Evaluating a New Intrauterine Pressure Catheter

Mark Dowdle, M.D.

OBJECTIVE: To evaluate the performance and verify the safety of the Koala Intrauterine Pressure Catheter (IUPC) in clinical use.
STUDY DESIGN: Twenty IUP Koala Catheters were placed in laboring women. IUPC monitoring provided diagnostic information in assessing the pressures generated by the myometrium during the labor and delivery process. Information was recorded pertaining to the catheters' safety, ease of use, accuracy, zeroing, drift and amnioinfusion capability. Comparisons were made to a preexisting IUPC.
RESULTS: The Koala catheter was safe to introduce into the intrauterine cavity, There were no problems with amnioport communications, connectors, placental perforation, unusual patient discomfort or infections with either the Koala or Intran fluid-filled system. The numerical ratings were compared using the Mann-Whitney test and showed no significant difference between the two groups in safety, zeroing and drift. A statistically significant difference at the .01 level for ease of use, accuracy and setup in favor of the Koala was found.
CONCLUSION: Clinical study of the Koala Intrauterine Pressure Catheter vs. Intran and the other fluid-filled catheters demonstrated the Koala to be as safe and as functionally effective as, or more effective than, standard IUPCs. (J Reprod Med 1997;42:506-513)

Keywords: electronic fetal monitoring, labor, intrauterine pressure catheters.

> The Koala was as safe as, or safer than, and as functionally effective as, or more effective than, currently used IUPCs.

Introduction

Fifteen to twenty percent (600,000-800,000) of the 4 million deliveries annually in the United States are monitored with an intrauterine pressure catheter. This procedure provides diagnostic information that is useful to the clinician in assessing the pressures generated by the myometrium and in following the condition of the fetus during labor and delivery.[1,2]

Fetal monitoring systems provide continuous information regarding uterine activity. Internal, or direct, intrauterine pressure measurement permits evaluation of uterine contraction frequency, duration and amplitude and of resting uterine tones.[3]

Intrauterine pressure has historically been obtained via an open-end, fluid-filled intrauterine pressure catheter (IUPC) attached to an external strain gauge transducer. Presuming that intrauterine and intracatheter fluid is a closed system, Pascal's law provides that the intrauterine pressure generated by a contraction will be transmitted directly to the pressure transducer. The transducer-monitor unit then displays the intrauterine pressure in graphic form on a fetal monitoring strip chart.[4]

While the fluid-filled IUPC system (IUPC catheter, catheter sleeve, external pressure transducer, normal saline, syringe and three-way stop-cock) provides valuable clinical information, some technical and logistic

From the Department of Obstetrics and Gynecology, Cassia Memorial Hospital, Burley, Idaho.
Address reprint requests to: Mark Dowdle, M.D., Department of Obstetrics and Gynecology, Cassia Memorial Hospital, 2311 Park Avenue, Burley, ID 83318.

0024-7758/97/4208-0506/$1.50/0

problems exist. Insertion of the IUPC typically requires an amount of preparation and assistance that occasionally thwarts timely insertion. Upon successful catheter placement, the system must be equilibrated to atmospheric pressure to ensure the accuracy of intrauterine pressure monitoring. Recalibration ("re-zeroing") and flushing of the system is often necessary, especially if the height of the pressure transducer relative to that of the amniotic fluid level changes-e.g., elevation of the patient's bed, sitting, etc. While the calibration procedure is relatively simple, this inconvenience can compromise the accuracy of IUPC data. Further, the fluid-filled IUPC system, as designed, is subject to the introduction of artifact secondary to maternal movement and catheter manipulation.[5]

Since mid-1987, a direct intrauterine pressure device (Intran, Utah Medical Products, Inc., Midvale, Utah) has been available for clinical use; it functions without the fluid-filled catheter apparatus. This device consists of a micro-pressure transducer, located at the tip of the catheter, that is inserted directly into the uterine cavity. With such a system, many of the inconveniences associated with the standard system are eliminated.[6,7]

The Koala IUPC (Clinical Innovations, Inc., Murray, Utah) is equivalent in function to the Intran but has a softer, smaller and more flexible tip. In addition, it has the ability to zero the transducer while the catheter is *in utero*, making it more convenient and accurate (Figure 1).

