Effect of Frequent Vaginal Saline Lavage On Maternal Infection Prevention During Mechanical Labor Induction

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Research Article

Keywords: Maternal Infection, Transcervical Balloon Catheter, Mechanical Labor Induction, Antiseptic, Vaginal Preparation

Posted Date: January 3rd, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1102121/v1>

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Abstract

Background: Induction of labor is performed in up to 25% of pregnancies. The major concern in mechanical labor induction is that it increases the chance of infection when a foreign device is introduced into the cervix. The aim of the study is to test the effectiveness of a vagina saline lavage procedure on infection prevention during labor induction by transcervical double balloon catheter.

Methods: Enrolled pregnant women were randomly divided into two groups. The control group received standard aseptic vaginal cleansing with 5% betadine solution. In addition to the standard aseptic preparation, the study group received vaginal lavage with 0.9% saline solution before the device placement and once every 4 hours after the insertion.

Results: There was no statistical difference in the demographic characteristics or the indications for induction between the two groups ($P > 0.1$). The final delivery modes and complication rates were not significantly different ($P > 0.05$) between the two groups, except for the maternal infection rate ($P < 0.05$). The rate of infection dropped from 10.6% to 2.9% when the frequent vaginal lavage procedure was performed.

Conclusions: Excessive vaginal aseptic preparation by saline solution is easy to apply, safe and effective in reducing maternal infection during mechanical labor induction.

Background

An unripe cervix in post-term gestation causes prolonged labor and increases rates of instrumental delivery or cesarean birth. Study shows that induction of Labor is a common obstetric procedure performed in up to 25% of pregnancies [1–3]. There are a variety of induction methods, including pharmacological, mechanical, and the combined use of the two methods.

The induction of labor intervention isn't without risks. The pharmacological cervical ripening methods, via oral administration, Injection of Vein (IV), or external vaginal insertion, may cause harmful side effects and complications, including excessive uterine activities (hyperstimulation or uterine rupture), tachysystole, and abnormal fetal heart rates [4][5]. The pharmacological procedures also require continuous fetal monitoring and close nursing care. At the same time, there are several medical contraindications for the use of medical reagents.

On the other hand, the mechanical induction of labor involves frequent vaginal operations and the introduction of a foreign device into the cervix, which would allow infectious organisms ascending to the uterus through the cervical canal and thus cause maternal and neonatal infections, such as chorioamnionitis, endometritis, or even sepsis [6–8].

However, the clinical benefits of labor induction for women and babies outweigh the deficiencies in post-term pregnancy. The choice of induction method, pharmacological or mechanical, is still a question of

debate. Many studies have compared various cervical ripening methods, in terms of efficacy and safety [9–13]. The mechanical methods, especially the transcervical Balloon catheters have some advantages including simplicity, reversibility, low cost, and less adverse effects [12][14]. Most importantly, the balloon catheter gently stretches and ripens the cervix by mimicking the physiology of labor setting more closely [15]. The inserted and inflated catheter would naturally stimulate the release of local prostaglandins from myometrium and amnionic cells, causing cervical ripening [15][16].

With the above benefits, it's necessary to explore a way to reduce the rate of infection during mechanical labor induction, without using prophylactic antibiotics. This study aims to test the hypothesis that frequent vaginal saline lavage would reduce the rate of infection during mechanical labor induction by double balloon catheters.

Methods

The clinical study was conducted at the Department of Obstetrics of the Institution between Jan 2020 and June 2021. The study was approved by the Research Ethics Committee of the Institution.

As shown in Figure 1, this study included 288 pregnant women, aged between 22 to 36 years old, who met the study criteria and volunteered to receive double balloon catheter for labor induction. Originally, 144 women were randomly assigned by computer to enroll in each group, but only 140 patients received the intended procedure in the aseptic preparation group. The primary outcome of the study was the maternal infection rate.

