Original Paper

The Effect of Zinc Oxide Scallop-shell Powder and Complications After Coronary Angiography

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ABSTRACT

Introduction: Coronary angiography is often associated with complications such as hemorrhage and hematoma that should be considered and be minimized.

Objective: This study aimed to determine the effect of Zinc oxide scallop-shell powder as a topical hemostatic agent (composed mainly of calcium) on complications after coronary angiography. These complications include hemostasis time, low back pain, hemorrhage, hematoma, the necessity of sandbags, and patient ambulation.

Materials and Methods: The current research was a blind, parallel, randomized clinical trial done on 150 patients under coronary angiography. They were randomly divided into three equal groups of A (control), B (case 1), and C (case 2). In group A, hemostasis was done with manual compression, use of ChitoHem powder, putting sandbag for 4-6 h in a supine position, and getting out of bed after 24 h. In group B, instead of ChitoHem powder, we used Zinc oxide scallop-shell powder. In group C, hemostasis was done with manual compression, Zinc oxide scallop-shell powder, putting sandbag for 1 h in a supine position, and getting out of bed after 2 h. The duration of hemostasis, bleeding, and hematoma after hemostasis and the severity of low back pain were investigated at 8 point intervals during 24 h. Data analysis was done using descriptive statistics indicators and Kolmogorov-Smirnov, ANOVA, Chi Square, Fisher exact test and Kruskal-Wallis tests.

Results: The Mean±SD ages of groups of A, B, and C were 60.08±11.32, 60.22±10.30, and 61.69±10.61, respectively, which was not statistically different. Furthermore, there was no significant difference between these three groups regarding their demographic information. There were statistically significant differences between groups about the amount of low back pain at the second, third, and fourth h after angiography (P=0.001). There was a significant difference in the amount of bleeding between the three groups (P=0.017). The difference in time of hemostasis in the three groups was not statistically significant.

Conclusion: The Zinc oxide scallop-shell powder reduces catheter site bleeding after coronary angiography and bed rest time and ultimately the severity of low back pain. Performing a similar study is recommended.

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Highlights

• After using a material with a high coagulation property, the time of holding sandbag and absolute rest (as the sleep status) on the bed decreased and, in turn, increased the patients' convenience.

• Research has shown that Zinc oxide scallop-shell powder is an exceptional absorption topical hemostasis powder composed of Zinc oxide.

• Scallop-shell is cheap, abundant, and is simply made.

• Zinc oxide scallop-shell powder after angiography did not create vascular complications, such as hematoma, bleeding.

Plain Language Summary

To decrease the complications after angiography, different care procedures are done, such as complete bed rest in the supine position with the head angle of 15-30 degrees for 8-24 h while keeping a 4-kg sandbag on the femoral catheter insertion area for approximately 3-8 h. Shortening the length of sandbag use, decreasing hemostasis time without vascular complications, using topical and noninvasive agents in angiography access sites can induce hemostasis quickly and provide comfort and ease for the patient. Ideal local hemostatic factors such as ChitoHem (oxidized regenerated cellulose) and Celox (contains polymer, N-acetylglucosamine, and Chitosan) have remarkable hemostatic effects, including low tissue reactions and comfort sterilization. While they can meet particular needs in the body, they are absorbable and cost-effective. The present study evaluates the effect of Zinc oxide scallop-shell powder as a topical hemostatic agent (which mainly includes calcium) on hemostasis time, low back pain, bleeding, formation of hematoma, using sandbags, and patient ambulation. This study demonstrated that reducing the duration of keeping sandbag over catheter insertion site from 6 to 1 h did not change the vascular complications (hematoma, bleeding) frequency. Furthermore, the Zinc oxide scallop-shell decreased the severity of low back pain and increased the patient's comfort. It consequently reduced the necessity of taking analgesics and massage to relieve the pain. Thus, according to the findings of this study, further studies on the use of Zinc oxide scallop-shell powder are recommended.

