Türk Kardiyol Dern Arş - Arch Turk Soc Cardiol 2013;41(6):478-485 doi: 10.5543/tkda.2013.27243

Kalp kateterizasyonu ve elektif perkütan girişimlerde periferik damar komplikasyonları açısından femoral arter pnömotik kompresyon cihazının kum torbası yöntemi ile karşılaştırılması

Comparison of pneumatic compression device and sand bag with respect to peripheral vascular complications in elective cardiac catheterization and percutaneous femoral artery interventions

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ÖZET

Amaç: Koroner anjiyografi (KAG) ve perkütan koroner girişim (PKG) sonrası işlem bölgesinde kanama kontrolü ve lokal damarsal komplikasyonların önlenmesi amacıyla klasik kum torbası yöntemi ve kompresyon cihazları yaygın olarak kullanılmaktadır. Çalışmamızın amacı, KAG ve PKG sonrası oluşan lokal damarsal komplikasyonları değerlendirmek ve bu komplikasyonlar açısından kum torbası ile pnömotik kompresyon cihazını (Close Pad) karşılaştırmaktır.

Çalışma planı: Haziran 2011 ile Kasım 2011 tarihleri arasında Uludağ Üniversitesi Tıp Fakültesi Kardiyoloji Anabilim Dalı'nda KAG ve PKG yapılan 434 hasta çalışmaya alındı. Olguların 396'sına KAG, 38'ine PKG uygulandı. Hastaların 209'una kum torbası, 225'ine Close Pad uygulandı. Transfüzyon gerektiren kanamalar, 10 cm^2'den büyük hematom, psödoanevrizma veya arteriyovenöz (AV) fistül saptanması majör lokal komplikasyon olarak tanımlandı. Verilerin değerlendirilmesi amacıyla lojistik regresyon analizi kullanıldı.

ABSTRACT

Objectives: After coronary angiography (CAG) and percutaneous coronary intervention (PCI), the classic sand bag method and compression devices are widely used for control of bleeding and prevention of vascular complications on the intervention site. The purpose of our study was to assess the major peripheral vascular complications and compare the sand bag and a pneumatic compression device ("Close Pad") in terms of major peripheral vascular complications occurring after CAG, and PCI.

Study design: Between June 2011 and November 2011, a total of 434 patients who were admitted to the Department of Cardiology of Uludag University Faculty of Medicine were included in the study. 396 patients underwent coronary angiography and 38 patients, PCI. Sand bag, and Close Pad were applied in 209, and 225 patients, respectively. Bleeding requiring transfusion, hematomas larger than 10 cm^2, pseudoaneurysm, and arteriovenous (AV) fistula were defined as the major local complications. Logistic regression analysis were used to evaluate the data.

Submitted on: 09.24. 2012 *Accepted for publication on:* 04.26. 2013
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Bulgular: Koroner anjiyografi işlemi için majör damarsal komplikasyon oranı %2, PKG işlemi için ise %13,2 saptandı (p=0,003). Majör damarsal komplikasyon sıklığı kum torbası uygulanan hastalara göre Close Pad uygulananlarda anlamlı olarak yüksek bulundu (%0,5 ve %5,3, p=0.007). Sigara kullanımı, PKG, Close Pad uygulaması, klopidogrel ve antikoagülan kullanımının majör lokal komplikasyon riskini artırdığı saptandı. Lojistik regresyon analizinde sadece sigara ve Close Pad kullanımının majör lokal damarsal komplikasyon riskini artıran bağımsız değişkenler oldukları görüldü (p<0.05).
Sonuç: Tanı ve tedavi amacıyla kardiyak kateterizasyon yapılan hastalarda kum torbası ile karşılaştırıldığında Close Pad kullanımı lokal damarsal komplikasyon gelişme riskini artırmaktadır. Özellikle PKG sonrası Close Pad kullanılacak hastalar daha dikkatli seçilmelidir.

