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Study the effectiveness of manual vacuum aspiration method in addition to conventional method for prevention and management of postpartum haemorrhage

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Abstract
Background: Postpartum Haemorrhage (PPH) is commonly defined as a blood loss of 500 ml or more within 24 hours after birth. The purpose of this study was to find out the applicability and efficacy of MVA Syringe in management of PPH along with AMSTL in reducing the rate of PPH and the amount of blood loss during PPH.
Materials and Method: This study was done to assessthe effectiveness of manual aspiration method in addition to conventional methods for prevention and management of postpartum haemorrhage. The study population has been calculated by using G-power software which was determined to be 200 patients with 100 patients in each group. The student t-test and chi-square test was applied for comparison.
Results: In this study the age group of the patients varied between 25-39 years with maximum number of patients in25-30 years. This study is comparable to a study conducted by Dr. Samartha ram *et al* where they selected patients in the age group of 19-33 years.
Blood was significantly reduced with the use of MVA syringe in addition to the conventional method, AMTSL, With mean blood loss of 223 ml as compared to loss of 299.0 ml with the use of only conventional methods.
In a similar study by Samartha ram *et al* in 2014; bleeding stopped less than 4 minutes of application of cannula.
Conclusion: PPH is an obstetric emergency which every obstetrician has to face often unexpectedly. Even after so much of technological advances, very few practical and affordable solutions are available today to decrease PPH related morbidity and mortality . MVA is an effective way to prevent Postpartum Haemorrhage.

Keywords: MVA, obstetric emergency, parity, postpartum Haemorrhage

Introduction
Postpartum Haemorrhage (PPH) is commonly defined to be blood loss of 500 ml or more occurring within first 24 hours after birth, while severe PPH has defined as a blood loss of 1000 ml or more occurring within similar time period. PPH affects about 2% of women giving birth. It is one of the leading causes of maternal mortality in majority of the low-income countries. PPH is one of the significant contributors to the maternal morbidity and long-term disability along with the number of other maternal conditions that are linked with more quantity of blood loss, including shock and organ dysfunction [1-3].
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. In addition, PPH may be described as third or fourth stage depending on whether it occurs before or after delivery of the placenta, respectively [1].
Primary (immediate) postpartum hemorrhage is defined as excessive bleeding that occurs within the first 24 hours after delivery. About 70% of immediate PPH cases are due to uterine atony. Atony of the uterus is defined as the failure of the uterus to contract adequately after the child is born. Secondary (late) postpartum hemorrhage is defined as excessive bleeding occurring between 24 hours after delivery of the baby and 6 weeks postpartum. Most late PPH is due to retained products of conception, or infection, or both combined [5, 6].
Uterine atony is the most common cause of PPH, but genital tract trauma (i.e. vaginal or cervical

(i.e. vaginal or cervical lacerations), uterine rupture, retained placental tissue, or maternal coagulation disorders may also result in PPH. Although the majority of women who experience PPH complications have no identifiable clinical or historical risk factors, grand multiparity and multiple gestation are associated with an increased risk of bleeding after birth. 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 [7].

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 as many women develop PPH without any associated risk factors. Thus, PPH is a complication that needs effective preventive measures that is designed to suit varied needs of women and is possible to execute in a low resource setting [8].

During the second half of the 20th century, a package of interventions performed during the third stage of labour became the cornerstone for the prevention of PPH. This approach became known as the "active management of the third stage of labour" and consisted initially of the following components: the administration of a prophylactic uterotonic after the delivery of a baby, early cord clamping and cutting, and the controlled traction of the umbilical cord. Uterine massage is also frequently included as part of the active management of the third stage of labour. In contrast to *active* management, *expectant* management involves instead waiting for signs of placenta separation and allows for the placenta to be delivered spontaneously, or aided by nipple stimulation or gravity. Compared with expectant management, the active management of the third stage of labour is associated with a substantial reduction in the occurrence of PPH [8].

