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The Usefulness of Zhukovsky Double Balloon in Obstetric Hemorrhage

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Abstract

Objective: To evaluate the effectiveness of the use of a modified Zhukovsky double (vaginal and uterine) balloon to improve the results of treatment in women with obstetric hemorrhage.

Methods: We conducted an observational controlled study including 701 puerperas, which were divided into two groups: The main group consisted of 508 women, who underwent a combined management, that is, traditional (transfusion of fresh frozen plasma, erythrocyte mass, uterotonics, hemostatic agents), surgical hemostasis in cases of caesarean section, and insertion of a double Zhukovsky balloon; while the comparison group included 193 patients, who were managed traditionally. The main group and the comparison group were divided into subgroups according to the main etiology of obstetric hemorrhage: IA and IB—postpartum; IIA and IIB—placenta accreta; IIIA and IIIB—postpartum hysterectomy.

Results: The most frequent causes of massive obstetric hemorrhage were atony of the uterus (39.2%), placenta previa (29.1%), and placental abruption (11.5%). Of the 508 balloon insertions, 345 (70.7%) were inserted for hemorrhage during cesarean section and 148 (29.3%) for obstetric hemorrhage after spontaneous delivery. Among the obstetric hemorrhage at caesarean section, lower segment bleeding prevailed (78.1%), caused mainly by placenta previa, placenta accreta, placental abruption, polyhydramnios, and uterine scar defects. Combined management, including surgical hemostasis and insertion of vaginal and uterine balloon of Zhukovsky, reduced blood loss by 1.5 times and the number of hysterectomies by 6.72 times compared to controls.

Conclusion: The use of a modified Zhukovsky double balloon in the management of obstetric hemorrhage may reduce the number of hysterectomies and the amount of blood loss.

Keywords: Obstetric hemorrhage; Placenta previa; Accrete; Vaginal wall rupture; Uterine ligation; Hypotonic hemorrhage

Introduction

Obstetric, and particularly postpartum, hemorrhage plays a leading role among the causes of maternal morbidity and mortality.[1,2] It is known that only 62%–65% of vaginal births are accompanied by physiological blood loss (within 500 mL of blood),[3] one third of patients have blood loss of 500–1000 mL, and in 3%–8% of cases the volume of blood loss exceeds 1.5% of the maternal weight, and this is considered a massive loss, requiring transfusions and often removal of the uterus.[4]

The risk factors of obstetric hemorrhage are multifaceted[5,6]: age of primiparous women (older than 35 years), parity (more than six previous deliveries), a high number of previous caesarean sections, a short time interval from the previous abdominal delivery, and multiple pregnancy.[7,8] Some authors consider anomalies of placentation, the placenta accreta spectrum disorders, and placental abruption[9–12] as the leading causes of the development of massive obstetric bleeding, while others report atony of the uterus as the main cause.[13,14] The main goal in the management of all these cases is the early cessation of hemorrhage. Therefore, any new method that allows stopping the bleeding with a conservative approach and has been proven to be effective should certainly be introduced into clinical practice.[15]

In recent years, a number of invasive procedures, such as balloon tamponade, compression stitches, uterine artery embolization, ligation of the uterine, and internal iliac arteries, have been proposed as an effective alternative and/or to avoid traditional hysterectomy.[16–18] In particular, balloon tamponade replaces the most traditional package of tissues for uterine tamponade; it shows better results and a lower percentage of infections.[19,20]

Since 2010 the balloon of Zhukovsky, used in Russian-speaking countries, is available in three models: a single uterine, a single vaginal, and a double balloon (combining

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the two previous ones).[21] A double balloon can effectively cope with any postpartum hemorrhage, in case of both vaginal delivery and after cesarean section.[22,23]

Unlike other analogues, in particular the Bakri balloon, the Zhukovsky double (vaginal and uterine) balloon ensures close contact of the intrauterine balloon to the uterine walls, thus preventing the accumulation of blood between them. As a result of the addition of many directional force vectors created by the two balloons, from both the uterus and the vagina, new mechanisms for stopping postpartum hemorrhage, such as compression of the lower segment with a balloon, have been postulated.[24,25]

The purpose of this study was to evaluate our experience with the Zhukovsky modified double balloon to improve the results of the management of women with obstetric hemorrhage.