Results: Major vascular complications occurred in 2% of diagnostic angiography and in 13.2% of PCIs (p=0.003). The major vascular complications were significantly higher with the Close Pad device compared with sand bag (5.3% vs. 0.5%, p=0.007). Smoking, PCI, Close Pad application, use of clopidogrel, and anticoagulants were observed to have increased risk for major local complications. In the logistic regression analysis, only smoking and Close Pad usage were evaluated as independent variables that increased the risk of major vascular complications (p<0.05).
Conclusion: Close Pad usage increases risk of vascular complications when compared with the sand bag in patients undergoing cardiac catheterizations. Especially after PCI, patients who will use Close Pad should be selected carefully

Abbreviations:

ASA Acetylsalycylic acid
AV Arteriovenous
BMI Body mas index
DM Diabetes mellitus
HL Hyperlipidemia
HT Hypertension
CAG Coronary angiography
PCI Percutaneous coronary intervention

Nowadays, coronary angiographic (CAG) procedures, and percutaneous coronary interventions (PCI) are increasingly prevalent. The most frequently seen postinterventional local vascular complications include bleeding, hematoma, pseudoneurysm, and arteriovenous (AV) fistula. These complications can be seen nearly in 1-7 % of the patients.[1-8] Hematomas are usually confined, however for pseudoaneurysms, and AV fistulas surgical intervention might be required. Hospital stay of inpatients especially with larger hematomas who also develop pseudoaneurysm, and AV fistula is relatively longer. Therefore local vascular complications seen related to interventional procedures are considerably responsible for morbidity, and mortality .[9]

Since femoral artery is generally utilized in coronary angiography, and PCIs, local vascular complications are most frequently seen in this region. For postprocedural bleeding control, conventional sand bag application, vascular closure devices, and compression devices are prevalently used. In the sand bag method, after hemostatic control by manual compression on the femoral region, generally a sand bag weighing 2.3-4.5 kg is placed on this site. Generally 4-6 hours later hemostasis is achieved, and sand bag is removed. During this period, movements of the patient are restricted, and the patient is requested to lie on his/her back. Recently, pneumatic compression device (Close Pad) is also used in increasing frequency, and it has replaced sand bag method. Close Pad is an innovative pneumatic compression device developed to sustain previously

applied brief manual compression on femoral artery. Close pad with its transparent window, and a balloon bag is placed on the site of the intervention for compression (Figure 1). Advantages of Close Pad over sand bag include improved patient comfort, brief bed rest, and relatively rapid hemostasis, decreased requirement for extra personnel, and shorter time to discharge [10]

Previous studies have compared manual compression, and vascular closure devices, but comparative studies with Close Pad have not been conducted so far. In our study, conventional sand bag method, and Close Pad have been compared with respect to procedural site vascular complications following CAG, and PCI.

PATIENTS AND THE METHOD

The study enrolled 434 patients who had undergone CAG, and elective PCI between June 2011, and November 2011 in the Laboratory of Hemodynamics, Uludag University Faculty of Medicine, Department of Cardiology. Coronary interventions were performed through femoral artery using Seldinger technique, and 6Fr sheaths for CAG, and 7 Fr, and 8 Fr sheaths for PCI. Informed consent forms were obtained from patients. Their age, gender, coronary artery risk factors, and medication use were interrogated.

Exclusion criteria were as follows: history of primary PCI, hemorrhagic diathesis, femoral artery surgery, an INR >1, intractable hypertension (HT) (≥180/110 mmHg) detected during removal of the femoral catheter, ST – segment elevation noted within 24 hours, systemic infection, active ischemia or local infection on the access site, history of anticoagulant or thrombolytic treatment within 12 hours, puncture of bilateral femoral arteries, femoral artery surgery within 30 days, development of complication(s) before removal of the sheath, and reluctancy to sign informed consent forms.

When activated coagulation time (ACT) dropped below 160 secs within 30 minutes after coronary angiography following elective PCI procedure, femoral catheter was removed by the attendant physician., and manual compression was applied for 10-15 minutes. After hemostatic control, the patients were randomized into application of sand bag or Close Pad. Sand bag was placed so as to compress the femoral region. Sand bag weighed 4.5 kg. Close Pad has a transparent window, and a ballon bag inflated with air. Baloon bag of the Close Pad was placed on the femoral access site. For the compression on the site of femoral catheterization balloon bag was inflated with 40-50 cc air using a syringe (Figure 1).[10,11] The patients were started to be mobilized 5, and 3 hours after sand bag, and Close Pad applications, respectively. Femoral access sites were evaluated following withdrawal of the sheath, immediately after the patients' ambulation, and one week later. The study was approved by the Ethics Committee of Uludag University Clinical Researches with the decree # 2011-2/2.

Complications

Hematoma was defined as a palpable non-pulsatile mass, and divided into 2 groups as major (> 10 cm^2) and minor (≤ 10 cm^2) hematomas based on their dimensions. In suspect cases, diagnosis of pseudoaneurysm, and AV fistula, was made using color-Doppler ultrasound.

