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Efficacy of Prostaglandin Analogues for Induction of Labour and Associated Complications: A Retrospective Research Study conducted in Latifa Women and Children Hospital

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Introduction

Induction of labour has become a more common worldwide medical intervention during the last few years [1]. The ideal cervical ripening agent must be effective, safe, easy to be administered and acceptable for the pregnant woman. Utilizing prostaglandins (PG) for cervical ripening during induction of labour (IOL) was first described in the 1960s [2]. Since that time various types of prostaglandins including PGF2α, PGE2 (Dinoprostone) and PGE1 (Misoprostol) were extensively studied to elicit the best prostaglandin pharmacological agent for pre-induction cervical ripening [2]. Dinoprostone was found to be superior to the others, as it increased the rates of successful vaginal delivery within 24 h without increasing the operative delivery rates. Vaginal route was found to be a safe and effective approach of bringing on labor.[2]

There are different pharmacological and mechanical methods that have been approved to ripen the unfavourable cervix [3]. Prostaglandins are the most effective drugs that cause cervical ripening by increasing inflammatory mediators in the cervix and inducing cervical changes. Prostaglandin E1 (PGE1) and prostaglandin E2 (PGE2) have different effects on these processes and on myometrium contractility [4]. The PGE2 is available for cervical ripening as a 3mg Dinoprostone vaginal pessary and also as a controlled release pessary (Propess®), which releases 10 mg of Dinoprostone over 24 hours. Prostin tablet is inserted into the vagina every 6 hours, with a maximum of 3 doses, as per our hospital protocol.

The effect of PGE2 has been investigated and there are many studies in the literature comparing the efficacy of the different formulations available in the market [5]. The incidence of Induction of labour is rising in the current era, with the advancement of technology viz. increasing frequency of ultrasound studies and CTG for fetal monitoring and assessment of fetal wellbeing by fetal medicine units. An appropriate and well tolerated pharmacological method of induction of labour cannot be decided without doing a detailed and in-depth analysis of the two commonly used drugs.

This research study was conducted to compare the efficacy of Propess and Prostin for induction of labor and their complications according to national and international standards.

Therefore, it will help us to update the current hospital guideline of Induction of Labour and eventually improve patient care.

Methodology

This is a retrospective study conducted over a period of 6 months from 1/10/2019 to 31/3/2020. The data was analysed from 597 patients in Latifa Hospital, Dubai, United Arab Emirates for the period of 12 months (1/10/2019 to 30/9/2020). The efficacy of two drugs Prostin and Propess, for induction of labour were compared with respect to their progression to labour and associated complications. The data was collected from the labour room records. Inclusion criteria included pregnant females that were 18-45 years old, gestational age of 28 weeks or more, singleton pregnancy, and cephalic presentation. Exclusion criteria included previous caesarean section/uterine surgery, any contraindication to vaginal delivery, suspected cephalo-pelvic

disproportion, multiple pregnancy, and unexplained antepartum haemorrhage. The data was collected using MS excel sheet.

Demographics

A total of 622 patients were enrolled in this study. Complete data was available for 597 out of them. These were distributed into two groups according to whether Prostin (56.8%) or Propess (43.2%) was used for induction of labour (IOL). Variations between the two groups were accounted for in terms of the following demographic factors: age, gestational age, parity, and indications for IOL. The mean age of women who received Prostin in our study was 31.6 (SD 0.32) and this was higher than that of Propess which was 29.6 (SD 0.33). The gestational ages between both groups were rather similar with the mean of Prostin being 38.4 weeks (SD 0.10) and Propess was 38.6 weeks (SD 0.12). Nulliparity was the most common parity amongst our study group with a valid percent of 37.4%. This was double the incidence of the next common parity which was 1 (18.6%). A varied range of indications for IOL existed amongst these patients ranging across Medical (HTN, DM, Cholestasis of pregnancy etc) and Obstetric (post successful ECV for unstable lie, IUGR, post term, foetal demise). The common indications were Diabetes Mellitus (31.5%) followed by post term (10.2%) and followed by intrauterine growth restriction (9.7%).

Statistical Analysis

Numerical data are presented as mean ± standard deviation or median (min/max) as appropriate and categorical data are presented as a percentage. Chi squared test or Fischer's exact test was used to compare categorical variables (viz. complications) between the two groups of the study. T-test or Mann-Whitney test was used to compare numerical variables between the two study groups as appropriate.

All the tests are 2-sided tests and P value <0.05 indicates statistically significant results. SPSS 24 was used for data analysis.

Efficacy of drugs

The efficacy of these drugs was assessed by whether labour started or not after induction of labour. It was shown that a total of 79.1% of women from both categories collectively progressed into labour while 20.9% did not. 81.4% of those who were induced with Prostin progressed to labour while 76.0% of those who were given Propess progressed into labor. Using the Pearson Chi-Squared test this had a p-value of 0.105(not significant). Reinduction, which is defined as multiple doses of prostaglandin, was required in 1.84% of our patient population.

