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A Comprehensive Literature Review of the use of The Bakri Balloon for Managing Postpartum Hemorrhage

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Abstract:

Postpartum hemorrhage (PPH) remains a significant cause of maternal mortality and morbidity worldwide. It is defined as excessive bleeding, typically more than 500 ml of blood loss within the first 24 hours after childbirth. The Bakri Balloon technique has emerged as a promising solution for managing PPH, offering a minimally invasive approach to achieving hemostasis and preventing the need for more invasive surgical procedures.

Aims: The aim of this paper review is to provide an overview of the effectiveness of intrauterine balloon tamponade in managing PPH.

Methods: We conducted this paper review by selecting articles, retrospective cohort studies and reviews from clinical trials from PubMed.

Results: Numerous studies have shown high success rates of treating PPH using The Bakri Balloon intrauterine tamponade.

Conclusions: The Bakri Balloon intrauterine tamponade is an effective method in the management of primary postpartum hemorrhage.

Key words: Postpartum hemorrhage, balloon tamponade, intrauterine tamponade, bakri balloon.

Introduction

Postpartum hemorrhage (PPH) is commonly defined as blood loss of ≥500 mL after vaginal delivery or ≥1,000 mL after cesarean section within 24 hours of birth. [10][11][12] Some definitions emphasize a cumulative blood loss of ≥1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after birth. [10][13] A stronger definition

of PPH should include both the amount of blood loss and clinical signs of cardiovascular changes, such as the shock index (heart rate divided by systolic blood pressure), to aid in more accurate diagnosis. [14][15] Visual estimation of blood loss is often inaccurate, and there are no universally accepted cut-off limits for estimated blood loss. Accurate estimation methods, such as calibrated bags, are recommended. [15] PPH affects approximately 6% of all deliveries globally, with severe PPH affecting about 1.86%. [16] It remains the leading cause of maternal mortality worldwide. [17]

Given its potential severity, preventing and managing PPH is a critical aspect of obstetric care. PPH can occur either due to uterine atony (failure of the uterus to contract after childbirth), trauma during childbirth, retained placental tissue, or coagulation disorders. Healthcare providers must be trained to recognize risk factors for PPH, such as nulliparity, retained placenta, high neonatal body weight, prior postpartum hemorrhage, placenta previa, placental abruption and low ante-partum hemoglobin levels.

Effective management strategies may include uterine massage, administration of uterotonic drugs, manual removal of retained placental tissue, and surgical interventions such as uterine artery ligation or in severe cases -hysterectomy. One of the methods used in managing PPH is the use of intrauterine device, namely The Bakri Ballon. The Bakri Balloon, named after its inventor, Dr. Haytham Bakri is a silicone, obstetrical balloon specifically designed to treat postpartum hemorrhage (PPH). The device is used for the "temporary control or reduction of postpartum hemorrhage when conservative management of uterine bleeding is warranted.

Bakri Balloon method- general description

The Bakri Balloon consists of a soft, inflatable silicone balloon attached to a 24 French, 54 cm-long, silicone catheter with a filling capacity of 500 mL. During the procedure, the deflated balloon is inserted into the uterus and positioned in the uterine cavity. Once in place, the balloon is inflated with sterile saline solution, exerting pressure against the uterine walls and compressing the bleeding vessels. This pressure promotes hemostasis and helps reduce blood loss, thereby preventing further complications associated with PPH.

Before begining the procedure, the patient should be transported to the operating room and placed in the lithotomy position. It is necessary to assess the degree of uterine contraction and make sure that no fragments of the placenta remain in the uterine cavity, check for and treat any damage to the soft tissues of the birth canal, and administer farmacological uterine contracting agents.

The balloon is inserted transvaginally or through the uterine wound made during a caesarean section. After vaginal birth the deflated balloon is lubricated to ease insertion and minimize discomfort and then gently inserted uterine cavity through the cervix using a speculum or other appropriate instrumentation, it is recommended to stabilize the cervix by grasping its anterior lip with a fenestrated forceps. Ultrasonography can be usefull in assesing the propper placemnt of the ballon. During a cesarean section, the balloon is placed in the uterine cavity through a wound of the uterus made during a cesarean section in the lower uterine segment, and a drain is led out through the vagina. After inserting the balloon, the wound is closed and the balloon is inflated to the recommended volume while observing the activity of the lower uterine segment. In all cases, it is necessary toinsert a Foley catheter into the bladder (if itwas not previously inserted) in order to assess diuresis.

