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Effects of Sandbag-Free Follow-up After Manual Compression in Patients Who Underwent Transfemoral Access for Percutaneous Intervention

Transfemoral Perkütan Girişim Uygulanan Hastalarda Manuel Kompresyon Sonrası Kum Torbasız Takibin Değerlendirilmesi

ABSTRACT

Objective: Femoral access site complications (ASC) are frequent yet significant conditions associated with percutaneous intervention procedures that affect patient-physician comfort. In this study, we compared ASC rates between patients who received compression with a sandbag, the standard practice in many clinics, and patients monitored solely with bedrest without sandbag compression.

Methods: This study included patients undergoing any transfemoral percutaneous intervention (mostly coronary interventions) between April 2019 and May 2023 at our clinic. Patients were classified into two groups: those monitored without a sandbag (n = 160) and those with a sandbag (n = 158). ASC rates (ecchymosis, pseudoaneurysm, hematoma, bleeding) were compared between the two groups.

Results: No differences were observed between the two groups in gender, age, sheath size, and bed rest times. Complications were observed in 16.9% (n = 27) of patients without sandbags and 25.3% (n = 40) of patients with sandbags. The most common complication was ecchymosis, seen in 10.6% (n = 17) of the no-sandbag group and 13.9% (n = 22) of the sandbag group.

Conclusion: Following manual compression after femoral sheath removal, patients receiving bedrest without sandbag use are less likely to develop ASC. Additionally, dismissing sandbag use leads to a significant increase in patient comfort.

Keywords: Access site complications, percutaneous intervention, sandbag, transfemoral access

ÖZET

Amaç: Femoral erişim yeri komplikasyonları, perkütan girişim işlemiyle ilişkili sık görülen ancak hasta-hekim konforunu etkileyen önemli durumlardır. Bu çalışmada, birçok klinikte standart uygulama olan kum torbası ile kompresyon uygulanan hastalar ile kum torbası kompresi yapılmadan sadece yatak istirahati ile izlenen hastalar arasındaki komplikasyon oranlarını karşılaştırdık.

Yöntem: Bu çalışmaya kliniğimizde Nisan 2019 ile Mayıs 2023 tarihleri arasında transfemoral perkütan girişim (çoğunlukla koroner girişimler) uygulanan hastalar dahil edildi. Hastalar kum torbası olmadan (n = 160) ve kum torbasıyla (n = 158) izlenenler olarak sınıflandırıldı; İki grup arasında komplikasyon oranları (ekimoz, psödoanevrizma, hematom, kanama) karşılaştırıldı.

Bulgular: İki grup arasında cinsiyet, yaş, sheath boyutu ve yatak istirahati süreleri açısından fark gözlenmedi. Kum torbası olmayan hastaların %16,9'unda (n = 27), kum torbası olan hastaların ise %25,3'ünde (n = 40) komplikasyon görüldü. En sık görülen komplikasyon ekimoz olup kum torbası olmayan grupta %10,6 (n = 17), kum torbası kullanan grupta ise %13,9 (n = 22) görüldü.

Sonuç: Femoral sheathin çıkarılmasının ardından manuel kompresyon sonrası, kum torbası kullanılmadan yatak istirahati alan hastalarda komplikasyon gelişme olasılığı daha düşüktür. Ayrıca kum torbası kullanımının bırakılması hasta konforunda da ciddi bir artışa yol açmaktadır.

Anahtar Kelimeler: Giriş yeri komplikasyonları, perkütan girişim, kum torbası, transfemoral erişim

ORIGINAL ARTICLE
KLİNİK ÇALIŞMA

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Coronary interventions primarily recommend the use of radial artery access to reduce access site complications (ASC), a practice widely adopted in many medical centers.[1] However, femoral access is still commonly used for various reasons.[2] In femoral interventions, complications related to the access site remain the most notable drawback, affecting procedural success and negatively impacting patient satisfaction.[3] In clinical practice, access site complications are reported to occur in 5-10% of cases in various studies;[4] these complications include bleeding, hematoma, arteriovenous fistula, pseudoaneurysm, and retroperitoneal bleeding.[5] Although vascular closure devices are effective in preventing these complications, their routine use has not been adopted in procedures using sheaths smaller than 10F.[6] In many centers, compression with a sandbag on the access site is applied for approximately 4-5 hours following sheath removal.[7] However, there are limited data to support the concept that this practice reduces the risk of bleeding at the access site. The aim of this study is to investigate if, following sheath removal and achieving stasis, observation without sandbag compression and relying solely on bed rest will affect the risk of bleeding in patients undergoing femoral access.

