac catheterization and percutaneous coronary interventions (PCIs) performed via the femoral artery.

Methods: The study included 8469 patients enrolled between January 2007 and December 2009 on whom cardiac catheterization, coronary and/or peripheral angiography and PCIs via the femoral artery were performed. All data, including clinical characteristics and complications, were obtained retrospectively from patient chart records.

Results: Pseudoaneurysm was detected in 65 (0.76%) patients. Pseudoaneurysm was ascertained more frequently in patients with a history of coronary artery disease (0.9% *vs.* 0.4%; p=0.012), in females than in males (1.4% *vs.* 0.5%; p<0.001), in patients older than 65 years (1.2% *vs.* 0.6%; p=0.002), in patients with a history of femoral artery intervention (1.2% *vs.* 0.6%; p=0.01), in hypertensives than in normotensives (1.3% *vs.* 0.5%; p<0.001), in patients taking low molecular weight heparin (1.0% *vs.* 0.2%; p<0.001), in patients taking clopidogrel (1.0% *vs.* 0.4%; p=0.007), and in patients with chronic renal disease (3.8% *vs.* 0.7%; p<0.001). There was no statistically significant trend (1.2% *vs.* 0.7%; p=0.053) towards more pseudoaneurysm formation in emergent interventions than in elective procedures.

Conclusion: Patients with a higher risk of pseudoaneurysm development following intervention via the femoral artery should be specified and extra attention given during the intervention. These patients should be informed of the increased risk of this complication and its results, and should be under close follow-up concerning development of iatrogenic femoral pseudoaneurysm.

ÖZET

Amaç: Bu çalışmanın amacı femoral yol ile koroner anjiyografi, kalp kateterizasyonu ve perkütan koroner girişim (PKG) yapılan hastalarda, psödoanevrizma sıklığını ve psödoanevrizma gelişiminin öngördürücülerini belirlemektir.

Yöntemler: Bu çalışmaya Ocak 2007 ile Aralık 2009 tarihleri arasında femoral yoldan kalp kateterizasyonu, koroner ve/veya periferik anjiyografi ve PKG yapılan 8469 hasta alındı. Hastaların klinik özellikleri ve komplikasyonlar gibi tüm veriler geriye dönük olarak hasta dosya kayıtlarından elde edildi.

Bulgular: Çalışmaya alınan hastaların 65'inde (%0.76) psödoanevrizma tespit edildi. Risk faktörleri psödoanevrizma komplikasyonu açısından değerlendirildiğinde, psödoanevrizma koroner arter hastalığı tespit edilen hastalarda olmayanlara göre (%0.9, %0.4; p=0.012), kadın hastalarda erkek hastalara göre (%1.4, %0.5; p<0.001), 65 yaş üstü hastalarda 65 yaş ve altı hastalara göre (%1.2, %0.6; p=0.002), femoral arteryel girişim öyküsü olanlarda olmayanlara göre (%1.2, %0.6; p=0.01), hipertansiyon öyküsü olanlarda olmayanlara göre (%1.3, %0.5; p<0.001), düşük molekül ağırlık heparin kullanılanlarda kullanılmayanlara göre (%1.0, %0.2; p<0.001), klopidogrel alanlarda almayanlara göre (%1.0, %0.4; p=0.007) ve böbrek yetersizliği olanlarda olmayanlara göre (%3.8, %0.7; p<0.001) anlamlı olarak daha fazla ortaya çıkmıştır. Elektif olarak yapılan girişimlere göre acil girişimlerde psödoanevrizma oranı daha fazla olarak bulundu (%0.7, %1.2), ancak sonuçlar istatistiksel olarak sınırda anlamlıydı (p=0.053).

Sonuç: Femoral arter yoluyla girişim yapılırken psödoanevrizma gelişimi açısından yüksek riskli hastalar belirlenmeli ve bu gruptaki hastalara girişim daha dikkatli yapılmalı, hastalar bu komplikasyon ve sonuçları açısından bilgilendirilmeli ve girişim sonrası iyatrojenik femoral psödoanevrizma açısından yakın takip edilmelidir.

