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Role of PPH clamp as a first aid in management of PPH in central India population

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ABSTRACT

Background: PPH is most significant and common cause of maternal morbidity and mortality in developing and developed countries both due to uncontrolled bleeding. It is responsible for 30% of maternal death. Around, two-thirds of the obstetric morbidity is related to haemorrhage. From many studies, found that PPH 50 times increases the risk of the morbidity and 5 times higher morbidity than mortality.

Materials and Methods: This is a prospective cohort study, which is done in the Department of Obstetrics & Gynaecology of MGM Medical College and M.Y. Hospital, Indore over a period of one year in 60 patients.

All the patients who developed PPH with failed medical management and give proper consent for application of clamp included. Patients with cervical cancer and patients who do not give consent are excluded.

Statistical Test: All the data analysis was performed using IBM SPSS ver. 20 software. Frequency tables and cross tabulation is used to prepare the tables. Categorical data was expressed as number and percentages whereas quantitative data was expressed as mean and standard deviation. Categorical data was compared using chi square test whereas means were compared using one-way Anova. Microsoft word and excel used to generate graph, table etc. P value of less than 0.05 was considered as significant.

Results: In our study, more than half (56.7%) clamping were successful. In this study, more than half (56.7%) clamping were successful. Patients with lower parity had more chances of successful clamp as compared with those with higher parity. Blood loss was significantly less in those with successful clamp (1127.94) as compared to without successful clamp (1384.62) as revealed by the highly significant p value of <0.001.

Conclusion: In the present study, we evaluated requirement of further surgical procedure and clamp success rate and results showed that majority of the patients who had successful clamp does not require further surgical procedure to undergo as compared to those without successful clamp. Blood loss was significantly less in those with successful clamp as compared to without successful clamp.

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1. Introduction

Postpartum Haemorrhage (PPH) is defined as blood loss ≥ 500 ml after a vaginal delivery and ≥ 1000 mL after a caesarean delivery within 24 hours after birth.¹ PPH is most common and significant cause of maternal morbidity and

mortality in developing and developed countries both. It is responsible for 30% of maternal deaths.¹

The overall worldwide prevalence is 6 to 11 percent of births with some variation across various regions. Death from PPH occurs in about 1/1000 deliveries in low-resource countries while 1/100,000 deliveries in higher-resource countries.²

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PPH is classified into two category primary and secondary, it is called primary when it occurs within 24 hours of birth, or secondary when. Bleeding occurring within 24 hours after delivery and 6 weeks postpartum. PPH also classified as 3rd or 4th stage depending on whether it occurs before delivery of placenta or after delivery of the placenta, respectively.³

Around up to 25 percent of a patient's blood volume (≥ 1500 mL in pregnancy) can be lost before BP falls and HR rises. Hb and Hct values are poor indicators of acute blood loss, but a low fibrinogen level (less than 200 mg/dL) is good predictive marker of severe PPH, indication for multiple units of blood and blood products transfusion, the need for angiographic embolization or surgical management of haemorrhage, or also leads to maternal death.

California maternal quality care collaborative staging system — The California maternal quality care collaborative OB haemorrhage emergency management plan -

1. Stage 0 – Every woman in labour/giving birth.
2. Stage 1 – Blood loss >500 mL vaginal delivery or >1000 mL caesarean delivery or change in vital signs (by >15 percent or HR ≥ 110 beats/minute, BP $\leq 85/45$ mmHg, SpO₂ below 95%.
3. Stage 2- continuous bleeding with total blood loss less than 1500 ML.
4. Stage 3 - more than 1500ml total blood loss or transfusion of more than 2 units PRBC or unstable vital signs or suspicion of DIC.

Common causes of PPH are- uterine atony, distended bladder, tissue (retained placenta and clots), trauma (vaginal, cervical, or uterine injury) thrombin (coagulopathy). Uterine atony is responsible for the majority of cases around 75%. Myometrial contraction is primary protective mechanism for immediate haemostasis after delivery causing occlusion of uterine blood vessels, for these reasons it is called living ligatures of the uterus.⁴

AMTSL has recently gained acceptance for bleeding prevention and 4 global policies support its scale-up.

