

Perkütan koroner girişim sonrası -mobiliteye izin veren- kontrollü baskı

kemerinin kum torbasıyla karşılaştırılması: Pilot çalışma

Comparison of controlled pressure belt -allowing mobility-to sandbags after percutaneous coronary intervention: pilot study

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ÖZET

Amaç: Yeni geliştirdiğimiz ve patentini aldığımız, koroner işlemler sonrası mobiliteye izin veren, femoral artere ayarlanabilir baskı uygulamaya yarayan kemerin (Anjiobelt®) etkinlik ve güvenilirliği araştırıldı.

Çalışma planı: Çalışmaya Ekim 2012 ve Nisan 2013 tarihleri arasında perkütan koroner girişim planlanan ardışık 189 hasta alındı. Kum torbası konulan grupta 96 Anjiobelt® kullanılan grupta 93 hasta yer aldı. Femoral artere primer hemostaz sağlanana kadar elle baskı uygulandı. Hemostaz sağlandıktan sonra 4-5 kilogramlık kum torbası veya Anjiobelt® yerleştirildi. Anjiobelt®'li hastaların ihtiyaç halinde mobilizasyonuna izin verildi. İşlem sonrası 24. saatte femoral bölgedeki yüzeysel morluklar görsel olarak, femoral arter Doppler ultrasonuyla hematoma, psödoanevrizma ve arteriyovenöz fistül gibi komplikasyonlar değerlendirildi.

Bulgular: Hematom kum torbası konulan grupta daha fazla gelişti. Bir cm'den küçük hematomlar kum torbası grubunda 52, Anjiobelt® grubunda 25 hastada görüldü (p<0.0001). 1-5 cm arasındaki hematoma ise

ABSTRACT

Objectives: We aimed to investigate the efficacy and safety of a belt mechanism (Anjiobelt®), which we developed recently and patented, which allows mobility after coronary operations and the application of adjustable pressure on the femoral artery.

Study design: Between October 2012 and April 2013, 189 consecutive patients undergoing percutaneous coronary intervention electively or due to acute coronary syndrome were enrolled. There were 96 patients in the sandbag group and 93 patients in Anjiobelt® group. Manual compression was applied to the femoral artery until primary homeostasis was achieved. Then, a 4-5 kilogram sandbag or Anjiobelt® was placed. Mobilization was allowed in case of need in the Anjiobelt® group. Twenty-four hours after the procedure, using Doppler ultrasound femoral artery complications such as superficial bruising in the femoral region, hematoma, pseudoaneurysm, and arteriovenous fistula were noted.

Results: Hematoma occurred more frequently in the sandbag group. Hematoma of <1 cm

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kum torbasında beş hastada, Anjiyobelt grubunda ise üç hastada gelişti ($p<0.0001$). Çalışmamızda femoral arter psödoanevrizması dört hastada görüldü. Bunların ikisi Anjiyobelt® kullanılan hasta diğer ikisi kum torbası konulan hastalardı ($p=0.975$).

Sonuç: Perkütan koroner girişim yapılan hastalarda Anjiyobelt klasik kum torbalarına göre hematoma sıklığını önemli derecede azaltmaktadır. Diğer femoral bölge komplikasyonları bakımından da kum torbalarına benzer etkinlik ve güvenilirlikte olduğu görülmektedir. Bu hastaların en önemli sıkıntılarından olan hareket kısıtlanması da Anjiyobelt® ile ortadan kaldırılmış olmaktadır.

Abbreviation:

PCI Percutaneous coronary intervention

Percutaneous coronary interventions are frequently applied through femoral artery because of its easy accessibility, and higher rates of success.[1] However, following the procedure, the patients should remain in bed rest for a long time. Besides compression devices used after the procedure to ensure hemostasis impair the patient's comfort considerably. To that end femoral closure device for early hemostatic control have been developed. These devices provide comfort to the patient after the procedure, whereas risk of embolism, and their higher cost constitute a disadvantage for the patients.[1]

After interventions performed for coronary artery access, complications involving femoral region convey critical importance. In patients who underwent percutaneous coronary interventions (PCI) using larger catheter sheaths, higher doses of anticoagulants, and antiaggregants, the risk of developing complications involving

developed in 52 patients with sandbag and in 25 patients with Anjiyobelt® ($p<0.0001$), while hematoma of 1-5 cm developed in 5 patients with sandbag and in 3 patients with Anjiyobelt® ($p<0.0001$). Femoral artery pseudoaneurysm was seen in 4 patients (2 with anjiyobelt, 2 with sandbag; $p=0.975$).

