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

James A. McGregor 1, Marti Perchac 1, Janice L. French 2, Jane Hanson-Ernstrom 3
1 Group B Strept International, 2 LA Best Babies Network, 3 Denver College of Nursing

"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

Abstract

Background/Introduction:
Fetal membrane stripping or scraping (FMS) is a "traditional" obstetric procedure intended to induce labor, shorten gestation, or, more recently, reduce the incidence of preterm labor (≥ 23 weeks). FMS is considered a low-risk 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 reduce risk for women and fetuses. Inherent risks (involving patient discomfort and potential fetal/maternal injury) are unclear. Conclusion: We present a consensus statement that provides recommendations for informed consent before performing FMS.

Results: No epidemiologic information was found.
1) Membrane stripping is not routinely reported to be common in most hospitals.
2) In other settings and practices the procedure was not performed or “rarely” performed because of: a) concerns about pain and discomfort
b) absence of formal informed consent
3) Concerns regarding ascending infection or other anticipated adverse effects
d) Lack of compensation
5) No formal consent statement was presented
6) No information regarding complications including preterm birth or maternal morbidity was found

Conclusions:
1) There is very little information available to clinicians and patients regarding the epidemiology, outcomes and risks of membrane "sweep" or separation.
2) No information regarding the frequency or nature of possible adverse effects was obtained.
3) Rarely an analysis of cost/benefit was performed.
4) Studies which claim no adverse effects were underpowered, and poorly documented, except for Keenan et al. 2013.
5) We constructed a simple consensus in English.
6) No previous FMS procedure FMS was formally explained, consented, and recorded.

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

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

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

"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."

Comment: We considered the lack of written consent for membrane stripping/sweeping

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

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

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

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

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

References: