"A RANDOMISED PROSPECTIVE COMPARATIVE STUDY OF EFFICACY OF VACCUM RETRACTION CANNULA AND INTRAUTERINE FOLEY BALLOON TAMPONADE IN ATONIC POST PARTUM HEMORRHAGE"

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BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled **"A RANDOMISED PROSPECTIVE COMPARATIVE STUDY OF EFFICACY OF VACCUM RETRACTION CANNULA AND INTRAUTERINE FOLEY BALLOON TAMPONADE IN ATONIC POST PARTUM HEMORRHAGE"** is the bonafide work done by **Dr. R.KARTHIKA,** Post Graduate in the Department of Obstetrics and Gynaecology, Madras Medical College, Chennai, towards partial fulfilment of the requirements of The Tamil Nadu Dr. M.G.R University for the award of M.S Degree in Obstetrics and Gynaecology.

PROF. Dr.Devika, M.D. OG.,
Department of obstetrics and gynaecology,
Institute Of Social Obstetrics and
Government Kasturba Gandhi Hospital
For Women And Children,
Triplicane,Chennai

Prof. Dr. S. VIJAYA, MD., DGO.
Director,
Institute of Obstetrics and
Gynaecology
Govt. Hospital for Women and
Children
Madras Medical College,
Chennai – 600 003.

PROF. DR. E. THERANIRAJAN, MD., DCH., MRCPCH(UK)., FRCPCH(UK)

Dean

Madras Medical College, Chennai

PLACE:

DATE:

DECLARATION

I solemnly declare that this dissertation entitled **"A RANDOMISED PROSPECTIVE COMPARATIVE STUDY OF EFFICACY OF VACCUM RETRACTION CANNULA AND INTRAUTERINE FOLEY BALLOON TAMPONADE IN ATONIC POST PARTUM HEMORRHAGE"** was prepared by me under the guidance and supervision of **PROF. Dr.DEVIKA, M.D. OG.,** Department of obstetrics and gynaecology, Institute Of Social Obstetrics And Government Kasturba Gandhi Hospital For Women And Children, Triplicane, Chennai

This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfilment of the University regulations for the award of the degree of M.S. (Obstetrics and Gynaecology).

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Place: Chennai

Date: **DR.R.KARTHIKA**

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CONTENTS

INTRODUCTION

Worldwide the leading cause of maternal morbidity and mortality is Postpartum Haemorrhage (PPH).After giving birth 2-6% of women encounters Post partum hemorrhage. Postpartum hemorrhage alone leads to 25% of the maternal deaths (1).It is declining now a days but since it is the first major cause of maternal mortality. Usually 115000 maternal deaths occurs in a year.Among these deaths majority i.e 99% occurs in the low resource setting. Around 30% of the maternal death which occurs in India is due to Postpartum hemorrhage.Since 1990 the maternal death has been decreased to 43% and the maternal mortality is found to be high in the middle income countries and in low income countries(2).

Vaginal bleeding which occurs in excess of 500 ml within the 24 hours of delivery is known as post partum hemorrhage.It is considered to be very dangerous and it is life threatening(3).The long lasting complications which occurs due to the postpartum hemorrhage were the anemia which is severe and the sheehans syndrome and sequelae due to it. The major cause of the postpartum hemorrhage is due to uterine atony.

Atonic postpartum hemorrhage is caused by many risk factors like accidental haemorrhage,obstructed prolonged labour, big babies etc.Though risk factors plays many role it is still unknown that why this PPH occurs in some and not in others.Atonic Postpartum Hemorrhage was always unpredictable.

The first 1-2 hours of the haemorrhage is called as the ‘Golden hours’ due to its rapid onset(4).Some women will die within the one to one and half hours after the onset of the bleeding(4)(5).For some women coagulation failure occurs and multiorgan dysfunction syndrome.Hemorrhagic shock occurs as a result of the postpartum haemorrhage.

Uterine atony treatment is based on a stepwise approach which is well defined.The treatment varies from the drugs,managing through mechanical interventions and the last and the final approach is the Surgery.The management strategy which is used even nowadays also is the ‘Watchful Expectancy” and to act appropriately.

In low resource setting simple techniques uterine packing,uterotonics drugs,uterine massage and balloon tamponade were used.But in higher Centers B-lynch suturing,internal iliac ligation,stepwise ligation and uterine artery embolisation. The world health organization in the year 2012 recommended the use of the uterine balloon tamponade (UBT) for the uterus where the

uterotonic drugs or medical management fails.In 1991 Uterine balloon tamponade was introduced which is considered as the non surgical popular interventions because of its simplicity and because of its easy use.

Balloon tamponade therapy principle is to fill the cavity with negative pressure which in turn close all the bleeding sites.The given increased intrauterine pressure will be considered as more superior than the capillary blood vessels pressure and so it arrests the bleeding.The inward and outward pressure given by the intrauterine balloon is greater than the systemic arterial pressure and it turn arrests the bleeding.According to the Millineum Development goal only if proper PPH management is prioritized the maternal mortality reduction can be achieved.Many studies stated that through prompt recognition and timely management the Postpartum hemorrhage can be prevented.

AIM AND OBJECTIVE

The aim of the study to compare the efficacy of vaccum extraction cannula and Foleys tamponade in arresting post partum hemorrhage in normal vaginal deliveries.

Hypothesis:

Null Hypothesis H0: Vaccum extraction cannula is not effective over Foley's tamponade in arresting post partum hemorrhage

Alternate Hypothesis H1: Vaccum extraction cannula is effective over Foley's tamponade in arresting post partum hemorrhage

REVIEW OF LITERATURE

Postpartum hemorrhage (PPH) is defined as blood loss of 500ml or more following vaginal delivery or blood loss of 1000ml or more following caesarian section. ACOG defines Post partum hemorrhage as blood loss that decreases hematocrit by 10%

Types of PPH:

- Primary PPH: Blood loss of more than or equal to 500ml during the first 24 hours of the birth is called the primary PPH
- Secondary PPH: When blood loss occurs beyond 24 hours within puerperium is called secondary PPH

Causes:

Causes of postpartum hemorrhage expressed as 4T's (RCOG)

- Tone - atonicity of uterus is the most common cause.
- Tissue- retained bits of placenta and blood clots cause postpartum hemorrhage due to imperfect uterine retraction.
- Trauma- trauma to genital tract usually involving cervix, vagina, paraurethral region and perineum. Rarely due to uterine rupture.

- Thrombin- blood coagulation disorders.

Atonic uterus:

Uterine atony accounts for about 80% of cases of PPH (6). After separation of placenta, uterine sinuses that are torn cannot be compressed in atonic uterus due to imperfect contraction and retraction of uterine musculature (7). The following conditions interferes with uterine retraction

- Grand multipara
- Over distended uterus
- Big baby
- Hydramnios
- Multiple pregnancy
- Prolonged labour
- Anemia
- Precipitate labour
- Placenta previa
- Abruptio placenta
- Morbidly adherent palcenta
- Uterine fibroid
- Mismanaged third stage of labour
- Previous PPH.

However, only 40% of women will have identifiable risk factors (8). Hence all women are at risk of PPH.

Technical consultation held by World Health Organization (WHO) on postpartum hemorrhage has also highlighted the fact that PPH cannot always be prevented. But its incidence and its magnitude can be reduced by assessing the risk factors and following the guidelines(9).

ANTENATAL:

- Antenatal women hemoglobin should be kept above 10gm/dl so that patient can with stand certain amount of blood loss
- Blood grouping for all women should be done antenatally
- Ultrasound should be done in all pregnant women for placental localisation
- Patient with previous caesarean section should have their placental localisation by ultrasound to determine morbid adherent placenta
- High risk patients are to be screened and delivered in well equipped hospital

INTRANATAL:

- Active management of third stage of labour should be followed in all women to reduce PPH by 60%
- Exploration of uterovaginal canal for evidence of trauma

- Patient has to be observed for two hours after delivery in labour room and ensure that uterus is well contracted
- If oxytocin is used for augmentation of labour, it has to be continued for one hour after delivery
- During caesarean section spontaneous separation of placenta and delivery will reduce blood loss by 30%
- Placenta and membranes should be examined routinely to detect any missing part.

Skilled supervision, early detection will prevent from disastrous consequences. Golden “one hour” period is the time during which resuscitation should be started to ensure better chance of survival. Rule of 30 and assessment of shock index act as clinical guide in the management of patient.

Rule of 30:

- Systolic blood pressure fall by 30 mmHg
- Heart rate rise by 30 beats/minute
- Respiratory rate rise to >30 breaths/minute
- Haematocrit drops by 30%
- Urine output decreases <30ml/hour
- With this observation, 30% of patient blood volume has been lost

Shock index:

Shock index = Heart rate/systolic blood pressure

Normal range: 0.5-0.7

Obstetrics shock index >1 indicates massive haemorrhage that requires blood transfusion in about 80% of the cases.

Management of true postpartum hemorrhage

Principles:

- Simultaneous Approach
- Communication
- Resuscitation
- Monitoring
- Arrest of bleeding
- Call for help
- Two large wide bore intravenous cannula
- Take blood for cross matching
- Send blood for complete blood count, renal function test, liver function test, coagulation profile and fibrinogen
- Rapidly infuse two litres of crystalloids or colloids to re expand the vascular bed

- Give oxygen 10-15L/min
- Injection oxytocin 20 units in 1L normal saline at rate of 60 drops/minute
- Monitor vitals - pulse, blood pressure, temperature, respiratory rate, saturation and urine output.
- Palpate the fundus and feel the uterus. If it is flabby, bleeding is due to atonicity. If uterus is firm and well contracted, bleeding may be of traumatic origin.

ATONIC UTERUS:

Step 1:

- Uterine massage
- Injection oxytocin drip 20U in 1000ml of normal saline at a rate of 60 drops/minute
- Injection methergine 0.2mg intravenously
- Catheterise the bladder and keep it empty
- Examine expelled placenta and membranes

Step 2:

- Exploration under general anesthesia
- Inspection of cervix, vagina and paraurethral region to exclude bleeding sites

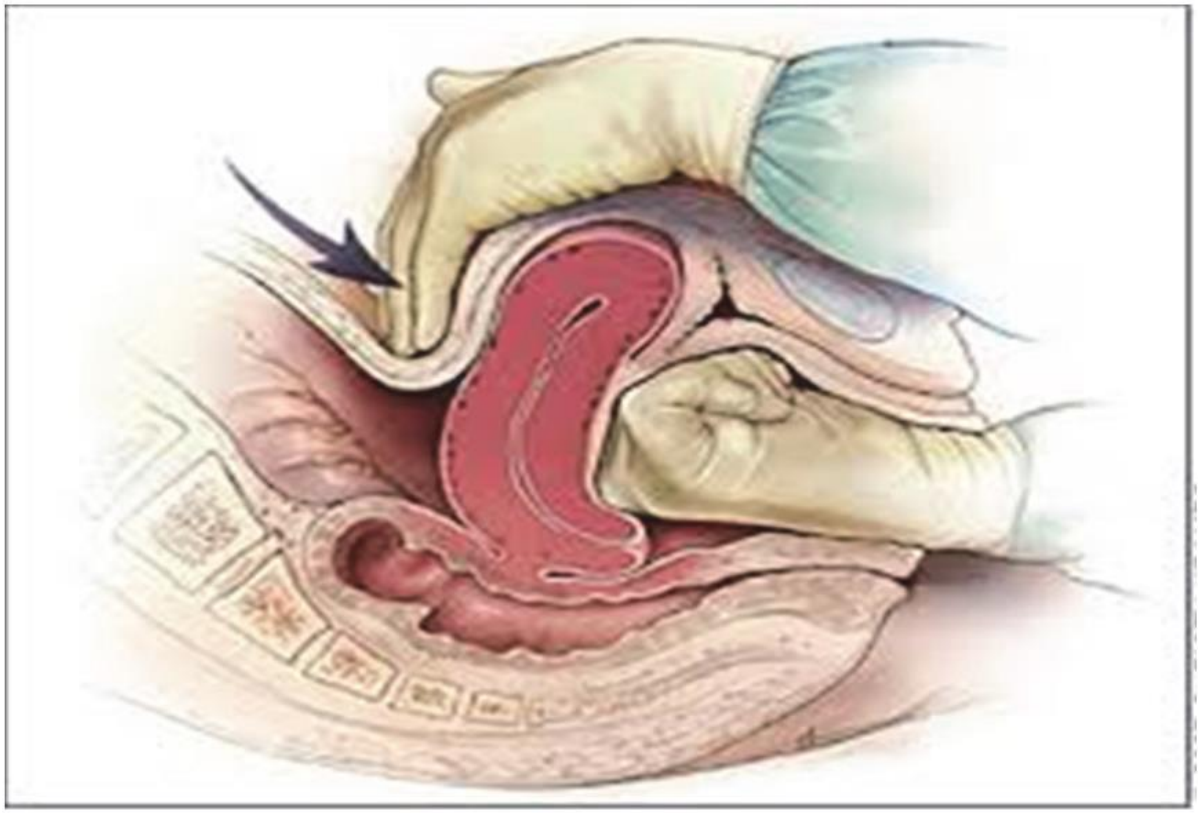
In refractory cases:

- Injection 15 methyl prostaglandin F2α 250 micro gram intramuscular can be repeated every 15 minutes upto to maximum dose of 2 mg
- Misoprostol(PGE1) 1000 microgram per rectum
- Injection tranexamic acid 1gm iv
- If uterine atony is due to tocolytics, 1gram of injection calcium gluconate is given slow iv

Step 3:

- Uterine massage and bimanual compression of the uterus.

Figure 1: Method of bimanual compression of uterus in atonic uterus.



Step 4:

Uterine tamponade

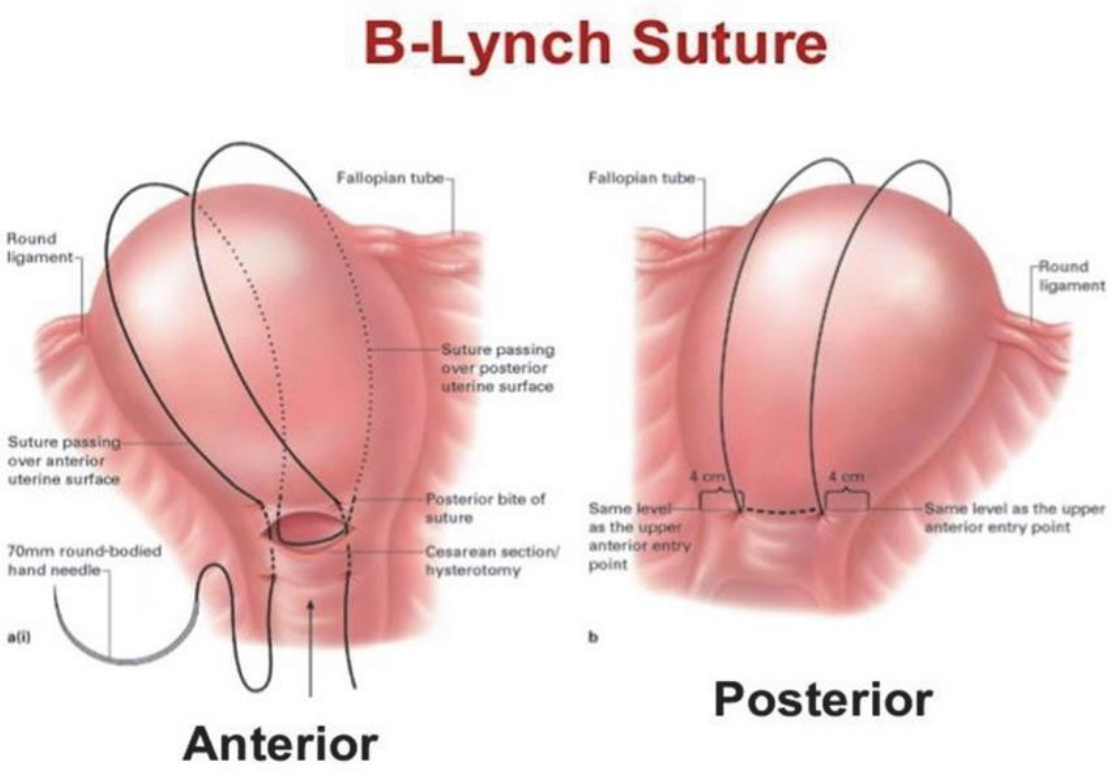
- Intrauterine packing – should be removed after 24 hours
- Balloon tamponade with foley catheter, condom catheter, bakri balloon21,
- sengstaken – blackmore tube, it is kept for 4-6 hours
- Non- pneumatic anti shock garment
- Compression of abdominal aorta

Step 5:

