Original Article

Comparative Study of Glandin Tablet versus Glandin Gel for Successful Labour Induction

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Abstract

Objectives: To compare the therapeutic effectiveness of glandin (Dinoprostone) Tablet and Gel for successful labor induction and delivery in term alive pregnancy.

Methodology: A randomized controlled trial study was conducted at department of Obstet. and Gynae Al-Aleem Medical College attached with Gulab Devi Educational Complex Lahore, after approval from Institutional Review Board over a period of nine months from December 2020 to August 2021. Non-probability purposive sampling technique was used. A total of 100 women satisfying the inclusion and exclusion criteria were enrolled in the study, they were divided into two groups A & B 50 women in each. Women in group A were induced with Glandin Tablet and women in group B received Glandin Gel.

Results: The mean age of the women in group A was 27.79 ±1.5 years and 26. 35 ±.34 years in group B, major chunk of the in both groups were prim gravidas. In group A, gestational age > than 40 weeks was observed in 80%, and 84% in group B. Bishop's score was more than 6 in 38% and 54% in group A & B, respectively, the commonest indications for induction in both groups were postdates pregnancy. In group B both shorter duration from induction to active labor and induction to delivery intervals were observed compared to group A, it showed statistically significant P-Value (0.011, 0.031), highlighting that Glandin gel had a quicker effect as compared to Glandin tablet as inducing agent. Women in Group B had SVD 70%, instrumental delivery 4% and caesarean section 26% as compared to group A 52% , 6% and 42% respectively, statistically significant P-Value was observed (0.053) regarding mode of delivery.

Conclusions: There was a great difference in women delivered within 24 hours induced with Glandin (Dinoprostone) gel than Glandin tablet due to shorter induction to labor, delivery intervals and the mode of delivery concluding Glandin gel is superior to Glandin tablet.

Key Words: Term alive pregnancy, Glandin (Dinoprostone) Gel, Glandin Tablet, Effectiveness.

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Introduction

The induction of labor is said to be the intentional starting of cervical ripening and painful uterine contraction for delivering fetus earlier rather than waiting for spontaneous onset of labor. It is a commonly performed obstetrical procedure worldwide, especially in underdeveloped countries like Pakistan.[1] It is indicated in those women, when waiting for spontaneous labor onset can endanger the health of either mother or fetus. Roughly twenty percent of all pregnant women experienced induction of labor, the commonest indication was a post-dates pregnancy.[2] When labor is induced by pharmacological methods, approximately two-thirds of women delivered normal vaginally, nearly 15% required instrumental delivery and roughly 22% ended emergency caesarean section.[3] According to recommendations of National Institute for Health and Clinical Excellence (NICE, 2021) Guidelines, endorsed with RCOG, (2021) responds on Induced labor that vaginal dinoprostone is the preferable method for labor induction it would help in easy onset of labor and fruitful

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vaginal delivery within 24 hours.[4,5] Different preparations of Dinoprostone are available in the market, it can be used oral, intravenous, extra amniotic, Vaginal or intracervical. Vaginal Dinoprostone (Prostaglandin) are available in tablet, gel, suppository and pessary forms but RCOG guidelines, (2021) concluded that tablet and gel formulations are superior from pessary or suppository.[6] Failed induction is defined as failure to achieve birth within 24 hours after induction, or according to Rayburn it is defined" Failure to establish labor after one cycle of treatment & reported up to 15%" and its incidence is reported by different researches to 15%.[7,8] The new formulation of Dinoprostone, 'GLANDIN E2' vaginal gel 2mg and 'GANDIN E2' vaginal tablets 3mg are used for labor Induction. The rationale of the present study was to compare the therapeutic effectiveness of Glandin E2 tablet and Glandin E2 gel for successful labor induction and delivery in term pregnancy, it would also help to generate new data for the Pakistani population.

Methodology

A randomized controlled trial study was conducted at department of Obstet. and Gynae Al-Aleem Medical College attached with Gulab Devi Educational Complex Lahore, after approval from the Institutional Review Board over a period of nine months from December 2020 to August 2021. Non probability purposive sampling technique was used. A total of 100 women fulfilling the inclusion and exclusion criteria were enrolled in the study. Inclusion criteria were willing pregnant women, singleton alive pregnancy, cephalic presentation, gestational age of > 37 weeks, intact membranes. Exclusion criteria were unwilling pregnant women, multiple pregnancy, mal-presentation, scared uterus, dead fetus and those conditions where vaginal delivery is contraindicated. One hundred recruited women were divided into two groups (A & B) of 50 in each by using lottery method. Single blind technique was used. Group A was given Glandin E2 tablet placed in the posterior fornix of vagina and Group B received Glandin gel placed in posterior fornix of vagina, second dose could be repeated after 6 hours if labor is not established in either group. Partogram was maintained after onset of active labor and fetal monitoring was carried out by intermittent auscultation. Maternal vital signs were monitored every 4 hours. The main outcomes which were measured in the study were from the onset of induction to active phase of labor, from the start of induction till patient delivered and the mode of delivery. Induction of labor was labelled as failed if women did not go into active phase of labor after second dose of Glandin tablet / Gel or not delivered within 24 hours after induction. Data was collected after verbal informed consent from all women recruited in the study including demographic characteristics. All the data was entered, rechecked and then analyzed using SPSS version 20. Mean ±SD was calculated for age of women (in years), Descriptive Statistics was used to check frequency, percentages all quantitative variables. Chi-square test was applies for association between two variables to get P-Value, the P-Value < than 0.05 is considered to be statistically significant.