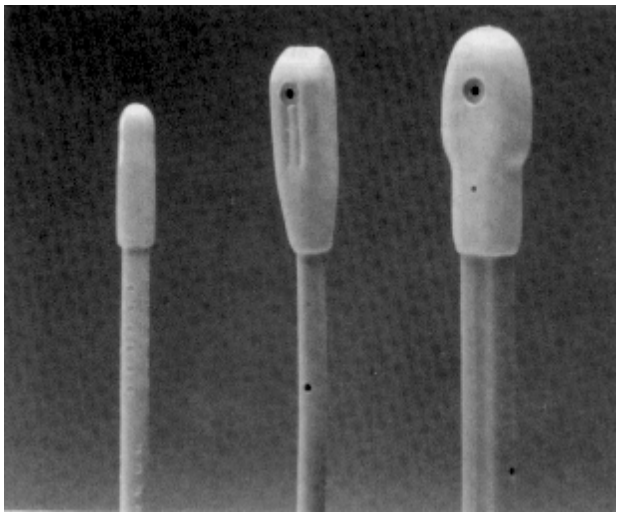

Figure I Koala catheter tip (left) as compared to Intran Plus (center) and SoftTrans (right) (Graphics Control, Buffalo, New York).

Materials and Methods

Clinical studies were carried out to test the safety and performance of the Koala on 20 women in actual clinical use and in comparison to commonly used intrauterine pressure catheters.

Clinical testing on patients receiving intrauterine monitoring with the Koala were set up to test its usefulness as a safe and effective device. The general requirements for the study were:

- At all times throughout the clinical study, confidentiality was observed by all parties involved.
- All data were secured against unauthorized access.
- All relevant parties were qualified to perform their tasks.
- In the event of unforeseen or increased risks to subjects, suspension or termination of the clinical study was planned; however, it was not required.
- The clinical study was designed to collect data to demonstrate whether the device was suitable for the population of pregnant women undergoing labor and delivery.
- The institutional review board (IRB) was provided with information to assess whether the risks to subjects were justified by the collective benefit.
- The clinical study was not started until its approval by the IRB.

Training was given on the proper placement of the Koala as indicated by the manufacturer. Instruction on proper placement of the Koala included the following: vaginal examination to determine dilation, effacement, fetal position, preferred intrauterine quadrant and evaluation of safety due to placental location at the cervix. Directions for use were reviewed and followed.

Pregnant women who agreed to enter the study were randomly selected. The procedure was performed, questionnaire filled out and data collected. Informed consent forms were signed prior to the procedure. All intrauterine pressure catheters were single-use devices sterilized by gamma radiation. Women undergoing delivery who had the following conditions were excluded: uterine cavity bleeding or infection, placenta previa or inadvisable use of an IUPC for any reason as determined by physician.

Patients were evaluated after the procedure in the hospital and on follow-up examination within one to two weeks for any complications, such as bleeding or infection.

Table I Koala lUPC

Case no.	Catheter no.	Time in use (h)	Parity	Insertion data	Safe to insert	Safety rating	Easy to insert
1	960151-20	3	4004	4/80/-3	Y	4	Y
2	960151-18	2	2002	7/80/-2	Y	4	Y
3	960151-17	1.5	150215	7/80/-2	Y	4	Y
4	960411-18	1	1001	4/80/-2	Y	4	Y
5	960134-6	9	0000	3/90/-2	Y	4	Y
6	960411-19	3	0000	2/80/-2	Y	4	Y
7	960411-16	11	0000	4/100/-2	Y	4	Y
8	960403-2	2.5	0000	6/100/-2	Y	4	Y
9	960411-34	3	4004	4/80/-2	Y	4	Y
10	960411-35	1	0000	8/100/-l	Y	4	Y
11	960403-01	.75	1001	4/80/-2	Y	4	Y
12	960403-05	12	0000	4/100/-2	Y	4	Y
13	960318-04	4.5	1001	4/100/-2	Y	4	Y
14	960318-03	4.5	1001	7/100/-2	Y	4	Y
15	960151-19	3.5	1001	3/80/-3	Y	4	Y
16	960134-7	14	0010	3/80/-2	Y	4	Y
17	960411-17	2.5	1001	6/100/-2	Y	4	Y
18	960411-20	9	0000	2/80/-2	Y	4	Y
19	960411-33	1.5	0000	4/80/-2	Y	4	Y
20	960151-21	3	3003	3/80/-3	Y	4	Y
Average		4.6125				4	

Y = yes, N = no, N/A = not applicable.
[a]These units required disconnecting and reconnecting the catheter to obtain a proper baseline.

