Title: Comparison of celox and bakri balloon in management of primary atonic postpartum hemorrhage
OBJECTIVE: Postpartum hemorrhage is a leading cause of maternal death in developing countries. Mechanical compression techniques as bakri balloon and the recently introduced chitosan gauze (celox) were used in the management of primary atonic postpartum hemorrhage in cases where medical uterotonic agents failed. This study was designed to show the effectiveness of intrauterine insertion of celox in comparison to the standard application of the Bakri Balloon. STUDY DESIGN: Un-blinded randomized parallel prospective study. Primary endpoint was any need for further surgical interventions (e.g. peripartum hysterectomy) as a failure of the mechanical method. Secondary endpoints (e.g. post insertion fever, admission to the intensive care unit) were also recorded. RESULTS: Preliminary data showed failure rate which lead to peripartum hysterectomies were 9.7 % (3/31) in the celox group compared to 40 % (12/30) in the bakri balloon group. Low grade fever (38-38.5 degreeC) was recorded in 19.35 % (6/31) in the celox group compared with none in the bakri balloon group. Admission to the intensive care unit (ICU) was 41.9 % (13/31) (average stay 5 days) in the celox group compared to 33.3 % (10/30) (average stay 7 days) in the bakri balloon group. CONCLUSION: Celox appears to be a potentially effective method in the management of atonic PPH. It further is inexpensive, easy to use and has well manageable side effects compared to the standard intrauterine bakri balloon.

Publication Type: Journal: Conference Abstract

Source: EMBASE
DESIGN: Women suffering from PPH were treated according to guideline management and by additional uterine packing with Celox, if bleeding persisted. Since the introduction of Celox there were 15,198 deliveries at Marienkrankenhaus Hamburg (MKH), Marienhaus Neuwied and Klinikum Bielefeld. In addition, data obtained at the MKH were compared with a 26 mth period before introduction of Celox with the same basic management of PPH. Reduction of postpartum hysterectomies was evaluated by chi-square test with Yates’s correction. RESULTS: Celox was used in 98 cases of PPH (0.7% of 15,198 births). Patients were 32 (+/-4) years of age and in their 2 (+/-1) pregnancy. 68 (71%) received red cell-, 39 (41%) plasma- and 18 (19%) thrombocyte concentrates. In 3 cases (3%) coiling of uterine vessels was necessary. In all cases CRP was increased up to 142 (+/-69) mg/l, leucocytes up to 19 (+/-4) /nl. 10 (10%) patients developed fever, however none showed signs of sepsis. The gauzes were removed after 24 (+/-6) hours. In 6 cases of severe PPH (6%) a hysterectomy was necessary, that is 0.04% referring to above mentioned overall birth rate. After the introduction of Celox at MKH the rate of ppHE was significantly reduced (0.05% vs. 0.18%, OR 0.28; p=0.0183). Two patients had an uncomplicated pregnancy following treatment with Celox. Maternal mortality was 0 after the introduction of Celox. CONCLUSION: Celox can be used effectively in treating severe cases of postpartum hemorrhage. So far no major adverse events were observed or reported. Moreover use of Celox significantly reduces the number of ppHE. The gauze is easy to apply and cost-efficient. (Table Presented).

Publication Type: Journal: Conference Abstract

Source: EMBASE

Title: Uterine packing with chitosan-covered gauze (Celox) for control of postpartum hemorrhage (PPH)

Citation: American Journal of Obstetrics and Gynecology, January 2015, vol./is. 212/1 SUPPL. 1(S358-S359), 0002-9378 (January 2015)

Author(s): Maul H., Steinmacher S., Saade G., Gebauer G., Rolf N., Schmid B.

Language: English

Abstract: OBJECTIVE: Celox gauze (7.5 cm wide, 3 m long) is covered with chitosan, a hemostatic agent derived from chitin. The objective of our analysis was to compare a 26 mth period before and a 38 mth period after the introduction of Celox in the treatment of PPH and to evaluate the numbers of postpartum hysterectomies (ppHE). STUDY DESIGN: Women suffering from severe PPH at the Marienkrankenhaus Hamburg, Germany, were treated by uterine packing with Celox through the hysterotomy in cesarean delivery (CS), or transvaginally. In CS packing was generally combined with B-Lynch and/or Pereira stitches. 15036 consecutive births before and after the introduction of Celox (n=5498 vs. n=9538 deliveries) were analyzed. 1-tailed Fisher exact test was used for statistics. RESULTS: Celox was used in 65 cases of PPH including 21 severe cases where ppHE seemed inevitable. 35 women had delivered vaginally (1 vacuum), 27 by elective (n=13) or emergency (n=14) CS. In
6 out of 35 vaginal deliveries laparotomy was necessary to apply compression sutures. Celox was left in utero for up to 48 hrs (mean 20.63) before extraction. Compared with 26 mth before, in the 38 mth after introduction of Celox the rate of ppHEs was significantly reduced (10 vs. 5; OR 3.47, 95% CI 1.19-10.16; p=.023). Indications for HEs were uterine rupture (n=2), failure of compression sutures (n=2, in one case no Celox was used), recurrence of PPH after removal of Celox after 48 hrs due to preexisting thrombopenia (18 thr per nl, n=1). The longest period without ppHE after Celox was 23.5 months. One of the Celox treated patients is pregnant again (34 wks gestation). Maternal mortality after the introduction of Celox was 0. CONCLUSION: Celox is a viable option in the treatment of PPH and reduces ppHE significantly. It can safely be used after both vaginal and CS, and we observed no specific treatment associated morbidity. It is inexpensive compared to other treatments, making it suitable for use also in low resource-countries, where the death toll due to PPH is high.

