

## EFFECT OF ACTIVE MANAGEMENT IN LATENT PHASE OF LABOR WITH INTRAVAGINAL PROSTAGLANDINS VERSUS EXPECTANT MANAGEMENT ON MATERNAL AND NEONATAL OUTCOMES

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### ABSTRACT

**Background:** Active versus conservative management of labor influences perinatal morbidity, mortality, mode of delivery, neonatal mortality and length of labor. Although aggressive management of active phase of labor is now largely accepted as the better modality, there is considerable doubt as to which protocol is best for management of latent phase, active or conservative.

**Patients and Methods:** This randomized controlled trial included 150 primigravida patients with singleton pregnancies and vertex presentation, 75 in the active (aggressive) management group and 75 in the expectant (conservative) management group. The active management group had augmentation with PGE<sub>2</sub> and two hourly digital cervical examinations whereas the expectant group had four hourly digital cervical examinations.

**Results:** Amongst 75 patients in each study group, 76% of expectant group delivered within 12 hour as compared to 88% patients in the aggressive group, 76% patients had spontaneous vaginal delivery, 4% had forceps or Vacuum assisted vaginal delivery and 20% had caesarean section as compared to 90.7%, 2.7% and 6.7% respectively in the aggressive group. The caesarean section rate was significantly lesser in the aggressive group;  $p=0.046$ . The mean apgar score at 5 minutes was  $9.01\pm 1.08$  in the expectant group as compared to  $9.48\pm 0.844$  in the aggressive group. In the expectant group 96% babies had an apgar score of  $>7$  at 5 minute as compared to 98.7% in the aggressive group;  $p=0.311$ . The risks of C- Section (RR 0.5, 95% CI 0.24-1.04) and prolonged labor (RR 0.33, 95% CI 0.12-0.87) were lower in aggressive group as compared to the expectant group.

**Conclusion:** Patients managed with aggressive management protocol had significantly shorter duration of labor, lower caesarean rate and better mean apgar scores at 5 minute. Thus aggressive management is associated with better labor and neonatal outcome.

**KEYWORDS:** Aggressive Management, Intravaginal Prostaglandins, Latent Phase of Labor, Prolonged Latent Phase

### INTRODUCTION

Labor is defined as the physiological process by which a fetus is expelled from the uterus to the outside world. As described by (O driscoll, 1973)<sup>1</sup> it is the presence of regular uterine contractions accompanied by any one of the following: Bloody show, Rupture of the membranes, progressive effacement/dilatation of cervix. The initial stage of this process is the latent phase; the latent phase of labor is the phase that entails from the onset of regular, painful contractions,

to 3 cm dilatation of the cervix. The duration of latent phase lasts from 10 -12 hours in primiparas and 8 -10 hrs in multiparas.<sup>2</sup> This is followed by an active phase during which changes in cervical dilation accelerate to at least 1 to 2 cm per hour and the fetus descends into the birth canal. The active phase usually starts at 4 cm dilation and ends when the cervix is fully dilated.

Active management of labor comprises of 3 essential elements: careful diagnosis of labor, strict monitoring by partogram, vaginal exam after every 2 hours, use of PGE2 for cervical ripening amniotomy and oxytocin use once the alert line on partogram is crossed after excluding cephalopelvic disproportion. Expectant management on the other hand involves 4 hourly vaginal examinations. Use of amniotomy and oxytocin are well established to benefit the patient. Our study aims to highlight the benefits of prostaglandins e.g PGE2 in latent phase

Administration of prostaglandins results in dissolution of collagen and an increase in the submucosal water content of the cervix. Prostaglandins also cause the uterus to contract.<sup>3-4</sup> The efficacy of prostaglandins was demonstrated in a Cochrane review.<sup>5</sup> Compared to placebo, use of PGE2 (intra cervical or vaginal) resulted in a significantly lower risk of continuing to have an unfavorable cervix after 12 to 24 hours (RR 0.53, 95% CI 0.35-0.79), a lower need for oxytocin augmentation (RR 0.72, 95% CI 0.63-0.85), and a lower rate of failing to achieve a vaginal delivery within 24 hours (18 versus 99 percent, RR 0.19, 95% CI 0.14-0.25).

