COMPARISON OF INDUCTION OF LABOR WITH FOLEY CATHETER AND PROSTAGLANDINS IN POSTDATE PREGNANCIES

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ABSTRACT

Objective: To compare the success of Foley catheter and prostaglandin E2 (PGE2) in females presenting with postdates pregnancy.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of obstetrics and gynecology, Combined Military Hospital (CMH), Quetta Jun 2015 to Oct 2015.

Material and Methods: Through non-probability, consecutive sampling technique 150 cases were included in the study. Informed consent and demographic details were noted. All females were randomly divided in two equal groups by using lottery method. In group A, Foley catheters, were administered. Speculum examination was performed, and 16F standard latex Foley catheter was inserted, using aseptic technique, above the internal cervical os and inflated with 30 mL of sterile water. The catheter was taped to the inner thigh with slight traction, and spigot inserted to occlude the lumen. In group B, PGE2 gel was inserted into the posterior vaginal fornix. Initially 2 mg dose per vaginum for nulliparous and 1 mg per vaginum for multi parous women was used. A post-insertion cardiotocography (CTG) was performed for at least 30 minutes. The cervix was re-examined after six hours and, if required, the procedure repeated using a further 1 mg PGE2 (regardless of parity). Success was labelled for those females who delivered vaginally within 24 hours. Statistical analysis was performed using SPSS version 16. Both groups were compared for success in terms of vaginal delivery within 24 hrs by using chi-square test. A *p*-value ≤0.05 was taken as significant.

Results: The mean age of the patients was 28.33 ± 5.79 years, the mean gestational age was 42.00 ± 0.82 weeks. Success was achieved in 76 cases in which 26 were from group A and 50 were from group B. Statistically highly significant difference was found between the study groups and success of the patients i.e. *p*-value=0.000.

Conclusion: PGE2 showed significantly greater success in terms of vaginal delivery within 24 hrs as compared to Foley catheter in females presenting with postdates pregnancy.

Keywords: Amniotic fluid, Foley's catheter, Induction of labor, Postdate pregnancy, Prostaglandin E2.

INTRODUCTION

Pregnancy beyond 42 weeks or 294 days often invokes maternal concern about delay past the expected date of delivery. The incidence of postdate pregnancies is between 4-14%. Post-mature births can carry risks for both the mother and the infant, including fetal malnutrition which increases perinatal mortality[1].

Postmaturity is the condition of a baby that has not yet been born after 42 weeks of gestation, two weeks beyond the normal 40 weeks. Weeks post-term, postmaturity, prolonged pregnancy, and post-dates pregnancy all refer to postmature birth[2].

The most common cause of prolonged pregnancies is inaccurate dating. The use of standard clinical criteria to determine the estimated delivery date (EDD) tends to overestimate gestational age and consequently increases the incidence of postterm pregnancy. Clinical criteria which are commonly used to confirm gestational age include last menstrual period (LMP), the size of the uterus as estimated by bimanual examination in the first trimester, the perception of fetal movements, auscultation

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of fetal heart tones, and fundal height in a singleton pregnancy[3].

When postterm pregnancy truly exists the cause is usually unknown. Common risk factors include primiparity, previous postterm pregnancy, male fetus, obesity, hormonal factors and genetic predisposition. It is not known how body mass index (BMI) affects the duration of pregnancy and timing of delivery, but interestingly obese women have a higher incidence of postterm pregnancy, while women with low BMI have a higher incidence of preterm labour (delivery before 37 weeks of gestation)[3].

Induction of labour is the intentional or artificial initiation of cervical ripening and uterine contraction for the purpose of accomplishing delivery, prior to onset of spontaneous parturition. Induction of labor is indicated where the benefits to mother or to the fetus outweighs the benefit of continuing pregnancy[4-6].

In postdates, different procedures could be performed for induction of labor. Vaginal prostaglandins E2 are effective whatever the cervical conditions. Insertion of catheter is a reliable method without any pharmacological effect. It opens interesting perspectives but with caution about the possibly increased risk of infections. A Foley catheter is a flexible tube passed through the urethra and into the bladder to drain urine. It is the most common type of indwelling urinary catheter[7]. The mechanical action of the Foley catheter strips the fetal membranes from the lower uterine segment and causes rupture of lysosomes in the decidual cells, part of which is phospholipase A. These lytic enzymes act on phospholipase to form arachidonic acid which is converted to prostaglandin, thereby improving the consistency and effacement of the cervix. The advantage of this method over the pharmacological preparation includes simplicity of preservation, lower cost and reduction of side effects[8].

The rationale of this study was to compare the success of Foley catheter and prostaglandin E2 (PGE2) in females presenting with postdates pregnancy. It has been noticed in routine as well as through literature that PGE2 is a more effective method for induction of labor and has benefits in terms of early spontaneous delivery without compromising the health of fetus and mother. But we have also observed that there is controversy in results of already conducted studies and the studies which have been mentioned above were conducted on small sample size. So we intend to find a more suitable and beneficial method of induction of labour and to conduct this study on a larger sample size in order to make this study more reliable. Our study will help us in implementing a more suitable method for induction of labour.

