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Pain management for Elderly Patients with Multiple Rib Fractures, using Ketamine Infusion

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Kugler NW, Carver TW, Juul J, Peppard WJ, Boyle K, Drescher KM, et al. Ketamine infusion for pain control in elderly patients with multiple rib fractures: Results of a randomized controlled trial.(Report)(Author abstract). The journal of trauma and acute care surgery. 2019;87(5):1181.

Abstract: ***Introduction*: Rib fractures are responsible for 25% of all the trauma associated deaths; this occurs in approximately 40-80% of the patients diagnosed.[1] Intensive care support is necessary for some cases of these patients to check on the risks factor and initiate the treatment program for them.[2] Rib fractures are common problem and are very painful for the patients; giving them appropriate pain relievers will be an excellent way to handle the patients; besides, this will reduce the incidences leading to pneumonia and other complications like a respiratory failure.[3] When the treatment of patients with multiple rib fractures is delayed, they can also result in hypoventilation. Pain management is an essential factor for preventing complications associated with their conditions because there can be underlying injuries within the body. There is a necessity to have adequate pain control in handling the rib fractures and have effective respiratory therapy to reduce pulmonary complications and mortality.[4] However, a need to find an alternative pain management intervention became crucial after discovering the adverse effects the opioids have on the elderly patients. Kugler's study[5] aims to find alternative analgesics (ketamine) used in rib fracture management since opioids have been associated with related negative consequences.***

Keywords: Ketamine; rib fractures; opioids; elderly; trauma

1. Methodology

The research study selected participants using a prospective randomised, double-blind placebo-controlled trial on participants with their ages above or equal to 65. The patients must have three or more rib injuries and be admitted to the same hospital facility. Participants were excluded if they had a Glasgow Coma Scale of <14, chronic opiate usability, acute coronary syndrome and severe hypertension. Patients who were not able to communicate clearly with the staff were not included in the study. The groups of the patients were randomised to either a low-dose of ketamine (LDK) level at 2µgkg-1min-1 or an equivalent placebo rate of 0.9% sodium chloride. The primary outcome tested was the level of reduction in the numerical pain scores (NPS). This research was carried out in Froedtert Hospital, an American college of surgeon's hospital with a group I trauma centre, serving Milwaukee's urban and suburban populations. All the patients having blunt trauma and having three or more rib related injuries seen as eligible for research were contacted and, in this study. Therefore, the study design is appropriate since it was approved and registered with clinicaltrials.gov (NCT02432456).

The sample size was determined using the past institution's data collected on patients who were studied; the sample size needs to give significant results and not be too expensive to study.[6] Therefore, it was decided that the 26 patients would suffice a group of 80% power and an alpha of 0.05. A planned arrangement was also fixed to 60 participants, which allowed for an estimation of 15% attrition rates. After this study, the sample size was also carried out at the elapse of the enrolment periods so that the estimates obtained would be used for the research design.

2. Results and Discussion

The study showed 61 patients were enrolled, and 59 were randomised to placebo, where they received different interventions assigned by chance.[7,8] The male participants' median age was 74 years, and they composed 59.3% of the total sample studied. The primary cause of most of the patients' injuries was caused by falls amounting to 50.8% of the cases; this figure showed no significant difference between the demographic groups on injury characteristics. 1.7% of the individuals used less than 12 hours during infusion, while 3.4% used less than 24 hours. The majority of the patients, 89.8% of the participants, used more extended periods exceeding 36hours; however, the difference between the groups was not significant. It was shown that there was no statistical difference between the use of different medications in the patient population. The nerve blocks occurred on 46.7% of the participants and 62% of the placebo arms with significance P=0.17. Primary outcomes had no significant difference in NPS at 12 hours, 24, or 48 hours; on the same note, OME total had no significant difference for the hospital's total stay. However, it was noted that LDK fails to reduce NPS within any participant groups.[9] There was a lower NPS in the severity of the placebo group's injuries at 48 hours.

3. Conclusion

Despite numerous studies focused on analgesic therapy for patients with ribs fractures, opioids are still considered the medication of choice. Alternative pain killers to treat injured patients must be continued to seek, due to undesirable complications caused by opioids.

