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BRIEF REPORT

Aromatherapy with Isopropyl Alcohol versus Intravenous Ondansetron in Management of Mild Brain Trauma Nausea and Vomiting; a Randomized Clinical Trial

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Abstract: **Introduction:** Nausea and vomiting are common complaints among patients who refer to the emergency department with head trauma. This study aimed to compare the effect of aromatherapy with isopropyl alcohol versus intravenous ondansetron in management of mild head trauma nausea and vomiting. **Methods:** This randomized clinical trial was conducted on patients with isolated mild head trauma complaining of nausea and vomiting who were referred to emergency department during a 6-month period. Patients were randomly divided into control (IV ondansetron + aromatherapy with saline) and intervention (IV saline + aromatherapy with isopropyl alcohol) groups. The frequency of vomiting and the severity of nausea (from 0 to 100 with the verbal scaling) were written before, and 10 and 30 minutes after intervention and compared between groups. **Results:** A total of 210 patients (105 patients in each group) with a median age of 38 years were included in the study, 112 (54.3%) of which were male. Ten minutes after aromatherapy, no significant difference was observed in nausea and vomiting between the two groups ($p > 0.05$). Nausea score after 30 minutes ($p = 0.015$) was significantly lower in the intervention group compared to the control group, but vomiting after 30 minutes ($p < 0.001$) was higher in the intervention group. **Conclusion:** Aromatherapy using isopropyl alcohol significantly reduced nausea of patients with mild isolate head trauma after 30 minutes. Regarding vomiting, no favorable result was observed in this study. However, the frequency of vomiting was reduced in both control and intervention groups.

Keywords: Aromatherapy; Odorants; Head Injuries, Closed; Brain Injuries, Traumatic; 2-Propanol

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1. Introduction

One of the main causes of mortality and disability in persons between the ages of 1 and 45 is a traumatic brain injury (TBI). The most frequent triggers of TBI are trauma, falls, car accidents, and sports-related injuries (1, 2). Driving accidents are the most significant and frequent cause of head injuries in Iran and Asia (3, 4). Since the number of patients with head trauma complaints in the emergency room is high and nausea and vomiting are common complaints among these patients (5), finding a safe, fast and effective treatment solution in the emergency room is needed and many medications are presented in literature for nausea control, while evidence on post-head trauma nausea is less available (6-9). Aromatherapy is a safe, low-cost, and non-invasive solution, which can complement existing therapeutic strategies. Aromatherapy aims to use scents and aromatic oils by inhalation or even with massage and sometimes orally to eliminate various unpleasant conditions such as nausea, vomiting, pain, stress, mental restlessness, insomnia, and reaching the desired state (10). Numerous tests have shown that isopropyl alcohol is effective in treating nausea and vomiting after surgery (10). Several animal models have shown the safety of isopropyl alcohol (11, 12). Human studies have not been conducted after inhalation of isopropyl alcohol (10). In a meta-analysis con-

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ducted by Gong et al. with the aim of evaluating the effect of aromatherapy on anxiety in patients, the results showed that aromatherapy with different essential oils can significantly reduce anxiety regardless of the cause of anxiety.
However, the proper dosage of essential oils needs more research (13). Since anti-nausea injection treatments have their own concerns, such as lack or absence of drugs, and drug allergies, finding another solution to get rid of these symptoms is useful. In addition, with aromatherapy, the patient can control the symptoms of nausea and vomiting by him/herself, and there is no need for a nurse to be constantly present at the patient's bedside in the emergency room. Aromatherapy has been used to control nausea and vomiting for various reasons (14) but no article has been published about the control of nausea and vomiting caused by mild head trauma by aromatherapy, yet. This study aimed to compare the effect of aromatherapy with isopropyl alcohol versus intravenous ondansetron in management of nausea and vomiting following mild isolated head trauma.

2. Methods

2.1. Study design and setting

The present study is a randomized, single-blind clinical trial that was conducted on patients with nausea and vomiting following isolated mild head trauma, who were referred to the emergency department of Shahid Hashminejad Hospital, Mashhad, Iran, during a 6-month period from December 2019 to June 2020.
Before entering the patients in this study, the research process was explained and informed consent was obtained from them. In all stages of the study, the researchers adhered to the ethical principles of Helsinki Declaration and the confidentiality of patient information. All the costs of this project were covered by the researchers and no additional costs were incurred by the patients. This study was approved by the Ethics Committee of Mashhad University of Medical Sciences under the ethical code "IR.MUMS.MEDICAL.REC.1398.840" and registered in the Clinical Trial Center of Iran with the code "IRCT20161226031577N3"

2.2. Participants

Patients referring to the emergency room due to isolated head trauma who were complaining from nausea (with severity level 1) and/or vomiting were selected for inclusion. Isolated head trauma could be due to reasons such as an accident where only the patient suffered head trauma, accidents at work, or head trauma with a hard object. Patient non-cooperation; Glasgow coma scale (GCS) <13; the presence of neurological defects; patient dissatisfaction; age below 14 years; the presence of olfactory defects before the trauma; prescribing medicine to the patient that causes nausea or vomiting (such as prescribing narcotics for the patient's headache); the period of reduced level of consciousness less than 30 minutes; any forgetfulness of events before or after the accident (less than 24 hours after the accident); any change in the mental state at the scene of the accident (feeling lost, lack of awareness of time or place or person, confusion); were among the exclusion criteria. In addition, all subjects with missing data were excluded from the study and sampling was continued until reaching the required sample size.

2.3. Intervention

Patients were divided into two groups, A and B, based on the table of random numbers. In group A (control), ondansetron was given intravenously and saline as aromatherapy, and in group B (intervention) saline was administered intravenously and isopropyl alcohol was applied for aromatherapy with 3 cc sprinkled on a gauze pad, which the patient used to inhale.

2.4. Data gathering

All demographic variables of the patient, vital signs of the patient at the time of visit, and the initial outcome after receiving ondansetron or isopropyl alcohol were recorded in a checklist. First, the frequency of vomiting and the severity of nausea was scored from 0 to 100 using Verbal scaling criteria, and then the presence of vomiting and the degree of nausea were evaluated and scored from 0 to 100 using Verbal scaling criteria on 2 other occasions, 10 and 30 minutes later. The difference in the score given by the patient showed the response to the treatment.
The checklist included items such as age and gender of the patients, their medication history, the patient's vital signs on arrival (O2 Saturation (SAT) and pulse rate (PR) measured by Fingertip Pulse Oximeter, Contec Company, China; Respiratory rate per minute; and blood pressure measured by OMRON Blood Pressure Monitor, made in Japan), the feeling of nausea before intervention based on Verbal Scaling (from zero to 100, zero showing no feeling of nausea and 100 indicating the worst nausea that the person can imagine), and the presence or absence of vomiting before intervention. Vital signs and nausea were measured before and 10 minutes after intervention; presence or absence of nausea and vomiting were asked at 10 and 30 minutes after intervention. No further follow-ups were conducted after 30 minutes from intervention.

2.5. Statistical analysis

Based on April et al.'s study (15) that reported mean nausea score of 16±19 in the aromatherapy group and 29±25 in the ondansetron group after intervention based on Visual Analogue Scale (VAS), and considering alpha 0.05 and power of

Table 1: Baseline characteristics of studied participants at the time of admission to emergency department

Variable	Total	Intervention	Control	P
Age (year)				
Median (Q1-Q3)	38 (25.75-53.25)	35 (25-50)	41 (27-56)	0.122
Gender				
Male	112 (53.3)	55 (52.4)	57 (54.3)	0.782
Female	98 (46.7)	50 (47.6)	48 (45.7)	
Vital sign				
Pulse rate (/min)	70 (64-84)	67 (61.78)	75 (64-86)	0.026
Respiratory rate (/min)	20 (18-24)	22 (18-24)	20 (16-23)	0.003
Oxygen saturation (%)	98 (97-100)	98 (97-100)	98 (97-99)	0.756
SBP (mmHg)	130 (110-140)	130 (110-145)	130 (112-140)	0.312
Nausea score				
Median (Q1-Q3)	40 (30-60)	50 (30-60)	40 (30-70)	0.916
Vomiting				
Yes	86 (40.95)	50 (47.6)	36 (34.3)	0.049
No	124 (59.05)	55 (52.4)	69 (65.7)	

Data are presented as median (interquartile range; IQR) or frequency (%). SBP: Systolic blood pressure.

