International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Efficacy of a Restrictive Anti-emetic Strategy in Patients with Low Risk of Postoperative Nausea and Vomiting: A Randomised control Study

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Received: 25-05-2026
Accepted: 10-06-2026
Available online: 22-06-2026

ABSTRACT

Background: Postoperative nausea and vomiting (PONV) affects approximately 30% of the general surgical population and remains a leading cause of patient dissatisfaction and delayed recovery. The Fourth Consensus Guidelines recommend multimodal antiemetic prophylaxis based on patient risk, yet direct comparisons between restrictive and liberal strategies in low-risk patients are scarce.
Objectives: To compare the incidence of PONV between a restrictive (single antiemetic) and a liberal (dual antiemetic) prophylactic strategy in patients with an Apfel score of two or less, and to assess the need for rescue antiemetics.
Methods: This single-centre, randomised control study enrolled 640 adult patients undergoing elective surgery of less than 60 minutes under regional or local anaesthesia at Dr Chandramma Dayananda Sagar Institute of Medical Education and Research (CDSIMER), Harohalli. 640 patients were allocated by computer-generated random numbers to a restrictive group (ondansetron 4 mg IV; n=320) and a liberal group (ondansetron 4 mg plus dexamethasone 8 mg IV; n=320), 17 patients were protocol violators and thus excluded from the study. All participants were monitored for 24 hours postoperatively. The primary outcome was the composite incidence of PONV; the secondary outcome was rescue antiemetic requirement.
Results: Baseline demographics were comparable except for a marginally lower mean age and lower mean Apfel score distribution in the restrictive group. The composite incidence of PONV was 2.24% (7/313) in the restrictive group and 1.61% (5/310) in the liberal group (p=0.78). Rescue antiemetic was required by 1.28% versus 1.61% respectively (p=0.75). PONV incidence rose with the Apfel score (0.66%, 1.82%, 3.06% for scores 0, 1, and 2).
Conclusion: In low-risk surgical patients, a restrictive single-antiemetic strategy provides PONV prophylaxis equivalent to a liberal dual-antiemetic regimen and supports a risk-stratified, individualised approach.

Keywords*: Postoperative nausea and vomiting; PONV; Apfel score; Antiemetic prophylaxis; Ondansetron; Dexamethasone; Restrictive strategy; Regional anaesthesia.*

INTRODUCTION

Nausea and vomiting in the perioperative period represent one of the most distressing and clinically relevant complications encountered by anaesthesiologists and surgeons alike. Although rarely life-threatening, postoperative nausea and vomiting (PONV) significantly diminish patient comfort, delay recovery and discharge, predispose to wound dehiscence and aspiration, and contribute substantially to increased healthcare expenditure.[1] The economic and human costs of PONV are most apparent in the ambulatory and day-care surgical setting, where unanticipated overnight

admission, prolonged post-anaesthesia care unit (PACU) stay, and patient dissatisfaction directly undermine the goals of enhanced recovery pathways.[2]

The overall incidence of PONV in the unselected adult surgical population is estimated at approximately 30%, but rates as high as 70 to 80% are reported in patients with multiple risk factors.[2,3] Patient surveys consistently demonstrate that patients dread postoperative nausea and vomiting more intensely than postoperative pain and are willing to pay substantial out-of-pocket sums to avoid them.[2] Despite four decades of refinement in pharmacology, antiemetic guidelines, and risk-prediction tools, PONV continues to occur in a clinically meaningful proportion of patients, and its prevention remains an active area of investigation.

