Comparison of Two Intrauterine Pressure Catheters During Labor

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OBJECTIVE: To compare the Koala® air-charged coupled catheter (Clinical Innovations, Inc., Murray, Utah) for monitoring intrauterine pressure (IUP) during active labor with an electronic pressure

transducer-tip catheter, Intran® Plus (Utah Medical Products, Midvale, Utah). STUDY DESIGN: Simultaneous recordings with Koala® and Intran® catheters bound together at their tips were made in 18 term patients

using comparably calibrated fetal monitors.

RESULTS: Coefficients of correlation between the two IUP catheter systems for mean uterine baseline, peak pressures, contraction frequency and duration were .78, .90, 1.00 and .63 respectively. Both systems functioned equally well in displaying abnormal uterine activity. Some difficulty was encountered in placing the combined catheters in the amniotic fluid space: 4 of 18 (23%) were placed outside the chorionic membrane, in the extraovular space.

CONCLUSION: Comparisons of the recordings from both the Koala[®] and Intran[®] Plus catheters showed similar mean baseline uterine tone, peak pressures, *contraction frequency and duration.* (J Reprod Med 2003;48:501-505)

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The 2 catheter types appear to yield similar quantitative registration of uterine activity. Today, intrauterine pressure (IUP) is commonly measured during labor to indicate uterine tone and contraction strength. This is especially true in the

obese or thrashing patient, for whom external tocography is problematic. In the past, IUP monitoring was done by using resistive strain gauges, hydraulically coupled to external fluid-filled domes with catheters placed in the amniotic fluid in the uterus. Devoe¹ reported on a study that compared 2 methods of intrauterine pressure monitoring, 1 used a fluid-filled system and the second an electronic pressure transducer-tip catheter. Devoe found both systems to detect abnormal uterine activity equally well. His study used the Intran IUP system (Utah Medical Products, Midvale, Utah) which he described as based on a pressure-sensitive Wheatstone bridge transducer located in the catheter tip and that had to be properly

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zeroed to atmospheric pressure prior to insertion. Arulkumaran² reported a study involving 19 patients of whom 9 had two IUP catheters tied together to ensure they were placed in the same uterine pocket. That author found no significant difference in the catheters. Margano³ compared IUP catheter measurements in 15 patients, upper vs. lower uterine segments, and showed a difference in segmental contraction pressures. Ross⁴ monitored 8 laboring patients with transducer-tipped IUP catheters to show elevated uterine pressure measurements in resting tone.

IUPs were measured as early as 1867 using intrauterine balloons by Kehrer⁵; and Schatz⁶, in 1872, inserted the balloons between the membranes of the uterus and uterine wall. In 1927, IUP measurements were performed by inserting a catheter through the patient's abdominal wall and uterus and into the amniotic cavity. Graphic recordings of this method were not reported until 1950, by Alvarez and Calderyo-Barcia⁷. Transcervical introduction of IUP catheters did not become standard practice until the late 1960s⁸. The simultaneous continuous monitoring of the fetal heart rate and continuous IUP measurement interfaced into 1 clinical monitoring unit prompted the use of this less traumatic method of intrauterine catheter insertion. Since then, 2 varieties of IUP catheter have been used, water column and electronic microtip.

The water column method was the first to be introduced and widely used. It is a cumbersome form of pressure monitoring. First, the transducer is not situated to measure pressure at the source: as the pressure is transmitted through a water column to a transducer located at the monitor site. The associated problems include (1) a messy water setup, (2) having to level the system for calibration, (3) keeping the laboring woman still and in 1 place to avoid movement artifact, (4) staff unwillingness to allow the patient to rise and walk because of having to set up the system all over again, and (5) inability to perform meconium sampling with the system.

