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OPEN PEER REVIEW

Is Inferior Alveolar Nerve Block Beneficial in Fracture Mandibular Surgeries? A Randomized Controlled 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 · 8 Nov 2024 – 10 Nov 2024

Referee 1 Reviewer

MAJOR REVISION 8 Nov 2024

The comments are uploaded via the attached file.

Referee 2 Reviewer

ACCEPT 10 Nov 2024

The research is well done.

Editor-in-Chief

MAJOR REVISION 10 Nov 2024

Dear Contributors,
Thank you for your great contribution to the JCMA.
Based on the reviewers' comments, the manuscript needs major revision.

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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.

We are grateful that the reviewers took the time to read our work and offer insightful feedback. The current version may have been improved as a result of your insightful and helpful feedback. The authors have given great thought to the comments and have made every effort to address them all. Those changes are highlighted within the manuscript.

➢Reviewers' Comments to the Authors:

- **Reviewer 1:**

  Question:

  The words mentioned as keywords can be related to Medical Subject Headings (MeSH) terms, While "Fractures, Mandible" and "Surgical Procedures, Operative" are MeSH terms, the exact phrase "Fracture Mandibular Surgery" is not a single MeSH term. However, it can be broken down into relevant MeSH terms such as "Mandible" and "Fractures" combined with "Surgical Procedures, Operative". Also, in MeSH terms, “Pethidine” would be categorized under "Meperidine" or related opioid analgesics.

  Answer:

  I appreciate you bringing this up. The reviewer is right, and the manuscript's keywords have been updated. The updated text appears on Abstract keywords page 2 as follows.

  “Keywords: pain, meperidine, mandibular fractures, nerve block, opioid”

- **Reviewer 2:**

  Question:

  A significant flaw in the manuscript is the absence of any mention of a sample size calculation. The authors acknowledge that the sample size is small but do not provide a justification for the chosen number of participants. A clear explanation of the sample size determination is crucial for assessing the study's adequacy.

  Answer:

  The sample size calculation has been incorporated into the manuscript on Page 3, within the initial paragraph of the methods section “The sample size was calculated by using the PASS 15 program, setting power at 90% and alpha error of 0.05 and according to Mesgarzadeh et al, 2014, the expected rate of need for analgesia of 20% in the IANB group compared to 70% in the control group”

  Since there aren't many studies using IAN blocks under general anesthesia in mandibular fracture surgeries, we pointed out in the discussion section that the sample size was small, suggesting that larger study is needed to clarify our findings.

- **Reviewer 3:**

  Question:

  The number of patients assessed for eligibility, those who were excluded with reasons, those randomized, those who received the intended intervention, those lost to follow-up, and those included in the analysis were not mention in the manuscript.

  Answer:

We have added the suggested content on the manuscript on page 3 last paragraph on the methods section.

"As per the Consort statement, a total of 58 were assessed for eligibility. Twelve patients were excluded from the study due to coagulopathy (n=2), a history of addiction (n=3), American Society of Anesthesiologists (ASA) Physical Status Class IV (n=4), and refusal to participate (n=3). A total of 46 patients were included in this experiment and randomized to two equal groups (Figure 1)."

