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**RESEARCH ARTICLE**

# COMPARATIVE ANALYSIS OF APPROPRIATE SECOND LINE THERAPIES FOR MANAGEMENT OF SEVERE POSTPARTUM HEMORRHAGE – A PROSPECTIVE STUDY

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**ABSTRACT**

**Objective:** To explore appropriate second line therapies for management of severe postpartum hemorrhage at caesarean and vaginal delivery.

**Methods :** A prospective study was done of 100 women at Lalla Ded Hospital of GMC, Srinagar, of primary postpartum hemorrhage unresponsive to standard medical therapy. In all of these PPH cases, women were treated with appropriate oxytocic agents and prostaglandin analogues. Intravenous infusions of oxytocin, intravenous methergine and / or intramuscular carboprost tromethamine were all used in accordance with our hospital protocol. 50 patients of failed medical therapy were managed with utero vaginal packing, and in another group of 50 patients Sengstaken Blakemore Oesophageal Catheter [SBOC] was inserted. Women with traumatic PPH and secondary infection were excluded from our study. Coagulation studies were carried out in all patients to exclude coagulopathy as the cause of, or a catalyst for the hemorrhage.

**Result :** In the SBOC group, balloon tamponade succeeded in arresting hemorrhage in 47 patients out of 50 (94% success rate), whereas 3 patients who developed PPH after caesarean section failed the tamponade test and underwent urgent caesarean hysterectomy, (6% failure), due to the ongoing hemorrhage.

In the uterine packing group, success was achieved in arresting hemorrhage in 39 patients (78% success rate) and failed in 11 patients (22% failure rate). 6 underwent caesarean hysterectomy and 5 patients who developed PPH after normal vaginal delivery underwent postpartum hysterectomy. Statistically, there was a significant difference with respect to outcome of tamponade procedure between the two groups (p-value = 0.021). There was no statistical significance with respect to the cause of PPH, mode of delivery, duration of labour or gestation at delivery.

**Conclusion :** The results from our observations strongly support the use of balloon tamponade for unresponsive postpartum hemorrhage. Balloon tamponade showed a higher success rate of 94%, as compared to 78%, in the uterine packing group, with least morbidity and lower intervention rates.



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## INTRODUCTION

Postpartum hemorrhage (PPH) is a dreadful complication of third stage of labors with a possible grave maternal outcome. An estimated blood loss in excess of 500ml following vaginal birth, or loss of greater than 1000ml following caesarean birth often has been used for the diagnosis. ACOG (American College of Obstetricians and Gynaecologists) has defined PPH as a decrease in hematocrit by 10%, or a need for blood transfusion in 24 hours after delivery.

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The Scottish Confidential Audit (Scottish Programme for clinical effectiveness in reproductive health (SPCERH) 2004) of severe Maternal Morbidity defines as major hemorrhage an estimated blood loss more than 2500ml, or the transfusion of 5 or more units of blood or treatment for coagulopathy [fresh frozen plasma, cryoprecipitate, platelets].

Postpartum hemorrhage is classified as primary or secondary. Primary PPH occurs within the first 24 hours after delivery, and secondary PPH occurs between 24 hours and 6 to 12 weeks postpartum. Globally about 11% of women having live birth have severe PPH amounting to 14 million women a year. Severe PPH kills 40,000 women yearly (Abou Zahrc, 2003). There are many causes of postpartum hemorrhage acting

individually or in combination. Uterine atony in which there is failure of uterine muscle to contract normally following delivery of the baby and placenta, is responsible for upto 70% of all causes of PPH. It also results in cases with retained placental fragments, morbid adhesion of placenta, and lower genital tract lacerations. Relatively uncommon causes are uterine rupture, uterine inversion and coagulopathy (ACOG education bulletin, 1998). The management of PPH includes less invasive methods, such as uterine massage and administration of uterotonics agents and aggressive surgical techniques, such as a peripartum hysterectomy.

First line treatment of PPH include the manual removal of retained placental tissue, uterine massage, application of bimanual compression, continuous intravenous application of oxytocin and volume replacement. If first line therapies are not successful, second line treatment of PPH must be undertaken. Although a variety of surgical options have been proposed to avoid hysterectomy including uterine artery ligation, ovarian artery ligation, internal iliac ligation, compression sutures and B-lynch brace suture (Mousa and Walkinshaw, 2001; Huang *et al*., 2012), a suitable conservative technique is still lacking (Tamizian and Arulkumaran, 2001), and all proposed options have risks as well as advantages (Drife, 1997). The appropriate second line procedure may achieve hemostasis of intractable hemorrhage and prevent the need for more surgical procedures. Uterine tamponade is one of the main methods to achieve hemostasis in patients with PPH.

