# A Preventive Approach to Obstetric Care in a Rural Hospital: Association Between Higher Rates of Preventive Labor Induction and Lower Rates of Cesarean Delivery

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Conflicts of interest: The pilot study for this project was funded by Forest Pharmaceuticals, Inc, in 2000. In addition, Forest Pharmaceuticals bas provided, at no cost, its dinoprostone vaginal insert cervical ripening product for use in an ongoing randomized clinical trial of AMOR-IPAT. This prospective study, which is supported by the NICHD/ NIH and the Pennsylvania Hospital Foundation, is being performed within the University of Pennsylvania Health System.

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#### ABSTRACT

**PURPOSE** Annual cesarean delivery rates in North America are increasing. Despite the morbidity associated with cesarean delivery, a safe preventive strategy to reduce the use of this procedure has not been forthcoming. During the 1990s, clinicians in a rural hospital developed a method of care involving prostaglandin-assisted preventive labor induction. An inverse relationship was noted between yearly hospital rates of labor induction and cesarean delivery. The purpose of our study was to compare cesarean delivery rates between practitioners who often used preventive induction and practitioners who did not, while controlling for patient mix and differences in practice style.

**METHODS** Between 1993 and 1997, different hospital practitioners used riskguided prostaglandin-assisted preventive labor induction with differing intensity. We used a retrospective cohort design, based on the practitioner providing prenatal care, to compare birth outcomes in women exposed to this alternative method of care with those in women not exposed. Multiple logistic regression analysis controlled for patient characteristics and clustering by practitioner.

**RESULTS** The exposed group (n = 794), as compared with the nonexposed group (n = 1,075), had a higher labor induction rate (31.4% vs 20.4%, P <.001), a greater use of prostaglandin E<sub>2</sub> (23.3% vs 15.7%, P <.001), and a lower cesarean delivery rate (5.3% vs 11.8%, P <.001). Adjustment for cluster effects, patient characteristics, and the use of epidural analgesia did not eliminate the significant association between exposure to this preventive method of care and a lower cesarean delivery rate. Rates of other adverse birth outcomes were either unchanged or reduced in the exposed group.

**CONCLUSIONS** A preventive approach to reducing cesarean deliveries may be possible. This study found that practitioners who often used risk-guided, prostaglandin-assisted labor induction had a lower cesarean delivery rate without increases in rates of other adverse birth outcomes. Randomized controlled trials of this method of care are warranted.

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#### INTRODUCTION

esarean delivery is a major surgical procedure. Although modern techniques have made cesarean delivery safer than in years past, its use is still associated with greater morbidity than vaginal delivery.<sup>1-3</sup> Policy makers have suggested that population cesarean delivery rates of 15% would be optimal<sup>4,5</sup>; however, US annual cesarean delivery rates have remained greater than 20% for several decades and are currently increasing.<sup>6</sup> In 2005, the overall US cesarean delivery rate reached an all-time high of 30.2%.<sup>7</sup> Many reasons have been postulated to explain

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the discrepancy between the recommended and actual cesarean delivery rates, including changing patient demographics, changing practice standards related to both malpresentation and assisted vaginal delivery, and medical-legal issues.<sup>4,8,9</sup> Risk-based primary preventive strategies, commonly used to reduce untoward outcomes in other fields of medicine,<sup>10</sup> have not been developed for preventing cesarean delivery, however.

Between 1984 and 1997, a rural New England hospital experienced large variations in its annual cesarean delivery rates. An inverse relationship was noted, in this clinical setting, between annual cesarean delivery rates and annual labor induction rates. This study analyzes births during the final 4 years of this time period (1993-1997), when labor induction rates were at their highest levels and cesarean delivery rates were at their lowest levels. We hypothesized that preventive labor induction, if used in response to an individual woman's risk profile and if assisted as needed with prostaglandin  $E_2$  (PGE<sub>2</sub>) cervical ripening, might represent a strategy for the safe reduction of cesarean delivery use. We call this method of care the Active Management of Risk in Pregnancy at Term (AMOR-IPAT).

The AMOR-IPAT method of care has its basis in fundamental preventive theory. Preventive theory suggests that a preventive method of medical care must contain 4 key components: the identification of an undesirable outcome, the recognition of risk factors for that outcome, the isolation of a latent period between the identification of risk factors and the development of the outcome, and the use of an intervention within the latent period that either modifies or prevents the development of the outcome.<sup>10,11</sup> AMOR-IPAT envisions the term period of pregnancy (ie, between 38 weeks', 0 days' gestation and 41 weeks', 6 days' gestation) as a latent period between the identification of prenatal risk factors and the development of a need for cesarean delivery. Because the 2 main indications for primary cesarean delivery—cephalopelvic disproportion and uteroplacental insufficiency-increase as a function of increasing gestational age during the term period of pregnancy,<sup>12</sup> and because the effect of increasing gestational age on cesarean delivery is exacerbated by the presence of specific obstetric risk factors for cephalopelvic disproportion and uteroplacental insufficiency,<sup>13,14</sup> the optimal time of delivery varies depending on each woman's individual risk profile.<sup>15</sup> If spontaneous labor does not develop before the upper limit of each woman's optimal time of delivery, then AMOR-IPAT uses preventive induction to ensure that delivery occurs within the optimal time of delivery. The estimation of each woman's upper limit of the optimal time of delivery is directly related to the number and nature of her obstetric risk factors (see Supplemental Appendixes 1 and 2, available onlineonly at http://www.annfammed.org/cgi/content/ full/5/4/310/DC1).<sup>11,16</sup> Within the term period, the greater the identified risk, the earlier preventive labor induction is offered. PGE<sub>2</sub>, either in gel form or as a vaginal insert, is used before preventive labor induction when the cervix is unfavorable (modified Bishop score <6).<sup>17,18</sup> AMOR-IPAT was frequently used at the study hospital during the 4-year study period evaluated by this investigation.

