The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/ijmf20

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To cite this article: Anna M. Dueckelmann, Paulina Hermann, Carolin Biele, Clara Leichtle, Charlotte Waldner, Thorsten Braun & Wolfgang Henrich (2024) Short and long-term menstrual, reproductive, and mental health outcomes after the intrauterine use of chitosan tamponade or the Bakri balloon for severe postpartum hemorrhage: an observational study, The Journal of Maternal-Fetal & Neonatal Medicine, 37:1, 2354382, DOI: 10.1080/14767058.2024.2354382

To link to this article: https://doi.org/10.1080/14767058.2024.2354382

Published online: 23 May 2024.

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE
2024, VOL. 37, NO. 1, 2354382
https://doi.org/10.1080/14767058.2024.2354382

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ORIGINAL ARTICLE

Short and long-term menstrual, reproductive, and mental health outcomes after the intrauterine use of chitosan tamponade or the Bakri balloon for severe postpartum hemorrhage: an observational study

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ABSTRACT

Objective: This retrospective follow-up study analyzes the effect of intrauterine postpartum hemorrhage (PPH) therapy on menstrual, reproductive, and mental health outcomes.

Methods: All women who delivered at a university hospital between 2016 and 2021 with PPH and who needed intrauterine therapy were included. A questionnaire on well-being, menses, fertility, and reproductive outcomes was mailed to the patients. Those who did not reply were surveyed by telephone.

Results: A total of 214 women treated with chitosan-covered gauze (group A) and 46 women treated with a balloon tamponade (group B) were recruited, and their short-term courses were analyzed. For long-term follow-up, 71 women of group A (33%) and 21 women of group B (46%) could be reached. A total of 89% of group A and 95% of group B had regular menstrual bleeding in the most recent 12 months; 27% (group A) and 29% (group B) were trying to conceive again, and all of them did so successfully. There were 12 deliveries, 3 ongoing pregnancies, 3 miscarriages, and 2 terminations of pregnancies (TOP) in group A and 4 deliveries, 1 miscarriage, and 2 TOPs in group B. More than half of our study participants was sorted into grade II or III of the Impact of Events Scale, indicating they experienced clinical impacts in the form of psychological sequelae. One-quarter of patients had symptoms of post-traumatic stress disorder.

Conclusion: Chitosan gauze as well as balloon tamponade appear to have few adverse effects on subsequent menstrual and reproductive function. Women after PPH are at increased risk of long-term adverse psychological outcomes.

ARTICLE HISTORY
Received 21 March 2024
Revised 4 May 2024
Accepted 7 May 2024

KEYWORDS
Celox; balloon tamponade; PPH; follow-up; fertility; psychological disorders

Introduction

All around the world, postpartum hemorrhage (PPH) remains the leading cause of maternal morbidity and mortality [1], with approximately 25% of 300,000 deaths worldwide being attributed to hemorrhage every year [2]. Due to a rising number of patients with advanced maternal age, multiple pregnancies, cesarean deliveries, previous cesarean sections with abnormal placentation, and infertility treatment, the number of PPH cases is increasing [3–7].

Although PPH has a global incidence of around 1–6% of all deliveries [8], there are only a few reports on maternal mental health after PPH [9]. The effects can be profound: in one study [9] two-thirds of the participants with PPH viewed childbirth negatively and 6% wished not to get pregnant again in fear of recurrent PPH. Additionally, 60% of the participants who did become pregnant again suffered from anxiety throughout their pregnancies [9,10].

The first-line therapy of PPH is the administration of various uterotonics and hemostatic drugs. With further escalation of bleeding, selective devascularization, uterine compression sutures, or intrauterine packing can be used. The last resort is the performance of a hysterectomy [11]. Since 1999, the Bakri balloon tamponade (BT) has been a well-established method of treating severe PPH [12,13]. It has proven to be

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ineffective in 10–15% despite a reported decrease in hysterectomies [3, 14–17].