Materials and methods

This study included 701 patients with obstetric hemorrhages. Patients were divided into two groups: the main group (IA, IIA, IIIA) consisted of 508 women who underwent a combined management, that is, some traditional methods (transfusion of fresh frozen plasma, erythrocyte mass, uterotonics, hemostatic agents), surgical hemostasis in the cases of caesarean section, and the insertion of the Zhukovsky double balloon; the comparison group (IB, IIB, IIIB) included 193 women who were managed traditionally. The main and the comparison groups were divided into subgroups, depending upon the main etiology of obstetric hemorrhage: IA ($n=446$) and IB ($n=122$) postpartum hemorrhage; IIA ($n=47$) and IIB ($n=45$) placenta accreta; IIIA ($n=15$) and IIIB ($n=26$) postpartum hysterectomy. In subgroup IA ($n=446$), hemorrhage was stopped using a combined management in 145 patients after spontaneous delivery and in 201 after cesarean section. In IB ($n=122$), traditional management was used in only 29 patients after cesarean section and in 93 patients after spontaneous labor. The trial was carried out under the ethical approval by the Omsk State Medical Academy Ethics Committee (approval reference #104, issued on November 14, 2013).

At first, after spontaneous labor the birth canal was examined, the injuries were sutured, and if necessary, manual examination of the uterine cavity was performed (removal of blood clots, assessment of the integrity of the uterine wall). In cases of inefficiency of the above-mentioned maneuvers, the insertion of the uterine balloon of Zhukovsky was carried out. After the introduction of a vaginal speculum, two fenestrated forceps were placed into the cervix, and the uterine balloon was passed through the cervical canal, reaching the fundus of the uterus. Keeping the contact of the distal end of the catheter with the uterine fundus, the open (proximal) end of the catheter was connected to the reservoir tube and filled with saline (Fig. 1). The presence of a balloon in the uterine cavity averaged 3–6 hours. Great importance was given to the position of the uterine balloon and its contact with the uterine walls, which was controlled by ultrasound.

It should be noted that there were certain difficulties in keeping the balloon in uterus, especially when overstretching the lower uterine segment. Therefore, since 2014, we have used a double balloon tamponade

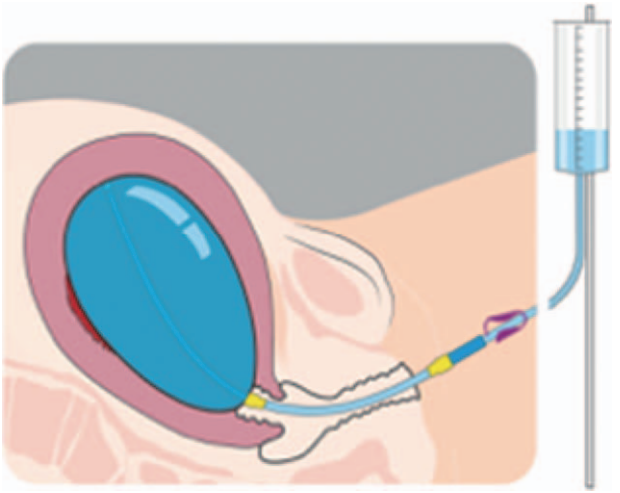

Figure 1. Installation of a single uterine balloon of Zhukovsky.

(combination of vaginal and uterine balloon of Zhukovsky) to stop hemorrhage. The technique was as follows: A modified uterine balloon was inserted passing through the cervical canal, it was then filled with saline, and thereafter a vaginal module was fed through a conductor to the uterine balloon, filling it with 150 mL of saline. The duration of maintaining the vaginal and uterine catheters was 6–8 hours (Fig. 2).

During a cesarean section, given the higher risk of hemorrhage in the above groups, when blood loss was superior to 1000 mL, surgical management was applied, that is, ligation of the descending branch of the uterine artery from the posterior wall of the uterus (Fig. 3), ligation of the bleeding vessels of the placental site, and application of our original external-uterine supraplacental assembly hemostatic sutures (Fig. 4). A distinctive feature of hemostatic external-uterine supraplacental assembly sutures is their location in the area of the placental site. Vicryl thread (1/0) is laid on one third of the myometrium and tightened in the transverse direction in the manner of an assembly seam with one thread. This modification of the suture from the outside of the uterine wall allows surgical hemostasis from the placental site, without reducing the volume of the uterine cavity. Then a modified uterine balloon was inserted using a guide through a hysterotomy incision, passing it through the cervical canal. After suturing the uterus, the balloon was filled with saline and then the vaginal module was injected intravaginally through the guide to the uterine balloon, filling it with 150 mL of saline (Fig. 2). The duration of the vaginal and uterine catheters was 10–14 hours.

