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 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 potentially inoculating the lower uterine segment with microorganisms known to cross intact membranes causing fetal injury and death) vs. benefit ratios.

Methods:
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.

Results:
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 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

As part of a logic model review and analysis of FMS we:
1) Reviewed available literature
2) Constructed a matrix of possible adverse effects
3) Used a Delfi model of experienced practitioners and patients to explore clinical experience with the procedure
4) We reviewed the recommendation of making informed consent of the maternal patient (and possibly the father) prior to this procedure

Methods

1) Available information sources were sought using publically available computerized indexes (Medline, PubMed, etc.). We focused on critical reviews, e.g., Cochrane Reviews.
2) We reviewed our accumulated professional files.
3) We gathered experienced practitioners (midwives, obstetricians) to share information.
4) We made enquiries of patient contributors to GBSI for their experience.
5) Grey (unpublished) literature was identified through searching medical societies and clinical practice guidelines as well as health technology-related agencies.

"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
   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 evaluation.
6) NO information regarding complications including perinatal or maternal morbidity was found.

"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 back Monday morning to be induced.

Labor did not begin over the weekend so on Monday morning I went to the hospital to find out my precious daughter was gone. Well, it is so far from fine that I can barely breathe."

Pam McDonald, mother of Hannah who was stillborn due to group B strep

"Birth practices differ substantially around the world, and home births and less invasive procedures during hospital births might limit the risk of GBS sepsis in the newborn."
Anne Schuchat, MD.
Group B Streptococcus. *The Lancet*. 353: 51-6. 1999.

"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 membranes."

Amrita Lal-Paterson, mother of Nola who lived 30 minutes due 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 doctor.

The nurse handed me a mini-pad afterwards and said I might bleed a little bit.

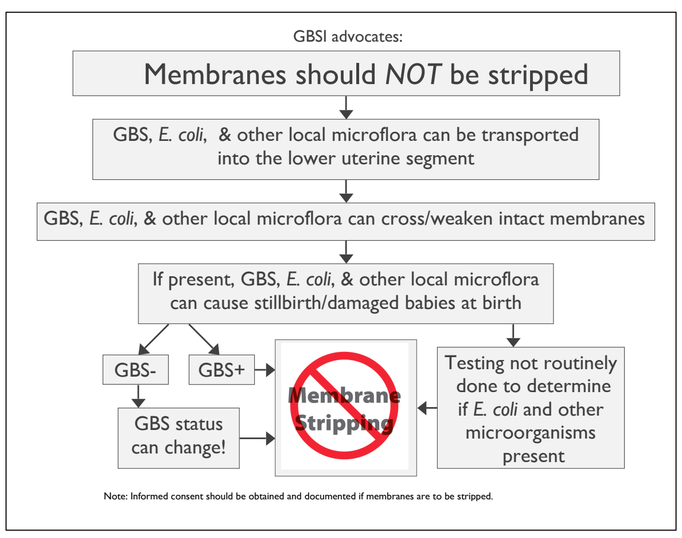
Over an hour later I could still feel the forcefulness of his exam. This was my fourth pregnancy four days before my due date so I'd had my fair share of cervical exams. Never had I had a doctor bear down on me like that before. Maybe he got to have a nice Fourth of July weekend. I did not."

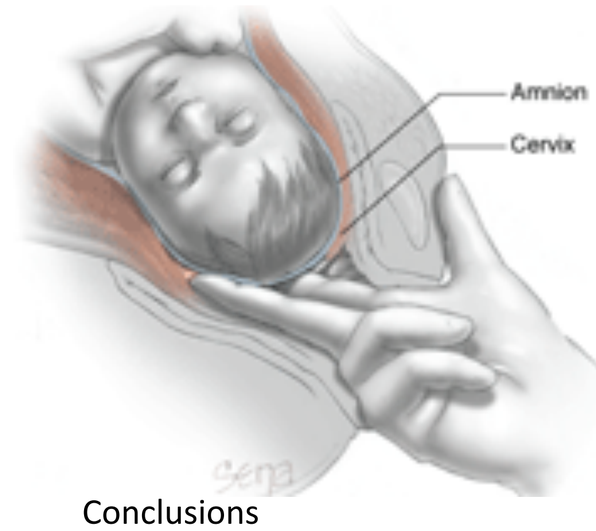
Marti Perhach, mother of Rose who was stillborn due to group B strep 15 hours after her mother's "cervical exam"

" 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.

