

## The Role of Local Hemostatic Agent (Gelfoam) in the Control of Postpartum Hemorrhage

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### Abstract

**Background:** Post Partum Hemorrhage (PPH) is considered as one of the most important causes of maternal mortality all across the world, especially in developing countries. Topical hemostatic agents are utilized as adjuncts to control intraoperative bleeding in situations including: bleeding near vital organs or nerves, at needle-holes, from raw surface areas, in friable or attenuated tissues and in patients who are anticoagulated, have bleeding diatheses or have platelet dysfunction. Physical agents and biologically active agents comprise the two main categories of topical hemostatic agents. The use of local hemostatic agents for intraoperative hemorrhage control has been described by various surgical specialities including cardiovascular, otolaryngology, urology, gynecology, and others.

**Objective:** The aim of this study was to evaluate the role of a local hemostatic agent (Gelfoam) in the control of PPH.

**Patient and methods:** This cross-section study was conducted at Benha Teaching Hospital, Obstetrics and Gynecology Department (Emergency Unit) for delivery. The study included 30 pregnant females who underwent cesarean section and vaginal deliveries and developed PPH.

**Conclusion:** Pregnant women are at risk of PPH and blood loss during labor that cannot be always prevented. Good antenatal care help is needed in the early detection of risk factors for PPH. Those technically simple procedures such as the use of Gelfoam at the bleeding sites should have the priority in cases of PPH, because they are effective, reliable, and can be performed under easy instructions and by less trained personnel.

**Keywords:** Gelfoam; Local hemostatic agents; Postpartum hemorrhage

### Introduction

Post Partum Hemorrhage (PPH) is considered one of the most important causes of maternal mortality all across the world, especially in developing countries<sup>[1]</sup>. It occurs either due to placental site bleeding or traumatic lacerations of the female genital tract. Many measures are used to control PPH including uterine massage, uterotonics, bimanual or aortic compressions, intrauterine bags or catheters, compression sutures, and de-vascularization of the uterus<sup>[2]</sup>.

Topical hemostatic agents are utilized as adjuncts to control intraoperative bleeding when standard surgical techniques (such as suturing, cautery or pressure) are insufficient or impractical to implement<sup>[3]</sup>.

The use of local hemostatic agents (LHAs) for intraoperative hemorrhage control has been described by various surgical specialties including cardiovascular, otolaryngology, urology, and others<sup>[4]</sup>.

The use of LHAs in gynecologic surgery have been reported including laparoscopy, myomectomy, oncologic debulking, and inguinal lymphadenectomy<sup>[5]</sup>.

The basic mechanism of action of passive (mechanical) hemostatic agents is to provide a physical structure around which the platelets can aggregate and form a clot<sup>[6]</sup>, whereas the biologically active (physical) topical hemostatic agents stimulate the coagula-

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tion cascade, primarily through the transformation of fibrinogen to fibrin by thrombin’s enzymatic action<sup>[7]</sup>. Fibrin sealants, a category of hemostats that are designed to mimic the final steps of the blood coagulation cascade, form a stable, physiologic fibrin clot<sup>[8]</sup>.

The aim of this study was to evaluate the role of LHA (Gelfoam) in the control of PPH.

### Patients and Methods

This is a cross-section study conducted at Benha Teaching Hospital, Obstetrics and Gynecology Department (Emergency Unit) for delivery. The study included 30 pregnant females who underwent cesarean section (CS) and developed PPH.

#### Inclusion criteria

- Maternal age ranged from 18 to 45 years.
- Gestational age between 37 and 40 weeks.
- All cases were normotensive.

#### Exclusion criteria

Pregnant women having any medical disorders such as chronic hypertension, diabetes mellitus, renal diseases, cardiac diseases, and also cases of twin pregnancy.

Women fulfilling the inclusion criteria were subjected to complete history-taking, general, abdominal, and vaginal examination. Preoperative investigations were done including complete blood count and coagulation profile (prothrombin time, partial thromboplastin time, international normalized ratio) and obstetric ultrasonography.