Surgical methods

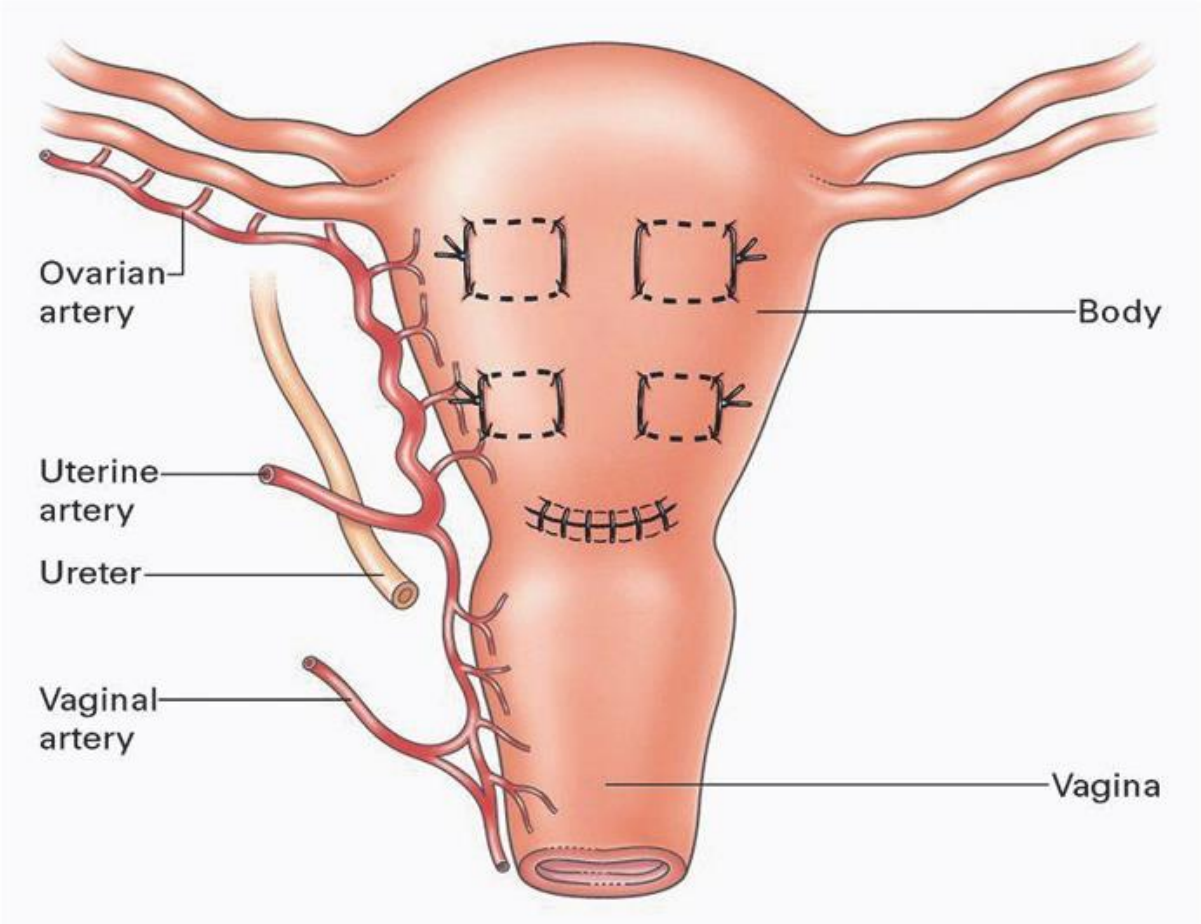
- B – Lynch compression suture

Figure 2: B-Lynch compression suture technique.



- Hemostatic multiple square suturing

Figure 3: Multiple square suturing technique for hemostasis.



- Stepwise uterine devascularisation involves ligation of uterine artery, ligation of ovarian and uterine artery anastomosis, ligation of anterior division of internal iliac artery
- Angiographic selective arterial embolization

Step 6:

Hysterectomy as last resort

Therapeutic goal is to maintain:

Hemoglobin > 8gm/dl

Platelet count > 50 x 109/L

Fibrinogen > 2gm/L

aPTT < 1.5 times the normal

PT (prothrombin time) < 1.5 times the normal

Postpartum hemorrhage accounts for quarter of maternal death worldwide. Its incidence is increasing in developed world (10,11). In developed countries PPH has become preventable and manageable but in developing countries PPH remains to be high. It is an important contributor of maternal morbidity and long term disability.

THIRD STAGE OF LABOUR

Third stage of labour commences from delivery of the baby till the delivery of the placenta. The mean length for third stage of labour is around 15 minutes.

Physiology of third stage of labour

Uterine contractions continue after the birth of the fetus and intrauterine pressure continues to rise rhythmically. The uterine muscle contract and retract following the delivery of the baby resulting in shortening of the upper segment. This shortening will reduce the area of uterine surface to which the placenta is attached.

Separation of placenta occurs primarily from retraction and disproportion created by unchanged size of placenta and reduced size of the underlying implantation site. Separation of placenta occurs through the deep spongy residual layer and it is forced towards the lower uterine segment (Mac person & Wilson 1965). Oxytocin and prostaglandins are the main uterotonic hormones responsible for uterine contraction. Normal blood flow through placenta at term is 700ml/minute. This bleeding has to be arrested within seconds following separation of placenta to prevent serious hemorrhage. (12)

Physiological mechanism behind the arrest of hemorrhage are given below,

- Retraction of oblique muscle fibres in the middle layer of myometrium act as a living ligature to the torn vessels at the placental site.
- Effective uterine contraction brings uterine wall into opposition so further pressure is exerted on placental site.
- Transitory activation of coagulation and fibrinolytic system at the placental site result in intensification of clot formation in the torn vessels.
- Any impairment in any of these mechanisms may lead to postpartum hemorrhage.

Mechanism of placental separation:

1. Mathew Duncan method: Marginal separation of placenta occurs and the maternal lower edge presents at the vaginal outlet first.

2. Schultz method: Formation of retroplacental hematoma occurs during the process of placental separation. Central portion of the placenta delivered first followed by rest of the placenta. So, placental-fetal surface appears at the vaginal outlet first with membranes covering the maternal surface.

Signs of placental separation:

1. The earliest sign to appear- uterus become globular and firmer.
2. Extra vulval lengthening of umbilical cord.
3. Uterus raises in the abdomen as a result of descent of placenta into lower uterine segment and thereby displaces the uterus upward.
4. Sudden gush of blood.

Factors that increase risk for hemorrhage at Admission:		
Low Risk	**Moderate Risk**	**High Risk**
Singleton pregnancy	Prior uterine surgeries	Placenta previa
≤4 prior vaginal deliveries	Multifetal gestation	Suspected placenta accreta syndrome
No known bleeding disorder	>4 prior vaginal deliveries	Hematocrit<30 (%) AND risk factors
No prior history of PPH	Prior history of PPH	Platelets < 100 ($x10^3/\mu L$)
	Uterine fibroids	Active bleeding on admission
		Known coagulopathy
Factors that may develop in labor increasing hemorrhage risk:		
• Prolonged second stage		
• Prolonged oxytocin use		
• Active bleeding		
• Chorioamnionitis		
• Magnesium sulfate infusion in labor		
• Operative assisted birth (Vacuum/forceps)		
• Retained placenta		

MANAGEMENT OF THIRD STAGE OF LABOUR

1. Physiological or expectant management: As long as the uterus remains firmly contracted with no unusual bleeding, can wait until the placenta get separated and deliver the placenta by maternal efforts. If the placenta is not separated spontaneously, pressure is exerted on the fundus to propel the placenta into vagina after ensuring the uterus is firmly contracted. This does not recommend uterotonics until placental delivery. (13)
2. Active management of third stage of labour(Reproductive Health Research, WHO, 2003)(14):

- Administration of oxytocin injection 10 units intramuscular within one minute of delivery of baby after ruling out additional baby.
- Controlled cord traction with counter traction only during uterine contraction.
- Uterine massage after placental delivery.

Active management of third stage of labour was first described in 1998 by Thilaganathan & collegues(15).

COMPONENTS OF ACTIVE MANAGEMENT:

1. Uterotonic agents:

    Uterotonic agents are administered within one minute of delivery of baby after ensuring no other additional baby. WHO recommend oxytocic agent during third stage of labour for prevention of postpartum hemorrhage. There are three groups of uterotonics-

a) Oxytocin 10 units intramuscular
b) Methyl-ergometrine 0.2mg intramuscular/intravenous
c) 15- methyl PGF2α – 0.25mg intramuscular.

Ergometrine should not be used in hypertensive disorders of pregnancy and cardiac diseases.

2. Controlled cord traction (modified Brandt-Andrews method):
    - Cord is clamped close to the perineum using sponge forceps. Hold the clamped cord and forceps with one hand.
    - Palmar surface of the other hand is placed just above the symphysis pubis approximately at the junction of upper and lower uterine segment.
    - The body of the uterus is pushed backward and upward with left hand and with the right hand steady traction is given in the backward and downward direction holding the clamp until the placenta is delivered. This procedure is done only when the uterus is hard and contracted.
    - If the palcenta is not delivered during controlled cord traction do not continue to pull the cord. Instead wait for the next contraction.
    - With next contraction repeat controlled cord traction method to deliver the placenta.
    - As placenta delivers, hold the placenta with both the hands and gently twist it until the membranes are twisted and slowly pull to complete the placental delivery.

3. Uterine massage:

- Uterus is massaged immediately after delivery of the placenta to make it hard and contracted.

- Palpate for the contracted uterus for every fifteen minutes and repeat uterine massage for the first two hours of delivery.
- Ensure that the uterus does not relax intermittently.

EXAMINATION OF PLACENTA AND MEMBRANE:

- Placenta is placed on the tray after removal and look for any missing cotyledon.
- Maternal surface is first inspected for its completeness.
- The cotyledons are placed normally in close approximation and any gap in between indicates a missing cotyledon.
- The membranes - chorion and amnion are carefully examined for completeness and presence of any abnormal vessels.
- Absence of any cotyledons or evidence of missing membrane demands immediate exploration.

Causes of postpartum hemorrhage are uterine atony, trauma, retained placenta or placental abnormalities, and coagulopathy, commonly referred to as the "four Ts"

- Tone: uterine atony is the inability of the uterus to contract and may lead to continuous bleeding. Retained placental tissue and infection may contribute to uterine atony. Uterine atony is the most common cause of postpartum hemorrhage.

- Trauma: Injury to the birth canal which includes the uterus, cervix, vagina and the perineum which can happen even if the delivery is monitored properly. The bleeding is substantial as all these organs become more vascular during pregnancy.
- Tissue: retention of tissue from the placenta or fetus as well as placental abnormalities such as placenta accreta and percreta may lead to bleeding.
- Thrombin: a bleeding disorder occurs when there is a failure of clotting, such as with diseases known as coagulopathies.

Other risk factors include obesity, fever during pregnancy, bleeding before delivery, and heart disease.

Oxytocin is typically used right after the delivery of the baby to prevent PPH. Misoprostol may be used in areas where oxytocin is not available. Early clamping of the umbilical cord does not decrease risks and may cause anemia in the baby, and thus is usually not recommended.

Active management of the third stage is a method of shortening the stage between when the baby is born and when the placenta is delivered. This stage is when the mother is at risk of having a PPH. Active management involves giving a drug which helps the uterus contract before delivering the placenta by a gentle but sustained pull on the umbilical cord whilst exerting upward pressure on the lower abdomen to support the uterus (controlled cord traction).

Another method of active management which is not recommended now is fundal pressure during the delivery of the placenta. A review into this method found no research and advises controlled cord traction because fundal pressure can cause the mother unnecessary pain. Allowing the cord to drain appears to shorten the third stage and reduce blood loss but evidence around this subject is not strong enough to draw solid conclusions.

Nipple stimulation and breastfeeding triggers the release of natural oxytocin in the body, therefore it is thought that encouraging the baby to suckle soon after birth may reduce the risk of PPH for the mother.[15] A review looking into this did not find enough good research to say whether or not nipple stimulation did reduce PPH. More research is needed to answer this question.[15] Uterine massage is a simple first line treatment as it helps the uterus to contract to reduce bleeding. Although the evidence around the effectiveness of uterine massage is inconclusive, it is common practice after the delivery of the placenta. Intravenous oxytocin is the drug of choice for postpartum hemorrhage. Ergotamine may also be used. Oxytocin helps the uterus to contract quickly and the contractions to last for longer. It is the first line treatment for PPH when its cause is the uterus not contracting well. A combination of syntocinon and ergometrine is commonly used as part of active management of the third stage of labour. This is called syntometrine. Syntocinon alone lowers the risk of PPH. Based on limited research available it is unclear whether syntocinon or

syntometrine is most effective in preventing PPH but adverse effects are worse with syntometrine making syntocinon a more attractive option. Ergometrine also has to be kept cool and in a dark place so that it is safe to use. It may reduce the risk of PPH by improving the tone of the uterus when compared with no treatment, however it must be used with caution due to its effects of raising blood pressure and worsening pain. More research would be useful in determining the best doses of ergometrine and syntocinon.

Oxytocin requires refrigeration, which may not always be available, particularly in low-resourced settings. When oxytocin is not available, misoprostol can be used. Misoprostol does not need to be kept at a certain temperature and research into its effectiveness in reducing blood loss appears promising when compared with a placebo in a setting where it is not appropriate to use oxytocin. Misoprostol can cause unpleasant side effects such as very high body temperatures and shivering. Lower doses of misoprostol appear to be safer and cause less side effects.

Giving oxytocin in a solution of saline into the umbilical vein is a method of administering the drug directly to the placental bed and uterus. However quality of evidence around this technique is poor and it is not recommended for routine use in the management of the third stage. More research is needed to ascertain whether this is an effective way of administering uterotonic drugs. As

a way of treating a retained placenta, this method is not harmful and has shown low certainty evidence of effectiveness.

Carbetocin compared with oxytocin produced a reduction in women who needed uterine massage and further uterotonic drugs for women having caesarean sections. There was no difference in rates of PPH in women having caesarean sections or women having vaginal deliveries when given carbetocin. Carbetocin appears to cause less adverse effects. More research is needed to find the cost effectiveness of using carbetocin.

Tranexamic acid, a clot stabilizing medication, may also be used to reduce bleeding and blood transfusions in low-risk patients, however evidence as of 2015 was not strong. A 2017 trial found that it decreased the risk of death from bleeding from 1.9% to 1.5% in women with postpartum bleeding.[3] The benefit was greater when the medication was given within three hours.

In some countries, such as Japan, methyl ergometrine and other herbal remedies are given following the delivery of the placenta to prevent severe bleeding more than a day after the birth. However, there is not enough evidence to suggest that these methods are effective.

Surgery may be used if medical management fails or in case of cervical lacerations or tear or uterine rupture. Methods used may include uterine artery ligation, ovarian artery ligation, internal iliac artery ligation, selective arterial embolization, B-lynch suture, and hysterectomy. Bleeding caused by traumatic causes should be management by surgical repair. When there is bleeding due to uterine rupture a repair can be performed but most of the time a hysterectomy is needed.

There is currently no reliable evidence from randomised clinical trials about the effectiveness or risks of mechanical and surgical methods of treating postpartum bleeding.

The World Health Organization recommends the use of a device called the non-pneumatic anti-shock garment (NASG) for use in delivery activities outside of a hospital setting, the aim being to improve shock in a mother with obstetrical bleeding long enough to reach a hospital. External aortic compression devices (EACD) may also be used.

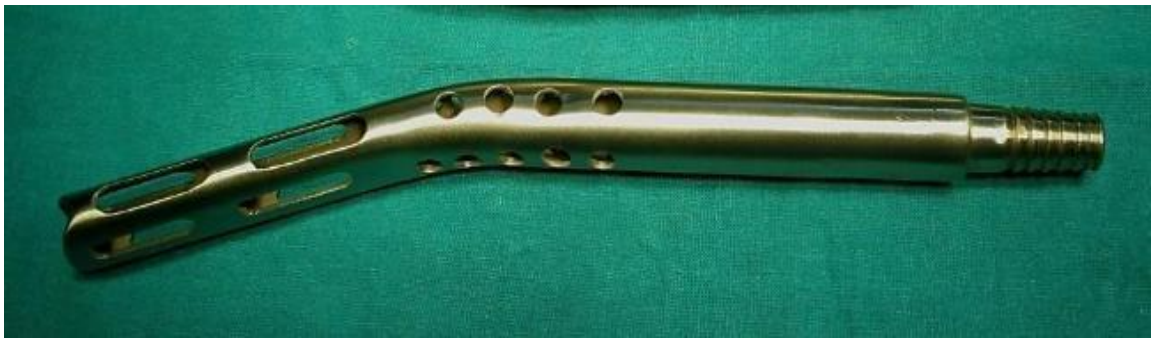
Uterine balloon tamponade (UBT) can improve postpartum bleeding. Inflating a Sengstaken–Blakemore tube in the uterus successfully treats atonic postpartum hemorrhage refractory to medical management in approximately 80% of cases. Such procedure is relatively simple, inexpensive

