A COMPARISON OF FOLEY CATHETER AND INTRAVENOUS OXYTOCIN VERSUS INTRAVAGINAL PROSTAGLANDIN E2 FOR MID-TRIMESTER PREGNANCY TERMINATION

Abed El-Nabi Al-Bdour, MD, Wafa Najdawi, MD*, Hassan Malkawi, MD**

ABSTRACT

Objective: To compare the efficacy, safety and adverse side effects of Foley catheter with intravenous oxytocin versus intravaginal prostaglandin E2 for second trimester termination of pregnancy.

Methods: This study was carried out on 92 women at King Hussein Medical Center between January 1999 and June 2000. All women were in need of second-trimester uterine evacuation and were divided into two groups: Group 1 consisted of 46 women who were allocated to the cervical Foley catheter plus intravenous oxytocin modality for induction, while group 2 consisted of the 46 women for whom two doses of 3 mg intravaginal prostaglandin E2 at 12-hour intervals were used.

Results: Using the t-test, the mean time from initiation of termination to uterine evacuation was not significantly different between the two groups. The rate of successful fetal evacuation at 24 hours was the same. The success rate and the incidence of adverse effects were similar in both groups.

Conclusion: The use of a Foley catheter with intravenous oxytocin for mid-trimester pregnancy termination is safe and the success rate is compatible with intravaginal prostaglandin E2.

Key words: Foley catheter, Prostaglandin E2, Mid-trimester abortion.

JRMS June 2003; 10(1): 25-28

Introduction

Local application of prostaglandin E2 (PGE2) into the posterior fornix of the vagina has been widely used as a medical means of second trimester uterine evacuation. Published reports indicated that the intravaginal administration of PGE2 suppositories is safe and effective when used for this purpose [1,2].

The vaginal administration of PGE2 has been extensively studied, and a consensus exists as to its efficacy [3]. Safety is the main concern in all studies because of the occurrence of excessive uterine contractions in a dose-related basis [4]. Most of the obstetric clinical trials have evaluated the vaginal administration of different types of prostaglandins including PGE2 [4]. In our study we decided to examine the success rate of mid-trimester pregnancy termination by using an intracervical Foley catheter with intravenous oxytocin for a 24-hour period, and compare the efficacy and safety of this method with the vaginal PGE2 method.

Methods

This study was carried out on 92 women attending the antenatal outpatient clinic of King Hussein Medical Center (KHMC) between January 1999 and June 2000. All women were admitted for termination of pregnancy.

Patients were considered candidates for this study if they had a singleton pregnancy between 16-26 weeks gestation according to ultrasonographic measurements of the biparietal diameter or femur length. Patients were excluded from the study if there was contraindication to the use of the Foley catheter (e.g. spontaneous rupture of membranes) or prostaglandins (e.g. bronchial asthma).

*From the Department of Obstetrics and Gynecology, King Hussein Medical Center, (KHMC)
Correspondence should be addressed to Dr. A. Al-Bdour, P. O. Box 536 Amman 11953 Jordan
Manuscript received August 27, 2000. Accepted 5, August 2001

They were divided into an odd-numbered and an even-numbered group. In the odd-numbered group (group 1), Foley catheter with intravenous oxytocin was used while in the even-numbered group (group 2), intravaginal PGE2 was used. At our unit, provided there were no contraindications, intravenous oxytocin was given routinely with the intracervical Foley catheter in the following manner: the infusion was made of 15 units of intravenous oxytocin added to 500 ml of normal saline solution (one ml = four drops per minute). Infusion rate was increased and was titrated against strength and frequency of contractions. Patients assigned to the intracervical Foley group had a 16 F balloon-tipped Foley catheter inserted into the cervix under direct visualization by sterile techniques. Prophylactic intravenous antibiotics (single dose of 1 gm Cefloxitin) were routinely administered for this group. A speculum was placed into the vagina and the cervix was cleaned with an antiseptic solution. A 16 F balloon-tipped Foley catheter was passed through the cervix beyond the internal os and was inflated with 40 ml of normal saline solution. The catheter was taped under gentle traction to the inner aspect of the patient's thigh to release endogenous prostaglandins from the cervix. The balloon was deflated, and the Foley catheter was removed after 24 hours provided it had not been spontaneously expelled. Intravenous oxytocin was started concomitantly with the insertion of the Foley catheter.

Women assigned to the vaginal PGE2 group received a 3 mg tablet 12 hourly over a 24-hour period. Prior to each dose administration, each patient was evaluated and a cervical examination was performed. A complete blood cell count and blood type and screen were obtained for all patients at the time of admission. Pethidine 100 mg was administered intramuscularly at the patient's request for analgesia. All patients who did not have abortion at 24 hours were considered to have a therapeutic failure, and they were discharged from hospital for retrial after one week by the same method of termination, that was initially used. The duration of abortion was defined as the time in hours from the initiation of therapy until the expulsion of the fetus. A successful evacuation was defined as expulsion of the fetus within 24 hours.

