ORIGINAL ARTICLE

Outcomes after Internal versus External Tocodynamometry for Monitoring Labor

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ABSTRACT

BACKGROUND

It has been hypothesized that internal tocodynamometry, as compared with external monitoring, may provide a more accurate assessment of contractions and thus improve the ability to adjust the dose of oxytocin effectively, resulting in fewer operative deliveries and less fetal distress. However, few data are available to test this hypothesis.

METHODS

We performed a randomized, controlled trial in six hospitals in the Netherlands to compare internal tocodynamometry with external monitoring of uterine activity in women for whom induced or augmented labor was required. The primary outcome was the rate of operative deliveries, including both cesarean sections and instrumented vaginal deliveries. Secondary outcomes included the use of antibiotics during labor, time from randomization to delivery, and adverse neonatal outcomes (defined as any of the following: an Apgar score at 5 minutes of less than 7, umbilical-artery pH of less than 7.05, and neonatal hospital stay of longer than 48 hours).

RESULTS

We randomly assigned 1456 women to either internal tocodynamometry (734) or external monitoring (722). The operative-delivery rate was 31.3% in the internal-tocodynamometry group and 29.6% in the external-monitoring group (relative risk with internal monitoring, 1.1; 95% confidence interval [CI], 0.91 to 1.2). Secondary outcomes did not differ significantly between the two groups. The rate of adverse neonatal outcomes was 14.3% with internal monitoring and 15.0% with external monitoring (relative risk, 0.95; 95% CI, 0.74 to 1.2). No serious adverse events associated with use of the intrauterine pressure catheter were reported.

CONCLUSIONS

Internal tocodynamometry during induced or augmented labor, as compared with external monitoring, did not significantly reduce the rate of operative deliveries or of adverse neonatal outcomes. (Current Controlled Trials number, ISRCTN13667534; Netherlands Trial number, NTR285.)

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The monitoring of uterine contractions by means of internal tocodynamometry during induction or augmentation of labor is advocated by professional societies in obstetrics and gynecology. Induction or augmentation is necessary in approximately 20% of all deliveries, and internal monitoring is thought to quantify the frequency, duration, and magnitude of uterine activity more accurately than does external tocography.[1-3] The American College of Obstetricians and Gynecologists (ACOG) and the Society of Obstetricians and Gynaecologists of Canada (SOGC) advise the use of internal tocodynamometry in selected circumstances, such as when the mother is obese, when one-on-one nursing care is not available, or when the response to oxytocin is limited. The Dutch Society of Obstetrics and Gynaecology recommends its use in all cases of induction or augmentation of labor.[2] For patients in whom labor must be induced or augmented, monitoring by means of internal tocodynamometry might improve both maternal and fetal outcomes by allowing better adjustment of oxytocin, thus preventing uterine hyperstimulation and fetal hypoxia, or by improving the interpretation of abnormal fetal heart-rate patterns in relation to uterine activity. However, clinical data to support such hypotheses are limited, and recommendations are based on expert opinion. The recent report by the National Institute of Child Health and Human Development working group on electronic fetal monitoring concluded that studies are needed to evaluate associations between measures of uterine contraction (frequency, strength, and duration) and both fetal heart rate and clinical outcomes.[4]

We are aware of only three small, randomized clinical trials that compared internal tocodynamometry with external monitoring with respect to the clinical outcome.[5-7] None of these studies showed a significant reduction in the rate of operative delivery or a significant improvement in neonatal outcomes with internal as compared with external monitoring. However, the small samples in these trials resulted in limited power to detect differences and in wide confidence intervals around estimated risk reductions. For instance, the plausible effect of internal versus external tocodynamometry on the operative-delivery rate in a trial involving 239 patients in whom labor was induced ranged widely, from a 42% reduction to an 82% increase (95% confidence interval [CI], 0.58 to 1.82).[4]

We conducted a randomized, multicenter clinical trial involving a large number of patients to assess whether the use of an intrauterine pressure catheter during labor leads to better outcomes than those associated with the use of external monitoring.

METHODS

STUDY DESIGN

The trial was conducted in six hospitals in the Netherlands. The study protocol was approved by the medical ethics committee of the Máxima Medical Center in Veldhoven, the Netherlands, as well as by local committees of the other hospitals. All the authors took part in gathering the data and writing the manuscript. Costs related to performing the study were provided by the departments of the participating hospitals.

