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**Date:** 06 Nov 2017

**Sources Searched:** Medline, Embase, PubMed.

## Celox and Pregnancy/Postpartum Haemorrhage

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### 1. Uses of chitosan for treating different forms of serious obstetrics hemorrhages.

**Author(s):** Carles, G; Dabiri, C; Mchirgui, A; Saoudi, E O; Hcini, N; Pouget, K; Seve, B; de Matteis, B

**Source:** Journal of gynecology obstetrics and human reproduction; Aug 2017

**Publication Date:** Aug 2017

**Publication Type(s):** Journal Article

**PubMedID:** 28864269

**Abstract:** Postpartum hemorrhage is a major cause of maternal death worldwide. Many therapeutic strategies have been developed to reduce maternal morbidity and mortality like oxytocin, prostaglandin, and uterine balloons. A new member of the therapeutic arsenal has recently emerged, the chitosan (Celox®), used since several years by military doctors to stop bleeding of combat wounds. In 2012, a first study was reported with the successful use of chitosan-coated gauze to treat severe postpartum hemorrhage. We report here four cases of the use of chitosan to treat life-threatening obstetric bleeding. In the first case, a pelvic packing with chitosan gauze after hemostatic hysterectomy with persistent bleeding. In the second case, the use of chitosan powder in a case of severe bleeding from multiple vaginal tears. In the third case, the use of chitosan gauze in uterine packing for postpartum hemorrhage by atonia. In the fourth case, the use of chitosan powder for stop bleeding during a hemorrhagic cesarean section. Postpartum hemorrhage of uterine origin resistant to treatment with prostaglandins can be treated with chitosan-coated gauze. This treatment requires no training and its costs are one fifth those of a Bakri® intrauterine balloon. Using these two forms of chitosan, powder and gauze, we have a new therapeutic method at our disposal for dealing with the most serious cases of bleeding.

**Database:** Medline

## **2. Comparison of celox and bakri balloon in management of primary atonic postpartum hemorrhage**

**Author(s):** Von Beckerath A.-K.; Maul H.; Elmohandes A.M.; Shaaban M.; Habib D.M.; Nasr A.; Abdel-Kawi A.F.

**Source:** American Journal of Obstetrics and Gynecology; Jan 2016; vol. 214 (no. 1)

**Publication Date:** Jan 2016

**Publication Type(s):** Conference Abstract

**Abstract:**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.

**Database:** EMBASE

## **3. Use of chitosan-covered gauze (Celox) in 98 cases of severe postpartum hemorrhage-a multicenter registry analysis**

**Author(s):** Von Beckerath A.-K.; Maul H.; Gebauer G.; Abdel-Kawi A.F.; Rolf N.; Saade G.; Bader W.; Kusnierczak D.; Berger R.; Kienast C.; Kienemund J.; Schmid B.

**Source:** American Journal of Obstetrics and Gynecology; Jan 2016; vol. 214 (no. 1)

**Publication Date:** Jan 2016

**Publication Type(s):** Conference Abstract

**Abstract:**OBJECTIVE: Celox is a gauze covered with chitosan, a hemostatic agent derived from chitin, originally developed for military traumatology. The objective of this multicenter Celox registry analysis is to report on potential side effects of Celox and to verify, if the use of Celox reduces the rate of postpartum hysterectomies (ppHE) or not. STUDY 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 chisquare 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).

**Database:** EMBASE

#### **4. Uterine packing with chitosan-covered gauze (Celox) for control of postpartum hemorrhage (PPH)**

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

**Source:** American Journal of Obstetrics and Gynecology; Jan 2015; vol. 212 (no. 1)

**Publication Date:** Jan 2015

**Publication Type(s):** Conference Abstract

**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.

**Database:** EMBASE

## **5. Evaluation of a novel technology for cesarean delivery skin incision closure: Cold helium plasma and chitosan plaster (BioWeld1)**

**Author(s):** Hants Y.; Kabiri D.; Drukker L.; Parkes I.; Ezra Y.; Haik J.

**Source:** American Journal of Obstetrics and Gynecology; Jan 2015; vol. 212 (no. 1)

**Publication Date:** Jan 2015

**Publication Type(s):** Conference Abstract

**Abstract:**OBJECTIVE: BioWeld1 is a novel skin closure technology utilizing cold helium plasma and incorporating chitosan plaster. The objective of this study was to determine the safety and effectiveness of BioWeld1 for skin closure of cesarean incisions compared with staples or sutures, in an animal model. STUDY DESIGN: Six adult swine of similar weight were included and divided to three groups (A-C). All surgical sites were prepared using the same sterile technique. Groups A and B: on each swine, 4 full thickness incisions (16 cm) were performed; two bio-welded and two stapled; Group C: on each swine, 30 full-thickness incisions (5 cm) were performed: 16 bio-welded and 14 stapled or sutured (Ethicon, Nylon ETHILON™, 3.0). Plasters, staples and stitches were removed 7 days post-operatively. Outcomes were mortality, systemic response, surgical site visual evaluation (groups A-B), and tensile strength evaluation (group C). A visual inspection grading was performed for dehiscence (0-2), thermal injury (0-4), redness or edema (0-2) and encrustation (0-2) at day 7 (group A) and day 7 and 14 (group B). Surgical sites were evaluated for tensile strength at 4, 7, 14 or 21 days post-operatively. Statistics: Chi2, student t-test, P<0.05 significant. RESULTS: No mortality or systemic responses were observed in any of the swine throughout the study period. A significantly higher grade of redness and edema were apparent on day 14 in incisions closed with staples compared to bio-welded incisions (P=0.028); no other statistically significant macroscopic findings were noted (Table). In group C, there were no statistically significant differences in tensile strength measurements between the various closure techniques. CONCLUSION: Closure of skin incisions using BioWeld1 is comparable in terms of safety and effectiveness to closure with skin staples and sutures. This preclinical study lends support to further human trials using the BioWeld1 system for wound closure in cesarean sections. Figures are a summary of adverse outcome scores, P-Value<0.05 significant. (Figure Presented).

