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The Risks and Benefits of Internal Monitors in Laboring Patients

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Abstract

Objective—To estimate the impact of internal monitors (fetal scalp electrodes [FSE] and intrauterine pressure catheters [IUPC]) on maternal and neonatal outcomes.

Study Design—Retrospective cohort of all women admitted for labor 2004–2008. Women with internal monitors (FSE, IUPC, or both) were compared to women without internal monitors. Maternal outcomes were maternal fever and cesarean delivery (CD). Neonatal outcomes were a composite of 5-minute Apgar 3 , cord pH<7.1, cord base excess <-12, or admission to level 3 nursery. Logistic regression was performed to estimate the impact of internal monitors while adjusting for confounding variables, including time in labor.

Results—Of 6,445 subjects, 3,944 (61.2%) had internal monitors. Women with internal monitors were more likely to develop a fever than women without internal monitors (11.7% versus 4.5%, adjusted odds ratio (AOR) 2.0, 95% confidence interval (CI) 1.6-2.5). FSE alone was not associated with an increased risk of fever (AOR 1.5, 95% CI 1.0-2.1), but IUPC alone was (AOR 2.4, 95% CI 1.8-3.2). The risk of CD was higher in women with internal monitors (18.6% versus 9.7%, AOR 1.3, 95% CI 1.0-1.5). Risk of CD was lower in women with FSE alone (AOR 0.5, 95% CI 0.4-0.7) but higher in women with both an FSE and IUPC (AOR 1.6, 95% CI 1.4-2.0). Risk of the composite neonatal outcome was not higher in women with internal monitors (3.3% versus 3.6%, AOR 0.8, 95% CI 0.6-1.1).

Conclusions—Routine use of IUPC in laboring patient should be avoided due to increased risk of maternal fever.

Keywords

labor; internal monitors; cesarean; chorioamnionitis; endometritis

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Condensation: The need to use internal monitors should be weighed against the increased risk of maternal febrile morbidity.

Introduction

Intrauterine pressure catheters (IUPC) and fetal scalp electrodes (FSE) are commonly used devices for intrapartum monitoring and management. Although the internal monitors used are sterilely packaged, they travel through the vaginal canal into the uterine cavity, providing a potential pathway for contamination and ascending infections. Studies are conflicting on whether or not internal monitors are associated with maternal and neonatal infections, but amniotic fluid specimens collected after IUPC insertion have been found to be contaminated with bacteria in 50% of subjects.¹ Additionally, numerous case reports exist of scalp abscesses after monitoring with FSE, and one case control study of infants with GBS sepsis suggest that monitoring with FSE may be associated with a greater risk of death.²

Because the IUPC can be used to calculate Montevideo units and adequacy of contractions, they are frequently placed when labor dystocia is a concern.³ However, randomized control trials comparing the use of internal and external monitors for labor management have not demonstrated a decrease in the risk of cesarean when internal monitors are used, although they also do not demonstrate an increased risk of infectious morbidities. 4, 5

In spite of this, the use of internal monitors is widespread. At some institutions, it is routine to place internal monitors at the time of membrane rupture. Several factors are at work in the continued use of internal monitoring in the face of demonstrated lack of benefit. The selection of a highly specific patient population (i.e. labor dystocia) makes these trials less generalizable, as several indications exist for internal monitoring. Secondly, the statement that internal and external monitoring are equivalent inherently assumes that external monitoring is possible. As obesity, and particularly morbid obesity, becomes more prevalent, external monitoring of fetal heart rate and contractions may not be possible.

Therefore, we sought to estimate the impact of internal monitors on maternal and neonatal outcomes in a modern population of unselected women in labor.

Materials and Methods

This is a retrospective cohort study of all consecutive women admitted at a single institution from 2004–2008. Institutional review board approval was obtained from Washington University School of Medicine.