Conclusion: Anjiyobelt® significantly reduces the incidence of hematoma in comparison to conventional sandbag in patients undergoing percutaneous coronary intervention. Other complications of the femoral region in terms of efficiency and safety appear to be similar to those observed with sandbag. The main problems occurring in these patients due to absolute immobilization have been eliminated with the application of Anjiyobelt®.

femoral region increases.[2] Besides these patients should have a strict bed rest for prolonged time intervals.[3] We recently developed, and patented (TPE 2011/00581) an adjustable femoral artery compression device, Anjiyobelt®, for use following coronary interventions. Operating mechanism of Anjiyobelt® is based on the principle of applying controlled pressure on femoral artery which allows mobilization of the patient in case of need.

The objective of our study is to evaluate, and compare the efficacy, safety, and reliability of Anjiyobelt® or sandbags used as femoral artery compression devices in patients who had undergone PCI.

PATIENTS AND METHOD

Between October 2012 and April 2013, 191 consecutive patients who had undergone PCI were included in the study. There were 96 patients in the sandbag and 93 patients in Anjiyobelt® group. In two patients scheduled for Anjiyobelt® application, primary hemostasis could not be achieved, and manual compression followed by sandbag application was required. These two patients were excluded from the study. In

compliance with the method used, a local anesthetic (10-20 ml, 2 % lidocaine) was injected around the access site over the femoral artery, then femoral artery puncture was performed using Seldinger technique, and 6-7 F sheath was inserted based on the requirements of the coronary procedure. All patients received dual antiaggregant therapy (300 mg acetylsalicylic + 75 mg clopidogrel) before the procedure. During the procedure they were given 100 U/kg unfractionated heparin (UFH). Femoral sheath was removed 4 hours later, and manual compression was applied on the femoral artery until achievement of primary hemostasis. Ninety-six hours after achievement of hemostasis sandbags weighing 4-5 kg were placed on the femoral access site, and strict bedrest was maintained for further 4 hours. Application of Anjiobelt[®] continued for 4 hours in 93 patients (Figure 1 a). During this period, in case of need, mobilization of the patients in the Anjiobelt[®] group was allowed (Figure 1b). At 24. hours after the procedure the patients were examined visually as for the presence of local bruising, and Doppler US was used to evaluate early postoperative complications as hematoma, pseudoaneurysm, and arteriovenous fistula. Doppler US images of the femoral region were videotaped. To eliminate patient, and physician bias, video recordings of the patients were analyzed by a physician blinded to the patient information, and the method applied. The ecchymotic area was categorized as small (< 10 cm) or large (> 10 cm) based on the diameter of the area involved. Based on Doppler US findings, hematomas were evaluated as those with a diameter of <1 cm, 1-5 cm or > 5cm. The study was initiated after approval of the local ethics committee was obtained.

Operating mechanism of Angiobelt[®]

The inventor had undergone angiographic procedures twice, and he lied in bed immobilized with a 4-5 kg sandbag on his femoral region. Once during his confinement to bed, he couldn't tolerate his so called 'bedridden' status, and sandbag slipped down from its place leading to the development of complications as bleeding, and hematoma. The problems encountered by the patient, urged him to invent this compression belt system. Since essential problem encountered after angiographic procedures is compression applied on the arterial access site for a certain time period, it has been concluded that the problem of compression can be solved by cramp-carpenter's wrench logic, and as a fulcrum of force, the dorsal region of the body might be used which can be ensured by a specially designed compression belt. Because arterial access point is on a flexible part of the body, ie. femoral region, it should be as small as possible. On the other hand, compression belt should have a controlled mechanism of applying adequate amount of pressure adjustable to the flexibility of the body, and individuals of every size (obese, thin, slender, thickset) Besides, this belt should be fastened rapidly following angiographic procedures. With this invented belt all of these problems are considerably solved, and this belt provides the patient (not forgetting that he/she is a patient) many comfortable advantages as ambulation, and relieve his/her needs. With Angiobelt[®], the center of a pressure disc with a diameter of 4-5 cm, is applied on the the puncture site, and the utmost tolerable pressure by the patient is applied by squeezing the controllable clamping screw of the device. Thus the chance of mobilization is offered to the patient. Therefore the possibility of developing

hematoma is reduced to zero with informing the patient beforehand, and avoiding extreme mobility. Besides, the advantage of mobilization provides

comfort to the patient including meeting his/her some certain needs, ambulation during waiting period, and relieving the pressure from other parts of his/her body



Statistical analysis

For statistical analysis of the results “SPSS for Windows 15.0” was used. $P < 0.05$ was considered as the level of significance. For the comparison of bivalent variables (as gender) and rates chi-square test was used. Normality of distribution of the measured variables was assumed, and Student’s *t* test was used to evaluate intergroup differences. Multiple logistic regression analysis was used to evaluate the association between the femoral access site complications, and risk factors.

