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Comparison of Short-Term Complications of Hemostatic Powders and Surgical on Posterior Bladder Bleeding During Hysterectomy: A Randomized Clinical Trial

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ABSTRACT

Background & Objective: As bleeding is a serious complication during and after hysterectomy, this paper aims to compare the short-term outcomes of ChitoHem and Surgicel use in posterior bladder bleeding during hysterectomy.

Materials & Methods: In the present clinical trial, 46 patients who were candidates for abdominal hysterectomy in Hajar Hospital in Shahrekord, were randomly divided into two groups. In group A, superficial cauter and Surgicel were used and in group B, superficial cauter and ChitoHem were used to control bleeding. Hematocrit and hemoglobin levels were determined before, and six and 12 hours after surgery. Drain discharge volume, time to stop bleeding and bleeding volume were also determined. The pain was determined by the VAS scale at the time of recovery, 48 hours postoperatively, and one and three months postoperatively. Data were analyzed by SPSS statistical software.

Results: Based on repeated-measures test, the mean of hemoglobin in the studied times showed a significant difference, so that in six and 12 hours after surgery they were significantly less than the ones before surgery, but their mean was not significantly different between the two groups. The mean pain score one month after surgery in group B was significantly lower than group A ($P < 0.001$). The mean volume of drainage and clotting time in group B were significantly lower than group A ($P < 0.01$). The mean volume of intraoperative bleeding, the frequency of vaginal bleeding and cuff-related complications were not significantly different in the two groups.

Conclusion: The results of the present study show that ChitoHem is probably effective in reducing bleeding during hysterectomy surgery.

Keywords: ChitoHem, Hysterectomy, Surgicel, Bladder

Introduction

Hysterectomy, as a major surgical procedure in women, is the second most performed after cesarean section (1). One of the most important and common complications of hysterectomy is intraoperative bleeding (2). Many women around the world undergo this type of surgery for various reasons. It is estimated that about 33% of women will undergo a hysterectomy during their lifetime (3). To control intraoperative bleeding, homeostasis is performed using sutures, electrocautery, ultrasonic coagulation, ablation lasers, staples and clips, manual pressure or the use of hemostatic products (4). It also reduces the size of blood vessels by prescribing gonadotropin-releasing hormones (GnRH and Mifepristone) before surgery (a few months before surgery) (5). Extensive blood loss is the loss of 20% or more of the body's total blood volume. Trauma and surgery are major causes of extensive bleeding, with blood loss during surgery accounting for a larger share. Extensive loss of blood can endanger a person's life so that if not compensated, insufficient blood flow will eventually lead to irreversible functional impairment of the body's organs (6). The average amount of blood lost during a hysterectomy varies slightly from study to study, but an average of 500 ml of blood is lost during this surgery (7). Trying to come up with new methods to control bleeding in surgeries is a constant challenge. The available methods to prevent such bleeding are cauterization, suturing, or tying, as well as the use of hemostatic agents. Electronic devices such as cauters burn tissue, and by using them the process of wound healing takes longer, so patients experience more pain than those using hemostatic agents (8). Hemostatic agents are popular tools for reducing postoperative

bleeding, the use of which can reduce the rate of periodic patient visits and postoperative analgesia compared to cauters **(9)**.

Surgicel is a hemostatic agent made from oxidized cellulose polymer and its units are Polyanhydroglucuronic Acid. Surgicel prevents bleeding and postoperative complications by forming clots and is quite economical and useful. Surgicel is absorbable and usually does not cause a particular complication, but in some patients, it can cause problems with impaired absorption or tissue reaction **(10)**. ChitoHem is a sterile, absorbable homeostatic powder containing oxidized regenerated cellulose that can be used in all types of bleeding. This ChitoHem powder is sprayed directly on the bleeding surface by an applicator so that the bleeding surface is completely covered by the powder and the bleeding stops within two minutes **(11)**. In a study by Kordestani, Noohi **(12)** it was stated that ChitoHem powder had no side effects and was safe. Due to the high prevalence of bleeding during hysterectomy as well as the complications of bladder suture and cauterization, this study was performed to determine and compare the effect of hemostatic powders and Surgicel on posterior bladder bleeding during hysterectomy.

Methods

In the present randomized clinical trial, 46 candidates for elective abdominal hysterectomy in Hajar Hospital in Shahrekord were selected by convenience sampling method. Inclusion criteria include the age range of 40–70 years, patient informed consent, no pregnancy and use of birth control pills, no systemic diseases and inherited or acquired coagulation disorders, no history of ischemic heart disease, no history of medication use (Anticoagulants and or any drug affecting on bleeding rate) and no consumption of tobacco and alcohol. The exclusion criteria were the need for re-surgery and the need to receive blood and blood products.

