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)*

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Date: Jun 17, 2022
To: "Ann M Bruno" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-906

RE: Manuscript Number ONG-22-906

Weight-based versus fixed dose enoxaparin prophylaxis after cesarean delivery: A randomized controlled trial

Dear Dr. Bruno:

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 performed an unmasked, randomized controlled trial to compare the effectiveness of two dosing regimens of enoxaparin to achieve prophylactic anti-Xa levels among patients after cesarean delivery. They found that weight-based dosing was more effective at achieving prophylactic anti-Xa levels than fixed dosing. I commend the investigators on a well-written report and filling a knowledge gap on enoxaparin dosing for VTE prophylaxis, particularly in the nonobese population. My main concern, which can be expanded on in the discussion, was the higher rate of hematoma and wound complications in the weight-based group (although not statistically different from the fixed-dose group, likely due to sample size). My specific comments and suggestions are listed below:

Methods
1. Page 7, line 106, was the clinical care team blinded to the group assignment when evaluating for wound complications postpartum?
2. Page 7, line 111, 18% difference seems very specific. How did you decide on an 18% difference for your sample size?
3. Page 8, lines 140-145, I suggest moving this paragraph to the first paragraph of the Methods section on page 5

Results
4. Page 11, lines 190-191, what group did the three patients with wound separation/bruising belong to? Also, is the chief complaint of the 6 ED evaluations available?

Discussion
5. Page 12, lines 226-231, although not statistically significant, five wound complications in the weight-based group versus one in the fixed-dose group may be clinically relevant and should be acknowledged. In addition, you should acknowledge that Lu et al. study's enoxaparin dosing regimen was that of fixed dosing, which may be the reason for the lower rates of wound complication (0.4% and 0.7%).
6. Page 12-13, lines 232-235, I suggest deleting this paragraph as it does not add to the discussion.

7. Page 14, lines 261-267, I suggest adding this paragraph to the last paragraph since it is a continuation of the study's limitations.

Reviewer #2:

The prophylactic use of heparin after cesarean section remains a standard of care. While consensus about which precise regimen to use, and which patients are appropriate candidates for therapy, has not been reached, it is clear that heparin will continue to be a mainstay of post-cesarean section care for many women. Therefore extending studies of weight-based dosing previously reported among obese women is a worthwhile project. A few clarifications could help determine the utility of this work in that regard:

1. The methodology employed, an RCT is clearly the jewel in the crown for these sorts of efforts. However, the manner in which it was carried out raises some questions. Why were research personnel not blinded?
2. What weight was used to determine dose? Was the patient weighed post-operatively? If not, the last weight obtained prior to surgery would not reflect the loss that would occur as fluid, placenta and fetus are removed. Could that, in extreme circumstances lead to an "over dosing"? Conversely, if they used the weight from the first prenatal visit that would not reflect weight gain and could result in under dosing.
3. There is a slight tendency to use language that suggests evidence of absence when in fact they have absence of evidence. I say this in relation to how they describe wound issues. As opposed to how they describe rates of sub-prophylactic levels, which are presented as rates per group, the wounds are just given as a total and not given as a separate number in each group (line 29). Clearly the numbers are too small to be statistically interesting, but they are not identical in the two groups, and if the differences were sustained with a larger sample they might be clinically relevant. In any event, they certainly did not have the power to rule out a wound risk. I assume they had no episodes of post-op, post treatment bleeding that required any sort of intervention (e.g., transfusion or return to OR).
4. In regard to post-op complications, were they able to ascertain outcomes of patients who might have gone to urgicenters or other hospitals' ERs for wound issues?
5. To what do they attribute the poor follow-up rate? Could it have led to a misestimating of complication rates in both groups since complications may have led to increased (or decreased) follow-up rates?
6. I was unclear about the primary outcome. They say 4-6 hours after at least the third dose. Did they stratify the outcomes by the number of doses, since "at least" implies that the number of doses varied?
7. They discuss "self-reported" compliance. How reliable do they think that is? Did they use any social desirability measure or any technique to probe responses?
8. They note that the diagnosis of wound complications was at the discretion of the care team. Did the same team see both groups? Was there any sort of joint training so the same standards were used for everyone?
9. Why did they choose an 18% difference between groups as the basis for their power calculations?
10. Line 148: I don't understand how they got from 1,800 patients screened to only 146 meeting criteria and consenting. Did patients know they were going to have to have blood draws in order to participate, since so many withdrew because of the need for the draws? Also, the results (line 162) use a denominator that incudes women who withdrew. If that is intention to treat, they should also share a per protocol result. This is even more important when considering levels at the post-operative visit.
11. On line 180 the groups have 60 and 57 patients. That seems to differ than what would have been expected based on numbers given on lines 148-153. Maybe I'm just having a bit of a problem following the numbers.