In the case of placenta accreta after catheterization of the bladder, prior to operative delivery, the vaginal module of the balloon (without filling it with fluid) was inserted, and only after extracting the fetus, the vaginal module was filled with 150 mL of saline. Further operative manipulations were carried out with the inserted module. The next stage was surgical hemostasis. After detachment of the placenta, the placental site was examined. When the placenta was found invading one third of the myometrium, this pathological area was excised with simultaneous ligation of the bleeding vessels and stitching of the

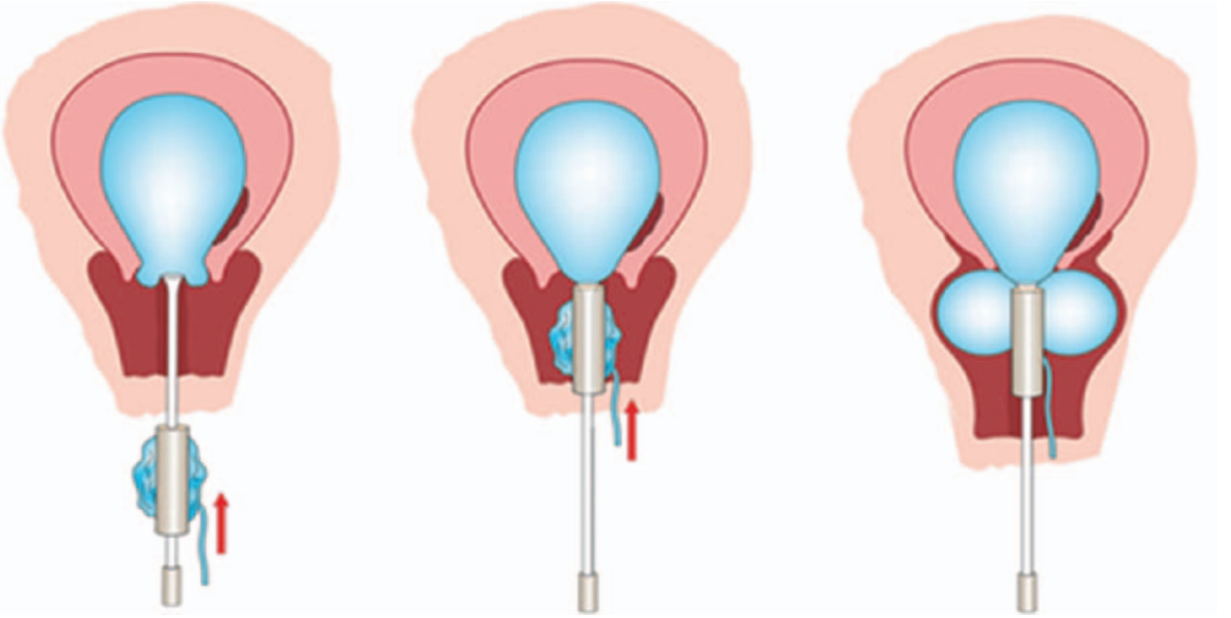

Figure 2. Installation of double (vaginal and uterine) balloons of Zhukovsky.