After passage of the fetus, all patients received intravenous oxytocin as 30 units in one liter of lactated Ringer's solution infused at 150 ml/hour. The abortion was considered complete if the placenta and membranes were delivered within two hours of delivery of the fetus and there was absence of heavy bleeding requiring manual removal of the placenta or curettage. After abortion, the cervix and vagina were examined for lacerations. Blood loss was estimated by the physician attending the delivery. A post-delivery hematocrit was obtained approximately six hours after delivery. Maternal fever was defined as a single temperature reading more than 37.5^{o}C. The clinical data for each participant were collected and recorded on a data sheet. The primary aim was successful uterine evacuation of the fetus within 24 hours. Other aims included measuring the time interval from the start of termination to expulsion of the fetus, maternal adverse effects, the rate of complete and incomplete abortion, rate of failure and estimated blood loss.

Results

The demographic characteristics between the two groups were identical (Table I). The indications for termination were similar with the majority undergoing uterine evacuation for fetal malformations and missed abortion (Table II). Evacuation outcome variables were shown in Table III.

Table I. Demographic characteristics of the study population

	Group 1	**Group 2**	**Significance**
Mean maternal age (years)	26±8	27±2	NS
Mean gestational age (week)	19±3	19±5	NS
Primigravida (no.)	19	20	NS
Multigravida (no.)	27	26	NS

Table II. Indications for termination

	Group 1	**Group 2**
Anencephaly	6	6
Hydrops	3	2
Cystic hygroma	2	3
Aneuploidy	4	5
Abdominal wall defects	1	1
Hydrocephaly	6	5
Missed abortion	10	10
Neural tube defect	8	8
Renal anomaly	2	1

Table III. Evacuation outcome

	Group 1	**Group 2**	**Signifi-cance**
Mean evacuation time (h)	18±6.2	17±9.5	NS
Evacuation at< 24 h	40 (87%)	42 (89%)	NS
Complete evacuation	40 (87%)	42 (89%)	NS
Failure to abort	6 (13%)	4 (11%)	NS
Estimated blood loss (ml)	150±50	130±40	NS

The mean time from initiation of termination until uterine evacuation was similar in both groups (Foley catheter 18±6.2 hours; PGE2 17±8.5 hours), with no statistical significance ($p>0.5$). A large number of patients in both groups delivered the fetus successfully within 24 hours (87% vs. 89%). The six patients in the Foley catheter group and the four patients in the PGE_2 group who did not deliver by 24 hours were discharged from the hospital and were readmitted for termination

after one week by the same method used in the first trial. The incidence of side effects, nausea, vomiting, diarrhea, and fever were similar in both groups (Table IV). The number of patients requiring intramuscular analgesia was high, and was similar between the two groups (96% vs. 92%). Of those receiving analgesia, the average dose of pethidine was similar in both groups. The estimated blood loss was slightly greater in the Foley catheter group (150±50 ml) compared to the PGE2 group (130±40 ml), but this was not statistically significant ($p>0.05$). Only seven patients in both groups required blood transfusion. There were no cervical or vaginal lacerations that required surgical repair. Five patients in the Foley catheter group (12%) and six patients in the PGE2 (14%) had an incomplete abortion and required curettage for retained placental tissue ($p >0.05$). Two patients in the Foley catheter group and one patient in the PGE2 group had post-abortion endometritis requiring intravenous antibiotic therapy.

Table IV. Adverse reactions

	Group 1	Group 2	Significance
Nausea	4	5	NS
Emesis	3	4	NS
Diarrhea	1	2	NS
Fever	3	2	NS

