DEM Journal Club

Article Appraisal

Article: Aromatherapy Versus Oral Ondansetron for Antiemetic Therapy Among Adult Emergency Department Patients: A Randomized Controlled Trial

Date of Journal Club: Apr 16, 2019

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Background and Study Objective(s):

Nausea and vomiting account for 4.8 million annual ED visits in the United States. No antiemetics have been proven superior in symptom management in such patients. A small 2015 randomized trial demonstrated that isopropyl alcohol aromatherapy was superior to an inhaled placebo agent; this was confirmed by a 2018 Cochrane review looking the post-operative setting. This study compared isopropyl alcohol aromatherapy with ondansetron to treat nausea and vomiting in ED patients.

Study Design:

The study was a single-centre, double-blinded randomized controlled trial that electronically randomized 122 ED patients between 3 treatment arms: inhaled isopropyl alcohol and oral placebo (IPA), oral ondansetron liquid and inhaled saline placebo (O), and a dual non-placebo group which received both inhaled ispropyl alcohol and oral ondansetron liquid (IPA+O) (The inclusion of a non-placebo group was to more effectively blind participants to the oral agent they were receiving.)

Participants were recruited from a convenience sample identified by ED nurses. The study included ED patients aged 18 or older with a chief complaint of nausea or vomiting, with a self-reported nausea severity of 3 or greater on a 10-point numeric verbal response scale, and no intravenous access. Exclusion criteria were as follows: allergies to the treatment agents, unable to inhale through their nares, had recently taken medications contraindicating administration of alcohol, altered mental status, prior QT prolongation, or suspected serotonin syndrome. The study was powered to detect a difference in nausea reduction of 20mm, which was previously identified as the boundary of the 95% confidence interval for a minimally clinically significant difference in for nausea. The anticipated standard deviation in the primary outcome measure of 29mm yielded a suggested sample size of 40 patients per treatment arm.

Patients were blinded to the agents they were receiving by having the oral agents dispensed in unmarked syringes, and the labels on the inhaled agents obscured by tape. Investigators were blinded to the agents dispensed by having them affixed with participant labels by pharmacists and assistants not otherwise affiliated with the study. Each patient provided select baseline information and was asked to provide subjective scores for both nausea and pain on

separate 0 to 100mm Visual Analog Scales (VAS). After receiving their initial treatment, each participant was reassessed and asked to repeat their pain and nausea VAS at 10, 20, 30 and 60 minutes, then hourly, and finally at time of final ED disposition. At each reassessment except at disposition, patients were permitted to repeat their inhaled treatment if desired. The primary outcome was VAS reduction at 30 minutes, and a secondary outcome was need for rescue medications.

Results:

208 patients were screened; 25 declined and 61 were excluded, leaving 122 participants. The IPA + O group had 40 patients and the other had 41 each. The groups appeared similar at baseline. For the primary outcome, mean nausea reduction at 30 minutes was 30mm in the IPA+O group, 32mm in the IPA group, and 9mm in the O group. The main secondary outcome was the higher rate of rescue medications in the O group (45.0%) as compared to both the IPA and IPA+O group (25.0% and 27.5%, respectively).

Other measures, including change in pain and nausea score, satisfaction scores, vomiting, admission, and ED length of stay, were similar.

Validity of Results:

The study methodology was robust: randomization was appropriate, follow-up was thorough, and outcomes were clinically relevant and explicitly stated. The investigators took reasonable means to ensure blinding, even though IPA has a characteristic odor; in a questionnaire, only half of patients guessed their treatment arm. The difference in primary outcome was significant, with both IPA groups clearly having greater improvement than the O group.

Generalizability of Results:

The results of this study are generalizable to ED patients. Even though the relatively young and healthy participants included in the study might not be reflective of the typical ED population overall, patients like this still account for a proportion of those seen at many EDs each year. It is further important to note that patients did not have intravenous access.

The Bottom Line:

Inhaled isopropyl alcohol appears clinically superior to oral ondansetron in the treatment of nausea and vomiting in the ED. Its low cost and minimal side effect profile enhance this. Emergency physicians should consider adding IPA to their toolbox for managing these symptoms. Although not addressed by the study, it is possible that IPA administration in low-resource or community settings, at triage, or in the prehospital environment, may be effective.