

# A RANDOMIZED DOUBLE BLIND STUDY TO EVALUATE EFFICACY OF PALONOSETRON WITH DEXAMETHASONE VERSUS PALONOSETRON ALONE FOR PREVENTION OF POSTOPERATIVE AND POSTDISCHARGE NAUSEA AND VOMITING IN SUBJECTS UNDERGOING LAPAROSCOPIC SURGERIES WITH HIGH EMETOGENIC RISK

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**Summary:** Postoperative nausea and vomiting (PONV) and postdischarge nausea and vomiting (PDNV) are common occurrences (50%–80%) after laparoscopic surgery. Palonosetron (Pal), the newest 5-HT<sub>3</sub> antagonist, is an effective antiemetic that has advantages in treating PDNV due to its prolonged duration of action. We hypothesized that a combination of Pal and dexamethazone (Dex) could further improve the efficacy of the treatment in comparison to Pal alone in patients at high risk for PONV. Patients scheduled to undergo laparoscopic surgeries under general anesthesia were randomized to receive 8-mg dexamethasone + 0.075-mg palonosetron (Pal + Dex) or an equivalent volume of saline + 0.075 mg palonosetron (Pal). Data was collected at defined postoperative times (2, 6, 12, 24, and 72 hours). All patients also completed an 18-question QOL–Functional Living Index-Emesis instrument at 96 hours. We enrolled 118 patients, ASA 1-2, with at least 3 PONV risk factors, who were undergoing outpatient surgery. Both groups had a low incidence of vomiting in the PACU (Pal + Dex, 1.7%; Pal, 6.8%) and at 72 hours (0.0% both groups). Complete response (no vomiting, no rescue medication) was not different between treatment groups for any time intervals. Cumulative success rates over the entire 72 hours were 60.4% (Pal + Dex) versus 60.0% (Pal). The Pal + Dex group showed a trend toward greater satisfaction on the QOL-Functional Living Index-Emesis scores with the greatest differences in the “nausea domain”. The combination therapy of palonosetron + dexamethasone did not reduce the incidence of PONV or PDNV when compared with palonosetron alone. There was no change in comparative efficacy over 72 hours, most likely due to the low incidence of PDNV in both groups.

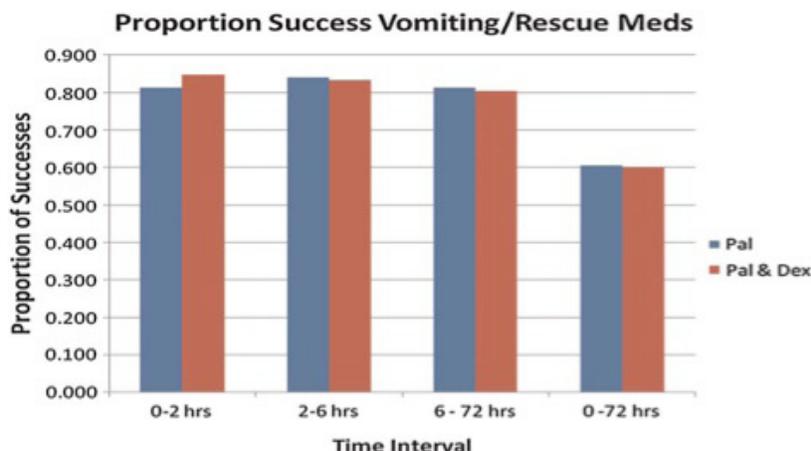


FIGURE 1. The proportion of successes for the 2 treatment groups (Palonosetron—blue bars; Palonosetron plus dexamethasone—red bars) are plotted for 4 time intervals (shown on horizontal axis). The 95% confidence intervals for the differences underlying these comparisons varied between 13% and 18%, less than the 20% reduction assumed in our sample size assumptions.