Comparison Between Topical Oxidized Regenerated Cellulose Versus Gelfoam in A Case of Uterine Incision Hemorrhage at Time of Caesarean Section : A Randomized Clinical Trial

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Abstract

Background: Caesarean section is a common operation in obstetrics which is regarded generally safe but can be associated with significant morbidity. We aimed to compare successful usage of topical oxidized regenerated cellulose versus Gelfoam in a case of uterine incision hemorrhage at time of caesarean section refractory to traditional treatment.

Methods: We performed a prospective randomized open label clinical trial on 60 who underwent cesarean delivery and had intraoperative bleeding aged >18 years old. Patients were randomly divided in two equal groups. Group I were managed by oxidized regenerated cellulose and group II were managed by Gelfoam. All patients were subjected to demographic data, history of comorbidities, laboratory assessment. In both groups, the placenta was delivered by controlled cord traction. The uterus was closed with a single layer polyglactin (vicryl) suture

Results: Blood loss of 500 cc or more occurred in 9 (30%) patients in group I and 17 (56.67%) patients in group II. 6 (20%) patients in group I and 12 (40%) patients in group II needed blood transfusion. Blood loss of 500 cc or more and need for blood transfusion was lower in group I compared to group II with no statistically significant difference between both groups.

Conclusion: Local hemostatic agents; oxidized regenerated cellulose and gel foam was useful in adjuvant in control of postpartum bleeding in cesarean section. Oxidized regenerated cellulose use was associated with an increased incidence of post-operative fever significantly higher post-operative Hb levels compared to gelfoam.

Keywords: Topical Oxidized Regenerated Cellulose; Gelfoam; Uterine Incision; Hemorrhage; Caesarean Section.

Introduction

Caesarean section is a common operation in obstetrics which is regarded generally safe but can be associated with significant morbidity [1]. Caesarean section is associated with varying degrees of blood loss, and it is accepted that the estimated blood loss is not measured accurately and may account for a wide variation of values reported. It may be carried out electively or on an emergency basis with the latter being associated with greater estimated blood loss [2].

Spinal subarachnoid block is associated with significantly lower blood loss at caesarean section because of its hypotensive effect [3]. There is a significant association between higher blood loss and post operative infectious morbidity as anaemia predisposes to infections because of the resulting tissue hypoxia and decreased ability of the body to fight infection. Hence measures to minimize intraoperative blood loss

should be employed during caesarean section to reduce the need for blood transfusion and to minimize maternal morbidity [4].

The standard management for uterine hemorrhage during caesarean section is uterine massage, intravenous oxytocic, intramuscular and intra-myometrial prostaglandin injection, uterine or internal artery ligation and in refractory cases hysterectomy. However, bleeding may continue to occur in spite of these efforts and has led to the development of absorbable hemostatic agents in order to control hemorrhage [5].

Literature within the hepatic and spinal surgery fields has supported the efficacy of these agents. Recently, advances in biotechnology have resulted in the development of topical hemostatic agents that are currently available to the surgeon. Such agents range from absorbable topical haemostats, such as gelatine, micro fibrillar collagen and regenerated oxidized cellulose, to biologically active topical haemostats such as thrombin, biological adhesives, and other combined agents [6, 7].

Oxidized-regenerated cellulose and microfibrillar-collagen have been used at the time of cesarean delivery. The mechanism by which these agents accelerate clotting is not completely understood but it is theorized that a physical effect and/or an alteration of normal physiologic processes may be at play. These agents are typically placed over the uterine incision closure at the time of cesarean delivery to provide hemostasis in addition to conventional methods using suture. In spite of its benefits, use of absorbable hemostatic agents may not necessarily be without risk and may cause a probiotic microenvironment that can contribute to bacterial proliferation.[8].

A study performed by Anderson et al. [9] investigated the association of gelatine thrombin matrix use and abscess formation in patients undergoing hysterectomy and found that nine patients developed an abscess with gelatine-thrombin use as opposed to only two patients who developed an abscess in the absence of gelatine-thrombin use. However, no study to date has assessed the association between routine absorbable hemostatic agent use, as a means of preventing post-operative bleeding, and post-operative fever and abscess formation in women undergoing cesarean delivery.

Gelfoam sterile compressed sponge is a water-insoluble, hemostatic device prepared from purified porcine skin gelatine, and capable of absorbing up to 45 times its weight of whole blood. The absorptive capacity of Gelfoam is a function of its physical size, increasing as the size of the gelatine sponge increases [10].

