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Steroid-Sparing De-escalation of Antiemetic Prophylaxis After Initial Control with a Four-Drug Regimen in Anthracycline/Cyclophosphamide Chemotherapy

Yoshihiro Yamamoto
pal-mt38@dpc.agu.ac.jp

Aichi Gakuin University
Tomohiro Fukuoka
Komaki City Hospital
Norio Watanabe
Aichi Gakuin University
Hiroki Hayashi
Komaki City Hospital
Motozumi Ando
Aichi Gakuin University
Midori Furukawa
Komaki City Hospital
Go Hirano
Komaki City Hospital
Sumiyo Noda
Komaki City Hospital
Yuko Deguchi
Komaki City Hospital

Research Article

Keywords: breast cancer, chemotherapy-induced nausea and vomiting, highly emetogenic chemotherapy, de-escalation strategy, dexamethasone

Posted Date: November 11th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10615919/v1

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Additional Declarations:
No competing interests reported.

Tables 1 to 3 are available in the Supplementary Files section.

Title

Steroid-Sparing De-escalation of Antiemetic Prophylaxis After Initial Control with a Four-Drug Regimen in Anthracycline/Cyclophosphamide Chemotherapy

Running title

De-escalation of Antiemetic Therapy in AC Chemotherapy

Yoshihiro Yamamoto[1], Tomohiro Fukuoka[2], Norio Watanabe[1], Hiroki Hayashi[2], Motozumi Ando[1], Midori Furukawa[3], Go Hirano[3], Sumiyo Noda[3], Yuko Deguchi[2]

[1]Department of Pharmaceutical Sciences, School of Pharmacy, Aichi Gakuin University, Nagoya, Aichi, Japan

[2]Departments of Pharmacy, Komaki City Hospital, Komaki, Aichi, Japan

[3]Department of Surgery, Komaki City Hospital, Komaki, Aichi, Japan

Correspondence to: Yoshihiro Yamamoto, Department of Pharmaceutical Sciences, School of Pharmacy, Aichi Gakuin University, Nagoya, Aichi, Japan 464-8650, Japan

1 Tel.: +81 527512561

2 Fax: +81 527576799

3 Email: pal-mt38@dpc.agu.ac.jp

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Abstract

Purpose: The 2023 Japanese provide a weak recommendation for limiting dexamethasone administration to a single day in anthracycline/cyclophosphamide (AC) regimens. Since April 2022, our institution has been using a four-drug regimen, including olanzapine. To reduce steroid exposure, we implemented a steroid-sparing strategy from the second cycle onward in patients with adequate first-cycle control. This study aimed to evaluate the feasibility and clinical outcomes of this approach.

Methods: This single-center retrospective study included hospitalized patients with breast cancer who received AC regimens between April 2022 and April 2024. The endpoints included the complete response (CR) rate during the first cycle and incidence of nausea, vomiting, appetite loss, and other adverse events after dexamethasone omission. In patients with no or mild first-cycle nausea, de-escalation was proposed after explanation, and dexamethasone was reduced or omitted from the second cycle upon agreement.

Results: Forty patients were analyzed, and the first-cycle CR rate was 72.5%. Among the 13 patients who underwent steroid omission, the CR rate decreased from 69.2% to 46.2%. Nausea increased from 53.8% to 76.9% and vomiting from 0% to 23.1%. Most worsening events were

low grade, and no severe complications were observed.

Conclusion: Early steroid omission was temporally associated with the deterioration of gastrointestinal symptoms in a substantial proportion of patients. These findings do not conclusively negate steroid-sparing strategies in AC regimens, but suggest that de-escalation should be cautiously implemented, with careful patient selection and attention to timing. Prospective studies are warranted to clarify the optimal candidates and refine the de-escalation approaches.

Keywords**:** breast cancer; chemotherapy-induced nausea and vomiting; highly emetogenic chemotherapy; de-escalation strategy; dexamethasone

Introduction

Anthracycline and cyclophosphamide combination regimens (AC regimens) for breast cancer are classified as highly emetic chemotherapy (HEC) and carry a high risk of chemotherapy-induced nausea and vomiting (CINV) [1,2]. Therefore, effective prophylactic antiemetic therapy is essential to maintain treatment adherence and patient quality of life.