This study is based on one of the recently reported conservative measures to control hemorrhage- internal uterine tamponade. Tamponade refers to plugging the uterus with some type of device to stop the flow of blood. The uterine cavity can be packed with a gauze pack or a balloon catheter, which may avoid the need for conservative surgical procedures, such as selective arterial embolization and arterial ligations. Apart from atony, this technique is also useful for PPH arising from placenta previa/accreta and can be easily carried out by doctors in training while awaiting help from a senior colleague. Internal tamponade procedures have been used successfully alone (Katesmark *et al*., 1994; Johanson *et al*., 2001; Bakri *et al*., 2001; Ferrazzani *et al*., 2004), or in combination with the Brace suture (Danso and Reginald, 2002) to reduce or arrest massive PPH. Diemert, *et al*. (2012) reported 60% of patients with severe PPH were successfully treated with the balloon alone.

Literature on the most appropriate second line treatment method for the management of PPH is sparse. The aim of the present study was to compare the two appropriate internal tamponade procedures: uterovaginal packing with Sengstaken Blakemore Oesophageal Catheter, as second line therapy for management of severe primary PPH.

Uterovaginal packing with sterile gauze (Drucker and Wallach, 1979; Lester *et al*., 1965; Bagga *et al*., 2004) has been used in the clinical management of severe PPH, and as the last resort before hysterectomy. The use of the Sengstaken Blakemore Oesophageal Catheter is described in the literature for the control of massive PPH due to an atonic uterus not responding to uterotonics (Condous *et al*., 2003; Chan *et al*., 1997; Condie *et al*., 1994) or due to placenta accreta. (Frenzel *et al.,* 2005)

## MATERIALS AND METHODS

A prospective study was conducted at Lalla Ded Hospital of Govt Medical College, Srinagar. 100 patients of primary postpartum hemorrhage unresponsive to standard medical therapy, after vaginal / caesarean delivery between April 2013 to March 2015 were included. The women were in the age group of 25-34 years, and were similar in demographic profiles and clinical conditions. Written and informed consent for the appropriate procedure was obtained from the patient and or / attendant where applicable, and ethical committee clearance was obtained for the study.

The uterotonics used were intravenous infusions of oxytocin, intravenous methergine and / or intramuscular carboprost tromethamine, all in accordance with our hospital protocol. On failed medical treatment, tamponade with uterovaginal packing was done in 50 patients and Sengstaken Blakemore Oesophageal Catheter [SBOC] inflation was done in 50 patients.

Patients with traumatic PPH, uterine rupture, retained products of conception and documented uterine infection were excluded from the present study.

A detailed medical and obstetric history, especially regarding duration of labor, mode of delivery, cause of bleeding, estimated blood loss, intrapartum and postpartum blood and blood products transfused, and medical treatment received was taken.

A quick and thorough general physical and systemic examination was performed. Local examination included per speculum for any local injury, and bimanual examination regarding the cause of the postpartum hemorrhage. If uterine atony persisted, in spite of uterotonics, after ruling out exclusion criteria, intrauterine tamponade was carried out in the OT using minimal analgesia or regional- general anesthetic and nursing staff and blood transfusion service backup. The two tamponade techniques used in our study were:

**Uterine packing:** Intrauterine packing was done with a variable length of sterile ribbon gauze soaked in povidone iodine solution. Firm packing was done, layering from fundus to cervix until it filled the uterine cavity to achieve a smooth and uniform application. Tip of the ribbon gauze was observed for soakage and free trickle of blood.

**SBOC:** The Sengstaken–Blakemore Oesophageal Catheter was inserted into the uterine cavity via the cervix or through caesarean wound intraoperatively. The balloon was inflated with warm normal saline in aliquots followed by reassessment. The distended balloon was palpable per abdomen, as a well contracted uterus and just visible at the cervical canal. If no or minimal bleeding was observed via the cervix, and there was minimal bleeding into the gastric lumen of the Sengstaken Blakemore tube, the tamponade test result was considered positive and surgical intervention with possible hysterectomy avoided. Vital signs and use of intravenous fluids, blood and blood products were monitored. Uterotonics were administered to keep the uterus contracted over 12-24 hours. All women

received intravenous broad spectrum antibiotics. The hemoglobin status and coagulation profiles were monitored and treatment was provided as appropriate. The mean time for leaving tamponade balloon or uterine packs ranges from 8 to 48 hours.

