

Journal Club Eastern Virginia Medical School Therapy Article

Presenter: Drexel Proctor

Date: 8/31/20

Citation: Benary D et al, **Ondansetron Prescription Is Associated With Reduced Return Visits to the Pediatric Emergency Department for Children With Gastroenteritis**, *Annals of Emergency Medicine*, Ann Emerg Med. 2020 May 26:S0196-0644(20)30262-6. 2020,

I. WHAT IS BEING STUDIED?	
1. Study Objective	<p>Primary objective: to evaluate whether a prescription for ondansetron on discharge from the pediatric ED or urgent care center in patients with vomiting or gastroenteritis was associated with a difference in return rates in 72 hours.</p> <p>Secondary objectives: to evaluate the association between ondansetron prescription and return rates in patients specifically receiving a diagnosis of gastroenteritis, and to assess whether there was an association between an ondansetron prescription and alternate diagnoses on return visits.</p>
2. Study Design	Retrospective cohort study that included a single large urban tertiary care pediatric ED and 11 of its urgent care centers from 4/2010-12/2017
3. Inclusion Criteria	Age 6mo-18years, index visit to the pediatric ED or urgent care center, diagnosis of gastroenteritis, vomiting, vomiting and diarrhea, or gastritis.
4. Exclusion Criteria	Admission to hospital, relevant pre-existing medical conditions.
5. Interventions Compared	ICD-9 & 10 based diagnostic codes using EMR review of discharged patients with or without ondansetron prescription
6. Outcomes Evaluated	Scheduled or unscheduled 72-hour return rate; alternate diagnosis at return visit within 7 days. Authors used logistical regression that included 8 of 15

	demographic features for multivariate analysis: Age, race, IVF bolus, Ondansetron, rads. Study, ins. Location (ED vs. UC), MD (peds EM, peds, md)
II. Are the results of the study valid	
1. Was the assignment of patients randomized?	No. This was a retrospective cohort chart review study
2. Was randomization concealed (blinded)?	N/A
3. Were patients analyzed in the groups to which they were randomized?	N/A
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	They were grossly similar, but there were statistically significant differences between the groups that did and did not receive ondansetron at discharge. Specifically, those who did receive a prescription were older, and Medicaid and black patients were less likely to receive a prescription. (It says that <i>Non</i> -Hispanic patients were less likely to receive a prescription, but my reading of their chart as presented suggests the opposite.)
III. Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?	
1. Were patients aware of group allocation?	N/A
2. Were clinicians aware of group allocation?	Yes
3. Were outcome assessors aware of group allocation?	No. Outcome assessors doing chart reviews can be blinded to the research objective. No mention of blinding of those individuals.
4. Was follow-up complete?	Yes, although there is no way to account for patients that may have had return visits to facilities outside the health system or their primary care physicians.
IV. What were the results?	

Answer the questions posed below

1. How large was the treatment effect? (Difference between treatment and control group).

Table 3. Predictors of 72 hour return visits in patients with gastroenteritis or vomiting.

Characteristic	Unadjusted	Adjusted
	OR (95% CI)	OR (95% CI)
Prescription of ondansetron at discharge	0.84 (0.76-0.92)	0.84 (0.75-0.93)
Age, y	0.95 (0.94-0.95)	0.95 (0.94-0.95)
Race		
White	1 (Reference)	1 (Reference)
Black	0.63 (0.55-0.73)	0.65 (0.56-0.76)
Other/unknown	1.0 (0.87-1.14)	0.98 (0.86-1.13)
IV fluid bolus during visit	1.41 (1.26-1.56)	1.48 (1.32-1.67)
Ondansetron given during visit	1.08 (1.01-1.15)	1.11 (1.04-1.19)
Radiologic study during visit	1.22 (1.11-1.25)	1.25 (1.14-1.37)
Insurance		
Medicaid	1 (Reference)	1 (Reference)
Commercial	0.74 (0.68-0.80)	0.76 (0.72-0.85)
State	0.78 (0.59-1.01)	0.99 (0.75-1.31)
Self-pay	0.62 (0.48-0.79)	0.69 (0.53-0.88)
Treated in ED (vs UCC)	1.17 (1.09-1.25)	1.11 (1.03-1.20)
Treated by pediatric emergency medicine physician (vs pediatrician)	0.89 (0.82-0.96)	0.86 (0.78-0.94)

Adjusted OR 0.84 (95%CI 0.75-0.93) for group that received prescription, or 16% decreased odds of 72 hour return with ondansetron prescription.

Overall 72 hr return visit rates were within the national average (2.7-8%).

13.3% of all patients were given Rx for ondansetron (“Any prescription at discharge”)

After adjustment, younger age, black race, receiving an intravenous fluid bolus, being treated by a pediatric emergency medicine–trained physician, ondansetron given during index visit, a radiologic study obtained during visit, and being treated in the ED were associated with 72 hr return rates. (Table 3)

2. What was the estimated treatment effect at a 95% confidence interval? (Precision)

(95%CI 0.72-0.95)

V. Will the results help me in caring for my patients? (Applicable?)

1. Were the study patients similar to my patient?

Yes. Patients age 6 mo- 18 years with vomiting, gastroenteritis, gastritis. Tertiary care center with UC satellites is very similar

2. Were all clinically important outcomes considered?

Most. It was important to consider return visits, and possible returns with alternate diagnoses. It might also be of some value to assess how many patients *developed* diarrhea after starting ondansetron, and even to consider the possibility of QT prolongation, especially in patients receiving other medications. No assessment of potential harms. No economic analysis.

3. Are the likely treatment benefits worth the potential harm and costs?

Yes. Zofran is relatively well tolerated, and there was no correlation between receiving Zofran prescription and returning with alternate diagnoses.

Study Limitations

1. Chart review study of EMR generally far inferior to RCT's with a host of confounding factors not measured or controlled for in a retrospective observational study design.
2. No blinding of data assessors which can protect from some bias. .
3. There was no way to assess whether patients had follow-up in another health system or with their PMD
4. NNT=138 The study did have a large number needed to treat (138) due to the baseline low return rate for these complaints.
5. There was no data on the amount of ondansetron prescribed, either dosing or doses, and there was no way to follow up on if the prescriptions were filled.
6. No accounting for patients that may have been redirected to the ED for re-assessment

Clinical Bottom Line:

This study suggests that ondansetron prescriptions may decrease (NNT=138) the odds of 72-hour return visits with gastroenteritis and/or vomiting. This makes sense logically, and it was reassuring that there was no association seen between ondansetron prescription and return with an alternate diagnosis. Further evaluation with a randomized study design would be helpful, as previous retrospective studies have differed in their findings on this topic, but might be somewhat difficult due to current prescribing practices in the ED.