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Supplemental Figures for:
Ramosetron Versus Ondansetron in Combination with Aprepitant and Dexamethasone for the Prevention of Highly Emetogenic Chemotherapy-induced Nausea and Vomiting: A Multicenter, Randomized Phase III Trial, KCSG PC10-21
Jin-Hyoung Kang et al.

Figure S1. CONSORT diagram. m-ITT: modified intention-to-treat.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8,9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	Suppl
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8,9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	9

	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Suppl fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Suppl fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Suppl fig 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10, 11 & table2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10, 11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	11,12, table3
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Not applicable
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14, 15
Other information			

Registration	23	Registration number and name of trial registry	8
Protocol	24	Where the full trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Criteria

Inclusion Criteria:

1. Age > 19 years and a diagnosis of a malignancy that can be treated with highly emetogenic chemotherapeutic agents (NCCN guideline v1.0 2011 anti-emesis).
2. ECOG performance status of 0–2.
3. Ability to receive orally administered study drugs.
4. Submission of informed consent for indicating an awareness of the investigational nature of the study in keeping with the policy of the hospital.

Exclusion Criteria:

1. Severe hypertension, severe heart disease, kidney disease (serum creatinine > 3 mg/dL), or liver disease (AST or ALT level > 3 times the upper normal range, ALP level > 2 times the upper normal range).
2. GI obstruction, active gastric ulcer, or other diseases that could cause nausea and vomiting.
3. Nausea and vomiting during the week before chemotherapy.
4. Use of steroids, antiemetics, pimozide, terfenadine, astemizole, cisapride, rifampin, carbamazepine, phenytoin, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, or nelfinavir for the treatment of other diseases.
5. A brain tumor, brain metastasis, or seizure.
6. Chemotherapy treatment within 12 months before enrollment.
7. A need for radiation therapy during the study period or treatment with radiation therapy within 2 weeks before chemotherapy.
8. Development of known allergies or severe side effects in response to drugs used in this study.
9. Pregnant or lactating women, or women who wish to become pregnant.
10. Patients judged inappropriate as subjects for this study by the investigator.

Figure S2. Frequency of vomiting (A) and usage of rescue medication (B) in the modified intention-to-treat (m-ITT) population (n = 299). There was no significant difference between the RAD and OAD groups (A: Wilcoxon rank-sum test, B: Chi-squared test). RAD: ramosetron, aprepitant, and dexamethasone; OAD: ondansetron, aprepitant, and dexamethasone. Error bars show standard deviation.

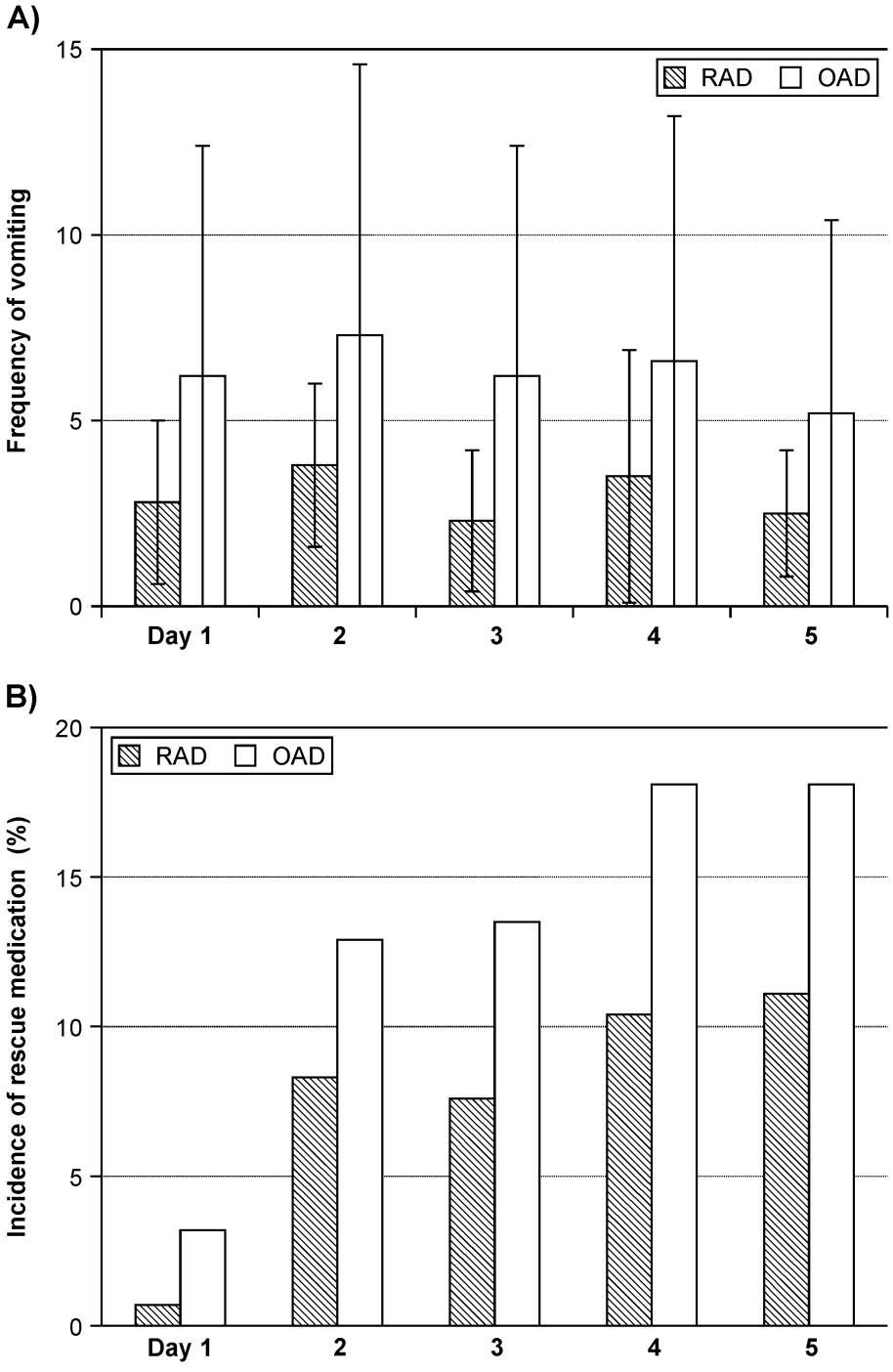

Figure S3. Daily nausea, vomiting, and retching by the Rhodes index (INV-2) (14) in the modified intention-to-treat (m-ITT) population (n = 299). There was no significant difference in the proportion of nausea, vomiting, and retching incidents between the RAD and OAD groups by Fisher's exact test. RAD: ramosetron, aprepitant, and dexamethasone; OAD: ondansetron, aprepitant, and dexamethasone.