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Uterine packing with chitosan-covered gauze compared to balloon tamponade for managing postpartum hemorrhage

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ABSTRACT

Background: Postpartum hemorrhage (PPH) is a major cause of maternal death worldwide. Management of PPH includes the administration of uterotonics, and intrauterine packing techniques.
Objective: In this study the effectiveness and safety of chitosan covered gauze versus a balloon tamponade for managing severe PPH should be assessed.
Study design: This retrospective cohort study was conducted at the Department of Obstetrics, Charité, university hospital Berlin, between October 2016 and June 2018. Women with PPH were treated according to management guidelines. When bleeding persisted, we applied additional uterine packing with either chitosan covered gauze or a balloon tamponade. The primary outcome was uterine bleeding termination without additional surgical interventions. Secondary outcomes included the amount of blood loss, the amount of blood transfusions and maternal complications.
Results: Among the 78 patients included in this study, 47 (60.3%) received chitosan covered gauze tamponade and 31 (39.7%) received a balloon tamponade. The major reason for PPH was atonic bleeding, no statistically significant group differences were observed. With respect to the outcomes monitored, the groups were not significantly different in postpartum vital signs, hemoglobin levels, blood loss, admission to intensive care unit, or inflammation parameters. However, three patients in balloon tamponade group required a hysterectomy. No hysterectomy was required in gauze group.
Conclusion: Chitosan covered gauze is an excellent option for treating PPH, it appeared to be at least equivalent to the balloon tamponade, in our experience particularly suitable for atony or placenta bed bleeding after spontaneous delivery or during cesarean sections, in cases of lower uterine segment atony, placenta previa bed bleeding, and/or coagulopathy.

Introduction

Obstetric hemorrhage is the world's leading cause of maternal death [1]. Postpartum hemorrhage (PPH), often caused by uterine atony, is the most common type [2–4]. When PPH results from uterine atony, management includes the administration of uterotonic drugs, selective devascularization (either with angiographic embolization or suture ligation), the application of uterine compression sutures, and intrauterine packing. In cases of severe PPH, a hysterectomy is the final option after conservative second line strategies have failed [5,6].

Chitosan impregnated gauze (Celox gauze, Medtrade Products Ltd., Crewe, UK) [7] was recently introduced in obstetrics for treating PPH as an effective tamponade in combination with potential local hemostasis stimulating properties in the uterine cavum [8,9]. Chitosan is a hydrophilic biopolymer obtained through the deacetylation of chitin, a major component of crustacean shells, such as crab or shrimp. Celox gauze is a CE (Conformité Européene)-marked, class III medical device in the EU, and it is approved by the Federal Drug Administration in the US for bleeding control. A study on the use of chitosan bandages in patients allergic to shellfish demonstrated its safety, even in this population [10], probably because tropomyosin is the major allergen in shellfish allergy, not components of the shell [11]. The effect of Celox gauze in PPH is based

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on three principles: mechanical compression, adhesion of the gauze and improved local primary hemostasis.

The Bakri postpartum balloon (Cook Medical LLC, Bloomington, U.S.A.) [12] was introduced in 1999 [13,14]. The Bakri balloon is an obstetric device that consists of a 24 French silicone catheter, 54 cm long, with a filling capacity of 500 ml. It was designed to provide temporary control or reduction of postpartum uterine bleeding by reducing uterine arterial perfusion pressure [15] and compressing the placental bed when conservative management is warranted.

In this retrospective analysis we aimed to compare the outcomes of Celox gauze with the use of Bakri balloon catheter, as a well established PPH management approach.

Materials and methods

We included women that delivered at the Department of Obstetrics, Charité University Hospital in Berlin, Germany, and experienced PPH [2]. Blood loss was measured using a plastic collector bag. Women were considered candidates for intrauterine tamponade treatment as healing trial, when the PPH did not respond to standard management (i.e., uterine massage, volume replacement, and standard medical treatment with uterotonic and antifibrinolytic agents).

The protocol followed German-Austrian-Swiss guidelines [5], which called for uterotonic treatment first (i.e., intravenous oxytocin or carbetocin), followed optionally by misoprostol (given rectally or sublingually, off label use), and tranexamic acid, when bleeding was not controlled. When bleeding persisted, Sulproston was given. Additionally, tranexamic acid was applicated as first line antifibrinolytic agent (1–2 g i.v.) when PPH occurs. Dependent on the hemostatic state and hemodynamic changes in case of ongoing bleeding, fibrinogen as well as fresh frozen plasma or red blood cell transfusion was given according to PPH-treatment algorithm [5]. Before considering interventional radiological procedures or surgical interventions, such as a B-Lynch suture, iliac artery ligation, or hysterectomy, the responsible obstetrician implemented intrauterine packing and decided which type of intrauterine packing would be used.

