



COMPARISON BETWEEN THE EFFECTIVENESS OF UTERINE GAUZE PACKING AND UTERINE BALLOON TAMPONADE IN THE MANAGEMENT OF POSTPARTUM HAEMORRHAGE (PPH) DURING CAESAREAN SECTION: A PROSPECTIVE STUDY

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ABSTRACT

Background: Post-partum haemorrhage (PPH) is major cause of maternal mortality and morbidity in the developing world. Different options for the management of PPH have been in use including use of oxytocin, prostaglandins, ligation or angiographic embolization of uterine/internal iliac arteries & hysterectomy. Conservative surgical measures such as Uterine balloon tamponade (UBT) and Uterine gauze packing (UGP) were introduced to avoid hysterectomy as it is associated with major complications & sterility. Uterine packing was questioned & criticized because of the potential risk of postpartum infection, uterine trauma, and ineffective packing. The procedure has regained interest in its usage as being simple, safe, quick, cheap, and requiring no special equipment & has undergone several modifications in recent years.

Objective: To compare the effectiveness of Uterine Gauze Packing (UGP) vs Uterine Balloon Tamponade (UBT) in the management of post-partum haemorrhage during c-section.

Place & Duration: Our study was performed over 6-months in the Department of Obstetrics & Gynaecology of Umaid Hospital, Dr. S.N. Medical College, Jodhpur.

Methods: It was a prospective interventional study of all the cases having primary PPH delivered via caesarean section in which UGP/UBT was used as the second-line treatment for PPH, after failure of initial conventional measures to stop bleeding. Success was considered as having no requirement for either a further therapy or hysterectomy for postpartum haemorrhage. Patients having PPH due to genital tract trauma and coagulation abnormalities were excluded.

Result: The included PPH patients were subdivided further into two groups, in which UGP or UBT was used as second-line treatment for women undergoing caesarean sections. Of all patients initially treated by basic managements for expected PPH, 77 cases underwent UGP & 23 UBT as the second-line therapies to stop persistent bleeding. The rates of success for UGP & UBT were 90.91% and 95.65%, respectively. The respective rates of puerperal morbidity were 6.49% and 4.35%, with risk ratio of 1.49 (95% CI: 0.18, 12.15).

Conclusion: In our study, no significant difference is observed in the rates of success for UGP vs UBT. Although our results indicate higher rate of puerperal morbidity, UGP could be included in the treatment modalities of PPH together with the provision of suitable training & maintenance of proper asepsis, especially in resource-poor settings because of its low-cost and easy availability.

KEYWORDS

Postpartum Haemorrhage, PPH, Uterine Gauze Packing, UGP, Uterine Balloon Tamponade, UBT, Caesarean Section

INTRODUCTION

"Taj Mahal – One of the Seven Wonders of the world, one of the greatest monuments, dedicated to the memory of "Queen Mumtaz" by her husband "Emperor Shah Jahan", is testimony & a grim reminder of the tragedy of maternal mortality due to bleeding during child birth, that can befall any woman in childbirth."

Postpartum haemorrhage is a key reason for maternal morbidity & mortality across the world and more in so developing nations. The assessed mortality rate in developing countries due to severe PPH is approximately 140,000/year or one death per four minutes^[1]. It has been estimated by WHO that out of the 5,29,000 maternal deaths occurring every year, 25.7% (1,36,000 deaths) occur in India with 2/3 of them occurring after delivery, with PPH as the most frequently stated problem^[2]. Approximately, 6% of all caesarean & 4% of all vaginal deliveries are complicated by PPH^[3].

Postpartum haemorrhage is defined as more than or equal to 500ml of blood loss within 24hours after birth or change of 10% in the hematocrit value following the birth of baby or any amount of blood loss making the patient haemodynamically unstable^[4]. PPH can be classified into "minor" i.e. blood loss of 500 – 1000ml or "major" with more than 1000ml blood loss. Major PPH can be further divided into "moderate" with 1000 – 2000 ml blood loss and "severe" with blood loss of more than 2000ml^[5]. The well-known main causes of postpartum haemorrhage are uterine atony, placental factors, lacerations, and coagulation disorders. Haemorrhage often occurs suddenly and unpredictably with high volume bleeding in a short period of time, which may be life threatening to the puerpera if it cannot be dealt with rapidly and adequately. If there is persistent bleeding despite treatment with the first-line conventional basic measurements such as uterotonic drugs and other conservative interventions, second-line intervention should be used without further delay^[5,6]. The second line measures consist of surgical, radiological or new medical therapies, like "recombinant activated factor VIIa" (rFVIIa)^[5]. Association of hysterectomy with considerable

complications and sterility has resulted in active attempts to introduce conservative surgical measures for avoidance of such last resort. "Uterine Balloon tamponade" (UBT) and "Uterine Gauze packing" (UGP) are two of the conservative surgical interventions included in the management of PPH^[7,8].