**Publication Type:** Journal: Conference Abstract

**Source:** EMBASE

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**Title:** Uterine packing with chitosan-covered gauze for control of postpartum hemorrhage

**Citation:** American Journal of Obstetrics and Gynecology, January 2014, vol./is. 210/1 SUPPL. 1(S281-S282), 0002-9378 (January 2014)

**Author(s):** Maul H., Gebauer G., Rolf N., Saade G., Rezniczek G., Schmid B.

**Language:** English

**Abstract:** OBJECTIVE: To describe 26 months of experience with Celox, a gauze covered with chitosan, a potent hemostatic agent derived from chitin, in the treatment of postpartum hemorrhage (PPH) and to evaluate its effect on maternal outcome. STUDY DESIGN: Patients suffering from severe PPH at the Marienkrankenhaus Hamburg, Germany, were treated by uterine packing with Celox gauze, either through the hysterotomy in patients with cesarean delivery, or transvaginally. The gauze was left in the uterus for up to 24 hours before extraction. 1-tailed Fisher’s exact test was used for statistical analysis. RESULTS: Celox gauze was used in 35 cases of PPH due to uterine atony, placenta praevia, and placenta increta, including 10 severe cases where a hysterectomy (HE) seemed inevitable otherwise. 19 women had delivered vaginally, 16 by elective (n=7) or emergency (n=9) cesarean. Over comparable periods of time (26 months) and births (n=5498 vs. n=6222) before and after the introduction of the chitosan gauze in our clinic, the rate of peripartum hysterectomies was significantly reduced (10 vs. 2; odds ratio, 5.66; p = .011). The last postpartum HE after introduction of Celox was performed more than 23 months ago. Changes of the menstrual period have not been reported. In the meantime one of the Celox treated patients is pregnant again. CONCLUSION: Celox gauze is a viable option in the treatment of (severe) PPH. It is easy to apply and requires no special training. It can be used after both vaginal and
cesarean deliveries, and we observed no specific treatment associated morbidity. Furthermore, it is inexpensive compared to other treatment options, making it suitable for use also in low resource-countries, where the death toll due to PPH is high. Although obstetric management was not changed during the observation interval before and after we hypothesize that the effect on maternal outcome is attributed to introduction of Celox. However, randomized controlled trials though difficult to perform are needed to proof the specific effects of chitosan.

**Publication Type:** Journal: Conference Abstract

**Source:** EMBASE

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**Title:** Uterine packing with chitosan-covered gauze for control of postpartum hemorrhage

**Citation:** American Journal of Obstetrics and Gynecology, September 2013, vol./is. 209/3(225.e1-225.e5), 0002-9378;1097-6868 (September 2013)

**Author(s):** Schmid B.C., Rezniczek G.A., Rolf N., Saade G., Gebauer G., Maul H.

**Language:** English

**Abstract:** Objective To describe the use of gauze covered with chitosan, a potent hemostatic agent derived from chitin, in the treatment of postpartum hemorrhage (PPH). Study Design Patients suffering from postpartum hemorrhage were treated by uterine packing with chitosan-covered gauze, either through the hysterotomy in case of cesarean delivery or transvaginally, for up to 24 hours. Results Chitosan-covered gauze was used in 19 cases of postpartum hemorrhage due to uterine atony, placenta accreta/increta, or anticoagulation, including 5 severe cases where a hysterectomy seemed inevitable otherwise. In all but one case, the bleeding stopped and further interventions were avoided. Over comparable periods of time (18 months) and births (3822 vs 4077) before and after the introduction of the chitosan gauze in our clinic, the rate of peripartum hysterectomies was reduced by 75% (8 vs 2; odds ratio, 4.27; P =.044). Conclusion Chitosan-covered gauze is a viable option in the treatment of (severe) postpartum hemorrhage. It is easy to use and requires no special training. It can be used after both vaginal and cesarean deliveries, and there are no adverse side effects. Furthermore, it is very inexpensive compared with other treatment options, making it suitable for use also in low resource-countries, where the death toll due to postpartum hemorrhage is especially high. © 2013 Mosby, Inc. All rights reserved.

**Publication Type:** Journal: Article

**Source:** EMBASE

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**Title:** Postpartum hemorrhage: use of hemostatic combat gauze.
Cheap and simple interventions that are intended to minimize postpartum hemorrhage are of major public health concern. We report a case of postpartum hemorrhage in which conservative interventions had failed. The use of a chitosan-covered gauze that originally was developed for combat trauma allowed us to achieve hemostasis, and a seemingly inevitable hysterectomy was avoided. Copyright © 2012 Mosby, Inc. All rights reserved.