Original Article

The impact of the Apfel scoring system for prophylaxis of post-operative nausea and vomiting: A randomized controlled trial

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Abstract

Background and Aims: Post-operative nausea and vomiting (PONV) is common, undesirable, and stressful following surgery. By focusing attention and resources on those groups of patients most likely to develop PONV, the quality of care provided to the patients can be improved. The primary objective was to compare the incidence of PONV after implementation of the Apfel scoring system with the control group receiving prophylaxis for every surgery. The secondary objective was to identify the effect on the patient's expenditure/savings with respect to management of PONV.

Material and Methods: This prospective randomized controlled double-blinded study enrolled 70 patients undergoing surgeries under general anesthesia. Patients were randomized to group A (control group – all received PONV prophylaxis) and group B (Apfel stratification performed for PONV prophylaxis). Based on the Apfel system, the risk of PONV was classified as the grades low, moderate, and high risk. Patients at moderate and high risk received PONV prophylaxis in group B. Patients were monitored for PONV during 24 h after surgery and rescue medication given as required. The effect of implementing Apfel risk stratification on the incidence of PONV (primary outcome measure) and on patient expenditure was compared.

Results: Compared to administering prophylaxis for all patients, the incidence of PONV [group A-5 patients (14.3%)] did not increase (P = 0.428) after implementing the Apfel scoring system [group B-2 patients (5.7%)]. The number of patients spending on prophylaxis for PONV in group A [35 (100%)] was higher than that in group B [17 (48%)], without increasing expenditure on PONV treatment.

Conclusion: Withholding prophylaxis on the basis of the Apfel scoring system did not increase the incidence of PONV compared to providing prophylaxis for all the patients. The overall cost of prevention and treatment of PONV is less when the Apfel scoring system is used.

Keywords: Apfels` scoring system, post-operative nausea and vomiting, prophylaxis for PONV

Introduction

Post-operative nausea and vomiting (PONV) is undesirable, stressful, and detrimental, especially in the first 24 h of the post-operative period. PONV pathogenesis is multi-factorial and may be initiated by various peri-operative stimuli, such as opioids, volatile anesthetics, anxiety, adverse drug reactions, and pain.[1] It could result in many adverse events such as discomfort, dehiscence of sutures, gastric content aspiration, and esophageal rupture and result in delayed discharge from the hospital.[2] The incidence may be as high as 20–30%.[3]

The intent in providing prophylaxis for PONV is to mitigate the possibility of PONV, thereby improving the quality of

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care. The practice of PONV prophylaxis for every patient undergoing surgery under general anesthesia is seen in many institutions.[4] This practice has been questioned because not all patients undergoing surgery under general anesthesia develop PONV.[5] Scoring systems to predict PONV and identify patients at increased risk for PONV are described in the literature.[4] Such scoring systems or risk stratification systems as introduced by CC Apfel *et al*.[6,7] (Germany) and Koivuranta M *et al*.[8] (Finland) are used to provide PONV prophylaxis to only those patients at high risk for PONV.[4]

This study evaluates the effect of applying risk stratification of the Apfel scoring system on the incidence of PONV and its impact on patient expenditure/savings.

The primary objective was to compare the incidence of PONV after implementation of the Apfel scoring system with the control group receiving prophylaxis for every surgery**.** The secondary objective was to identify the impact of the scoring system on the patient's expenditure/savings with respect to management of PONV.

Material and Methods

This prospective, randomized controlled double-blinded trial was conducted after obtaining approval from Institutional ethics committee and registration at the Clinical Trial Registry of India (CTRI/2019/01/017007). The study was conducted at a tertiary care referral and teaching hospital over a period of 2 years. Conducted over a span of 2 years, the study included patients of either gender, aged between 18 and 65 years, belonging to the American Society of Anesthesiologists physical status I and II, scheduled for various elective surgeries under general anesthesia with tracheal intubation. Patients whose trachea was not extubated after surgery, with known allergy to ondansetron and in whom the metoclopramide drug was used for aspiration prophylaxis were excluded from the study.

Pre-operative evaluation was performed by the anesthesiologist on the day prior to surgery, and written informed consent was obtained from the participants. Standard guidelines for fasting and pre-medication were advised as per the concerned anesthesiologist. During the pre-anesthetic checkup, patients' risk for PONV was assessed as per the Apfel scoring system. Accordingly, the risk factors stated by the scoring system, namely, female gender, non-smoking status, previous history of PONV, and post-operative use of opioids were awarded with a score of 1, with the total score ranging from 0 to 4. The risk of PONV was classified as the grades low (scores 0, 1), moderate (score2), and high risk (scores 3, 4).

