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INTRAUTERINE BALLOON TAMPONADE CONDOM FOLEY'S CATHETER VS CG BALLOON CATHETER IN MANAGEMENT OF ATONIC PPH IN A TERTIARY CARE HOSPITAL OF RAJASTHAN

Gynecology

Preeti Baghel* Senior Resident Department of OBG, Mahila Chikitsalaya , SMS Medical College, Jaipur *Corresponding Author

Urmila Mahla Assistant Professor Department of OBG, Mahila Chikitsalaya , SMS Medical College, Jaipur

Seema Mehta Senior Professor Department of OBG, Mahila Chikitsalaya , SMS Medical College, Jaipur

Manju Sharma Senior Professor Department of OBG, Mahila Chikitsalaya , SMS Medical College, Jaipur

ABSTRACT

Introduction: Uterine balloon tamponade technology is nowadays popularly used to control post partum haemorrhage. Among various methods, Foley's catheter tamponade is simple,
easy to use and is effective. The study evaluates outcome of Foley's catheter tamponade.
Material and Methods: In this prospective observational study, foley's catheter tamponade was applied to twelve cases with post partum hemorrhage of different severity, refractory
to all pharmacologic measures. The effciency of the Balloon Tamponade Technology in the management of severe PPH was assessed along with any complications.
Results: The foley's catheter tamponade stopped bleeding in all the cases. Only two cases showed evidence of sepsis.
Conclusions: Thus, foley's catheter tamponade is an effective method to control intractable PPH. It is an easy procedure which does not require expertise to use. Hence it proves to an invaluable tool, especially in places with low resource settings.

KEYWORDS

Balloon Tamponade, Intrauterine, Post Partum Haemorrhage

INTRODUCTION

World Bank data states MMR for India 174 per 100, 000 live births in 2015, which is a significant decline from the 215 figure that was reported in 2010.[1]MMR in the Rajasthan state has taken a dip from 318 deaths per 100,000 live births in 2007-09 to 255 deaths per 100,000 live births in 2015.Major cause of world wide maternal morbidity and mortality (MMM) is Obstetrical haemorrhage.[2,3] World health organization, states that obstetrics hemorrhage accounts 127,000 deaths annually worldwide .It is mainly due to retained placental tissues, uterine rupture, lower genital tract trauma, consumptive coagulopathy etc.[4]

A PPH is defined as >500 ml approximate blood loss after vaginal delivery or >1000 ml after caesarean section (CS).[5] Diagnosis is confirmed to be atonic PPH after excluding uterine and cervical trauma, deficient coagulation or retained placental tissue.Presently ACOG, RCOG guidelines advocatesUterine Balloon Tamponadefor the management PPH after the exclusionof retained products and genital tract trauma.[6] ,failure of use of first line uterotonics(such as oxytocin, ergometrine,misoprostol and prostaglandin F2 alpha).

Overall success of balloon tamponade outcomes have been reported in the rangeof 80–100%.[5,7]We report 40 cases of failed medical treatment of primarypostpartum hemorrhage secondary to uterine atony which weremanaged with (20 cases each) condom foleys catheter andCG balloon catheter tamponade.

The uterine-specific devices to control atonic PPH available commerciallyare designed with an intrauterine drainage port but have relatively higher cost. Low resource settings have to rely on lower cost adaptations like condom catheter balloon and CG Ballon tamponade which are the most cost-effective second-line management option for atonic PPH

Several types of uterine-specific and non-uterine balloons have been successfully used to manage and treat PPH. All UBT devices are inflated with fluid in amounts that are determined by the health care provider based on how fast the bleeding stops. The balloon is inflated incrementally until the bleeding is controlled—this is often referred to as the "tamponade test." On average, from 250 ml to 350 ml of fluid are needed to control bleeding .

The precise mechanism of action for UBT is still unclear. The placenta is a low-pressure system, so it seems likely that when the placenta is the source of hemorrhage, the direct pressure of the balloon, even well below systemic pressure, will halt bleeding. When the hemorrhage is instead from an arterial source in the endometrium, it is possible that the balloon's exerted pressure exceeds the arterial pressure and thus promotes clot formation. A third possibility is that the introduction of the balloon in the atonic uterus causes it to contract.[9] Further study is needed to determine the mechanism of action, which will in turn help ensure proper placement and monitoring.

Condom Foley's catheter tamponade: PPH following vaginal delivery, the foleys catheter was inserted transvaginally (using sponge holding forceps or manually into uterine cavity using ring forceps to hold the cervix). After insertion, the balloon was inflated with normal saline usually from 100-250 ml until resistance was felt or bleeding was controlled –in our study.