The addition of olanzapine to conventional triple antiemetic therapy (a neurokinin-1 receptor antagonist, a 5-hydroxytryptamine-3 receptor antagonist, and dexamethasone) has significantly improved the control of both acute and delayed CINV [3-5]. Reflecting accumulating evidence, the 2023 Japanese antiemetic guidelines recommend a four-drug regimen, including olanzapine, as the standard prophylaxis for HEC, including AC regimens [1].

Building on these advances, “steroid-sparing” strategies that shorten the duration of dexamethasone administration have gained attention as a means of reducing corticosteroid exposure while preserving antiemetic efficacy. Although dexamethasone remains a key component of prophylaxis, concerns regarding cumulative steroid exposure [6] have prompted investigations into abbreviated dosing schedules.

Regarding dexamethasone duration, evidence from a randomized controlled trial

demonstrated that a steroid-sparing strategy was not inferior to cisplatin-based regimens, whereas non-inferiority was observed in patients receiving AC regimens [7]. Based on these findings, the 2023 Japanese guidelines issue a weak recommendation for limiting dexamethasone administration to a single day, specifically for AC regimens, rather than for all HEC regimens [1].

However, this recommendation is supported by a limited body of evidence, and the overall balance between the benefits and harms has not been fully established [1]. Notably, a trial demonstrating the non-inferiority of steroid reduction in AC regimens was conducted using a three-drug antiemetic regimen without olanzapine [7,8]. As contemporary standard practices increasingly incorporate olanzapine into prophylactic therapy, the effectiveness of dexamethasone de-escalation within the four-drug regimens for AC chemotherapy remains unclear.

In clinical practice, avoiding unnecessary medication exposure while maintaining adequate CINV control is an important objective. At our institution, patients receiving AC regimens are treated with a four-drug antiemetic regimen during the first cycle. For patients who achieve favorable antiemetic control, dexamethasone is reduced or omitted from the second cycle

onward as a de-escalation strategy. However, the feasibility and clinical outcomes of this approach have not been systematically evaluated.

Therefore, this study aimed to assess the feasibility and clinical utility of a steroid-sparing strategy implemented from the second cycle onward in patients with breast cancer who achieved adequate antiemetic control during the initial cycle of AC chemotherapy.

Study methods

1. Study Design and Patient Eligibility

This single-center, retrospective observational study included consecutive adult patients (aged ≥ 18 years) with breast cancer who received AC regimens, either doxorubicin plus cyclophosphamide or epirubicin plus cyclophosphamide, as neoadjuvant or adjuvant therapy at Komaki City Hospital between April 2022 and April 2024.

Eligible patients received a four-drug antiemetic regimen, including olanzapine, during the first chemotherapy cycle. Patients were excluded if they did not adhere to the prescribed four-drug regimen, including olanzapine, were concurrently receiving opioids or other medications known to induce nausea or vomiting, or had electrolyte abnormalities or organic conditions potentially

contributing to nausea or vomiting.

This study was conducted in accordance with the Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects issued by the Japanese government and was approved by the Institutional Review Board of Komaki City Hospital (approval no. 251033).

2. Antiemetic Regimen and De-escalation Strategy

Beginning in April 2022, a four-drug antiemetic regimen was adopted as standard prophylaxis at our institution, in agreement with breast surgeons. On day 1, the patients received palonosetron (0.75 mg intravenously), dexamethasone (12 mg intravenously), aprepitant (125 mg orally), and olanzapine (5 mg orally after dinner). From day 2 onward, olanzapine (5 mg orally after dinner) was continued until day 5, dexamethasone (8 mg orally) on day 4, and aprepitant (80 mg orally) on days 2 and 3. Metoclopramide 5 mg was prescribed as a rescue medication up to three times daily, as required.