On the day of surgery, adequate fasting was confirmed and patients were shifted into the operating room. Consenting adults were randomly allotted to receive routine PONV prophylaxis (group A) or PONV prophylaxis (group B) as per the risk by opening the sealed envelope containing the group allocation for the patient based on the computer-generated random number table. In GROUP A, PONV prophylaxis was provided to all patients with intravenous (IV) ondansetron 0.1 mg/Kg, rounded off to the nearest unit decimal, administered about 30 min prior to expected completion of the surgery. In GROUP B, PONV prophylaxis was provided to the patients with IV ondansetron 0.1 mg/Kg, rounded off to nearest unit decimal, administered about 30 min prior to expected completion of the surgery on the basis of the Apfel score [i.e., only the moderate (score 2) and high (score 3, 4) risk patients received prophylaxis, whereas the low risk patients (score 0, 1) did not receive prophylaxis]. The group allocated was not revealed to the patient, and the specially instructed nurse or anesthesiology resident assessed the number of episodes of nausea and vomiting in the post-anesthetic care unit for 24 h after surgery, thus ensuring blinding.

The standard monitors of pulse oximetry, non-invasive blood pressure, and five-electrode electrocardiography were attached to the patient, and baseline values were documented. Suitable IV access was secured. A standard general anesthesia technique with tracheal intubation was followed by the concerned anesthesiologist in all the patients. Pre-oxygenation was performed for 3 minutes with 100% oxygen. Anesthesia was induced with IV fentanyl and IV propofol. The ease of manual ventilation was confirmed, and neuro-muscular blockade was achieved using IV vecuronium/IV atracurium and ventilated with 2% isoflurane/sevoflurane in 100% oxygen. After 3 minutes of giving the muscle relaxant, intubation was performed with suitable-sized tracheal tubes. Anesthesia and analgesia were maintained according to the discretion of the concerned anesthesiologist with fentanyl/morphine intravenously and/or epidurally (intra-operative/post-operative analgesia) along with non-steroidal anti-inflammatory drugs (NSAID) or paracetamol. Anesthesia was maintained with nitrous oxide or air, oxygen, isoflurane/sevoflurane, and intermittent boluses of vecuronium/atracurium. Use of dexamethasone in the intra-operative period (as for empirical anti-inflammatory/anti-edema measure) and the use of nasogastric tubes in the peri-operative period were noted. The anesthetic technique used in every patient was recorded, and the requirement of post-operative use of opioids was decided pre-operatively based on the type of surgery. At the end of the surgery, all inhalational anesthetic agents were tapered. Once the patient began to have some spontaneous respiratory efforts, reversal of

neuro-muscular blockade was performed using a combination of IV neostigmine and glycopyrrolate based on the weight of the patient and extubation was performed. PONV was monitored for 24 h as episodes complained by the patient or observed by the nurse. The rescue antiemetic that was used in the case of PONV was IV metoclopramide 10 mg. If the PONV episodes persisted despite this rescue medication, then IV dexamethasone 0.2 mg/kg was administered. The requirement for rescue medications was recorded. There were two observers in the study. Observer 1 was the anesthesiology resident who performed the pre-operative evaluation, enrolled the participants based on inclusion and exclusion criteria, obtained written informed consent, and was not blinded to the patient's allocated group. Observer 2 was the specially instructed nurse or anesthesiology resident who was blinded to the group allocation and assessed the number of episodes of nausea and vomiting in the post-anesthetic care unit for 24 h after surgery.

The primary outcome measure was the incidence of PONV. Vomiting or retching, as reported by the patient or observed by the nurse, was considered as an emetic episode. This was assessed in the post-operative period for the first 24 hours. The secondary outcome measures were the cost for prophylaxis and treatment of PONV. This was calculated by data from the actual cost of ondansetron, metoclopramide, and dexamethasone when used or there was a potential use for prophylaxis.

Sample size was calculated using the formula for comparison of two proportions, $n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1-p_1)+p_2(1-p_2))/(p_1-p_2)^2$, where, n = size of the group, $p_1 = 0.3$ (assuming 30% incidence in group A), $p_2 = 0.4$ (incidence of 40% in group B), p_1-p_2 = clinically meaningful difference in proportions of the outcome, β = power of study, $Z_{\alpha/2}$ = two-tailed significance level (1.96 for α at 5% significance), and $Z_{\beta} = 0.84$ for 80% power of study. Sample size was estimated based on the comparison of incidence of PONV among group A and group B. Assuming 30% incidence of PONV in group A and considering an increase in incidence of PONV by 10% in group B because of curtailed PONV prophylaxis to low risk patients in group B, as significant, the sample size required was 35 in each group with 80% power and 5% level of significance. The incidence was based on the audit of PONV incidence in the institution, which matched with the incidence quoted in the literature.[3]

Data were analyzed using *SPSS version 16* for Windows in consultation with the department of medical statistics. Numerical and categorical data were analyzed using the Student t-test, Chi-square test, or Fisher exact test as appropriate. Patient characteristics (age, body weight, body mass index) were compared with the Student t-test. Gender distribution and distribution of Apfel scores in both the groups were compared with the Chi-square test. The incidence of PONV was compared with the Fisher exact test. A *P* value less than 0.05 was considered significant.