Women with a singleton pregnancy with a gestational age of more than 36 weeks, a fetus in the cephalic position, and an indication for either induction or augmentation of labor with intravenous oxytocin were eligible for the trial. Women with a uterine scar, positive results on serologic tests for human immunodeficiency virus or hepatitis B virus, or signs of an intrauterine infection or fetal distress were not eligible. All women were informed about the trial by the attending physician or midwife on the delivery ward, and all provided written informed consent before enrollment. Subsequently, the participants were randomly assigned to either internal tocodynamometry or external monitoring. Randomization was performed in a 1:1 ratio by means of a computer program, with the use of a minimization method[8] that took into account whether labor was augmented or induced and whether a woman was primiparous or multiparous, and was stratified according to hospital. The group assignments were not concealed from patients or physicians.

OBSTETRICAL MANAGEMENT

Labor was induced with amniotomy; if the attending obstetrician or midwife judged that contractions were insufficient 1 hour after amniotomy, oxytocin was administered. In cases of arrest of spontaneous labor (defined as failure of cervical dilatation to progress for at least 2 hours), intra-

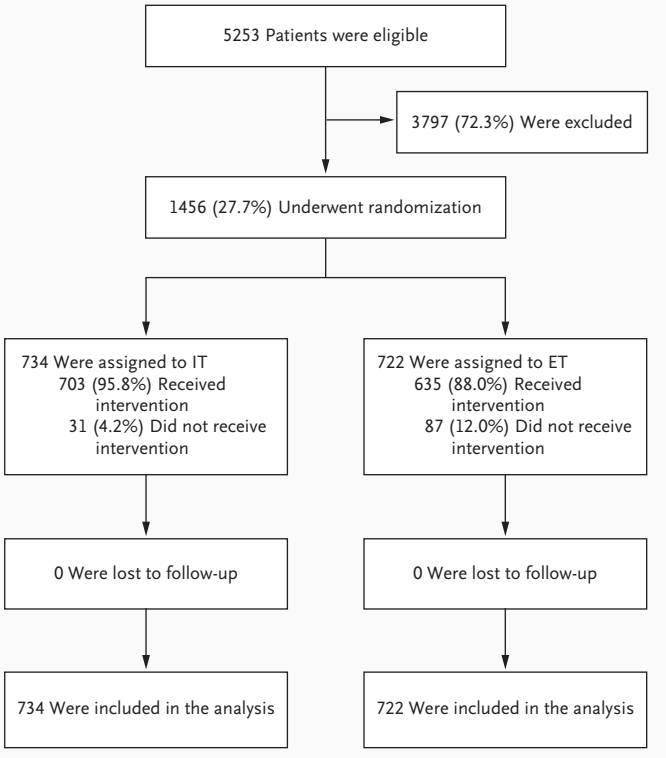

Figure 1. Eligibility, Randomization, and Follow-up.
ET denotes external tocodynamometric monitoring, and IT internal tocodynamometric monitoring.

venous oxytocin was used for augmentation. In the participating hospitals, oxytocin was continuously infused through a syringe pump at an initial dose of 3.3 mU per minute; this dose was then increased every 30 minutes until three or four contractions occurred within a 10-minute period, up to a maximal infusion rate of 33.3 mU per minute.

In the women assigned to the internal-tocodynamometry group, a sensor-tipped intrauterine catheter system (Koala, Clinical Innovations) was used. The catheter was inserted during the first vaginal examination after randomization. In the other group, external uterine activity was monitored with an external tocodynamometer (Hewlett–Packard, Philips Medical Systems).

Oxytocin was administered intravenously in increasing doses according to local protocol until 200 Montevideo units had been recorded or progression of cervical dilatation was deemed adequate at fewer Montevideo units. Adequate progression was defined as softening and effacement of the cervix and, after the cervix was fully effaced, an increase in cervical dilatation of at least 1 cm per hour. Progression of cervical dilatation was measured by digital examination at regular intervals in both study groups and according to local protocol. One-on-one care is routine practice in the Netherlands.

The use of an intrauterine pressure catheter in the external-monitoring group was allowed if cervical progression was absent for 2 hours, the frequency of uterine contractions was not sufficient, or cesarean section was being considered.

