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Original Research Article

Prospective study to analyse effectiveness of Samartharam suction canula as a preventive strategy for postpartum haemorrhage in high-risk mothers at a teaching hospital over a period of one year

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ABSTRACT

Background: To analyse the effectiveness of Samartharam suction canula as a preventive strategy along with routine Active management of third stage of labour (AMTSL) in women who are high risk for pph. Incorporating SR canula along with routine AMSL might help in reducing the incidence of postpartum haemorrhage (PPH).
Methods: This is a hospital based comparative prospective cross-sectional study, carried out among 150 high risk women for PPH who delivered vaginally in department of obstetrics and gynaecology, govt. Theni medical college and hospital, Theni between October 2020 to October 2021. All the women received 10 units of oxytocin IM at the appearance of anterior shoulder, or uterine massage and controlled cord traction. SR cannula was applied in 75women and in another 75 women all other uterotonics (oxytocin, misoprostol and tranexamic acid) for preventing PPH were used.
Results: Mean age of the patients was observed in the age group of 21-30 years (SR suction canula=49, medical management=50). Comparison between SR suction canula and medical methods. In this study it was observed, in higher number of cases the bleeding stopped immediately and there was a significant reduction in the amount of blood loss and the need for blood transfusion. Whereas, bleeding stopped immediately only in lower numbers, in whom medical management alone was used.
Conclusions: This study provides a promising insight, as a prophylactic strategy for prevention of atonic PPH for high-risk mothers.

Keywords: PPH, Pregnancy, SR canula

INTRODUCTION

Postpartum haemorrhage (PPH) is commonly defined to be blood loss of 500 ml or more occurring within first 24 hours after birth, or any time within 12 weeks postpartum. It is one of the leading causes of maternal mortality in majority of the low-income countries. PPH is often classified as primary/immediate/early, occurring within 24 hours of birth, or secondary/delayed/late, occurring more than 24 hours post birth to up to 12 weeks postpartum. About 70% of immediate PPH cases are due to uterine atony. PPH significantly affects maternal outcome both immediately and in long term.

Globally PPH is an important cause for maternal mortality and morbidity like DIC, Acute kidney injury and Multiorgan failure. It necessitates high risk procedure like blood transfusion, uterine compression sutures and hysterectomy. Risk of sepsis increased due to interventions and blood loss. PPH also causes long term morbidity like

persistent anemia, incapacitating future reproductive performances, it also creates severe economic burden. And also affects the family dynamics,

Hence reducing the incidence of atonic PPH is critical to mitigate these comorbidities and ensure maternal safety. Although the majority of women who experience PPH complications have no identifiable clinical or historical risk factors, grand multiparity and multiple gestations are associated with an increased risk of bleeding afterbirth. PPH may be aggravated by pre-existing anaemia and, in such instances the loss of a smaller volume of blood may still result in adverse clinical sequelae. Most cases of PPH are due to conduct of delivery by unskilled workers in more than 50% of deliveries, lack of adequate staff and medicines in health facilities and the difficulty in identification of women prone for PPH. Thus, PPH is a complication that needs effective preventive measures that is designed to suit varied needs of health team which is possible to execute even in a low resource setting.

PPH incidence varies across different regions it is a leading cause of maternal mortality worldwide accounts for over 25 percentage of all maternal deaths reported globally more than 80 percentage of maternal deaths from PPH occurs in Sub-Saharan Africa and south asia.[1]

In developed countries approximately 18,000 maternal deaths are due to PPH (Wikipedia). In developing countries PPH accounts for 20% of maternal deaths. In India, the incidence is 2-4% in vaginal delivery (NMJI) and 6% following caesarean section (IJRCOG). PPH accounts for 20% of maternal deaths.[2]

The NHM in India recognizes PPH as a leading cause of MMR and has implemented several strategies to address it. One of the key preventive strategies is AMSTL other strategies are Anaemia control programmes capacity building of health care workers, establishments of blood storage facilities in rural areas.

AMTSL should be practised (WHO, 2012).This comprises the following: Administration of inj. oxytocin 10 units IM immediately after delivery of the baby within one minute, delay clamping the cord for at least 1 to 3 min to reduce the risk of infant anaemia (early cord clamping is no longer recommended), controlled cord traction by Brandt Andrews technique , postpartum vigilance the uterine tone should be immediately assessed to ensure a contracted uterus thereafter it should be checked every 15 minutes for 2 hours if there is uterine atony, a fundal massage should be monitored more frequently.