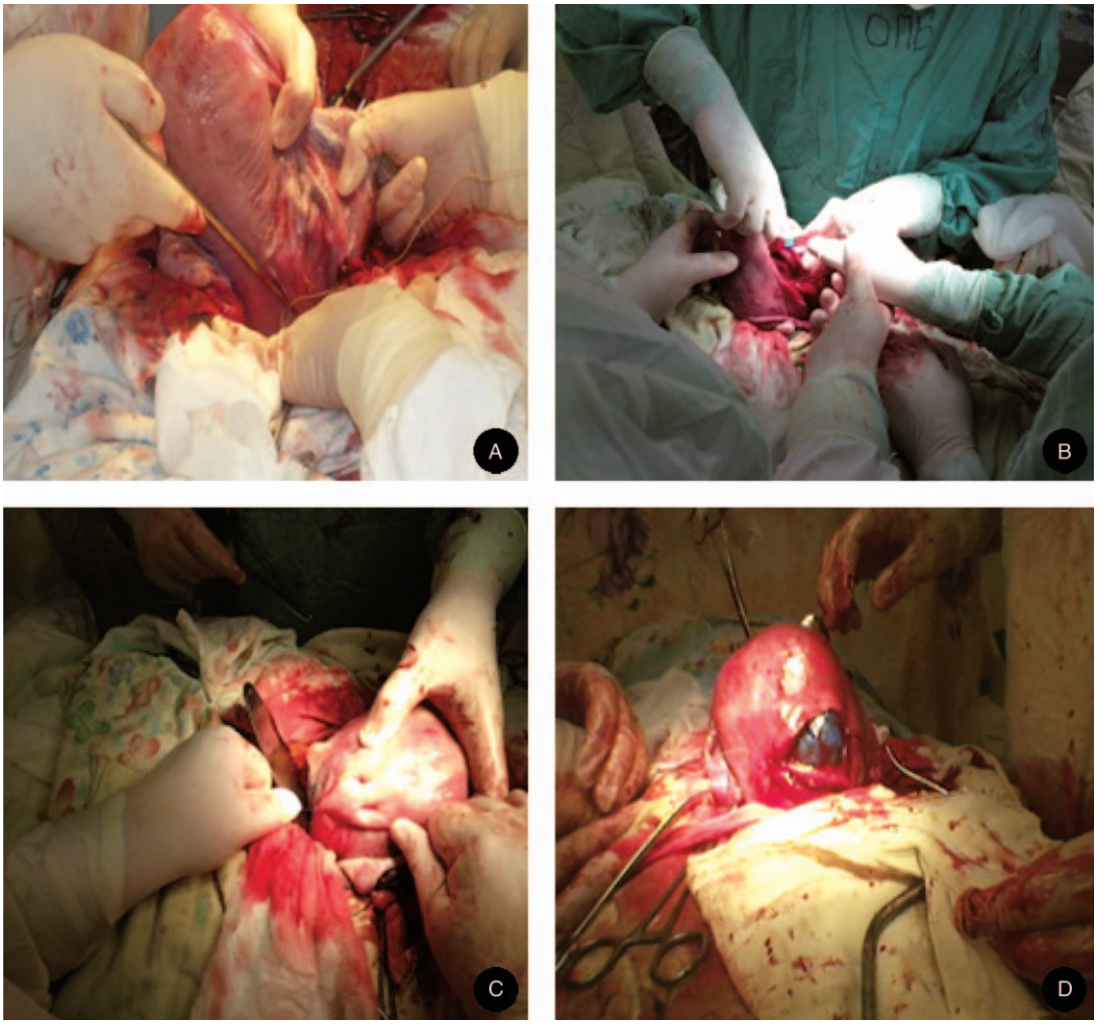

Figure 3. Stages of stopping postpartum hemorrhage. A Ligation of uterine vessels. B Removal of blood clots and hemostasis. C Imposition of a hemostatic external-uterine supraplacental assembly sutures. D Installation of uterine balloon.

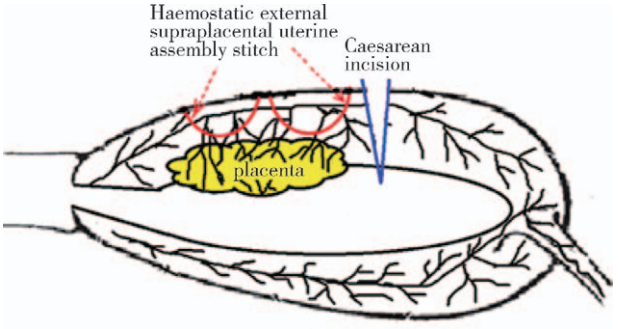

Figure 4. Technique of imposing hemostatic external-uterine supraplacental assembly suture.

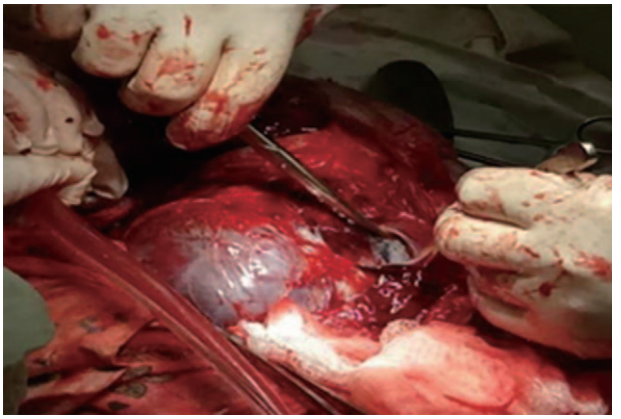

Figure 5. Placenta percreta. Separation of the hernial sac.

placental bed with a ∞-shaped suture. Subsequently, the separation of the vesico-uterine fold downward and the application of a hemostatic external-uterine supraplacental assembly suture were performed. When placenta was invading more than two thirds of the thickness of the myometrium or more than 5 cm in diameter, the section of the uterus involved was cut off with the area of placenta. Separation of the vesico-uterine fold and the application of a hemostatic external-uterine supraplacental assembly suture were performed below the intended cutoff of the uterine wall.

In the case of placenta percreta, a high transverse incision on the uterus was done to extract the fetus, and then the uterine wall with the placenta was cut off and a metroplasty was performed: The hernia sac was isolated (Fig. 5), then the vesico-uterine fold was removed, and thereafter the hemostatic external-uterine supraplacental assembly suture was applied below the intended cutoff of the uterine wall. Subsequently, the uterine wall was also reinforced with separate vicryl sutures. After this surgical stage, the intrauterine balloon of Zhukovsky was inserted through a hysterotomy incision. After suturing the uterus, the uterine module of balloon was filled with saline. The duration of the balloon tamponade using vaginal and uterine catheters was 10–14 hours (Fig. 6).

