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THE COMPARATIVE STUDY OF PRE-OPERATIVE SUBLINGUAL MISOPROSTOL VS CONVENTIONAL INTRAVENOUS OXYTOCIN DURING CAESAREAN DELIVERY

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ABSTRACT

The comparative study of pre-operative sublingual misoprostol vs conventional intravenous oxytocin during Caesarean delivery. Objectives: To evaluate the superiority of sublingual misoprostol to conventional intravenous oxytocin in Caesarean delivery. Methods &Materials: More than one hundred pregnant women were selected among those planned for Caesarean delivery for varied indications. They were assessed according to study criteria and randomised into two groups- Group A (cases, n=50)(treated with 600 µg sublingual misoprostol) and group B (n=50) (treated with conventional intravenous oxytocin -20 IU in 1litre iv fluid @ 60 drops / min) Results: The primary outcomes of each group (Blood loss, transfusion required, chest discomfort, hypotension and admission to ICCU / RCU, death), secondary outcome included short term for women (operation time, oral intake time, mobilisation time, pyrexia, loosemotion, pain, wound healing, satisfaction), short term for baby (delivery time, birth trauma, meconium staining, Apgar score, NICU admission, hospital stay, re-admission, costs) are analysed. Conclusion: As compared to conventional oxytocin, misoprostol can be considered as a better alternative uterotonic drug during Caesarean delivery.

KEYWARD: Sub-lingual misoprostal, conventional oxytocin, caesarean delivery, uterotonic drug, PPH.

INTRODUCTION

Misoprostol is a synthetic PGE1 analogue, cheap, widely available, stable at room temperature, with fewer side effects, need not require parenteral administration, can be given oral, vaginal, sublingual, buccal or rectal route having shortest time to act with highest peak[1] concentration and great bioavailability in sublingual route. No clinically significant adverse haematological, endocrine, immunological, respiratory, ophthalmological, coagulation and cardiovascular effects are seen with misoprostol.[2] The side effects are mostly dose dependant and seen maximum in a dose of 800 µgm, though hyperstimulation and hypotension are commonly observed in pregnant women without significant neonatal compromise.[3] Oxytocin, an octapeptide was synthesised by Du Vigneand et al and was used from the period of Sir beckwith Whitehouse and Rawson till to date, acts through estrogen dependant receptors and through prostaglandin receptors in uterus. It has faster action but short lived, may cause uterine rupture, hypotension, antidiuresis, angina, pituitary shock, birth asphyxia and neonatal jaundice. Oral prostaglandins (misoprostol) should therefore be considered in low-resource setting where safe administration and / or appropriate storage condition for injectable oxytocin andergot alkaloids are not possible.[4] That is why "Acomparative study of sublingual misoprostol vs conventional intravenous oxytocin duringCaesarean delivery" has been conducted.

MATERIALS AND METHODS

After getting certificate from the Institutional Ethics Committee of the Institute of Post graduate Medical Education & Research, Kolkata, this study was conducted from _Dec' 2011 to _March 2013. The CONSORT flow chart (Figure 1) describes the selection and randomisation of the women under study.

The selection of cases for Caesarean delivery in each group: *Post-caesarean pregnancy (15),** Dystocia with cephalopelvic disproportion (10),*** Prolonged pregnancy with failed induction 2 (15),****Cephalopelvic disproportion with elective Caesarean delivery (5) ***** breech (5) to keep bothgroups comparable.

Exclusion Criteria: hypersensitivity, asthma, cardiovascular disease, renal Disease, fetal distress, caesarean under general anesthesia.

Total 54 women required because of two cases failed spinal anesthesia required general anesthesia and two cases vomited out.

In group A: Misoprostol (600 µg) administered sublingually after induction of spinal anesthesia and baby delivered within 10 minutes of drug administration. In group B: Oxytocin started as intravenous infusion drip as per conventional regimen (20 units in 1 litre of Lactated Ringer's solution @ 60 drops /min) after delivery of anterior shoulder.The primary and secondary outcome of individual groups in respect of mother and baby analysed.

RESULTS AND ANALYSIS

Table 1 shows the primary maternal outcomes and Table 2 shows the secondary maternal outcomes in control and study groups. Table 3 shows the secondary outcomes from fetal perspective.

Table 1. Comparison of primary outcome between group A (cases) and group B (controls).
Parameters Cases (n=50) Controls (n=50) p-value test done

Parameters	Cases (n=50)	Controls (n=50)	p-value	test done
1. Estimation of blood loss:				
Fall in Hb%	0.65±0.5	0.9 ±0.05	0.007	(unpaired t test)
Fall in PCV	2.35 ± 1.68	2.93 ± 0.96	0.036	(unpaired t test)
Increase in mop weight (gm)	423.68 ± 112.82	678.19± 170.45	<0.001	(unpaired t test)
2. Transfusion / Infusion required				
Whole blood:	nil (0%)	05 (10%)	0.05 (Fisher's exact test)	
Volume expander:	03 (6%)	27 (54%)	<0.0001 (Fisher's exact test)	
3. Hypotension:	01 (2%)	11(22%)	0.0038 (Fisher's exact test)	
4. Chest Discomfort	04 (8%)	16 (32%)	0.005 (Fisher's exact test)	
5. ICCU/ITU for observation	2 (for fever)	05 (for PPH)	0.43 (Fisher's exact test)	
6. Death	nil	nil	Not applicable	

Table. 2: Comparison of secondary outcomes in mother (both short and long term) Short term maternal secondary outcome.

