Section: Obstetrics and Gynaecology

Original Research Article

A COMPARATIVE STUDY ON USE OF FOLEY TAMPONADE VERSUS SAMARTHA RAM'S SUCTION RETRACTION(SR) CANNULA IN THE MANAGEMENT OF ATONIC POSTPARTUM HEMORRHAGE IN A TERTIARY CARE CENTRE

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Received : 05/01/2025
Received in revised form : 17/02/2025
Accepted : 03/03/2025

Keywords:
Postpartum hemorrhage, foley tamponade, suction retraction cannula, blood loss, blood transfusion, surgical intervention.

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DOI: 10.47009/jamp.2025.7.3.165

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (3); 848-853

ABSTRACT

Background: Postpartum hemorrhage (PPH) is a condition in which excessive bleeding happens from the genital tract at any time following the baby's birth up to six weeks after delivery. The average blood loss following vaginal delivery, caesarean delivery and caesarean hysterectomy is 500 ml,1000 ml and 1500 ml respectively. The primary cause of postpartum hemorrhage is uterine atony. It is an obstetric emergency and ranks among the top five causes of maternal mortality worldwide. **Objective:** To compare and evaluate the maternal outcomes and the effectiveness of foley tamponade and SR Suction cannula in the immediate management of PPH. **Material and Methods:** The study is an interventional randomized controlled study. Mothers who delivered vaginally and by caesarean section and incurred postpartum hemorrhage were managed by foley tamponade and SR cannula and analysed in our center. **Result:** This study analyzed 60 atonic PPH cases (excluding certain deliveries), finding the highest incidence in mothers aged 26-30 (23%), multigravida with nulliparity, and vaginal deliveries (52%), with key risk factors being gestational hypertension, anemia, and macrosomia. Two cases (both managed with Foley tamponade) required surgical intervention, and this group also needed significantly more blood transfusions than the SR cannula group. the study showed that there is a significant difference in the outcome between the two methods with SR cannula being the better option which was assessed in terms of amount of blood loss, need for blood transfusion and the need for surgical intervention. **Conclusion:** The most important fact to be considered is that Postpartum hemorrhage is absolutely preventable. Identifying the high-risk factors during the antenatal period and following up of these patients can help in preventing a large proportion of deaths due to postpartum hemorrhage. SR cannula can be used for the management as well as prophylactically in women with high chances of experiencing Postpartum hemorrhage. It is a simple, cheap and easily usable method to prevent postpartum hemorrhage.

INTRODUCTION

Postpartum hemorrhage (PPH) is a condition in which excessive bleeding from the genital tract at any time following the baby's birth up to six weeks after delivery. Hemorrhage may occur before, during, or after delivery of the placenta. The average blood loss following vaginal delivery, cesarean delivery and cesarean hysterectomy is 500 ml,1000 ml and 1500 ml respectively.

CLINICAL DEFINITION: Any amount of bleeding from or into the genital tract following birth of the baby or upto the end of the puerperium which adversely affects the general condition of the patient evidenced by rise in pulse rate and falling in blood pressure.

In PPH, Rule of 30 refers to:

- a 30% fall in hematocrit
- a 30 mmHg fall in systolic blood pressure
- an increase by 30 beats/min of pulse rate
- a 30% fall of hemoglobin (approximately 3 g/dl) and
- an approximate blood loss of 30% of normal (70 ml/kg in adults; 100 ml/kg throughout pregnancy.[1])

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Postpartum hemorrhage (PPH) can be classified into two types: primary and secondary

Primary PPH: This type of PPH occurs within the first 24 hours after giving birth.

Secondary PPH: This type of PPH occurs between 24 hours and 12 weeks after giving birth. It can be unusual or heavy bleeding.

