
**“A one year double blind randomized controlled trial of
sublingual misoprostol (400 µg) versus intramuscular
oxytocin (10 IU) in the prevention of postpartum blood
loss at KLES DR. Prabhakar Kore charitable hospital,
Belgaum”**

**By
Dr. Tara D.**

Dissertation

**Submitted to the
KLE University, Belgaum,
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**in partial fulfillment
of the requirements for the degree of**

Master of Surgery (M.S.)

In

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Under the Guidance of

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May – 2009

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ABBREVIATIONS

ANC	Ante Natal Care
χ^2	Chi- square
C.I.	Confidence Interval
DBP	Diastolic Blood Pressure
GA	Gestational Age
Hb	Haemoglobin
Hr.	Hours
ID	Identification Digit
IM	Intramuscular
IV	Intravenous
IU	International Units
μg	Microgram
mm Hg	millimeter of Mercury
Min.	minutes
PPH	Postpartum Haemorrhage
RCT	Randomized Controlled Trial
SBP	Systolic Blood Pressure
S.D.	Standard Deviation
WHO	World Health Organization

ABSTRACT

Background : Sublingual misoprostol which has an early onset of action with high peak concentration compared to oral route needs to be studied against quick acting injectable oxytocin as in earlier studies it is proved to be more effective than oral misoprostol. Till date there is no published study comparing sublingual misoprostol with intramuscular (IM) oxytocin. Accurate measurement is now possible with use of drape along with addition of weight of soaked swabs.

Objective : To compare the effectiveness of sublingual misoprostol 400µg versus IM oxytocin 10 IU for prevention of postpartum bloodloss.

Methods :

Study design: Double blind randomized controlled trial.

Data Collection: Pregnant women in labor admitted to labor room in KLES Dr. Prabhakar Kore Charitable Hospital attached to J N Medical College, Belgaum.

Sample Size: 652 (actual enrolled 672)

Randomization: Computer generated randomization list with block size of two.

Intervention: One group received 400µg misoprostol powder (two 200µg powdered tablets) sublingually and 2ml placebo IM injection, while the other group received a placebo powder sublingually, and 2ml IM injection of oxytocin (10 IU) within one minute after clamping and cutting the cord. The other two principles of active management of third stage of labour (early cord clamping and controlled cord traction to deliver the placenta) were followed in both the groups.

Measurement of Blood loss: With BRASSS –V drape + from soaked swabs with correlation of haematocrit change from pre to post delivery.

Results :Total enrolled 672 (333-misoprostol, 339-oxytocin), Mean blood loss with sublingual misoprostol was 189.77ml as compared with 367.77ml seen with 10 IU IM oxytocin ($p<0.001$). The fall in postpartum haematocrit by $>10\%$ and the incidence of PPH was significantly more with 10 IU IM oxytocin compared to 400 μ g sublingual misoprostol ($p<0.001$). Shivering was significantly more with misoprostol but same as that observed with oral misoprostol.

Conclusion:

Sublingual misoprostol is more effective with statistical significance than IM oxytocin in reducing the blood loss and incidence of PPH which is evidenced by increased incidence of fall in haematocrit (10%) in IM oxytocin group

Key words: Sublingual Misoprostol; Intramuscular Oxytocin; Postpartum bloodloss; Haematocrit; Haemoglobin; Postpartum Hemorrhage (PPH)

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