#### METHODS

We used a retrospective cohort design, based on prenatal care practitioner, to evaluate the hypothesis that women exposed to AMOR-IPAT would have lower rates of cesarean delivery than women exposed to more traditional care. In addition, we sought to evaluate the hypothesis that women exposed to AMOR-IPAT would not have higher rates of other adverse birth outcomes.

We used the following definitions in our study. Pregnancy at term refers to 38 weeks', 0 days' to 41 weeks', 6 days' gestation. Labor augmentation indicates situations wherein labor had started and/or delivery was inevitable, but additional stimulation was needed (eg, prodromal labor, premature rupture of membranes, secondary arrest of labor, or dystocia). Labor induction denotes an intervention that artificially initiated a chain of events resulting in uterine contractions, cervical dilatation, and delivery. An indicated induction is an induction initiated for reasons approved by the American College of Obstetricians and Gynecologists (ACOG),<sup>19</sup> whereas a preventive induction is an induction based on AMOR-IPAT risk scoring. An elective induction is an induction not supported by either ACOG or AMOR-IPAT criteria. An unfavorable cervix indicates one with a modified Bishop score of less than 6.17,18

Institutional review board approval was obtained from both the University of Pennsylvania and the study hospital. During the 1990s, approximately 700 infants per year were delivered in the study hospital. Data concerning individual practitioner induction activities during the 4-year study period (1993-1997) were collected. Practitioners were identified as high users of AMOR-IPAT if their 4-year rates of overall labor induction and PGE2 use both were 21% or greater and their preventive labor induction rate was greater than 15%. Practitioners were identified as low users if their 4-year rate of overall labor induction or PGE<sub>2</sub> use were less than 21%, or their rate of preventive labor induction was less than 15%. These percentages were calculated for each practitioner using data from all women treated by that practitioner during

the 4-year study period as the denominator. There were marked variations in the rates of labor induction, preventive labor induction, and PGE<sub>2</sub> use among the hospital's maternity-care practitioners, and these practitioners generally fit into either a higher or a lower combined-use category. For example, 2 of the authors (J.M.N., D.L.Y.) practiced at the study hospital during the study period, and they both had high rates of overall labor induction, preventive labor induction, and  $PGE_2$  use. Both were clearly high users, as were 3 of their colleagues. By these same criteria, 10 practitioners were clearly low users. The AMOR-IPAT status of 1 practitioner was somewhat ambiguous. This family physician had a 20.4% induction rate and a 16.3% preventive labor induction rate, but a PGE<sub>2</sub> usage rate of only 10.2%. In addition, this physician worked closely with 2 other physicians who were definitely low users. For the purpose of this study, this practitioner was considered a low AMOR-IPAT user.

Women who received their prenatal care from high users of AMOR-IPAT were considered exposed whether they gave birth after induced, augmented, or spontaneous labor. Women who received their prenatal care from low users were considered nonexposed. We used exposure status, rather than mode of labor onset, to determine study group assignment because of our belief that a high rate of prostaglandin-assisted preventive labor induction changes the nature of induction in each study group and lowers the average gestational age at delivery in the induced, augmented, and spontaneous labor portions of any given exposed group.<sup>16</sup>

A pilot study showed that exposure to AMOR-IPAT was associated with a reduction in cesarean delivery rate from 15% to 9%. A power analysis ( $\alpha$ , .05,  $\beta$ , 0.9) indicated that we would need approximately 700 term births in each study group, or 2 years of hospital data, to determine that this rate reduction was statistically significant. Because we were interested in other, less common outcomes and wished to perform a variety of subgroup analyses, we chose to evaluate 4 full years of hospital data.

We considered for this study all women who gave birth at the study hospital between October 1, 1993, and September 30, 1997. Using the hospital's delivery logbook, we identified 2,371 potential participants. We excluded those who gave birth before 38 weeks, 0 days of gestation (407) and duplicate logbook entries for the same pregnancy (33). We also excluded those with multiple gestations (31), those who did not receive prenatal care from a study hospital practitioner (11), and those with a uterus not compatible with a trial of labor, defined as having more than 2 previous cesarean deliveries, a major uterine anomaly, or prior transmural surgery (10). Finally, we excluded women who gave birth before hospitalization (5), women with placenta previa (4), and women whose labor and delivery chart could not be located (5). Some women had several exclusion factors. The remaining 1,869 women were identified as study participants.

