



Cesarean Delivery Rates Among Nulliparous Women With Elective Induction of Labor Compared With Expectant Management at 39 Weeks' Gestation

Written by Toni Rizzo

Elective induction of labor (IOL) is not uncommon at 39 weeks' gestation, but prospective data on perinatal outcomes and ultimate mode of delivery are limited compared to expectant management (EM). The Elective Induction of Nulliparous Labor study [Miller NR et al. *Obstet Gynecol* 2014; NCT01076062] was presented by Nathaniel Miller, MD, Carl R. Darnall Army Medical Center, Fort Hood, Texas, USA. The researchers' objectives were to evaluate the incidence of cesarean delivery and perinatal outcomes among women who deliver by elective IOL compared with spontaneous labor.

A total of 8899 pregnant women were screened between March 2010 and February 2014. Nulliparous women, aged 18 to 40 years, with an uncomplicated pregnancy and a Bishop score ≥ 5 receiving care at a single medical center who met the inclusion criteria and consented to randomization were randomized to IOL at 39 weeks (n=82) versus EM (n=80). Exclusion criteria included multiparity, <38.0 or $>38+6$ weeks estimated gestational age (EGA); nonvertex presenting; contraindications to labor; multiple

gestation; and current medical indication for IOL. The women randomly assigned to EM received standard of care, including routine clinic appointments until delivery, and nonstress testing during their 41st week if they had not delivered by then. Women in the EM group who did not go into labor by 42 weeks were scheduled for IOL. The a priori power analysis assumed a cesarean delivery rate of 20% in the control/EM group, and was designed using a p of 0.05 and a power of 0.8 to detect a 2-fold increase in the cesarean delivery rate in the IOL group.

Baseline analysis found a significantly higher body mass index in the IOL group (32.2 ± 4.5 kg/m²) versus the EM group (30.2 ± 4.1 kg/m²; p=0.03) and a higher Bishop score at admission in the EM group (7.7 ± 2.7) versus the IOL group (5.2 ± 2.4 ; p<0.01).

Analysis found an increased trend but no statistically significant difference in cesarean deliveries when comparing the IOL group (30%, n=25) with the EM group (18%, n=14; relative risk, 1.7; 95% CI, 0.97 to 3.06; p=0.06; Table 1).

There were no significant differences in perinatal maternal or neonatal outcomes, with the exception of increased maternal length of stay on the delivery floor in the IOL group (1464 ± 544 minutes) compared with the EM group (1028 ± 544 minutes; p<0.01; Table 2).

There were no statistically significant differences in indications for cesarean delivery between the 2 groups, including fetal heart rate abnormalities, arrest of descent, and suspected macrosomia. Cesarean deliveries were

Table 1. Mode of Delivery by Arm of Randomization

Mode of Delivery	EM (n=79)	IOL(n=82)	Relative Risk (95% CI)	p Value
Cesarean	18% (14)	30% (25)	1.7 (0.97-3.06)	0.06
Spontaneous or operative vaginal delivery	65% (82)	57% (70)	0.8 (0.71-1.01)	0.06

EM=expectant management; IOL=induction of labor.

Table 2. Secondary Maternal and Neonatal Outcomes

Outcome	EM	IOL	p Value
Chorioamnionitis	9% (11)	12% (14)	0.5
Meconium stained amniotic fluid	14% (18)	6% (7)	0.08
Maternal transfusion	4% (5)	3% (4)	0.5
Neonatal ICU admission	12% (15)	12% (15)	0.6
Neonatal birth weight (grams, mean [SD])	3513 (493)	3401 (393)	0.1
EBL (mL, mean [SD])	374 (271)	4445 (301)	0.1
Maternal L&D length of stay (minutes, mean [SD])	1028 (544)	1464 (544)	<0.01

EM=expectant management; IOL=induction of labor; ICU=intensive care unit; EBL=estimated blood loss; L&D=Labor and Delivery; SD=standard deviation.

Table 3. Indications for Cesarean Delivery by Arm of Randomization.