Results

The table I highlight the demographic data of the study population. The mean age of the women in group A was 27.79 ±1.5 years and 26. 35 ±1.34 years in group B, major chunk of the women in both groups were primigravida. In group A gestational age > than 40 weeks was observed 80%, and 84% in group B.

Table I Demographic Data of Study Population (n=100)

Variables	Group A (n=50)		Group B (n=50)		p-value
	No of Cases	%	No of cases	%	
Age (Years)					
15 – 25	20	40.0	19	38.0	0.201
26 – 35	23	46.0	26	52.0	0.251
>35	7	14.0	5	10.0	0.098
Parity					
Primigravida	32	64.0	35	70.0	0.064
< than 3	13	26.0	7	14.0	0.051
> 3	5	10.0	8	16.0	0.073
Duration of Pregnancy					
< than 40 Weeks	10	20.0	8	16.0	0.277
>than 40 Weeks	40	80.0	42	84.0	0.355
Bishop Score					
< than 6	31	62.0	23	46.0	0.073
> 6	19	38.0	27	54.0	0.042
Syntocinon Augmentation					
	28	56	13	26.0	0.063
Indications of Induction					
Post- date pregnancy	31	62.0	32	64.0	0.065
Pregnancy Induced HT	10	20.0	9	18.0	0.051
Pregnancy with Diabetes	6	12.0	5	10.0	0.091
Leaking P/V	3	6.0	4	8.0	0.032

Bishop's score was more than 6 in 38% and 54% in group A & B, respectively, the commonest indications for induction in both groups postdates pregnancies. The main outcome measures were shown in table ll as induction to labor interval, and induction to delivery interval. In group B shorter induction to labor and

induction to delivery intervals were observed as compared to group A, it showed statistically significant P-Value (0.011, 0.031), highlighting that glandin gel had quicker effect as compared to Gliadin tablet as inducing agent including mode of delivery in study population. Women in Group B had SVD 70%, instrumental delivery 4% and caesarean section 26% as compared to group A 52%, 6% and 42% respectively. Statistically significant P-Value was observed (0.053) proving that Glandin gel is more effective in successful labor induction and delivery, the main indication for caesarean section was fetal distress and failure to progress of labor.

Table II: Mean Time Taken for Onset of Labor/Mode of Delivery (n=100)

Variables	Study Population	Mean ±SD	P – Value
Doses of Drug Used (Maximum 2 dose 6 hours after first one)	Group A	1.65 ±0.64	**0.569**
	Group B	1.35 ± 0.47	
Induction Labor Interval (hours)	Group A	11.2±6.38	**0.011**
	Group B	6.43 ±4.32	
Induction Delivery Interval (hours)	Group A	15.1 ±7.15	**0.031**
	Group B	10.1 ±5.91	
Mode of Delivery			
SVD	26 (52%)	35 (70%)	**0.053**
Instrumental	03 (6%)	02 (4%)	
C –Section	21 (42%)	13 (26%)	
	50 (100%)	**50 (100%)**	

Discussion

The induction of labor is still a challenge for Obstetricians, about 20% of all pregnancies require induction for different indications, and its incidence had increased in last decade.[9, 10] The mean age of the study population was 27.79 years which was tallying with other studies.[11, 12] In our study, the majority of women in both groups A (64%), group B (70%) were Primigravida, these findings are consistent with work of other researchers [13, 14.] According to NICE guidelines 2021 induction should be planned from 41 weeks. In this study post-date pregnancy was the commonest indication in both groups (Group A, 80%), (Group B, 84%) which was comparable with the results of other studies.[13, 14,] In this study Glandin gel was found to be more effective as

compared to Glandin tablet for ripening of the cervix and improving the bishops score, confirmed by a statistically significant P-Value (0.011) regarding shortening of interval between onset of induction and starting active phase of labor, Pay et al & Lokeshwari et al also proved in their studies that Prostaglandin (Dinoprostone) E2 gel could be used as a good tool for induction of labor as cervical ripening agent.[15,16, 17] The study had proved that Glandin (Dinoprostone) Gel is superior than Tablet due to shorter duration of interval in both from the onset of induction till women went to active phase of labor and from induction till women delivered either normal, instrumental or caesarean section these findings were tallying with other studies.[18, 19] But studies conducted by KHO Ee Min, and Khan ZA proved in their studies that there is no difference in outcome between prostaglandin gel and tablet/pessary.[19, 20] In our study it had been observed that women who received tablet for labor induction 56% required Syntocinon for augmentation as compared to gel where only 26% required Syntocinon these findings are mimicking with other studies.[13, 14, 16] In this study women in which induction was done with Glandin gel had more fruitful outcome in all aspects 70% delivered normal vaginally, 4% required instrument to deliver by vaginal route and only 24% ended up to caesarean section. Whereas those who were induced with Glandin tablet 52% delivered normal vaginally, 6% required instruments and 42% had cesarean section, concluding that Glandin gel is superior to tablet for the induction of labor, and mode of delivery (vaginally) these findings were consistent with other studies.[18, 19]

Conclusion

There was a great difference in women delivered within 24 hours induced with Glandin (Dinoprostone) gel than Glandin tablet due to shorter induction to labor, delivery intervals and the mode of delivery concluding that Glandin gel was more effective and superior than Glandin tablet for elective induction of labor.

Study Limitations: As this study was carried out in one tertiary care hospital the results of the study could not be generalized. More studies both longitudinal and Cross Sectional are required to get better results.

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