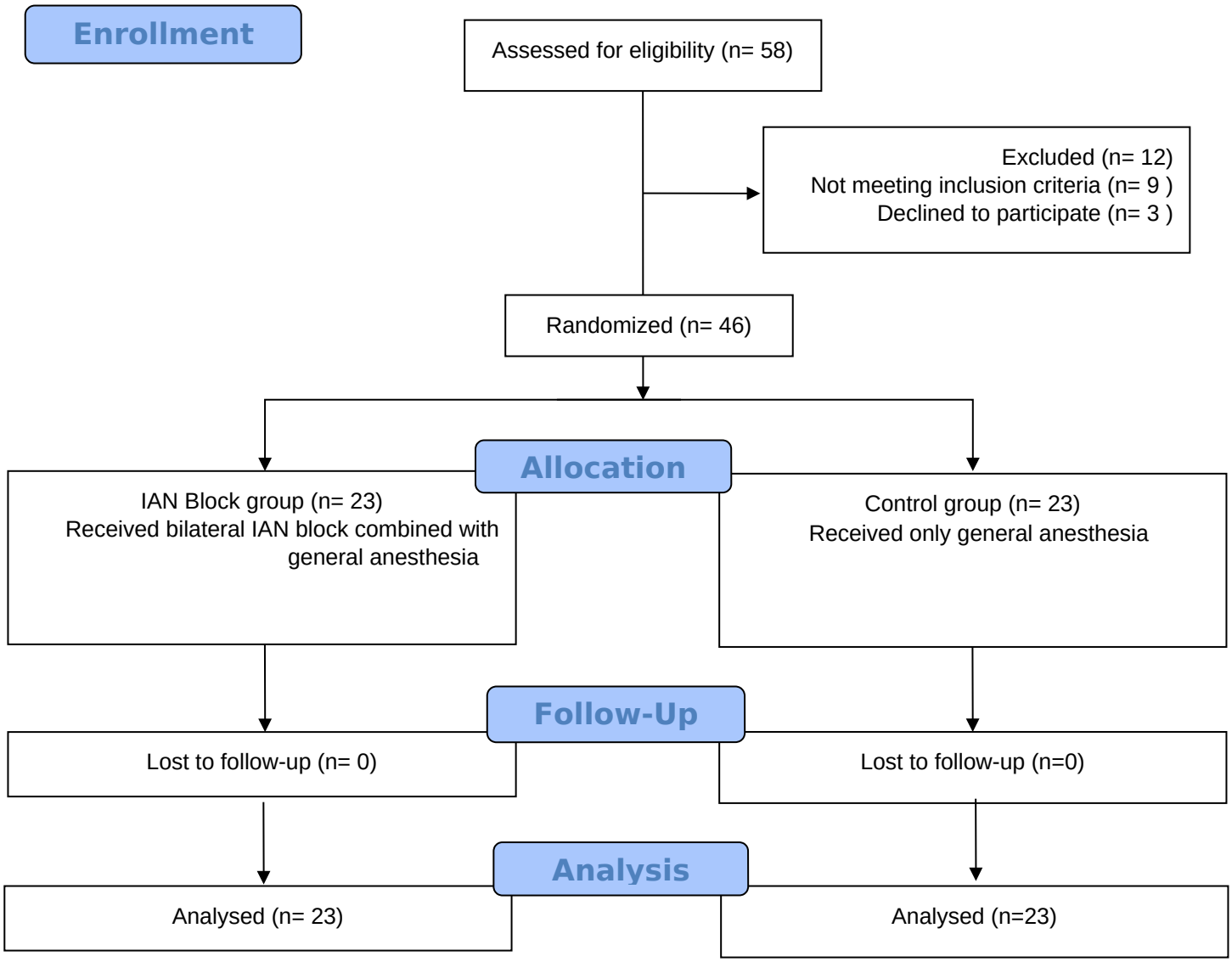


Figure (1): Flow chart of the studied cases

- **Reviewer 4:**

Question:

The clarity regarding allocation concealment is confusing. The sentence "An impartial therapist administered an IAN block and then, using a numerical sequence chose an opaque, sealed envelope from a box to determine the allocation" raises questions about the sequence of events and the maintenance of allocation concealment. Specifically, it is unclear whether the IAN block was administered before or after the patient's group assignment was revealed. If the therapist knew the group allocation before administering the block, this could introduce bias, as they might subconsciously alter their technique or patient interaction.

Answer:

Thank you for pointing this out. The sequence of allocation concealment has been corrected on the manuscript page 3 last paragraph under methods section

- “After choosing an opaque sealed envelope from a box based on a computer-generated numerical sequence, an impartial therapist who was not involved in the study prepared and administered an IAN block The patients were blinded, as well as the second investigator who collected the data and administered rescue analgesics if necessary.”

- **Reviewer 5:**

Question:

While the authors mention using a numerical sequence to allocate patients from a box containing sealed envelopes, the process of generating the randomization sequence is not explicitly described.

Answer:

We have added the suggested content on the manuscript on page 3 last paragraph on methods section

- ““After choosing an opaque sealed envelope from a box based on a computer-generated numerical sequence, an impartial therapist who was not involved in the study prepared and administered an IAN block The patients were blinded, as well as the second investigator who collected the data and administered rescue analgesics if necessary.”

- **Reviewer 6:**

Question:

The manuscript describes the methods of the IAN block administration in future tense (e.g., "Patients in Group A (IAN block group) will have bilateral inferior alveolar nerve blocks..."1). This inconsistency in tense can be confusing and disrupt the flow of the paper. It is standard practice to describe study methods in the past tense because they refer to procedures already completed.

