Should Written Consent Be Required before Fetal Membrane Stripping **Especially among GBS Carriers?**

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Sir Astley Cooper

Abstract
Background/ Introduction:
Fetal membrane stripping or sweeping (FMS) is a "traditional" obstetrical procedure intended to induce labor, shorten gestation, or, more recently, reduce the occurrence of prolonged gestation (> 42 weeks) Among pregnancy providers, FMS is considered a long-accepted procedure which 1) does not require accepted procedure wmcn 1 Jodes not require procedural explanation or patient consent prior to performance and 2) does not have any known billing code or electronic medical record (EMR) category. This procedure has not been evaluated with rigorous scientific methods to demonstrate effectiveness and determine risk (including patient discomfort and notantially incrudation the Invest uteria segment with potentially inoculating the lower uterine segment with microorganisms known to cross intact membranes causing fetal injury and death) vs. benefit ratios.

1) We surveyed obstetric and midwife providers employed at the University of Colorado Anschutz Medical Center and group B strep (GBS) parents through a parent-interest group (Group B Strep International [GBSI]), using both internet and personal contacts to determine the current use of FMS procedural consents or patient informational "handouts" prior to the procedure. Semi-qualitative methods were used.

2) We reviewed recognized criteria for patient-informed consent for clinical procedures.

No providers or GBS parents reported use of any No providers or GBS parents reported use of any procedural consent, information sheet, or generation of a patient bill. Three GBS mothers reported feeling violated that such an invasive procedure was performed without any forewarning in the course of a routine cervical exam.

Conclusion:

We proposed a procedural consent and companion we proposed a procedural consent and companion information statement for providers to inform patients about the potential risks vs. benefits of FMS and obtain patient consent prior to the procedure.

Background

Fetal membrane stripping or sweeping or separation (FMS) is a traditionally practiced midwifery procedure that entails placing the practitioner's finger(s) through the cervix and separating the intact amnion chorion from the cervical/lower uterine decidua surface. The procedure is considered "evidence-based" to reduce . the chance of prolonged gestations (>42 weeks). It is not considered a recommended way to induce labor The procedure is anecdotally associated with intrauterine infection and/or chorioamnionitis and/or intraamniotic infection (IAI) with possible complication of fetal/perinatal sepsis.

Goals

Methods

As part of a logic model review and analysis of FMS we:

1) Reviewed available literature

1) Available information sources

available computerized

reviews, e.g., Cochrane

3) We gathered experienced

practitioners (midwives

obstetricians) to share

4) We made enquiries of patient

was identified through searching medical societies and clinical practice guidelines as well as health technology related agencies.

contributors to GBSI for their experience.
5) Grey (unpublished) literature

professional files.

information.

were sought using publically

indexes (Medline, PubMed, etc.). We focused on critical

2) We reviewed our accumulated

- Constructed a matrix of possible adverse effects
 Used a Delfi model of experienced practitioners and
- patients to explore clinical experience with the procedure
- 4) We reviewed the recommendation of making informe consent of the maternal patient (and possibly the father) prior to this procedure

GBSI's Advocacy Algorithm (below) is available at gbsi.me/AdvocacyAlgorithm





"We should ask ourselves, whether, placed under similar circumstances, we should choose to submit to the pain and danger we are about to inflict." Sir Astley Cooper, 1840 (English surgeon, anatomist, multiple historical contributions)

"The action should separate the membranes of the (fetus') amniotic sac surrounding your baby from your cervix"

"A membrane sweep can be uncomfortable. Some women find the procedure painful." "The procedure may also be called "stretch and sweep."

"a membrane sweep is (intended) to avoid going too overdue (42 weeks pregnancy)" E Dufficy. Baby Centre, babycentre.co.uk assessed 19 Jan 2018.

Results: No epidemiologic information was found.

- 1) Membrane sweeping is anecdotally reported to be common in some locations
- 2) In other settings and practices the procedure was not performed or "rarely" performed because of:
 - a) "concerns about pain or discomfort" b) absence of formal informed consent
- c) "concern regarding ascending infection or other anticipated adverse effects
- d) lack of compensation

"The test came back positive. The doctor said, 'Don't worry,

all you need is antibiotics during delivery, everything will be fine.' I was 41 weeks

pregnant when the doctor decided to do an internal exam

and then proceeded to strip my membranes without my

permission. This was on Friday. He said I worked my magic

(with a swooping motion of his forefinger.) He then told me to go home, 'have lots of sex,' and

wait for either labor to begin ('I started things up') or to come

Labor did not begin over the

weekend so on Monday morning

I went to the hospital to find

that I can barely breathe."

