OPEN PEER REVIEW

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Advantages of "Open Peer Review" process

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You can find out more at:
https://sites.kowsarpub.com/kowsar/knowledgebase/category/tree.html#opr.html

Anesthesiology and Pain Medicine
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Peer Review Report for "Effect of Sequential Compression Device on Hemodynamic Changes After Spinal Anesthesia for Caesarean Section: A Randomized Controlled Trial"

Author(s): Fatemeh Javaherforooshzadeh, Mohammad Reza Pipelzadeh, Reza Akhondzadeh, Sara Adarvishi, Mostafa Alghozat

Review Timeline:

Submit Date: 20 May 2020
Revised Date: 29 Jun 2020
Accepted Date: 26 Jul 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (0)

26 May 2020

Dear AE,
Although this topic has been studied in related researches due to its importance, it seems that this study deserves to be published in the journal.
The following should be corrected:
1- In the topic, you need to correct the dictation of the word "sequential".
2- How was the randomization of all groups? explain in detail.
3- Why did you exclude parturients with multiple gestations? What was the effect of multiple gestations on the study?
4- Please add peripheral vascular disease in exclusion criteria, because of using SCD.
5- If the sample size had been larger, the power of the study would have been much more. Why did you remove 24 parturients from the study?
6- You must mention that what would you do if bradycardia had occurred after spinal anesthesia?
7- In the results of this study there are some contrasts. you found that there was no different hypotension between the groups, but the administered ephedrine dosage was lower

in the SCD group than in the control group, therefore why did you administrate ephedrine?
8- In the conclusion part you mentioned "this study showed that using of SCD can be reduced extensive changes of hemodynamic parameters", whereas in the result part you mentioned, "only diastolic blood pressure was higher in SCD than the control group, not systolic and mean blood pressure".
Thanks.

REFEREE: Reviewer | **Revision** (0) 2 Jun 2020

Dear AE,
Comments for the authors:
- Randomization?
- Effect of multiple gestation?
- add peripheral vascular disease in exclusion criteria, because of using SCD.
- Why did you delete 24 parturients from the study?
- What was your plan if bradycardia had occurred after SA?
- You found that there was no different hypotension between the groups, but the ephedrine dosage was lower in the SCD group!, why did you give ephedrine?
Thanks.

REFEREE: Reviewer | **Revision** (0) 22 Jun 2020

Dear AE,
First of all, a major revision of the English context, in terms of grammar and punctuation, is very much needed.
The complete words should be written when the first time an abbreviation is used. For example, “SCD” could be put after “sequential compression device” in the first sentence of the abstract section.
Different names have been given to the study groups in different parts of the manuscript which needs to be unified, for instance, they have named “SCD and control groups” in the abstract and results, whereas they are named M group and C group in other parts of the manuscript.
Abstract:
- This sentence is somewhat vague and a clear explanation is required:
“About the heart rate changes, RM ANOVA was showed a significant difference in the effect of time, groups, and interaction of two factors ($P<0.0001$, $P<0.0001$, $P<0.0001$)respectively.”
Introduction:
- What was the point of using “main” in this sentence: “the main side effect of this procedure is the reduction of maternal blood pressure”? If the meaning was “the most common side effect”, it needs to be clarified.
Methods trial design
- Seventy- six patients were selected and were divided into two groups, but 35 patients in the SCD group and 38 patients in the control group make 73 patients and it needs to be corrected.
Study settings and interventions:
- What was the importance of blindness of the anesthesiologist to the patients’ study group

who evaluated the patient preoperatively and what was the reason to mention it?
- How the fluid therapy was managed? The protocol for fluid therapy is indicated.
- Noninvasive blood pressure cannot be monitored continuously and the following sentence needs to be revised: “The patients were monitored continuously for noninvasive blood pressure, electrocardiogram changes, and pulse oximetry.”
- There are disparities between the time intervals of blood pressures measurements in the methods with those recorded, for example, according to study settings and interventions: “during each minute of the experiment, the arterial blood pressure was measured until delivery. Afterward, the procedure was repeated every three minutes for 10 minutes, and subsequently, every five minutes until transport to the recovery room”, but the recordings were all taken at every five minutes.
- The following sentence needs to be clarified: “An anesthesiologist blinded to the protocol treated potential hypotension using 5mg intravenous ephedrine increment boluses simultaneous with the administration of the intravenous fluid.” How did the blinded anesthesiologist to the protocol, follow the protocol correctly? If it means that the anesthesiologist was blinded to the study groups, please explain how it was made possible, while some patients had the compression device on and some didn’t.
Results:
- The following sentence needs to be explained clearly: “About the heart rate changes RMANOVA was showed a significant difference in the effect of time, groups, and interaction of two factors ($P<0.0001$, $P<0.0001$, $P<0.0001$)respectively.”
- As it was reported in the results: “Post-hoc Tukey test showed that heart rate was significantly greater in the 3 and 15 min after spinal anesthesia in SCD than the control group ($P<0.05$).” What was the amount of P-value? What about the difference between the study groups at times other than 3 and 15 minutes?
- It seems that Figure 1 depicts mean values of heart rates of the patients rather than changes in heart rates, hence, the explanation needs to be corrected.
- What were the P-values of comparing Apgar scores at 1 and 5 minutes?
Discussion:
- It is better to discuss the possible reason or reasons for higher heart rates in the M group at 3 and 15 minutes.
- The incidence of hypotension was not recorded in the current study, therefore, it can’t be declared that the results of this study are not consistent with the study of Sujata N.… (11) in terms of the incidence of hypotension.
- Reporting the incidence and the extent of hypotension in the study groups could have made this manuscript more valuable.
Thanks.