Patient Selection Criteria include unfavorable cervix with a bishop score less than 6, full-term pregnancy, complete fetus, intact membrane, no prior Caesarean section, and negative Group B Streptococcus (GBS) testing. Exclusion criteria of the study include placenta praevia or abruption, premature rupture of membranes, scarred uterus, lethal fetal congenital anomaly, known hypertension, or other contraindications for mechanical labor induction.

Maternal infection is defined as intrapartum fever ($> 38^{\circ}\text{C}$), uterine tenderness, endometritis, chorioamnionitis. All enrolled women were monitored for uterine contraction and fetal heart rate abnormalities. An abnormal FHR was defined as persistent variable decelerations, late decelerations, or fetal bradycardia. The transcervical double balloon catheter used in this trial is the Cervical Ripening Balloon (Cook Medical LLC, Bloomington, IN, USA).

Procedure

Standard Aseptic Treatment Group

After emptying the bladder, the patient was placed in the lithotomy position. The vulva was cleaned with providone iodine (betadine 5%) solution. A sterile speculum was placed and the Balloon catheter was

inserted through the cervical canal under direct visualization. The uterine balloon was inflated with 40 mL of normal saline solution, and then the catheter was pulled back until the uterine balloon was close to the cervix. The vaginal balloon was filled with 20 mL of saline solution. After removal of the speculum, saline water was infused into the catheter until both balloons were filled with 80mL of solution. The catheter was then taped to the patient's thigh with loose traction. Uterine contraction and fetal conditions were closely monitored. The double-balloon catheter was removed after 12 hrs unless spontaneously expelled, followed by hydrostatic drops of oxytocin if no regular contractions appear. In case of fetal distress, placental abruption, or prolonged labor, Caesarean Section was performed.

Frequent Vaginal Saline Lavage Group

In addition to procedures outlined in the control group, patients in the saline lavage group went through cervical saline lavage during the catheter placement and once every 4 hours afterward. Before the catheter insertion, the vagina and cervical vault were cleaned by injecting 20 mL of 0.9% saline solution into the vagina and then allowing it to flow out naturally. This procedure was repeated three times and the vagina was carefully swabbed. While the catheter was in place, vagina douching with saline solution (about 100 mL each) was performed every 4 hrs, together with standard Povidone-Iodine (5% solution) cleaning of the vulva. Saline lavage was also performed after the catheter was expelled. The 0.9% saline solution was kept at 37°C to avoid patient discomfort.

Results

The IBM SPSS Statistics 23 software was used for data analysis by t test or Chi Square test. The basic demographic characteristics of the two groups were not statistically different ($P > 0.1$). The results showed that the patients in each group were not biased towards any characteristics. Patients in both groups underwent mechanical induction of labor using the double balloon catheters, with post term pregnancy and pregnancy induced hypertension being major indications for labor induction with no statistical difference ($P > 0.1$), as shown in Table 1.

Table 1
Patient Baseline Characteristics and Primary indications for Labour Induction.

Characteristic	Standard Prep (n=144)	Saline Lavage (n=140)	P Value
Maternal Age (Years)	29.76 (3.63)	30.29 (3.60)	0.297
Gestational Age (Weeks)	40.16 (1.00)	39.88 (1.07)	0.150
Bishop Score (Mean Initial)	3.26 (1.11)	3.85 (0.90)	0.840
Time of Catheter in Place (hrs)	11.03 (5.42)	12.46 (5.52)	0.867
Bishop Score (Mean After Induction)	5.18 (1.59)	5.85 (0.72)	0.498
Nulliparous (Number)	101 (70.1%)	93 (66.4%)	0.513
Multiparous (Number)	43 (29.9%)	47 (33.6%)	0.513
Induction Delivery Interval (hrs, Mean)	6.51 (5.06)	5.94 (5.99)	0.228
Indications for Induction of Labour			
*Post term Pregnancy	52 (36.1%)	56 (40.0%)	0.592
*Elective (Psychosocial Reasons)	13 (9.0%)	14 (10.0%)	0.709
*Diabetes Mellitus	7 (4.9%)	6 (4.3%)	0.821
*Pregnancy Induced Hypertension	49 (34.0%)	45 (32.1%)	0.826
*Oligohydramnios	11 (7.6%)	12 (8.6%)	0.703
Others	12 (8.3%)	7 (5.0%)	0.238