Answer:

Thank you for pointing this out. The tense has been corrected to past tense in the manuscript page 4 first paragraph in methods section.

“Patients in Group A (IAN block group) received bilateral inferior alveolar nerve blocks after endotracheal intubation and before surgical placement and incision, As a control, patients in Group B received intravenous multimodal analgesia according to established protocol rather than the block treatment.”

- **Reviewer 7:**

Question:

The study is described as double-blind, but it's unclear how blinding was achieved for patients and outcome assessors. Describing the specific measures taken to mask group allocation would enhance the study's internal validity. For example, who prepared and administered the nerve blocks and rescue analgesia? Were they blinded to group assignment?

Answer:

Thank you for pointing this out. We illustrated it in the manuscript in page 3 last paragraph under methods section.

- ““After choosing an opaque sealed envelope from a box based on a computer-generated numerical sequence, an impartial therapist who was not involved in the study prepared and administered an IAN block The patients were blinded, as well as the second investigator who collected the data and administered rescue analgesics if necessary.**”**

- **Reviewer 8:**

Question:

The use of the Visual Analog Scale (VAS) for pain assessment is appropriate and widely accepted. However, the authors should clarify whether a single or multiple VAS measurements were taken at each time point postoperatively. Additionally, while the statistical methods are generally appropriate, the authors should consider reporting effect sizes (e.g., Cohen's d) to provide a more clinically meaningful interpretation of the results.

Answer:

Thank you for pointing this out. As regard VAS score, we illustrated it in the manuscript in page 5 second paragraph under Methods section:

“The Visual Analog Scale (VAS) was used to assess and manage postoperative pain upon arrival to the PACU and after 30 min, then in the surgical ward recorded every 2 hours during the first 6 hours and then every 6 hours for 24 hours postoperatively.”

As regard statistical methods, we added the Cohen's to the result in result section Page 8

Relative effect **Cohen’s d** **95% CI**	**^p-value**	**Control group (Total=23)**	**IAN block group (Total=23)**	**Postoperative time**	
NA	NA	0.0±0.0	0.0±0.0	**Mean±SD**	**Hour-0**
		0.0–0.0	0.0–0.0	**Range**	
NA	NA	0.0±0.0	0.0±0.0	**Mean±SD**	**Hour-0.5**
		0.0–0.0	0.0–0.0	**Range**	
-1.9	**<0.001***	0.8±0.4	0.1±0.3	**Mean±SD**	**Hour-1**
-2.6–-1.2		0.0–1.0	0.0–1.0	**Range**	
-4.7	**<0.001***	3.9±0.8	0.7±0.5	**Mean±SD**	**Hour-2**
-5.8–-3.5		2.0–5.0	0.0–1.0	**Range**	
-2.3	**<0.001***	3.7±0.9	1.7±0.8	**Mean±SD**	**Hour-4**
-3.0–-1.5		2.0–5.0	1.0–3.0	**Range**	
-0.6	**0.038***	3.4±0.9	2.9±0.7	**Mean±SD**	**Hour-6**
-1.2–0.0		2.0–5.0	2.0–4.0	**Range**	
-0.6	0.066	3.0±0.5	2.7±0.7	**Mean±SD**	**Hour-12**
-1.1–0.0		2.0–4.0	2.0–4.0	**Range**	
-0.5	0.103	2.3±0.4	2.0±0.6	**Mean±SD**	**Hour-18**

-1.1–0.1		2.0–3.0	1.0–3.0	**Range**	
-0.5	0.080	1.7±0.5	1.4±0.5	**Mean±SD**	**Hour-24**
-1.1–0.1		1.0–2.0	1.0–2.0	**Range**	

- **Reviewer 9:**

Question:

The discussion provides a good overview of the findings, linking them to previous research. However, the authors could strengthen the discussion by addressing the clinical implications of their findings in more detail. For instance, what is the potential impact of reduced opioid consumption on patient outcomes, such as length of hospital stay or postoperative complications? Furthermore, it could be strengthened by addressing strategies to enhance block success rates. The authors mention that inferior alveolar nerve blocks (IANBs) have a failure rate ranging from 10% to 39%. This variability highlights the need to explore methods that could improve the precision and effectiveness of the block. Specifically, they should consider incorporating a paragraph addressing the use of ultrasound guidance for IAN blocks and suggest it.