Active management of latent phase of labor is believed reduce the rate of prolonged labor and its associated risks of increased cesarean section rates, perinatal asphyxia, maternal exhaustion postpartum hemorrhage, pelvic floor injury, fistula formation and intrapartum infection.<sup>6</sup>

A study revealed that a greater percentage of females in labor induction group deliver within 12 hrs of onset of labor than in the expectant group (75 vs 58 %).<sup>7</sup>

There is increasing evidence that induction of labour from 37 weeks of gestation improves perinatal outcomes.<sup>8-10</sup>

A study in Scotland proved that active management of labor in term pregnancy decreases perinatal mortality from 0.18 % to 0.08%.<sup>11</sup>

However, it is postulated that decreased mortality from induction of labor comes at the cost of increased neonatal admissions<sup>11</sup> but there was no difference with respect to the use of analgesia or episiotomy or in neonatal outcome with respect to the Apgar score at 1 or 10 minutes.<sup>7</sup>

These benefits of labor induction are even more marked in patients with premorbid conditions. If induction of labour is carried out after 37 weeks' gestation in the presence of medical indications such as gestational hypertension, it reduces the risk of adverse maternal outcomes.<sup>12</sup>

The effect of active management on rates of caesarean section are more marked with a reduction of as high as 16 - 20 % in the rates of caesarean section.<sup>6,13-14</sup>

The findings of our study will contribute to determine better and effective management protocol for latent phase of labor and also lowering risk of maternal and fetal complications.

## MATERIALS AND METHODS

### Materials and Methods

This Randomized control trial was conducted at Department of Obstetrics and Gynecology, Benazir Bhutto Hospital, Rawalpindi. Ethical approval was sought from Institutional Research Forum, Rawalpindi Medical College prior to initiation and permission from the head of department was also taken.

Sample size was calculated using the WHO calculator, keeping level of significance 5% and power of single sided test 90%, for both outcome variables that were using anticipated probability of achieving a vaginal delivery within 24 hours (18% vs 99%) and anticipated mean difference of APGAR of 1.04, with anticipated variance 2. The minimally required sample sizes were calculated to be 5 and 32 in each group respectively for each of the outcome variables. But we included 75 patients in each group with a total of 150 Pregnant women presenting in the latent phase of labor. All primigravida women with diagnosis of being in labor (regular painful uterine contractions leading to cervical dilatation less than 3 cm, show and/ or spontaneous rupture of membranes) were included. It was ensured through record of abdominal ultra sonography and non stress CTG that the fetus was viable, cephalic and singleton.

Whereas all the women with any sign or diagnosis of Obstructed labor, fetal distress, severe maternal disease (pre-eclampsia, liver disease, gestational diabetes mellitus), cervix dilated more than 3cm, gestational age < 37 weeks, estimated fetal weight < 2500grams or > 4500 grams or cephalopelvic disproportion were excluded.

After detailed history, thorough general physical examination and systemic examination was carried out. Per abdominal and vaginal examinations were carried out. Upon confirmation of fulfillment of the selection criteria, the women and their husbands were explained the procedure of the study in detail and informed written consent was taken by both. The sampling technique was simple random sampling where an SPSS generated random number list of 150 numbers, randomly divided into 75 each in group A and 75 in group B was used. Each patient fulfilling the selection criteria was allotted the group mentioned in the list in chronological order.

The patients were randomly allocated to the active management or conservative group. The active management group had PGE<sub>2</sub> placed intravaginally and had two hourly digital cervical examinations as compared to the conservative group which only had four hourly digital cervical examinations. Oxytocin was administered in both the groups. Each woman was then followed up till delivery for maternal and neonatal outcomes. All the data was recorded in structural performas specially designed for this study. The outcome variables were maternal outcomes; type of delivery i-e SVD or Caesarean section and duration of delivery as within 12 hours or prolonged labor (>12 hrs). The neonatal was assessed by using APGAR scores at one and five minutes of age.