RESULTS

Sandbags (n=96) or Anjiobelt® (n=93) was used in a total of 189 (143 men, and 46 women) patients included in the study. Mean age of the patients was 58 ± 11 years. Demographic, and clinical characteristics of both groups are shown in Table 1.

In our study, hematoma formation was more frequently seen in the sandbag group. Hematomas less than 1 cm in diameter were seen in 52 patients in the sandbag, and only 25 cases in the

Anjiobelt® group, respectively. Hematomas measuring 1-5 cm in diameter were noted in 5 patients in the sandbag, and 3 cases in the Anjiobelt® group, respectively ($p < 0.0001$). Hematomas larger than 5 cm were not observed in both groups. In correlation analyses, except for the smoking status, and the number of previous angiographic examinations, any significant correlation was not found between the hematoma, and the parameters analyzed including age, gender, body height, and weight of the patients, number of platelets, diabetes mellitus, hypertension, diameter of femoral artery, size of the sheath used ($p > 0.05$). In logistic regression analysis, a significant correlation existed between the development of hematoma, smoking status ($p = 0.006$), and the number of previous angiographic procedures ($p = 0.03$).

In our study, femoral artery pseudoaneurysms (sandbag group, n=2; Anjiobelt® group, n=2) were seen in four patients. Any significant intergroup difference was not detected as for the development of pseudoaneurysm

($p=0.975$). In the logistic regression analysis a significant negative correlation

existed only between the development of hematoma, and body height ($p=0.008$).

Table 1. Demographic, and clinical characteristics of the patients

	Sandbag (n=96)		Anjiobelt (n=93)		
	n	Mean \pm SD	n	Mean \pm SD	<i>p</i>
Age (yrs)		59,7 \pm 11,0		58,1 \pm 11,6	0,313
Gender (Male/Female)	71/25		72/21	0,582	
Body mass index (m ² /kg)		28,0 \pm 4,7		28,0 \pm 3,9	0,950
Body weight (kg)		79,7 \pm 14,4		80,5 \pm 12,8	0,717
Body height (cm)		165,9 \pm 17,7		168,6 \pm 13,1	0,240
Femoral artery diameter (mm)		8,0 \pm 1,1		8,1 \pm 1,5	0,654
Sheath (6F/7F)	25/71		21/72		0,421
Previous number of angiographies		2,2 \pm 1,2		2,0 \pm 1,2	0,282
LDL-cholesterol (mg/dL)		117,8 \pm 42,1		112,2 \pm 33,5	0,392
HDL-cholesterol (mg/dL)		34,8 \pm 13,2		35,9 \pm 7,1	0,543
Triglyceride (mg/dL)		162,9 \pm 101,2		172,7 \pm 91,1	0,555
Total cholesterol (mg/dL)		177,1 \pm 59,8		179,6 \pm 37,7	0,772
Diabetes mellitus	37		39		0,372
Hypertension	57		59		0,336
Smoking	41		34		0,237
Chronic total occlusion procedure	19		16		0,394
Hemoglobin (g/dL)		13,9 \pm 1,7		13,8 \pm 1,6	0,812
Platelets (10 ³ /mm ³)		248,0 \pm 62,0		254,0 \pm 69,1	0,492

Table 2. Complications of coronary angiography

	Sandbag (n=96)	Anjiobelt® (n=93)	<i>p</i>
	n	n	
Hematoma (< 1 cm/1.5 cm)	52/5	25/3	<0,0001
Ecchymotic area (<10 cm />10cm)	20/0	23/1	0,345
Pseudoaneurysm	2	2	0,975

In our study ecchymotic areas with a diameter less than 10 cm was detected in 21.1 % (n=20 in each group) of the patients in both groups without any intergroup statistical significance ($p=0.345$). An ecchymotic area of more than 10 cm in diameter was seen in only one patient in the Anjiobelt® group without any significant difference between

groups. The frequency of complications seen in patients after coronary angiographic examinations are shown in Table 2.

DISCUSSION

In our study, in comparison with sandbags, we evaluated efficacy, safety, and reliability of Anjiobelt® recently

manufactured with the aim of compression on femoral artery in patients undergoing PCI. Based on the result of our study, Angiobelt® which allows mobilization of the patient, can be used safely, and efficiently in patients undergoing PCI. The risk of hematoma formation decreases considerably in patients using Angiobelt®. The risk of femoral region complications apart from hematoma is comparable between Angiobelt®, and sandbag users.