4. Critique

The aim of this study is clearly stated, and its intent is to assess whether ketamine infusion is safe and effective in controlling the pain in elderly patient with ribs fractures. In the study introduction, the author provides a solid argument based on proven evidence of reduced opioid reliance and pain control using ketamine, thereby validating the importance and utility of the study. This issue has a practical significance in healthcare as it helps to determine the most effective medication for pain control in these patients after having outlined the lack of proven efficacy in tackling this issue in healthcare practice. Controlling pain using such a drug can protect patient health and avoid the adverse effects, dependency issues, and worldwide opioid crisis.The study considered the significant results of the variables reducing in NPS after 24 hours since the start of the infusion; an area calculated it under the slope of the pain trajectory for a 12 to 24-hour time. The institution used standardized 11point NPS to assess the pain before and after the medication for the sample size. The data was collected by nursing staff for the participants for the entire stay in the hospital, and the data obtained were then used for statistical analysis. Hence, the participants' enrolment met the minimum requirements since it had over 90% of the power detecting a 1.5-point difference. The sample size was appropriate for this study and helped develop necessary conclusions since it was nicely calculated.

In addition, this paper reports the finding of a randomised, double-blinded control trial that was carried out via Investigational Drug Services. The patients were randomised to low ketamine or an equal amount of placebo. How randomisation was achieved in this study was not reported whether they used simple randomisation, block randomisation, stratified randomisation, or covariate adaptive randomisation. Despite the technique used in randomisation, double-blinded placebo randomisation is appropriate for this study. A correctly done randomisation removes the significant biases associated with the trial.[10] Randomisation used in this study helped eliminate the bias in the allocation of intervention and facilitates the blinding of the identity of treatment methods the respective participants or the assessors.

The study does not report on any allocation concealment methods applied in its research. The absence of allocation concealment suggests the course did not use the correct techniques. Allocation conceal meant reducing selection bias.[11-13] Appropriate methods of allocation concealment will result in correct randomisation. Lack of information about allocation concealment does not disapprove of the presence of bias during the study. The trial investigators could not know the patient’s allocation and the group assigned if there is no influence on randomisation. The results will, therefore, give a fair representation of the trial findings of the study. Consequently, it was not appropriate for this study to have shown the allocation concealment report applied during the study.

On the other hand, all the participants involved in this study were blinded from what the study intended to find out unless on occasions where the medical necessity arise, requiring the subjects to be unblinded. The use of blinding techniques as applied in this study was appropriate for RCT, and it served the purpose of the study to conceal as many individuals as possible during the trial.[14] Blinding means preventing different treatment groups during the problem and how the various assessment outcomes were found. It implies that neither subjects nor the investigators of the study assisting participants are not shown the kind of intervention assigned to them until the end of the study.[15] This technique was appropriately used double-blinding the subjects were possible and combined with the randomisation ensured the study's appropriateness to conceal the subjects and prevent as much biasness as possible.

Patients' follow-up was executed throughout the admission, and until the elapse of 30 days after, they were discharged from the facility. Follow-up time was appropriate for the RCT trial, which is meant to give the study appropriateness by finding the effects of the interventions on patients. Having a short follow up time reduces statistical power and increases the chance of bias occurrence.[16] Post follow up of the patients after the trial serves to provide more insights into the findings of the side effects, which could be taking a long time to emerge while at the same time is more expensive to implement. Short follow up on the study would not have given investigators the appropriate information about the trial being studied. Time used in follow-up was sufficient enough to determine the healing rates and side effects of the medication in case of any. Llewellyn, Bowman and Bulbulia[17] suggest that clinical trials have a short follow-up time.

Intention to-treat is the method meant to analyse the study results where all the patients are randomised; besides, statistical analysis of the data obtained is interpreted according to the group they assigned initially without considering the intervention. The intention to treat as applied in this study was to preserve the advantages obtained from randomisation; it also allowed the investigator to accept unbiased conclusions on the intervention's effect. It is also meant to protect the benefits of randomisation by allowing the investigators to draw accurate conclusions concerning the interventions studied.[18] This technique was appropriately applied in the study; analysis of the results considered the number of groups present. Data analysis of the findings used Fisher's exact test for studies between groups and t-test, and symmetric distribution. All the finding of these studies was analysed and reported using SAS 9.4, which also appropriate for this study. To sum up, this paper qualifies to present the findings for adoption into the field with the necessary changes and omitted information fixed. Since the study used more than 59 patients which their results were filed analysed and interpreted, it can be concluded that the study achieved a significant part of the requirements of the RCT study. The

question applied in this study was appropriate and very correct to the current issues associated with opioids. There must be the appropriateness of the item for a review to be scientifically acceptable. One centre study like this requires strict adherence to randomisation, blinding, and allocation concealment methods to make the study sufficiently appropriate for adoption. Moreover, the trial concluded that opioids are still the primary drug administered to patients, with rib fractures, although there has been a widespread call to use multimodal analgesics. [(19)] Alternatives to this drug must be sought; given opioids have associated dependency problems. This study found that, there was no difference in NPS for the patients contacted, but there was a reduction in OME for the participants who were injured severely. Using a low dose of ketamine would lead to reduced opioid consumption for patients with severe injuries. OME changes were not associated with admission to ICU general trauma ward, suggesting that findings were based on the patient's accumulated injuries and not the effect of the condition they were cared for. However, it was not determined whether a specific additional injury sustained by the patient contributed a significant change in the findings obtained. Patients older than sixty years were found to have significantly increased patient pain threshold, showing that they may have reduced pain sensitivity. Therefore, with the limitations in the findings, it is recommended that further research should be conducted in order to validate the use of LDK in hospitals.