Infusion of fluid into the amnion for intrapartum management of meconium-stained amniotic fluid was allowed, either before trial entry or after randomization. In women assigned to external monitoring who were given an amnion infusion, an intrauterine pressure catheter was placed for the infusion but was not connected to the pressure monitor for the registration of contractions. Fetal surveillance was performed with electronic fetal heart-rate monitoring in combination with fetal-blood sampling when these measures were deemed indicated by the managing clinician.

STUDY OUTCOMES

The composite primary outcome was operative delivery, defined as cesarean section or instrumented vaginal delivery. Secondary outcomes included complications from use of the intrauterine pressure catheter (abruptio placentae, antepartum hemorrhage, fetal-vessel damage, uterine rupture, or sepsis), use of analgesia, use of antibiotics during labor, total amount of oxytocin used, time from randomization to delivery, and adverse neonatal outcomes (a composite variable defined as a 5-minute Apgar score below 7, an umbilical-artery pH below 7.05, or a neonatal admission longer than 48 hours).

STATISTICAL ANALYSIS

The sample size was calculated on the basis of an expected reduction in the rate of operative deliveries from 35% to 28% in the internal-tocodynamometry group. To detect this difference with a power of 80% and a type I error of 5% (two-sided test), we needed 1382 patients for whom data could be analyzed. Assuming a 5% rate of study dropouts or protocol violations, our goal was to have 1450 patients eligible for randomization.

The analysis was performed according to the

Table 1. Baseline Characteristics of the Study Population.*

Characteristic	IT Group (N=734)	ET Group (N=722)
Maternal age — yr	31.2±5.2	31.0±5.1
Primipara — no. (%)	465 (63.4)	456 (63.2)
Body-mass index before pregnancy†	25.3±5.2	25.4±5.6
Gestational age — days		
Mean	281	281
Range	252–300	252–300
Birth weight — g	3516±536	3536±521
Induced labor — no. (%)	482 (65.7)	474 (65.7)
Indications for induction — no./total no. (%)		
Post-term date	101/482 (20.9)	102/474 (21.5)
Meconium-stained amniotic fluid	57/482 (11.8)	59/474 (12.4)
Membranes ruptured >24 hr earlier	71/482 (14.7)	72/474 (15.2)
Diabetes	32/482 (6.6)	14/474 (3.0)
Hypertension or preeclampsia	64/482 (13.3)	86/474 (18.1)
Deterioration of fetal condition‡	31/482 (6.4)	36/474 (7.6)
Request of mother	56/482 (11.6)	47/474 (9.9)
Other indications	70/482 (14.5)	58/474 (12.2)
Cervical effacement ≥50% at time of induction — no. (%)	444/482 (92.1)	435/474 (91.8)
Cervical dilatation at time of induction — cm		
Median	2	2
Range	0–10	0–8
Augmented labor — no. (%)	252 (34.3)	248 (34.3)
Cervical dilatation at time of randomization — cm		
Median	4	4
Range	1–10	0–10

* Plus–minus values are means ±SD. There were no significant differences in baseline characteristics between the two study groups. ET denotes external tocodynamometric monitoring, and IT internal tocodynamometric monitoring.
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ This category includes small fetal size for gestational age, reduction in fetal movement, and decrease in amniotic fluid.

intention-to-treat principle. Continuous variables were compared with the use of analysis of variance for normally distributed variables and the Mann–Whitney U test otherwise. For categorical variables, we used the chi-square test. P values of 0.05 or less were considered to indicate statistical significance. For dichotomous outcomes, we calculated relative risks and 95% confidence intervals. Time to delivery was assessed with the use of Kaplan–Meier analysis and was compared between groups by means of the log-rank test.

We performed post hoc analyses to compare outcomes of internal tocodynamometry with those of external monitoring in subgroups defined according to the following factors: type of labor (induced or augmented), parity (primiparous or multiparous), and body-mass index (the weight in kilograms divided by the square of the height in meters, ≤30 or >30). We tested for interactions between treatment and each of these three factors for the composite end points of operative delivery and adverse neonatal outcomes.

All reported P values are two-sided and were not adjusted for multiple testing. No interim analyses were planned or performed. Analyses were performed with the statistical data-management package of SPSS, version 14.0.2, for Windows 2000 (Microsoft).

RESULTS

PATIENTS

Between May 2004 and November 2007, a total of 1456 women were randomly assigned to either the internal-tocodynamometry group (734) or the external-monitoring group (722). Of the 5253 women who were eligible for the trial, 72.3% declined participation or were not informed about the trial for various reasons (Fig. 1). The baseline characteristics of the two randomized groups were similar (Table 1).

