

September monthly news!

COOK CATHETER is here!

COOK Cervical Ripening Balloon
PRE-INDUCTION CERVICAL DILATION



New Studies in the works to start in mid September 2012!

Cook Cervical Ripening Ballon (CRB) study is to compare the CRB plus Pitocin to Pitocin alone for induction in term and near term PROM patients not in labor. Cervical ripening and induction of labor continues to be a significant problem for patients with premature rupture of membranes (PROM) at term and near term with an unfavorable cervix. Despite the fact that some chemical means of effecting cervical ripening exist, their effectiveness is unpredictable in PROM patients.

SCREENING CRITERIA

1. Singleton or twin pregnancy, ≥ 18 years old and agrees to participate
2. GA 34w0d to 42w0d @ time of enrollment
3. Premature rupture of membranes (PROM) not in labor
4. Bishop score ≤ 6
5. No evidence at time of enrollment of:
 - Chorioamnionitis
 - Malpresentation

- History of previous C-section or uterine surgery
- Major fetal anomaly
- Significant vaginal bleeding
- Any other contraindication to vaginal delivery

PROCEDURE

1. Screen patient & if eligible, obtain written consent (ICF)
2. Randomize patient using the RAPID phone system, to CRB catheter with Pitocin (Group A), or Pitocin alone (Group B)
3. Cook catheter placement (for Group A) and starting of Pitocin for both group A & B to take place within 1 hr. of signing consent
4. Cook CRB catheter to be inflated with 60cc, and the vaginal balloon will be inflated with 30cc, and remain in situ for up to 12 hrs. or until it falls out
5. Vaginal exams for mBS to be done at 6, 12, & 18 hrs. after CRB is placed
6. Continuous EFM/CTG monitoring until delivery

Dr Miller's Quote of the Month

"When a man goes through six years training to be a doctor he will never be the same. He knows too much."



Enid Bagnold on doctor...

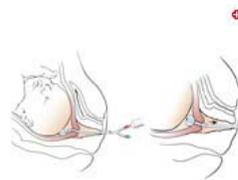
Dr. Hugh Miller

Step 1



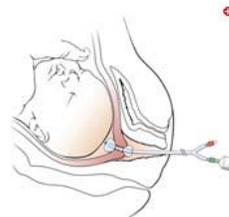
Advance the Cervical Ripening Balloon through the cervix until both balloons have entered the cervical canal.

Step 2



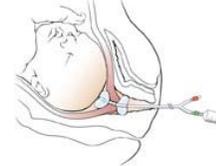
Inflate the uterine balloon with 60 cc of saline. Once the uterine balloon is inflated, the device is pulled back until the balloon abuts the internal cervical os.

Step 3



The vaginal balloon is now visible outside the external cervical os and is inflated with 30 cc of saline.

Step 4



Once the balloons are situated on either side of the cervix, placement of the balloon should be timed so that it is in place no longer than 12 hours before active labor is induced.

Fetal Cell-Free DNA In Maternal Blood Unaffected By Trisomy Risk, Study 31 Aug 2012

Findings Support Applicability of Non-invasive Prenatal Testing in General Screening Population

A study published in *The Journal of Maternal-Fetal and Neonatal Medicine* demonstrates that the fraction of fetal cell-free DNA (cfDNA) in maternal blood is unaffected by the mother's presumed risk for trisomy, offering support for the use of non-invasive prenatal testing (NIPT) for detecting genetic conditions such as Down syndrome in a broad patient population. Lead and senior authors of the study were Dr. Herb Bar, Director of Riverside Perinatal Diagnostics Center, and Dr. Mary Norton, Professor of Obstetrics and Gynecology, Lucile Packard Children's Hospital at Stanford University, respectively.

Results of the study, a post-hoc comparative analysis of the previously published "Non-invasive Chromosomal Evaluation" (NICE) study, showed that there were no significant differences in the fraction of fetal cfDNA in maternal blood in women who were stratified into three different trisomy risk groups based on maternal age, prenatal screening results or nuchal translucency measurement. The amount of fetal cfDNA in maternal blood is the principal factor in successfully detecting trisomies with NIPT. Trisomy refers to the presence of three chromosomes rather than two. Certain trisomies are known to cause genetic conditions.

