Implementation of a risk-stratified approach to prevent postoperative nausea and vomiting in an institution with high baseline rates of prophylaxis

Kadhiresan R. Murugappan, Mario Moric¹, Xuanji Wang², Jessica Kruse¹, Ariel Mueller, Myles D. Boone³, Cristina Barboi⁴

Department of Anesthesia, Critical Care and Pain Medicine, Beth Israel Deaconess Medical Center, One Deaconess Road, West/MB 660, Boston, MA, ¹Department of Anesthesiology, Rush University Medical Center, 1653 W. Congress Pl, Jelke 7, Chicago, Departments of ²Surgery and ³Anesthesiology, Loyola University Medical Center, 2160 S. First Ave, Maywood, IL, ⁴Department of Anesthesiology, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, New Hampshire, USA

Abstract

Background and Aims: Although a risk-adjusted approach to preventing postoperative nausea and vomiting (PONV) is generally recommended, the successful implementation of such practice without mandated protocols remains elusive. To date, such a strategy has never been adapted to curb high baseline rates of prophylaxis.

Material and Methods: We conducted an observational study on a cohort of patients undergoing elective surgery before and after the implementation of a quality improvement initiative including a risk-stratified approach to prevent PONV. The primary outcome was the number of prophylactic interventions administered. Secondary outcome included the repetition of ineffective medications and the need for rescue medication in the post-anesthesia care unit (PACU).

Results: A total of 636 patients were included; 325 patients during the control period and 311 after the intervention. The educational program failed to reduce the amount of prophylactic antiemetics administered (2.0 vs. 2.6, \(P < 0.001\)) and the repeat administration of ineffective medications for rescue (16% vs. 20%, \(P = 0.15\)). More patients in the intervention group required rescue medication compared to the control group (16.9% vs. 9.7%; \(P = 0.04\)).

Conclusion: Implementation of best practices to combat PONV remains elusive. Our results indicate that difficulties in changing provider behavior also apply to institutions with high prophylactic antiemetic administration rates.

Keywords: Postoperative nausea and vomiting/diagnosis, postoperative nausea and vomiting/prevention and control, postoperative nausea and vomiting/therapy, risk factors

Introduction

Postoperative nausea and vomiting (PONV) affects nearly one-third of patients undergoing surgery.¹ This complication is feared by patients and providers alike due to associated morbidity and increased healthcare expenditure. In the last decade, multimodal management for PONV has become popular. PONV prophylaxis is increasingly being used as a marker for quality of anesthesia care due to the risk for prolonged post-anesthesia recovery unit (PACU) stays and unplanned readmission following ambulatory surgery.²⁻⁴

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The optimal strategy to prevent PONV remains a subject for debate.[3] Proponents of a liberal approach advocate for the prophylactic administration of multiple antiemetics to patients independent of their particular susceptibility. Others support the use of prophylaxis only when called for based on each individual patient’s risk factors as determined by one of the available validated risk scores.[6-10] The Society for Ambulatory Anesthesia (SAMBA) endorsed this paradigm in their PONV Consensus Guidelines.[11] Despite potential shortcomings, multiple investigators have found that the use of risk scores can reduce institutional rates of PONV.[12-14]

To date, no group has successfully implemented a non-protocolized risk-adjusted strategy in a large cohort of patients with varying levels of baseline risk across multiple surgery types. Furthermore, a risk-adjusted approach has never been adapted to reduce high baseline rates of prophylaxis. Our aim was to introduce a risk-based approach without mandating antiemetic administration to promote patient-specific care. We hypothesized that a quality improvement initiative utilizing risk stratification to guide PONV prophylaxis would reduce the amount of prophylactic antiemetic interventions administered by providers.

**Material and Methods**

We performed an observational before-and-after study in the main operating rooms at an urban tertiary care center. The investigation was conducted between April and May 2016 (control period), followed by an implementation phase (May-June, 2016) and an intervention period (June-July, 2016). Because optimal prophylaxis and treatment patterns varied, with both approaches falling well within the standard of care, the requirement for obtaining informed consent was waived. The study was approved by the Institutional Review Board at Rush University Medical Center.

Adult patients (age ≥18 years) undergoing elective surgery with recovery in the PACU were included. Obstetric patients and those receiving fast-track protocols that mandated multimodal PONV prophylaxis were excluded. Patients in the pre-intervention control cohort were given prophylaxis and treatment according to clinician preference. Prior to the intervention, clinicians liberally managed the prophylaxis of PONV by routinely administering combinations of transdermal scopolamine, parenteral dexamethasone, and parenteral ondansetron independent of the patient’s risk for PONV.

