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Intra Cervical Foley's Versus Combination Of Intra Cervical Foley's And Extra Amniotic Saline Infusion As Cervical Ripening Agent For Induction Of Labor

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Abstract

Objective: To compare IntraCervical Foleys (ICF) and intracervical Foleys along with Extra Amniotic Saline Infusion (EASI) as a cervical ripening agent for Induction Of Labour(IOL).

Methods: It was carried out at the Department of Obstetrics and Gynecology Holy Family Hospital, Rawalpindi. In this comparative study, we included 100 patients with singleton cephalic presentation, intact membranes and a BISHOP score ≤ 6. These were further subdivided into two groups, Group A (ICF) and Group B (ICF with EASI),50 in each group.

In Group A, Foley's catheter was placed cervically while in Group B extraamniotic saline infusion was also administered in the urine drainage port at midnight. PGE2/ Augmentation with syntocinon was considered according to the bishop score at 6 am. Improvement in BISHOP score, induction to delivery interval, and feto-maternal outcomes were noted in both groups.

Results: Data analysis showed that the mean improvement in the BISHOP score of the patients in Group A was 3.78 ± 1.75 while that of Group B was 3.56 ± 1.79(pvalue = 0.508). The induction to delivery interval in group A patients was 14.6 ± 4.75 hours while that of group B was 13.22 ± 4.54 hours (p =0.103). Only 14/100 patients had failed IOL and underwent C- C-sections and 8/100 neonates had NICU admissions and were discharged later on.

Conclusion: Both Intra Cervical Foley's and a Combination Of Intra Cervical Foley's And Extra Amniotic Saline Infusion are equally effective as cervical ripening agents for induction Of labour with high chances of successful vaginal delivery and good feto-maternal outcome**.**

Keywords: Induction of labour, Intracervical folleys, Extra-amniotic saline infusion, BISHOP score.

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1. Introduction

Induction of labour can be defined as the artificial initiation of uterine contractions before its natural onset, to deliver the feto- placental unit. It is indicated in conditions with obstetric or medical problems, where the benefit of expeditious delivery outweighs the risk of continuing pregnancy.[1] The common indications are post-date pregnancy, gestational hypertension, preeclampsia, maternal diabetes mellitus, fetal compromise and for logistic reasons. The method of induction must be both safe and effective. [2] Before induction of labour, it is mandatory to examine the favorability or ripeness of the cervix to determine the likelihood of successful induction of labour. BISHOP scoring system is used to determine the cervical status to assess the favorability of IOL. It includes dilatation, effacement, consistency, cervix position, and fetal head station. The BISHOP score ≤4 shows that the cervix is not favourable enough for artificial induction of labour and requires inducing agents that help in softening/ripening of the cervix.[3-6] While, a BISHOP score ≥ 6 is believed to be a favourable one, with a better likelihood of successful induction of labour.[7]

Hippocrates' original descriptions of breast stimulation and mechanical dilatation of the cervical canal are the origins of labour induction. Mechanical methods including amniotomy, membrane sweeping, and intra-cervical devices (hygroscopic dilators, laminaria tents, intra-cervical foleys, and intra-cervical foleys with Extra Amniotic Saline Infusion EASI) were the first methods utilized for cervical ripening in the unfavourable cervix. Mechanical methods are widely available, simple to use, and inexpensive.

The procedure involves compressing and stretching the cervix to gain access to the fetal membranes, which results in the release of local prostaglandins.[8] Pharmacological methods like Dinoprostone (prostaglandin E2), misoprostol (prostaglandin E1 analogue), and intravenous oxytocin are used for

ripening of the cervix as well as inducing the contractions of uterine smooth muscles.