Women were included in the cohort if they carried a singleton pregnancy in vertex presentation and attempted a trial of labor. We excluded women who had a fetus with congenital anomalies or who underwent cesarean delivery without labor. For this analysis, women were excluded if their maximum temperature or the use of internal monitors was unknown. We extracted detailed information on maternal sociodemographic, obstetric and gynecologic history, medical and surgical history, prenatal history, antepartum records, and labor and delivery records. The labor and delivery records included medications, labor type, cervical examination times, dilation and station, length of labor stages, mode of delivery, maximum temperature, time of maximum temperature, postpartum record, and neonatal outcomes. All data were extracted using close-ended forms by trained research assistants who underwent regularly scheduled training.

At our institution, sterile vaginal examinations are performed in labor approximately every two hours in active labor, or more frequently as indicated by patient symptoms or fetal heart rate tracing. Artificial rupture of membranes is typically performed to augment labor when the fetal vertex is engaged. Internal monitors are not placed routinely at the time of rupture, but are typically placed for indications such as inability to externally monitor, oxytocin

dosage >20 milliunits/minute, and labor dystocia. Umbilical cord blood gases are routinely obtained at all deliveries when possible.

For this study, women with internal monitors were compared to women without internal monitors. In the primary analysis, women were considered to have internal monitors if they had either an FSE or an IUPC, or both. The primary maternal outcomes were maternal temperature 38.1°C at any point in hospitalization and cesarean delivery. Secondary outcomes considered maternal temperature ≥38.1°C prior to delivery and maternal temperature 38.1° C at least 12 hours after delivery. The primary neonatal outcome was a composite outcome of 5-minute Apgar score $\,$ 3, cord blood pH<7.1, cord blood base excess <-12, and admission to level 3 nursery.

Secondary analyses were performed to assess the individual impact of FSE versus IUPC use on maternal and neonatal outcomes. Women with an FSE alone were compared to women with no internal monitors; women with an IUPC alone were compared to women with no internal monitors. The impact of internal monitors on cesarean delivery was assessed by indication of cesarean delivery. Women were classified as having a cesarean for an arrest of labor if the indication for cesarean was listed as arrest of dilation, arrest of descent, labor dystocia, failed induction, or failure to progress. Women were classified as having a cesarean for non-reassuring fetal status if the indication for cesarean was listed as nonreassuring fetal status, Category 3 tracing, fetal bradycardia, or decelerations.

Patients with and without internal monitors were summarized and compared with descriptive and bivariate statistics using unpaired Student's t-test or Mann-Whitney U test for continuous variables and 2 or Fisher's exact test for categorical variables, as appropriate. Normality was tested using the Kolmogorov-Smirnov test. Potentially confounding variables of the exposure-outcome association were identified in stratified analyses. Multivariable logistic regression models for the primary and secondary outcomes were developed to better estimate the effect of internal monitors while adjusting for potentially confounding effects. Clinically relevant covariates for initial inclusion in multivariable statistical models were selected using results of the stratified analyses, and factors were removed in a backward stepwise fashion, based on significant changes $(>10%)$ in the exposure adjusted odds ratio (AOR) or significant differences between hierarchical models using the likelihood ratio test. Covariates considered include: maternal age, race, parity, body mass index (BMI), time in labor, induction of labor, maternal medical comorbidities, regional anesthesia, mode of delivery (for endometritis and neonatal outcomes), maternal fever (for neonatal outcomes), and gestational age at delivery (for cesarean and neonatal outcomes). As the number of exams correlated strongly with time in labor, only time in labor was used in the analysis to avoid co-linearity. Time in labor was considered as both a continuous and categorical variable. The statistical analysis was performed using STATA, version 11 Special Edition (StataCorp, College Station, TX).

Results

Of 8,390 women in the cohort, 6,445 (76.8%) were included. Reasons for exclusion were: 1,496 for cesarean without attempt at labor, 144 for delivery prior to arrival on the labor unit, 68 excluded for unknown maximum temperature, 9 for unknown status regarding use of internal monitors, and 228 for incomplete date and time information. Of the 6,445 women included in the study, 3,944 (61.2%) had internal monitors. Of these, 625 (15.9%) had FSE only, 789 (20.0%) had IUPC only, and 2,530 (64.2%) had both. Women with internal monitors were more likely to be primiparous, black, obese, have chronic hypertension, preeclampsia, or diabetes, have their labor induced or augmented, receive regional anesthesia, and receive antibiotics for group B streptococcus prophylaxis (Table 1). Women

with internal monitors had longer times from admission to delivery, rupture of membranes to delivery, and more vaginal exams.