Celox (FG08834011, Medtrade Products Ltd.) was applied according to the advice and experience of Dr. Maul and colleagues [9]. In our study, at least one complete gauze (3 m long, 7.6 cm wide) was used for each patient, either after vaginal delivery or intraoperatively, during a cesarean section. In cases of spontaneous deliveries, the gauze was inserted transvaginally. Briefly, the patient was placed in a lithotomy position, and with the aid of a speculum, the cervix was grasped with an atraumatic instrument, if necessary, and the gauze was manually inserted into the uterine cavity, up to the fundus, with ultrasound guidance. The vagina may be stuffed by a second gauze for compression of ascending vessels and stability, in the case of twin pregnancies and additional vaginal injuries. In cases of cesarean deliveries, the uterine cavity was packed with gauze either through the hysterotomy or transvaginally by dressing forceps, and one end of the gauze was passed through the cervix, into the vagina, for subsequent removal appr. 24 h later. All patients received a wristband for identification until removal. The gauze was removed by simply pulling on the end that had been placed in the vagina.

According to manufacturer instructions, the deflated Bakri balloon was inserted into the uterine cavity transvaginally. Two towels were inserted into the vagina secondary to a PPH after vaginal birth before inflating the balloon with water to avoid displacement of the catheter, until the bleeding stopped.

Catheters of patients who had received a peridural anesthesia initially were reloaded for pain relief. In all except two of the cases, antibiotics were administered for three days after the procedure. We recorded demographic and epidemiological data, in addition to factors associated with PPH. We also evaluated secondary outcomes such as postoperative leukocytes and CRP, arterial pH and Apgar scores. All patients provided consent for the inclusion of their case data in this report.

Statistical analysis was performed using IBM SPSS Statistics Version 21.0 (IBM Corp. Armonk, NY, USA). Differences between Celox and Bakri were analyzed using Mann-Whitney U test or independent-samples *t*-test according to normality distribution assessed by Shapiro-Wilks-test. Differences of nominal data between Celox and Bakri were analyzed with Chi-squared test or the Fisher's exact test. Statistical significance was accepted at $p < 0.05$. Results are presented as arithmetic mean ± standard error.

Results

A total of 9560 women delivered between October 01 2016 and June 30 2018; of these, 657 (6.9%) developed PPH (≥ grade 1). Among the women with severe bleeding or at risk for occult bleeding/coagulopathy or patients with abnormal signs/labs/oliguria, 78 (11.9%) received intrauterine packing. These women were enrolled in the present study, and medical records were reviewed. Among these 78 women, 47 (60.3%) received a Celox gauze tamponade (Celox group), and 31 (39.7%) received a Bakri balloon tamponade (Bakri group) (Table 1). The statistical analysis showed no significant differences between the two groups (Table 2).

Placenta previa resulted in a primary cesarean section in 6 (13%) and 8 (26%) of patients in Celox and Bakri groups, respectively. Severe PPH was due to atony in 34 (72%) and 26 (84%) of Celox and Bakri groups, respectively. In two patients of Celox group and five

Table 1
Patient demographics and indication for the use of Celox and Bakri. Values are given as arithmetic mean ± standard deviation and range. In cases of delivery mode, placental pathology, injuries and atony data are presented with absolute numbers and percentage of total within the group Celox vs. Bakri. Postpartum hemorrhage is defined as grade 0 with blood loss <500 ml after vaginal birth and <1000 ml after cesarean section; grade 1 with 500–1000 ml after vaginal birth and 1000–1500 ml after cesarean section; grade 2 with 1000–1500 ml after vaginal birth and 1500–2000 ml after cesarean section and grade 3 with >1500 ml after vaginal delivery and >2000 ml after cesarean section. Differences between Celox and Bakri were analyzed using the Mann-Whitney U test (U), the independent-samples *t*-test (t), the Chi-squared test (X) or the Fisher's exact test (F) and significance was accepted for $p < 0.05$. Significant differences are presented in bold. NA = analysis not available due to low numbers.

