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Prom at and beyond 34 weeks of gestation: Comparative study of immediate induction using prostaglandin PGE2 gel versus oxytocin

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Abstract

Aim: To compare immediate induction using prostaglandin pge2 gel versus oxytocin,

Material and method: After recruitment to the study; past, present, obstetrical, menstrual history and identification data was obtained from the subjects. Detailed history regarding the leakage of the liquor and risk factor involved was taken. The period of gestation was calculated from the last date of menstrual period and was confirmed with obstetrical examination. This was followed by a thorough general clinical examination and obstetrical examination. A sterile speculum examination was performed to confirm obvious leakage of amniotic fluid.

Result: In PGE2 group, 32.38% women had PROM-delivery interval of <12 hours, 50.47% of 12-24 hours and 17.14% of women had PROM-delivery interval >24hours. In oxytocin group, 33.33% women had PROM-delivery interval of <12hours, 57.77% of 12-24 hours and 8.88% women had >24 hours.

Conclusion: The incidences of maternal and fetal untoward effects are similar with use of the two inducing agents, with no significant difference in induction delivery interval. Intracervical administration of PGE2 gel in a dose of 0.5mg is an effective alternative of oxytocin for labour induction at and beyond 34 weeks of gestation with pre-labour rupture of membranes.

Keywords: Oxytocin, prostaglandin

Introduction

Pre-labour rupture of membranes is amniorrhexis in the absence of labour (uterine contractions) [1]. When it occurs before 37 weeks of gestation it is termed as preterm pre-labour rupture of membranes [1, 2]. Pre-labour rupture of membranes is associated with significant maternal and neonatal morbidity and/or mortality. It presents the obstetrician with a management dilemma. Despite the amount of research done in this area, there is still no universally accepted policy for management. At term approximately 75% of women will go in labour within 24 hours of membrane rupture. The latency tends to be longer with decreasing gestational age [3].

Despite exhaustive research, clinical management of patients with pre-labour rupture of membranes at or near term remains a matter of debate. There is a general agreement that the term and near term pregnant patients with pre-labour rupture of membranes should be delivered to avoid infection to both mother and the infant. Options include expectant treatment or induction with mechanical methods; vaginal prostaglandins or intravenous oxytocin [4].

In modern obstetrics, as there has been the shift of focus not only from measures to reduce maternal mortality to perinatal morbidity and mortality, but also to reduce the duration of hospital stay. Therefore induction of labour in at or near term patients is gaining interest [5].

Material and Method

The present study is prospective comparative clinical study comparing two drugs i.e. intracervically administered PGE2 gel and intravenous Oxytocin for induction of labour at and beyond 34 weeks of gestation with pre-labour rupture of membranes, conducted in the department of Obstetrics and Gynecology, conducted at Krishna Institute of Medical

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Sciences, Karad, from May 2008 to September 2010. The study was commenced following approval by the ethical committee of Krishna Institute of Medical Sciences. The time from the onset of induction to vaginal delivery was chosen as the primary outcome, within 240 minutes difference being considered significant on the basis of a previous survey of physician, health care providers and patients.

After recruitment to the study; past, present, obstetrical, menstrual history and identification data was obtained from the subjects. Detailed history regarding the leakage of the liquor and risk factor involved was taken. The period of gestation was calculated from the last date of menstrual period and was confirmed with obstetrical examination. This was followed by a thorough general clinical examination and obstetrical examination. A sterile speculum examination was performed to confirm obvious leakage of amniotic fluid. Cases in which there was any doubt about the diagnosis of PROM were excluded from the study. A pelvic digital examination was performed with aseptic precautions to assess the cervical score and the exclude occult cord prolapsed. In each case Bishops score at zero hours was recorded. Before entering the labor room each patient received simple enema, intravenous line was secured and blood availability was confirmed.