### Data Analysis

All the data was recorded in structured performas that were later entered and analyzed using Statistical Package of Social Sciences (version 22). The categorical variables like time of onset of labour, mode of delivery, delivery within 12 hours or not, APGAR <7 or not and frequencies along with percentages were calculated. The continuous variables like APGAR scores were presented as means and standard deviations.

Both the study groups were compared for outcome variables like mode of delivery and duration within 12 hours or not, APGAR<7 or not, using Pearsons Chi square test at 5% level of significance. Whereas to compare the mean APGAR score in both study groups, independent sample t test at 5% level of significance was applied. Relative risk along with 95% confidence intervals were also calculated to compare risk of cesarean section, prolonged labour and APGAR<7 in both study groups. Exclusion of value of 1.00 from the 95% Confidence Interval determined the statistical significance of the relative risk.

## Results

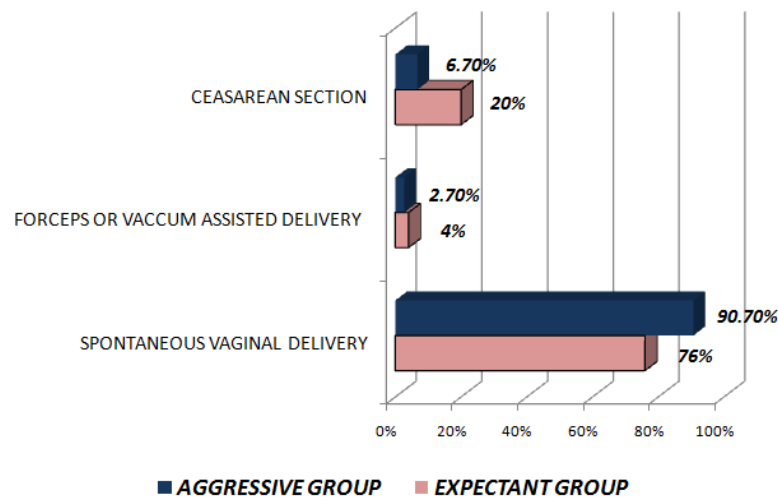
Our study included 150 patients, 75 in the active (aggressive) management group and 75 in the expectant (conservative) management group. All were primigravidas with singleton pregnancies.

The age ranged from 18-35 years with a mean age of  $22.83 \pm 3.6$  years.

The mean age of the expectant group was  $22.5 \pm 3.4$  and the mean age of the aggressive group was  $23.11 \pm 3.7$  years; the difference between the two groups was not significant;  $p = 0.356$ , indicating that both groups were homogeneous based on age.

## Mode of Delivery

In both study groups majority of women had spontaneous vaginal delivery however this rate was higher in aggressive group (90.7%) as compared to expectant group (76%) and the difference was statistically different with a p value of 0.046. The comparison is exhibited in figure 1



**Figure 1: A Bar Chart Displaying the Comparison of Mode of Delivery in Both Study Group (75 in Each Group, Total 150 Patients)**

The risk of cesarean section was found to be three times less in aggressive group as compared to expectant group and this difference in risk was statistically significant ( $RR=0.33$ , 95%  $CI= 0.12-0.87$ )

