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Comparative Study on Effect of Hygroscopic Dilators Versus Foleys Balloon Catheter Insertion on Outcome of Preinduction of Labour: Prospective Study

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Abstract

Introduction: A procedure to artificially start uterine contractions that eventually cause cervix to elongate and efface is known as inducing labor. The infant should therefore preferably be delivered vaginally.

Before initiating induction, it is important to confirm gestational age and fetal lung maturity.

Labor induction is one of the interventions that is most frequently utilized today. Up to 20% of women worldwide have labor that is induced using one of two methods. "The advancement in oxytocics and induction techniques has made the process of induction easier, safer, more efficient, and predictable compared to the older methods"2.

Aim:

To calculate the impact of hygroscopically dilators on uterine cervix ripening.

To research the progression and results of labor during hygroscopically induced labor.

To calculate the impact of the Foley catheter on uterine cervix ripening.

To examine the progression and results of labor when it is induced using a Foley catheter.

In the context of labor induction, the goal is to assess how hygroscopic dilators and the Foley catheter affect cervical dilation, the length of induction, maternal outcomes, and fetal outcomes.

Methodology:

The prospective study was carried out at Chennai's Government RSRM Lying In Hospital between December 2018 and September 2019. For 120 patients who were term pregnant moms eligible for induction, Bishop scores were determined. If the bischop score was less than 6, they were randomly assigned to the hygroscopic dilator group and the foleys group. Between these 2 group, analyses and comparisons of patient characteristics and outcomes were made. The mode of delivery was the study's main endpoint. "Measured and analyzed secondary outcomes included post-insertion bishop score, insertion delivery interval, induction delivery interval, apgar at 1 and 5 minutes, and need for PGE2 gel"3.

Results:

Compared to 71.7% in control group, 73.3% in study group experienced natural labor (p value = 0.838). 20% of the study group underwent emergency LSCS, compared to 26% of the control group (p value = 0.387). Consequently, the major result between these groups does not differ statistically from the other groups.

In comparison to 60.5% of instances in the control group, the insertion delivery interval was between 12 and 24 hours in 77.1% of patients with primi (p value = 0.025).

"For Multigravida insertion delivery interval is 12 to 24 hours in study group in 80% of instances, 12 to 24 hours in study group in 40.9% of cases, and more than 24 hours in 40.9% of cases"4. The gap between induction delivery was insignificant (p value = 0.671). In 10% of instances in the research group and 31.7% of cases in the control group, no PGE 2 gel was applied. In the study group, one gel was utilized in 76.7% of instances, two gels in 11.7%, and three gels in 1.7% of cases.

One gel was used in 36% of cases and two gels in 5% of instances in the control group. The difference between the study group's and control group's use of PGE 2 gel is statistically significant. "The study group and control group do not show a statistically significant difference (p value = 0.120) in the 1- and 5-minute Apgar scores"6. However, there is a significant statistical difference (p value = 0.033) between the post-insertion Bishop scores of study group and control group, with the former having higher scores.

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Conclusion:
Dilapan S has preinduction results that are safe and comparable to those of a foleys balloon catheter when used at term.

1. Inclusion criteria

(1) When a singleton pregnancy is present, there are no medical conditions that would prevent a vaginal delivery.

(2) Monitoring the fetal heart rate.

(3) Fetal or maternal symptoms that indicate a need to induce labor

Exclusion criteria

1) less than 37 weeks along in the pregnancy
2) Placenta premature
3) Possibly chorioamniotic
4) Parity > 3
5) A history of uterine operations or a previous caesarean delivery
6) Pregnancy's previous attempts at induction of labor
7) cephalopelvic imbalance.

"The study compared and examined differences between groups in terms of age, parity, Bishop score before and after induction, need for a second induction, insertion-to-delivery interval, induction-to-delivery interval, and final mode of delivery"[7]. The newborns' birth weight, rates and indications of Caesarean section and APGAR score were registered and tallied. P value less than 0.05 was considered significant following statistical analysis.

2. Study protocol

Study Observation and Results

Based on inclusion criteria, 120 cases were accepted for the study during the study period, and each of the two groups of 60 cases was randomly assigned to them. 65% of patients in the hygroscopic category are between the ages of 21 and 25. The study group's average age was 23.49 years.

Age group

AGE IN YEARS			
		No of patients	Percent
Age	18-20	7	11.7
	21-25	39	65.0
	26-30	11	18.3
	31-35	3	5.0
	Total	60	100.0

Table 1

Obstetric code

There were 42% multigravida patients and 58% primigravida patients in the hygroscopic group.

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Obstetric code		
	Frequency	Percent
Primi	35	58.3
Multi	25	41.7
Total	60	100.0

Table 2

Gestational age in weeks

The distribution of gestational age is seen in the table below. Inductions were performed on about 65% of the research group's patients between 40 weeks and 40 weeks and 6 days. Induction at 40 weeks and 3 days was conducted if NST and AFI monitoring were normal procedures.

