CERVICAL PRIMING WITH SINGLE INTRAMUSCULAR INJECTION OF 15(S) 15 METHYL PROSTAGLANDIN F_2 ALPHA PRIOR TO VACUUM ASPIRATION IN 8-16 WEEKS OF PREGNANCY

by

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Vacuum aspiration (V.A.) is most commonly used method for pregnancy termination in first trimester. Recently its use is being extended to second trimester (Rajan *et al* 1980). However, cervix needs to be mechanically dilated prior to V.A. or primed by preinsertion of laminaria or Isap tents. which have its known infective morbidity. In addition, tents have added disadvantage that patient has to stay overnight in the hospital. It has been shown that prostaglandins also cause cervical dilatation and thereby resulting in easy and more complete evacuation of uterus (Toppazada *et al,* 1973; Ganguli *et al,* 1977; Karim and Prasad, 1979). Multiple intramuscular (I.M.) administration of F analogue, showed considerable promise for cervical dilatation but the gastrointestinal side effects were high with the dosage used to date. However, single I.M. injection does not seem to have been evaluated for obtaining preoperative cervical dilatation. As most of the women seeking pregnancy termination in Indian hospitals are multiparous, it was felt that lesser dosage of drug might be required to make the cervix soft and achieve adequate dilatation for V.A. With this in view a pilot study by authors in 20 multiparous women with 8 to 12 weeks of pregnancy revealed that single I.M. administration of 250 micrograms of 15(S) 15 methyl PGF_2 alpha THAM (Corboprost Tromethamine or Prostin 15 M) given 3 hours prior to V.A. effectively dilated the cervix in most of the patients without significant gastrointestinal side effects. The results seem to indicate that pretreatment with Prostin 15 M probably reduced the blood loss at operation. To investigate this further the effect of prostin 15 M was compared with group of control cases where no treatment with Protin 15 M was given and cervix had to be mechanically dilated.

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Patients and Methods

The study included 180 patients who were divided as follows:

Group I (8-12 weeks)

(a) Study group—56 women (3 nulliparae, 53 multiparae).

(b) Control group—35 women (2 nulliparae, 33 multiparae).

Group II (12 to 16 weeks)

(a) Study group—54 (6 nulliparae, 48 multiparae).

(b) Control group—35 (4 nulliparae, 31 multiparae).

All patients were hospitalised on day care basis for 5 to 6 hours. Women in study group received a single I.M. injection of 250 micrograms of Prostin 15 M in the gluteal region. 3 hours later, the degree of cervical dilatation was measured using the largest Hegor dilator that could be passed through the internal os without resistance. V.A. was then carried out. At operation amount of blood loss (including products) and other operative complications were recorded. Vital signs, gastrointestinal side effects, demand for analgesic and preoperative abortions if any, etc. were noted. No premedication with antidiarrhoeal or antiemetic agents was used in this study. The results of pretreatment with prostin 15 M were classified as good (cervical dilatation of 8 mm or more), fair (4-8 mm) and poor (0-4 mm).

Patients with known cardiac, pulmonary, renal, hepatic, epileptic or allergic disorders was excluded from the study. The patients were followed up weekly for 2 weeks. The data were analysed using student 't' test.

Results

Profile of study groups and control cases with clinical outcome and side effects is shown in Table I.

Cervical dilatation: Good cervical dilatation was noted in 80.35 per cent cases in group I and 79.62 per cent cases of group II within 3 hours of prostin 15 M treatment and no further mechanical dilatation

TABLE I

Pretreatment With Single I.M. Injection of Protein 15 M 3 Hours Prior to V.A. Profile, Clinical Outcome and Side Effects

(Data are mean ± S.D.)