In recent decades, there has been a surge in the use of pharmacological treatments to induce labour,

Which have mostly replaced mechanical approaches.[5,6,8] However, pharmaceutical approaches can have unfavourable side effects such as uterine hyperstimulation and fetal distress.[9]

In contrast, the intra-cervical Foley catheter is found to be more effective than prostaglandins for pre-induction cervical softening.[10,11] Without producing uterine contractions and associated with a high vaginal delivery rate.[12] The use of a cervical Foley catheter has been advocated as a safe, low-cost, mechanical method of cervical ripening.[13,14] The main argument against the use of Foley catheters has been a theoretical risk of the introduction of infection, which can be reduced with aseptic precautions. Another meta-analysis of randomized studies comparing mechanical against pharmacological approaches reported a decreased risk of uterine hyperstimulation and fetal heart rate abnormalities.[3,5] There are studies reported in the literature which used Extra Amniotic Saline Infusion (EASI) to complement the intra-cervical Foleys for pre-induction cervical softening. Schreyer et al. were the first to use EASI with a single balloon catheter for labour induction, and they demonstrated that it is safe, quick, and effective .[14,15,16] Single and double-balloon catheters, which can be used with or without extra amniotic saline infusion (EASI), are common members of the "mechanical ripeners" family.[17,4,11] A retrospective investigation found that the use of a balloon catheter in conjunction with EASI has some hazards, including fever, bleeding, and pain. As a result, there is some disagreement in the literature about the efficacy and safety profile of adding EASI to the balloon catheter.

The goal of this study is to evaluate the advantages and risks of combining EASI with a balloon catheter for cervical ripening. The comparison of both of these methods will help obstetricians choose a more appropriate mechanical method for the induction of labour in an unfavourable cervix. This can aid in preventing the delay in induction to delivery time and improving maternal and neonatal outcomes. This study was designed to compare intra-cervical Foleys versus a combination of intra-cervical Foleys and Extra Amniotic Saline Infusion as cervical ripening agents for induction of labour.

An increase in 16 % of pathogenic organisms in the cervix after the insertion of a Foley catheter for induction of labour even after adjusting for potential risk factors. The risk was significantly higher for infection with B-hemolytic Streptococcus group-E and Candida albicans/glabrata. Studies comparing the Foley catheter with other methods for the induction of labour have focused on its economics and effectiveness for cervical ripening, but have not addressed its potential of increasing chances for infection. [44-49]

2. Materials & Methods

This was a comparative interventional study carried out over 6 months (September 2021 to February 2022). A total of 100 Patients, who are eligible for induction of labour (IOL) presenting in Holy Family Hospital, Rawalpindi, Pakistan were included in the study via non-probability convenient sampling. The candidates for IOL were those with singleton alive fetuses and cephalic presentation and having Intact membranes and reassuring CTG. These patients had BISHOP scores of less than or equal to 6.

Those patients with known contraindications to labour induction, spontaneous labour, malpresentation, multiple gestation, previous cesarean delivery, antepartum haemorrhage, fetal heart rate abnormalities and absent membranes were excluded from the study.

After obtaining informed consent, a comprehensive history was taken with special emphasis on age, parity, gestational age, indication for IOL and past obstetric history. All these patients have general physical and vaginal examination. BISHOP's score of the patients was calculated. The patients were divided into two groups (50 patients in each group).

Group A: Intra Cervical Foley's (ICF)

Group B: IntraCervical Foley's with Extra Amniotic Saline Infusion (ICF+EASI)

In group A, All the patients had a pre-luminary vaginal examination to assess the BISHOP score at midnight followed by a speculum examination to expose the

cervix. A 24Fr Foley catheter was inserted aseptically into the cervix with the help of a sponge holder and the balloon of the catheter was inflated with 80 ml of normal saline injected in the balloon port.

The urine drainage port was attached with a urine bag filled with 1000ml of normal saline for mechanical traction. The patient was reassessed vaginally after six hours i.e., at 6 am and any change in BISHOP score was noted. If the foleys were expelled then amniotomy followed by augmentation of labour with oxytocin infusion was commenced according to unit protocol and labour was monitored using a WHO partogram. If foley was not expelled then prostaglandin E2 pessary was placed and repeated after 6 hours according to the BISHOP score.

Primary maternal outcomes were mean improvement in BISHOP score, induction to delivery interval and mode of delivery (SVD/Cesarean section). Primary neonatal outcome was Apgar score at birth, at 5 minutes and NICU admissions. The secondary maternal outcome was PPH and indications of C-sections.

In group B, All the patients had a preliminary vaginal examination to assess the BISHOP score at midnight followed by a speculum examination to expose the cervix. A 24Fr Foleys catheter was inserted aseptically into the cervix with the help of a sponge holder and the balloon of the catheter was inflated with 80 ml normal saline through a balloon port.