In the last few years, chitosan-impregnated gauze (Celox, CX) has become a more frequently used treatment for PPH. It works as an effective tamponade through mechanical compression, swelling, and gelling, with local hemostasis caused by electrostatic interactions between chitosan and erythrocyte membranes [12, 18–21]. On the basis of several cohort studies [12,20,22] and the pioneering study of Schmid et al. [19], the effectiveness of CX was shown followed by a reduced hysterectomy rate about 50–78%. Since September 2022 CX PPH is registered as class III CE-marked medical device. According to the German–Austrian–Swiss guidelines, the insertion of either a CX or a BT is the next step in treatment if bleeding continues after the application of various uterotonics and manual compression [23].

Study objectives

Here the short and long-term outcomes after PPH treatment with CX or BT are evaluated regarding safety aspects and adverse events as well as their effects on reproductive and gynecological health. We aimed to analyze as a secondary outcome the mental impact of this event and its influence on the decision to try to conceive again.

Methods

Over 5 years all women with severe PPH who received a treatment with CX or BT at a huge perinatal university center were included in our study. The study was approved by our local ethics committee (EA2_229_20, 01.12.2020) and was conducted according to the Helsinki Declaration. To evaluate the severity of PPH, we graded it as grade I (500–999 ml of blood loss after vaginal birth, 1000–1499 ml after C-section); grade II (1000–1499 ml of blood loss after vaginal birth, 1500–1999 ml after C-section); or grade III (≥1500 ml after vaginal birth, ≥2000 ml after C-section). All women were treated following the German–Austrian–Swiss guidelines [23]. This implies that the first treatment for PPH is a uterotonic drug (i.e. intravenous oxytocin or carbetocin). If bleeding persists, sulprostone, an analog of prostaglandin E2, is used, as well as tranexamic acid as a first-line antifibrinolytic agent. Depending on hemodynamic changes, the next step for ongoing hemorrhage is treatment with fibrinogen, fresh frozen plasma, or a red blood cell transfusion. If the bleeding persists, the use of either BT or CX according to published instructions [12,19,20] is the next step of the algorithm. In this study, it was the responsible obstetrician's choice to use BT or CX. With further severeness of hemorrhage, radiological procedures or surgical interventions like compression sutures or ligature of uterine arteries were performed, or as last resort, a hysterectomy.

Exclusion criteria were as follows: double treatment with CX and BT, any other treatment in addition to uterotonics and intrauterine therapy, fetal death for any reason, hysterectomy, or maternal death. We had questionnaires only in German or English; therefore, patients not speaking these two languages did not participate. All remaining women gave informed consent for their participation in the study and were divided into two groups: group A who received CX and group B who received BT. Epidemiological and clinical data were retrieved from medical records, and compared between these two groups. The short-term follow-up included hemoglobin levels, postpartum fever, sign of infection (CRP, leucocytes), admission to intensive care, the length of hospital stay, and treatment with blood products.

For the long-term follow-up, all patients received a questionnaireregarding the performance and their retrospective perception of the chosen treatment method, their general health (current symptoms, previous or current diseases, medication, allergies, and smoking), their menstruation cycle since giving birth, their satisfaction with the treatment and stay at the hospital, their mental health, desire for another child, and any subsequent pregnancies or births since the last time they delivered. We added the Impact of Event Scale (IES) to our questionnaire to measure current subjective distress related to the birth experience. If the questionnaire was not returned within 4 weeks, a telephone survey was conducted.

Statistical methods

We performed the statistical analysis by using IBM SPSS Statistics Version 26.0 (IBM Corp. Armonk, NY). The Mann–Whitney *U* test or independent-samples *t*-test according to the normality distribution assessed by histograms was used to assess differences between the two groups. An analysis of nominal data was performed with chi-square test. Statistical significance was accepted at $p < .05$. Results are presented as the arithmetic mean ± standard deviation with minimum and maximum values or as median and quartiles. Since there was no correction for multiple testing, all results remain explorative. 1:1 match using propensity score matching was performed between both groups.

Results

Between June of 2016 and May of 2021, a total of 321 women with severe PPH or showing signs of hypovolemia received a treatment with CX and/or BT at a perinatal university center with >5000 deliveries per year. According to our exclusion criteria, 260 women were included in the final analysis (see Figure 1). Of those, 214 received CX (group A), and 46 received BT (group B). An interview was performed on average 29.1 ± 10.3 months (range 13–53 months) after the index event. More than half (16/21) of the BT group received their treatment in 2016–2018, while most of the women (62/71) in the CX group were treated more recently, in 2019–2021.

