New risk scoring system for femoral pseudoaneurysm formation after cardiac catheterization (Ateş Scoring System)

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Aim: To create a new scoring system for femoral pseudoaneurysm (FPA) formation after diagnostic or interventional cardiac catheterization.

Materials and methods: We evaluated 41,322 transfemoral catheterization procedures performed in our center within 7 years. Among all procedures, 630 FPAs developed that required surgical repair. Eighty-five cases were managed by compression with duplex guidance. As a case-control group, 1260 patients were selected from the patients who had been catheterized during the same time period but did not develop FPA. We created the risk scoring system according to body mass index, hypertension, diabetes mellitus, catheter diameter, coronary artery disease, atherosclerosis, and number of patients treated per day in a particular room.

Results: FPA required operative repair in 1.1% of patients who underwent cardiac catheterization for diagnosis and in 4.7% of cardiac interventional procedures. We determined that if the risk score is greater than 15, the probability of formation of a FPA is 7 times greater than normal.

Conclusion: This study confirms that FPA is a morbid situation, and high risk scores are important because FPA formation is 7 times greater than normal. This novel method of calculating risk score allows for the stratification of patients into 4 levels of risk.

Key words: Femoral pseudoaneurysm, femoral catheterization, risk scoring

1. Introduction
Pseudoaneurysms are pulsatile masses that connect with arterial lumen, destroying the wall entirely. Pulsatile mass, palpable thrill, and audible to-and-fro murmur are characteristics for the diagnosis of pseudoaneurysms (1).

Vascular complications at the puncture site represent an ongoing hazard of percutaneous coronary and peripheral vascular catheterizations. Although many complications remain minor and can be corrected conservatively or with minimal surgery under local anesthesia, these treatments extend the length of hospitalization, the cost of the underlying catheter procedure, and patient discomfort.

Femoral pseudoaneurysm (FPA) occurs in 0.1% to 0.2% of diagnostic angiograms and 0.8% to 2.2% of cases following interventional procedures (2). With more than 1 million cardiac catheterizations being performed in the United States each year, postprocedure pseudoaneurysm is a relatively rare occurrence. The incidence of this complication has recently increased with the more frequent use of thrombolytic antiplatelet agents and anticoagulants, and larger-sized cannulae for interventional procedures (3). FPAs are usually caused by punctures of the femoral artery that are too distal, at the level of bifurcation of the femoral artery or below (4). With the advancement of technology in intravascular catheters and increased experience of physicians, the number of angiographic and interventional procedures increases progressively. However, local vascular complications of percutaneous procedures such as bleeding, vessel thrombosis, emboli, dissection, and arteriovenous fistulae present significant clinical problems following catheterization procedures. FPA constitutes the most common of these complications, reported to have an incidence of 0.2%–2% (5). In predicting patients at high risk for FPA, more rigorous measures can be taken for the prevention of this complication. In this way, the number of rehospitalizations and surgical interventions can be reduced.

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We previously reported the correlation between FPA formation and risk factors of body mass index, hypertension, diabetes mellitus, catheter diameter, coronary artery disease, atherosclerosis, and number of patients treated per day in a particular room (6). Here, we want to introduce a new risk scoring system for FPA formation with these factors.

2. Materials and methods
Between 1 January 1997 and 31 December 2003 at our center, 36,218 diagnostic and 5104 interventional catheterization procedures (total = 41,322) for cardiac disease were performed via the femoral artery, and 630 of these patients required surgical repair for FPA formation. During this time, 85 of the small FPA cases could be managed by compression therapy with duplex guidance. These nonsurgical cases were not included in the study. As a case-control group, 1260 patients were selected randomly from the patients who had been catheterized in our institute during the same time. Two control patients were selected for each FPA case. The study and control patients were matched according to age, sex, and catheterization day. Body mass index (BMI), hypertension (HT), diabetes mellitus (DM), coronary artery disease (CAD), catheter diameter, antiaggregant therapy, and the number of patients treated per day in a particular room were evaluated retrospectively as risk factors. P and R values and odds ratios were calculated for each of the 7 parameters. The results were rounded and used to construct the risk score index of each parameter. The risk scores of each parameter with respect to their odds ratios are presented in Table 1, and the scores for BMI (≥28), daily number of patients in a particular room (≥18), catheter number (≥7), presence of CAD, presence of DM, presence of HT, and use clopidogrel were 2, 2, 5, 1, 1, 2, and 7, respectively.