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Vascular complications are common after coronary angiography, cardiac catheterization and percutaneous coronary intervention (PCI).[1] Recent trials have shown that while complication due to interventions via the femoral artery is 1.8% in diagnostic procedures, it is approximately 4% in interventional procedures.[1] Potential complications include hemorrhage, thrombosis, peripheral embolism, dissection, aneurysm, pseudoaneurysm, arteriovenous fistula, infections and trauma to surrounding tissues.[2–7] There are various factors for development of pseudoaneurysm of the femoral artery.[8] The complication of pseudoaneurysm has become more important because of its increased prevalence due to greater numbers of diagnostic and interventional percutaneous procedures and their complexity.[9] While iatrogenic pseudoaneurysm of the femoral artery does not enhance mortality, it augments morbidity.[9] It prolongs duration of hospital stay and raises expenditure by virtue of additional diagnostic examinations and treatments.

Pseudoaneurysm may be diagnosed with conventional angiography, computed tomography (CT), magnetic resonance imaging (MRI) and even with scintigraphy. However, ultrasonography is the most commonly preferred technique.[10] Doppler arterial examination is the gold standard, with a 100% diagnostic accuracy in defining iatrogenic pseudoaneurysm.[11] Ultrasonography may also be used as a part of the treatment modality.

This study aimed to detect and define the prevalence and predictors of pseudoaneurysm after coronary angiography, cardiac catheterization and PCIs via femoral artery.

METHODS

This retrospective study comprised 8469 patients on whom cardiac catheterization, coronary and/or peripheral angiography and PCI via femoral artery was performed between January 2007 and December 2009. The following were all evaluated retrospectively: Patient demographic features; presence of coronary artery disease (CAD); presence of risk factors for CAD including diabetes mellitus (DM), hypertension (HT), age, gender, smoking and hyperlipidemia; manner of procedure (emergent or elective); the respective effects of diagnostic angiography and interventional procedure; history of vascular entry; administered antiaggregant (acetylsalicylic acid, clopidogrel and tirofiban) and anticoagulant; accompanying comorbidities; utilisation of an intraaortic balloon pump (IABP); and presence of a concomitant venous sheath. Patients with pseudoaneurysm were registered. Records of catheter laboratory and surgery rooms, and reports of ultrasound were utilised in addition to patient files and epicrises. The study was approved by the local review board and ethics committee.

Abbreviations:

BMI	*Body mass index*
CAD	*Coronary artery disease*
DM	*Diabetes mellitus*
HT	*Hypertension*
IABP	*Intraaortic balloon pump*
LMWH	*Low molecular weight heparin*
PCI	*Percutaneous coronary intervention*
PTCA	*Percutaneous transluminal coronary angioplasty*
UFH	*Unfractionated heparin*

Process of femoral vascular entry

Interventions were performed using the Seldinger method via the femoral artery. 8F and 9F sheaths were used for patients who were implanted with an IABP, while 6F and 7F sheaths were chosen in patients without an IABP. 6F and 7F sheaths were used for venous entry necessitated concomitantly.

Procedure of anticoagulant and antiaggregant therapy

Unfractionated heparin (UFH) or low molecular weight heparin (LMWH) were not routinely administered to those patients undergoing diagnostic coronary angiography. Patients undergoing PCI were administered 100 unit/kg UFH if they had not been in prior receipt of any other anticoagulants. Antiaggregant agents were determined by the responsible physician according to patient clinical status and procedure performed.

