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Comparison of Efficacy of Sublingual Misoprostol and Intravenous Syntometrine In the Active Management of Third Stage of Labour

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ABSTRACT

Objective: To compare the efficacy of sublingual misoprostol and intravenous syntometrine in the active management of the third stage of labour. **Study Design:** It was an interventional, quasi experimental. **Setting:** Obstetrics and Gynecology department of Allied Hospital\Punjab Medical College, Faisalabad **Duration:** From 1st Nov, 2007 to 30th April 2008. **Methods:** 100 women were selected and randomly divided into two groups, group A (odd number) and group B (even number) by using random numbers table.600 micrograms sublingual misoprostol was given to Group A and 1 ml of intravenous syntometrine (1ml=5 IU syntocinon and 0.5 mg ergometrine) was given to Group B at the delivery of anterior shoulder of the baby. **Results:** As regards the efficacy of sublingual misoprostol and I.V. syntometrine, the amount of mean blood loss and use of additional uterotonics, results were not statistically significant. None of the patients required manual removal of placenta and there was no case of prolonged third stage of labour (≥ 30 min) in both the groups. None of the patients developed blood loss ≥ 500 ml and no blood transfusion required in both groups. There was no statistically significant difference in incidence of nausea and vomiting but shivering and fever were more frequent in misoprostol group. **Conclusion:** Misoprostol is as effective as I.V. syntometrine in the management of third stage of labour and can be used as safe and cheaper alternative.

Keywords: PPH, Third stage of labour, Misoprostol, Syntometrine.

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INTRODUCTION

The third stage of labour is timed from the delivery of fetus until the delivery of the placenta and membranes. This normally takes 5 to 15 minutes. If it is longer than 30 minutes, it should be regarded as prolonged. A major complication of the third stage of labour is primary postpartum hemorrhage (PPH), which is defined as the loss of greater than 500 ml of blood through the genital tract after the delivery of fetus in the first 24 hours postpartum.[1]

It is one of the leading causes of maternal morbidity and mortality in the developing world.[2] It occurs in approximately 4% of vaginal deliveries.[3] The most common cause of PPH is Uterine atony, and its frequency seems to be related to both risk factors and management of the third stage of labour.[4] Most commonly used uterotonic drugs such as syntocinon and syntometrine (1ml=syntocinon 5 IU and ergometrine maleate 0.5 mg) need parenteral administration, storage at proper temperature and protection from light which is not feasible in under resourced settings where many deliveries occur at home. So, most maternal deaths occur during home deliveries when there is no trained birth attendant to implement active management of the third stage of labour.

Misoprostol is a prostaglandin E1 analogue which is a rapid and potent myometrial stimulant. It has range of potential benefits including ease of administration, low cost, stability at room temperature and long shelf life.[5] The sublingual route of misoprostol is a convenient way that allows quick absorption and faster peak action than the oral route.

The rational of my study is to determine whether sublingual misoprostol is as effective as intravenous syntometrine in the active management of the third stage of labour and to find out an acceptable alternative in settings where parenteral drugs are not available. The purported significance of my study is that it will be its kind of first study in this setting and will bring confidence on a drug which is effective, safe, economical, has easy route of administration and can be an acceptable alternative in settings where parenteral Uterotonic drugs cannot be used or not available.

Pregnancy and child birth involve significant health risks even for woman with no preexisting health problems. Postpartum hemorrhage is a leading cause of maternal morbidity and mortality in developing and developed countries. Pakistan is a developing country, with our most women getting delivered at home by trained or untrained birth attendants. Most maternal deaths occur during home delivers when there is no trained birth attendant to implement active management of the third stage of labour.

Rationale of the study was to find out an acceptable alternative in settings where parenteral uterotonic drugs are not available and to determine, whether sublingual misoprostol was as effective as intravenous syntometrine in the active management of the third stage of labour.

The significance of the study was to establish confidence on drug which is effective, safe, economical, has easy route of administration and can be an acceptable alternative in settings where parenteral uterotonic drug administration cannot be used or not available.

Objective: The objective of this study was to compare the efficacy of sublingual misoprostol and intravenous syntometrine in the active management of the third stage of labour.

Operational Definition: The efficacy of two drugs was measured by following parameters.