Groups	No. of patients	Mean duration of pregnancy (weeks)	Mean cervical dilatation (mm)	Mean blood loss including conceptus (ml)	Side effects Mear number of		Preoperative bleeding	Request for analgesic
					Vomiting	Diarrhoea		
Group I	Study — 56	10.39	8.92 ± 2.30	55.6 ± 21.6 (N = 36)	0.17	0.23	9	1
	Control — 35	10.52	3.42 ± 1.53	64.76 ± 20.94 (N = 21)	0	0	0	0
Group II	Study — 54	12.48	9 ± 2.49	98.46 ± 39.68 (N = 48)	0.11	0.16	7	1
	Control — 35	12.00	4.42 ± 1.62	142.42 ± 57.89 (N = 35)	0.05	0	0	0

was necessary prior to V.A. In the additional 17.85 per cent cases in group I and 19.39 per cent cases in group II, there was fair cervical dilatation along with softening of cervix, thereby further mechanical dilatation of cervix was very easy. Only in 1 case in each study group, who happened to be a nullipara, there was no cervical dilatation and lot of resistance was encountered in dilating the tight internal os. Both these women experienced severe gastrointestinal side effects.

The mean cervical dilatation in study groups was 8.98 ± 2.30 mm in group I and 9 ± 2.49 mm in group II while in control cases, it was significantly less i.e. 3.42 ± 1.53 mm in group I and 4.42 ± 1.62 mm in group II respectively ($P < 0.01$). There was no detectable cervical injury in any of the patients in both study and control groups.

Blood loss: The mean blood loss increased with increasing period of gestation. However, the mean blood loss (including the conceptus) was lower in both study groups as compared to the control groups. The difference was most striking in group II study cases ($P < 0.01$). However, the difference was also observed in group I but it was not statistically significant ($P > 0.05$).

Side effects: Gastrointestinal side effects were infrequent in the study groups. The mean frequency of vomiting and diarrhoea was 0.17 and 0.23 per patient respectively in group I and 0.11 and 0.16 per patient respectively in group II. Although most patients experienced uterine cramps, only 2 nulliparous patient required analgesic for uterine pain who were later found to have no cervical dilatation. There was one instance of incomplete abortion in study group I. While 2 each of the controls cases in group I and II required subsequent curettage for incomplete abortion.

Ninety-three women of study groups came for subsequent follow-up. There was demonstrable evidence of pelvic infection in one case (1.07 per cent). However it was noted to be higher (4.9 per cent) in 61 control cases who came for follow up.

Discussion

Important role of prostaglandins in softening and ripening the cervix prior to termination of pregnancy, whether at term, preterm or in the second trimester or during first trimester has been recently realised. This subject has been reviewed by Kirton (1980). Cervical priming with prostaglandins reduces the likelihood of damage posed by mechanical dilatation and thereby avoiding immediate operative complications (like splitting of cervix. creation of false passage, injuries to vessels and bowel and uterine perforation) and possibly late complications of spontaneous abortion and preterm labour in subsequent pregnancies.

We achieved 80.35 per cent and 79.62 per cent success in group I and II respectively in obtaining good cervical dilatation (i.e. 8 mm or more) with single I.M. injection of Prostin 15 M given 3 hours prior to V.A., which is a fair indication that this procedure is effective for cervical dilatation in multiparous women.

The risk of excessive haemorrhage is present equally if not greater at abortion as with full term delivery. Rapid evacuation of uterus and uterine contraction and oxytocics will remain a corner stone in the management of such cases. The results of this study suggest that cervical priming with prostin 15 M may offer advantage over mechanical dilatation in minimising blood loss at operation, and at the same

time decrease the incidence of incomplete abortion. This may be of special importance in tropics where pre-existing anaemia in pregnancy is common in women seeking pregnancy termination. Cervical priming with Prostin 15 M given intramuscularly has the attraction of simplicity of technique and theoretically may avoid constant risk of intrauterine infection, inherent with the use of 'tents'. However, further studies are required to determine the optimum dose of Prostin 15 M to achieve effective and adequate cervical dilatation in nulliparous patient and also comparing cervical priming with prostin 15 M and laminaria or Isap tents.

Summay

Experience of single I.M. injection of 15 (S) 15 methyl PGE_2 alpha for cervical priming prior to V.A. between 8-16 weeks of pregnancy is presented. High efficacy, acceptable side effects and hospital stay of 5-6 hours, fulfill the basic requirements for its usage as an out-patient procedure prior to V.A. in 8-16 weeks of pregnancy in multiparous patient.

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