Complications

The most common complications following IOL were non-reassuring cardiotocography (CTG) and hyperstimulation/tachysystole. These had an overall occurrence of 90.3% and 8.2% for Prostaglandins respectively. Other complications such as abruptio placenta and postpartum haemorrhage (PPH) were not seen as frequently with a percentage of 0.5%. While comparing the drug used for IOL, non-reassuring CTG was seen in 10.9% in women who received Prostin while it occurred in 6.2% in women who received Propess. Hyperstimulation/tachysystole was seen in 1.2% of Propess patients while there were none that experienced it in Prostin patients. The Pearson chi-squared test analysing this correlation had a p-value of 0.024 (significant). The incidence of no complications was significantly common too, with 92.6% of those on Prostin having no complications and 87.2% of those with Propess similarly. Fisher's exact test was used to analyse the above correlation resulting in a p-value of 0.011(significant). The mean age of those who had complications was found to be 28.76 years for both Prostin and Propess and mean parity for the same was 0.91 (SD 0.251). Median parity of those who had complications is nulliparity. Test used for this comparison was Mann-Whitney test with p-value <0.001 (significant).

Mode of delivery

Those that had normal vaginal delivery (NVD) were 78.9% of the study population whilst the remaining 21.1% delivered via lower segment caesarean section. Progression to normal vaginal delivery was more common in women who received Prostin (81.4%) compared to those who received Propess (75.6%). Pearson chi-squared test revealed a p-value of 0.084 (not significant).

Discussion

The present study compared the induction of labour using Prostin vs Propess through a retrospective analysis in the hospital setting. Prostin 3mg was administered 6 hourly vaginally up to 3 doses, whereas Propess (10mg) controlled release single pessary was administered vaginally and left in place for up to 24 hours. The success rates, which was defined as onset of labour, of Prostin and Propess were 81.4% and 76% respectively. This was not statistically significant (p value= 0.105). Following induction of labor with both the agents, the incidence of "reinduction" was rather insignificant and did not bear weight on the outcomes of our study. Many studies that have investigated the efficacy of prostaglandin E2 in the induction of labour showed that Propess had a higher success rate than Prostin [6,7]. A most recent study evaluated the effect of Dinoprostine vaginal insert (Propess) compared to that of the vaginal tablet (Prostin) in primigravida specifically [8], and showed that Propess was the preferred and a better tolerated Prostaglandin E2 tablet for IOL because of the reduced need for vaginal examinations. On the other hand, our analysis shows an insignificant difference in efficacy between the two Prostaglandins E2, which was the primary outcome in this study. This is supported by multiple randomised control trials that also showed no significant difference between the two groups resulting in no preference of one drug over the other in terms of better efficacy [9-11].

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The secondary outcome, being the complications resulting between the two drugs, proved to be a non-reassuring CTG and hyperstimulation/tachysystole combined. In our research, non-reassuring CTG was shown in 10.9% of the Prostin cohort while 6.2% of the Propess cohort which is insignificant (p value= 0.084). A study done in 1992, supports our results by showing that non-reassuring CTG was similar in both PGE2 pessary vs placebo groups [12]. Tachysystole was defined as more than 5 contractions/10mins minutes for two consecutive 10-minute periods. Hyperstimulation is defined as either > 5 contractions in ten minutes over a 30minute period, or contractions lasting more than 2 minutes in duration, or contractions of normal duration occurring within 60 seconds of each other as written by the NHS Wales protocol. But many authors define Hyperstimulation as exaggerated uterine response with late fetal heart rate decelerations or fetal tachycardia of more than 160 beats per minute or other worrisome fetal heart rate changes [13,14]. Our results indicate that the combination group of hyperstimulation/ tachysystole was higher in the Propess cohort while none of the Prostin cohort experienced this complication (p value=0.0024). Similarly, the same comparison done in Walsall, UK resulted in more cases of tachysystole in Propess rather than Prostin [11]. Walsall also had a higher rate of uterine hyperstimulation in both prostaglandins compared with the placebo. However, in all the cases, hyperstimulation resolved within 15 min after removal of the pessary indicating that the direct cause was from the effect of the prostaglandins.

The complications in IOL among nulliparous women is greater than that in multiparous as shown in a 2020 study done in Ireland. Many nullipara (32.63%) had undergone caesarean section compared to the multipara (4.37%). Therefore, it is in conjunction with our results that nulliparous women had a greater number of complications in comparison to other parities within our study (p value<0.001). Moreover, previous studies show that induction of labour in medically uncomplicated nulliparous women at term carries higher risk of emergency Cesarean section, compared to those who underwent spontaneous labour [13]. However, our study showed an insignificant difference between the rate of NVD versus caesarean section in the IOL with Propess and Prostin collectively (p=0.084).

A limitation of our study included the lack of a control/ placebo group which could have been used for a more effective comparison.

Conclusion

The results of our study concluded that the success of inducing labour between Prostin and Propess is not statistically significant and either can be used for a favourable outcome. Complications following their viz. non-reassuring CTG, failure of induction, re-induction of labor, higher risk of emergency Cesarean section and are quite similar with both agents. However, tachysystole/ hyperstimulation was more with Propess. These complications, however, are greater seen in nulliparous women compared to multiparous.

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