In conservative management techniques are first line treatment, such as uterotonic medications, external uterine massage, and bimanual compression. If these are failed then used surgical options include curettage, uterine and other pelvic artery ligation, uterine compression sutures, and hysterectomy.³

When first-line conservative management has failed to control bleeding and can be considered second-line interventions like uterine balloon tamponade and uterine artery embolization.⁵

The present study is intended to evaluate role of PPH clamp/forceps as a first aid in management of PPH.

2. Aims and Objectives

This prospective cohort study on done in the Department of Obstetrics & Gynaecology of MGM Medical College and M.Y. Hospital, Indore over a period of one year in 60 patients. The aim of study is-

To study the role of PPH clamp/forceps as a first aid in management of PPH.

3. Objectives

1. To study the role of PPH clamp in prevention of excessive bleeding following delivery.
2. To study the efficacy of PPH clamp.
3. To study the role of PPH clamp in prevention maternal death in hospitals and low resource health care centres.
4. To reduce need of blood transfusion.
5. To reduce the surgical intervention.
6. To study the association of parity status and postpartum haemorrhage.
7. To study the efficiency and time responsiveness of the interventions used for prevention of postpartum haemorrhage.

4. Materials and Methods

4.1. Sample size

60 cases which were divided into those with and without successful clamp.

4.2. Ethical issue

Written Informed consent obtained by study subject.

Ethical clearance from IRB and IEC.

4.3. Inclusion criteria

All the patients who developed PPH with failed medical management and give proper consent for application of clamp. Exclusion criteria: Cervical cancer and Patients who do not give consent for application of clamp.

4.4. Methodology

1. All patients were selected after taking informed consent for paracervical clamps (PPH clamp) and all surgical interventions.
2. To manage PPH in low-resource health care settings, a low-tech, reusable, portable, and affordable set of stainless steel paracervical clamps were introduced.
3. We anticipated that the device may be used in any birthing setting to significantly decrease the blood loss.
4. These specially design clamps, introducing through vagina to reach and temporarily obliterate the uterine arteries against the uterine wall (after delivery).
5. Occlusion of the uterine artery [source of 90% of blood flowing to the uterus], instantaneously reduce

pph.

- If these clamps applied before the separation and expulsion of placenta leads to uterine artery occlusion, may also create a clotting-cascade and leads to placenta to detach with greater ease. The device results similar to surgical procedures used in developed to treat PPH; however, it achieves these results through a minimally invasive and simplified, transvaginal application.

Procedure and investigation details

- Patient placed in lithotomy position.
- Explore cervix.
- Use low tech, stainless steel paracervical clamp.
- With the help of ring/sponge forceps grasp anterior and posterior lip of cervix.
- To preventing of ureter, occlude the right uterine artery with cervix pulled to the left and sponge forceps/Paracervical clamp is applied over tissue within the lateral fornix.
- Forceps/clamps to be locked, for crushing prevention only by one lock.
- This procedure is also applied on opposite side.
- Ring/sponge forceps holding anterior and posterior lip of cervix is removed.
- Immediate stoppage of bleeding occurs and Patient is monitored on that time. If any vitally un-stabilised or if bleeding continues patient is shifted to surgical management.
- Cervical and vaginal tears sutured.
- Urine output is monitored.

The application of clamp, compress the cervical branch of uterine artery and the anterior and posterior cervical wall, which can reduce the bleeding in the lower segment of the uterus. Thus, reduce the flow of uterine artery and stimulate the contraction of uterus. In vaginal delivery, cervix is more expanded by delivery and becomes more elastic and softer in the influence of hormones produced in pregnant period than in non-pregnant period, clamping is easy to be performed. Stretching and clamping of the uterine cervix downward may twist the uterine artery.

4.5. Measurement of blood loss

Calibrated under thigh sheets or vaginal pads was used to estimates blood loss following delivery.

4.6. Quantify blood loss

- Routine quantification of blood loss (QBL) with standardized processes is strongly recommended for all births.
 - Collected blood in graduated measurement containers, including drapes with calibrated pockets.



Fig. 1: Picture of the clamp

- Used visual aids (ex- posters) that correlate the size and appearance of blood on specific surfaces (ex, maternity pad, bed sheet, lap sponge) with the volume of blood absorbed by that surface.
- Measured the total weight of bloody materials and subtract the known weight of the same materials when dry.

Investigations done- Haemoglobin, PTINR, RFT, LFT, Serum Electrolyte, Blood group, Fibrinogen Level, FDP and D-Dimer.