Result

Figure 1 shows the consort flow chart of the study. Patient characteristics are given in Table 1. Table 2 shows the Apfel scores of the patients from the two groups. Although patients in group A did not receive PONV prophylaxis based on Apfel scores, all received the prophylaxis; Apfel scoring was performed to see if the risk for PONV was comparable between the two groups. The types of surgeries (including the laparoscopic surgeries) undergone by the patients of both the groups were analyzed and found to be comparable between the two groups. The comparison was performed because the Apfel scoring system does not take into account the type of surgery as a risk factor for identifying patients at high risk for PONV.

Table 3 gives the Apfel scores of patients who had PONV. In group B, patients who were stratified to have a low risk for PONV (and hence did not receive prophylaxis) did not have PONV.

The incidence of PONV during the first 24 h is given in Table 4. There was no significant difference in the incidence of PONV because of implementation of the Apfel scoring system in group B when compared with the incidence of PONV in group A. The incidence of PONV does not increase after application of the Apfel scoring system. The opioid consumption was compared between the two groups

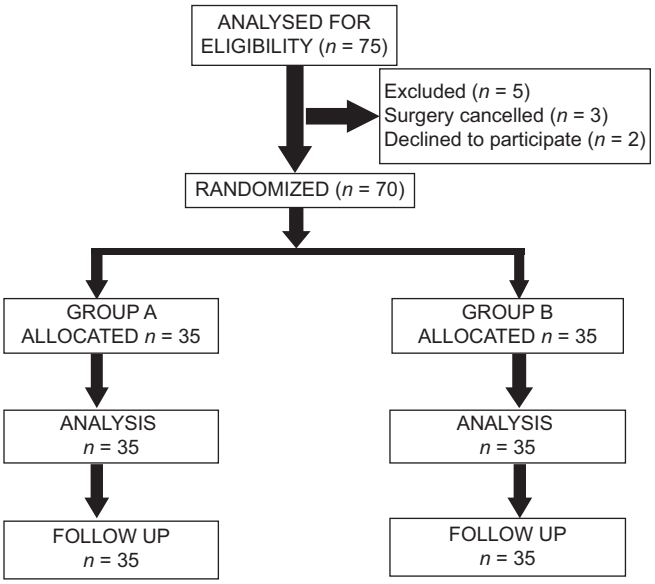

Figure 1: CONSORT flow chart of the study

Table 1: Patient characteristics

	Group A	Group B	*P*
Age (years)	35.9 (12.2)	40.1 (11.7)	0.153
Height (centimeters)	166.8 (8.0)	165.8 (8.6)	0.627
Weight (kilograms)	64.8 (12.1)	63.8 (12.2)	0.724
Body Mass Index (kg/m^2)	23.2 (3.6)	23.1 (3.1)	0.850
Gender (Male/Female)	17/20	18/15	0.473

Data are mean (standard deviation) for age, height, weight, and body mass index; Student t-test used. Data are absolute numbers for gender distribution; Chi-square test used

Table 2: Apfel score of patients in both groups

Apfel Score	Group A *n* (%)	Group B *n* (%)	*P**
0	4 (11.4)	7 (20.0)	
1	8 (22.9)	11 (31.4)	0.172
2	18 (51.4)	9 (25.7)	
3	5 (14.3)	6 (17.1)	
4	0 (0.0)	2 (5.7)	
Total	35 (100)	35 (100)	

**Chi-square test*

Table 3: Patients who had PONV and their Apfel score from both the groups

Apfel score	Group A (*n*)	Group B (*n*)
0	1	0
1	1	0
2	2	1
3	1	1
4	0	0
Total	5	2

Table 4: Incidence of post-operative nausea and vomiting in 24 h

Episodes of PONV in 24 hrs	Group A *n* (%)	Group B *n* (%)
Yes	5 (14.3)	2 (5.7)
No	30 (85.7)	33 (94.3)
Total	35 (100)	35 (100)

Fisher's Exact test; P=0.428

and found to be comparable. None of the patients received dexamethasone intra-operatively nor had nasogastric tubes. All anesthetics included the air–oxygen mixture, and nitrous oxide was not used. All patients who had PONV were treated with the rescue medication IV metoclopramide 10 mg. No patient had to be given IV dexamethasone because of persistent PONV despite treatment with metoclopramide.