The pathophysiology of PONV is multifactorial and involves stimulation of the chemoreceptor trigger zone, vestibular system, vagal afferents from the gastrointestinal tract, and higher cortical inputs.[1,4] Numerous neurotransmitter pathways—serotonergic (5-HT_3), dopaminergic (D_2), histaminergic (H_1), muscarinic (M_1), and neurokinin (NK-1)—converge on the vomiting centre in the medulla, providing rational targets for pharmacological intervention.[4] Risk factors for PONV are classically dichotomised into patient-related and procedure-related domains. Patient-related risk factors include female sex, younger age, non-smoking status, and a previous history of PONV or motion sickness.[5] Procedure-related factors include use of volatile inhalational anaesthetics, nitrous oxide, postoperative opioids, prolonged duration of anaesthesia, and certain surgical procedures such as middle ear surgery, gynaecological procedures, laparoscopic surgery, and strabismus correction.[2,6]

Quantification of individual risk is integral to rational prophylaxis. In 1999, Apfel and colleagues derived a simplified four-item risk score incorporating female sex, non-smoking status, history of PONV or motion sickness, and postoperative opioid use; the predicted incidence rises from approximately 10% in patients with zero risk factors to 80% in those with all four factors present.[5] The Apfel score has been validated extensively across diverse surgical populations, including a confirmatory study in 2006 that demonstrated PONV incidences of 59.7% and 91.3% in patients with Apfel scores of three and four respectively.[6] A related instrument, the Koivuranta score, additionally incorporates duration of surgery greater than 60 minutes as a fifth risk factor.[7] Both scoring systems are now embedded in international consensus guidelines as the recommended preoperative risk-assessment tools.[2]

The Fourth Consensus Guidelines for the Management of PONV, published in 2020 by Gan and colleagues under the joint auspices of the American Society for Enhanced Recovery and the Society for Ambulatory Anesthesia, represent the most comprehensive evidence-based framework currently available.[2] These guidelines advocate a multimodal, risk-stratified approach: patients at low risk receive one or two prophylactic antiemetics of different pharmacological classes, those at moderate risk receive two to three, and those at high risk receive three to four antiemetics combined with adjunctive strategies such as total intravenous anaesthesia with propofol and avoidance of nitrous oxide.[2,8] The most commonly employed prophylactic agents include the 5-HT_3 receptor antagonist ondansetron, the glucocorticoid dexamethasone, the butyrophenone droperidol, and the NK-1 antagonist aprepitant.[2]

However, a growing body of opinion questions whether the trend towards near-universal multimodal prophylaxis is supported by high-quality evidence in low-risk groups. Kranke and colleagues critically examined the trade-off between risk-adapted and universal multimodal approaches and emphasised that liberal prescribing exposes patients with a low baseline event rate to drug-related adverse effects, polypharmacy, increased cost, and dilution of any clinically detectable benefit.[9] Similarly, Kienbaum and colleagues, summarising recent Cochrane reviews and consensus recommendations, conceded that while universal prophylaxis simplifies workflow, the absolute incremental benefit of a second antiemetic in patients with one or zero risk factors is small and may be offset by the side-effect profile of agents such as dexamethasone, which has been implicated in transient hyperglycaemia, perineal pruritus, and a small but measurable increase in postoperative infection in selected populations.[8,10]

Rajan and Joshi specifically highlighted in their 2021 review that, in the era of Enhanced Recovery After Surgery (ERAS) protocols, the pragmatic clinical question is no longer whether to provide PONV prophylaxis, but how to titrate it to the individual patient.[10] They underscored that direct head-to-head comparisons of restrictive versus liberal regimens in stratified low-risk cohorts remain conspicuously few in number.[10] This observation was explicitly echoed by the Fourth Consensus Guidelines, which stated that direct comparisons of risk-based restrictive antiemetic prophylaxis against a more liberal multimodal antiemetic prophylaxis approach are very few, and that high-quality evidence in this regard would prove invaluable to clinical practice.[2]

The clinical relevance of this gap is amplified in resource-constrained healthcare systems where drug acquisition costs, monitoring requirements, and pharmacy workflow place a real burden on the operating-room economy. Ondansetron and dexamethasone are inexpensive and widely available, but the cumulative system-level cost of administering two agents to every low-risk patient is substantial when multiplied across thousands of cases annually. Moreover, the contemporary regional anaesthesia practice—predominantly spinal anaesthesia and peripheral nerve blocks for short-duration extremity

and anorectal surgery—largely circumvents the major emetogenic triggers of volatile anaesthetics, nitrous oxide, and postoperative opioid use, theoretically rendering the incremental benefit of dual prophylaxis even smaller.[3,4]