We developed a data abstraction form based on Microsoft Access (Microsoft Corp, Redmond, Washington) that contained 186 fields. Trained study personnel performed data abstraction, and the data were entered into a Microsoft Access database. These procedures were validated during the pilot study. Ten percent of chart abstractions and data entries were repeated during the course of the study to confirm reliability.

Study data were transferred to STATA version 5.0 (Stata Corp, College Station, Texas). Means, medians, ranges, and standard deviations were calculated for continuous variables present in the 2 study groups. Parametric and nonparametric variables were compared using the Student *t* test and the Wilcoxon rank sum test, respectively. Categorical variables and collapsed continuous variables were compared using  $\chi^2$  analysis (Fisher exact method, when appropriate). Risk ratios (RRs), 95% confidence intervals (CIs), and P values were tabulated. A P value of less than .05 identified statistical significance. The association between AMOR-IPAT exposure and cesarean delivery was initially measured with  $\chi^2$  analysis and then further assessed using multiple logistic regression analysis to adjust for possible confounding covariates. With the exception of epidural analgesia, covariates considered for our multiple logistic regression models were those that could be identified before 38 weeks of gestation. We used this cutoff because covariates that occurred after 38 weeks, such as preeclampsia, premature rupture of membranes, and intrapartum fever, were believed to possibly lie in the causal pathway between nonexposure status and cesarean delivery.<sup>16</sup> Rates of induction and cesarean delivery were determined for various risk substrata.

Based on our study design, we gave special attention to evaluating the potential impact of clustering (of births with practitioners) on our primary outcome. We determined the intracluster correlation coefficient (ICC) for cesarean delivery in each study group using prenatal care practitioner as the cluster variable. The finding of a high ICC would suggest that an important cluster effect was present. We also determined the magnitude of design effect in the evaluation of different levels of cesarean delivery in the 2 study groups. The magnitude of the design effect in a given study for a given outcome is directly related to the impact of cluster-related issues on the statistical significance of study outcomes.<sup>20,21</sup> Specifically, the closer the design effect is to unity (ie, 1.000), the less clustering affects study findings. Finally, we included adjustment for clustering by prenatal care practitioner in our final logistic regression modeling of the relationship between study group and cesarean delivery. We then compared the point estimates and CIs of this final model with the model that did not include cluster adjustment.

To evaluate the safety of the AMOR-IPAT method of care, we measured rates of birth outcomes other than cesarean delivery and compared them between the 2 study groups. Neonatal intensive care unit admission, major perineal trauma (3rd- or 4th-degree tear), assisted (vacuum or forceps) vaginal delivery, and low Apgar scores (1-minute score <4, 5-minute score <7) were identified a priori as major adverse birth outcomes. For the analyses of these birth outcomes, we did not apply Bonferroni or Holm corrections because our primary intent was to identify potential safety issues rather than claim additional benefits. We performed number needed to treat analyses to provide 2 estimates: (1) the number of pregnancies that would need to be exposed to the AMOR-IPAT method of care to prevent 1 cesarean delivery, and (2) the number of additional inductions that would be needed using AMOR-IPAT to prevent 1 cesarean delivery.

#### RESULTS

Five practitioners were identified as high AMOR-IPAT users, and women who received prenatal care from these practitioners comprised the exposed group (n = 794). The remaining 11 practitioners were identified as low users, and women who received prenatal care from these practitioners comprised the nonexposed group (n = 1,075) (Table 1). We (J.M.N., D.L.Y.) observed that practitioners with lower preventive induction and PGE<sub>2</sub> use rates were somewhat wary of the AMOR-IPAT approach, although their use of preventive labor induction and PGE<sub>2</sub> was higher during the study period than before or after. We also observed that practitioners with higher preventive labor induction and PGE<sub>2</sub> use rates were openly enthusiastic about implementing the AMOR-IPAT approach. The division of women in this study based on prenatal practitioner is therefore supported by both actual rates of AMOR-IPAT-related clinical activities and the authors' firsthand knowledge of attending physician attitudes concerning AMOR-IPAT.

The exposed and nonexposed groups had both similarities and differences (Table 2). The use of Bonferroni corrections for multiple comparisons would have made the 2 study groups appear more similar.

Consistent with our study design, the exposed group, as compared with the nonexposed group, had statistically higher rates of labor induction (31.4% vs 20.4%, P <.001), preventive labor induction (21.2% vs 8.1%, P <.001), and PGE<sub>2</sub> use (23.3% vs 15.7%, P < .001 (Tables 2 and 3). These differences were present across the nulliparous, multiparous, and previous cesarean delivery subgroups (data not shown). In con-

Practitioner Specialty*	Number of Deliveries <sup>†</sup>	Overall Induction Rate, %	Preventive Induction Rate, %	PGE₂ Use Rate, %	Attendance Rate,‡ %
Exposed group (n = 794 deliveries)					
Family physician 1	104	50.0	38.5	40.4	91.3
Family physician 2	80	35.4	15.8	24.4	95.1
Family physician 3	91	38.5	19.8	27.5	95.6
Obstetrician 1	438	29.0	17.1	20.8	90.8
Family physician 4	79	25.3	15.2	21.5	91.1
Nonexposed group (n = 1,075 deliveries)					
Obestritician 2	231	28.1	10.8	10.4	90.8
Family physician 5	49	20.4	16.3	10.2	87.5
Family physician 6	75	18.7	9.3	21.3	96.0
Family physician 7	136	19.8	7.4	16.2	94.0
Jbstetrics group§	584	18.8	5.1	18.2	97.7

Table 1. Practitioner Characteristics by Study Group Exposure to Active Management of Risk in

 $PGE_2 = prostaglandin E_2$ 

Notes: Number of deliveries and practitioner rates of labor induction (all types), preventive labor induction, PGE2 usage, and attendance at continuity delivery.