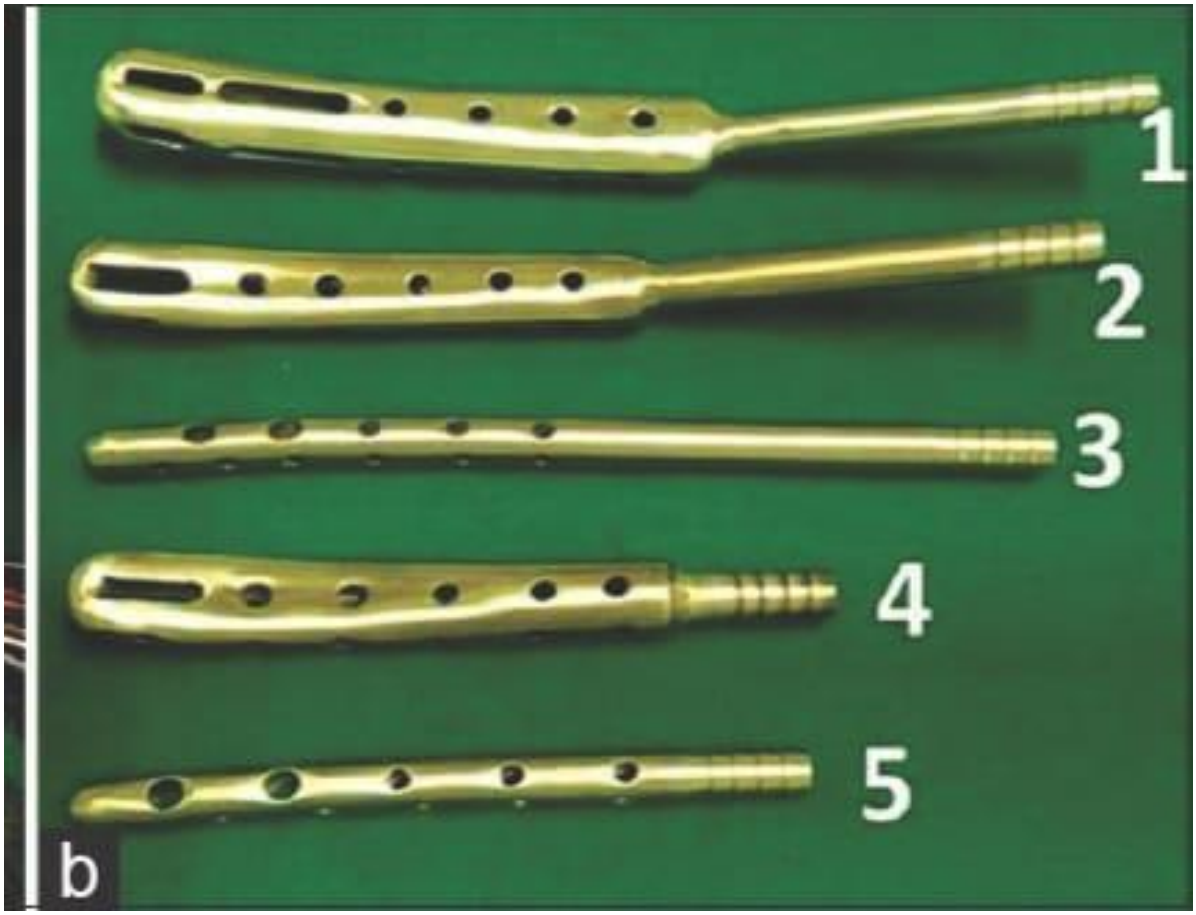
and has low surgical morbidity. A Bakri balloon is a balloon tamponade specifically constructed for uterine postpartum hemorrhage. While effective, commercially available devices may be expensive for settings in which postpartum hemorrhage is most common. Low-cost devices, such as the ESM-UBT, have been shown to be effective without the need for operative intervention.

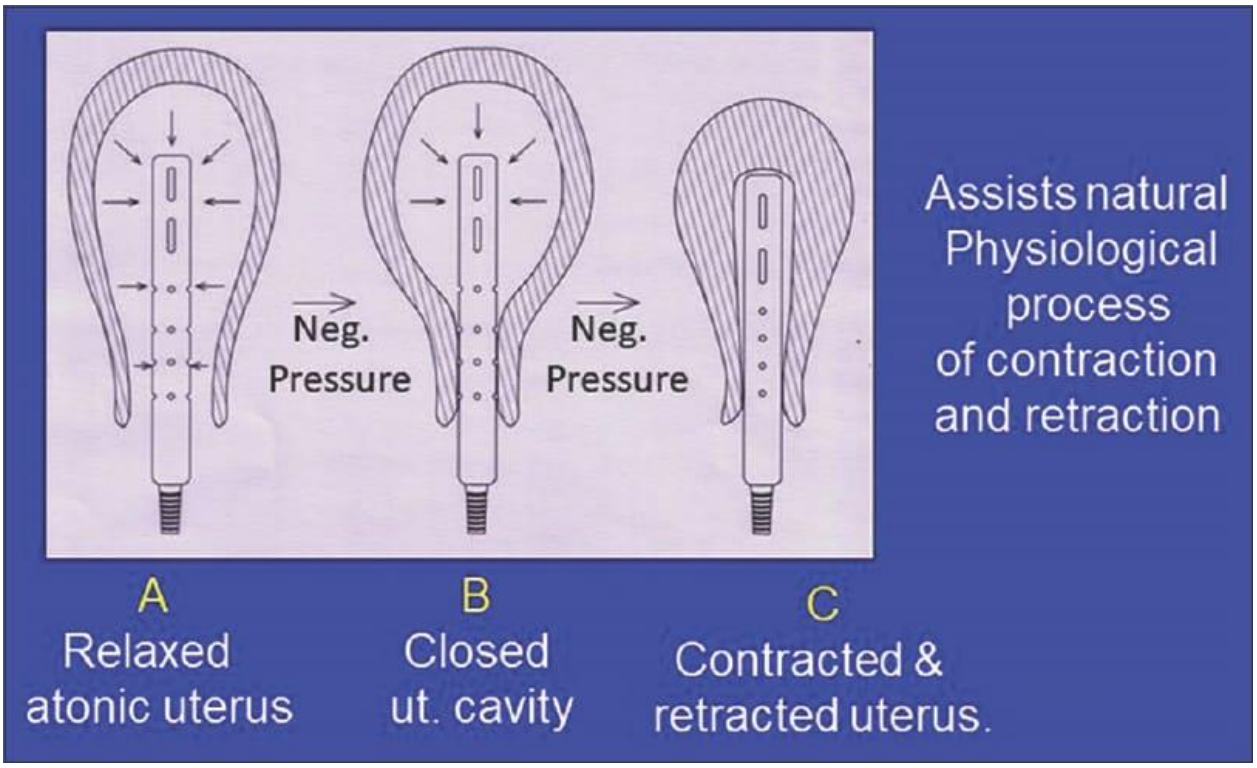
Protocols to manage postpartum bleeding are recommended to ensure the rapid giving of blood products when needed. A detailed stepwise management protocol has been introduced by the California Maternity Quality Care Collaborative. It describes four stages of obstetrical hemorrhage after childbirth and its application reduces maternal mortality.

- Stage 0: normal - treated with fundal massage and oxytocin.
- Stage 1: more than normal bleeding - establish large-bore intravenous access, assemble personnel, increase oxytocin, consider use of methergine, perform fundal massage, prepare 2 units of packed red blood cells.
- Stage 2: bleeding continues - check coagulation status, assemble response team, move to operating room, place intrauterine balloon, administer additional uterotonics (misoprostol, carboprost tromethamine), consider: uterine artery, dilatation and curettage, and laparotomy with uterine compression stitches or hysterectomy.

- Stage 3: bleeding continues - activate massive transfusion protocol, mobilize additional personnel, recheck laboratory tests, perform laparotomy, consider hysterectomy.






Neg.
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A
Relaxed
atonic uterus
B
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C
Contracted &
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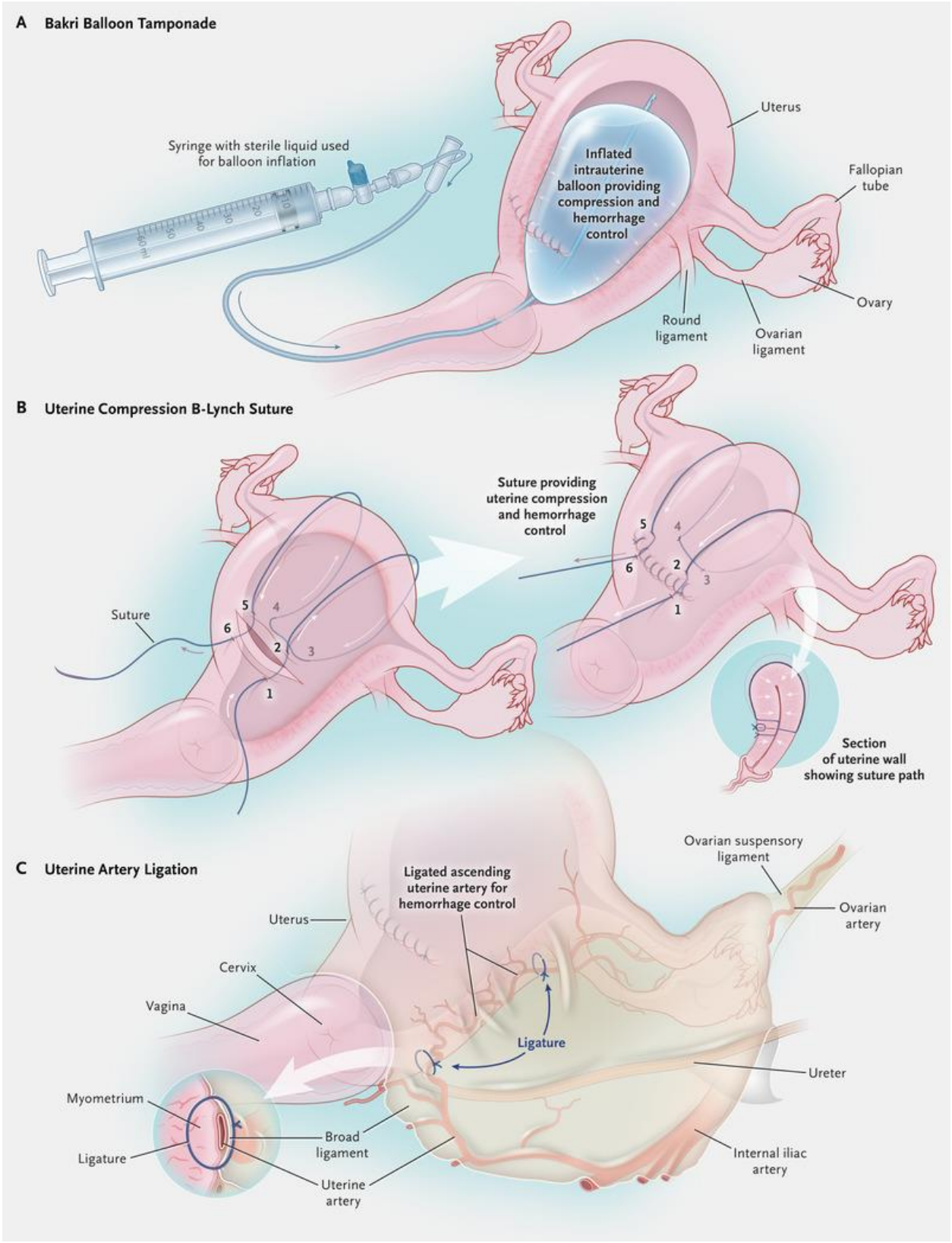
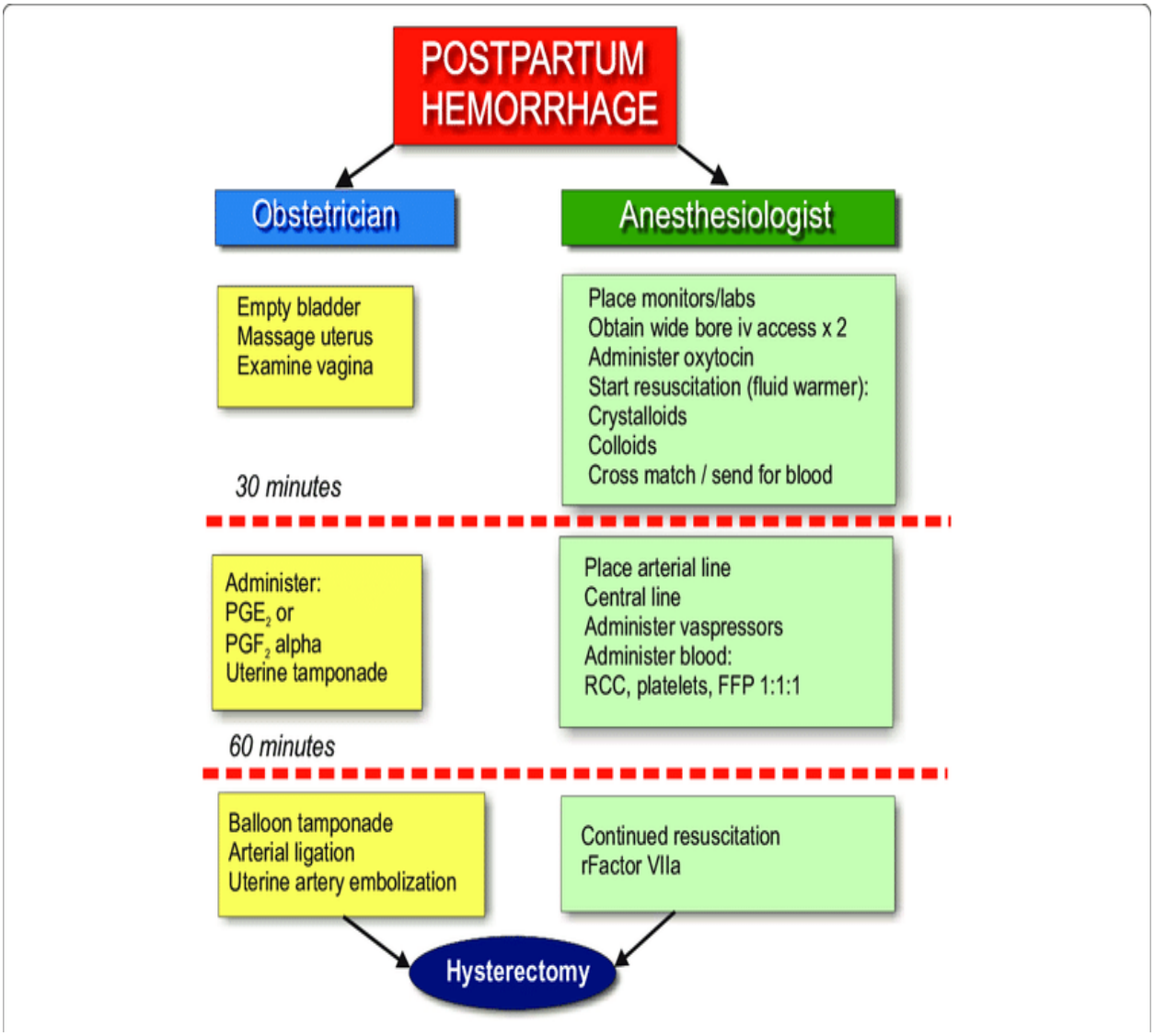

A Bakri Balloon Tamponade
Syringe with sterile liquid used for balloon inflation
Inflated intrauterine balloon providing compression and hemorrhage control
Uterus
Fallopian tube
Ovary
Round ligament
Ovarian ligament
B Uterine Compression B-Lynch Suture
Suture
Suture providing uterine compression and hemorrhage control
Section of uterine wall showing suture path
C Uterine Artery Ligation
Ligated ascending uterine artery for hemorrhage control
Uterus
Cervix
Vagina
Ligature
Myometrium
Broad ligament
Uterine artery
Ovarian suspensory ligament
Ovarian artery
Ureter
Internal iliac artery

A Cochrane review suggests that active management (use of uterotonic drugs, cord clamping and controlled cord traction) during the third stage of labour may reduce severe bleeding and anemia. However, the review also found that active management increased the patient's blood pressure, nausea, vomiting, and pain. In the active management group more patients returned to hospital with bleeding after discharge, and there was also a reduction in birth weight due to infants having a lower blood volume. The effects on the baby of early cord clamping was discussed in another review which found that delayed cord clamping improved iron stores longer term in the infants. Although they were more likely to need phototherapy (light therapy) to treat jaundice, the improved iron stores are expected to be worth increasing the practice of delayed cord clamping in healthy term babies.

For preterm babies (babies born before 37 weeks) a review of the research found that delaying cord clamping may lead to fewer babies with bleeding in the brain, compared to early cord clamping.

Another Cochrane review looking at the timing of the giving oxytocin as part of the active management found similar benefits with giving it before or after the expulsion of the placenta.

There is no good quality evidence on how best to treat a secondary PPH (PPH occurring 24 hrs or more after the birth).



Postpartum anemia is common after an episode of uterine atony and postpartum hemorrhage. Severe anemia due to PPH may require red cell transfusions, depending on the severity of anemia and the degree of symptomatology attributable to anemia. A common practice is to offer a transfusion to symptomatic women with a hemoglobin value less than 7 g/dL. In

most cases of uterine atony-related postpartum hemorrhage, the amount of iron lost is not fully replaced by the transfused blood. Oral iron should thus be also considered. Parenteral iron therapy is an option as it accelerated recovery. Most women with mild to moderate anemia, however, resolve the anemia sufficiently rapidly with oral iron alone and do not need parenteral iron.

The Joint Commission recommends that obstetrical staff undergo interprofessional team training to teach staff to work together and communicate more effectively when postpartum hemorrhage (most due to uterine atony) occurs. The Commission is in favor of clinical drills to help staff prepare for the clinical event, as well as conducting debriefings after such events to evaluate team performance and identify areas for improvement. Simulation team training can help to identify areas that need strengthening, and regular, unannounced, simulated, postpartum hemorrhage scenarios in real-life settings, such as the labor and delivery units or post-anesthesia care units, may also increase comfort with the protocols and teamwork required in such emergencies.

Prendiville et al (1988) highlighted the fact that prevention is the primary aim. Active management of third stage of labour reduces PPH by 30-40%. (16)

Prendiville at al (2002) observed that active management was superior to expectant management. There was significant reduction in postpartum blood loss, need for therapeutic oxytocics and postnatal blood transfusion (17).

