Original Article

Comparison of the Effectiveness of Hydrostatic Membrane Sweeping Versus Cervical Foley's Balloon for Pre-Induction Cervical Ripening

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Abstract

Objective: To compare the efficiency of hydrostatic membrane sweeping versus cervical Foley's ballooning alone in terms of mean bishop score and insertion delivery interval for induction of labor.

Methodology: A comparative data analysis was carried out at the Department of Obstetrics and Gynecology Unit, POF wah cantt. The duration of the study was 6 months conducted from Oct 2014 to April 2014 in which a total 500 were taken with 250 patients allocated in each group. In group A induction of labor done with cervical foleys balloon method and groupB with hydrostatic membrane sweeping. Data was collected sampling technique was nonprobability consecutive sampling technique and analyzed in terms of insertion delivery interval and improvement in mean bishop score.

Results: Regarding demographics, the mean age of patients in Cervical Foley's Balloon Method was 30 ± 1.24 years while the mean age in Hydrostatic Membrane Sweeping was 31 ± 1.31years. Moreover improvement in mean bishop score in Cervical Foley's Balloon Method was 4 ± 6.31 while improvement in mean bishop score in Hydrostatic Membrane Sweeping was 5 ± 4.95. Similarly mean Insertion delivery interval in Cervical Foley's Balloon Method was 29 ± 3.41hours and mean Insertion delivery interval in Group B Hydrostatic Membrane Sweeping, was 24 ± 2.69hours.

Conclusion: Both foley's catheter balloon method and hydrostatic membrane sweeping were cheap and safety profile is good .foley's catheter gets the edge of being not expensive, easily available, can be easily reversed and does not any need for storage. In majority of patients both improved the bishop score and vaginal delivery but hydrostatic membrane sweeping is more efficacious in improving bishop score and attaining vaginal delivery.

Keywords: Hydrostatic membrane sweeping, cervical Foley's ballooning, bishop score, insertion delivery interval, induction of labor

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Introduction

Induction of labor (IOL) is the commencement of labor via artificial methods other than natural. It is the most common procedure done in obstetrics.[1] The rate has risen markedly in the recent past. It is performed for postdate pregnancies, patients with pre-eclampsia, pregnancy with diabetes mellitus, IUGR, PPROM .[2,3]

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Being the most common procedure, the method used should be cost-effective with a low side effect profile. for an unripe cervix the amount of uterine pressure required is more than that of the ripe cervix. With unripe cervix, induction of labor unlikely leads to Successful vaginal delivery and is linked by the failure of induction, protracted labor, fetal distress and increase cesarean section. The assessment of cervical ripening is accomplished using bishop scoring. Cervical ripening agents are indicated when bishop score is less than 6. [3]

Various methods have been used for cervical ripening like mechanical methods i.e. hygroscopic dilators, laminaria tents, cervical foley catheters, or specifically designed balloon catheters. Among pharmacological methods prostaglandins E1 and E2, mifepristone, and oxytocin are the most commonly used modalities. [4]

For pre-induction, intracervical Foley's catheter balloon is safe, more successful, can be easily reversed and acceptable to the patient and have lesser side effects.[5,6] For both methods mechanism of action is by releasing prostaglandins and thus improving cervical bishop but hydrostatic membrane sweeping results in better improvement in bishop score, shorter insertion delivery interval and a lower rate of primary cesarean section [6,7]

Previously a few studies had been done comparing the effectiveness of hydrostatic membrane sweeping verses cervical balloon for pre-induction cervical ripening. One study showed no difference between these two agents.[8] While another study did locally show a significant difference in the effectiveness in terms of mean bishop score and insertion delivery interval[7]. Mean B.S was 7.08±1.97 in cervical foley`s balloon alone group (group A) and 8.08±2.266 in hydrostatic membrane sweeping group (group B). ($p<0.06$), Insertion Delivery Interval was 22.30±4.03 hours in Group A and 20.53±3.71 hours in group B,($p<0.05$). [7] However it included the primigravidae as well as multigravidae from beyond 37weeks.[7] This study will be including only the primigravidae with an engaged head at 40 to 41 weeks.

The rationale of our study is that since both methods are practiced locally, this study may recommend the more effective one i.e. hydrostatic membrane sweeping for pre-induction cervical ripening in primigravidae at term to prevent postdates.

Methodology

Comparative research was steered at POF hospital wah Cantt obstetrics and gynecology dept. The sample size was calculated with WHO calculator,by taking the level of significance =5%, power of test=80%, pooled standard deviation 3.87, test value of population means=22.37, anticipated population mean=20.53. Making each group of 250 patients in each group. It was randomized control trial. all Primi_Gravida with Singleton live pregnancy, Bishop Score <6, Aged 20-35, gestational age between 40 to 41 weeks and an engaged Vertex presentation were included in the study.