Oxidized regenerated cellulose has proven antibacterial activity and is now available as a large 6.9 in absorbable hemostatic mesh for large surfaces (Sugicel Nu Knit) [11].

The aim of the present study is to compare successful usage of topical oxidized regenerated cellulose versus Gelfoam in a case of uterine incision hemorrhage at time of caesarean section refractory to traditional treatment.

PATIENTS AND METHODS

We performed a prospective randomized open label clinical trial on 60 who underwent cesarean delivery and had intraoperative bleeding aged >18 years old and received their post-operative care admitted to Department of Gynecology Benha University Hospitals after approval of the institutional ethical committee (Approval number: 1-7-2023). The informed written consent was obtained from the patients. Every patient received an explanation of the purpose of the study and had a secret code number.

Exclusion criteria were patient refusal and those who underwent procedures in addition to cesarean delivery such as bilateral tubal ligation, myomectomy, and lysis of adhesions.

Randomization:

Patients were randomly divided in two groups (according to a computer-generated random sequence with a 1: 1 ratio). Group I: 30 women were managed by oxidized regenerated cellulose and group II: 30 women were managed by Gelfoam.

All patients were subjected to the following: Demographic data (age, BMI, menstrual history, type, duration, number of prior cesarean deliveries, Parity and gravidity, and amount of bleeding, any medications), History of comorbidities (HTN, diabetes, smoking, dyslipidaemia , Clinical examination including HR, BP, Laboratory assessment including CBC, Hgb level, hematocrit, prothrombin time and concentration, INR, and kidney function.

In both groups, the placenta was delivered by controlled cord traction. The uterus was closed with a single layer polyglactin (vicryl) suture. Despite good approximation, there was a constant oozing of blood from the incision site. Extra hemostatic sutures were taken at incision site to control local ooze, but bleeding continued. The uterus was moderately contracted. Oxytocin drip was started and the injection ergometrine was given intravenously. Uterine massage was performed. Prostaglandin F2 alpha (prostodin) was injected intramyometrially. However, the oozing from the incision site continued.

In Oxidized generated cellulose group: Oxidized regenerated cellulose (Surgicel Nu Knit, Ethicon, INC, Somerville, USA) available as a 15.2·22.9 cm2 absorbable hemostat was placed on the incision site thoroughly wrapping the bleeding site. It was stitched on the bleeding site with two interrupted vicryl sutures and local pressure was given. Bleeding stopped and the site was observed for 10 min for hemostasis. The abdomen was closed in layers. There was no post-partum hemorrhage. The patient was given intravenous antibiotics and fluids as per the hospital protocol. It works by activation of extrinsic cascade and provides scaffold for platelets aggregation and clot formation.

In Gelfoam group (Gelatins): It has been demonstrated that gelatine sponges containing 1% w/v gelatine and 0.5% w/v glutaraldehyde had good mechanical strength, improved water absorption ability, and hemostatic effectiveness without any risk of cytotoxicity. Currently, there are several commercially available gelatine-based products, such as GelFoam (Pfizer, New York, GelFoam, a solid gelatine-based product, can swell up to twice its size after absorbing water from the blood, which provides a tamponade effect to stop bleeding. However, the tamponade effect may cause compression-related side effects, such as compression of nerves in the spinal cord, Bleeding continues check coagulation status, assemble response team, move to operating room, place intrauterine balloon, administer additional uterotonics (misoprostol, carboprosttromethamine), consider uterine artery embolization, GelFoam, dilatation and curettage,

Patients' evaluation:

Estimated blood loss, incidence of administration of pre- and post-operative antibiotics, pre- and post-operative complete blood counts and incidence of post-operative fever and abscess.

Oxidized regenerated cellulose and gelfoam were used at the time of cesarean, it will be placed over the uterine incision after uterine incision closure. All patients received pre-operative antibiotics and will receive the same pre-operative antibiotic post-operatively for up to 24 hours after surgery, unless the provider determine that the post-operative antibiotic regimen should be changed. Postoperative complications such as infection, allergic reactions and immunologic events, fever were recorded.