Common causes of postpartum hemorrhage

1. Uterine atony [Tone]
2. Injuries to the upper and lower genital tract – lacerations, hematoma etc.[Trauma]
3. Retained placenta or tissue bits or invasive placenta [Tissue]
4. Coagulopathy [Thrombin]

INCIDENCE

The MMEIG (Maternal Mortality Estimation Inter-Agency Group) indicated in 2020 that India's maternal mortality rate decreased from 384 in 2000 to 103 in 2020. At the same time, the global maternal mortality rate fell from 339 to 223 in 2020. Postpartum hemorrhage (PPH) being the leading cause of maternal mortality worldwide, causes about 70,000 deaths each year. In India, PPH is responsible for 19.9% of maternal deaths, with an incidence of 2–4% after vaginal delivery and 6% after caesarean section.[1] The mortality rate for primary PPH is 5.4% The most common cause of PPH is uterine atony. Uterine atony means the inadequate contraction of the uterine myometrial cells in response to the endogenously released oxytocin as a part of the physiology of labour. The spiral arteries that are present in the myometrial space are unique and lack musculature thus necessitating the adequate contraction of the myometrium to arrest the bleeding. The primary cause of postpartum hemorrhage, considered an obstetric emergency, is uterine atony. It ranks among the top five causes of maternal mortality worldwide.[1]

HAEMOSTASIS ALGORITHM in PPH management

H - Ask for help
A- Assess and resuscitate
E - Establish aetiology
M-Massage the uterus
O-Oxytocic administration
S- Shift to OT
T-Tissue and trauma to be excluded and proceed to Tamponade
A-Apply compression sutures
S-Systematic pelvic devascularization
I- Interventional radiology
S-Subtotal or total hysterectomy

UTERINE BALLOON TAMPONADE

A silicon balloon is inflated inside the uterine cavity to achieve hemostasis.

Mechanism of action

1. Exerting in inward-to-outward pressure > systemic arterial pressure: prevents continual bleeding
2. Hydrostatic pressure effect of the balloon on the uterine arteries

Contraindications

- Uterine infection
    - Allergy to rubber/latex products, such as the rusch balloon and the condom catheter

Method of Inflation

Minimal amount of uterine distension to accomplish haemostasis, whereas the over-inflating of the balloon leads to distension of the uterus, significant pain and

Method of Removal

In most cases, 4-6 hours of tamponade should be adequate to achieve hemostasis, and most have it removed within 24 hours preferably in the daytime in the presence of senior doctors.

The balloon can be deflated and left in place for some time to check if the bleeding occurs again before its complete removal.

SR CANNULA

Dr. Samartha Ram, an obstetrician and gynecologist from Kerala, invented the SR PPH suction cannula to treat and prevent postpartum hemorrhage. The SR cannula is a simple device that is used when other medical methods have failed. This uniquely designed cannula with its perforations creates a negative pressure inside the cavity of the uterus simulating the natural physiological process of contraction and retraction thus controlling the hemorrhage.

DESCRIPTION

There are two available sizes of cannulas, each 25 cm long and featuring a vaginal angle.[2]

The uterine section is 14 cm long and comes in two diameters: 24 mm and 18 mm.

The vaginal section has a length of 10 cm and a diameter of 12 mm.

The perforations on the fundal section are large and elongated, while those on the cervical section are small and round.

The vaginal section has no perforations,[3]

For a caesarean section

The shorter cannulas, measuring 14cm in length, are utilized during caesarean deliveries. When the cervix is not dilated, the cannula with a 12mm diameter is employed. The other cannula has an 18mm diameter. A high vacuum suction device, or vacuum suction pump capable of generating negative pressure of up to 650mm Hg, is required.[4]

PROCEDURE OF INSERTION OF THE CANNULA

In the event of vaginal delivery:

When atonic PPH remains unmanageable despite standard medical treatment, the woman is positioned in lithotomy, and the bladder is catheterized. All blood clots are cleared from the uterine cavity by performing bimanual compression.