Interventional procedures through femoral artery have been used frequently because of their higher success rates. [4] In addition to achievement of postprocedural hemostasis of the femoral artery bleeding, early mobilization is important as for the comfort of the patient.[1] Although thanks to currently gained experiences, the incidence of complications have decreased, the investigators still consider femoral region complications, most prominently hematoma, in procedures where larger sheaths and intensive doses of antiaggregants, and anticoagulants are used as important problems.[5] In various studies, bleeding requiring blood transfusions is seen in 1.5-5.8 % of the cases.[6] However when evaluated together with asymptomatic or clinically insignificant minor hematomas, incidence of bleeding is not known clearly, and in nearly half of the patients who had undergone PCI through femoral route, development of local complications has been reported.[7] Based on our study results, development of hematoma increases with smoking, and increased number of previous angiographic procedures.

Immediately after puncture of the femoral artery, manual compression followed by strict bed rest are generally resorted conventional practices. However strict bed rest constitutes an important

problem as for the comfort of the patient. Besides, achievement of hemostasis is seen as a time-consuming procedure from the viewpoint of the healthcare personnel. To that end, mechanical compression devices have been planned. Classical mechanical compression devices do not decrease vascular complication rates, whereas time loss by healthcare personnel is prevented.[8] Also in our clinic, sandbags are frequently used to compress the bleeding site. The patients remain motionless for a long time, and generally elder patients tolerate sandbags with difficulty. Therefore in recent years vascular closure devices have been introduced. However their higher cost curtails their widespread use. In addition, incidence of local complications related to closure devices is higher when compared with conventional manual compression, and serious cases of embolism associated with these devices have been reported. [9-11] Use of Anjiobelt® decreases the frequency of hematoma formation significantly relative to sandbags. Since our device exerts adjustable pressure on the femoral artery, it also prevents risk of ischemic complications. However recommendation of mechanical compression for the mainstay treatment of hematomas developed following strict bed rest after application of vascular closure device or manual compression, emphasizes the importance of efficient mechanical compression.. Anjiobelt® costs approximately 50 Turkish liras. Besides, different from other compression devices, it is suitable for sterilization which decreases hospital expenditures.

The complication of hematoma was seen more frequently in our study, because of inclusion of cases with asymptomatic, and minor complications in our medical files. In patients using Anjiobelt® the incidence of hematoma

decreases considerably. Recurrent femoral punctures in patients with a history of femoral catheterization become more painful, and difficult procedures. Partially absorbed, organized, and calcified asymptomatic or minor hematomas might contribute to these problems. Therefore, Angiobelt® might decrease the risk of difficult femoral artery punctures in further procedures.

In addition, the heavy burden of sandbags, and long-term bed rest which immobilizes the patient are the leading distresses suffered by the patients. Oral, and intravenous hydration are important for the rapid clearance of the contrast agent used, and prevention of nephrotoxicity. Hydration in these patients, increases urine output, and cause urgency of urination. Especially for elder patients who don't want to be catheterized for transurethral urinary drainage or those with severe prostatic diseases urgent need to urinate becomes a critical issue. Different from other methods of compression used to achieve hemostatic control, Angiobelt® allows mobilization of the patient which ensures the patients to fulfill their requirements. In addition, mobilization does not increase the complication rates in these patients.

The incidence of the femoral artery pseudoaneurysm has been reported as 2-9 percent.[5] In all of our patient population, femoral artery aneurysm was seen in only 4 (2.1 %) patients. The frequency of pseudoaneurysm was similar in Angiobelt® and sandbag users. In our study patients with short stature is seen as a risk factor for the development of pseudoaneurysm. Still, based on our study results, the incidence of ecchymotic area less than 10 cm² was detected in 21.1 % of the cases. The incidence of ecchymosis was similar in both groups. An ecchymotic area larger than 10 cm in diameter was

seen only in one patient in the Angiobelt® group. However intergroup difference was not statistically significant. Besides, in our study, any hemorrhagic complication necessitating transfusion did not develop.

In conclusion, in patients undergoing PCI, Angiobelt® decreases the incidence of hematoma considerably when compared with conventionally used sandbags. It appears to have comparable safety, and efficacy relative to sandbags with respect to the incidence of other complications of the femoral region including pseudoaneurysm, an ecchymosis. Absolute immobilization which is one of the most important distresses encountered by the patients is discarded by Angiobelt®.

Conflict of Interest. None declared.

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Key words: Anjiobelt®; femoral artery; hemostasis, surgery/instrumentation/method; percutaneous coronary intervention/adverse effect/methods.