OUTCOMES ACCORDING TO ASSIGNED TREATMENT

Operative delivery, the primary outcome, was carried out in 230 women (31.3%) assigned to the internal-tocodynamometry group and in 214 women (29.6%) assigned to the external-monitoring group (relative risk with internal monitoring, 1.1; 95% CI, 0.91 to 1.2). The frequencies of secondary outcomes were also similar in the two groups (Table 2). There were no reported complications from the use of the intrauterine pressure catheter, and no neonatal or maternal deaths occurred in either group.

Table 2. Primary and Secondary Outcomes According to Treatment Group.*

Outcome and Related Factors	IT Group (N=734)	ET Group (N=722)	Relative Risk (95% CI)	P Value
Outcome according to assigned treatment				
Operative delivery, primary composite outcome — no. (%)†	230 (31.3)	214 (29.6)	1.1 (0.91–1.20)	0.50
Cesarean section	120 (16.3)	113 (15.7)	1.1 (0.83–1.30)	0.74
Indications for cesarean section				
Fetal distress	29 (4.0)	29 (4.0)		
Failure to progress	82 (11.2)	71 (9.8)		
Fetal distress and failure to progress	9 (1.2)	13 (1.8)		
Ventouse extraction	106 (14.4)	96 (13.3)		
Forceps extraction	4 (0.5)	5 (0.7)		
Indications for Ventouse or forceps extraction				
Fetal distress	40 (5.4)	46 (6.4)		
Failure to progress	61 (8.3)	46 (6.4)		
Fetal distress and failure to progress	9 (1.2)	8 (1.1)		
Spontaneous vaginal delivery — no. (%)	504 (68.7)	508 (70.4)		
No. of catheters inserted — no. (%)				
0	31 (4.2)	584 (80.9)		
1	640 (87.2)	135 (18.7)		
2	59 (1.2)	3 (0.4)		
3	4 (0.5)	0		
Amnion infusion — no. (%)	57 (7.8)	51 (7.1)	1.1 (0.76–1.60)	0.62
Use of antibiotics — no. (%)				
Prophylactic	8 (1.1)	13 (1.8)		
Therapeutic	30 (4.1)	43 (6.0)	0.81 (0.61–1.10)	0.10
None	697 (95.0)	666 (92.2)		
Use of analgesia — no. (%)	407 (55.4)	394 (54.6)	1.0 (0.84–1.30)	0.75
Epidural	289 (39.4)	274 (38.0)		
Morphine	118 (16.1)	120 (16.6)		
Time from randomization to delivery — min				
Induction group	313±299	358±247		0.93
Augmentation group	299±239	386±280		0.94

Table 2. (Continued.)

Outcome and Related Factors	IT Group (N=734)	ET Group (N=722)	Relative Risk (95% CI)	P Value
Adverse neonatal outcome, composite — no. (%)‡	105 (14.3)	108 (15.0)	0.95 (0.74–1.20)	0.70
Apgar score				
<7 at 5 min	16 (2.2)	8 (1.1)	2.0 (0.85–4.60)	0.11
<10 at 10 min	41 (5.6)	28 (3.9)	1.4 (0.90–2.30)	0.13
Umbilical-artery pH				
<7.15	81 (11.0)	61 (8.4)	1.3 (0.95–1.70)	0.12
<7.05	11 (1.5)	12 (1.7)	0.89 (0.40–2.00)	0.75
Neonatal admission§	134 (18.3)	152 (21.1)	0.87 (0.70–1.1)	0.19
Any hospital stay				
Hospital stay >48 hr	93 (12.7)	99 (13.7)	0.95 (0.71–1.2)	0.54
Indications for neonatal admission				
Signs of infection	42 (5.7)	56 (7.8)	0.74 (0.50–1.1)	0.14
Asphyxia	26 (3.5)	28 (3.9)	0.99 (0.88–1.1)	0.78
Other indications	66 (9.0)	68 (9.4)	0.83 (0.52–1.3)	0.79
Outcome according to actual treatment				
Operative delivery, composite — no./total no. (%)†	240/755 (31.8)	204/698 (29.2)	1.1 (0.94–1.3)	0.28
Cesarean section — no./total no. (%)	124/755 (16.4)	109/698 (15.6)	1.1 (0.83–1.3)	0.68
Adverse neonatal outcome, composite — no./total no. (%)‡	105/755 (13.9)	108/698 (15.5)	1.0 (0.98–1.1)	0.40

* Plus–minus values are medians ±SD. CI denotes confidence interval, ET external tocodynamometric monitoring, and IT internal tocodynamometric monitoring.
† Operative delivery, the composite primary outcome, was defined as cesarean section or instrumented vaginal delivery.
‡ The composite outcome was defined as an Apgar score of less than 7 at 5 minutes, an umbilical-artery pH of less than 7.05, or neonatal admission for longer than 48 hours.
§ This outcome was defined as admission of the neonate to the maternity ward, pediatric ward, or neonatal intensive care unit for medical reasons.