Women with internal monitors were more likely to develop a maternal fever than women with no internal monitors (11.7% versus 4.5%, odds ratio 2.8, 95% confidence interval (CI) 2.3-3.5) (Table 2). After adjusting for confounding variables (time from rupture to delivery

≥12 hours, black race, primiparity, GBS status and regional anesthesia), the risk of any maternal fever remained elevated (adjusted odds ratio (AOR) 2.0, 95% CI 1.6-2.5). Women with internal monitors had increased risk for both fever prior to delivery (4.2% versus 1.4%, AOR 1.8, 95% CI 1.3-2.7) and fever greater than 12 hours after delivery (5.8% versus 2.5%, AOR 1.9, 95% CI 1.4-2.6). While women with internal monitors appeared to have a higher rate of cesarean delivery (18.6% versus 9.7%), the association was not statistically significant after adjusting for relevant confounding factors (AOR 1.3, 95% CI 1.0-1.5). Women with internal monitors did not have a significantly different risk of the composite neonatal outcome compared to women with no internal monitors (3.3% versus 3.6%, AOR 0.8, 95% CI 0.6-1.1).

The risk of maternal fever, cesarean, and the composite neonatal outcome was considered by the type of internal monitor used (Table 3). When only FSE was used, the risk of any maternal fever (AOR 1.5, 95% CI 1.0-2.1), maternal fever prior to delivery (AOR 1.8, 95% CI 1.0-3.2), and maternal fever more than 12 hours after delivery (AOR 1.4, 0.9-2.3) were not significantly different compared to no internal monitors. Use of FSE alone was associated with a decreased risk of cesarean delivery compared to no internal monitors (7.5% versus 9.7%, AOR 0.5, 95% CI 0.4-0.7). The composite neonatal outcome was not significantly different compared between the FSE and no internals groups (2.5% versus 3.7%, AOR 0.8, 95% CI 0.5-1.5).

The use of IUPC alone or in conjunction with an FSE was associated with increased risk of any maternal fever (IUPC alone AOR 2.4, 95% CI 1.8-3.2, IUPC & FSE AOR 2.0, 95% CI 1.6-2.6), maternal fever prior to delivery (IUPC alone AOR 2.4, 95% CI 1.5-3.9, IUPC & FSE AOR 2.0, 95% CI 1.3-3.0), and maternal fever more than 12 hours after delivery (IUPC alone AOR 2.4, 95% CI 1.6-3.5, IUPC & FSE AOR 1.9, 95% CI 1.4-2.6). The use of an IUPC alone was not associated with a change in the risk of cesarean delivery (IUPC alone AOR 0.9, 95% CI 0.7-1.1). The use of an IUPC and FSE together was associated with an increase in the risk of cesarean delivery (AOR 1.6, 95% CI 1.4-2.0). The risk of the composite neonatal outcome was not altered by the use of an IUPC (IUPC alone AOR 0.9, 95% CI 0.5-1.4, IUPC & FSE AOR 0.8, 95% CI 0.5-1.1).

Table 4 displays the two most common indications for cesarean, arrest of dilation or descent and non-reassuring fetal status, by internal monitor status. Compared to no internal monitors, FSE use alone was not associated with an increased risk of cesarean for arrest (AOR 0.8, 95% CI 0.5-1.4) or non-reassuring fetal status (AOR 0.8, 95% CI 0.5-1.2). IUPC use alone was associated with an increased risk of cesarean for arrest (AOR 1.7, 95% 1.1-2.5) but not for non-reassuring fetal status (AOR 0.9, 95% CI 0.6-1.3). Use of both types of monitor was associated with an increased risk of cesarean for both indications (AOR for arrest 1.7, 95% CI 1.2-2.3, AOR for non-reassuring fetal status 2.6, 95% CI 2.1-3.3).

Comment

In this large, cohort of all women admitted for labor at a single tertiary care center, the use of IUPC, but not FSE, was associated with an increased risk of maternal fever. The use of an FSE, but not IUPC, was associated with a decrease in the risk of cesarean delivery. The combined use of FSE and IUPC was associated with a slight increase in the risk of cesarean.

