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Can Cervical Ripening at Term Reduce Cesarean Section Rate? A Comparative Study of Cervical Ripening Versus Expectant Management at Term

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ABSTRACT

Objective: To compare the obstetrical outcome in cervical ripening versus expectant management at term and evaluate the efficacy of Dinoprostone as a cervical ripening agent in unfavorable cervix.
Study Design: Quasi-experimental study.
Place and Duration of Study: Department of Obstetrics and Gynecology, Combined Military Hospital Lahore, Pakistan from Jan 2020 to Jun 2021.
Methodology: Five hundred pregnant women were recruited through nonprobability consecutive sampling; the women were randomly placed into two groups of 250 patients each. Group-1 received Dinoprostone Vaginal pessary while Group-2 was the control group with no intervention and expectant management. All women were followed till delivery. The mode of delivery in the two groups and the time interval from cervical ripening till delivery was analyzed and compared.
Results: Mean age of the patients was 30.43±4.16 years. Comparison of mode of delivery yielded a statistically significant difference with comparatively greater number of vaginal deliveries (86% vs 64%) in the cervical ripening group as compared to the control group. Mean interval from cervical ripening to delivery in Group-1 was 20.75±3.859 hours, minimum interval being 12 hours while the maximum interval was 48 hours. In both the groups, a significantly greater number of primigravidae (96, 33.1%) were found to have undergone LSCS more than the multigravidae (29, 27.6%).
Conclusion: Cervical ripening with Dinoprostone at term is an effective, safe and acceptable method in women with unripe cervix. Dinoprostone application resulted in effective cervical ripening, shortened application delivery interval and decreased cesarean delivery rate.

Keywords: Cervix, Cervical Ripening, Cesarean Section, Prostaglandins.

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INTRODUCTION

There has been a marked rise in caesarean births globally, especially over the last 2 decades.[1] According to statistics from Australia, Germany and the United States, about one in every three births is through Caesarean Section (CS). In Asian Countries as well a significant rise in CS has been recorded including Pakistan, where the rate has increased significantly to approximately 32.7 per cent in 2018.[2,3] exceeding the World Health Organization (WHO) recommended rate of 10-15%.[4]

Cesarean sections are performed for various indications, most common being dystocia, previous caesarean section delivery, cephalopelvic disproportion, extended labor, rising birth weights, higher maternal obesity, multiple gestation and maternal request.[5]

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Cesarean deliveries are not without risks and are associated with several short term and long term complications both for mother and baby, such as blood loss, injury to internal organs, scarring/adhesions, placental abnormalities (accrete, increta, percreta, previa) and respiratory problems in neonate requiring breathing assistance and oxygen supplementation.[6] This demands research targeted on methods and procedures including induction of labor which may reduce the rising trend of cesarean deliveries. However, induction of labor produces a favorable outcome in terms of vaginal delivery only when induction is done on a favorable Bishop score.[7] The procedure of cervical ripening has been utilized by several researchers for improving the Bishop score, using different techniques including membrane sweeping, mechanical methods (balloon catheters, osmotic dilators), cervical massage and prostaglandin E2.[8] The results of these studies offer hope in terms of improvement in Bishop score and increased chances of vaginal deliveries.

Prostaglandin E2 has been used in multiple studies for induction of labor in cases with an unfavorable Bishop score.[9] When applied locally, it induces collagen breakdown, dispersion and fluid absorption by stromal tissue for effective cervical ripening. It is available in the form of intracervical gel or vaginal pessary. Evidence suggests that controlled-release vaginal pessary achieves cervical ripening in shorter time period as compared to intracervical gel.[10]

Keeping in mind the maternal and neonatal risks associated with CS delivery in a low-resource country like Pakistan, every effort should be made to reduce the CS rate. The current study aimed to evaluate the efficacy of Dinoprostone as a cervical ripening agent in unfavorable cervix. The objective of the current study was to compare the obstetrical outcome in cervical ripening versus expectant management in patients at term with an unfavorable cervix, which may help in formulating protocols to reduce the CS rate and hence reducing the morbidity associated with CS.