Active management of the third stage of labour (AMTSL) reduces PPH risk by reducing postpartum blood loss. Prophylactic uterotonics in the third stage of labor decrease the risk of PPH by 60%. PPH is to be expected to occur in all deliveries, and preventive measures of PPH should be followed after very birth. Women are counseled prenatally to have institutional deliveries or to be delivered by trained health staff. However, in low-resource settings, many uterotonics used in the prevention of PPH may not be useful because they require refrigeration and/or skilled health staff for administration [9].

Harvey Karman, in 1972, designed the vacuum syringe and described the principles of MVA for surgical uterine evacuation. The principle of MVA is exactly the same as routine surgical management of miscarriage except that it involves the use of a handheld syringe as a source of suction instead of an electric suction [10].

It is generally assumed that by preventing and treating PPH, most PPH-associated deaths could be avoided. 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. To reach these objectives, health workers in developing countries should be given access to appropriate medications and be trained in procedures relevant to the management of PPH. Countries also need evidence-based guidance to inform their health policies and improve their health outcomes [11].

The purpose of this study is to find out the applicability and efficacy of MVA Syringe in management of PPH along with AMSTL in reducing the rate of PPH and the amount of blood loss during PPH.

Materials and Method

This study was done to assess the effectiveness of manual aspiration method in addition to conventional methods for prevention and management of postpartum haemorrhage after clearance from Board of Studies and Ethical committee in the Department of Obstetrics and gynaecology, Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh during the period 2018-2020.

Sample Size

The study population has been calculated by using G-power software with 80% of the power and 5% of the significance level. The sample size consisted of 200 patients with 100 patients in each group.

Study procedure

After approval from the Institutional Ethical committee all patients were selected. A detailed history, complete physical examination and routine & appropriate investigations were done for all patients.

The study included all women who deliver vaginally develop primary or secondary PPH, inspite of use of uterotonics and AMTSL. They were randomly categorized into 2 groups:

a) Group A (control group), in which only conventional method (AMTSL) for prevention of PPH was used.

b) Group B (test group), in which addition to above criteria in group A; MVA syringe was used for prevention of PPH.

Blood loss in all the three groups was measured, Vital monitoring after 15 minutes of admission followed by vital monitoring after 30 mins and 2 hours was done.

MVA syringe was used after delivery of head of fetus within 1 minute of delivery, after expulsion of the placenta. MVA with karmans cannula was insertred into uterine cavity upto fundus and outer end connected to suction machine. A negative pressure of 650mm hg was created and kept for a period of 10 mins.

Haemoglobin status of the patient just before the procedure, followed by repeat Hb after 24 hours and 48 hours was done. Follow-up of the patient with Hb levels was done after 3 days followed by 15 days. The results in all the groups was compared to see the efficacy of MVA syringe.

Statistical analysis

The data was entered into the Microsoft excel and the statistical analysis was performed by statistical software SPSS version 21.0. The Quantitative (Numerical variables) were present in the form of mean and SD and the Qualitative (Categorical variables) were present in the form of frequency and percentage.

The student t-test was used for comparing the mean values between the 2 groups whereas chi-square test was applied for comparing the frequency. The p-value was considered to be significant when less than 0.05.

Results

The mean age of the study population was 33.12±3.14 years with a range of 25-39 years with no difference between the two groups, Group A which included only the use of conventional methods and Group B (Test group, which included the use MVA syringe in addition to conventional methods. The distribution of Parity did not differ significantly between Group A (AMTSL) and Group B (Test group). The birth weight of the baby did not differ significantly between the two groups, with average weight of 2.7 kgs.

On comparing the blood loss between two groups, significant differences were found. After the use of MVA syringe in

addition to conventional methods; blood loss was controlled in 77% cases as compared to 56% cases, where only conventional methods were used. The mean blood loss with the use of MVA Syringe in addition was 223 ml as compared to 299 ml with use of only conventional methods.