Answer:

The proposed content has been incorporated into the manuscript on page 10, in the final paragraph of the discussion section, and on page 11, in the initial paragraph.

"Only 2 of 23 patients exhibited hematoma at the local anesthetic injection site, which resolved spontaneously. Therefore, a bilateral inferior alveolar nerve block is a safe technique for mandibular fracture surgeries, as it diminishes pain intensity during the perioperative period, reduces total opioid consumption and associated adverse effects, and shortens recovery time and hospital stay"

"The IAN block has a failure rate of approximately 15%, which could be diminished with accurate needle placement, since a frequent error involves inserting the needle excessively anteriorly or posteriorly to the target location, along with the utilization of ultrasound-guided IAN blocks "

- **Reviewer 10:**

Question:

While the manuscript provides a good review of the literature, many of the cited references are relatively old. Out of the 18 references cited, only three were published within the past five years. Relying heavily on older literature may not accurately reflect the current state of knowledge and practice related to inferior alveolar nerve blocks and pain management in mandibular fracture surgeries.

Answer:

Thank you for raising this concern. We updated seven references from the previous five years. However, we are unable to locate more recent references relevant to our study scope, as the inferior alveolar nerve block has been inadequately researched in the context of mandibular fracture procedures conducted under general anesthesia.

1. Bohringer C, Astorga C, Liu H. The Benefits of Opioid Free Anesthesia and the Precautions Necessary When Employing It. Transl Perioper Pain Med. 2020;7(1):152-157. PMID: 31712783; PMCID: PMC6844148.

2. de Carvalho Sampaio TR, Barbosa LM, Lopes AC, de Albuquerque Cavalcanti Almeida R, do Egito Vasconcelos BC, Gomes ACA, de Souza Andrade ES. Does Maxillomandibular Fixation Affect Respiratory Function? A Systematic Review. J Craniofac Surg. 2022 Nov-Dec 01;33(8):2455-2459. doi: 10.1097/SCS.0000000000008521. Epub 2022 Feb 4. PMID: 35119397.

3. Famurewa BA, Oginni FO, Aregbesola SB, Erhabor GE. Effects of maxillomandibular fixation and rigid internal fixation on pulmonary function in patients with mandibular fractures. Int J Oral Maxillofac Surg. 2020 Sep;49(9):1193-1198. doi: 10.1016/j.ijom.2020.01.027. Epub 2020 Feb 13. PMID: 32061431.

4. Wang YH, Wang DR, Liu JY, Pan J. Local anesthesia in oral and maxillofacial surgery: A review of current opinion. J Dent Sci. 2021 Oct;16(4):1055-1065. doi: 10.1016/j.jds.2020.12.003. Epub 2020 Dec 17. PMID: 34484571; PMCID: PMC8403808.

5. Roi CI, Roi A, Nicoară A, Motofelea AC, Riviș M. Retromolar Triangle Anesthesia Technique: A Feasible Alternative to Classic? J Clin Med. 2023 Sep 7;12(18):5829. doi: 10.3390/jcm12185829. PMID: 37762770; PMCID: PMC10532414.

6. Lee CR, Yang HJ. Alternative techniques for failure of conventional inferior alveolar nerve block. J Dent Anesth Pain Med. 2019 Jun;19(3):125-134. doi: 10.17245/jdapm.2019.19.3.125. Epub 2019 Jun 30. PMID: 31338418; PMCID: PMC6620537.

7. Sarfaraz I, Pascoal S, Macedo JP, Salgado A, Rasheed D, Pereira J. Anesthetic efficacy of Gow-Gates versus inferior alveolar nerve block for irreversible pulpitis: a systematic quantitative review. J Dent Anesth Pain Med. 2021 Aug;21(4):269-282.

https://doi.org/10.17245/jdapm.2021.21.4.269.