Data are presented as mean (standard deviation) or n (%). Data analysis is performed by t test or Chi Square test. A P value less than 0.05 is considered statistically significant.

Table 2 showed that modes of delivery were not significantly different in the two groups ($P > 0.1$), which meant that the aseptic procedure did not affect the final delivery modes. There were several different maternal and neonatal complications reported in the study, but the complications were not statistically different between the two groups ($P > 0.05$), except for maternal infection ($P < 0.05$). The results showed that the vaginal douching procedure didn't increase the chance of maternal or neonatal complications and that there was significant reduction of intrapartum infection rate in the Aseptic Saline Lavage group comparing to that in the Standard Preparation group.

Table 2
Mode of Delivery and Maternal Complications.

	Standard Prep (n=144)	Aseptic Lavage (140)	p Value
Mode of Delivery			
*Spontaneous Vaginal Delivery	95 (66.0%)	87 (62.1%)	0.564
*Caesarean Section	10 (6.9%)	12 (8.6%)	0.606
*Instrumental Delivery (OFV/VD)	39 (27.1%)	41 (29.3%)	0.680
Maternal Complications			
**Fetal Distress	23 (16.0%)	27 (19.3%)	0.576
**Abnormal Fetal Position	3 (2.1%)	4 (2.9%)	0.771
**Tachysystole	13 (9.0%)	10 (7.1%)	0.628
*Uterine Hypertonicity	7 (4.9%)	6 (4.3%)	0.821
**Placenta Abruptio	3 (2.1%)	2 (1.4%)	0.835
*Uterine Rupture/Perforation	1 (0.7%)	0	0.426
*Hyperstimulation	5 (3.5%)	6 (4.3%)	0.792
*Intrapartum Infection	15 (10.4%)	4 (2.9%)	0.049

Data are presented as n (%). Data analysis is performed by t test or Chi Square test. A P value less than 0.05 is considered statistically significant.

Discussion

The study results showed that frequent vaginal saline lavage did not increase the chance of maternal or neonatal complications, while the aseptic procedure significantly reduced the rate of infection. This finding could be meaningful when comparing the safety and effectiveness of different induction methods.

Labor induction has been an important obstetric intervention procedure worldwide [1]. Successful induction of labor can increase the chance of natural delivery, reduce the time from intervention to delivery, and minimize the adverse effects of prolonged pregnancy [3]. The main goal of labor induction is to ripen the cervix that is accessed by the bishop score. There are many cervical ripening methods including pharmacological, mechanical, and the combined or subsequent use of the two methods.

The pharmacological methods focus on the administration of cervix ripening medicines orally, via IV, or intracervical [17]. Some ripening medicines include oxytocin, dinoprostone, misoprostol, mifepristone, and

relaxin. Intracervically administered agents include different forms of prostaglandins gels such as PGE1, PGE2, etc. Pharmacological cervical ripening is quick and effective, but there are some associated harmful side effects and complications [18].

Excessive uterine activity is a serious complication from the use of pharmacological agents, and it can sometimes lead to hyperstimulation or even uterine rupture. The use of pharmacological agents can also cause tachysystole and fetal heart rate abnormalities. As a result, continuous monitoring of uterine activities and fetal conditions are highly encouraged after administration, which would increase the overall cost of delivery [6]. The ideal method of cervix ripening should not increase the chance of hyperstimulation.