- Duration of the third stage of labour ≥ 30 min
- blood loss ≥500 ml
- Need for manual removal of placenta
- Need for additional uterotonic drugs
- Need for blood transfusion
- Presence or absence of adverse effects like nausea, vomiting, shivering, fever (>100 ^{0}F)

Hypothesis: Efficiency of sublingual misoprostol is comparable to intravenous syntometrine for the active management of third stage of labour.

METHODOLOGY

Study Design: Interventional; Quasi Experimental

Setting: Obstetrics and Gynecology Department of Allied Hospital, Punjab Medical College, Faisalabad Pakistan.

Duration: Six months study from Nov, 2007 to April 2008.

Sample Size: Total 100 cases were included in this study and were divided in two groups of 50 each. Keeping in mind the approximate number of uncomplicated vaginal births and duration of study period of six months, sample size was selected.

Sampling Technique: It was non-probability purposive sampling.

Inclusion Criteria:

- Women presented in labour ward of Allied Hospital Faisalabad, with singleton uncomplicated term pregnancies (37-42 weeks) with vertex presentation and spontaneous onset of labour anticipated to end up in vaginal delivery (diagnosed on the basis of history and examination) were included in this study.

Exclusion Criteria

- Women having medical disorders (hypertension, cardiac disease, and known cases of bleeding disorders)
- Previous history of third stage complications
- Those having known hypersensitivity to drugs (on the basis of history & examination).

Data Collection Procedure: Patients fulfilling the above mentioned inclusion criteria were selected for study from admitted patients in first stage of labour throughout door and emergency after explaining the benefits (easy route of administration, low cost and stability at room temperature of misoprostol) and risks (occasional nausea, vomiting, rise in temperature and sometimes shivering) addressing the ethical issues and taking informed consent.

Patients with medical disorders (hypertension, cardiac disease, known cases of bleeding disorders), previous history of third stage complication and known hypersensitivity to drug (all diagnosed on the basis of history) were excluded from study to control the confounding variables. Ethical committee approval was taken.

All the patients were evaluated by taking detailed history including gestational age, demographic data

Clinical examination and baseline investigations (blood group and Rh factor, hemoglobin, RBS, HBs Ag anti HCV and Urine C/E) were carried out. Patients were divided into 2 groups A (odd number) & B (even number) each having 50 patients, by using Random numbers table.

Group A received 600 µg sublingual misoprostol while group B received 1 ml of intravenous syntometrine (1 ml=5 IU syntocinon and 0.5 mg ergometrine) at the delivery of anterior shoulder of the baby. If oxytocin infusion was used during the second stage of labour, it was stopped immediately after delivery.

Third stage of labor, was managed by early cord clamping and controlled cord traction during uterine contraction. If placenta was not delivered within 30 minutes of delivery of baby, manual removal under general anesthesia was done and urogenital trauma was also looked for.

During the third stage, patients were under regular observation for general condition, amount of vaginal blood loss, size and consistency of uterus, blood pressure, pulse rate and respiratory rate. These observations were continued up till 24 hours after delivery in the post-natal ward.

White linen was used to drape the perineal area during delivery. Any blood clots at delivery were collected and measured by a bed pan. All socked pads and white linen were weighed one hour after delivery of placenta. The difference in weight before and after weight was calculated. A 100gm increase in weight was considered to be equivalent to 100 ml blood. If clinically blood loss was more than 500ml and uterus was not well contracted, an additional dose intravenous syntometrine (1 ml) was given. Blood transfusion was done if blood loss was in excess of 1000 ml from genital tract. Adverse effects of drugs (Nausea, vomiting, fever (>100°F), shivering) were recorded.

Observations regarding efficacy included the following:

- Amount of blood loss
- Duration of third stage ≥ 30 minutes
- Need for manual removal of placenta
- Need for additional uterotonic drugs
- Clinical estimation of blood loss ≥ 500 ml
- Need for blood transfusion.
- Presence or absence of maternal and side effects (nausea, vomiting, fever > 100°F, shivering). Data was collected through specially designed proforma.

Data Analysis Procedure: Data analysis was computer based using SPSS-21. Percentages were calculated for age groups, socioeconomic status, PPH (clinical estimation of blood loss ≥ 500 ml), prolonged third stage of labour (≥30 minutes), need for additional uterotonic drugs, need for manual removal of placenta, need for blood transfusion and maternal side effects of drugs (nausea, vomiting, fever >100°F, shiverng) for both the study groups. Chi-square test was applied to compare all the

variables between group A & B. P value ≤ 0.05 was taken as significant.