METHODOLOGY

This Quasi-experimental study was carried out in Department of Obstetrics and Gynecology, Combined Military Hospital Lahore for one and a half year from 1st January 2020 to 30th June 2021. Study commenced after approval from the Ethical Review Committee of the hospital (vide 1831/2019/Trg/Adm). A minimum sample size of 320 was calculated with 5% significance level with power of 80% and p1 of 23.1%,[11] p2 of 37.5%,[11] where p1 was the expected proportion (cesarean section rate) in population 1 and p2 was the expected proportion (cesarean section rate) in population 2. However, a sample size of 500 (250 patients in each group) was finalized for the study. Non-probability consecutive sampling technique was used.

Inclusion Criteria: Women with singleton pregnancy with a specific indication for induction, cephalic presentation, no uterine scar or chromosomal malformations in the foetus and a Bishop scoring12 of 4 or less at ≥37 weeks' gestation were included in the study.

Exclusion Criteria: Women with low lying placenta, individuals with an asthmatic history or excessive vaginal hemorrhage were excluded from the study.

Demographic information of patients fulfilling the inclusion criteria was taken. Informed consent was taken from each patient while ensuring confidentiality and explaining that there is no risk involved to the patient while taking part in this study. The subjects were divided into two groups (Figure). 250 patients were put in cervical ripening group or Group-1 while 250 patients were in control group or Group-2 with expectant management. Expectant management was defined as no active intervention for 24 hours after admission. In Group-1, the patients underwent cervical ripening with insertion of Dinoprostone vaginal pessary while the patients in Group-2 were kept as controls and no placebo was used. A 20 minute Cardiotocography (CTG) was carried out prior to cervical ripening. If the CTG was reassuring, 3 mg Dinoprostone vaginal pessary was inserted in the posterior fornix of vagina. CTG was repeated after the insertion. If there was no onset of labor within 24 hours, induction of labor was done. Patients of Group-2 were induced 24 hours after the admission if they did not go into spontaneous labor. All women in Groups 1 and 2 were followed till delivery. Feto-maternal surveillance was carried out according to the unit protocol. Progress of labor was recorded on partogram. The mode of delivery in the two groups and the time interval from cervical ripening till delivery was analyzed and compared. Birth weight and Apgar score at 5 minutes after birth was recorded. Data was entered in specially designed proforma and analyzed through SPSS 16. Frequency and percentage were computed for qualitative variables, and Mean±SD was presented for quantitative variables. Chi-square test was applied to compare mode of delivery of the two groups while independent samples t test was used to compare the ripening to delivery interval in relation to parity, taking $p \leq 0.05$ as significant.

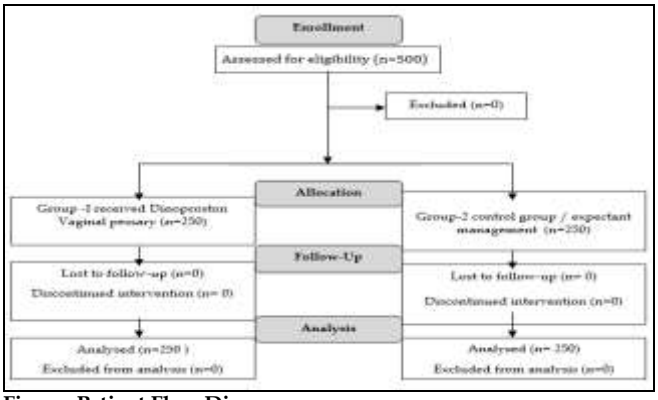

Figure: Patient Flow Diagram

RESULTS

A total of 500 women were included in the study, 250 women were in cervical ripening group (Group-1)

while 250 were in the control group (Group-2). Mean age of the patients was 30.43±4.16 years, the range being 21-42 years. Mean body mass index was 28.01±2.9 kg/m^2. Mean gestational age at delivery was 39.958±0.73 weeks with statistically significant difference in gestational age at delivery between the two groups, with lesser mean gestational age at delivery in the cervical ripening group (Table-1). Majority of the patients were primigravida (56.4%). Majority of patients were at more than 39 weeks' gestation (76%). Post dates pregnancy was found to be the most common indication (33.6%) for induction followed by pre labor rupture of membranes (23.2%). In Group-1, 175 patients delivered with cervical ripening alone while 75 patients required induction, while 104 patients required induction in Group-2, with majority of patients requiring induction being primigravidae in both the groups.

