

# COMPARISON OF MISOPROSTOL VAGINAL TABLET WITH DINOPROSTONE PGE 2 VAGINAL PESSARY FOR INDUCTION OF LABOUR IN FULL TERM PREGNANCY

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## ABSTRACT

**Background:** Initiation of labour in cases when it is full term pregnancy has multiple options, before spontaneous onset for delivery of fetoplacental unit. **Objective:** To compare the efficacy of misoprostol with dinoprostone for the labour induction, in full term pregnancies. **Methodology:** Study Design: Randomized controlled trial. Setting: Department of Gynaecology and Obstetrics, Sheikh Zayed Medical College/ Hospital, Rahim Yar Khan. Duration: 1<sup>st</sup> August 2011 to 31<sup>st</sup> January 2012. A total of 118 patients (59 in each group) were included in this study. Patients in group A were induced with 50 µg misoprostol, vaginal tablet repeated at 4 hourly intervals with maximum of 3 doses. Patient in group B dinoprostone, vaginal pessary repeated as 6 hours interval or maximum of two doses. Ethical approval was sought from Institutional Review Board. Data was entered in and analyzed by using SPSS version 11. **Results:** In group A and group-B mean age of the patients was 31.2 ± 1.3 years and 31.9 ± 1.8 years respectively. Mean induction to delivery time (hours) was low in misoprostol group than dinoprostone group. (11.90 ± 6.46 vs 17.20 ± 11.31). (p= 0.002) **Conclusion:** This study showed that misoprostol was more effective for induction of labour in terms of duration of induction time than dinoprostone.

**Keyword:** Misoprostol, Dinoprostone, Induction of labour.

## INTRODUCTION

Induction of labour is defined as, planned initiation of labour before spontaneous onset of pain for delivery, and its rate varies.<sup>1,2,3</sup> Onset, for the purpose of delivery of the fetoplacental unit.<sup>1</sup> The rate of induction varies and in many centers is currently more than 20%.<sup>2,3</sup> Induction of labour is an important and common procedure, performed for medical, obstetric and social indications.<sup>4</sup> Overall induction of labor at term has all most doubled in prevalence during the past 15 years.<sup>4,5</sup> However, one of the potential effect of planned induction is usually increased chance of caesarean section delivery and related complications.<sup>6-11</sup> Nulliparous women and having unfavorable cervix are at increased chance of caesarean delivery.<sup>12,13</sup> When the cervix is unfavorable for initiation of labor, cervical ripening is usually recommended as so to increase the chances of induction and delivery.<sup>1,7-9</sup> Prostaglandins for induction of labour are used in some of the confinement.<sup>14</sup> Misoprostol, a prostaglandin E1 analogue is used nowadays for cervical ripening.<sup>15-16</sup> It was marked as cytoprotective agent in gastric mucosa but also endorsed by American College of Obstetrician & Gynaecologists and also by Royal College of Obstetrician and Gynaecologists.<sup>17,18</sup> Advantages include its low price and stability at room temperature.<sup>19</sup> In a country like Pakistan where average income is low, for the most people it is difficult to afford expensive drugs.<sup>21</sup> This study was planned in our setup to compare the

efficacy of misoprostol and dinoprostone in terms of induction time in full term pregnancy among intentional induction.

## METHODOLOGY

**Study Design:** Randomized controlled trial. **Setting:** Department of Gynaecology and Obstetrics, Sheikh Zayed Medical College/ Hospital, Rahim Yar Khan. **Duration of Study:** From 1<sup>st</sup> August 2011 to 31<sup>st</sup> January 2012. **Sample size:** A total of 118, 59 in each group admitted in labor room for planning delivery was selected randomly with 5% required size of error. 80% power of study. **Inclusion Criteria:** Women having alive, singleton pregnancy of 37-42 weeks on ultrasound, women with age between 20-40 years, women having cephalic presentation diagnosed on abdominal and vaginal examination. **Exclusion Criteria:** Multiple pregnancy as diagnosed on ultrasonography, previous cesarean section, placenta praevia, women with ruptured membranes, intrauterine fetal demise as diagnosed on ultrasonography, pregnancy induced hypertension, diabetes mellitus and cardiac disorders. After approval from the Institutional Review Board, 118 patients (59 patients in each group) having singleton alive, term pregnancy diagnosed on ultrasound, who fulfilled the inclusion and exclusion criteria, were selected from the labour room of Obstetrics and Gynaecology Department. Informed verbal consent was taken from patients to use their data for study. Patients were allocated to two groups using the

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random numbers table. Patients in group-A were induced with 50µg misoprostol, vaginal tablet repeated at 4 hourly intervals with maximum of 3 doses. Patients in group B dinoprostone, vaginal pessary was repeated as 6 hours interval or maximum of two doses by the doctors on duty. All patients were carefully monitored and mode of delivery was decided according to the current protocols followed in the department. Induction to delivery interval (time) was measured in hours.

