

## Comparative Study between Efficacy of oral Misoprostol & Vaginal Misoprostol & Foley Bulb with oxytocin Induction in Prolonged Pregnancy and Study of Maternal & Fetal Outcome

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### Abstract:

**Background:** The present study is undertaken to compare the safety and efficacy of 25ug oral Misoprostol with that of 25ug vaginal Misoprostol & foley bulb with oxytocin induction in prolonged pregnancy (>41 Weeks) & study of the maternal & fetal outcome.

**Methods:** About 150 women are to be randomized to either oral Misoprostol or vaginal Misoprostol or foley bulb with oxytocin induction. The effect on labour induction and induction – delivery interval is studied. The mode of delivery, the maternal and fetal outcome between 3 groups are compared. The cost effectiveness between 3 methods of induction is assessed.

**Results:** Induction to delivery interval was shortest in oral Misoprostol group. Labour natural was maximum in oral Misoprostol group followed by vaginal Misoprostol. The incidence of Meconium stained amniotic fluid was maximum in Oral Misoprostol. Tachysystole and Postpartum Haemorrhage, GIT effects was more in vaginal misoprostol.

**Conclusions:** With this comparative study it is possible to reduce the perinatal mortality which is high in prolonged pregnancy and the rate of cesarean delivery due to failed induction in prolonged pregnancy. Hence would improve the maternal and fetal outcome.

**Keywords:** Foley bulb, Induction, Misoprostol, Prolonged pregnancy.

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### I. Introduction

Induced labour is one in which pregnancy is terminated artificially. It causes uterine contractions, progressive dilatation and effacement of cervix. History reveals an understandable reluctance to interfere with the course of labour by hastening the onset because the methods were uncertain, bizarre & often dangerous. However penalties of failure and hazards of prolonged labour have been recognized for centuries and influenced ideas in Obstetrics. Now induction of labour has become most popular in modern obstetrics. The reasons for the rising rates of induction of labour are: Improved ability of Physicians to determine gestational age accurately with early dating scans, thus avoiding the possibility of Iatrogenic prematurity, Wide spread availability of cervical ripening agents, Improved knowledge of methods and indication for induction, More relaxed attitude towards marginal/elective indications both of Physicians and the patient, Litigation constraints. There are numerous indications for the labour induction. It includes Obstetric conditions and medical conditions aggravated by pregnancy.

#### 1.1. Medical Conditions:

**1.1.1. Maternal:** Hypertensive Disorders of pregnancy, Diabetes, PROM, other conditions where continuation of pregnancy does not outweigh termination and it is beneficial to mother and fetus.

**1.1.2. Fetal:** Post-term, Intra uterine growth restriction, oligohydramnios, lethal fetal anomalies, Intra uterine fetal Demise.

A successful induction of labour aims at healthy mother and baby without any morbidity or mortality. Failure of induction occurs due to various reasons and may resort to cesarean section. The indication, method of induction, progress, complications and success rate varies from patient to patient. Prolonged pregnancy is defined when the gestational age is more than 41 completed weeks. Incidence of Prolonged pregnancy is 11%. Prolongation of pregnancy beyond 40 weeks occurs in 1 in 10 pregnancies. Perinatal morbidity and mortality is high in postdated pregnancy. Cesarean rate is high in postdated pregnancy. Hilder et al demonstrated that the risks of still birth and infant mortality increase significantly in prolonged pregnancy when expressed per 1000 ongoing pregnancies. Associated morbidity includes an increased risk of fetal distress, shoulder Dystocia, labour dysfunction, obstetric trauma and perinatal complications like meconium aspiration syndrome, asphyxia, fractures, nerve injuries, septicemia and Pneumonia. Since there are no conclusive

information about effectiveness of the induction methods, this study is undertaken to compare intracervical foley catheter with oxytocin, vaginal and oral Misoprostol in Postdated pregnancy.