Reviewer #3:

The authors performed a randomized trial assessing weight-based vs fixed dose enoxaparin for VTE prophylaxis.

Introduction: Well constructed. Identifies gap. Clearly defines the primary and secondary aims.

Methods:
1. Please clarify what the institutional criteria for prophylaxis entails. Line 63-64
2. In the power analysis why was an 18% difference chosen? Line 111

Results

3. How did authors determine that all participants received therapy consistent with randomization arm (lines 158-159).

Discussion: Appropriate without overstating findings

STATISTICS EDITOR COMMENTS:

Tables 1,2,3: Given the size of N for each column, should round all %s to nearest integer, not to 0.1% precision.

Table 2: Since CIs are included, should omit the column of p-values. Should include in separate columns the counts for wgt based without missing data, then a column with the imputed worst case, then the total (ie, the present column for wgt based. Likewise for the fixed dose cohort. The analysis will be the same, but the reader will better understand the worst-case methodology. Also, prophylactic vs sub-prophylactic peak levels should be mutually exclusive and sum to the total, but in Table 2, the sum =73, not 74. Need to clarify. Also, why are both reported if they are complementary values?

Table 3: For out-pt prophylactic peak anti-Xa, the proportion missing results in so few with data that the results are potentially biased and cannot be generalized. That is, if there were actually only 15/27 vs 5/33 with out-patient measurements, then the imputation in Table 2 amounts to imputation of 33/74 (44%) measurements for the wgt-based and 24/72 (33%) for the fixed dose. This is more frequent loss of data than can reasonably be accounted for by imputation. Also, for the calculation itself, using 15/27 vs 5/33, I get RR = 3.67 (1.53-8.80), not the value included. Same issue with prophylactic vs non-prophylactic, should sum to 60, but is only 59. Need to clarify.

Tables 2, 3: The counts for VTE, any wound complication and its subcomponents are few, and there is insufficient stats power to generalize from these data the conclusion that there is no difference in those outcomes. Would require much larger sample size to come to those conclusions.

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 em@greenjournal.org, and only the revision letter will be posted.

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:
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* 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.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the

manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf.

5. 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."

6. The journal follows ACOG's Statement of Policy on Inclusive Language (https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

7. Clinical trials must include a data sharing statement. Please add the following questions and your answers to the end of the manuscript after the References section:

Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

8. 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.

9. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Original Research: 3,000 words

10. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

* 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 or indicate whether the meeting was held virtually).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

11. 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.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Original Research: 300 words

12. Abstracts for clinical trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online at http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf and edit your abstract as needed.

13. 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.

14. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. 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.

15. In your abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or

noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.

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

17. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the formal reference list. Please cite them on the line in parentheses.

If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document. In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

Please make sure your references are numbered in order of appearance in the text.

18. Figure 1: Please reclassify as a box.
Figure 2: Please upload as a figure file on Editorial Manager.

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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.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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,

Dwight J. Rouse, MD

Deputy Editor, Obstetrics

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

July 8, 2022

Dear Editors,

Thank you for the opportunity to revise our manuscript, “Weight-based versus fixed dose enoxaparin prophylaxis after cesarean delivery: A randomized controlled trial." We appreciate the review and constructive suggestions. I can confirm that I have read the ‘Instructions for Authors.’ Attached is the revised manuscript with tracked changes. Below are the Editor, Reviewer, and Editorial Office comments with point-by-point responses including how and where the manuscript text was modified when able. Additional minor edits were made to the Discussion for brevity. All authors have reviewed and approve of the submitted revision.

Thank you for your ongoing consideration of our work.

