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A Comparative Study of Intracervical Instillation of PGE2 Gel (O.5mg) Versus Vaginal Tab PGE1 (600µg) for Second Trimester MTP

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Abstract: ***Objective: A Comparative Study Of Intracervical Instillation Of PGE2 Gel (O.5mg) Versus Vaginal Tab PGE1(600µg) For Second Trimester MTP. Material and Methods: The study was undertaken in the department of Obstetrics and Gynecology at New Civil Hospital, Surat from March 2015-November 2015. Sixty consenting women willing for 2nd trimester MTP coming to New Civil Hospital Surat were randomly divided in two groups. Group A (30 subjects) induction was done with intracervical instillation of 0.5mg PGE2 gel 12hrly after reassessment for maximum 3 doses. Group B (30 subjects) induction was done with tab PGE1 600µg per vaginally after reassessment every 6 hrly upto maximum 4 doses. Result: Mean age of subjects was 24years in Group A(PGE2) and 23.9 years in Group B(PGE1). Most of the subjects enrolled for second trimester MTP were having pregnancy between 14-16weeks.The mean drug instillation of group A was 2.1 times while in group B was 2.9 times which was statistically significant.The mean induction abortion interval in group A was 21.5hours and that of group B was 15.4 hours which was statistically significant. The success rate of group A was 93.3% while that of group B was 96.6% The difference in final outcome was statistically not significant. Conclusion: Second trimester termination of pregnancy using PGE1 (Misoprostol) was found safe and effective with shorter induction abortion interval . Compared to other drugs available for second trimester MTP PGE1(Misoprostol) is cost effective, can be stored at room temperature, lesser side effects and complications and with higher success rate.***

Keywords: MTP, second trimester, Misoprostol, PGE1

1. Introduction

India pioneered in legalizing induced abortion (Medical Termination of Pregnancy (MTP) Act of 1971) under which a woman can legally avail abortion if the pregnancy carries the risk of grave physical injury, endangers her mental health, or results from a contraceptive failure in a married woman or from rape or is likely to result in the birth of a child with physical or mental abnormalities.

According to the MTP act, abortion is permitted up to 20 weeks of pregnancy duration and no spousal consent is required.
Though second trimester abortions account for a small percentage of all induced abortions, it is associated with high rate of morbidity.

Two thirds of major abortion related complications and half of abortion related mortality occur in pregnancies terminated after 13 weeks of gestation[1].

PGE_1(Misoprostol) has emerged as a critical component of these regimens both as a stand-alone method and in combination with other medications like Mifepristone[2]. It is widely used because it is inexpensive and stable at room temperature. It can be absorbed via oral, vaginal, sublingual, buccal and rectal routes. Many clinical trials have found vaginal administration to be more effective than oral administration[3].

The naturally occurring prostaglandin E_2 is known as Dinoprostone. It has important effects in labour (softening the cervix and causing uterine contraction). It is available as vaginal insert, vaginal suppositories, cervical gel.

Therefore we conducted the study to compare the efficacy of vaginal PGE_1tab(Misoprostol) with intracervical instillation of PGE_2 gel (Dinoprostone) in second trimester MTP (≥ 12 and ≤ 20 weeks).

Aims & Objectives:

1) To compare the induction abortion interval in PGE_2 induced group versus PGE_1 induced group.
2) To compare the side effects of PGE_2 versus PGE_1 induced group.
3) To compare the complications of PGE_2 versus PGE_1 induced group.

2. Material and Methods

The study was undertaken in the department of Obstetrics and Gynecology at New Civil Hospital, Surat from March 2015-November 2015. Sixty consenting women willing for 2nd trimester MTP coming to New Civil Hospital Surat were randomly divided in two groups. Group A (30 subjects) induction was done with intracervical instillation of 0.5mg PGE_2 gel 12hrly after reassessment for maximum 3 doses. Group B (30 subjects) induction was done with tab PGE1 600µg per vaginally after reassessment every 6 hrlyupto maximum 4 doses.

Inclusion Criteria:

1) Pregnant woman coming for 2nd trimester MTP between gestational age of 14 to 20 weeks.
2) Those patients who understood the medical regimen and gave informed written consent for induction with regimen.

Exclusion Criteria

1) Contradictions to (PGE1): Mitral Stenosis, Glaucoma, Sickle Cell Disease, Severe Asthma, K/C/O allergy to Prostaglandins.
2) Contradiction to (PGE2): Asthma, Glaucoma, Pulmonary Disease, Hepatic Disease, k/c/o allergy to prostaglandins.
3) Previous 2 or more L.S.C.S.
4) Past H/O Classical C.S.
5) Past history of rupture uterus/myomectomy.
6) Woman who did not give consent.

