

OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*
- Email correspondence between the editorial office and the authors*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:

obgyn@greenjournal.org.

Date: Mar 14, 2019
To: "Oluyemisi Adeyemi-Fowode" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-253

RE: Manuscript Number ONG-19-253

Intrauterine Foley Balloon Catheter to Manage Acute Heavy Menstrual Bleeding in Adolescents.

Dear Dr. Adeyemi-Fowode:

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 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 Apr 04, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a well-written case report on the use of Foley balloon tamponade for acute bleeding in an adolescent.

I have a few questions:

1. As this was discussed in an international expert consensus panel published in 2011 (James et al. Europ J Obstet Gynecol Reprod Biol, 2011. - reference #11), what is the data on use even in the adult population? What literature search terms did you use to confirm no other papers were available? This technique is referenced in UpToDate as an option for acute menorrhagia (not specific to age range).
2. There is a case report (ref #12) on a 19 year old with persistent hypomenorrhea. can you elaborate on the potential risks for these young patients? any evidence after use in postpartum hemorrhage of long term risks for bleeding and fertility?
3. Doxycycline was used as prophylactic antibiotics but does help control bleeding in women with chronic endometritis - is there any indication that she had endometritis which may have responded better to the antibiotic than the balloon?

Reviewer #2:

ONG-19-253

TITLE: Intrauterine Foley Balloon Catheter to Manage 1 Acute Heavy Menstrual Bleeding in Adolescents.

Short title: Foley catheter to manage menstrual bleeding

TYPE: Case Report

Precis: Foley catheter placement is an effective, safe, low-cost, and readily accessible option for intrauterine tamponade in the adolescent female with acute heavy menstrual bleeding.

Disclosures: None

Overall: Intrauterine balloon tamponade is a well-known and utilized option in the treatment of post-partum hemorrhage refractory to pharmacologic interventions. It has not been well-studied in the adolescent population for treatment of acute

heavy menstrual bleeding. The authors describe the case of a 10 year old with massive vaginal bleeding during menarche who was subsequently diagnosed with a bleeding disorder. They walk through the medical and eventual surgical management.

Abstract: no comments

Teaching Points: Well presented.

1. Line 89: perhaps the word should be spares?

Introduction: A brief overview is presented.

Case: Case is well presented. The management steps are very clearly presented such that the methods could be replicated.

Discussion: Thoughtful, complete discussion.

2. Line 187: again perhaps the word should be spares?

References: Seem appropriate.

Figures:

3. Consider separating the schematics and the ultrasound pictures into 2 separate figures.

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.

- one case report doesn't prove it is efficacious--it worked in this girl. Please reword.
- perhaps mention that this is recurrent heavy menstrual bleeding
- spares
- it isn't a sign of diagnosing a problem--its the first sign of the problem.
- perhaps, you could say here..."he successful use of an intrauterine Foley catheter that is low-risk, low-cost and readily available and familiar to obstetrician-gynecologists in the care of women with post partum hemorrhage?
- did her family provide any additional history?
- "Work-up" is jargon. Please change to evaluation for or testing for.
- In the surgical and OB setting, TXA is best used within 3 hours of the injury (trauma, surgery, etc). Do you have a reference to include in your discussion for using it as described here?
- I thought you had told her to skip her placebos. Was that for the first month only? Could you make that clear? On line 147, it seems like it wasn't just for the first month.
- why, since on her first hospitalization she responded to a longer course and IV course of TXA and E. Did she have a recurrent hematocolpos imaged?
- Don't start a sentence with a numeral. Either spell it out or edit your sentence to avoid it.
- Do you have longer term follow up? Did the IUCD resolve her problem long term?
- potentially effective?

- These are why on the basis of case report, we are not comfortable describing an intervention as "safe"--I suggested low-risk above. For rare complications, it would require a large trial to demonstrate safety. As well, my reminders to change the word "effective" throughout is similarly motivated. It worked or was associated with a cessation of bleeding, in your patient but its not known if it would be effective in other girls.

- use a colon instead.

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. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:

Lines 185-6 ("Surgical management should...medical management").

5. 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 has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Case Reports should not exceed 8 typed, double-spaced pages (2,000 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

7. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Case Reports, 125 words. Please provide a word count.