In case of hemorrhage after spontaneous labor, as well as in cases of cesarean section when no effect of conservative treatment in group IIIA was observed, the double Zhukovsky balloon was inserted. Hysterectomy was performed according to a standard technique. After access to the vaginal fornix, the uterine catheter was removed, and hysterectomy was performed on an established vaginal catheter that remained in the vagina for 6–8 hours after completion of the operation (Fig. 7). In group IIIB, uterus tamponade using a hemostatic bandage was applied to reduce blood loss (Fig. 8).

Another pathology of the postpartum period that presents certain technical difficulties in stopping hemor-

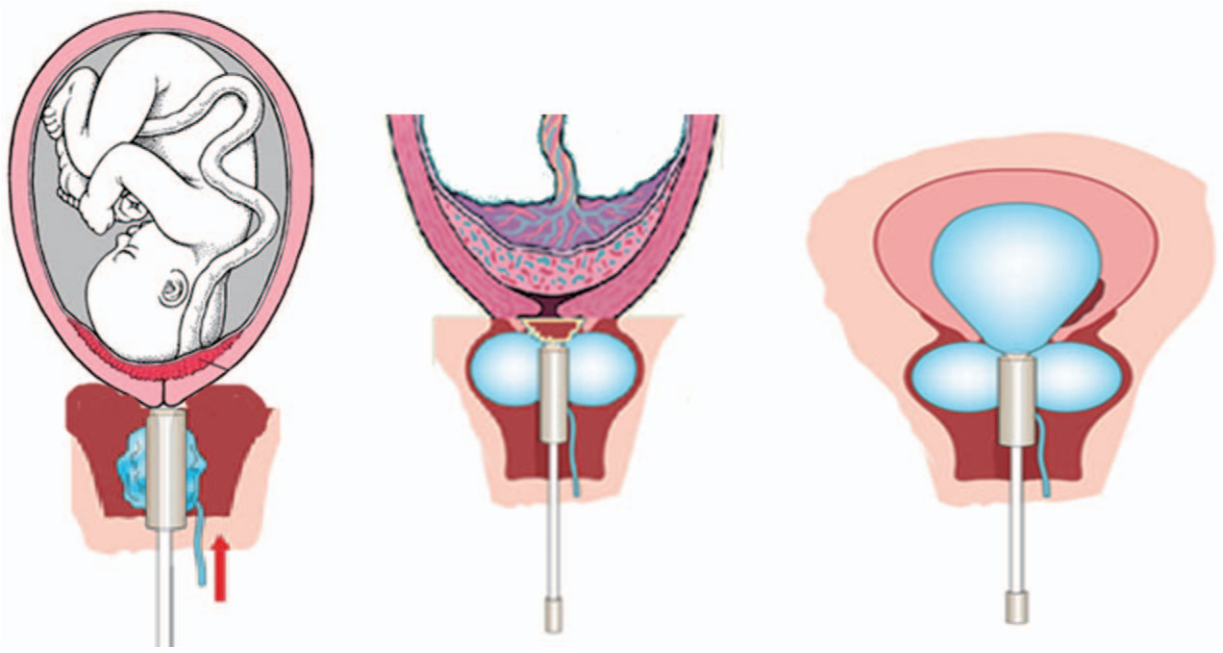

Figure 6. Installation of vaginal and uterine catheters of Zhukovsky in the case of placenta previa.

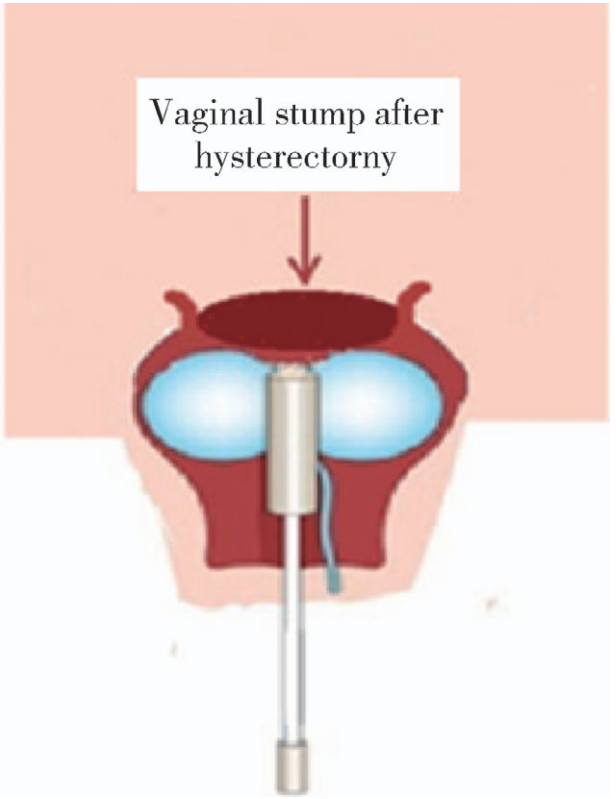

Figure 7. Hysterectomy on an established vaginal balloon.

