Original Research Article

A prospective randomized comparative study of Misoprostol and balloon tamponade using condom catheter to prevent postpartum hemorrhage at M. Y. H., Indore, India in vaginal delivered patients

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ABSTRACT

Background: PPH is responsible for quarter of maternal deaths occurring worldwide and its incidence is increasing in developed world. According to Confidential Enquiries into Maternal and Child Health (CEMACH) report obstetric hemorrhage occurs in around3.7 per 1000 births. The objective of the study is that it was a prospective randomized comparative study of misoprostol and balloon tamponade via condom catheter to prevent postpartum hemorrhage in normal delivered patients at MYH.

Methods: A sample size of 200 normal delivered patients between age group 18 and 45 years is chosen with excessive bleeding after third stage of labour and after administration of oxytocics. These 200 patients are divided into two groups: First group receiving Misoprostol and applying condom catheter in other group. Both groups are evaluated for PPH.

Results: It was found that CG balloon condom catheter was a much better and more effective alternative in controlling PPH than Misoprostol as the failure rate with CG balloon condom catheter were much less than that with misoprostol. Due to its cost effectiveness and being easily available at primary health center and due to absence of any drug reactions and easy technique of formation makes it a better modality in controlling PPH even at PHC.

Conclusions: Patients with condom catheter in situ must show better result than patients receiving misoprostol.

Keywords: Active management of third stage of labour (AMTSL), Antepartum hemorrhage (APH), Chattisgarh balloon (CG balloon), Condom catheter (CC), Misoprostol, Oxytocics, Postpartum haemorrhage (PPH), Pregnancy induced hypertension (PIH), Sengstaken-Blakemore oesophageal catheter (SBOC)

INTRODUCTION

Postpartum hemorrhage may occur in 1-5% of deliveries in developed countries and is still the most significant cause of maternal morbidity and mortality.[1-3] The WHO estimates that PPH accounts for nearly 30% maternal deaths worldwide with an estimated 20 million cases annually. Classically, PPH has been defined as a blood loss greater than 500ml after a vaginal delivery and greater than 1000ml after a cesarean section.[1] Underestimation of post-delivery blood loss is not uncommon, and is likely contributed to, at least in part, by the ability of healthy pregnant women to lose up one liter of blood acutely without a noticeable drop in hemoglobin or significant hemodynamic change.[4,5]

Postpartum hemorrhage may develop in patients with no risk factors; however, reported risk factors include: multiparity, operative deliveries (forceps or vacuum assisted deliveries), previous postpartum hemorrhage, antepartum hemorrhage, prolonged third stage of labor (delivery of the placenta more than 30 minutes after

delivery of the fetus), abnormal placentation (placenta previa, accreta or increta), oxytocin use, maternal obesity, and a distended uterus (from a large baby, multifetal gestation or excessive amniotic fluid).[6-8] In developed countries, the maternal mortality of such hemorrhage has been reported to be on the order of 0.1% of all deliveries.[8]

The aim of this study is to prevent maternal death at a primary health care center. The objective is to study the outcome among the medical method i.e. misoprostol and interventional method i.e. CC CG Balloon for preventing postpartum hemorrhage; to study the association of high-risk factors and the postpartum hemorrhage; to study the association of parity status and postpartum hemorrhage and to study the efficiency and time responsiveness of the interventions used for prevention of postpartum hemorrhage.

METHODS

It was a randomized prospective study carried out from 1st March 2016 to 31st August 2017 (18 months). Number of cases were 200.

Inclusion criteria

- All the vaginal delivered patients with atonic PPH at MYH after active management of third stage of labour during the duration of study.

Exclusion criteria

- Rule out causes due to traumatic PPH.
- Arterial bleeding requiring exploration and ligation or angiofigureic embolization.
- Cases indicating hysterectomy or when uterine rupture is suspected.
- Non gynaecological causes like cervical cancer.

All the cases were divided into two groups: one receiving 800 microgram misoprostol per rectally/sublingually and other group receiving CC. In around 105 cases Misoprostol was used and in another 95 cases CC was used. Cases were allocated using randomization by alternately allocating the cases to Misoprostol and CC group. After AMTSL wherever Misoprostol was used, authors watched for 10 minutes for bleeding to stop but if it did not stop authors insert CC to prevent deterioration of the cases. Further, if CC fails after 30-40 minutes cases are shifted to operation theatre and planned for sequential devascularization. Further when either of the options failed i.e. even after failure of stepwise devascularisation, authors proceed for hysterectomy.

RESULTS

Table 1 showing distribution of cases with booked cases 77% and unbooked cases 23%.