RESULTS

A total of 100 patients were selected for this study and were randomized to either sublingual misoprostol or I.V syntometrine group with 50 patients in each group. Different variables like age, socioeconomic status, booking status, efficacy and side effects of the given drug were noted. There were no significant differences in the participants characteristics between the two groups at randomization.

Out of 100 selected women for study, most were in the age group of 21-25 years. 66 women were in the age group of 21-25 year, 25 were in the age group of 26-30 year, 07 were in the age group of 31-35 years and 02 patients were in the age group of 15-20 years (Table 1). Most of the patients in this study were having monthly income < 10,000 rupees. Out of 100 patients, 64 were having income <10,000 rupees, 33 were having income 10-25,000 and only 3 patients were having income >25,000 rupees (Table 3). Due to poor socioeconomic conditions and illiteracy, the women remained un booked throughout their pregnancy and admitted in labour ward when labour pains started. Out of 100 selected women, 60 were Un booked and 40 were booked.

Table 1: Distribution of cases according to age

Age Group	Frequency	Percentage
15-20 years	2	2%
21-25 years	66	66%
26-30 years	25	25%
31-35 years	7	7%
Total	100	100%

Table 2: Distribution of cases according to booking status.

Booking Status	Frequency	Percentage
Booked	40	40%
Un-booked	60	60%
Total	100	100%

Table 3: Distribution of cases according to socioeconomic status

Socioeconomic status	Frequency	Percentage
<10,000	64	64
10-25,000	33	33
>25,000	03	03
Total	100	100

There was not significant difference in amount of estimated-blood loss and the incidence of postpartum hemorrhage (≥ 500 ml) or severe postpartum hemorrhage (≥ 1000 ml) between the misoprostol group and the syntometrine group. Mean blood loss was found to be 246.22 ± 16.92 ml in misoprostol group and 240.40 ± 17.96 in syntometrine group (P value=0.099)

Table 4: Amount of blood loss N=50

Drug Used	Mean ± SD
Group A	246.22 ± 16.92
Group B	240.40 ± 17.96

T. Test = 1.668,
DF = 98,
P. Value = 0.099

None of the patients in my study required manual removal of placenta and there was no case of prolonged third stage (≥ 30 min) of labour (Table 6).

There were more women in misoprostol group who required additional Uterotonics, but the difference was not statistically significant. 6% (3) of women in misoprostol groups and 2% (1) of women in syntometrine group needed additional uterotonics. No blood transfusion required in both groups (Table 7).

Regarding the side effects, nausea and vomiting was present in 6% (3) of women in misoprostol group and 8% (4) of women in syntometrine group.

30% of women in the misoprostol group suffered from shivering while none of women in syntometrine group developed pyrexia and shivering.

Fever (> 100 °F) was found in 16% (8) of women in misoprostol group.

Table 5: Occurrence of prolonged third stage of labour (≥ 30 min) N=50

Prolonged 3rd stage of labour	Yes	No
Group A Frequency	0	50
Group A Percentage	0%	100%
Group B Frequency	0	50
Group B Percentage	0%	100%

Table 6: Need for manual removal of placenta N=50

Manual Removal	Yes	No
Group A Frequency	0	50
Group A Percentage	0%	100%
Group B Frequency	0	50
Group B Percentage	0%	100%

Table 7: Need for additional uterotonics N=50

Need for additional Uterotonics	Yes	No
Group A Frequency	3	47
Group A Percentage	6	94
Group B Frequency	1	49
Group B Percentage	2	98

Chi-square Value =1.042,
DF = 1,
P. Value = 0.307

Table 8: Occurrence of PPH (blood loss ≥ 500 ml) N=50

PPH (Blood loss ≥ 500 ml)	Yes	No
Group A Frequency	0	50
Group A Percentage	0%	100%
Group B Frequency	0	50
Group B Percentage	0%	100%

Table 9: Need for blood transfusion N=50

Need for Blood Transfusion	Yes	No
Group A Frequency	0	50
Group A Percentage	0%	100%
Group B Frequency	0	50
Group B Percentage	0%	100%