## OBSERVATIONS AND RESULTS

Statistical analyses were performed using Pearson Chi-Square and Asymp. Sig (2 sided) p-value. P<0.05 was considered statistically significant. Continuous variables are presented as mean ± SD.

**Results:** A total of 100 women were included in the study. The characteristics and treatment of patients in group 1 (n=50) and group 2 (n=50) are shown in tables below.

**Table 1.**

| S. No. | Variables | SBOC Group | Intrauterine packing | P-Value |
|---|---|---|---|---|
| 01. | Cause of PPH | | | |
| | a) Uterine atony | 34 | 38 | 0.165 |
| | b) Placenta previa | 10 | 07 | |
| | c) Adherent Placenta | 03 | 02 | |
| | d) Placenta Previa, atony | 03 | 03 | |
| 02. | Mean Age | 30.22 | 29.30 | 0.079 |
| 03. | Gravidity | | | 0.212 |
| 04. | Parity | | | 0.128 |
| 05. | Mean gestation in weeks | 37.04 | 36.56 | 0.480 |
| 06. | Type of labour | | | 0.216 |
| 07. | Duration of labour (hrs.) | 9.27 | 8.01 | 0.146 |
| 08. | Mode of delivery | | | 0.461 |
| 09. | Estimated blood loss mean (ml) | 2162 | 1722 | |
| 10. | Postpartum hospital admission (Mean Days) | 5.56 | 5.86 | 0.493 |

**Table 2. Outcome of tamponade procedure**

| Group | Failed | Success | P-Value |
|---|---|---|---|
| SBOC | 3 (6%) | 47 (94%) | 0.021 |
| Intrauterine Packing | 11 (22%) | 39 (78%) | |
| Post procedure intervention | | | |
| Group | Caesarean hysterectomy | Postpartum hysterectomy | Nil |
| SBOC | 03 | 0 | 47 |
| Intrauterine Packing | 06 | 05 | 39 |
| | P value = 0.03 | | |

**Table 3. Post intervention Results**

| Group | Time of Removal (Mean and range in hrs.) | |
|---|---|---|
| SBOC | 18 (8-26) | N = 47 successful cases |
| Intrauterine Packing | 30 (24-36) | N = 39 Successful cases |

| Group | Morbidity | | |
|---|---|---|---|
| SBOC (n = 47) | Concealed Hemorrhage<br>Endometritis<br>Difficult removal<br>Delayed hemorrhage<br>Concealed hemorrhage | | |
| Intrauterine Packing (n=39) | Endometritis | 05 | 12.82% |
| | Difficult removal | 09 | 23.07% |
| | Delayed hemorrhage | | |

There was no statistical significance with respect to outcome in terms of variables like age, gravidity, parity, gestation of pregnancy in weeks, the type and duration of labour, mode of delivery and the cause of postpartum hemorrhage.

The mean blood loss in the SBOC group was 2162ml and the intrauterine packing had a mean estimated blood loss of 1722 ml. Variable amounts of blood transfusions and blood products were required in each group.

In the SBOC group, balloon tamponade succeeded in arresting hemorrhage in 47 (94% success rate), whereas 3 patients who developed PPH after caesarean section failed the tamponade test and underwent urgent caesarean hysterectomy, (6% failure), due to the ongoing hemorrhage. In the uterine packing group success was achieved in 39 patients (78% success rate) and failed in 11 patients (22% failure rate). 6 underwent caesarean hysterectomy and 5 patients who developed PPH after normal vaginal delivery underwent postpartum hysterectomy. Statistically there was a significant difference with respect to outcome of the tamponade procedure (p-value = 0.021) and the post procedure intervention required (p-value=0.03) between the two groups.

The mean duration of balloon tamponade was 18 hours, whereas packing was kept for a mean of 30 hours. 5(12.82%) patients with gauze tamponade developed endometritis who responded well to antibiotic therapy. Removal of pack was difficult in 9 (23.07% cases). There was no morbidity in terms of concealed hemorrhage, endometritis, delayed hemorrhage, or difficult removal in the SBOC group.

There was no statistical significance with respect to number of days of hospital admission between the two groups. P-value = 0.493.

## DISCUSSION

A variety of surgical techniques have been proposed to avoid hysterectomy when uterotonic drugs fail to control massive postpartum hemorrhage. Each has its advocates and is associated with identifiable benefits and risks. The morbidity of these surgeries and the desire to preserve fertility has led to the development of new therapies including, internal uterine tamponade.