#### Procedure

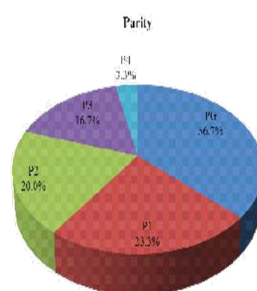
Gelfoam absorbable-gelatin sponge is a mechanical hemostatic agent used locally at the site of bleeding (inside the uterine cavity in case of uterine atony, at placental site bleeding, outside the uterine cavity, on the uterine suture or on the complicated obstetric genital lacerations). We cut the sponge to fit the size of the bleeding site and hold it in place for few minutes. Curaspon is a sterile hemostatic absorbable gelatin sponge, STANDARD-REF CS-010 80×50×10 mm (CuraMedical B.V., Assendelft, and the Netherlands). Curaspon gelatin sponge has a porous structure that activates the thrombocytes at the moment blood comes in contact with the matrix of the sponge, this causes the thrombocytes to release a series of substances promote their aggregation at the same time as their surfaces change character, thus enabling the formation of the fibrin.

In case of uterine atony, we cut the Gelfoam sponge in fingers and applied them in the uterus compressing it and added intrauterine gauze pack for 24 h. In case of failure to control bleeding with LHAs, we proceeded to uterine devascularization procedure and uterine artery ligation.

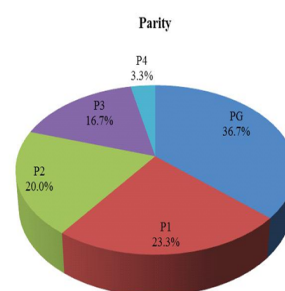
The following observations were recorded for every case. Vital signs (pulse rate, temperature, and blood pressure), uterine contractility, need for blood transfusion, need for surgical intervention such as uterine artery ligation.

### Results

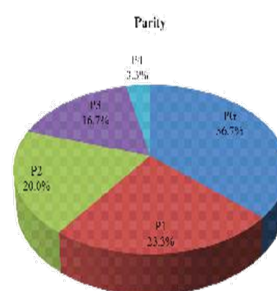
We included six cases of vaginal delivery and 24 cases of CS.



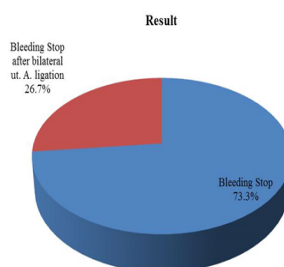
**Figure 1:** Shows that the percentage of cases who are P1 was 23.3%, P2 (20%), P3 (16.7%), P4 (3.3%) and PG (36.7%) according to parity.



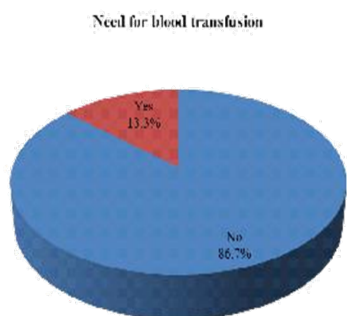
**Figure 2:** Shows that the percentage of cases who delivered by CS was 80%, and those delivered vaginally were 20%, according to the mode of delivery.



**Figure 3:** Shows that the percentage of cases who needed one piece of Gelfoam was 43.3%, two (40%), and three (16.7%), according to number of pieces used.



**Figure 4:** Shows that the percentage of cases that showed stoppage of bleeding with the use of Gelfoam was 73.3% and those proceeded to bilateral ut. A. ligation was 26.7%.



**Figure 5:** Shows that the percentage of cases that did not need blood transfusion was 86.7%, and those who needed were 13.3%.

**Table 1:** Shows statistically significant difference between stoppage of bleeding with Gelfoam and stoppage of bleeding after proceeding to bilateral ut. A. ligation, according to parity.

Outcome [n (%)]				
Parity	Bleeding stop	Bleeding stop after bilateral ut. A. ligation	$\chi^2$	P value
P1	6 (27.3)	1 (12.5)	12.662	0.013
P2	2 (9.1)	4 (50.0)		
P3	2 (9.1)	3 (37.5)		
P4	1 (4.5)	0 (0.0)		
PG	11 (50.0)	0 (0.0)		
Total	22 (100.0)	8 (100.0)		

**Table 2:** Shows no statistically significant difference between stoppage of bleeding with Gelfoam and stoppage of bleeding after proceeding to bilateral ut. A. ligation, according to previous CS.