The use of internal monitors did not impact the neonatal outcomes. These findings suggest that FSE use may have benefit for patients; however, the use of an IUPC should be limited to clinical indications rather than routine placement due to the increased risk of maternal fever without an associated decrease in cesarean with IUPC placement.

Prior studies have been conflicting regarding the association of internal monitors and the risk of maternal infectious morbidity (chorioamnionitis and endometritis). Insertion of an IUPC has been associated with colonization of the amniotic cavity with bacteria; in a study of 30 consecutive labors, amniotic fluid was obtained from the IUPC at insertion and one hour later.¹ While the fluid obtained at the time of insertion was sterile, 50% of patients had bacterial colonization of the amniotic fluid 1 hour later and 36% developed a post-partum fever, although no correlation between bacterial count and fever was found. However, as data was not available on the timing of rupture of membranes, it is unclear from this study whether bacterial colonization was caused by the IUPC or by membrane rupture.

In both retrospective and prospective cohort studies, Gibbs et al demonstrated that in women undergoing cesarean delivery, internal monitors did not place women at increased risk of endometritis.^{6, 7} The main risk factors for endometritis were labor and rupture of membranes prior to cesarean. However, as both these studies were conducted in an era prior to routine antibiotic prophylaxis for cesarean, they may no longer be applicable in today's patient population. Additionally, chorioamnionitis was not considered as an outcome in either study.

Maternal fever and chorioamnionitis have been examined as secondary outcomes in studies that have randomized women to IUPC placement. In a study by Bakker et al, women were randomized to either IUPC or external tocography for labor dystocia.⁵ There was no difference in the use of therapeutic antibiotics between groups. In a secondary analysis of the randomized control trial, no difference between groups was found with regards to clinical signs of maternal or neonatal infection. In a randomized control trial of amnioinfusion for meconium, no difference was found between those randomized to amnioinfusion versus controls for the risk of peripartum fever; although, it is unclear whether or not women who did not receive amnioinfusion had an IUPC for other reasons.⁸

Although amnioinfusion for variable decelerations decreases the risk of cesarean, routine IUPC placement for labor management has not been demonstrated to be associated with an altered risk of cesarean.^{9, 10} A large, randomized control trial of internal versus external tocography during induction and augmentation of labor failed to demonstrate a decrease in operative delivery with internal tocography.⁵ The findings that external tocography performs as well as internal tocography assumes that external tocography can be performed, but 12% of women randomized to external monitoring received internal monitoring due to either inability to adequately monitor externally or arrest of dilation. The mean BMI of this population was 25, suggesting a much lower incidence of obesity and morbid obesity than is currently encountered in the U.S. population. Therefore, the findings of this study may not be applicable to the general U.S. population.

A recent study sought to explain differences in cesarean delivery rates between two area hospitals by comparing patients and practice patterns.¹¹ The authors reviewed charts at two hospitals, one with the lowest cesarean delivery rates and one with the highest cesarean delivery rates. FSE and IUPC use was approximately 2-fold higher in the hospital with the lowest cesarean delivery rates, although this study did not distinguish use of an FSE alone, IUPC alone, or both.

The decrease in the risk of cesarean delivery when using an FSE alone found in this cohort may be related to an improved ability to monitor fetal heart tones with an FSE compared to

external monitoring. In this tertiary center, patients are unlikely to be allowed to labor when it is not possible to monitor fetal heart tones. Therefore, the placement of an FSE may allow labor when external monitoring is not possible. Alternatively, placement of an FSE may simply be a marker of a more dilated cervix, applied fetal head, and the ability to rupture the membranes, all of which are associated with vaginal delivery.

IUPC use was associated with an approximately 2-fold increase in the risk of maternal fever before or after delivery. Although maternal fever is a surrogate marker of infection, this is a clinically significant finding as maternal fever is associated with labor dystocia, prolonged second stage, post-partum hemorrhage, meconium-stained fluid, neonatal sepsis, neonatal seizures, and neonatal death.^{12–14} The difference in the risk of maternal fever with the use of an IUPC versus an FSE may be related to location. An FSE, being placed on the fetal scalp, places a fetus at risk of scalp abscess but does not provide a route of ascending infection to the maternal uterus. On the other hand, an IUPC abuts the chorionic membranes adjacent to the uterine wall. Ascending bacteria would therefore be implanted onto the chorionic membranes, potentially leading to chorioamnionitis, a significant risk factor for endometritis.