In our study, conducted in the Department of Obstetrics and Gynaecology, Lalla Ded Hospital, we compared the two methods of Uterine tamponade namely, Uterovaginal Packing with a Sengstaken Blakemore Oesophageal Catheter in the management of primary PPH, unresponsive to standard medical therapy. Standard therapy after delivery included oxytocin intravenous followed by intravenous methergine, intramuscular prostaglandin F2 alpha [prostodin] and rectal misoprostol and curettage, as needed. Tranexemic acid was also used in appropriate cases.

If the hemorrhage is affected by other factors such as a bleeding placental vessel, the first measure was to suture the bleeding site. Suturing of an exposed placental vascular bed does not necessarily prevent PPH from uterine atony, so

intrauterine tamponade might still be required, but sutures are necessary if an exposed placental vascular bed has severe active bleeding.

In our study, uterine packing was successful in arresting hemorrhage in 39(78%) cases and failed in 11 (22%). In 11 failed cases, the cause of hemorrhage was atony in 8 cases. Among these 8 cases, complete placenta previa was associated with one case of atony, coagulation failure in 5, fibroid uterus and focal placenta accreta in one case each. The cause of hemorrhage was complete placenta previa, placenta previa, accreta, with coagulation failure, and focal placenta accreta in the remaining 3 cases respectively. Similar results were reported by Robert C. Maier (1996) in 1993, in a retrospective review of 9 cases of primary PPH managed with uterine packing, with a success rate of 77(78%). Sherry Boshert (Sherry Boschert, 2002) in 2002, in her small study reported success rate of 66.66% after uterine packing. Dr. Hendsch of Baystate Medical Centre, Spring field, mass reported a 67% success rate. It avoided hysterectomy and preserved the uterus in 10 patients.

Dr. Nagina Fatima Liaquat *et al*. in 2008, in a study of 39 patients reported a success rate of 82.1% (32 cases) and failure in 7 (17.9%) cases. The mode of delivery was CS in 23(58.97%) and vaginal delivery in 16 (41.02%). Among seven failed cases, cause of PPH was uterine atony in 5, and placenta previa and DIC in 1 case each. Internal iliac ligation was carried out in 3, hysterectomy in 1, internal iliac ligation followed by hysterectomy in 3 patients.

Impact of mode of delivery, parity and underlying cause of PPH on the outcome was statistically not significant with p-values of 0.461, 0.128 and 0.165 respectively. Similar statistical non-significance has been stated in the study by Dr. Nagina Fatima, *et al* in 2008[23] for the above mentioned variables, with p-value of 0.91, 0.49 and 0.91 respectively.

In the present study, packing was kept for a mean duration of 30 hours with a range of 24-36 hours. 5 (12.82%) patients developed endometritis and removal of pack was difficult in 9 (23.07%) cases but none required general anesthesia. Similar analogy has been reported in the literature by Dr. Nagina Fatima, *et al*. in 2008, with a mean duration of packing of 22±51 hours (range 12-36 hours). Four (12.5%) patients developed endometritis, treated by antibiotics, 7 patients had difficult removal of pack but none required general anesthesia.
Though packing of uterine cavity was frequently practiced in early part of 20th century, arguments were presented in 1930s' and 1940s'that the procedure was "unphysiologic" and therefore, unacceptable (Eastman, 1950; Leff, 1939; Cosgrove, 1936). The technique fell out of favour in the 1950's as it was thought to conceal hemorrhage and cause infection (Leff, 1939; Cosgrove, 1936).

Hsu, *et al.* in 2003, reported a case of pelvic abscess in the post operative period following failed packing in a patient who later underwent post partum hysterectomy. Another argument which negates its use is the blind insertion which may cause trauma to the uterine cavity.

It takes time to insert and if not packed tightly will not cause effective tamponade. Also, success of procedure will not be known immediately as blood has to soak through the pack to reveal itself. Another reason for its infrequent use was adherence of packing material to bleeding surface, followed by delayed hemorrhage by dislodging the clot after removal of pack.

G.S. Condous, *et al*. in 2003 used balloon tamponade in their prospective study of intractable cases of PPH and stated that uterine packing with gauze packs is outdated and be reserved only when balloon catheter is unavailable. The use of the Sengstaken-Blakemore oesophageal catheter (SBOC) has been well described in the literature for the control of massive PPH due to atonic uterus not responding to oxytocic's, including prostaglandins. It has also been used to control bleeding from vaginal lacerations (Chan *et al*., 1997; Victor Dabelea *et al*., 2007). It is equally effective in creating tamponade when the uterus is well contracted and there is ongoing hemorrhage from the placental bed.