## II. Methods

It is a Prospective randomized control study conducted at Government Mohan Kumaramangalam Medical College, Salem from January 2015-August 2015. Sample size included 300 women with prolonged pregnancy who were randomized to either oral Misoprostol or vaginal Misoprostol or foley bulb with oxytocin induction.

**2.1 Inclusion Criteria:** Gestational Age >41 weeks, Singleton pregnancy, Cephalic presentation, Bishop's score < 6, Completed 41 weeks of gestational age, Live fetus showing no signs of fetal compromise on admission CTG, Adequate Liquor.

**2.2 Exclusion Criteria:** Multiple pregnancy, Non cephalic presentations, Bishop's Score > 6, previous scar, Uterine Surgery, Any medical Conditions complicating Pregnancy, Hydramnios, IUGR, Gestational age < 41 weeks, Women in active labour, Ruptured membranes, Cephalo pelvic disproportions, Hypersensitivity to Prostaglandins, Allergy or asthma, Vaginal bleeding, Previous cesarean section.

Informed consent obtained for Misoprostol group of patients. 25 µg of Misoprostol given either orally or vaginally. Dose is repeated at the interval of 4hrs to the maximum of 3 doses. Pelvic examination done every 4 hrs. 16 French Foley catheter inserted intracervically & bulb inflated with 80 ml of normal saline. Pelvic assessment done after 12hrs if the inflated balloon is not passed spontaneously. If cervical dilation is equal to or >2 cm, ARM should be done & induction with oxytocin should be done.

Detailed history of the patient is taken including her menstrual history, obstetric history, relevant past history, medical and surgical history, history of drug allergy. General examination is done for the patient. Parameters noted are Pallor, Pedal edema, temperature, pulse rate, blood pressure, cardiovascular and respiratory system. Ultrasound is done for gestational age, lie, liquor. Early scans of the patient is verified to confirm the gestational age. Bishop scoring is done by looking for the cervical dilatation, effacement, position, consistency and station of the fetal head. Pelvic examination done and major degrees of CPD are ruled out. CTG is done –patients with non-reactive CTG are excluded.

## III. Results

The mean age in Foley group was 23.90. In Oral misoprostol group the mean age was 23.23 and in Vaginal Misoprostol it was 24.48. Maximum number of patients were Primi gravida. 69% was Primi in Foley group & 31% were Multigravida. 71% were Primi gravida, 29% were Multigravida in Oral Misoprostol Group, 70% Primi gravida, 30% Multi gravida in vaginal Misoprostol group.

Bishop score at '0' hour was similar in all the three groups. In Foley group the Bishop score at '0' hour was 2.46, in Oral Misoprostol group the Bishop score at '0' hour was 2.59, in vaginal Misoprostol group the Bishop score at '0' hour was 2.57. The Bishop score at '4' hours in Foley group was 5.08, in oral Misoprostol group the Bishop score at '4' hour was 8.53, in vaginal Misoprostol group the Bishop score at '4' hours was 8.37. In foley group the Bishop score at '8' hours was 9.38, in Oral Misoprostol group the Bishop score at '8' hours was 10.15, in vaginal Misoprostol group the Bishop score at '8' hours was 10.15.

The induction delivery interval was shorter in oral Misoprostol group which was 8.82 hours. Though the induction delivery interval in vaginal Misoprostol group was comparable to oral Misoprostol group it was slightly longer-8.88 hours. Longest induction delivery interval was in the foley group -13.72 hours.