Removal of sheath and establishment of local hemostasis

Sheaths were retracted immediately after diagnostic angiography or cardiac catheterization unless the patients were anticoagulated. Sheaths were retracted after normalization of Activated Partial Thromboplastin Time (APTT) if the patients were anticoagulated. Manual compression was applied increasingly to a point 2 cm above the incision while the sheath was being withdrawn, and applied for 15–20 minutes until local hemostasis was achieved. Compression with sandbag was then implemented for 6–8 hours. A venous sheath, if present, was retracted 3–5 minutes after arterial sheath withdrawal using the same

technique. No vascular closure device or groin band was utilised. The groin entry point was checked during hospital stay and just before discharge. Ultrasonographic examination was performed if there was any suspicion of groin complication, particularly pain or swelling at the entry point and/or tenderness or pulsatile mass in the groin.

Diagnosis of pseudoaneurysm

Pseudoaneurysm diagnosis was made with 2-dimensional ultrasonographic and colored Doppler examination by radiologists working in our institution. Apart from ultrasonography, no invasive or non-invasive diagnostic modality was used. The pseudoaneurysm sac is visualized in 2-dimensional ultrasonographic examination as a hypoechogenic cavity with a thin neck connecting to the lumen of the main artery. To-and-fro flow is shown typically in the neck of the pseudoaneurysm and the yin-yang view in the sac is seen with Doppler examination. Iatrogenic pseudoaneurysms developing after femoral artery interventions were registered from patient records in our trial. Pseudoaneurysm size and the artery from which it was stemming were recorded.

Statistical analysis

Data were presented as numbers and percentages and analyzed with the Statistical Package for the Social Sciences (SPSS) software version 15.0 for Windows. Normally distributed numerical data were analyzed with the Kolmogorov-Smirnov test. Analysis of data was two-stage. Univariate analysis was done in the first stage. The chi-square test was used to compare categorical variables, and the t test to assess continuous variables. In the second stage, CAD, manner of procedure, gender, age, history of vascular entry, HT, use of LMWH, use of clopidogrel and renal disease were evaluated for impact on the pseudoaneurysm using multivariate backward logistic regression analysis. Those factors having an impact on the pseudoaneurysm were assessed with Odds ratio. A P-value of <0.05 was considered statistically significant.

RESULTS

The study included 8469 patients (6110 male; 72.1%, 2359 female; 27.9%). Patient mean age was 58.6±12.2 years (male mean age; 58.1±11.9, female mean age; 59.9±12.8). Diagnostic coronary and/or peripheral angiography was performed on 5663 (66.9%) patients. A PCI (balloon angioplasty and/or stent implantation) was performed on 2656 (31.3%) patients, with right and left cardiac catheterization performed on 150 (1.8%) patients. Emergent interventions were performed on 1452 (17.1%) patients via the femoral artery route. Clinical characteristics of the patients are shown in Table 1.

A history of femoral artery entry was present in 2423 patients (28.6%). Peripheral artery disease was present in 221 patients (2.6%), while 6270 patients (74%) had CAD. Acetylsalicylic acid (ASA) was administered to 7717 patients (91.1%), LMWH to 5915 (69.8%), clopidogrel to 5559 (65.6%), and tirofiban infusion to 1286 (15.1%) on the day of intervention via the femoral artery. An IABP was utilised in 52 patients (0.6%) during coronary angiography and/or percutaneous intervention. Pseudoaneurysm did not develop in any patient with IABP. Concomitant femoral vein entry was provided in 348 patients (4.1%).

Table 1. Clinical features of patients (n=8469)

	%
Age (year) (Mean±SD)	58.6±12.2
Older than 65 years	30.1
Female gender	27.9
Coronary artery disease	74
Emergent intervention	17.1
Percutaneous coronary intervention	31.3
Peripheral artery disease	2.6
History of femoral arterial entry	28.6
Diabetes mellitus	17.5
Hypertension	34.6
Hyperlipidemia	74.5
Smoking	23.5
Use of aspirin	91.1
Use of low molecular weight heparin	69.8
Use of clopidogrel	65.6
Use of tirofiban	15.1
Use of thrombolytic agent	0.8
Presence of renal dysfunction	1.5
Presence of heart failure	10.3
Utilisation of intraaortic balloon pump	0.6
Concomitant femoral vein entry	4.1
Right and left cardiac catheterization	1.8
Pseudoaneurysm	0.76