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

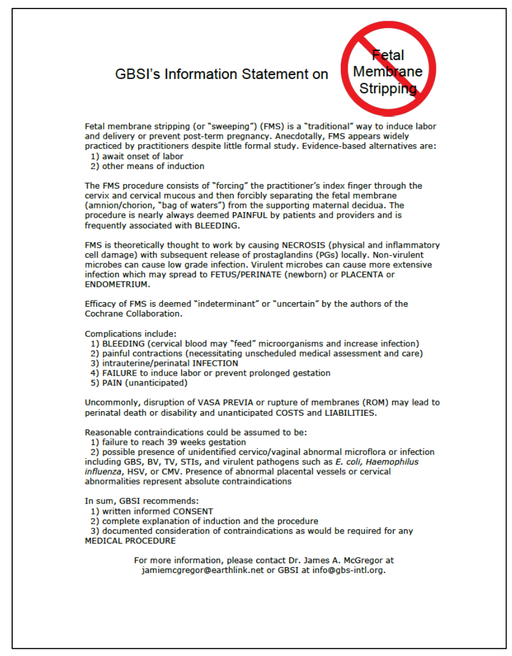




Conclusions

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, bleeding, infection, or false labor. Neither was an analysis of cost/savings found.
3) Studies which claim no adverse effects were underpowered, and poorly documented except for Kabiri D, et al. 2017. PLOS One (542 women, 135 GBS positive)
4) NO examples of systematic documentation (electronic medical records (EMR), etc.) or billing codes were documented.
5) We constructed a simple consent in English.
6) Like any INVASIVE PROCEDURE FMS should be formally explained, consented, and recorded.

GBSI's Information Statement (below) is available at gbsi.me/FMSInfoStatement



GBSI's Information Statement on Fetal Membrane Stripping

Fetal membrane stripping (or "sweeping") (FMS) is a "traditional" way to induce labor and delivery or prevent post-term pregnancy. Anecdotally, FMS appears widely practiced by practitioners despite little formal study. Evidence-based alternatives are:
1) await onset of labor
2) other means of induction

The FMS procedure consists of "forcing" the practitioner's index finger through the cervix and cervical mucous and then forcibly separating the fetal membrane (amnion/chorion, "bag of waters") from the supporting maternal decidua. The procedure is nearly always deemed PAINFUL by patients and providers and is frequently associated with BLEEDING.

FMS is theoretically thought to work by causing NECROSIS (physical and inflammatory cell damage) with subsequent release of prostaglandins (PGs) locally. Non-virulent microbes can cause low grade infection. Virulent microbes can cause more extensive infection which may spread to FETUS/PERINATE (newborn) or PLACENTA or ENDOMETRIUM.

Efficacy of FMS is deemed "indeterminant" or "uncertain" by the authors of the Cochrane Collaboration.

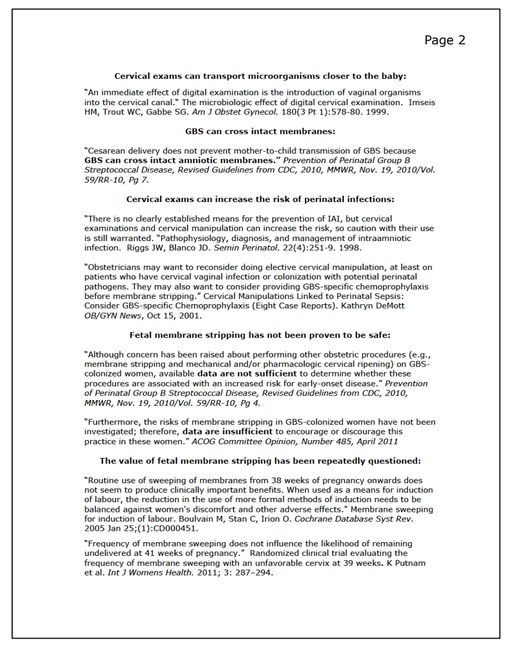
Complications include:
1) BLEEDING (cervical blood may "feed" microorganisms and increase infection)
2) painful contractions (necessitating unscheduled medical assessment and care)
3) intrauterine/perinatal INFECTION
4) FAILURE to induce labor or prevent prolonged gestation
5) PAIN (unanticipated)

Uncommonly, disruption of VASA PREVIA or rupture of membranes (ROM) may lead to perinatal death or disability and unanticipated COSTS and LIABILITIES.

Reasonable contraindications could be assumed to be:
1) failure to reach 39 weeks gestation
2) possible presence of unidentified cervico/vaginal abnormal microflora or infection including GBS, BV, TV, STIs, and virulent pathogens such as *E. coli, Haemophilus influenza*, HSV, or CMV. Presence of abnormal placental vessels or cervical abnormalities represent absolute contraindications

In sum, GBSI recommends:
1) written informed CONSENT
2) complete explanation of induction and the procedure
3) documented consideration of contraindications as would be required for any MEDICAL PROCEDURE

For more information, please contact Dr. James A. McGregor at jamiemcgregor@earthlink.net or GBSI at info@gbs-intl.org.



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Cervical exams can transport microorganisms closer to the baby:

"An immediate effect of digital examination is the introduction of vaginal organisms into the cervical canal." The microbiologic effect of digital cervical examination. Imseis HM, Trout WC, Gabbe SG. *Am J Obstet Gynecol.* 180(3 Pt 1):578-80. 1999.