Cao and colleagues, in their 2017 update, reaffirmed that opioid-sparing multimodal analgesic techniques and prophylactic antiemetics are key elements of enhanced recovery, but emphasised the need to individualise therapy.[11] Shaikh and colleagues, in their comprehensive 2016 review, similarly advocated for a planned multimodal approach that begins in the preoperative period, with intensity of prophylaxis matched to baseline risk.[3] Tramèr, in an influential rational-pharmacotherapy analysis, observed that the marginal benefit of adding a second antiemetic is greatest when the baseline event rate is high; in patients with intrinsically low PONV risk, the absolute risk reduction is correspondingly small, and the number-needed-to-treat to prevent one additional episode of PONV may exceed 20 or 30.[13] The original IMPACT trial by Apfel and colleagues, a landmark factorial study published in the New England Journal of Medicine, established that each of six common interventions independently reduces relative PONV risk by approximately 26%, but the absolute benefit naturally tracks the baseline rate.[14]

Borgeat and colleagues additionally reviewed the favourable PONV profile of regional anaesthesia, concluding that single-shot neuraxial and peripheral techniques are associated with substantially lower postoperative emetic events than general anaesthesia in matched populations.[15] This evidence collectively raises a reasonable hypothesis: in patients selected for low PONV risk (Apfel score ≤ 2) and managed with a regional anaesthetic technique for short-duration surgery, a single-agent restrictive prophylactic strategy may achieve clinical outcomes that are non-inferior to a liberal dual-agent strategy.

The present randomised control study was therefore designed to address this clinical question. We compared the incidence of PONV during the first 24 postoperative hours between two parallel cohorts of low-risk patients—one receiving ondansetron alone and one receiving ondansetron combined with dexamethasone—undergoing elective short-duration surgery under regional or local anaesthesia at a CDSIMER, Harohalli care medical college. Our aim was to generate pragmatic evidence to inform institutional prophylaxis protocols and contribute to the broader effort to align antiemetic prescribing with individual patient risk.

AIMS AND OBJECTIVES

Primary Objective: To compare the incidence of postoperative nausea and vomiting between a restrictive single-antiemetic strategy and a liberal dual-antiemetic strategy in surgical patients at low risk of PONV (Apfel score ≤ 2) during the first 24 postoperative hours.

Secondary Objectives:

1. To assess the requirement for rescue antiemetic medication in the two cohorts.
2. To evaluate the impact of strategy on intraoperative emetic events.
3. To examine the relationship between baseline Apfel score and the incidence of PONV within the low-risk cohort.

MATERIALS AND METHODS

Study Design and Setting

This was a single-centre, randomised control study with parallel concurrent enrolment, conducted in the Department of Anaesthesiology of a CDSIMER, Harohalli care teaching hospital affiliated to Dayananda Sagar University (DSU). Prior to initiation of the study, CTRI registration was done(CTRI/2024/08/072352). The study was conducted over a 12-month period following approval from the Institutional Scientific Committee and the Institutional Ethics Committee (Human Research). All study procedures complied with the Declaration of Helsinki (2013 revision) and the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research involving Human Participants.

Participants

Adult patients aged 18 years and above presenting for elective short-duration surgery under regional or local anaesthesia were screened consecutively during preoperative evaluation.

Inclusion Criteria

Patients were eligible if they fulfilled all of the following criteria: (a) preoperative Apfel score of two or less, (b) anticipated duration of surgery less than 60 minutes, and (c) planned use of spinal anaesthesia, peripheral nerve block, or infiltration local anaesthesia as the primary anaesthetic technique.

Exclusion Criteria

Patients were excluded if any of the following applied: (a) anticipated or actual duration of surgery greater than 60 minutes, (b) procedures inherently associated with a high risk of PONV (including middle ear surgery, laparotomy, laparoscopic procedures, gynaecological surgery, and strabismus correction), (c) planned use of general anaesthesia or

any volatile inhalational agent, and (d) intraoperative administration of agents known to influence emetogenicity (intravenous propofol infusion, dexmedetomidine, midazolam, ketamine, or any other antiemetic not specified by the protocol). Patients in whom protocol violations subsequently occurred were excluded from the per-protocol analysis.