Introduction

Coronary artery disease is one of the most common chronic, dangerous, and life-threatening cardiovascular diseases [1, 2]. The frequency of coronary artery disease in Iran outnumbers what is reported in western countries [3]. To assess coronary artery disease, different diagnostic methods have been introduced [4]. Of them, cardiac catheterization has widely been used [5]. It has been reported that approximately three million cardiac catheterizations are conducted in the United States of America per year [6]. To carry out cardiac catheterization, the femoral artery is used in nearly 95% of angiographies [7]. This procedure is often associated with complications, including arrhythmia, vascular complications (bleeding, hematoma, and thrombosis), coronary artery perforation, hemodynamic collapse, injury and myocardial ischemia, a cerebrovascular accident such as a transient ischemic attack, allergy to contrast media and acute renal failure [8, 9]. The amount of vascular complications of coronary interventions are estimated to 7% to 28% [10].

Hematoma and bleeding are the most significant complications among these vascular complications, and they mostly happen 2-3 h after angiography [11]. To decrease the complications after angiography in Iran, different care procedures are done such as supine position, complete bed rest with the head angle of zero degrees for 8-24 h, and keeping a 4-kg sandbag on the catheter insertion area for approximately 3-8 h [12]. Various studies have confirmed several complications after angiography [13, 14]. Patient discomfort, back pain, and a longer time of hospitalization are caused by using sandbags and bed rest [15]. Among these complications, late groin bleeding accompanied by significant hematomas or pseudoaneurysms can be mentioned [16-18].

For providing comfort and ease for the patient, shortening the length of sandbag use, and decreasing hemostasis time without vascular complications, we can use a topical and noninvasive agent in angiography access site

that can quickly induce hemostasis [15]. Ideal local hemostatic factors such as ChitoHem (oxidized regenerated cellulose) [15] and Celox (contains polymer, N-acetylglucosamine, and Chitosan) [19] have remarkable hemostatic effects, including low tissue reactions and comfort sterilization. While they can meet particular needs in the body, they are absorbable and cost-effective [19, 20].

Calcium carbonate is the most important mineral section of the scallop shell and is an important ion in the coagulation cascade [21]. Zinc oxide (ZnO) is a compound for repairing tissues and accelerating wound healing [22]. Its antimicrobial, immunomodulatory, and cytoprotective properties for the clinical effects have been proved [23]. The scallop shell is found in the oceans and seas worldwide and is a member of the Pectinidae family, an aquatic bivalve mollusk, which belongs to a cosmopolitan family [24].

One of the fundamental actions after coronary angiography via the femoral artery is to reduce vascular complications. ZnO scallop-shell powder is an absorption topical hemostasis powder composed of ZnO and scallop shell that is cheap, abundant, and is simply made. Because of the powder's superabsorbent nature, when it is applied to the puncture site, the serum of the jetting blood is absorbed by the powder after removing the catheter.

The present study aimed to evaluate the effect of ZnO scallop-shell powder (which mainly includes calcium) on hemostasis time, bleeding, formation of hematoma, using sandbags, low back pain, and patient ambulation, in comparison with conventional hemostasis procedures. These procedures consist of manual compression and the application of sandbags followed by overnight bed rest.

Materials and Methods

The current research was based on a blind randomized clinical trial and conducted by a parallel method. It was carried out in the educational and therapeutic center of Guilan University of Medical Sciences, Rasht City, Iran, from June to August 2017. A total of 150 subjects were selected and assigned randomly to different groups of A (routine: hemostasis with manual compression, use of ChitoHem powder, putting sandbag for 4-6 h), B (hemostasis with manual compression, use of ZnO scallop-shell powder, putting sandbag for 4-6 h), and C (hemostasis with manual compression, ZnO scallop-shell powder, putting sandbag for 1 h) which were studied in the first, second, and third days, respectively.

Fifty participants were put in each group (considering 95% confidence interval, 90% power, and 20% data reduction). The number of samples for this study was determined using the Mean±SD of 380.94±206.87 min (hemostasis time in case group) and 546.88±258.318 min (hemostasis time in the control group) [19].