Thereafter, the Foley's was attached through the urine drainage port with continuous 0.9% Normal Saline infusion at the rate of 10drops/min for 6 hours

The patient was reassessed vaginally after six hours i.e., at 6 am and any change in BISHOP score was then noted. If the foleys was expelled then amniotomy followed by augmentation of labor with oxytocin infusion was commenced. According to unit protocol labour was monitored using a WHO partogram and broad-spectrum IV antibiotics given in both groups. If foley was not expelled then infusion was discontinued and prostaglandin E2 pessary was placed. The rest of the labour was monitored. The first PgE2 pessary was placed at 6 am and the second was placed after 6 hours according to BISHOP score and labor was monitored till delivery.

Primary maternal outcomes were mean improvement in BISHOP score, induction to delivery interval and mode of delivery (SVD/Cesarean section). Primary neonatal outcome was Apgar score at birth, at 5 minutes and NICU admissions. Secondary maternal outcomes were PPH and indications of Cesarean.

The collected data was entered and analyzed using SPSS version 25.0 (Statistical Package of the Social Sciences).

Quantitative variables were represented in Mean ± S.D. Graphs or tables were presented for both qualitative variables, wherever needed.

The chi-square test was applied to observe associations between quantitative variables.

An Independent sample test was applied to compare the means for quantitative data. A p-value of less than 0.05 was considered statistically significant.

In our study, the frequency of primi and multigravida are almost equal in number.

The major reason for IOL in both groups was post-date pregnancy 40+6 weeks according to unit protocol. and other causes include decreased fetal movement, diabetes mellitus, preeclampsia, and obstetric cholestasis.

3. Results

A total of 100 patients were included in our study. Out of these 100 patients, 50 patients were in Group A (ICF group) and 50 patients belonged to Group B (ICF and EASI). In our study, the frequency of primi and multigravida are almost equal in number. The major reason for IOL in both groups was post-date pregnancy 40+6 weeks according to unit protocol. and other causes include decreased fetal movement, diabetes mellitus, preeclampsia, and obstetric cholestasis.

Induction to delivery time was a little longer in the ICF group but the difference is not statistically significant. Regarding the mode of delivery, a total of 14 patients underwent Cesarean-section while 86 patients had spontaneous vaginal delivery (SVD). A total of 8 patients in group A and 6 patients in group B had Cesarean Section.

The sole reason for C-sections in group B was failed induction. While in group A, the major reason was Grade 2 meconium followed by failed induction.

Table 1: Shows the comparable demographic details in both the groups.

Parameter	Group A (ICF) (n=50)	Group B (ICF+EASI) (n=50)	Total Patients (n=100)	P-value
Age (mean±SD)	26.48±4.	26.10±4.49	26.29±4	0.857
Minimum	12	18	.92	
Maximum	20	38	18	
	36		38	
Weeks of gestation (Mean±SD)	39.21±1.	39.39±1.08	39.31±1	0.789
	24	37	.16	
	36	41	36	
Minimum	42		42	
Maximum				
BISHOP score at induction (Mean ±SD)	3.84±1.7	4.10±2.27	3.97±2.	0.527
	8	0	037	
	0	6	0	
Minimum	6		6	
Maximum				

Table 2: Comparison of induction to delivery time in both groups

Parameter	Group A (ICF) (n=50)	Group B (ICF+EASI) (n=50)	Total Patients (n=100)	P-value
Induction to delivery Time (Mean±SD)	14.6±4.75	13.22±4.54	13.93±4.68	0.103
Minimum	8	7	7	
Maximum	26	24	26	

Postpartum haemorrhage was the only maternal complication observed among the study participants(n=3). These include 2 patients from group A and 1 patient from group B.

A total of 8 neonates born had NICU admission. These include 5 patients from group A and 3 patients from group B.

All 8 neonates went to NICU due to acute fetal distress and were discharged after 6-12 hours of observation. This result was not statistically significant (p=0.461).

