ORIGINAL ARTICLE

Outcome of Early Versus Delayed Oxytocin Augmentation in Nulliparous Women on the Duration of Labour and other Obstetric and Neonatal Outcome - A Randomized Controlled Trial

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ABSTRACT

Objectives: To determine the outcome of early versus delayed Oxytocin augmentation in nulliparous women on the duration of labor and other obstetric and neonatal outcomes.

Study Design: A prospective randomized trial.

Place and Duration of study: The study was conducted at Pakistan Railways Hospital, for the duration of 1 year with effect from January 2010 January, 2011. It is 400 bedded teaching hospital affiliated with IIMC-T of Riphah International University, Islamabad

Materials and Methods: In healthy nulliparous women with normal pregnancy,the progress of labor was thoroughly monitored and documented every 23 hours. If there was still no progress 1 hour after amniotomy, the woman was randomly allocated to either labor augmentation by oxytocin infusion or to postponement of oxytocin augmentation for 3 hours (expectant group, n = 158). Women whose labors had progressed satisfactory (1 cm/hour) after amniotomy were not randomized. Participants were managed according to a standard protocol entailing continuous documentation of the progress of labour, the amount of oxytocin administered, and obstetrical and neonatal outcomes. Oxytocin infusion was started at 6 mU/minute and was raised by 6 mU/minute every 30 minutes until efficient contractions were established in the early oxytocin group. In the expectant group, if no progress occurred after 3 hours, the women were reassessed regarding the need for oxytocin augmentation. Data were analyzed with SPSS 15.0. The MannWhitney U test was used to compare means. Proportions of events were compared with Fisher's exact test or chi-square analysis. Statistical significance was set at a P value of <0.05.

Results: The caesarean section rate was 9% in the early oxytocin group and 10.7% in the expectant group (OR 0.8, 95% CI 0.51.4), and instrumental vaginal delivery 17% in the early oxytocin versus 12% in the expectant group (OR 1.5, 95% CI 0.972.4). Early initiation of oxytocin resulted in a mean decrease of 85 minutes in the randomization to delivery interval.

Conclusion: Early administration of oxytocin did not change the rate of caesarean section or instrumental vaginal delivery but shortened labor duration significantly in women with a 2-hour arrest in cervical dilatation. No other clear benefits or harms were seen between early and delayed administration of oxytocin.

Key words: *Oxytocin augmentation, prolonged labor, fetal distress.*

Introduction

The active phase of labor may be augmented routinely as in active management of labor or selecting when progress of labor is considered to be inadequate. [1]

Prolonged labor is most common among nulliparous women and is related to increased caesarean section rate i.e. nearly 25% birth in England (Pakistan-40-50% in some private institutes) of which 30% are due to failed progress.[2] WHO recommend best outcome of mothers and babies to occur with c/section rates of 5-10%.The world health organization recommends the use of partogram with an alert line indication normal progress, defines as a cervical dilatation of 1cm/hr and an action line 4 hrs to the right to detect and treat prolonged labour.[3]

It has been argued for long time that active management reduces the duration of labour and incidence of labour lasting more than 12 hrs, as well as c/section rate however this is

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not supported in recent Meta analysis.[4]
Aim of our study was to study effects of early augmentation versus post ponemant of oxytocin administration on obstetrical and neonatal outcomes in nulliparous women with spontaneous but prolonged labour.