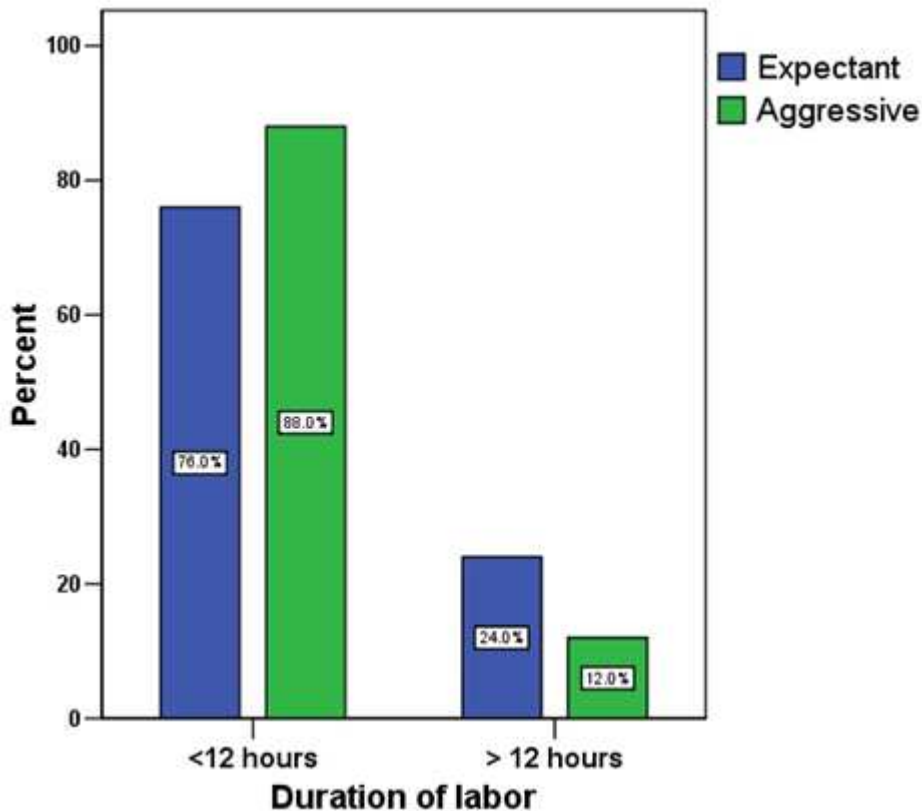
## Diagnosis of Labor

Onset of labor was heralded by uterine contractions with either cervical effacement and dilatation or show or spontaneous rupture of membranes occurring in varying combinations. All (100%) patients presented with regular painful

progressive uterine contractions. 8 patients (5.3%) presented with spontaneous rupture of membranes, 130 (87%) patients presented with cervical effacement and dilatation and 29 (19.3%) presented with show.

**Duration of Labor**

57 (76%) patients in the expectant group delivered within 12 hour and 18 (24%) delivered after 12 hours of onset of labor. 66 (88%) patients in the aggressive group delivered within 12 hour and 9 (12%) delivered after 12 hours of onset of labor. This difference was statistically significant;  $p= 0.06$ The risk of delivering after 12 hours was twice in the expectant group as compared to aggressive group. (RR or relative risk 0.5, 95% confidence interval =0.24-1.04) but this difference in risks was not statistically significant.



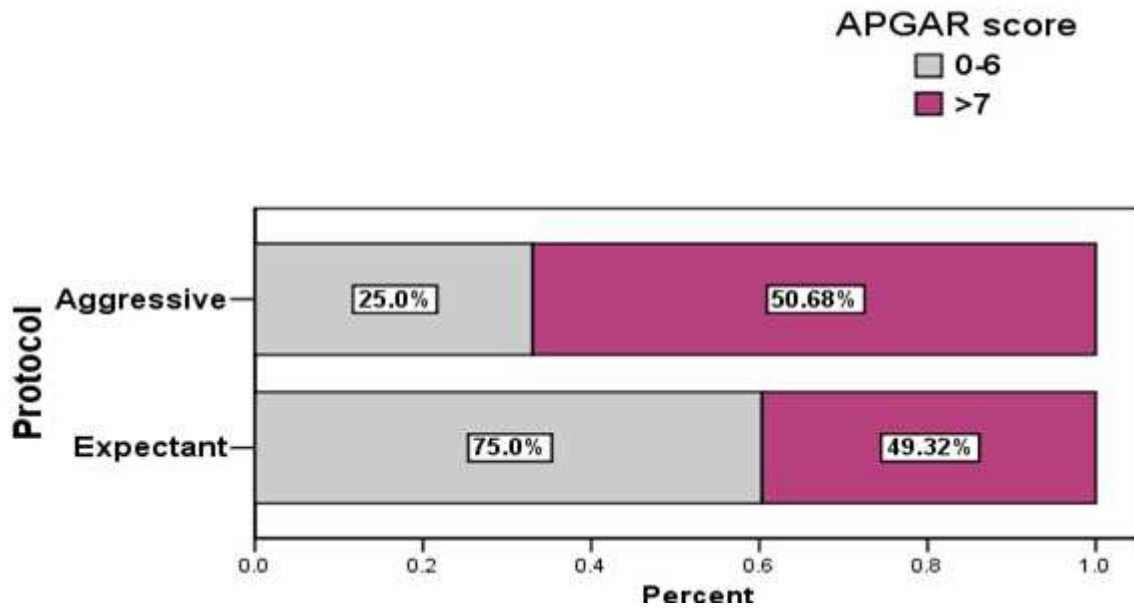
**Figure 2: Bar Graph Comparing Duration of Labor in the Expectant vs Aggressive Groups**