Out of 100 pateints in AMTSL group, only 12% cases had loss of less than 200 ml as compared to 43% cases where both MVA and conventional methods were used.

45% cases had blood loss of 233-300 ml with use of AMTSL as compared to 52% where both the methods, MVA and AMTSL were used. The difference between the immediate haemoglobin levels postdelivery and haemoglobin levels 24 hours after delivery did not differ significantly.

Table 1: Descriptive Statistics

	Minimum	Maximum	Mean	Std. Deviation
Age	25.00	39.00	33.12	3.14

The mean age of the study population was 33.12±3.14 years with a range of 25-39 years

Table 2: Comparison between the age of presentation of haemorrhage and utilisation of uterotonics in Group A and both uterotonics and MVA syringe in Group B

	Age				
Groups	**Mean**	**Std. Deviation**	**Mean Difference**	**t-test value**	**p-value**
Group A (AMTSL)	32.98	3.21	-0.27	-0.608	0.544
Group B (Test group)	33.25	3.07			

Table 3: Comparison between birth weight of the baby between the two groups

	Birth weight				
Groups	**Mean**	**Std. Deviation**	**Mean Difference**	**t-test value**	**p-value**
Group A (AMTSL)	2715.79	77.31	-7.89	-0.706	0.481
Group B (Test group)	2723.68	80.77			

Table 4: Comparison of blood loss between Group A(conventional method) and Group B(use of MVA additionally)

Excessive blood loss after preventive method	**Groups**		**Total**
	Group A (AMTSL)	**Group B (AMTSL & MVA))**	
Not present	56	77	133
	56.0%	77.0%	66.5%
Present	44	23	67
	44.0%	23.0%	33.5%
Total	100	100	200
	100.0%	100.0%	100.0%
Chi-square value = 9.898, p-value = 0.002*			

Chi- square test * Significant differenc

After the use of MVA Syringe in addition to conventional methods, blood loss was controlled in 77% cases in comparison to 56% cases, where only conventional method-AMTSL was use

Graph 5: Comparison of blood loss between Group A (conventional method) and Group B (use of MVA additionally)

Table 5: Distribution of complications after complete hemostasis

Complications	**Groups**		**Total**
	Group A (AMTSL)	**Group B (Test group)**	
No	68	79	147
	68.0%	79.0%	147.0%
Yes	32	21	53
	32.0%	21.0%	53.0%
Total	100	100	200
	100.0%	100.0%	100.0%
Chi-square value = 3.025, p-value = 0.029*			

Chi- square test * Significant difference

After achieving complete hemostasis, complications were found to be significantly more in group A with only conventional methods i.e in 32% cases as compared to only 21% cases where MVA syringe was used in addition to conventional methods.

Table 6: Distribution of Mean postpartum Haemoglobin on third postnatal day.

	AMTSL	**MVA Syringe in addition to AMTSL**
Haemoglobin(g/dl)	9.1±0.3	10.2±0.3

Table 7: Comparison of haemoglobin at admission and repeat Haemoglobin at 24 hrs

	Mean Hb(g/dl) In group A (Mean±SD)	Mean Hb(g/dl) In group B (Mean±SD)
Use of Conventional method only	9.3±0.3	9.1±0.3
MVA syringe in addition to Conventional methods	9.4±0.3	9.1±0.3

Table 8: Comparison of quantity of blood loss in two groups

Blood loss (in ml)	Conventional method only (AMTSL)	MVA syringe in addition to conventional method
<200ml	12 (12%)	43 (43%)
200-300ml	45 (45%)	52 (52%)
300-400ml	35 (35%)	01 (1%)
400-500ml	3 (3%)	-
500-600ml	2 (2%)	1(1%)
600-700ml	3 (3%)	2(2%)
700-800ml	-	1
	100	100

Table 9: comparison of mean blood loss (in ml) between two groups

	Groups	
Blood loss (in ml)	**Conventional Methhods (group A)**	**MVA syringe in addition to Conventional methods (group B)**
	299.0±103	223±99.2
	P value (<0.001) significant	

Discussion

PPH is one of the leading causes of maternal mortality and an important cause for serious morbidity in the developing and developed world. Morbidity from PPH mainly includes surgical interventions, sepsis and severe anemia. Uterine atony, in which there is failure of the uterine muscle to contract normally following delivery of the baby and placenta, is responsible for up to 70% of all causes of PPH [12].