Materials and Methods

Compliance with Ethical Standards

The study was reviewed and approved by Necmettin Erbakan University Non-Drug and Medical Device Research Ethics Committee (Approval Number: 2021/3168, Date: 02.04.2021), adhering to the principles of the Helsinki Declaration. Written informed consent was obtained from all participants. Artificial intelligence-supported technologies were not used in the study.

Study Design

From April 2019 to May 2023, a total of 318 patients who presented to our hospital and underwent angiography and/or percutaneous intervention via femoral access for elective or emergency reasons were included in this observational prospective study. The purpose was to compare patients with and without sandbag compression. The allocation of patients into groups-some receiving follow-up care with a sandbag and some without-was determined by simple randomization.

Patient Evaluation and Follow-up

In this randomized study, 318 patients who underwent femoral access using a 6F or 7F sheath and the Seldinger technique were divided into two groups: those monitored without a sandbag (n = 160) and those with a sandbag (n = 158). The patients' demographic characteristics, risk factors, and medical treatment histories were also assessed. Following percutaneous intervention, when the activated clotting time (ACT) reached <160-180 seconds, the femoral sheath was removed and 15-20 minutes of manual compression was applied. After achieving hemostasis, patients were randomized to be monitored with or without a sandbag. The standard weight of the sandbag was 4 kg. Mobilization was allowed after 3-4 hours of bed rest for those treated with a 6F sheath and after 5-6 hours for those treated with a 7F sheath. Access site complications were evaluated in patients both before mobilization and on the subsequent day. They were classified as recurrent bleeding, ecchymosis, hematoma, and pseudoaneurysm. Ecchymosis was defined as a color change greater than 1 cm but smaller than 5 cm resulting from subcutaneous blood leakage.[8] Hematoma was defined as a non-pulsatile mass on palpation.[9] In doubtful cases, pseudoaneurysm and arteriovenous (AV) fistula diagnoses were made using color Doppler ultrasound.

Statistical Analysis

All statistical analyses were performed using the IBM Statistical Package for the Social Sciences (SPSS) Version 23.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive analyses expressed frequency data using numbers (n) and percentages (%), while numerical data were expressed as mean ± standard deviation. Categorical data were compared using the chi-square (χ^2) test and Fisher Exact test. The Kolmogorov-Smirnov test assessed the normal distribution of numerical data. Student's T-test analyzed normally distributed numerical data in two independent groups, while the Mann-Whitney U test analyzed non-normally distributed numerical data. Body mass index (BMI) distribution between two independent groups (sandbag-complication) was examined by two-way analysis of variance. Results were assessed at a 95% confidence interval, and significance was set at $P < 0.05$.

Results

Gender distribution was statistically similar between the groups ($P > 0.05$). The mean age of the patients in the no-sandbag group was 60.86 ± 12.58 years, while in the sandbag group it was 62.50 ± 11.62 years ($P >0.05$). The rate of diabetes mellitus (DM) in patients without sandbag use was significantly higher than in those with sandbag use ($P = 0.044$). There were no differences between the groups in terms of other demographic characteristics, chronic illnesses, and smoking habits (Table 1).

The distribution of the procedural characteristics of angiography based on sandbag usage is presented in Table 2. No statistically significant differences were observed in terms of the following parameters: hospital admission, procedure, sheath size, sheath removal time between groups, vital signs before sheath removal, bleeding cessation time, immobilization time, and medication administration during the procedure ($P >0.05$). The distribution of hematological parameters among groups prior to and following the procedure is displayed in Table 3, showing statistically higher activated partial thromboplastin time (APTT) values in patients without sandbag use compared to those with sandbag use ($P < 0.001$). Other parameters had similar distributions among patient groups ($P >0.05$).