Mechanical induction of labor has been a popular method that intracervically introduces a device to locally stimulate the cervical ripening. Some mechanical devices are transcervical balloon catheters with or without Extra Amnionic Saline Infusion (EASI), Foley Catheters, hygroscopic cervical dilators, Laminaria tents, etc. Mechanical labor induction is shown to have similar effects on the overall cesarean delivery rates comparing to pharmacological methods, and it is relatively simple to apply [10][19][20].

The transcervical balloon catheter gently stretches and ripens the cervix by triggering local inflammatory reactions to release natural prostaglandins [14][16], and it is associated with less pain and better maternal experience [21]. In addition to the mentioned benefits, the double balloon catheter mimics the physiology of the labor setting closely by pressuring both inner and outer cervical muscles, leading to more effective natural ripening [11].

Although mechanical devices induce cervical ripening without causing uterine contractions, the main argument against the usages is that the procedure lead to longer labor duration [22], and it introduces a foreign device into the cervix, bringing in local organisms that may cause maternal and neonatal infections, despite undertaking standard aseptic measures [7][8].

It is clinically important to explore an effective way to reduce the introduction of living organisms through the cervix. Most of the induction related maternal infections are caused by vaginal bacteria introduced to the uterus through the cervical canal [23].

Theoretically, excessive aseptic treatment of vagina could be effective in preventing infectious organisms from ascending to the cervix. Roeckner et al has conducted a systematic review and concluded that vaginal aseptic preparation immediately before cesarean section surgery could significantly reduce the risk of endometritis, postoperative wound infections and fever [24]. Scholz et al has conducted a retrospective study of 3,637 patients and concluded that a surgical site infection bundle could significantly reduce the rate of infection for Cesarean Delivery patients [25].

Another question of debate is what antiseptic agents could be used in the aseptic preparation. Prophylactic antibody is not the ideal choice, because it may lead to microbial antibiotic resistance [25], and that the rates of asthma and childhood obesity increase with maternal usages of antibiotics [26][27].

In our study, a simple and low cost saline solution was used for frequent vaginal douching before and during the course of mechanical labor induction by double balloon catheter.

Our study results showed that frequent saline lavage of the vagina can significantly reduce the infection rate by killing the infectious organisms introduced to the cervix by mechanical induction devices. This simple and preventative method avoids using antibiotics prophylactically. The procedure is mild and does not cause any irritation or allergic reactions. The clinical implication of the study is that infection could be reduced during mechanical labor induction with excessive aseptic vaginal preparation.

The conducted study had its limitations. Due to the intended intervention nature, the procedure operators were not blinded, and the bishop score examined might be biased. The vagina was not swabbed before or after the lavage procedure for culture studies to compare the difference in bacteria existence. The vaginal saline lavage with syringes caused some spills and cleanup was needed after each application. Aseptic saline lavage every 4 hours could be labor intensive and it require obstetricians or nurses to closely follow the timeline by setting the alarms.

Conclusion

In this study, frequent vaginal saline lavage significantly decreased the overall maternal infection rate from 10.6–2.9% ($P < 0.05$). The results showed that extra aseptic measures could reduce the introduction of infectious organisms to the cervix when a foreign body was inserted. This vaginal saline lavage procedure is easy to apply, safe and effective. The conclusion could potentially ease the major concern of maternal infection caused by mechanical induction of labor.

Declarations

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of the Fourth Hospital of Shijiazhuang, with reference number 20190023. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all patients enrolled in the study.

Consent for publication

Not Applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

Not Applicable

Authors' contributions

Hong Xin made substantial contributions to the conception, design and revision of the work. Jing Gao performed the data collection and drafted the work. Jing Huang and Ruijing Chang made substantial contribution to the analysis and interpretation of data. All authors read and approved the final manuscript.

Acknowledgments

Special thanks to Hebei Medical University for the study design and guidance.

Footnotes

Not Applicable

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Figures

Figure 1

Flow Chart Demonstrating Study Design