Considering the total risk score as 20, we defined 4 risk groups based on gradation of risk values as follows: values 1 through 5 were considered minimal risk, 5–10 moderate risk, 10–15 high risk, and above 15 severe risk. Referencing this scoring system, scores of the control and study groups were evaluated and their respective percentile ratios were derived.

BMI was calculated using this formula: BMI (kg/m²) = weight/height². The procedures were performed by 30 different cardiologists, who treated 250 to 300 patients per year, in 4 catheterization laboratories in our center. Catheter diameters ranged from 6 F to 8 F. For definite diagnosis and location of the neck, size, and depth of the FPA, a complete vascular examination was performed by color-flow duplex ultrasonography (ATL 3500; HDI, Milwaukee, WI, USA) using a linear probe (5–7.5 MHz). Color-flow Doppler was used to determine the flow into the FPA and was also used for determination of occlusions by detecting the diminishment of the color saturations. The volume of the FPA was calculated with the formula FPA = (width × length × height) × 0.52. All dimensions were measured from the outermost border of the FPA neck. Neck size and length were also determined. Patients with FPAs of 5 cm² or smaller and neck lengths of 8 mm or longer underwent duplex ultrasound-guided compression (n = 85), and all others underwent surgical repair (n = 630).

For the diagnostic angiography procedures, we did not use any anticoagulant or antiplatelet agents. For interventional procedures, 10,000 U of heparin was given by intravenous bolus, followed by 5000 U/h to keep the

<table>
<thead>
<tr>
<th>Variable</th>
<th>Study group (n = 630)</th>
<th>Control group (n = 1260)</th>
<th>P-value</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>28.69 ± 3.33</td>
<td>24.85 ± 3.12</td>
<td>0.001</td>
<td>2.220 (≥28)</td>
</tr>
<tr>
<td>Daily patients in a particular room</td>
<td>18.1 ± 2.8</td>
<td>16.1 ± 2.5</td>
<td>0.001</td>
<td>1.852 (≥18)</td>
</tr>
<tr>
<td>6 F catheter</td>
<td>390 (61.9%)</td>
<td>858 (68.1%)</td>
<td>0.001</td>
<td>5.132 (≥7)</td>
</tr>
<tr>
<td>CAD</td>
<td>410 (65.0%)</td>
<td>712 (56.5%)</td>
<td>0.022</td>
<td>1.025</td>
</tr>
<tr>
<td>DM</td>
<td>280 (44.4%)</td>
<td>453 (35.9%)</td>
<td>0.039</td>
<td>1.125</td>
</tr>
<tr>
<td>HT</td>
<td>390 (61.9%)</td>
<td>712 (56.5%)</td>
<td>0.011</td>
<td>1.825</td>
</tr>
<tr>
<td>Use of clopidogrel</td>
<td>232 (36.8%)</td>
<td>178 (14.2%)</td>
<td>0.001</td>
<td>7.121</td>
</tr>
</tbody>
</table>

activating clotting time between 250 and 300 s. We used clopidogrel (Plavix; Bristol-Myers Squibb, New York, NY, USA) as a single dose of 300 g 6 h before the procedures and continued the clopidogrel at 75 mg/day after the procedures. In diagnostic catheterization procedures, our routine postprocedure hemostasis protocol is manual compression for approximately 20 min and then mechanical compression by sandbag for approximately 2 h. Patients are kept on bed rest for approximately 6 h. Cardiology residents or physician assistants perform this compression. In interventional catheterization procedures, we stabilize the introducer by suturing it to the skin for 6 h, after which we remove the introducer and then apply the same compression as for diagnostic catheterization. All patients who undergo interventional catheterization are observed for at least 1 night in the hospital.

Inclusion criteria for surgical therapy of FPA were rapid expansion of the site of puncture at the groin area, increased skin pressure (tenderness), marked pain, hypotension, pulsatile hematoma, a new thrill or bruit, concomitant distal ischemia or neurological deficit due to local pressure, and a short, noncompressible neck (<8 mm) on Doppler ultrasonography. An FPA volume of more than 5 cm$^2$ in other patients who did not fulfill these criteria was treated conservatively. Eighty-five patients who had a compressible neck and a mass volume of 5 cm$^2$ or less were managed conservatively without operation.

