IJPSR (2025), Volume 16, Issue 4 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 18 November 2024; received in revised form, 21 December 2024; accepted, 23 December 2024; published 01 April 2025

# THE EFFECTIVENESS OF BALLOON TAMPONADE IN THE PREVENTION AND TREATMENT OF POSTPARTUM HEMORRHAGE

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**Keywords:**

Postpartum hemorrhage, Balloon tamponade, Hysterectomie, Pregnancy

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**ABSTRACT:** Postpartum hemorrhage (PPH) is one of the leading causes of maternal morbidity and mortality, ranking third after thromboembolism and hypertensive disorders. The primary goal of this study was to determine the effectiveness of balloon tamponade in the prevention and treatment of postpartum hemorrhage. The principle of balloon tamponade is to apply direct pressure to the bleeding vessels of the placental area using the wall of an inflated balloon within the uterus. The basic study included both retrospective and prospective research. The retrospective study group (no balloon tamponade performed) consisted of 72 patients, of whom 34 delivered vaginally and 38 underwent cesarean section. The prospective study group (balloon tamponade performed) included 40 women (20 with vaginal deliveries and 20 with operative deliveries). The effectiveness of the treatment was assessed based on two criteria: the volume of blood loss and the number of hysterectomies performed. In our study, the effectiveness of balloon tamponade was found to be 95%, based on the complete cessation of bleeding and the reduction in the length of hospital stay. This research is relevant and presents scientific and practical interest in terms of applying and implementing the modern and innovative balloon tamponade for managing PPH as a safe, effective, accessible, and controllable technique.

**INTRODUCTION:** Postpartum hemorrhage (PPH) is one of the leading causes of maternal morbidity and mortality, ranking third after thromboembolism and hypertensive disorders [1]. Despite the scientific and practical achievements of global medicine in obstetric practice and the highly qualified obstetric and gynecological care provided to pregnant women and mothers, PPH remains a significant concern.

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DOI: 10.13040/IJPSR.0975-8232.16(4).1093-99

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(4).1093-99

According to WHO materials, PPH is defined as blood loss exceeding 500 ml following vaginal delivery or more than 1000 ml after a cesarean section [2]. According to statistical data, over 130,000 women worldwide die annually from postpartum hemorrhage (PPH), which is the leading and direct cause of maternal mortality (MM).

More than half of these deaths are attributed to women with uterine atony [3]. The mortality rate from pregnancy and childbirth complications reaches approximately 529,000 women annually [1, 4]. Hemorrhage is the cause of death in at least one out of every four cases. Thus, according to WHO data, PPH is an obstetric emergency that transforms

a normal physiological childbirth process into a life-threatening condition. Some authors suggest that up to 86.3% of maternal mortality cases could be prevented or avoided if not only the risk factors and causes (considering the genesis of hemorrhages) leading to fatal outcomes were identified but also if cases of preventing critical situations in obstetrics were analyzed [5, 6]. Therefore, organ-preserving surgeries, aimed at restoring the impaired functional activity of organs, have become the dominant approach today. The protocol for providing basic care in cases of postpartum hemorrhage (PPH) continues to rely on both conservative and surgical methods. Currently, the primary strategy in combating PPH is its cessation through conservative methods [7].

One recognized method for stopping PPH is uterine balloon tamponade (BT), which is considered a highly effective treatment and prevention method in modern medicine [8]. This method can be applied in the early stages of postpartum hemorrhage, preventing large-scale blood loss, which is particularly relevant for everyday obstetric practice. The use of balloon tamponade results in a 3.5-fold reduction in massive blood loss, a 4-fold decrease in the frequency of hysterectomies, a 4.5-fold reduction in the incidence of septic complications, and shorter hospital stays for patients during the postpartum period following cesarean sections. Thus, the relevance of this study is highlighted by the lack of consensus regarding the indications, conditions, techniques, and types of balloons used in postpartum hemorrhages. Given the high prevalence of obstetric hemorrhage, new effective methods for managing PPH will not only preserve a woman's reproductive function but also prevent complications and avoid cases of maternal mortality. The primary goal of this study was to determine the effectiveness of balloon tamponade in the prevention and treatment of postpartum hemorrhage.