Table 1: Distribution of cases depending on booked and unbooked status.

Registration status	Number of cases	Cases (in percentage)
Unbooked	46	23
Booked	154	77
Total	200	100

Table 2 showing distribution of cases depending upon the age group suggesting most commonly affected age group was of 21 to 25 years age group contributing to 42% of cases followed by 26 to 30 years age group contributing to 32% of cases. It is followed by age groups of 16 to 20 years (14.5%), 31 to 35 years (9%), and lastly >35 years (2.5%). Modality of treatment used suggests most commonly used is CC i.e. in 61% cases and misoprostol in 52.5% cases. However, Misoprostol failed in around 13.5% cases and hysterectomy was done in around 2.5% cases.

Table 2: Distribution of cases depending upon the age group and modality of treatment used.

Age group (in years)	Misoprostol cases	Misoprostol failure cases	CC cases	Hysterectomy cases	Total cases	Cases (in percentage)
16-20	15	4	18	1	29	14.5
21-25	49	12	47	2	84	42
25-30	25	4	43	1	64	32
31-35	11	6	13	1	18	9
>35	5	1	1	0	5	2.5
Total	105	27	122	5	200	100

Table 3 showing distribution of cases depending upon parity status; most commonly affected were third gravida group contributing 35% cases followed by second gravida 24% cases and primi gravida and more than or equal to four gravida contributing 29.5% and 11.5 % cases, respectively. The parity status with most common being third gravida group with 34 cases managed using Misoprostol and 47 cases managed using CC and 2 cases

underwent hysterectomy because of failure of either method.

However, 3 cases underwent hysterectomy among primigravida after failure of either method.

Table 3: Distribution of cases depending upon the parity and the respective modality of treatment used.

Parity status	Misoprostol cases	Misoprostol failure cases	CC cases	Hysterectomy cases	Total cases	Cases (in percentage)
1	24	7	42	3	59	29.5
2	29	4	23	0	48	24
3	34	11	47	2	70	35
>4	18	5	10	0	23	11.5
Total	105	27	122	5	200	100

Table 4: Distribution of cases depending upon pregnancy outcome and modality of treatment used.

Pregnancy status	Misoprostol cases	Misoprostol failure cases	CC cases	Hysterectomy cases	Total cases	Cases (in percentage)
Preterm	25	3	18	1	40	20
Term	58	10	70	4	118	59
Post term	9	2	13	0	20	10
Postnatal	13	12	21	0	22	11
Total	105	27	122	5	200	100

Table 5: Distribution of cases depending on associated high-risk factor and procedure used.

Associated high risk factors	Misoprostol cases	Misoprostol failure cases	CC cases	Hysterectomy cases	Total cases	Cases (in percentage)
Anemia	20	7	35	0	48	24
Jaundice	9	4	8	1	13	6.5
Pregnancy induced hypertension	17	7	26	2	36	18
Antepartum hemorrhage	10	3	18	1	25	12.5
Obstructed labour	7	3	4	1	8	4
Amniotic fluid disorders	14	0	7	0	21	10.5
Twins	2	2	5	1	5	2.5
Atonic PPH	2	2	3	0	3	1
Uterine inversion	0	0	2	0	2	1.5
No high-risk factor	25	0	16	0	41	20.5
Total	106	28	124	6	202	100

Some cases may belong to superimposed category.

Table 4 showing distribution of cases depending upon the pregnancy outcome with most cases belonging to category of Term pregnancy (59%) followed by preterm pregnancy (20%), postnatal cases (11%) and post term pregnancy (10%). And modality of treatment used with 35% of the cases of term pregnancy managed using CC and around 26% of the cases managed using Misoprostol. However, with failure of either method Hysterectomy was done in 2% cases.

Table 5 showing distribution of cases depending on associated high-risk factor and procedure used with most cases of Anemia nearly 48 (24%) cases followed by no high-risk factors i.e. 20.5% cases. The CC controlled PPH in 35 cases with Anemia, 26 cases with PIH and 18 cases with APH.

Table 6: Distribution of cases depending on intervention used.

Procedure used	Number of cases in which procedure was unsuccessful	Number of cases in which procedure was successful
Misoprostol	27	78
CC	5	117
Hysterectomy	0	5
Total	32	200

Some cases may belong to superimposed category.

Table 6 showing distribution of cases depending on intervention used; The Pearson chi square test was applied to see the association between whether PPH was controlled and the procedure used to do so. The value of this test was 47.028 and p value for this was 0.00 which was found to be clinically significant as p value is less than 0.05. Misoprostol was used successfully in 36% cases and CC was used successfully in 56.5% but misoprostol failed in 13.5% cases and CC failed in 2.5% cases.

