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OPEN PEER REVIEW

The Effect of Co-treatment of Lidocaine and Epinephrine in Pain and Bleeding Intensity During and After Episiotomy in Primigravida Women: A Randomized Single-Blinded Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

3 comments · 26 Aug 2024 – 2 Feb 2025

Referee 1 Reviewer

MAJOR REVISION 26 Aug 2024

Dear AE,
The authors need to review and address the following comments:

1. Include the type of study in the title.
2. Include the time and location in the abstract.
3. Include the random allocation method and the main statistical analysis in the abstract.
4. Was the pain intensity the same during and after in both groups? Something is wrong.
5. How about the sampling method and process?
6. How about the sample size calculation?
7. Report the RCT code.
8. How about the other statistical analyses?

Kind Regards

Referee 2 Reviewer

ACCEPT 1 Feb 2025

Dear AE,
All of the comments have been carefully addressed by the authors, and this manuscript is now recommended for publication.
Kind Regards

Editor-in-Chief

MAJOR REVISION 2 Feb 2025

Dear Author,
We have reviewed your manuscript carefully. This is to inform you that this manuscript needs major revision.
Kind Regards
EIC

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear editors and Reviewers

Thank you for valuable comments

Here, please find the responses.

Dear Reviewer 1:

1. Include type of the study in the title. Was done.

The Effect of Co-treatment of Lidocaine and Epinephrine in Pain and Bleeding Intensity During and After Episiotomy in Primigravida Women: A Randomized Double-blinded Clinical Trial

2. Include the time and location in the abstract. Was done.

This randomized double-blinded clinical trial was conducted on 200 primigravida women admitted for NVD in Yas Hospital Complex, Tehran, Iran, 2018.

3. Include the random allocation method and the main statistical analysis in the abstract. Was done.

A simple randomization method was used to assign participants (at an a1:1 ratio) to the study groups.

The data were analyzed with SPSS software version 24. The independent t-test or Mann–Whitney U test was used in quantitative variables according to the data distribution. Crosstabs and Fisher exact test were used. A p-value less than 0.05 was considered statistically significant.

4. The pain intensity was the same during and after in both groups? Something is wrong. Thank you for your attention, it was corrected.

The pain intensity was significantly less in the intervention group versus the control group during (1.61±1.49 vs. 1.95±1.63, p-value=0.029) and after (1.94±1.04 vs. 2.46±1.46, p-value=0.007) episiotomy.

5. How about the sampling method and process?

The sampling method was convenience.

6. How about the sample size calculation?

The sample size was determined based on the effect of lidocaine in reducing bleeding volume. Considering the mean number of pads used in the lidocaine group (7±3.34), study power of 90%, and type one error of 5%, the sample size was estimated at 174 participants (87 in each group). By considering the 20% attrition risk, 220 participants were enrolled in the study.

7. Report the RCT code.

The study was conducted in compliance with the Helsinki Declaration. It was confirmed by the Tehran University of Medical Sciences ethics committee (IR.TUMS.MEDICINE.REC.1396.4134) and the study IRCT registry number was IRCT20200421047160N1.

8. How about the other statistical analysis?

Finally, the data were analyzed with SPSS software version 24. Mean ± standard deviation was applied for continuous variable description and frequency and percentage for qualitative data in descriptive presentation. The independent t-test or Mann–Whitney U test was used in quantitative variables according to the data distribution. Crosstabs and Fisher exact test were used. A p value less than 0.05 was considered statistically significant.

Dear Reviewer 2:

Thank you for your Acceptance.

Dear Associate Editor:

The discussion section should be expanded. Please explain more if there is any experience about epinephrine.

It was done and the discussion was completed.

The standard of the drugs should be checked; where Lidocaine and where epinephrine are used.

Lidocaine is used as a local anesthetic during episiotomies. Guidelines recommend local anesthesia via infiltration with 10 ml of 1% lidocaine prior to performing the episiotomy. After the episiotomy, 10-15ml of lidocaine 1% (150mg) may be used for the subsequent repair, but the maximum volume of lidocaine 1% (200mg) between the episiotomy and repair should not exceed 20ml.