With adequate lighting, the vaginal walls are held open using a speculum, while the anterior lip of the cervix is grasped with sponge forceps. The uterine end of the SR cannula should be carefully inserted under visualization until it reaches the fundus. The opposite end of the cannula is attached to the suction device. The left hand maintains pressure at the

ISSN (O): 2687-5365; ISSN (P): 2753-6556

fundus, while the right hand carefully positions the cannula into the fundus. With suction device is activated, creating negative pressure of up of 650 mmHg for 10 minutes. This negative pressure allows the tissues to be drawn into the openings located on the cervical section of the cannula. Negative pressure must be applied each hour over a span of 3 hours.[5]

In the event of a caesarean section

One end of the suction tube is attached to the cannula. The other end should be inserted through the uterine incision and extended outside through the vagina. The size of the cannula is chosen based on the cervix. The external end of the suction tube is then connected to the suction machine. After positioning the cannula and bringing the edges of the wound together, negative pressure should be applied. The uterine incision will be closed while the negative suction pressure is active. The cannula should remain in place for as long as possible due to the potential for bleeding recurrence, or even for up to 24 hours.

CANNULA REMOVAL

Following the procedure, when attempting to withdraw the cannula, it may not easily detach. This difficulty arises from the development of temporary adhesions due to the suction of the soft cervical tissues into the perforations of the cervical portion of the cannula. The cannula is subsequently extracted after gently separating these adhesions through manual manipulation.[6]

The process involved in vacuum constriction entails that the negative pressure leads to the physical constriction of the uterus, which supports the body's natural contraction and retraction process. When negative pressure is applied, the flexible cervical tissues surrounding the cervical section of the cannula are drawn into the perforations of the cannula initially. This action effectively closes the uterine cavity. Continued application of negative pressure results in consistent constriction, contraction, and strong retraction of the uterus.[7]

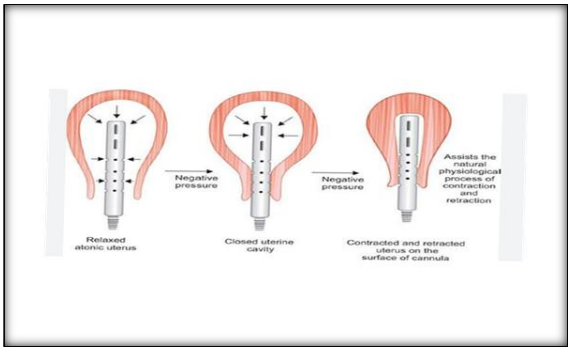

IMAGE 1: SHOWING SR CANNULA MECHANISM OF ACTION

Since the blood flow to the uterus remains uninterrupted, the uterotonic medications keep functioning and support the process of contraction and retraction. Blood that accumulates in the uterine cavity is extracted and collected in a suction bottle, aiding in the assessment of blood loss. Given that this procedure requires minimal time and skills, even maternity nurses can be trained to perform it, allowing for immediate intervention to halt the bleeding.[8]

MATERIALS AND METHODS

This interventional study was conducted in the Department of Obstetrics and Gynaecology, Chengalpattu government medical college and hospital for a period of one year. 60 Women admitted for delivery and incurred Postpartum hemorrhage during delivery were randomized into two groups managed by Foley Tamponade and SR cannula insertion.

METHOD OF STUDY

Following a thorough examination of the cases using exclusion criteria, followed by comprehensive history taking and getting informed consent, the outcomes of patients with atonic PPH treated with foley tamponade and suction cannula were analysed in terms of

- Mode of delivery
- Time taken to control the bleeding
- Amount of blood collected
- Need for blood transfusion in both types of management

Patients going into postpartum hemorrhage and managed by one of these methods are monitored once in 15 minutes for upto 2 hours postpartum and assessed based on the following parameters

VITALS MONITORING

PULSE RATE:
BLOOD PRESSURE:
SATURATION:

- URINE OUTPUT:
- PER ABDOMEN: WHETHER UTERUS IS CONTRACTED OR NOT
- BEDSIDE ULTRASOUND: Uterine contour/ hemoperitoneum/ RPO
- BLOOD LOSS; AMOUNT OF BLOOD COLLECTED IN FOLEY TAMPONADE/ SUCTION APPARTUS

Based on the above parameters decision regarding continuation of the same method or change of method or surgical management is done.

Statistical Analysis

The mean along with standard deviation were employed for continuous variables, while percentages were used for categorical variables. An unpaired t-test was conducted to assess significant differences in blood loss between the two groups. The association of risk factors with blood loss was evaluated using a chi-square test. A p-value of < 0.05 was fixed as statistically significant.

