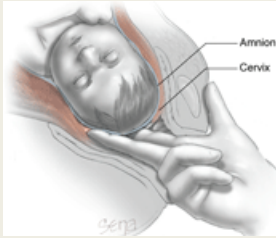


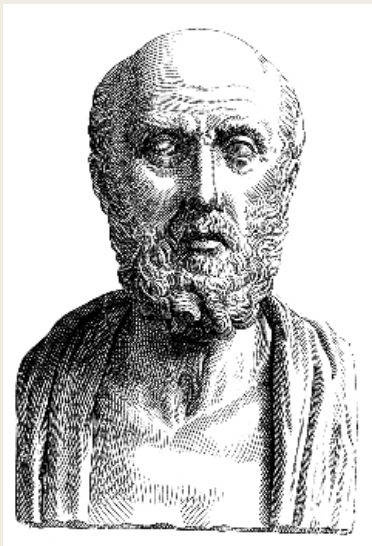
RED FLAG: IS WRITTEN CONSENT REQUIRED BEFORE FETAL MEMBRANE STRIPPING ESPECIALLY AMONG GBS CARRIERS?



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Student's ETHICAL IMPERATIVES

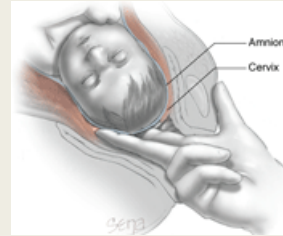


Hippocrates

1. Beneficence/Do No Harm (Malfeasance)
2. Autonomy
3. Empathy
4. Justice (Society)

Background

- Fetal membrane stripping (FMS) or “sweeping” or separation is a traditionally practiced procedure.
- It entails placing the practitioner’s finger(s) through the cervix and separating the intact amnion chorion from the cervical/lower uterine decidua surface (releasing prostaglandins).



Background (continued)

- The procedure is “Cochrane evidence-based” to reduce the chance of prolonged gestation (>42 weeks).
- It is NOT a recommended way to induce labor. May “bolster” standard induction techniques.
- The procedure is anecdotally associated with intrauterine infection and/or chorioamnionitis and/or intraamniotic infection (IAI) with possible complication of fetal/perinatal sepsis/ perinatal death.
- Cervical manipulation is shown to increase uterine “up suck”/ transport in small series.
- Multiple processes @ microbes/products/vaginal molecules can reach uterus/ contents. (diffusion, “Upsuck”, “counter current”, iatrogenic)

- “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.



“We should ask ourselves, whether, placed under similar circumstances, we (ourselves) should choose to submit to the pain and danger we are about to inflict.”

*Sir Astley Cooper, 1840
(English surgeon, anatomist, multiple historical contributions)*

Goals

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

1. Reviewed available literature
2. Constructed a matrix of possible adverse effects
3. Used Delphi and “crowd source” models of 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 including Cochrane Reviews.
2. Grey (unpublished) literature was identified through searching medical societies and clinical practice guidelines as well as health technology-related agencies.
3. Reviewed our accumulated professional files.
4. Gathered experienced practitioners (midwives and obstetricians) to share information.
5. Made enquiries of patient contributors to Group B Strep International for their experience.

“Traditional” OB/GYN Treatments

Women*:

- Episiotomy
- Genital mutilation ~ circumcision
- Abdominal massage (Mayan, South East Asia)
“vaginal steaming” (S Brashear, 2015)
- Herbal remedies

Male: circumcision

*Universal absence of participatory decision making

“Husband’s Stitch” “Husband’s Knot” Julie ML Dobbeleir, Sem in Plastic Surgery 2011

- A. “Husband’s knot”
 - *Vaginal tightening surgery has been around since the 1950’s legal case @ improve a woman’s well-being e.g., “hoodectomy”*
- B. Genital Mutilation: multiple forms, many cultures
- C. Gender inequality, control women’s sexuality
 - *Social exclusion*
 - *No known health benefits vs cultural autonomy”*
 - *Vaginal steaming: “presumption of dirtiness”*

Reproductive Tract is NOT Sterile

JF Moreno et al 2016 AJOG; JRavel et al Proc Nat Acad 2011; 108:4680

- “Microbes present in urogenital tract @ 9% of total Human Microbiome”
- Formerly culture-identified bacterial ~ GBS ~ 2-33% of females (vaginas)
- Varies:
 - a) *Ovarian cycle : more stable @ ↑ Estrogen*
 - b) *Vaginal hygiene behaviors*
 - c) *Sex activity*
 - d) *Partners*
 - e) *Products used*

Pathological: * BV, STIs

- a) *Early, late miscarriage and early late PTB*
- b) *IVF, transfer catheter (mixed flora)*



Gwyneth Paltrow





Results:

- Little epidemiologic (RCT, Graded) information was found.

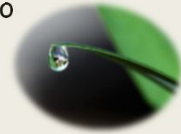
- 1) Membrane sweeping is anecdotally reported to be common in some locations.
- 2) In other settings and practices the procedure was not performed or “rarely” performed because of:
 - a) *“concerns about pain or discomfort”*
 - b) *absence of written/oral informed consent*
 - c) *“concern regarding ascending infection or other anticipated adverse effects” (vasa previa, placenta membranacea)*
 - d) *lack of compensation and payor documentation*
 - e) *no formal recognition regarding electronic billing practice (eCodes for billing)*
- 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 @ formally MEASURING PAIN, DISCOMFORT, BLEEDING, unanticipated care visits, or need for labor induction or c/s.
- 6) NO systematic information regarding complications including perinatal or maternal morbidity noted.