Patients were randomly divided into two groups of 23 people using Random Allocation Software: A (superficial cauter with ChitoHem) and B (superficial cauter with Surgicel). The researcher did not know how each patient was placed in each group. Before surgery, demographic information (such as age and cause of hysterectomy) was recorded for all patients, and they were divided into groups that were the same in terms of age range. Written consent was obtained from patients, and they were informed about the study and confidentiality of the information. Blood samples were taken after admission to the ward, before surgery and 12 hours after hysterectomy to perform a complete blood count test. The amount of bleeding during surgery was determined by three methods:

1) Visual estimation scale **(13, 14)**,

2) Determination of bleeding volume based on comparison of hemoglobin and hematocrit before and after surgery **(15)**,

3) Volume of drainage by observing the drainage pack and recording the amount of discharge 24 and 48 hours later.

The clotting time was also measured after treatment. After treatment at three different times, including postoperative, one month and three months after surgery, information about pain, vaginal bleeding and cuff-related complications (presence of vaginal discharge and foreign body discharge) were measured through observation, examination and telephone call. Patients' pain was measured by the VAS questionnaire. It should be noted that the study was approved by the ethics committee of Shahrekord University of Medical Sciences with the ethics code IR.SKUMS.REC.1397.256. The research was also registered on the site of “Iranian Registry of Clinical Trials (IRCT)" with the code IRCT20200316046787N1. After collection, the data were entered into SPSS software, version 18 (IBM, USA) and analyzed using descriptive statistics and analytical statistics (independent t-test, repeated-measures test, Chi-square test, Cochran's test and McNemar’s test).

Results

In the present study, 46 patients who were candidates for abdominal hysterectomy were evaluated in groups A and B. Two patients in group A and one patient in group B were eliminated, and statistical analysis was performed on 21 patients in group A and 21 patients in group B. The mean and standard deviation of the age was 54.13 ± 8.37 years in group A and 57.83 ± 7.96 years in group B, which did not differ significantly (P> 0.05). The mean of hemoglobin in the two groups did not show a statistically significant difference (P=0.318, F=1.04(1.04)), but the mean of hemoglobin in the studied periods showed a significant difference (P=0.000, F=188.773(88/2)). Mean hemoglobin at six and 12 hours postoperatively was significantly lower than preoperative time (P <0.001). The mean of hematocrit in the two groups did not show a statistically significant difference (P=0.277, F=1.211(1.44)), but the mean of hematocrit in the studied periods showed a significant difference (P=0.000, F=142.580(88/2)). The mean hematocrit at six and 12 hours postoperatively was significantly lower than preoperative time (P <0.001) (Table 1).

Table 1. Comparison of hemoglobin and hematocrit in the two groups in the studied periods

Variable	Level	Group A (superficial cauter with ChitoHem	Group B (superficial cauter with Surgicel)
Hemoglobin	Before	12.74±1.71	12.29±1.80
	6 hours after	12.51±1.51	11.06±1.42
	12 hours after	10.39±1.33	9.99±1.33
Hematocrit	Before	38.57±4.75	37.17±5.30
	6 hours after	35.15±4.36	33.12±4.18
	12 hours after	31.57±2.75	30.91±4.32

The mean pain score in the studied periods showed a significant difference (P=0.000, F=105.456 (3.32)). The mean pain score at 48 hours, one and three months after surgery was significantly lower than the recovery time (P <0.001). The mean pain score at one month postoperatively showed a significant difference between the two groups (P <0.001) but in groups A and B at postoperative times in recovery, 48 hours later and three months after it did not show a significant difference (P>0.05), (Table 2). The mean volume of drainage and the clotting time in group B was significantly lower than group A (P <0.01), but the mean volume of intraoperative bleeding in the two groups did not show a statistically significant difference (P> 0.05), (Table 3). Cochran's test showed that in each group, the frequency of vaginal bleeding significantly decreased during the study period. There were seven postoperative bleeding in group A which decreased to one, in one and three months after surgery and six occasions in group B which decreased to two, in one month after surgery and no bleeding was observed three months after the operation (Tables 4, 5).

Table 2. Comparison of patients' pain (VAS) in the study groups in the studied periods

Variable	Level	Group A (Superficial cauter with ChitoHem	Group B (superficial cauter with Surgicel)
Pain	after surgery	8.74±0.54	8.91±0.51
	48 hours after surgery	4.87±0.11	5.17±1.19
	1 month after surgery	2.35±0.71	1.57±0.66
	3 months after surgery	1.39±0.89	1.04±0.37

Table 3. Comparison of drain discharge volume, clotting time and bleeding volume in the studied groups

variable	Group A	Group B	P value
Drain discharge volume (cc)	(Superficial cauter with ChitoHem	(superficial cauter with Surgicel)	*0.002
Clotting time (seconds)	113.64±41.35	68.26±42.39	*0.001
Bleeding volume (CC)	53.48±10.27	41.74±13.62	0.185

Table 4. Cochran test results for vaginal bleeding at the studied times in each of the groups

studied times	Group A (superficial cauter with ChitoHem		Group B (superficial cauter with Surgicel)	
	yes	No	yes	No
Postoperative time	7	16	6	17
1 month after	1	22	2	21
3 months after	1	22	0	23
P value	**0.005		*0.019	

The values calculated in the table are (frequency) and P <0.01 and P <0.05 *

Table 5. McNemar's test results for cuff-related complications at the time of study in each of the groups

cuff-related complications		Group A (Superficial cauter with ChitoHem		Group B (superficial cauter with Surgicel)	
		3 months after		3 months after	
		yes	No	yes	No
1 month after	**yes**	1	2	0	1
	No	2	18	0	22
P value		0/668		0/500	

The values calculated in the table are (frequency).