The epidemiological data of the two groups were similar (Table 1). Furthermore, no significant difference was detected in blood loss, the number of days spent in hospital, postpartum fever, and in hemoglobin, leucocyte, or CRP levels (Table 2). Clearly more women delivered vaginally in group A (56%) than in group B (35%), whereas more patients delivered *via* cesarean section in group B (50%) than in group A (32%). The rate of admission to the intensive care unit was considerably lower in group A (30%) than in group B (54%).

We had 92 women who fulfilled our criteria and were able to participate in our long-term follow-up: group A consisted of 71 patients (33%) who received CX while the remaining 21 patients of group B (46%)

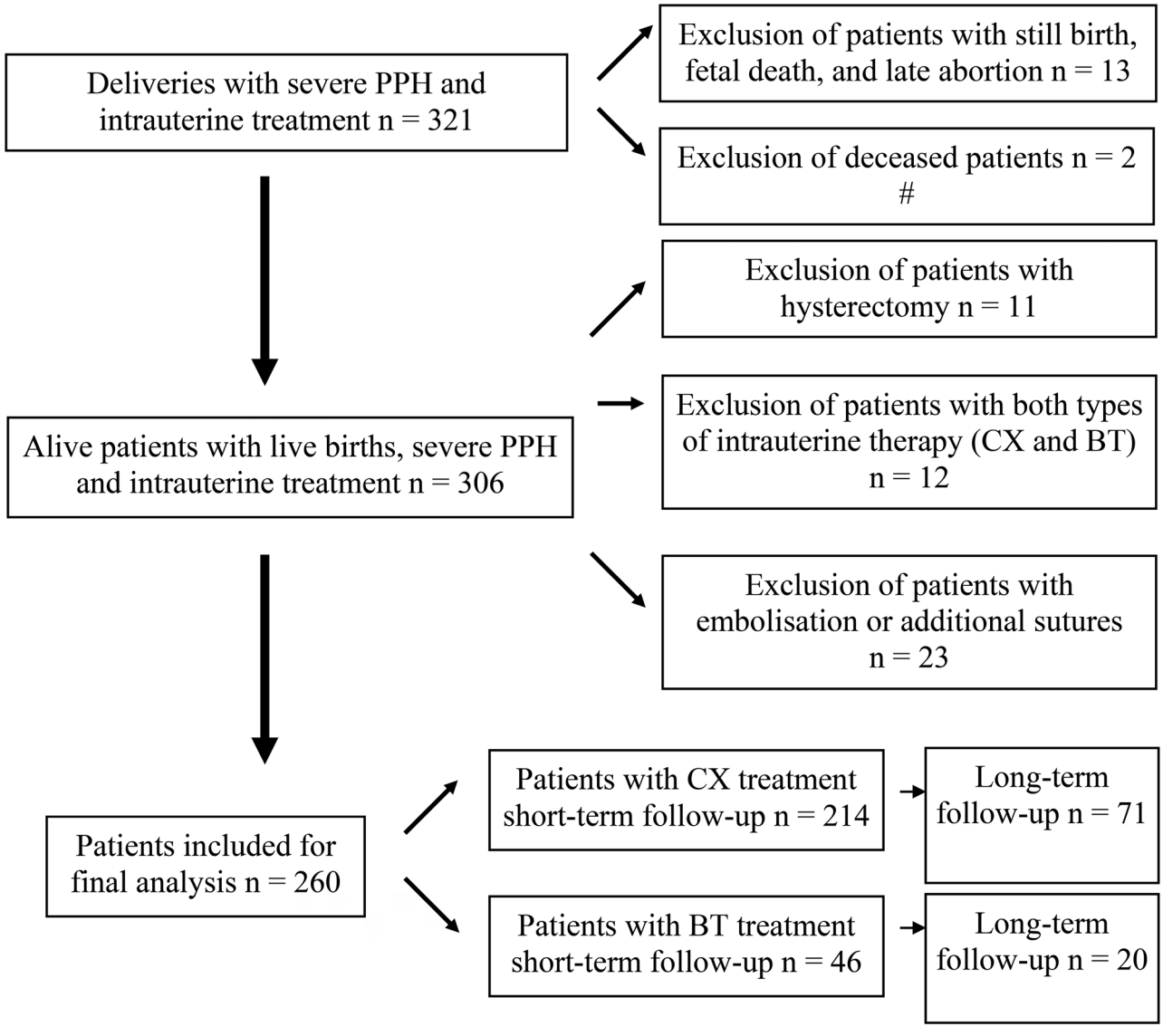

Figure 1. Flow diagram showing the process of inclusion in our study, dividing patients into group A (CX) and group B (BT). CX: intrauterine chitosan-covered gauze (Celox); BT: balloon tamponade. #: 2 maternal deaths due to amniotic fluid embolism and anaphylactic shock after sulprostone application.

Table 1. Presentation of CX (group A) and BT (groub B): epidemiological and clinical data.

	Group A ($n=214$)	Group B ($n=46$)	p Value
Maternal age (years)	33.0 ± 6.2 (17-47)	32.0 ± 5.6 (19-42)	.676[T]
Gestation at delivery (weeks)	40.0 ± 3.7 / 213 (21-43)	40.0 ± 3.5 (29-42)	.397[U]
Parity			
Primiparous	112 (52.3%)	27 (58.7%)	.561[X]
Multiparous	102 (47.7%)	19 (41.3%)	.561[X]
Multiple pregnancy	24 (11.2%)	7 (15.2%)	.408[X]
Mode of delivery			
Normal vaginal	119 (55.6%)	16 (34.8%)	**.006**[X]
Instrumental	27 (12.6%)	6 (13.0%)	.651[X]
Cesarean section	69 (32.2%)	23 (50.0%)	**.015**[X]
Causes of severe PPH			
Uterine atony	210 (98.2%)	46 (100.0%)	
Placenta previa/accreta	32 (15.0%)	8 (17.4%)	
Genital tract trauma	76 (35.5%)	10 (21.7%)	
Blood loss (ml)	1500 ± 765.4/213 (300–5000)	1800 ± 728.8 (700-4000)	.129[U]
Grade of PPH	0.818X		
Grade I	42 (19.6%)	9 (19.6%)	
Grade II	43 (20.1%)	9 (19.6%)	
Grade III	129 (60.3%)	28 (60.9%)	

