

ABSTRACT

Introduction: Vaginal misoprostol has shown to be effective and safe in the management of missed miscarriage. However since the optimum dose for that indication is not established, in this study our aim was to find out a cost effective dose of misoprostol for the management of missed miscarriage in our setting.

Objective: To compare effectiveness and safety of two misoprostol regimes (400 µg versus 800 µg vaginal misoprostol) for the management of missed miscarriage

Design & setting: A randomized controlled trial carried out at the Professorial Unit, Colombo South Teaching Hospital, Kalubowila, Sri Lanka for a period of 8 months commencing 1st July 2007.

Method: One hundred and eighty four women with missed miscarriage between 8 to 20 weeks of POA were randomized to receive 400µg or 800µg vaginal misoprostol.

Main outcome measures: The principle outcome measures were success of misoprostol treatment, completeness of medical evacuation, need for surgical evacuation, patient satisfaction and side effects.

Results: Comparison of vaginal misoprostol, 800µg and 400µg doses in management of missed miscarriage, revealed that there was no statistically significant difference in success (p value=0.35), completeness of evacuation(p value=0.38), need for surgical evacuation(p value=0.38) and also patient satisfaction(p value=0.25). Though there was more success and completeness of evacuation noted with 800µg dose in earlier gestations (≤ 12 weeks) compared with

400µg dose, it did not reach statistical significance(p value=0.06 and 0.05). Further, the dose of 800µg was more successful in the management of early gestations ($\leq 12w$) as compared with later gestations which was statistically significant (p value=0.02). The common side effects were compared between the two groups. There was no statistically significant difference between the two groups regarding the occurrence of diarrhoea, vomiting fever or abdominal pain. However the percentages of all side effects are higher in the 800µg group as compared with 400µg group.

Conclusions: Management of missed miscarriage by using vaginal misoprostol, both 800µg and 400µg doses are equally effective considering success, completeness of evacuation, need for surgical evacuation and also patient satisfaction. Although there was no statistical proof ,the results of this study is tempting to favour 800µg over 400µg dose regarding success and rate of complete evacuation for early gestations (POA $\leq 12w$). There is no statistically significant difference in the common side effects (PV pleading, diarrhoea, vomiting, fever and abdominal pain) between 2 doses. However the frequency of all observed side effects were less with 400µg dose.

Recommendation: For the management of missed miscarriage when the POA > 12weeks 400µg dose of vaginal misoprostol can be recommended as a better cost-effective and safe regimen compared with 800µg dose.