The data recorded on the evaluation forms were tabulated and summarized. Each quantitative category was totaled, averaged and compared to determine significant differences. The following are explanations of the categories:

- *No*. The patient number in the study.
- *Catheter no.* Designation of the manufacturing catheter lot number and catheter designation for traceability.
- *Time in use.* Number of hours the Koala

Table II Intran IUPC

Case no.	Catheter no.	Time in use (h)	Parity	Insertion data	Safe to insert	Safety rating	Easy to insert
1	960151-20	3	4004	4/80/-3	Y	3	Y
2	960151-18	2	2002	7/80/-2	Y	3	Y
3	960151-17	1.5	150215	7/80/-2	Y	4	Y
4	960411-18	1	1001	4/80/-2	Y	3	Y
5	960134-6	9	0000	3/90/-2	Y	4	Y
6	960411-19	3	0000	2/80/-2	Y	3	Y
7	960411-16	11	0000	4/100/-2	Y	4	Y
8	960403-2	2.5	0000	6/100/-2	Y	3	Y
9	960411-34	3	4004	4/80/-2	Y	4	Y
10	960411-35	1	0000	8/100/-l	Y	3	Y
11	960403-01	.75	1001	4/80/-2	Y	3	Y
12	960403-05	12	0000	4/100/-2	Y	3	Y
13	960318-04	4.5	1001	4/100/-2	Y	4	Y
14	960318-03	4.5	1001	711001-2	Y	4	Y
15	960151-19	3.5	1001	3/80/-3	Y	4	Y
16	960134-7	14	0010	3/80/-2	Y	4	Y
17	960411-17	2.5	1001	6/100/-2	Y	4	Y
18	960411-20	9	0000	2/80/-2	Y	4	Y
19	960411-33	1.5	0000	4/80/-2	Y	4	Y
20	960151-21	3	3003	3/80/-3	Y	4	Y
Average		4.6125				3.6	

Y = yes, N = no, N/A = not applicable.

Ease rating	Accurate reading	Accuracy rating	Easy to set up	Setup rating	Accurate zeroing	Easy to zero	Zeroing rating
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
3	Y	4	Y	4	Y	Y	3
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	3	Y	4	N[a]	Y	4
4	Y	4	Y	4	Y	Y	4
4	Y	2	Y	4	N[a]	Y	4
4	Y	1	Y	3	N[a]	Y	4
4	Y	4	Y	4	Y	Y	4
3.9.5		3.7		3.95			3.95

catheter monitored the patient.

- *Parity*. Patient's pregnancy reccord.
- *Insertion data*. Patient's cervical dilation, effacement and fetal station at the time of the catheter placement.
- *Insertion safety*. Physician's evaluation of the safety of inserting the device.
- *Safety Rating*. Physician's clinical evaluation of the rating of the safety of the device as compared to that of other intrauterine pressure catheters.

Ease rating	Accurate reading	Accuracy rating	Easy to set up	Setup rating	Accurate zeroing	Easy to zero	Zeroing rating
3	Y	3	Y	3	Y	Y	3
4	Y	3	Y	3	Y	Y	4
3	Y	3	Y	3	Y	Y	4
4	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	4
4	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
4	Y	3	Y	3	Y	Y	4
4	Y	3	Y	3	Y	Y	4
3	Y	3	Y	3	Y	Y	4
3	Y	3	Y	3	Y	Y	4
4	Y	3	Y	3	Y	Y	4
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3	Y	3	Y	3	Y	Y	3
3.3		3		3			3.4

Drift acceptable	Drift rating	Amino-infusion	Flushed catheter	Catheter responded	Connector problems	Patient infection	Uterine perforation	Resting tone (mm Hg)	Comments
Y	4	N	N	N/A	N	N	N	19	No problems
Y	4	N	5 mL	Y	N	N	N	12	
Y	4	Y	N	N/A	N	N	N	12	Grand multipara
Y	4	N	N	N/A	N	N	N	20	Great again
Y	4	N	10 mL	Y	N	N	N	17	No problems
Y	4	Y	N	N/A	N	N	N	13	
Y	4	N	N	N/A	N	N	N	15	Worked well
Y	4	N	N	N/A	N	N	N	10	Worked great this time.
Y	4	Y	N	N/A	N	N	N	10	Worked well
Y	4	N	N	N/A	N	N	N	19	
Y	4	N	N	N/A	N	N	N	19	Worked well, no problems
Y	4	N	5 mL	Y	N	N	N	15	Worked well
Y	4	N	N	N/A	N	N	N	15	No problems
Y	4	Y	N	N/A	N	N	N	12	Worked well
Y	4	N	N	N/A	N	N	N	14	Great, no problems
Y	4	N	5 mL	Y	N	N	N	25	
Y	4	Y	N	N/A	N	N	N	15	
Y	4	N	N	N/A	N	N	N	5	
Y	4	N	N	NI/A	N	N	N	12	Worked well
Y	4	Y	5 rnL	Y	N	N	N	14	
	4							14.65	

Rating of not safe was 1, and that of very safe was 4.