Sincerely,

Ann Bruno

REVIEWER COMMENTS:

Reviewer #1:
The authors performed an unmasked, randomized controlled trial to compare the effectiveness of two dosing regimens of enoxaparin to achieve prophylactic anti-Xa levels among patients after cesarean delivery. They found that weight-based dosing was more effective at achieving prophylactic anti-Xa levels than fixed dosing. I commend the investigators on a well-written report and filling a knowledge gap on enoxaparin dosing for VTE prophylaxis, particularly in the nonobese population. My main concern, which can be expanded on in the discussion, was the higher rate of hematoma and wound complications in the weight-based group (although not statistically different from the fixed-dose group, likely due to sample size). My specific comments and suggestions are listed below:

Thank you for these comments. Please see responses below to individual questions and comments.

Methods
1. Page 7, line 106, was the clinical care team blinded to the group assignment when evaluating for wound complications postpartum?

Thank you for this question. Patients and care teams were unmasked to study arm allocation (lines 133-134) in this pragmatic trial. Wound complication diagnosis and management were at the discretion of usual clinical care (i.e., evaluated by inpatient or outpatient care teams at point of presentation of patient) (Line 163). This is a limitation of the study and further language has been added to the discussion.

Textual edits –

- Line 344: "The trial was unmasked which may have introduced bias."

2. Page 7, line 111, 18% difference seems very specific. How did you decide on an 18% difference for your sample size?

Thank you for this question. Two prior studies (Overcash et al and Stephenson et al) evaluated fixed (or body mass index) based enoxaparin in comparison to weight-based enoxaparin in patients with obesity. These studies were used to inform the baseline expected rate of prophylactic anti-Xa level in the fixed dose group and inform effect size.[1,2] Using a conservative estimate based on the effect size from these two prior studies along with the selected parameters (beta 0.2, alpha 0.05), the sample size was determined for this trial for an estimated difference of 18% between the two dosing groups. This effect size is smaller than would be expected based on prior studies in individuals with obesity. However, this conservative 18% estimate was used for the overall sample size calculation to allow for additional power for sub-group comparisons by body mass index and weight categories and considering the planned enrollment of individuals across all BMI categories. This difference was also thought to be clinically meaningful. The subgroup analyses were not completed following cessation of the trial early for efficacy at time of interim analysis. Clarification has been added to the manuscript text regarding the selected 18% difference.

Textual edits –

- Lines 1659-187: "Two prior studies (Overcash et al and Stephenson et al) evaluated fixed (or BMI) based enoxaparin in comparison to weight-based enoxaparin dosing in patients with class II and III obesity. These studies were used to inform the baseline expected rate of prophylactic

anti-Xa level in the fixed dose group (26%) and the effect size (60%) for individuals with obesity.[13,14] A more conservative but still clinically meaningful effect size was used for the overall sample size calculation considering planned inclusion of individuals across all BMIs, and to allow additional power for robust subgroup comparisons by BMI and weight categories. We determined to have 80% power to detect an 18% difference in the proportion of individuals with prophylactic anti-Xa levels with weight-based compared to fixed enoxaparin dosing with a two-sided type I error rate of 5%, 121 individuals per arm were required for the study. Allowing for 10% loss to follow-up, we planned to recruit 266 individuals."

3. Page 8, lines 140-145, I suggest moving this paragraph to the first paragraph of the Methods section on page 5

Thank you for this comment. In accordance with the recommendation, the paragraph has been moved.

Textual edits –

- Lines 105-111: "This study was approved by the Institutional Review Board (IRB) of the University of Utah (#00130494). The trial was registered at ClinicalTrials.gov in advance of initiation of study enrollment (NCT04305756). Study data were collected and managed using REDCap (Research Electronic Data Capture) hosted at University of Utah.[17] All analyses were performed using SAS 9.4 (Cary, NC, USA). The study was reported following the CONsolidated Standards of Reporting Trials (CONSORT) guidelines.[18]"

Results

4. Page 11, lines 190-191, what group did the three patients with wound separation/bruising belong to? Also, is the chief complaint of the 6 ED evaluations available?

Thank you for these questions. We do have further information on these patients. For the three patients identified with superficial wound separation or bruising: two patients were in the weight-based dose group and one patient was in the fixed dose group. Further details on these three patients were not provided in the manuscript text as the patients required no additional evaluation or intervention, and therefore, were not thought to represent any complications outside of routine care. For the six patients with the reported adverse event (AE) of emergency department evaluation, chief complaints included:

- Abdominal pain with negative evaluation (fixed dose group)
- Urinary symptoms/urinary tract infection (weight-based dose group)
- Mastitis (fixed dose group)
- Rash (fixed dose group)
- Gallstone pancreatitis (weight-based dose group)
- Vaginal bleeding with negative evaluation (fixed dose group)

Details of these emergency department visits are not currently included in the manuscript text. All of the adverse events have been added to a supplemental Appendix 2.