Patients with Cephalopelvic disproportion, APH (placenta previa &abruption), Ruptured membranes (leak seen on p/s examination) and evidence of infection (pyrexia, raised TLC), Scarred uterus and evidence of strong uterine contractions >3per 10 minute were excluded from study.

After taking consent from the ethical committee of the hospital, all patients involved in research methodically assessed with history, examination, assessment of bishop score and ultrasound with CTG. Once the patient fulfills the inclusion criteria, she was randomly assigned through lottery method, to either Group A, using cervical Foley's catheter ballooning method for cervical ripening or to Group B, using hydrostatic membrane sweeping. IOL was done in the standard way by first-year postgraduate trainee under strict asepsis under direct vision using Cusco`s speculum. For Group A, 16 Fr Foley`s was placed in the cervix and advanced up to 5cm till it is in the uterine cavity then about 30 cc distill water was injected to inflate the balloon. The catheter was pulled down gently so that it lies in the endocervical canal and strapped to

the inside of the patient's thigh with tape to put it under strain.

For Group B, the technique of HMS, Foley`s Catheter was passed and strapped to the inside of the thigh by the same technique as for Foley`s catheter ballooning method. Then 40 ml sterile water was injected slowly extra-amniotically through the urine draining channel of a catheter and this channel was clamped. Foetal monitoring was carried out hourly in all the patients.

Within 18 hours of intervention in form either foley's catheter balloon or in the form of hydrostatic membranesweaping, Amniorrhexis completed in both sets at this time and intravenous drip containing 5 IU of oxytocin in 500ml Ringlet started I/V for IOL. The main outcomes included was the mean Bishop Score and Insertion delivery interval.

Data was entered and analysed in SPSS Version 10.0. Mean ± standard deviation were calculated for quantitative variables (age, G.A, Insertion delivery interval & mean bishop score). The student`s t-test was used to test the statistical significance between mean bishop score & insertion delivery interval between the two groups. p<0.05 was taken as the level of significance

Results

Age distribution amid two groups was evaluated as in Group A Mean age was 30 years with SD ± 1.24. Whereas in Group B (Hydrostatic Membrane Sweeping) the mean age was 31 years with SD ± 1.31. (Table I)

Period of gestation amid two categories was evaluated as in Group A (Cervical Foley's Balloon Method) the mean gestational age was 41^{+6} weeks with standard deviation ± 4.83. Whereas in Group B (Hydrostatic Membrane Sweeping), the mean gestational age was 41^{+5} weeks with standard deviation ± 3.77.

Table I: Age distribution (n=490)

Age	Group A	Group B
20-25 years	44(18)	49(20%)
26-30 years	91(37%)	86(35%)
31-35 years	110(45%)	110(45%)
Total	**245**	**245**
Mean ± SD	**30 ± 1.24**	**31 ± 1.31**

The pre-induction mean bishop score among group A was 2.3+SD 6.3 while pre-induction means bishop score in group B was 2.7 ± SD 6.7, which was not statistically significant (p-value >0.05). Status of Bishop score amid two categories was evaluated as in Group A (Cervical Foley's Balloon Method), Mean Bishop score was 4 with SD ± 6.31. Whereas in Group B (Hydrostatic Membrane Sweeping), Improvement Mean Bishop score was 5 with SD ± 4.95. (Table II)

Table II: Status of bishop score (n=490)

Bishop Score	Group A	Group B
1 – 2	25(10%)	17(7%)
3 - 4	93(38%)	81(33%)
5 - 6	127(52%)	147(60%)
Total	**245**	**245**
Mean ± SD	**4 ± 6.31**	**5 ± 4.95**

Group A: Cervical Foley's Balloon Method
Group B: Hydrostatic Membrane Sweeping
P-value = 0.035

Status of Insertion delivery interval among two groups was analyzed as in Group A (Cervical Foley's Balloon Method ,Mean delivery interval was 29 hours with SD ± 3.41. While in Group B (Hydrostatic Membrane Sweeping), the Mean delivery interval was 24 hours with SD ± 2.69. (**Error! Reference source not found.**)

Table III: Status of insertion delivery interval

Insertion Delivery Interval	Group A	Group B
12 – 18 hours	15(6%)	24(10%)
19 – 24 hours	71(29%)	81(33%)
25 – 30 hours	86(35%)	91(37%)
31 – 36 hours	73(30%)	49(20%)
Total	**245**	**245**
Mean ± SD	**29 hours ± 3.41**	**24 hours ± 2.69**

