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- Comments from the reviewers and editors (email to author requesting revisions)
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**Date:** Jun 17, 2022

**To:** "Robert B. Gherman"

**From:** "The Green Journal" em@greenjournal.org

**Subject:** Your Submission ONG-22-1009

RE: Manuscript Number ONG-22-1009

The Yaari Extractor: A novel device for the management of shoulder dystocia

#### Dear Dr. Gherman:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

### **REVIEWER COMMENTS:**

Reviewer #1: The authors present a description of three cases using the Yaari extractor for treatment of shoulder dystocia. This device wraps around the fetal shoulder and results in improved treatment of shoulder dystocia. While the device appears to be novel and may assist in management of shoulder dystocia a large amount of study is needed to conclude safety and efficacy of the device.

Abstract: the conclusion is overstated as only three cases are presented and the limited data precludes the ability to state the device will revolutionize management.

### Introduction:

Line 28- should include references to case reports and brief references to current recommended management.

Line 41- prior reports do include use of a sling (from catheter) as a device for treatment of shoulder dystocia and the authors should comment on this as comparison.

### Methods:

Line 75- a video may aid in the descriptions and cut down on verbiage.

## Experience:

Line 135- did the patients provide consent for use of this device?

Line 143- all three cases had episiotomy, is this standard practice? Were any additional maneuvers included in management?

Similarly for the second a third cases, did the authors use the extractor first line or include mcroberts or other maneuvers? Was the device in use for the majority of the time of the shoulder dystocia?

1 of 5 6/27/2022, 3:50 PM

Line 164- impressive that the infant had APGAR of 10/10.

Discussion: The discussion should also include any available data on current recommendations and how this device may improve outcomes over current recommendations. Additionally discussion of potential complications with the device is needed (potential inability to place, delay in treatment while inserting device, maternal morbidity associated with device).

Reviewer #2: This is a manuscript describing a new medical device (The Yaari Extractor) directed at improving the management of shoulder dystocia.

Overall the description of the application of the device is reasonable, though a few further details should be considered to improve the description of the device, rationale for use and for the reader to interpret the case application.

- 1. One of the rationales provided by the author for a new device is to standardize the level of force applied by the delivering provider. It is not clear from the description provided how this new device would standardize forces. Is there a mechanism on the device to indicate the level of force provided? Is there something about the shape/structure that provides a standard level of force. It seems similar to forceps or vacuum there the level of force could be provider dependent. If there is a mechanism this should be made clearer in the description.
- 2. To this end, it would be useful to more clearly state/describe the advantage the device providers over the Robin's or Woodscrew maneuvers, which as the author's state, this device mimics.
- 3. Case selection, and testing of the device: Some explanation as to the choice of study setting? Why India and not the US/India where the develop's experience was.
- 4. Consent for participants was consent obtained prior to the onset of labor, 2nd stage, or at the time of the shoulder dystocia
- 5. Case selection: how were cases selected?
- 6. What was the indication for episiotomy in the participants? Were these performed as part of a standard of practice in the study setting, or due to the shoulder dystocia, particularly since all participants in the study appear to be multiparous. Were any other standard maneuvers for should dystocia attempted in each case?
- 7. If available it would be helpful to break down the length of time between diagnosis of the shoulder dystocia, into time to successful placement of the device, and then time to successful resolution.

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- \* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- \* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- \* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.
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- 7. 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 data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.
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- 13. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

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If you submit a revision, we will assume that it has been developed in consultation with your coauthors and that each author has given approval to the final form of the revision.

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD Editor-in-Chief

2020 IMPACT FACTOR: 7.661

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5 6/27/2022, 3:50 PM

Dear Green Journal,

Please find attached revisions to our article entitled, "The Yaari Extractor: A novel device for the management of shoulder dystocia" for sole consideration for publication in the journal. This article has not been submitted, nor is under consideration for, publication in any other journal. A point-by-point discussion of the reviewer and Editor's comments follows below.

Sincerely,

Robert Gherman, MD 21636 Ripplemead Drive Laytonsville, MD 20882

Abstract: the conclusion is overstated as only three cases are presented and the limited data precludes the ability to state the device will revolutionize management.

We have modified the final sentence of the abstract to read, "The Yaari Extractor is a novel technology that can be used to successfully resolve shoulder dystocia."

# Introduction:

Line 28- should include references to case reports and brief references to

current recommended management. We have added references.

