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Comparison of ChitoHem Powder and Sand Bag for Controlling Bleeding After Femoral Angiography

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Abstract

Background and Objective: Controlling bleeding after angiography is very important and vital. Hemorrhage occurs due to ineffective local hemostasis and hemostatic factors play an important role in controlling it. This study was performed to compare the ChitoHem powder and sand bag in controlling bleeding after femoral angiography.
Methods: This clinical trial study was performed randomly on 136 patients undergoing angiography in 2 groups of sand bag and ChitoHem. Data were collected using a demographic questionnaire collected by interview, patient records, and checklist, which is documented in clinical information. Data analysis was performed using descriptive and inferential statistical methods using SPSS software.
Results: The mean time of homeostasis, bed rest time, and amount of bleeding in the sand bag group compared to ChitoHem group was significantly different in terms of statistics (p = 0.00), in the way that the post - angiography complications in ChitoHem are less than sand bags.
Conclusions: The results showed that ChitoHem powder had a significant positive effect on controlling bleeding and reduces the time of anesthesia homeostasis; therefore, its use is suggested after coronary angiography.

Keywords: Angiography, Sand Bag, Bleeding Control, ChitoHem Powder

1. Background

Nowadays, cardiovascular diseases are the most commonly reported serious ones in advanced countries and the first cause of death in all races and ages (1). Among cardiovascular diseases, coronary artery disease is the most common chronic and life - threatening one that causes disability, economic damage, and death more than any other disease (2). According to the Center for Disease Control and Prevention (2015), 1.5 million people worldwide die from cardiovascular disease each year, with deaths of 15% to 65% of them (3). Due to an increase in coronary artery disease, timely diagnosis and treatment of these diseases leads to fewer complications and fewer deaths (2). Coronary angiography is a selective method for confirming or rejecting coronary artery disease and collecting information to decide about the patients' need for medication, angioplasty, or coronary artery bypass graft surgery (4).

Although this invasive technique can play an important role in the diagnosis of coronary artery disease, it has many complications. The most common complications after angiography are hemorrhage (43.4%), hematoma (47.5%), and embolism at the catheter entrance (27.3%). The importance of these complications is that they can be associated with fever, pain, immobility, coldness, and numbness in the limbs, as well as a significant drop in hemoglobin due to prolonged and uncontrollable bleeding, and it ultimately leads to increase in the duration of hospitalization and even threatening the patient's life (5).

Taking care of the patient is the focal point many health - related words, however, in nursing, it is known as the central concept. Regarding the continuous contact and the comprehensive contact between the nurse and patient, as well as continuous relationship with other members of treatment team, long - term continuous examination of the patient has been considered as one of the im-

portant roles of the nursing, has recently exceeded the patient's control, and is considered as monitoring of patient (6).

In traditional methods of bleeding control, which has been left several centuries ago, tape bandaging, direct manual strain, pressure dressing, sand bag, tourniquet, and direct clamping to achieve homeostasis have been used. In order to reduce the time of hemostasis and faster removal of the pod, as a consequence, the earlier patient's walking, some tools were designed and developed for comfort, easy usage and patient safety, however, the use of these tools has not been uncomplicated and failure to use them is still happening. In addition, the high cost of their use is likely to affect hospital costs significantly (7).

In developing countries, including Iran, the use of traditional methods to control bleeding is relatively tangible. In these countries, manual strain is considered as an inexpensive way to establish a homeostasis in the pancreas, and the sand bag is used to maintain hemostasis after the catheter sheath is removed. Working with a sand bag is easy, without the need for training and expertise, and it being non - consumable as well as durable is a benefit to most health centers in these countries (6).

Among the important points in reducing complications and risks after an angiography are removal of inefficient agents and the use of effective agents, such as homeostasis. Ideal topical hemostatic drug should have significant hemostatic effects, low tissue reaction, easy sterilization, ability to digest in the body and low cost and can be used for specific needs (8). Among topical hemostatic agents shuffle tapes containing chitozan Quikclat, powder dressing containing zeolite, celox powder (9), and more recently ChitoHem granules can be mentioned.

Another topical hemostatic materials is ChitoHem powder. Of the most important features and benefits of ChitoHem powder, fast contractor of venous and arterial bleeding, reduced patient admission time, solvability and absorbability, reduced need for blood transfusion, and easy and non - allergenic use. When ChitoHem powder is sprayed onto the wound, once contacted with blood or exudate, along with manual strain on the wound, it quickly creates a strong physiological barrier or adhesive that completely covers the wound and causes homeostasis. This powder is used for all types of bleeding, especially arterial bleeding (10). The shorter duration of homeostasis may be due to the ChitoHem powder surrounding the vein and the formation of a clot, resulting in faster closure of the wound area and, consequently, faster homeostasis (11). Kurdistani et al., in 2013, showed that 1 gram of ChitoHem powder in reducing arterial homeostasis is more effective than conventional dressing (12).