rhage is represented by the deep traumatic vaginal injuries and the paravaginal hematomas. In such cases ($n=15$, in our experience reported here), we autonomously applied the vaginal balloon. The first step of treatment was to close the wound of the vaginal wall, and then a vaginal balloon was inserted in the wound, filled with saline in the volume of 180 mL. The hole in the axial tube of the vaginal balloon

Figure 8. Application of a hemostatic bandage in obstetric hemorrhage.

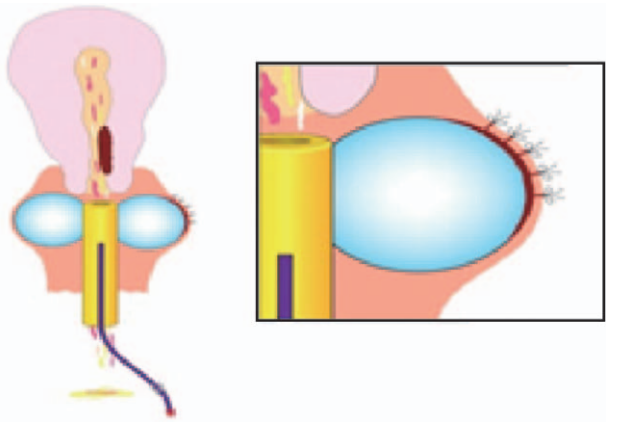

Figure 9. Installation of a single vaginal balloon of Zhukovsky.

allowed the free flow of lochia (Fig. 9). In the comparison group, we used a hemostatic bandage tamponade on the site of vaginal rupture, which increased blood loss, hampering the outflow of lochia.

The presence of continuing hemorrhage with the inserted double balloon tamponade is an indication for laparotomy. In our study, hemorrhage occurred in six patients, which required exhaustive surgical manipulations to stop it. In these situations, laparotomy was performed on the background of a double balloon tamponade, ligation of the descending branch of the uterine vessels (Fig. 3). The next step was hysterotomy, emptying the uterine balloon and bringing it down into the axial tube of the vaginal balloon. Furthermore, assessment of the placental site was carried out: In cases of detection of placenta accreta, this was excised in toto; in other cases we performed ligation of the bleeding vessels of the placental site. In all cases we applied supraplacental hemostatic suture and then the uterine balloon was reintroduced into the uterine cavity. In order to evaluate the effectiveness, we conducted manipulations during an operational pause with a filled balloon for 3–5 minutes. If the hemorrhage stopped, the uterus and anterior abdominal wall were sutured. In such cases, the balloon remained in uterus for further 10–14 hours.

Statistical analysis was carried out using SPSS 17.0 and Statistical 10.0. Normally distributed continuous variables are presented as mean ± standard deviation (*SD*). Continuous variables, which were not normally distributed, are presented as median and 25% and 75% percentiles [median (25%, 75%)]. Continuous and ordinal variables were analyzed using nonparametric statistics: Kruskall-Wallace test, Mann-Whitney *U*-test, and Wilkoxon W-test. Differences were considered significant at $P<0.05$.

Results

In the Omsk Regional Perinatal Center during January 1, 2011 to December 31, 2017, there were 25,486 deliveries, of which 12,437 (48.8%) were cesarean section. The percentage of obstetric hemorrhage (over 1000 mL of blood loss) was 3.3%. During 2011–2012, to stop hemorrhage, only surgical hemostasis method was used; from 2013 to 2014, surgical method combined with the

Table 1

The volume of transfusion therapy in two groups

Parameters	Groups		P
	IA ($n=446$)	IB ($n=122$)	
The volume of transfusions (mL)	2437.2±730.1	4440.8±907.0	0.041
Fresh frozen plasma (mL)	1196.1±414.9	2497.6±502.7	0.034
Erythrocyte mass (mL)	1203.2±313.7	1525.4±570.1	0.063
Thromboconcentrate (dose)	1.14±0.60	0.95±0.72	0.057

insertion of a Zhukovsky single uterine balloon was used; from 2014 we have used Zhukovsky double balloon. In general, during the reporting period, we performed 508 balloon tamponades. Of these, 348 (70.7%) were inserted to stop hemorrhage during cesarean section, 145 (29.3%) after spontaneous delivery, and 15 during hysterectomy.