**MATERIALS AND METHODS:** We examined 112 postpartum women with varying degrees of postpartum hemorrhage (PPH). All women experienced varying degrees of PPH. Depending on the treatment strategy, the women with hemorrhage were divided into two main levels. We applied a combined strategy (retrospective study - no balloon tamponade performed), which included n=72 patients (34 of whom had vaginal deliveries and 38 had operative deliveries), where traditional obstetric management was employed, constituting Level I. A prospective study was conducted on 40 women who underwent balloon tamponade using the method of Zhukovsky Ya.G. (20 after vaginal delivery and 20 after cesarean section), comprising Level II. Level III included the control group (CG), which consisted of 30 conditionally healthy fertile women who did not experience PPH during childbirth. The age of the women examined ranged from 18 to 44 years and older, with an average age of 31±13 years. The clinical examination included anamnesis, general clinical, and laboratory-instrumental methods.

The obstetric-gynecological history was studied with a focus on the morphofunctional characteristics of the reproductive system, the course and outcomes of previous pregnancies complicated by hemorrhage. To obtain the most comprehensive information on obstetric-gynecological history, the course of the current pregnancy, childbirth, and the early puerperal period, additional delivery histories were developed and used. The clinical assessment of the condition of pregnant women and women in labor was carried out (based on voluntary informed consent) according to the generally accepted rules in obstetrics, in accordance with the recommendations of clinical protocols, WHO, and the Ministry of Health of the Republic of Azerbaijan: active management of the third stage of labor. The management of delivery (vaginal or operative), measures to prevent hemorrhage, the volume of blood loss, and the volume of compensation with infusion-transfusion fluids during delivery were studied.The dynamics of hemorrhage development, the treatment strategy, and the outcomes were analyzed.

General clinical examinations of all pregnant women were conducted 1-2 weeks before delivery, and of women in labor at the beginning of the first stage of labor, using standard general and laboratory hemostasiogram indicators, which included clinical and biochemical analyses: a coagulation profile with determination of platelet count, fibrinogen, activated partial thromboplastin time, and prothrombin time; blood clotting time according to the Lee-White method; as well as

instrumental methods such as ultrasound, cardiotocography, Doppler sonography, and assessment of the biophysical profile of the fetus. The examinations were performed before delivery, then 1-3 hours and 24 hours after delivery. PPH diagnosis was carried out immediately after the delivery of the placenta (external examination of the uterus to assess its contours, size, and tone); monitoring signs of bleeding in the postpartum period; controlling the volume of external bleeding; ruling out intra-abdominal bleeding; assessing the condition of the mother; and monitoring blood deposition in the uterine cavity using ultrasound and monitoring the main hemodynamic indicators. The condition was assessed by determining blood gas levels, blood type incompatibility, Rh factor, testing for infections, and screening for hepatitis "B" and "C". According to WHO materials on the "prevention and treatment of postpartum hemorrhage" [2], PPH was classified into four severity levels. The condition of the mothers was also studied during the postpartum period.

A complete blood count was performed using the automatic analyzer "MYTHIC 22" (France). Biochemical blood analysis was conducted on the automatic analyzer "BIOLIS" (Japan). Hemostasiogram parameters were assessed using the automatic analyzer "SIEMENS CA-50" (Germany). Thrombin time was determined using "Hemostat Thrombin" reagents ("Human Gesellschaft für Biochemica und Diagnostica mbH, Germany") for diagnosing disorders in the final stage of coagulation. Prothrombin time (PT) was assessed using "Thromblastin-SI Hemostat" ("Human Gesellschaft für Biochemica und Diagnostica mbH, Germany") on the "Sysmex CA-50" coagulation analyzer (Japan).

Activated partial thromboplastin time (APTT) was measured using reagents from "Human Gesellschaft für Biochemica und Diagnostica mbH, Germany." Fibrinogen concentration was determined with the "HEMOSTAT Fibrinogen" reagent (fibrinogen test) ("Human Gesellschaft für Biochemica und Diagnostica mbH, Germany") by measuring the clotting time of diluted citrated plasma with an excess of thrombin. All pregnant women underwent fetal cardiomonitoring using the "EDAN F9 Expert Class" cardiotocograph (Korea). Ultrasound and Doppler examinations of the pelvic organs were conducted using the "Voluson 8" device (Germany), with the following probes: 1) abdominal RAB 4-8-D; 2) vaginal RIC 5-9-D; 3) linear 11L-3D; 4) convex AB 2-7-D, with frequencies ranging from 2 to 15 MHz. The following methods were used to determine the volume of blood loss: visual assessment; measurement of circulating blood volume (CBV); percentage of total blood loss (Nelson's formula); hematocrit method (Moore F.D., 1965); gravimetric method (Libov's formula, 1960); measurement with a graduated container; shock index (ratio of heart rate to systolic blood pressure); and calculation of blood loss based on blood density and hematocrit.