If patient did not go into labour within 6 hours of instillation then intravenous oxytocin was started with escalating doses as mentioned below. Patients allotted to oxytocin group were administered 2 units oxytocin in 500 ml of Ringer lactate solution, with a starting dose of 2 mU/min. Dose was increased in step wise manner after every 30 minutes, till 4-5 contractions lasting for 45-60 seconds in 10 minutes were obtained. Maximum dose administered was 30 mU/min. Patients in both the groups received Injection Cephazolin 1 gram IV after test dose followed by 500 mg 6 hourly till delivery. Postnatal each mother received Tab. Cephalexin 750 mg 12 hourly for 5 days. Patients were monitored every 30 minutes in latent phase and every 15 minutes in active phase of labor, with respect to pulse, uterine contractions (frequency and duration), fetal heart rate and any side effects/complains. Blood pressure and temperature was monitored every hourly.

The data was analyzed in the statistical package for social sciences (SPSS, 10.5). The back ground data is first presented with the measure of central tendencies (mean, median and mode) and the measures of dispersion (range and standard deviation). The parity and the period of gestation were categorized to facilitate understanding its distribution in the study population. The treatment group was first compared with respect to their means to ensure similarity in the background characteristics of the study populations. The mean induction – delivery time in the two treatment groups was calculated and compared using the independent sample t-test at 5% level of significance. The maternal complications and neonatal outcome in the two treatment arms were compared using the chi-square test for the difference between the proportions at 5% level of significance.

Results

The present study is prospective clinical study Comparing two drugs-intracervically administered pge2 gel and Intravenous oxytocin for induction of labour in pre-labour rupture of Membranes at and beyond 34 weeks of gestation.

Table 1: Analysis of age distribution in two groups

Age (Years)	Group		p-value	t-value
Mean	22.3	22.64	0.345	-0.95
SD	± 2.45	± 2.67		
Minimum age	19	19		
Maximum age	30	32		

In PGE2 group, out of 105 women, 68.6% delivered within 12 hours of induction, 29.5% women took more than 12 hours but less than or equal to 24 hours to deliver. Only 1.9% women delivered after 24 hours of induction. Hence, 98.1% women delivered within 24hours after induction either by vaginal delivery or by caesarean section.

In oxytocin group, out of 90 women 78.9% women took _12 hours from induction to delivery, 21.1% delivered after 12 hours but before 24 hours. Hence, 100% delivered within 24 hours either by vaginal delivery or by caesarean section. Mean induction to delivery interval in PGE2 group was 10.71 hours and in oxytocin group was 9.98 hours with p value of 0.248. By using 2 independent sample t-test p-value>0-05, therefore there is no statistically significant difference between two groups with respect to induction delivery interval. using two independent sample t-test p-value >0.05 (p=0.427),therefore there is no statistically significant difference between two groups with respect to induction-vaginal delivery interval.

In PGE2 group, 32.38% women had PROM-delivery interval of <12 hours, 50.47% of 12-24 hours and 17.14% of women had PROM-delivery interval >24hours. In oxytocin group, 33.33% women had PROM-delivery interval of <12hours, 57.77% of 12-24 hours and 8.88% women had >24 hours.

Discussion

In our study 90.5% of PGE2 group and 82.2% women of oxytocin group were nulliparous while 9.5% and 17.8% were parous in each group respectively. There was no difference in the two groups with regard to parity (p=0.095). In study by Mahmood T.A. *et al* all subjects belonged to nulliparous group according to their inclusion criteria. Thakor Umed *et al*, ME Hannah *et al*, Chaudhuri Snehamay *et al* and George Susan Shanti *et al* had nearly equal distribution of nulliparous and multiparous women between two groups in their study. Though there is difference with regard to parity in above studies but the two treatment arms in all show no difference to avoid confounding factor as in present study. Parity distribution in any study depends on the sociodemographic distribution of the parity in the study population [6].