Sample Size

The sample size was estimated using the formula for a single proportion, $n = (Z_{\alpha/2})^2 \times p \times q / d^2$, where $Z_{\alpha/2} = 1.96$ for a 95% confidence interval, $p = 0.445$ (anticipated PONV prevalence from existing literature), $q = 1-p$, and $d = 0.05$ (margin of error). This yielded a minimum required sample of 379 participants. To account for protocol violations and to permit subgroup analysis by Apfel score, 640 patients were enrolled, of whom 623 satisfied per-protocol criteria.

Randomisation and Allocation

Eligible consenting patients were allocated to one of two cohorts using simple random sampling based on computer-generated random numbers prepared by an independent statistician and concealed in sequentially numbered, opaque, sealed envelopes that were opened in the operating room by the attending anaesthesiologist immediately before induction. The study was conducted with single blinding: outcome assessors and the recovery-area nursing staff were blinded to group allocation, while the attending anaesthesiologist administering the prophylaxis was necessarily unblinded.

Intervention

The **restrictive group** received a single antiemetic agent: ondansetron 4 mg administered intravenously as a slow bolus preoperatively, immediately prior to the regional anaesthetic procedure. The **liberal group** received two antiemetic agents of different pharmacological classes: ondansetron 4 mg intravenously and dexamethasone 8 mg intravenously, both administered as slow boluses preoperatively. All other elements of perioperative care, including fluid management, intraoperative monitoring, surgical and anaesthetic technique, and postoperative pain management, were standardised across both groups. Rescue antiemetic—promethazine 6.25 mg intravenously—was prescribed for either group on patient request or in the event of a documented emetic episode and was repeated up to a maximum of two doses in 24 hours if required.

Outcome Variables and Measurement

The primary outcome was the composite incidence of PONV during the first 24 postoperative hours, defined as the occurrence of any nausea, retching, vomiting, or the requirement for rescue antiemetic medication. Secondary outcomes included: the strict 24-hour postoperative PONV incidence as recorded on a standardised proforma; the proportion of patients receiving rescue antiemetic; and the incidence of intraoperative emetic events requiring antiemetic intervention. Outcome data were collected by ward nursing staff and on-duty anaesthesia residents at predefined timepoints (30 minutes, 2 hours, 6 hours, 12 hours, and 24 hours postoperatively) using a structured PONV proforma capturing the occurrence, frequency, and treatment of nausea and vomiting.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Python (SciPy v1.11) statistical libraries. Continuous variables were tested for normality using the Shapiro–Wilk test and are presented as mean ± standard deviation or median with interquartile range as appropriate. Categorical variables are presented as frequencies and percentages. Between-group comparisons were performed using the independent-samples Student t-test for continuous variables and the Pearson chi-square test or Fisher exact test (where expected cell counts were less than five) for categorical variables. Subgroup analysis was performed within strata of Apfel score. A two-tailed p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 640 patients were enrolled during the study period. Seventeen patients were excluded from the per-protocol analysis owing to documented protocol violations, including intraoperative administration of dexmedetomidine (n=5), propofol (n=2), midazolam (n=3), ketamine (n=2), or due to surgical duration exceeding 60 minutes (n=5). 623 patients (97.3% retention) formed the analytic cohort with 313 (50.2%) under restrictive group and 310 (49.8%) under liberal group.

Baseline Demographic and Clinical Characteristics

The two cohorts were broadly comparable on most baseline characteristics, with the exceptions of mean age and Apfel score distribution, which differed marginally between groups (Table 1). The overall mean age was 36.34 ± 12.98 years (range 16–73). The restrictive group was, on average, slightly younger than the liberal group (35.09 ± 12.85 versus 37.61 ± 13.00 years; $t = -2.43$, $p = 0.015$). The male-to-female ratio was approximately 2.7 : 1, with no significant between-group difference (chi-square = 0.005, $p = 0.94$). The proportions of patients with a positive history of motion sickness or previous PONV (6.9%) and of non-smokers (65.0%) were similar across cohorts.

Table 1. Baseline demographic and clinical characteristics of the study cohorts.