Data are presented in means ± standard deviation (minimum and maximum values) or absolute numbers and percentages. The tests used to analyze differences between group A (CX) and group B (BT) were the Mann-Whitney-U test (U), the independent-samples t-test (T), or the Chi-squared test (X). Results were considered significant for $p < .05$ and the significant results are presented in bold.
PPH grade I: 500–999 ml of blood loss after vaginal birth, 1000–1499 ml after C-section; grade II: 1000–1499 ml of blood loss after vaginal birth, 1500–1999 ml after C-section; grade III: ≥1500 ml after vaginal birth, ≥2000 ml after C-section.

Table 2. Short-term follow-up data.

	Group A ($n=214$)	Group B ($n=46$)	p Value
Time in months after index event	26.5 ± 8.3 (min 13, max 48)	38.1 ± 11.3 (min 18, max 53)	.025[X]
Admission intensive care unit	64 (29.9%)	25 (54.3%)	**.012**[X]
Days spent at hospital	4 ± 3.2/201 (2–31)	4 ± 1.4/45 (2–10)	.160[T]
Prolonged (>3 days)	117/202 (57.9%)	28/44 (63.6%)	.719[X]
Women receiving blood transfusion	82 (38.3%)	18 (39.1%)	.565[X]
Amount of blood transfusion	1.02 (0–14)	0.78 (0–6)	
Fever postpartum	11 (5.1%)	1 (2.2%)	.338[X]
Leukocytes (/nl)	15.4/211 (5.3–39.6)	16.4/45 (6.8–37.7)	.695[T]
Lowest hemoglobin (g/dl)	7.0 ± 1.5 (4.2–12.1)/208	7.1 ± 1.6 (4.5–11.2)	.641[T]
Drop in hemoglobin (g/dl)	4.1 ± 1.7 (0.8–8.5)/187	4.9 ± 1.9 (1.2–7.5)/38	.915[T]
CRP (mg/dl)	86.2/95 (1.0–434.0)	89.2/20 (4.0–258.0)	.934[U]

Data are presented in means ± standard deviation (minimum and maximum values) or absolute numbers and percentages. The tests used to analyze differences between group A (CX) and group B (BT) were the Mann-Whitney U test (U), the independent-samples t-test (T), or the Chi-squared test (X). Results were considered significant for $p < .05$ and the significant results are presented in bold.

received BT. The analysis of the demographic data between those women recruited versus those who could not be contacted for recruitment showed no significant differences.