Indication	EM (n=14)	IOL (n=28)	Relative Risk (95% CI)	p Value
Fetal heart rate abnormalities	5 (36%)	4 (14%)	0.4 (0.13-1.26)	0.14
Arrest of dilation	5 (36%)	18 (64%)	1.8 (0.85-3.83)	0.09
Arrest of descent	3 (21%)	5 (18%)	0.8 (0.23-3.0)	0.78
Suspected macrosomia	1 (7%)	0 (0)	NA	

EM=expectant management; IOL=induction of labor.

more likely to have been done for arrest of dilation in the IOL group (64%) compared with the EM group (36%). The difference was not statistically significant, but the study was not designed to be powered to detect a difference in this outcome (Table 3).

Using the analysis criteria stated earlier, the authors of this study concluded that women who received IOL at 39 weeks did not have a statistically significant increase in cesarean delivery compared with those expectantly managed. Larger prospective multicenter studies are needed to produce further evidence on the common practice of elective IOL.

Mifepristone and Misoprostol as Effective as Osmotic Dilation for Second-Trimester Termination

Written by Nicola Parry

Amy E. Paris, MD, Boston University School of Medicine, Boston, Massachusetts, USA, presented results from a prospective randomized clinical trial demonstrating that when compared with mechanical methods, pharmacologic cervical preparation does not prolong procedure times in patients undergoing surgical evacuation of second-trimester pregnancies and is acceptable to both operators and patients [Paris AE et al. *Obstet Gynecol* 2014].

Cervical preparation is recommended before surgical evacuation of second-trimester pregnancies, and in the United States, it is achieved via mechanical methods (osmotic dilators [ODs]), pharmacologic agents (misoprostol and mifepristone), or a combination of both techniques [Fox. *Contraception* 2014; Newmann. *Cochrane Database Syst Rev* 2010]. Mifepristone is considered more effective than misoprostol for first-trimester surgical abortion and between 14 and 16 weeks of gestation, but it is noninferior to ODs with respect to procedure time [Borgatta L et al. *Contraception* 2012; Kapp N et al. *Cochrane Database Syst Rev* 2010; Carbonnel JL et al. *Contraception*

2007]. The combination of mifepristone and misoprostol may also effectively permit evacuation, and it has been shown to be more effective than misoprostol alone for second-trimester surgical abortion.

Although prostaglandins and ODs have been used and studied as cervical preparations before second-trimester surgical abortion, there is no consensus as to which method is superior with regard to safety, procedure time, need for additional dilation, ability to perform the procedure, or patient and physician acceptability [Newmann SJ et al. *Cochrane Database Syst Rev* 2010]. With this in mind, Prof. Paris and colleagues conducted a randomized controlled study to compare the efficacy of pharmacologic versus mechanical cervical preparation before surgical evacuation at 15 to 18 weeks.

The primary endpoint of the study was total abortion time (from insertion of the speculum to its removal) and total operative time. Secondary outcomes were operator- and patient-related experiences.

Fifty women (age, 18 to 45 years; gestational age, 15 to 18 weeks) undergoing surgical abortion were prospectively and randomly assigned to 2 cervical preparation groups. Baseline characteristics were similar in both groups (mean age, 26 years; mean gestational age, 16±2 weeks; 30% were nulliparous; 20% had undergone a previous second-trimester surgical abortion via ODs).

Women in the pharmacologic preparation group received mifepristone (200 mg, orally) 24 hours before the procedure and misoprostol (400 µg, buccally) 2 hours before. Those in the mechanical preparation group underwent OD insertion 24 hours before the procedure.

There was no difference between the pharmacologic and OD groups in the primary outcome of median total abortion time (13.5 vs 14.0 minutes; p=0.99) and operative time (from intrauterine instrumentation to speculum removal; 7.0 vs 8.5 minutes; p=0.51).

With respect to secondary outcomes, physicians rated the ease of procedure similarly for both methods. However, women in the OD group reported more discomfort overnight and indicated that they would prefer mifepristone if they ever needed another procedure.