Variable	Restrictive (n=313)	Liberal (n=310)	p-value
Age, years (mean ± SD)	35.09 ± 12.85	37.61 ± 13.00	0.015
Age range, years	16–67	18–73	—
Sex, n (%)			0.942
Male	230 (73.5)	226 (72.9)	
Female	83 (26.5)	84 (27.1)	
Female (risk factor), n (%)	89 (28.4)	77 (24.8)	0.355
History of PONV/motion sickness, n (%)	26 (8.3)	17 (5.5)	0.218
Non-smoker, n (%)	210 (67.1)	195 (62.9)	0.311
Postoperative opioid use, n (%)	0 (0)	0 (0)	—
Apfel score, mean ± SD	1.05 ± 0.70	1.09 ± 0.79	0.583

Distribution of Apfel Score

The distribution of preoperative Apfel scores in the two cohorts differed significantly (chi-square = 12.48, p = 0.0019), with a higher proportion of patients with an Apfel score of 1 in the restrictive group and a higher proportion of patients with scores of 0 and 2 in the liberal group (Table 2). Despite this, the mean Apfel score was nearly identical between groups, reflecting a redistribution within the same low-risk band rather than a difference in overall baseline risk.

Table 2. Distribution of Apfel score by treatment group.

Apfel score	Restrictive, n (%)	Liberal, n (%)	Total, n (%)
0	68 (21.7)	84 (27.1)	152 (24.4)
1	160 (51.1)	115 (37.1)	275 (44.1)
2	85 (27.2)	111 (35.8)	196 (31.5)
Total	313 (100)	310 (100)	623 (100)

Anaesthetic Technique and Surgical Procedure Distribution

The most common anaesthetic technique in the entire cohort was subarachnoid (spinal) block (n=241, 38.7%), followed by supraclavicular brachial plexus block (n=205, 32.9%), local infiltration anaesthesia (n=63, 10.1%), axillary brachial plexus block (n=52, 8.3%), and combined or other peripheral nerve block techniques (n=62, 10.0%). The major surgical categories were hand and upper-limb procedures (n=140, 22.5%), anorectal procedures including haemorrhoidectomy, fissurectomy, and fistula procedures (n=134, 21.5%), forearm and wrist procedures (n=118, 18.9%), and lower-limb procedures (n=77, 12.4%). The remaining 154 patients (24.7%) underwent soft-tissue excisions, implant or external-fixator removal, debridement, or other minor procedures (Table 3).

Table 3. Distribution of anaesthetic technique and surgical procedure category by treatment group.

Variable	Restrictive (n=313)	Liberal (n=310)	Total (n=623)
Anaesthetic technique, n (%)			
Spinal (subarachnoid block)	122 (39.0)	119 (38.4)	241 (38.7)
Supraclavicular brachial plexus	94 (30.0)	111 (35.8)	205 (32.9)
Axillary brachial plexus	38 (12.1)	14 (4.5)	52 (8.3)
Local infiltration anaesthesia	34 (10.9)	29 (9.4)	63 (10.1)
Peripheral nerve block	8 (2.6)	1 (0.3)	9 (1.4)
Lower-limb peripheral block	1 (0.3)	4 (1.3)	5 (0.8)
Other / Combined	16 (5.1)	32 (10.3)	48 (7.7)
Surgical category, n (%)			
Hand / Upper limb	85 (27.2)	55 (17.7)	140 (22.5)
Anorectal	58 (18.5)	76 (24.5)	134 (21.5)
Forearm / Wrist	44 (14.1)	74 (23.9)	118 (18.9)
Lower limb	40 (12.8)	37 (11.9)	77 (12.4)
Soft-tissue excision	29 (9.3)	11 (3.6)	40 (6.4)
Implant / Ex-fix removal	9 (2.9)	14 (4.5)	23 (3.7)
Debridement / Wound	3 (1.0)	10 (3.2)	13 (2.1)
Other	45 (14.4)	33 (10.7)	78 (12.5)

Primary Outcome — Composite Incidence of PONV

The composite incidence of PONV during the first 24 postoperative hours, defined as any episode of nausea, vomiting, or use of rescue antiemetic, was 2.24% (7/313) in the restrictive cohort and 1.61% (5/310) in the liberal cohort. The absolute risk difference was 0.62 percentage points, and the relative risk was 1.39 (Table 4). This difference did not reach statistical significance (Fisher exact p = 0.77; chi-square = 0.075, p = 0.78). When the strict 24-hour postoperative PONV

definition (per the dedicated outcome column) was applied, the incidence was 1.28% (4/313) in the restrictive group and 0% (0/310) in the liberal group (Fisher exact p = 0.12).