Table 2. Risk factors of pseudoaneurysm

Variables		Pseudoaneurysm		*p*
		n	%	
Coronary artery disease	–	8	0.4	0.012
	+	57	0.9	
Emergent or Elective	Elective	48	0.7	0.053
	Emergent	17	1.2	
Gender	Male	31	0.5	<0.001
	Female	34	1.4	
Age	≤65	34	0.6	0.002
	>65	31	1.2	
Percutaneous coronary intervention	–	34	0.6	NS
	+	31	1.1	
Peripheral arterial disease	–	61	0.7	NS
	+	4	1.8	
History of femoral artery entry	–	37	0.6	0.01
	+	28	1.2	
Diabetes mellitus	–	50	0.7	NS
	+	15	1.0	
Hypertension	–	28	0.5	<0.001
	+	37	1.3	
Hyperlipidemia	–	11	0.5	NS
	+	54	0.9	
Smoking	–	51	0.8	NS
	+	14	0.7	
Low molecular weight heparin	–	6	0.2	<0.001
	+	59	1.0	
Aspirin	–	3	0.4	NS
	+	62	0.8	
Clopidogrel	–	12	0.4	0.007
	+	53	1.0	
Tirofiban	–	47	0.7	NS
	+	18	1.0	
Renal dysfunction	–	60	0.7	<0.001
	+	5	3.8	
Heart failure	–	58	0.8	NS
	+	7	0.8	
Concomitant femoral vein entry (%)	–	60	0.7	NS
	+	5	1.4	
Right and left cardiac catheterization	–	62	0.8	NS
	+	3	2.0	

NS: Non-significant (p>0.05).

Table 3. Multivariate backward logistic regression analysis in patients with femoral artery entry regarding development of pseudoaneurysm

Variables	Risk ratio	95% confidence interval	*p*
Emergent intervention	3.86	0.309–0.998	0.049
Female	20.8	0.176–0.500	<0.001
History of femoral artery entry	8.84	0.270–0.764	0.003
Hypertension	4.94	0.332–0.993	0.026
Low molecular weight heparin	7.25	0.125–0.721	0.007
Renal dysfunction	10.71	0.078–0.528	0.001

A total of 65 of the 8469 patients (0.76%) developed pseudoaneurysm.

Pseudoaneurysm was ascertained more frequently in patients with a history of coronary artery disease (0.9%, 0.4%; p=0.012), in females than in males (1.4%, 0.5%; p<0.001), in patients older than 65 years (1.2%, 0.6%; p=0.002), those with a history of femoral artery intervention (1.2%, 0.6%); p=0.01), in hypertensives than in normotensives (1.3%, 0.5%; p<0.001), those taking LMWH (1.0%, 0.2%; p<0.001), those taking clopidogrel (1.0%, 0.4%, p=0.007), and in patients with chronic renal disease (3.8%, 0.7%; p<0.001). The number of pseudoaneurysms was more prevalent in emergent cases than in elective cases (1.2% *vs.* 0.7%). However, it was statistically borderline significant (p=0.053).

Pseudoaneurysm development was ascertained to be greater, but not to a statistically significant level, in patients who underwent a PCI (balloon angioplasty and/or stent implantation) (1.1% *vs.* 0.6%), those with peripheral arterial disease (1.8% *vs.* 0.7%), in patients with DM (1% *vs.* 0.7%), with hyperlipidemia (0.9% *vs.* 0.5%), in patients using ASA (0.8% *vs.* 0.4%), those using tirofiban (1% *vs.* 0.7%), in patients with a concomitant femoral venous sheath (1.4% *vs.* 0.7%) and in those undergoing right and left cardiac catheterization (2% *vs.* 0.8%).