\* All obstetricians and no family physicians or certified nurse-midwives had cesarean delivery privileges at the study hospital.

+ Total N = 1.869 deliveries

‡ The percentage of labors the practitioner attended; 21 patients did not have information concerning delivering physician.

§ This large obstetrics group had 7 practitioners and shared both prenatal care and deliveries. The composition of this group—practitioner type (number of deliveries)was obstetrician (256), obstetrician (132), obstetrician (12), certified nurse-midwife (143), obstetrician (3), certified nurse-midwife (2), and obstetrician (36).



trast, rates of rupture of membrane on admission and rates of ACOG-approved induction indications were similar in the 2 groups. Epidural analgesia for labor was uncommon at the study hospital, and the exposed group had a lower rate than the nonexposed group (6.0% vs 15.4%, P <.001).

The primary study outcome, cesarean delivery rate, was significantly lower in the exposed group as

## Table 2. Comparison of Demographic, Prenatal, and Intrapartum Risk Factors Between Study GroupsExposed or Not Exposed to Active Management of Risk in Pregnancy at Term (AMOR-IPAT)

	Exposed	Noneynosed	Pick Patio	D
Factor	(n = 794)	(n = 1,075)	(95% CI)	r Value
Demographic				
Age, mean, y	26.0	26.7	-	.005*
Advanced age (≥35 y) at delivery, %	7.7	8.7	0.92 (0.75-1.13)	.44
Single, %	34.3	28.6	1.16 (1.04-1.29)	.008
Private medical insurance, %	61.7	71.4	0.78 (0.70-0.87)	<.001
White, %	98.0	97.3	1.20 (0.81-1.78)	.36
Family physician practitioner, %	44.7	24.1	1.65 (1.49-1.83)	<.001
Prenatal				
Nulliparous, %	42.1	45.2	0.92 (0.83-1.03)	.19
Multiparous, no prior cesarean, %	51.3	46.3	1.12 (1.01-1.24)	.04
Aultiparous, prior cesarean, %	6.7	8.5	0.86 (0.69-1.07)	.16
.ate prenatal care (>4th mo), %	9.7	9.6	1.01 (0.84-1.20)	.94
Dating ultrasound (12-20 wk), %	71.8	62.5	1.28 (1.13-1.45)	<.001
Ligarette use, %	29.0	29.4	0.99 (0.88-1.11)	.88
History of hypertension, %	2.5	2.0	1.15 (0.84-1.58)	.42
History of asthma, %	7.8	7.3	0.96 (0.79-1.19)	.79
Previous cervical surgery, %	20.6	20.9	0.99 (0.87-1.13)	.91
Previous assisted (vacuum or forceps) vaginal delivery, %	3.2	2.4	1.16 (0.87-1.54)	.39
Previous macrosomia (>4,000 g), %	0.8	1.3	0.91 (0.77-1.09)	.37
Previous low birth weight (<2,500 g), %	1.8	2.9	0.72 (0.47-1.13)	.13
short stature (≤62 in), %	26.1	30.0	0.89 (0.79-1.01)	.06
ligh BMI (≥30 kg/m²) at conception, %	17.5	15.5	1.08 (0.95-1.24)	.26
excess weight gain (>30 lb), %	44.5	50.8	0.86 (0.78-0.96)	.008
ize greater than dates (≥3 cm), %	7.6	5.4	1.21 (1.01-1.46)	.07
size less than dates (≤3 cm), %	1.4	2.8	0.64 (0.41-0.98)	.04
Anemia in first trimester (Hgb <11 g/dL),† %	6.0	3.7	1.33 (1.05-1.66)	.03
High glucose (>135 mg/dL) on 50-g glucose test, %	26.0	24.3	1.06 (0.91-1.23)	.47
Gestational diabetes, %	7.4	6.9	1.04 (0.86-1.28)	.65
suspected IUGR or oligohydramnios, %	0.9	3.0	0.42 (0.21-0.82)	.002
ntrapartum			· · ·	
Gestational age on admission (calculated)	39 wk 5 d	39 wk 6 d	_	.01*
Bishop score on admission, mean	4.97	5.12	_	.05*
Bishop score <6 on admission, %	55.9	50.0	1.15 (1.03-1.28)	<.01
PGE <sub>2</sub> gel cervical ripening, %	23.3	15.7	1.30 (1.15-1.46)	<.001
Ruptured membrane on admission, %	23.7	22.7	1.03 (0.91-1.17)	.62
MAP on admission, mean, mm Hg	93.4	94.0	_ /	.09*
Preeclampsia, %	3.6	3.7	0.99 (0.74-1.31)	1.00
Aalpresentation (nonvertex), %	1.6	3.4	0.62 (0.39-0.99)	.03
ntrapartum oxytocin use (any), %	49.5	51.6	0.95 (0.86-1.06)	.37
Epidural analgesia, <sup>‡</sup> %	6.5	15.7	0.39 (0.28-0.53)	<.001
Temperature maximum >100.4°F. %	0.8	1.5	0.64 (0.32-1.27)	.19
Fhick meconium on ROM, %	1.2	3.8	0.45 (0.25-0.75)	.001
Elective repeated cesarean, %	0.9	1.2	0.82 (0.45-1.50)	.65