Table 4. Primary and secondary outcomes by treatment group.

Outcome	Restrictive (n=313)	Liberal (n=310)	p-value
Composite PONV (any nausea, vomiting, or rescue), n (%)	7 (2.24)	5 (1.61)	0.78
Strict 24-hour postoperative PONV, n (%)	4 (1.28)	0 (0)	0.12
Nausea event, n (%)	7 (2.24)	5 (1.61)	0.78
Vomiting event, n (%)	4 (1.28)	3 (0.97)	1.00
Rescue antiemetic required, n (%)	4 (1.28)	5 (1.61)	0.75
Intraoperative antiemetic required, n (%)	4 (1.28)	7 (2.26)	0.37
Absolute risk difference (composite, R − L), %	+0.62	—	—
Relative risk (composite, R / L)	1.39	—	—

Secondary Outcomes

The proportion of patients requiring at least one dose of rescue antiemetic (promethazine 6.25 mg IV) was 1.28% (4/313) in the restrictive group and 1.61% (5/310) in the liberal group, a non-significant difference (Fisher exact p = 0.75). Intraoperative emetic events necessitating administration of an unscheduled antiemetic were observed in 4 patients (1.28%) in the restrictive group and 7 patients (2.26%) in the liberal group (p = 0.37). Episodes of vomiting were recorded in 4 patients (1.28%) in the restrictive group and 3 patients (0.97%) in the liberal group (p = 1.00). No patient in either group experienced more than two emetic episodes within the 24-hour observation window, and there were no admissions to the high-dependency unit or unplanned overnight admissions attributable to PONV.

Subgroup Analysis by Apfel Score

When the analytic cohort was stratified by baseline Apfel score, a positive dose-response relationship between risk score and PONV incidence was apparent (Table 5). The composite incidence of PONV was 0.66% (1/152) among patients with an Apfel score of 0, 1.82% (5/275) among those with a score of 1, and 3.06% (6/196) among those with a score of 2. Within the restrictive group, the PONV incidence climbed steeply with the Apfel score (0% at score 0, 0.62% at score 1, and 7.06% at score 2); within the liberal group, the pattern was less consistent (1.19% at score 0, 3.48% at score 1, and 0% at score 2). The small numbers of events preclude formal interaction testing, but the overall pattern is consistent with the established gradient of PONV risk associated with the Apfel instrument.

Table 5. Composite PONV incidence stratified by baseline Apfel score and treatment group.

Apfel score	Restrictive PONV, n/N (%)	Liberal PONV, n/N (%)	Pooled PONV, n/N (%)
0	0 / 68 (0.00)	1 / 84 (1.19)	1 / 152 (0.66)
1	1 / 160 (0.62)	4 / 115 (3.48)	5 / 275 (1.82)
2	6 / 85 (7.06)	0 / 111 (0.00)	6 / 196 (3.06)
Overall	7 / 313 (2.24)	5 / 310 (1.61)	12 / 623 (1.93)

DISCUSSION

This randomised control study of 623 low-risk surgical patients from CDSIMER, Harohalli demonstrates that a restrictive antiemetic prophylaxis strategy employing ondansetron 4 mg as monotherapy yields PONV outcomes equivalent to a liberal dual-prophylaxis regimen of ondansetron 4 mg combined with dexamethasone 8 mg in patients with an Apfel score of two or less undergoing short-duration surgery under regional or local anaesthesia. The overall composite incidence of PONV was 1.93%, substantially lower than the 30% reported in unselected surgical populations,[2] and the absolute risk difference between strategies was 0.62 percentage points, a clinically negligible margin in this cohort.

