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Original article

Comparison of granisetron and metoclopramide in the treatment of pain and emesis in migraine patients: A randomized controlled trial study

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ABSTRACT

Objectives: One of the irritating features of migraine is emesis that can compromise taking oral medications. We designed this study to compare the effectiveness of granisetron and metoclopramide in reducing pain and treating emesis in migraine patients.

Methods: We included a total of 148 patients with migraine headache presenting to two referral hospitals in a prospective, double-blinded randomized controlled trial. We compared the effect of granisetron (2 mg intravenous) with metoclopramide (10 mg intravenous). Pain intensity and emesis episodes were recorded before drug administration, one, two and four 4 h after drug administration.

Results: Of the 148 patients, 47 were male and 101 were female. 75 patients received granisetron and 73 metoclopramide. Mean pain intensity before the administration of the medications was 7.67 ± 1.30 in granisetron group and 7.68 ± 1.13 in metoclopramide group with an insignificant difference. Mean pain intensity at one, two, and 4 h after drug administration was 3.20 ± 1.37, 2.39 ± 1.28, and 1.31 ± 0.52 in granisetron group and 5.04 ± 1.77, 4.1 ± 1.8, and 1.56 ± 0.68 in metoclopramide group (P = 0.03). Mean emesis episodes before drug administration were 1.85 ± 0.81 and 1.80 ± 0.77 in granisetron and metoclopramide groups, respectively. These episodes were 1.33 ± 0.66, 0.25 ± 0.49, and 0.04 ± 0.19 in granisetron group and 1.38 ± 0.73, 0.21 ± 0.47, and 0.41 ± 0.19 in metoclopramide group at one, two, and 4 h after the drug administration (P = 0.7).

Conclusion: To came in conclusion, compared to metoclopramide, granisetron is a better choice in acute migraine ATTACK because it decreases the patients' pain as well as their emesis.

1. Introduction

Migraine is a common, chronic, and occasionally incapacitating neurovascular headache. This headache is often unilateral, pulsating in quality, and moderate to severe in intensity. Possible associated signs and symptoms include nausea, vomiting, anorexia, photophobia, phonophobia, osmophobia (aversion to odors), blurred vision, lightheadedness, and nasal congestion. Migraine affects 10% of the world population and accounts for approximately 1 million visits to the emergency departments (EDs) every year [1,2]. The frequency of the migraine headache is quite variable. Some patients experience several episodes per month. Early theories postulated abnormal vasculature as the root cause of migraine headaches with vasoconstriction to be responsible for the aura and rebound vasodilatation for the pounding headache, nausea and vomiting, anorexia, photophobia and phonophobia [2]. Migraine is incapacitating because of both severe headache and other related symptoms. One of the irritating features of migraine is emesis which can compromise taking oral medications and can be resistant to therapy.

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Metoclopramide is used as an antiemetic drug in migraine. It also has a prokinetic effect due to the agonism of the 5HT4 receptors (3). Metoclopramide inhibits the dopamine effects in the central nervous system and other organs. Its effects on the chemoreceptor trigger zone (CTZ) of the medulla makes it beneficial as a usual anti-emetic drug while it may also be a 5HT3 receptor antagonist [4]. Metoclopramide, with this mechanism, may be effective in the treatment of migraine. Adverse effects of metoclopramide include restlessness, Akathisia, sedation, extrapyramidal symptoms, anxiety, dystonia, headache, seizure, and hallucination [3].

Granisetron is a potent selective antagonist of 5-HT3 receptor used mainly for the treatment of chemotherapy-induced emesis. Its adverse effects include headache, diarrhea, constipation, anxiety, and insomnia [5].

Regarding the fact that many patients with migraine headache do not respond to metoclopramide administration, this study was designed to compare the effectiveness of granisetron and metoclopramide in reducing pain and treating emesis in migraine patients.

2. Material and methods

After approval of Ethics Committee of Iran University of Medical Sciences, registration of the study and taking written consent form we enrolled the patients. In this prospective, double-blinded randomized controlled trial, we evaluated patients with migraine headache presenting to the EDs of two referral centers in Tehran. We included all patients older than 18 years old presenting with headache with a previous history of migraine headache diagnosed by a neurologist. We excluded the patients if they were pregnant or breast-feeding, had suddenly initiated headache (different from the previous attacks), had abnormal neurologic findings or head trauma within the last month, were uncooperative, needed for additional doses of morphine and had an uncertain diagnosis.