Complications were observed in 16.9% of patients in the no-sandbag group (n = 27) and 25.3% of patients in the sandbag group (n = 40). Ecchymosis was the most frequent complication, occurring in 10.6% (n = 17) of the no-sandbag group and 13.9% (n = 22) of the sand group (Table 4). There were no statistically significant differences in the distribution of complications and

ABBREVIATIONS

ACT	Activated clotting time
ASC	Access site complications
AV	Arteriovenous
BMI	Body mass index
DM	Diabetes mellitus

Table 1. Comparison of Demographic Characteristics, Chronic Diseases, and Smoking

	Without sandbag (n = 160)	With sandbag (n = 158)	*P*
Sex, n (%)			
Female	43 (26.9)	49 (31.0)	0.416*
Male	117 (73.1)	109 (69.0)	
Age (years)	60.86 ± 12.58	62.50 ± 11.62	0.327**
BMI (kg/m^2)	28.21 ± 4.27	28.20 ± 4.35	0.897**
Central Obesity; n (%)	37 (23.1)	43 (27.2)	0.401*
HT, n (%)	73 (45.6)	85 (53.8)	0.145*
DM, n (%)	67 (41.9)	49 (31.0)	**0.044***
Atrial Fibrillation; n (%)	13 (8.1)	14 (8.9)	0.814
CRF, n (%)	15 (9.4)	11 (7.0)	0.432*
Smoking, n (%)	43 (26.9)	43 (27.2)	0.946*

*: Pearson Chi-square test, **: Mann-Whitney U test.
BMI, Body Mass Index; CRF, Chronic Renal Failure; DM, Diabetes Mellitus; HT, Hypertension.

Table 2. Comparison of Procedure-Related Features

		Without sandbag (n = 160)	With sandbag (n = 158)	*P*
Admission to the Hospital				
Acute Coronary Syndrome		85 (53.1)	90 (57.0)	0.492*
Elective Procedure		75 (46.9)	68 (43.0)	
Antiplatelet-Anticoagulant Treatment Before the Procedure				
ASA		118 (73.8)	106 (67.1)	
Clopidogrel		49 (30.6)	46 (29.1)	
Ticagrelor		6 (3.8)	4 (2.5)	-
Prasugrel		3 (1.9)	1 (0.6)	
Warfarin		6 (3.8)	8 (5.1)	
DOAC		10 (6.3)	8 (5.1)	
PCI (n, %)		116 (72.5)	107 (67.7)	0.352*
Sheath				
6F		83 (51.9)	89 (56.3)	0.425*
7F		77 (48.1)	69 (43.7)	
Medication Given during the Procedure				
None		42 (26.3)	50 (31.6)	
Heparin		81 (50.6)	68 (43.0)	0.380*
Heparin + Tirofiban		37 (23.1)	40 (25.3)	
Sheath Removal Time (min)		203.75 ± 173.79	169.62 ± 123.36	0.058**
Compression Time (min)		24.25 ± 13.39	22.29 ± 13.53	0.069**
Activated Clotting Time (sec)		135.01 ± 16.70	120.89 ± 24.91	**<0.001****
6F Sheath Sedentary Follow-up Time (min)		235.96 ± 64.22	225.56 ± 38.33	0.176**
7F Sheath Sedentary Follow-up Time (min)		348.64 ± 54.03	346.09 ± 38.53	0.760**
Vital Signs Before Sheath Removal	**Systolic BP (mmHg)**	126.01 ± 14.87	124.77 ± 14.66	0.429**
	Diastolic BP (mmHg)	75.21 ± 10.02	75.15 ± 10.63	0.893**
	Heart Rate (beats/min)	75.22 ± 13.00	77.06 ± 13.12	0.265**

#: Some patients have more than one treatment, *: Pearson Chi-square test, **: Mann Whitney U test
ASA, Acetyl Salicylic Acid; BP, Blood Pressure; DOAC, Direct Oral Anticoagulant; PCI, Percutaneous Coronary Intervention.