CI = confidence interval; BMI = body mass index; Hgb = hemoglobin; IUGR = intrauterine growth restriction; PGE<sub>2</sub> = prostaglandin E<sub>2</sub>; MAP = mean arterial pressure; ROM = rupture of membranes.

\* Calculated using the Wilcoxon rank-sum test.

+ Numerator/denominator were 39/649 in the exposed group and 36/981 in the nonexposed group.

‡ Epidural analgesia during labor, excluding patients given epidural analgesia immediately before cesarean delivery.

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compared with the nonexposed group (5.3% vs 11.8%; RR = 0.56; 95% CI, 0.43-0.73) (Table 3), and in all 3 parity subgroups (nulliparous: 8.1% vs 14.2%, P = .008; multiparous: 1.2% vs 4.2%, P = .008; previous cesarean:

Table 3. Labor Induction and Cesarean Delivery: Rates and Indications

18.9% vs 40.1%, P = .01). The 2 major indications for cesarean delivery—cephalopelvic disproportion and fetal intolerance of labor—both occurred less frequently in the exposed group. The results of the final

Measure	Exposed (n = 794)	Nonexposed (n = 1,075)	Risk Ratio (95% CI)	P Value
Induction rates				
Overall induction	31.4	20.4	1.37 (1.23-1.52)	<.001
Preventive induction	21.2	8.1	1.70 (1.53-1.89)	<.001
Indicated induction	10.2	12.3	0.88 (0.74-1.06)	.18
Nulliparous induction	27.8 (93/334)	20.6 (100/486)	1.25 (1.05-1.50)	.02
Multiparous induction	31.7 (129/407)	19.3 (96/498)	1.40 (1.21-1.62)	<.001
Previous cesarean induction	50.9 (27/53)	25.3 (23/91)	1.95 (1.29-2.96)	.002
Induction indications				
ACOG-approved indication				
Postdates 41-42 wk	5.5	6.0	0.96 (0.76-1.21)	.76
Postdates >42 wk	0.3	0.5	0.67 (0.21-2.17)	.71
Preeclampsia	1.9	3.0	0.75 (0.49-1.14)	.18
Fetal compromise	1.4	1.5	0.96 (0.61-1.52)	1.00
History of rapid labor	0.5	0.4	1.18 (0.59-2.36)	.73
Other	0.6	0.9	0.78 (0.38-1.61)	.60
Preventive			. ,	
Impending macrosomia	7.2	2.4	1.66 (1.42-1.94)	<.001
Previous cesarean delivery	2.4	0.7	1.67 (1.30-2.15)	.005
Impending preeclampsia	1.4	0.4	1.74 (1.27-2.37)	.02
Gestational diabetes	0.6	0.6	1.07 (0.56-2.05)	1.00
Other	9.6	4.0	1.56 (1.34-1.80)	<.001
Cesarean delivery rates			. ,	
Overall cesarean delivery	5.3	11.8	0.56 (0.43-0.73)	<.001
Nulliparous – overall	8.1 (27/334)	14.2 (69/486)	0.66 (0.48-0.92)	.008
Noninduced labor	7.1 (17/238)	6.8 (25/368)	1.03 (0.71-1.51)	.87
Induced labor	7.5 (7/93)	26.0 (26/100)	0.39 (0.20-0.77)	<.001
Planned cesarean delivery	100 (3/3)	100 (18/18)	-	
Multiparous – overall	1.2 (5/407)	4.2 (21/498)	0.42 (0.19-0.93)	.008
Noninduced labor	1.1 (3/276)	1.8 (7/398)	0.73 (0.28-1.89)	.54
Induced labor	0.0 (0/129)	10.4 (10/96)	0	.001
Planned cesarean delivery	100 (2/2)	100 (4/4)	_	_
Previous cesarean delivery – overall	18.9 (10/53)	40.7 (37/91)	0.48 (0.27-0.87)	.01
Noninduced labor	5.3 (1/19)	32.7 (18/55)	0.16 (0.02-1.12)	.03
Induced labor	7.4 (2/27)	26.1 (6/23)	0.42 (0.12-1.43)	.12
Elective repeated cesarean delivery	100 (7/7)	100 (13/13)	-	-
Cesarean delivery indications	5			
CPD/failure to progress	2.0 (16/794)	4.7 (51/1,075)	0.55 (0.36-0.85)	.001
Fetal intolerance	0.9 (7/794)	2.7 (29/1,075)	0.45 (0.23-0.88)	.006
Malpresentation (nonvertex)	1.3 (10/794)	2.6 (28/1,075)	0.61 (0.36-1.05)	.05
Elective repeated	0.9 (7/794)	1.2 (13/1,075)	0.82 (0.45-1.50)	.65
Other*	0.3 (2/794)	0.6 (6/1,075)	0.59 (0.18-1.95)	.48

CI = confidence interval; ACOG = American College of Obstetricians and Gynecologists; CPD = cephalopelvic disproportion.