Table-I: Comparison of Descriptive statistics of Quantitative Variables Between Cervical Ripening and Control Groups (n=500)

Baseline characteristics	Group 1Mean±SD (n=250)	Group 2 Mean±SD (n=250)	Total (n=500)	*p*-value
Age (years)	30.38±4.37	30.43±3.96	30.43±4.16	0.781
BMI (kg/m^2)	27.95±3.33	28.06±2.48	28.01±2.9	0.682
Gestational age at delivery (weeks)*	38.794±0.58	39.122±0.83	39.958±0.73	0.001

*BMI: Body Mass Index *p value< 0.05*

Comparison of mode of delivery yielded a statistically significant difference with comparatively greater number of vaginal deliveries (86% vs 64%) in the cervical ripening group as compared to the control group. Overall, significantly greater number of primigravidae (96,33.1%) were found to have undergone Lower Segment Caesarean Section more than the multigravida (29, 27.6%) (Table-II). There was no significant difference between the two groups with regards to birth weight and Apgar score at 5 minutes after birth with majority of the babies having birth weight more than 2.5 kg and Apgar score of more than 7. Mean interval from cervical ripening to delivery in Group-1 was 20.75±3.859 hours, minimum interval being 12 hours while the maximum interval was 48 hours.

DISCUSSION

Our study demonstrated that the Dinoprostone insertion resulted in effective cervical ripening, shortened application delivery interval and decreased cesarean delivery rate. The rising rate of cesarean section globally has resulted in increased risk in terms of maternal and neonatal morbidity and mortality. Cervical ripening and induction of labor are the procedures performed to reduce this rising trend.[12-13] The rates of induction vary in different regions from 1.4% to 35.5%. However, on average, annually 10% of pregnancies are induced.[14]

Table-II: Comparison of Parity, Mode of Delivery, Induction, Birth Weight and Apgar Score Between Cervical Ripening and Control Groups (n=500)

CATEGORY	GROUP 1 (n=250) n(%)	GROUP 2 (n=250) n(%)	TOTAL (n=500) n(%)	*p*-value
Parity				
Primigravida	141(56.4)	149(59.6)	290(58)	0.526
Multigravida	109(43.6)	101(40.4)	210(42)	
Indications for induction*				
Post dates pregnancy	76(30.4)	92(36.8)	168(33.6)	0.001*
Prelabour rupture of membranes	50(20)	66(26.4)	116(23.2)	
Gestational diabetes mellitus	54(21.6)	28(11.2)	82(16.4)	
Hypertensive disorders	42(16.8)	56(22.4)	98(19.6)	
Others	28(11.2)	8(3.2)	36(7.2)	
Gestational age				
37-39 weeks	60(50)	60(50)	120(24)	1.000
>39 weeks	190(50)	190(50)	380(76)	
Mode of delivery*				
Vaginal	215(86)	160(64)	375 (75)	0.001*
Primigravida	111(57.2)	83(42.8)	194(66.9)	
Muti gravida	104(57.46)	77(42.54)	181(72.4)	
LSCS	35(14)	90(36)	125(25)	
Primigravida	30(31.25)	66(68.75)	96(33.1)	
Muti gravida	5(17.24)	24(82.76)	29(27.6)	
Required induction*				
Yes	75(30)	104(41.6)	179(35.8)	0.005*
No	175(70)	146(58.4)	321(64.2)	
Birth weight (kg)				
< 2.5	13(5.2)	8(3.2)	21(4.2)	0.373
>2.5	237(94.8)	242(96.8)	479(95.8)	
Apgar Score at 5 mins				
<7	4(1.6)	5(2)	9(1.8)	0.752
>7	246(98.4)	2459(98)	491(98.2)	