Age of pregnancy in weeks		
	Frequency	Percent
37 weeks	3	5.0
38weeks	9	15.0
39 weeks	9	15.0
40 weeks	39	65.0
Total	60	100.0

Table 3

Signal for Induction

The most frequent justification for induction (51.7%) was postdatism. gestational hypertension and Oligohydramnios (15%) affecting pregnancy (10%) were the other two symptoms.

Indication for Induction		
	Frequency	Percent
Post Dated	31	51.7

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GDM	5	8.3
GHTN	6	10.0
IUGR	1	1.7
Oligohydramnios	9	15.0
Overt DM	2	3.3
GDM/GHTN	2	3.3
RH Negative	3	5.0
Chronic HTN	1	1.7
Total	60	100.0

Table 4

Bishop modified Score before insertion

The distribution of the research group's Bishop's Score is shown in the table below. “Before the placement of the hygroscopic dilator, 29 patients had a Modified Bishop's Score of 2. Modified Bishop's Score 2 was the average”.[1]

Pre Insertion Score			
		Frequency	Percent
Score	1	8	13.3
	2	29	48.3
	3	15	25.0
	4	7	11.7
	5	1	1.7
	Total	60	100.0

Table 5

Score after insertion

Bishop's Score, Results are displayed in the table below twelve hours after the hygroscopic dilator was inserted. 36 patients (60%), who had received Dilapan S for 12 hours, had a bishop score of 5.

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Bishops score- Post Insertion (After 12 hours)			
		Frequency	Percent
Score	3	3	5
	4	12	20
	5	36	60
	6	9	15
	Total	60	100.0

Table -6

Score improvement

After insertion, score increased by three points as a result of increased cervical dilatation, effacement, and a reduction in cervix length.

QUANTITY OF RODS USED

This table shows the number of dilapan S rods needed for cervical ripening. 29 people received one rod, compared to 24 patients who had two rods. Just 7 patients got 3 rods.

NUMBER OF RODS USED			
		No of cases	Valid Percent
Valid	1	29	48.3
	2	24	40
	3	7	11.7
	Total	60	100

Table-7

Delivery method

60 patients made up the study group, 44 (73%) of whom delivered vaginally as usual, and 12 (20%) of whom underwent LSCS. A vacuum with an episiotomy was used to deliver 3 patients (5% of patients), as opposed to 1 patient (1.7% of patients) who employed outlet forceps.

Indication of LSCS		
Mode of Delivery – hygroscopic group		
	Frequency	Percent
Labour Natural	44	73.3
Emergency LSCS	12	20.0
Outlet Forceps	1	1.7
Vaccum	3	5.0
Total	60	100.0

Table 8

Indication of LSCS

In the study group, LSCS delivered 20% of the instances. Two (3.3%) cases of failed induction and five (8.3%) occurrences of fetal distress were treated.

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Three (5%) cases were completed for failure to advance

	Frequency	Percent
NA	48	80.0
CPD In labour	2	3.3
Failed Induction	2	3.3
MSAF/Fetal Distress	5	8.3
Failure to Progress	3	5.0
Total	60	100.0

Table 9

Apgar score - Neonatal outcome

In this study, 76.7% of newborns had an apgar score of 7 at one minute after delivery. At 5 minutes, 81.7% of newborns had an apgar score of 8. The respiratory distress, prenatal depression, and delivery asphyxia were three main reasons why the five newborns had lower apgar scores. They recovered following their admission to the NICU.

Apgar at 1 Minute			
		No of cases	Percent
Score	3	2	3.3
	5	3	5.0
	6	6	10.0
	7	46	76.7
	8	3	5.0
	Total	60	100.0

Table 10

Apgar at 5 Minute			
		No of cases	Percent
Score	6	1	1.7
	7	7	11.7
	8	49	81.7
	9	3	5.0
	Total	60	100.0

Table 11

Insertion Delivery Interval

In our trial group, it took patients an average of 19 hours from the time that Dilapan S was inserted until they gave birth. The following table displays the study group's insertion delivery interval.