Outcome [n (%)]				
Previous CS	Bleeding stop	Bleeding stop after bilateral ut. A. ligation	$\chi^2$	P value
0	16 (72.7)	3 (37.5)	5.150	0.272
1	2 (9.1)	1 (12.5)		
2	1 (4.5)	2 (25.0)		
3	2 (9.1)	2 (25.0)		
4	1 (4.5)	0 (0.0)		
Total	22 (100.0)	8 (100.0)		

CS, cesarean section.

**Table 3:** Shows statistically significant difference between stoppage of bleeding with Gelfoam and stoppage of bleeding after proceeding to bilateral ut. A. ligation, according to the indication to use Gelfoam.

Outcome [n (%)]				
Indication to use Gelfoam	Bleeding stop	Bleeding stop after bilateral ut. A. ligation	$\chi^2$	P value
Atony	5 (22.7)	4 (50.0)	14.545	0.006
Placenta previa	1 (4.5)	4 (50.0)		
Placental site bleeding	6(27.3)	0 (0.0)		
Suture oozing	4 (18.2)	0 (0.0)		
Vaginal laceration	6 (27.3)	0 (0.0)		
Total	22 (100.0)	8 (100.0)		

**Table 4:** Shows statistically significant difference between stoppage of bleeding with Gelfoam use and stoppage of bleeding after proceeding to bilateral ut. A. ligation, according to number of pieces used.

Outcome [n (%)]				
Number of pieces used	Bleeding stop	Bleeding stop after bilateral ut. A. ligation	$\chi^2$	P value
1	13 (59.1)	0 (0.0)	12.273	0.002
2	8 (36.4)	4 (50.0)		
3	1 (4.5)	4 (50.0)		
Total	22 (100.0)	8 (100.0)		

**Table 5:** Shows highly statistically significant difference between stoppage of bleeding with Gelfoam and stoppage of bleeding after proceeding to bilateral ut. A. ligation, according to need for blood transfusion.

Outcome [n (%)]				
Need for blood transfusion	Bleeding stop	Bleeding stop after bilateral ut. A. ligation	$\chi^2$	P value
No	22 (100.0)	4 (50.0)	12.692	<0.001
Yes	0 (0.0)	4 (50.0)		
Total	22 (100.0)	8 (100.0)		

## Discussion

PPH plays a major role in maternal morbidity and mortality, especially in developing countries<sup>[1]</sup>. It represents a risk that attends every delivery, and is an impending danger to every child-bearing woman in the world<sup>[9]</sup>.

The prediction of PPH using antenatal risk assessment is poor, only 40% of women developing PPH have an identified risk factor develop PPH<sup>[10]</sup>.

However, with changes in the obstetric population (e.g., increased mean maternal age at childbirth, increasing number of women with complex medical disorders becoming pregnant, increasing maternal obesity, and macrosomic infants) and advances in technology (e.g., assisted reproduction leading to an increased rate of multiple pregnancy, increasing CS rates leading to placenta previa and its sequelae), some of these risk factors may become more important and others less important<sup>[11]</sup>.

In the future, women with these risk factors should be transferred to centers with transfusion facilities and an ICU for delivery, if there are not available locally<sup>[12]</sup>.

A variety of techniques have been described to control the bleeding associated with placenta previa. The B-Lynch suture and the multiple square suturing technique, intrauterine package by pads or balloon devices, vessel ligation either of the uterine or the internal iliac arteries, may provide hemostasis<sup>[13]</sup>.

The use of LHAs has been adopted in different surgical fields including cardiovascular, urologic, and neurologic surgery. These agents have been poorly evaluated in gynecologic surgery and even less in obstetric surgery<sup>[14-18]</sup> failed to demonstrate a clear impact of aging on the PPH rate. Older mothers had the highest percentage for cesarean delivery, placenta previa, retained placenta tissues, macrosomia, uterine rupture, and more frequent medical complications. Increasing maternal age has been consistently described to be a substantial risk factor in all registers of obstetric hysterectomy for PPH.

Thus all the above mentioned facts emphasize the importance of not deferring pregnancy to an older age to prevent exposure of the mothers to the risk of pregnancy in old age.