For patients who did not experience vomiting and nausea or only experienced grade 1 nausea during the first cycle, the feasibility of antiemetic de-escalation and proposed steroid omission was assessed by physicians or pharmacists. When de-escalation was considered clinically

acceptable, the potential risks and benefits of antiemetic prophylaxis reduction were explained to the patients. Dexamethasone reduction or omission, discontinuation of olanzapine, or modification of both agents from the second cycle onward was implemented only when both the attending physician and patient agreed to the change.

Several de-escalation patterns were implemented in clinical practice. For analytical purposes, the patients were classified into the following groups from the second cycle onward into the following groups: (1) steroid-sparing group, defined as patients who underwent dexamethasone omission without changes to other antiemetic agents; (2) no de-escalation group, defined as patients who continued the original four-drug regimen without modification; and (3) mixed de-escalation group, defined as patients who underwent modification with both dexamethasone and olanzapine or olanzapine discontinuation alone.

Comparative analyses were performed between the steroid-sparing and no de-escalation groups to specifically evaluate the clinical impact of steroid omission. Patients in the mixed de-escalation group were excluded from the comparative analyses but were described in the patient flow diagram.

3. Chemotherapy Regimens

The patients received either doxorubicin (60 mg/m²) plus cyclophosphamide (600 mg/m²) or epirubicin (90 mg/m²) plus cyclophosphamide (600 mg/m²) intravenously on day 1. The regimens were repeated every 3 or 2 weeks in a dose-dense schedule. For patients with triple-negative breast cancer, pembrolizumab was concomitantly administered on day 1. The relative dose intensity was calculated based on cytotoxic agents only, and immune checkpoint inhibitors were excluded from this calculation.

4. Data Collection and Outcome Measures

All patients who received AC regimens with four-drug antiemetic prophylaxis during the first cycle were included in the overall cohort (n = 40). The first-cycle efficacy and safety were assessed in the entire population. From the second cycle onward, the outcomes were evaluated in the steroid-sparing (n = 13) and no de-escalation (n = 16) groups. Patients in the mixed de-escalation group (n = 11) were excluded from the primary comparative analysis to isolate the effects of steroid modification. The incidences of nausea, vomiting, anorexia, and other adverse events were descriptively compared between the two groups.

The primary efficacy endpoint was the complete response (CR) rate, defined as no emetic episodes and no use of rescue antiemetic medication during the overall phase (0–120 h). The

secondary endpoints included the incidence of nausea and vomiting during the acute (0–24 h), delayed (24–120 h), and overall phases, use of rescue medications, and incidence of anorexia. Baseline characteristics collected from the medical records included age, sex, Eastern Cooperative Oncology Group performance status, clinical stage, chemotherapy regimen, and relative dose intensity.

The patients were provided with a self-administered diary to record adverse events, including nausea, vomiting, food intake, constipation, and hiccups. At each subsequent visit, the pharmacists conducted structured interviews using a standardized checklist to confirm and document chemotherapy-related events. Adverse events were graded according to the Common Terminology Criteria for Adverse Events version 4.0.

5. Statistical Analyses

Continuous variables are presented as medians with ranges and categorical variables as frequencies and percentages. Given the small sample size and exploratory nature of this study, formal statistical hypothesis testing was not performed, and results are descriptively presented. The exact 95% confidence intervals (CIs) for the proportions were calculated using the Clopper–Pearson method.

Results

1. Patient Demographics

A flowchart of the patient selection process is shown in Fig. 1. Of the 82 screened patients, 40 met the inclusion criteria. The remaining 42 patients were excluded because of treatment for advanced or recurrent disease (n = 6) or deviation from the protocol-specific antiemetic regimen (n = 36). From the second cycle onward, 13, 16, and 11 patients were classified into the steroid-sparing, no de-escalation, and mixed de-escalation groups, respectively.