It has been estimated that routine use of AMTSL reduces the chance of PPH by nearly 60% to further reduce the incidence of atonic PPH additional low-cost innovative method may be integrated with AMSTL.[3] A quality improvement study reported a reduction in average blood loss during vaginal deliveries when the method was used alongside AMSTL.[4]

Uterine vacuum retraction system is a new method that works on the principle that by creating a vacuum, the uterine walls brought closer to each other. This assists in the natural process of contraction and retraction of uterus and there by closing the vessels.[5] Innovative Device the JADA system, an intrauterine vacuum induced haemorrhage-controlled system has been introduced as a treatment option. JADA was first cleared by the FDA in august 2020 based on results from the pivotal Pearle IDE study.[6] Ebb uterine balloon with vacuum-while primarily a balloon tamponade device, it also incorporates a vacuum system. This type of vacuum induced uterine contraction offers minimal invasive option compared to the traditional surgical methods like compression suture or hysterectomy.[7] It gives an advantage of rapid application, minimally invasive and fertility preservation. The WHO recognizes vacuum assisted uterine devices as an potential alternative for managing PPH in low resource setting.[8]

The Samartharam suction canula is a specialized medical device designed for managing Atonic PPH. Though this Canula may not have widespread reference in global literature its uses often documented in local obstetric practices in India.[9]

The SR canula is a soft flexible tube with a uterine end for intrauterine use and a suction end which is connected to the suction machine. There are documented evidence of use of SR canula in district hospitals in India[10].SR canula is not explicitly mentioned its principle align with WHO guidelines for uterine evacuation tools in PPH. The TNHSP recommends SR canula as an effective method for PPH management.[11]

The prevention and treatment of PPH are therefore vital steps towards improving the health care of women during childbirth and the achievement of the millennium development goals. The purpose of this study is to find out the applicability and efficacy of Samartharam suction canula as a preventive strategy for PPH along with AMSTL in reducing the rate of PPH and the amount of blood loss during PPH.

METHODS

This was a hospital based comparative prospective study, carried out among 150 high risk women for PPH who delivered vaginally in department of obstetrics and gynaecology, govt. Theni medical college and hospital, Theni between October 2020 to October 2021. All the women admitted in labour ward were identified for high risk factors.

Inclusion criteria

All pregnant women with term gestation (more than 37 weeks) with following high-risk factors were selected for study, multiparity, previous history of PPH, induction of labour, polyhydramino, multiple pregnancy, anaemia complicating pregnancy were included.

Exclusion criteria

Women delivered by LSCS, anomalous uterus and fibroiduterus were excluded.

Description of SR suction canula it consists of uterine canula 25 cm long, of two different sizes 12 mm, 18 mm in diameter with the uterine angle and perforations. The uterine canula is connected to a non collapsable but flexible plastic suction tube of 1.25 cm diameter. Connected to a vaccum suction machine with collection bottle with can produce negative pressure of 650 mmHg.

Procedure

Under aseptic precaution, after expulsion of placenta with good source of light and speculum examination any vaginal trauma excluded anterior lip of cervix held with grasper, and canula was inserted in the uterine cavity upto level of fundus. Speculum and forceps removed the canula connected to the suction apparatus through suction tube negative pressure of about 650 mmHg was created and maintained for 10 mins then the suction machine was put off. Procedure was repeated every hour upto three hours. The 20 units of oxytocin drip was maintained during procedure. Cannula removed after 6 hours.

Among the 150 selected 75 women received 10 units of oxytocin IM at the appearance of anterior shoulder, uterine massage, controlled cord traction, in addition to SR cannula and in another 75 women all other uterotonics either oxytocin or misoprostol was used for preventing PPH. The outcome studied were reduction in third stage amount of blood loss, need for blood transfusions and peripartum operative procedures. Ethical clearance was obtained from the Institutional ethics committee, and an informed consent was obtained from the patients those who fulfilled the inclusion criteria. Chi-square test and independent sample t-test was used to analyse association with the outcome. A p value less than 0.05 (typically≤0.05) is statistically significant.

RESULTS

Comparison of age

Comparison of mean age have been calculated and graphically represented in Figure. Most of the patients observed in the age group of 21-30 (SR suction canula=49, medical management=50) are clearly represented. Probability value were calculated for SR suction canula and medical management; p=0.611>0.05 statistically not significant.