Textual edits –

- Line 271: "…the secondary outcomes (Appendix 2)."
- Supplemental Appendix 2.

Discussion

5. Page 12, lines 226-231, although not statistically significant, five wound complications in the weight-based group versus one in the fixed-dose group may be clinically relevant and should be acknowledged.

In addition, you should acknowledge that Lu et al. study's enoxaparin dosing regimen was that of fixed dosing, which may be the reason for the lower rates of wound complication (0.4% and 0.7%).

Thank you for these comments. We have made textual edits reflecting that while not statistically significant, the differences by dosing group may be clinically significant. We have also clarified that the chemical prophylaxis guideline implemented in the Lu et al study is a fixed dose protocol.

Textual edits –

- Line 311: "…after fixed-dose chemical thromboprophylaxis guideline implementation…"
- Lines 314-315: "Although not statistically significant, differences between groups may be clinically significant."

6. Page 12-13, lines 232-235, I suggest deleting this paragraph as it does not add to the discussion.

Thank you for this comment. Current postpartum chemical thromboprophylaxis guidelines differ in their recommendations for length of therapy (e.g., inpatient only, 10-14 days postpartum, 6 weeks postpartum).[3-5] This trial utilized an extended prophylaxis approach with enoxaparin continued for 14 days after hospital discharge consistent with current institutional practice. Patients were followed in the outpatient setting including a repeat peak anti-Xa level at postoperative day 10-18 (secondary outcome). The difference in rates of prophylactic anti-Xa level between weight-based and fixed dosing persisted at this outpatient follow-up (Lines 246-248; lines 263-265; Table 2; Table 3). We think these findings have value when considering future approach to both clinical care and research; therefore, we prefer to keep this information in the Discussion.

7. Page 14, lines 261-267, I suggest adding this paragraph to the last paragraph since it is a continuation of the study's limitations.

Thank you for this comment. The specified paragraph immediately continues the discussion of limitations but the paragraph is separated as a natural break in ideas. We have kept this as two separate paragraphs for easy of reading.

Reviewer #2:
The prophylactic use of heparin after cesarean section remains a standard of care. While consensus about which precise regimen to use, and which patients are appropriate candidates for therapy, has not been reached, it is clear that heparin will continue to be a mainstay of post-cesarean section care for many women. Therefore, extending studies of weight-based dosing previously reported among obese women is a worthwhile project. A few clarifications could help determine the utility of this work in that regard:

Thank you for these comments. Please see responses below to individual questions/comments.

1. The methodology employed, an RCT is clearly the jewel in the crown for these sorts of efforts. However, the manner in which it was carried out raises some questions. Why were research personnel not blinded?

Thank you for this question. This was a pragmatic trial with blinding precluded for feasibility and for limitations of funding. Blinding to enoxaparin dosing would have required opaque syringes, placebo injections, and dispensing through a research pharmacy which would have been cost prohibitive. While

we recognize the bias that a lack of blinding can introduce, the primary outcome is an anti-Xa level, which is a quantitative measure that is not subjective or in any way influenced by the lack of blinding. We acknowledge the lack of blinding as a limitation of the study; a sentence further emphasizing this has been added to the discussion of limitations.

Textual edits –

- Line 344-345: “The trial was unmasked which may have introduced bias. However, this would not have affected the primary outcome which was an objectively measured anti-Xa level.”

2. What weight was used to determine dose? Was the patient weighed post-operatively? If not, the last weight obtained prior to surgery would not reflect the loss that would occur as fluid, placenta and fetus are removed. Could that, in extreme circumstances lead to an "over dosing"? Conversely, if they used the weight from the first prenatal visit that would not reflect weight gain and could result in under dosing.

Thank you for these comments and questions. The reviewer highlights an area of complexity when determining the correct timepoint for weight assessment in consideration of postpartum prophylaxis. This study used admission weight for enoxaparin dosing determination consistent with prior studies and current guidelines.[1,2] Clarification has been added to the text.

Textual edits –

- Line 132: “Admission weight was used for dosing.”