"The results of this study were particularly significant because they showed that fetal fraction of cfDNA does not vary significantly among pregnant women regardless of their predetermined trisomy risk," said Dr. Herb Brar. "This adds to the growing amount of research that suggests NIPT can offer an effective prenatal screening option in the general pregnant population."

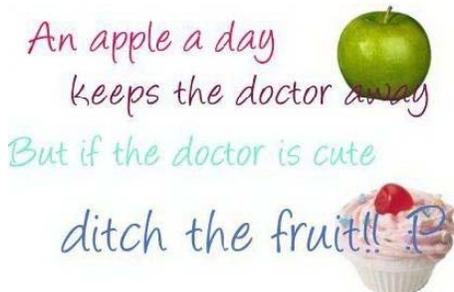
NIPT is a new screening option that analyzes cell-free fetal DNA circulating in maternal blood to evaluate the risk of having a baby with Down syndrome and other common genetic conditions. It involves a single blood draw as early as 10 weeks' gestation and delivers a greater than 99 percent detection rate for trisomy 21, which causes Down syndrome. NIPT, using the Harmony™ Prenatal Test, also has shown to have fewer false positive test results; up to 50 times less than traditional prenatal screening options such as maternal serum screening.

References:

Source: Ariosa Diagnostics, Inc.
<http://www.medicalnewstoday.com/releases/249681.php>

Previous studies of the entire cohort of the NICE study demonstrated that fetal fraction did not vary with race, ethnicity, maternal age, or trisomy type. It also showed that the fraction of fetal cfDNA was similar in pregnancies of gestational ages between 10 and 22 weeks. The NICE study was a prospective cohort study of more than 4,000 pregnant women of at least 10 weeks' gestational age across 50 clinical sites internationally. The study evaluated the performance of Ariosa Diagnostics' Harmony Prenatal Test in detecting fetal trisomy 21 and 18, which cause Down syndrome and Edwards syndrome, respectively. The NICE study evaluated any patient undergoing invasive prenatal testing, such as chorionic villus sampling (CVS) or amniocentesis, not just those who were determined to be at higher risk of having a baby with a genetic condition.

"We believe strongly that scientific research supports NIPT as a screening option for any pregnant woman, empowering them and their physicians to make the best decisions for individual circumstances. This is simply good patient care," said Ariosa Diagnostics CEO Ken Song, M.D. "NIPT has proven effective in thousands of patients, with a high accuracy and low false positive rate of less than 0.1% for each trisomy tested. It offers several advantages over traditional screening tests and can more appropriately triage those women who should undergo invasive procedures, namely amniocentesis and CVS, which carry a small risk of miscarriage."



THE 7 TYPES OF PHYSICIAN HANDWRITING

5 YEAR OLD HANDWRITING:

Patient seen and examined

IMMACULATE, ILLEGIBLE SCRIPT:

Ultrasound performed, results sent

SANSKRIT:

ॐ नमो भगवते वासुदेवाय

EVERY 4TH WORD LEGIBLE:

Very critical and in STAT!

EVERY WORD MUST TOUCH LINE MARGINS:

Patient is also and oriented x

TEENY TINY:

Patient has history of hypertension and diabetes

HAD 30 SECONDS TO WRITE NOTE:

me

Current Studies Enrolling

In Patient

- **17 PPROM weekly Makena Progesterone injection vs Placebo for patients who have ruptured their membranes between 23w0d and 31w6d at time of enrollment**
- **Removal vs Retention of Cerclage in PPROM between 22w-32w 6/7 GA, Cerclage in place ≥ 1 week. ACTIVE labor is excluded**

Outpatient

- **Makena 17P weekly progesterone injection vs Placebo for patients with a history of pre-term delivery at < 37 weeks GA**
- **Family Alliance Study, Smoking Intervention for pregnant smokers with a viable GA ≥ 14 weeks – 28w 6/7. Must be fluent in English**

Contact W.O.M.B with any questions or comments:



Watching Over Mothers and Babies

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Fun Facts

“4000 years of Medicine”

- 2000 BC: Here, eat this root.
- 1000 AD: The root is heathen! Here, say this prayer.
- 1865 AD: The prayer is superstition! Here, drink this potion.
- 1935 AD: The potion is snake oil! Here, swallow this pill!
- 1975 AD: The pill is effective. Here, take this antibiotics.
- 2000 AD: The antibiotic is poison! Here, eat this ROOT.