- *Insert ease.* The obstetrician's subjective evaluation of the ease of inserting the IUPC into the uterine cavity.
- *Ease rating*. Clinician's subjective comparative rating of ease of insertion. It was based on a scale of 1-4, with 1 difficult and 4 very easy.
- *Accuracy*. This was the physician's subjective

Drift acceptable	Drift rating	Amino-infusion	Flushed catheter	Catheter responded	Connector problems	Patient infection	Uterine perforation	Resting tone (mm Hg)	Comments
Y	3	N	N	N/A	N	N	N	N/A	Standard product
Y	4	N	5 mL	Y	N	N	N	N/A	Standard product
Y	3	Y	IN	N/A	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	3	N	10 mL	Y	N	N	N	N/A	Standard product
Y	4	Y	N	N/A	N	N	N	N/A	Standard product
Y	3	N	N	N/A	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	Y	N	N/A	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	N	5 mL	Y	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	Y	N	N/A	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	N	5 mL	Y	N	N	N	N/A	Standard pro uct
Y	4	Y	N	N/A	N	N	N	N/A	Standard product
Y	4	N	N	NIA	N	N	N	N/A	Standard product
Y	4	N	N	N/A	N	N	N	N/A	Standard product
Y	4	Y	5 mL	Y	N	N	N	N/A	Standard product
	3.8								

Table III P Values of Rated Parameters

Parameter	P	Significant difference
Safety	.03	No
Ease of insertion	.0004	Yes
Accuracy	.0002	Yes
Setup	.0004	Yes
Zeroing	.03	No
Drift	.08	No

evaluation of whether the IUPC accurately reflected the patient's clinical assessment of intrauterine pressure.

•*Accuracy rating.* The physician's estimation of the IUPC's level of accuracy as compared with that of standard intrauterine catheters, with 1 inaccurate and 4 accurate.

•*Setup ease.* The physician's estimation of whether the catheter was easy to set up for use.

•*Setup rating.* The physician's evaluation of the ease of setup of the Koala, based on 1 for difficult and 4 for very easy.

•*Zero accuracy.* The obstetrician's evaluation of how the catheter's zero compared to clinical assessment of resting tone.

•*Zero ease.* The obstetrician's evaluation of whether the catheter was easily zeroed.

•*Zero rating,* Evaluation of the physician's assessment of the ease of zeroing the catheter as compared to zeroing standard IUPCs; 1 was difficult and 4 easy.

•*Drift.* Physician's assessment of the catheter's signal drift during monitoring.

•*Drift rating.* Physician's subjective comparison of the catheter's signal drift during monitoring; 1 was high and 4 low.

•*Infuse.* Whether the catheter's amnioport was used for infusion of saline solution.

•*Flushed catheter.* How much saline (if the catheter was flushed) and used to flush the catheter for a poor signal.

•*Response.* Indication of whether the catheter responded to the trouble shooting of rotation, retraction or flushing, if applicable.

•*Connectors.* The clinician's clinical assessment of whether the connectors and signal transmission to the monitor were satisfactory.

•*Patient infection. A* record of whether there were any infections attributable to the device used.

•*Placental perforation.* Record of whether the placenta (or uterus) was penetrated or perforated during the procedure.

•*Resting tone.* Baseline tone of the IUPC.

•*Comments.* Record of any comments or observations that the clinician made. Included any comments by the clinician on whether the catheter slipped out during monitoring and had to be reinserted.

Table I shows the summarized data as recorded on the Koala, and Table II shows the summarized data as recorded on the Intran. The Intran was compared to the Intran III and Intran Plus, and the fluid-filled IUPC was the Corometrics Standard Fluid-Filled IUPC System. The numerical ratings between the Koala, Intran and fluid-filled catheters were compared using the Mann-Whitney test (a non-parametric method using ranking for unpaired measurements).