RESULTS

Analysis of both the methods used for the management of 60 patients who incurred atonic postpartum hemorrhage after the exclusions in labour

ISSN (O): 2687-5365; ISSN (P): 2753-6556

natural, operative vaginal delivery and caesarean section was done and the following results were obtained. Among the mothers studied PPH was the highest in mothers of age group 26-30 years contributing to 23%. Multigravida with nulliparity was found to have the highest incidence. Vaginal delivery had more PPH occurrence than caesarean sections. Among the risk factors, gestational hypertension followed by anemia and big babies were found to have strong associations with PPH.

Among the 60 cases two cases needed surgical intervention. These two cases belonged to the group managed with foley tamponade.

The need for blood transfusion and the number of units of blood transfused was significantly higher in the group managed with foley tamponade.

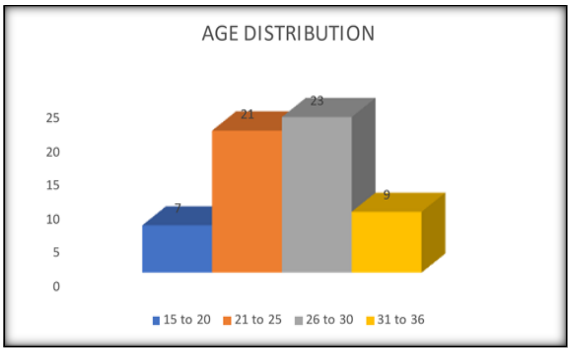

Figure 1: Distribution of Women According to Age

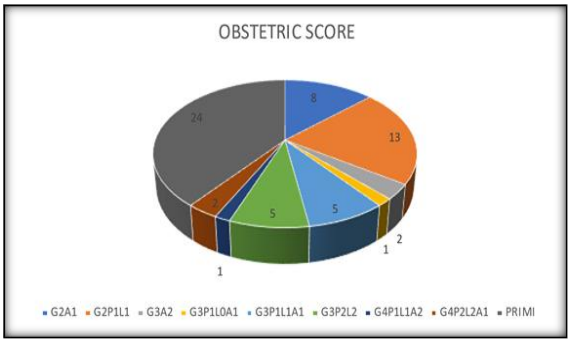

Figure 2: Distribution according to obstetric score

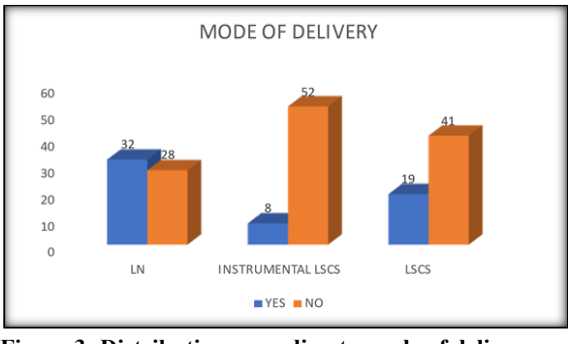

Figure 3: Distribution according to mode of delivery

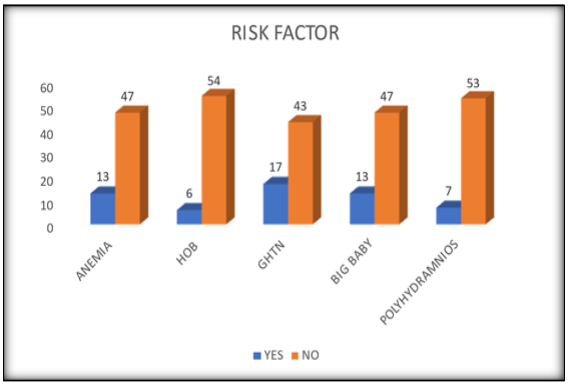

Figure 4: Risk factors for postpartum hemorrhage

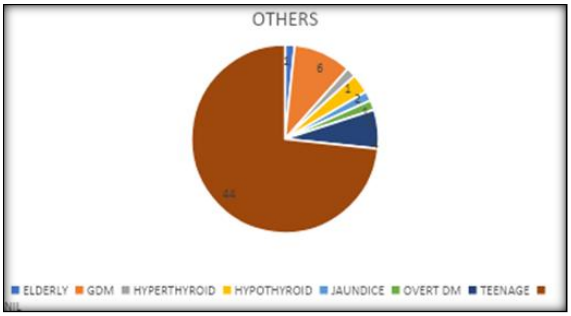

Figure 5: Other risk factors associated

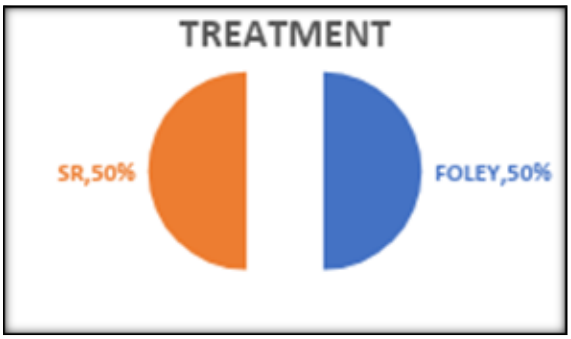

Figure 6: Distribution of management method

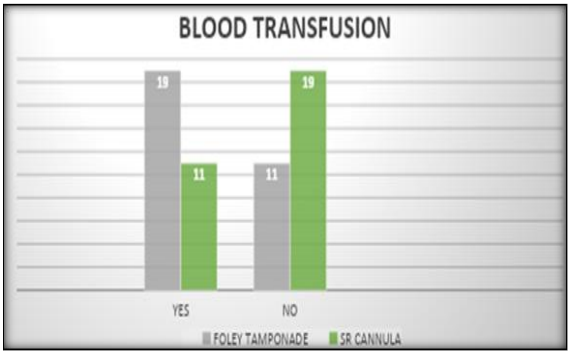

Figure 7: Distribution of the need for blood transfuion in both the methods

Table 1: Showing need for surgical intervention

SURGICAL	NUMBER	PERCENTAGE
NO	58	96.67
YES	2	3.33

