Addition of Lignocaine in Intramuscular Injection of Magnesium Sulfate: Does It reduce Pain in Women with Severe Preeclampsia and Conscious Eclamptic Women—A Randomized Controlled Trial

ABSTRACT

Objective: To find whether the addition of 1 mL of 2% lignocaine with magnesium sulfate (MgSO₄) in intramuscular (IM) injection reduces the pain at injection site, when used in severe preeclampsia and conscious eclamptic women using visual (faces) analog scale of 0 to 10.

Design: Randomized controlled trial.

Setting: Labor room of Department of Obstetrics and Gynecology, teaching hospital attached to KLE University’s J N Medical College, Belagavi.

Population: Women with severe preeclampsia and conscious eclampsia who were eligible to receive MgSO₄ regimen and who were willing to participate in the study.

Materials and methods: Totally, 90 eligible women were randomly divided into two groups by using sequentially numbered opaque sealed envelope (SNOSE) technique: 1. Group I: magnesium sulfate with 1 mL of 2% lignocaine 2. Group II: magnesium sulfate alone.

Injection was given deep IM at upper and outer quadrants of both buttock alternatively. Pain assessment was done by using visual (faces) analog scale in both the groups within 5 minutes of 1st injection, at the end of 4 hours of giving 1st injection, and at end of 24 or 4 hours of the last dose, whichever is later.

Results: The pain scores were evaluated using visual (faces) analog scale within 5 minutes of 1st dose, 4 hours after 1st dose of injection, at the end of 24 or 4 hours of last dose of injection. There was no statistically significant difference in mean pain scores between two groups within 5 minutes of 1st injection (p-value 0.897), 4 hours after 1st injection (p-value 0.138), and the end of 24 or 4 hours of the last dose of injection (p-value 0.423). There was no difference between minimum 4, 0 and maximum 8, 4 (group I) and 6 (group II), 4 mean pain scores between the groups at different intervals respectively.

Conclusion: It is evident that the addition of 1 mL of 2% lignocaine along with 50% MgSO₄ is not beneficial in reducing the pain associated with IM injection.

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INTRODUCTION

Worldwide, magnesium sulfate is the drug of choice for eclampsia, which is used parenterally by intravenous (IV) and IM routes. In most of the European countries, the IV regimen is practiced, which is more efficacious in achieving stable serum levels of magnesium, but requires the use of an infusion pump for safe delivery of drug and has a greater potential for inadvertent overdose. However, in low-resource settings or developing countries like India, the use of IV infusion set is not common. So, IM regimen is the standard of care used in most hospitals in India.1,2 Though it is potentially safer, it requires large volume (10 mL) and repeated IM injections, which are painful.3 The World Health Organization4 guidelines recommend addition of 1 mL 2% lignocaine to IM injection of MgSO₄. This recommendation is only consensus-based and there is lack of sufficient data on whether addition of lignocaine reduces pain at the site of injection.

MATERIALS AND METHODS

This randomized controlled trial was conducted in the labor room of the Department of Obstetrics and Gynecology at KLE University’s teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi, Karnataka, India. Ethical clearance was obtained from Institutional Review Board of KLE University’s Jawaharlal Nehru...
Women with severe preeclampsia and conscious eclampsia were informed about the study, who were admitted to the labor room of the Department of Obstetrics and Gynecology at KLE University’s teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi, and who met the eligibility screening and informed consent was taken. Exclusions included women not willing to participate in the study and women who were in active labor (>4 cm) at the time of consent. Informed consent was documented via the woman’s signature or thumbprint. Information on the pain score was collected by midwives and residents’ details were entered into a standardized data collection instrument.

Sample size was estimated using pain as the primary variable. Depending on the previous clinical experience and assuming a standard deviation of 1 cm, 17 women were required in each group to have a β error 0.2 to detect a difference of 1 cm on the visual (faces) analog scale at the type I error 0.05 level of significance.5

The feasibility component of the study was analyzed from April 2014 to August 2014. Total labor room admissions were 4,047 during the study period from September 2014 to April 2015. Total sample size of 90 women were studied, who were eligible and consented for the study. However, only 73 women were enrolled in final outcome analysis as complete Pritchard’s regimen was not given in 17 women (Flow Chart 1). The total number of severe preeclampsia and eclampsia women enrolled is 62 and 28 respectively. In group I, the number of severe preeclampsia and eclampsia women was 32 and 14, whereas in group II, it was 30 and 14 respectively (Flow Chart 2).

Numerical outcomes were analyzed by mean and standard deviation. Main outcome of the study is the mean pain score of two groups and that was compared with Student’s unpaired “t” test. Statistical significance p-value of the study was kept at 0.05.