Statistical analysis

Statistical analysis was done by SPSS v27 (IBM©, Chicago, IL, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analyzed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were analyzed by Mann Whitney-test. Qualitative variables were presented as frequency and percentage (%) and analyzed using the Chi-square test or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

RESULTS

In this study, 87 patients were assessed for eligibility, 19 patients did not meet the criteria and 8 patients refused to participate in the study. The remaining 60 patients were randomly allocated into 2 groups (30 patients in each). All allocated patients were followed-up and analyzed statistically. **Figure 1**

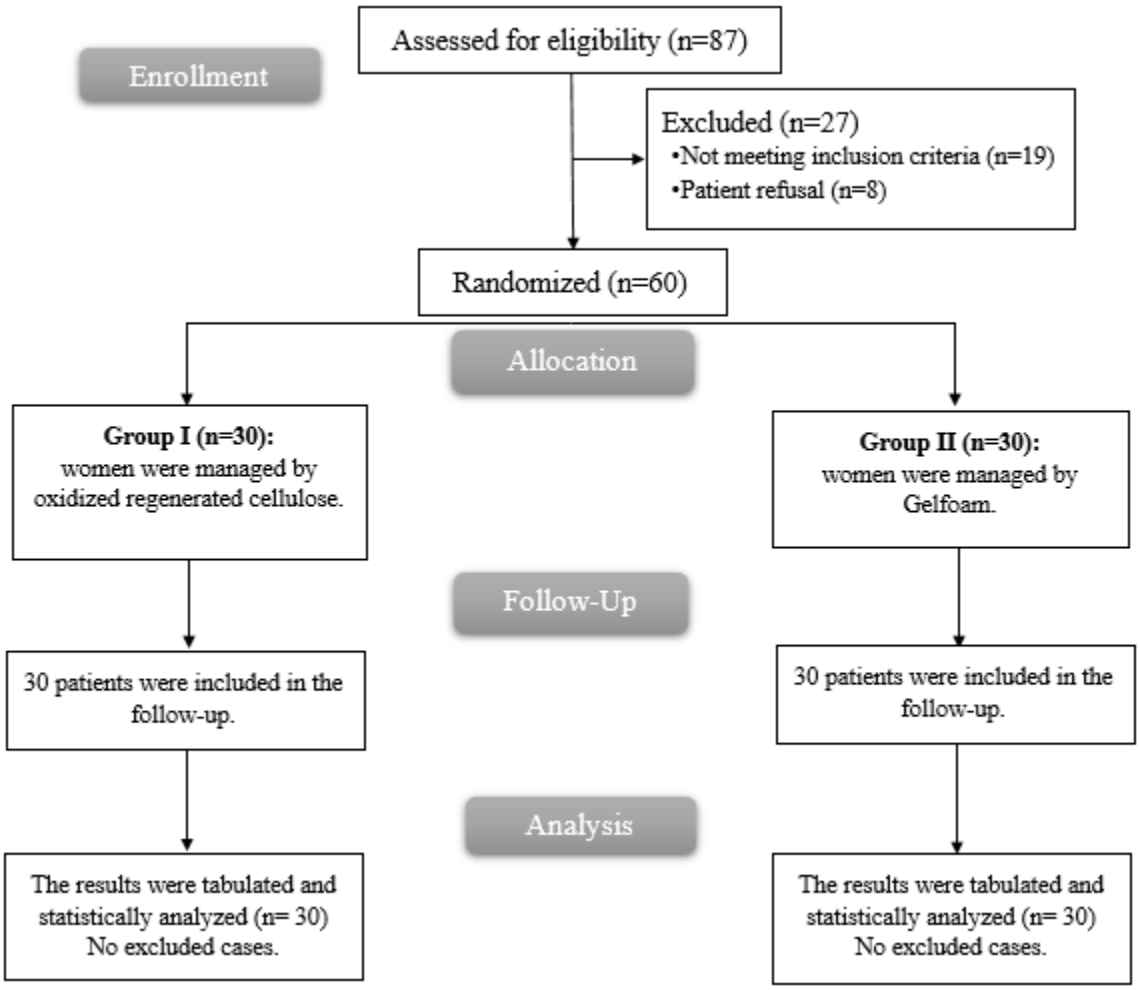

Figure 1: CONSORT flowcahrt of the enrolled patients

Table 1 demonstrates the baseline characteristics of the studied groups, where age, weight, height, BMI, and associated comorbidities as HTN, DM and smoking were insignificantly different between both groups.

Table 1: Baseline characteristics of the studied groups

		Group I (n=30)	Group II (n=30)	P value
Age (years)		27.03 ± 5.26	27.1 ± 4.96	0.960
Weight (Kg)		73.77 ± 8.47	74.47 ± 9.06	0.758
Height (m)		1.61 ± 0.05	1.62 ± 0.05	0.339
BMI (Kg/m^2)		28.47 ± 3.69	28.38 ± 4.19	0.928
Comorbidities	**HTN**	9 (30%)	8 (26.67%)	0.774
	DM	14 (46.67%)	11 (36.67%)	0.600
	Smoking	13 (43.33%)	10 (33.33%)	0.595

Data presented as mean ± SD or frequency (%), HTN: hypertension, DM: diabetes mellitus

Table 2 shows that there was insignificant difference between both groups regarding gestational age, parity and gravidity.