Table 3. Distribution of Hematological Parameters Before and After the Procedure

		Without sandbag (n = 160)	With sandbag (n = 158)	*P*
Before Procedure	**APTT (sec)**	30.88 ± 3.25	28.96 ± 3.69	**<0.001***
	INR	1.06 ± 0.19	1.06 ± 0.13	0.897*
	PLT (10^3/μL)	255.54 ± 79.78	272.67 ± 88.59	0.100*
	Hemoglobin (g/dl)	13.65 ± 2.01	13.80 ± 1.84	0.472**
	Hematocrit (%)	41.10 ± 5.92	41.73 ± 5.27	0.318**
After Procedure	**Hemoglobin (g/dl)**	12.65 ± 1.86	12.87 ± 1.69	0.397*
	Hematocrit (%)	38.16 ± 5.48	39.01 ± 5.01	0.151**

*: Mann-Whitney U test, **: Student's t test.
APTT, Activated Partial Thromboplastin Time; INR, International Normalized Ratio; PLT, Platelet.

Table 4. Comparison of the Complications Between the Groups

	Without sandbag (n = 160)	With sandbag (n = 158)	*P*
Complication			
No	133 (83.1)	118 (74.7)	0.065*
Yes	27 (16.9)	40 (25.3)	
Complication Type			
Ecchymosis	17 (10.6)	22 (13.9)	0.340*
Hematoma	5 (3.1)	7 (4.4)	
Re-bleeding	5 (3.1)	10 (6.3)	
Pseudoaneurysm	0 (0.0)	1 (0.6)	
Complication Development Time (min)	83.87 ± 192.08	121.39 ± 348.33	0.711**

*: Pearson Chi-square test, **: Mann-Whitney U test

Table 5. Gender and Body Mass Index (BMI) Distribution According to the Presence of Complications

	Without Sandbag			With Sandbag		
	Complication - (n = 133)	Complication + (n = 27)	*P*	Complication - (n = 118)	Complication + (n = 40)	*P*
Sex						
Female	34 (25.6)	9 (33.3)	0.406*	37 (31.4)	12 (30.0)	0.873*
Male	99 (74.4)	18 (66.7)		81 (68.6)	28 (70.0)	
BMI (kg/m^2)	28.15 ± 4.46	28.51 ± 3.18	0.443**	28.51 ± 4.43	27.29 ± 4.00	0.181**

*: Pearson Chi-square test, **: Mann-Whitney U test

the time of complication development between groups (*P* > 0.05). Statistically significant differences were not observed in the distribution of gender and BMI between the sandbag and sandbag-free groups in relation to the presence of complications (*P* >0.05) (Table 5).

Discussion

Access site complications (ASC) are common in patients undergoing femoral access, leading to increased morbidity, prolonged hospital admission, and increased procedural costs.[10,11] The RIVAL (RadIal Vs femorAL access for coronary intervention) study conducted in acute coronary syndrome patients found a major vascular complication rate of 3.7%.[12] According to reports by Karakuş and colleagues,[13] complication rates after femoral access procedures were found to be 1.3%.

Current guidelines recommend radial access in all possible patients,[1] and despite the increasing use of radial interventions for coronary angiography in the last decade, femoral access continues to be widely used in many centers for various reasons.

The Braunwald Textbook recommends sheath removal after the activated clotting time reduces below 160-180 seconds in patients who have undergone femoral access using heparin, and achieving hemostasis through manual compression 2.5-5 cm above the access site. Subsequently, bed rest is advised for a duration of 2 hours for 4F-6F sheaths and 3-4 hours for