The inclusion criteria were being over 18 years old, having done angiography via the femoral artery, using needle entry to reach the artery only once, using F 7 and 6 for accessing to the artery, lacking thrombolytic treatment and bleeding disorder, lacking deep vein thrombosis before the procedure, not having previous experience of back pain, immune deficiency or using immunosuppressive drugs, lactating and being pregnant in women. The exclusion criteria were systolic pressure above 160 mm Hg and diastolic pressure greater than 100 mm Hg, complications during the procedure such as hematoma and bleeding, arrhythmia and lack of consciousness during and after angiography, and history of allergy. It should be pointed out that six patients were excluded from the study: in group A, two patients because of having systolic blood pressure ≥160 mm Hg and diastolic blood pressure ≥100 mm Hg, in group B, two for bleeding before pulling out shit, and in group C, two for hematoma and bleeding around shit before pulling it out. However, these excluded participants were replaced by the successive patients who entered the ward for angiography. To randomly assign the participants in each group, groups A, B, and C were studied on the first, second, and third day, respectively.

Scallop shells were collected from the sea beach of Anzali City in Gilan Province (Iran) and then washed with water and dried in sunlight. They were grinded using a hammer mill. The obtained material was dried in an electric furnace at 1000°C for 5 h and sieved (50 meshes). A co-precipitation method was carried out to prepare ZnO scallop-shell powder [21]. The scallop shell was added to the solution of Zinc chloride at a ratio of 1:1 (w/w). Sodium hydroxide solution was added dropwise to the precursor solution to obtain a white, gelatinous Zinc oxide/scallop shell product. The synthetic reaction was fundamentally performed with mixing for 7 h. The obtained product was washed with distilled water to remove free Zinc oxide particles and then dried at 100°C in an oven for 12 h. The procedure of immobilization of Zinc oxide nanosheets on scallop shells is shown in Figure 1. The crystallinity and phase, functional groups on the surface, the morphological and chemical composition of the samples were measured by X-Ray Diffraction (XRD), Fourier Transform Infrared Spectroscopy (FTIR), Scanning Electron Microscope (SEM), and

