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Evaluation of a New Drug – Misoprostol – For Induction of Labor

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Summary

One hundred & fifty cases of high-risk pregnancy, which needed induction of labor with Bishops score less than 4 have been evaluated with 50μgm Misoprostol through intravaginal route. 109 had vaginal delivery and 64 delivered with misoprostol alone. While 45 needed augmentation with PG tab or oxytocin The study shows it to be effective in most of the cases and probably needs extensive trials to determine the dose and the route of administration.

Introduction

Search for a cheap, effective, safe and relatively easy to administer drug for induction has been going on for quite a long time. Synotocinon-synthetic oxytocin was introduced in 1955. In 1986 Karim introduced Prostlagladine PGE_2 infusion for induction of labor. In 1986 PGE2 cervical gel was introduced which is more effective and shortened the induction delivery interval. In 1987 RU486 has been tried. In 1991 Misoprostol (Norman 1991) has been introduced.

Misoprostol is a synthetic PGE1 analogue used for prevention and treatment of gastroduodenal ulcers. It has a strong uterocontractive and abortifacient properties and is used in 1st and 2nd trimester abortions and for induction of labor. Its advantages are: 1) Stable at room temperature 2) No bronchoconstrictive action and slight bronchodilatory action 3) Inexpensive and readily accessible 4) Orally active.

Pharmacokinetics: It is rapidly absorbed following oral administration reaching a peak level in 30 min. It is rapidly de-esterified to misoprostol acid and is further metabolized by fatty acid oxidizing system present in numerous tissues of the body. Zieman et al (1997) compared the absorption kinetics of misoprostol after oral and vaginal administration. He showed that after oral Misoprostol, the plasma concentration of the drug rose quickly, peaked between 12.5 and 60 min. after the administration and fell steeply by 120 min. In contrast plasma concentration of the drug in women receiving vaginal dose rose gradually, reached maximum levels between 60 and 120min and declined slowly to an average of 61% of the peak level at 240 min after administration and the bioavailability of the drug was 3 times higher than that after administration probably due to its bypassing the gastrointestinal and hepatic metabolism.

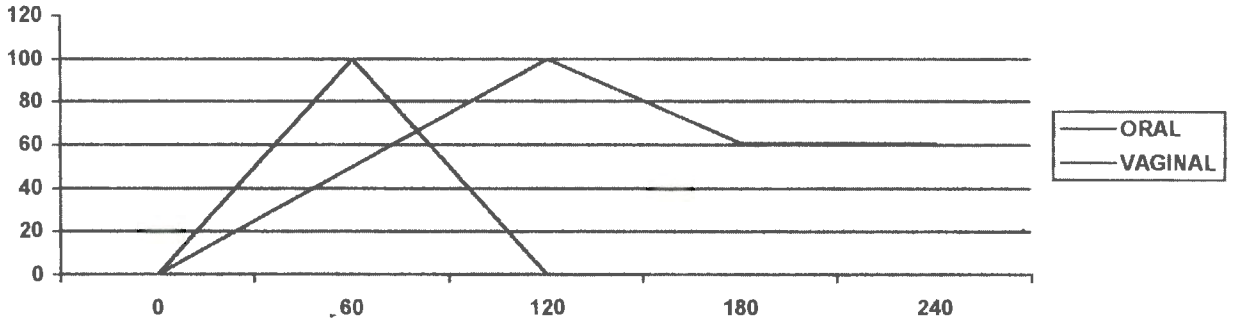

Fig 1: It shows vaginal administration is superior as plasma concentration rose gradually, reached maximum level between 60-120 min and declined slowly to an average of 61% of peak level by 240 min. Bioavailability of the drug is three times higher.

Materials and Methods

This study was conducted in 150 cases that required induction of labor for various reasons at Apoorva Hospital, Visakhapatnam – a private hospital. Only those cases with 1) clear indication for induction, 2) vertex presentation, 3) Bishops cervical score less than 4, 4) reactive suspicious pattern on CTG, 5) no evidence of CPD and 6) no placenta praevia, 7) no previous uterine scar were included in the study. These cases had 50ugm of misoprostol introduced into posterior fornix of the vagina. They were followed up carefully for any untoward effects, hyperstimulation, tachysystole or foetal distress and reviewed every 3-6 hrs by the obstetrician. A 2nd dose of 50ugm was administered intravaginally if the Bishop's score did not improve after 6 hrs. They were reviewed again after 3hrs and depending on the obstetrician's choice for accelerating the labor either PG tab orally or syntocinon drip was utilized. An improvement of Bishops score by 4 points from the original score was taken as successful induction.

Observation

Table I – Age

Out of 150 cases more than 90% cases are within the age group of 30 yrs.

Less than 20 yr	7	- 4.6%
20 to 29 yrs	133	- 88.6%
30 to 39 yrs	10	- 6.62%

Table II: Parity

Primi 92	61.1%
II gravida 38	25%
III above 20	14%

Table III: Indications of Induction

Past dates	45
Oligo amnios	37
IUGR	22
PROM	11
PIH	17
Others	18

Table IV: Results

Total no. of cases	150
Successful with one application of misoprostal	107
Successful with second dose	38
Failed to respond	5

Table V: Mode of delivery

Total of vaginal deliveries	109 cases
Only misoprostal	64 cases
Misoprostal + syntocinon + PG tab	45 cases
Caesarean section	41 cases

Table VI: Indications for Caesarean Section

Total No	41
Foetal Distress	17
Big baby	8
Occipito posterior	10
Cord Prolapse	1
Failure of Induction	5

Discussion

Srisomboon et al (1997) from Thailand compared 100 mg of misoprostol inserted intracervically/intravaginally in 50 cases each and found no difference in Bishops score and induction delivery interval. He found 24%-32% tachysystole in his cases that resolved quickly with Inj Terbutaline and found no evidence of foetal distress. Lee HY from

Malaysia (1997) compared 3mg dinoprostone gel with intravaginal misoprostol-200 ug and found labor was successfully established in 92% of misoprostol cases compared to 64% dinoprostone group and was not associated with foetal distress. Danielian et al (1999) similarly compared dinoprostone gel 1 mg 6hrly to 50 ug misoprostol vaginally 4hrly and found reduced induction delivery interval with misoprostal (14.4 hrs/ 22.9 hrs). More women delivered with single dose of misoprostal and required use of oxytocin augmentation. More than 95% delivered within 12-24 hrs. Our results were similar to the above results and we have not found any cases of hyperstimulation, probably because we have used minimal dose and at a larger interval. In our series too we found that 42.6% delivered normally without any other drug for acceleration, another 30% delivered vaginally with augmentation either with PG tab or oxytocin. 27.3% had C-section and the indications are as shown in the Table VI. The induction delivery interval too was approximately 12-14hrs. In conclusion, misoprostol seems to be a relatively safe, cheap, easy to administer and quite effective, which is a boon to all the developing countries and needs more extensive trials to determine the effective dose, safety, side effects, etc.

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