Detailed history, examination and conselling were done. Eligible candidates were explained about the two arms of the study. After enrollment, gestational age was estimated by last menstrual period, clinical examination and USG. Randomization was done.

Routine investigations necessary prior to MTP i.e. Hb estimation, blood grouping, urine albumin sugar were done in all subjects. Written informed consent was taken.

The subjects were monitored for onset of pains, uterine contractions and bleeding. Pelvic examination was performed every 6 hrly before the next dose.

Induction abortion interval was defined as time period between first dose to the expulsion of products of conception. The primary outcome measure was the success rate at 30 hr of first instillation. Success was defined as the expulsion of products of conception whether complete or incomplete within 30 hrs of the first dose.If abortion did not occur within this time limit then it was considered as "failure".In the event of failure ,pre consent was taken that termination of pregnancy would be done by surgical methods(hysterotomy) or mechanical dilatation of cervix with oxytocin infusion.

3. Observations and Discussion

Epidemiological factor	Group-A(PGE_2) (n=30)	Group-B(PGE_1) (n=30)
Mean age(years)	24	23.9yrs
Meangestational age(weeks)	17.2	17

	Dose of PGE_2 gel	Group A	Dose of PGE_1 tab	Group B	P value
Once	0.5mg	01	600µg	01	<0.5
2 times	1.0mg	25	1200 µg	05	<0.001
3 times	1.5mg	04	1800 µg	20	<0.001
4 times			2400 µg	04	-

- Mean drug instillation of group A was 2.1 times while in group B was 2.9 times which was statistically significant(P=0.0001)(unpaired Ttest)

Induction abortion Interval[hours]	Group-A (n=28/30)		Group-B (n=29/30)		P value
<6	0	0%	1	3.3%	-
6-12	1	3.3%	5	16.6%	0.22
13-18	5	16.6%	20	66.6%	0.29
19-24	20	66.6%	2	6.6%	0.39
24-30	2	6.6%	1	3.3%	0.19
Failure(>30)	2	6.6%	1	3.3%	
Mean (in hours)	21.5hr	-	15.4hr	-	<0.0001

- Majority of subjects (67%) in group A delivered between 19-24 hours, whereas majority of subjects (67%) in group B delivered between 13-18 hours, which is more important for emotional wellbeing of patient.

(As shorter induction delivery interval reduce the chances of emotional trauma to the patient). Subjects delivered within 12 hours in group A were 1 out of 30(3%) while the same in group B were 5 out of 30(17%).

Comparision of mean IAI between different studies

	Induction Abortion Interval	
	PGE_2	PGE_1
PRESENT	21.5hr	15.4hr
JAIN &MISHELL(1994)	10.6hr	12hr
M.KHOOSHIDEH(2007)	15.1hr	13.2hr

Mean induction abortion interval in PGE_2 is 21.5hr and PGE_1 is 15.4hr which was statistically significant(P<0.0001)(unpaired T-test). However in Jain and Mishell[4] et al 1994 and M.Khooshideh[5] et al 2007,the induction abortion interval in PGE_2 and PGE_1 were nearly similar and statiscally not significant

Final Outcome	*Group A(PGE_2) (n=30)*		*Group B(PGE_1) (n=30)*	
Successful	28	93.3%	29	96.6%
Failure	2	6.6%	1	3.3%

- The success rate of group A was 93.3% while that of group B was 96.6% The difference in final outcome was statistically not significant (Chi-square test).
- The failure rate of group A was 6.6% while that of group B was 3.3%.

Side effects	*Group A (PGE_2)*	*Group B (PGE_1)*
Nausea	5	7
Vomiting	2	4
Fever	4	2
Need for analgesics	3	1
Shivering	4	6
Headache	1	0
Total no. of patients	15	12

- The above table shows the relation of side effects between two groups 50% and 40% subjects in group A(PGE_2) and group B(PGE_1) respectively had side effects.
- The common side effects in both groups ware nausea,shivering, fever and vomiting .

Complication	*Group A (PGE_2)*	*Group B (PGE_1)*
Hemorrhage	02	0
Shock	0	0
Hypertonic Uterine contraction	0	0
Uterine Rupture	0	0

2 subjects in group A had hemorrhage, while in group B no subject had complication. This complication was due to prolong induction abortion interval and this was controlled by oxytocics only without any need for blood transfusion or other surgical interventions.

4. Conclusions

Second trimester pregnancy termination is still a complicated procedure in developing countries especially in rural areas. There is constant search going on for an ideal method which is 100% reliable, safe and cheap.

Second trimester termination of pregnancy using PGE_1 (Misoprostol) was found safe and effective with shorter induction abortion interval .

Compared to other drugs available for second trimester MTP PGE1 (Misoprostol) is cost effective, can be stored at room temperature ,lesser side effects and complications and with higher success rate.

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