

Patients' obstetric history in mid-trimester termination of pregnancy with gemeprost: Does it really matter?[☆]

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Abstract

Objective: The objective was to investigate the importance of previous obstetric history for termination of pregnancy in the second-trimester with gemeprost alone.

Study design: A consecutive series of 423 mid-trimester inductions of abortion at our teaching hospital was reviewed. Termination of pregnancy was carried out with 1 mg of vaginal gemeprost every 3 h up to three doses over a 24-h period, repeated the following day if necessary. Failed induction was defined as women undelivered by 96 h. The study population was then stratified by gestational age, parity, gravidity and previous uterine scars. Main outcome parameters were failed induction and complication rates. Statistical analysis was performed using the χ^2 test or Fisher's exact test for categorical data, and the *t*-test and linear regression for continuous variables.

Results: No significant differences were found in the primary outcome parameters with regard to the obstetric parameters considered. The failed induction rate was 1.2% with an overall incidence of complications of 7.4%. Parity was the main factor that affected clinical response (time to abortion interval and number of pessaries).

Conclusion: Patients' obstetric history does affect the clinical response to gemeprost, but its safety and effectiveness are preserved. These data provide clinicians with important information for correct counselling.

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Keywords: Medical abortion; Gemeprost; Obstetric history; Previous uterine surgery; Counselling

1. Introduction

Different techniques for termination of pregnancy (TOP) are usually considered [1], mainly according to gestational age, and specific counselling is offered to the patient [2]. Nowadays, prostaglandin analogues are widely used, especially for second-trimester induction of abortion and several protocols have been proposed [3], reporting different failure of induction and complication rates according to medication (alone or in combinations), dosage, route of administration and patients' obstetric history. Recently, almost all studies on TOP use misoprostol in combination

with mifepristone since it is highly cost-effective [4,5]. Misoprostol is not registered for such use in many countries though, and there is a lack of large surveys on gemeprost alone and its complication rates. In fact, gemeprost is the only prostaglandin analogue that has been licensed for induction of abortion so far, although it is an expensive drug [3].

This survey aims to establish the importance of obstetric history and its impact on treatment outcomes in mid-trimester termination of pregnancy using gemeprost alone.

2. Materials and methods

Four hundred and twenty-three women have required second-trimester termination of pregnancy at the University Hospital of Bari over the past 5 years. A retrospective survey

[☆] The study took place at the General Hospital of Bari, Department of Obstetrics and Gynaecology, University of Bari, Bari, Italy.

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of all complete records was carried out in order to assess the impact of each patient's obstetric history on the outcome. We identified and selected all patients with a single viable foetus and stratified them by gestational age (confirmed by ultrasound), parity, gravidity and history of a previous uterine scar (transmural myomectomy, caesarean section), excluding from the analysis multiple pregnancies (3) or intrauterine foetal deaths (11). Induction of abortion in twin pregnancies and foetal demises was carried out using the same regimen protocol of gemeprost, but they were excluded from the analysis in order to have a homogenous sample. In fact, expulsion of dead fetuses usually requires a low dose of prostaglandins (less than three pessaries). There were only three multiple pregnancies. The study population was then made up of 409 women who had undergone medical induction of abortion, receiving gemeprost pessaries (Cervidil, 1 mg; Sero Pharma, Rome, Italy) vaginally in a dose of 1 mg every 3 h up to three pessaries over a 24-h period, after which a second course was given according to the same dosage schedule. Failed induction was defined as women undelivered after four completed 24-h courses (96 h), after which different abortion procedures were considered (oxytocin infusion or surgical uterine evacuation).

Intramuscular ergometrine maleate (Methergin, 200 µg; Novartis Farma, Origgio, Italy) was administered following expulsion of the foetus and placenta, and surgical curettage of the uterus was routinely carried out.

Main outcome parameters were failure of abortion rate, incidence of major complications (uterine rupture, need for blood transfusion) and minor complications (severe bleeding, need for vaginal/uterine packing) and were compared with some obstetric history parameters (gestational age, parity, previous abortion, previous uterine surgery). Heavy bleeding was considered to be a haemoglobin level drop exceeding 2 g/dl.

Number of pessaries for complete abortion and induction-to-abortion interval, defined as the time (hours) from the administration of the first pessary to delivery of the foetus, were recorded as secondary outcome measures.

Categorical variables were compared using the two-tailed Chi-squared test with Yates correction or Fisher's exact test and odds ratios with confidence intervals were calculated using the approximation of Woolf, as appropriate. Continuous variables were assessed using the unpaired *t*-test, whereas linear regression was performed to evaluate the relationship between secondary outcome measures and the obstetric parameters. Data were analysed using GraphPad InStat (version 3.00, GraphPad Software Inc., San Diego, CA, USA) and a *p*-value <0.05 was considered significant.

3. Results

All case records of the selected patients were available. The mean maternal age of our study population was

Table 1

Characteristics of patients and treatment outcome

	Patients, <i>n</i> = 409
Maternal age (years) (mean, S.D.)	29.9 ± 7.3
Gestational age (weeks) (mean, S.D.)	18.7 ± 3.6
Induction to abortion interval (hours) (mean, S.D.)	23.3 ± 17.0
Delivery within 24 h	246 (60.1%)
Delivery within 48 h	369 (90.2%)
Failed induction	5 (1.2%)

29.9 ± 7.3 years (range 14–49) with a gestational age of 18.7 ± 3.6 weeks (range 13–23; Table 1). Sixty-four women had had previous uterine surgery, 56 of whom had undergone one low-segment transverse caesarean section (LSCS), five had two and one had three previous LSCS; two patients had previous transmural myomectomy.

The study population was divided into equal groups using the average maternal age and gestational weeks as cut-off values.

We found no statistically significant difference in the incidence of failed induction in women younger and older than 30 years, although a greater odds ratio was reported (OR 3.62, 95% CI 0.40–32.71; Fig. 1a). Moreover, there was no statistically significant difference in failure of induction according to gestational age, parity, or previous uterine surgery.

Major complications occurred in four patients (0.98%) regardless of previous obstetric history (Fig. 1b). Three patients required a blood transfusion due to severe bleeding during the procedure. A 40-year-old unipara at 20 weeks' gestation with previous spontaneous vaginal delivery, no significant past medical history including no uterine or cervical surgery, underwent emergency laparotomy due to sharp abdominal pain and suspected uterine rupture on ultrasound (intraperitoneum collection) 8 h after the beginning of the induction (three pessaries administered). A large uneven right uterine side-wall rupture was seen and a total hysterectomy with conservation of both ovaries was carried out with uneventful postoperative recovery.

The overall rate of minor complications was 6.4% (26/409) with no significant differences with respect to maternal age, gestation, parity and gravidity (Fig. 1c).

Number of pessaries and induction-to-abortion interval were significantly inversely related to maternal age and parity whereas gestation did not affect treatment outcomes (Table 2). Fewer pessaries were needed and a shorter expulsion interval was found in the subgroup of patients with uterine scars compared with nulliparous patients.

4. Discussion

Counselling for mid-trimester termination of pregnancy is often difficult, and mainly evaluates the likelihood of failed induction and the risk of complications, taking into account the woman's obstetric history [6]. In Italy, as in

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