**Neonatal Outcome**

The mean apgar score at 5 minute was  $9.01\pm 1.08$  in the expectant group as compared to  $9.48\pm 0.844$  in the aggressive group. This difference was statistically significant;  $p = 0.004$ .

In the expectant group 72 (96%) babies had an apgar score of >7 at 5 minute and only 3 (4%) had an apgar score of 0-6. In the aggressive group 74 (98.7%) babies had an apgar score of >7 at 5 minute and only 1 (1.3%) had an apgar score of 0-6. This difference was not statistically significant;  $p= 0.311$ .

The risk of having APGAR <7 in neonates of mothers in both study groups was almost equal (RR=0.97, 95% CI= 0.92-1.02) and this difference in risks was not statistically significant.



**Figure 3: Stacked Bar Graph Comparing Neonatal Apgar Score at 5 Min in the Expectant Vs Aggressive Groups**

## DISCUSSIONS

Prostaglandin administration is an important part of active management of labor. The optimal route, frequency, and dose of prostaglandins have not been determined. Local administration of prostaglandins to the vagina or the endocervix is preferred because of better side effect profile while maintaining an acceptable clinical response.

A study assessed the effect of active management on latent phase in 197 nulliparous women. Active management resulted in a significant shortening of the latent phase but had no effect on active phase labor.<sup>15</sup> A study revealed that a greater percentage of females in labor induction group deliver within 12 hrs of onset of labor than in the expectant group (75 vs 58 %).<sup>7</sup> Our study had very similar results. 76% patients in the expectant group delivered within 12 hour as compared to 88% patients in the aggressive group;  $p=0.05$ .

In the expectant group 76% patients had spontaneous vaginal delivery, 4% had forceps or Vacuum assisted vaginal delivery and 20% had caesarean section as compared to 90.7%, 2.7% and 6.7% respectively in the aggressive group. The caesarean section rate was significantly lesser in the aggressive group;  $p=0.046$ . The results of our study with respect to caesarean section rate are in agreement with many international studies,<sup>6, 13-14,16</sup> however it is in disagreement with some other studies<sup>12,17-20</sup> which postulate that active management has minimal or adverse effect on the rates of caesarean section.

The mean apgar score at 5 minutes was significantly lower in the expectant group as compared to the aggressive group,  $p=0.004$ . By extension, this finding supports the claim of many studies that active management of labour decreases perinatal mortality.

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The skill of supporting labor during its early phases is an art that requires focused attention, development and additional research. Now interest is increasing in early hospitalization during the latent phase of labor for active management though this will increase the cost of labor management but can potentially reduce the complications associated with prolonged latent phase.

The limitations of our study are that it did not document the complications of prostaglandin use and also did not include the indications of caesarean delivery. However it was one of the first studies in this population to determine the effect of aggressive management. Large scale studies with more maternal and neonatal outcomes as well as incidences of complications are recommended on a larger scale to document the efficacy of active management in latent phase of labor beyond doubt..

## CONCLUSIONS

Patients managed with aggressive management protocol in latent phase of labor had significantly shorter duration of labor, lower caesarean rate and better neonatal apgar scores. The risks of cesarean section and prolonged labour were lower in aggressive group as compared to expectant group; whereas the risk of poor APGAR was similar in both groups.

Thus aggressive management is associated with better labor and neonatal outcome.

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