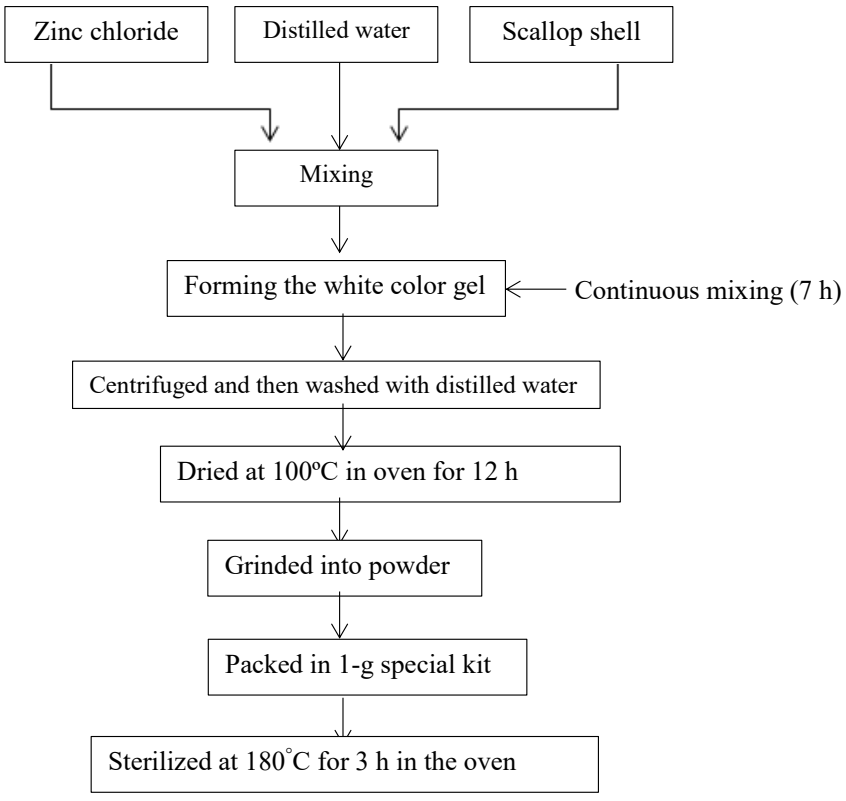

Figure 1. Procedure of immobilization of zink oxide nanosheets on scallop shell

Energy-Dispersive X-ray spectroscopy (EDX), respectively. The EDX analysis illustrated that weight percentages of Zinc and oxygen for the Zinc oxide were 57.28% and 42.72%, and percentages of Zinc, oxygen, and calcium in the Zno scallop-shell powder were 45.64%, 30.23%, and 24.13%, respectively. Hence the presence of Zinc oxide on the scallop shell was proven. All models of these devices have been reported in our previous article [21]. Finally, the samples were packaged in a 1-gr special kit and sterilized at 180°C for 3 h in the oven.

Figure 2 shows the flow chart for the implementation procedure, and Table 1 presents the position change protocol in three groups. After assigning the participants to different groups, the hemostatic powder was poured by the nurse responsible for pulling out shit. Moreover, the same nurse was responsible for studying the dependent variables like bleeding, hematoma, and back pain. It should be noted that all nurses of the ward have been trained according to a specific protocol, and they accordingly performed their duties. To monitor the patient during the study, the catheter entry site was checked for bleeding and hematoma in all three groups every 15 min in the first hour, every 30 min in the second hour, and every hour from the third to the tenth. Also, low back pain was checked on the exact time of their arrival, in the last 15 min of the first hour, in the first 30 min of the second hour, and finally every 60 min from the third to the tenth hour. If the complications appeared after leaving the bed, the patient would be put to rest in the supine position immediately, and bleeding was controlled by the pressure of the hand.

The study data were collected from June to August 2017. The study data were collected by taking demographic information (personal information, gender, age, Body Mass Index [BMI]), clinical information, which consisted of the results of clotting tests (platelet count, prothrombin time, partial thromboplastin time, and international normalize rate), measuring blood pressure at regular intervals, sheet size, duration of angiography, homeostasis method, and other conducted nursing actions which took place during the complete rest. Any hemorrhage and hematoma were considered as the research factor in the current study. Bleeding was measured by weighing bloody bandages on a 0.1-gr scale made in Japan (Standard Feutre). To assess hematoma level, a standard transparent flexible ruler was utilized, and low back pain was evaluated with Visual Analoge Scale (VAS) numerical criteria. The duration of homeostasis was measured with a stopwatch. None of the patients, researchers, and statistic consultants was aware of the type of powder used. The statistic consultant generated the ran-

Table 1. The position change protocol in three groups

Groups	Variation	Results				
A	Time	1 h after angiography	2 h after angiography		3 h after angiography	4 h after angiography
			30	30		
	Position	Supine	Supine	Supine	Supine	Supine
B	Time	1 h after angiography	2 h after angiography		3 h after angiography	4 h after angiography
			30	30		
	Position	Supine	Supine	Supine	Supine	Supine
C	Time	1 h after angiography	2 h after angiography		3 h after angiography	4 h after angiography
			30	30		
	Position	Supine	Left lateral	Right lateral	Out of bed	Free position in bed

Groups	Variation	Results				
A	Time	5 h after angiography		6 h after angiography	10 h after angiography	24 h after angiography
		30	30			
	Position	Left lateral	Right lateral	Free position in bed	Out of bed	Discharged
B	Time	5 h after angiography		6 h after angiography	10 h after angiography	24 h after angiography
		30	30			
	Position	Left lateral	Right lateral	Free position in bed	Out of bed	Discharged
C	Time	5 h after angiography		6 h after angiography	10 h after angiography	24 h after angiography
		30	30			
	Position	Free position in bed	Free position in bed	Free position in bed	Exit	Discharged

dom allocation sequence; the researcher enrolled and assigned participants to the intervention group.

The Kolmogorov-Smirnov test was done for assessing the normal distribution of data. Analysis of Variance (ANOVA) test was used for normal quantitative data and the Kruskal-Wallis test for abnormal quantitative and qualitative data. The Mann-Whitney U was used for comparing two groups if significant differences were found among the three groups. In addition, the Chi-square and Fisher exact tests were conducted to compare the three groups in terms of demographic, clinical, and procedural quality. Furthermore, the Kruskal Wallis test was used to compare quantitative variables. All data analysis was done in SPSS v. 21. The significance level of the tests was considered less than 0.05.