**Database:** EMBASE

## **6. Preliminary evaluation of novel skin closure of Pfannenstiel incisions using cold helium plasma and chitosan films.**

**Author(s):** Hants, Yael; Kabiri, Doron; Drukker, Lior; Razmik, Abrahamyan; Vruyr, Grigoryan; Arusyak, Harutyunyan; Vahe, Gyulghasyan; Di Renzo, Gian Carlo; Ezra, Yossef

**Source:** Journal of Maternal-Fetal & Neonatal Medicine; Nov 2014; vol. 27 (no. 17); p. 1637-1642

**Publication Date:** Nov 2014

**Publication Type(s):** Academic Journal

**PubMedID:** 24405020

**Database:** CINAHL

## **7. Uterine packing with chitosan-covered gauze for control of postpartum hemorrhage**

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

**Source:** American Journal of Obstetrics and Gynecology; Jan 2014; vol. 210 (no. 1)

**Publication Date:** Jan 2014

**Publication Type(s):** Conference Abstract

**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.

**Database:** EMBASE

## **8. Uterine packing with chitosan-covered gauze for control of postpartum hemorrhage.**

**Author(s):** Schmid, Bernd C; Rezniczek, Günther A; Rolf, Norbert; Saade, George; Gebauer, Gerhard; Maul, Holger

**Source:** American journal of obstetrics and gynecology; Sep 2013; vol. 209 (no. 3); p. 225

**Publication Date:** Sep 2013

**Publication Type(s):** Journal Article

**PubMedID:** 23727525

**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.

**Database:** Medline

#### **9. Postpartum hemorrhage: use of hemostatic combat gauze.**

**Author(s):** Schmid, Bernd C; Reznicek, Günther A; Rolf, Norbert; Maul, Holger

**Source:** American journal of obstetrics and gynecology; Jan 2012; vol. 206 (no. 1); p. e12

**Publication Date:** Jan 2012

**Publication Type(s):** Case Reports Journal Article

**PubMedID:** 22011588

**Abstract:** 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.

**Database:** Medline

## Strategy 307849

#	Database	Search term	Results
1	Medline	(Celix).ti,ab	48
2	Medline	(Chitosan).ti,ab	20011
3	Medline	exp CHITOSAN/	14502
4	Medline	(1 OR 2 OR 3)	20651
5	Medline	(pregnan*).ti,ab	431500
6	Medline	exp PREGNANCY/	818879
7	Medline	((("post partum" OR postpartum OR postnatal* OR "post natal*") ADJ2 (bleed* OR hemorrhag* OR haemorrhage*)).ti,ab	5542
8	Medline	exp "UTERINE HEMORRHAGE"/ OR exp "POSTPARTUM HEMORRHAGE"/	19618
9	Medline	(5 OR 6 OR 7 OR 8)	920106
10	Medline	(4 AND 9)	35
11	Medline	(obstetric*).ti,ab	82335
12	Medline	(4 AND 11)	3
13	EMBASE	(Celix).ti,ab	52
14	EMBASE	exp CHITOSAN/	24818
15	EMBASE	(chitosan).ti,ab	25657
16	EMBASE	(13 OR 14 OR 15)	29501
17	EMBASE	(pregnan*).ti,ab	565611

18	EMBASE	exp PREGNANCY/	683856
19	EMBASE	((("post partum" OR postpartum OR postnatal* OR "post natal*") ADJ2 (bleed* OR hemorrhag* OR haemorrhage*)).ti,ab	8644
20	EMBASE	exp "POSTPARTUM HEMORRHAGE"/ OR exp "OBSTETRIC HEMORRHAGE"/	14299
21	EMBASE	exp "OBSTETRIC PATIENT"/	1395
22	EMBASE	(19 OR 20 OR 21)	17008
23	EMBASE	(16 AND 22)	11
24	PubMed	(celox OR chitosan).ti,ab	20780
25	PubMed	(postpartum OR postnatal* OR "post natal*" OR "post partum" OR pregnan* OR obstetric*).ti,ab	1165965
26	PubMed	(24 AND 25)	0
27	PubMed	(pregnan* OR postpartum).ti,ab	940236
28	PubMed	(24 AND 27)	38
29	EMBASE	exp "CESAREAN SECTION"/	83344
30	EMBASE	(16 AND 29)	14
31	Medline	(caesarean OR cesarean).ti,ab	50983
32	Medline	exp "CESAREAN SECTION"/	40116
33	Medline	(31 OR 32)	63503
34	Medline	(4 AND 33)	6
35	CINAHL	(celox OR chitosan).ti,ab	280



36	CINAHL	(pregnan*).ti,ab	58967
37	CINAHL	exp PREGNANCY/	114249
38	CINAHL	((("post partum" OR postpartum OR postnatal* OR "post natal*") ADJ2 (bleed* OR hemorrhag* OR haemorrhage*)).ti,ab	1222
39	CINAHL	exp "POSTPARTUM HEMORRHAGE"/	1556
40	CINAHL	exp "UTERINE HEMORRHAGE"/	3141
41	CINAHL	(36 OR 37 OR 38 OR 39 OR 40)	129895
42	CINAHL	(35 AND 41)	8