References

[1] Tignanelli CJ, Rix A, Napolitano LM, Hemmila MR, Ma S, Kummerfeld E. Association between adherence to evidence-based practices for treatment of patients with traumatic rib fractures and mortality rates among US trauma centers. JAMA network open. 2020;3(3):e201316-e.
[2] Lin FC-F, Li R-Y, Tung Y-W, Jeng K-C, Tsai SC-S. Morbidity, mortality, associated injuries, and management of traumatic rib fractures. Journal of the Chinese Medical Association. 2016;79(6):329-34.
[3] Durant E, Dixon B, Luftig J, Mantuani D, Herring A. Ultrasound-guided serratus plane block for ED rib fracture pain control. The American Journal of Emergency Medicine. 2017;35(1):197.e3-.e6.
[4] Witt CE, Bulger EM. Comprehensive approach to the management of the patient with multiple rib fractures: A review and introduction of a bundled rib fracture management protocol. Trauma surgery & acute care open. 2017;2(1).
[5] Kugler NW, Carver TW, Juul J, Peppard WJ, Boyle K, Drescher KM, et al. Ketamine infusion for pain control in elderly patients with multiple rib fractures: Results of a randomized controlled trial.(Report)(Author abstract). The Journal of Trauma and Acute Care Surgery. 2019;87(5):1181.
[6] Zhong B. How to calculate sample size in randomized controlled trial? Journal of Thoracic Disease. 2009;1(1):51-4.
[7] Boutron I, Estellat C, Guittet L, Dechartres A, Sackett DL, Hróbjartsson A, et al. Methods of blinding in reports of randomized controlled trials assessing pharmacologic treatments: A systematic review. PLoS medicine. 2006;3(10):e425-e.
[8] Jargensen L, Paludan-Muller AS, Laursen DRT, SavoviA J, Boutron I, Sterne JAC, et al. Evaluation of the cochrane tool for assessing risk of bias in randomized clinical trials: Overview of published comments and analysis of user practice in cochrane and non-cochrane reviews. Systematic Reviews. 2016;5(80).
[9] Lee EN, Lee JH. The effects of low-dose ketamine on acute pain in an emergency setting: A systematic review and meta-analysis. Plos one. 2016;11(10):e0165461-e.
[10] Sil A, Kumar P, Kumar R, Das N. Selection of control, randomization, blinding, and allocation concealment.(Research Snippets). Indian Dermatology Online Journal. 2019;10(5):601.
[11] Andrew DMK, David JT, Marion KC, Adrian MG. Subversion of allocation concealment in a randomised controlled trial: A historical case study. Trials. 2017;18(1):1-6.
[12] Higgins JPT, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The cochrane collaboration's tool for assessing risk of bias in randomized trials.(Report). British Medical Journal. 2011;343(7829):889.
[13] SavoviA J, Weeks L, Sterne JAC, Turner L, Altman DG, Moher D, et al. Evaluation of the cochrane collaboration's tool for assessing the risk of bias in randomized trials: Focus groups, online survey, proposed recommendations and their implementation. Systematic reviews. 2014;3(1).
[14] Karanicolas PJ, Farrokhyar F, Bhandari M. Blinding: Who, what, when, why, how?(PRACTICAL TIPS FOR SURGICAL RESEARCH)(Report). Canadian Journal of Surgery. 2010;53(5):345.
[15] Smith PG, Morrow RH, Ross DA. Randomization, blinding, and coding: Oxford university press; 2015.
[16] McCarthy O, French RS, Roberts I, Free C. Erratum to: Simple steps to develop trial follow-up procedures.(Correction notice). Trials. 2016;17(1).
[17] Llewellyn-Bennett R, Bowman L, Bulbulia R. Post-trial follow-up methodology in large randomized controlled trials: A systematic review protocol. Systematic reviews. 2016;5(1).
[18] McCoy CE. Understanding the Intention-to-treat principle in randomized controlled trials. The Western Journal of Emergency Medicine. 2017;18(6):1075-8.
[19] Ho MHA, Karmakar KM, Critchley AHL. Acute pain management of patients with multiple fractured ribs: A focus on regional techniques. Current opinion in critical care. 2011;17(4):323-7.