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Table 2: Association between various risk factors blood loss and the mode of management

	TREATMENT	SURGICAL INTERVENTION		TOTAL	p value	
		NO	YES			
	FOLEY	28	2	30	0.15	
	SR	30	0	30		
	Total	58	2	60		
AMOUNT OF BLOOD LOSS		N	Mean	Std. Deviation	Std. Error Mean	p value
TREATMENT	FOLEY	30	1208.33	289.197	52.800	< 0.0001
	SR	30	893.33	237.709	43.400	
ANEMIA	NO	31	917.74	245.135	44.028	< 0.0001
	YES	29	1193.10	305.522	56.734	
HOB	NO	54	1030.56	310.115	42.201	0.126
	YES	6	1233.33	216.025	88.192	
GHTN	NO	43	1048.84	297.307	45.339	0.937
	YES	17	1055.88	339.062	82.235	
BIG BABY	NO	47	1059.57	323.305	47.159	0.678
	YES	13	1019.23	246.254	68.299	
POLYHYDRAMNIOS	NO	53	1070.75	307.976	42.304	0.168
	YES	7	900.00	270.801	102.353	

Table 3: Distribution of the need for blood transfuion in both the methods

BLOOD TRANSFUSION	FOLEY TAMPONADE	PERCENTAGE	SR CANNULA	PERCENTAGE
YES	19	63	11	37
NO	11	37	19	63

Table 4: Showing the need for blood transfusion and its associations

BLOOD TRANSFUSION		NO	YES	TOTAL	p value
TREATMENT	FOLEY	9	21	30	< 0.0001
	SR	21	9	30	
ANEMIA	NO	24	7	31	< 0.0001
	YES	6	23	29	
HOB	NO	29	25	54	0.085
	YES	1	5	6	
GHTN	NO	23	20	43	0.39
	YES	7	10	17	
BIG BABY	NO	24	23	47	0.754
	YES	6	7	13	
POLYHYDRAMNIOS	NO	25	28	53	0.228
	YES	5	2	7	

DISCUSSION

PPH is a highly concerning complication that can be avoided through specific standard measures. This study aimed to examine the magnitude of atonic PPH by determining its incidence, and its risk factors, and their management hemorrhage utilizing the SR cannula and Foley tamponade. and to compare both so as to identify the better and the best method thereby aiding in the early and prompt management of the condition.