“Crowdsourced Testimonial”

“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. I could still feel the forcefulness of his exam over an hour later.

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 overwhelming GBS 15 hours after her mother’s “cervical exam”



Membrane Sweeping at Initiation of Formal Labor Induction: A RCT

PC Tan, R Jacob, SZ Omar (Malaysia) 2006; Ob/Gyn 107:569-75

Benefit of membrane sweeping at initiation of induction of labor?

■ Study: 264 women

	Sweep N=136	No Sweep N=128	P-value
Spontaneous Delivery	69%	56%	0.41
Shorter Induction to Delivery Time (Mean hours)	14	19	0.003
Post Sweeping Pain Score	4.7	3.5	<0.001

Membrane sweeping at initiation of labor indication increased spontaneous delivery, reduced oxytocic agent use and shortened time to birth and improved patient satisfaction

◇ ? Start GBS prophylaxis and induction

“Birth practices differ substantially around the world. 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.

Conclusions

- 1) There is only scant information available to clinicians and patients regarding the epidemiology and results of membrane “sweeps” or separation (FMS).
- 2) No GRADED information found 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.

“ 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; we propose evaluation of a model “learning consent” to promote IRB approved investigation.

Mina Pulitzer, *National Woman's Health Network Newsletter*. Nov/Dec 2017, pg 8.

“WE’VE GOT TO GROW UP”:

“The only way to shift the conversation (paradigm) from “gross” to “healthy” life is to educate and empower women about their bodies...*We should take pride in the processes that allow us to reproduce and build our families...The processes that are fundamental for human life and progress.*”

“Membrane Sweep” Proposal:

1) “Delphi group” recommendations:

- A. *Informed consent includes:*
 - a. *“Common”: Pain*
 - b. *“Rare”: infection, significant bleeding*
 - c. *“More rare”: vasa previa, placenta previa, placental membranacea*
- B. *Large, appropriately powered prospective RCTs*
- C. *Large observational quasi-experimental studies*
- D. *Ethics discussion of “traditional practices”*

2) Individual practice/practices “Policies & Procedures”

Specify indications and procedures:

- A. *Prevention of prolonged pregnancy, i.e., > 42 WKS*
- B. *How done, how often, exclusions, pain management?*

3) Make “Membrane Sweep” part of pregnancy/birth plan discussions; obtain informed consent prior to procedure (also before episiotomy, forceps, VEs)

Participatory Decision Making Learning Consent for Cervical/Fetal Membrane Stripping/Sweeping/Separation

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 _____

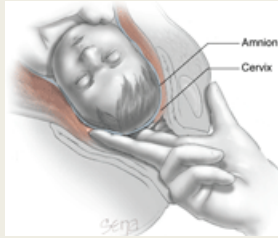
Witness _____

Clinician _____

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SHOULD WRITTEN CONSENT BE REQUIRED BEFORE FETAL MEMBRANE STRIPPING ESPECIALLY AMONG GBS CARRIERS?



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“Crowdsourced Testimonials”

“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 GBS



“Crowdsourced Testimonials”

“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 GBS



“Crowdsourced Testimonials”

“I was near 40 weeks when the doctor stripped my membranes. I was unsure, it was painful and something really unexpected. I asked, “What are you doing.” And she [the doctor] was not very clear about what she was doing. From what I understand it’s a common procedure, apart from GBS, used to start labor.

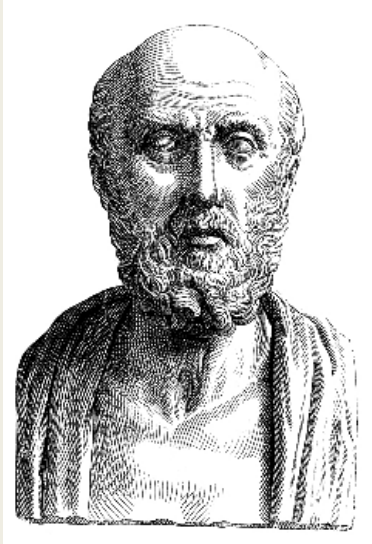
I was not late in my pregnancy at this point. I don’t know why she would try to induce labor. As a French citizen, we are allowed to go up to 41 weeks before being considered late, so I was really not late at this point. I was really happy about the baby still being inside me and I loved feeling the kicks and everything. There was no need for stripping the membranes.

Given the choice, I would have never said yes. So I strongly feel that women should be able to say no and I don’t think doctors and nurses should be promoting it.”

Pregnant French woman
near 40 weeks gestation



Student's ETHICAL IMPERATIVES



Hippocrates

1. Beneficence/Do No Harm (Malfeasance)
2. Autonomy
3. Empathy
4. Justice (Society)

Research Suggestion:

- Pain scale analysis
- Prospective analysis of benefits and harms
- Randomized controlled trial
 - OB/baby benefits/harms
 - Family and economic benefits
 - Satisfaction measures