Table 2: Comparison of patients' studied outcomes between the two groups 10 and 30 minutes after the intervention

Outcomes	Intervention	Control	P value
Vomiting 10 min			
Yes	45 (42.9)	32 (30.5)	0.63
No	60 (57.1)	73 (69.5)	
Vomiting 30 min			
Yes	40 (38.1)	6 (5.7)	0.001
No	65 (61.9)	99 (94.3)	
Nausea score 10 min			
Median (IQR)	40 (20-60)	30 (0-70)	0.95
Nausea score 30 min			
Median (IQR)	10 (0-30)	20 (0-65)	0.015

Data are presented as median (inter quartile range; IQR) or frequency (%). Min: minutes.

80% in the formula for estimating the mean in two independent communities, the required sample size was estimated to be 96 people in each group and considering 10% attrition, 105 people were included in each group (Figure 1).

After collecting the data, they were entered into SPSS version 22 software and described using appropriate tables, graphs, and indices, and then the chi-square or Fisher test was used to compare qualitative variables in the two groups, if necessary. Mann-Whitney test was used to compare quantitative variables (according to variable distribution). The significance level in all tests was considered less than 0.05.

3. Results

3.1. Baseline characteristics of studied cases

In total, 210 patients were included in the study, 112 (54.3%) were male and the rest were female with a mean age of 38 (IQR=27.5) years. Baseline characteristics of all the study samples are provided in table 1. The vomiting rate had a lower incidence among the controls than among intervention group (p = 0.049). Respiratory rate was lower in controls than in intervention group (p = 0.003) and the pulse rate was higher in the control group (p = 0.026).

3.2. Comparing the studied outcomes

Nausea after 30 minutes (p = 0.015) in the intervention group was significantly less than = the control group. But vomiting after 30 minutes in the intervention group was more than the control group (p < 0.001). While 10 minutes after intervention, no significant differences were observed in case of vomiting rate or nausea score (p > 0.05).

32.38% (95% CI: 22.09 - 42.68) of patients experienced vomiting after 30 minutes under aromatherapy that they would not have under ondansetron. Based on the number needed to harm (NNH), for every 3.1 (95% CI: 2.3, 4.5) patients treated with aromatherapy, 1 vomiting after 30 minutes will occur beyond those that would have happened under ondansetron.

