Oxytocin and misoprostol versus oxytocin alone in reduction of blood loss in emergency caesarean section in Mulago Hospital Uganda, RCT

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Abstract

Background: The commonest cause of excessive bleeding at caesarean section is uterine atony. Bolus oxytocin is usually given to prevent uterine atony but mothers undergoing emergency caesarean section for required additional uterotonic. It is also uncertain if routine use of a combination of oxytocin and misoprostol is superior, inferior or equivalent to oxytocin alone in preventing uterine atony and blood loss. This randomized clinical trial was designed to compare the effectiveness of combination of bolus oxytocin and rectal misoprostol with bolus oxytocine alone in reducing blood loss at emergency caesarean section in Mulago Hospital, Uganda.

Methods: Mothers at 38-42 weeks of gestation undergoing caesarean section in Mulago Hospital were enrolled into the study from 10th January 2011 to 27th February 2011. The study participants received either intravenous bolus oxytocin 10IU plus rectal misoprostol 600,cg or intravenous bolus oxytocin 600,cg at caesarean section. The primary outcome was mean blood loss (millitres) and secondary outcomes included the proportion of participants who required additional uterotonic, the change in mean haemoglobin concentration, proportion of participants who developed side effects and proportion of participants who required extra interventions. Data analysis was by intention to treat. The Mann Whitney U test was used to compare the blood loss and relative risk with (95%) confidence interval calculated for the stratified analysis. The paired student t-test was used to compare the change in mean haemoglobin concentration. The categorical outcomes were compared using the chi square test.

Results: 212 women were enrolled into the study, 105 in the oxytocin and misoprostol group and 107 in oxytocin alone group. The two groups were comparable. There was no significant difference in mean blood loss in the two groups: (813.5 ± 633.3) mls in the oxytocin and misoprostol group compared to (955.7± 670.6) ml in the oxytocin alone group (P=0.11). There was no significant difference in change in mean haemoglobin concentration in the two groups: (2.5 ± 1.6) g/dL in the oxytocin and misoprostol group compared to (2.7 ± 1.7) g/dL in the oxytocin (P=0.43). The combination of oxytocin and misoprostol compared to oxytocin alone was associated with a reduced risk of blood loss less than 1000 mls (RR 0.6 (CI 0.42 – 0.93)). There was a significant difference in the proportion of participants who required additional uterotonic in the two groups: (9.6%) in the oxytocin and misoprostol group compared to (26.2%) in oxytocine alone group (P=0.002). There was a significant difference in the proportion of participants who developed fever and shivering in the oxytocin and misoprostol group compared to oxytocin alone group (8.9% Vs 0 P=0.00, 54.3% Vs 37.4% P=0.01) respectively. There was no significant difference in proportion of participants who required extra interventions in the two groups.

Conclusion: There was a reduction of 11.7% in mean blood loss in the oxytocin and rectal misoprostol group compared to oxytocin alone but this was neither statistically nor clinically significant. The risk of blood loss in excess of 1000mls was reduced when a combination of oxytocin and misoprostol was used compared to oxytocin alone. There was an increased proportion of participants who required additional uterotonic in oxytocin alone group compared to oxytocin and rectal misoprostol group at caesarean delivery. There was an increased proportion of participants who developed fever and shivering in the oxytocin and misoprostol group compared to the oxytocin alone group at emergency caesarean section.