The general management of PPH starts by conservative measures like uterine massage and uterotonics drugs. Severe postpartum blood loss in hemodynamically unstable patients is more likely to need hysterectomy which can be one of the dangerous procedure and cause permanent loss of fertility. Since last decade, conservative surgical procedures have been successfully used in various circumstances and forms. Conservative surgical approach not only controls PPH but also preserves the woman's reproductive functions and avoids hysterectomy and its related complications and consequences [13].

Postpartum hemostasis normally depends on mechanical events which induce strong contractions of the uterine musculature [14]. The simple mechanical and physiological measures of massaging the fundus, bimanual uterine compression and emptying the bladder to stimulate uterine contraction represent time-honored first-line management of PPH. No published studies were identified to provide an evidence-base for these interventions; nevertheless, professional consensus supports their continued use [15] However, the techniques of external compression like uterine massage and bimanual uterine compression are not able to maintain constant pressure which is taken care of by the suction pump in this technique.

Prendiville and colleagues' meta-analysis [16] demonstrated the benefits of AMTSL to prevent and reduce PPH after vaginal delivery for women at low risk of PPH. The meta-analysis concluded that active compared with expectant management significantly reduced the risk in all areas, including mild PPH (estimated blood loss > 500 mL;OR = 0.38), severe PPH (estimated blood loss > 1000 mL; OR = 0.32), low postpartum hemoglobin level (< 9 g/dL; OR 0.38), need for transfusion (OR = 0.33), and need for additional uterotonic medication (OR = 0.17). It was found that there was significantly more nausea and hypertension in the actively managed group given ergonovine (OR = 1.83).

In the study by *Makhija et al*, [17] Suction and evacuation was successful in 88.9% cases for control of post-partum haemorrhage. *Hsu et al* reported the safety and effectiveness of uterine packing for stopping haemorrhage in patients following delivery and pregnancy termination. Only 1 patient had failure of packing resulting in postpartum hysterectomy. There was no significant morbidity secondary to packing [18].

A study conducted by *Robert et al* showed that successful treatment of haemorrhage was clinically evident after procedure was completed, although packing material became heavily stained with serosanguinous fluid. Fever after uterine packing was minimal and of no clinical significance [19].

Two case reports from Pakistan on uterine packing showed successful management and it was recommended that packing should be practiced at tertiary hospitals if women wishes to preserve fertility [20]. B Lynch Brace Suture which is another conservative surgical approach but not in practice. *Roman* described that "re-emergence" of uterine packing, which fell out of use largely due to concerns of concealed haemorrhage [21]. *Doumouchtsis et al* showed that success rates of 90.7% for arterial embolization, 84.0% for balloon tamponade, 91.7% for uterine compression sutures, and 84.6% (81.2%-87.5%) for iliac artery ligation or uterine devascularization [13].

Examination under anesthetic and surgical evacuation of the uterus should be considered if retained placental tissue is suspected clinically or after ultrasound examination. This intervention has good reported success rates, with bleeding stopping promptly in all 72women undergoing evacuation of the uterus for secondary PPH in one study, despite only 36% having proven histological evidence of retained tissue [22].

Retained placental tissue is likely to be associated with infection and, therefore, broad spectrum intravenous antibiotics should begiven in conjunction with surgical evacuation. AS serum concentrations of most antibiotics peak 1 hour after intravenous administration, these should be administered just prior to surgery; [24] in women who are hemodynamically stable, however, it may be appropriate to administer 12-24 hours of antibiotic cover prior to surgery [23].