2 Revision 1

5 comments · 30 Nov 2024 – 6 Dec 2024

Referee 3 Reviewer

REJECT 30 Nov 2024

Summary:
The manuscript investigates the effectiveness of incorporating a preemptive inferior alveolar nerve block (IAN block) compared to traditional systemic intravenous analgesia for managing perioperative pain in mandibular fracture surgeries. This prospective, randomized, double-blind comparative study involved 46 adult patients divided into two groups: one receiving the IAN block and the other receiving standard intravenous multimodal analgesia. The primary outcomes measured were the intensity and duration of analgesic effects, and secondary outcomes included block-related complications. The study found that the IAN block group required significantly less intraoperative fentanyl and postoperative pethidine, demonstrating effective pain control for up to six hours post-surgery.
Strengths:
The study is well-structured with a clear objective and methodology, employing a randomized, double-blind design that strengthens the validity of the findings. The focus on reducing opioid consumption is timely and relevant, contributing to the ongoing efforts to minimize opioid-related side effects and dependencies. The manuscript provides a comprehensive analysis of both intraoperative and postoperative pain management, highlighting the potential benefits of the IAN block.
Major Concerns:
1. Novelty: The reviewer notes that the topic of IAN block for mandibular surgeries has been extensively investigated, and the manuscript lacks novelty. The authors should clarify how their study adds to the existing body of knowledge.
2. Sample Size: Given the reported failure rate of IAN block (10 to 39%), the sample size of 46 patients may be insufficient to draw robust conclusions. A larger sample size could provide more reliable data.
3. Data Collection: The statement "Vital signs (HR, MAP) will be recorded every 10 minutes intraoperatively till the end of surgery" suggests that data collection has already been completed. The authors should ensure that this is clearly reported in the past tense.
Minor Concerns:
1. Language and Clarity: The manuscript would benefit from a review by a native English speaker to improve language clarity and readability.
2. Funding Information: The manuscript should include detailed information about the sources of funding and the role of funders in the study.
Recommendation:
Major revision is required. The manuscript needs to address the concerns regarding novelty and sample size. Additionally, language improvements and detailed funding information should be provided to enhance the manuscript's clarity and transparency.

Referee 4 Reviewer

ACCEPT 5 Dec 2024

The manuscript, after revisions, presents a study on the effectiveness of a pre-emptive inferior alveolar nerve block (IAN block) compared to traditional systemic intravenous analgesia for managing perioperative pain in mandibular fracture surgeries. The study involved 46 adult patients in a randomized double-blind design, assessing the analgesic effects and opioid consumption.
The revised manuscript effectively addresses previous concerns, maintaining a clear and structured approach.

The methodology is robust, and the findings contribute valuable insights into pain management strategies that could reduce opioid use, which is a significant contribution to the field.
There are no major concerns following the corrections. The manuscript now adequately addresses previous issues related to novelty, sample size, and data presentation.
Minor language and formatting issues have been corrected, and the manuscript now includes comprehensive funding information.
My recommendation:
Accept as is. The authors have successfully addressed the necessary corrections, making the manuscript suitable for publication.

Referee 1 Reviewer

ACCEPT 6 Dec 2024

The revised manuscript presents a study evaluating the effectiveness of a pre-emptive inferior alveolar nerve block (IAN block) versus traditional systemic intravenous analgesia for managing perioperative pain in mandibular fracture surgeries. The study employs a randomized double-blind design with 46 adult participants, focusing on analgesic effects and opioid consumption.

The authors have significantly improved the manuscript by clarifying methodological details, particularly the randomization and blinding processes, which enhance the study's credibility. The structured presentation of results, along with clearer statistical analyses, facilitates a better understanding of the findings. The expanded discussion section provides a thorough context for the results within existing literature, addressing discrepancies and implications for clinical practice effectively.

There are no major concerns following the revisions. The manuscript now presents a coherent and robust study, addressing previous methodological and contextual gaps. All minor concerns have been addressed, including language clarity and presentation of statistical data.

Accept as is. The authors have effectively addressed all questions raised during the review process, resulting in a stronger and more informative manuscript suitable for publication.

Associate Editor

MINOR REVISION 6 Dec 2024

Dear EIC
The manuscript evaluates the effectiveness of a preemptive inferior alveolar nerve block (IAN block) compared to traditional systemic intravenous analgesia for managing perioperative pain in mandibular fracture surgeries. It employs a randomized, double-blind design with 46 adult participants, focusing on analgesic effects and opioid consumption.

The study is well-structured and methodologically sound, with improvements made to clarify the randomization and blinding processes. The presentation of results is clear, and the expanded discussion provides valuable context within the existing literature, enhancing the manuscript's contribution to the field.
I still have some concerns about the manuscript:
Novelty: The title suggests a lack of novelty, as similar studies have been conducted. The authors should justify the rationale for repeating this study, possibly by highlighting any unique aspects or specific gaps in the literature that this study addresses.
Sample Size: The small sample size should be explicitly acknowledged as a limitation in the manuscript. The authors should discuss how this might affect the generalizability of the findings and suggest future research

directions to address this limitation.
All previous minor concerns have been addressed, including language clarity and statistical presentation.