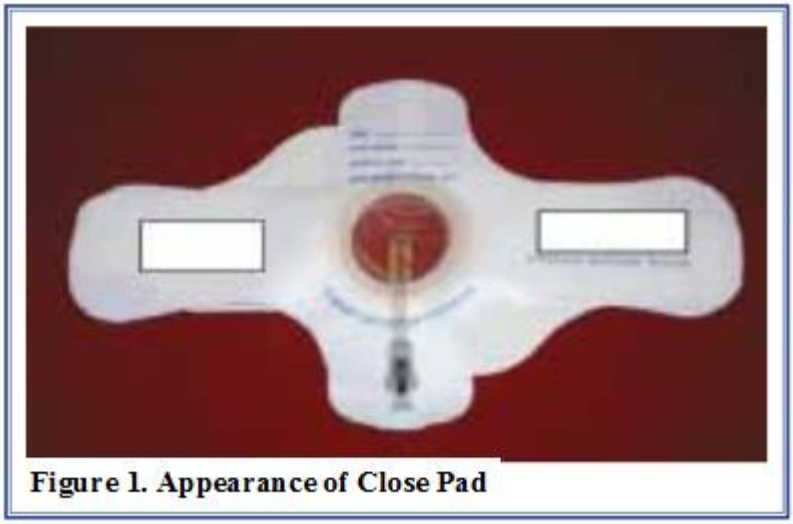

Figure 1. Appearance of Close Pad

Table 1. Basic clinical characteristics of the cases enrolled in the study

	All patients (n= 434		Sand Bag (n=209)		Close Pad (n=225)		*p*
	n	%	n	%	n	%	
Gender (Male/Female)	172/262		103/106		69/156		<0,001
Age (yrs) (Mean ± SD)	59,53±12,37		59,03±13,42		60±11,32		
(median, min, max)	61 (18-85)		60 (18-85)		61 (20-82)		0,707
Diabetes mellitus	156	35,9	77	36,8	79	35,1	0,707
Hypertension	254	58,5	126	60,3	128	56,9	0,473
Smoking	73	16,8	27	12,9	46	20,4	0,036
Obesity	126	29	65	31,1	61	27,1	0,360
BMI (kg/m²)	27 (18-49)		27 (18-49)		27 (18-49)		0,909
Hyperlipidemia	209	48,2	103	49,3	106	47,1	0,651
Medications							
ASA	293	67,5	127	60,8	166	73,8	0,004
Clopidogrel	95	21,9	43	20,6	52	23,1	0,523
Heparin /LMWH)	67	15,4	27	12,9	40	17,8	0,162
Method							
CAG	396		193		203		0,434
PCI	38		16		22		0,434

SD, standard deviation; BMI, body mass index; ASA, acetylsalicylic acid; DMWH, low-molecular weight heparin; CAG, coronary angiography; PCI, percutaneous coronary intervention; min, minimum; max, maximum

Major hematoma, pseudoaneurysm, AV fistula, and bleeding requiring transfusion were defined as major local vascular complications.

Statistical Analysis

For statistical evaluation "Statistical Package for Social Scienses for Windows" (SPSS) v. 13.00 package program was used. Continuous variables in group data were indicated as mean ±standard deviation (mean ±SD), median, minimum, and maximum (median, min., max.). Categorical variables were expressed as numbers, and percentages. In intergroup comparisons, according to the distribution of continuous variables, in independent groups without parametric distribution, non-parametric tests (Mann-Whitney U, and Kruskall Wallis tests) were used. In comparison of categorical variables *chi*-square test was used. For the analysis of correlation between variables, parametric, and non-parametric (Pearson, and Spearman) correlation analyses were performed. Uni-, and multivariate logistic regresion analyses were used to identify variables [age, body mass index (BMI), gender, obesity, diabetes, HT, hyperlipidemia (HL), smoking, drugs used, method, and procedure) which might effect major vascular complications. Level of statistical significance was determined as $p< 0.05$.

RESULTS

Mean age of the patients (men, 60.4 %, and women, 39.6 %) included in the study was 59.53±12.37 years. The patients underwent CAG (n=396) or PCI (n=38). The patients were using acetylsalycylic acid (67.5 %), clopidogrel (21.9 %) or anticoagulant therapy (15.4 %, unfractionated or low-molecular weight heparin). Clinical characteristics of the patients are shown in Table 1.

Minor hematoma was seen in 32.5 % of the patients, while 15 major local vascular complications were detected in 13 patients. Besides, major hematoma, (n=6), pseudoaneurysm (n=4), AV-fistula (n=1) , and both major hematoma, and pseudoaneurysm (n=1) developed during the study period. Transfusion requiring hematoma was not seen in any study patient.