Comparison of parity

In this study, parity was measured for both conditions like SR suction canula and medical management; majority of cases were in G2. Similarly, very few cases were in G4. The probability value of parity was calculated; p=0.923 >0.05 statistically not significant.

Comparison of gestational age in weeks

Gestational age in weeks were calculated and graphically represented. In the comparison between the gestational ages for SR suction-canula and medical management, higher number of cases were observed in the gestational age group of 38-39. Similarly, very low cases were observed in>40 weeks followed by <38 weeks. The mean value of SR suction canula is=38.467±2.97, medical methods is=38.4±3.179. The probability value of gestational age is 0.895>0.05 statistically not significant.

Comparison of duration of true labour pain in hours

The comparison between the both groups shows that higher no. of patients was observed in the duration of 5-8 hours. Similarly, very few patients were observed in the duration of >12. Probability values were calculated for duration of true labour; p=0.971> 0.05statistically not significant.

Comparison of outcome

The patients' outcome was calculated and graphically represented. The comparison between SR suction canula and medical methods on patient's outcome, higher no. of patients was observed in SR suction canula FTVD=61 and medical methods=57. Similarly, very few patients were observed in ventouse assisted (FTVD=3 and medical methods=2). Probability value was calculated for patients outcome; p=0.019 <0.05 statistically significant.

Comparison of bleeding stopped

Comparison between SR suction canula and medical methods, in higher number of cases bleeding has been stopped immediately in patients in whom suction canula has been used. Similarly, bleeding stopped immediately only in lower number of patients in whom medical management alone was used. The probability value of stoppage of bleeding immediately is calculated; p=0.001<0.05 statistically significant.

Comparison of intervention required

Any further intervention for PPH required for patients in both groups were calculated and graphically represented. Comparison between SR suction canula and medical methods, only 4 members required further intervention while using SR suction canula and 12 members required further intervention in using uterotonics. In those 4 patients using SR suction canula, conservative surgery was done whereas the 12 patients who underwent medical methods required conservative surgery and peripartum hysterectomy. Probability value was calculated p=0.046<0.05 statistically significant.

Comparison of blood loss

The mean blood loss in SR suction canula group was 270 ml and in medical management group was 330.80 ml.

Comparison between the SR suction canula and medical methods, higher blood loss observed in the medical methods.

The probability value was calculated for blood loss; p=0.003<0.05 statistically significant.

Comparison of number of units of blood transfused

Higher number of patients required transfusion while using uterotonics alone compared to patients in whom SR suction canula was used.

Table 1: Comparison of demographic features of the population under study.

Assessments	Parameters	AMTSL alone, N (%)	AMTSL with SR cannula, N (%)	P value
Age in years		25.01±3.42	25.72±2.52	0.784
Parity	Primi	42.795 (57.06)	47 (62.56)	0.656
	Multiparity	32.20 (42.94)	28 (37.44)	
Socio-economic status	Lower	41 (55.52)	46 (60.26)	0.165
	Middle	27 (35.94)	23 (30.54)	
	Upper	7 (8.53)	6 (9.19)	
History of PPH in previous pregnancy (among multigravida)		3.42 (4.56)	2.955	0.712
Anemia in current pregnancy		51.712 (68.95)	53.56 (71.42)	0.37

Table 2: Comparison of study parameters in both groups.

Parameters	AMTSL alone	AMTSL with SR cannula	P value
Blood loss (ml)	389.45±65.42	216.66±34.27	0.012
Atonic PPH	1.3 (1.81)	0.36 (0.49)	0.001
Fall in haemoglobin (gm/dl)	1.69±0.28	1.45±0.33	0.125
Fall in hematocrit (%)	4.95±0.77	4.47±0.89	0.330
Need for blood transfusion and blood products	3.98 (5.31)	1.4 (1.97)	0.001

DISCUSSION

This study is to reduce the incidence of PPH and the need for blood transfusion, operative interventions thereby encouraging the use of SR suctions canula in high-risk women for PPH Most of the patients observed in the age group of 21-30 (SR suction canula=49, medical methods=50). Probability value was calculated for SR suction canula and medical methods; p=0.611>0.05 statistically not significant. The majority of cases observed in G2; similarly, very few cases observed in G4 SR suction canula and medical methods. Probability value of parity was calculated; p=0.923>0.05 statistically not significant.