Bristol third stage trial, showed incidence of postpartum haemorrhage was 5% in actively managed group where as 7.9% in control group (18).

Brandt (1983) explained placental separation mechanism and its expulsion in detail. Brandts technique allowed clamping of umbilical cord near to vulva immediately after the delivery of the baby. Gentle palpation of uterus is done to determine whether the uterus is contracted. Change in size and shape of uterus after several uterine contractions indicates placental separation. With one hand, clamp near the vulva is held firmly and other hand is placed over the abdomen and pressed between pubic symphysis and fundus. If placenta is separated traction of cord will deliver the placenta (19).

Andrews (1940) described method of expulsion of the placenta and shown good result with Norman Kimbell modified the technique. He used forceps to grasp the umbilical cord instead of using hand (20).

Dee-Lee Green hill (1947), Kimbell (1958), Elwin (1960), Clyne (1963), Donald (1964) extensively advocated Brandt-Andrews technique and found to be simple, safe and free from uterine inversion(21).

Spencer (1962) described modified Brandt-Andrews method by combining Brandt-Andrews method with oxytocic intravenously during the delivery of anterior shoulder and replaced the term with controlled cord traction(22).

Djahanhakhch and Vere (1978) recommended intramuscular oxytocic agent for prophylactic management of third stage of labour(23).

Thornton et al (1988) described natural Vs active management of third stage of labour and oxytocic in third stage of labour. It recommends oxytocin intramuscularly during third stage (24).

Elbourne D (1988) stressed upon prophylactic use of oxytocin reduces PPH by 40%(25).

De Groot AN (1995) described that postpartum hemostasis mainly depends on mechanical events that induces contraction of uterine musculature(26).

The Cochrane Systemic review (2000) compared expectant Vs active management of third stage of labour. Active management were associated with shorter third stage, reduced risk of PPH, reduced risk of anemia, decreased use of additional uterotonics and decreased the need for blood transfusion (27).

Bibi (2007) described uterine artery is responsible for 70% of all causes of Postpartum hemorrhage (28).

Stanton CK et al (2013) assessed the safety effects and feasibility of oxytocin in prevention of PPH by the health care providers at home births. They concluded that health care planners adopted this technique to extend oxytocin use into peripheral settings (29).

Pantoja et al (2016) assessed safety of oxytocin in non-facility birth settings in third stage of labour to prevent PPH. The intervention decreased the incidence of PPH, maternal morbidity and mortality (30).

Garabedian C et al (2016)51 in their study concluded that routine use of 5 units of oxytocin injection reduces the risk of moderate PPH but it does not affect the risk of severe PPH (31).

Samartha Ram H et al (2014)52 studied that creating negative pressure within the uterine cavity results in the shrinkage of uterus which aid the natural physiological process of retraction and contraction of uterus, thereby it stops atonic PPH. This study was conduct on 20 women who developed atonic PPH out of which 16 were delivered vaginally and 4 delivered by caesarean section. Uterine cannula measuring 25cm long and 20/18mm diameter with uterine angle of with multiple perforation of cervical and uterine portion of cannula were used. When the uterus is atonic and does not contract and retract in routine medical measures, the cannula is inserted into uterine cavity until it reaches the fundus of the uterus. Thick walled suction tube is used to connect the cannula to suction apparatus negative pressure of 650 mmHg was created and maintained for 10 minutes. This was repeated every hour for 3 hours or when there is recurrence of bleeding. After creating negative pressure the uterus becomes firm and contracted and uterine bleeding stops. For all patients bleeding arrested within 4 minutes of initiation of procedure. Amount of blood collected in suction bottle vary from 150-250ml. This study concluded that vacuum shrinkage of uterus assist the physiological process of uterine contraction and retraction for atonic PPH. This will avoid laparotomy and can be used even in low resource setting. This is cost effective, simple, life saving and fertility saving technique (32).

Bela makhija et al (2014) conducted study on 9 patients who developed atonic PPH refractory to medical management. Suction and evacuation of uterine cavity done and cannula was inserted inside the uterine cavity for about 20-30 minutes and negative pressure was maintained at 400-600 mmHg. It was an retrospective observational study conducted from July 2011 till December 2012. Out of 9 patients 6 was delivered by caesarean section and 3 by normal vaginal delivery. Prolonged labour was the commonest cause for uterine atony. PPH was effectively controlled in 8 patients and 1 patient went in for life saving hysterectomy. Author concluded that this technique is less challenging and can be used in low research setting that requires only minimal straining (33).

Purwosunu Y et al (2016) used vacuum induced tamponade as an alternative approach to balloon tamponade in treatment of postpartum haemorrhage due to uterine atony. In this study 10 women with vaginal delivery who failed medical management of PPH, tamponade was used. Vacuum induced uterine tamponade device was inserted into uterine cavity transvaginally. Device shaft has a built in occlusion balloon and inflated at the level of external os and uterine seal is created with self contained vacuum pump. In all the 10 cases, 50-250ml of blood was evacuated from uterine cavity. Uterus collapsed and regained its tone within ten minutes and PPH controlled. The device is left in place for 1 hour and upto 6 hour 30 minutes in one case (34).

Panicker (2017) proposed safe and simple technique for prevention and management of PPH thereby decreasing maternal morbidity and mortality. This study was conducted in 65 women out of which 40 women delivered vaginally and 15 women by LSCS who developed PPH in a low resource maternity hospital. All the women had atonic PPH inspite of all uterotonic drugs being used. A specially designed stainless steel cannula or plastic cannula of 25cm in length and 12mm in diameter with multiple perforation of 4mm diameter is introduced into uterine cavity upto fundus. Then suction apparatus is connected to the cannula and negative pressure of about 700 mmHg was created. The negative pressure created results in aspiration of blood in uterine cavity. About 50-300ml of blood sucked and when the blood was sucked out, bleeding ceased. The negative pressure was maintained for about 30 minutes and the cannula is slowly removed after releasing the suction. The uterus was well contracted and no bleeding per vagina. 5 patients had bleeding from vaginal tears and the same sutured (35).

Meena M and Meena P et al conducted a study to find the use of vacuum suction cannula in the management of atonic PPH in a tertiary care hospital in Rajastan in the year 2018. Twenty five women with different risk factors for atonic PPH like obstructed prolonged labour, accidental haemorrhage, PIH, anaemia complicating pregnancy, multifetal pregnancy, and hydramnios, either

alone or in combination, and who delivered either normally or by caesarean section were included in this study. Age, parity, gestational age at delivery was recorded. The uterine portion of the cannula was inserted into the uterine cavity up to the level of fundus immediately after placental delivery in both cases of vaginal and caesarean deliveries. The nipple of the cannula was connected to suction machine with thick walled flexible non collapsible suction tube. A negative pressure of 650 mmHg was created inside the uterine cavity and maintained for 10-15mints. Application of negative pressure was repeated every hour for 10mints for 3hours. The cannula was removed one hour after last suction procedure. The blood collected in suction bottle was measured and recorded. Complete cessation of bleeding which was associated with contraction and firm retraction of uterus was observed in mostly women within 4mns after initiation of procedure. The amount of blood collected in suction bottle ranged from 50ml to 350ml. They concluded that vacuum shrinking of uterus is a very effective physical method which can assist the natural physiological process of contraction and retraction to stop atonic postpartum haemorrhage. This simple, cost effective, life-saving, and fertility saving technique, which can avoid laparotomy can be made available in any setting, and can become the first defence against atonic PPH (36).

Ram HS et al conducted a study to find the effectiveness of Vacuum retraction of uterus for the management of atonic postpartum hemorrhage in

Kerala in the year 2014. Sixteen women who had normal vaginal delivers, and 4 women who underwent caesarean sections, who developed atonic postpartum hemorrhage, and who did not respond well for routine use of Inj. methergine, oxytocin, and Carboprost were included in the study. A specially designed uterine cannula measuring 25cm long and with 12/18mm diameter, with uterine angle, and with multiple perforations on uterine portion was used. When bleeding did not stop due to uterine atony in vaginal deliveries in spite of routine measures, the uterine portion of the cannula was inserted in to uterine cavity up to fundus, and the outer end was connected to suction machine with thick walled flexible tubing. A negative pressure of 650mmHg was created inside the uterine cavity and maintained for 10mns. This procedure was repeated every hour for 3 hours. After this the negative pressure was created whenever there was recurrence of bleeding. In case of caesarean section, the cannula was inserted through the uterine wound and brought outside through vagina. Negative pressure was applied after closure of uterine wound. The cannula was removed in all women 6 hours after initiation of procedure. Complete cessation of bleeding which was associated with contraction and firm retraction of uterus was observed in all women within 4mns after initiation of procedure. The amount of blood collected in suction bottle ranged from 150ml to 250ml. This study also found that vacuum shrinking of uterus is a very effective physical method which can assist the natural physiological process of contraction and retraction to stop atonic postpartum hemorrhage. This simple,

cost effective, life-saving, and fertility saving technique, which can avoid laparotomy can be made available in any setting, and can become the first defense against atonic PPH .

Pingray V et al did a systemic review to find the effectiveness of uterine tamponade devices for refractory postpartum haemorrhage after vaginal birth. They included all randomized and non randomized comparative trials published since inception till the year 2021. Composite outcome including surgical interventions (artery ligations, compressive sutures or hysterectomy) or maternal death, and hysterectomy. All included studies were at high risk of bias. The certainty of the evidence was rated as very low to low. One randomised study measured the effect of the condom-catheter balloon compared with standard care and found unclear results for the composite outcome (relative risk [RR] 2.33, 95% CI 0.76–7.14) and hysterectomy (RR 4.14, 95% CI 0.48–35.93). Three comparative studies assessed the effect of including uterine balloon tamponade in institutional protocols. A stepped wedge cluster randomised controlled trial suggested an increase in the composite outcome (RR 4.08, 95% CI 1.07–15.58) and unclear results for hysterectomy (RR 4.38, 95% CI 0.47–41.09) with the use of the condom-catheter or surgical glove balloon. One nonrandomized study showed unclear effects on the composite outcome (RR 0.33, 95% CI 0.11–1.03) and hysterectomy (RR 0.49, 95% CI 0.04–5.38) after the inclusion of the Bakri balloon. The second non-randomised study

found unclear effects on the composite outcome (RR 0.95, 95% CI 0.32–2.81) and hysterectomy (RR 1.84, 95% CI 0.44–7.69) after the inclusion of Ebb or Bakri balloon. The authors felt that the effect of uterine tamponade devices for the management of atonic refractory PPH after vaginal delivery is unclear, as is the role of the type of device and the setting. (37)

Pingray V et al conducted a systemic review and meta analysis to find the effectiveness of uterine tamponade devices for the management of refractory post partum haemorrhage after vaginal birth. They included studies published in databases PubMed, EMBASE, CINAHL, LILACS and POPLINE. Twenty-four types of tamponade devices were identified. The Bakri and the condom-catheter balloon were the most frequently reported. One randomised controlled trial suggests non-significant increases in the composite outcome (RR 2.33, 95%CI 0.76-7.14) and hysterectomy (RR 4.14, 95%CI 0.48-35.93) are associated with the use of the condom-catheter balloon vs. no device. Another RCT suggests a non-significant reduction in the composite outcomes (RR 0.60; 95%CI 0.16-2.31) and hysterectomy (RR=0.5; 95%CI 0.05- 5.25) with the Bakri balloon vs the condom-catheter balloon. Three comparative studies assessed the effect of introducing UBTs into clinical settings. A stepped-wedge study suggests an increase in the composite outcome (RR 4.08, 95%CI 1.07-15.58), and a non-significant increase in hysterectomies (RR 4.38, 95% CI 0.47-41.09) associated with the use of the condom-catheter or surgical glove balloon. Conversely, the

pooled estimate of the non-randomised studies showed a non-statistically significant reduction (RR=0.61, 95%CI 0.27-1.40) in the composite outcome and no effect on hysterectomy associated with the use of the Bakri balloon(38)

Haslinger C et al did a study to find the effectiveness of vacuum induced tamponade for treatment of postpartum haemorrhage. All women treated with vacuum-induced tamponade using a modified balloon system were included in this study. Aiming to reduce uterine size for control of postpartum hemorrhage, the intrauterine balloon was filled to 50–100 mL and connected to a vacuum device. Success rate of vacuum-induced tamponade, defined as no need for additional interventional treatment, was analyzed by etiology of postpartum hemorrhage and time period of use. Vacuum-induced tamponade was applied in 66 women. Success rate was 86% in women with uterine atony (n=44) and 73% in women with postpartum hemorrhage due to placental pathology (n=22). Success rate improved over the study period, culminating in a success rate of 100% in women with postpartum hemorrhage due to uterine atony in the second half of the observation period (n=22). This observational study supports our pathophysiologic understanding of uterine atony: to treat an atonic uterus, uterine volume must be reduced, leading to coiling of the uterine spiral arteries and, hence, reduced blood loss(39)

Dildy GA et al conducted a study with the objective of finding the use of tamponade of the uterus in decreasing hemorrhage secondary to uterine atony when uterotonics fail to fail to cause sustained uterine contractions and satisfactory control of hemorrhage. A total of 57 women were enrolled: 55 women had the diagnosis of postpartum hemorrhage, and 51 women had uterine balloon placement within the uterine cavity. This study reports the outcomes in the 51 women who had uterine balloon placement within the uterine cavity for treatment of postpartum hemorrhage, as defined by the "Instructions for Use." We further assessed 4 subgroups: uterine atony only (n = 28 women), placentation abnormalities (n = 8 women), both uterine atony and placentation abnormalities (n = 9 women), and neither uterine atony nor placentation abnormalities (n = 6 women). The median (range) time interval between delivery and balloon placement was 2.2 hours (0.3-210 hours) for the entire cohort (n = 51 women) and 1.3 hours (0.5-7.0 hours) for the uterine atony only group (n = 28 women). Bleeding decreased in 22/51 of cases (43%), stopped in 28/51 of cases (55%), thus decreased or stopped in 50/51 of the cases (98%) after balloon placement. Nearly one-half (23/51) of all women required uterine balloon volumes of >500 mL to control bleeding. They concluded that uterine/vaginal balloon tamponade is very useful in the management of postpartum hemorrhage because of uterine atony and abnormal placentation (40)

Suarez S et al conducted a systematic review and meta-analysis to assess the efficacy, effectiveness, and safety of uterine balloon tamponade for treating postpartum hemorrhage. They included all studies from electronic databases (from their inception to August 2019) and bibliographies. The primary outcome was the success rate of uterine balloon tamponade for treating postpartum hemorrhage (number of uterine balloon tamponade success cases/total number of women treated with uterine balloon tamponade). Ninety-one studies, including 4729 women, met inclusion criteria (6 randomized trials, 1 cluster randomized trial, 15 nonrandomized studies, and 69 case series). The overall pooled uterine balloon tamponade success rate was 85.9% (95% confidence interval, 83.9-87.9%). The highest success rates corresponded to uterine atony (87.1%) and placenta previa (86.8%), and the lowest to placenta accreta spectrum (66.7%) and retained products of conception (76.8%). The uterine balloon tamponade success rate was lower in cesarean deliveries (81.7%) than in vaginal deliveries (87.0%). A meta-analysis of 2 randomized trials that compared uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to uterine atony after vaginal delivery showed no significant differences between the study groups in the risk of surgical interventions or maternal death (relative risk, 0.59; 95% confidence interval, 0.02-16.69). A meta-analysis of 2 nonrandomized before-and-after studies showed that introduction of uterine balloon tamponade in protocols for managing severe postpartum hemorrhage significantly decreased the use of

arterial embolization (relative risk, 0.29; 95% confidence interval, 0.14-0.63). A nonrandomized cluster study reported that use of invasive procedures was significantly lower in the perinatal network that routinely used uterine balloon tamponade than that which did not use uterine balloon tamponade (3.0/1000 vs 5.1/1000; P < .01). A cluster randomized trial reported that the frequency of postpartum hemorrhage-related invasive procedures and/or maternal death was significantly higher after uterine balloon tamponade introduction than before uterine balloon tamponade introduction (11.6/10,000 vs 6.7/10,000; P = .04). Overall, the frequency of complications attributed to uterine balloon tamponade use was low (≤6.5%). The results of this extensive systematic review and meta-analysis show that uterine balloon tamponade has a high success rate for treating severe postpartum hemorrhage and appears to be safe. The evidence on uterine balloon tamponade efficacy and effectiveness from randomized and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect, in contrast with observational studies. Further research is needed to determine the most effective programmatic and healthcare delivery strategies on uterine balloon tamponade introduction and use(41)

Wright CE et al conducted a systematic review to find out the role of bakri balloon in the management of post partum haemorrhage. They included all studies published in PubMed database from the year 2001 to 2013. A total of 12 studies were included in the analysis. Four reports provided the frequency of

Bakri use during the study period, with the overall rate being 0.20% (138/69, 174; 95% CI, 0.17-0.25%). Two-thirds of use followed cesarean delivery (67%; 182/273). Uterine atony was specified as the underlying etiology of postpartum hemorrhage in 75% (9/12) of publication. The rate of balloon displacement was 10% (95% CI, 6-16%) and need for transfusion, 43% (95% CI, 32-55%). Hysterectomy was undertaken in 6% (95% CI, 4-10%)(42)

Quandalle A et al designed a study to assess the impact of intrauterine balloon tamponade as a second-line technique before resorting to emergency peripartum hysterectomy in cases with severe postpartum hemorrhage and uterotonic treatment failure following vaginal delivery. They conducted a retrospective, monocentric study evaluating cases of uterotonic treatment failure with severe postpartum hemorrhage following vaginal delivery between January 2005 and June 2018. Cases of cesarean section, amniotic embolism, uterine rupture, placenta accreta, and postpartum hemorrhage by vaginal laceration were excluded. The primary study outcome was incidence of emergency peripartum hysterectomy before and after use of intrauterine balloon tamponade was initiated. Among the 55,776 women who gave birth vaginally at our site during the study period, 161 (0.3 %) had severe postpartum hemorrhage with medical treatment failure (78 during the period prior to intrauterine balloon tamponade use, and 83 after intrauterine balloon tamponade use was initiated). The intrauterine balloon tamponade failure rate was 21.9 % (n = 18).