3. There is a slight tendency to use language that suggests evidence of absence when in fact they have absence of evidence. I say this in relation to how they describe wound issues. As opposed to how they describe rates of sub-prophylactic levels, which are presented as rates per group, the wounds are just given as a total and not given as a separate number in each group (line 29). Clearly the numbers are too small to be statistically interesting, but they are not identical in the two groups, and if the differences were sustained with a larger sample they might be clinically relevant. In any event, they certainly did not have the power to rule out a wound risk. I assume they had no episodes of post-op, post treatment bleeding that required any sort of intervention (e.g., transfusion or return to OR).

Thank you for these comments. In the abstract, postpartum wound complications are given as the overall rate (line 66) as the reviewer notes secondary to word limitations. Within the manuscript body, the wound complications by dosing group with specifics regarding the wound complications are further delineated (lines 252-257; Tables 2 & 3). There were no events of return to the operating room or blood transfusion related to wound or bleeding complications. We agree with the reviewer that we have insufficient power to definitively evaluate this secondary outcome. Thus, the discussion specifies the secondary outcomes should be considered exploratory (lines 350-351). Additional language has now been added about the potentially clinically significant differences between groups for wound complications.

Textual edits –

- Lines 314-315: “Although not statistically significant, differences between groups may be clinically significant.”

4. In regard to post-op complications, were they able to ascertain outcomes of patients who might have gone to urgicenters or other hospitals' ERs for wound issues?

Thank you for this question. Final outcome ascertainment was through 6 weeks postpartum based on medical record review and patient report from clinical follow up within our healthcare system (e.g., 2- and 6-week postoperative visits). If a patient reported complications for which they were evaluated elsewhere, patient self-report was recorded and records obtained (if possible). An additional sentence has been added to the Methods for clarity. However, there remains a possibility that patients were seen outside of our healthcare system for complications that may not have been ascertained. We recognize this is a limitation and further language has been added to the limitations in the Discussion.

Textual edits –

- Lines 165-167: "If a patient reported complications for which they were evaluated outside our healthcare system, patient self-report was recorded and records obtained, if possible."
- Lines 342-344: "There remains a possibility that patients were seen outside of our healthcare system and outcomes were not ascertained."

5. To what do they attribute the poor follow-up rate? Could it have led to a misestimating of complication rates in both groups since complications may have led to increased (or decreased) follow-up rates?

Thank you for this question. We hypothesize that the COVID-19 pandemic was one source of loss to follow-up as this impacted clinical care (e.g., increase in virtual visits and diminished in-person care) and research (e.g., changes in practice for safety of patients and research team staffing). Patients were also discharged earlier from the hospital than anticipated during the pandemic and were not willing to have home visits from the research staff for ascertainment of the primary outcome following discharge from the hospital for fear of contracting SARS-CoV-2. Other factors may have also contributed. The loss to follow-up is a limitation of our study and is recognized in the discussion (lines 332-333). To address missing outcomes, analysis was undertaken to compare individuals with and without missing outcomes, and to complete both a modified intention to treat analysis and a complete case analysis (lines 222-236). Further language on this limitation has been added to the Discussion.

Textual edits –

- Lines 334-336: "Patients were discharged earlier from the hospital than anticipated during the pandemic and were not willing to have home visits from the research staff for ascertainment of the primary outcome following discharge for fear of contracting SARS-CoV-2."

6. I was unclear about the primary outcome. They say 4-6 hours after at least the third dose. Did they stratify the outcomes by the number of doses, since "at least" implies that the number of doses varied?

Thank you for this clarification. Enoxaparin steady state is not achieved until between the second and third dose of therapy, and therefore best practice is for collection of anti-Xa level after at least the third dose.[3,6,7] The primary outcome in this study was anti-Xa level measured at steady state (i.e., after at least the third dose) and as a peak (i.e., 4-6 hours after dose). The collection of anti-Xa level "after at least the third dose" was a pragmatic selection to allow some flexibility to our research team for collection of anti-Xa level after ideally the third dose, but after later doses if necessary based on time of dosing and availability of research team. For example, for a patient on q12 hour dosing (at 9am and 9pm), the research staff may preferentially draw the peak after the fourth dose (at 9am) than the third dose (at 9pm) based on availability of research staff. The majority of outcomes were ascertained after

the third dose of enoxaparin (95%) with a small subset (5%) collected after the fourth dose. Additional language has been added to the Methods for clarity.