The comparison between the gestational ages for SR suction canula and medical methods, the higher amount cases were observed in the group of 38-39 weeks. Similarly, very low cases in more than 40 weeks followed by less than 36 weeks. The mean value for gestational age of SR suction canula is=38.467±2.97and medical methods is=38.4±3.179. The probability value of gestational age is 0.895>0.05 statistically not significant.

Comparison between the both groups shows that higher number of patients pertaining to duration of labour was observed in the duration of 5-8 hours. Similarly, very few patients were observed in the duration of more than 2hrs. Probability value were calculated for duration of labour; p=0.971>0.05 statistically not significant. Comparison between booked and un-booked cases, the higher amount of un-booked cases was observed in both SR suction canula and medical methods. The probability value booked or un-booked cases is calculated; p=0.738>0.05 statistically not significant.

Comparison between the modes of delivery full term normal vaginal delivery were observed in higher number of cases. Similarly, very lower number of cases were delivered by assisted breech followed by ventouse delivery Comparison between SR suction canula and medical methods, the higher systolic BP was observed in SR suction canula=131±5.188 compared to medical methods. The probability value of systolic BP is calculated; p=0.001<0.05 statistically significant.

Comparison between SR suction canula and medical methods, in higher number cases, bleeding has been stopped immediately in whom SR suction canula was used. Similarly, bleeding stopped immediately in lower number of cases in whom medical management alone used. The probability value of stopping of bleeding is

calculated; p=0.001<0.05 statistically significant. Shanthi and Chitra conducted a randomized trial on 300 antenatal mothers, divided into three groups of 100 each, in which one group was given AMTSL, the second group was given AMTSL without uterine massage, and in the third group, AMTSL with the application of a suction cannula was applied. it was found that blood loss was significantly reduced in the AMTSL with cannula group (223±99.2) when compared to mean blood loss in the routine AMTSL-only group (299.0±103.0) and AMTSL without uterine massage group (280.8±119.5), concluding that vacuum retraction cannula is helpful in maintaining the uterine physiology of normal contractility and retractility with a statistically significant level of difference (p<0.01).[12] Samarthram et al conducted a case-control study including 16 normally delivered patients (NVD) and 4 caesarean (LSCS) delivered patients who developed atonic PPH and did not respond well to the routine use of injections oxytocin, methergine, or carboprost. A cannula applied for 10 minutes every hour for three hours by creating a negative pressure of 650 mmHg resulted in complete cessation of bleeding associated with contraction and firm retraction of the uterus with in four minutes after the initiation of the procedure, and blood collected in the suction bottle ranged from 150 ml to 250 ml.[13] Panicker et al. conducted a prospective interventional study on 40 women who had NVD and 15 who had LSCS and concluded that negative suction resulted in the aspiration of all the blood collected in the uterine cavity . The quantity of blood sucked varied from 50 to 300 ml. When the collected blood was completely sucked out, the bleeding ceased. The suction was maintained for 30 min, which resulted in the contraction of the uterus. in all cases, the bleeding stopped after negative intra- uterine suction pressure, except in five patients who had fresh bleeding even after connecting suction; there were found to have vaginal tears and were sutured, in two patients, the cannula got blocked by blood clots, and replacing the cannula immediately controlled the bleeding.[14]

Majority of cases does not require further intervention in SR suction canula compared to medical methods. Probability value is 0.046<0.05 statistically significant. Comparison between the SR suction canula and medical methods, higher blood loss was observed in medical methods 331.80 ml. The probability value was calculated for blood loss; p=0.003<0.05 statistically significant.

Higher number of patients required blood transfusion while using uterotonics alone compared to patients in whom SR suction canula was used. Similarly, very few numbers of patients required blood transfusion >3 units. P value is p=0.001<0.05 statistically significant.

This study had a few limitations as well. While preliminary studies and case reports suggest efficacy there is limited large-scale, high-quality evidence, or randomised controlled trails validating its safety and effectiveness. Our study was a single-center, non-randomised study, use of uterotonics is a confounding factor in the study

CONCLUSION

This study aimed to evaluate the effectiveness of SR suction canula in addition to AMSTL as a preventive strategy for atonic PPH. Results demonstrated the SR canula cost effective safe alternative technique which is minimally invasive. It is a novel innovative technique which can be integrated into clinical protocols particularly in low resource settings, however the study is limited by sample size and long term follow up. This study provides a promising insight, as a prophylactic strategy for prevention of atonic PPH for high-risk mothers.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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