While applying effective uterine tamponade, it is necessary to:

- Monitor the patient's vital functions:
    - blood pressure, heart rate, uterine fundus height and the volume of vaginal bleeding and the drains of the balloon, every 30 minutes.
    - The volume of urine, every hour
    - body temperature, every 2 hours
- administer and continue an intravenous infusion of Oxitocin
- intravenously administer broad-spectrum antibiotics and continue the administration for the 3 following days.

Contraindications and possible complications:

Uterine balloon tamponade is contraindicated in the following cases:

- arterial bleeding requiring surgical treatment or embolization under angiographic guidance;
- existence of indications for a hysterectomy;
- presence cervical carcinoma;
- presence of pyogenic infections of the cervix, uterus or vagina;

- incidence of uncorrected uterine defects;
- incidence of intrauterine disseminated clotting;
- the localization of haemorrhage rendering it impossible to control the bleeding with the balloon method.

While it is generally effective, its use can be associated with various complications which may include:

I. Balloon Displacement and Migration:

A. The rate of Bakri balloon displacement is approximately 9-10%. [18] [19].

B. Cases of balloon migration through unsuspected uterine perforations have been reported, leading to severe complications such as hemoperitoneum and necessitating hysterectomy [20] [21]

II. Need for Additional Interventions:

A. Hysterectomy was required in 1-6% of cases where the Bakri balloon was used, indicating that it may not always be sufficient to control bleeding [18] [19].

B. Failure of the Bakri balloon to control bleeding was associated with factors such as maternal age, cesarean delivery, high blood loss, and coagulopathy [22] [23]

III. Transfusion Requirements:

A. A significant proportion of patients (43%) required blood transfusions following Bakri balloon placement, highlighting the severity of bleeding in these cases [18]

IV. Infection and Other Complications:

A. No major infections or long-term complications were reported in several studies, suggesting that the Bakri balloon is generally safe when used correctly [24] [25].

Methods

This literature review was conducted by selecting articles, retrospective cohort studies and reviews from clinical trials from PubMed to asses the efectivness of intrauterine tamponade using the Bakri balloon in management of postpartum hemorrhage.

Results and discussion

An article by Hui Yang et al. (2022) retrospectively analyzed 169 cases of PPH treated with a Bakri balloon during delivery. Convetional hemostatic measures (uterotonic agent injection, uterine massage, and/or various sutures) failed to control the bleeding. There were no signifficant differences in maternal or gestational age, number of pregancies, history of cesarean cestions or abortions, delivery mode or newborn weight, as well as balloon infusion volume between the successful and failed groups. Of the 169 cases of Bakri balloon hemostasis, 148 were successful giving a success rate of 87.6%. In this study, 15 of the 21 failure cases relate to placental factors, which include placental adhesion with placental accreta among 11 of the cases (52.4%). [1]

Chanyun Xiao et al. in an article published in 2023 show the results of a cohort study of 279 women treated using the Barki balloon method as a treatment of PPH. Primary outcome analysis showed a success rate of 88.89% (248/279 cases). Between the failure and success groups no significant differences in maternal or gestational age, delivery mode, parity, weight or past medical history have been found. [2]

In a retrospective cohort study by Hu Y et al. (2024) the success rate of Bakri balloon tamponade was 84.5% (168/198). Among the 198 women recruited analysis of baseline data revealed no notable differences in demografic or other parameters (parity, delivery mode, and past medical history) between the success and failure cases. Furthermore, this study alanyzed the effects of Bakri intrauterine balloon tamponade on maternal outcomes in women with placenta accreta . In women with placenta accreta, a Bakri success rate of 82.9% (87/105) was observed with no significant difference from that in women without placenta accreta (87.1%, 81/93). [3]

