Comment

Comments on “Intravenous Mannitol reduces intra-compartmental pressure following tibia fractures: A randomized controlled trial”——relevant questions demanding attention related to the study

Prateek Behera*, John Ashutosh Santoshi, Manish Dwivedi, Rajkumar Selvanayagam

All India Institute of Medical Sciences, Bhopal, India

ARTICLE INFO

Article history:
Available online 21 January 2021

Dear authors:

We would like to congratulate Nesaraj et al., for their study. This is an exciting study, but there are few pertinent points which must be clarified.

1. It is known that the relative intra-compartmental pressure changes in different compartments of the leg after a tibial fracture. The authors have not specified in which of the four compartments the compartment pressure has been measured. Also, the pressure in each compartment depends on the position of the ankle. This appears to be a significant flaw of the study methodology, as many cases of compartment syndrome of the leg involve the posterior compartments, and non-measurement of pressure in these compartments might result in a potential failure to detect a compartment syndrome.

2. The authors have reported that the baseline compartment pressures were different in the two groups, which is difficult to comprehend. The authors have conducted a randomized controlled trial, and randomization is performed to ensure the comparability and avoid any selection bias. Additionally, if the baseline pressures were different, one would assume that the natural course in these patients would be different too, irrespective of whether any intervention was performed or not.

3. Only the patients with closed tibia fractures were enrolled in the study. What was the presumption of excluding open fractures, as it is already known that patients with open tibia fractures can also land up in compartment syndrome?

4. The Mannitol doses administered to an individual has not been clearly mentioned in the manuscript, since a repeat dose might have helped in further reduction of the compartment pressure.

5. The authors have considered patients of age > 14 years as adults. Is there any scientific evidence for this assumption?

6. Whether the side ported and non-coring needle was kept inserted in a patients’ leg for the entire 3 h when measurements were made, or was it removed and then re-inserted for each time, is not clear. Was only one measurement taken in each time or was it a mean of more values? It is not clear.

7. The time since injury is rightly acknowledged as a factor for acute compartment syndrome; however, this information of patients in detail is missing. The maximum time interval between injury and Mannitol administration has not been defined. In the absence of this detail, the results of this study must be interpreted cautiously.

8. We see that the saline group has a preponderance of Tscherne Grade 1 cases and hence, a lower compartment pressure at time 0 - is this not a confounding factor?

9. Including only those who presented with a specified compartment pressure in relation to the diastolic blood pressure would probably have made the groups more comparable.

We believe that clarification of these points is essential for improving the generalization of this study’s results. This can then act as a guide for treating clinicians to prevent any acute compartment syndrome development in their practice.

* Corresponding author.
E-mail address: prateek.ortho@aiimsbhopal.edu.in (P. Behera).

Peer review under responsibility of Chinese Medical Association.

https://doi.org/10.1016/j.cjtee.2021.01.005

© 2021 Chinese Medical Association. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
Reply from Authors.
We are happy to clarify the questions raised. The answers are below.

1. All the pressures were measured from the anterior compartment with the ankle and knee splinted in neutral position as mentioned in the Abstract. We used the anterior compartment as this was the most commonly involved compartment most easily accessible, and we also wanted to ensure uniformity for the study protocol. Moreover, the main objective of the study was done to assess the effect of Mannitol on elevated compartment pressures.

2. We did not expect the difference in baseline pressures between the 2 groups. However as pointed out in the limitations of the study, this could be due to the relatively smaller numbers. Larger trials could likely address this issue. Moreover to assess the power of blinding, the investigator had marked what he thought the study drug was as either Mannitol or normal saline, at the time of 3 h pressure measurement. After the drugs were unblinded, the measure of agreement was calculated and the kappa is 0.2, which showed that the blinding was effective.

3. Open fractures were excluded as there would again be wide variability of patient presentations and the idea of a controlled randomized trial is to keep the 2 groups as comparable and uniform as possible except for the effect being measured.

4. Only a single dose of Mannitol/saline was given and the pressures were measured at 0, 1 and 3 h following this.

5. In our institution, patients less than 14 years are managed by the Department of Paediatric Orthopaedics.

6. The pressure was measured using the Stryker pressure manometer, by inserting the needle once. The needle was inserted thrice for each patient as 3 separate readings were taken at 0, 1 and 3 h.

7. This study was done for patients who presented within 12 h of injury. The primary aim of the study was not to detect compartment syndrome, but to evaluate the effect of Mannitol on compartment pressure. Therefore the time of injury is not important for this study.

8. There were 9 patients with Tscherne Grade 1 in the Mannitol group versus 13 in the saline group. This is a result of blinding and the randomization process as has been explained earlier.

9. We agree with the author on this point and we could focus on this in the future studies.

In summary, this was a blinded randomized controlled trial to show the efficacy of Mannitol on compartment pressures. This study also highlights the difficulty of performing randomized controlled trials in orthopaedics. Future studies with larger numbers and stratification to make sure initial pressures are comparable need to be performed before intravenously Mannitol can be regarded as the standard of care, as mentioned in the study.

References

1. Nesaraj J, Varghese VD, Boopalan PR, et al. Intravenous Mannitol reduces intracompartmental pressure following tibia fractures: a randomized controlled trial. Chin J Traumatol. 2021;24. https://doi.org/10.1016/j.cjtee.2020.11.006.

2. Lor KKH, Yeoh NCS, Wong KP, et al. Raised compartment pressures are frequently observed with tibial shaft fractures despite the absence of compartment syndrome: a prospective cohort study. J Orthop Surg. 2017;25. https://doi.org/10.1177/2309499017717362, 2309499017717362.

3. Shuler FD, Dietz MJ. Physicians’ ability to manually detect isolated elevations in leg intracompartmental pressure. J Bone Joint Surg Am. 2010;92:361–367. https://doi.org/10.2106/JBJS.I.00411.

4. McQueen MM, Court-Brown CM. Compartment monitoring in tibial fractures. The pressure threshold for decompression. J Bone Joint Surg Br. 1996;78:99–104.