Preparation of CG balloon under all aseptic precautions are as follows[8] (Fig. 1):

(1) Collect a Foley's catheter of size 20–22, a packed condom, scissors, two 20-ml syringes and 500-ml bottle of saline in a tray.
(2) From the drainage tube of the catheter, cut two rings of approximately 1–2 mm width (Fig. 1a).
(3) Excise (not merely incise) the bulb of the catheter after inflating it with air (Fig. 1b).
4) Unfold the condom over distal one-third of the catheter (Fig. 1c).
(5) Use these rings encircling twice only (like a rubber band in a ponytail) to secure the condom over catheter leaving 1.5–2 cm from both the ends of condom (Fig. 1d).
(6) Excise the tip of the Foley's catheter and condom together to facilitate drainage of blood (Fig. 1e). Wash the device with antiseptic soltion.

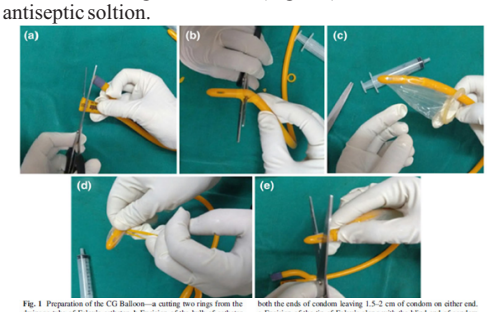

Fig. 1 Preparation of the CG Balloon—a cutting two rings from the drainage tube of Foley's catheter. b Excision of the bulb of catheter subsequent to inflation with 2–5 ml of air. c Rolling of condom over catheter. d Tying condom to catheter using the rings twice around both the ends of condom leaving 1.5-2 cm of condom on either end. e Excision of the tip of Foley's along with the blind end of condom together 0.5 cm away from the tied ring. Leaving both the rings with CG Balloon

MATERIALAND METHODS

This study was a prospective study done in the Departmentof Obstetrics and Gynecology, Mahila Chikitsalaya Sangneri Gate Attached To SMS Medical College Jaipur from Jan 2017 to March 2018.

INDICATION :

1 Uterine atony,
2 Bleeding following cesarean sections, in cases of placenta previa and accreta

CONTRAINDICATION:

1 Pregnancy,
2 Arterial bleeding,
3 Cervical or uterine cancer,
4 Danger of uterine rupture,
5 Infections, and
6 Uterine anomaly.

We report 40 cases of failed medical treatment of primary postpartum hemorrhage secondary to uterine atony which were managed with (20 cases each) condom foleys catheter and CG balloon catheter tamponade All cases who underwentballoon tamponade(Condom Foley's and CG balloon) to control massive PPH after vaginaldelivery, which was not controlled by medical management were includedin the study. Data which was analyzed includesMode of delivery, Cause of PPH, Other causes of bleeding, Volume Of blood loss, PPH to balloon inflation interval time, Balloon tamponade volume ,inflation to haemostasis interval ,Inflation deflation interval ,Surgical intervention if required .

In cases of atonic PPH, to keep the uterus well contracted over the balloon, oxytocin infusionwas continued for a minimum of 4 hours. In all cases, as a rule the catheter was left in situ for the duration minimum 24 hrs and longest 72 hrs of balloon tamponade and in all patients vitals were closely monitored. Clinical success was defined as control of bleeding following balloon insertion without further intervention.[4]

That tamponade can be used to control bleeding even in the face of coagulopathy.[10] Condoms do not allow for drainage of the uterine cavity. Eventhough some blood can flow over the surface of the condom intothe vagina, it is also possible for the blood to accumulate above the condom. There is therefore the need for close monitoring ofthe patient's vital signs and the fundal height of the uterus to identify failure early and proceed with further treatment.[11]

Case	Mode of delivery	Cause PPH	Other causes bleeding	Volume Of blood loss	PPH to condom balloninflation interval time	Condom tamponade Volume	Condom inflation to haemostasis interval	Inflation deflation interval	Surgical intervention if required
1	Vaginal	Atonic	-	1200	12min	380cc	10min	24hr	NO
2	Vaginal	Atonic	-	1100	20min	300cc	16min	18hr	
3	LSCS	Atonic	Placenta Praevia	1150	12min	320cc	Haemostasis not achieved		Laprotomy
4	Vaginal	Atonic	-	1800	18min	290cc	18min	20hr	NO
5	LSCS	Atonic	Polyhydo Amnios	1500	08min	340cc	15min	18hr	NO
6	Vaginal	Atonic	Cx&vaginal tear	2000	10min	330cc	18min	16hr	Cx&vaginal tear repair
7	LSCS	Atonic	Twins	1250	12min	300cc	19min	15hr	NO
8	Vaginal	Atonic	-	1800	20min	340cc	14min	20hr	NO
9	Vaginal	Atonic	-	1100	16min	320cc	15min	16hr	NO
10	Vaginal	Atonic	DIC	1800	18min	320cc	Haemostasis not achieved		Laprotomy
11	Vaginal	Atonic	-	1400	22min	280cc	08min	22hr	NO
12	LSCS	Atonic	-	1750	14min	290cc	14min	18hr	NO
13	Vaginal	Atonic	-	1300	16min	300cc	12min	22hr	NO
14	Vaginal	Atonic	-	1100	10min	310cc	11min	20hr	NO
15	Vaginal	Atonic	-	1300	09min	330cc	10min	23hr	NO
16	Vaginal	Atonic	-	1400	15min	310cc	12min	24hrs	NO
17	LSCS	Atonic	Placenta Praevia	1550	18min	340cc	15min	72hrs	NO
18	Vaginal	Atonic	-	1400	12min	280cc	14min	18hrs	NO
19	Vaginal	Atonic	-	1800	10min	320cc	Haemostasis not achieved		Laprotomy
20	Vaginal	Atonic	-	1500	14min	300cc	11min	22hrs	NO