	Celox (n = 47)	*Bakri (n = 31)*	*p value*
***Maternal Age** (years)*	31.4 ± 5.9 (22-44)	33.7 ± 6,6 (21-46)	0.114^{t}
Gestational age	38.0 ± 2.9 (27-41)	37.7 ± 3.1 (29-41)	0.518^{U}
No of newborns *singletons*	44 (93.6%)	28 (90.3%)	0.677^{F}
twins	2 (4.3%)	3 (9.7%)	0.381^{F}
triplets	1 (2.1%)	–	NA
Vaginal delivery	**27 (57.5%)**	**7 (22.6%)**	**0.002^{X}**
Vacuum delivery	**1 (2.1%)**	**7 (22.6%)**	**0.006^{F}**
Cesarean section	19 (40.4%)	17 (54.8%)	0.211^{X}
Placenta previa	6 (12.8%)	8 (25.8%)	0.227^{X}
Abnormally invasive placenta	21 (44.7%)	9 (29.0%)	0.235^{X}
Manual removal of placenta	24 (51.1%)	13 (41.9%)	0.492^{X}
Curettage	21 (44.7%)	12 (38.7%)	0.646^{X}
Injury (birth canal, cervix)	8 (17.0%)	2 (6.5%)	0.300^{F}
Post partum hemorrhage *Grade 0*	3 (6.4%)	1 (3.2%)	0.938^{X}
Grade I	8 (17.0%)	5 (16.1%)	
Grade II	10 (21.3%)	7 (22.6%)	
Grade III	26 (55.3%)	18 (58.1%)	

Table 2
Additional measures and outcome related to the use of Celox and Bakri. Values are given as arithmetic mean ± standard deviation and range. In cases Oxytocin, sulprostone, Misoprotol, B-Lynch, embolisation, hysterectomy, anesthesia, intensive care unit and antibiotics data are presented with absolute numbers and percentage of total within the group Celox vs. Bakri. Differences between Celox and Bakri were analyzed using the Mann-Whitney U test (U), the independent-samples *t*-test (t), the Chi-squared test (X) or the Fisher's exact test (F) and significance was accepted for $p < 0.05$. Significant differences are presented in bold. NA = analysis not available due to low numbers.

	Celox (n = 47)	*Bakri (n = 31)*	*p value*
Oxytocin	47 (100%)	31 (100%)	NA
Sulprostone	36 (76.6%)	28 (90.3%)	0.144^{F}
Misprostol	15 (31.9%)	12 (38.7%)	0.537^{X}
Cyclocaprone (g)	1.6 (0-5)	1.6 (0-5)	0.808^{U}
Fibrinogen (g)	**0.9 (0-8)**	**0.3 (0-2)**	**0.019^{U}**
Estimated blood loss (mL)	2017.7 (700-7000)	1756.6 (800-5000)	0.225^{U}
Perioperative lowest hemoglobin (g/dl)	7.46 (4.5-10.3)	7.11 (4.24-11.0)	0.332^{T}
Number of red cell units	1.9 (0-17)	1.5 (0-14)	0.664^{U}
Number of fresh frozen plasma units	1.9 (0-18)	1.6 (0-22)	0.885^{U}
B-Lynch	2 (4.3%)	3 (9.7%)	0.381^{F}
Embolisation	1 (2.1%)	0 (0%)	NA
Hysterectomy	0 (0%)	3 (9.7%)	NA
Anesthesia			
spinal	4 (8.5%)	4 (12.9%)	0.706^{F}
epidural	12 (25.5%)	10 (32.3%)	0.518^{X}
general	31 (66.0%)	17 (54.8%)	0.323^{X}
Intensive care unit	21 (44.7%)	19 (61.3%)	0.151^{X}
Antibiotics	47 (100%)	29 (93.5%)	0.155^{F}
Postoperative leucocytes (/nl)	16.7 (6.8-26.3)	16.2 (7.5-26.0)	0.676^{T}
Postoperative CRP (mg/l)	**56.8 (4.0-181.6)**	**111.9 (2.5-342.7)**	**0.046^{U}**

patients of Bakri group, postpartum atony occurred several hours (2–5 h) after delivery. One woman in Celox group experienced severe bleeding three weeks after delivery, due to retained placental tissue. Injury of the cervix or birth canal occurred in 8 (17%) and 2 (6%) of Celox and Bakri groups, respectively. PPH in Celox group was due to abnormally invasive placenta in 9 out of 13 non-atony cases, the 4 remaining cases had substantial vaginal injuries. In Bakri group bleeding occurred in 5 non-atony cases because of abnormally invasive placenta (twice), placenta previa (twice) and vaginal injury (once). 76.6% of Celox group and 80.7% of Bakri group had PPH grade II or III. The groups were not significantly different regarding postpartum vital signs, hemoglobin levels, blood loss, admission to ICU, and inflammation parameters. 21 (45%) of Celox group were admitted to the intensive care unit, and 19 (61%) of Bakri group were monitored. Average blood loss was appr. 2018 ml and 1757 ml in Celox and Bakri groups, respectively, with no significant difference. There was no relevant blood loss after balloon/gauze placement in any case, except for those cases with necessary further surgical intervention. Perioperative lowest Hb-levels were 7.46 g/dl and 7.11 g/dl in Celox and Bakri groups, respectively. Data on the interval change in hemoglobin before and after delivery were not available. No patient of any group developed fever (> 38.0 °C) or sepsis. In all patients in both groups, fetal arterial pH values were >7.10 and Apgar scores at 5 min after birth were ≥7. To date, no patient of the study cohort has had a subsequent pregnancy after the treatment in the present study.