Similarly, the association between use of both an FSE and IUPC with an increase in the risk of cesarean delivery may not be causative. Rather, the need to place both internal monitors may simply be a marker for women at high risk of cesarean delivery. For example, these monitors tend to be used in obese women, women with longer labors, cases of fetal heart rate decelerations, and women undergoing induction of labor, all of which are associated with an increased risk of cesarean. This is also suggested by the fact that IUPC use alone was not associated with a change in the risk of cesarean delivery. However, insertion of an IUPC, alone or with an FSE, increased the risk of maternal fever without decreasing the risk of cesarean.

The main strength of this study is its generalizability; our study was a population-based cohort of all subjects admitted for labor. Consequently, our findings may be applied to a broad range of patients, although we do note that our patient population is largely African-American and has a high incidence of obesity. Additionally, we had detailed clinical information for each patient, including the length of time in labor and the length of time in labor after rupture of membranes. This enabled us to adjust for relevant confounding factors. We were also able to distinguish between maternal fever prior to delivery (suggestive of chorioamnionitis) and maternal fever more than 12 hours after delivery (suggestive of endometritis). Finally, we were able to examine neonatal outcomes in addition to maternal outcomes. Although we did not have adequate power to examine individual components of the component outcome, we had greater than 90% power to detect a 1.5-fold difference in the composite outcome.

One of the weaknesses of the study is that while IUPC or FSE placement is welldocumented, the number of insertion attempts, timing of internal monitor placement, and the indication for their use are potential confounding variables that we were not able to consider. However, we feel that the use of internal monitors in our routine obstetric practice approximates real-world experience and is therefore generalizable to a broad population. Additionally, we had other information that acts as surrogates for some of these confounding factors, such as time in labor, time since rupture (which practicably represents the earliest time that internals could have been placed), and number of exams. Additionally, we cannot rule out the possibility of residual confounding by unknown or unmeasured variables. Some maternal fevers occurring prior to delivery may have occurred prior to insertion of the IUPC as we do not have documentation of the time of IUPC placement; however, this would not impact the finding that post-partum fever was increased in women with an IUPC. We also

do not have amniotic fluid or endometrial culture results documenting the microorganisms in the amniotic fluid and endometrium in women with and without internal monitors as these tests are not routinely sent in practice. This information could potentially strengthen our findings, but our findings are biologically plausible even without this information.

In sum, the use of FSE alone was associated with a decrease in the risk of cesarean delivery with no increase in maternal fever in this large, generalizable cohort. However, IUPC use did not decrease the risk of cesarean or the risk of cesarean for arrest and resulted in an increased risk of maternal fever, either before or after delivery. Although maternal fever did not appear to negatively impact neonatal outcomes, maternal fever is associated with increased costs, antibiotic use, and increased length of stay. Therefore, we recommend that the use of internal monitors, particularly IUPC, should be used in laboring patients with a clinical indication such as inability to monitor externally and fetal heart rate decelerations. Routine use of intrauterine pressure catheters in every laboring patient with ruptured membranes is not necessary, as it does not appear to reduce cesarean and may increase the risk of maternal fever.

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Table 1

Maternal & Labor Characteristics

Data presented as mean \pm standard deviation, n(%), or median (interquartile range) as appropriate

All p<0.01

Table 2

* Adjusted for time from rupture to delivery 12 hours, regional anesthesia, black race, primiparous, and GBS status Adjusted for time from rupture to delivery ≥12 hours, regional anesthesia, black race, primiparous, and GBS status

 $^{\prime}$ Adjusted for time from rupture to delivery $~$ 12 hours, regional anesthesia, primiparous, GBS status Adjusted for time from rupture to delivery 21 hours, regional anesthesia, primiparous, GBS status