Emergency peripartum hysterectomy was performed in 7 cases prior to intrauterine balloon tamponade use and 2 cases during use of intrauterine balloon tamponade. Thus, we observed a nonsignificant decrease in emergency peripartum hysterectomy after use of intrauterine balloon tamponade was implemented (9.0 % vs. 2.4 %, p = 0.09). However, the decrease was significant among patients who underwent conservative surgical treatment before intrauterine balloon tamponade use (53.8 % vs. 12.5 %, p = 0.041). Though they did not find a significant overall reduction in emergency peripartum hysterectomy following implementation of intrauterine balloon tamponade, there was a decrease in these cases when conservative surgical treatment was followed by intrauterine balloon tamponade(43).

Ramler PI et al conducted a cohort study to compare the outcomes of women who were initially managed by intrauterine balloon tamponade or uterine artery embolization because of persistent postpartum hemorrhage demanding an immediate intervention to control bleeding. This 1:1 propensity score-matched cohort study comprised of 50 women who had intrauterine balloon tamponade and 50 women who underwent uterine artery embolization at a blood loss between 1000 and 7000 mL. There was no statistically significant difference in the hysterectomy risk between the two groups (n = 6 in each group, odds ratio [OR] 1.00, 95% confidence interval [CI] .30-3.34), in total volume of blood loss (median 4500 mL, interquartile range [IQR] 3600-

5400) for balloon vs 4000 mL (IQR 3250-5000) for embolization, P = 0.382) or in total units of packed red blood cells transfused (median 7 (IQR 5-10) for balloon vs 6 [IQR 4-9] for embolization, P = 0.319). Fifteen women (30%) who were initially managed by an intrauterine balloon still underwent uterine artery embolization, of whom one had an embolization-related thrombo-embolic event. Maternal mortality occurred in neither of the intervention groups. They concluded that there was no difference in the risk of peripartum hysterectomy and/or maternal death was observed between women who had intrauterine balloon tamponade and women who underwent uterine artery embolization as an initial management for persistent postpartum hemorrhage(44).

Yoong W et al in their study tried to find the effectiveness of uterine compression suture in association with intrauterine balloon tamponade (uterine sandwich) in women who had had unsuccessful medical treatment for postpartum hemorrhage. Ten of the 11 patients had cesarean sections (complicated by placenta previa and uterine atony) and one had a normal delivery. The median estimated blood loss and units of blood transfused were 1500ml (range 750-4000ml) and two units (range 0-9), respectively. B-Lynch sutures were placed in two patients and Hayman's modification was used in nine. Bakri balloon tamponade was in place for a median of 22 hours (range 17-27 hours), while the median volume infused in the balloon was 300ml (range 150-350ml). The combined technique was successful in avoiding hysterectomy in all cases, and there was no documented postpartum morbidity. They concluded that this is a simple and quick surgical technique that can be used to treat atonic postpartum hemorrhage, particularly in conjunction with placenta previa(45)

Alton ME et al conducted a study with an objective to evaluate the effectiveness and safety of an intrauterine vacuum-induced hemorrhage-control device for postpartum hemorrhage treatment. A multicenter, prospective, single-arm treatment study of a novel intrauterine device that uses low-level vacuum to induce uterine myometrial contraction to achieve control of abnormal postpartum uterine bleeding and postpartum hemorrhage was undertaken at 12 centers in the United States. The primary effectiveness endpoint was the proportion of participants in whom use of the intrauterine vacuum-induced hemorrhage-control device controlled abnormal bleeding without requiring escalating interventions. The primary safety endpoint was the incidence, severity, and seriousness of device-related adverse events. Secondary outcomes included time to bleeding control, rate of transfusion, and device usability scored by each investigator using the device. Out of 107 participants enrolled with primary postpartum hemorrhage or abnormal postpartum uterine bleeding, 106 received any study treatment with the device connected to vacuum, and successful treatment was observed in 94% (100/106, 95% CI 88-98%) of these participants. In those 100 participants, definitive control of abnormal bleeding was reported in a median of 3 minutes (interquartile range 2.0-5.0) after connection to vacuum. Eight adverse events deemed possibly related to the device or procedure were reported, all of which were outlined as risks in the study and all of which resolved with treatment without serious clinical sequelae. Transfusion of 1-3 units of red blood cells was required in 35 participants, and

five participants required 4 or more units of red blood cells. The majority of investigators reported the intrauterine vacuum-induced hemorrhage-control device as easy to use (98%) and would recommend it (97%). Intrauterine vacuum-induced hemorrhage control may provide a new rapid and effective treatment option for abnormal postpartum uterine bleeding or postpartum hemorrhage, with the potential to prevent severe maternal morbidity and mortality(46).

Matin E in their retrospective case series evaluated maternal outcomes following uterine balloon tamponade in the management of postpartum hemorrhage in France. All women who underwent balloon tamponade treatment for primary postpartum hemorrhage were included in this study. Uterine tamponade was used after standard treatment of postpartum hemorrhage had failed. The study population was divided into two groups, successful cases where the bleeding stopped after the balloon tamponade, and failures requiring subsequent surgery or embolization. The m**ain outcome measure was** success rate. Uterine tamponade was used in 49 women: 30 (61%) after vaginal delivery and 19 (39%) after cesarean section. Uterine atony was the main cause of hemorrhage (86%). The overall success rate was 65%. Of 17 failures, surgery was required in 16 cases, including hysterectomy in 11, and uterine artery embolization in one case. Demographic and obstetric characteristics did not differ significantly between the success and failure groups. No complications

were directly attributed to the balloon tamponade in the postpartum period. Two women had a subsequent full-term pregnancy without recurrence of postpartum hemorrhage. They concluded that balloon tamponade is an effective, safe and readily available method for treating primary postpartum hemorrhage and could reduce the need for invasive procedures(47)

Gauchotte E et al conducted a study to assess the impact of tamponade when uterotonic agents fail, on the need for surgery or interventional radiology. All women who received sulprostone for postpartum hemorrhage were retrospectively compared over two periods [December 2008 to December 2010 without use of tamponade (period 1) and June 2011 to June 2013 with use of tamponade (period 2)] were included in the study. During period 2, interventional radiology or surgery was used only in the case of tamponade failure. **A total of** 165 women were included (74 for period 1, 91 for period 2). The rate of interventional radiology or surgery significantly decreased from period 1 (21 of 74 women, 28.4%) to period 2 (six of 91 women, 6.6%, p = 0.0003). The rate of assumed failure of uterotonic agents was higher for period 2: 22 of 74 women (29.7%) during period 1, and 41 of 91 (45.1%, p = 0.0439) during period 2. The success rate of tamponade was 92.1% (35 of 38 women). The findings of this study confirm that tamponade significantly reduces the need for interventional radiology or surgery for postpartum hemorrhage treatment (48)

Park JE et al did a study to determine the effect of intrauterine balloon tamponade (IUBT) on the outcomes of postpartum hemorrhage (PPH) according to the balloon volume and to investigate the clinical factors associated with poor PPH outcomes. This study was a retrospective cohort study in which patients with PPH underwent IUBT from January 2016 to August 2018. Patients with an IUBT volume greater than 350 mL (n=76) were compared to patients with an IUBT volume less than 350 mL (n=213). The clinical outcomes related to PPH included blood transfusion, estimated blood loss (EBL) after balloon placement, uterine artery embolization (UAE) after IUBT, and postpartum hospitalization. The results were analyzed by multivariate logistic regression models. None of the clinical outcomes related to PPH and evaluated in our study were favorable in patients with an IUBT volume greater than 350 mL. Other factors associated with poor PPH outcomes after IUBT were placental site hemorrhage, shock index (SI) before IUBT, and antenatal hemoglobin. They concluded that it is better to avoid unnecessary balloon inflation in IUBT if the bleeding is reduced, and more attention should be paid to the procedure when the balloon is large (≥350 mL) than when it is small (<350 mL)(49)

METHODOLOGY

Study site

Department of Obstetrics and Gynaecology, Government Kasturba Gandhi hospital, Triplicane,Chennai-05

Study Design

Randomized study

Study Period

October 2019 to September 2021

Selection of study population

All patients in the labour room of ISO KGH ,developing atonic postpartum hemorrhage with failed medical management were the study population .

Procedure:

In our study around 100 study participants were recruited as they developed postpartum hemorrhage which is of atonic type in the labour room. Through computer generated random numbers all the even numbers were taken in group 1 where SR Cannula management will be given and all the off numbers were taken in group 2 where the Foley's tamponade were used for the management.With the help of foley's catheter the bladder is emptied initially

and then uterine massage is applied.40IU of oxytocin is mixed in500 ml NS at a rate of 60 drops per minute.Per rectally tablet misoprostol 1000 micrograms was kept.After applying all these measures also if the bleeding is uncontrolled and if the uterus appears flabby then the foley's catheter or vaccum retraction technique with the SR cannula is employed.-

In 50 women (Group 1-SR cannula) the bleeding is controlled using the SR vaccum retraction cannula.In good source of light the vaginal speculum of wide blade is applied and the anterior lip of the cervix is holded with the sponge holding forceps and the cannula's uterine side is inserted into the uterine cavity upto the level of fundus.The cannula's outer end through tubing is connected to the suction machine.With the help of the left palm through per abdomen fundus is supported and and the outer end of the cannula is held with the right fingers and then the cannula is pushed gently to the fundus.In this position the suction machine is on and a negative pressure of 650 mm Hg is created and for 10 minutes it is maintained.Then the suction machine is put off.This negative pressure makes the cannula to be hold in its position by the sucking effect of the soft tissues through the perforations on the cervical portion of the cannula.For every hour negative pressure should be created for 10 mins.Like this we will do the creation of negative pressure for 3 hours.If there is a recurrence of bleeding then the negative pressure should be created.The

cannula has to be hold in the position as long as there is threat for the recurrence of bleeding or till 24 hours which ever is long.

In 50 women (Group 2-Foleys tamponade) the bleeding is controlled using foley's tamponade .The foleys catheter of size 24F inside the uterus is introduced with the help of sponge holding forceps or can be manually into the uterine cavity using the ring forceps which helps in holding the cervix.Then after introducing the catheter the foley's catheter is inflated with the 40ml of normal saline.Then in order to measure the bleeding amount a urobag is connected.The urobag will contain marking through which amount of bleeding is measured.After 24 hours of the postpartum hemorrhage the catheter is deflated and removed.

Inclusion criteria

- All atonic Post partum hemorrhage women in the labour room with the failed medical management

Exclusion Criteria

- Women with latex energy
- Women diagnosed of traumatic PPH
- Women delivered an IUD fetus
- Women with coagulopathy or the sepsis

The patients baseline characteristics related to the study were gathered from the patients information sheet and then the details of the bleeding profile taken from the laboratory test.

Data Collection Method:

a. Data collection was done in the study area after obtaining permission from the Dean, Madras Medical college,Chennai and the Head of the Department, Department of Obstetrics and Gynecology and approval from the Institute Ethical Committee(Annexure)
b. All the patients with atonic PPH in the labour ward of Obstetrics and Gynecology department were recruited for the study.Patient history will be collected through the patient information sheet and laboratory test were done to find the bleeding.

Study Methods

- The patients who have satisfied inclusion and exclusion criteria will be enrolled in the study
- Participant will be given the informed consent and were considered in our study.
- The patients were divided into two groups the SR group and the Foley's group randomly.A total of 50 study participants in each group

- Detail history taking done as per the proforma with regard to menstrual cycles regularity,Obstetrical, medical and history obtained

Sample Size

All the Atonic PPH study participants in the labour ward were taken .Around 100 study participants were recruited within the study period.Each group contains 50 study participants

Sampling Method

Consecutive Sampling

Data collection tools:

Statistical Analysis

Descriptive statistics was expressed in terms of mean and percentages. statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test and Anova test. Categorical variables were analysed with the Chi-Square Test . $P < 0.05$ is considered as significance. The data was analysed using SPSS Version 16. Microsoft Excel 2007was used to generate charts.

Ethical Considerations

The following ethical guidelines were followed till the end of the research period:

- The dignity and wellbeing of patients was protected at all times.
- Research data is kept confidential throughout the research process, and researchers have obtained permission from patients to use their real names in research reports.

Research protocol was presented in Institutional Ethical review Board and due permission was obtained to undertake the study

Conflict of interest

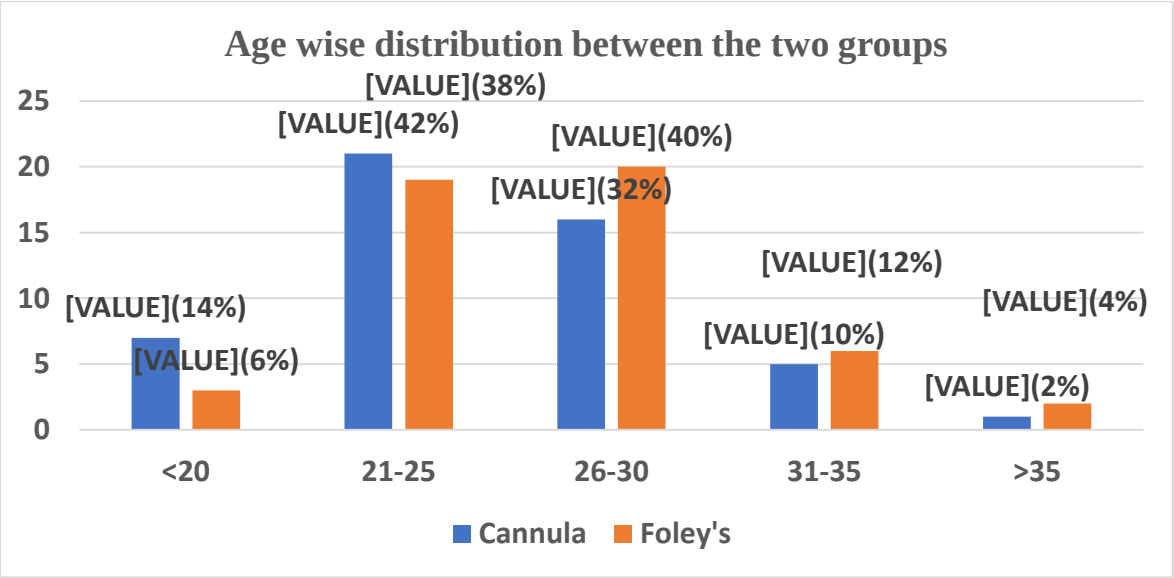
Study runs on your own with the support of the institution.. There is no commercial or conflict of interest

Operation definitions:

- **Postpartum hemorrhage:**It is defined by World health organisation as the blood loss of 500 ml or more than that within 24 hours after the delivery or giving birth.

RESULTS

Figure 1 :Age wise distribution of the study participants



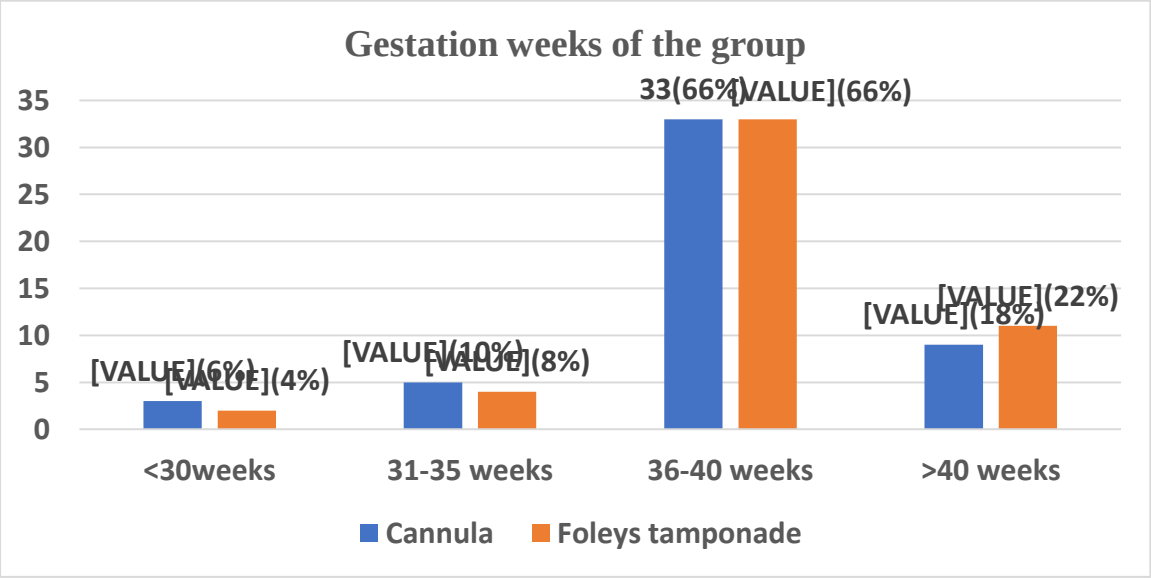
Among the study participants each group consist of 50 participants.Majority of our study participants belongs to the 21-25 years of age group in both the group followed by 26-30 years of age .In cannula group of participants 21(42%) belongs to 21-25 years of age followed by 16(32%) 26-30 years of age.7(14%) belongs to <20 years of age and 1(2%) belongs to >35 years of age.In foley's tamponade group 20(40%)belongs to the 26-30 years of age followed by 19(38%) .2(4%) belongs to >35 years of age group.