9. 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.

10. 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.

12. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG 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 (exceptions could include manuscripts that address items of historical interest). 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 an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

13. Figure 1: When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

14. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

15. 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 and that each author has given approval to the final form of the revision.

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 Apr 04, 2019, 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

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>) Please contact the publication office if you have any questions.

February 8, 2019

Dr. Nancy C. Chescheir,
Editor-In-Chief, Obstetrics & Gynecology.

Dear Dr. Chescheir:

I am writing to submit our case report entitled, "Intrauterine Foley Balloon Catheter to Manage Acute Heavy Menstrual Bleeding in Adolescents" for consideration for publication.

The main objective of this case report is to educate providers on foley catheter placement being an effective, safe, low-cost, and readily accessible option for intrauterine tamponade in the adolescent female with acute heavy menstrual bleeding. We wanted to provide a step-by-step description of our technique in the hope that this would encourage providers to manage acute heavy menstrual bleeding that does not respond to first line medical management (when appropriate), in the most conservative and minimally invasive surgical manner.

We describe the outcome in an adolescent patient who presented with heavy menstrual bleeding at menarche and symptomatic anemia who underwent intrauterine tamponade with the Foley catheter to control the heavy bleeding and was eventually diagnosed with a platelet dysfunction.

The institutional review board at Baylor College of Medicine approved this study under protocol number H-30321: Clinical and surgical outcomes in pediatric and adolescent gynecology. Written informed consent for publication has been obtained from the patient. Permission from the illustrator to publish artwork has been obtained.

This manuscript describes original work; it has not been published and is not under consideration by any other journal. All authors approved the manuscript and this submission and there are no conflicts of interest. I confirm that this manuscript is an honest, accurate, and transparent account of the technique being reported; that no important account of the technique and experience has been omitted; and that any discrepancies have been explained.

Thank you for receiving our manuscript and considering it for review. Please address all correspondence concerning this manuscript to me at Baylor College of Medicine and feel free to correspond with me by e-mail [REDACTED].

We appreciate your time and look forward to your response.

Sincerely,

Oluyemisi Adeyemi-Fowode, MD

[REDACTED]

RESPONSE TO REVIEWERS

We would like to thank the reviewers for taking the time to read our manuscript and offering suggestions on improvements. All suggestions have been addressed, please see below in bold the authors response. We opt-in to having our responses published.

REVIEWER COMMENTS:

Reviewer #1:

1. As this was discussed in an international expert consensus panel published in 2011 (James et al. Europ J Obstet Gynecol Reprod Biol, 2011. - reference #11), what is the data on use even in the adult population? What literature search terms did you use to confirm no other papers were available? This technique is referenced in UpToDate as an option for acute menorrhagia (not specific to age range).

Data on use of Foley catheter balloon for the indication of heavy menstrual bleeding in adults is limited and references included in this manuscript cover available literature. A literature search of Medline (Ovid) was conducted using both MeSH headings (Uterine Hemorrhage, Menstruation, and Balloon Occlusion) and keywords/phrases (menstruat*, "uterine bleed*", "uterine hemorrhage*", foley*, and balloon*). After limiting to the English language, 626 results remained, which were screened based on title, abstract, or full text where applicable. There are reports of use in the adult after operative hysteroscopy treatment of intrauterine pathology (ashermans syndrome , uterine septum, postmyomectomy), dilation and curettage and cervical/cesarean scar pregnancy. The use in adults is mentioned in the discussion section with references 8,9 and 10 cited.

2. There is a case report (ref #12) on a 19 year old with persistent hypomenorrhea. can you elaborate on the potential risks for these young patients? any evidence after use in postpartum hemorrhage of long term risks for bleeding and fertility?

There is a paucity of data regarding adverse effects on menstrual and reproductive function after the use on intrauterine balloon tamponade in post-partum hemorrhage. Available literature suggests no significant long term adverse effect and this has been included in the discussion with an additional reference provided. Asherman's syndrome being a likely cause of hypomenorrhea in this 19 year old has also been included in the manuscript under the discussion section

3. Doxycycline was used as prophylactic antibiotics but does help control bleeding in women with chronic endometritis - is there any indication that she had endometritis which may have responded better to the antibiotic than the balloon?