Moreover, there was no statistical difference regarding pseudoaneurysm development among patients who smoked (0.7% *vs.* 0.8%) and patients with heart failure (0.8% *vs.* 0.8%). The risk factors for pseudoaneurysm are given in Table 2.

According to ultrasonographic examination, a pseudoaneurysm developed in the common femoral artery in 41 patients (63%), in the superficial femoral artery in 21 (32%), and in the deep femoral artery in 3 (5%).

Mean body mass index (BMI) was 28.1±3.4 in patients with pseudoaneurysm. However, there was no statistical significance between male and female patients with pseudoaneurysm (28.3±3.4 in females, 27.7±3.4 in males; p>0.05).

Multivariate backward logistic regression analysis showed femoral artery entry in patients with emergent conditions (p=0.049), female gender (p<0.001), history of femoral artery entry (p=0.003), presence of HT (p=0.026), use of LMWH (p=0.007) and presence of renal dysfunction (p=0.001) to be independent predictors of iatrogenic femoral artery pseudoaneurysm development (Table 3).

DISCUSSION

Increasing numbers of diagnostic and therapeutic femoral interventions and usage of recently-introduced antiaggregant drugs contribute to the enhancement of pseudoaneurysm as a complication. The number of studies to demonstrate the impact of these new antiaggregants on frequency of pseudoaneurysm is inadequate. Specifying patients at high risk of pseudoaneurysm development may stimulate us to pay more attention in order to prevent this complication and, in the event of its occurrence, diagnose and treat it earlier.

Alhan et al. stated that peripheral vascular complications necessitating surgery were determined to be 0.7% with color Doppler ultrasonography among 1949 patients undergoing coronary intervention.[12] Our trial similarly detected the incidence of pseudoaneurysm necessitating surgery as 0.76%.

Katircibaşi et al.[13] reported pseudoaneurysm development in 5.9% of 321 patients undergoing percutaneous transluminal coronary angioplasty (PTCA). In

that study, formation of pseudoaneurysm was found more prevalent in female patients, those older than 65 years, those with a history of PTCA, those administered fibrinolytic treatment, and those with femoral venous access for transient pacemaker implantation and patients with an IABP. In contrast, administering glycoprotein IIb/IIIa inhibitors before or after PTCA did not enhance frequency of pseudoaneurysm. An increased frequency of pseudoaneurysm in patients with recurrent ipsilateral femoral artery entry was attributed to difficulty of femoral artery puncture by virtue of locally developed fibrosis owing to recurrent trauma of prior punctures. Furthermore, in the same study an increase in pseudoaneurysm in patients with an IABP was attributed to use of wider sheaths (8F and 9F) and continuation of heparin during stay of the IABP. In our study, age of 65+ years and history of ipsilateral femoral entry were also found to be related to pseudoaneurysm development. Additionally, history of femoral entry was detected to be an independent predictor of pseudoaneurysm. Use of tirofiban, a Gp IIb/IIIa inhibitor, resulted in enhanced pseudoaneuryms. However, the difference was not of statistical significance. Use of clopidogrel was not found to be an independent predictor, albeit that its use was ascertained to increase the risk of pseudoaneurysm development. The number of pseudoaneurysms detected was greater in patients with concomitant femoral venous sheath, although this was not of statistical significance. On the other hand, pseudoaneurysm was not ascertained in patients with an IABP. This could be due to the fact that IABP patients were more morbid as cardiogenic shock. Most of these patients died in the early term. Furthermore, this could be due to use of smaller diameter balloons, a lack of cautious follow-up of femoral pulse and entry site and less attentive and firm bandage application. Hence, it demonstrates that firm bandage and cautious follow-up of entry site might diminish frequency of development of pseudoaneurysm.