Table 1:Mean age of the study participants between the two groups

Groups	Mean	Standard deviation	P value
Cannula	25.18	4.59	0.14
Foley's tamponade	26.50	4.45	

The mean age of the cannula group is 24.18±4.59 and Foley's tamponade is 26.50±4.45 .There is a difference between the study groups but the difference is not statistically significant.

Figure 2:Gestational age wise distribution among the study groups



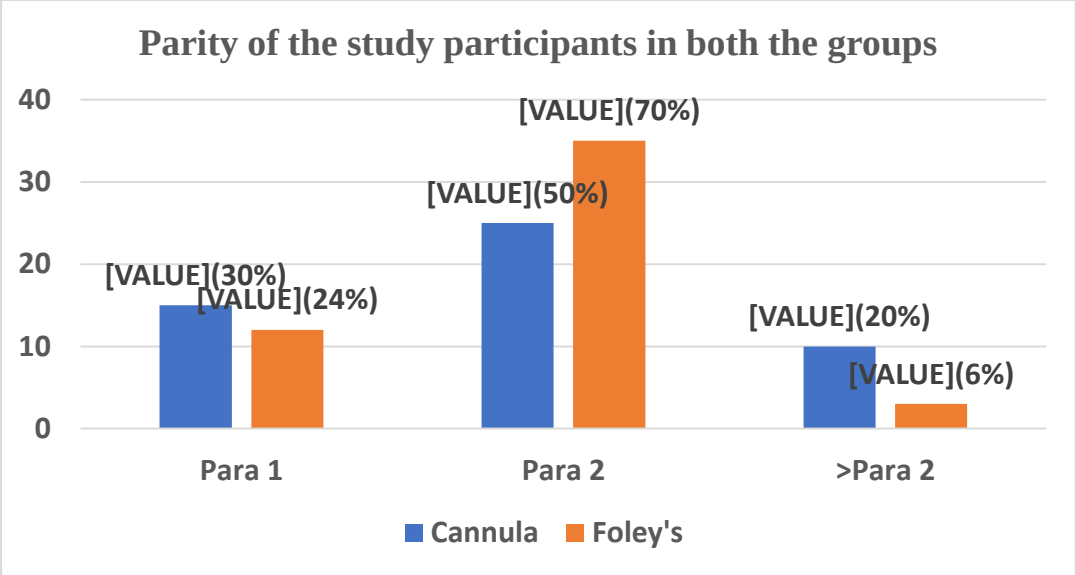
Majority of the participants have 36-40 weeks of gestation 33(66%) in both groups.In cannula group 3(6%) have gestational weeks <30 ,5(10%) have 31-35 weeks of gestation and 9(18%) have >40 weeks of gestation.In Foley's tamponade group 2(4%) have gestation of <30 weeks,4(8%) have 31-35 weeks of gestation and 11(22%) have >40 weeks of gestation.

Table 2:Gestation weeks of the two groups

Gestational weeks	**Cannula**	**Foley's**	**P value**
<30 weeks	**3**	**2**	**.000***
31-35 weeks	**5**	**4**	
36-40 weeks	**33**	**33**	
>40 weeks	**9**	**11**	
Total	**50**	**50**	

There is a difference between the two groups .There is statistical difference between the two groups.

Figure 3:



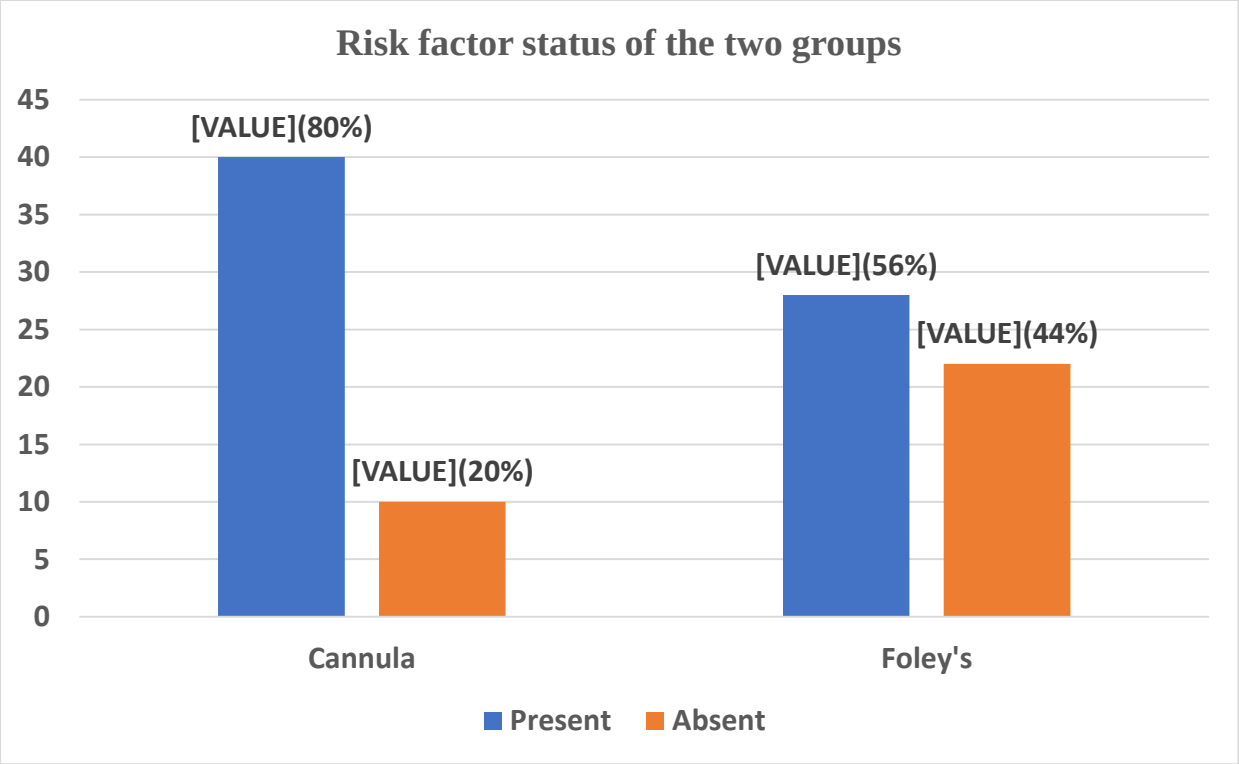
In our study majority of study participants were 2 Para.In Cannula group 15(30%) have para 1,25(50%) have para 2 and 10(20%) have more than para 2.In Foley's tamponade group 12(24%) have para 1,35(70%) have para 2 and 3(6%) have more than 2 para.

Table 3:Parity status of the study participants

Parity	Cannula	Foley's tamponade	P value
Para 1	15	12	0.56
Para 2	25	35	
>Para 2	10	3	
Total	50	50	

Among the both the groups in our study there is no difference between the groups and it is not statistically significant.

Figure 4:Risk factor status among the study participants:



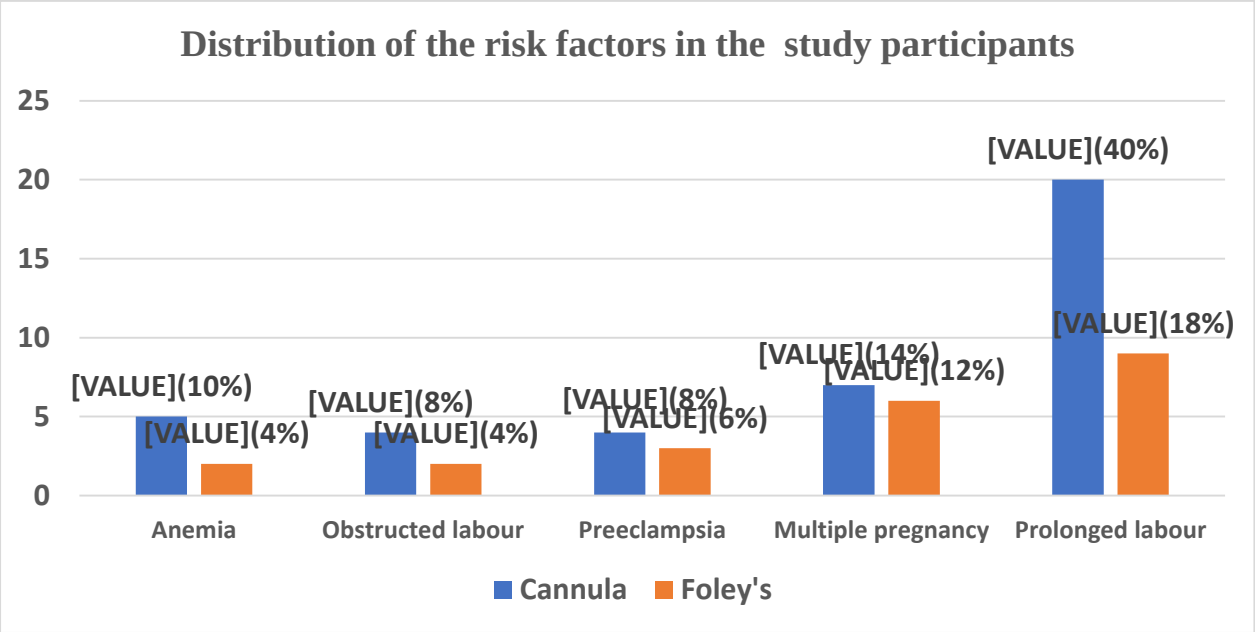
Among the study participants in Cannula group 40(80%) have risk factors whereas 10(20%) doesn't have risk factors.In Foley's tamponade group 28(56%) have risk factors whereas 22(44%) doesn't have risk factors.

Table 4:Risk factors of the study participants:

Risk factors	Cannula	Foley's	P value
Present	40(80%)	28(56%)	.000*
Absent	10(20%)	22(44%)	
Total	50	50	

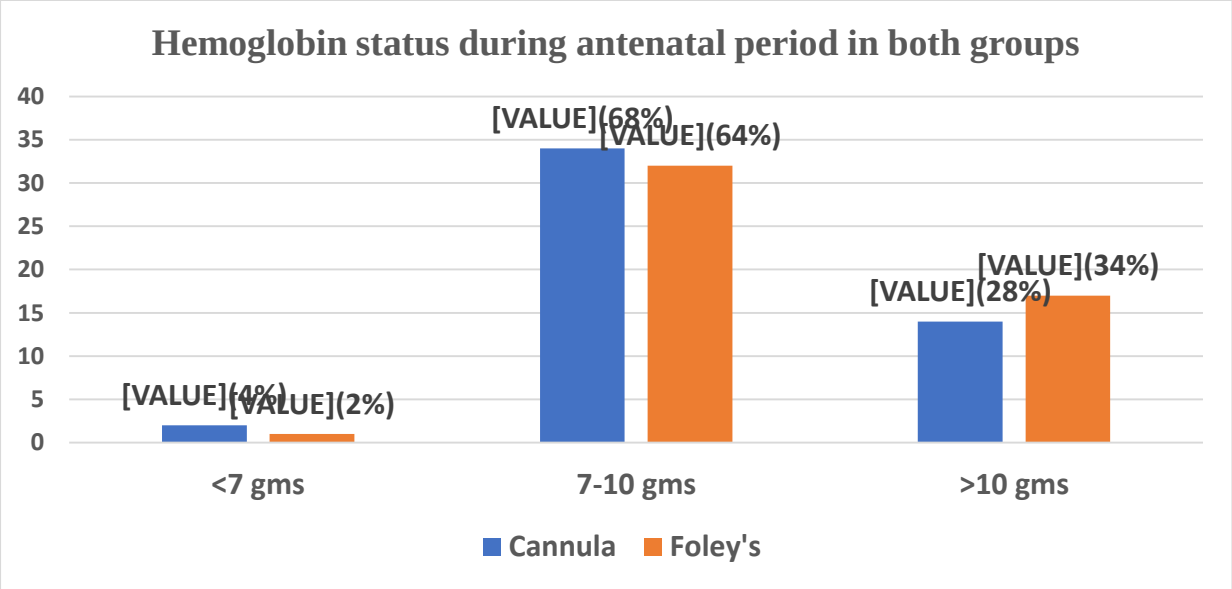
The risk factors was present more in the Cannula group 40(80%) compared to Foley's tamponade group 28(56%).There is a difference between the groups and the difference is found to be statistically significant.

Figure 5:Distribution of the risk factors in both the groups



The most common risk factor in both the groups is Prolonged labour (Cannula-20(40%),Foley's tamponade 9(18%)) followed by Multiple pregnancy (Cannula-7(14%) and Foley's tamponade 6(12%).Preeclampsia is the third risk factor found in both the groups (Cannula 4(8%) and Foley's tamponade 3(6%).Obstructed labour and Anemia is also found in both the groups.

Figure 6:Antenatal hemoglobin status of the study participants



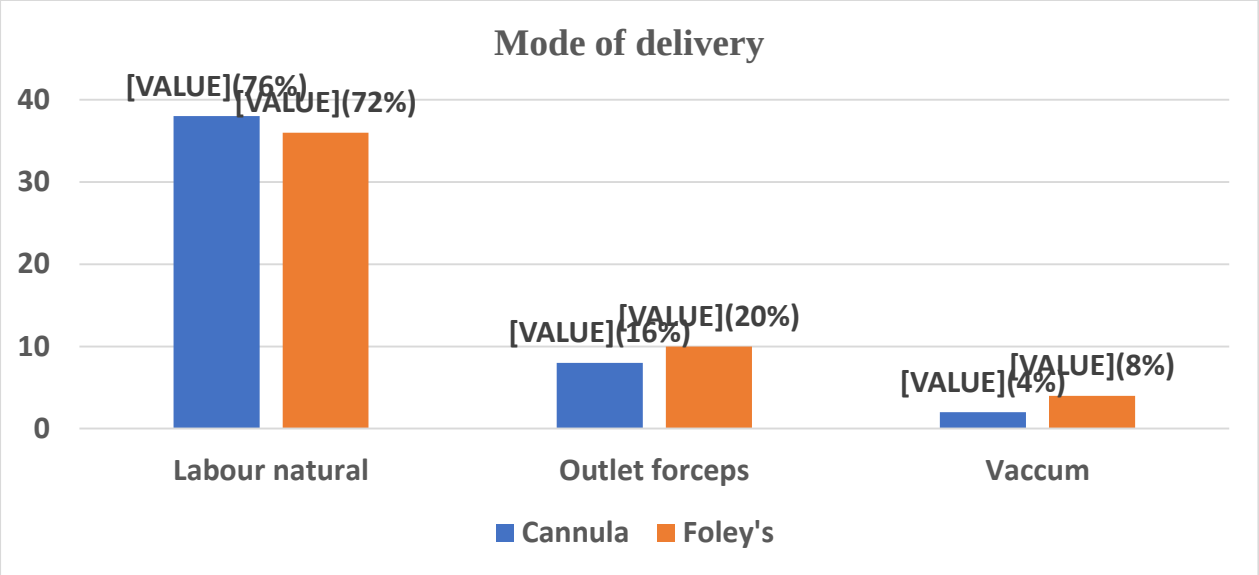
In Cannula group 2 34(68%) have 7-10 gms of hemoglobin and 14(28%) have >10 grams of hemoglobin .Only 2(4%) have <7 grams of hemoglobin.In Foley's tamponade group 32(64%) have 7-10 grams of hemoglobin,17(34%) have >10 grams of hemoglobin.Only 1(2%) have <7 grams of hemoglobin.

Table 5:Antenatal hemoglobin of the study participants

Hemoglobin	Cannula	Foley's tamponade	P value
<7 gms	2(4%)	1(2%)	.000*
7-10 gms	34(68%)	32(64%)	
>10 gms	14(28%)	17(34%)	
Total	50	50	

Majority of the study participants have 7-10 grams of hemoglobin followed by >10 grams of hemoglobin.There is a difference between the two group and it is found to be statistically significant.