Heavy menstrual bleeding/symptoms of anemia at the onset of menarche was the only presenting symptom in this non-sexually active patient with no recent history of a uterine procedure which made suspicion for endometritis low but definitely agree that this is on the differential. No tissue sampling was performed intraoperatively in an attempt to be as minimally invasive as possible. She received doxycycline only for the short period of time (compared to the longer course prescribed for endometritis) that the balloon was in place with cessation of bleeding which further supports that the etiology of the heavy menstrual bleeding was less likely inflammation.

Reviewer #2:

Abstract: no comments

Teaching Points: Well presented.

1. Line 89: perhaps the word should be spares?

This has been corrected

Introduction: A brief overview is presented.

Case: Case is well presented. The management steps are very clearly presented such that the methods could be replicated.

Discussion: Thoughtful, complete discussion.

2. Line 187: again perhaps the word should be spares?

This has been corrected

References: Seem appropriate.

Figures:

3. Consider separating the schematics and the ultrasound pictures into 2 separate figures.

Figures have been separated.

EDITOR COMMENTS:

- one case report doesn't prove it is efficacious--it worked in this girl. Please reword.

The word effective/efficacious being used to describe the foley catheter option has been removed from the manuscript

- perhaps mention that this is recurrent heavy menstrual bleeding

Her second presentation has been clarified as recurrent heavy menstrual bleeding.

- spares

Spare has been changed to spares

- it isn't a sign of diagnosing a problem--its the first sign of the problem.

This has been corrected in the introduction section

- perhaps, you could say here..."he successful use of an intrauterine Foley catheter that is low-risk, low-cost and readily available and familiar to obstetrician-gynecologists in the care of women with post partum hemorrhage?

The section has been re-worded keeping the word count limit in mind. It now reads "Additionally, the devices typically used for intrauterine tamponade are designed for the enlarged, postpartum uterus. In this report, we describe the successful use of the Foley catheter as a low-risk, low-cost, and readily available modality for intra-uterine tamponade in the adolescent population"

- did her family provide any additional history?

Family denied any history of bleeding/clotting disorder, no additional history was provided. Personal and family history mentioned under the case section.

- "Work-up" is jargon. Please change to evaluation for or testing for.

Changed to evaluation throughout the manuscript

- In the surgical and OB setting, TXA is best used within 3 hours of the injury (trauma, surgery, etc). Do you have a reference to include in your discussion for using it as described here?

A sentence has been added to the discussion section that reads "In addition to intravenous estrogen, tranexamic acid was utilized as it is an effective first-line treatment of heavy menstrual bleeding with the intravenous route having a faster onset of action compared to oral formulation" Reference 3 and 11 were cited.

- I thought you had told her to skip her placebos. Was that for the first month only? Could you make that clear?

On line 147, it seems like it wasn't just for the first month.

She was instructed to skip placebos until a normal hemoglobin was noted, for clarity this information has been added to the case section and now reads "Approximately 2 months after the initial episode, her hemoglobin was normal at 14 g/dL and she was cleared to take placebo pills."

- why, since on her first hospitalization she responded to a longer course and IV course of TXA and E. Did she have a recurrent hematocolpos imaged?

During her second admission, an intraoperative ultrasound was performed prior to Foley catheter placement, no hematocolpos was noted at the time however her endometrial strip was noted to be 11mm, this has been included in the Case section.

- Don't start a sentence with a numeral. Either spell it out or edit your sentence to avoid it.

This has been edited and now reads “She returned to the operating room 24 hours later for catheter removal and placement of a 52 miligram levonorgestrel intrauterine device”

- Do you have longer term follow up? Did the IUCD resolve her problem long term?

Longer term follow up has been added as the last paragraph of the case section .

- potentially effective?

The word effective/efficacious being used to describe the foley catheter option has been removed from the manuscript

- These are why on the basis of case report, we are not comfortable describing an intervention as "safe"--I

suggested low-risk above. For rare complications, it would require a large trial to demonstrate safety. As

well, my reminders to change the word "effective" throughout is similarly motivated. It worked or was

associated with a cessation of bleeding, in your patient but its not known if it would be effective in other girls.