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Insertion Delivery Interval			
		Frequency	Percent
Hours	< 12	4	6.7
	12-24	47	78.3
	> 24	9	15.0
	Total	60	100.0

Table 12

Induction Delivery Interval

The induction delivery window for the trial group is six to twelve hours. Six out of the 60 cases in our study group (approximately 10%) required oxytocin augmentation instead of PGE2 gel induction after the removal of Dilapan S

Induction Delivery Interval			
		Frequency	Percent
Hours	< 6	21	35.0
	6-12	27	45.0
	> 12	6	10.0
	Total	54	90.0
Not Induced	System	6	10.0
Total		60	100.0

Table 13

Requirement of PGE2 GEL

The study group, which comprised of 60 people, received 60 doses of PGE 2 gel, as shown in the table. Out of the total participants, 46 received a single dose, while 7 received two doses. In one patient, due to the inability to progress, three doses of PGE2 gel were administered, ultimately resulting in a cesarean section. Out of the seven patients who received two doses during labor, two delivered vaginally, while four required cesarean section due to failed induction, lack of progress, and cephalopelvic disproportion.

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PGE2 GEL DOSE			
		No of cases	Percent
Unit	1	46	76.7
	2	7	11.7
	3	1	1.7
	Total	54	90.0
No Gel	0	6	10.0
Total		60	100.0

Table 14

Gestational age

The majority of instances (65%) in the study group were 40 weeks gestational age, compared to 46.7% in the control group and 35% of patients in that group who were 38 weeks gestational age. Patient demographics were provided in the table below.

Final analytic data

Primary outcome –Hgroscopic dilator vs foleys group

Outcome	Foley's (n = 60)	Hygroscopic (n = 60)
Mode of delivery		
Labour Natural	43(71.7)	44(73.3)
Emergency LSCS	16(26.7)	12(20.0)
Outlet Forceps	1(1.7)	1(1.7)
Vacuum	0(0)	3(5.0)
Indication for LSCS		
CPD in labour	3	2
Failed induction	4	2
MSAF/fetal distress	3	5
Failure to progress	4	3
Failure to alarm signal	2	-

Table 15

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3. Discussion

Cervical ripening procedures frequently employ mechanical dilators. These dilators are the best preinduction agents of choice due to their safety profile and affordability. The gold standard preinduction technique for decades has been the Foley balloon catheter. Due to its advantages over expectant management, induction of labor has increased since the release of Grobman et al.'s ARRIVE experiment.

When compared to intravaginal prostaglandins, mechanical methods for inducing labor did not result in an increase in the overall number of women who did not give birth within 24 hours, according to a 2012 Cochrane review (three trials; 586 women; RR 1.72; 95% CI 0.90 to 3.27). No distinction in Significant maternal and newborn morbidity was seen between the groups.

Although Dilapan-S is a well-known cervical ripening agent during the initial phases of pregnancy, there is a scarcity of clinical data available in the literature regarding its usage.

"Saad et al reported noninferiority of dilapan compared to Foley's balloon for pre-induction of labor, despite the randomized controlled DILAFOL study not finding any statistically significant differences between the two methods"[17]. "Although there was no statistically significant difference in the mode of delivery or the requirement for LSCS between the use of dilapan and Foley's catheter for pre-induction in our study, we observed significant differences in secondary outcome measures such as the bishop score post-insertion and the insertion delivery interval"[18]. Furthermore, the use of Dilapan for pre-induction is associated with greater patient satisfaction and adherence compared to using Foley's catheter.

"In a recent study, Gupta et al. reported that the overall vaginal delivery rate was 77% with dilator use up to 12 hours, statistically significantly decreasing to 65% after 12 hours"[21]. Within a 24-hour period, the vaginal delivery rate was 46%, and within a 48-hour period, it rose to 76%.

Due to the fact that there were no cases of hyperstimulation in our study, dilapan and foleys preinduction also have a low rate of hyper stimulation.

With regard to rates of unsuccessful labor induction and cesarean delivery, many studies have found that Foley balloon catheters are comparable to pharmaceutical approaches. "Due to their affordability and reduced incidence of uterine hyperstimulation, they are an excellent resource for both developed and developing countries. Their safety profile also makes them an attractive option for cervical ripening even in outpatient settings". A subsequent essay will explain this obstetric approach.

"By using hygroscopic balloon catheters, R. Shindo et al. showed that the rate of vaginal delivery was comparable to that with Foley balloon catheters". Additionally, their study found a lower incidence of vaginal instrumental deliveries, intrapartum hemorrhages, and postpartum hemorrhages compared to other methods when hygroscopic dilators were used.

4. Conclusion

The following table contrasts the results of different pre-induction techniques

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Study	Rate of vaginal delivery	Rate of LSCS	Change in bishop score
Gupata et al (Dilapan)	69.8%	30.1%	3.6
Crosby et al (Dilapan vs dinoprostone)	74%	26.9%	3.3
Saad et al (Dilapan vs foleys)	81.3%	18.8%	3
Present study (Dilapan vs foleys)	73.3%	20%	3

Table 16

Dilapan S is a preinduction procedure that is safe and effective at term, with results that are comparable to those of a foleys balloon catheter during labor induction. Both Foley's catheter and Dilapan S have good safety profiles. The patient satisfaction rating at Dilapan S is higher

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