Table 2: Maternal data of the studied groups

		Group I (n=30)	Group II (n=30)	P value
Gestational age (Wks.)		39.53 ± 1.98	38.87 ± 1.76	0.173
Parity	**Primiparous**	9 (30%)	5 (16.67%)	0.360
	Multiparous	21 (70%)	25 (83.33%)	
Gravidity		2.73 ± 1.2	2.6 ± 1.19	0.661
		3 (2-4)	3 (1.25-4)	

Data presented as mean ± SD, median (IQR) or frequency (%), HTN: hypertension, DM: diabetes mellitus

Hb level was significantly higher in group I after 24hr and 48hr compared to group II (P=0.025, 0.002). Preoperative Hb level, preoperative platelets, and platelets after 24hr and 48hr were comparable between both groups. **Table 3**

Table 3: Labortaory investigations of the studied groups

		Group I (n=30)	Group II (n=30)	P value
Hb (g/dL)	**Preoperative**	13.03 ± 0.57	13.13 ± 0.69	0.516
	After 24 hr.	11.88 ± 2.26	10.46 ± 2.53	**0.025***
	After 48 hr.	11.31 ± 1.0	10.57 ± 0.77	**0.002***
Platelets (*10^9/L)	**Preoperative**	280.77 ± 55.92	263.9 ± 55.52	0.246
	After 24 hr.	256.87 ± 29.24	240.63 ± 40.11	0.078
	After 48 hr.	205.76 ± 54.91	185.03 ± 58.18	0.165

Data presented as mean ± SD, or frequency (%), Hb: hemoglobin, *: statistically significant as P value <0.05

Blood loss of 500 cc or more occurred in 9 (30%) patients in group I and 17 (56.67%) patients in group II. 6 (20%) patients in group I and 12 (40%) patients in group II needed blood transfusion. Blood loss of 500 cc or more and need for blood transfusion was lower in group I compared to group II with no statistically significant difference between both groups. **Table 4**

Table 4: Blood loss and transfusion of the studied groups

	Group I (n=30)	Group II (n=30)	P value
Blood loss of 500 cc or more	9 (30%)	17 (56.67%)	0.068
Blood transfusion	6 (20%)	12 (40%)	0.159

Data presented as or frequency (%),*: statistically significant as P value <0.05

Regarding the incidence of complications, infection occurred only in 2 (6.67%) patients in group II, fever occurred in 6 (20%) patients in group I and 2 (6.67%) patients in group II and allergic reaction did not occur to any patients in both groups. Incidence of complications (infection, fever) was insignificantly different between both groups**. Table 5**

Table 5: Complications of the studied groups

	Group I (n=30)	Group II (n=30)	P value
Infection	0 (0%)	2 (6.67%)	0.491
Fever	6 (20%)	2 (6.67%)	0.254
Allergic reaction	0 (0%)	0 (0%)	--

Data presented as frequency (%)

DISCUSSION

Over the past decade, the use of hemostatic agents to control bleeding has increased significantly. These hemostatic agents can be divided into physical, absorbable, biologic and synthetic agents [12]. Topical hemostatic agents like oxidized regenerated cellulose (surgical), absorbable gelatine sponge (GelFoam) and topical thrombin have been used successfully to achieve hemostasis in oral, intestinal, vascular and gynaecological surgery [13]. Gelatine sponge and topical thrombin have no antibacterial activity. Thrombin being bovine in origin can cause auto immunity and the development of antibodies. Oxidized cellulose has proven local hemostatic efficacy and antibacterial activity and is safe and inexpensive [14].

Oxidized regenerated cellulose has a low pH, it may cause red blood cell lysis which may trigger hematin formation thus accelerating clotting with the help of normal physiologic processes. However, the acidic nature of oxidized regenerated cellulose may increase inflammation in surrounding tissue and delay wound healing [15]. Oxidized regenerated cellulose absorption typically lasts between two and six weeks but histologic evidence of oxidized cellulose fibers several years after cardiac surgery has been reported [16].

Research has been limited regarding adverse effects of use of this agent, but cases have been reported in which oxidized regenerated cellulose was used for hemorrhage control during thoractomy and the cellulose passed through the intervertebral foramen and caused cord compression [17].