REFEREE: Associate Editor | **Revision** (0) 26 Jun 2020

Dear EIC,
Based on the reviewer's comments this manuscript needs some corrections
Final decision: Major revision
Regards

REFEREE: EIC | **Revision** (0) 26 Jun 2020

Dear Author,

The reviewers' comments are mentioned. Please correct the details as mentioned above carefully according to reviewers' request.

Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear* reviewers*: We corrected all the raised comments and marked the corrections by yellow color to simplify the reviewing process. I appreciate you and your reviewers in advance

Reviewers' Comments:

Reviewer 1:
Although this topic has been studied in related researches due to its importance, it seems that this study deserve to be published in the journal.
The followings should be corrected:
1- In the topic you need to correct the dictation of the word "sequestional".

were corrected
2- How was randomization of all groups? explain in details.

Were explained
3- Why did you exclude parturient with multiple gestation? What was the effect of multiple gestation on the study?

Because these parturient will have more hypotension after spinal anesthesia and that in itself caused bias

4- Please add peripheral vascular disease in exclusion criteria, because of using SCD.

peripheral vascular disease in exclusion criteria was added

5- If the sample size had been more larger, the power of the study would have been much more. Why did you remove 27 parturients from the study?

The reason for removing 27 patients from the study is in the Concert diagram

6- You must mention that what would you do, if bradycardia had occurred after spinal anesthesia?

This was mentioned and Were explained

7- In the results of this study there are some contrasts. you found that there was no different hypotension between the groups, but the administered ephedrine dosage was lower in the SCD group than in the control group, therefore why did you administrate ephedrine?

Although statistical analysis did not show significant difference according to clinical individuals status, some patients in control group need more ephedrine administration due to more hypotension than SCD group

8- In the conclusion part you mentioned "this study showed that using of SCD can be reduced extensive changes of

hemodynamic parameters" ,whereas in the result part you mentioned "only diastolic blood pressure was higher in SCD than control group, not systolic and mean blood pressure".

Was corrected as “This study showed that using of SCD can be reduced extensive changes of diastolic blood pressure as an important hemodynamic parameters and incidence of nausea vomiting”

Reviewer 2:
Dear EIC
- Randomization?

Were explained
- Effect of multiple gestation?

Because these parturient will have more hypotension after spinal anesthesia and that in itself caused bias

- add peripheral vascular disease in exclusion criteria, because of using SCD.

peripheral vascular disease in exclusion criteria was added

- Why did you delete 27 parturients from the study?

The reason for removing 27 patients from the study is in the Concert diagram

- What was your plan if bradycardia had occurred after SA?

This was mentioned and Were explained. Ephedrine both improved blood pressure and corrected bradycardia

- You found that there was no different hypotension between the groups, but the ephedrine dosage was lower in the SCD group!, why did you gave ephedrine?

Although statistical analysis did not show significant difference according to clinical individuals status, some patients in control group need more ephedrine administration due to more hypotension than SCD group

Reviewer 3:

First of all, major revision of English context, in terms of grammar and punctuation, is very much needed.

The complete words should be written when the first time an abbreviation is used. For example, "SCD" could be put after "sequential compression device" in the first sentence of the abstract section.

Were corrected

Different names have been given to the study groups in different parts of the manuscript which needs to be unified, for instance, they are named "SCD and control groups" in the abstract and results, whereas they are named M group and C group in other parts of the manuscript

Were unified

Abstract:

This sentence is somewhat vague and clear explanation is required:

"About the heart rate changes, RM ANOVA was showed a significant difference in the effect of time, groups, and interaction of two factors (P<0.0001, P<0.0001 ,P<0.0001) respectively."