Statistical analyses were performed using SPSS 11 (SPSS Inc., Chicago, IL, USA). Data were analyzed with the Pearson test for numeric variables and the Spearman test for nonparametric variables. Stepwise backward logistic multivariate regression analysis was applied to analyze associations between risk factors and FPA formation. Age and sex were added to these parameters to check for good matching. All values were expressed as mean ± standard deviation. P < 0.05 was considered to be statistically significant.

3. Results
The mean procedure times (interval between sheath insertion and the end of the procedure) for diagnostic angiography and interventional catheterization were 16 ± 6 min and 37 ± 12 min, respectively. Two patients with FPAs died during operation and during the early hospitalization period. In both cases, FPA was repaired concomitantly with coronary artery bypass grafting surgery. The time from the puncture of the femoral artery to FPA diagnosis was 2.1 ± 0.7 days. During FPA repair, 72 patients underwent concomitant femoral embolectomy, and in 83 patients FPA was repaired during coronary artery bypass grafting. Our incidence of FPAs that required surgical repair was 1.1% in diagnostic procedures and 4.7% in interventional procedures. Our overall FPA rate was 1.5%.

Between the evaluated risk factors, the highest risk factor for the development of FPA was the use of clopidogrel. Development of FPA was observed to have a 7-fold increase in patients taking clopidogrel. Similarly, using 7 F catheters will increase the FPA risk 5-fold. BMI over 28, more patients seen daily in a particular room, DM, presence of HT, and presence of CAD will also cause increases in the development of FPA at different rates.

Percent ratios of risk scoring groups and statistical results for the control and study groups are shown in Table 2 and the Figure.

Table 2. Scoring system and percent ratios.

<table>
<thead>
<tr>
<th>Score</th>
<th>Study group (n = 630)</th>
<th>Control group (n = 1260)</th>
<th>Study group (% ratio)</th>
<th>Control group (% ratio)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–5</td>
<td>26</td>
<td>441</td>
<td>4</td>
<td>35</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>5–10</td>
<td>96</td>
<td>391</td>
<td>15</td>
<td>31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10–15</td>
<td>223</td>
<td>331</td>
<td>35</td>
<td>26</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>15–20</td>
<td>285</td>
<td>97</td>
<td>45</td>
<td>8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Figure. Graphical view of scoring system. FPA: femoral pseudoaneurysm.
4. Discussion
There are many risk scoring systems in cardiac surgery (7,8) designed according to patient characteristics and focused on mortality and morbidity. We designed a new scoring system for FPA formation according to independent risk factors that had been previously found. The incidence of FPA has increased dramatically in recent years and is estimated at 0.5% for diagnostic procedures; it may increase to 9% or more for therapeutic procedures. This increasing incidence is associated with the increased number of arterial punctures performed for diagnostic or therapeutic purposes and with their complexity and duration.

There are many risk factors for FPA. It has been reported that anticoagulation or antiplatelet therapy before catheterization speeds pseudoaneurysm formation. Other risk factors for the development of FPA are age older than 60 years, female sex, catheter size greater than 7 F, and concurrent anticoagulation (9). We created our new scoring system for FPA from these risk factors and we are using this scoring system. We think that this scoring system is basic and easily used. If the risk score is greater than 15, the probability of formation of FPA is 7 times greater than normal. If a patient has a score above 15, cardiologists are informed and operate with care.

Risk stratification will inform patients and clinicians of the likely risk of FPA. The use of antiplatelet agents stands out as the biggest risk factor. The second most important risk factor is the use of catheters with larger diameters. Proper selection of smaller catheter diameters for patients will reduce this risk. The complication rate was increased in parallel with the faster circulation of patients in a particular room. In addition, controlling HT can reduce FPA complications. We suggest that applying more meticulous compression for patients with risk factors might significantly decrease FPA. Therefore, proper and optimal local compression should be crucial in day-to-day practice for busy interventionists, whatever the cost. To show the importance of compression for decreasing FPA complications, further controlled studies should be initiated. Cardiologists may use this scoring system for FPs, and this scoring system will be improved in the future.

This study confirms that femoral pseudoaneurysm is a morbid situation, that a high risk score is important because FPA formation is 7 times greater than normal in such cases, and that a novel calculating of risk scores allows for the stratification of patients into 4 levels of risk.

References