A new method of IUP recording, the Koala® IUP catheter system (Clinical Innovations, Inc., Murray, Utah) was recently introduced. This system employs air-coupling technology from a distally mounted flexible balloon in the uterus to an external, reusable transducer in the monitor cable and connector. This study compared the IUP recordings obtained with the Koala® system with those from the Intran® Plus catheter placed in third-trimester parturients who required intrapartum uterine activity monitoring. The goal was to determine whether there were differences

in the abilities of the 2 systems to record and measure standard parameters of intrapartum uterine activity: (1) peak contraction intensity, (2) resting baseline tone, (3) duration of contractions, and (4) interval, or frequency, of contractions.

Materials and Methods

Eighteen patients were enrolled in the study after signing informed consent forms for entering protocol approved by the hospital internal review board committee. All patients had clinical indications for IUP monitoring: (1) spontaneous or artificial rupture of membranes, (2) need for oxytocin enhancement of uterine activity, (3) inadequate external recording of uterine activity, (4) maternal obesity or uterine overdistention, and (5) previous cesarean section.

The two catheter systems were bound together in a parallel fashion with flexible heat shrink-wrap tubing continuously to 15 cm of their distal tips (Figure 1). This ensured that both catheters were at the same intrauterine location. The catheters were packaged, sealed and sterilized before use. A G.E. Medical Systems monitor (Corometrics, Model 120. Milwaukee, Wisconsin) was used to record the Koala® catheter system, and fetal heart rate (FHR) from a fetal scalp electrode, while a Hewlett Packard monitor (model 8040A, Andover, Massachusetts) was used to record the Intran® Plus Signal. The monitors were precalibrated and zeroed before use. The instructions for use included with each catheter were followed to zero and interface them to their respective monitor and reusable cable.



Figure 1 Two bound catheter systems.

Table I Summary of Patient Data

Parameter	Mean (± SD)	Range
Maternal Age (yr)	23.8±6.8	14-37
Gravidity	2.1±1.1	1-5
Parity	1.1±1.2	0-4
Cervical dilation (cm)	3.8±1.7	1-7
Gestational Age (weeks)	38.7±1.1	35.9-40.4
Fetal Birth Weight (gm)	3330±430	2402-4082
Length of Labor (hr)	12.2±5.3	6.2-30.5
Length of uterine monitoring (hr)	3.1±1.6	1-5.5
Number of contractions monitored by both systems	78±45	40-167

After intrauterine placement, simultaneous recordings from both catheters were begun and continued until delivery. One catheter combination (Intran Plus and Koala banded together) caused precipitous bradycardia and was immediately removed. Four of the remaining 17 (24%) catheter combinations were found, on removal, to be placed outside the amniotic membranes (blood and endometrial tissue on catheter tips). These results are comparable to those found by other reports.⁹⁻¹¹

Following completion of delivery, both strip charts were compared visually, and the individual uterine activity baselines and contractions were measured. Any recording abnormalities or technical problems, such as an artifact, signal loss or abnormal baseline patterns, were also noted. For each patient, mean frequency and interval of uterine contractions, resting baseline uterine tone, intensity of uterine contractions and duration of uterine contractions were determined. The means and standard deviations for those parameters were then calculated for all the recordings made with each system.

Statistical comparisons between recordings on each system were performed using 2-tail, paired *t*-tests, χ 2 tests and simple regression analyses. A P value of < .05 was considered statistically significant. Data from combination catheters placed outside the amniotic membranes were not used in the analysis.

Results

The 13 patients whose data were used in the study were in the active phase of labor (cervical dilation > 3 cm, effacement > 90%) at the time of catheter insertion (Table I). The minimum cervical dilation at the time of catheter insertion was 1 cm and the minimum effacement 60%; the highest pelvic

station of the vertex was -3. One catheter combination showed poor amplitude and erratic waveforms, and a second combination dual catheter was inserted. The dual systems' IUP catheter functioned satisfactorily after initial insertion and calibration. The 4 combination catheters that were placed outside the membranes required flushing, repositioning and signal loss. Data from these catheters were not used due to the poor quality of their waveforms. IUP catheters that are placed outside the membranes do not accurately represent amniotic fluid pressure as there is a membrane between the pressure sensor and fluid that pushes on the fetus. In addition, this situation is prone to placental abruption and perforation and can be unsafe in the event that amnioinfusion is instituted.