During the procedure, a surgical team was kept stand-by readyfor surgical intervention (laparotomy and other necessarymeasures). If the bleeding did not stop within half an hour oftamponade application, the method was termed unsuccessfuland surgical intervention sought. Thouroughout the procedure, adequate antibiotic coverage was maintained along with oxytocin drip and vaginal packing, the condition of the patientcontinuously monitored in the Intensive care unit, speciallynoting the amount of bleeding and any other complications.

STATISTICALANALYSIS

Data was analysis was done with SPSS 16 . To interpret the data, descriptive statistics like mean and percentages were used.

RESULTS

Case details of women with atonic PPH managed by Condom Foleys catheter Balloon Out of 20 patients in which Condom Foleys catheter Balloon was used 15 had normal vaginal delivery (among 15 patients 1 had cervical and vaginal tear which was repaired in OT) and 5 had LSCS (among 5 patients causes of LSCS was placenta praevia in 2, twin in 1 and polyhydroamnios in 2)

Among 20 patients 3 patient (out of 3 patient 1 had LSCS for placenta praevia and 2 had normal vaginal delivery) does not respond to Condom Foleys catheter Balloon and underwent laparotomy followed by hysterectomy, making efficacy of Condom Foleys catheter Balloon 85% (17/20).

Among 20 patients, maximum 1800cc blood loss was there and minimum 1100cc blood loss was there in which Condom Foleys catheter Balloon was used.

Mean time from PPH to Condom Foleys catheter Balloon inflation was 14 min in 20 patients, among it longest time interval for balloon inflation was 22 min and smallest time interval for balloon inflation was 8 min.

Case	Mode of delivery	Cause PPH	Other causes bleeding	PPH volume	PPH to CG Balloon InflationInterval time	CGB tamponade volume	CGB tohaemostasis Interval time	Inflation deflation interval time	Surgical intervention if required
1	LSCS	Atonic	Placenta Praevia	1000	15min	280 cc	12 min	12 h	No
2	Vaginal	Atonic	–	1500	14min	250 cc	05 min	12 h	No
3	Vaginal	Atonic	–	1100	10min	300 cc	14 min	14 h	No
4	Vaginal	Atonic	–	1300	18min	290 cc	Haemostasis not achieved		Laprotomy
5	LSCS	Atonic	Polyhydroamnios	1250	15min	300 cc	10 min	12 h	No
6	Vaginal	Atonic	Cx tear	1600	17min	320 cc	15 min	24 h	Cx tear repair
7	LSCS	Atonic	Twins	1700	15min	250 cc	10 min	12 h	No
8	LSCS	Atonic	Polyhydroamnios	1450	10min	350 cc	06 min	12 h	No

9	vaginal	Atonic	DIC	1800	16min	250 cc	Haemostasis not achieved		Laprotomy
10	Vaginal	Atonic	–	1950	12min	200 cc	10 min	15 h	No
11	Vaginal	Atonic	–	1500	15min	270 cc	12 min	12 h	No
12	Vaginal	Atonic	–	1750	17min	370 cc	10 min	16 h	No
13	Vaginal	Atonic	–	1200	13min	265 cc	13 min	22 h	No
14	LSCS	Atonic	Placenta praevia	1400	11min	250cc	12min		No
15.	Vaginal	Atonic	-	1800	18min	300cc	07min	12h	No
16.	LSCS	Atonic	Prolonged labour	1200	12min	260cc	12min	14h	No
17.	Vaginal	Atonic	-	1800	15min	300cc	07min	12h	No
18.	Vaginal	Atonic	Cx tear	1550	13min	320cc	11min	24hr	Cx tear repair
19.	Vaginal	Atonic	-	1600	10min	280cc	06min	14hr	No
20.	Vaginal	Atonic	-	1500	14min	300cc	12min	12hr	No

Mean volume to inflate Condom Foleys catheter Balloon in 20 patients was 315cc, among it maximum volume required to inflate Condom Foleys catheter Balloon was 380cc and minimum volume required to inflate Condom Foleys catheter Balloon was 280cc.