Meliza CW Kong et al. (2013) retrospective study included cases of 19 patients in whom the Bakri balloon catheter was used. In 15 of the cases PPH was succefully managed without the need for additional procedures, giving the success rate of 79%. [4]

Sayori Nagai et al. (2016) in their article present a study of 10 patients exhibiting massive PPH and resistance to conventional hemostatic managements. The case includes 5 patients with uterine atony, 3 with placenta previa, and 2 with low-lying placenta. The Bakri balloon tamponade was considered a successfull method of stopping the hemorrhage in 9/10 (90%) cases. The method proved unsuccessful in the case of uterine atony of a patient suffering from a large uterine leiomyoma measuring 10 cm in diameter. [5]

Grange J. et al. (2018) conducted a retrospecitve case-series where the Bakri Balloon was used as a second line therapy for persistent PPH after failure of bimanual uterine massage and

uterotonics to stop bleeding after vaginal delivery in 108 women. The bleeding was successfully stopped in 80/108 cases giving the success rate of 74.1% (80/108). Additional invasive procedures were required in 28 women (19 embolization and 9 surgical procedures with 5 peripartum hysterectomies). The study also points to pre-pregancy obesity (BMI≥30kg/m2) being a risk factor of intrauterine balloon tamponade failure as it was notably more frequent in the failure group (25.9% vs 6.1% in the success group). [6]

İsmet Alkış et al. (2015) conducted a retrospective cohort study of 47 patients diagnosed with massive postpartum bleeding who were treated with Bakri Balloon tamponade after failed uterotonic agents treatment. The hemorrhage was successfully managed in 43 patients giving the overall success rate of 91.4%. [7]

Another retrospective study was conducted by Laura Aibar et al. (2012) in which the effectiveness of the Bakri balloon as a conservative treatment option for PPH was investigated. The study group consisted of 24 women for whom the balloon was inserted vaginally and after cesarean delivery if standard PPH management methodes prooved unsuccessfull. Of the 24 deliveries, 19 cesarean sections were perfomed and five were vaginal. The success rate for this study was 87.5% (21/24), the method was successfull in all patients who delivered vaginally. [8]

Conclusions

The Bakri Balloon intrauterine tamponade is a highly effective method of managing primary postpartum hemorrhage. It provides a minimally invasive, easily deployable option of managing PPH after vaginal delivery as well as cesarean section. Many published clinical studies and case reports consistently support its efficacy in controlling the bleeding in cases where other conventional methods, such as pharmacological uterotonic agents, have failed thereby minimizing the risk of severe complications and the need for invasive surgical procedures such as hysterectomy.

However, while the Bakri Balloon can be a significant component of treating PPH, it is not a standalone solution. It should be integrated into a broader PPH management plan that includes prompt recognition of hemorrhage, the use of uterotonic agent, and the readiness for further interventions if necessary. Its effectiveness can be influenced by factors such as the timing of deployment, operator experience, and the specific cause of hemorrhage.

Disclosures:

Authors' contribution:

Conceptualization, Joanna Kowal and Paweł Połujański; methodology, Piotr Cyran; software, Jan Paleczny; check, Filip Jaroszyński, Robert Parobczak, Adrianna Wiśniewska; formal analysis, Joanna Winciorek; investigation, Anna Jaroszyńska; resources, Piotr Cyran; data curation, Paweł Połujański ; writing - rough preparation, Joanna Kowal; writing - review and editing, Joanna Winciorek and Anna Jaroszyńska; visualization, Robert Parobczak; supervision, Jan Paleczny; project administration, Adrianna Wiśniewska; receiving funding, Filip Jaroszyński.

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Conflict of Interest Statement

The authors declare no competing of interest.

References:

1. Yang H, Sun G, Cheng Y, Cao D, Zhao Y. Bakri balloon tamponade to treat postpartum hemorrhage. Chin Med J (Engl). 2022 Sep 20;135(18):2258-2260. doi: 10.1097/CM9.0000000000002387. PMID: 36525607; PMCID: PMC9771167.

2. Xiao C, Wang Y, Zhang N, Sun GQ. Bakri Balloon for Treatment of Postpartum Hemorrhage: A Real-World 2016-2020 Study in 279 Women from a Single Center. Med Sci Monit. 2023 Mar 1;29:e938823. doi: 10.12659/MSM.938823. PMID: 36855288; PMCID: PMC9987168.