The word safe has been changed to low-risk and the word effective being used to describe the Foley catheter option has been removed from the manuscript

- use a colon instead.

Colon added

From: [REDACTED]
To: [Randi Zung](#)
Subject: Re: Your Revised Manuscript 19-253R1
Date: Monday, April 15, 2019 2:46:50 PM
Attachments: [19-253R1_msadeyemiresponse \(4-15-19\).docx](#)

Thank you for all the suggestions in making this manuscript better.

All suggestions have been addressed. Please see attached document with tracked changes.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

All changes have been reviewed.

2. Title and elsewhere: The edits on your paper we've suggested as they relate to substitution for the word "adolescents" may seem odd. ACOG wouldn't use this term for a 10 year, despite the fact the girl is menstruating. I am going through your paper and suggesting a change to "perimenarchal girl" or "10-year-old girl". I don't think "young girl" is right because that to me would not suggest a girl who has gone through menarche. "Female" isn't right because it is too broad. You may have a different term for this, but it needs to not include "adolescent".

I have added "perimenarchal" and agree with the comment.

3. Precis: As this is a case report, it's important not to make broad statements. Please consider something like: "Intrauterine foley catheter tamponade for perimenarchal girls with acute heavy menstrual bleeding resistant to medical management may be a low-risk and low-cost treatment."

Added young girls and adolescents here as well in order to stay consistent.

4. Abstract-Case: Your Case needs to be clear that this is recurrent bleeding and that she had responded to medical therapy with the previous bleeding. Was this her second menses? Please make this clear.

This was her second menses, I have deleted "at menarche."

5. Line 123: Do you approve? I've tried to make this a bit more succinct.

I agree and made some very minor changes if acceptable to you.

6. Line 132: Please clarify "Amid menarche". Is this her first menses? I think it's really important to be clear in your presentation. As I've read this, her initial presentation was her first menses. The use of the foley was in her second menses. Is that true? Menarche may require clearer definition as I thought it was the first menses and that is the definition I can find. Would you consider on line 132 to write: ... "blood loss anemia due to prolonged and heavy bleeding with her first menstrual period."

Yes you are correct, initial presentation was at menarche and the Foley was placed during her second menses. I agree with your suggestion.

7. Line 137: This change addresses my request earlier to indicate that her family also indicated that there was no family history. I wouldn't accept a 10-year old's knowledge of a family history of a clotting disorder, would you?

Agree that I would not accept a 10-year-old's knowledge of family history. Agree with the change.

8. Line 140: What was her hemodynamic status at admission? Did she have a physical examination including pelvic exam or inspection at admission?

I have added notable vital signs and also what was noted on external genitalia exam.

9. Line 152: In your revision letter, you mentioned that this was only until she achieved a normal hgb. You mention

this in the next paragraph, but would you consider: “She was instructed to take oral contraceptive continuously, skipping her placebo pills until she achieved a normal hemoglobin level.” Then in next paragraph: “Approximately t months after the initial episode, she was cleared to take placebo pills as her hemoglobin was 45 g/dL.”

The suggested changes have been made.

10. Line 155: Was she amenorrheic during this time? Was this her 2nd menses?

She was amenorrheic and this was her 2nd menses. I have changed the paragraph slightly to reflect this.

11. Line 160: Edits are to make this active voice. Please review.

Agree, thank you.

12. Line 171: Please note that for this readership, reason for speculum placement should be well known.

Agree

13. Line 176: Did the foley in the uterus immediately drain blood? If so, how much?

Some blood was noted in the tubing but none in the bag, given no measurable amount of blood, this was left out.

14. Line 181: Please describe the course of bleeding from placement to day 1. Can you tell us how much blood drained and how quickly?

She continued to have no measurable amount in the bag and minimal amount on her pad. I have added this at the end of the sentence.

15. Line 184: Why did you use the large progesterone IUD rather than the smaller one? Which did you replace later?

Typically preferred in this age group as we have better data on amenorrhea rates, it is also the only type of IUS that has been studied in a bleeding disorder population, lastly preferable as it lasts 5 years compared to some smaller ones that don't last as long. We replaced it with another 52 mg Mirena IUD and this has been added.