LSCS: Lower segment cesarean section, *p value< 0.05

The most common indication for induction of labor in our study was postdates pregnancy (33.6%) followed by pre-labor rupture of membranes (23.8%) and medical disorders. The findings are comparable to a regional study by Gupta in which 34.8% patients were induced due to postdates pregnancy.[10] Successful

outcome for induced labors in terms of vaginal delivery depends to a larger extent on cervical ripeness assessed on Bishop scoring. Bishop score of less than 6 is considered unripe cervix, and when induced leads to increased risk of operative delivery. Cervical ripening is therefore recommended in such cases for favorable outcome.[15] Multiple nonpharmacological and pharmacological agents used for cervical ripening include membrane sweeping, mechanical methods (balloon catheters, osmotic dilators), cervical massage and prostaglandin E2.[16,17] Among them, Dinoprostone is known to have a better effect on cervical ripening.[18]

In our study, intravaginal Dinoprostone resulted in greater number of vaginal deliveries in exposed group (215, 86%) as compared to the control group (35,14%). Similar results were seen in a study in India where a Dinoprostone application was found to be effective in 92.5% of cases.[19] In 1996, a multicenter trial was carried out in Africa by Noah *et al.*, which is the largest reported study on cervical ripening, resulting in vaginal delivery in 83% of cases.[20] A local study by Raza carried out in Peshawar, using Dinoprostone, also resulted in vaginal delivery in 82 % of cases.[18] Contrasting results were obtained in a study by Nicholson where similar rates of vaginal and cesarean deliveries were noted among the exposed and control groups, despite a higher rate of cervical ripening (40.4% vs 17.2%) in the exposed group.[21] In another regional study, vaginal delivery was achieved in 71.6% cases with single application of Dinoprostone.[22]

Varied results have been obtained in studies in the cervical ripening to delivery interval. In our study, mean ripening to delivery interval was 20.75±3.859 hours, minimum interval being 12 hours while the maximum interval was 48 hours. In the study by Calder *et al.*, the improvement noted in cervical score occurred from 2.3 to 6.3 in 6 hours.[23] The duration varies, ranging from 9 hours20 to 10 hours in a study by Calder *et al.*, 23 to 16.43 hours22 to 20.2 hours in a study done by Jackson.[24] The parity of the patients did not influence the rate of cervical ripening in our study. The ripening to delivery interval in primigravidae was 20.67±4.21 hours and in multigravidae was 20.65±3.35 hours. This is in contrast to the study by Bashutheen,[22] in which mean induction to delivery interval in primigravidae was 20.6 hours and in multigravidae was 10.8 hours. This could be due to the greater mean gestational age in the multigravidae in our study as compared to the study by Bashutheen.

The rate of primary cesarean delivery has been on the rise with an increase of 19.1% in 1995 to 43.2% in 2019.[25] Overall, a significantly greater number of primigravidae (96, 33.1%) were delivered by LSCS than the multigravidae (29, 27.6%) in our study. These results are comparable to the results obtained by Nicholson *et al.*, where the cesarean delivery rates were 18.5% and 2.8% in primigravidae and multigravidae respectively.[21] There was no significant difference between the exposed group and the control group with regards to birth weight and Apgar score at 5 minutes after birth. The results are similar to other studies where majority of babies were found to have birth weights of more than 2.5 kg with good Apgar score in both the exposed and control groups.[18,22]

Limitations of the study included the research being single-centered and not comparing with other methods of cervical ripening. Larger, randomized multicenter clinical trials, comparing with other methods of cervical ripening are needed to further corroborate the findings of the current study.

CONCLUSION

The study showed that intravaginal insertion of Dinoprostone is an effective, safe and acceptable method for cervical ripening in women with unripe cervix. There was no increase in maternal and neonatal morbidity and mortality with this procedure. Hence Dinoprostone can be recommended as a useful and potent method of cervical ripening with an unfavorable cervix.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SB & ZS: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

ST 7 SG: Data acquisition, data analysis, approval of the final version to be published.

RK & HOJ: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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