In current study all patients belonged to 34-42 weeks with mean of 38.60±1.46 weeks and 38.52±1.65 weeks respectively in PGE2 and oxytocin arms (p=0.723). The distribution of period of gestation in current study is similar to Thakur Umed *et al*, Wing and Paul, ME Hannah *et al*, George Susan Shanti *et al* and Chaudhuri Snehamay *et al*. Mahmood T.A. *et al* had mean gestational age of 39.2±1.4 weeks which was more than our study [7]. Period of gestation determines outcome of labour especially in induced labour. The Bishop's score improves with increasing gestation and response of these patients to induction is better as pregnant uterus has maximum oxytocin receptors at term [8].

In current study, 81% women needed only single application and only 19% required augmentation, with intravenous oxytocin, of labour. This is more than the observations of John H. Shepherd and Mahmood T.A. *et al*, and less than the

observations by Gonen *et al.* and Chaudhuri Snehamay *et al.* This wide variation in the observations could be due to different methods of application of PGE2 gel, duration of PROM and the interval after which augmentation of labour was done^[9].

There is a wide variation in PROM-delivery interval between trials, which could be due to variation in the method, dosing interval and timing of oxytocic used and duration of PROM to admission. Mean PROM-delivery interval in current study was 17.19±8.19 hours in PGE2 group and 15.94±5.79 hours in oxytocin group (p=0.217), showing no significant difference between the PROM-delivery interval in two groups. Mahmood *et al* and ME Hannah *et al* had mean PROM-delivery interval in PGE2 group of 20.05±4.6 hours and 23.0±5.5 hours respectively, which is 3.8 hours and 6.9 hours more than our study. Chaudhuri Snehamay *et al* had mean PROM-delivery in PGE2 group of 7.10±10.3 hours which is similar to our study^[10].

In the current study, 75.2% women in PGE2 group and 84.4% women in oxytocin group had spontaneous vaginal delivery which is similar to study done by ME Hannah *et al* for PGE2 group. The incidence of vaginal deliveries in different studies mentioned in the table had ranged from 74%-88% in PGE2 group and 55%-92% in oxytocin group^[12].

Mahmood *et al* and Chaudhuri Snehamay *et al* had higher rate of spontaneous vaginal deliveries in PGE2 group as compared to our study. In oxytocin group, George Susan Shanti *et al* had higher rate of spontaneous vaginal deliveries than our study^[11]. Thakur Umed *et al*, ME Hannah *et al* and Chaudhuri Snehamay *et al* had lower rate of spontaneous vaginal deliveries as compared to our study.

Indications of caesarean sections in various studies was FHR (foetal heart rate) abnormality, arrest disorder and failed induction. In current study only 20.9% in PGE2 group had caesarean delivery, out of which 59.1% were due to arrest disorder, 36.4% were due to FHR abnormality and 4.5% due to failed induction; which is almost similar to Mahmood *et al*. Chaudhuri Snehamay *et al* has 80% caesarean sections for arrest disorder and 20% for FHR abnormality^[13].

Wing and Paul *et al* had 58.8% of caesarean sections in oxytocin group for arrest disorder and 23.6% for FHR abnormality, which can be explained on the basis that they have used a low dose regimen of oxytocin infusion. In our study, in oxytocin group, 54.5% of caesarean sections were due to FHR abnormality which may be due to cord compression because of oligohydramnios, meconium stained liquor and at high doses of oxytocin if proper titration is not done. Mahmood *et al* had 7.7% and Wing and Paul had 17.6% caesarean sections due to failed induction. Failed induction in their study was defined as "if patient does not progress into active labour despite good uterine contractions after 9-10 hours of labour"

Conclusion

Finding from Current study after comparative clinical study comparing two drugs shows

i.e. 0.5mg PGE2 gel administered intracervically and intravenous Oxytocin for induction of labour at and beyond 34 weeks of gestation with pre-labour rupture of membranes. The incidences of maternal and fetal untoward effects are similar with use of the two inducing agents, with no significant difference in induction delivery interval. Intracervical administration of PGE2 gel in a dose of 0.5mg

is an effective alternative of oxytocin for labour induction at and beyond 34 weeks of gestation with pre-labour rupture of membranes.

Conflict of interest: No conflict of interest

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