Table 7 showing Fischer's exact test was applied to see the association between PPH controlled and the high-risk factor associated with it. The p value for Fischer's exact test was 0.000 and this is less than 0.05 hence found to be clinically significant. Thus, there is positive association between PPH controlled and the associated high-risk factor.

Table 7: Distribution of cases showing association of high-risk factors and PPH was controlled or not.

Associated high risk factors	PPH controlled	PPH not controlled	Total cases
Anemia	41	7	48
Jaundice	9	4	13
Pregnancy induced hypertension	29	7	36
Antepartum hemorrhage	22	3	25
Obstructed labour	5	3	8
Uterine inversion	2	0	2
Amniotic fluid disorders	21	0	21
Twins	4	1	5
Atonic PPH	3	0	3
No high factors	41	0	41
Total	175	27	202

Some cases may belong to superimposed category.

Table 8 showing distribution of cases according to booking status and modality of treatment used. The Fischer's Exact test was applied to see the association between PPH controlled and the Booking status of the cases. The p value for the test was 0.047 and it is less than 0.05 which is found to be clinically significant.

Table 8: Distribution of cases according to booking status and modality of treatment used.

Intervention used	Number of booked cases	Number of unbooked cases
Misoprostol cases	87	18
Misoprostol failure cases	25	7
CC cases	92	30
Hysterectomy cases	0	5
Total	204	55

Table 9 showing independent t tests were applied and it was observed that the PPH to CG balloon interval, CG balloon inflation to hemostasis interval and hemostasis interval was found to be significant with the p value of 0.000 (<0.05). Thus, whether PPH is controlled or not is affected by the hemostasis interval, PPH to CG balloon Insertion interval and CG balloon inflation to hemostasis interval.

Table 9: Comparison of hemostasis interval between cases in whom PPH was controlled or not.

Outcome	Cases in which PPH was controlled	Cases in which PPH was not controlled
PPH to CG balloon insertion interval	8.07	17.07
CG balloon inflation to hemostasis interval	7.13	15.32
Hemostasis interval (in minutes)	12.69	22.96

Table 10 showing distribution of cases receiving blood transfusion; 53% cases received blood transfusion while 47% cases did not receive blood transfusion.

Table 10: Distribution of cases receiving blood transfusion.

Blood components	Number of cases	Percentage of cases
Transfused	106	53
Not transfused	94	47
Total	200	100

Table 11 showing quantification of amount of blood loss on whether PPH was controlled or not; The amount of blood loss affects whether PPH was controlled or not. Independent t test was applied, and its p value was 0.000 (<0.05) which is found to be significant.

Table 11: Quantification of amount of blood loss on whether PPH was controlled or not.

Outcome	Amount of blood loss (in milliliter)	Number of cases
PPH was controlled	663.80	173
PPH was not controlled	1100.00	27

DISCUSSION

The mean age group in present study was 25.27±4.636 years. Out of total of 200 cases, 48% cases belong to age group of 21 to 25 years of age, 14.5% cases in the age group of 17 to 20 years, 32% cases in age group of 26-30 years, 9% cases in the age group of 31 to 35 years and 2.5% cases in the age group of >35 years. However, age

has no significant association with whether PPH is controlled or not as p value is 0.334 (>0.05).

In study by Tort J et al, Parity status is found to be non-significant w.r.t PPH.[9] Also pregnancy status is found to be non-significant w.r.t PPH. However, in present study, Pregnancy status affects the outcome i.e. whether PPH is controlled or not. In my study most of the cases belong to third gravida status i.e. 35% cases followed by primi gravida i.e. 29.5% cases, second gravida cases being 24% cases, and lastly four and more gravida included 11.5% cases. However, study conducted by Gurung BS, et al showed parity ranged from 1-4, with a median of 2.[10] In present study, 48 (24%) cases belong to category of anemia and 25 (12.5%) cases belong to category of APH, however, in the study conducted by Parpillewar MB et al included 13.8% cases with anemia and 22.22% with APH.[11] Moreover, in study by Mishra N et al, primi and para two women were five each and remaining three were para three.[12]