MATERIAL AND METHODS

This randomized controlled trial was conducted at the department of obstetrics and gynecology, Combined Military Hospital (CMH) Quetta from, June 2015 to October 2015. Sample size of 150 cases; 75 cases is calculated with 80% power of test, 5% level of significance and taking expected percentage of success i.e. 60% with Foley catheter and 37.1% with PGE2 in females presenting with postdates pregnancy. Non probability, consecutive sampling was used. Pregnant women aged 20-40 years of parity <5 presenting with postdates pregnancy (as per operational definition) with Bishop Score <6 were included in the study. While exclusion criteria was multiple pregnancies or non-cephalic presentation (on USG), females with hypertension (BP ≥140/ 90 mmHg) or hypotension (BP <110/70 mmHg), renal problems (creatinine >1.2 mg/dl), or deranged hepatic function (AST >40 IU, ALT >40 IU), cardiac diseases (abnormal ECG and medical record), history of severe asthma, palpitation, anemia (Hb <10 mg/dl), pregnancy with antepartum hemorrhage (on clinical evaluation) and unsuitable for randomization to either PGE2 (e.g. previous caesarean section) or catheter use (e.g. latex allergy), or prior attempted induction of labour (IOL) in this pregnancy.

After taking approval from hospital ethical committee, 150 females fulfilling selection criteria was enrolled in the study from OPD of Department of Obstetrics and Gynecology, CMH, Quetta. Informed consent was obtained. Demographic details (name, age, gestational age and parity) were also noted.

All females were randomly divided in two equal groups by using lottery method. In group A, Foley catheter was administered. Speculum examination was performed, and 16F standard latex Foley catheter was inserted, using aseptic technique, above the internal cervical os and inflated with 30 ml of sterile water. The catheter was taped to the inner thigh with slight traction, and spigot inserted to occlude the lumen. In group B, PGE2 gel; received initial 2 mg dose per vaginum (PV) for nulliparous and 1 mg PV for parous women was inserted into the posterior vaginal fornix. A post-insertion CTG was performed for at least 30 minutes.

Patient was re-assessed after 6 hours and if there was no improvement in Bishop Score, patient was subjected to another dose of 1 mg PGE2 (regardless of parity). If a female delivered within 24 hours, then success was labeled (as per operational definition). All this information was recorded on a proforma.

Data Analysis

Statistical analysis was performed using SPSS version 16. Descriptive mean and standard deviation were calculated for age and gestational age. Frequency and percentage was calculated for parity success.

Both groups were compared for success by using chi-square test. A *p*-value ≤0.05 was taken as significant. Effect modifiers were controlled through stratification of age and parity. Chi square test / Fisher's exact were applied for post-

Table-I: Comparison of success of labor in both study groups.

		Study Groups		Total
		Group A	Group B	
Success	Yes	26	50	76
	No	49	25	74
Total		75	75	150

Group A= Foley's Catheter, Group B= PGE2, Chi value= 15.36, *p*-value= 0.000 (Significant)

Table-II: Comparison of success in both study groups stratified by age.

Success			Study Groups		Total	*p*-value
			Group A	Group B		
Age (years)	Below 30	Yes	1	37	38	0.001
		No	35	21	56	
	Above 30	Yes	25	13	38	0.54
		No	14	4	18	

Group A= Foley's Catheter, Group B= PGE2

Table-III: Comparison of success of labor in both study groups stratified by parity.

Success			Study Groups		Total	*p*-value
			Group A	Group B		
Parity	No Parity	Yes	3	21	24	0.001
		No	16	9	25	
	One	Yes	11	15	26	0.247
		No	13	9	22	
	Two	Yes	8	14	22	0.047
		No	14	7	21	

Group A= Foley's Catheter, Group B= PGE2

stratification. A *p*-value ≤0.05 was taken as significant.

RESULTS

In this study a total of 150 cases were enrolled. The mean age of the patients was 28.33 ± 5.79 years with minimum and maximum ages of 20 and 40 years respectively.

The study results showed that 49 (32.67%) patients appeared with no parity, 48 (32%) patients appeared with parity one, 43 (28.67%) patients appeared with parity two and 10 (6.5%) patients appeared with parity three (fig). In this study the mean gestational age of the patients was 42.00 ± 0.82 weeks with minimum and maximum gestational ages of 41 and 43 weeks respectively. In our study the success was found in 50% patients and success was not found in 25% patients.

The study results showed that the success was achieved in 76 cases in which 26 were from group A and 50 were from group B, similarly the success was not achieved in 74 cases in which 49 were from group A and 25 were from group B. Statistically a highly significant difference was found between the study groups and success of the patients. i.e. *p*-value=0.001 (table-I).