The study showed that the percentage of cases who are PI is 23.3%, P2 (20%), P3 (16.7%), P4 (3.3%), and PG (36.7%) of parity, showing few number of cases with high parity in this study. Also, Humphrey<sup>[19]</sup> did not demonstrate any relation between multiparity and PPH.

Yousef and Haider<sup>[20]</sup> have reported an association between grand multiparity and PPH. However<sup>[21,7,22]</sup> reported that multiparity was not a risk factor probably due to few numbers of women with actually higher numbers of deliveries<sup>[16,23]</sup> reported that primiparity was a significant risk factor for PPH<sup>[24,16]</sup>. concluded that primiparous women were more at risk, as they were predisposed to prolonged labor, operative vaginal deliveries, perineal trauma, and uterine atony.

Our study showed that cases with previous CS represented 36.7%, with ongoing CS was 43.3% and natural vaginal delivery was 20% of the mode, delivery, showing that PPH can complicate any labor, not only cases with previous CS. Knight<sup>[25]</sup> showed that, previous delivery by CS is associated with increased risk of PPH, abnormal placentation, peripartum hysterectomy, and uterine rupture.

The use of LHAs has been reported in urologic, neurologic, and cardiovascular surgery, as well as in other surgical fields. Nevertheless, its use in obstetrics is rarely reported, and the information we relay on is merely based on case reports and case series<sup>[26]</sup>.

Portilla *et al.*<sup>[27]</sup> described the use of a LHA Surgicel (oxidized regenerated cellulose, plant origin) for the management of PPH due to bleeding of the placental bed in patients undergoing CS due to placenta previa, and reported an inverse association between the use of LHAs in patients with PPH due to bleeding of the placental bed and the need to perform an emergency obstetric hysterectomy. In addition to the use of LHA, there was a significant reduction in the mean duration of hospital stay, use of hemo derivatives and admission to the ICU<sup>[27]</sup>.

Whiteside *et al.*<sup>[28]</sup> described the use of the topical hemostatic agent, Tisseel a fibrin sealant, in a case study where it was applied to vulval and vaginal bleeding lacerations in a patient who delivered vaginally and was complicated by obstetric genital lacerations. The patient showed good, sustained response, and stopped bleeding within 10 min<sup>[28]</sup>.

Our study showed that by using one (43.3%), two (40%) and three (16.7%) number of pieces the bleeding stopped in 73.3% of the patients, after bilateral ut. A. ligation, bleeding stopped in 26.7% of the patients, and 86.7% of the patients needed a blood transfusion, whereas 13.3% of the patients did not need a blood transfusion.

Fuglsang and Petersen<sup>[29]</sup> evaluated the effect of hemostatic fleece Tacosil (a fibrin sealant patch) when the fleece was applied directly onto the bleeding surfaces of the lower uterine segment during CS in patients with placenta previa. They concluded that in patients with PPH during CS due to placenta previa, the use of a LHA on the bleeding surface is technically easy, and suggest that this procedure should be considered in these cases.

Law *et al.*<sup>[30]</sup> reported a case report of a 35-year-old woman who had PPH, despite the use of uterotonics 2 h after

cesarean delivery for major placenta previa. On relaparotomy, heavy oozing from the placental site was found. Difficult accessibility and profuse bleeding prompted the consideration of an alternative treatment with the topical application of hemostatic gel, Floseal, over the lower segment, which achieved hemostasis within minutes. Floseal is a type of hemostatic matrix that contains a combination of human thrombin solution and gelatin-based matrix from bovine collagen. They concluded that Floseal hemostatic gel is easily applicable and provides quick and effective hemostatic control in the lower segment, where surgical intervention may be difficult<sup>[3]</sup>.

## Conclusion

It can be concluded that pregnant women are at risk of PPH that cannot be always prevented, as it occasionally occurs in women who have no apparent risk factors.

It is important to highlight that technically simple procedures such as the use of Gelfoam at the bleeding sites should have the priority in cases of PPH, because they can be performed under easy instructions and by less trained personnel. Researches including more cases should be performed for more evaluation of Gelfoam.

## Conflicts of interest

None declared.

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