Textual edits –

- Lines 146-148: "Enoxaparin steady state is reached between the second and third doses; collection after at least the third dose of enoxaparin was selected to ensure drug steady state was achieved prior to outcome ascertainment.[4,8,16]"

7. They discuss "self-reported" compliance. How reliable do they think that is? Did they use any social desirability measure or any technique to probe responses?

Thank you for these questions. Patient self-report of compliance carries limitations as the reviewer notes. This limitation is included in our discussion (line 342: "Participant compliance to therapy after hospital discharge is uncertain."). Beyond patient self-report of compliance, survey data were collected reflecting patient views of enoxaparin therapy. These survey results are not included in the current manuscript but may be explored in a future analysis.

8. They note that the diagnosis of wound complications was at the discretion of the care team. Did the same team see both groups? Was there any sort of joint training so the same standards were used for everyone?

Thank you for this question. The diagnosis of wound complications was at the discretion of the clinical care team (Line 163). For example, the inpatient or outpatient care teams (e.g., residents, attendings, advanced practice clinicians) assessed patients inpatient or outpatient for concerns about wounds consistent with standard care guidelines. This was a single center study with patients in both study arms cared for by the same institutional clinicians. There was no specialized training on wound complications specific to the study. This was a pragmatic approach but consistent with what would be expected in usual care.

9. Why did they choose an 18% difference between groups as the basis for their power calculations?

Thank you for this question. Please see response to reviewer 1, comment 2.

10. Line 148: I don't understand how they got from 1,800 patients screened to only 146 meeting criteria and consenting. Did patients know they were going to have to have blood draws in order to participate, since so many withdrew because of the need for the draws? Also, the results (line 162) use a denominator that incudes women who withdrew. If that is intention to treat, they should also share a per protocol result. This is even more important when considering levels at the post-operative visit.

Thank you for these comments. There were 1,813 patients assessed for eligibility with the majority of patients excluded secondary to enrollment in another study that did not permit co-enrollment in this trial, or research staff being unavailable to approach/enroll (Figure 1). There was a smaller proportion of patients excluded secondary to decline to participate in research at all, or more specifically this study. Patients were informed of the study procedures (e.g., enoxaparin prophylaxis and blood draws) prior to consent.

In the primary modified intention to treat analysis, we included all patients enrolled (e.g., analyzed 74 in weight-based and 72 in fixed dose group) (lines 188-191; lines 238-241; Table 2). All participants

received therapy consistent with randomization arm (line 236) and therefore a secondary per-protocol analysis was not completed. Textual edits have been made for clarification. A secondary complete case analysis was completed for participants with complete outcome ascertainment (lines 194-196). This resulted in the reduced denominator identified and presented (lines 258-267, Table 3). Results of the intention to treat and complete case analysis were similar demonstrating that the findings were robust.

Textual edits –

- Line 237: "…and therefore, per protocol analysis was not completed."

11. On line 180 the groups have 60 and 57 patients. That seems to differ than what would have been expected based on numbers given on lines 148-153. Maybe I'm just having a bit of a problem following the numbers.

Thank you for this comment. The primary analysis presented is a modified intention to treat analysis including all individuals enrolled and randomized (e.g., 74 assigned to weight-based enoxaparin and 72 assigned to fixed enoxaparin) (lines 188-191; lines 238-245; Table 2). A secondary complete case analysis was completed (lines 194-196). The complete case analysis uses only those patients with complete outcome ascertainment which is reflected in the reduced denominators (e.g., 60 assigned to weight-based enoxaparin and 57 assigned to fixed enoxaparin) with results presented in lines 258-267 and Table 3.

Reviewer #3:
The authors performed a randomized trial assessing weight-based vs fixed dose enoxaparin for VTE prophylaxis.

Introduction: Well-constructed. Identifies gap. Clearly defines the primary and secondary aims.

Thank you for these comments.

Methods:
1. Please clarify what the institutional criteria for prophylaxis entails. Line 63-64

Thank you for this clarification. The institutional criteria for prophylaxis are outlined in Figure 1 (now Box 1). These criteria are not expanded in the manuscript text at present for length.

2. In the power analysis why was an 18% difference chosen? Line 111

Thank you for this question. Please see response to reviewer 1, comment 2.

Results
3. How did authors determine that all participants received therapy consistent with randomization arm (lines 158-159).