In present study the mean amount of blood loss is 663.80ml in the cases in which PPH was controlled i.e. in 86.5% cases and 1100.00ml in the cases in which PPH was not controlled i.e. 13.5% cases. The minimum amount of blood loss was 400ml and the maximum was 1500ml. In study by Sheikh L et al, the mean blood loss was 2431±1817ml (range:1500-9000ml while in study by Tort J et al, the mean amount of blood loss is 800ml and in the study conducted by Martin et al, the mean blood loss before putting CC was 1343±223ml while mean blood loss after condom balloon insertion was 308±83.42ml.[9,13,14] Mean comparison of blood loss before and after condom balloon insertion was done and found to be statistically significant (p<0.001). The same result was found in my study that the PPH to CG balloon interval, CG Balloon inflation to hemostasis interval and Hemostasis interval was found to be significant with the p value of 0.00 which is less than 0.05 and was found to be significant. In study by Thapa K et al, CC was applied to fourteen cases with varying degrees of PPH, not controlled with pharmacologic measures.[15] Average amount of blood loss was 1221ml and it was 1480ml in study conducted by Ahmad SN et al.[16] In a study of case series by Mishra N et al, the mean blood loss was 1611ml.[12]

In the study by Ahmad SN et al, the mean time taken to arrest bleeding after the application of the CC was 6.66 minutes.[16] In my study the mean Hemostasis interval in 86.5% cases with PPH controlled was 12.69 minutes and the 13.5% cases in with PPH not controlled was 22.96 minutes. In the latter group, 2.5% cases ended in hysterectomy. In study of case series by Mishra N et al, the mean time interval between the diagnosis of atonic PPH and introduction of CC was 19.6 min.[12] In a study of case series by Mishra N et al, control of PPH was achieved in 12 cases in the mean time of 12.6min.[12] In study by Doumouchtsis SK et al, in cases where the balloon was successful it was removed around 24 hours late.[17] The mean duration for which CC was left in situ was 27.5 hours. In study by Tort J et al, the average time during which the CC was left in place was 9 hours 11 minutes.[9]

In present study, the mean time for which CC in situ with PPH controlled was 22.67 hours and PPH not controlled was 24.67 hours. Minimum and maximum duration for which C in situ was 2 hours and 48 hours respectively. In study by Moushmi B et al, the average duration for CC in situ was 30 hours 14 minutes.[11] The CC in situ for a mean duration of 19.94±3.84 hours in the study by Ahmad SN et al.[16] Minimum duration for keeping CC in situ was 13 hours and the maximum was 24 hours. In a study of case series by Mishra N et al, CC in situ for at least 12-24 hours.[12]

In present study, the mean amount of fluid inflated in CG balloon was 416.8 4 ml in 95 cases and 418.18 ml in 22 cases respectively in cases with PPH controlled and not controlled. However, the minimum amount of fluid inflated in CG balloon was 200 ml and the maximum was 600ml. In study conducted by Tort J et al, the average fill volume was 443.3ml.[9] However, the mean volume of fluid used to create tamponade was 381.06 ml in the study by Ahmad SN et al.[16]

In the study conducted by Martin E et al, uterine tamponade was used in 49 women; 61% after vaginal delivery and 39% after cesarean section.[14] 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 while in study by Sheikh L et al, Cesarean hysterectomy done in 3 cases.[13] However, In study by Ahmad SN et al CC successfully controlled haemorrhage in 31 out of 33 patients.[16] In both the failed cases, hysterectomy was required (6%). However, in my study CC controlled PPH in 95 cases including 27 cases with Misoprostol failure and it failed in 5 cases for which hysterectomy was done.

In study by Moushmi B et al, CC inserted in 23 cases.[11] Out of these cases, 18 were successful without further intervention. 5 cases had failure and in 4 cases abdomen was opened, devascularisation was carried out and only 1 case responded. In remaining 3 cases hysterectomy had to be done.

In study by Doumouchtsis SK et al, there were 27 women who had placement of the SBOC.[17] In 22 cases hemostasis was achieved, while in 5 cases the SBOC failed in arresting hemorrhage and hysterectomy was done. In study by Majumdar A et al, 22 cases in which the Rusch balloon was used to control massive PPH.[18] Out of 22 cases,13 cases required no further interventions after balloon tamponade and 7 cases underwent hysterectomy. However, in study by Kong MC et al, out of 35 cases, there were 19 cases in whom the Bakri balloon catheter was used.[19] Within the same period,

there were 6 peripartum hysterectomies, 2 of which involved attempted use of the Bakri balloon catheter.

CONCLUSION

Outcome is affected by the booking status of cases. Age has no significant association with whether PPH is controlled or not. Parity status does not affect whether PPH is controlled or not. Outcome is significantly affected by the hemostasis interval, PPH to CG balloon insertion interval and CG balloon inflation to hemostasis interval. CC was found to be more cost effective, being cheaper and easily available at primary health care centre. Misoprostol can be misused for MTP and unwanted pregnancies, so we can aptly use CC for saving life.

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