Data analysis was done by using SPSS version 11. The demographic variables of the age, parity, gestational age and duration of induction to delivery interval (time) was presented as mean and standard deviation.

The outcome variables were induction to delivery interval (time) and side effects were listed separately for two study groups and compared between two groups for statistical significance. A p value of  $\leq 0.05$  was taken significance. Independent “t” test was applied on the induction to delivery interval (time). Fisher's exact test was applied on comparison of induction failure and side effects in misoprostol and dinoprostone groups.

## RESULTS

A total of 118 patients were included in this study. Fifty-nine patients received vaginal tablet of misoprostol 50µg (Group A) and in fifty-nine patients labour induction was done by dinoprostone vaginal pessary (Group B). Mean induction to delivery interval (hours) was less in misoprostol group (Group A) as compared to dinoprostone (Group B). ( $11.90 \pm 6.46$  vs  $17.20 \pm 11.31$ ).

**Table I: Induction to delivery interval (hours)**

Group	Mean $\pm$ SD	P value
Group-A (Misoprostol)	$11.90 \pm 6.46$	0.002
Group B (Dinoprostone)	$17.20 \pm 11.31$	

Side effects in misoprostol group i.e. nausea and vomiting were found in 5 patients (8.4%) with p value 0.057, fever in 3 patients (5%) and induction failed in 22 patients (37.2%) in group A and in 28 patients (47.5%) in group B Results were statistically not significant with p value 0.063.

**Table II: Side effects and failure of induction in both groups**

Side effects	Group-A (Misoprostol)		Group-B (Dinoprostone)		P-Value
	Number	%	Number	%	
Nausea	5	8.4	-	-	0.057
Vomiting	5	8.4	-	-	0.057
Diarrhoea	-	-	-	-	-
Fever	3	5.0			0.243
Induction Failure	Group-A (Misoprostol)		Group-B (Dinoprostone)		P- Value
	Number	%	Number	%	
Yes	22	37.2	28	47.5	0.063
No	37	62.8	31	52.5	
Total	59	100.0	59	100.0	

## DISCUSSION

Intentional induction of labour is a routinely performed procedure carried out to ensure more benefits to mother or fetus. Oxytocin was one of the common agent used for introduction in past but now a days a prostaglandins are used better agents when cervix is unripe.<sup>22-26</sup>

Misoprostol PGE1 has been reported to be used cervical ripening agents using three routes oral, sublingual, vaginal and dose of 25µg and 50µg.<sup>24,25</sup> These studies show that it is an effective cervical ripening agent. In current study, vaginal misoprostol 50µg provided a better alternative. In current study conducted on a total of 118 patients, in Group A of 59 women, misoprostol 50µg was used and in Group B of 59 women, dinoprostone vaginal pessary was used. We have observed improvement in induction to delivery interval (hours). We found that there was statistically significant difference among both of the groups in terms of induction to delivery time. ( $p=0.002$ ) Prostaglandin E2 is used effectively since long time for induction of labour. Cost of prostaglandin E2 is reported to be more as compared to Misoprostol.<sup>26</sup> Misoprostol role in induction of safe labour when cost is a problem like developing countries, however; with continuous monitoring.<sup>27</sup>

In current study, administration of PGE1 vaginally, resulted than PGE2 ( $11.90 \pm 6.46$  vs  $17.20 \pm 11.31$ ). In comparison similar to our study, a study showed that misoprostol was better than PGE2 in terms of a shorter induction to delivery time. In current study, rate of cesarean section was less in misoprostol group as compared to dinoprostone group. Similar results were reported in studies carried out in Greece and India.<sup>28,29</sup> Hofmeyr et al, in a review assessed role in induction by misoprostol and other conventional prostaglandins and showed that the misoprostol was

more effective labour induction.<sup>30</sup> Huang et al also demonstrated the similar results.<sup>31</sup>

## CONCLUSION

This study showed that vaginal misoprostol is more effective for induction of labour, by its high success rate in terms of shorter induction to delivery interval, as compared to vaginal dinoprostone, however, careful monitoring is recommended.

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