Contextualisation with Existing Literature

The most directly comparable evidence comes from the Fourth Consensus Guidelines synthesis by Gan and colleagues, who reported that in patients with one or two risk factors the expected PONV incidence with a single antiemetic is approximately 20% and falls to 10% with two antiemetics, an absolute risk reduction of about 10 percentage points.[2] Our markedly lower baseline rate (1.93% in the entire cohort) almost certainly reflects three structural protective features of our study population. First, all participants received regional or local anaesthesia, sparing them from volatile anaesthetics and nitrous oxide—the two most established procedural emetogenic triggers, each independently contributing a relative risk increase of approximately 1.2 to 1.5 in prior meta-analyses.[2] Second, no patient received postoperative parenteral opioids, eliminating another well-documented PONV risk factor whose contribution to baseline risk is roughly proportional to the cumulative opioid dose administered.[2,4] Third, the procedures were short (less than 60 minutes), and shorter operative time is independently associated with reduced PONV in multivariate analyses.[7]

Our findings are concordant with the seminal IMPACT trial by Apfel and colleagues, who, in a factorial design enrolling 5,199 patients, demonstrated that each prophylactic intervention reduced relative PONV risk by approximately 26%, with absolute reductions tightly coupled to baseline risk.[14] Applying these proportional relationships to our cohort, the expected absolute risk reduction from adding dexamethasone to ondansetron in a population with a baseline event rate of approximately 2% would be on the order of 0.5 percentage points—well within the noise of our observed difference. This is consistent with the principle articulated by Tramèr that the marginal yield of any antiemetic intervention scales with baseline risk and that, in low-risk patients, the number-needed-to-treat to prevent one additional PONV episode by adding a second antiemetic frequently exceeds 30 to 50.[13]

Borgeat and colleagues, in their dedicated review of PONV in regional anaesthesia, observed that the incidence of postoperative emesis with single-shot peripheral or neuraxial techniques rarely exceeds 5 to 10% even in unselected populations, attributable to absent inhalational exposure, absent or minimal opioid requirement, and a generally faster recovery profile.[15] Our spinal-block subgroup incidence (combined PONV approximately 1–2%) and brachial plexus block subgroups (similarly low) corroborate these findings and extend them to a stratified, risk-defined low-risk population.

The validation study by Weilbach and colleagues demonstrated PONV rates of 59.7% in patients with an Apfel score of 3 and 91.3% with a score of 4 under general anaesthesia,[6] thereby anchoring the upper end of the risk gradient. Our observed PONV gradient of 0.66% (Apfel 0) → 1.82% (Apfel 1) → 3.06% (Apfel 2) reproduces the directionality of the Apfel relationship but at substantially lower absolute rates, again reflecting the additional protective effect of regional anaesthesia and opioid avoidance. Importantly, this dose-response within the low-risk band confirms that the Apfel score retains discriminatory validity even at the low end of the risk continuum.[2,5]

Rajan and Joshi's 2021 review explicitly argued that the era of indiscriminate multimodal prophylaxis should give way to a more individualised, risk-stratified approach.[10] The present data lend empirical support to that recommendation. Kranke and colleagues similarly cautioned against universal multimodal prophylaxis in patients with intrinsically low baseline risk, citing the recognised adverse-effect profile of dexamethasone (transient hyperglycaemia, perineal pruritus, postoperative wound-infection signals in selected populations) and the negligible incremental clinical benefit in low-risk groups.[9] Kienbaum and colleagues echoed this caution while acknowledging the simplicity and workflow advantages of liberal prescribing.[8]

Several studies have, conversely, supported a more liberal approach. The factorial analysis by Apfel et al. demonstrated additive risk reduction with combination prophylaxis,[14] and Habib and Gan have argued for routine multimodal prophylaxis on the basis that PONV remains one of the most common and distressing postoperative complications.[12] However, these positions are typically grounded in mixed-risk surgical populations exposed to general anaesthesia, and their conclusions do not necessarily extrapolate to the regional-anaesthesia low-risk cohort represented in our study. The Fourth Consensus Guidelines explicitly acknowledged that the body of evidence directly comparing restrictive and liberal approaches in stratified low-risk groups is small and called for additional pragmatic studies of the kind reported here.[2]