Repeated measure ANOVA is type of two way ANOVA that indicate 3 p value, that 1st for significance changes in the time, 2nd for significance changes in each groups and 3rd for interaction of the both. The above sentences were add to manuscript

Introduction:
What was the point of using "main" in this sentence: "the main side effect of this procedure is the reduction of maternal blood pressure"? If the meaning was "the most common side effect", it needs to be clarified.

Was corrected

Methods trial design
Seventy- six patients were selected and were divided in two groups, but 35 patients in SCD group and 38 patients in control group makes 73 patients and it needs to be corrected.

Was corrected this was mistake.

Study settings and interventions:
What was the importance of blindness of the anesthesiologist to the patients' study group who evaluated the patient preoperatively and what was the reason to mention it?

To prevent divergence

How the fluid therapy was managed? The protocol for fluid therapy is indicated.

The protocol for fluid therapy was mentioned.

Noninvasive blood pressure cannot be monitored continuously and the following sentence needs to be revised: "The patients were monitored continuously for noninvasive blood pressure, electrocardiogram changes, and pulse oximetry."

This sentences were corrected

There are disparities between the time intervals of blood pressures measurements in the methods with those recorded, for example according to study settings and interventions: "during each minute of the experiment, the arterial blood pressure was measured until delivery. Afterward, the procedure was repeated each three minutes for 10 minutes, and subsequently, each five minutes until transport to the recovery room", but the recordings were all taken at every five minutes.

Were corrected

The following sentence needs to be clarified: "An anesthesiologist blinded to the protocol treated potential hypotension using 5mg intravenous ephedrine increment boluses simultaneous with administration of the intravenous fluid." How the blinded anesthesiologist to the protocol, followed the protocol correctly? If it means that the anesthesiologist was blinded to the study groups, please explain how it was made

possible, while some patients had the compression device on and some didn't.

It means that the anesthesiologist was blinded to the study groups and explained in method section.

Sleeves were applied to lower limbs of the patients in the both groups. Patients in the SCD group received discontinuous compression at 50 mmHg pressure ,and patients in the control group don't received discontinuous compression. The anesthesiologist was blinded to the study groups

Results:

The following sentence needs to be explained clearly: "About the heart rate changes RMANOVA was showed significant difference in effect of time ,groups, and interaction of two factor(P<0.0001 ,P<0.0001 ,P<0.0001)respectively."

As it was reported in the results: "Post-hoc Tukey test showed that heart rate was significantly greater in the 3 and 15 min after spinal anesthesia in SCD than control group (P<0.05)."

What was the amount of P-value? What about the difference between the study groups at times other than 3 and 15 minutes?

It seems that Figure 1 depicts mean values of heart rates of the

patients rather than changes in heart rates, hence, the explanation needs to be corrected.

Repeated measure ANOVA is type two way ANOVA that indicate 3 p value, that 1st for significance changes in time, 2nd for significance changes in groups and 3rd for interaction both. The above sentences were add to manuscript. About significance difference between 3 and 15 Post-hoc test of RM-ANOVA showed significance difference between exact point of time.

What were the P-values of comparing Apgar scores at 1 and 5 minutes?

The P-values of comparing Apgar scores were at 1(P=0.65) and 5 (P=0.9) minutes were mentioned in result part

Discussion:
It is better to discuss the possible reason or reasons of higher heart rates in M group at 3 and 15 minutes.

Although sympathetic block produce hypo-tension and bradycardia, reflex tachycardia occur for compensate of heart physiology. Also volume of venous return increase from lower limbs in SCD group simultaneously that cause tachycardia. 15 minutes after spinal anesthesia, is the time after the delivery. Therefore, a large volume of blood enters the heart, that can be

causes a tachycardia to reduce the volume overload. This phenomenon is prominent in the SCD group due to increased the venous return from the lower limbs.

This was mentioned in discussion part

The incidence of hypotension was not recorded in the current study, therefore, it can't be declared that the results of this study are not consistent with the study of Sujata N…. (11) in terms of the incidence of hypotension.
Reporting the incidence and the extent of hypotension in the study groups, could have made this manuscript more valuable.

No changes in systolic blood pressure have been reported because trends of changes reported in this study. According to the request of the reviewer, the data was checked. The incidence was reported to 51%±21 in the control group and 45%±20 in the SCD group, which did not differ significantly (p = 0.28).

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (1) 26 Jul 2020

Dear AE,
I read this revised manuscript, and the author replied to the majority of requested items.
Sincerely

REFEREE: Associate Editor | **Revision** (1) 26 Jul 2020

Dear EIC,
Based on reviewers' comments, this revision format is acceptable for publishing at Anesth Pain Med.
For author attention, please mention Footnotes including Authors' Contribution, Clinical Trial Registration Code, Conflict of Interests, Ethical Approval, Funding/Support, and Informed Consent during the publishing process.
Regards

REFEREE: EIC | **Revision** (1) 26 Jul 2020

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.