

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

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Sir Astley Cooper

“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.



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 information “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 (AI) with possible complication of fetal/perinatal sepsis.

Goals

- 1) Reviewed available literature
- 2) Constructed a matrix of possible adverse effects
- 3) Used a Delphi 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

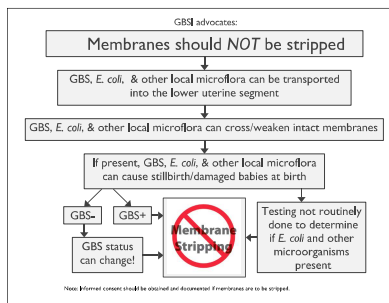
Methods

- 1) Available information sources were sought using publicly 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.

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



“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.

“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 infernal 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

“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 Learning Consent (left) is available at gbsi.me/FMSLearningConsent

References

- 1) Bouvain M, Stan C, Itron O. Membrane sweeping for induction of labour. Cochrane Database of Systematic Reviews. *BMC Pregnancy Childbirth* 11:54.
- 2) Kabiri D, Hants Y, et al. Antepartum Membrane Stripping in GBS Carriers, Is it Safe? (The STRIP-G Study). *PLOS ONE* 2015. Doi 10.1371/journal.pone.0131731
- 3) Consent to Treatment. *NHS Choices*. nhs.uk/conditions/consent-to-treatment/ Accessed 1/19/2018.
- 4) Borghesi A, Stronati M, Fellay J. Neonatal Group B Streptococcal Disease in Otherwise Healthy Infants: Failure of Specific Neonatal Immune Responses. *Front Immunol.* 2017 Mar 7;8:215.
- 5) Fleming N, O’Driscoll T. Adolescent Pregnancy Guidelines. *J Obstet Gynaecol Can.* 2015 Aug; 37(8):740-756.
- 6) Bernat E. Liability risks in gynecology and obstetrics under German and Austrian law. *Med Law.* 1995;14(5-6):413-23.
- 7) Pierre F, Bardin-Bedu C, et al. [What are the medico-legal implications of induced labor?]. *Article in French J Gynecol Obstet Biol Reprod (Paris).* 1995;24(1 Suppl):120-8.
- 8) Tropea PF. (Medico-legal controversies in obstetrics and gynecology: an important current problem). *Article in French J Gynecol Obstet.* 1995 Sep;47(9):401-7.
- 9) Ngure K, Trinidad SB, et al. The role of male partners in women’s participation in research during pregnancy: a case study from the partners demonstration project. *Reprod Health.* 2017; 14(Suppl 3): 160.
- 10) Fitzharris L. The Butcher Art. *Scientific American.* 2017 NY, NY p 58.

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