Title:
Comparison of the Effects of Promethazine 6.25 mg and Promethazine 12.5 mg in Treating Post-operative Nausea and Vomiting: A Randomized Clinical Trial

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Introduction:  PACU nurses noticed that giving promethazine 6.25 mg to older and/or sedated patients rather than the standard dose of 12.5 mg produced the same antiemetic effect and caused less sedation. They questioned whether lower doses of promethazine could be given to adults, in general, and to older and sedated patients specifically.

Identification of the Problem:
Despite the availability of intra-operative anti-emetic medications, post operative nausea and vomiting (PONV) continues to be one of the most common adverse effects of anesthesia and opioid administration in surgical patients. Uncontrolled PONV requires additional nursing care, delays patient recovery time, extends the length of stay for ambulatory patients and increases patient dissatisfaction with the services provided.

Purpose of the Study:
The purpose of this study is to determine whether or not a smaller dose of promethazine (6.25 mg) achieves levels of relief from post operative nausea and vomiting (PONV) comparable to the standard dose of 12.5 mg.

Study Hypotheses
H1: Subjects receiving low dose promethazine (6.25 mg) will achieve PONV relief comparable to subjects receiving standard dose promethazine (12.5 mg).
H2: Levels of early post-surgery sedation will be lower for subjects receiving low dose promethazine (6.25 mg) than for subjects receiving standard dose promethazine (12.5 mg).
Subjects receiving.

Research Question
Does the extent of dose effect differ according to subject characteristics (e.g., age, gender)?

Methodology:
A randomized, double blind clinical trial is being undertaken to compare differences in promethazine dosage in ambulatory surgery patients.

Setting - The study is being conducted in the Post Anesthesia Care Unit (PACU) and Ambulatory Surgical Center (ASC) of a 600 bed teaching hospital in the Northeast. The PACU is a 32 bed Phase I recovery area staffed by 45 full-time equivalent (FTE) registered nurses (RNs). The ASC is a 39 bed Phase II recovery short-stay area staffed by 28 FTE RNs.

Subjects - Adult patients who have undergone elective surgery. Inclusion criteria: age between 18 and 75 years; undergoing elective urologic, neurologic, general surgery, thoracic, vascular, otolaryngology, orthopedic, oral maxillofacial, gynecologic, or colorectal surgery; English speaking; able to consent to participation. Exclusion criteria: pregnancy; known allergy to promethazine; and refusal or inability to sign study consent. Also excluded are enrolled
participants with a sedation level greater than “3” on our internal sedation scale and any enrolled participant with limited IV access requiring IV placement in the lower extremities. A power analysis has determined that we need 130 subjects (65 per group) to detect significant differences across groups.

*Intervention* - Promethazine dosage is determined by chance, with neither the nurse administering the medication or the patient knowing which dose is received. Extent of PONV and sedation are measured prior to medication administration and at 30 minute intervals thereafter until the patient is discharged from the setting. A rating scale of 0 to 10 is being used to measure extent of PONV. Level of sedation is being measured using a scale ranging from 0 (awake, alert and interactive) to 5 (unresponsive; unable to arouse).

*Data Analysis* – Experimental and control groups will be compared for differences in extent of PONV relief and sedation using Student’s t Test. Subject characteristics, including age and gender, also will be examined.

*Results:*
The promethazine study is currently underway. To date we have enrolled 388 subjects. As of October 2009, 69 have received the study medication and are part of the study comparison group. A safety check midway demonstrated no differences in outcomes between experimental and control group.

*Implications for perianesthesia nurses and future research*
If the study demonstrates that Promethazine 6.25 mg is equally effective for controlling PONV and sedation levels are less, using this lower dose could become a standard practice in the PACU and ambulatory settings across the country. Future research may be done to substantiate our findings.