GBS can cross intact membranes:

"Cesarean delivery does not prevent mother-to-child transmission of GBS because **GBS can cross intact amniotic membranes."** *Prevention of Perinatal Group B Streptococcal Disease, Revised Guidelines from CDC, 2010, MMWR, Nov. 19, 2010/Vol. 59/RR-10, Pg 7.*

Cervical exams can increase the risk of perinatal infections:

"There is no clearly established means for the prevention of IAI, but cervical examinations and cervical manipulation can increase the risk, so caution with their use is still warranted. "Pathophysiology, diagnosis, and management of intraamniotic infection. Riggs JW, Blanco JD. *Semin Perinatol.* 22(4):251-9. 1998.

"Obstetricians may want to reconsider doing elective cervical manipulation, at least on patients who have cervical vaginal infection or colonization with potential perinatal pathogens. They may also want to consider providing GBS-specific chemoprophylaxis before membrane stripping." Cervical Manipulations Linked to Perinatal Sepsis: Consider GBS-specific Chemoprophylaxis (Eight Case Reports). Kathryn DeMott *OB/GYN News*, Oct 15, 2001.

Fetal membrane stripping has not been proven to be safe:

"Although concern has been raised about performing other obstetric procedures (e.g., membrane stripping and mechanical and/or pharmacologic cervical ripening) on GBS-colonized women, available **data are not sufficient** to determine whether these procedures are associated with an increased risk for early-onset disease." *Prevention of Perinatal Group B Streptococcal Disease, Revised Guidelines from CDC, 2010, MMWR, Nov. 19, 2010/Vol. 59/RR-10, Pg 4.*

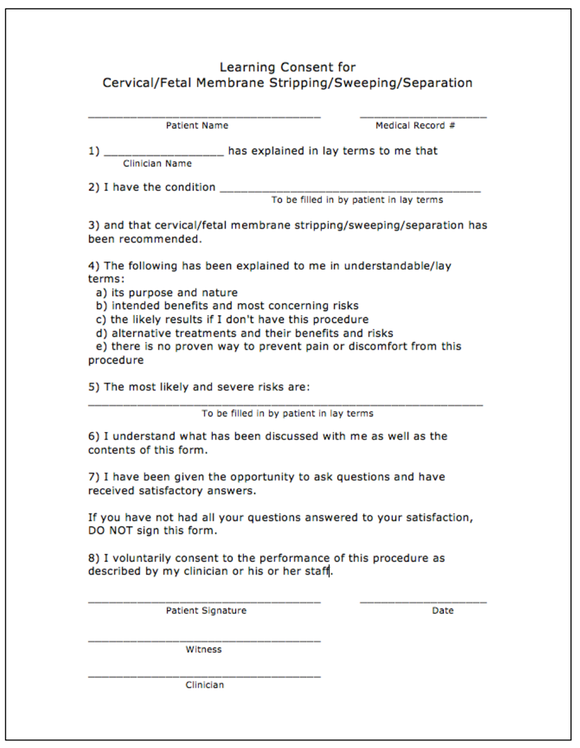
"Furthermore, the risks of membrane stripping in GBS-colonized women have not been investigated; therefore, **data are insufficient** to encourage or discourage this practice in these women." *ACOG Committee Opinion, Number 485, April 2011*

The value of fetal membrane stripping has been repeatedly questioned:

"Routine use of sweeping of membranes from 38 weeks of pregnancy onwards does not seem to produce clinically important benefits. When used as a means for induction of labour, the reduction in the use of more formal methods of induction needs to be balanced against women's discomfort and other adverse effects." Membrane sweeping for induction of labour. Boulvain M, Stan C, Irion O. *Cochrane Database Syst Rev.* 2005 Jan 25;(1):CD000451.

"Frequency of membrane sweeping does not influence the likelihood of remaining undelivered at 41 weeks of pregnancy." Randomized clinical trial evaluating the frequency of membrane sweeping with an unfavorable cervix at 39 weeks. K Putnam et al. *Int J Womens Health.* 2011; 3: 287–294.

GBSI's Learning Consent (left) is available at gbsi.me/ FMSLearningConsent



Learning Consent for
Cervical/Fetal Membrane Stripping/Sweeping/Separation

_____ _____
Patient Name Medical Record #

1) _____ has explained in lay terms to me that
Clinician Name

2) I have the condition _____
To be filled in by patient in lay terms

3) and that cervical/fetal membrane stripping/sweeping/separation has been recommended.

4) The following has been explained to me in understandable/lay terms:
a) its purpose and nature
b) intended benefits and most concerning risks
c) the likely results if I don't have this procedure
d) alternative treatments and their benefits and risks
e) there is no proven way to prevent pain or discomfort from this procedure

5) The most likely and severe risks are:
_____
To be filled in by patient in lay terms

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

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

If you have not had all your questions answered to your satisfaction, DO NOT sign this form.

8) I voluntarily consent to the performance of this procedure as described by my clinician or his or her staff.

_____ _____
Patient Signature Date

_____
Witness

_____
Clinician

References

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