Figure 7:Mode of delivery



Majority had labour natural followed by outlet forceps**.**

Table 6:Mode of the delivery in both groups:

Mode of delivery	**Cannula**	**Foley's tamponade**
Labour natural	**38(76%)**	**36(72%)**
Outlet forceps	**8(16%)**	**10(20%)**
Vaccum	**2(4%)**	**4(8%)**
Total	**50**	**50**

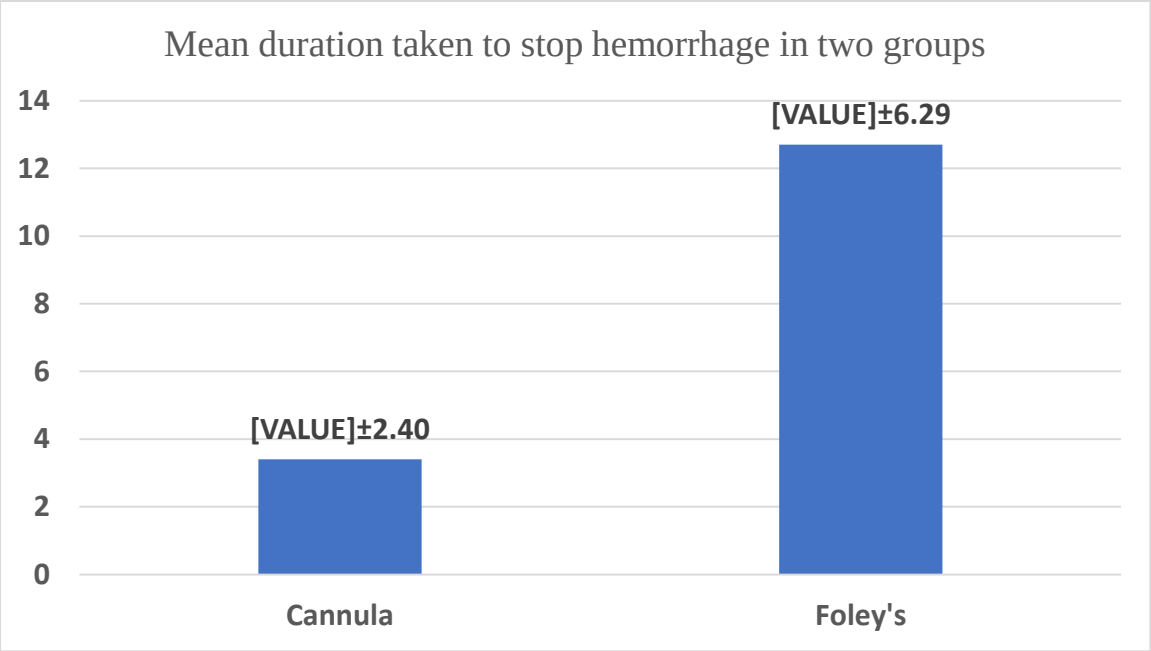
Among the Cannula group majority underwent labour natural 38(76%) followed by outlet forceps 8(16%).Vaccum is applied in 2(4%) of the participants.In Foley's tamoponade group 36(72%) underwent labour natural followed by forceps 10(20%) which in turn followed by 4(8%) vaccum.

Table 7:Duration of third stage of labour

Duration	Cannula	Foley's tamponade	P value
<5 minutes	33(66%)	32(64%)	0.41
>5 minutes	17(34%)	18(36%)	
Total	50	50	

In our study the duration of the third stage of the labour in majority of the participants is < 5 minutes (Cannula-33(66%) and Foley's tamponade 32(64%).There is no difference between the groups and it is not statistically significant

Figure 7:Time taken to stop the bleeding in two groups



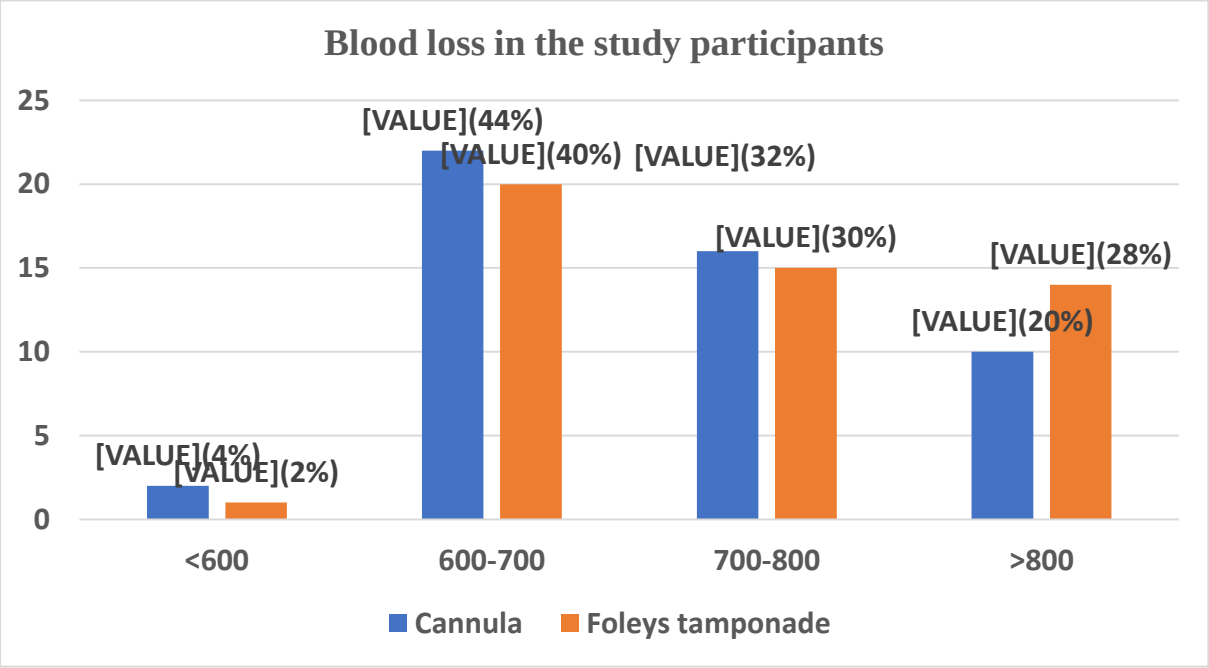
The mean time taken for the Cannula to stop the hemorrhage is 3.4±2.40 which is lesser than Foley's tamponade where the time taken to stop is 12.7±6.29.

Table 7:Mean duration to stop bleeding on both groups

	Cannula	Foley's tamponade	P value
Mean	3.4	12.7	**<.0001***
Standard deviation	2.40	6.29	
Total	**50**	**50**	

The Mean duration taken to stop bleeding is 3.4±2.40 which is lesser than the Foley's tamponade 12.7 ±6.29.There is a difference between the two groups and it is statistically significant.

Figure 8:Blood loss in the study participants:



In cannula group 22(44%) have 600-700 ml blood loss followed by 16(32%) have 700-800 ml blood loss.10(20%) have >800ml of blood loss.In Foley's tamponade group 20(40%) have blood loss followed by 15(30%) 700-800 ml of blood loss.14(28%) have blood loss more than 800 ml.

Table 8:Blood loss in the study participants:

Blood loss	**Cannula**	**Foley's tamponade**	**P value**
<600 ml	**2(4%)**	**1(2%)**	**0.27**
600-700 ml	**22(44%)**	**20(40%)**	
700-800 ml	**16(32%)**	**15(30%)**	
>800 ml	**10(20%)**	**14(28%)**	
Total	**50**	**50**	

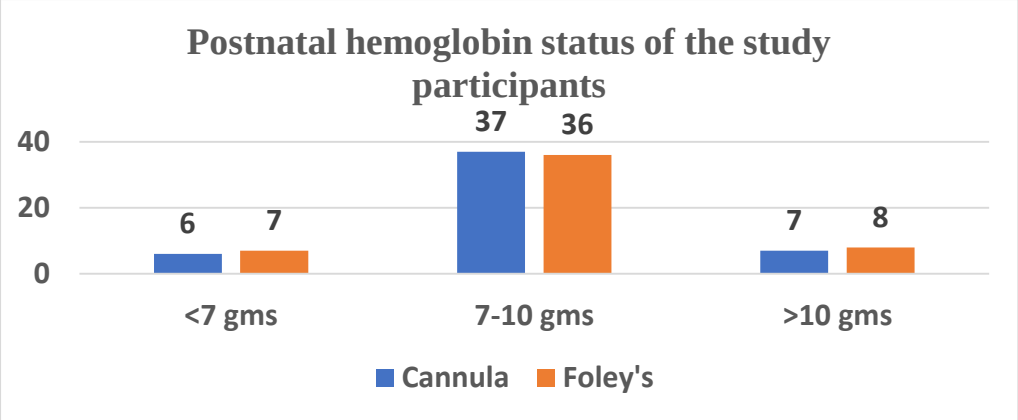
There is difference between the two groups but it is not statistically significant.

Table 9:Blood transfusion for the study participants:

Blood transfusion	**Cannula**	**Foley's tamponade**
Yes	25(50%)	40(80%)
No	25(50%)	10(20%)
Total	**50(100%)**	**50(100%)**

Among the cannula group only (25)50% received blood transfusion whereas in the Foleys tamponade 40(80%) received the blood transfusion**.**

Figure 9:Postnatal hemoglobin status of the study participants



Majority of the study participants have 7-10 grams of hemoglobin followed by >10 grams of hemoglobin in both the groups

Table 10:Postnatal hemoglobin status:

Hemoglobin	**Cannula**	**Foleys tamponade**	**P value**
<7 gms	**6(12%)**	**7(14%)**	**0.38**
7-10 gms	**37(74%)**	**36(72%)**	
>10 gms	**7(14%)**	**8(16%)**	
Total	**50**	**50**	

In Cannula group 37(74%) has 7-10 grams of hemoglobin followed by 6(12%) have <7 grams of hemoglobin.In Foley's tamponade group 36(72%) have 7-10 grams of hemoglobin followed by < 7 grams of hemoglobin 7(14%) .There is a difference between the groups and it is not statistically significant.

DISCUSSION

In developing world the most common cause of the maternal death is atonic postpartum hemorrhage.It is difficult to save mother due to the competent man power and compatible blood and transport.There are inadequate techniques available in the low resource setting to control the bleeding.In recent years an increase in trends is observed in atonic PPH.We doesn't know the reason why some develop PPH and some Not.Though many risk factors like Prolonged labour, anemia and big baby were the most important cause of atonic PPH.The rapidity with which the women slips to the coagulation failure and so multiorgan failure occurs due to hemorrhagic shock is alarming.Due to these reasons the maternal mortality is not decreasing in the developing countries.Thus a simple technique is needed to stop bleeding temporarily until further referral or to get some time to tide over the crisis.

In our study the majority of the study participants (41%)belongs to 21-25 years and (32%)26-30 years.Which is also similar to the study done by Samartha ram H et al (50)where the age ranges from 19-33 years of age.Similar findings is also seen in Bela Makhija et al (51)which also had age range between the 22-36 years of age.In our study majority were multigravida followed by primigravida which is similar to Bela Makhija et al(51) study .Primi gravida will always have a low blood loss compared to multigravida.

In our study more than half of the study participants 33(66%) have >40 weeks of gestation which may also plays a key role as a factor influencing Post partum hemorrhage.In our study more than 50% have risk factors in both the groups which is comparatively higher than Bela Makhija et al (51)study where the risk factor prevalence was found to be 18.3%

In our study more than 60% of the study participants in both the groups found to have 7-10 grams of hemoglobin which is similar to Suryanaryan et al(52) study .Thus anemia plays major role in pregnancy related complications.The mean duration to stop bleeding of the Cannula was found to be <4 minutes which is lesser than the Foley's tamponade group.Similar results was also found in the Samartha ram et al(50) in her study where the bleeding stopped in <4 mins after applying cannula.Similar results was also seen in theVasudev Panicker(53)et al study.

In our study the need for blood transfusion was less in cannula group (25)50% compared to the group which used Foleys tamponade 40(80%)The blood loss was less in cannula group compared to the foleys tamponade group.Similar results was also found in the Purwosunu et al(54) in his study where the minimal blood loss is seen in patients using uterine cannula.In our study there is a significant association is observed between the gestational weeks.Similarly in Samartha ram et al (50) it was said that the gestational age

has an influence on the blood loss and in Bela Makhiji et al (51) the gestational age was performed in gestational weeks 37-41 weeks.

In our study risk factors were found to have association with the PPH and it was found to be statistically significant.Risk factors including older age,multiple pregnancy,fetal macrosomia,preterm births ,genital tract injuries and non use of oxytocin ,intrauterine fetal death were also responsible for the PP.In our study the first risk factor is prolonged labour followed by multiple pregnancies and anemia.Whereas in a study done by Fukuami et al (55)anemia was found to be the first risk factor.

Thus the vaccum cannula is found to be better in reducing the blood loss by early arrest of bleeding compared to the balloon tamponade and also acts quickly.The need for blood transfusion is also found to be less compared to the balloon tamponade.All these factors makes vaccum cannula a better modality to stop PPH in low resource setting.

SUMMARY

In our study each group i.e the Cannula group and the Foley's method was used to compare the effectiveness on the postpartum hemorrhage .Each group consist of 50 participants..A total of 100 participants.

- Majority of the study participants belongs to 21-25 years of age (Cannula-21(41%) ,Foley's-19(32%) followed by the 26 to 30 years
- The mean age of the study participants in the Cannula group is 25.18±4.59 and that of the Foley's tamponade is 26.30±4.59
- There is no difference between the mean age of the study participants in both the groups and it is found to be not significant.
- In both the groups majority of the study participants have 36-40 weeks of gestation 33(66%)
- Nearly more than half of the study participants has gestation weeks 36-40 weeks
- There is difference between the gestational weeks in both the groups and it is found to be statistically
- Majority of the study participant have the pariy more than 2 followed by para 1
- There is no difference in the parity status of the study participants and it is found to be not statistically significant

- Risk factors was present in majority of the study participants (Cannula - 40(80%) and foleys-28(56%)
- The most common risk factor is the Prolonged labour (Cannula -20(40%) and foleys-9(18%)
- The second most common risk factor is multiple pregnancy(Cannula-7(14%) and Foleys tamponade-6(12%)
- Majority of the study participants have 7-10 grams of Antenatal hemoglobin Cannula-34(68%) and Foleys tamponade-32(64%)
- There is a difference exist between the antenatal hemoglobin and the difference is found to be statistically significant.
- Most of the study participants stated that the delivery was conducted by the Labour naturalis in both the groups It is observedCannula-38(76%) and Foleys tamponade- .72(64%)followed by the outlet forceps
- The duration of the third stage of labour in Cannula group and Foleys tamponade group were similar in<5 mins of age (Cannula-33and Foleys - 32%
- There is no difference exist on duration of the third stage of labour and it is not found to be clinically stable.
- The mean duration to stop bleeding in Cannula is 3.4±2.40 and the Foley's tamponade is 12.7±6.29

- There is a difference in the mean duration to stop bleeding between the two groups and it is found to be statistically significant.
- The blood loss observed after applying negative pressure was found to be 20% in the Cannula group and 28% in the Foley's tamponade group
- There is a difference in the blood loss between the groups but it is not found to be statistically significant.
- In postnatal hemoglobin status majority of the study participants have 7-10 grams in cannula group 37(74%) and in the Foley's tamponade it is 36(72%).
- There is a difference in the postnatal hemoglobin status between the group and it is not found to be significant.

CONCLUSION

- One of the preventable cause of maternal morbidity and mortality is Postpartum Hemorrhage.
- Simple methods can be used to reduce the disaster.
- For assisting the normal physiological process of contraction and retraction Vaccum retraction is used
- Vaccum extraction is simple and it is cost effective technique used to decrease the blood loss
- Vaccum extraction method can be used in low resource setting and can also be considered to keep the instruments together with the delivery tray
- Even the labour room staff should be trained in how to apply this technique and when to apply it.

LIMITATIONS

- Our sample size is small so more explorations couldn’t be made
- We didn’t follow up the patients after the techniques to find any sideeffects or disturbances like long term ishchemia on the cervix and the uterus parts due to the effect of vaccum

RECOMMENDATIONS

- Vaccum method is considered to be the best method for the low resource setting due to its inexpensiveness
- Train the staff about how to manage PPH with this vaccum technique.
- With large number of sample size Randomised control study have to be done to explore further findings.

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PROFORMA

Name DATE

Age TIME

IP NO

Occupation

Obstetric score

LMP EDD GA

History of presenting complaints

Menstrual history

Marital history

Obstetric history

Past history

General examination

PR BP RR

Time of delivery

Time of application of vacuum retraction cannula/ balloon tamponade

Time taken to arrest PPH

Amount of blood loss

Pre-Op and Post –Op Haemoglobin

Need for packed cell transfusion

Mode of Delivery

INFORMATION SHEET

Name of the investigator: Dr.R.Karthika

Name of the Participant

Purpose of Research To compare the efficacy of vaccum retraction cannula and balloon tamponade in post partum hemorrhage

Study Design: randomized control study

Study Population : women with atonic PPH after vaginal delivery

Possible Risks: No risks to the patient

Confidentiality of the Information obtained from you: The privacy of the patients in the research will be maintained throughout the study.
In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Can you decide to stop participating in the study?
Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at anytime.

How will your decision to not participate in the study affect you?
Your decision will not result in any loss of benefits to which you are otherwise entitled.

Signature of Investigator Signature of Participant

Date:
Place:

PATIENT CONSENT FORM

Patient may check **( )** these boxes:

( ) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask questions and all my questions and doubts have been answered to my complete satisfaction.

( ) I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving reason, without my legal rights being affected.

( ) I understand that sponsor of the clinical study, others working on the sponsor's behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that maybe conducted in relation to it, even if I withdraw from the study I agree to this access.

( ) However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

Study title: : ***A RANDOMISED CONTROLLED STUDY TO COMPARE THE EFFICACY OF VACUUM RETRACTION CANNULA AND INTRA UTERINE BALLOON TAMPONADE IN MANAGEMENT OF ATONIC POST PARTUM HEMORRHAGE***
Study Centre: MMC, Chennai.

Patient's Name:

Patient's Age:

In/Out Patient Number:

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to

immediately in form the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study.

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests and to undergo treatment.