Although all the 35 patients belonging to group A spent on the ondansetron ampoules for PONV prophylaxis, only 17 patients from group B had to spend on the ondansetron ampoule because of implementation of Apfel's risk stratification. This translates to additional expenditure of Rs 24 per head in group A, whereas only 17 patients in group B spent this amount. It is noteworthy that although 18 patients did not receive the prophylaxis for PONV from group B as they belonged to low risk group based on the Apfel scoring system, there was no significant increase in the incidence of PONV in group B when compared to the incidence in group A.

Since the number of episodes of PONV in the first 24 h was comparable the cost involved in treatment of PONV (Rs 5 per ampoule of metoclopramide) was also comparable between the two groups.

Discussion

In this study, we determined the impact of implementing the Apfel scoring system for prophylaxis of PONV on the incidence of PONV. We also evaluated the impact of the Apfel scoring system on the expenditure/saving pertaining to the prophylaxis and treatment of PONV.

In total, about six scoring systems have been listed in the literature to anticipate the occurrence of PONV.[6] The scoring systems available to predict the incidence of PONV were compared in a clinical study which found that the Apfel and Koivuranta scoring systems are appropriate instruments to provide a rational and economical antiemetic prophylaxis.[6]

Hence, we picked up the scoring system described by Apfel CC *et al.*[6,7] to determine its impact in predicting the incidence of PONV and on the expenditure/saving if implemented in our daily clinical practice.

This study shows that the Apfel scoring system is effective in identifying the high risk groups for the occurrence of PONV. Even though about 51.4% participants of group B did not receive prophylaxis for PONV based on their Apfel score, this did not result in an increase in the incidence of PONV when compared to group A. This prevents unnecessary exposure of the low risk group of patients for prophylaxis of PONV.

The simplified scoring system demonstrated by Apfel *et al.*[7] in the year of 1998 showed that the low risk group of patients with an Apfel score of 0 or 1 could also have a likelihood for the occurrence of PONV at an incidence of 10% and 21%, respectively. This result when compared with our study showed that out of the 51.4% low risk group participants who did not receive any prophylaxis against PONV, only 5.7% participants had PONV in the 24 h post-operative period. Thereby, our study result was comparable to their findings.

The Apfel scoring system effectively reduces the expenditure in the context of prophylaxis for PONV without causing an increase in the further treatment of PONV. More than half

of the participants of group B (51.4%) did not spend for the prophylaxis of PONV. Only two participants out of the 18 participants who did not receive prophylaxis in group B had PONV as against five participants in group A who had to spend on the treatment of PONV despite receiving the prophylaxis. The extent of saving depends on the actual cost of ondansetron and metoclopramide, which varies from country to country.

Sebastian Pierre and co-workers compared the Apfel scoring system with the scoring system described by Sinclair *et al*.[9] (which considers the type and duration of the surgery as additional risk factors along with the risk factors described by Apfel *et al.*[6,7]). In this study, patients belonged to ASA 1 to 3 and underwent different types of surgeries under general anesthesia with endotracheal intubation. They found that the scoring system described by Apfel *et al*. was better than the scoring system described by Sinclair *et al.*,[9] even though the scoring system of Sinclair *et al*. considered additional important risk factors for developing PONV.[10] Therefore, despite addition of risk factors in other risk stratification systems for PONV, the Apfel system still remains one of the widely used, simple, and validated methods. In a recent validation study, the Apfel scoring system was found to have a favorable sensitivity and specificity in identifying the incidence of PONV and in customizing the antiemetic strategy.[11]

The presence or absence of multiple factors that could have influenced the incidence of PONV (apart from the patient characteristics and the type of surgery which are analyzed in the results) was sought for post-hoc after the study. This included the use of nasogastric tubes, nitrous oxide, duration of surgery, opioid consumption in the intra-operative period, any use of intra-operative steroids, and post-operative feeding patterns. It was found that none of these confounded the results as they were uniformly distributed between the two groups and comparable.

There were some limitations in this study. Multiple factors influencing the incidence of PONV were analyzed post-hoc. These could have been standardized in both the groups in the beginning to avoid their confounding effects. Similarly, the study was not powered sufficiently to interpret whether adverse effects of ondansetron were avoided by implementation of Apfel scoring.

Conclusion

The incidence of PONV does not increase following the implementation of the Apfel scoring system compared to providing prophylaxis for all the patients. Also, the scoring system prevents the unnecessary expenditure on prophylaxis of PONV in the low risk group without increasing the expenditure on treatment of PONV. Hence, implementing the Apfel scoring system is an effective approach to anticipate PONV and to identify patients in whom PONV prophylaxis is warranted.

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Conflicts of interest
There are no conflicts of interest.

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