Material and Methods

This prospective randomized trial was conducted Pakistan Railways Hospital, IIMC-T, Riphah International University, Islamabad.
Healthy nulliparous women with normal pregnancies received written information about the study in the third trimester at their antenatal clinics. Inclusion criteria were nulliparity, a singleton fetus in cephalic presentation, spontaneous onset of active labour with regular contractions and an effaced cervix dilated between 4 and 9 cm, at a gestational age between 37 + 0 and 41 + 6 weeks. The choice of a minimum of 4-cm dilatation was to ensure that the active phase of labour was established at the time of inclusion into the study. The latent phase was defined as the interval between start of contractions (women's report) until active labour was established at inclusion into the study. Women with spontaneous rupture of the membranes together with regular contractions were also included in the study. Exclusion criteria were non-cephalic presentation, prelabour rupture of membranes, serious maternal disease and fetal death.
During the study period 350 women fulfilled the inclusion criteria. At admission to the delivery ward, only the women given the study information antenatally were asked to participate in the study. Participation into the study was accepted by 315women who were included in active labor.
The progress of labour was thoroughly monitored and documented every 23 hours according to the departmental guidelines. Slow progress of labour was defined as an arrest in cervical dilatation for two hours or a dilatation less than 1 cm for 3 hours in the first stage of active labour. If labour was slow and the membranes were intact amniotomy was first performed. If there was still no progress 1 hour after amniotomy, the woman was randomly allocated to either labour augmentation by oxytocin infusion within 20 minutes (early oxytocin group, n = 157) or to postponement of oxytocin augmentation for 3 hours (expectant group, n = 158). Women whose labours had progressed satisfactory (1 cm/hour) after amniotomy were not randomized.
Participants were managed according to a standard protocol entailing continuous documentation of the progress of labour, the amount of oxytocin administered, and obstetrical and neonatal outcomes. Oxytocin infusion was started at 6 mU/minute and was raised by 6 mU/minute every 30 minutes until efficient contractions were established in the early oxytocin group. Maximum dose of oxytocin infusion during the opening phase was 40 mU/minute. In the expectant group, if no progress occurred after 3 hours, the women were reassessed regarding the need for oxytocin augmentation. . Data were analyzed with SPSS 15.0. The MannWhitney U test was used to compare means. Proportions of events were compared with Fisher's exact test or chi-square analysis. Statistical significance was set at a P value of

<0.05.

Results

During the study period 315 consenting women were randomised. Primary analysis was done according to intention to treat with all cases as randomized. The two study groups were well balanced against each other in relation to the baseline characteristics, for example, maternal age, gestational age, proportion of women with spontaneous rupture of membranes before inclusion, intensity of labour pain and cervical dilatation at inclusion and at randomisation. In accord with the study protocol, oxytocin augmentation was started earlier, administered more often and in higher doses in the early oxytocin group.

There were no significant differences in the primary outcome, mode of delivery. The instrumental vaginal deliveries were all vacuum extractions except two forceps deliveries in the early oxytocin group. The interval from randomisation to delivery was 85 minutes shorter in the early oxytocin group. There was no difference in duration of the second stage between the groups. Shows the percentages of women giving birth from time of randomisation in both groups. The rate of postpartum blood transfusion did not differ significantly between the two groups.

No neonatal outcome variable differed significantly between the study groups. Birth weight is similar. There were no significant differences between the study groups in 5-minute Apgar score below 7, admission to NICU or phototherapy for jaundice. There were no perinatal deaths.

Table I Baseline characters n=315

	Early oxytocin grp n=157	Expectant grp n =158	P value
Maternal age (yrs)	28 ± 4	28 ± 4	0.36
Gestational age (days)	283 ± 6	283 ± 6	0.78
Duration of latent phase (hrs)	17 ± 12	17 ± 13	0.46
Cervical dilatation at randomizatio n (cm)	6 ± 1	6 ± 1	0.08

Table II Administered oxytocin treatment n=315

	Early oxytocin grp n=157	Expectant grp n=158
Labour augmented with oxytocin	155 (99%)	137 (87%)
Mean internal from randomization to oxytocin infusion (minutes)	29 ± 48	190 ± 110

Data given as mean + standard deviation (median) or as n(%)