Mean time from Condom Foleys catheter Balloon inflation to achievement of haemostasis was 13.6 min in 17 patients, among it longest time interval for achievement of haemostasis was 19 min and smallest time interval for achievement of haemostasis was 10 min.

Among 17 patients, mean inflation to deflation time of Condom Foleys catheter Balloon was 20.4 hrs, among it longest time interval for balloon inflation and deflation was 72 hrs and smallest time interval for balloon inflation was and deflation was 15 hrs.

Case details of women with atonic PPH managed by CG Balloon
Out of 20 patients in which Condom Foleys catheter Balloon was used 14 had normal vaginal delivery (among 15 patients 2 had cervical tear which was repaired in OT) and 6 had LSCS (among 6 patients causes of LSCS was placenta praevia in 2, twin in 1,polyhydroamnios in 2 , prolonged labour in 1)

Among 20 patients 2patient (out of 2 patient both had normal vaginal delivery) doesnot respond to CG catheter Balloon and underwent laparotomy followed by hysterectomy, making efficacy OF CG catheter Balloon 90% (18/20).

Among 20 patients, maximum 1950cc blood loss was there and minimum 1000cc blood loss was there in which CG catheter Balloon was used.

Mean time from PPH to CG catheter Balloon inflation was 14min in 20 patients, among it longest time interval for balloon inflation was 18 min and smallest time interval for balloon inflation was 10 min.

Mean volume to inflate CG catheter Balloon in 20 patients was 290cc, among it maximum volume required to inflate CG catheter Balloon was 370cc and minimum volume required to inflate CG catheter Balloon was 250cc.

Mean time from CG catheter Balloon inflation to achievement of hemostasis was 10.2 min in 18 patients, among it longest time interval for achievement of hemostasis was 13 min and smallest time interval for achievement of hemostasis was 5 min.

Among 18 patients, mean inflation to deflation time of CG catheter Balloon was 14hrs, among it longest time interval for balloon inflation and deflation was 24 hrs and smallest time interval for balloon inflation was and deflation was 12hrs.

DISCUSSION

Postpartum hemorrhage (PPH) is one of the direct cause of maternal death worldwide. It can be prevented and treated, but in low-resource settings additional care needed .Uterine balloon tamponade (UBT) has been recognized as a relatively easy-to-use and effective second-line option for managing severe PPH, but cost and other factors limit its use in low-resource settings.

A retrospective and prospective studies done by Georgiou (2009) for the management of PPH by uterine balloon tamponade showed that the procedure was successful in 97/106 (91.5%) cases.[7] and that of our study was 35/40 (87.5%) cases uterine balloon tamponade was successful.

The Scottish Confdential Audit of Severe Maternal Morbidity (2009) states that balloon tamponade was successful for the management of major PPH in 57 cases and in 50 (88%) women with refractory PPH in whom hysterectomy was prevented.[11] Our study shows similar success outcome.

Dabelea et al reported 23 cases of PPH managed successfully with intrauterine balloon tamponade which were unresponsive to medical therapy [12] as in our cases out of 40 cases 35 were managed successfully with intrauterine balloon tamponade.

Among other forms of tamponade Johanson R et al used Rüsch urological hydrostatic balloon catheter in two cases, in which medical therapy failed to control PPH, in them catheter worked and avoided further surgical interventions.[13]

Doumoouchtisis SK et al used Sengstaken-Blakemore Oesophageal Catheter (SBOC) on 27cases of PPH not responding to medical management. Bleeding stopped in 22 of them, but five required surgical intervention (four had hysterectomy). [14]

Limitation of study was that in condom catheter blood collects behind the condom and so uterine height should be monitored in them for effectiveness of PPH control whereas in CG Balloon through drainage pipe actual amount of blood collecting can be measured and surgical interventions can be planned based on that results.

CONCLUSION

Our study concludes that balloon tamponade is an effective means of controlling severe PPH. At times when PPH do not respond to pharmacologic measures, intra-uterine tamponade would be an emergency lifesaving procedure, especially in low-resource settings.Condom-loaded Foley's catheter is as effective as CG Ballon in the management of primary atonic PPH following vaginal delivery but requires a significant bit longer time to stop the PPH.

As this technology avoids the need for further interventions including invasive surgical procedures like hysterectomy, it reduces the hospital stay and recovery period and hence it proves to be cost effective. Further studies are needed to standardize the ideal volume of fluid for balloon inflation, need for concurrent oxytocin infusion with dosage, duration of balloon tamponade and whether to be removed in single step or multiple steps; their merits and demerits.

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