Parameters recorded - Vitals (pulse, blood pressure, respiratory rate, oxygen saturation), age 40, Occupation, SES, Residence, Parity, Past Menstrual cycle, Blood loss, Haemoglobin level, Mode of delivery, Uterine tone, further surgical process required.

4.7. Statistical test

All the data analysis was performed using IBM SPSS ver. 20 software. Frequency distribution and cross tabulation was performed to prepare the tables. Categorical data was expressed as number and percentages whereas quantitative data was expressed as mean and standard deviation. Categorical data was compared using chi square test whereas means were compared using one-way Anova. P value of less than 0.05 was considered as significant.

5. Observation and Results

Table 1: Clamp successful rate

Clamp successful	Frequency	Percentage
No	26	43.3
Yes	34	56.7
Total	60	100

It was found that 60 clamp performed, 34 [56.7%] went successful.

Table 2: Comparison of age with clamp successful

Age [years]	Clamp successful	Clamp not successful	Total	p-value
20-25	17	9	26	0.443
26-30	9	12	21	
31-35	5	4	9	
More than 35	3	1	4	
Total	34	26	60	

Out of 34 successful clamp, majority of the patients had age between 20- 25 years (n=17) followed by 9 patients who had age between 26-30 years whereas those where clamp was not successful majority had age between 26-30 years (n=12). However, the age distribution between the status of successful clamp was similar as revealed by the insignificant p value of 0.443.

It was found that majority of the patients who had successful clamp were housewife, similarly those who did not had successful clamp were also house wife. This highlights that occupation of patients did not have any association with the successful of clamp as revealed by the insignificant. There was no significant association of SES class and the status of clamp successful as revealed by the insignificant.

Table 3: Comparing parity with clamp successful

Parity	Clamp not successful	Clamp successful	Total	p-value
P0	3	6	9	0.034
P1	8	6	14	
P2	4	13	17	
P3	3	4	7	
P4	6	0	6	
P5	2	3	5	
P6	0	1	1	
P7	0	0	0	
P8	0	1	1	
Total	26	34	60	

It was found that patients with lower parity had more chances of successful clamp as compared with those with higher parity as revealed by the significant p value of 0.034.

Table 4: Comparing past menstrual cycle with Clamp successful

Past menstrual cycle	Clamp successful	Clamp not successful	Total	p-value
Irregular	6	2	8	0.667
Regular	28	24	52	
Total	36	26	60	

Out of 60 patients, 52 were having regular menstruation cycle, while 8 were having irregular menstruation cycle. It was found that presence of past menstrual cycle status did

not have any association with the successful of the clamp as revealed by the insignificant p value of 0.667.

Table 5: Comparing haemoglobin and PTINR with clamp successful

Parameter	Clamp successful	Clamp not successful	p-value
Haemoglobin	8.42±1.23	8.93±1.45	0.021
PT-INR	1.24±0.05	1.40±0.03	0.011

It was found that mean HB (p=0.021) and PTINR (p=0.011) was low in those with successful clamp as compared to those with unsuccessful clamp.

No significant abnormality in renal function test and liver function test was detected in those with successful clamp as compared those without as revealed by the insignificant.

No significant different was there in blood group distribution between those with and without successful clamp as revealed by the insignificant.

Table 6: Comparing estimated blood loss with Clamp successful

Clamp successful	Average estimated blood loss [ml]	p-value
No	1384	0.001
Yes	1127	
Total	1239	

Table 6 shows the comparison of estimated blood loss with Clamp successful. It was found that blood loss was significantly less in those with successful clamp (1127.94) as compared to without successful clamp (1384.62) as revealed by the highly significant p value of less than 0.001.

Average use of PRP (p=0.022), FFP (p=0.001) and PCV (0.012) was significantly less among those with successful clamp as compared to those without.

There was no significant difference in the presence of patients with hypertension or hypotension as revealed by the insignificant p value of 0.869. It highlights that clamp does not lead to increase or decrease in the blood pressure.

Table 7: Comparing mode of delivery with clamp successful

Mode of delivery	Clamp not successful	Clamp successful	Total	p-value
LSCS	13	11	24	0.001
NL	13	19	32	
NL with epi	0	2	2	
PTL	0	1	1	
PTSVD	0	1	1	
Total	26	34	60	

It was found that majority of the patients who had successful clamp underwent normal vaginal delivery as compared to those without successful clamp. The association was highly significant with p value of 0.001.