Results

The demographic and clinical data consisted of the mean values of age, height, weight, BMI, systolic blood pressure, diastolic blood pressure, prothrombin time, partial thromboplastin time, platelet count, international normalized ratio, and homeostasis time length. Demographic and clinical data were homogenous among the three groups. Table 2 presents the baseline demographic and clinical characteristics of the patients in three different groups. No statistically significant differences were observed between groups regarding age, height, weight, and BMI. Moreover, no significant difference was shown in the duration of angiography, systolic and diastolic blood pressure, platelet count, prothrombin time, and partial thromboplastin time. Hemostasis time in 3 groups was not statistically significant (P=0.354). No statistically significant difference was demonstrated between groups of patients regarding the amount of back pain in the first hour after entering the post-angiography unit, while a significant difference was shown at the second, third, and fourth hours (P=0.001). Table 3 presents the detailed comparison of the level of back pain in 3 groups. Therefore, the amount of back pain in groups A and B was more than group C. Figure 3 displays the rate of pain mean variation in the groups at different times. A significant difference in the percentages of bleeding rate was observed among the

Table 2. Baseline demographic and clinical characteristics of the participants in three groups

Variables	Mean±SD			Sig.*
	(Group A)	(Group B)	(Group C)	
Age (y)	60.08±11.32	60.22±10.30	61.69±10.61	0.702
Height (cm)	164.10±7.84	162.84±7.85	164.61±8.75	0.532
Weight (kg)	71.32±11.93	71.16±12.34	72.92±12.83	0.728
BMI	26.39±3.43	26.84±4.39	26.94±4.50	0.775
Time of hemostasis (s)	7.55±3.06	7.12±2.32	7.86±2.34	0.354
Plt count	204060±66570.32	213060±55180.37	211788.46±54352.99	0.710
PT	12.32±1.09	12.18±0.42	12.35±0.95	0.572
PTT	31.28±4.40	31.98±5.07	32.25±4.11	0.542
INR	1.05±0.18	1.02±0.06	1.05±0.14	0.623
SBP before angiography	122.50±14.18	119.90±12.51	121.15±12.58	0.613
DBP before angiography	77.20±8.27	74.10±7.40	73.07±8.23	0.028
SBP after angiography	133.70±19.91	138.00±18.04	130.28±17.52	0.112
DBP after angiography	81.50±11.16	82.40±9.48	78.84±9.93	0.191
SBP 2 h after angiography	123.50±19.09	125.20±19.05	120.38±18.75	0.430
DBP 2 h after angiography	78.30±12.80	77.40±11.48	72.88±12.22	0.058
SBP 4 h after angiography	126.60±19.80	120.90±19.42	122.59±18.61	0.318
DBP 4 h after angiography	79.20±11.88	74.40±13.07	75.48±10.94	0.113
SBP 6 h after angiography	123.70±18.03	120.20±17.92	121.92±16.60	0.608
DBP 6 h after angiography	76.90±10.73	74.00±10.87	74.51±11.12	0.368

BMI: Body Mass Index; INR: International Normalize Rate; Plt count: Platelet Count; PT: Prothrombin Time; PTT: Partial Thromboplastin Time; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; SD: Standard Deviation; * ANOVA.

Table 3. Detailed comparison of level of back pain between three groups

Groups	Mean±SD			
	First h	Second h	Third h	Fourth h
A	1.26±2.95	2.18±3.60	3.02±4.06	3.50±4.45
B	1.06±2.12	2.66±3.25	4.30±3.82	6.40±4.11
C	1.11±2.49	0.50±1.90	0.03±0.27	0.001±0.001
Sig.*	0.86	0.001	0.001	0.001

* Kruskal-Wallis test.

three groups (P=0.017). Bleeding was observed in 3 patients (6%) in group A and 1 patient (2%) in group B in the first hour after entering the post-angiography unit. In addition, bleeding was seen in 2 patients (4%) in the second hour in group A, and hematoma formation was observed in just 1 patient (2%) in group A.

