ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 9, Issue – 6, December – 2024 , Page No. : 130 – 133

Cervical Catheter in Addition To Prostaglandin for Induction of Labour in Second Trimester IUFD

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Citation this Article: Dr. Divya Upadhyay, Dr. Suchitra Narayan, Dr. Ayesha, Dr. Dharamendra Singh Fatehpuriya, "Cervical Catheter in Addition To Prostaglandin for Induction of Labour in Second Trimester IUFD", IJMSIR - December - 2024, Vol – 9, Issue - 6, P. No. 130 – 133.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Aim: This study is to assess the efficacy of transcervical catheter with misoprostol, as compared to misoprostol alone for termination of pregnancy after a fetal death in second trimester.

Method: This is a single center, non-randomized, prospective study which included, women requiring interruption in pregnancy either after fetal death or in a fetus with lethal anomalies between 14 to 28 weeks of gestation. The participants were non randomly allocated to groups with induction by misoprostol (400ug every 6 hourly vaginally) alone or added with transcervical catheter. This study attempts to synthesize the existing evidence for the use of cervical catheter in addition with misoprostol.

Results: The outcomes measured out of the study are time duration to delivery, clinical chorioamnionitis (raised maternal temperature and tachycardia) and any other adverse outcomes. The composite evidence suggests that a regimen combining cervical catheter and misoprostol shortens the time to expulsion, though the overall success rates are similar to those seen with misoprostol only regimen but it did result in occurrence of clinical chorioamnionitis.

Keywords: Clinical Chorioamnionitis, Termination Of Pregnancy, Creatinine, Pragmatic

Introduction

The need of termination of a pregnancy in second trimester is usually uncommon and is typically either due to fetal demise or in a fetus with lethal anomalies. Nonetheless, the treatment options become more limited at this gestational period as surgical methods are less availed in these circumstances. Here in this study, the efficacy of a cervical catheter in addition to misoprostol has been studied in second trimester of pregnancy. The goal is to provide clinical recommendations for induction of labor in second trimester. Both pharmacologic and mechanical methods have been used for cervical ripening and labour induction yet there is no recognized single best method to achieve the goal, without any known

adverse scenario. Evidence of safety and efficacy of the combination methods of cervical ripening and labour induction is abundant and many agents have been used in combination in routine practices. The trials that compare these combination are powered to detect duration of time in between induction and delivery, maternal hemorrhage and clinical chorioamnionitis. There is clinical experience on the safety and efficacy of oral and vaginal misoprostol supported by ACOG. Based on prior studies of dosing and administration regimen vaginal misoprostol 100ug given every 4 hourly for a maximum of four doses is currently the standard of care in second trimester with unfavorable cervix and with no uterine scar. Mechanical methods include insertion of a balloon catheter or placement of a hygroscopic dilator. Out of which former is more commonly applied. The purpose of this study was to determine the added benefit of cervical catheter to misoprostol, when both arms received the same standardized labor management. Our hypothesis was that additional use of cervical catheter with misoprostol shortens the duration of time between induction and delivery.

Methods

This was a single center, pragmatic, non-randomized study conducted in accordance with the published and consolidated standards of reporting trials. The study was approved by the institutional review board ethical board and by the office of research administration of our hospital. The women undergoing induction were verbally informed about all the induction methods that are considered standard practice at our institution including misoprostol, with or without cervical catheter. Risk and benefits of delivery were discussed as part of routine consent for a delivery and was obtained from all patients. Sample size was based on an inferiority margin of 10%, power 90% and an estimated frequency of vaginal delivery of 90% in misoprostol alone regimen and 94% in misoprostol with additional foleys balloon.

Total sample size of 50 participants who were chosen randomly according to the following inclusion criteria : patient with IUFD or viable pregnancy with lethal anomalies. Primi, previous one lower segment caesarean section woman, singleton pregnancy, and gestational age of baby from 14 to 24 weeks. Exclusion criteria were women with medical disorders eg. DM, HTN Asthma etc, previous two or more than two scars, history of previous myomectomy (in which endometrium was known to be breached), previous uterine scar like previous repair of rupture uterus or perforation, women who have coagulation defects, women who have placenta low lying or near internal os. Then pregnant women presenting to our unit for management of 2nd trimester miscarriage, and who met inclusion and exclusion criteria were counselled for treatment options. Advantages and drawbacks of each were explained to them and written consent taken. Then, they were non randomly assigned in a 1:1 ratio to either misoprostol(M) only or misoprostol with Foley balloon (FB) group.