Table III. Maternal outcome

Mode of delivery	Early oxytocin n=157	Expectant grp n=158	Odds ratio 95% CI	P value
c/section	14 (9.2%)	17 (10.8%	0.8	0.17
Instrumental vaginal delivery	27 (17%)	19 (12%)	1.5	
Spontaneous vaginal delivery	115 (73.6%)	122 (77.2%)	0.8	
INDECATIONS FOR C/SECTION				
Fetal distress when Cx dilated 4-9cm	11 (7%)	16 (10%)	0.8	0.36
Fetal distress in second stage	9 (6%)	32%	4.2	
Failure to Preogress b/w 4-9 cm without fetal distress	13 (8%)	19 (12%)	0.7	
Failure to progress in 2nd stage without fetal distress	13 (8%)	16 (10%)		
INDICATIONS FOR INSTRUMENTAL DELIVERY				
Fetal distress	12 (17%)	21 (13%)	0.9	0.82
Failure to progress without fetal distress	58 (37%)	39 (25%)	1.1	
Duration from randomization to delivery (hrs)	5.2 ± 2.8	6.7 ± 3.2	NA	<0.001
Duration from full cervical dilatation to delivery (hrs)	1.7 ± 1.2	1.8 ± 1.3	NA	0.68
Post partum hemmorrhage	5 (3.5%)	9 (6%)	0.6	
Post partum blood transfusion	Nil	Nil		
Sphineter laceration	Nil	Nil		

Discussion

Some or all components of active management of labor have been adopted since 1970's.[1] Several randomized control studies have been carried out different components of active management of labour are: strict diagnostic criteria for labour, early amniotomy, early use of oxytocin and continuous professional support.[2]

The rise of operative delivery particularly ceasarean section continous to be an obstetric concern. Continuous increased caesarean section rate may have influence on maternal and neonatal mortality & morbidity.[3] Prolong labour has been described one of the leading indications for

caesarean section. [4]

Our study is relates to the oxytocin augmentation of labor. Since the formulization of high dose protocol for oxytocin administration several papers have published on ability of oxytocin to fasten labor and decrease caesarean section rate.[6, 11] In this protocol oxytocin infusion is started at equalent of 6miu/min and increasing 6miu every 30 minutes to maximum 40 miu/min. Evidence of fetal distress on CTG or FBS is the only contraindication for oxytocin administration.

Satin et al demonstrated that duration of labour may be decreased by 3 hours to lead less ceasarean section but his study included both nulliparous and multiparous women. [6, 13] Other randomized controlled trial has not realized the decreased rate of ceasarean section but site similar reduction in duration of labor.

Our study has shown that although early or delayed use of oxytocin did not make any difference in mode of delivery but it is very obvious from results that every oxytocin group had a significant shortened length of labour and there was also a clear reduction in rate of operative vaginal deliveries. There was no significant difference in rate of PPH, Apgar score of neonatal and need for NICU admission.

This study had the following weakness. Obstetrician was not blinded to the treatment group. The decision to perform caesarean section or operative vaginal delivery may be tailored by knowledge of treatment arm. There is no current Cochrane review of effect of oxytocin used as a single intervention in labour. There are only a few small trials for oxytocin alone. [10, 13, 15]

A Meta analysis suggested that there was no effect on caesarean section rate.[7, 13] Our study also supported that a Meta analysis by observing lack of any statistical difference in caesarean section rate.

Although the shortening of labour has long been widely assured with active management of labour. [8, 14, 13] Our study has reliably shown an 85 minutes reduction in total duration of labour, which is similar to previous studies which show 50-160minute reduction.

Conclusion

In this study no significant differences were seen between early versus expectant administration of oxytocin stimulation in nulliparous women with slow labour in relation to the mode of delivery, postpartum haemorrhage, postpartum blood transfusions, neonates with a 5-minute Apgar score below 7 or neonatal admission to NICU. The interval from randomization to delivery was 85 minutes shorter in the early oxytocin group. No other clear benefits or harms were seen between early administration and expectancy of oxytocin

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