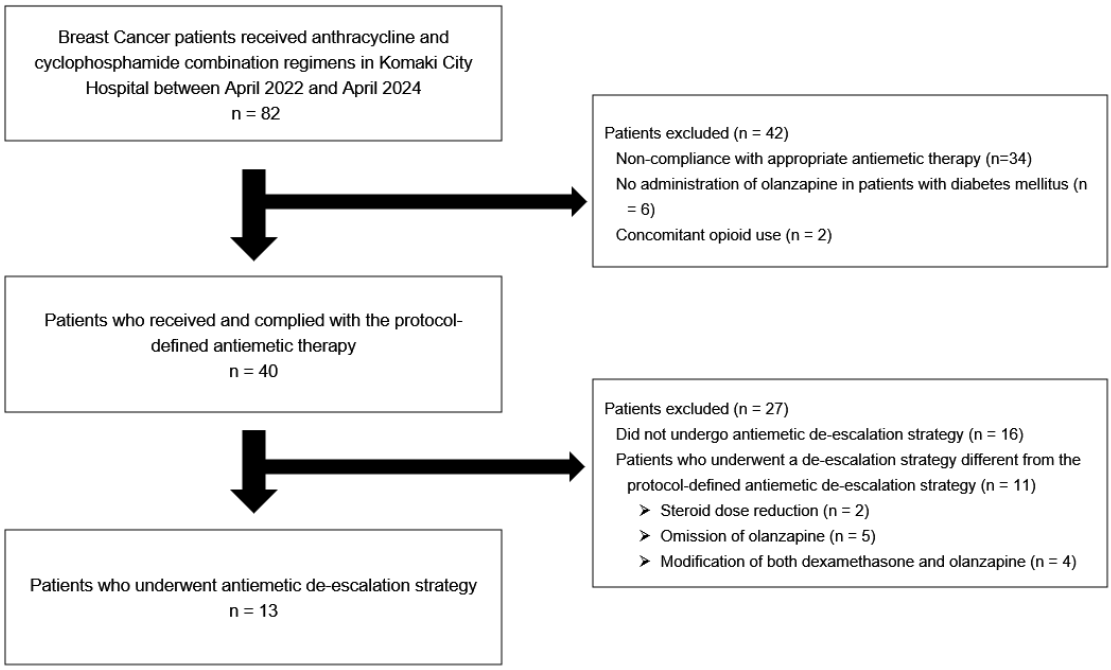


Figure 1

The baseline characteristics of the overall cohort and the steroid-sparing and no de-escalation groups are summarized in Table 1. No clinically apparent imbalances were descriptively noted

between the steroid-sparing and no de-escalation groups with respect to age (median, 50 vs. 60 years), performance status, clinical stage, chemotherapy regimen, and relative dose intensity. Approximately half of the patients received epirubicin- or doxorubicin-based AC regimens, and the dose-dense schedule was exclusively used in the epirubicin regimen. The median relative dose intensity was 97.7% (range, 72.6–103.4%). None of the patients had renal or hepatic dysfunction, electrolyte abnormalities, or history of diabetes mellitus at baseline.

2. Efficacy of Antiemetic Therapy

2-1. Efficacy of the four-drug antiemetic regimen, including olanzapine

During the first chemotherapy cycle, the overall CR rate was 72.5% (95% CI, 56.1–85.4%) (Table 2). The incidence rate of nausea was 37.5% (all grade 1 in severity), and no vomiting events were observed. Importantly, none of the patients experienced grade 2 or higher nausea or vomiting during the first cycle. Loss of appetite was observed in 57.5% of the patients, including two patients with grade 2 anorexia.

Based on first-cycle outcomes, 38 of the 40 patients (excluding two patients with grade 2 anorexia) were considered eligible for antiemetic de-escalation by pharmacists, and this recommendation was communicated to the attending physicians. Among these 38 patients, 24

provided consent and subsequently underwent antiemetic de-escalation from the second cycle onward.

