

MISOPROSTOL AS AN ADJUNCTIVE MEDICATION IN LATE SURGICAL ABORTION

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Brief title: Misoprostol in Late Surgical Abortion

Synopsis: Post-amniotomy intrauterine misoprostol may reduce amniotomy-to-procedure time in a late surgical abortion protocol, and it may also reduce intraoperative blood loss.

A previous case-series comparison of patients receiving misoprostol treatment within an established protocol for late abortion suggested an advantage for patients receiving misoprostol (Cytotec®; Pharmacia, GD Searle, Chicago). They had shorter amniotomy-to-procedure times and a lower variability in these intervals [1]. There did not appear to be any increased risk of complication for patients receiving misoprostol.

This report analyzes the experience with 1040 patients in a non-blinded controlled clinical trial with sequential treatment allocation. Gestations ranged from 18 through 38 weeks. All abortions were performed by a single physician in an outpatient setting. All procedures were performed over a period of 5 years ending in June, 2004. The standard protocol consisted of the induction of fetal demise by intrafetal digoxin injection on the first day of treatment, cervical placement of one laminaria on the day 1 or 2, replacement by several (4-6) laminaria on day 2 or 3, amniotomy at the beginning of day 3 or 4 followed by the immediate post-amniotomy placement of 400µg of misoprostol in lower uterine segment, induction of labor by oxytocin drip, and assisted fetal expulsion or surgical evacuation of the uterus in the operating room.

From the beginning of April, 1999, patients were alternately assigned to receive post-amniotomy misoprostol or not. There was no substitution on a given day for patients who were excluded because of criteria such as the occurrence of a spontaneous rupture of membranes prior to the scheduled amniotomy, visible membranes at the time of amniotomy, or unusually rapid fetal expulsion (30 minutes or less following amniotomy). Of 1204 consecutive patients, 164 were excluded for these and other criteria such as specific indications or contraindications for misoprostol use.

Treatment patients (N=522) received 400µg of misoprostol placed in the lower uterine segment just after amniotomy on the final (3rd or 4th) day of treatment. Control patients (N=518) did not receive misoprostol. All patients were informed of a wide variety of specific known risks associated with the abortion procedure within this established protocol by a trained counselor. Following a review of the protocol, alternatives, and risks with the patient, consent was obtained and witnessed by the physician. No separate consent for the use or nonuse of misoprostol was sought or obtained, but all patients gave informed consent prior to the first step on the first day.

Following amniotomy and labor induction on the final day of treatment, the judgment of when the patient was taken to the operating room for completion of the procedure by assisted fetal expulsion or surgical evacuation was made on a case-by-case basis.

We defined major complications using criteria at the Centers for Disease Control: major unintended surgery, hemorrhage requiring transfusion, or pelvic infection with 2 or more days of fever and a peak of at least 40°C or with hospitalization for 11 or more days [2].

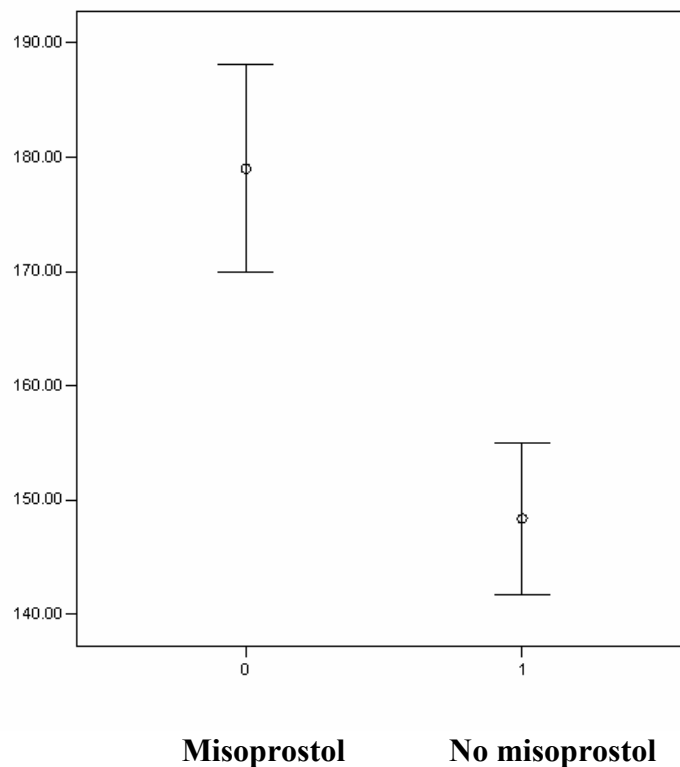
Pre-operative estimates of fetal age ranged from 18 to 38 menstrual weeks. Follow-up contact was obtained with 51% of all patients. Seventy six patients (6.3%) had a history of previous cesarean section, and 20.8% (N=250) of all patients sought assistance because of a diagnosed fetal disorder. There were 16

cases of multiple gestation including one case of conjoined twins and one triplet gestation. Ten of the patients with multiple gestation, including one with conjoined twins, were included in the controlled study.

The final estimate of gestational age as defined by fetal foot length [3] was 18-38 menstrual weeks, with a median of 24. The median procedure time for all cases was 8 min, with a mean of 10.8 and a range of 5 to 453. The median blood loss was 200 ml, with a mean of 235 and a range of 10-1250. While both gestational age and procedure duration were positively correlated with increased blood loss ($t = 4.886$, $t = 4.625$, $P < .0001$), misoprostol tended to reduce blood loss ($F = 5.21$; $P = 0.023$) as well as procedure duration ($F = 1.875$; $P = .171$, N.S.)

Mean amniotomy-to-procedure times were shorter by 30 min for patients receiving misoprostol (177 min vs. 147 min; Figure 1), and there was 26% more variability among controls not receiving misoprostol (ANOVA $F=33.037$, $P<0.0001$).

Fig 1. Mean Amniotomy-to-Procedure Times, In Minutes, by Treatment With Misoprostol, with 95% Confidence Intervals



In this series, there were 92 minor complications (8.9%) of which 74 were blood loss of more than 500 ml. Nine patients required re-aspiration (0.9%). Three of the four patients (0.4%) who experienced minor cervical lacerations, all sutured primarily, had received misoprostol.

Patients receiving misoprostol had a lower rate of an intraoperative blood loss of more than 500 ml ($X^2 = 765$, $P < .0001$), but patients with a history of cesarean delivery ($N = 67$) had a generally higher risk of this minor complication ($X^2 = 789$, $P < .0001$). There were no cases of uterine rupture or uterine perforation, and there were no major complications of any kind. References

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