Both treatment modalities successfully controlled primary atonic PPH in the majority of cases. In Celox group, one (2%) patient received uterine vessel coiling, due to placenta accreta with consecutive atony. In two (4%) cases, additional B Lynch sutures were necessary to stop the bleeding. One (2%) patient required temporary dialysis because of kidney failure after extensive blood loss and consequently suffered from cardiomyopathy. In the Bakri group, PPH recurred after the Bakri insertion in two (6%) cases, and finally, a hysterectomy was required. Two (6%) patients needed resuscitation due to cardiac decompensation because of amniotic fluid embolism after emergency c-section. All hysterectomies, three (10%) patients, were performed in the Bakri group, and none in the Celox group.

The indications for the hysterectomies were:

1 Amniotic fluid embolism after vacuum extraction. This occurred in one patient that developed disseminated intravascular coagulopathy (DIC). The patient received a Bakri catheter because of atony grade 3. Then she underwent laparotomy, B Lynch sutures, and a hysterectomy. Consecutive injuries occurred to the ureter, and the estimated blood loss was 7000 ml.
2 Atony four hours after delivery, due to a partially retained placenta, which was initially missed. After curettage and the insertion of Bakri catheter the patient experienced DIC, hematoma at the adnexa, and an estimated blood loss of 3000 ml.
3 Atony after two hours with B Lynch sutures in addition to the Bakri catheter. The total blood loss was 4000 ml.

During an observation period of 18 months before (5414 deliveries) and 18 months (5430 deliveries) after introduction of Celox at one clinic location four and two, respectively, PPH-related hysterectomies had to be performed. Thus, the rate of peripartum hysterectomies was reduced by 50%.

Comment

An intrauterine balloon catheter for treating PPH has been well established in our university hospital for several years. Previous evidence has suggested that inserting the balloon tamponade and monitoring blood loss was a straightforward technique with high effectiveness [16–18]. The Bakri balloon has shown an overall success rate of about 85% [19,20], but the rate was higher in vaginal deliveries than in C sections [21–23].

In a pioneering study on Celox, Schmid et al. tested chitosan-covered gauze in 19 cases of PPH due to uterine atony, placenta accreta/increta, or anticoagulation [9]. They found a 75% reduction in peripartum hysterectomies after introducing chitosan gauze into the clinic. In another multicenter registry analysis of the same study group, 98 patients with severe PPH were treated with Celox [24]. Two patients had an uncomplicated pregnancy following treatment, and only 6% required a hysterectomy. Celox was

introduced in our clinic in 10/2016, and those results have confirmed the good results reported by Schmid et al. [9] and Carles et al. [25]. Celox is effective, easily applied, free of adverse events, and relatively inexpensive. Celox gauze costs approximately 50€, vs. Bakri: 250€, in Germany (about 50USD and 250USD, respectively). We observed no side effects and no specific treatment-associated morbidity in both groups. During the follow-up period of 6 weeks there was no readmission, endometritis, postpartum wound infection in any of the patients. A descriptive comparison of characteristics of Celox and Bakri is presented in Table 3.

Compressing the lower uterine segment is important in preventing or stopping PPH, particularly when the placenta bed is bleeding due to placenta previa [26]. However, strong contractions of the uterine body can eject the balloon into the vagina (balloon prolapse). Balloon displacement occurs in about 10% of cases [27]. However, in our experience, Celox tamponade displacement did not occur; indeed, Celox may be superior to the balloon in PPH treatment after full dilatation of the cervix, particularly after vaginal delivery or secondary cesarean section, in the late second stage of labor, in cases of a low lying placenta and placenta previa bed bleeding.

The insertion of intrauterine balloon catheters may entail risks, particularly in an emergency situation. For example, cesarean scar dehiscence was associated with an intrauterine balloon tamponade placement after a second-trimester dilatation and evacuation [28]. Moreover, Ajayi et al. [29] reported a rare case of an unexpected uterine rupture after a uterine curettage followed by a balloon tamponade for the management of PPH. Leparco et al. [30] described the migration of a Bakri balloon through an unsuspected uterine perforation during the treatment of secondary PPH, which necessitated a hysterectomy. Considering those risks, Celox might be safer than a balloon tamponade; indeed, the gauze tamponade softens when it contacts fluid, and it conforms well to the shape of the uterus or vagina. The amount of gauze used by the operator can be modulated individually, with ultrasound guidance to verify that the tip of the tamponade is really placed in the fundus of the uterus (see Fig. 1).