Majority of the patients (32) were having normal vaginal delivery. Majority of the patients who had successful clamp does not require further surgical procedure to undergo as compared to those without successful clamp as revealed by the highly significant p value of <0.001.

6. Discussion

Paracervical clamps application is a novel, effective, simple and minimally invasive surgical technique for preventing excess blood loss in PPH. It provides timely intervention and also avoiding hysterectomy and consumption coagulopathy and preserves reproductive life of patients. It can be used in setting-with or without facility. It is prophylactic as well as therapeutic. It is less expensive, accessible to all and easy to use. Traumatic as well as atonic PPH both can be managed. It can be used as temporary measures and shift the patient for further management from periphery to higher centres.⁶

In our study, we aimed to reduce the immediate blood loss following delivery and evaluate the applicability and effectiveness of a new non-pharmacological maneuver.

In this study, we found that out of 60 clamps performed, 34 went successful. This suggest that more than half (56.7%) clamping were successful. Unsuccessful clamping accounted for the 43.3% and that was mostly due to lack of surgeon's skills and coordination between staffs.

A study done by Ramalingappa CA et al. found that higher success rates of 95% of application of paracervical clamps as a non-invasive technique. Similar study done by Knight M et al, National Perinatal Epidemiology Unit, University of Oxford, Old Road Campus, Oxford, UK. In this study, they found that 25% of women had successful intrauterine tamponade before the use of another second-line therapy.⁷ 16 patients required further surgical management. Two patients succumbed to death. Haemorrhage was effectively controlled in 304 (95.1%) patients and only 16 patients“ required further 61 surgical management. This non-invasive simple procedure has reduced the rates of surgical management of PPH and the associated morbidity.⁶

Similar another study done by Nahar et al. in a tertiary care centre, Bangladesh 53 cases of PPH were managed by intrauterine balloon tamponade, success rate of this is 98%.⁸

Thirmur S et al, Russells Hall Hospital, Dudley Hospitals NHS Foundation Trust, Dudley, UK. Balloon tamponade was effective in 41 of 47 cases (87.2%) of PPH. They use for different causes such as uterine atony, placenta previa, and placental bed bleeding. It was also effective in avoiding hysterectomy in 93.6% women.⁹

In the present study, found that out of 34 successful clamp, majority of the patients had age between 20-25 years (n=17) followed by nine patients who had age between 26-30 years whereas those where clamp was not successful majority had age between 26-30 years (n=12). However, the

age distribution between the status of successful clamp was similar as revealed by the insignificant p value of 0.443.

Ramalingappa CA et al. showed that majority of the patients 60.5% were from age group of 20-25 years. In that study, the mean age of patient was 25.1 years.⁶ The study done by Gai et al. showed that the mean age was 29.71±4.18 years, which was similar to the other study.¹⁰

We have also compared occupation with clamp successful rate, which showed that majority of the patients who had successful clamp were housewife, similarly those who did not had successful clamp were also house wife. This reveals that occupation of patients did not have any association with the successful of clamp. Results showed that highest number (18) of successful rate was found in lower SES, while highest number (16) of failure was also noted with the same group.

The effect of parity on clamp success rate is different among various studies, so we have studied and showed that patients with lower parity had more chances of successful clamp as compared with those with higher parity as revealed by the significant p value of 0.034. Out of total 60 patients, majority of them were having second parity (17) followed by first parity (14). A study done by Ramalingappa CA et al showed that 48.7% of the patients were primipara. Similar to the study conducted by Al-Zirqi I et al University of Oslo, Norway.¹¹

Grand multiparous women were treated as a high-risk group. Another study conducted by Bhavana et al at Deccan College of Medical Sciences, Hyderabad, and Telangana, India has similar results.¹²

Association of menstrual cycle and clamp success rate was also noted in the present study and showed that presence of past menstrual cycle status did not have any association with the successful of the clamp.

We have compared PTINR and RFT/LFT with clamp success rate and results showed that mean HB (p=0.021) and PTINR (p=0.011) was low in those with successful clamp as compared to those with unsuccessful clamp. Comparison of RFT/LFT with clamp success rate showed that no significant abnormality in renal function test and liver function test was detected in those with successful clamp as compared those without as revealed by the insignificant p value of 0.668.

