OBSTETRICS & GYNECOLOGY

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

Date: Oct 18, 2018
To: "Alexander M Friedman" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1769

RE: Manuscript Number ONG-18-1769

Hypertensive Postpartum Admissions among Women without a History of Hypertension or Preeclampsia

Dear Dr. Friedman:

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 Nov 08, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

The authors reviewed a national database containing readmission data for approximately half of all births in the U.S. from 2010-2014, more than 14 million births. They studied readmissions for hypertensive complications among women without evidence of hypertension during (or prior to) the delivery hospitalization. Although limited by the data available in this dataset and by ICD-9 coding (rather than record review), this study provides valuable information about an important topic, and the paper is very well written. Comments and questions follow.

1. Abstract. Overall this is a faithful summary of the manuscript.
a. Please do not report results as percentage increase (rather, report RR, aRR, and 95% CI only).
b. The conclusion is that shorter-interval postpartum follow-up is indicated. This is in keeping with recent ACOG positions, but it is not a study finding or summary per se. The authors did not report exactly when the women were readmitted. How short should the interval be?

2. Introduction. The introduction is concise and raises important points about maternal morbidity and mortality. Minor: As the paper is about readmission for hypertensive complications, might also start the introduction writing about hypertension complicating pregnancy rather than preeclampsia.

3. Methods. Overall this section is clear and logical. The following are minor.
a. Based on the criteria of 48 hours to 6 weeks postpartum (line 122), why did the authors evaluate rehospitalizations within 60 days postpartum?
b. Are data about age, ethnicity, and weight or BMI available? If not, please include as limitations in the discussion.
c. Renal disease and SLE are very often associated with hypertension. Is there concern that if these diseases were recognized, hypertension might not be coded?
d. Were hospital bed size and teaching status of the hospital coded using standard criteria? If so, would either include these or provide a reference.

4. Results.
a. The authors start by reporting the number of delivery hospitalizations in women without hypertensive complications. Would consider a flow chart of all the deliveries and depicts the N (%) of the excluded groups, e.g. chronic hypertension, gestational hypertension, preeclampsia, to allow readers to see the proportion with each condition captured by the coding system. It is also relevant because data about hypertension during the delivery admission are included in table 3 and in the supplemental tables (so it should probably be included throughout).
b. Table 1 appears to be lacking demographic characteristics that would normally be considered relevant for these

outcomes - such as maternal race/ethnicity and obesity. There appear to be differences between non-readmitted and readmitted groups in terms of percent delivered at a metropolitan teaching hospital and percent with cesarean delivery (among other variables). It will be important to address these differences and what might be causing them. Why weren't p-values included in table 1?
c. Suggest including data from supplemental table 1 as a 3rd group in table 1. As written, data about women with hypertension during the delivery hospitalization appears only at the end of the results and in the discussion. Suggest making this group a consistent part of the paper.
d. Lines 236-250. Here and elsewhere in the manuscript (like the abstract), please do not refer to risk ratios as percentage increase. A modest ratio of 1.5 sounds far more concerning as a 50% increase (inflates the association). Please report just the RR or aRR with 95% CI.

5. Discussion. The discussion is concise and provides a good summary of the study limitations. Would include something about characteristics such as BMI and ethnicity that were not studied. Also, regarding lines 310-315 (conclusion), if nearly 90% of readmissions occurred within 10 days of delivery, when should shorter-interval postpartum follow-up be performed?

REVIEWER #2:

This research work provides new insights on postpartum readmissions secondary to hypertensive conditions in women who did not have hypertension during delivery hospitalization. As a secondary outcome, the authors evaluated the risk of severe maternal morbidity (SMM) during postpartum readmission hospitalization for women with and without history of hypertension during the delivery. The manuscript is well written and organized. The objectives are clear. The study is well designed, the results are well interpreted, and the use of a large Database offers a sample size that allows the analysis of the primary and secondary outcomes. However, the following issues need to be addressed:

1. Correct the discordance between the delivery hospitalization number reported in line 98 and the number provided in line 211.

2. Add CI after 95% in line 101.

3. What was the reason to choose 60-day readmission time frame and not 42 days which is a more standard?

4. Women with superimposed preeclampsia should be excluded from the no-hypertension postpartum readmission group because this diagnosis implies underlying chronic hypertension.

5. Explain the analysis performed when one patient had multiple underlying chronic diseases such as chronic renal disease and lupus.

6. The authors stated that SMM during the delivery hospitalization was excluded for the analysis of postpartum readmission SMM. Report how many cases were excluded for the hypertension and no-hypertension groups. It is important to determine if exclusion of these cases has any influence on the reported postpartum SMM rates for each group.

7. The authors analyzed the association of hypertension-related postpartum readmission rates for multiple maternal morbidities such as chronic kidney disease, lupus, and asthma; however, they did not analyze maternal obesity, a prevalent co-morbidity highly associated with hypertensive disease and SMM. If data are available, conduct an analysis of postpartum readmission risk for hypertension conditions in the non-obese and obese population.