Patient monitoring is an integral part of managing PPH. Follow up transabdominal scans are recommended in the first 6 h to visualize the packed cavum uteri and detect further intrauterine bleeding [31]. In a stable situation, removing a Celox or Bakri within 24 h is recommended to reduce the risk of infection. Short-term use of hemostatic agents prevents the dressing particles from entering into the bloodstream, which could lead to embolus formation [32]. The Bakri balloon and Celox are preferable to other balloons, because both devices allow blood loss quantification

Table 3
Descriptive comparison of advances and disadvantages of Celox and Bakri.

	Celox	*Bakri*
Application	easy	more difficult
Dislocation	none	possible
Local hemostyptic effect	yes	no
Pain	less	more painful
Possible use intravaginally	yes	no
Possible combination with other measures (sutures)	yes	yes
Inflammation	CRP lower	CRP elevated
Presence of drainage	Cervical os may be sealed/blocked, possible collection of blood above the gauze	yes
Compression of uterine vessels	low	high
Approval	Off-label use in obstetrics	FDA approved
Costs	cost-effective	More expensive
Uterine rupture	no published cases	rare

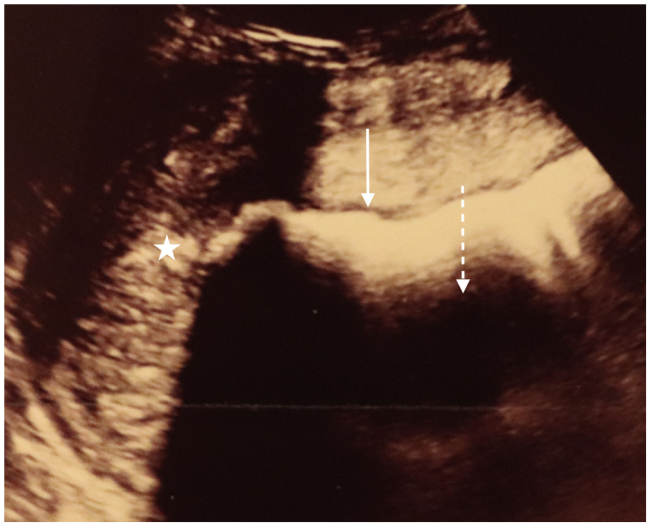

Fig. 1. Transabdominal ultrasonographic image of a Celox tamponade in utero. The uterus, at three hours after delivery, is filled with little organized clotted blood in the fundus (*).The Celox tamponade (arrow) is visible as a hyperechogenic structure, in the dorsal part of the uterus, with a dorsal acoustic shadow; hence, the posterior uterine wall is not visible (dotted line).

postoperatively, either via the drainage catheter or a saturated tamponade.

The main limitation of our study is that it was not randomized; consequently, we cannot definitively conclude that Celox was more effective than a balloon tamponade. However, the Celox group did not require any hysterectomies, and the Bakri group required three hysterectomies. In addition, before the introduction of Celox at our hospital, four versus two PPH-related hysterectomies had to be performed, thus, the rest of peripartum hysterectomies was reduced by 50%. In our study the decision in each case which tamponade was used was at the discretion of the managing clinician so there may be a selection bias. Moreover, the blood loss in both groups was only estimated semi-quantitatively, not based on anthropometric and laboratory data, as the preoperative Hb levels were not available. In about 20% in both groups the estimated blood loss was only moderate, the main indication for Celox or Bakri was then diffuse placenta bed bleeding in case of abnormally invasive placenta.

The safety and effectiveness of this new, second stage intervention for PPH should be assessed in larger prospective studies with longer follow-up times for evaluating the outcome of subsequent pregnancies after a Celox gauze tamponade.

Conclusion

Celox gauze is an excellent treatment for PPH; it appeared to be at least equivalent to the Bakri balloon tamponade for treating severe PPH. In our cohort study, no major adverse events or specific treatment-associated morbidity were associated with Celox. In our opinion, Celox is particularly suitable for atony or placenta bed bleeding after spontaneous delivery, or during cesarean sections, when the cervix is fully dilated, in cases that involve lower uterine segment atony, placenta previa bed bleeding, and/or coagulopathy. Moreover, the five-fold lower price makes it an attractive option not alone for lower-income countries.

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