Table 3: Comparison of APGAR Score at 1 min in both groups

Parameter	Group A (ICF) (n=50)	Group B (ICF+EASI) (n=50)	Total Patients (n=100)	P-value
APGAR score at 1 min (Mean±SD)	7.98±0.31	8.08±0.39	8.03±1.36	0.070
Minimum	7	7	7	
Maximum	9	9	9	

Table 4: Comparison of APGAR Score at 5 min in both groups

Parameter	Group A (ICF) (n=50)	Group B (ICF+EASI) (n=50)	Total Patients (n=100)	P-value
APGAR score at 5 min (Mean±SD)	8.9±0.34	9.0±0.45	8.96±0.34	0.080
Minimum	7	7	7	
Maximum	9	10	10	

4. Discussion

In our study, the total maternities during 6 months were 5,319 out of which vaginal deliveries were 3,373 and the induction was done in 474 patients and the prevalence of IOL was 14%. In contrast, another study done in Pakistan shows the prevalence of induction of labour as 30% 20. In developed countries, induction of labour is carried out in over 20% of pregnancies.43 The reason for the low percentage of IOL may be that being a tertiary care hospital, the majority of the patients received were with high-risk factors and already eligible candidates for Cesarean section and the referral added fuel on the fire, which increased Cesarean section rate i.e.,37% in our hospital. Furthermore, decreased fetal movements and Diabetes Mellitus are indications of IOL, their effect on fetal distress was not the primary outcome of our study. Our primary comparison was between two methods of IOL and their effect on the improvement of the bishop score. Satisfaction of mother is a qualitative component so it was not incorporated in our study.

Obstetricians encounter a significant problem when labour has to be initiated in patients with an unfavourable cervix. Proper cervical ripening results in successful vaginal delivery in 89% of cases.[18,19]Many researches have been reported

worldwide to decide a single best method but each method has its risks and benefits. Mechanical methods of induction are widely utilized because they are easily accessible, cost-effective, reversible and need no cold chain maintenance.[16,21]

Vaginal Prostaglandin (PGE2), artificial rupture of membranes (ARM), and oxytocin infusion are also used in conjunction with mechanical methods, however, they are associated with untoward side effects. Furthermore, there is a paucity of objective data on the efficacy of PGE2 vaginal gel in terms of dose.[22-24]

In this study, we used intracervical Foley catheters alone in comparison to intracervical Foley's with extra amniotic saline infusion keeping in mind the advantage of low cost, reversibility and lack of systemic side-effects in unfavourable cervix.

Our study compared the effect of ICF and ICF plus EASI on cervical ripening and labour induction. Overall, the mean age of our study participants was 26.29 ± 4.92 years. Another study performed in Pakistan showed similar demographic details with most of the patients ranging between 20-30 years of age27.In our study, 53 patients were primigravidas. Other studies also showed similar statistics in which more than 50% of the patients eligible for IOL were primigravida. [21,27,28] Reason is that most of the multigravida went into spontaneous labour because of previous vaginal deliveries as compared to primigravidas. [28,29,30,31]

Although the mean gestational age of all the patients was 39.31 ± 1.16 weeks the major reason for IOL in our study was post-dates.i.e., 42% which is comparable to another study which showed that the majority of patients were 40 to 41 weeks.32. All the included patients in our study had a BISHOP score ≤ 6. The majority of patients in both groups had a mean BISHOP Score of 3.97 ± 2.03 at the time of induction (i.e. at 0 hours). After 6 hours, the mean BISHOP Score in both groups was 7.64 ± 2.64. Overall, the mean improvement in BISHOP Score in both groups was 3.67 ± 1.65, although the results are not statistically significant. In a randomized prospective study by Dahiya et al reported mean improvement in Bishop Score was 4.18 ± 1.81 after 12 hours of initiation of IOL among patients with ICF 33 these findings are similar to our study. In contrast, another study demonstrated that EASI resulted in a better improvement in BISHOP SCORE.34 In this review of 11 studies reported, it has been suggested that ripening efficacy by catheter balloon is similar to or better than other methods.This shows that the efficacy of mechanical methods in the induction of labour is proven to be effective. Even though some studies claim that ICF and EASI yield better improvement in BISHOP score, our study shows that both ICF and ICF + EASI equally improve the BISHOP.

Dhakal et al. also compared ICF and EASI for IOL and showed similar results in which 44 out of 50 patients in the ICF group and 42 out of 50 patients in the ICF and EASI group underwent successful labour.[28] The findings are comparable to our study where 42 /50 in group A and 44/50 in group B were delivered vaginally.