Within the first 12 months after birth, the vast majority of women (80% in group A and 86% in group B) reported a return of menses (Table 3). From the remaining 14 patients (20%) with no return of menses in group A, 12 (85.7%) were still breast-feeding one year after birth. For group B, two out of three patients with no return of menses were breast-feeding for a period longer than a year. When asked about their menstrual cycle within the last 12 months, 89% of group A and 95% of group B reported a return of their menstruation (Table 4). Three out of 8 patients in group A with no menstrual cycle fell pregnant again within this time period, two patients used a continuous contraceptive method stopping their menstrual cycle, and three women were still breast-feeding. The one patient of group B missing her period used a contraceptive, which stopped her menses. There were no significant differences between the two groups concerning cycle regularity, duration, and menstrual flow or dysmenorrhea. There were also no differences in the rate of breast-feeding mothers and in the duration of lactation: the average duration of breast-feeding was 10 months in group A and 7 months in group B.

After stratified analysis by birth mode the amount of flow within the first 12 months after birth was significantly less ($p = .036$) and the duration of flow was longer ($p = .013$) in group A compared to group B. All other parameters did not differ considerably between the two groups, notably the rate of admission to the intensive care unit was comparable.

The gynecological complaints reported by the patients varied within both groups. In group A there

Table 3. Outcome 12 months after birth between group A (CX) and group B (BT).

	Group A ($n=71$)	Group B ($n=21$)	p Value
Duration of breastfeeding (months)	10/69 (0–36)	7 (0–24)	.136[U]
No breast feeding	5/69 (7.2%)	4 (19.0%)	.114[X]
Return of menses after delivery (months)	5.5/66 (0–24)	7/19 (1–18)	.349[U]
No return of menses			
Within 12 months after birth	14/71 (19.7%)	3 (14.3%)	.669[X]
Cycle regularity			.321[X]
Regular (28 days ± 7 days)	37/57 (64.9%)	15/18 (83.3%)	
Short (<21 days) or long (>35 days)	9/57 (15.8%)	1/18 (5.6%)	
Totally irregular cycles	11/57 (19.3%)	2/18 (11.1%)	
Duration of flow			.083[X]
Short (<2 days)	2/57 (3.5%)	0/18 (0%)	
Normal (3–7 days)	44/57 (77.2%)	18/18 (100%)	
Prolonged (>7 days)	11/57 (19.3%)	0/18 (0%)	
Menstrual flow			.226[X]
Heavy	31 / 57 (54.4%)	7/18 (38.9%)	
Normal	19/57 (33.3%)	10/18 (55.6%)	
Scanty	7/57 (12.3%)	1/18 (5.6%)	
Dysmenorrhea			.868[X]
Not present	18/57 (31.6%)	8/18 (44.4%)	
Mild	22/57 (38.6%)	5/18 (27.8%)	
Severe requiring medication	17/57 (29.8%)	5/18 (27.8%)	

Data are presented in means ± standard deviation (minimum and maximum values) or absolute numbers and percentages. The tests used to analyze differences between group A (CX) and group B (BT) were the Mann-Whitney U test (U), the independent-samples t-test (T), or the Chi-squared test (X). Results were considered significant for $p < .05$ and the significant results are presented in bold.

Table 4. Menstrual outcome within the last 12 months between group A (CX) and group B (BT).