Our study population is 60 patients. Antenatal term mothers admitted for delivery were taken for study. The primary aim is to analyse the best method of management between Foley tamponade and SR cannula. 30 patients were managed with Foley Tamponade and 30 patients were managed with SR cannula. Other factors influencing the incidence and severity of postpartum hemorrhage such as Age, Parity, Risk factors were also analyzed.

Our study revealed that the incidence of postpartum hemorrhage is common on 26 to 30 years which was 38% of the total population. This was in similarity with studies conducted by Mudanur SR,[9] et al. and Damor. P et al,[10] in which the mean age group of women was 21 to 30 years of age. According to parity the incidence was found to be more in primigravidae, which was 40%. This was also in concurrence with the findings of the study conducted by Mudanur et al. in our study postpartum hemorrhage was found to be more following vaginal delivery followed by caesarean delivery. Two patients who had more than 1500ml blood loss belonged to the group managed with foley tamponade. These patients eventually needed surgical intervention. Among 60 patients only two patients needed surgical intervention. Statistically the difference could not be shown. However both the patients who needed surgical intervention were managed with foley tamponade. Hence there is a significant difference between both. Postpartum hemorrhage was found to have association with risk factors such as anemia, gestational hypertension and big baby. In our study higher order birth and polyhydramnios were found to be associated less with postpartum hemorrhage.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

A total of 30 patients among the 60 needed blood transfusion. The need for blood transfusion was more in the foley tamponade group. 19 out of the 30 patients managed with foley tamponade needed blood transfusion whereas only 11 patients of the SR cannula group needed blood transfusion, the number of units needed was also lesser in the group managed with SR cannula.

The time in minutes taken to control the bleeding could not be assessed and documented accurately due to the operational difficulties. However other findings still prove to be in favour of SR cannula.

The study showed that a lot of factors influence the incidence and prognosis of Postpartum hemorrhage. One of the most important factors is the early initiation of treatment. The first one hour is considered to be "THE GOLDEN HOUR" during which all the interventions done have a huge impact on the outcome.

Hence it should be always kept in mind that quick and prompt action is necessary. This also includes decisions regarding the use of the correct method.

In our study, two patients were initially managed with foley tamponade but when the bleeding was not brought into control with foley tamponade these patients were managed with SR Cannula. Thus SR cannula proved to be better than foley tamponade in managing postpartum hemorrhage.

The final outcome proved SR cannula to be a better option for managing PPH than foley tamponade in all types of deliveries. This was shown by the Independent T test in which the p value was less than 0.005 and hence considered significant.

The only concerning disadvantage of the method is the difficulties incurred during removal of the cannula. The cervical soft tissues that get sucked in the perforations due to the negative pressure might get stuck there making it difficult to remove the cannula after 24 hours. This can cause trauma to the cervical tissues. More research into this and ways to avoid this complication are to be studied.

CONCLUSION

SR cannula is a simple, cost-effective tool for preventing and managing postpartum hemorrhage (PPH), especially in low-resource settings. It requires no specialized training, enabling midwives to use it promptly, reducing delays in care. However, tissue trauma during removal remains a concern. Further research with large scale multicenter studies is needed to optimize its safety while maintaining its life saving potential.

Limitations

1. Being Single-center, small-scale study —future research should involve multi-center trials with larger populations for better evaluation of the cannula.
2. Excluded severe fatal cases and combined atonic/traumatic PPH, limiting generalizability.
3. Optimal duration of SR cannula use and safe removal techniques need further investigation.
4. Standardized protocols for SR cannula application must be developed to enhance efficacy and safety.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556