Results

The patients in both groups were from similar populations and were similar in age, race, gravidity, parity, presenting condition and risk factors. The average time of IUPC use was 4.6 hours. The Koala, Intran and fluid-filled catheter were rated safe to use by the clinicians. Subjective evaluations of ease of insertion, accuracy of signal, ease of setup, ease of zeroing, drift acceptability and connector problems were good and similar in both IUPC groups. There were no problems with amnioport communication, placental perforation, unusual patient discomfort or infections with either the Koala or Intran fluid-filled systems. The resting tone was recorded only for the Koala since the Intran IUPCs were a mixture of fluid filled and sensor tipped. It has been the author's experience that resting tone pressures in fluid-filled systems average approximately 10 mm Hg. Table III shows the *P* values of the rated parameters. The Mann-Whitney test numerical ratings for (1) safety during insertion, (2) signal zeroing, and (3) signal drift showed no significant difference between the two groups (Tables I and II). A statistically significant difference at the .01 level between the two groups (Koala vs. Intran and fluid filled) was found for (1) ease of insertion, (2) level of clinical accuracy, and (3) setup ease of use, all three in favor of the Koala over the Intran and fluid-filled IUPC. No catheters came out inadvertently during the study.

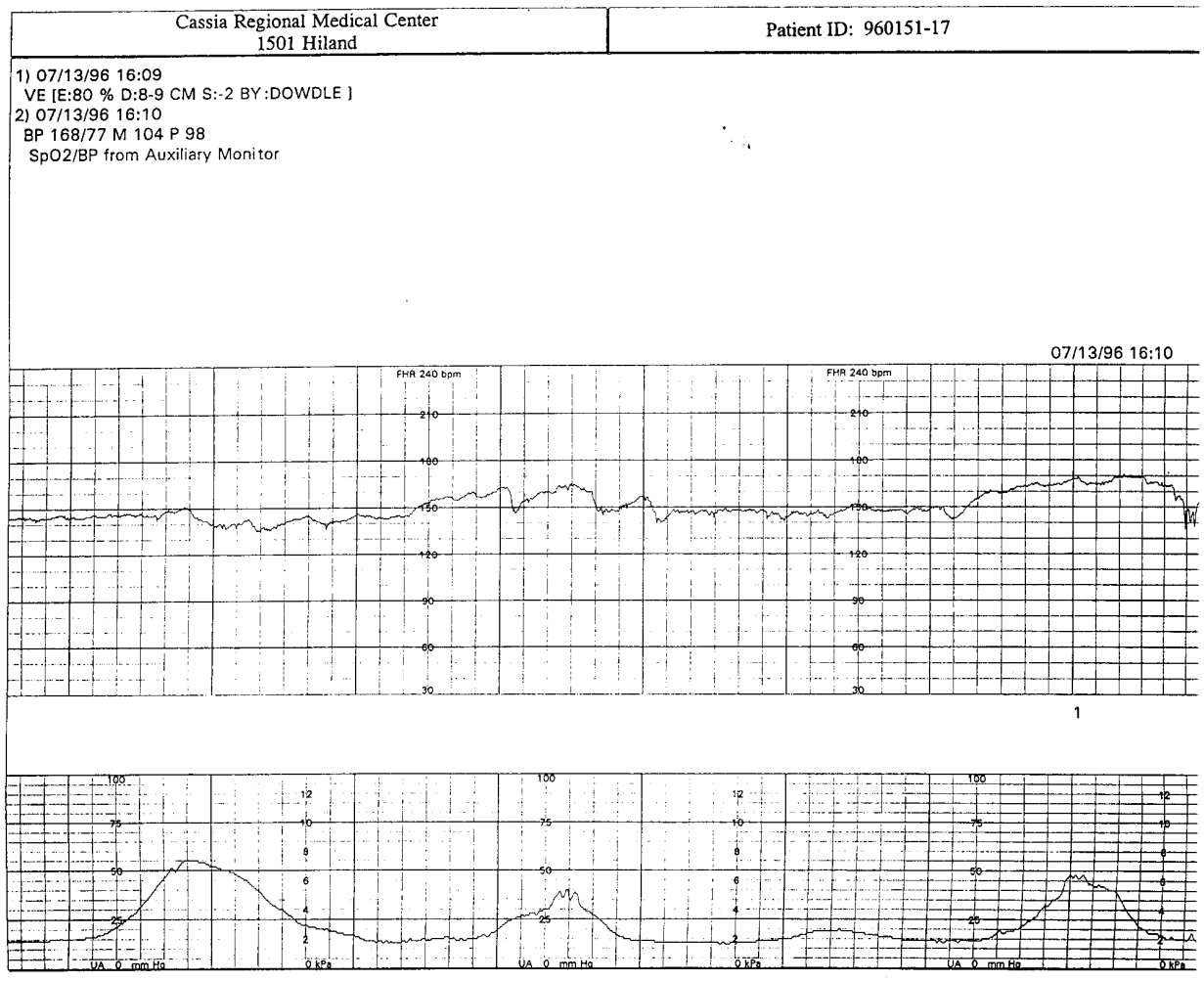

Figure 2 Segment of a patient's strip chart recording.