8. Racial disparity is a well-known demographic risk factor of SMM as well as for pre-existent and gestational hypertensive disease. The analysis of this risk factor is also important for this study.

9. In addition, it will be interesting to analyze other risk factors for the primary and secondary outcomes such as preterm delivery, nulliparity, mental health disease, and substance abuse.

10. What was the criteria used to select the reference for payer status, hospital bed size, and hospital teaching status?

11. The authors found that 97.9% of the readmissions occurred within 20 days after the delivery. They stated the 'shorter-interval postpartum is indicated for women with underlying obstetric and medical comorbidity.' Add specific recommendations about how soon after delivery these patients need to be seen. What other prevention actions can be implemented to reduce readmissions? I also suggest to narrow down the recommendations for the groups that showed to have the greatest risk for hypertension-related postpartum readmissions such as women with lupus, chronic kidney disease, and women 40 years old or older.

REVIEWER #3:

This paper is well written, clear and concise. It addresses a very important issue and provides a reminder that we need to focus more on women at risk for PP hypertensive complications requiring readmission and not just chronic hypertensives

and preeclamptics. It also states when the readmissions tend to occur. They admit and clearly state the weaknesses of the study. They state that close, tighter and earlier follow up is required in order to avert the readmissions and/or lower morbidity.

I am just wondering if we could expound on some issues. One of the problems is that we have been asked over the years to discharge women earlier. Payments are fixed and we are being given one agreed upon amount for an obstetric admission. Therefore, the longer the patient is in the hospital the lower the profit margin. This may lead us to discharge women earlier than we may want. In this study we cant tell if they were discharged to early because do not have the ability to carefully determine the BP trends and other information that would allow us to determine the appropriateness of the discharge. This is a major flaw but we are under some economic pressure. On the other hand we need to educate ourselves that if there is a requirement to go beyond the accepted days allotted to an obstetric admissions you can get reimbursed at a "daily" beyond the fixed bundled rate with proper documentation. Then you can do what is medically appropriate and get reimbursed for your care.

But this paper is important in that it again depicts who is the majority of the patients who are responsible for the readmissions for post partum hypertension and associated morbidities, and emphasizes who should not be seen 6-8 weeks after birth. Can the authors give suggestions on how we should in practice we should follow up these patients or leave it to our imagination. Do they want to discuss giving patients discharge instructions as to the signs and symptoms that they should look for? Prescription for BP cuffs? Emailing or faxing the data daily? Telephone numbers to contact there primary care givers? Should the patient be told to call in daily for several days? etc. etc. I am just wondering if this should be part of the discussions in order to clinically address the issue and avoid readmissions and lessen or avoid morbidity.

Otherwise this is very good for what it is worth which is research using databases with their inherent weaknesses, addressing a very important issue.

STATISTICAL EDITOR'S COMMENTS:

There is no problem with calculation of the RRs and aRRs. However, the estimates are all relative, not absolute counts. The absolute counts are actually all very low, so that implementation of earlier PP follow-up for an entire subgroup would result in a high proportion of those women not requiring early admission or having SMM events.

For example, among the maternal age 40-54 y, there were 1.7 million women not admitted and 3755 readmitted. The relative risk was more than twice, but evaluating all of that cohort would result in the vast majority not requiring readmission, nor being at risk of a SMM event.

Even among the more obvious risk groups (ie, SLE or chronic renal disease), the relative risks were in the 2-3x range, but the majority among even those groups did not experience an adverse event.

A more relevant metric, besides the RR and aRR would be the number needed to screen to identify a case (with appropriate CIs). Then the reader could assess the trade-off in terms of resources to screen earlier vs risk of an adverse event.

Associate Editor's Comments:

We would be interested in a revision with the following large caveat: that you restructure the paper to focus on absolute rather than relative risks. Our take on these data was that rather than being concerning, they were largely reassuring.

1) For example, even if 12% of the low risk women who were re-admitted had severe maternal morbidity, the actual risk that a low risk women would be readmitted and have SMM is something like 0.15% (or 0.0015) X 12% (.12) = .00018 or ~ 1 in 5,000';

2) The modestly elevated odds ratios for the conditions you studied translate to still low rates of re-admission and SMM;

3) Under current guideline, a follow-up PP visit should occur in I think 3-7 days for women with hypertension in pregnancy, so your data would not really suggest a change in that approach

4) As per the statistical editors suggestions (Reviewer #4), please rather than percentage increases, make actual numbers and numbers need to see early the focus of your analysis;

5) Finally, it is not a given that seeing patients sooner after discharge would obviate most or even much of the observed morbidity

EDITORIAL OFFICE COMMENTS:

1. 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:

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b) All authors must disclose any financial involvement that could represent potential conflicts of interest in an attachment to the author agreement form.

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3. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

4. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), and quality improvement in health care (ie, SQUIRE 2.0). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, or SQUIRE 2.0 guidelines, as appropriate.

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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

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* 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).

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Nov 08, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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