The study results showed that in patients below 30 years of age success was achieved in 38 cases in which 1 case was from group A and 37 cases were from group B, in patients above 30 years of the success was achieved in 38 cases in which 25 were from group A and 13 were from group B. Statistically a highly significant difference was found between the two study groups and success of the patients with age below 30 years. i.e. *p*-value=0.001 (table-II).

In our study in patients with no parity, success was achieved in 24 cases in which 3 cases were from group A and 21 cases were from group B, in patients with parity the success was achieved in 26 cases in which 11 were from group A and 15 were from group B, similarly in patients with parity two success was achieved in 22 cases in which 8 were from group A and 14 were from group B. Statistically significant difference was found between the study groups and success of the patients with no parity. i.e. *p*-value=0.001 table-III.

DISCUSSION

While many studies have been conducted on postterm pregnancies, some of the fetal risks such as presence of meconium, increased risk of neonatal acidemia, and even stillbirths have been described as being greater at 41 weeks of gestation and even at 40 weeks of gestation as compared with 39 weeks' gestation[9].

In one study, the rates of meconium and neonatal acidemia both increased throughout term pregnancies beyond 38 weeks of gestation. In addition to stillbirth being increased prior to 42 weeks of gestation, one study found that the risk of neonatal mortality also increases beyond 41 weeks of gestation[10].

In our study success was found in 76 (50.67%) patients in which 26 were from Foley catheter group and 50 were from PGE2 group, similarly success was not achieved in 74 cases in which 49 were from Foley catheter group and 25 were from PGE2 group. Statistically there is highly significant difference between the study groups and success of the patients. i.e. *p*-value=0.000. Our study results showed PGE2 a better treatment as compared to Foley catheter in females presenting with postdate pregnancy.

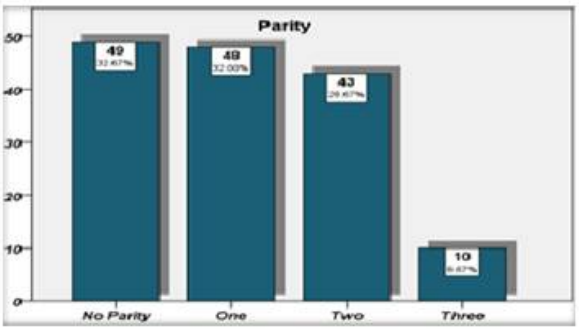

Figure: Frequency distribution of parity among cases.

Through a randomized trial one study has found that PGE2 has more deliveries within 24 hours i.e. 53% (n=51) case while with Foley catheter (n=50), there were 28% deliveries which occur within 24 hours of induction in postdates pregnancies. The difference was found to be significant and PGE2 is more effective than induction through Foley catheter (p=0.011)[11].

One study reported that cervical priming as well as labor induction in grand multiparous women is safe and effective when using either PGE2 tablets or Foley catheter, together with the use of oxytocin if needed for labor augmentation. The use of PGE2 3 mg vaginal tablets is preferred to the intracervical Foley catheter[12,13].

But another trial supported the evidence and reported that PGE2 has more deliveries within 24 hours i.e. 37.1% (n=35) case while with Foley catheter, there were 60% (n=35) deliveries which occur within 24 hours of induction in postdates pregnancies. But the difference was found to be insignificant, however, Foley catheter was found to be more effective than induction through PGE2 (p>0.05)[14]. Ezimokhai and Nwabinelli found that ripening effect of a Foley catheter on the cervix in 21 primigravida to be similar to that of 5 mg of PGE2 in vaginal gel in 14 primigravida[15].

Deshmukh et al showed that for pre-induction cervical ripening there is no difference in efficacy between intra cervical PGE2 gel or intra cervical Foley catheter. Also, other factors like induction-delivery interval, maternal and neonatal outcome and need for oxytocin for further augmentation were similar in both the groups[16].

Another found that the Foley catheters are efficacious with a shorter induction to-delivery time than PG for induction of labor with an unfavorable cervix[17].

Both agents have similar CS rates, but Foley catheters result in increased need for oxytocin stimulation and there is more tachysystole with PG[18].

One randomized controlled trial reported that in women with an unfavorable cervix at term, induction of labor with a Foley catheter is similar to induction of labor with prostaglandin E2 gel, with fewer maternal and neonatal side-effects[19]. A clinical study by Rashid et al[20]. Found favorable and beneficial effect of Foley catheter. Vaknin et al[21] performed a meta-analysis comparing the efficacy and safety of cervical ripening and labour induction by Foley catheter balloon versus locally applied prostaglandin in third trimester of pregnancy.

CONCLUSION

PGE2 showed significantly greater success in terms of vaginal delivery within 24 hrs as compared to Foley catheter in females presenting with postdates pregnancy.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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