 $^{\sharp}$ Adjusted for time from rupture to delivery 12 hours, black race, GBS status, primiparous, cesarean delivery $*$ Adjusted for time from rupture to delivery $\,$ 12 hours, black race, GBS status, primiparous, cesarean delivery

 8 Adjusted for time from rupture to delivery 12 hours, induction of labor, body mass index, prior vaginal delivery, chorioamnionitis, and regional anesthesia Adjusted for time from rupture to delivery ≥12 hours, induction of labor, body mass index, prior vaginal delivery, chorioamnionitis, and regional anesthesia

Adjusted for time from rupture to delivery in hours, induction of labor, black race, body mass index, primiparous, and gestational age at delivery Adjusted for time from rupture to delivery in hours, induction of labor, black race, body mass index, primiparous, and gestational age at delivery

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Table 3

Risk of Adverse Maternal and Neonatal Outcomes by Type of Internal Monitor Risk of Adverse Maternal and Neonatal Outcomes by Type of Internal Monitor

Adjusted for time from rupture to delivery 12 hours, primiparous, regional anesthesia and induction of labor Adjusted for time from rupture to delivery ≥12 hours, primiparous, regional anesthesia and induction of labor

 $\mathring{\wedge}$ Adjusted for time from rupture to delivery 12 hours, primiparous, and induction of labor $^{\prime}$ Adjusted for time from rupture to delivery $\,$ 12 hours, primiparous, and induction of labor

 2 Adjusted for time from rupture to delivery 12 hours, black race, GBS status, primiparous, and regional anesthesia $*$ Adjusted for time from rupture to delivery $\,$ 12 hours, black race, GBS status, primiparous, and regional anesthesia

 $\stackrel{\text{\normalsize{8}}}{\text{\normalsize{A}}}\text{djusted for time from rupture to delivery}$ $\,$ 12 hours, induction of labor, and primiparous Adjusted for time from rupture to delivery ≥12 hours, induction of labor, and primiparous

Adjusted for time from rupture to delivery 12 hours, body mass index, primiparous, and regional anesthesia Adjusted for time from rupture to delivery ≥12 hours, body mass index, primiparous, and regional anesthesia

 $\mathbb{M}_{\rm{adjused}}$ for time from rupture to delivery $~$ 12 hours, primiparous, and cesarean delivery $^{\prime\prime}$ Adjusted for time from rupture to delivery $\,$ 12 hours, primiparous, and cesarean delivery

**
Adjusted for time from rupture to delivery 12 hours, black race, body mass index, prior vaginal delivery, maternal fever prior to delivery, gestational age at delivery, and regional anesthesia Adjusted for time from rupture to delivery 22 hours, black race, body mass index, prior vaginal delivery, maternal age at delivery, and regional anesthesia

 $^{\prime\prime}$ Adjusted for induction of labor, black rack, gestational age at delivery, and cesarean delivery ${}^{t}\hbar$ Adjusted for induction of labor, black rack, gestational age at delivery, and cesarean delivery

No internal monitors used as reference group No internal monitors used as reference group * Adjusted for prior vaginal delivery, rupture of membranes >12 hours, gestational age at delivery, induction of labor, black race, maternal fever prior to delivery, and regional anesthesia Adjusted for prior vaginal delivery, rupture of membranes >12 hours, gestational age at delivery, induction of labor, black race, maternal fever prior to delivery, and regional anesthesia 2 Adjusted for prior vaginal delivery, rupture of membranes >12 hours, gestational age at delivery, obesity, induction of labor, black race, maternal fever prior to delivery, and regional anesthesia /Adjusted for prior vaginal delivery, rupture of membranes >12 hours, gestational age at delivery, obesity, induction of labor, black race, maternal fever prior to delivery, and regional anesthesia

 2 Adjusted for prior vaginal delivery, gestational age at delivery, black race, induction of labor, obesity, and regional anesthesia $*$ Adjusted for prior vaginal delivery, gestational age at delivery, black race, induction of labor, obesity, and regional anesthesia

 $^{\circ}$ Adjusted for prior vaginal delivery, gestational age at delivery, induction of labor, and obesity Adjusted for prior vaginal delivery, gestational age at delivery, induction of labor, and obesity