Patients included in the study (n=434) were divided into 2 groups as for femoral closure method. Sand bag (48.2 %), and Close Pad (51.8 %) were applied. Close Pad was more frequently applied for male patients, while sand bag was more often used for female cases ($p<0.001$). Any significant difference was not found between groups regarding age, BMI, obesity, diabetes mellitus (DM), HT, HL, use of clopidogrel, and anticoagulants ($p>0.05$). In comparison with the Close Pad group, rates of smoking were higher in the sand bag group ($p=0.036$). Higher percentage of patients (73.8 %) in the Close Pad group used ASA (sand bag group, 60.8 %) ($p=0.004$) (Table 1). Frequency of major, and minor hematomas was statistically significantly higher in the Close Pad group ($p=0.043$, and san bag group, 0.033, respectively) (Table 2). A significant difference was not found between 2 groups as for development of pseudoaneurysm, and AV fistula ($p>0.05$). Major vascular complication was more frequently (n=12) encountered in the Close Pad group (sand bag group, n=1) ($p=0.003$) (Table 2).

	All patients (n= 434		Sand Bag (n=209)		Close Pad (n=225)		*p*
	n	**%**	**n**	**%**	**n**	**%**	
Minor hematoma	141	32,5	59	28,2	82	36,4	0,043
Major hematoma	8	1,8	1	0,5	7	3,1	0,033
Pseudoaneursima	6	1,4	1	0,5	5	2,2	0,217
AV fistula	1	0,2	0	0	1	0,4	1,000
Number of patients who developed major local vascular complications	13	3	1	0,5	12	5,3	0,003

Major hematoma, and psudoaneurysm were detected in one patient both in the sand bag , and Close Pad groups,.

Major and minor local vascular complications developed in 13, and 15 patients, respectively.

Patients who had or had not developed major local vascular complications were compared for various parametres. Both groups did not differ in terms of age, BMI, gender, obesity, DM, HT, HL, and usage of ASA. Rate of smoking was higher in patients with major local complications (53.8 % *vs* nonsmokers, 15.7 %; p=0.002). In the group which developed major local complications, clopidogrel, and anticoagulants were more frequently used (53.8 % *vs* 20.9%, p=0.011, and 38.5 % *vs* 14.7%, p=0.036). One patient in the sand bag group (0.5 %) , and 12 (5.3 %) patients in the Close Pad group developed major local complications (p=0.007) (Table 3).

In our study, smoking, PCI, Close Pad application, clopidogrel, nd anticoagulant use increased the risk of major local complications. In logistic regression analysis of all these variables, only smoking, and Close Pad application were accepted as independent variables (Figure 2). In logistic regression analysis smoking, and use of Close Pad increased the risk of major complications 4, and 9-fold, respectively ($p<0.05$) (Table 4).

DISCUSSION

Following diagnostic PCI, and CAG, vascular complications developed on the access site are especially postprocedural bleedings requiring transfusion leading to prolonged hospital stays, increase in costs, and enhanced long-term morbidity, and mortality. [12-15]

Table 3. Comparison of cases who had or had not developed major complications

	Patients who developed major vascular complications (n=13)		Patients who did not develop major vascular complications (n=421)		*p*
	n	%	n	%	
Gender (Male/Female)	7/6		165/256		0,438
Age (yrs) (Mean ± SD)	65,61±9,86		59,34±12,4		
(median, min, max)	70 (47-82)		60 (18-85)		0,064
Diabetes mellitus	4	30,8	152	36,1	0,778
Hypertension	11	84,6	243	57,7	0,098
Smoking	7	53,8	66	15,7	0,002
Obesity	3	23,1	123	29,2	0,764
BMI (kg/m²) (median, min., max.)	27	(22-33)	27	(18-49)	0,873
Hyperlipidemia	7	53,8	202	48	0,893
Medications					
Acetylsalicylic acid	8	61,5	285	67,7	0,765
Clopidogrel	7	53,8	88	20,9	0,011
Heparin /LMWH)	5	38,5	62	14,7	0,036
Coronary angiography	8	2	388	98	
Percutaneous coronary intervention	5	13,2	33	86,8	0,003
Sand bag	1	0,5	208	99,5	
Close Pad	12	5,3	213	94,7	0,007

BMI, body mass index; SD, standard deviation

Major hematoma, and psudoaneurysm were detected in one patient both in the sand bag , and Close Pad groups,.