16. Line 193: Do you mean that she elected or that her parents elected this on her behalf? You are pediatric/adolescent gynecologists and may be used to describing your patients as having agency for this type of decision, but I really am not sure that an 10-year-old could make this decision on her own. And certainly, you counseled both her and her parent/guardian. As we do not, unfortunately, receive many papers about pediatrics and adolescent gynecologic issues, I may be misunderstanding your standard of care, but for the general readership, it seems important to address the involvement of the parent/guardians.

We did counsel both the mother and child, I have added this. Thank you for pointing that out.

17. Line 195: Was this the same size?

Yes, same size was used and this has been added.

18. Line 203: I'm not sure that this captures exactly what you mean. In your original version, “adolescents” was used which may be the right thing to use here. But, the issue of avoiding hysterectomy in any female who has not completed child bearing seems relevant. Please edit as you see appropriate but avoid just using “adolescent” since it does not apply to your patient.

I agree with this wording and it includes adolescents.

19. Line 207: For clarity, it's not the systemic arterial pressure (as in 120/80 in the brachial artery), really that is important. It's the perfusion pressure at the endometrial and myometrial levels. The balloon was not exerting any direct pressure on the uterine arteries really, was it?

That was taken directly from the reference, they did put uterine arteries in quotation marks. I have reworded and hope it reads better and more accurately in this revised form.

20. Line 234: I've changed to "could" from "can" as you did not study this.

Agree.

21. Line 234-237: This statement (highlighted) about medical management seems to come out of nowhere in your description of the use of the catheter.

Added here as medical therapies was mentioned. This sentence was included in an effort to address a prior concern from a reviewer in terms of why IV and oral formulation was used. If acceptable, we can remove the entire sentence.

22. Line 245: In some places you capitalize Foley and in otherwise you use lower case. Please find out what the correct way to write this and be consistent.

The F in Foley should be capitalized, this has been changed throughout the manuscript.

23. Line 254: To be clear, you've not done a study.

Agree.

24. Line 257: This sentence (highlighted) isn't clear. It would seem that you are saying that Asherman's should be considered in the differential diagnosis if future hypo or amenorrhea develops. But you are talking about things you might do to try to prevent complications, not making a later diagnosis. Perhaps something like "Hypothetically, protracted periods of balloon inflation may lead to endometrial injury with resulting Asherman's syndrome". (I would avoid putting a time frame on this given the information provided. Also, you would want to keep it in place until bleeding is controlled, or you change tactics, correct?)

I agree, I have changed the wording to reflect this.

Oluyemisi Adeyemi- Fowode M.D., FACOG

[Redacted signature block]

From: Randi Zung <RZung@greenjournal.org>

Sent: Friday, April 12, 2019 9:50 AM

To: Adeyemi-Fowode, Yemi

Subject: Your Revised Manuscript 19-253R1

*****CAUTION:*** This email is not from a BCM Source. Only click links or open attachments you know are safe.**

Dear Dr. Adeyemi-Fowode:

[FROM DR. CHESCHEIR]

Thank you for submitting your revision. We have made a variety of suggestions to help focus the paper, avoid generalizations beyond what a case report can report, and to manage the correct terminology for this patient. As you will see on the attached, we are stuck with the problem that journal style and ACOG use adolescents for females age 13-17 years. Your patient is of course only 10. [END]

In several places, the editor has made some editorial suggestions for wording. In all instances, it is critical that these are acceptable to you, that they do not change the intention or the spirit of what you wrote. Her suggestions are to use active voice and parsimonious word choice.