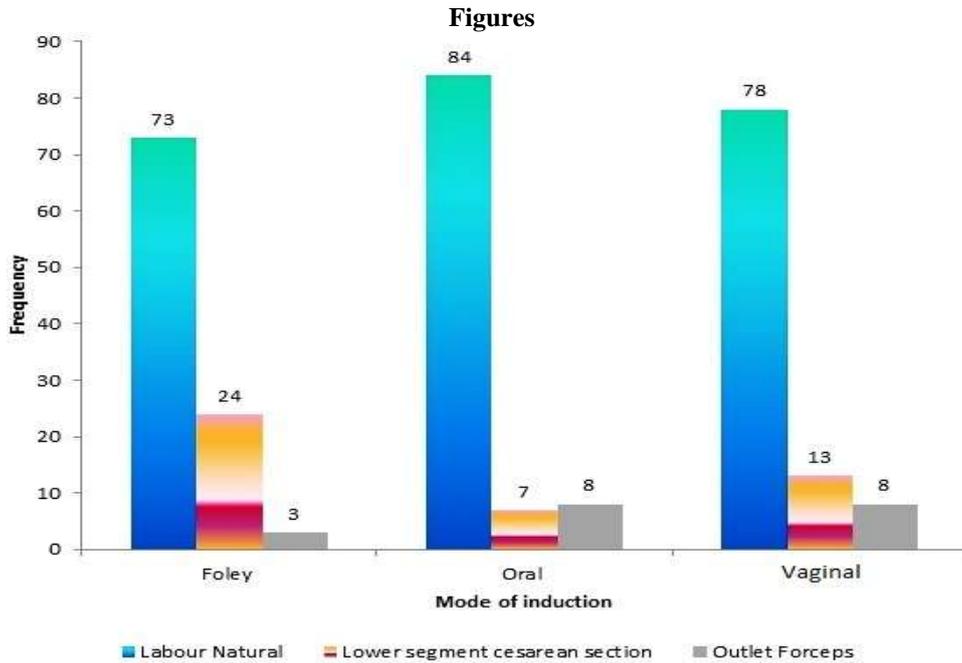
Mode of delivery was compared in three groups –Labour natural was 73% in Foley group, 84% in oral misoprostol group, 78% in Vaginal Misoprostol group. Comparison of LSCS rate in three groups-maximum number was recorded in the Foley group -24%, followed by vaginal Misoprostol -13%, and 7% in oral misoprostol group.

The incidence of meconium stained amniotic fluid was 1% in Foley group, 3% in oral misoprostol group, 2% in Vaginal Misoprostol group. Total of 6% was meconium stained. Incidence of Non-Reactive CTG was 2% in Foley Group, 1% in Oral Misoprostol and 3% in Vaginal Misoprostol group. The rate of NICU admission was 2% in Foley group, 1% in Oral misoprostol group, 3% in vaginal Misoprostol. The incidence of APGAR < 7 was 1% in Foley group, 5% in Oral misoprostol group, 10% in vaginal Misoprostol group.

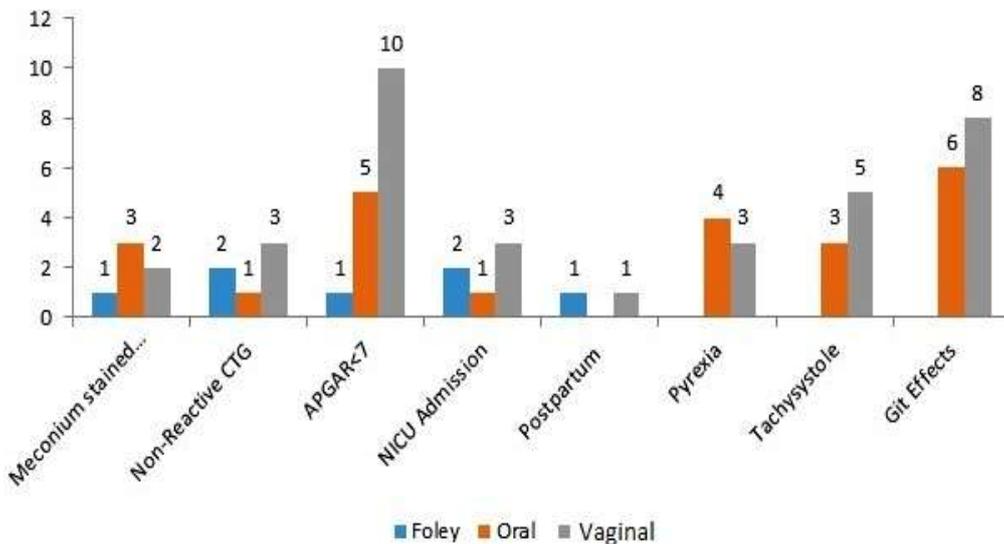
There was no tachysystole in Foley group. The rate of tachysystole was 3% in Oral Misoprostol group and 5% in vaginal Misoprostol group. There was 1 case of Postpartum Haemorrhage in Foley group, and 1 case in Vaginal Misoprostol group. There were 6 cases with GIT side effects in oral Misoprostol group and 8 cases in vaginal Misoprostol.