For ages, manual compression, and conventional sand bag have been used for hemostatic control. In many studies, manual compression is accepted as a gold standard.[16-20] Though it has been successful in the majority of patients, these applications might impair patient's comfort, cause severe pains, and prolong bed rest. Therefore, various compression devices which improve patient's comfort, and shorten hospital stay have been developed.. One of these innovations is pneumatic compression device, Close Pad.

In this prospective study, effectiveness of sand bag, and Close pad applications was evaluated in patients who had undergone elective diagnostic cardiac catheterization, and PCI with respect to prevention of femoral artery access site complications. In our study, frequency of major vascular complications was 2 % in the CAG, and 13.2 % in the PCI groups.

Table 4. Logistic regression analysis of local major vascular complications, and independent variables

Variable	Odds ratio	Standard error	Wald	*p*	Ekspirasyon (β)	Odds ratio 95 % CI	
						Min.	Max.
Smoking	1,387	0,614	5,097	0,024	4,004	1,201	13,350
PCI	1,061	0,762	1,937	0,164	2,890	0,648	12,880
Close Pad	2,236	1,061	4,439	0,035	9,354	1,169	74,870
Clopidogrel	-0,840	0,809	1,076	0,300	0,432	0,088	2,111
Anticoagulant	-0,126	0,788	0,025	0,873	0,882	0,188	4,133

SE, standart error; CI, confidence interval; Min. minimum; Max., maximum; PCI, percutaneous coronary intervention

In our study, rates of major vascular complications were similar to those indicated in previous studies. [21-27] However, standard classification is not available for peripheral vascular complications developing after diagnostic catheterization or coronary angioplasty. In studies performed by Gibbs et al. . [28] and Johnson et al. [29] defined peripheral vascular complications as those requiring repair by only vascular surgery. In other studies, relevant complications were reported as transfusion requiring bleedings, infections, pseudoaneurysm, AV fistulas, thrombosis, embolization, and hematoma. [21,30-34] However in our study, major vascular complications were accepted as transfusion requiring bleedings, major hematoma, pseudoaneurysm or AV fistula. Higher incidence of major vascular complications in the PCI might be attributed to the advanced age of PCI patients, use of 7 Fr, and 8 Fr catheters, administration of more intensive antiaggregant, and anticoagulant therapy, and removal of the catheter at a later date. Besides, scarce number of patients in the PCI group might contribute to these higher incidence rates.

Among modalities used in our study, when compared with the sand bag group, in the Close Pad group hematoma, and major local complications were more frequently detected.

When patients who had or had not developed major vascular complications were compared, smoking, PCI, Close Pad application, clopidogrel, and anticoagulant use increased risk of complications. However, logistic regression analysis of all of these variables detected only smoking, and Close Pad use as independent risk factors for major local vascular complications. In the logistic regression analysis, smoking, and use of Close Pad increased risk of major vascular complication 4, and 9-fold, respectively ($p<0.05$). As demonstrated by studies performed, smoking decreases platelet aggregation stimulated by collagens, and when used in combination with aspirin, and clopidogrel they inhibit platelets. Besides alfa, and beta carbolines contained in cigarettes increase bleeding risk .[35-40] Our study results do not substantiate previously reported risk factors as female gender, age, and lower BMI.[12,24,41-43] On the other hand, in a study performed by

Arora et al. [26] independent variables were reported as chronic renal insufficiency, prolonged procedure time, female gender, advanced age (> 70 years), , and non-elective interventions. However, in our study, duration of intervention, and creatinine levels of the patients were not evaluated.

Limitations of the study

Our study was performed in one center with restricted number of patients within a limited time. ASA was more frequently used in the sand bag group rather than Close Pad group. However in the analysis performed, any significant difference was not detected between groups with or without major local vascular complications (61.5 % *vs* 67.7%, p=0.765). Apart from that, the patients were recalled one week later for physical examination. Therefore, complications that can develop within a period longer than one week might have been overlooked. In the assessment of local vascular complications, since we couldn't perform ultrasonography or other imaging modalities on every patient, some complications might be skipped.

In conclusion, hemostatic control, and prevention of local vascular complications following CAG, and PCI on the access sites, manual compression, followed by use of sand bag are more successful than only Close Pad application. Patients who will use Close Pad after PCI should be carefully selected.

Conflict of interest: None declared

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Anahtar sözcükler: Anjiyoplasti, balon, koroner / yan etki; Close Pad; kan damarları; kardiyak kateterizasyon; koroner anjiyografi; koroner hastalık / tedavi; kum torbası.

Key words: Angioplasty, balloon, coronary/adverse effect; Close Pad; blood vessels; cardiac catheterization; coronary angiography; coronary disease / therapy; sand bag.