No significant different was there in blood group distribution between those with and without successful clamp as revealed by the insignificant p value of 0.648. Highest number of patients having blood group A+ were 17 followed by B+ (16) in our study. Lowest numbers of patients were noted in O- blood group in only 1 patient.

The present study showed that blood loss was significantly less in those with successful clamp (1127.94) as compared to without successful clamp (1384.62) as revealed by the highly significant p value of less than 0.001.

The results showed that average use of PRP (p=0.022), FFP (p=0.001) and PCV (0.012) was significantly less

among those with successful clamp as compared to those without.

No significant difference in the presence of patients with hypertension or hypotension as revealed by the insignificant p value of 0.869. It highlights that clamp does not lead to increase or decrease in the blood pressure. Majority of the patients were having normal BP (39); 12 were hypertensive and 9 were hypotensive.

Majority of the patients who had successful clamp underwent normal vaginal delivery as compared to those without successful clamp. The association was highly significant with p value of 0.001. Majority of the patients (32) were having normal vaginal delivery. Similarly, Ramalingappa CA et al. showed that out of 680 cases of PPH, 411 (60.7%) delivered vaginally and 214 (31.3%) delivered by LSCS. 55(8%) patients had instrumental delivery.⁶

In the present study, we evaluated requirement of further surgical procedure and clamp success rate and results showed that majority of the patients who had successful clamp does not require further surgical procedure to undergo as compared to those without successful clamp as revealed by the highly significant p value of less than 0.001.

7. Conclusion

The MMR [maternal mortality rate] has been used as a measure of the quality of the health care. Apparently, two-thirds of the obstetric morbidity is related to haemorrhage. PPH increases the risk of the morbidity 50 times and that it has 5 times higher morbidity than the mortality.¹³ There is no doubt that women in the developing countries have a high risk of dying from PPH which can be related to poor health services provided to them. Thus, innovations to improve their care are indispensable.¹⁴

The most common symptoms of PPH include uncontrolled bleeding. The WHO and other professional bodies recommend active management of the third stage of labour (AMTSL) for all vaginal births.^{6,14}

In this study, more than half (56.7%) clamping were successful. Unsuccessful clamping accounted for the 43.3% and that was mostly due to lack of surgeon's skills and coordination between staffs.

Majority of the patients had age between 20-25 years (n=17) followed by nine patients who had age 71 between 26-30 years whereas those where clamp was not successful majority had age between 26-30 years (n=12).

Majority of the patients who had successful clamp were housewife, in lower SES.

Patients with lower parity had more chances of successful clamp as compared with those with higher parity. Out of total 60 patients, majority of them were having second parity (17) followed by first parity (14).

Presence of past menstrual cycle status did not have any association with the successful of the clamp. Out of 60

patients, 52 were having regular menstruation cycle, while 8 were having irregular menstruation cycle.

Mean HB (p=0.021) and PTINR (p=0.011) was low in those with successful clamp as compared to those with unsuccessful clamp. No significant abnormality in renal function test and liver function test was detected in those with successful clamp as compared those without.

No significant different was there in blood group distribution in our study between those with and without successful clamp as revealed by the insignificant p value of 0.648. 19. Highest number of patients having blood group A+ were 17 followed by B+ (16) in our study.

Lowest numbers of patients were noted in O- blood group in only 1 patient. 20. Blood loss was significantly less in those with successful clamp (1127.94) as compared to without successful clamp (1384.62) as revealed by the highly significant p value of <0.001.

Blood loss was significantly less in those with successful clamp (1127.94) as compared to without successful clamp (1384.62) as revealed by the highly significant p value of <0.001.

Average use of PRP (p=0.022), FFP (p=0.001) and PCV (0.012) was significantly less among those with successful clamp as compared to those without.

There was no significant difference in the presence of patients with hypertension or hypotension. Clamp does not lead to increase or decrease in the blood pressure.

Majority of the patients who had successful clamp underwent normal vaginal delivery as compared to those without successful clamp.

Majority of the patients who had successful clamp does not require further surgical procedure to undergo as compared to those without successful clamp.

8. Source of Funding

None.

9. Conflict of Interest

None.

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