3. Hu Y, Cui L, Zhang C, Chen F. Timely use of Bakri intrauterine balloon tamponade contributes to the effectiveness in controlling severe postpartum hemorrhage. Exp Ther Med. 2024 Mar 1;27(5):177. doi: 10.3892/etm.2024.12465. PMID: 38515648; PMCID: PMC10952343.

4. Kong MC, To WW. Balloon tamponade for postpartum haemorrhage: case series and literature review. Hong Kong Med J. 2013 Dec;19(6):484-90. doi: 10.12809/hkmj133873. Epub 2013 May 6. PMID: 23650196.

5. Nagai S, Kobayashi H, Nagata T, Hiwatashi S, Kawamura T, Yokomine D, Orita Y, Oki T, Yoshinaga M, Douchi T. Clinical Usefulness of Bakri Balloon Tamponade in the Treatment of Massive Postpartum Uterine Hemorrhage. Kurume Med J. 2016;62(1-2):17-21. doi: 10.2739/kurumemedj.MS65004. Epub 2016 Mar 1. PMID: 26935443.

6. Grange J, Chatellier M, Chevé MT, Paumier A, Launay-Bourillon C, Legendre G, Olivier M, Ducarme G. Predictors of failed intrauterine balloon tamponade for persistent postpartum hemorrhage after vaginal delivery. PLoS One. 2018 Oct 26;13(10):e0206663. doi: 10.1371/journal.pone.0206663. PMID: 30365539; PMCID: PMC6203390.

7. Alkış İ, Karaman E, Han A, Ark HC, Büyükkaya B. The fertility sparing management of postpartum hemorrhage: A series of 47 cases of Bakri balloon tamponade. Taiwan J Obstet Gynecol. 2015 Jun;54(3):232-5. doi: 10.1016/j.tjog.2014.03.009. PMID: 26166332.

8. Aibar L, Aguilar MT, Puertas A, Valverde M. Bakri balloon for the management of postpartum hemorrhage. Acta Obstet Gynecol Scand. 2013 Apr;92(4):465-7. doi: 10.1111/j.1600-0412.2012.01497.x. Epub 2012 Aug 21. PMID: 22762694.

9. Belowska, Anna i in. „Zastosowanie tamponady balonowej macicy w hamowaniu krwotoku poporodowego = Intrauterine balloon tamponade in the management of

postpartum hemorrhage / Ryszard Poręba, Krzysztof Nowosielski, Aneta Poręba, Anna Belowska ; Katedra i Oddział Kliniczny Ginekologii i Położnictwa w Tychach. Śląski Uniwersytet Medyczny w Katowicach." Zastosowanie tamponady balonowej macicy w hamowaniu krwotoku poporodowego = Intrauterine balloon tamponade in the management of postpartum hemorrhage. N.p., 2009. Print.

10. Shields, L., Goffman, D., & Caughey, A. (2017). Practice Bulletin No. 183: Postpartum Hemorrhage.. Obstetrics & Gynecology. https://doi.org/10.1097/AOG.0000000000002351.

11. Alejandra, G., Angel, R., & Lisbeth, K. (2021). Postpartum Hemorrhage: Risk Factors and Preventive Strategies. Journal of Gynecology and Obstetrics. https://doi.org/10.11648/J.JGO.20210906.13.

12. Ngwenya, S. (2016). Postpartum hemorrhage: incidence, risk factors, and outcomes in a low-resource setting. International Journal of Women's Health, 8, 647 - 650. https://doi.org/10.2147/IJWH.S119232.

13. (2017). Practice Bulletin No. 183 Summary: Postpartum Hemorrhage.. Obstetrics & Gynecology. https://doi.org/10.1097/AOG.0000000000002346.

14. Borovac-Pinheiro, A., Pacagnella, R., Cecatti, J., Miller, S., Ayadi, A., Souza, J., Durocher, J., Blumenthal, P., & Winikoff, B. (2018). Postpartum hemorrhage: new insights for definition and diagnosis.. Obstetric Anesthesia Digest. https://doi.org/10.1097/01.aoa.0000557648.35006.16.