The patients were randomly assigned into metoclopramide (10 mg/intravenously bolus [IV]) or granisetron (2mg/IV bolus) based on random block design. The drugs were stored in syringes with A and B tags and both the patients and the administrating physician were blind to the type of the medication in the syringe. Pain intensity and emesis episodes were evaluated before and 1, 2, and 4 h after drug administration. The chief investigator carefully examined all patients and recorded any drug adverse reactions. If there was a need for additional doses of morphine or if the clinician had used another analgesic, the patient's data was not used for pain intensity analysis. Demographic data including age and sex were recorded. A VAS (visual analogue scale) was used to analyze the pain intensity by the investigator. The Number of emesis episodes was asked from the patient and recorded, as well.

The data was analyzed using statistical package for social sciences (SPSS) software version 15. Descriptive statics and sample T-test were used to analyze data. A *P* value less than 0.05 were considered to be statistically significant.

3. Results

During 16 months, 148 patients fulfilled the inclusion criteria and were enrolled in the study (47 males and 101 females). Mean age was 33.5 years. A total of 75 patients received 2 mg IV granisetron and 73 patients received 10 mg IV metoclopramide.

Mean pain intensity before the administration of the medications was 7.67 ± 1.30 in granisetron group and 7.68 ± 1.13 in metoclopramide group with an insignificant difference. Mean pain intensity at one, two, and 4 h after drug administration was 3.20 ± 1.37, 2.39 ± 1.28, and 1.31 ± 0.52 in granisetron group and 5.04 ± 1.77, 4.1 ± 1.8, and 1.56 ± 0.68 in metoclopramide group ($P = 0.03$; Fig. 1).

Mean emesis episodes before drug administration were 1.85 ± 0.81 and 1.80 ± 0.77 in granisetron and metoclopramide groups, respectively. These episodes were 1.33 ± 0.66, 0.25 ± 0.49, and 0.04 ± 0.19 in granisetron group and 1.38 ± 0.73, 0.21 ± 0.47, and 0.41 ± 0.19 in metoclopramide group at one, two, and 4 h after the drug administration ($P = 0.7$, Fig. 2). Mean pain intensity and emesis episodes showed no significant difference between the different age and gender groups, either (all P values greater than 0.05).

4. Discussion

Migraine headache is a complex, recurrent headache disorder

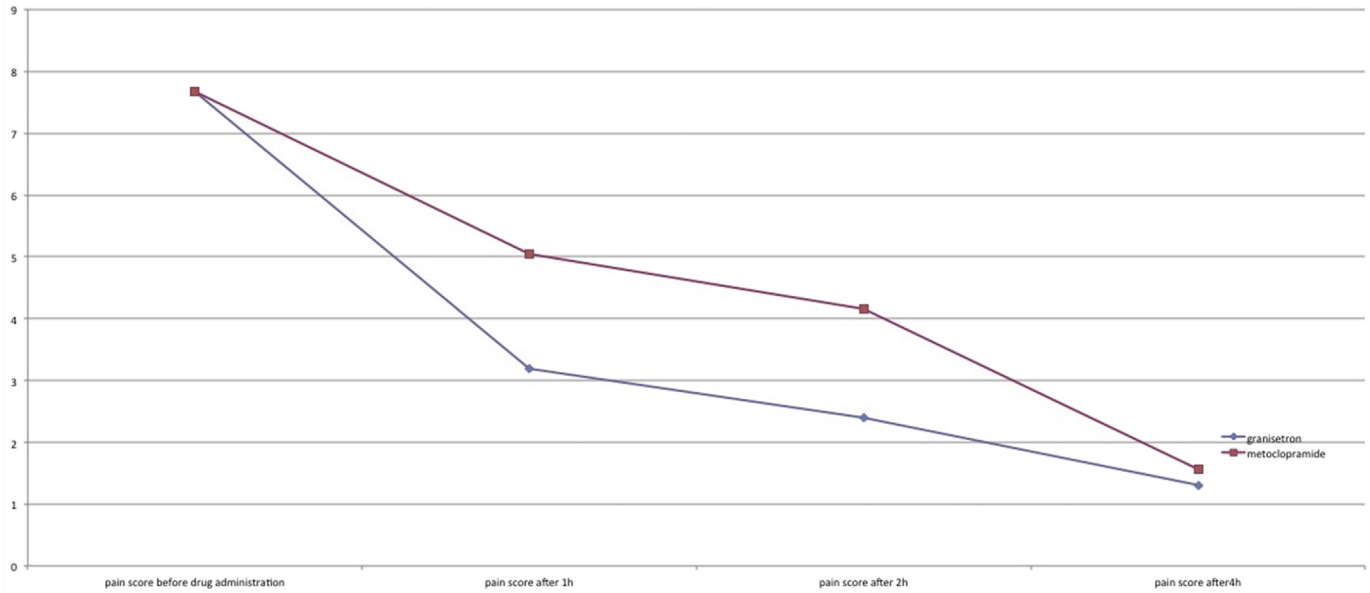

Fig. 1. Pain intensity in the study groups at 1, 2, and 4 h after the drug administration.

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