In the present study, we found that balloon tamponade with SBOC was highly effective in the management of PPH unresponsive to standard therapy and was associated with no significant complications. Hemorrhage was arrested in 47 (94%) out of 50 patients. 23 patients had delivered vaginally and hemorrhage was controlled in all cases. Hence 23 laparotomies were prevented. 27 patients had a caesarean delivery and balloon tamponade was successful in 24 of them. In the 3 failed cases, the cause of hemorrhage was complete placenta previa, adherent placenta previa, with atony, and total placenta previa accreta respectively. All three cases went through urgent caesarean hysterectomy. Condous and Colleagues in 2003, managed 16 cases of intractable hemorrhage by the tamponade test with a SBOC. More than 87% of these patients (14/16) with postpartum hemorrhage had a positive tamponade test, and did not require surgery. In two cases, continued blood loss warranted immediate laparotomy, which was performed. Seror and colleagues in 2005, reported the results of tamponade treatment with a SBOC in a series of 17 cases with massive PPH despite medical treatment. Surgery was prevented in 88% patients.

In the SBOC group of our study, apart from uterine atony in 29 patients, PPH occurred due to placenta previa; adherent placenta in 21 patients, and balloon tamponade was highly successful with only 3 patients requiring surgical intervention. Ferrazzani, *et al*. in 2006 reported success rate of the "tamponade test" in 12 out of 13 cases (92%) in post caesarean hemorrhage related to placenta previa / accreta in which two were associated with uterine atony. Bakri, *et al*. in 2001, reported the success with a large volume, fluid filled tamponade balloon in five women with PPH caused by low lying placenta / placenta previa. Japaraj and Raman in 2003 describe a case of massive PPH after caesarean section for placenta previa, managed with the use of a SBOC.

In the present study the duration of balloon tamponade ranged from 8 to 26 hours with mean duration of 18 hours. The mean volume of inflation of the gastric balloon of the SBOC in our study was 228 ml with a range of 80ml – 550ml. Seror and

colleagues in 2005, chose an inflation volume of 250ml, since this value corresponds to the approximate volume of the uterine cavity after delivery.

Condous *et al*. in 2003, inflated the balloon for an average of 26 hours and 14 min, range 8 hours 55 min – 43 hours 40min, with a mean inflation volume of 167 ml per balloon (range 70-300ml of normal saline).

There were no cases of endometritis, concealed hemorrhage, difficult removal and delayed hemorrhage in the SBOC group. In a similar study by Condous, *et al*. in 2003, no case of infection, difficult removal and no re-bleeding after removal of the SBOC was reported. Victor Dabelea, *et al*. in 2007, reported no adverse effects from the use of the balloon other than the inconvenience of prolonged monitoring. There were no reports of excessive uterine tension or suture line breakage as a result of inflation after closure of a uterine incision.

Analyzing the results of tamponade in the two groups of the present study, there was no statistical significance with respect to age, gravidity, parity, mode of delivery and cause of PPH on the group outcome, but as far as the effectiveness of the tamponade procedure was concerned, SBOC has shown a higher success rate (94%) with less morbidity, compared to the success rate of 78% in the uterine packing group.

p-value of (0.021), shows a significant statistical difference with respect to the outcome of the procedure between the two groups. These results are supported by the previous clinical experiences. Ferrazzani, *et al.* in 2006, stated that as opposed to the traditional gauze packing, the technique with the balloon catheter provides immediate knowledge of its effectiveness in controlling the PPH, so that subsequent surgery can be expedited in failed cases. Victor Dabelea, *et al*. in 2007, state that the advantages of using balloon tamponade include its case of use, rapid placement, immediate results, and ability to measure further bleeding after the catheter is placed. Using balloon tamponade in a management algorithm will allow the clinician to decide quickly if more morbid therapies are needed.

**Conclusion**

In conclusion, when PPH is unresponsive to drugs, second line therapy should be administered quickly. The results from our observations strongly support the use of balloon tamponade for unresponsive postpartum hemorrhage, The SBOC takes minutes to insert and is unlikely to cause trauma and it is possible to insert it with minimal anesthesia, whereas its removal is painless and easy. The success in controlling PPH is known immediately and subsequent surgery can be expedited in failed cases. Early management leads to better results. The longer the time before application of second line therapy, the greater the blood loss, the decrease in fibrinogen levels, and the risk of DIC. Balloon tamponade as second line therapy showed a higher success rate of (94%) as compared to (78%) in the uterine packing group with least morbidity and lower intervention rates. It should be an integral part of all obstetric emergency protocols for massive PPH.

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