	Group A ($n=71$)	Group B ($n=21$)	p Value
Menstrual pattern no return of menses	8/71 (11.3%)	1 (4.8%)	.378[X]
Cycle regularity			.886[X]
Regular (28 days ± 7 days)	50/63 (79.4%)	16/20 (80.0%)	
Short (<21 days) or long (>35 days)	8/63 (12.7%)	3/20 (15.0%)	
Totally irregular cycle	5/63 (7.0%)	1/20 (5.0%)	
Duration of flow			.674[X]
Little (<2 days)	2/63 (3.2%)	0/20 (0%)	
Normal (3–7 days)	53/63 (84.1%)	18/20 (90.0%)	
Prolonged (>7 days)	8/63 (12.7%)	2/20 (10.0%)	
Menstrual flow			.138[X]
Heavy	17/63 (27.4%)	10/20 (50.0%)	
Normal	40/63 (64.5%)	8/20 (40.0%)	
Scanty	5/63 (8.1%)	2/20 (10.0%)	
Dysmenorrhea			.853[X]
Not present	33/63 (52.4%)	10/20 (50.0%)	
Mild	14/63 (22.2%)	5/20 (25.0%)	
Severe requiring medication	16/63 (25.4%)	5/20 (25.0%)	

Data are presented in means ± standard deviation (minimum and maximum values) or absolute numbers and percentages. The tests used to analyze differences between group A (CX) and group B (BT) were the Mann-Whitney U test (U), the independent-samples t-test (T), or the Chi-squared test (X). Results were considered significant for $p < .05$.

were two cases of urinary incontinence, delivery mode was spontaneous in both cases. One woman suffered from dyspareunia and another from an irregular menstrual cycle; both issues were already present before the index event. Furthermore, there were three cases of previous fibroid removals, two cases of ovarian cyst removals, one case of endometriosis, and one case of suspected adenomyosis, and one patient stated current pregnancy symptoms as a gynecological complaint. Finally, one patient reported persistent pain from genital tract trauma 3 years after delivery. There was one patient with endometriosis in group B; that diagnosis was confirmed before the index delivery with PPH. No correlation between postpartum clinical outcome and genital tract lacerations was found.

Most patients were satisfied with their treatment (group A, 86%; group B, 80%) and their stay at the hospital (group A, 89%; group B, 90%) (Table 5). The two reasons indicated for dissatisfaction were communication issues with the medical staff and discomfort during the stay at the postnatal ward.

No significant differences could be found between the two groups regarding mental health or reproductive outcome.

In the evaluation of the new mothers' mental health, almost one-half (43%) in both groups were sorted into grade I of the IES, in the subclinical range. No differences in current subjective distress related to the birth experience were detected between the two groups, taking the IES scores in total (Table 5). There was no significant influence by the severity of PPH on psychological outcome in neither group.

In regard to the questions of the IES score in detail, 28 out of 70 of group A and 5 out of 21 of group B thought sometimes or often of the index birth without wanting to; 6* out of 70 of group A and 4 out of 21 of group B tried to avoid remembering this event (sometimes or often); 10 out of 69 of group A and 3 out of 21 of group B tried not to speak about this experience; and 27 out of 70 of group A and 8 out of 21 of group B had unwanted mental pictures related to the experience. For 39 out of 70 of group A and 7 out of 21 of group B, being reminded of the index birth caused all their feelings about it to return. For 9 out of 70 of group A and 3 out of 21 of group B, their emotion about the index birth was sometimes or often one of feeling stunned.

Concerning reproductive outcome in group A, 19 women (27%) were trying to conceive again, and all of them did so successfully. One woman became unintentionally pregnant. Thus, there were 20 subsequent pregnancies, of which 3 (15%) ended in an early miscarriage. Two women chose to terminate a pregnancy, one stating that she had already completed her family

Table 5. Mental health evaluation and gynecological report after birth and reproductive outcomes between group A (CX) and group B (BT).