2-2. Efficacy after the antiemetic de-escalation strategy

Among the 24 patients who underwent de-escalation, 13 were classified into the steroid-sparing group (without modification of other antiemetics) and 11 were categorized into the mixed de-escalation group. Because the mixed de-escalation group involved heterogeneous modifications of antiemetic therapy (e.g., olanzapine discontinuation or combined changes), these patients were not included in the primary comparative analysis to isolate the effects of steroid omission. In the steroid-sparing group (n = 13), steroid omission was initiated from the second cycle in seven patients and from the third cycle in six patients. The CR rate and other antiemetic outcomes after implementation of the steroid-sparing strategy are presented in Table 2. Following steroid omission, antiemetic control deteriorated. The CR rate decreased from 69.2% (95% CI, 38.6–90.9%) in the first cycle to 46.2% (95% CI, 19.2–74.9%) after steroid sparing. In the acute phase, vomiting was generally well controlled. Only one patient required rescue antiemetic therapy during the acute phase of the fourth cycle, and no acute-phase vomiting events were observed. In the overall cohort, the acute-phase CR rate was 92.5%. Vomiting

control remained largely preserved, and the observed deterioration in antiemetic outcomes was primarily driven by increased nausea and appetite loss, rather than severe vomiting. The incidence rate of nausea increased from 53.8% to 76.9%, and vomiting occurred in three patients (23.1%), all grade 1 events. Among the patients who had grade 1 nausea prior to steroid sparing, three experienced worsening to grade 2 nausea. Overall, eight of the 13 patients (61.5%) in the steroid-sparing group experienced some degree of worsening of gastrointestinal symptoms, including nausea, vomiting, or appetite loss, following steroid omission. A similar, although less pronounced, increase in gastrointestinal symptoms over successive cycles was also observed in the no de-escalation group (Table 2).

In an exploratory descriptive comparison within the steroid-sparing group, no clear differences were apparent between the patients with and without deterioration in CINV control across the evaluated baseline variables.

3. Safety of Antiemetic Therapy

Adverse events were descriptively compared between the steroid-sparing and no de-escalation groups (Table 3). The overall incidence rate of adverse events was similar between the two groups in the descriptive comparison. However, the steroid-sparing group had a lower incidence

and severity of fatigue (69.2% vs. 93.4%, respectively) and fewer grade 2 cases than the no de-escalation group. Insomnia was observed in both groups (61.5% vs. 75.0%), whereas hyperglycemia was observed in one (6.3%) patient in the no de-escalation group and in none of the patient in the steroid-sparing group. No grade 3 or higher adverse events were observed in either group.

Discussion

The findings of this study can be summarized in two main points.

First, the four-drug antiemetic regimen, including olanzapine, achieved a CR rate of 72.5% in patients receiving AC chemotherapy. In the present study, CR was evaluated during the first chemotherapy cycle. Reported CR rates in AC regimens widely vary depending on study design and antiemetic combinations, ranging from approximately 45% to 82% in three-drug regimens and approximately 48–58% in four-drug regimens, including olanzapine [7–10]. Because the evaluation cycles and endpoint definitions differ across studies and are not always clearly described, direct comparisons should be interpreted with caution. Nevertheless, our observed CR rate was within the range of previously reported outcomes, suggesting that the incorporation of olanzapine into contemporary antiemetic prophylaxis may contribute to favorable antiemetic

control in this setting.

Second, this study provided exploratory real-world data on a steroid-sparing de-escalation strategy during subsequent cycles of AC chemotherapy in the context of four-drug prophylaxis. Evidence regarding steroid sparing, specifically in AC regimens, remains limited, particularly in regimens that already include olanzapine [9,10]. Therefore, the present findings provide clinically relevant information to this evolving field.

In the steroid-sparing group, a decline in the CR rate and worsening of gastrointestinal symptoms were observed after steroid omission. Notably, 61.5% of the patients experienced some degree of deterioration in nausea, vomiting, or appetite loss. However, most events were low grade and did not result in severe clinical consequences. Importantly, some fluctuations in gastrointestinal symptoms across successive cycles were observed in patients who continued the original antiemetic regimen. Cycle-to-cycle variability in CINV control has been previously reported. Prospective data suggest that nausea and composite antiemetic endpoints change across later chemotherapy cycles, despite guideline-based prophylaxis [11]. Conversely, other analyses have demonstrated heterogeneous symptom trajectories rather than uniformly progressive worsening [12]. As these studies were conducted in different antiemetic contexts,

extrapolation to contemporary four-drug regimens should be performed with caution. Nonetheless, these observations indicate that CINV control may not remain stable across chemotherapy cycles and that the deterioration observed in our cohort may partly reflect natural variability rather than steroid omission alone.