Pam McDonald, mother of

Hannah who was stillborn due to group B strep

back Monday morning to be

- e) no formal recognition regarding electronic practice
- 3) Information regarding evidence-based efficacy was limited to "reducing risks of the pregnancy proceeding to greater than 42 weeks, and requiring formal induction of labor 4) NO examples of written consent were discovered in any language.
- 5) NO information was found MEASURING PAIN or DISCOMFORT or BLEEDING or need for labor
- 6) NO information regarding complications including perinatal or maternal morbidity was found.

around the world, and home birth: and less invasive procedures durin hospital births might limit the risk of GBS sensis in the newborn Anne Schuchat, MD.

"I'm not sure if she stripped my membranes, though I think she did. She did a cervical exam but it was so much more painful than the other ones I had up to that point. At that point I was 5 days past my due date.

The next day when I was in labor, she said that she must have stirred the pot. She said that while twirling her index finger in the air. Between that and the horrible back pain I had after the exam, my guess is that she did strip my

Amrita Lal-Paterson, mother of to group B strep

"I thought 'What the hell? Is he trying to see if I still have my tonsils in from the wrong end?' For a split second, I thought I should take my foot out of the stirrup and kick him in the face, but, of course, that would be wrong to do to a

pad afterwards and said I might bleed a little bit.

Over an hour later I could still feel the forcefulness of his exam. This was my fourth pregnancy four days before my due date so I'd had my fair share of cervical exams. Never had I had a doctor bear down on me like that before. Maybe he got to have a nice Fourth of July weekend. I did not."

Marti Perhach, mother of Rose who was stillborn due to group B strep 15 hours after her mother's "cervical exam"

The nurse handed me a mini-

Incommonly, disruption of VASA PREVIA or rupture of membranes (RO

Conclusions

1) There is only scant information available to

clinicians and patients regarding the

epidemiology and results of membrane

"sweeps" or separation.

2) No information regarding the frequency or

nature of possible adverse effects (pain

was an analysis of cost/savings found. Studies which claim no adverse effects were underpowered, and poorly documented

(542 women, 135 GBS positive) 4) NO examples of systematic documentation (electronic medical records (EMR), etc.) or

billing codes were documented.

bleeding, infection, or false labor. Neither

except for Kabiri D. et al. 2017, PLOS One

5) We constructed a simple consent in English.
6) Like any INVASIVE PROCEDURE FMS should

GBSI's Information Statement (below) is

available at gbsi.me/FMSInfoStatement

be formally explained, consented, and

 written informed CONSENT
 complete explanation of induction and the procedure
 documental consoleration or contramelications as would be For more information, please contact Dr. James A. McGregor at jumiemcorecombearthlink and or GRGI at info@abe-infl.org.

An immediate effect of digital examination is the introduction of vaginal organi into the cervical canal. The microbiologic effect of digital cervical examination. HNL Trout WC, Gabbe SG, Am J Obster Genecol. 18073 Pt 11:576-80. 1999.

Turthermore, the risks of membrane stripping in 035-colorized women have investigated; therefore, data are insetficient to encourage or discourage this

"On your or an architecture or againg that not influence that Databased of remaining undelivered at 41 weeks of preparency." Foundamezed clinical triol evaluating the frequency of membranes seetings with an unfluoreable cervice at 30 weeks. K Putsians et al. Set. J Prosecus results, 2011; 31: 207-204.

" A surgeon carrying out surgery without patient's consent may be guilty of severe damage or premeditated manslaughter in the event that the patient is injured." (PF Tropea. Minerva Ginecol. 1995 Sep;47(9):401-7.)

> Comment: We considered the lack of written consent for membrane stripping/sweeping/ separation an urgent area of concern which we attempt to remedy by creating a model "learning consent" to promote formal investigation.

> > I have the condition ______
> > To be filled in by patient in lay terms

5) The most likely and severe risks are:

To be filed in by patient in lay terms

(6) I understand what has been discussed with me as well as the contents of this form.

I have been given the opportunity to ask questions and have received satisfactory answers.

GBSI's Learning Consent (left) is available at

gbsi.me/

FMSLearningConsent

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