The use of hemostatic agents reduces the time to build hemostasis and quickly exits the catheter from the crust. As a result, it allows patient's walk sooner than the due and reduced cost of treatment. Although the ChitoHem powder has been developed by the researchers of the country, has been introduced as an effective hemostatic method, and has been defined as large venous bleeding and arterial bleeding, its usage and function have not been widely studied. Therefore, it is to be introduced as a quick and effective hemostatic agent and it is necessary to investigate the effect of this powder on arterial bleeding. Due to the fact that it is used in traditional and ineffective devices in the care sectors and less attention is paid to these products, it is desirable that the efficacy and efficiency of this product on arterial bleeding, including bleeding after femoral angiography, be compared and investigated in various societies. Therefore, we aimed to investigate the effect of ChitoHem powder and sand bag on controlling bleeding after femoral angiography in patients who referred to Golestan Hospital of Ahvaz.

2. Methods

This is a clinical trial study conducted in 1396 with the aim of comparing ChitoHem powder and sand bag in controlling bleeding after femoral angiography in Ahvaz. The study population included all volunteer patients with femoral angiography who referred to the research environment during the research. In this study, according to the sample size formula:

$$\begin{aligned} n &= \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left(S^2{}_1 + S^2{}_2\right)}{\left(\overline{X}_1 - \overline{X}_2\right)^2} \\ &= \frac{(1.96 + 1.28)^2 \left(1.3^2 + 4.4^2\right)}{2^2} \\ &= 56 \end{aligned} \tag{1}$$

Having obtained license from the University Ethics Committee and referral from Jundishapur University's vice chancellor with code IR.AJUMS.REC.1395.727 and registering his clinical trial plan on the IRCT site with code (IRCT2017030432858N1), the researcher referred to the Department of Angiography of Golestan Hospital of Ahvaz and while introducing himself and explaining his objectives accurately, reached their agreement of the relevant authorities for the study. In this study, according to the sample size formula, 136 people entered the study based on the entry criteria. Then, using randomized block allocation method (one person in each group), patients were divided into 2 groups: intervention (68 recipients) and control group (68 people using sand bag). The allocation of samples to each of the groups was randomized block using 6 rows of quadruple blocks.

In this study, for the ChitoHem group in the operating room, after removing sheath, one gram of ChitoHem powder was used to control the bleeding by nurse with little hand pressure (to prevent blood jets). To measure the amount of bleeding, the number of blood gauzes was calculated. In case of complete hemostasis (no blood exhaust or leakage from the catheter exit site), hemostasis time was recorded and the used gas was counted and discarded and the exit site of the catheter was dressed. During this time, the patient was resting in supine position and the affected limb was kept still. From the 2nd hour onward, in case of patient's tendency, the head of the bed was raised from 15 to 30 degrees. From the 4th hour onward, the patient was able to sit up and from the 8th hour onward, if desired, could exit the bed. The time of each position change was also recorded in the checklist in the relevant table. In the sand bag group, in the operating room, after removing sheath by applying manual strain, hemostasis was done and after bleeding stop and absence of bleeding and primary hemostasis, the time was recorded and a few tubes sterilized gauzes were placed on the puncture, then it was dressed. To maintain hemostasis, based on the routine, sand bag weighing 8 kg was applied to the dressing and kept in place for 6 hours. In this study, the patients in both groups were evaluated in terms of hematoma formation at the first hour every 15 minutes and from 2nd to 8th hour, every hour and 24th hour. Clinical information was recorded in the checklist. Then the results from both groups were compared. The criteria for entering the study include: age from 20 to 70 years, complete awareness, no psychological problems, no congenital disease such as hemophilia A, B, no bleeding disorder, no infection in the groin area, no anticoagulants, receiving no narcotics and analgesics over the past 12 hours, systolic blood pressure less than 190, and diastolic less than 110 mmHg. The exclusion criteria included: active hemorrhage from the angiography site before removal of the skin, keeping the shield in place for the next therapeutic measures, systolic hypertension above 190, or diastolic over 110 mmHg. This study was conducted under the supervision of Dr. Haybar, cardiologist at Golestan Hospital in Angiography and Post Angiography. Finally, the results were analyzed using descriptive and analytical statistics using SPSS.22 software. The significance level of the test was considered 0.05.