Line 41- prior reports do include use of a sling (from catheter) as a device for treatment of shoulder dystocia and the authors should comment on this as comparison. We have added a sentence (and appropriate reference) about the use of the sling catheter for the management of shoulder dystocia.

# Methods:

Line 75- a video may aid in the descriptions and cut down on verbiage. We have included a video for inclusion with our submission.

# Experience:

Line 135- did the patients provide consent for use of this device? As noted in our original manuscript submission, the listed patients provided written informed consent prior to application of the device.

Line 143- all three cases had episiotomy, is this standard practice? Were any additional maneuvers included in management? Liberal use of episiotomy is standard practice, in India. As already described in the Experience section, no other additional maneuvers were employed.

Similarly for the second a third cases, did the authors use the extractor first line or include mcroberts or other maneuvers? Was the device in use for the majority of the time of the shoulder dystocia? As noted in the manuscript, "In each of the cases described, the patients were allowed to push in an exaggerated dorsal lithotomy position, and the device was employed as a primary technique once shoulder dystocia was identified." No other maneuvers were employed.

Line 164- impressive that the infant had APGAR of 10/10. We thank the reviewer for this comment, but do not believe that additional clarification is needed as these were the assigned Apgar scores at birth.

Discussion: The discussion should also include any available data on current recommendations and how this device may improve outcomes over current recommendations. Additionally discussion of potential complications with the device is needed (potential inability to place, delay in treatment while inserting device, maternal morbidity associated with device). Additional studies are needed to clarify how this device could improve shoulder dystocia outcomes; we do not have published data to provide at this time and therefore cannot comment on this. We have added a comment about how the device could compare to McRoberts maneuver. We have added comments in the discussion section as to the potential risks associated with device application.

- 1. One of the rationales provided by the author for a new device is to standardize the level of force applied by the delivering provider. It is not clear from the description provided how this new device would standardize forces. Is there a mechanism on the device to indicate the level of force provided? Is there something about the shape/structure that provides a standard level of force. It seems similar to forceps or vacuum there the level of force could be provider dependent. If there is a mechanism this should be made clearer in the description. As we do not yet have published objective data concerning standardization of force, we have removed the sentence in the introduction postulating the benefit of the device in this regard.
- 2. To this end, it would be useful to more clearly state/describe the advantage the device providers over the Robin's or Woodscrew maneuvers, which as the author's state, this device mimics. We have added a comment with regards to our belief that the device offers advantages over the standard rotational maneuvers.
- 3. Case selection, and testing of the device: Some explanation as to the choice of study setting? Why India and not the US/India where the develop's experience was. We have added comments as to why India

# was chosen as the testing site.

- 4. Consent for participants was consent obtained prior to the onset of labor, 2nd stage, or at the time of the shoulder dystocia. Consent was obtained at the time of admission to labor and delivery. A comment on this has been added to the manuscript.
- 5. Case selection: how were cases selected? Cases were selected based on a clinical suspicion of fetal macrosomia. We have commented on this in our revised manuscript.
- 6. What was the indication for episiotomy in the participants? Were these performed as part of a standard of practice in the study setting, or due to the shoulder dystocia, particularly since all participants in the study appear to be multiparous. Were any other standard maneuvers for should dystocia attempted in each case? Liberal use of episiotomy is standard practice, in India. As already described in the Experience section, no other additional maneuvers were employed.
- 7. If available it would be helpful to break down the length of time between diagnosis of the shoulder dystocia, into time to successful placement of the device, and then time to successful resolution. **Unfortunately, we do not have this information to provide for the manuscript.**

## EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at <a href="mailto:em@greenjournal.org">em@greenjournal.org</a>, and only the revision letter will be posted. We agree that the point-by-point responses can be published as supplemental digital content.

- 2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
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- \* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable). **Not applicable**
- \* Name the IRB or Ethics Committee institution in the Methods section (if applicable). **Not applicable**
- \* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context. We have added information about the specific location of the study.
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- 4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women." We have performed this, to the best of our abilities.

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- 7. 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 data definitions at <a href="https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions">https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions</a>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter. We have performed this, to the best of our abilities.
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- 11. Provide a short title of no more than 45 characters, including spaces, for use as a running foot. Do not start the running title with an abbreviation. **This has been performed.**
- 12. Provide a précis for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents." This has been performed.
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