Surgical methods for stopping bleeding were employed, including balloon tamponade of the uterus, recommended as the first-line surgical method for controlling hypotonic hemorrhage when uterotonics are ineffective. A "tamponade test" was performed, which included: a "positive test" (where bleeding stops after balloon inflation), indicating that laparotomy was not necessary. A "negative test" (where bleeding continues after balloon inflation) indicated the need for laparotomy. Additionally, compression sutures were applied to the uterus (using the B-Lynch method) as required. If necessary, ligation of the internal iliac arteries was performed (considered a conservative surgical intervention). Hysterectomy was applied based on indications. For controlling postpartum hemorrhage, we used uterine balloon tamponade according to Zhukovsky Ya.G. [9]. The indication for using uterine balloon tamponade was ongoing bleeding after manual examination of the uterine cavity: uterine atony or hypotonia, and exclusion of other possible causes of bleeding (such as retained placental fragments or blood clots in the uterine cavity, trauma to the birth canal, coagulopathy, *etc*.).

Statistical analysis of the results was performed using the biometric method with the "STATISTICA-10" software package, and graphs were created using "ORIGIN-6.1" and "EXCEL-7." Differences were considered statistically significant at $p<0.05$ and ($p<0.01$, $p<0.001$). These criteria meet the standards for medical-biological research.

**RESULTS AND DISCUSSION:** Parity analysis revealed that primiparous women accounted for

32(44.4%) in Level I, compared to 7(17.5%) in Level II. Multiparous women constituted 40(55.6%) in Level I and 33(82.5%) in Level II. Thus, the majority of women were multiparous - 73(65.2%); primiparous women made up 39(34.8%) of the cases. Postpartum hemorrhage (PPH) was most frequently observed in women of late reproductive age, accounting for 76(67.9%) cases, while women of active reproductive age had PPH in 36(32.1%) cases. Analysis of the reproductive history of the women revealed the onset of menstruation at 13.35±0.55 years, compared to 12.85±0.35 years in the control group (CG). The structural characteristics of extragenital diseases among women with PPH showed a predominance of blood disorders (iron deficiency, hemorrhagic, hypercoagulable anemias, thalassemia, HELLP syndrome) in 56(50%) cases. Endocrine disorders were present in 13(11.6%) cases; cardiovascular diseases in 6(5.4%) cases; gastrointestinal diseases in 5(4.5%) cases; infectious diseases (hepatitis "B" and "C") in 4(3.6%) cases; eye diseases in 2(1.8%) cases; and genitourinary disorders in 1(0.9%) case. The structural characteristics of gynecological conditions among women with PPH showed a predominance of uterine fibroids (including multiple fibroids, fibromyomas, and myomatous nodes) in 13(18%) cases, and cervical erosion in 3(2.7%) cases.

The risk factors for PPH among the women in our study included: maternal age over 35 years - 16(14.3%); threat of miscarriage - 11(9.82%); spontaneous abortion - 6(5.35%); preeclampsia and HELLP syndrome - 4(3.57%); medical abortions - 23(20.5%); trauma to the soft birth canal - 13(11.6%); antenatal fetal death - 4(3.57%); induction of labor - 11(9.82%); arterial hypertension - 3(2.7%); obesity class II-IV - 5(4.46%); and large fetal size - 9(8%), among others. Thus, all women are at risk for PPH, even in the absence of predisposing factors.

**Comparative Statistical Analysis of Hemostasiogram in Women with PPH:** A comparative statistical analysis of the hemostasiogram in women with PPH revealed a significant decrease in hemoglobin (HGB): 86.95±2.26 g/L in Level I and 103.5±1.95 g/L in Level II, compared to the control group (CG) at 114.7±1.66 g/L ($p<0.05$; 95% CI). Hematocrit (HCT) also showed a significant decrease: 27.63±0.65% in Level I and 31.74±0.76% in Level II, compared to the CG at 35.7±0.5% ($p<0.05$; 95% CI). There was a significant reduction in white cell volume (WCV): 77.80±1.04 fL in Level I and 81.42±1.44 fL in Level II, while the CG recorded a WCV of 85.73±1.47 fL ($p<0.05$; 95% CI). A significant increase in red cell distribution width (RDW) was observed: 16.03±0.37% in Level II and 16.17±0.38% in Level I, compared to the CG at 13.03±0.2% ($p<0.05$; 95% CI).