The most frequent causes of massive obstetric hemorrhages were atony of the uterus (39.2%), placenta previa (29.1%), placental abruption (11.5%). Other causes included pre-eclampsia (8.3%), uterine scar defects (6.6%), deep ruptures of the vaginal wall (4.4%), and large uterus myoma (0.9%).

The indications for cesarean section were placenta previa in 31.93% of cases, multiple pregnancy 21.85%, placental abruption 12.61%, uterine scar defects 11.77%, extragenital pathology 10.08%, severe pre-eclampsia 7.56%, and pregnancy after IVF (precious baby, upon maternal request) 4.2%.

Blood loss of 2000 mL or more was recorded in 16.2% of women in the study group and in 27.6% of cases among patients in the comparison group ($P=0.03$). The total blood loss of women in group IA was significantly less than in group IB [(2502±203) mL versus (1836±108) mL]. The type of therapy aimed at restoring hypovolemic disorders and correcting hemostatic parameters was significantly different in both groups (Table 1). In the comparison group, a larger volume of infusion therapy was required for the correction of hypovolemia [(4441±907) mL versus (2437±730) mL, $P=0.041$], and the volume of infusion of fresh frozen plasma was significantly lower in patients of the main group [(1196±415) mL versus (2498±503) mL, $P=0.034$].

Of the 206 patients with placenta previa, 92 (44.6%) were detected with placenta accreta. In 44 (47.8%) of these cases, the accretism affected one third of myometrium, in 30 (32.6%)—two thirds of the myometrium and/or more than 5 cm, and 18 (19.6%) had a placenta percreta. Metroplasty was performed in 29 (31.5%) patients. The management comprising the insertion of a double balloon tamponade allowed performing metroplasty 2.8 times more often in group IIA compared with group IIB and reduced the need for blood transfusion by 1.9 times ($P=0.414$). Additionally, the introduction of a vaginal balloon reduced the need of blood transfusion by 2.4 times ($P=0.0459$). Significant differences in the frequency of use of the Cell-Server apparatus were not identified.

The total volume of blood loss in group IIIB was 1.3 times more than in group IIIA [(2591±381.1) mL versus (2010±238.2) mL, $P=0.04$] and the volume of intraoperative blood loss in these groups was (1525±270.1) mL versus (991.3±207.2) mL, respectively ($P=0.03$). In group IIIB, for the correction of hypovolemic disorders, a larger volume of infusion therapy was required, whereas in patients of group IIIA, the volume of injected fresh frozen plasma [(953±268.4) mL versus (1362±333) mL, $P=0.034$] and red blood cell mass [(707.7±132) mL versus (1004.1±157.9) mL, $P=0.023$] were significantly less than in group IIIB.

During hysterectomy, in group IIIA compared to IIIB, the use of vaginal and uterine balloons of Zhukovsky allowed reducing the total blood loss by 1.3 times ($P=0.04$), intraoperative blood loss by 1.5 times ($P=0.04$), the volume of transfused fresh frozen plasma by 1.4 times ($P=0.034$), and the erythrocyte mass transfusion by 1.4 times ($P=0.023$).

The morphological study of the uterus revealed chorionic villi or trophoblastic tissue into the myometrium in 22 cases of hysterectomy, signs of purulent endometritis in 10 cases, uterine leiomyoma in 7 cases, and platelets and fibrin filaments in the uterine vessels in 2 cases.

Discussion

Based on the results of the study, the main reasons for the development of a massive obstetric hemorrhage are the morphological changes in the structure of the myometrium associated with placenta accreta and the placental abruption. Other causes of the hemorrhage in the postpartum period are alteration of the contractile activity of the lower segment, the presence of multiple fetuses, and uterine scar defects. Our data confirm previous obervations.[26–28]

A distinctive feature of our original hemostatic external-uterine supraplacental sutures is to ensure the absence of compression-ischemic damage to the myometrium, without reducing the volume of the uterine cavity and creating conditions for inserting the uterine balloon.[29–32] The Zhukovsky double (uterine and vaginal) balloon tamponade, in contrast to other double balloon models used in obstetric practice, according to its technical characteristics, allows using a separate vaginal module for deep vaginal ruptures and postpartum hysterectomy. Also, the Zhukovsky balloon provides a close contact between the balloon and the walls of the uterus, which prevents the accumulation of blood between them and the development of hematoma. This effect is achieved by direct pressure on the damaged vessel, when the wall of the filled balloon exerts pressure directly on the open bleeding spiral arteries of the placental site, leading to the closure of their walls, stopping the bleeding, and the subsequent formation of blood clots in these vessels.