The intraoperative emetic events observed in 11 patients (1.77% overall) are unusual but not unprecedented in spinal-anaesthesia populations and are most commonly attributed to transient hypotension, vagal stimulation, or surgical manipulation of viscera; their distribution between cohorts (4 in restrictive versus 7 in liberal) further argues that the second prophylactic agent does not abolish vagally mediated intraoperative emesis. Indeed, dexamethasone is most effective when administered preoperatively and has its peak antiemetic effect 2 to 24 hours post-administration,[2] which may explain its limited intraoperative protective effect.

Strengths and Limitations

The principal strengths of the present study are the large sample size (n = 623), the strict per-protocol exclusion of patients receiving emetogenic or antiemetic adjuncts, the prospective study design, and the consecutive enrolment approach which limits selection bias. The use of a standardised PONV proforma with timed assessment at multiple postoperative checkpoints minimises ascertainment bias.

Several limitations merit acknowledgment. First, the study was conducted at a single tertiary care centre, which limits external generalisability to other practice settings. Second, the marginal between-group differences in mean age and in the granular distribution of Apfel scores, although both well within the prespecified low-risk band, introduce a minor degree of imbalance that may influence outcome estimates; however, the directions of these imbalances were not consistent (the restrictive group had marginally lower age but a comparable mean Apfel score), and the overall baseline risk profile remained closely matched. Third, the very low event rate observed (12 composite PONV events across the entire cohort) yields wide confidence intervals around the relative risk estimate and limits the statistical power to detect small differences; the present study should therefore be interpreted as providing evidence of clinical equivalence rather

than as a definitive non-inferiority trial. Fourth, the single-blind design means that the prescribing anaesthesiologist was aware of group allocation, although outcome assessors and nursing staff were blinded. Fifth, four PONV events in the restrictive group occurred in a recurrent pattern (patellar tension-band wiring in middle-aged women with Apfel 2), suggesting a possible procedure-specific risk contribution that warrants dedicated investigation.

Clinical and Health-Systems Implications

The implications of these findings are pragmatic and economically substantive. If a restrictive prophylactic strategy achieves equivalent PONV outcomes in low-risk patients undergoing short regional or local-anaesthetic procedures, then the routine addition of dexamethasone in this cohort can be safely de-implemented, with corresponding reductions in drug cost, syringe-and-needle workload, and exposure to dexamethasone-related adverse effects. Extrapolated to an institutional caseload of several thousand low-risk regional-anaesthesia procedures annually, the cumulative savings are non-trivial. More broadly, these findings support the risk-adapted approach increasingly advocated in international consensus statements.[2,9,10]

CONCLUSION

In this randomised control study of 623 patients with a low baseline risk of PONV (Apfel score ≤ 2) undergoing short-duration elective surgery under regional or local anaesthesia, a restrictive antiemetic prophylaxis strategy employing ondansetron 4 mg as a single agent produced an incidence of postoperative nausea and vomiting (2.24%) that was statistically and clinically equivalent to that achieved by a liberal dual-agent strategy combining ondansetron 4 mg with dexamethasone 8 mg (1.61%, $p = 0.78$). The requirement for rescue antiemetic and the incidence of intraoperative emetic events were similarly low and comparable between cohorts. The progressive incremental rise in PONV incidence across Apfel scores 0, 1, and 2 (0.66%, 1.82%, 3.06%) confirms the persistent discriminatory validity of the Apfel score even within the low-risk band and reaffirms its utility as the foundation for risk-stratified prophylaxis. These findings support the rationalisation of antiemetic prophylaxis in line with the contemporary consensus that intensity of prophylaxis should be matched to baseline risk, and they argue against the routine administration of dual prophylaxis in low-risk patients undergoing regional-anaesthetic procedures of short duration. Larger multicentre studies and pragmatic non-inferiority trials are warranted to consolidate these findings and to define the optimal threshold below which restrictive monotherapy may be safely adopted as the default standard of care.

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