The subsequent implementation period included provider education concerning risk stratification, available options for prophylaxis and treatment as part of a quality improvement initiative. A novel PACU order set focused on the treatment of PONV was designed to discourage re-administration of previously ineffective medications. In the preoperative period, to aid in decision-support, clinicians were provided with paper assessment forms that facilitated calculation of the Apfel simplified score[10] and provided a comprehensive reference for multiple validated[11,13-17] prophylactic interventions. Available interventions included transdermal scopolamine, oral gabapentin (800 mg[11]), intramuscular ephedrine (0.5 mg/kg[18]) and parenteral midazolam, metoclopramide, dexamethasone as well as ondansetron.

The suggested number of interventions was based on the four-point Apfel score.[10,11] Low-risk patients with one or fewer risk factors were recommended to receive no intervention. Moderate-risk patients with two or three points were suggested to receive one to two interventions. High-risk patients with each of the four risk factors included in the Apfel score were recommended to receive two or more interventions with no possibility of overtreatment.

Clinical data including age, sex, surgery type, anesthetic technique (general vs. other), billable anesthesia time, smoking status, PACU opioid prescription and administration was abstracted from the medical record. Apfel scores for the control group were generated based on chart review. For the intervention group, providers calculated Apfel scores after implementation of the risk stratification program.

The primary outcome of the analysis was the number of prophylactic interventions administered by the providers. The secondary outcomes were repeat administration of medications ineffective in prophylaxis as PACU rescue medication as well as requirement for rescue medication.[19,20]

Data is presented as mean ± standard deviation, median (quartile 1, quartile 3), or frequencies and proportions depending on variable type and distribution. Normality was assessed with the Shapiro-Wilk test. All reported P values are two-sided and significance was set at 0.05. Differences in baseline characteristics were identified using parametric or non-parametric t-tests, Chi-square test or Fisher’s Exact test as appropriate. Given the before and after design of the study and feasibility issues with paper assessment forms, no a priori power calculation was performed for the primary outcome.

The primary outcome was assessed via chart review and analyzed in a general linear regression model. Secondary outcomes were analyzed using univariate and multivariable logistic regression. Models were adjusted for clinically relevant risk factors for PONV based on multivariable analyses of large cohort studies.[11] Covariates included age, duration of anesthesia as well as the four components of the Apfel score.
Subgroup analyses were performed separately stratified by surgical procedure or anesthetic technique. All variables and subgroup analyses were established a priori. Regression diagnostics showed that assumptions of regression were reasonable and best fitting models were used in each analysis. All analyses were conducted using SAS version 9.3 (SAS Institute Inc., Cary, NC), with two-sided $P$ values < 0.05 considered statistically significant.

**Results**

A total 636 patients were included in the study. Of these, 325 patients were observed in the control period and 311 patients presented during the intervention period. There were no significant differences between the groups with regard to age, gender, height, weight, surgery type, duration of billable anesthesia time and postoperative opioid use [Table 1]. More patients in the intervention group underwent general anesthesia (78% vs. 69%; $P = 0.02$). Additionally, there were more smokers in the intervention group (23% vs. 12%; $P = 0.0003$).

Evaluation of pre-intervention practice revealed the expected liberal prophylaxis pattern with a mean of 2.0 interventions for the control group as a whole. When stratified by Apfel score, all groups received an average of more than one intervention [Table 2]. The mean number of prophylactic interventions given after implementation of the risk-stratified approach exceeded that of the control cohort (2.6 vs. 2.0, $P = 0.0001$; Table 2). Mean values were consistent with overtreatment for all Apfel applicable scores.

Medications ineffective in prophylaxis were re-administered for PACU rescue in 20% of the patients following our intervention compared to 16% of patients prior to our intervention. This difference was not statistically significant ($P = 0.15$; Table 3) despite the use of an electronic order set with evidence-based decision-support to discouraged this practice.

More patients in the intervention group received rescue medication compared to the control group (16.9% vs. 9.7%, $P = 0.01$; Table 3). This difference remained statistically significant after adjustment for potential confounding variables ($P = 0.04$; adjusted odds ratio, 1.68; 95% confidence interval, CI, 1.02-2.88). These results remained unchanged in subgroup analyses stratified by surgery type and anesthetic technique. When stratified by cases under general anesthesia only, statistically significant increases in rescue medication requirement (19.2% vs. 10.8%, $P = 0.01$; Table 4) occurred. No difference was observed for non-general anesthesia cases.