Group A: Cervical Foley's Balloon Method
Group B: Hydrostatic Membrane Sweeping
P-value = 0.026

Discussion

Obstetricians face a great challenge in inducing patients with unripe cervix .50 percent of woman undergoing induction have unfavorable bishop scores. cervical ripening before IOL ends up in 80-

98%cases to successful vaginal delivery [9]. Several studies being done in different countries has documented that ripening of cervix is successful in 52-82% with the use of intracervical foley catheter.[9]

In line with other studies, our study shows improvement in mean bishop score in Cervical Foley's Balloon Method was 4 with SD ± 6.31 while in Hydrostatic Membrane Sweeping, the improvement in mean bishop score was 5 with SD ± 4.95. Another tool for comparison was mean Insertion delivery interval in Cervical Foley's Balloon Method that was 29 hours with SD ± 3.41 while in Hydrostatic Membrane Sweeping, the mean insertion delivery interval was 24 hours with SD ± 2.69.

Mei dann et al study [7] compared Foley catheter to cook's catheter and results showed that cook catheter is costly at most places and showing no significant difference in time from insertion to removal but the significantly shorter time from insertion to delivery in cervical foleys and extra-amniotic saline infusion (EASI) group. The shortcoming of the study was which was overcomed in our study was that with a foleys catheter there is EASI but not with that of cooks balloon.

In another study, for cervical ripening double-balloon catheter with extra amniotic saline infusion was assessed, showed that both helps in shortening labor induction process. Catheter spontaneous expulsion rate was found high, insertion to delivery interval, and length of hospitalization was short and cesarean section rate and effective ripening rates were found comparable. A multivariate analysis found EASI to be an independent predictor of a shorter insertion to delivery interval.[11]

Another study was done comparing the effect of inserting catheter and sending patients home for 24 hours versus inducing patients at hospitals with prostaglandin E2 for the initiation of labor. Out-patient catheter insetion(OPC) group had short hospital stay before birth while in patient (IP) had the benefit of achieving vaginal birth within 12 hours of presentation to hospital. OPC and IP had similar vaginal delivery rates, the same induction to delivery time, and total inpatient time. OPC group felt less pain, had more time to sleep. OPC is easy, acceptable but after cervical preparation, there is an increased requirement for oxytocin use for achieving normal delivery.[12]

Induction of labor when compared between chemical and mechanical methods shows the same rate of cesarean section however there is less risk of tachysystole in mechanical method .In one study in which multiparous woman shows delayed delivery within 24 hours after IOL with a chemical method such as PGE2, but increased with mechanical method . mechanical method is better in decreasing cesarean delivery rate as compared to oxytocin.

Another study in which EASI, foley's catheter, and prostaglandins E2 were compared. This study showed that there is no difference in the improvement of bishop score among EASI and foleys catheter.[13] There was found an increased risk of cesarean delivery among women with failed induction which was found equal among all and the reason was maybe nulliparity as nulliparity is a significant risk factor for the cesarean section.[14]

In another study vaginal delivery was achieved in 90% of patients EASI in comparison to 78% in our study. However, the total sample size was very small compared to our sample. Another study showed that foley balloon with oxytocin and EASI have increased vaginal delivery rate and low rate of tachyarrhythmia.[15,16]

Incidental rupture of membranes leads to the introduction of infection is the main drawback associated with a foley catheter. In our study, there is no incidental rupture of membranes, thus no introduction of infection and it is because of the use of strict asepsis. we also avoided repeated vaginal examinations to calculate bishop score and only done after removal of catheter either spontaneously or manually or after palpable contractions gets started. Some studies may claim that the inserting foley catheter in the cervical canal is a weighty, ancient and creatively substandard procedure. However, this can be overwhelmed by

proper training, and it was well endured by our patients.

Another multivariate analysis showed that there is increased risk cesarean delivery when IOL was done with cervical foleys catheter followed by early use of oxytocin and in obese patients as well as in diabetic women. however, it was a small study and shortcoming in our study was we have not taken BMI.

Conclusion

Both Foley's catheter ballooning and hydrostatic membrane sweeping were low-priced and innocuous. Foley catheter is an operative method of cervical seasoning with the supplementary advantage of low price, reversibility, easy accessibility and lack of need for unusual storing. Both methods confer noteworthy enhancement in Bishop Score and in majority of patient's vaginal delivery is achieved. However hydrostatic membrane sweeping is more operative than foley catheter ballooning alone in refining Bishop score and attaining vaginal delivery.

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