

Ondansetron is Safe and Effective for the Prehospital Treatment of Nausea and Vomiting by Paramedics

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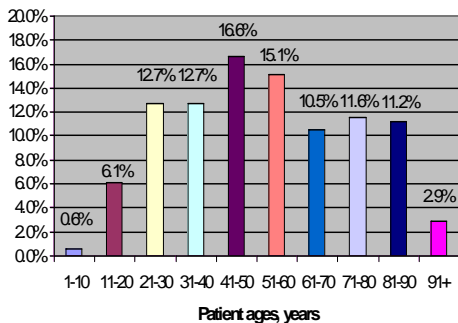


BACKGROUND

- Nausea and vomiting are common in prehospital patients, both prior to and during ambulance transportation, and can create significant distress.
- Oral and parenteral ondansetron is commonly used in inpatient and outpatient settings, but there is limited information on the prehospital use of intravenous (IV) or intramuscular (IM) ondansetron and no report on the oral dissolving tablet (ODT).

OBJECTIVES

- The primary objective was to evaluate the safety and efficacy of the paramedic administration of ondansetron in the out-of-hospital treatment of undifferentiated nausea or vomiting.
- The secondary objective was to determine the frequency of use of the medication in an EMS system.



Age distribution of study patients

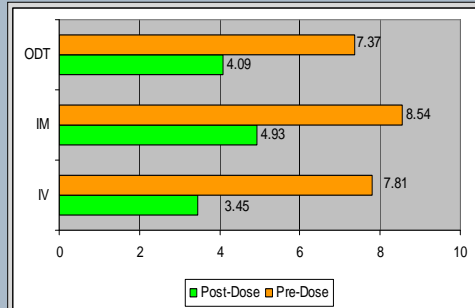
METHODS

- Prospective, observational, nonrandomized.
- Patients with severe nausea or intractable vomiting who were transported by paramedic-staffed ambulances in eight California counties were treated with ondansetron IV, IM, or ODT.
- All patients age ≥ 4 with no known sensitivity to HT3 antagonists were eligible.
- A dose of 4 mg IV (preferred route)/IM/ODT was used for all patients.
- Data were collected prospectively for a 6-month period using an online database (Survey Monkey, www.surveymonkey.com).
- Primary outcome measures were:
 - 1) efficacy as measured by a 10-point visual analog nausea scale, and;
 - 2) incidence of adverse effects.
- There were no control or placebo groups.
- Confidence intervals for the change in nausea score were calculated and P-values for the changes were calculated using the Wilcoxon signed-rank test.
- Differences in improvement of nausea scores by route were compared using the Wilcoxon rank-sum (Mann-Whitney) test.

RESULTS

- Ondansetron was administered to 2071 patients (3.1% of all patients transported during the study period).
- Most patients were adult, with only 66 less than 18 years old.
- 64% of treated patients were female, 36% male.
- 1321 subjects (64%) received ondansetron IV, 77 (4%) received ondansetron IM, and 674 (33%) received ODT.
- IV administration resulted in the largest improvements in nausea scores (mean 4.36, 95%CI [4.15, 4.37]), followed by IM (mean 3.61, 95%CI [2.95, 4.27]) and ODT (mean 3.28, 95%CI [3.06, 3.50]).
- Overall mean decrease in nausea score was 3.99 (95%CI [3.82, 4.08], $p < 0.001$) on a 10-point scale.
- After medication administration, four patients had mild hypotension that quickly resolved, one had hypertension, two had itching and/or rash, and one had a brief episode of supraventricular tachycardia that resolved spontaneously.

| Age | M/F | Dose | Route | Suspected Adverse Reaction |
|-----|-----|------|-------|---|
| 47 | F | 4 mg | ODT | Nausea/Vomiting, BP: 118/82 to 86/68 |
| 43 | F | 4 mg | IV | Nausea/Vomiting, B/P 130/94 to 90/60 |
| 60 | M | 4 mg | IV | Nausea, BP 162/145 to 98/57 |
| 52 | F | 4 mg | IV | Nausea/Vomiting, hypotension resolved w/ 400 ml IV NS |
| 88 | F | 4 mg | IV | Nausea, BP 159/89 to 210/88 |
| 25 | F | 4 mg | IV | Immediate erythema/pruritis at IV site, resolved w/ diphenhydramine |
| 67 | F | 4 mg | IV | Diffuse pruritis w/o rash |
| 48 | F | 4 mg | ODT | Transient PSVT at 170 for 5-10 seconds, self-limited |



Change in nausea scores in patients who received ondansetron for nausea. Positive numbers indicate improvement. N=2053.

| | N | Pre | Post | Change | 95% CI |
|--------------|------|-----|------|--------|-----------|
| Total | 2053 | 7.7 | 3.7 | 4.0 | 3.9 - 4.1 |
| IV | 1307 | 7.8 | 3.5 | 4.4 | 4.2 - 4.5 |
| IM | 77 | 8.4 | 4.8 | 3.6 | 3.0 - 4.3 |
| ODT | 669 | 7.4 | 4.1 | 3.3 | 3.1 - 3.5 |

Change in nausea score by route of administration

CONCLUSIONS

- Ondansetron is safe and effective for the out-of-hospital treatment of nausea and vomiting when administered by paramedics via the IV, IM and oral routes.
- When available to paramedics, it is used frequently, thus having potential to alleviate suffering for many patients.