Thank you for this clarification. While participants were inpatient, their enoxaparin therapy was prescribed consistent with randomization arm, and therapy confirmed consistent with randomization arm through the medication administration record (MAR). All participants received enoxaparin consistent with randomization arm using this monitoring while inpatient. After discharge, adherence to

therapy cannot be guaranteed but compliance (with randomized dosing) was assessed by patient report (lines 158-159; lines 248-251). This limitation is also discussed (line 342).

Discussion: Appropriate without overstating findings.

Thank you for this comment.

STATISTICS EDITOR COMMENTS:

Tables 1,2,3: Given the size of N for each column, should round all %s to nearest integer, not to 0.1% precision.

Thank you for this input. All tables have been updated with the %s rounded to the nearest integer.

Textual edits –

- See updated Tables 1, 2, 3

Table 2: Since CIs are included, should omit the column of p-values. Should include in separate columns the counts for wgt based without missing data, then a column with the imputed worst case, then the total (ie, the present column for wgt based. Likewise for the fixed dose cohort. The analysis will be the same, but the reader will better understand the worst-case methodology. Also, prophylactic vs sub-prophylactic peak levels should be mutually exclusive and sum to the total, but in Table 2, the sum =73, not 74. Need to clarify. Also, why are both reported if they are complementary values?

Thank you for this feedback. The p-value column has been removed consistent with the recommendation. We re-formatted Table 2 as recommended above but on review by the co-authors this was difficult to interpret, and therefore is not included. Rather, we added a Table 2 footnote clarifying the outcomes where imputation in the numerator was completed, as well as the number of values imputed. We are open to further edits at the discretion of the Editors.

In regards to the mutual exclusivity of outcomes, the three result options for anti-Xa level include: prophylactic, sub-prophylactic, or supra-prophylactic. The primary outcome is analyzed as dichotomous (prophylactic or not). The prophylactic and sub-prophylactic groups are not directly complementary values; there was a single instance of a supra-prophylactic anti-Xa level resulting in the summation to 73, rather than 74 for these two rows.

Textual edits –

- Table 2

Table 2. Primary and secondary outcomes by intention-to-treat (ITT) analysis

Outcome	**Weight-based dose** (N=74)	**Fixed dose** (N=72)	**Relative Risk (95% Confidence Interval)**
Prophylactic peak anti-Xa	49 (66)	32 (44)	1.49 (1.10-2.02)
Sub-prophylactic peak anti-Xa*	24 (32)	40 (56)	0.58 (0.40-0.86)
Supra-prophylactic peak anti-Xa*	15 (20)	15 (21)	0.97 (0.51-1.84)

Outpatient prophylactic peak anti-Xa	15 (20)	5 (7)	2.92 (1.12-7.61)
Venous thromboembolism	0 (0)	0 (0)	–
Any wound complication	5 (7)	1 (1)	4.86 (0.58-40.63)
Hematoma	3 (4)	0 (0)	–
Surgical site infection	2 (3)	0 (0)	–
Other	0 (0)	1 (1)	–

Data as n(%).

*Results with worst-case imputation in the numerator for missing data. For the weight-based group, 14/74 outcomes imputed for sub-prophylactic and supra-prophylactic peak anti-Xa. For the fixed dose group, 15/72 outcomes imputed for sub-prophylactic and supra-prophylactic peak anti-Xa.

Table 3: For out-pt prophylactic peak anti-Xa, the proportion missing results in so few with data that the results are potentially biased and cannot be generalized. That is, if there were actually only 15/27 vs 5/33 with out-patient measurements, then the imputation in Table 2 amounts to imputation of 33/74 (44%) measurements for the wgt-based and 24/72 (33%) for the fixed dose. This is more frequent loss of data than can reasonably be accounted for by imputation. Also, for the calculation itself, using 15/27 vs 5/33, I get RR = 3.67 (1.53-8.80), not the value included. Same issue with prophylactic vs non-prophylactic, should sum to 60, but is only 59. Need to clarify.

Thank you for these comments. Regarding outpatient peak anti-Xa level, this was the outcome with the largest loss to follow-up. The high rates of missing data may exceed a reasonable level for the employment of imputation. Consistent with the outlined methods, we completed both worst-case imputation in the primary analysis and used complete cases only in secondary analysis. We observed similar results between analyses (RR 2.92 and 3.41, respectively). Prior studies have not reported on outpatient anti-Xa levels. We find these results, despite their limitations, to be a contribution to the literature. Additional language has been added to the limitations in the Discussion reviewing the potential for bias but explaining the rationale for inclusion.