Erentuğ et al.[14] stated that 42 peripheral vascular complications necessitating surgical repair were ascertained in a retrospective series of 64,911 patients who underwent cardiac catheterization. The most common complication was thrombosis followed by pseudoaneurysm formation. Dissimilarly, there was no difference regarding frequency of complications between male and female patients and between patients older than 60 years and younger than 60 years. Moreover, a tendency towards more vascular complications necessitating surgical repair was detected in angioplasty/stent implantation patients. In our study, frequency of pseudoaneurysm was enhanced in PCI patients compared with diagnostic coronary angiography patients, although it did not reach statistical significance. The cause of increased frequency of pseudoaneurysm in patients undergoing a PCI might be due to use of larger catheters, longer procedure duration and utilisation of additional anticoagulant and/or antiaggregant drugs.

Contrary to the literature, femoral arterial entry in emergent interventions was ascertained to be an independent predictor of femoral pseudoaneurysm formation in our retrospective trial. The enhanced risk of pseudoaneurysm in emergent PCI patients may be a result of longer procedure duration and intense use of anticoagulant and antiaggregant drugs, as almost all interventions were performed due to acute coronary syndrome.

In our trial, no relevance for pseudoaneurysm development was found for ASA, which is indispensable in CAD treatment, or for smoking and hyperlipidemia, both of which are classical risk factors for CAD. Moreover, heart failure was not found to be associated with pseudoaneurysm, and no relationship was ascertained between femoral artery pseudoaneurysm and thrombolytic use before femoral artery entry. Primary PCI is the first line therapy of ST segment elevation myocardial infarction in our clinic. Patients administered thrombolytic therapy were almost all referred from other hospitals. Thus, the duration between thrombolytic treatment and PCI was more than 3-4 hours. Short-acting fibrin specific thrombolytics were commonly used before referral. Disappearance of impact of the thrombolytic agent prior to performing coronary intervention might explain the absence of an increase in pseudoaneurysm incidence. The frequency of pseudoaneurysm was enhanced in PCI patients due to use of larger size catheters, longer duration of procedure and additional use of anticoagulants and/or antiaggregants, albeit the difference was statistically insignificant.

Forty-one pseudoaneurysms stemmed from the common femoral artery, 21 from the superficial femoral artery and 3 from the deep femoral artery. If all other procedures were assumed to be performed via the common femoral artery, 24 out of 65 (37%) pseudoaneurysms stemming from other than common femoral artery may demonstrate a strong relationship

between wrong arterial entry and high vascular complications.

Use of LMWH, female gender and renal dysfunction were determined as independent predictors of pseudoaneurysm. Thrombocyte dysfunction owing to renal dysfunction could lead to a bleeding tendency and deterioration of local hemostasis, both of which may contribute to an enhanced risk of pseudoaneurysm. The number of pseudoaneurysms was higher, albeit without any statistical significance.

Ates et al.[15] stated that 630 patients underwent surgical repair of pseudoaneurysm among 41,322 patients undergoing intervention via the femoral artery route. HT, DM, presence of CAD, higher BMI (≥28 kg/m²) and use of larger catheters were demonstrated to be independent predictors of development of femoral pseudoaneurysm in this trial. HT was determined as an independent predictor of femoral pseudoaneurysm, but no significant correlation was detected with DM and the complication. Similarly, presence of CAD was found statistically significant regarding pseudoaneurysm development.

In contrast to the literature, this study found femoral artery entry during emergent cases to be an independent predictor of pseudoaneurysm. Almost all emergent cases were due to acute coronary syndrome which led to longer procedure duration and intensive anticoagulant and antiaggregant use. Thus, this could explain the increased risk of pseudoaneurysm in emergent cases.

In conclusion, extra attention is needed with patients at higher risk of pseudoaneurysm development during intervention via the femoral artery. These patients should be informed regarding the increased risk of this complication and its results, and should remain under close follow-up concerning development of iatrogenic femoral pseudoaneurysm.

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