While the search results acknowledge the use of lidocaine to manage pain associated with episiotomies, there is no mention of using epinephrine for pain control during episiotomy in the provided guideline search results.

2 Revision 1

2 comments · 6 Apr 2025 – 6 Apr 2025

Associate Editor

MINOR REVISION 6 Apr 2025

Dear EIC,
Based on the reviewers' comments, this manuscript needs minor revision.

1. Estimate the sample size based on the main aim.
2. How about the other statistical analyses? Include them all in the statistical methods.

Kind Regards
AE

Editor-in-Chief

MINOR REVISION 6 Apr 2025

Dear Author,
We have reviewed your manuscript carefully. This manuscript needs minor revision due to the reviewers' comments.
Kind Regards
EIC

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Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Associate Editor 1:

Thank you for valuable comments

Here, please find the responses.

1. Estimate the sample size based on the main aim.

The sample size was determined based on the effect of lidocaine in reducing pain. Considering the value reported in the previous study (15), study power of 80%, and type one error of 5%, the sample size was estimated at 174 participants (87 in each group). Considering the 20% attrition risk, 220 participants were enrolled in the study.

2. How about the other statistical analysis? Include all in the statistical methods.

Finally, the data were analyzed using SPSS software version 24. Mean ± standard deviation was applied for continuous variable description, frequency, and percentage for qualitative data in descriptive presentation. The independent t-test or Mann–Whitney U tests were used in quantitative variables according to the data distribution. The $\chi 2$ and Fisher's exact tests were used to evaluate categorical data. A p-value less than 0.05 was considered statistically significant.

3 Revision 2

2 comments · 24 Apr 2025 – 27 Apr 2025

Associate Editor

MINOR REVISION 24 Apr 2025

Dear EIC,
Based on the reviewers' comments, this manuscript needs minor revision.

In the sample size calculation, report the mean ± SD in each group.
Kind Regards
AE

Editor-in-Chief

MINOR REVISION 27 Apr 2025

Dear Author,
We have reviewed your manuscript carefully. This manuscript needs minor revision due to the reviewers' comments.
Kind Regards
EIC

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Revision 3

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Associate Editor 1:

Thank you for valuable comments

Here, please find the responses.

In the sample size calculation, report the mean± SD in each group.

The sample size was calculated based on the value reported in table 3 of Colacioppo et al study (15), which comparing presence of post episiotomy pain in women with and without vasoconstrictors using. Considering study power of 90%, type one error of 5% and attrition risk of 30%, 208 participants (104 in each group were enrolled in the study.

4 Revision 3

2 comments · 4 May 2025 – 4 May 2025

Associate Editor

MINOR REVISION 4 May 2025

Dear EIC,
Based on the reviewers' comments, this manuscript needs minor revision.

In the sample size calculation, report the mean ± SD in each group.
Kind Regards
AE

Editor-in-Chief

MINOR REVISION 4 May 2025

Dear Author,
We have reviewed your manuscript carefully. This manuscript needs minor revision due to the reviewers' comments.
Kind Regards
EIC

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Revision 4

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Associate Editor 1:

Thank you for valuable comments

Here, please find the responses.

In the sample size calculation, report the mean± SD in each group.

The sample size was calculated based on the pain intensity reported in Schinkel et al study (15), in women with local vasoconstrictors (16.8 ± 11.6) versus lidocaine (12.4 ± 9.7) injection for episiotomy repair. Considering study power of 80%, type one error of 5% and attrition risk of 10%, 208 participants (104 in each group) were enrolled in the study.

5 Revision 4

2 comments · 17 May 2025 – 18 May 2025

Associate Editor

ACCEPT 17 May 2025

Dear EIC,
As suggested by the reviewers, this manuscript is ready to be considered for publication.
Kind Regards
AE

Editor-in-Chief

ACCEPT 18 May 2025

Dear Authors,
This is to inform you that your manuscript has been accepted for publication.
Kind Regards
EIC