MATERIALS & METHODS

The present study was conducted over 6-months in the Dept. of Obstetrics and Gynaecology of Umaid Hospital, Dr. S.N. Medical College, Jodhpur. It was a prospective interventional study of all the cases having primary PPH delivered via caesarean section in which Uterine Gauze packing or Uterine Balloon Tamponade was used as the second-line treatment for PPH after failure of initial conventional measures to stop bleeding. The conventional basic treatments included uterotonic agents, massage and manual compression. Usually, the routine administration of uterotonic agents included oxytocin 10 iu intramuscularly and 20 iu intravenous infusion (4 ml/min running at 240 mL/hour), 250 µg carboprost tromethamine intra-muscularly. Cases with genital tract trauma and coagulopathies were excluded. In total 100 cases were randomly included; 77 cases underwent UGP and 23 UBT. All data was gathered on a pre-designed proforma. Clinical data from the Department of Obstetrics including notes by physicians and/or nurses concerning the hospitalization were reviewed.

Data collection was done in terms of variables such as age, parity, gestational weeks, operating time, blood loss (ml), birth weight, fetal number, cause of haemorrhage and need for additional surgical techniques due to bleeding (uterine artery ligation, embolization, intra-arterial balloon occlusion, pelvic vessel ligation, peripartum hysterectomy).

Management Procedure of UGP

The sterile gauze used was approximately 2 m long and 4 cm wide and was prepared preoperatively in our hospital. It was soaked with iodophor and then wrung out. The uterine cavity was packed with the gauze through the hysterotomy, with one of its ends passing through

the cervix into the vagina for subsequent removal. The gauze should be packed uniformly side to side & packed completely and tightly in uterine cavity before suturing the uterine incision. Attention should be paid to ensure that there is no active bleeding and to prevent suturing the gauze while closing the uterine incision. The gauze was removed after 12 to 24 hrs when hemostasis had been achieved. The gauzes should be removed gradually and manual compression on the fundus of the uterus should be provided simultaneously to achieve the desired effect of pressurization.

Management Procedure of UBT

The UBT used in our hospital was Bakri Balloon (Cook Medical, Bloomington, IN, USA). The distal end of the balloon shaft was pulled through the cervix into the opened uterus. After the balloon was inflated with about 100ml of sterile saline solution, the hysterotomy incision was closed carefully to avoid damaging the balloon. The balloon was then inflated with a total amount of sterile saline solution

usually ranging from 150 to 350 ml conforming to the size of the uterine cavity. The drainage port of the balloon was connected to a fluid collection bag to monitor haemorrhage. The balloon was kept inflated for 12-24hrs with careful monitoring.

Post-operative Treatments and Observation Indexes

All of the patients were infused with oxytocin and treated routinely with prophylactic antibiotics. Clinical parameters such as vital signs and uterine bleeding were strictly monitored. Definition of **Success**: Procedure of UGP or UBT was considered successful as no requirement for either a further therapy (such as embolization, intra-arterial balloon occlusion & pelvic vessel ligation) to treat PPH or hysterectomy. **Postpartum Infectious Risk**: It was measured as a surrogate endpoint i.e. puerperal morbidity: fever of 38°C and higher on any 2 of the first 10 days (measured 4 times each day with an interval of more than 4 h) following delivery exclusive of the first 24hrs [26].