The foley induction was costlier than the other two modes of induction. The mean cost of oral Misoprostol and vaginal Misoprostol was similar. The mean number of doses required for oral Misoprostol was 2.03 and for vaginal Misoprostol was 2.05. The mean induction delivery interval in Foley group was 14.71hrs in

Primi and 11.51 hours in Multigravida. In oral Misoprostol group it was 9.98hrs in Primi and 5.96 hours in multigravida. In vaginal Misoprostol group it was 9.88 hours in Primi and 6.54 hours in multigravida.



**Fig.1** Mode of Delivery



**Fig.2** Maternal and Fetal effects

#### IV. Discussion

In our study the mean age in each group correlates well with the study conducted by Tejaswini.B.Hiremath[1]. Parity in this study correlates with the study conducted by Tabowei et al (2003) and Murthy Bhaskar Krishnamurthy et al[2] (2006). Induction delivery interval correlates with the study conducted by Tejaswini.B.Hiremath et al. The mean Induction delivery interval correlates with the study conducted by Khadija et al were it was 9.45 hours.

This study correlates well with the study by Fatemeh vahid Roudsari et al, Sherman et al[4], Tuuli MG et al with regard to induction delivery interval. Comparing all the above studies Misoprostol has got shorter Induction delivery interval when compared to Foley catheter which correlates with present study. It is also evident in the present study that the Induction Delivery interval is shorter in Oral Misoprostol group. Correlates with the study conducted by Tejaswini.B.Hiremath<sup>1</sup>. Lscs rate in Foley group-24% in the present study correlates well with the study conducted by Jan william de Leeuw et al[5]-20%.

In the study conducted by Adeniji et al[6] Meconium stained amniotic fluid was 2% in foley group and 5% in misoprostol group which correlates with the present study. In a study conducted by Olimpio B.Moraes Filho[7] the incidence of NR CTG was 3.3% in Foley group and 4.2% in Vaginal Misoprostol group which correlates with the present Study. In a study conducted by Tejaswini .B.Hiremath et al[1] the rate of NICU admission was more in vaginal Misoprostol group-10% and 8% in oral Misoprostol group which correlates with the present study. In all above mentioned studies vaginal Misoprostol causes more Tachysystole than the Oral Misoprostol group. The present study correlates well with the results of the study conducted by C.David et al. In a study conducted by Tejaswini.B.Hiremath[1]the rate of GIT effects in Oral Misoprostol group was 6% and 8% in vaginal Misoprostol which correlates well with the present study.

## **V. Conclusion**

It is evident from the study that Oral Misoprostol is more effective than vaginal misoprostol and Foley bulb induction. Hence induction with oral Misoprostol in prolonged pregnancy provides shorter induction delivery interval, increases labour natural rate, decreases the incidence of meconium stained liquor and NICU admission, lesser maternal Tachysystole and postpartum hemorrhage. We conclude that induction with Oral Misoprostol in prolonged pregnancy enables better maternal and neonatal outcome.

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