**Analysis of Hemostasiogram Results:** A slight increase in white blood cell count (WBC) was observed at both levels: 10.4±0.4x$10^3$/μL at Level II and 10.69±0.33 x$10^3$/μL at Level I, compared to the control group (CG) at 9.24±0.3 x$10^3$/μL ($p<0.05$; 95% CI). Neutrophil percentage (NEYT) was elevated at Level I, showing 75.80±0.65%, while the values at Level II and the CG were similar, at 71.75±1.17% and 71.46±0.9%, respectively ($p<0.05$; 95% CI). Lymphocyte count (LYM) was significantly lower at Level I, at 15.96±0.6%, compared to Level II and the CG, which had values of 18.81±0.62% and 20.05±0.9%, respectively ($p<0.05$; 95% CI). A comparative analysis showed an increase in platelet count (PLT), with Level II averaging 270.9±10.2 x$10^3$/μL, Level I at 244.1±9.04x$10^3$/μL, and the CG at 228.2±10.06x$10^3$/μL ($p<0.05$; 95% CI). No significant changes were noted in mean platelet volume (MPV) or plateletcrit (PCT). Platelet distribution width (PDW) was reduced at Level I, at 12.36±0.23 fL, and 12.76±0.25 fL in the CG, while at Level II, PDW was higher at 13.37±0.2 fL ($p<0.05$; 95% CI). Erythrocyte sedimentation rate (ESR) was increased at Level II, at 43.97±1.96 mm/s, and 33.55±1.36 mm/s at Level I, compared to the CG at 33.2±1.04 mm/s ($p<0.05$; 95% CI).

**Hemostasis Function and Its Indicators:** Both endocrine and nervous systems play crucial roles in maintaining proper hemostasis. Reduced blood clotting, or hypocoagulation, poses a risk of uncontrolled bleeding, whereas hypercoagulation leads to clot formation, which can result in thrombosis and thromboembolism. Hemostasiogram is a set of blood indicators that assess its clotting ability. A key indicator of hemostasis system status is prothrombin time (PT), which

measures the time required for thrombin clot formation and reflects the coagulation (plasma) hemostasis. PT evaluates the first and second phases of plasma coagulation and the activity of factors II, V, VII, and X. This test assesses the extrinsic pathway of blood clotting. Our research demonstrated a shortened PT at the compared levels: 13.6±0.17 seconds at Level I and 13.89±0.2 seconds at Level II, compared to 14.96±0.13 seconds in the control group ($p<0.05$; 95% CI). This shortening of PT is characteristic of the final weeks of pregnancy.

Activated partial thromboplastin time (APTT) measures the effectiveness of stopping bleeding by plasma factors, reflecting coagulation (plasma) hemostasis, and is the most sensitive and precise indicator of the hemostasiogram. In our study, activated partial thromboplastin time (APTT) was recorded as follows: 30.67±0.42 seconds at Level I, 31.88±0.63 seconds at Level II, and 30.78±0.7 seconds in the control group ($p<0.05$; 95% CI). Comparative analysis of the coagulogram revealed that Quick values were 93.14±1.33% at Level I, 96.54±1.58% at Level II, compared to 82.6±1.18% in the control group ($p<0.05$; 95% CI). The Quick test measures prothrombin time according to the Quick method. Thrombin time (TT) is a significant basic coagulation test that characterizes the final stage of clotting: the conversion of fibrinogen to fibrin under the influence of thrombin. It is used to assess the anticoagulant activity of blood.

In our research, TT values were 10.51±0.16 seconds at Level II and 10.16±0.15 seconds at Level I, while in the control group, it was 10.08±0.13 seconds ($p<0.05$; 95% CI). Fibrinogen, known as Factor I in the plasma coagulation system, is a fundamental test for assessing hemostasis. Our results showed fibrinogen levels of 346.6±9.01 mg/dL at Level I, slightly higher compared to the control group at 291.5±8.77 mg/dL; at Level II, the fibrinogen level was 327.4±11.86 mg/dL compared to 291.5±8.77 mg/dL in the control group ($p<0.05$; 95% CI). The International Normalized Ratio (INR) is a standardized measure of prothrombin time, representing the ratio of a patient's PT to the PT of normal plasma, adjusted by the International Sensitivity Index. This value provides a mathematically adjusted metric for assessing clotting function. According to the generally accepted classification, comparative analysis of both levels revealed that early postpartum hemorrhage (PPH) was significantly more prevalent among the parturients, occurring in 103(97.3%) cases, while late PPH was observed in 3(2.7%) cases, respectively. The comparative analysis of PPH based on blood loss volume by levels showed: more than 500 ml was observed in 28(25%) cases; 600 ml in 8(7.2%); 650 ml in 1(0.9%); 700 ml in 8(7.2%); 800 ml in 9(8%); 850 ml in 1(0.9%); 900 ml in 11(9.8%); 1000 ml in 32(28.5%); 1500 ml in 8(7.2%); 1900 ml in 2(1.7%); 2000 ml in 3(2.7%); 2500 ml in 1(0.9%) cases, respectively **Fig. 1.**