RESULTS

Total labor room admissions were 4,047 during the study period from September 2014 to April 2015. In this study, a total of 151 cases were screened, out of which 112 were eligible and 90 gave consent for participating in the study. However, only 73 women were enrolled in final outcome analysis as complete Pritchard’s regimen was not given in 17 women (Flow Chart 1). The total number of severe preeclampsia and eclampsia women enrolled is 62 and 28 respectively. In group I, the number of severe preeclampsia and eclampsia women was 32 and 14, whereas in group II, it was 30 and 14 respectively (Flow Chart 2).
Addition of Lignocaine in Intramuscular Injection of Magnesium Sulfate

Table 1: Demographic characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Subgroups</th>
<th>Group I (n = 46)</th>
<th>Group II (n = 44)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. %</td>
<td>No. %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>Literate</td>
<td>42 91.30</td>
<td>41 93.18</td>
<td>0.525</td>
</tr>
<tr>
<td></td>
<td>Illiterate</td>
<td>4 8.70</td>
<td>3 6.82</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>46 100.0</td>
<td>44 100.0</td>
<td></td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td>Green card</td>
<td>23 50.00</td>
<td>22 50.00</td>
<td>0.956</td>
</tr>
<tr>
<td></td>
<td>White card</td>
<td>18 39.13</td>
<td>16 36.36</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yellow card</td>
<td>5 10.87</td>
<td>6 13.64</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>46 100.0</td>
<td>44 100.0</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Mean ± SD (years)</td>
<td>23.00 3.29</td>
<td>23.11 2.32</td>
<td>0.850</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>1.54 1.05</td>
<td>1.66 0.91</td>
<td>0.578</td>
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<tr>
<td></td>
<td>Mean ± SD (weeks)</td>
<td>34.72 5.31</td>
<td>35.07 4.73</td>
<td>0.741</td>
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<tr>
<td></td>
<td>Mean ± SD (kg/m²)</td>
<td>25.47 3.22</td>
<td>24.55 2.43</td>
<td>0.127</td>
</tr>
</tbody>
</table>

BMI: Body mass index; SD: Standard deviation; GA: Gestational age

DISCUSSION

This randomized controlled study aimed to know whether the addition of lignocaine reduces pain at the site of injection with IM MgSO₄ injections. Limited data are available on the reduction of pain with the usage of lignocaine with IM injections of magnesium sulfate.

Demographic characteristics were comparable in both the groups. In all the aspects, both the groups were well matched and there was no statistically significant difference (Table 1).

The pain scores were evaluated using visual (faces) analog scale within 5 minutes of 1st injection, 4 hours after 1st injection, and 4 hours after the last dose of injection or at the end of 24 hours later and compared between the groups. The minimum pain score within 5 minutes of 1st dose of injection was 4 and maximum was 8 in both the groups. At 4 hours after the 1st dose of injection, the minimum pain was 2 in both the groups and maximum pain in group I was 4 and 6 in group II. The minimum and maximum pain scores in both the groups after 4 hours of last dose or at the end of 24 hours, whichever is later (Graphs 1 to 3). There was no statistically significant difference in mean pain scores between two groups within 5 minutes of 1st dose of injection (p-value 0.897), 4 hours after 1st injection (p-value 0.138), and 4 hours after the last dose of injection or 24 hours later (p-value 0.423; Graph 4). In group I out of 38 women, 14 women (36.84%) and in group II out of 35 women, 14 women (40%) received IM injections of MgSO₄ for more than 24 hours.
As per the CONSORT flow diagram, 151 women were screened to participate in the study, of which 96 women were eligible, of them 90 women consented and were randomly divided into two groups by SNOSE method. Totally 46 women received MgSO₄ with 1 mL of 2% lignocaine and 44 women received MgSO₄ alone. Total severe preeclampsias and eclamptics were 62 and 28 respectively. Of these, 73 women completed planned course of Pritchard’s regimen, and 17 were given partial regimen, but were included in analysis of the result. Of these 17 women who received the partial regimen, 11 were assessed after 1st dose of injection in whom the prophylactic dosage of injection MgSO₄ was given and six were available for second assessment as they delivered and their blood pressure was within normal limits after delivery. So, the full planned course of Pritchard’s regimen was not given.

Pain score was assessed using visual (faces) pain analog scale within 5 minutes of 1st injection, at the end of 4 hours of 1st injection, and 4 hours of last dose of injection or at the end of 24 hours, whichever is later; it was compared with IM injection of magnesium sulfate alone.

There was no statistical significance and difference in mean pain scores between the two groups within 5 minutes of 1st injection (p-value 0.897), 4 hours after 1st dose of injection (p-value 0.138), and 4 hours after the last dose of injection or at the end of 24 hours (p-value 0.423). The minimum and maximum mean pain scores were also not statistically significant at different intervals between both the groups.

There was no statistical significance between the mean pain scores of the two groups in both severe preeclampsia and eclampsia immediately after 1st dose of injection, 4 hours after the 1st dose of injection, and 4 hours after the last dose of injection or at the end 24 hours, whichever is later.

It is evident from the present study that the addition of 1 mL of 2% lignocaine does not reduce pain in IM injection of magnesium sulfate at all intervals. Hence, there is a need to avoid the 1 mL of lignocaine, which adds to extra volume without any benefit. However, the findings of this study need to be confirmed with a larger sample multicentric study.

The strengths of the present study are:
- Randomization method by SNOSE eliminated the selection bias of the patient by the investigator.
- Multiple trained residents were involved in pain assessment.
- Pain assessment was done by visual (Faces) analog scale.

The limitations of the present study are:
- All the severe preeclampsia women did not receive the planned complete course of Pritchard’s regimen.

CONCLUSION

It is evident from the present study that addition of 1 mL of 2% lignocaine with 10 mL of magnesium sulfate (50%) does not reduce the pain at the IM injection site. Hence, there is a need to avoid the 1 mL of lignocaine, which adds to the extra volume without any additional benefit. The findings of the same study need to be confirmed by a larger multicenter trial.

REFERENCES