Parameters	Cases (n=50)	Controls (n=50)	p-value
1. Mean operative time (min)	28.73 ± 4.71	42.54±5.37	<0.0001 (unpaired t-test)
2. Mobilisation time (hours)	8.67 ± 0.82	10.07± 1.12	<0.0001 (unpaired t-test)
3. Oral Intake time: (hours)	7.39 ± 1.15	9.56 ± 0.94	<0.0001 (unpaired t-test)
4. Pyrexia	07 (2-observation 5-no treatment)	nil	0.012 (Fisher's exact test)
5. Loose motion	03 (no treatment)	nil	0.24 (Fisher's exact test)
6. Pain, wound healing and Patient satisfaction	early	delayed	

Table. 3: Comparison between neonatal outcomes in group A (cases) and group B (controls).

Parameters (n=50)	Cases (n=50)	Controls	p-value	test done
1. Apgar score (overall)			0.62	Chi-square test
8-10	40	36		
6-7	09	13		
Below 6	1	1		
2. Meconium staining	03	07	0.31	Fisher's Exact Test
3. Incision-Delivery Time (minutes)	2.55±0.37	6.94±0.85	<0.0001	Unpaired t-test
4. Birth Trauma	02	04	0.67	Fisher's Exact Test
5. Baby weight (overall significance)			0.96	Chi-square test
<1.5 kg	07	04		
1.5- 2.0 kg	09	09		
>2-2.5 kg	14	14		
>2.5 kg	20	23		
6. Admission to NICU	05	17	0.007	Fisher's Exact Test
7. Death	nil	nil		

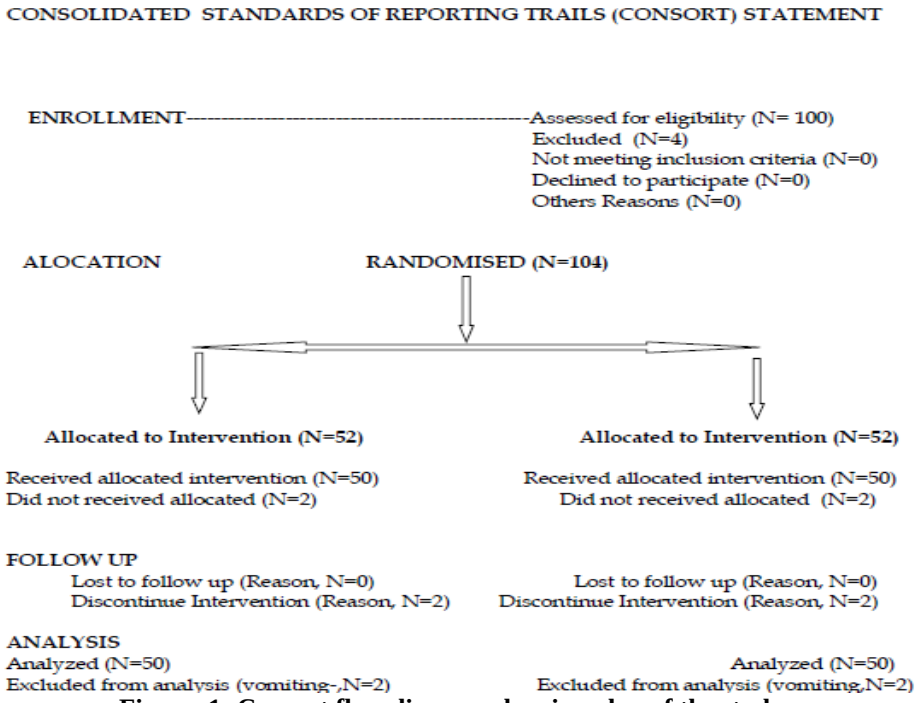

Figure. 1: Consort flow diagram showing plan of the study.

DISCUSSION

Though recent Cochrane review concluded that neither injectable prostaglandin nor misoprostol is preferable to conventional injectable uterotonics[5], but more recently, buccal misoprostol (200 microgram), when compared to placebo reduced the need uterotonic agents of additional during Caesarean delivery.[6] There was no difference in rate of hyperstimulation with FHR changes and Caesarean delivery rate in different routes and different doses.[7] It has been suggested that meconeum passage occurs in response to uterine hyperstimulation or as a direct effect of misoprostol or ingested castor oil metabolised in fetal GIT.[8] Oral Misoprostol is less effective than injectable uteritonics in preventing PPH and blood loss but less haemoglobin drop with known side effect including shivering with pyrexia (32-57%), nausea, vomiting and diarrhea.[9,10] 3 In our study, primary outcomes in group A in terms of blood loss, transfusion required,hypotension, chest discomfort and ICCU / HDU admission are significantly less compared to controls having zero mortality. The secondary outcomes of mother on short-term basis reveals operation time, mobilization time, oral intake time were less and pain relief, wound healing with satisfaction were better in study group. However, incidence of pyrexia and loose motion were higher though insignificant in study group. The secondary outcome of baby on short turn basis show Apgar score in higher group, less meconium stained baby

delivered within less time, minimal birth trauma required less NICU admission in group A (cases) but no death in both groups. The long term outcomes of both mother and baby disclose significantly least wound complications, hospital stay, readmission by minimal costs in group A (cases) compared to group B (controls)

CONCLUSION

As per recent guideline, WHO has already enlisted and recommended misoprostol for prevention and treatment of PPH which would address barriers to access that currently exist such as the requirement for refrigeration and parenteral administration of oxytocin and ergometrine. Our study shows in form of primary and secondary outcomes in relation to mother and baby favour its use in Caesarean delivery for safe pregnancy outcome which is key indicator of health in country. Conflict of Interest: The authors declare that they have no conflict of interest. Funding: There was no specific funding sought for funding. Acknowledgement: We would like to thanks institutional ethics committee for approval and department of Gynecology & Obstetrics for conducting this study. Authors' Role: All the author initiated, design performs statistical analysis and prepare manuscript. 4.

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