Discussion

A variety of medical and surgical techniques have been used for mid-trimester pregnancy termination. These techniques include intravenous infusion of oxytocin, intrauterine instillation of abortifacients, extrauterine administration of abortifacients, dilation and evacuation, and hysterotomy. Numerous investigations have compared these methods for second-trimester abortion; however, no method is clearly superior to all others. In this prospective randomized study (one of the rare studies to compare intracervical Foley catheter and intravenous oxytocin with intravaginal PGE2 for second trimester pregnancy termination), we found that there was no significant difference in efficacy and safety of both methods in mid-trimester abortion. However, several studies have suggested that prostaglandins are cost-effective in termination of pregnancy and induction of labor in general [5,6]. A critical issue in the analysis of cost-effectiveness involves the alternative with which the therapy was compared. In our study the alternative was a Foley catheter and intravenous oxytocin, which are relatively inexpensive (18 Jordan Dinar = 25.71 US Dollar for each PGE2 3 mg pessary compared to 2.5 Jordan Dinar = 3.57 US Dollar for a Foley catheter). Numerous studies have compared PGE2 with other abortifacients. The 88% successful termination rate within 24 hours in our PGE2 group was consistent with that noted by other investigators [4]. In our study we noted that patients with pregnancies complicated by intrauterine fetal death and with high gestational ages were terminated rapidly. Rapid fetal expulsion rate in such pregnancies could account, in part, for their higher 24 hours cumulative delivery rate of 97%, as well as their mean delivery time of 13 hours. The same outcome was reported by Ferguson *et al* [7]. Moreover, our cases were confined to gestational ages between 16-26 weeks. Ferguson *et al* [7] included pregnancies up to 27 weeks gestation and noted that the induction-to-delivery times correlated inversely with the gestational age.

The majority of previous investigations using intravaginal PGE2 for mid-trimester pregnancy termination reported a successful 24-hour evacuation rate of 40-62%. Our current study had a comparable success rate of 89%. This is similar to the rate reported by Jain and Mishell [8]. Our patient population, and Jain and Mishell's patient population differed from the majority of previous studies in that cases complicated by intrauterine fetal deaths were included.

Few complications were noted in our study and all were treated successfully. There was no case of uterine rupture or cervical laceration. The incidence of febrile morbidity however, was 8% for patients in the Foley catheter group and (4%) in the PGE_2 group.

Neither method of second-trimester pregnancy termination undertaken in our study offered an advantage over the other by having a significantly lower incidence of adverse effects. The overall incidence of adverse effects in both the Foley catheter group and the vaginal PGE2 group was similar to that previously reported [9-12].

We conclude that intravenous oxytocin with Foley catheter for mid-trimester termination of pregnancy, particularly in multiparous patients and patients with intrauterine fetal death are a reasonable alternative to PGE2 at the dose described in our study. However, further larger randomized controlled trials are warranted before we draw any definite final conclusion.

References

1. **Owen J, Hauth JC, Winkler CL, Gray SE.** Mid-trimester pregnancy termination: A randomized trial of prostaglandin E2 versus concentrated oxytocin. *Am J Obstst Gynecol* 1992; 167: 1112-1116.
2. **Hagar DL, Valley MT, Rayburn WF, Carey JC.** Mid-trimester pregnancy termination for fetal malformation. *J Reprod Med* 1997; 42: 497-500.
3. **Sanchez-Ramos L, Kaunitz AM, Wears RL, *et al.*** Misoprostol for cervical ripening and labor induction: A meta-analysis. *Obstet Gynecol* 1997; 89: 633-642.
4. **Wing DA, Paul RH.** A comparison of different dosing regimens of vaginal administered misoprostol for pre-induction cervical ripening and labor induction. *Am J Obstet Gynecol* 1996; 175: 158-164.
5. **Mundle WR, Young DC.** Vaginal misoprostol for induction of labor: A randomized controlled trial. *Obstet Gynecol* 1996; 88: 521-525.
6. **Kramer RL, Gilson GJ, Morrison DS, *et al.*** A randomized trial of misoprostol and oxytocin for

induction of labor: Safety and efficacy. *Obstet Gynecol* 1997; 89: 387-391

7. **Ferguson JE, Burkett BJ, Pinkerton JV, *et al.*** Intra-amniotic 15 (S)-15-methyl prostaglandin E2 and termination of middle and late second-trimester pregnancy for genetic indication: A contemporary approach. *Am J Obstet Gynecol* 1993; 169: 332-340.
8. **Jain JK, Mishel DR Jr.** A comparison of misoprostol with prostaglandin E_2 for termination of second-trimester pregnancy. *N Engl J Med* 1994; 331: 290-293.
9. **Perry KG Jr, Roberts WE, Magann EF, *et al.*** Comparison of intra-amniotic 15 (S)-15-methyl-PGE2 and intravaginal prostaglandin E2 for second-trimester uterine evacuation. *J Perinatol* 1998; 18: 24-27.
10. **Nutila M, Toivonen J, Ylikorkala O, Halmesmaki E.** A comparison between two doses of intravaginal misoprostol and gemeprost for induction of second-trimester abortion. *Obstet Gynecol* 1997; 90: 896-900.
11. **Jain JK.** A comparison of misoprostol with and without laminara tents for induction of second trimester abortion. *Am J Obstet Gynecol* 1996; 175: 173-177.
12. **Kierse MJ.** Foley catheter for cervical ripening. Cochrane database of systematic reviews. Review No. 05090, April 3, 1992.