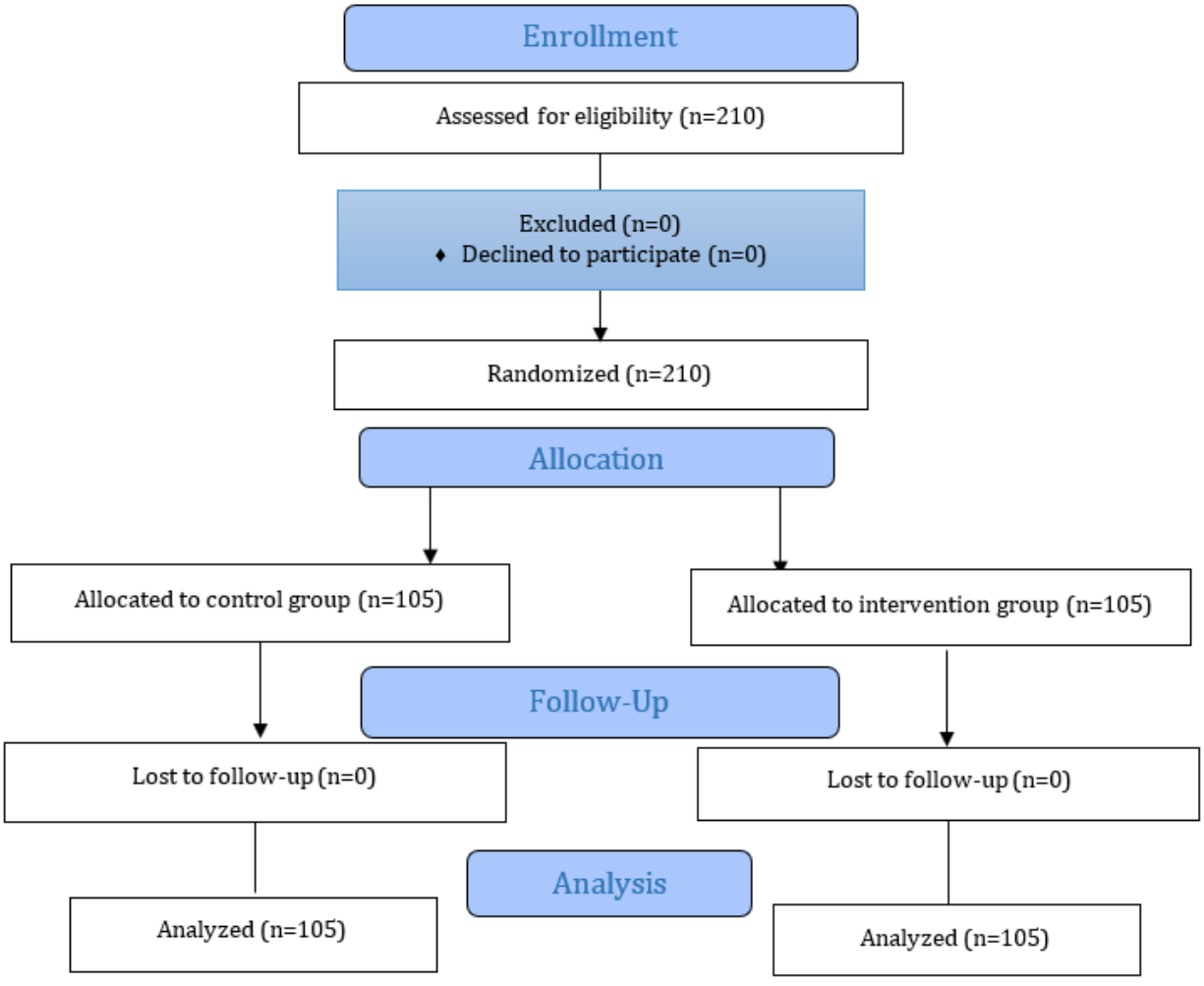

Figure 1: The study flowchart.

4. Discussion

The present study was conducted in order to investigate the effect of aromatherapy using isopropyl alcohol in comparison with intravenous ondansetron in controlling nausea and vomiting caused by mild head trauma in patients who referred to the emergency room with isolated head trauma. The results of our study showed that the rate of nausea of the patients, which was similar between the two groups at the beginning of the study, was significantly lower in the intervention group than in the control group after 30 minutes, and the aromatherapy performed in this group using isopropyl alcohol had significantly reduced nausea. Of course, this reduction of nausea in the intervention group was not observed after 10 minutes, and probably more than 10 minutes was necessary for isopropyl alcohol inhalation to show its effect.

Regarding vomiting, as mentioned, the amount of vomiting at the beginning of the study and before aromatherapy or ondansetron administration was higher in the intervention group than in the control group. After 30 minutes of the study, this difference still existed between the two groups. However, the vomiting of the patients was reduced in both the intervention group and the control group; but in the control group, this decrease in the incidence of vomiting was more obvious (from 34% to 5.7%). Apparently, in this study, isopropyl alcohol was not as effective as ondansetron in reducing vomiting. Since we did not have a third group (a group without medication) in this study, it is not possible to comment on whether the use of isopropyl alcohol has an effect on reducing vomiting or not. There are similar studies that have shown that isopropyl alcohol has been effective in reducing vomiting, which will be discussed below.

Inhalation aromatherapy's effect has been investigated for nausea control in different settings, ncluding the stem cell transplantation (15), stroke (16), and coronary bypass (17);

but most shreds of evidence are based on the trials of post-operative assessments (10).

The literature review did not reveal any study with similar aromatherapy treatment for traumatic brain injury patients. In the case of traumatic brain injury, evidence was limited to some experimental animal models (18). On the other hand, clinical studies on aromatherapy in the emergency room have not separated different causes of nausea. Isopropyl alcohol has been evaluated as the aromatherapy agent in some studies. In another study conducted in 2018 by Lindblad et al. (19) in Canada, the authors examined 122 adult patients presenting to the emergency department who complained of mild to moderate nausea and vomiting. In most patients, nausea and vomiting were caused by gastroenteritis. The results obtained from this study showed that on a scale of 1 to 100, the rate of nausea after 30 minutes from the start of treatment was 20 in the group of patients who inhaled isopropyl alcohol and 44 in the group of ondansetron patients. However, there was no significant difference between the two groups in the amount of vomiting and the length of hospital stay among the patients. No harmful side effects were observed in any of the groups.