Post hoc analyses showed no significant interactions between treatment and the type of labor (induced vs. augmented), parity (primiparous vs. multiparous), or body-mass index (≤30 vs. >30) for the primary outcome of operative delivery or for adverse neonatal outcomes (Fig. 2).

OUTCOMES ACCORDING TO TREATMENT RECEIVED

In the internal-tocodynamometry group, an intrauterine pressure catheter was not inserted in 31 women (4.2%) either because the catheter could not be inserted or because labor progressed rapidly. In the external-monitoring group, an intrauterine pressure catheter was placed in 51 women (7.1%) for amnion infusion and in 87 women (12.0%) on the basis of clinical judgment that there was insufficient progression of labor and inadequate monitoring. As compared with the 584 women who were treated according to protocol, these 87 women were more likely to be primiparous (82.6% vs. 63.2%), had a higher mean prepregnancy body-mass index (27.4 vs. 25.3), and were more likely to have hypertension or preeclampsia (33.8% vs. 10.3%); they were also more likely to have a cesarean section (33.0% vs. 16.0%). When we performed analyses according to actual treatment received, the results were similar to those of the intention-to-treat analysis, with no significant differences between groups in the rate of operative deliveries or of adverse neonatal outcomes (Table 2).

DISCUSSION

In this multicenter, randomized trial we found no significant difference in rates of operative delivery with internal tocodynamometry as compared with external monitoring of uterine contractions among women in whom oxytocin was used for induction or augmentation of labor. On the basis of the lower boundary of the confidence interval around the observed relative risk of the primary