Discussion

In this study, the rate of blood flow from the puncture site is decreased, leading to the acceleration of the clot formation. This study showed that the use of Zno scallop-shell powder after angiography did not create vascular complications, such as hematoma and bleeding. Thus, after using a material with a high coagulation property, the time of holding sandbag and absolute rest as the sleep status on the bed decreased and, in turn, patients felt more comfortable. In group C, in which Zno scallop-shell powder and hand pressure were used, the sandbag was lifted sooner, and the patient came down the bed; no bloodshed and hematoma were observed in them. While, in group A, which was performed according to the routine protocol of the section (using ChitoHem powder and hand pressure), five cases of bloodshed and one case of hematoma happened. The Kurdestani et al. study on arterial artery hemostasis via Chitotech

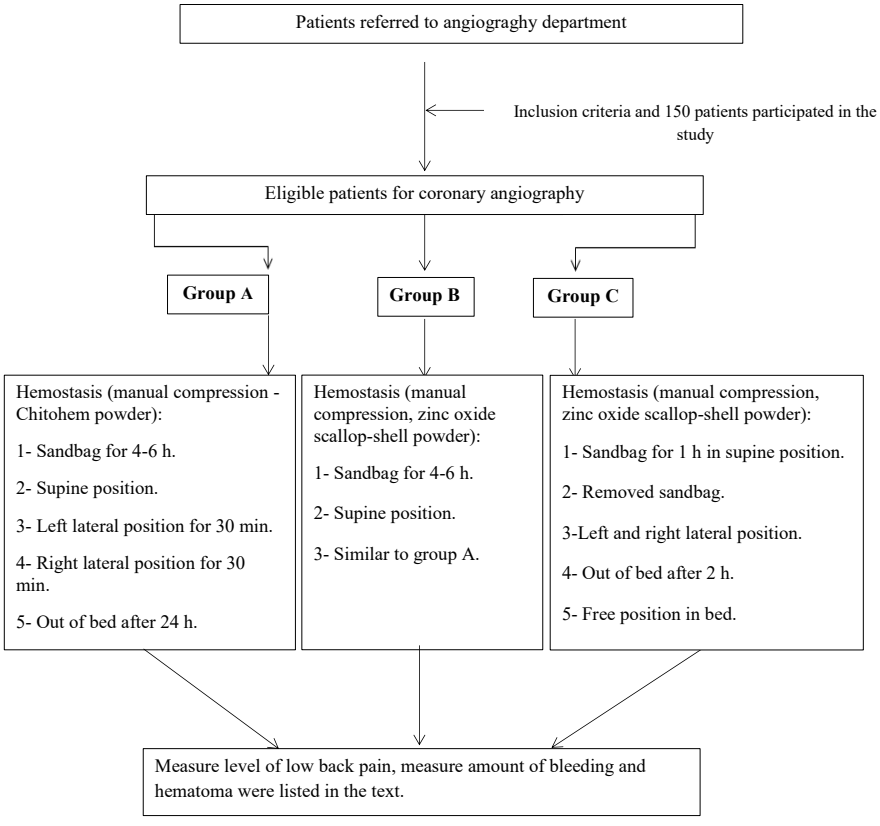

Figure 2. Flow chart for implementation procedure

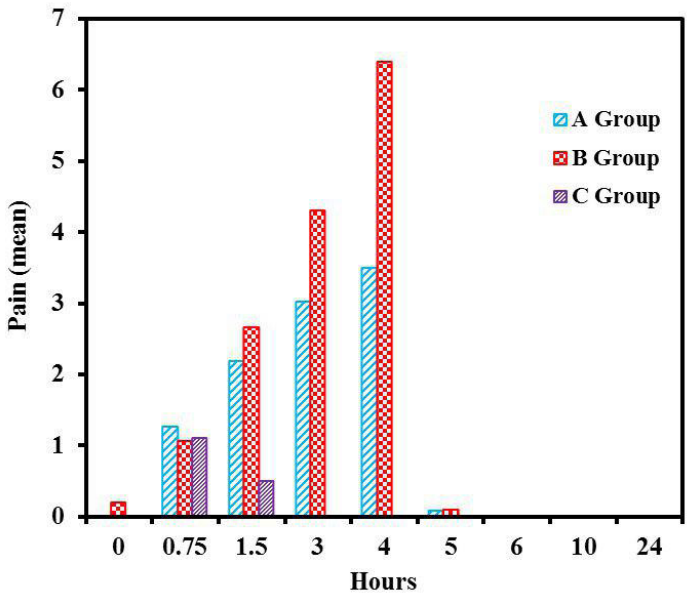

Figure 3. Pain mean variation rate in the groups at different times

powder in both study groups (1 gr of Chitotech powder with sandbag) and the control group (hand pressure with sandbag) indicated that in the intervention group, the coagulation time declined significantly compared to the control group. Moreover, there was no significant difference in hematoma formation and bleeding between the two groups [15]. Also, Hajizadeh et al. compared the application of Chitotech powder and sandbag for controlling bleeding after femoral angiogram in two groups of intervention (1 gr Chitotech powder with sandbag) and control (hand pressure with sandbag). They concluded that there was a statistically significant difference in the meantime of hematoma, rest, and the amount of bleeding between the two groups. Also, the complications after angiography in the intervention group were fewer than those of the control group [2]. Based on the results of these studies, utilization of Chitotech powder has been suggested after angiography.

In our study, there is no significant difference related to the time of blood coagulation among the three groups (there was not a difference between ChitoHem powder and Zno scallop-shell powder). Many studies have been conducted on the absolute rest time after catheterization and increased the convenience of a patient without dramatic vascular complications [24-28]. In all of these studies, the minimum absolute rest time and the start of the move and coming down the bed was 3 h. In another study, in which homeostasis was done by mechanical compression (for 1 h), the ambulance was performed 1.5 h after the procedure [21]. Therefore, using the Zno scallop-shell powder resulted in a decrease in both the time of using sandbag absolute rest time and an increase in patient's convenience without significant vascular complications.

Zinc oxide scallop-shell topical hemostasis powder, utilized in group C, was statistically superior both at decreasing the time to ambulation and the use of sandbags compared to groups A and B. The study results demonstrated that reducing the duration of keeping sandbag over catheter insertion site from 6 to 1 hour did not change the vascular complications (hematoma, bleeding) frequency. Furthermore, it decreased the severity of low back pain and increased the patient's comfort. Consequently, it reduced the necessity of taking analgesics and massage to relieve the pain. Thus, Zno scallop-shell powder as a safe and straight forward material may be helpful for patients' comfort and vascular complications reduction.

Although the findings can be clinically relevant, there are some study limitations. The researcher could not control how different nurses remove arterial sheaths, the amount of pressure they apply to make hemostasis, and the consequent hematoma and hemorrhage. Moreover, the patients' cultural differences can influence pain perception and intensity. In addition, the anxiety of illness and suggested treatments can affect the pain intensity. Also, at the beginning of the research, it was decided to use block randomization to randomize the samples. However, due to the participants' objections to using different methods for bleeding control and the time duration of putting sandbags on the angiography place, the statistic advisor applied daily randomized

sampling. Given the findings of the current study and its limitations, researchers suggest that similar studies be performed to determine the effect of Zno scallop-shell powder on complications after coronary angiography.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Guilan University of Medical Sciences (IR.GUMS.REC.2016.234) and the clinical trial (IRCT201610271083N8). Also, this research was confirmed as a patent (patent No. 95071, Iran) by the State Organization for Registration of Deeds and properties Intellectual Property Center. All participating patients signed an informed consent form.

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Authors' contributions

Conceptualization: Marjan Rahmani, Mohammad-Taghi Moghadamnia, Mehdi Shirzad-Siboni, Majid Pourshaikhian, Arsalan Salari; Writing – original draft: Marjan Rahmani, Majid Pourshaikhian, Mehdi Shirzad-Siboni, Data collection: Marjan Rahmani; Data analysis: Saeed Omidi, Marjan Rahmani, Mehdi Shirzad-Siboni; Supervision: All authors.

Conflict of interest

The authors declared no conflict of interest.

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