Discussion

The clinical study comparisons between the Koala, Intran and fluid-filled catheter demonstrated that the Koala was as safe as, or safer than, and as functionally effective as, or more effective than, currently used IUPCs. In addition, the Koala demonstrated the following advantages and features: (1) softer, smaller catheter tip, thus making it more easy to insert; (2) simpler, more streamlined design, making the Koala easier to use and safer to insert; (3) accurate signal transmission to monitor, perhaps due to the design of multiple holes in the catheter tip transmitting all amniotic fluid pressure to the transducer or due to no thermal changes since the transducer is located outside the body and thus does not undergo a change from room temperature to body temperature; (4) easier to set up and easier to zero *in utero* due to the simplicity of the transducer location in the reusable connector; (5) amnioport communication with sufficient flow for amnioinfusion or amniotic sampling; and (6) a more flexible body, which helps the Koala remain in place during monitoring.

The Koala hospital list price is $28 as compared to the Intran Plus of $35, for a 20% savings for the hospital.

One patient had a history worth detailing. She was a grand multipara (15 prior full-term deliveries) with a

low-amplitude contraction pattern. (Figure 2 shows a segment of the strip chart recording.) The maximum pressure that the myometrium generated was only approximately 50 mm Hg. Additional oxytocin did not induce the uterus to produce > 50 mm Hg of pressure. Shortly after the patient reached this intrauterine pressure level, the infant was born.

Contrary to the resting tone differences theorized in the literature,[8] only minimal differences between the Koala sensor-tipped catheter and the fluid-filled system were observed in this study (range from 5 to 25 mm Hg and average 14.6 mm Hg as compared to ~ 10 mm Hg for the fluid-filled devices). Perhaps this is because in the laboring uterus there exist pockets of fluid that do not always freely communicate. These loculated amniotic fluid pockets shift during contractions and fetal movement and eventually communicate with each other, thus creating the intrauterine pressure required to dilate and efface the cervix and push the fetus through the birth canal. With this in mind, differentiating the resting tone from hydrostatic pressure has little value since the important component is the total force or pressure created by the myometrium to deliver the fetus. Isolated pockets of fluid add little to the overall fetal hydrostatic pressure. Therefore, the simple model of a pear-shaped pool of amniotic fluid, having a free-floating fetus, is not an accurate representation. When questions arise concerning the differences between resting tone and hydrostatic head pressure, these differences can be evaluated with catheter-tipped IUPC systems by having the patient turn to different sides and by observing the effect on the baseline.

The Koala appears to be a practical intrapartum. device. The usual safeguards for intrauterine catheter insertion should be followed.

References

1. Herbert WNP, Stuart N, Butler LS: Electronic fetal heart rate monitoring with intrauterine fetal demise. J Obstet Gynecol Neonat Nursing 1987;16:249-251

2. Mead PB: Maternal and Fetal Infection Related to Internal Fetal Monitoring. Ithaca, New York, Perinatology Press, 1982, pp 127-129

3. Serr DM: Methods for recording the continuous fetal heart rate and uterine contractions. Clin Obstet Gynecol 1974;1: 1169-1190

4. Alverez H, Caldeyro R: Human uterine contractility by new methods. Surg Gynecol Obstet 1950;91:11-13

5. Devoe LD, Gardner P, Dear C, Searle N: Monitoring intrauterine pressure during active labor: A prospective comparison of two methods. J Reprod Med 1989;34:811-814

6. Murray M: Essentials of Electronic Fetal Monitoring: Antepartal and Intrapartal Fetal Monitoring. Albuquerque, New Mexico, Learning Resources International, Inc, 1988

7. Strong TH Jr, Paul RH: Intrapartum uterine activity: Evaluation of an intrauterine pressure transducer. Clin Obstet Gynecol 1989;73:432-434

8. Ross MG, Walton J: Artifactually elevated basal uterine tonus resulting from measurement of hydrostatic pressure by transducer-tipped intrauterine catheters. J Perinatol 1994;14: 408-410