The results obtained in this study regarding the nausea of patients were similar to our study and showed the significant effect of isopropyl alcohol in reducing nausea of patients referred to the emergency room. Of course, it is possible that the small sample size in Lindblad et al.'s study has reduced the accuracy of their results.

A clinical trial conducted by Candemir et al. (20) showed fascinating results, the average score of nausea and vomiting in the intervention group after 2 minutes was significantly lower than the control group. Also, the amount of nausea of the patients in the intervention group was reduced in each of the measured times compared to the previous time.

In general, the results obtained from this study were similar to our study and indicate the significant effect of isopropyl alcohol in reducing nausea among emergency patients. However, the difference between the two studies is that in our study, more time was needed for the anti-nausea effects of isopropyl alcohol to develop. The reason for the difference in the results of the two studies may be related to the difference in the patients included in the study, because in Candemir's study, all patients referring to the emergency room with complaints of nausea and vomiting were included in the study, but in our study, only patients with head trauma were included in the study and the trauma patients included in our study may have delayed the use of gauzes impregnated with isopropyl alcohol to deal with the trauma situation by a few minutes, and this issue has led to the delayed appearance of nausea reduction results.

In another study conducted in 2018 by April et al. in the United States, the authors divided 122 patients who referred to the emergency room with complaints of nausea and vomiting into three groups, which included oral ondansetron and inhaled isopropyl alcohol, oral placebo and inhaled isopropyl alcohol, and oral ondansetron and inhaled placebo. The obtained results showed that the average reduction of nausea after 30 minutes in patients of three groups (on a 100-point scale) was 30, 32 and 9 units, respectively. Also, in the mentioned groups, 27.5%, 25% and 45% of patients needed to receive additional medicine to reduce nausea. In April et al. study, as in our study, the positive effect of using isopropyl alcohol to reduce nausea in emergency patients has been reported. However, this study did not measure the vomiting rate of the patients. Also, in this study, similar to our study, the nausea of the patients decreased after 30 minutes. Our study had a larger sample size than this study (21).

In a 2016 study in the United States, Beadle et al. (22) investigated the effects of inhaled isopropyl alcohol on nausea and vomiting in emergency room patients. In this study, isopropyl alcohol was used as a placebo in one group of patients, and normal saline was used as a placebo in another group, and their nausea was checked after 10 minutes. 80 patients were included in the final analysis of the study. Median nausea among the patients of the isopropyl alcohol group was lower than that of the patients in the placebo group. Also, intervention group patients reported more satisfaction.

In general, the results of this study were consistent with our study and showed the positive effect of isopropyl alcohol in reducing nausea in patients. Also, considering that in this study, unlike our study, ondansetron was not prescribed for any of the two groups, we can be sure that the effects of reducing nausea observed in the intervention group were due to the inhalation of isopropyl alcohol.

5. Limitation

This study faced some limitations. First of all, there is a need for a placebo aromatherapy like a device with no essential oils and no effect on humidity for a double blinded method of RCT. Second, this was a single center study the results of which should be generalized to clinic after further larger studies with feasibility studies on implanting aromatherapy devices in emergency department. Third, this study's sample size was powered for nausea and vomiting that might have affected the results of vital signs assessment. Also, we only followed patients for 30 minutes, which does not seem sufficient.

6. Conclusion

Aromatherapy using isopropyl alcohol significantly reduced nausea of patients with mild isolate head trauma after 30 minutes. Regarding vomiting, no favorable result was observed in this study. However, the frequency of vomiting was

reduced in both control and intervention groups.

7. Declarations

7.1. Acknowledgments

None.

7.2. Authors' contributions

Mohd Idzwan and Tan Maw Pin designed the protocol on methodology, ethical approval, writing, review and editing the manuscript. Mohd Idzwan also supervised the completion of the manuscript. Nor Hadila was involved in research literature review, gaining ethical approval, sample collection, data analysis, writing and editing the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

7.3. Authors' contribution

BRK has designed the study. BRK, TG, and EVM planned the study protocols, samplings, and the interventions. ZAS and SMM collected the data. BRK and TG analyzed data. BRK, EVM, ZAS, and SMM provided the drafts of manuscript. All authors have contributed to revisions and have confirmed final version.

7.4. Conflict of interest

None declared.

7.5. Sources of funding

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