Table 1: Clinical characteristics of patients with PPH during caesarean section

Variable		UGP (77)	UGP (%)	UBT (23)	UBT (%)	Overall %	χ^2	p value
Age (year)	<=28	61	79.2%	21	91.3%	82.00%	1.752	0.1856
	>=29	16	20.8%	2	8.7%	18.00%		
	Median	25		24				
	IQR	6		6				
Gestational Age (week)	<37	23	29.9%	6	26.1%	29.00%	0.1231	0.7257
	>= 37	54	70.1%	17	73.9%	71.00%		
	Median	38		38				
	IQR	3		1.5				
Birth Weight (Kg)	<= 3	52	67.5%	19	82.6%	71.00%	1.955	0.1620
	> 3	25	32.5%	4	17.4%	29.00%		
	Median	2.8		2.6				
	IQR	0.7		0.875				
Blood Loss (ml)	<= 1000	26	33.8%	12	52.2%	38.00%	2.5471	0.1105
	> 1000	51	66.2%	11	47.8%	62.00%		
	Median	1300		1000				
	IQR	400		425				
Parity	<= 1	52	67.5%	18	78.3%	70.00%	0.9707	0.3245
	>= 2	25	32.5%	5	21.7%	30.00%		
# Foetus	1	64	83.1%	20	87.0%	84.00%	0.1943	0.6594
	>= 2	13	16.9%	3	13.0%	16.00%		
Main Bleeding Cause	Uterine Inertia	57	74.0%	22	95.7%	79.00%	4.9927	0.0255
	Placental Factors	20	26.0%	1	4.3%	21.00%		

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade; IQR, inter-quartile range.

Table 2: Outcome comparison between UGP and UBT

Variable	Outcome	UGP (77)	UGP (%)	UBT (23)	UBT (%)	RR	RR (95% CI)	χ^2	p value
Success	Yes	70	90.91%	22	95.65%	0.95	0.85 - 1.06	0.5413	0.4619
	No	7	9.09%	1	4.35%				
Puerperal Morbidity	Yes	5	6.49%	1	4.35%	1.49	0.18 - 12.15	0.1446	0.7043
	No	72	93.51%	22	95.65%				

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade; RR, Risk Ratios, i.e., ratios of success/morbidity rate were used as a measure of association between outcome and treatment.

Table 3: Multivariate logistic regression analysis of puerperal morbidity

Variable	OR	OR (95% CI)	χ^2	p value
Cause of bleeding (placental factors vs uterine inertia)	1.6559	0.04 - 75.27	0.4407	0.5068

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade

RESULTS

In the study period from May'2019 to Oct'2019, a total of 100 cases were recorded based on the inclusion and exclusion criteria. Out of these 100 cases, 77 underwent UGP and 23 underwent UBT. Clinical characteristics of the patients with PPH during c-section was studied and the distributions are shown in **Table-1** above. The median age of patients in both the groups was around 24-25 years with UGP group having higher number of older patients compared to UBT. **Table-1** also shows that the distributions for gestational weeks, parity, blood loss, number of fetus and birth weight were similar for the groups. Patients in UGP group had a median blood loss of 1300ml while those in UBT had a lower median blood loss of 1000 ml. The interquartile range for

both groups is similar around 400-425 ml. The leading cause of PPH for both UGP (74%) and UBT (95.7%) groups was uterine atony. UGP (26%) was used more than UBT (4.3%) for treating PPH caused by placental factors (such as placenta previa, placenta accrete and placenta adherence). A significant difference was observed in the cause of haemorrhage between the two groups as shown by p value of 0.0255 (<0.05) in **Table-1**.

As shown in **Table-2**, UGP was effective in 70 cases while UBT was effective in 22 cases. The rates of success for UGP & UBT were **90.91%** and **95.65%**, respectively. 9.09% (7 out of 77) of the cases required further interventions after UGP while only 1 out of 22 (4.35%) case in the UBT group failed and required hysterectomy to stop the bleeding. The success rates did not significantly differ for the two groups as shown by the p-value of 0.4619 (> 0.05).

Similar to success rates, no significant differences were seen for the puerperal morbidity between the two groups as shown in **Table-2**. The rates of puerperal morbidity were 6.49% and 4.35% in UGP and UBT, respectively. The risk ratio (RR) of UGP to UBT was 1.49 (95% CI: 0.18 – 12.15).

Multivariate logistic regression analysis was performed to adjust the potential confounding factors i.e. causes of PPH, among which puerperal morbidity was taken as outcome. The details are listed in

Table 3. The results indicated that adjustments do not significantly alter the interpretation of the crude RR of treatments.

DISCUSSION

"If you can fill the unforgiving minute with sixty seconds worth of distance, run." – Kipling

Post-partum haemorrhage is one of the major reasons of maternal deaths in developing & developed nations; with PPH leading to approximately 24% of the total maternal deaths in India. PPH is a rapid killer with the average estimated duration of 2 hours between onset of massive bleeding & death. The flow of blood to the placental bed changes with gestation but is roughly 750ml/min at term. A blood loss of as less as 30% may result in the patient becoming critically unwell over a few minutes, given that the blood volume in mothers may be only 7lts. Any blood loss may be life threatening due to unreplaced blood volume if the flow to the placental bed is not quickly halted with placental separation.