Note: Values in the Exposed and Nonexposed columns are expressed as percent alone or percent (numerator/denominator). Statistical analyses were performed using  $\chi^2$  tests (Fisher's exact test).

\* No "other" reason for cesarean occurred more than twice in either group.

multiple logistic regression models are presented in Table 4. A statistically significant association remained between AMOR-IPAT exposure and a lower cesarean delivery rate following adjustment for practitioner specialty, patient's short stature ( $\leq 62$  in), high body mass index ( $\geq 30 \text{ kg/m}^2$ ) before conception, epidural analgesia, parity status, previous cesarean delivery, and malpresentation (final odds ratio = 0.56; 95% CI, 0.37-0.88; P = .005).

The ICCs for cesarean delivery for the exposed group and the nonexposed group were 0.003 and 0.027, respectively. The low ICC in both groups, and the lower ICC in the exposed group, suggests that cluster-related issues had a negligible impact on the comparison of cesarean delivery rates. Furthermore, the design effect in this study relating to cesarean delivery was estimated to be 1.0002, which is extremely close to unity (1.000). This finding also suggests that clustering of birth outcomes by practitioner had a negligible impact on the comparison of group cesarean delivery rates. Finally, a logistic regression model that adjusted for possible cluster effects showed negligible change in the strength of association, or the statistical significance of this association, between AMOR-IPAT exposure and cesarean delivery rate (Table 4).

Compared with nonexposed women, exposed women were more likely to have an induced delivery if

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	Univariate		Multivariate			
Variable	Odds Ratio	95% CI	Odds Ratio	95% CI	95% CI*	
AMOR-IPAT exposure	0.42	0.29-0.60	0.56	0.37-0.88	0.37-0.88	
Family physician practitioner	0.41	0.27-0.62	0.55	0.34-0.91	0.35-0.87	
Short stature (≤62 in)	1.85	1.34-2.57	1.88	1.27-2.78	1.52-2.32	
High BMI (>30 kg/m²) at conception	2.07	1.44-2.98	2.43	1.55-3.81	1.64-3.60	
Epidural analgesia	4.72	3.25-6.85	3.18	2.03-4.97	2.37-4.25	
Nulliparous	1.73	1.26-2.38	4.82	2.77-8.40	2.20-10.55	
Previous cesarean delivery	6.42	4.33-9.52	20.55	10.9-38.6	10.38-40.69	
Malpresentation (nonvertex)	58.3	27.7-122.7	146.85	59.6-362	75.9-284	

\* Adjusted for clustering of births by prenatal care practitioner.

they had an advanced maternal age, defined as being 35 years or older at the time of delivery (34.4% vs 19.2%; RR = 1.56, P = .03), a high body mass index at conception, defined as 30 kg/m<sup>2</sup> or greater (42.4% vs 28.7%; RR = 1.37, P = .02), and previous macrosomia, defined as delivery of an infant weighing more than 4,000 g (52.4% vs 24.6%; RR = 2.0, P < .001). At the same time, exposed women were less likely than their nonexposed counterparts to have a cesarean delivery if they had an advanced maternal age (4.9% vs 16.0%; RR = 0.39, P = .04), a high body mass index at conception (10.1% vs 19.2%; RR = 0.63, P = .04), and previous macrosomia (1% vs 13.8%; RR = 0.12, P = .001). Similar risk ratios for labor induction and cesarean delivery were noted for other risk-defined substrata, although statistical significance was often limited by the small size of subgroups.

The rate of assisted (vacuum or forceps) vaginal delivery (17.5% in the exposed group vs 16.0% in the nonexposed group; RR = 1.06, P = .22) and rates of most adverse birth outcomes did not differ between groups (Table 5). Three important adverse birth outcomes were less frequent in the group exposed to AMOR-IPAT: neonatal intensive care unit admission (2.3% vs 4.2%; RR = 0.66, P = .03), thick meconium at rupture of membranes (1.2% vs 3.8%; RR = 0.45, P = .001), and repetitive late fetal heart tone decelerations (0.4% vs 1.7%; RR = 0.33, P = .007). There were no maternal or intrapartum perinatal deaths, but 1 woman in the exposed group examined at 38 weeks and 3 days had absent fetal heart tones and subsequently gave birth to a stillborn term infant.

The median time from admission to delivery was significantly longer in the exposed group (9.2 hours vs 8.7 hours, P = .02), but the median duration of the second stage of labor was significantly shorter (41 minutes vs 54 minutes, P < .001) and the length of maternal hospital stay did not differ. An analysis of the number needed to treat showed that 1 fewer cesarean delivery

occurred in the exposed group for every 15.4 women exposed to AMOR-IPAT. In addition, 1 fewer cesarean delivery occurred in the exposed group for every 1.7 additional labor inductions.