**Discussion**

Our initiative to curb the liberal administration of prophylactic interventions to patients by using a risk-stratified approach was unsuccessful in changing baseline provider practice. The number of medications administered prophylactically actually increased following the intervention. There was no significant difference in repeat medication administration for rescue in the PACU. Rescue medication administration in the PACU increased following our intervention.

These findings were somewhat surprising given prior studies showing reductions in PONV incidence following a risk-adjusted strategy, however, others have struggled to successfully integrate interventions combating PONV.\[21-23\] Using a similar educational strategy, Franck et al.\[23\] found that compliance with their intervention decreased with increasing patient risk, with compliance rates of 92.1%, 35.6%, and 18.6% for low-, moderate- and high-risk patients, respectively. As the low-risk group received no prophylaxis, their results imply that no antiemetics were routinely administered. During

### Table 1: Demographics

| Variable                              | Control | Intervention | $P$   |
|---------------------------------------|---------|--------------|-------|
| Age (years)                           | 55 (17) | 53 (17)      | 0.0810|
| Gender (% Female)                     | 185 (61%) | 195 (64%)  | 0.3741|
| Height (cm)                           | 168 (11) | 168 (11)     | 0.9442|
| Weight (kg)                           | 83 (23)  | 84 (24)      | 0.6525|
| Smoking (% Yes)                       | 34 (12%) | 67 (23%)     | 0.0003*|
| Anesthetic type (% General)           | 213 (69%) | 238 (78%)  | 0.0223*|
| Anesthesia duration (min)             | 135 (95) | 143 (78)     | 0.2783|
| Postoperative opioids (% Yes)         | 120 (39%) | 133 (44%)   | 0.2700|

Values are means (SD) or Count (%), * Significant

### Table 2: Interventions

| Interventions - Overall average | Control | Intervention | $P$    |
|---------------------------------|---------|--------------|--------|
| Suggested Number of Interventions | 1.5 (1.1) | 1.6 (1.2)     | <0.0001*|

Values are means (SD) or Count (%), * Significant
the control period, we observed that the baseline practice at our institution was to routinely administer multiple antiemetics to all patients and curbing this practice was similarly difficult.

Our results indicate an institutional tendency towards liberal prophylaxis. The primary drawback of a liberal approach is the potential risk for adverse effects. However, limitations in discriminative ability of existing risk models can mean certain individuals deemed to be low risk may develop PONV.[24-28] Without superior ways to assess risk, prevention of these unfavorable outcomes may only result from the routine use of indiscriminate multimodal prophylaxis.

Moreover, antiemetics carry a low risk of life-threatening toxicity. The primary concern is QT interval prolongation by agents, such as droperidol and ondansetron, resulting in a black box warning in the case of droperidol. Multiple experts have questioned justification for this black box warning.[29-31] We believe further consideration of these theoretical risks is merited.

Established practice patterns are difficult to break. Our intervention was a decision-support system affording provider freedom in clinical decision-making. Successful trials[12,13] utilizing a risk-stratified approach have employed rigid protocols. Such protocols may be a more feasible way to improve adherence but are impractical in routine clinical settings where patients may be excluded from receiving certain interventions based on comorbidities and/or procedural factors. We chose to focus on application of a risk-stratified approach in a real-world setting and our results underscore pragmatic challenges.

Our study has several limitations. First, the study is from a single center and suffers from limitations inherent to an observational study. Additionally, due to a lack of formal utilization of the Apfel score at our institution prior to the implementation of our program, scores were not available for the pre-intervention group and had to be calculated by chart review. Our cohort was limited to patients with returned intervention sheets portending risk for selection bias. The increase in rescue medication following our intervention likely represents educational bias, with PACU staff more likely to identify and treat PONV following the intervention. Lastly, we were unable to discern rescue treatment between nausea and vomiting due to limitations in existing medical records. Despite these potential shortcomings, this study evaluated implementation of a risk-stratified approach to PONV in a realistic clinical setting serving a generalizable population.

In conclusion, we found that a risk-adjusted strategy to prevent PONV increase was difficult to implement. Our experience highlights the practical issues hindering the widespread use of a risk-stratified approach to combat PONV.

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Conflicts of interest
There are no conflicts of interest.
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