The problem of retaining the balloon within the uterine cavity is considered a key condition for determining its effectiveness.[19,23,33] The current recommendations of the manufacturers of commercially available balloons for these purposes to tampon the vagina with gauze napkins, in our opinion, cannot be considered acceptable for many reasons. The described options for holding the balloon in the uterus, by imposing various stitches on the cervix and narrowing the cervical lumen, have potential risks. The developed vaginal module is able to provide a stable position of the balloon in the uterus due to its duration and high insertion in the vagina, thus avoiding the expulsion of the uterine balloon. As a result of the addition of multidirectional force vectors created by the two balloons, from both the uterus and the vagina, new mechanisms for stopping postpartum hemorrhage are activated. Among

these, in the first place should be noted the interballoon compression exerted by the uterine and vaginal balloons on the lower uterine segment. The presence of a hole in the axial tube of the vaginal module allows diagnosis of the ongoing bleeding and eventually change in the management. The insertion of the vaginal balloon before surgery in women with placenta previa and filled after fetal extraction allows performing an organ-preserving operation even in the case of placenta accreta. Additionally, insertion of the uterine balloon is the final method of stopping hemorrhage in such situations.

Since the leading causes of massive postpartum bleeding depending on morphological and structural changes in the myometrium, conservative measures often have no effect and hence in order to save the life of the patients, there is a need to perform a hysterectomy.[8,12] Postpartum hysterectomy is a technically difficult surgical procedure, in which the volume of external blood loss is important for a positive result of the operation. The various methods used to stop bleeding do not reduce the amount of blood loss. Therefore, for a positive result of the operation, it is important to reduce the volume of external blood loss. A number of surgeons[18,33,34] used the intrauterine insertion of a Bakri balloon for this purpose, but when performing hysterectomy, such a uterine catheter can be expulsed from the uterine cavity. The Zhukovsky vaginal balloon is able to provide a stable position of the catheter in the uterus due to its strong, as high as possible, setting in the vagina and thus avoids the expulsion of the uterine balloon, thereby ensuring a decrease in external blood loss. The inserted vaginal balloon after hysterectomy compresses the pelvic vessels and prevents the risk of pelvic hematomas, as well as it allows a timely diagnosis of ongoing hemorrhage, which contributes to a more favorable outcome of postpartum hysterectomy.

The use of combined management with a double balloon tamponade for obstetric hemorrhage at the Omsk Regional Perinatal Center from January 1, 2011 to December 31, 2017 reduced the percentage of hysterectomies from 1.68% to 0.25% (6.7 times).

Conclusions

The results of this study led to the following conclusions: (1) In our experience, the leading causes of massive obstetric hemorrhages were atony of the uterus (39.2%), placenta previa (29.1%), and placental abruption (11.5%). (2) The combined management of postpartum hemorrhage includes surgical hemostasis (ligation of the descending branch of the uterine artery and the application of a hemostatic external-uterine supraplacental assembly suture), mechanical pressure on the walls of the uterus, and pressure on the cervical vessels with the use of Zhukovsky double balloon that can prevent massive obstetric hemorrhage even in the case of performing hysterectomy. (3) In comparison to other similar devices, Zhukovsky double balloon allows separating the vaginal module in order to tampon the vagina during deep ruptures of the vaginal wall. (4) The use of a combined management with the Zhukovsky double balloon in patients with placenta accreta allows performing an organ-preserving operation (resection of the uterine wall) and significantly reduces blood loss. (5) After postpartum hysterectomy, it is difficult to control the continuing hemorrhage; the introduction of Zhukovsky vaginal balloon into the vaginal fornix allows monitoring the hemorrhage, and by compressing the pelvic vessels it reduces the risk of developing parametrium hematomas. (6) The use of combined management using a double balloon tamponade for obstetric hemorrhage allowed reducing the percentage of hysterectomies from 1.68% to 0.25% (6.72 times). (7) The use of Zhukovsky double balloon to stop obstetric hemorrhage is a reasonably inexpensive and safe method compared to other more expensive surgical methods and, therefore, it can be widely introduced in obstetric hospitals.

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Author Contributions

Irina V. Medyannikova, Anna V. Borisova, Irina V. Savelieva, Yulia I. Tyrskaya, and Tatyana V. Kadtsyna carried out the experiment and sample preparation, designed the model and the computational framework, and analyzed the data. Sergey V. Barinov wrote the article with support from Irina V. Medyannikova, Anna V. Borisova, Irina V. Savelieva, and Oksana V. Lazareva. Sergey V. Barinov supervised the project. All authors discussed the results and commented on the article.

Conflicts of Interest

None.

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