The main cause of postpartum haemorrhage is atonic uterus; with others being trauma, retained bits of placental tissue & coagulopathy, with atonic uterus accountable for 75-90% of primary PPH. Prolonged third-stage labor; a history of PPH secondary to uterine atony, abnormal labor, an overdistended uterus, amnionitis, abruptio placentae, high parity, placenta previa, preeclampsia, prolonged/deep inhalation anesthesia, myomas, and hypotension can result in uterine atony. In practice, postpartum haemorrhage can occur unanticipated with approximately 60% of cases occurring in women without any risk factors.

With increasing caesarean delivery, complications of postpartum morbidity also increase. Reasons for PPH include atonic uterus, bleeding from uterine incision or extension, placental abnormalities (placenta previa/adherent placenta), and uterine rupture; especially during and after c-section.

Numerous methods have been advocated for the management of postpartum haemorrhage, ranging from massaging the uterine fundus, to using pharmacological agents, embolization techniques, compression sutures, vascular occlusion & eventually hysterectomy. Several of the methods require availability of specific equipment and/or personnel (embolization techniques), a degree of surgical dexterity (compression sutures/vascular occlusion by surgical ligation), or the presence of a hemodynamically stable patient (embolization techniques). Management of intractable primary PPH, refractory to oxytocics & prostaglandins requires prompt action.

Studies have concluded that techniques such as Uterine Gauze Packing (UGP) and Uterine Balloon Tamponade (UBT) are simple, safe, fast, and require no special equipment or personnel. In the present study, success rates for both the methods were high with UGP having success in 90.91% cases and UBT in 95.65% cases, respectively. Similar studies have concluded success rates of uterine packing which are comparable with our study with the success ranging from 67% to 90%^[15,16,17,18,19,24]. Previous studies regarding Bakri Balloon Tamponade have only been performed on retrospective case-series and not on randomized control groups. The success rates of these case-series studies range from 80% to 100% similar to our own study^[20,21,22,23,28]. Although UGP appears to achieve a similar effectiveness of UBT, it has not been recommended for the treatment modalities of postpartum haemorrhage as UBT because of risk of causing concealed haemorrhage and increased risk of infections. Instead, Bakri Balloon Tamponade has certain advantages including allowance for the continuous flow of lochia, lower incidence of infections, & painless removal.

Puerperal morbidity has been pragmatically measured as the risk of postpartum infection, in our study. No significant differences were observed for the puerperal morbidity between the two groups, with rates of 6.49% and 4.35% in UGP and UBT, respectively. In our study, the UGP group has higher proportion of placental factors causing haemorrhage compared to the UBT group. It is commonly accepted that placental factors carry more risk for infection than uterine inertia, thus the crude risk ratio of 1.49 calculated in our study might be a biased estimation in favor of the UBT group. However, the adjusted risk ratio calculated from multivariate logistic regression was similar to the crude RR, indicating that adjustments did not significantly alter the interpretation of the crude risk ratio of treatments. Studies such as those by Maier et al.^[16] and Roman & Rebarber et al.^[27], have shown

that uterine packing resulted in minimal fever, which was of no clinical significance, & has confirmed that coverage with broad-spectrum antibiotics & removal of the pack within 24-36hrs reduces the risk of uterine infection. In recent decades, there have been several modifications in UGP procedure including "soaking of long gauze in a solution of povidone-iodine, metronidazole, or thrombin to prevent infection or to stop bleeding, & ensuring the size of the gauze to facilitate removal"^[9].

Bakri Balloon Tamponade has certain advantages over UGP but its usage in a developing country like India is limited due to its higher cost and inadequate availability. In India, each year, 18 million deliveries take place in peripheral areas where maternal & perinatal services are either poor or non-existent. Traditional packing, which is simple, easy, and can even be easily taught to midwives; can be used before the woman is shifted from periphery to hospital and in the hospital as a treatment measure or at times till preparations are made for surgical management.

CONCLUSIONS

In our study, no significant difference is observed in the rates of success for UGP vs UBT. Although our results indicate higher rate of puerperal morbidity, UGP could be included in the treatment modalities of PPH together with the provision of suitable training & maintenance of proper asepsis, especially in resource-poor settings because of its low-cost and easy availability.

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