#### DISCUSSION

In this 4-year study at a rural hospital, we found that patients of clinicians who practiced an alternative method of obstetric care, AMOR-IPAT, had a significantly lower cesarean delivery rate. AMOR-IPAT involves 2 components: the use of preventive labor induction to increase the likelihood that each woman gives birth within her optimal time of delivery, and the use of PGE<sub>2</sub> to ensure that adequate cervical ripening occurs before preventive labor induction.<sup>11,15,16</sup> With this new method of care, cesarean delivery rates were lower in the nulliparous, multiparous, and previous cesarean delivery subgroups. The overall association between AMOR-IPAT exposure and lower cesarean delivery rate remained statistically significant after adjustment for multiple potential confounding covariates and for the potential impact of clustering inherent in our study design. Rates of other adverse birth outcomes either appeared to be unchanged or were lower in the exposed group.

Our findings are at odds with the current belief that labor induction leads to increased rates of cesarean delivery and other adverse birth outcomes. Most previous investigations of labor induction have focused on women with accepted indications for induction, especially postdates pregnancy,<sup>17,18</sup> rather than on women with preventive labor induction, however. In this study, the exposed group had a 21.2% preventive (ie, nonindicated) labor induction rate. The few investigations that have studied nonindicated labor induction, furthermore, did not routinely address the need in women with low cervical Bishop scores for cervical ripening before induction.<sup>19,20</sup> In

Table 5. Other Outcomes of	Patients Exposed	or Not B	Exposed to	Active	Management
of Risk in Pregnancy at Terr	n (AMOR-IPAT)				

Outcome	Exposed (n = 794)	Nonexposed (n = 1.075)	RiskRatio (95% CI)	P Value
Material	(	( = 1,01.5)	(5576 Cl)	7 10100
Thick meaning at DOM 0/	1 2	2 0	0.45 (0.12,0,69)	001
Prostitive late deselections 0(	1.2	5.0 1.7	0.45 (0.15-0.00)	.001
Repetitive falle decelerations, %	0.4	1.7	0.25 (0.07-0.76)	.007
Major perineal trauma (3rd/4th degree), %	8.I 17.F	9.5	0.90 (0.74-1.10)	.32
Assisted (vacuum/forceps) vaginal delivery, %	17.5	16.0	1.06 (0.93-1.22)	.22
Estimated blood loss, mean, cc	290	323	-	<.001^
Estimated blood loss, >500 cc, %	7.8	11.1	0.78 (0.62-0.99)	.03
Use of carboprost, %	1.9	2.1	0.93 (0.62-1.38)	./4
Anemia (Hgb <9 mg/dL),† %	6.6	5.8	1.08 (0.88-1.34)	.48
Postpartum maximum temperature >100.4°F, %	3.5	4.7	0.83 (0.61-1.12)	.20
Transfer to ICU or tertiary care, %	0	0.1	0	1.00
Death, %	0	0	-	-
Infant				
Birth weight, mean, g	3,454	3,483	-	.17*
Birth weight >4,000 g	11.6	12.9	0.93 (0.78-1.10)	.43
Birth weight >4,500 g	0.8	2.2	0.48 (0.24-0.99)	.02
Birth weight <2,500 g	1.5	1.8	0.91 (0.58-1.42)	.72
Birth weight <3,000 g	14.2	14.9	0.97 (0.83-1.13)	.74
Birth head circumference, mean, cm	34.4	34.4	-	.67‡
Birth head circumference ≥37 cm, %	5.3	6.2	0.85 (0.58-1.25)	.41
Venous cord blood pH <7.2, %	2.9	3.3	1.16 (0.90-1.51)	.29
Apgar at 1 min <4, %	2.3	2.5	0.94 (0.65-1.35)	.76
Apgar at 5 min <7, %	0.76	1.0	0.83 (0.43-1.58)	.63
Apgar at 5 min <4, %	0.25	0.28	0.90 (0.15-5.39)	1.00
Regular nursery, %	94.3	92.6	1.02 (0.99-1.04)	.16
Possible sepsis, %	2.53	2.59	0.97 (0.52-1.81)	1.00
NICU admission, %	2.3	4.2	0.66 (0.45-0.99)	.03
Stillbirth, %	0.1	0.0	2.36 (2.23-2.48)	.42
Perinatal mortality, %	0.0	0.0	-	_
Time intervals				
Maternal admit to discharge, h	44.1	44.9	-	.59
Maternal admit to delivery, hr	9.2	8.7	-	.02
Maternal first stage, h	5.7	5.4	-	.66
Maternal second stage, min	41	54	-	<.001
Maternal delivery to discharge, h	35.5	36.6	-	.16
Infant delivery to discharge h	38.6	39.3	_	46

CI = confidence interval; ROM = rupture of membranes; Hgb = hemoglobin; ICU = intensive care unit; NICU = neonatal intensive care unit.

\* Calculated using the Wilcoxon rank-sum test.

† Numerator/denominator were 40/752 in the exposed group and 64/1,024 in the nonexposed group.