Table 10: Comparison of the side-effects of the drugs

	Side Effect		
	Nausea & Vomiting	Fever (> 100°F)	Shivering
Group A Frequency	3	8	15
Group A Percentage	6%	16%	30%
Group B Frequency	04	0	0
Group B Percentage	8%	0%	0%
$\chi 2$ Value	0.154	8.696	17.647
DF	1	1	1
P- Value	0.695	0.003	0.000

DISCUSSION

Globally, over half a million women die annually from causes related to pregnancy and child birth. The most common cause of maternal mortality is postpartum hemorrhage, accounting for one third of maternal deaths. 99% of these deaths occur in developing countries where women rarely receive prophylaxis against PPH because most of them give birth outside the hospital.[2]

The major cause of postpartum hemorrhage is uterine atony which is often preventable by uterotonics such as syntometrine and oxytocin alone. However, use of injectable uterotonics is not feasible in much of developing world where deliveries take place in rural areas without trained birth attendants.[3]

Syntometrine has the disadvantage of requiring special storage, requires the use of needle and syringe for parenteral administration. Misoprostol is an agent easy to be administered. The sublingual route is a convenient way that allows quick absorption and faster peak action than the oral route.

The use of misoprostol has therefore a practical role in uncomplicated low risk (spontaneous) vaginal delivery, especially in developing countries when resort to parenteral drug administration is difficult.

There are disadvantages using misoprostol orally at third stage of labor. Firstly, intake of water is required for the oral route and there is a risk of aspiration. Its action is slower because of first pass effect.

The rectal route on the other hand may not be preferred by most women if there is another route with similar efficacy. Sublingual administration of misoprostol has been used as prophylactic oxytocic in a few studies.[4]

Our institution is the site of about more than 6000 births annually and serves a population of low socioeconomic status. We perform more than 500 units of blood transfusions annually because of postpartum hemorrhage. In this setting using sublingual misoprostol in the active management of the third stage of labour proved as effective as I.V. syntometrine.

To the best of our knowledge, no study comparing sublingual misoprostol with the I.V. syntometrine for the active management of the third stage of labour has been previously done or published in literature in Pakistan.

The objective of this study was to compare the efficacy of sublingual misoprostol and intravenous syntometrine in the active management of the third stage of labour. For this purpose, I selected 100 women admitted in emergency ward with the anticipation of vaginal delivery and were randomized to either, group A or group B with 50 patients in each group. Keeping in mind, the approximate number of uncomplicated vaginal births and duration of study of 6 months, sample size was selected. The women in group A were given 600µg of sublingual misoprostol while in group B were given 1 ml of intravenous syntometrine, in the active management of the third stage of labour and results were noted. There was no withdrawal after randomization and total of 100 women completed the study. There was no statistically significant difference between the group. In this study, 600 µg of sublingual misoprostol was not less effective than 1ml of I.V. Syntometrine in reducing blood loss after delivery. The amount of blood loss was nearly same in misoprostol group and in syntometrine group, the difference was not statistically significant. In my study, amount of blood loss was 246.22 ± 16.92 ml Vs 240.40 ± 17.96 ml in the misoprostol group and syntometrine group respectively. None of the patients had prolonged third stage of labour (≥ 30 min) and there was no case of retained placenta requiring manual removal. These findings are comparable with the results of study conducted by Lam *et al* china in 2004.[68] While another trial conducted at department of Obstetrics and Gynecology, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin in 2007 also showed nearly same findings.[5]

A Multi center randomized controlled trial conducted at department of Obstetrics and Gynecology, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin in 2001 showed 0.4% Vs 1.4% incidence of manual removal of placenta in misoprostol and syntometrine groups. Probably this difference can be explained by the fact that they used misoprostol by oral route and the number of cases were too large in their study.[5,6]

In my study, there were more women in misoprostol group who required additional uterotonics but the difference was not statistically significant. 6% of women in the misoprostol group and 2% of women in syntometrine group needed additional uterotonics.