Please make the requested changes to the latest version of your manuscript that is attached to this email. **Please track your changes and leave the ones made by the Editorial Office.** Please also note your responses to the author queries in your email message back to me.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.
2. Title and elsewhere: The edits on your paper we've suggested as they relate to substitution for the word "adolescents" may seem odd. ACOG wouldn't use this term for a 10 year, despite the fact the girl is menstruating. I am going through your paper and suggesting a change to "perimenarchal girl" or "10-year-old girl". I don't think "young girl" is right because that to me would not suggest a girl who has gone through menarche. "Female" isn't right because it is too broad. You may have a different term for this, but it needs to not include "adolescent".
3. Precis: As this is a case report, it's important not to make broad statements. Please consider something like: "Intrauterine foley catheter tamponade for perimenarchal girls with acute heavy menstrual bleeding resistant to medical management may be a low-risk and low-cost treatment."
4. Abstract-Case: Your Case needs to be clear that this is recurrent bleeding and that she had responded to medical therapy with the previous bleeding. Was this her second menses? Please make this clear.
5. Line 123: Do you approve? I've tried to make this a bit more succinct.
6. Line 132: Please clarify "Amid menarche". Is this her first menses? I think it's really important to be clear in your presentation. As I've read this, her initial presentation was her first menses. The use of the foley was in her second menses. Is that true? Menarche may require clearer definition as I thought it was the first menses and that is the definition I can find. Would you consider on line 132 to write: ... "blood loss anemia due to prolonged and heavy bleeding with her first menstrual period."
7. Line 137: This change addresses my request earlier to indicate that her family also indicated that there was no family history. I wouldn't accept a 10-year old's knowledge of a family history of a clotting disorder, would you?
8. Line 140: What was her hemodynamic status at admission? Did she have a physical examination including pelvic exam or inspection at admission?
9. Line 152: In your revision letter, you mentioned that this was only until she achieved a normal hgb. You mention

this in the next paragraph, but would you consider: “She was instructed to take oral contraceptive continuously, skipping her placebo pills until she achieved a normal hemoglobin level.” Then in next paragraph: “Approximately t months after the initial episode, she was cleared to take placebo pills as her hemoglobin was 45 g/dL.”

10. Line 155: Was she amenorrheic during this time? Was this her 2nd menses?

11. Line 160: Edits are to make this active voice. Please review.

12. Line 171: Please note that for this readership, reason for speculum placement should be well known.

13. Line 176: Did the foley in the uterus immediately drain blood? If so, how much?

14. Line 181: Please describe the course of bleeding from placement to day 1. Can you tell us how much blood drained and how quickly?

15. Line 184: Why did you use the large progesterone IUD rather than the smaller one? Which did you replace later?

16. Line 193: Do you mean that she elected or that her parents elected this on her behalf? You are pediatric/adolescent gynecologists and may be used to describing your patients as having agency for this type of decision, but I really am not sure that an 10-year-old could make this decision on her own. And certainly, you counseled both her and her parent/guardian. As we do not, unfortunately, receive many papers about pediatrics and adolescent gynecologic issues, I may be misunderstanding your standard of care, but for the general readership, it seems important to address the involvement of the parent/guardians.

17. Line 195: Was this the same size?

18. Line 203: I’m not sure that this captures exactly what you mean. In your original version, “adolescents” was used which may be the right thing to use here. But, the issue of avoiding hysterectomy in any female who has not completed child bearing seems relevant. Please edit as you see appropriate but avoid just using “adolescent” since it does not apply to your patient.

19. Line 207: For clarity, it’s not the systemic arterial pressure (as in 120/80 in the brachial artery), really that is important. It’s the perfusion pressure at the endometrial and myometrial levels. The balloon was not exerting any direct pressure on the uterine arteries really, was it?

20. Line 234: I’ve changed to “could” from “can” as you did not study this.

21. Line 234-237: This statement (highlighted) about medical management seems to come out of nowhere in your description of the use of the catheter.

22. Line 245: In some places you capitalize Foley and in otherwise you use lower case. Please find out what the correct way to write this and be consistent.

23. Line 254: To be clear, you’ve not done a study.

24. Line 257: This sentence (highlighted) isn’t clear. It would seem that you are saying that Asherman’s should be considered in the differential diagnosis if future hypo or amenorrhea develops. But you are talking about things you

might do to try to prevent complications, not making a later diagnosis. Perhaps something like “Hypothetically, protracted periods of balloon inflation may lead to endometrial injury with resulting Asherman’s syndrome”. (I would avoid putting a time frame on this given the information provided. Also, you would want to keep it in place until bleeding is controlled, or you change tactics, correct?)

To facilitate the review process, we would appreciate receiving a response by April 16.

Best,
Randi Zung

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Randi Zung (Ms.)

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