	Group A ($n=71$)	Group B ($n=21$)	p Value
IES overall points	10 ± 13.0/70 (0–60)	11 ± 9.1 (0–30)	.425[T]
Grading IES	0.584X		
Grade I	30/70 (42.9%)	9 (42.9%)	
Grade II	24/70 (34.3%)	10 (47.6%)	
Grade III	10/70 (14.3%)	2 (9.5%)	
Grade IV	3/70 (4.3%)	0 (0%)	
Gynecological issues	13 (18.3%)	2 / 20 (10%)	.921[X]
Satisfaction with treatment	59/69 (85.5%)	16 / 20 (80%)	.210[X]
Satisfaction with hospital stay	61/69 (88.7%)	18/20 (90%)	.822[X]
Current use of contraception	16/67 (23.9%)	7/20 (35.0%)	.277[X]
Childwish	19/71 (26.8%)	6/21 (28.6%)	.870[X]
Subsequent pregnancies	20/71 (28.2%)	7 (33.3%)	.262[X]
Occurrence of interrupted pregnancy after index delivery			.353[X]
Miscarriage	3/20 (15%)	1/7 (14.3%)	
Termination	2/20 (10%)	2/7 (28.6%)	
Ectopic	0 (0%)	0 (0%)	
Deliveries			.347[X]
Vaginal delivery	10/12 (83.3%)	3/4 (75.0%)	
Cesarean section	2/12 (16.7%)	1/4 (25.0%)	
Presence of a new PPH	2/12 (16.7%)	0/4 (0%)	.237[X]
Anxiety/distress about giving birth			
Present throughout pregnancy			.334[X]
Yes	16/17 (94.1%)	3/4 (75.0%)	
No	1/17 (5.9%)	1/4 (25.0%)	

Data are presented in means ± standard deviation (minimum and maximum values) or absolute numbers and percentages. The tests used to analyze differences between group A (CX) and group B (BT) were the Mann-Whitney-U test (U), the independent-samples t-test (T), or the Chi-squared test (X). Results were considered significant for $p < .05$.
Abbreviation. IES, Impact of Event Scale.

while the other could not imagine going through another delivery again after having experienced PPH. The remaining 12 pregnancies all resulted in the delivery of a healthy child, 11 at term, one was a preterm delivery. Two patients had PPH again; one could be managed medically, while the other received CX again. There were 3 ongoing pregnancies at the time of the interview. In group B, 6 women (29%) desired another child, and there were 7 pregnancies. One pregnancy ended in a miscarriage, and 2 patients chose to terminate a pregnancy, one for financial reasons and one for fear of recurrent PPH. There were 3 deliveries at term and one preterm delivery. None of the patients suffered from PPH again. In both groups, most women ($n=16$ in group A, $n=3$ in group B) experienced fear of recurrent PPH and distress throughout their subsequent pregnancy (Table 5).

Discussion

When a new medical product is introduced to clinical routine, safety issues and (side) effects in the short and in the long term are of the utmost importance. Against the background of established treatment concepts in PPH, such as the intrauterine BT (group B) it has already been demonstrated that the recently introduced intrauterine chitosan-covered gauze (Celox, CX) (group A) is of superior effectiveness [12,19,20]. Prevention of maternal and neonatal morbidity and mortality in PPH is a big issue, but data about women's physical and emotional state post PPH is scarce. In women receiving intrauterine PPH therapy, post-event endometritis and synechia are concerns because they can subsequently impact fertility. This paper is the first to investigate short and long-term outcomes after intrauterine CX treatment in comparison with the use of intrauterine BT, focusing particularly on reproductive, gynecological, and mental health.

Main findings

Regarding immediate safety aspects, we did not find an elevated infection risk during the hospital stay while using the gauze (group A) or the balloon (group B) in our ever-expanding cohort, thus augmenting published data [20]. There were no differences in leucocytes and CRP levels nor in events of fever between the two study groups. A case-control study on 39 patients who received a BT also found no significant increase in the incidence of endometritis [3]. Only the rate of ICU admission varied significantly between the two groups, being lower in group A (30%) than in group B (54%); the reason for this difference may be explained by the higher rate of C-sections in group B. After matching by birth mode, the rate of admission to the ICU was similar in both groups.

About 5% of women in group A (2% in group B) developed elevated temperature after PPH, but the intrauterine therapy could not be identified as a focus of infection in any of them. There are previous reports of women developing low grade fever without clinical signs of infection after being treated with CX [27,31,32]. Misoprostol, which was given either sublingually or rectally to ~50% of women for PPH therapy (group A, 32/71, 45%; group B, 11/21, 52%) could be the most probable cause of increased body temperature in these cases [24].

Evaluating the first 12 months after the PPH event and the 12 months before the interview, we could not find any between-group differences concerning gynecological issues. The vast majority of patients had a return of regular menstruation within the preceding 12 months (89% of group A and 95% of group B); the remaining women were breast-feeding, pregnant, or using contraceptives. Cycle regularity, duration, and menstrual flow or dysmenorrhea did not change significantly after the PPH event and did not differ between the two groups. Studies on menstrual function after BT application are scarce [25]. Kong et al. showed that the menstrual pattern after BT application was largely normal compared with that in women with PPH who were successfully managed solely with uterotonics [3].