Group A: 25 women who had been scheduled for induction with unfavorable cervix, were given vaginal misoprostol in appropriate dose for cervical ripening. Group B: 25 women who had been scheduled for induction with misoprostol along with a transcervical Foleys balloon. Bulb was inflated with 30 -50 mL saline & prophylactic antibiotics were administered.

A complete history was taken from the patients including personal, past, family, obstetric and menstrual history. Detailed examination, such as general physical, abdominal, and local examination done. Basic investigation including laboratory investigation (CBC-PT-PC-urea – creatinine – FBS- 2HPP), and an Ultrasound to locate site of placenta were done. Then

local examination to assess cervix (position, dilatation, effacement) and for exclusion of any abnormality like polyp or any previous post partum tear.

The cervix was visualized with a sterile vaginal speculum and cleaned with povidone iodine. Foleys balloon was inserted into the cervical canal under direct visualization. The patient was instructed to report any excessive bleeding, pain, or other concerns to the attending doctor. The catheter was left in place until expulsion.

Along with this appropriate dose of vaginal misoprostol was given. Patients remained in the hospital but were allowed to ambulate, and perform regular activity in this duration. Our hospital induction protocol allows upto four doses of vaginal misoprostol 100ug, 4 hours apart in qualifying patients. The foleys bulb was deflated and removed at 12 hours, if not previously expelled, or when clinically indicated. Standard labor protocols continued during and after foleys removal.

Discussion

Abortion during the second trimester of pregnancy accounts for 10-15% of abortions performed worldwide. Women with previous CS have an increased risk of uterine rupture than patients with unscarred uterus, so IOL in these patients should be done after thorough and detailed counseling with both patient and their relatives. Many studies evaluated different methods of labor induction when the cervix is unfavorable, these methods were classified roughly into either pharmacological or mechanical methods.

Although misoprostol (PGE1) is widely used for labor induction, it has a high incidence of uterine hyperstimulation and subsequent rupture uterus which is a nightmare for an obstetrician, seen especially in women with previous CS, so misoprostol is not highly recommended in such patients. Since surgical options cannot be very readily used in second trimester IUFDs, misoprostol is administered with very close monitoring.

There are two common mechanical methods for cervical ripening: osmotic dilators, the transcervical Foley catheter.

All methods are thought to work by both directly dilating the cervix and by causing natural prostaglandin and/or oxytocin release. There is a lack of compelling evidence suggesting increased risk of uterine rupture because mechanical devices can be readily removed when needed. And these are also stable at room temperature.

Foley's catheter induces labor by both mechanical dilatation and stimulating endogenous release of prostaglandins. It produces an outward mechanical force in addition to prostaglandin release, causing collagen degradation that leads to cervical softening.

Results

The primary outcomes of the study were, the rate of vaginal delivery and duration to time to delivery. Secondary outcomes were, need of oxytocin or any other induction or augmenting agent, Clinical chorioamnionitis, uterine hyperstimulation, excessive blood loss, uterine rupture and hysterotomy.

Our standardized misoprostol and misoprostol plus foleys bulb labor induction protocol achieved a vaginal delivery rate of 94% and 97% respectively in a population of women with indicated labor induction. There was also a shortened duration of induction to delivery interval associated with added Foley bulb.

A marginal difference in need for oxytocin was also demonstrated. However, induction with oral misoprostol plus cervical catheter was associated with slightly increased risk of clinical chorioamnionitis.

The finding of 30% increased RR of clinical chorioamnionitis in the oral misoprostol plus Foley study arm is notable. The definition of clinical

chorioamnionitis used in our study was—a temperature of 38°C or greater during labor with or without fundal tenderness, and without other identified cause.

Table 1

	Total women assigned	Women delivering vaginally
Misoprostol only regimen	25	25
Misoprostol plus foleys bulb regimen	25	25

Table 2

	Women requiring additional induction agents	Average induction to delivery time	Women developing chorioamnionitis
Misoprostol only regimen	12	12 to 16 hours	2
Misoprostol plus foleys bulb regimen	7	8 to 11 hours	6

Conclusions

To sum up, we found some benefit in achieving vaginal delivery with the addition of the transcervical Foleys bulb to oral misoprostol within a standardized labor induction protocol and found a slight increase in the rate of clinical chorioamnionitis with this method

Furthermore, the addition of the Foleys bulb to oral misoprostol offered time advantage over use of misoprostol alone.

The results of this study may not be generalizable to all populations, although we believe the use of standardized labor induction protocols informs clinical decision making, improves maternal health outcomes, and provides a basic framework for design of subsequent labor induction trials

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