‡ Analyzed using Student's t test.

this study, AMOR-IPAT–exposed women who had an unfavorable cervix when scheduled for preventive labor induction routinely received PGE<sub>2</sub> gel. Although many previous studies have been based at urban academic centers, have been limited to nulliparas, have involved only obstetrician specialists, and/or have focused on women with low-risk profiles,<sup>22-24</sup> our study evaluated AMOR-IPAT exposure in a rural setting that had women of mixed parity, practitioners of several types (obstetrician, family physician, and midwife), and various levels of risk. This study also differs from previous studies in that it evaluated the impact of labor induction on cesarean rates from a practice-based perspective<sup>11,16</sup> rather than from the more traditional mode-of-labor-onset perspective.<sup>18,22-28</sup> That is, instead of comparing the outcomes of women who gave birth after induction of labor with those of women who gave birth after the spontaneous onset of labor, our study compared the outcomes of a group of women with a higher labor induction rate with the outcomes of a group with a lower labor induction rate. This strategy minimizes possible confounding by indication in the association between labor induction and cesarean delivery utilization. In fact, had we used the traditional mode-of-labor-onset perspective for this study, we would have reported that labor induction was associated with significant *increases* in cesarean delivery in both the nulliparous subgroup (17.1% vs 6.9%, P < .001) and the multiparous subgroup (4.4% vs 1.5%, P = .009). This traditional approach, however, would have missed the key finding that both primiparous and multiparous women cared for by AMOR-IPAT practitioners, namely, those with unusually high labor induction rates, had significantly lower cesarean delivery rates than women cared for by non–AMOR-IPAT practitioners.

There are several limitations to this study. First, it used a retrospective cohort design, and unknown confounding factors may have influenced the apparent association between exposure and outcome. We used multiple logistic regression analysis to adjust for known potentially confounding variables, but unmeasured differences in patient mix or labor management could have influenced our findings. We are not aware of any techniques other than timing of delivery, provision of PGE<sub>2</sub>, and use of epidural analgesia that were used differentially by the 2 types of practitioners. It has been suggested that perhaps practitioners of AMOR-IPAT waited longer during difficult labor before calling for a cesarean delivery; however, we believe that it is difficult to safely lower the frequency of cesarean delivery once considerable uteroplacental insufficiency or cephalopelvic disproportion has developed. Any systematic delay under these circumstances would be expected to increase the incidence of adverse birth outcomes, such as low Apgar scores, neonatal intensive care unit admission, and/or maternal fever. Higher levels of these morbidities were not seen in the exposed group. Second, the study took place at a rural hospital that treated primarily white women and that had relatively few maternity care practitioners. Although these factors render the generalizability of our results to other settings questionable, similar results using AMOR-IPAT have been reported from other settings.<sup>16</sup> Third, systematic charting problems may have been present, but information bias was unlikely to be present for the major covariates and outcomes. Finally, the determination of study group designation using prenatal care practitioner raises the possibility of misclassification bias, as some women in the exposed group may not have received active management of risk and vice versa. Misclassification bias usually tends to reduce the magnitude of an estimated association, however.

In support of our findings, a recent meta-analysis showed that induction of labor at 41 weeks, 0 days of gestation is associated with lower cesarean delivery rates as compared with expectant management beyond 41 weeks, 0 days of gestation.<sup>29</sup> Another review concluded that a similar approach is associated with reduced perinatal mortality.<sup>30</sup> Caughey and Musci<sup>12</sup> reported that the risk of cesarean delivery in low-risk women increases continuously as a function of increasing gestational age during the term period, and these authors questioned whether an increased use of labor induction before 41 weeks' gestation might lower cesarean risk. The AMOR-IPAT approach extends these important findings below 41 weeks' gestation and into the more clinically relevant domain of women with multiple common risk factors for cesarean delivery. Finally, a recently published article described our experience with AMOR-IPAT in an urban setting.<sup>16</sup> One hundred women exposed to this method of care experienced a 4% cesarean delivery rate, as compared with 300 nonexposed women who experienced a 16.7% cesarean delivery rate (RR = 0.27; 95% CI, 0.10-0.70). The study presented here provides strong corroborative evidence of a similar association in a rural setting.

At a time when national cesarean delivery rates have surpassed 30%,<sup>6,7</sup> when preventive primary cesarean delivery is being offered as an unproven means of preventing intrapartum perineal trauma,<sup>31</sup> and when the short- and long-term complications of cesarean delivery are still not completely understood, <sup>28,29,32,33</sup> we hope that practitioners might consider the potential benefits of an apparently safe alternative method of maternity care that is associated with high rates of successful vaginal delivery. The AMOR-IPAT approach uses accurate pregnancy dating and risk scoring to estimate an optimal time of delivery for each woman.<sup>11</sup> If spontaneous labor has not occurred before the upper limit of optimal time of delivery, then preventive labor induction, with cervical ripening if needed, is used to increase the likelihood that labor occurs before the fetus has grown too large for the maternal pelvis and/ or before the placenta has grown too old to support the fetus during labor. Adequately powered prospective randomized trials of AMOR-IPAT are warranted to assess its impact on rates of cesarean delivery and other birth outcomes.34,35

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