At the time of surgery, uterotonic agents such as Syntocinon, ergometrine and prostaglandins maybe helpful to aid uterine contractility and control hemorrhage. There is no clear evidence to support which method of evacuation should be used. Manual removal of tissue, use of a suction catheter and sharp curettage with a metal curette have all been described [24-26]

The risk of uterine perforation is much higher in postpartum uterine evacuation and may beeven further increased if associated with endometritis. Hoveyda and colleagues describe uterine perforation with both a suction and metalcurette. One woman went on to requirea hysterectomy, but the two others were managed conservatively [24-26].

One of the complicationis the risk of Asherman's syndrome. Limited evidenceis thereto confirm whether this risk is more for the postpartum uterine evacuation; however, in a large study of intrauterine adhesions, 21.5% cases had a postpartum curettage as a prior event [27]. The need for a second procedure due to

incomplete evacuation of retained tissue may also occur [24]. Hysterectomy may be required to control bleeding in up to 5% of cases [28]. In view of these significant complications, women should always be fully counselled of the risks and informed consent obtained.

Several studies have shown MVA to be a safe, effective and acceptable alternative to electric vacuum aspiration with very high success rates [29-36]. *Creinen and Edwards* [31] reported that MVA under local anaesthesia had complete uterine evacuation among 99.2% women. A pilot study in the UK involving 56 women showed that 98% of women had a successful procedure without the need for any further surgical or medical intervention. Also, 98% of women were satisfied with the procedure and 86% said they would recommend it to a friend. Eighty percent said they would undergo the same procedure again, if required in the future [35].

One of the studies using the MVA under local anaesthesia for first-trimester, early fetal demise and mid-trimester incomplete miscarriage had complete uterine evacuation among 95%, with only 5% requiring additional treatment [29]. A systematic review showed no difference was found in the number of complete evacuations and patient satisfaction. MVA was associated with lesser amount of blood loss and pain. But the operating time was lesser than women in the EVA group and physicians regarded it being easy to carry out [36].

A systematic review compared MVA with electronic vacuum aspiration for the termination of first trimester pregnancies and showed similar complete abortion rates [37]. Acochrane review [38] compared the safety and efficacy of MVA versus D&C and found no statistically significant differences in numerous intraoperative and postoperative factors including febrile morbidity, incomplete or need for repeat uterine evacuation procedures, and postoperative abdominal pain. One of the randomized controlled trial evaluated the MVA procedure compared with D&C and found significantly lower intraoperative blood loss with the MVA procedure, whereas postabortal sepsis and re-evacuation rates were similar [39].

Complications

Complications during MVA could include uterine and cervical injury, pelvic infection, incomplete evacuation, perforation, pain and vasovagal collapse. *Goldberg et al*. [40] conducted a controlled study of complications of MVA versus EVA in early first-trimester miscarriage, of which 1002 were MVAs and 724 were EVAs. There was no difference in the rates of respiration and complications between the two procedures [40].

Kerure et al. [41] showed that MVA in women with less than 10 weeks of gestation was associated with less blood loss than EVA. There were no cervical lacerations in the MVA group compared with 3% in the EVA group [41]. Regardless, the current common standard of practice does not include early US screening in uncomplicated asymptomatic cases. The MVA procedure is in wide use for early pregnancy termination and is considered a safe and simple method with an extremely low complication rate [38].

Summary and Conclusion

Women continue to suffer sequels from obstetric haemorrhage. Every maternity unit must be prepared and equipped to handle these often unexpected and occasionally critical emergencies at the frontline. PPH is an obstetric emergency which every obstetrician has to face often unexpectedly. Even after so much of technological advances, very few practical and affordable solutions are available today to decrease PPH related morbidity and mortality.

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