Studies have also compared EASI with Prostaglandins and reported that 37% of women in EASI group achieved a Bishop Score of ≥ 8 at 8 hours as compared to 14% who received Prostaglandins. [16,32,33]

The mean induction to the delivery interval in Group A (ICF) was 14.6 ± 4.75 hours and in Group B (ICF + EASI) it was 13.22 ± 4.54. However, this difference was not statistically significant. In another study, Daliya et al noted an induction to delivery interval in the ICF group to be 18.51 ± 8.52 hours which is higher than our study. [33] In another study, the mean induction to delivery time was 16.5 ± 7 hours in the EASI group compared with 21.4 ± 9.9 hours in the ICF group.[33]

Two systemic reviews and meta-analyses regarding induction of labour also showed that EASI is an independent predictor of shorter induction to delivery interval. [35,36] Moreover some studies also revealed that the Foleys catheter with oxytocin and EASI has an increased rate of vaginal delivery and a lower rate of tachyarrhythmias,[35,36] In contrast, another study compared the Foleys catheter to Cook's catheter showed that Cook's catheter is extremely expensive with no significant difference in induction to Delivery interval.[37,38]

None of the methods of IOL guarantee a 100% vaginal delivery, there is always some chance of failure present. In our study, 86 patients had SVD (Group A- 42, Group B- 44) and 14 patients (14%) underwent caesarean section. The p-value between the two groups was 0.56. Failure of Induction was the most common cause of LSCS. Out of these 14 patients,8 patients

belonged to Group A and 6 belonged to Group B. In a study done by Alam et al, the rate of LSCS was 21% with a p-value of 0.88 and the most common indication being Fetal distress. In another conducted by Erickson et al LSCS rate was 25% in the EASI group. Rashid R et al Conducted a study which showed that several instrumental and LSCS deliveries were less in the EASI group than in the ICF alone group.[39,40]

In our study, we observed the mothers for maternal complications. Post-partum haemorrhage was the complication that was observed in 2 mothers in the ICF group. Other studies have also shown lower rates of maternal complications. A study conducted in Pakistan showed that 1% of the patients with ICF for IOL had PPH20 while another study has shown no complications in both of the groups [33,34,40] APGAR Score is a 10-point scoring system to assess the well-being of newborns. Score at 1 minute and 5 minutes were assessed, if the score is high the likelihood of baby survival is high. In our study, the mean APGAR score at 1 minute was 8.03 ± 0.36 and at 5 minutes it was 8.96 ± 0.34 with a p-value of 0.08.

In many studies reported in the literature, all of the patients' babies were alive and healthy and none required NICU admission. [27, 28, 33, 40, 41]

In contrast, in our study, a total of 8 patients required NICU admissions. The difference might be due to the setting of a public sector hospital in a developing country where due to lack of resources, increased burden on the doctors and staff, illiteracy, poverty, along poor sanitary conditions predispose the neonates to various infections and risk factors that lead to NICU admission.[42]

Both of the mechanical methods for IOL are equally effective for the induction of labour. These methods are cost-effective and have low rates of feto-maternal complications such as PPH. NICU admissions. To conclude both of these methods can be utilized for effective and successful IOL.

5. Conclusion

Our study found that both ICF and ICF and EASI are equivalently efficient in improving BISHOP

Scores in IOL patients. Each of these techniques can help to improve the BISHOP score in unfavourable cervix Mechanical IOL methods should be used as they're more easily accessible in resource-limited areas. Furthermore, these methods have no negative side effects. Appropriate application of these methods can help reduce the need for caesarean sections and improve IOL success rates in the unfavourable cervix.

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Contributions:

H.J, H.N, H.B, L.E.K, I.K, N.B - Conception of study
H.J, H.N, H.B, L.E.K, I.K, N.B - Experimentation/Study Conduction
H.J, H.N, H.B, L.E.K, I.K, N.B - Analysis/Interpretation/Discussion
H.J, H.N, H.B, L.E.K, I.K, N.B - Manuscript Writing
H.J, H.N, H.B, L.E.K, I.K, N.B - Critical Review
H.J, H.N, H.B, L.E.K, I.K, N.B - Facilitation and Material analysis

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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