3. Results

In this study, 136 patients were evaluated, 68 in the ChitoHem group and 68 in the bag group. The highest frequency of age in the ChitoHem group was (48.5%) and in the sand bag group was (51.5%) and in the age group was 51 to 60 years. Also, the highest frequency of gender in the ChitoHem group (52.9%) and in the sand bag group (54.4%) were male. The highest frequency of education was observed in the ChitoHem group (50%) and in the sand bag group (5/48%) are illiterate. Ethnicity is the most frequent in the ChitoHem group (38.2%) and in the sandbag group (42.6%) are Arab. In terms of occupational status, the highest frequency was observed in the ChitoHem group (48.5%) and in the sand bag group 44.1% are housewives. Regarding the history of smoking, the highest frequency was observed in the ChitoHem group (72.1%) and in the bag group (61.8%) had no background of smoking. There was also no significant difference between the 2 groups regarding age, sex, education, ethnicity, occupation, history of smoking, using Chi - square test ($p > 0.05$) (Table 1).

Regarding the hemostasis time index in 2 groups, there was a significant difference between the 2 groups based on the paired *t* - test so that in patients who received ChitoHem powder (1.694 ± 0.445), the time of hemostasis was shorter than that of the patients under the sand bag (4.45 ± 1.68) ($p = 0.0001$) (Table 2). According to the paired *t* - test, there was a significant difference in the amount of bleeding in the 2 groups; therefore, the amount of bleeding in the ChitoHem group (0.310 ± 0.195) was less than the sand band group (0.588 ± 0.355) ($p = 0.0001$) (Table 3). Also, the mean absolute resting time in the bed was based on the paired *t* - test in the ChitoHem group (4.19 ± 0.029) and in the sand bag group (8.18 ± 1.34), indicating a reduction in resting time on the bed and pain in the ChitoHem group is in comparison to the bag group ($p = 0.026$) (Table 4).

In patients who received ChitoHem powder (4.45 ± 1.68), hemostasis time was shorter than patients undergoing sand bag (1.69 ± 0.445) ($p = 0.00$) (Table 2). In the ChitoHem group, the average rate of bleeding is (0.310 ± 195.03) and in the sand bag group is (0.588 ± 0.355), indicating a decrease in bleeding in the ChitoHem group compared to sand bag ($p = 0.00$) (Table 3). Also, the mean total resting time in the bed was 4.001 in the sand group (4.19 ± 0.029) and in the sand bag group (8.18 ± 1.34) indicating a reduction in resting time in bed and reduction in patients' pain in the ChitoHem group in relation to sand bag group ($p = 0.026$) (Table 4).

4. Discussion

The results of this study showed that ChitoHem powder contributes to hemostasis and accelerates it. In this regard, Kurdistani et al. (2012), showed that in the ChitoHem group, the time of homeostasis was shorter than that of the dressing group, 64.44 ± 106.96 seconds vs. 616.16 ± 126.16 ($p = 0.001$). In the study, in the ChitoHem group, there was a possibility of exiting the bed earlier due to hemostasis; however, in the pressure - dressing group it

Table 1. Frequency Distribution and Percentage of Research Units According to Demographic Data in the 2 Groups of Sand Bag and ChitoHem Powder

Demographic Information	ChitoHem Group		Sand Bag Group		P Value
	Frequency	Percentage	Frequency	Percentage	
Age, years					0.624
30-40	5	7.4	2	2.9	
41-50	15	22.1	13	19.1	
51-60	33	48.5	35	51.5	
61-70	15	1.22	18	26.5	
Sex					0.863
Male	36	52.9	37	54.4	
Female	32	47.1	31	45.6	
Education					0.778
Unread	34	50.0	33	48.5	
Primary school	9	13.2	12	17.6	
Junior school	8	11.8	8	11.8	
Diploma	12	17.6	13	19.1	
College education	5	7.4	2	2.9	
Nationality					0.652
Lor	23	33.8	26	38.2	
Arab	26	38.2	29	42.6	
Fars	17	25.0	11	16.2	
Other	2	2.9	2	2.9	
Job					0.100
Host	32	48.5	31	44.1	
Unemployed	6	8.8	1	1.5	
Worker	2	1.5	6	8.8	
Employee	12	17.6	11	16.2	
Self employed	16	23.5	20	29.4	
Smoking history					0.437
Yes	9	13.2	13	19.1	
No	49	72.1	42	61.8	
Quit	10	14.7	13	19.1	

Table 2. Comparison of the Mean and Standard Deviation of the Investigated Units' Evaluation in Terms of Hemostasis Time in the 2 Groups of Sand Bag and ChitoHem Powder

Indicator	Sandbag Group		ChitoHem Group		P Value
	Mean	Standard Deviation	Mean	Standard Deviation	
Time hemostasis	4.45	1.56	1.69	0.454	0.00

