

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Oct 04, 2018
To: "Nayo Shepard Williams" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1729

RE: Manuscript Number ONG-18-1729

"Best" mode of delivery for fetal anencephaly?

Dear Dr. Williams:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a significantly revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 25, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors write about shared decision making in a case of fetal anencephaly in a woman who decides to carry the pregnancy to its natural end and requests a cesarean.

This "clinical conundrum" is nicely written and reads easily.

Shared decision making, the role of ethics committees is nicely used.

Doing a cesarean for a life limiting anomaly plays out daily in MFM Units across the country.

I was surprised by your statement "limiting elective cesareans to 39 weeks" when the risk of stillbirth is as high as 20%.

This particular case could easily be argued to have enough risk to warrant an earlier cesarean between 37-39 weeks for medical indications.

Given that there is NO correct way for management and that the 39 week rule is designed for babies that are going to live on, many might deliver earlier as the entire reason to do the cesarean is to so that mom/parents/family and can bond and spend time with their infant.

Nice description of complex decision making.

Don't forget to mention folic acid 4mg and planning for the next delivery. Always nice to repeat this whenever you have a chance.

Reviewer #2: Good topic for discussion. The overall tone of the writing seemed a bit more relaxed than I recall usually seeing with these sorts of articles but not unpleasant as it read easily and should keep the audience attention and was quick for reading.

Reviewer #3: The authors present a clinical question regarding the mode of delivery in the setting of a lethal fetal anomaly

- anencephaly.

1. Is it appropriate to include a modified table from another manuscript in your manuscript? I don't know the answer to this, but would check. Perhaps could briefly mention details about the intrapartum stillbirths that occurred in that manuscript given that is reason that cesarean is being considered in these cases.

2. Why do you think there has been a shift in attitude about the diagnosis (line 57-58)? Is this secondary to counseling that is happening, or case reports of short term survivors?

For me, the clinical conundrum is not so much how to evaluate the mother and fetus, or what evidence is available (the diagnosis is lethal and there is no evidence about mode of delivery because it is not going to change the ultimate outcome), but are we willing to perform surgery on a woman on her request, for a fetus that will not survive? Are we willing to put her at risk, as well as increase her risk of morbidity in all future pregnancies for a fetus that will not survive? There are many anomalies that I am pretty certain won't survive, but cannot be 100% certain, but this one is certain.

In the section, "what is the evidence to counsel your patient?"

- In line 78-79, the authors state importance of addressing desires and values at time of diagnosis. It seems that at the time of diagnosis, many families cannot have a discussion about this given the devastating news. I would like to see a discussion on the importance of an on-going conversation about a families desires, as well as the lethality of the diagnosis. The values and desires may change throughout pregnancy as we continue to counsel and the family continues to learn about the diagnosis.

Antenatal management

- Another question that comes up, if antenatal testing is offered, and it is not reassuring, then this fetus with a lethal anomaly is clearly stressed, and I wonder at that point, what to do. Is it better to just have weekly visits for heart tones? If I have an NST that looks so bad, I am planning to move to delivery, and I am doing the testing because the parents want "everything done" and do a cesarean, I worry that fetus that I already know has a lethal anomaly is stressed and this increases my suspicion that the fetus won't live long. I would love to hear some thoughts about this. There is no evidence, but should be discussed in these cases when antenatal testing is started.

Intrapartum management

- Why does increased risk of shoulder dystocia increase the risk of cesarean? At the point that a shoulder dystocia is diagnosed, moving to cesarean is not a good option.
- I need further discussion about the difference between a non-anomalous fetus delivered by elective cesarean and a fetus that has a lethal condition to be delivered by cesarean. Anomalies are risk factors for stillbirth, as are many medical comorbidities, but we don't perform cesarean for these mothers to eliminate the risk of stillbirth.

There is no discussion in the conundrum about the benefits of the alternative method of delivery, a vaginal delivery. This not only reduces the risk to the mother, but if the fetus is born alive, allows the family to spend time with the baby immediately, as opposed to a cesarean that needs to be performed in an operating room with significant delay between the mother being able to be with her baby (when not flat on her back in an OR) due to the closure. Given the diagnosis, this 30-40 minutes that the patient remains in the OR may be the difference between meaningful time with the baby and no time at all.

I think this question of mode of delivery in lethal anomalies is really important, and for some families seeing an alive baby is all that is important to them, but this can happen without the morbidity of cesarean and needs to be discussed. I don't think we can say that the cesarean is being performed for fetal benefit (in your bottom line, lines 153-154) because there is absolutely NO evidence of this. We have no idea if a cesarean is beneficial. This sentence needs to be removed/edited. Sure a cesarean removes or greatly reduces risk of intrapartum stillbirth, but we can't quantify this. If we suggest there is fetal benefit to performing a cesarean, then seems like we need to offer it. I think part of the conundrum is that fact that cesarean offers no long term/survival benefit.