Discussion

According to the results, the mean decrease in hemoglobin after hysterectomy in Surgicel and ChitoHem groups was 2.35 and 2.3, respectively, and the mean decrease in hematocrit was 7 and 6.26, respectively, which despite the insignificant difference, it is slightly higher in the surgicel group **(16)**. The mean pain score at one month postoperatively was significantly lower in the ChitoHem group than in the Surgicel group. The mean volume of drainage was significantly lower in the ChitoHem group (68.26 ± 42.39) than in the Surgicel group (113.64 ± 41.35). Also, the mean clotting time in the ChitoHem group (41.74 ±13.62) was significantly shorter than the surgicel group (53.48 ± 10.27). There were seven postoperative hemorrhages in the surgicel group, which decreased to one, in one and three months after the operation. In the ChitoHem group, six people decreased to two people, one month after the operation and no cases were observed three months after the operation.

In the present study, for the first time, it was observed that ChitoHem was more effective in reducing clotting time, drainage volume, pain, and to some extent bleeding rate compared to surgicel. In several previous studies, the effectiveness of ChitoHem has been evaluated and compared by other homeostasis methods. Kordestani, Noohi **(12)** showed that ChitoHem powder is more effective in reducing arterial homeostasis time than conventional dressings. In the ChitoHem group, it was possible to get out of bed earlier than in the normal dressing group. In addition, patients reported less pressure and pain **(12)**. In study Hajizadeh, Shariati **(15)** it was observed that the mean of head position time, bed sitting time, time to get out of bed, homeostasis time, absolute bed rest time, and bleeding amount were less than sandbag in the ChitoHem group **(15)**.

In the study of Mirzaei, Mahjoobi **(17)** it was observed that although the clotting time in the use of cauter is shorter than ChitoHem powder, the improvement of pain and patient and physician satisfaction in using ChitoHem is significantly greater **(17)**. In the study of Daredor and Nezaminia **(18)** and Shafaeifard, Sarkarat **(13)** ChitoHem powder was more effective than the usual method (sterile gas) in reducing pain and bleeding caused by tooth extraction **(13, 18)**. In a 2014 study by Eshghi, Jenabzade and Habibpanah **(14)** it was found that ChitoHem tampons are capable of faster homeostasis than EpiCell tampons and tranexamic acid-impregnated tampons.

Some of the most important features and benefits of ChitoHem powder are the rapid clotting of venous and arterial bleeding, reduction of patient admission time, solubility and absorption, reduction of the need for

blood transfusion, easy use and no allergies **(17)**. This powder is used for all types of bleeding, especially arterial bleeding. The shorter duration of homeostasis in the use of ChitoHem compared to other hemostatic agents may be due to the vein being surrounded by ChitoHem powder and clot formation, which causes the wound area to close faster and, consequently, faster homeostasis **(15)**. No side effects have been reported in ChitoHem studies **(15, 17)**. Its safety has also been shown in patients undergoing diagnostic coronary angiography **(15)**.

In the present study, there was one complication in the Surgicel group at one month postoperatively and three complications at three months postoperatively, while no complication was reported in the ChitoHem group. This showed a higher prevalence of complications in the Surgicel group. Although Surgicel is considered a safe homeostasis agent, several unusual complications have been reported **(19)**. Several reports have previously shown the side effects of using Surgicel in abdominal surgery and neurosurgery in which Surgicel was seen as a granuloma or postoperative abscess **(19, 20)**.

In a 2010 study Gupta, Al Said **(21)** a case of long-term drainage following the use of surgicel in partial nephrectomy was reported **(21)**. In the postoperative period, a daily increase in drainage in the form of a thick yellowish liquid was observed, approximately 5-10 ml in 24 hours from the fourth postoperative day. Therefore, the researchers reported that although Surgicel is a relatively non-stimulant substance and, in most cases completely absorbed by the body, but it is an external compound and should be used in the least possible amount. Physicians and radiologists should also be familiar with the appearance of residual Surgicel in X-rays, ultrasound, and CT scans (20-23). Biochemical analysis of fluids in the form of creatinine and sodium was performed twice on the fifth and eighth days after surgery and was matched with serum levels, which confirmed the absence of urine leakage **(24)**. Microbiological analysis showed no inflammatory damage. Therefore, the presence of concentrated sterile yellow liquid was attributed to the thick layer of surgicel **(21)**. Reduction of drain discharge was associated with a decrease in Surgicel thickness followed by ultrasound and stopped after two weeks.

Conclusion

In the present study, it was observed that ChitoHem was more effective than Surgicel in reducing the clotting time, drainage volume, pain, and to some extent the amount of bleeding due to hysterectomy. There was also one complication in the Surgicel group at one month postoperatively and three complications at three months postoperatively, while no complications were reported in the ChitoHem group.

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Conflict of Interest

The authors declare no conflict of interest.

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