Previous randomized trials of AC regimens have demonstrated the non-inferiority of steroid-sparing approaches to conventional dexamethasone schedules [7,8,13]. However, these studies have also reported numerically lower CR rates and a higher incidence of nausea in steroid-sparing regimens than in standard dexamethasone regimens. Accordingly, our results should not be interpreted as definitive evidence for steroid-sparing strategies in AC regimens. Rather, they raise concerns regarding the timing of de-escalation when based solely on first-cycle tolerability. In our cohort, de-escalation was implemented in patients who experienced no or only mild nausea during the first cycle; however, mild residual gastrointestinal symptoms persisted in some patients. These findings suggest that early steroid omission in patients without complete symptom resolution is associated with an increased risk of subsequent deterioration. Future studies should consider stricter eligibility criteria, such as the complete absence of residual gastrointestinal symptoms at the end of the first cycle, and standardized de-escalation

protocols.

Psychological factors may contribute to variability in CINV control. Patients' expectations and anxiety regarding chemotherapy-induced nausea are independently associated with subsequent nausea severity [14]. In patients with breast cancer—who frequently possess established CINV risk factors, such as female sex, younger age, and low alcohol intake—the interaction between biological susceptibility and anticipatory conditioning may increase the vulnerability to symptom recurrence. However, psychological variables were not directly assessed in the present study, and these mechanisms remain speculative.

Importantly, we could not identify any clear clinical predictors of deterioration after steroid omission. Although exploratory comparisons did not reveal evident baseline differences between patients with and without worsening symptoms, the small sample size limited statistical power and precluded definitive conclusions. Selection bias cannot be excluded, as de-escalation was offered based on clinical judgment and patient preference. Furthermore, causal inferences cannot be made from this observational study.

Regarding safety, although the sample size was limited, the steroid-sparing group showed a tendency toward a lower incidence and severity of fatigue and no cases of hyperglycemia.

These observations are hypothesis-generating and should not be overinterpreted. Larger prospective studies are required to determine whether any clinically meaningful safety advantages exist.

This study has some limitations. This was a single-center, retrospective study with a small sample size. The de-escalation protocol was not fully standardized, and multiple modification patterns were implemented in routine practice. Consequently, only a subset of patients was eligible for steroid-specific comparative analysis. Formal statistical hypothesis testing was not performed because of the exploratory nature of this study, and the analysis may have been underpowered to detect subtle but clinically relevant differences.

In conclusion, this study evaluated steroid sparing as a de-escalation strategy from the second cycle of AC chemotherapy in the context of contemporary four-drug antiemetic prophylaxis. Although early steroid omission was temporally associated with the deterioration of gastrointestinal symptoms in a substantial proportion of patients, these findings do not conclusively negate the role of steroid sparing in AC regimens. Rather, they underscore the importance of careful patient selection, optimal timing, and standardized implementation. Prospective multicenter studies are warranted to further refine and individualize the antiemetic

therapy in this setting.

Statements & Declarations

Acknowledgements

Funding Statement

This study did not receive any specific grants from funding agencies in the public, commercial, or non-profit sectors.

Ethical Declaration

This study was designed and conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Komaki City Hospital (approval no. 251033). Information about the study was provided during the opt-out period, and all patients were given an opportunity to decline participation.

Conflict of Interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Authors' contributions

YY, TF, and SN contributed to the study conception and design. YY, TF, HH, and YD conducted the acquisition of data. The first draft of the manuscript was written by YY. NW, TF, and SN helped in manuscript drafting. All the authors have read and approved the final version of the manuscript.

Availability of data

The datasets generated and analyzed in this study are not publicly available because of privacy and ethical restrictions.

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Figure Legends

Fig. 1 Flow diagram of the patient selection process

Table Legends

Table 1. Patient characteristics.

Table 2. Antiemetic outcomes in the first cycle (n = 40) and subsequent cycle comparisons between the steroid-sparing and no de-escalation groups

Table 3. Incidence and severity of adverse events in the steroid-sparing and no de-escalation groups

Supplementary Files

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- Table.docx