All fetuses were singleton, without anomalies and in vertex presentation. No fetal trauma was noted upon delivery. All the infants were discharged from the nursery in good condition. Abnormal intrapartum FHR patterns were present in 2 cases, and those fetuses were delivered by cesarean section due to failure to progress and nonreassuring FHR patterns. The number of catheters requiring flushing or readjustment and the number of catheters producing signal loss were not significantly different between IUP catheter types. One Koala® and one Intran® Plus required flushing and readjustment. One Intran® Plus displayed a short segment of artifactual peak contraction. One Koala® and 1 Intran® Plus were zeroed improperly and required recalibration of the baseline.

Table II shows the results of the comparison for the major characteristics measured by the 2 catheters. A total of 1,013 contractions were measured simultaneously by the two systems. A power analysis

Table II Characteristics of Monitoring Systems

Characteristic	Koala	Intran	Р
Contraction frequency (min) (mean+SD)	2.1±.7	2.1±.7	1.00
Contraction duration (sec) (mean±SD)	87±15	87±16	0.77
Peak contraction intensity (mmHg) (mean±SD)	54.6±16.1	55±17.0	0.91
Resting uterine tone (mmHg) (mean±SD)	15.8±6.1	15.9±7.0	0.13
No. requiring flushing or readjustment	1	1	0.60
No. with unrecorded contractions (missing signal)	1	1	0.60



Figure 2: Fetal heart rate tracing, first stage of labor for (A) Koala® and (B) Intran®.

(90% level) shows that a difference of 2 mm Hg in peak contraction intensity and 0.8 mm Hg in resting uterine tone could be detected with a 95% certainty. No difference in either parameter was evident from the results.

The correlation coefficients of resting uterine tone, peak IUP, interval between uterine contractions and duration of uterine contractions were .78, .90, 1.00 and .63, respectively. Analysis of individual patient records showed no consistent trend in the discrepancies between the 2 catheter systems.

Visual inspection of the combined recordings suggested a high degree of similarity between the two systems for each patient (Figures 2 and 3). Uterine tetany or tachysystole were not observed in any case.

Inspection of the catheters after their removal at delivery failed to show any obvious damage or defects in either catheter type. Four of the catheter combinations had bloody endometrial tissue on their tips when removed. No untoward effects on the fetus or maternal tissue were found.

Discussion

The data suggest that the Koala® air-coupled balloon sensor system produce recordings of intrapartum alterations in uterine pressure that resembled those generated by Intran® catheters with respect to baseline tone, peak pressure readings and contraction timing. The performance of the Koala® system appeared acceptable using the criteria of single capture, rate of technical problems and ability to detect abnormal uterine activity patterns.

In the 4 combination catheters placed inadvertently outside the amniotic fluid space, that both IUP catheter systems displayed wandering baselines, poor peak contractions and erratic waveforms. The



gure 3: Fetal heart rate, second stage of labor, for (A) Koala® and (B) Intran®.

dual catheters placed in the amniotic fluid space displayed characteristically high quality signals and compared very well.

The comparison of uterine activity are based on a small patient sample surveyed over a limited period of active labor and may not be generalizable to larger samples with longer durations of invasive uterine monitoring. Given these constraints, the 2 catheter types appear to yield similar quantitative registration of uterine activity. The extraovular insertion rate may have been related to the larger mass represented by the tandem array of two catheters and/or different insertion techniques used during the trial.

There were no statistically significant differences between the 2 catheters with regards to contraction frequency, contraction duration, peak contraction intensity, resting uterine tone, number requiring flushing or number with unrecorded contractions. Thus it appears that the catheters compare well in measuring intrauterine pressure.

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