Signature/Thumb impression of the patient

Patient’s Name and Address:

Signature of Investigator

(Dr.R.Karthika)

அனுமதியுடனான ஒப்புதல் படிவம்

-இந்த ஆய்விற்கான செயல்முறையின் நோக்கத்தை நான் புரிந்துள்ளேன் என்பதை உறுதிப்படுத்துகிறேன். எனக்கு கேள்விகளை கேட்கவாய்ப்பு உள்ளது. என்னுடைய எல்லா கேள்விகளும் சந்தேகங்களும் என் முழு திருப்திக்கு பதில் அளித்துள்ளன.

-ஆய்வில் எனது பங்கேற்பு தன்னார்வமாக இருப்பதையும், என் சட்ட உரிமைகள் பாதிக்கப்படாமல், காரணத்தைத் தெரிவிக்காமல் எப்போது வேண்டுமானாலும் விலக்கிக் கொள்ளலாம் என்பதையும் நான் புரிந்து கொள்கிறேன்.

-ஆய்வில் இருந்து நான் விலகி வந்தாலும் கூட, ஆராய்ச்சிக்கு பொருந்தக்கூடிய என் உடல் நல ஆவணங்களைப் பார்க்க என் நெறிமுறைக் குழு மற்றும் ஒழுங்கு முறை அதிகாரிகளுக்கு எனது அனுமதி தேவையில்லை என்பதை நான் புரிந்து கொள்கிறேன். இந்த அணுகலை நான் ஏற்கிறேன்.

-இருப்பினும், சட்டத்தின் கீழ் தேவைப்பட்டாலன்றி, மூன்றாம் தரப்பினருக்கு வெளியிடப்பட்ட அல்லது வெளியிட்ட எந்த தகவலிலும் என் அடையாளத்தை வெளிப்படுத்த முடியாது என்பதை நான் புரிந்து கொள்கிறேன். இந்த ஆய்விலிருந்து எழும் எந்தவொரு தரவு அல்லது முடிவுகளின் பயன்பாட்டைக் கட்டுப்படுத்துவதை நான் ஏற்றுக் கொள்கிறேன்.

-மேலே உள்ள படிப்பில் கலந்து கொள்ளவும், ஆய்வின் போது கொடுக்கப்பட்ட அறிவுறுத்தல்களுக்கு இணங்கவும், ஆய்வுக்குழுவோடு ஒத்துழைக்கவும், என் உடல்நலம் அல்லது நலம் அல்லது எந்தவொரு எதிர்பாராத அல்லது அசாதாரண அறிகுறிகளிலும் நான் பாதிக்கப்படுகையில் உடனடியாக ஆய்வு ஊழியர்களுக்கு தெரிவிக்கவும், இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்கிறேன்.
நான் இதனுடன் முழுமையான மருத்துவ பரிசோதனை மற்றும் நோயறிதல் சோதனைகள் இரத்தம், உயிர்வேதியியல், கதிரியக்கசோதனைகள் உட்பட சிகிச்சைக்கு உட்படுத்த அனுமதிக்கிறேன்.

ஆய்வு தலைப்பு:சுகப் பிரசவத்தின் போது ஏற்படும் அதிக உதிரப்போக்கினை பலூன் கருவியுடன் வாக்குவம் கருவியை ஒப்பிடுதல் பற்றிய ஆய்வு
ஆய்வு மையம்: எம்.எம்.சி, சென்னை
பங்கேற்பாளரின் பெயர்:
பங்கேற்பாளரின் வயது:
நோயாளி எண்:

நோயாளியின் கையொப்பம்

நோயாளியின் பெயர் மற்றும் முகவரி: ஆராய்ச்சியாளரின் கையொப்பம்:

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013/RR-16
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.R.KARTHIKA,
Post Graduate – MS (Obstetrics and Gynaecology),
Madras Medical College,
Chennai-600003.

Dear Dr. R.KARTHIKA,

The Institutional Ethics Committee has considered your request and approved your study titled **"A RANDOMISED CONTROLLED STUDY TO COMPARE THE EFFICACY OF VACUUM RETRACTION CANNULA AND INTRA UTERINE BALLOON TAMPONADE IN MANAGEMENT OF ATONIC POST PARTUM HEMORRHAGE"- NO.21012021.** The following members of Ethics Committee were present in the meeting held on **19.01.2021** conducted at Madras Medical College, Chennai 3.

1. Prof.P.V.Jayashankar :Chairperson
2. Prof.N.Gopalakrishnan,MD.,DM., FRCP, Director, Inst.of Nephrology,MMC,Ch. : Member Secretary
3. Prof. K.M.Sudha, Prof. Inst. of Pharmacology,MMC,Ch-3 : Member
4. Prof. Alagarsamy Jamila ,MD, Vice Principal, Stanley Medical College, Chennai : Member
5. Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai : Member
6. Prof.S.Lakshmi, Prof. of Paediatrics ICH Chennai :Member
7. Tmt.Arnold Saulina, MA.,MSW., :Social Scientist
8. Thiru S.Govindasamy, BA.,BL,High Court,Chennai : Lawyer
9. Thiru K.Ranjith, Ch- 91 : Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003.

PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled **"A RANDOMISED PROSPECTIVE COMPARATIVE STUDY OF EFFICACY OF VACCUM RETRACTION CANNULA AND INTRAUTERINE BALLOON TAMPONADE IN ATONIC POST PARTUM HEMORRHAGE"** of the candidate **DR. R. KARTHIKA** with **Registration Number: 221916868** for the award of **M.S OBSTETRICS AND GYNECOLOGY (BRANCH II)**. I personally verified that the urkund.com website for the purpose of checking plagiarism. I found that the uploaded thesis file contains contents from introduction to conclusion and result shows **FOUR Percent** of plagiarism in the dissertation.(D123954838)

Guide & Supervisor sign with seal

Place : Chennai
Date :

PROF. Dr. DEVIKA, M.D O.G,
Department of Obstetrics and Gynaecology,
Institute of Social Obstetrics and
Government Kasturba Gandhi Hospital
For Women and Children
Triplicane, Chennai – 600 008

S.No	Name	Age	Agecat	Category	Gestational age	Gestational age Cat	Parity	Time to stop bleeding	Risk factors(Y/N)	Riskfactor	Blood transfusion	Blood collected
1	Indhra	31	31-35	Foleys	36	36-40	P2	10-20 mins	No	No	No	>800
2	Salomi	32	31-35	Foleys	37	36-40	P2	>20	No	No	No	>800
3	Jeyanthi	25	21-25	Cannula	40	36-40	P2	<3 min	Yes	Prolonged labour	Yes	600-700
4	Devi	21	21-25	Foleys	38	36-40	P2	10-20 mins	Yes	Preeclampsia	yes	<600
5	Rajakumari	29	26-30	Cannula	40	36-40	P3	>4 min	Yes	Anemia	No	600-700
6	Soniya	22	21-25	Cannula	37	36-40	P2	3-4 min	Yes	Prolonged labour	Yes	600-700
7	Monika	23	21-25	Cannula	31	31-35	P1	<10 mins	Yes	Multiplegravida	yes	>800
8	Subha	18	<20	Cannula	41	>40	P1	<3 min	No	No	Yes	600-700
9	Lakshmi	19	<20	Cannula	29	<30	P1	<3 min	No	No	Yes	600-700
10	Priyadharshini	23	21-25	Cannula	32	31-35	P1	<10 mins	Yes	Prolonged labour	yes	>800
11	Sujitha	26	26-30	Foleys	39	36-40	P2	10-20 mins	No	No	yes	>800
12	Sherin	21	21-25	Cannula	36	36-40	P1	<3 min	Yes	Prolonged labour	Yes	600-700
13	Jeyapriya	24	21-25	Cannula	32	31-35	P1	<10 mins	Yes	Multiplegravida	yes	>800
14	Shanthi	21	21-25	Cannula	36	36-40	P2	<3 min	Yes	Prolonged labour	Yes	600-700
15	Dhivyapriya	30	26-30	Cannula	36	36-40	P2	3-4 min	Yes	Anemia	No	600-700
16	Yogalakshmi	27	26-30	Foleys	39	36-40	P2	10-20 mins	No	No	yes	>800
17	Sangeetha	21	21-25	Foleys	40	36-40	P2	10-20 mins	Yes	Obstructed labour	yes	600-700
18	Anandhi	36	>35	Foleys	41	>40	P3	>20	No	No	No	>800
19	Nandhinin	24	21-25	Cannula	42	>40	P1	<3 min	Yes	Prolonged labour	Yes	600-700
20	Jeyalakshmi	23	21-25	Cannula	38	36-40	P1	<3 min	Yes	Prolonged labour	Yes	600-700
21	Devi	25	21-25	Cannula	41	>40	P1	<3 min	Yes	Prolonged labour	Yes	600-700
22	Pintudevi	21	21-25	Cannula	42	>40	P1	<3 min	No	No	Yes	600-700
23	Muthurathy	21	21-25	Cannula	31	31-35	P1	<10 mins	Yes	Prolonged labour	yes	>800
24	Shabana yasmin	19	<20	Foleys	41	>40	P1	<3 min	No	No	Yes	600-700
25	Lakshmi	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	>800
26	Kavitha	28	26-30	Foleys	38	36-40	P2	10-20 mins	No	No	yes	>800
27	Srimathi	22	21-25	Cannula	37	36-40	P2	<3 min	Yes	Prolonged labour	Yes	600-700
28	Shanthimalar	29	26-30	Cannula	40	36-40	P2	3-4 min	Yes	Multiplegravida	No	600-700
29	Bhavani	36	>35	Cannula	42	>40	P3	>4 min	Yes	Preeclampsia	No	700-800
30	Vasumathi	27	26-30	Cannula	38	36-40	P2	3-4 min	Yes	Prolonged labour	No	<600
31	Nandhini	36	>35	Foleys	41	>40	P3	>20	No	No	No	>800
32	Kanimozhi	31	31-35	Cannula	38	36-40	P3	>4 min	Yes	Obstructed labour	No	600-700
33	Sweety	26	26-30	Cannula	37	36-40	P2	>4 min	Yes	Anemia	No	<600
34	Saranya	28	26-30	Foleys	38	36-40	P2	10-20 mins	No	No	yes	>800
35	Nalini	27	26-30	Cannula	38	36-40	P2	>4 min	Yes	Anemia	No	>800
36	Amutha	22	21-25	Foleys	36	36-40	P2	<10 mins	Yes	Anemia	yes	>800
37	Sridevi	33	31-35	Cannula	42	>40	P3	>4 min	Yes	Preeclampsia	No	600-700
38	shanthakumari	26	26-30	Cannula	37	36-40	P2	3-4 min	Yes	Prolonged labour	No	>800
39	Kamatchi	27	26-30	Foleys	36	36-40	P2	10-20 mins	No	No	yes	600-700
40	Keerthana	25	21-25	Cannula	31	31-35	P1	<10 mins	Yes	Prolonged labour	yes	600-700
41	Vanitha	29	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	600-700
42	Preetha devi	23	21-25	Foleys	42	>40	P1	<3 min	No	No	Yes	600-700
43	Reehal	28	26-30	Foleys	38	36-40	P2	10-20 mins	No	No	No	600-700
44	Swetha	26	26-30	Cannula	37	36-40	P2	3-4 min	Yes	Multiplegravida	No	>800
45	Priya	28	26-30	Cannula	39	36-40	P3	>4 min	Yes	Anemia	No	>800
46	Archanadevi	21	21-25	Foleys	32	31-35	P2	<10 mins	Yes	Multiplegravida	yes	600-700
47	Poomathi	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	600-700
48	Deepa	21	21-25	Foleys	32	31-35	P1	<10 mins	Yes	Prolonged labour	yes	700-800

49	Kaveri	22	21-25	Foleys	37	36-40	P2	<10 mins	Yes	Multiplegravida	yes	600-700
50	Namitha	31	31-35	Foleys	41	>40	P3	>20	No	No	No	600-700
51	Kalpana	28	26-30	Cannula	39	36-40	P2	3-4 min	Yes	Multiplegravida	No	>800
52	Dhivya	26	26-30	Foleys	36	36-40	P2	10-20 mins	No	No	No	600-700
53	dhanalakshmi	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	600-700
54	Latha	21	21-25	Foleys	38	36-40	P2	10-20 mins	Yes	Preeclampsia	yes	600-700
55	Subha	26	26-30	Foleys	39	36-40	P2	10-20 mins	No	No	yes	600-700
56	Valarmathi	29	26-30	Cannula	40	36-40	P2	3-4 min	Yes	Multiplegravida	No	>800
57	Dhivya	25	21-25	Cannula	40	36-40	P2	3-4 min	Yes	Prolonged labour	No	>800
58	Kumareshwari	24	21-25	Cannula	39	36-40	P2	<3 min	Yes	Prolonged labour	Yes	600-700
59	Anandhi	24	21-25	Foleys	40	36-40	P2	<10 mins	Yes	Multiplegravida	yes	600-700
60	Sherin	26	26-30	Foleys	38	36-40	P2	10-20 mins	No	No	yes	600-700
61	Siddiqparveen	27	26-30	Foleys	39	36-40	P2	10-20 mins	No	No	yes	600-700
62	Sindhu	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	700-800
63	tamilarasi	19	<20	Foleys	36	31-35	P1	<10 mins	Yes	Prolonged labour	yes	700-800
64	Deepika	24	21-25	Cannula	39	36-40	P2	3-4 min	Yes	Prolonged labour	No	600-700
65	salma rani	34	31-35	Cannula	40	>40	P3	>4 min	Yes	Preeclampsia	No	700-800
66	Dowlath nisha	30	26-30	Cannula	36	36-40	P2	3-4 min	Yes	Multiplegravida	No	>800
67	Thamarai	30	26-30	Cannula	36	36-40	P3	>4 min	Yes	Obstructed labour	No	600-700
68	Preethi	21	21-25	Foleys	37	36-40	P2	10-20 mins	Yes	Obstructed labour	yes	600-700
69	Alli	19	<20	Cannula	29	<30	P1	<3 min	No	No	Yes	600-700
70	Mary	22	21-25	Foleys	38	36-40	P2	10-20 mins	Yes	Preeclampsia	yes	600-700
71	Subathra	23	21-25	Foleys	32	31-35	P1	<10 mins	Yes	Prolonged labour	yes	700-800
72	Maheshwari	32	31-35	Foleys	41	>40	P2	>20	No	No	No	700-800
73	revathy	25	21-25	Cannula	40	36-40	P2	<3 min	Yes	Prolonged labour	Yes	700-800
74	selvi	19	<20	Foleys	29	<30	P1	<10 mins	Yes	Prolonged labour	yes	700-800
75	Suganthi	21	21-25	Foleys	38	36-40	P2	<10 mins	Yes	Anemia	yes	700-800
76	Priya	18	<20	Foleys	41	>40	P1	<3 min	No	No	Yes	700-800
77	Mahima	31	31-35	Foleys	36	36-40	P2	>20	No	No	No	600-700
78	Latha	32	31-35	Foleys	38	36-40	P2	>20	No	No	No	600-700
79	shanthakumari	22	21-25	Cannula	37	36-40	P1	<3 min	Yes	Prolonged labour	Yes	700-800
80	Nithya	26	26-30	Foleys	39	36-40	P2	10-20 mins	No	No	yes	700-800
81	Vijayalakshmi	26	26-30	Cannula	37	36-40	P3	>4 min	Yes	Obstructed labour	No	700-800
82	Mallika	23	21-25	Cannula	38	36-40	P2	3-4 min	Yes	Prolonged labour	Yes	700-800
83	Ambika	24	21-25	Cannula	39	36-40	P2	<3 min	Yes	Prolonged labour	Yes	700-800
84	Vennila	27	26-30	Cannula	38	36-40	P2	3-4 min	Yes	Multiplegravida	No	>800
85	ramya	19	<20	Foleys	29	<30	P1	<10 mins	Yes	Prolonged labour	yes	700-800
86	Preetha	22	21-25	Cannula	36	36-40	P2	3-4 min	Yes	Prolonged labour	No	>800
87	Shailabanu	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	700-800
88	Jeya	28	26-30	Cannula	39	36-40	P2	3-4 min	Yes	Multiplegravida	No	700-800
89	vijayapriya	22	21-25	Foleys	42	>40	P1	<10 mins	Yes	Prolonged labour	yes	700-800
90	Shakilabanu	23	21-25	Foleys	41	>40	P1	<10 mins	Yes	Multiplegravida	yes	700-800
91	Sherin	18	<20	Foleys	42	>40	P1	<3 min	No	No	Yes	700-800
92	Abitha	19	<20	Cannula	29	<30	P1	<3 min	No	No	Yes	700-800
93	Thasmeen	27	26-30	Foleys	37	36-40	P2	10-20 mins	No	No	yes	700-800
94	Meena	22	21-25	Foleys	41	>40	P1	<3 min	No	No	Yes	700-800
95	Anjana	35	31-35	Cannula	41	>40	P3	>4 min	Yes	Preeclampsia	No	700-800
96	Salima	23	21-25	Cannula	38	36-40	P2	<3 min	Yes	Prolonged labour	Yes	700-800
97	Ambidevi	27	26-30	Foleys	36	36-40	P2	10-20 mins	No	No	yes	700-800
98	Padmavathy	21	21-25	Cannula	36	36-40	P2	3-4 min	Yes	Prolonged labour	Yes	700-800
99	Shanthimani	32	31-35	Cannula	41	>40	P3	>4 min	Yes	Obstructed labour	No	700-800
100	Vishali	28	26-30	Foleys	40	36-40	P2	10-20 mins	No	No	yes	700-800