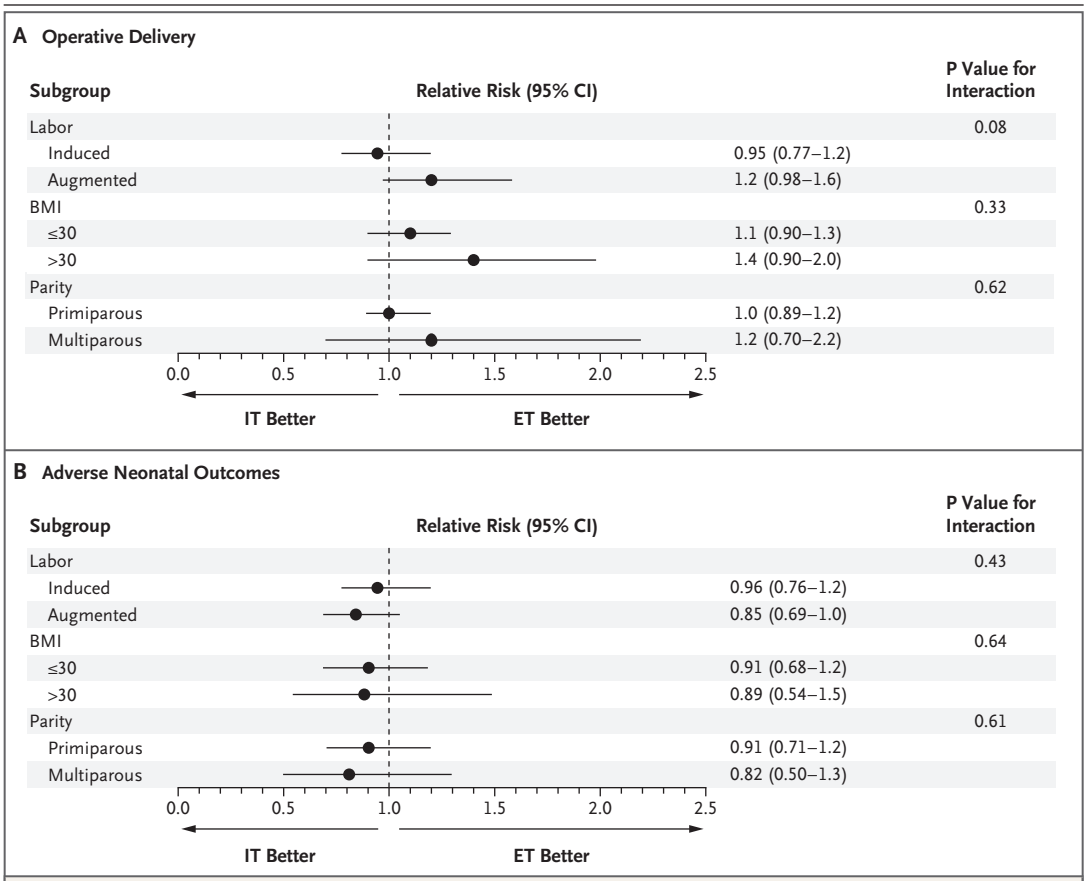

Figure 2. Relative Risks of Operative Delivery and Adverse Neonatal Outcomes in Subgroups of Patients, According to the Assigned Treatment.

BMI denotes body-mass index (the weight in kilograms divided by the square of the height in meters), ET external tocodynamometric monitoring, and IT internal tocodynamometric monitoring.

outcome, our data are plausibly consistent with no more than a 9% reduction and up to a 20% increase in the risk of operative delivery associated with internal tocodynamometry. For cesarean section alone, plausible results range from a 17% reduction in risk to a 30% increase in risk with internal tocodynamometry. These results are in concordance with those of three previous small trials that compared internal and external uterine monitoring (each including between 127 and 250 patients), all of which showed a nonsignificant increase in the frequency of cesarean sections in the internal-tocodynamometry group.[5-7]

Our trial also showed no significant difference between the two types of monitoring in the rates of adverse neonatal outcomes, rates of use of analgesia or antibiotics, or time to delivery. Similarly, none of the earlier studies showed significant benefits in terms of other maternal or neonatal outcomes with the use of an intrauterine pressure catheter.

The rates of operative delivery and epidural anesthesia in this trial appear to be lower than those in current obstetrical practice in the United States.[9] Although this observation might seem to suggest the possibility of a selection bias favoring the inclusion of women at lower risk, the rates in our study are consistent with those reported elsewhere in the Netherlands. In 2006, the overall rate of cesarean section in the Netherlands was 15.1%, the rate of instrumented vaginal delivery was 9.7%, and the rate of use of epidural anesthesia was 8.2%.[10]

The ACOG and the SOCG recommend the use of intrauterine monitoring of contractions during augmentation or induction of labor in selected patients, such as obese women.[1,3] We did not limit our inclusion criteria to these women be-

cause Dutch guidelines recommend the use of internal tocodynamometry routinely when labor is induced or augmented, and because the recommendations of all professional societies regarding internal tocodynamometry have been based primarily on expert opinion in the absence of definitive data. In a subgroup analysis, we found no evidence of a benefit with the use of an intrauterine pressure catheter in obese women, although this finding should be interpreted cautiously, since the analysis was post hoc and its power was limited.

We chose not to include women with a scarred uterus in our trial because they are at increased risk for uterine rupture, especially during induction of labor.[11,12] Although many clinicians elect to use an intrauterine pressure catheter in such women when vaginal delivery is attempted, with the expectation that it may facilitate the early diagnosis of uterine rupture,[13] this practice is not supported by data.

The limitations of our study should be noted. Whereas an intrauterine pressure catheter was used in more than 95% of the women assigned to internal tocodynamometry, 12% of the women assigned to external monitoring were nonetheless treated with an intrauterine pressure catheter at the physician's discretion. When we analyzed the data according to the actual treatment provided, the results were similar to those of the intention-to-treat analysis. Although our study was not blinded, it is unlikely that knowledge of the type of monitoring biased the obstetricians' decisions regarding the method of delivery.

Internal tocodynamometry has serious risks, including placental or fetal-vessel damage, infection, and anaphylactic reaction.[14-16] We did not observe any complications of internal monitoring in our study, but it was not powered to detect these events, which in previous studies had an estimated incidence of 1 in 300 patients and 1 in 1400.[17,18]

In summary, the results of our trial do not support the routine use of internal tocodynamometry for monitoring contractions in women with induced or augmented labor.

No potential conflict of interest relevant to this article was reported.

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