This result is comparable with the result of study conducted by Lam *et al*. at department of obstetrics and Gynecology, Queen Mary Hospital, Hong Kong SAR, China in 2004[68] Vimala *et al*. also showed the nearly same results with 8.3% need of additional uterotonics in misoprostol group.[7]

Another double-blind randomized trial conducted by Preeti Verma and Colleagues in India in 2006 showed the 4% need for additional uterotonics in misoprostol groups which is closed to results of my study.[8]

In a recent meta-analysis comparing misoprostol with injectable oxytocic agents or placebo, Lagenbach found that misoprostol was statistically superior to placebo in lowering the need for additional uterotonic drugs but inferior in this respect to injectable oxytocics, although not reaching statistical significance.[3,7] A multicenter randomized controlled trial of oral misoprostol and intramuscular syntometrine in the management of the third stage of labour conducted in 2001 in shatin, showed that the need for an additional oxytocic injection was significantly higher ($p<0.05$), in the misoprostol group with a RR of 1.62 (95% CI 1.34 - 1.96). This difference can be explained by the use of oral route of misoprostol instead of sub lingual route.[8]

None of the patients in our study required blood transfusion. A double-blind randomized trial conducted in 2009 in India by Gunjan Singh & colleagues showed that no blood transfusion required in misoprostol group.[4,7] This result is also consistent with the results of study conducted by Vimala *et al*.

None of the patients in this study had blood loss greater than 500 ml. This result in comparable to the result of a double-blind randomized trial conducted in India in 2009 which showed that none of patients in misoprostol group had blood loss ≥ 500 ml.[7,8] Study conducted in 2004 in New Delhi India by Vimela *et al*. showed 3.3% incidence of blood loss ≥ 500 ml probably due to lower dose of misoprostol (400 µg).[9]

Another study conducted in 2006 in Chandi garh India by Preeti Verma & Colleagues showed 1% incidence of PPH (≥500 ml blood loss) also probably due to use of low dose of sublingual misoprostol. They used 400 µg of sublingual misoprostol.[8]

Shivering is a well-known side effect of misoprostol when it is used in the management of third stage of labour. Other side effects of misoprostol were Fever, nausea and vomiting. In my study, shivering developed in 30% and fever in 16% of women in misprostol group which is significantly higher than in syntometrine group. These findings are comparable to the findings of study conducted by Lam *et al*. in 2004 in China, which showed 30% incidence of shivering and pyrexia.[6,8]

Another study conducted in 2006 in Egypt, showed 22.6% incidence of shivering and 23.0% incidence of Fever with 600 µg of misoprostol.[75] Study conducted in department of Obstetrics and Gynaecology, All India Institute of Medical sciences, New Delhi, India in 2004 by Vimela *et al*. showed shivering in 21.6% and Fever in 6.6% of women in misoprostol group (400 µg) probably due to low dose of misoprostol.[8]

Study conducted in Chandi garh, India by Preeti Verma and Colleagues showed 18% incidence of shivering and 6% incidence of Fever in women receiving 400 µg of sublingual misoprostol.[6,7]

Another study of Parsons and co-investigators showed 80.7% incidence of postpartum shivering probably due to use of higher dose of misoprostol (800 µg).

Misoprostol induced pyrexia is of interest in terms of possible prostaglandin related mechanisms and their relevance of thermoregulatory physiology. Shivering and pyrexia were well tolerated side effects in my study and were seemed to be dose-related.

Other side effects like nausea and vomiting were also present but there was no significant difference between the groups.

There are two major limitations in this study. First, this was not a double blinded study; potential bias in assessment of blood loss and the use of additional oxytocics could not be eliminated. However, this was minimized by having an independent nursing staff in the preparation and administration of the medication.

Second, although the amount of peripartum blood loss in my study was estimated more precisely by collecting blood in bed pan and weighing the drapes even then we could have overestimated it because of the addition of amniotic fluid or underestimated it because of the loss of blood outside the drapes. As these errors are likely to be distributed equally between the two groups, they are unlikely to have introduced any systematic bias that could have affected the significance of our results.

CONCLUSION

The result of this study indicates that sublingual misoprostol is as effective as I.V. syntometrine. The sublingual route is a convenient way that allows quick absorption and faster peak action than oral route. Syntometrine has the disadvantage of requiring special storage. It also requires the use of needle and syringe for parenteral administration.

When skilled providers and / or necessary supplies are not available to give an injection of syntometrine especially in rural settings in developing countries, misoprostol is clearly useful.

CONFLICT OF INTEREST

No conflict of interest is involved in this study.

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