

Pharmacology in Emergency Medicine



COMPARISON OF THERAPEUTIC EFFECTS OF MAGNESIUM SULFATE VS. DEXAMETHASONE/METOCLOPRAMIDE ON ALLEVIATING ACUTE MIGRAINE HEADACHE

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Abstract—Background: There is controversy about the efficacy of currently used treatment modalities to alleviate migraine headaches. **Objective:** We aimed to evaluate and compare the effects of magnesium sulfate and combined use of dexamethasone/metoclopramide on relieving acute migraine headache. **Methods:** We randomly divided 70 patients who had been referred to an emergency department, into two equal treatment groups with the two treatment plans, and analyzed pain severity at baseline using a numeric rating scale (NRS). We gave dexamethasone/metoclopramide to one group and magnesium sulfate to the other group, and evaluated pain severity at 20 min and at 1- and 2-h intervals after infusion. Finally, we used repeated-measure and two-way analysis of variance for intra- and inter-group evaluations of pain severity and complications, respectively. **Results:** We found no significant differences in demographic data and pain severity at baseline (8.2 vs. 8.0) between the two groups ($p < 0.05$). In the dexamethasone/metoclopramide group, pain severity (mean \pm standard deviation) was 7.4 ± 1.4 ($p = 0.36$), 6.0 ± 2.4 , and 2.5 ± 2.9 ($p < 0.0001$) at 20-min, 1-h, and 2-h intervals after treatment, respectively, with statistically significant differences between the baseline values and 1-h and 2-h interval values. Administration of magnesium sulfate was associated with decreased pain severity at the three intervals (5.2 ± 1.7 , 2.3 ± 1.9 , and 1.3 ± 0.66 , respectively), exhibiting significant differences

compared to baseline values and the corresponding time intervals in the dexamethasone/metoclopramide group ($p < 0.0001$). **Conclusions:** According to the results, magnesium sulfate was a more effective and fast-acting medication compared to a combination of dexamethasone/metoclopramide for the treatment of acute migraine headaches. © 2015 Elsevier Inc.

Keywords—migraine; treatment; magnesium sulfate; dexamethasone; metoclopramide

INTRODUCTION

In some parts of the world, the prevalence of migraine headache is up to 17% in females and 6% in males, and migraines account for > 22 million years lost due to disability (1). Migraine headaches can be disabling, they can recur up to 15 times a month and significantly decrease the patient's quality of life (2). In addition, treatment costs of migraine are very high; European countries spend approximately 18.5×10^9 Euros on treating migraine headaches every year (3).

When the migraine headache does not respond to usual medications (eg, antihypertensive, anticonvulsive, or nonsteroidal anti-inflammatory agents), patients are referred to emergency units or similar urgent care centers,

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and usually receive intravenous medications (4–6). Routine procedures used to relieve severe and refractory migraine headaches in such settings include the administration of intravenous fluids, dihydroergotamine, dexamethasone, magnesium sulfate, and anti-emetic dopamine antagonists, such as metoclopramide (7–17).

Magnesium has a role in the pathogenesis of headache, migraine, and aura due to its vascular effects (15–17). Intravenous administration of magnesium promptly relieves 80% to 86% of various headaches (18). It has very minor side effects and there is a wide gap between its therapeutic dose and toxic dose (therapeutic index). In addition, when kidneys are healthy, magnesium toxicity is very rare (19). Dexamethasone is also very effective in relieving or decreasing recurrence rate of migraine headaches due to its anti-inflammatory effects (20–23). In addition, administration of 10 or 20 mg metoclopramide decreases the severity of migraine headaches (24,25).

Marx et al. suggest administration of intravenous dihydroergotamine (DHE) and metoclopramide (to treat the DHE-caused nausea and vomiting) in cases of moderate to severe migraine headache attacks. Sumatriptan, the first approved medication of the triptan class, is a selective 5-HT_{1B} and 5-HT_{1D} receptor agonist and has also been suggested by Rosen for acute treatment (26). These medications might not be readily available in all areas of the world and evaluation of more accessible therapies in needed.

In Iran, DHE and sumatriptan have been replaced by dexamethasone, a steroid, in emergency departments. The use of steroids for treating migraine has been supported by anecdotal evidence that suggests they may be effective for prolonged migraine attacks refractory to standard therapies and for treating status migrainosus (26–28).

Although some studies showed metoclopramide and magnesium sulfate were effective in decreasing pain, other studies suggested that combination therapy with metoclopramide and magnesium sulfate decreased the efficacy of metoclopramide in relieving pain (29,30). Given the findings mentioned, evaluation of the efficacy of medications used in the treatment of migraine headaches requires more studies to derive a concrete and clear conclusion for treatment of migraine. Since magnesium sulfate has shown good accessibility, efficacy, and safety profile for the treatment of migraine, we aimed to compare the efficacy of combination therapy with dexamethasone/metoclopramide vs. magnesium sulfate (25). We undertook the present double-blind clinical trial to evaluate and compare the efficacy of these two strategies in the treatment of migraine headaches.

METHODS

Study Design

We designed a randomized, double-blind, clinical trial comparing the efficacy of dexamethasone/metoclopramide (8 mg dexamethasone and 10 mg metoclopramide) to magnesium sulfate (1 g in 100 mL normal saline) intravenously in the treatment of acute migraine. For ethical reasons, we did not have a placebo arm. This trial was approved by the Institutional Review Boards of Shahid Beheshti University of Medical Sciences, Tehran, Iran. We conducted the study in 2011.

Selection of Participants

We enrolled 70 patients older than 18 years of age who had been referred to the emergency department of an academic center in Tehran, Iran (Figure 1). An emergency room physician member of the team identified potential cases during shift work in the emergency department. This team member applied International Classification of Headache Disorders (ICHD) criteria, classified the headache, and alerted the research team on a potential subject. Our research team approached the patient for consent. The same emergency department physician established the diagnosis of migraine headache, based on ICHD criteria, listed as a form (31). These criteria were assessed for each patient. We randomly divided patients into two equal groups.

Inclusion criteria included the presence of headache at the time of administration of medicine, absence of previous treatment with antimigraine medications, absence of systemic diseases, and a numeric rating scale (NRS) score > 4 cm for the severity of headache. Exclusion criteria included inability to obtain/provide consent and lifetime history of fewer than five migraine attacks. We also excluded patients with hypersensitivity to metoclopramide, dexamethasone, magnesium sulfate, concurrent pregnancy, actively breastfeeding, history of renal insufficiency, use of other medications to relieve pain, and previous participation in the present study.

Intervention

After evaluation for inclusion and exclusion criteria, we randomized eligible patients using an online random-number generator to 1 of 2 treatment (by injection) groups: prepared solutions of dexamethasone/metoclopramide (8 mg dexamethasone and 10 mg metoclopramide in 100 mL normal saline solution, infused in 15 min) and magnesium sulfate (1 g in 100 mL normal saline, infused in 15 min).

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