There was an error in the denominator for the weight-based dosing group for the outpatient ant-Xa level peak. This has been corrected in the current draft, as well as the associated relative risk. Thank you for catching this mistake.

The three outcome options for peak anti-Xa level include prophylactic, sub-prophylactic, and supra-prophylactic. The three rows sum to the total N in Table 3. All three are presented as prophylactic and sub-prophylactic are not complementary values given a single occurrence of a supra-prophylactic level in the study population.

Textual edits –

- Lines 263-265: “At outpatient follow up, prophylactic peak anti-Xa level was achieved in 52% (15/29) in the weight-based group compared to 15% (5/33) in the fixed dose group (RR 3.41, 95% CI 1.42-8.24, p=0.002).”
- Table 3: Updated below

Table 3. Primary and secondary outcomes by complete case analysis

Outcome	**Weight-based dose** (N=60)	**Fixed dose** (N=57)	**Relative Risk (95% Confidence Interval)**
Prophylactic peak anti-Xa	49 (82)	32 (56)	1.45 (1.12-1.88)
Sub-prophylactic peak anti-Xa	10 (17)	25 (44)	0.38 (0.20-0.72)
Supra-prophylactic peak anti-Xa	1 (2)	0 (0)	–
Outpatient prophylactic peak anti-Xa*	15/N=29 (52)	5/N=33 (15)	3.41 (1.42-8.24)
Venous thromboembolism	0 (0)	0 (0)	–
Any wound complication	5 (8)	1 (2)	4.75 (0.57-39.42)
Hematoma	3 (5)	0 (0)	–
Surgical site infection	2 (3)	0 (0)	–
Other	0 (0)	1 (2)	–

Data as n(%). *Denominator reduced for outpatient prophylactic peak anti-Xa.

- Lines 338-341: "Additional individuals were lost to follow-up for outpatient peak anti-Xa level ascertainment, yielding high rates of imputation and potential for bias in this measure. Prior studies have not reported on outpatient peak anti-Xa levels; we report these findings, despite their limitations, as they add to the literature."

Tables 2, 3: The counts for VTE, any wound complication and its subcomponents are few, and there is insufficient stats power to generalize from these data the conclusion that there is no difference in those outcomes. Would require much larger sample size to come to those conclusions.

Thank you for these comments. With a population prevalence of venous thromboembolism (VTE) of 0.5-2 events per 1,000 pregnant or postpartum people, VTE was considered an exploratory secondary outcome from the outset.[6] We initially anticipated to have statistical power to detect differences between groups for wound complications. However, as a result of stopping the trial early with a reduced sample size overall, we agree that wound complications should also be considered exploratory. This is reflected in the discussion (lines 349-351: "While statistical power was retained for the primary outcome, differences in secondary outcomes should be considered exploratory."). Additional textual edits have been made to reflect the potentially clinically significant differences in wound complications identified.

Textual edits –

- Lines 314-315: "Although not statistically significant, differences between groups may be clinically significant."

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 em@greenjournal.org, and only the revision letter will be posted.

Yes, please publish my point-by-point response letter.

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* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* 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.

Thank you for this information.

- The funding information has been added to the title page and end of the abstract.
- The trial registration number is included at the end of the abstract.
- The IRB is now named in the Methods section.
- The location of the study has been added to the Methods section.

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4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Race and Ethnicity were self-reported by participants with more than one category allowed. This information is included in the Table 1 footnote. Race and Ethnicity were summarized and reported for the study population. Race and Ethnicity were not used in analyses.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

This has been completed.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead. Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf.

There was a small proportion of participants with missing/not reported data for Race and Ethnicity, classified as “missing” in Table 1. There were no individuals that identified as “None of the above.”

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Thank you for this information. The current manuscript draft uses person-first language.

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Thank you for this information. The current manuscript draft does not use gendered descriptions.

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Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
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When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

Thank you for this information. The ‘Data Sharing Statement’ outlined above has been added to the manuscript.

8. 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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Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.

Thank you for this information. P-values have been omitted from the results tables but are retained in addition to the reported relative risk within the results text. The percentages are rounded to integers in response to statistical editor comments as above.

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Figure 2: Please upload as a figure file on Editorial Manager.

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Thank you for this information. We intend to follow the traditional publication route.

References:

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