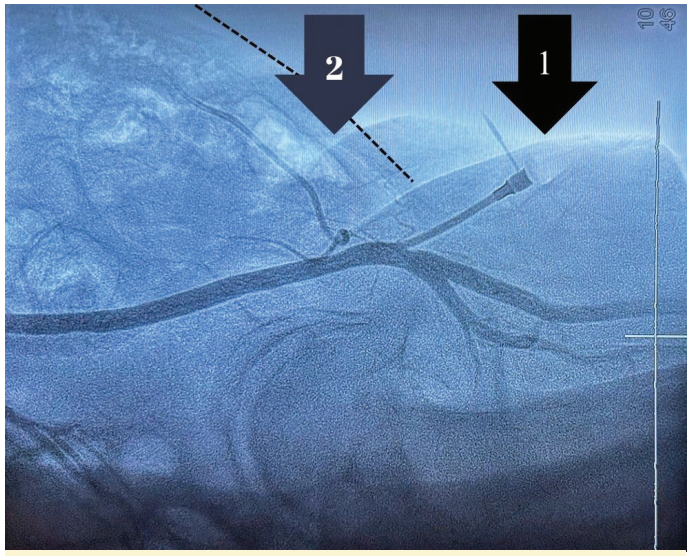

Figure 1. Fluoroscopic view of femoral artery entry and correct compression site

---: Line indicating abdominal contours in overweight patients
→ -1: Common site of sandbag application
→ -2: Optimal site for sandbag pressure application

sheaths above 6F.[14] Nevertheless, many facilities continue to use compression with sandbags on the entry site for 4-5 hours after achieving hemostasis with manual compression in clinical practice. Alternative techniques such as pressure bandages and compression devices are also used.[15]

Although there is widespread interest in vascular closure devices developed in recent years, these devices are also associated with frequent vascular complications.[16] The study by Lehmann et al.[17] compared sandbag closure with other techniques and found no difference in terms of complication development. Several post-sheath removal approaches, such as cold application, have been tested to reduce complications but have not been adopted in routine clinical practice.[18]

When compression is applied with any weight, such as a sandbag, precise application to the correct location is crucial for reducing the risk of bleeding-related complications. Since the Seldinger needle enters the skin at an approximate 45-degree angle, the entry point of the needle into the artery remains more proximal to the entry point into the skin. Therefore, compression with weight (i.e., a sandbag) should be applied not to the entry point of the skin but rather to the entry point into the femoral artery, preferably slightly proximal to it (Figure 1). However, sandbags placed proximal to the entry point into the artery in patients with femoral access are often displaced due to physical/anatomical reasons, and end up even distal to the entry point of the skin. Furthermore, the discomfort caused by the sandbag leads to attempts by patients to change their positions in bed, often resulting in the sandbags moving distal to the entry point.[19] Thus, sandbags placed for compression proximal to the entry point into the artery instead cause compression at a distal point, increasing resistance to blood flow and thereby increasing the risk of bleeding at the entry point where stasis had been accomplished.[20] Continuous bleeding within the tissue, which may remain unnoticed due to pressure applied not at the entry point into the artery but at the entry point into the skin, can lead to significant hematoma formation in the tissue. Furthermore, the presence of sandbags diminishes attention to bleeding monitoring by doctors, nurses, and patient relatives, providing a false sense of security. Additionally, patients experience prolonged immobility and discomfort due to sandbags placed in the femoral region. Manual compression without the use of sandbags not only improves comfort levels in patients but also allows for early detection and prevention of complications such as bleeding and hematoma.[21]

The results of our study indicate that sandbag application is not superior to patient monitoring and bed rest. In fact, although statistically insignificant, the complication rate is lower in the no-sandbag group. Therefore, in patients with femoral access who have achieved hemostasis through manual compression, we believe it is unnecessary to continue compression with weights, such as a sandbag, after sheath removal. We propose that close monitoring with 3-4 hours of bed rest is sufficient.

Limitations

The most significant limitation of our study is the limited number of cases. Another limitation was that not all patients could be examined with Doppler ultrasonography (USG) for possible complications.

Ethics Committee Approval: The study was reviewed and approved by Necmettin Erbakan University Non-Drug and Medical Device Research Ethics Committee (Approval Number: 2021/3168, Date: 02.04.2021).

Informed Consent: Written informed consent was obtained from all participants.

Peer-review: Externally peer-reviewed.

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