Table 3. Comparison of the Mean and Standard Deviation of the Investigated Units' Evaluation According to the Amount of Bleeding in the 2 Groups of Sand Bag and ChitoHem Powder

Indicator	Sandbag Group		ChitoHem Group		P Value
	Mean	Standard Deviation	Mean	Standard Deviation	
Amount of bleeding	0.588	0.355	0.310	0.195	0.00

Table 4. Comparison of the Mean and Standard Deviation of the Investigated Units' Evaluation According to the Amount of Bed Rest Time in the 2 Groups of Sand Bag and ChitoHem Powder

Indicator	Sandbag Group		ChitoHem Group		P Value
	Mean	Standard Deviation	Mean	Standard Deviation	
Bed rest time	8.18	1.34	4.19	0.629	0.026

was not possible to change the position due to the risk of bleeding. Patients reported more pressure and pain than the ChitoHem group (12). The study by Yasrebi Rad et al. (2013), showed that patients who were in the sand

bag group had a higher incidence of hemorrhage after extraction of the catheter and were hemorrhaging much faster than those in the bandage group ($p < 0/05$). Kurdistan et al., considered ChitoHem an effective way to prevent bleeding that could replace current methods (13). In this study, the amount of hemorrhage in the ChitoHem group decreased compared to the sand bag group. In this case, Zavala Alarcan reported the incidence of hematoma larger than 3 cm in 3.9% of their subjects and in 0.6% of cases of severe vascular complications (14). Furthermore, Rezaei Adriani et al. (2011), showed that the rate of hemorrhage and hematoma in the 2 groups of control and test at any time after the angiography was not significantly different. The total amount of hemorrhage and the total volume of hematoma formed in the catheter entrance area did not show any significant difference in the control and test groups (15). On the other hand, compared to the sand bag group, the severity of pain in the ChitoHem group decreased due to reduction of resting time and earlier departure of patient from bed. In this regard, Adriani et al., in a study with the title of "the effect of position change on fatigue severity and patient's satisfaction after coronary angiography" showed that fatigue severity and satisfaction after angiography in test group were significantly higher than those of the control group. They concluded that changes in posture after angiography were associated with decreasing fatigue and increasing patient satisfaction without increasing the risk of bleeding and hematoma formation (16). On the other hand, the study of Mohammadian et al. (2011), aimed at the effect of bed rest time and duration of sand bag keeping on the incidence of hemorrhage and hematoma of patients undergoing coronary artery angiography in Gilan. It was found that between 2 groups of case and control, in terms of the incidence of vascular complications (hemorrhage and hematoma) in the patients in the 2 groups, during 8 stages of investigation, there was no significant statistical difference by Fisher's exact test (16). The results of this study showed that early stimulation and post - angiographic changes do not increase the risk of complications after angiography, however, in some cases they can also reduce some complications. According to the results of this study, patients can easily change their position on the bed sooner than the time commonly used. A change in the situation of the bed can reduce the back pain and promote the comfort of the individual, another benefit of the position change early movement after angiography is reduce in the need for painkillers to relieve back pain. One of the limitations of this study is that the patient's mental state, the threshold of pain, and pain tolerance are different in people and the response to pain is different in people, which is outside the control of the researcher and of the strengths of such study is its conduction in Ahvaz.

4.1. Conclusion

Therefore, according to the results of studies and that of the present study, it can be stated that using ChitoHem powder has the same effect as a sandbag, with the difference that using ChitoHem reduces hospitalization time and accelerates the treatment process, due to the fact that according to the results of the study after using the angiography, the use of a sand bag is time consuming and problematic, and staying in a long bed rest period can cause problems such as non - complete filling of the lungs, accumulation of secretions, increase in cardiac preload, followed by increased heart work and feeling of affection, and in addition, immobilization often causes muscle contraction, followed by continuous acetylcholine secretion to sustain contraction as a chemical stimulant causes muscle pain. Since the use of a sand bag causes pain at the site of the catheter, and post - angiographic complications such as hemorrhage or hematoma are more likely to occur, and also the prolonged resting time and the use of sand bag increases hospitalization time, bed occupation at hospital and pain and discomfort of the patient, therefore, the use of other methods that do not have complications of the sand bag is effective in satisfying patients and reducing their fatigue and pain. ChitoHem powder, with no obvious and severe skin complications and allergic complications, has a significant positive effect on controlling hemorrhage and can reduce the time of anesthesia. It also reduces the duration of bed rest and admission, increases patient comfort, reduces the cost of treatment, and nurses' workload. Therefore, it can be considered as an adjunct to control hemorrhages caused by rupture or surgical wounds and coronary arteries angiography (17).

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