This almost feels more like an ethical debate within a provider as opposed to a clinical question and I don't think the conundrum is how to deliver anencephaly, but how to manage the delivery of lethal anomalies, i.e. do we offer or provide cesarean on request given concern the fetus won't tolerate labor and have an intrapartum stillbirth. Part of discussion should include a labored cesarean as this always comes up in cases like this. If we plan to induce labor, and fail, the risk of the cesarean has increased, but we may be able to avoid cesarean if induce and are successful.

Reviewer #4: The authors present a Clinical Conundrum of a parental desire for a planned cesarean for fetal anencephaly for "fetal" benefits.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- It's not clear in this section that you are dealing with a family who has decided to continue the pregnancy since you are still in the data gathering phase. (as noted in lines 72-73). As such, on line 68, you should include option of pregnancy termination.

What do you mean by "early detection"> Anencephaly is detectable at 12 ish weeks and beyond.

- do you have a percentage for amniotic bands?

- is common

- fetal anomaly

- with the specific diagnosis.

- I apologize if I sound like a Luddite, but what is the "shared decision making model" that makes it different than what has been common practice in prenatal diagnosis and frankly for many years in other areas in which the doctor and patient discuss a diagnosis, the doc lays out options based on that discussion and they agree (or not) on a plan? What is a "shared decision making model" that warrants a name?

- For clarity, would you consider "While the majority of the time when a prenatal diagnosis of a lethal fetal diagnosis is made the mother will opt for pregnancy termination,....."

- You now seem to have shifted to the point at which the woman has decided to continue the pregnancy. At this point I think the patients' goals in my experience have dichotomized. 1--they really want a live born baby or 2--they are morally against pregnancy termination and are committed to carrying the pregnancy to its natural conclusion. You could say something like: "For the woman who's goals are to have a live-born fetus, pregnancy planning may be different from those for the woman who is continuing the pregnancy based on her own beliefs about abortion. For some women, obtaining fetal heart tones at routine prenatal visits will be sufficient for her needs, while others may prefer a more intensive approach"

Why are serial growth ultrasounds a reasonable choice? What do you do with the information obtaining for looking at fetal growth? Would you deliver early for FGR? Would you do UA Dopplers? Hospitalize her for severe FGR? If you really mean-scan for clinical indications like size > dates (then you can talk about poly(or limited scans intermittently if the patient is particularly

- As well, the cause of the 20% still birth rate isn't well known. May not be placental insufficiency so not known if fetal monitoring is at all predictive. Also--need to recognize that fetal CNS disease, such as anencephaly, may result in a flat baseline, or lack of accelerations, so NST may not be the best choice if doing any testing.

- or delivery?

- This paragraph isn't really about intrapartum management which I would assume would relate to continuous fetal monitoring, augmentation, how to manage the infant (skin to skin? nursing? Do you have pediatrics presence?). This paragraph is about delivery planning. 2 real choices--let her go into labor on her own or deliver iatrogenically. If iatrogenic, induce or do a cesarean? When?

- The "39 week" rule is to prevent iatrogenic prematurity and resulting neonatal harm. That's not really an issue here. One could even argue that the delivery (if iatrogenic, by either route) should occur at 37 weeks or thereabouts IF the goal is to have a live baby at birth in order to avoid the 20% risk of stillbirth since late preterm birth is not a significant problem in this setting.

- Could you be clearer? Do you mean while the patient is in the hospital or after discharge? As noted by one of the reviewers, need to emphasize 4 mg dose of folate, effective pregnancy timing to ensure adequate folate. What about the father of the baby? Anything special there?

- We aren't really managing the fetus. We are managing the pregnancy care of a woman with an anencephalic

fetus. Please edit.

- This will vary--for instance, we have a perinatal palliative team--not just pediatric. What about genetics? What about transplant team? Some patients wish to donate organs in this setting

- The care plans are for women with fetal anencephaly. Likely best to say something like "The care plans for women who decide to continue a pregnancy complicated by fetal anencephaly are complex"

- So this isn't a case report, although obviously based on a real case. Please edit this section to avoid it reading like a case report highlighting the importance of

1. Maternal autonomy.
2. Ethics board role
3. Values of providers

Can you comment further (perhaps in the section on intrapartum management) about the possible management possible after delivery? I've eluded to some of these them above. --things like pictures, foot prints, religious blessing or baptism, etc.

- who died

- see my prior notes.

2. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

4. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

5. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

6. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

7. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly. If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at <http://www.acog.org/Resources-And-Publications>.

8. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at <http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 25, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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