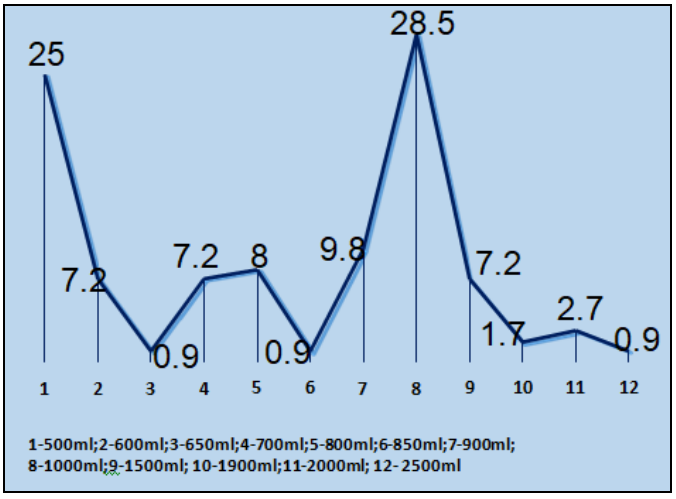


**FIG. 1: BLOOD LOSS VOLUME IN OBSERVED WOMEN**

According to the classification of PPH by severity: mild (Grade I) was observed in 66(58.9%) cases; moderate (Grade II) in 32(28.6%) cases; moderate-severe (Grade III) in 10(8.9%) cases; and severe (Grade IV) in 4(3.6%) cases **Fig. 2.**

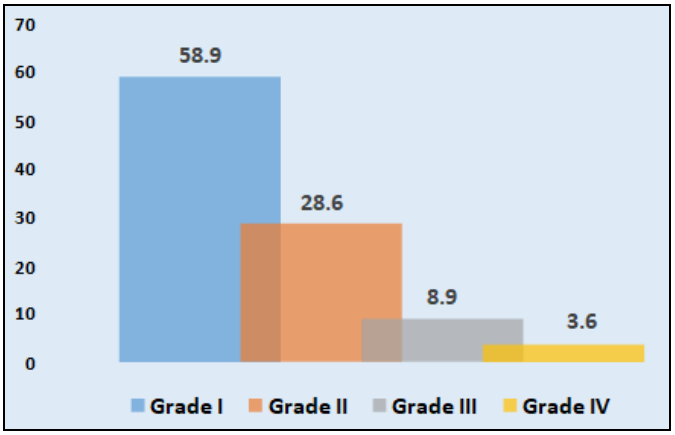


**FIG. 2: THE SEVERITY OF POSTPARTUM HEMORRHAGE IN OBSERVED WOMEN**

Our combined treatment approach for postpartum hemorrhage included: surgical hemostasis (ligation of the iliac arteries and application of compression sutures using the B-Lynch method); mechanical compression and drainage of the uterine cavity with balloon tamponade; and correction of coagulopathy. Traditional management for blood loss exceeding physiological levels included: manual and instrumental examination of the uterine cavity, uterine massage, infusion and transfusion therapy using fresh frozen plasma, red blood cell mass, thrombo-concentrate, protease inhibitors, and surgical hemostasis methods.

It should be noted that during delivery, the following interventions were applied (retrospective study Level I - Cesarean section): uterine massage; uterotonics (oxytocin, ergometrine, methylergometrine, misoprostol); infusion-transfusion therapy. Additionally, the following procedures were performed: hysterectomy (with/without appendages) in 14(36.84%) cases; total abdominal hysterectomy (with/without appendages) in 6(15.8%) cases; B-Lynch compression sutures in 8(21%) cases; relaparotomy in 3(7.9%) cases; ligation of major vessels (internal iliac arteries) in (2.6%) case; and only in 1(5%) case was a total abdominal hysterectomy (with/without appendages) performed in the prospective study Level II - vaginal delivery. Balloon tamponade of the uterus was performed in 40(35.7%) cases.

**Balloon Tamponade Technique:** The principle of balloon tamponade is to apply direct pressure to the bleeding vessels of the placental area using the wall of an inflated balloon within the uterus. Intrauterine pressure applied to the bleeding placental site with an inflated balloon is considered the method of choice and the first step when uterotonics fail to be effective, according to global obstetric practices. The effectiveness of the treatment was assessed based on two criteria: the volume of blood loss and the number of hysterectomies performed. In our study, the effectiveness of balloon tamponade was found to be 95%, based on the complete cessation of bleeding and the reduction in the length of hospital stay (prospective study: 5.0±1 bed-days for vaginal deliveries and 7.0±4 bed-days for cesarean sections). Comparative analysis of hospital stay duration showed that for vaginal deliveries, it was significantly longer in Level I (retrospective study) with 7.5±3.5 bed-days compared to Level II (prospective study) with 5.0±1.0 bed-days. For cesarean sections, there was also a significant increase in bed-days for Level I patients (retrospective studies) to 10.0±5.0 bed-days compared to Level II (prospective studies) with 7.0±4.0 bed-days, indicating the effectiveness of the balloon tamponade method for managing postpartum hemorrhage.

Thus, the balloon tamponade method, as developed by Zhukovsky, addresses three key objectives: first, it effectively and rapidly stops bleeding; second, it allows for the timely identification of patients who need laparotomy, enabling the procedure to be performed before hemodynamic disturbances develop; third, it helps to prevent inevitable complications. The use of this method is rational as balloon tamponade can be considered a vital emergency measure for managing postpartum hemorrhage in remote areas of our Republic where surgical options are not available. It is important to emphasize that balloon tamponade is controllable, allowing for the monitoring of bleeding and the volume of fluid introduced during intrauterine insertion. The uniqueness of this method lies in the design of the balloon catheter, which operates on the principle of an open system, in accordance with the law of communicating vessels, enabling control of ongoing bleeding from the lower segment (which is particularly crucial in cases of placenta previa).

The aspects outlined above fundamentally differentiate this method from other known balloons, such as Bakri or Foley balloons, which operate on a closed-loop principle. This method does not require special preparation or advanced skills and is relatively simple to implement technically. The proposed examination system and step-by-step measures for early cessation of postpartum hemorrhage (PPH) help reduce the risk of pathological blood loss, which is clinically significant for preventing maternal mortality and morbidity.

Thus, this research is relevant and presents scientific and practical interest in terms of applying and implementing the modern and innovative balloon tamponade method by Zhukovsky Y.G. for

managing PPH as a safe, effective, accessible, and controllable technique.

**CONCLUSION:** Risk groups for bleeding during pregnancy, childbirth, and the postpartum period should be formed based on the presence of conditions predisposing to pathological blood loss. Identifying and addressing these conditions is essential and mandatory in obstetric practice.All pregnant women in the high-risk group for postpartum hypotonic or atonic hemorrhage should be hospitalized in level III medical facilities for comprehensive pre-delivery preparation. This should occur several hours to 2 days before delivery to ensure the provision of high-quality care, including the development of a clear labor management plan and appropriate pre-delivery assessments. Rational management of the first and second stages of labor is crucial, avoiding prolonged use of labor-stimulating drugs. To prevent bleeding, active management of the third stage of labor and timely performance of operative delivery are necessary. Considering the role of coagulatory disorders in the etiology of early postpartum hemorrhages, screening for coagulation profiles should be conducted for high-risk pregnant women in the third trimester and during labor to enable timely correction of any existing disorders.The use of balloon tamponade, after manual examination of the uterine cavity at early stages of postpartum hemorrhages, allows for rapid (within 5 to 15 minutes) and highly effective (95%) control of bleeding, preventing significant blood loss.

**ACKNOWLEDGEMENT:** We are expressing our sincere thanks to the Scientific Research Institute of Obstetrics and Gynecology for the support and encouragement to complete scientific research.

**CONFLICT OF INTEREST:** No conflict of interest.

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**How to cite this article:**
Jamila G, Samaya A, Afat H and Saadat H: The effectiveness of balloon tamponade in the prevention and treatment of postpartum hemorrhage. Int J Pharm Sci & Res 2025; 16(4): 1093-99. doi: 10.13040/IJPSR.0975-8232.16(4).1093-99.