15. Rath, W. (2011). Postpartum hemorrhage – update on problems of definitions and diagnosis *. Acta Obstetricia et Gynecologica Scandinavica, 90. https://doi.org/10.1111/j.1600-0412.2011.01107.x.

16. Carroli, G., Cuesta, C., Abalos, E., & Gulmezoglu, A. (2008). Epidemiology of postpartum haemorrhage: a systematic review.. Best practice & research. Clinical obstetrics & gynaecology, 22 6, 999-1012 . https://doi.org/10.1016/j.bpobgyn.2008.08.004.

17. Watkins, E., & Stem, K. (2020). Postpartum hemorrhage.. JAAPA : official journal of the American Academy of Physician Assistants, 33 4, 29-33 . https://doi.org/10.1097/01.JAA.0000657164.11635.93.

18. Wright, C., Chauhan, S., & Abuhamad, A. (2014). Bakri Balloon in the Management of Postpartum Hemorrhage: A Review. American Journal of Perinatology, 31, 957 - 964. https://doi.org/10.1055/s-0034-1372422.

19. Ali, A., Faraag, E., Mohammed, M., Elmarghany, Z., Helaly, M., Gadallah, A., Taymour, M., Ahmad, Y., Eissa, A., Ogila, A., Ali, M., Abou-Taleb, H., Samy, A., & Abbas, A. (2019). The safety and effectiveness of Bakri balloon in the management of postpartum hemorrhage: a systematic review. The Journal of Maternal-Fetal & Neonatal Medicine, 34, 300 - 307. https://doi.org/10.1080/14767058.2019.1605349.

20. Leparco, S., Viot, A., Benachi, A., & Deffieux, X. (2013). Migration of Bakri balloon through an unsuspected uterine perforation during the treatment of secondary postpartum hemorrhage.. American journal of obstetrics and gynecology, 208 6, e6-7 . https://doi.org/10.1016/j.ajog.2013.02.052.

21. Rocher, G., Panel, P., Rollin, I., Wormser, A., Souiai-Hidoussi, A., Raynal, P., & Niro, J. (2019). Massive hemoperitoneum due to uterine perforation by the Bakri Balloon, during the treatment of postpartum hemorrhage.. Journal of gynecology obstetrics and human reproduction, 48 1, 75-76 . https://doi.org/10.1016/j.jogoh.2018.10.005.

22. Labarta, F., Recarte, M., Prieto, L., Arribas, C., Buján, J., Ortega, M., & León-Luis, J. (2021). Factors Associated with Failure of Bakri Balloon Tamponade for the Management of Postpartum Haemorrhage. Case Series Study and Systematic Review. Healthcare, 9. https://doi.org/10.3390/healthcare9030295.

23. Cho, H., Park, Y., Kim, Y., Jung, I., & Kwon, J. (2015). Efficacy of Intrauterine Bakri Balloon Tamponade in Cesarean Section for Placenta Previa Patients. PLoS ONE, 10. https://doi.org/10.1371/journal.pone.0134282.

24. Puente-Luján, M., Andrés-Orós, M., Álvarez-Sarrado, L., Agustín-Oliva, A., González-Ballano, I., Rodríguez-Solanilla, B., & Castán-Mateo, S. (2022). Bakri Balloon: an easy, useful and effective option for the treatment of postpartum haemorrhage. Journal of Obstetrics and Gynaecology, 42, 1788 - 1792. https://doi.org/10.1080/01443615.2022.2039903.

25. Gao, Y., Wang, Z., Zhang, J., Wang, D., Yin, B., Zhu, B., He, Y., Hou, H., Cao, W., Liu, X., Yu, Y., Pan, S., Liu, L., Wang, Z., & Su, F. (2014). [Efficacy and safety of intrauterine Bakri balloon tamponade in the treatment of postpartum hemorrhage: a multicenter analysis of 109 cases].. Zhonghua fu chan ke za zhi, 49 9, 670-5 . https://doi.org/10.3760/CMA.J.ISSN.0529-567X.2014.09.007.