Interpretation

The prevalence of postpartum post-traumatic stress disorder in community samples is generally estimated to be 3–4% [26–28]. It is well known that the experience of severe PPH independent of therapeutic interventions is a strong risk factor for consequent depression and post-traumatic stress disorder [10,29,30]. In a recent detailed review on longer-term health outcomes for women and their partners following primary PPH in high-income countries, data confirmed that women with PPH are more likely to have persistent physical and psychological health problems that may last for several years after the birth [31]. The present investigation covers a time period of almost 2.5 years on average after the index delivery. In regard to the new mothers' mental health, the incidence of adverse psychological outcomes was as common in our study as it is in the literature. Sentilhes et al. found that 68% of 68 women had negative experiences after the management of severe PPH; in 35% of the mothers, the main memory was a fear of dying [9]. More than half of our study participants (53% of group A, 57% of group B) was sorted into grade II or III of the commonly used and validated IES, indicating there was clinical impact in the sense of psychological sequelae. Interestingly the grade of PPH had no influence on the severity of the adverse psychological outcomes. Post-traumatic stress disorder is characterized by reliving experiences, avoidance of reminders of trauma, negative thoughts and mood, and hyperarousal [32]. This was the case in about 25% of our patients. Unfortunately, intensive counseling and support during and after PPH are often inadequate [33] though they may prevent long-term psychological sequelae and have to be strengthened in daily practice.

So far, only little information is available about the psychological impact of previous PPH on women's desire to have another child. Despite the high satisfaction with treatment during the index pregnancy the life-threatening experience of PPH is associated with fear of reoccurrence, which leads women to decide against or to intentionally delay another pregnancy [9,34,35]. Though there was a wish to conceive again in about one-quarter of our study patients, anxiety or distress throughout the subsequent pregnancy was also very common in our study cohort. This concern appears to be entirely justified, as women with previous PPH have a 3-fold increased risk of PPH in their second pregnancy (15%) compared with unaffected women [36]. Two women of our whole cohort even opted for an abortion due to fear of recurring PPH. Overall, all women ($n = 25$, 27%) trying to conceive again did so successfully.

Interestingly, there were no ectopic pregnancies in any of the two groups, indicating no inflammatory reaction in fallopian tubes after intrauterine therapy.

Strengths and limitations

The present study is the first follow-up study in obstetrics in case of PPH comparing the relatively new intrauterine device CX with BT. It is the first study on psychological aspects after the use of intrauterine devices for PPH.

Due to the retrospective character of the study, no randomization of cases was possible and possible confounders could therefore not be excluded completely. The sizes of the two study groups were unbalanced and group B was quite small, and there was no control group. As it was up to the responsible physician's decision whether to use CX or BT, selection bias is possible. Attitudes toward PPH management changed at our center over time: more than half of the BT group received their treatment in 2016 and 2017, while most women were treated with CX more recently, in 2020 and 2021. However, the groups did not differ significantly in epidemiological and clinical terms and our attention in this investigation was given mainly to the

follow-up. Only 33% of patients in group A and 46% in group B could be included in the long-term follow-up analysis. The women's mental health was evaluated with self-reported health questionnaires, but this is common practice because objective measurements, such as clinical diagnoses, are often missing or pending.

Conclusion

The intrauterine chitosan-covered gauze (Celox, CX) is a safe method to stop PPH without altering reproductive and gynecological health or subsequent fertility. This makes CX an excellent alternative to the widely used BT. Further studies will have to investigate the right indications of the correct therapy/medical device in PPH cases. Independent of therapy method, severe PPH may be experienced as a traumatic event by the mother, so counseling about fertility, subsequent pregnancy outcomes, and long-term physical and psychological sequelae is of the utmost importance, and screening for postpartum psychological disorders should be established.

Acknowledgment

We thank Mrs. Kollmus-Heege for statistical advice.

Disclosure statement

The authors report there are no competing interests to declare.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data availability statement

Data will be made available by the corresponding author upon request.

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