In my opinion and according to reviewers' comments, minor revisions are required. The authors need to justify the study's novelty and address the limitation of the small sample size in the manuscript. Once these issues are resolved, the manuscript will be more robust and informative for readers.

Editor-in-Chief MINOR REVISION 6 Dec 2024

Dear Authors
Based on the reviewers' results, minor revision is needed.
Please consider revising the manuscript based on the comments.
Thank you

3

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.

We are grateful that the reviewers took the time to read our work and offer insightful feedback. The current version may have been improved as a result of your insightful and helpful feedback. The authors have given great thought to the comments and have made every effort to address them all. Those changes are highlighted within the manuscript.

➢Reviewer 2 Comments to the Authors:

- **Major concern:**

1. Novelty: The reviewer notes that the topic of IANB for mandibular surgeries has been extensively investigated, and the manuscript lacks novelty. The authors should clarify how their study adds to the existing body of knowledge.

Answer:

Thanks for pointing this out. We evaluated IANB for mandibular surgeries under general anesthesia, both intraoperatively and postoperatively. Few studies have researched it under general anesthesia in mandibular fractures, and those studies have done it intraoperatively only. we illustrated this as a benefit of our research in the final paragraph on page 11**.**

"Being one of the rare studies on peripheral nerve blocks in fixation of fracture mandibular under general anesthesia intraoperatively and postoperatively, our study has this advantage"

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2. Sample Size: Given the reported failure rate of IANB (10 to 39%), the sample size of 46 patients may be insufficient to draw robust conclusions. A larger sample size could provide more reliable data.

Answer:

Thank you for raising this concern. The sample size was calculated by using the PASS 15 program, setting power at 90% and alpha error of 0.05, and mentioned in the manuscript on Page 3, within the initial paragraph of the methods section. In the discussion section, we identified the small sample size as a limitation in the manuscript on page 11 within the last paragraph of the discussion section.

"The sample size was calculated by using the PASS 15 program, setting power at 90% and alpha error of 0.05 and according to Mesgarzadeh et al, 2014, the expected rate of need for analgesia of 20% in the IANB group compared to 70% in the control group"

"A small sample size was taken and this could be regarded as our first stepping stone in this direction and few studies were using IAN block under general anesthesia in fracture mandibular surgeries"

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3. Data Collection: The statement "Vital signs (HR, MAP) will be recorded every 10 minutes intraoperatively till the end of surgery" suggests that data collection has already been completed. The authors should ensure that this is clearly reported in the past tense.

Answer:

Thank you for pointing this out. The tense has been corrected to past tense in the manuscript page 5 first paragraph in methods section.

> Vital signs (HR, MAP) was recorded every 10 minutes intraoperative till the end of surgery.

- **Minor revision:**

1. . Language and Clarity: The manuscript would benefit from a review by a native English speaker to improve language clarity and readability.

Answer:

Thank you for pointing this out. It was evaluated by a native English speaker.

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2. Funding Information: The manuscript should include detailed information about the sources of funding and the role of funders in the study.

Answer:

It is self-funding.

3 Revision 2

2 comments · 16 Jan 2025 – 17 Jan 2025

Associate Editor

ACCEPT 16 Jan 2025

The manuscript investigates the effectiveness of a preemptive inferior alveolar nerve block (IAN block) compared to traditional systemic intravenous analgesia in managing perioperative pain for mandibular fracture surgeries. This prospective, randomized, double-blind, comparative study involved 46 adult patients divided into two groups: one receiving the IAN block and the other receiving standard intravenous analgesia. The study primarily assessed the analgesic effect by measuring the time to the first dose and total doses of fentanyl and pethidine required. Results indicated that the IAN block group required significantly less intraoperative fentanyl and postoperative pethidine, demonstrating effective pain control for up to six hours post-surgery.
The study is well-structured with a clear objective and methodology, enhancing its reliability. The manuscript contributes to the field by offering evidence that supports the use of IAN blocks as a viable alternative to reduce opioid consumption, which is a significant concern in postoperative care.

I recommend accepting the manuscript in the current version, as the authors appropriately addressed all requested revisions.

Editor-in-Chief

ACCEPT 17 Jan 2025

Congratulations!
The revised manuscript is great.
We are proud to accept the latest version for publication.