The gelatine matrix is absorbed within four to six weeks case of use, low price and good hemostatic activity make topical haemostats with gelatine matrix a popular tool for reducing the morbidity caused by hemorrhage [18]. Local haemostats offer an alternative method for the hemostasis of bleedings [19]. Few studies till now has evaluated the use of oxidized regenerated cellulose and gelaton in obstetric surgery [20].

Therefore, we established this study to compare successful usage of topical oxidized regenerated cellulose versus Gelfoam in a case of uterine incision hemorrhage at time of caesarean section refractory to traditional treatment.

We found that Hb level was significantly higher in group I after 24hr and 48hr compared to group II (P=0.025, 0.002). Blood loss of 500 cc or more and need for blood transfusion was lower in group I compared to group II with no statistically significant difference between both groups.

In line with our findings, a case report done by Sharma et al. [21] found that oxidized regenerated cellulose has been successfully used for the control of hemorrhage from the uterine perforation site and fallopian tube hemorrhage in cases of sterilization during CS [22, 23]. It is now available as a large mesh to cover large bleeding areas like the liver and spleen. They covered the uterine incision site with the oxidized cellulose (Surgicel Nu Knit) and stitched it there with the successful control of blood loss from the incision site [21].

Abraham et al. [24] investigated 155 patients, oxidized cellulose was used in 77 (50%) underwent CS and found that Increase in pre- and post-operative white blood cell count (3.5 vs. 3.3, p=0.65) and decreases in pre- and post-operative hemoglobin (1.7 vs. 1.9, p=0.21) and hematocrit (4.5 vs. 5.1, p=0.29) were not significantly different between groups. They found that the routine use of oxidized regenerated cellulose as a means to prevent hemorrhage was associated with a significantly increased incidence of postoperative fever without significantly attenuating the decrease in hemoglobin and hematocrit that occurs before and after surgery.

Regarding gelfoam, El-Hofey et al. [25] studied the effect of Gelfoam in hemostasis as adjuvant in control of primary postpartum hemorrhage and found that was associated to reduce the use of systemic hemostats, shorten the time required to achieve hemostasis, decrease the need for transfusion and its associated risks, and shorten the duration of surgical operations with a prolonged time to passage of flatus and, thereby,

delayed discharge from hospital. Ma et al. [26] found that absorbable gelatine sponge could decrease the blood loss during hemostatic process and the postoperative drainage volume in posterior operation of lumbar degenerative disease. AGS is a safe and effective hemostatic agent in lumbar posterior surgery.

Our results should that regarding the incidence of complications, infectionoccurred only in 2 (6.67%) patients in group II, fever occurred in 6 (20%) patients in group I and 2 (6.67%) patients in group II and allergic reaction did not occur to any patients in both groups. Incidence of complications (infection, fever) was insignificantly different between both groups.

Regarding complications, Abraham et al. [24] reported that there were no cases of abscess formation. Given the increase in incidence of post-operative fever, it was expected that there would be an association between use of oxidized regenerated cellulose and increase in white blood cell count before and after surgery. This difference may be due to different population and surgical condition.

Oxidized regenerated cellulose may have a lower risk of infection compared with other physical hemostatic agents and has some bactericidal activity because of its acidic pH; however, excessive use still may cause infection [27, 28]. There is some evidence that physical hemostatic agents may mimic an abscess on imaging, even in the absence of infection [29]. Foreign body reactions such as granuloma formation and fibrosis have been reported with physical agents, including microfibrillar collagen, oxidized regenerated cellulose, and gelatine-based agents. Adhesions and small bowel obstruction at the site of previous application also have been reported with flowable thrombin-gelatine matrix products used alone [30, 31].

Regarding gelfoam, Özer and Köstü [7] aimed to determine the effects of use of a local hemostatic gelatine sponge (GS) on postoperative morbidity in patients undergoing cesarean section (CS). They found that use of local haemostats, shorten the time required to achieve hemostasis, decrease the need for transfusion and its associated risks, shorten the duration of surgical operations the mean time to first flatus during the postoperative period, and the duration of hospitalization are significantly prolonged using gelatine sponge as a local hemostat in cesarean section patients. The delay in the recovery of bowel motility may be due to the local hypersensitivity reaction caused by gelatine sponge and/or dislocation of this local hemostat. These findings imply that the type, amount, and localization of gelatine sponges should be recorded in surgery notes.

Conclusion: Local hemostatic agents; oxidized regenerated cellulose and gel foam was useful in adjuvant in control of postpartum bleeding in cesarean section. Oxidized regenerated cellulose use was associated with an increased incidence of post-operative fever significantly higher post-operative Hb levels compared to gelfoam.

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