A Comparison of Two Differing Doses of Promethazine for the Treatment of Postoperative Nausea and Vomiting

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Purpose: *To compare the use of promethazine 6.25 mg intravenous (IV) (experimental group) with promethazine 12.5 mg IV (control group) among adult ambulatory surgery patients to control established postoperative nausea or vomiting (PONV).*
Design/Methods: *In a double-blind, randomized controlled trial (n = 120), 59 subjects received promethazine 6.25 mg and 61 subjects received promethazine 12.5 mg to treat PONV. Study doses were administered postoperatively if the subject reported/exhibited nausea and/or vomiting. Outcomes for experimental and control groups were compared on the basis of relief of PONV and sedation levels.*
Findings: *Ninety-seven percent of subjects reported total relief of nausea with a single administration of promethazine at either dose. Sedation levels differed between groups at 30 minutes post-medication administration and at the time of discharge to home.*
Conclusions: *Promethazine 6.25 mg is as effective in controlling PONV as promethazine 12.5 mg, while resulting in less sedation.*

Keywords: *ambulatory surgery, nausea and vomiting, promethazine, sedation, perianesthesia nursing, research, RCT.*

ONE OF THE MOST COMMON adverse effects of surgery and anesthesia is postoperative nausea and vomiting (PONV).[1] These adverse effects may persist despite administration of intraoperative medications to prevent their occurrence.[2-4] Various agents including 5-HT_3 receptor antagonists (ondansetron, granisetron), glucocorticoids (dexamethasone), antihistamines (dimenhydrinate, cyclizine), cholinergic antagonists (scopolamine patch), dopamine antagonist (droperidol or haloperidol), metoclopramide, or neurokinin-1 receptor antagonists[4] are used to prevent or treat PONV, as is intravenous (IV) promethazine.

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Promethazine is a phenothiazine derivative that competitively blocks histamine (H [1]) receptors and exhibits anti-emetic and sedative properties.[5] Relief of PONV typically is achieved within 5 minutes of IV infusion of promethazine[6] and lasts for 2 to 6 hours.[5] The major drawback to the use of promethazine for ambulatory surgery patients is its sedating effect.[6]

Any adverse reaction to medication, including sedation, delays patients' postoperative recovery time,[7] resulting in delayed ambulation and fluid intake, increasing the need for nursing intervention, and decreasing patient satisfaction. The possibility of delayed discharge is an added inconvenience for both the patient and their family.

Because of the sedating effect of promethazine, recommendations exist for the use of doses lower than the current standard (12.5 to 25 mg) to achieve antiemetic relief.[8,9] Although limited research has been carried out related to promethazine dosing, some evidence exists for the administration of promethazine 6.25 mg in the presence of PONV. In a comparison of three IV doses (6.25, 12.5, and 25 mg), no differences were found in the effectiveness of promethazine doses in treating PONV among patients (n = 330) in a post-anesthesia care unit (Phase I).[10] In a similar comparison carried out among hospitalized elderly patients (n = 26), no difference in relief of symptoms was observed with the lower dose of promethazine (6.25 mg IV) for the treatment of nausea and vomiting.[11] Several investigators have examined the use of IV promethazine at doses of either 12.5 or 25 mg for treatment of PONV[11-14]; however, these studies compared IV promethazine with different classes of antiemetics or were carried out in settings other than perianesthesia. Moreover, a review of current literature revealed no studies that were focused on the use of promethazine 6.25 mg IV in the adult ambulatory surgery population.

Study Purpose

The purpose of this study was to compare two doses of IV promethazine (6.25 vs 12.5 mg) in a sample of adult ambulatory surgery subjects (n = 120) who were expected to be discharged home after an elective surgical procedure. Based on direct clinical experience and direct observation of adult ambulatory surgery patients over time by Phase I and Phase II (ambulatory surgical center) nurses, the following specific aims were generated:

1. To compare the effects of two different doses of promethazine (6.25 mg IV vs 12.5 mg IV) on PONV in a sample of adult ambulatory surgery patients undergoing elective surgery.
2. To compare levels of postoperative sedation between adult ambulatory surgery patients who received promethazine 6.25 mg IV (experimental group) vs promethazine 12.5 mg IV (control group).

Study Design

Between October 2008 and March 2011, a convenience sample of adult ambulatory surgical patients who were sent from the operating room (OR), per the determination of the anesthesiologist, to either Phase I or Phase II were randomized to receive promethazine 6.25 mg IV (experimental group) or promethazine 12.5 mg IV (control group) if PONV were to occur.

Setting

The study was conducted at a 750-bed teaching hospital in the Northeastern United States.

Preparation of Study Team

Phase I and Phase II nurses responsible for data collection were oriented to the study and subject enrollment procedures during educational sessions carried out by the investigators and supported by the institution's Clinical Nursing Research Center. In these sessions, data collection instruments were reviewed and regulations concerning the protection of human subjects' rights were discussed. Copies of the consent form, data collection tool, study design, study kits, and visual descriptive scale were provided and discussed in detail. Laminated cue cards were posted in each area for reference, and a nurse investigator was available to answer questions, address concerns, and monitor inter-rater reliability during data collection in both Phase I and Phase II areas.