Original Research Article

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Evaluation of aprepitant as an add-on therapy for prevention of chemotherapy induced nausea and vomiting in children

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ABSTRACT

Background: Chemotherapy-induced nausea and vomiting (CINV), represents a common and distressing side effect associated with antineoplastic treatment in pediatric patients. Aprepitant, a selective neurokinin-1 receptor antagonist, is recommended for preventing CINV in combination with a standard antiemetic regimen in children undergoing chemotherapy. This study aimed to evaluate the effectiveness of aprepitant as an add-on therapy to the standard antiemetic regimen for the prevention of CINV in children.

Methods: This randomized control study was conducted in the BSMMU, Dhaka, Bangladesh from February 2020 to October 2020. Forty-six children with malignancy undergoing moderately or highly emotogenic chemotherapy were divided into two arms: the Aprepitant arm (23 patients receiving granisetron, dexamethasone, and aprepitant) and the control arm (23 patients receiving Granisetron and Dexamethasone). Data were analyzed using SPSS version 22.0.

Results: The complete response rates for the aprepitant versus control arm during the acute and overall phase were 82% vs. 40% (p=0.003) and 65% vs. 26% (p=0.008), respectively. However, a higher percentage of patients who achieved complete response in the delayed phase was also observed, though statistically not significant (65% vs 40%, p=0.077). In the acute phase, there was a significant reduction in mild to moderate vomiting in the Aprepitant arm as compared to the control arm (p=0.01). In the overall phase, 35% of patients in the Aprepitant arm had mild to moderate vomiting as compared to 74% in the control group (p=0.027). No major adverse effects were reported by patients or caregivers.

Conclusions: Adding Aprepitant to the standard antiemetic regimen was effective and safe in preventing CINV, especially in the acute phase, in pediatric patients receiving the moderately and highly emetogenic chemotherapy (HEC).

Keywords: Aprepitant, Prevention, Chemotherapy, Nausea, Vomiting, Children

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INTRODUCTION

Chemotherapy-induced nausea and vomiting (CINV) is a prevalent and distressing adverse effect in pediatric cancer patients.1 CINV significantly impacts quality of life and can disrupt nutritional status and daily activities.² The incidence and severity of CINV are influenced by various factors, such as patient variability, the specific chemotherapeutic drugs used, dosage, schedule, and administration route in different chemotherapy regimens.³ CINV is categorized into acute and delayed phases based on symptom onset after chemotherapy. Acute vomiting manifests within 24 hours, while delayed vomiting occurs 25-120 hours post-chemotherapy. Ballatori et al reported that over 90% of patients experiencing acute/ delayed CINV also noted an impact on their daily activities.⁵ The national comprehensive cancer network (NCCN) classifies chemotherapeutics into four emetogenic potential classes: high risk (>90% chance of acute emesis), moderate risk (30 to 90%), low risk (10 to 30%), and very low risk (<10%). Current guidelines for preventing CINV in children are determined emetogenic risk of chemotherapy regimen (moderate or high), age (less than/ >6 months), drug interactions, and permissibility/ contraindication of dexamethasone use.⁶ The 2013 pediatric oncology group of Ontario (POGO) guidelines suggest antiemetic prophylaxis ondansetron plus dexamethasone, with/without aprepitant, for children scheduled for HEC, but this recommendation is specifically for children aged 12 years or more. The current guidelines from the multinational association of supportive care in cancer (MASCC) advise triple antiemetic prophylaxis (5-HT3 receptor antagonist, dexamethasone, and aprepitant) for pediatric patients, six months/older, receiving HEC/moderately emetogenic chemotherapy (MEC).8 Aprepitant, selective neurokinin-1 (NK-1) receptor antagonist, mitigates nausea and vomiting signals by blocking substance P's interaction with neurokinin-1 receptor. FDA approval for Aprepitant in children aged >6 months was granted on December 21, 2015. Bakhshi et al observed in a study of 93 patients that the addition of aprepitant, alongside ondansetron and dexamethasone, significantly controlled emesis in acute period with no grade 3/4 adverse events. 10 Meta-analysis of 3 pediatric randomized controlled trials, involving 451 patients aged 6 months-19 years, demonstrated a 52% relative risk reduction of overall CINV with aprepitant in addition to 5-HT3 receptor antagonist ± dexamethasone versus 5-HT3 receptor antagonist ± dexamethasone. 11 This study aims to evaluate aprepitant as an add-on therapy for preventing CINV in children.

METHODS

This was a randomized control study that was conducted at the department of pediatric hematology and oncology, Bangabandhu Sheikh Mujib medical university, Dhaka, Bangladesh from February 2020 to October 2020. A total of 50 pediatric patients of ages 5-18 years with documented malignancy undergoing MEC or HEC (as

defined in the POGO guidelines) were initially enrolled in the study. 12 However, 4 patients were lost to follow-up, resulting in a final analysis of 46 patients. Purposive sampling was employed for participant selection. The 46 children were divided into two arms: the aprepitant arm, comprising 23 patients receiving granisetron, dexamethasone, and aprepitant, and the control arm, comprising 23 patients receiving standard antiemetic regimen (Granisetron and dexamethasone). The study included a follow-up period of up to 120 hours (Acute phase 0-24 hours, delayed phase 25-120 hours, and overall phase 0-120 hours) after the completion of chemotherapy. Ethical approval was obtained from the hospital's ethical committee, and written consent was obtained from all participants before data collection. Exclusion criteria involved patients with vomiting 24 hours before emetogenic chemotherapy, symptomatic primary or metastatic CNS malignancy, abnormal laboratory values (SGPT >2 times and S. creatinine >1.5 times the upper limit of normal for age), recent radiation therapy, systemic steroid use, and specific drug interactions. Vomiting was categorized into nil (no vomiting), mild (1-2 episodes in 24 hours), moderate (3-5 episodes in 24 hours), and severe (≥ 6 episodes in 24 hours, tube feeding, total parenteral nutrition or need of hospitalization) for analysis. For patients receiving single-day chemotherapy, aprepitant was given per oral 30-60 min before starting of chemotherapy on day 1 and in the morning on days 2 and 3. For patients receiving multiple-day chemotherapy, aprepitant was given per oral 30-60 min before starting chemotherapy on each day. On day of chemotherapy, all patients received intravenous granisetron followed by intravenous/oral dexamethasone 30 min before chemotherapy. Dexamethasone doses were reduced by 50% when given in combination with Aprepitant to prevent potential pharmacokinetic interactions. Rescue medications (Ondansetron, granisetron, corticosteroids, benzodiazepines domperidone) were allowed to relieve recognized nausea or vomiting. Each patient was provided a vomiting card to record information about episodes of nausea, vomiting, or use of rescue medication during the assessment period. Date and time of each vomiting episode and the use of any rescue medication were recorded by patients, parents/guardians. Parents/guardians were instructed to immediately notify the investigator of any adverse events and were also questioned about adverse events during follow-up. Drug compliance was assessed by pill count at post-chemotherapy visit and compliance with vomiting card completion was checked by communicating directly with responsible person over telephone every day. Vital signs and adverse events were recorded at follow-up visits, and laboratory tests (CBC, SGPT, S. creatinine, and S. electrolyte) done before initiation of aprepitant and at 24 and 120 hours after completion of chemotherapy. Data processing, analysis, and presentation were performed using MS office and SPSS version 22.0. Chisquare and/or Fisher exact test performed to compare several parameters between 2 arms. A significance level of p<0.05 was considered in statistical analysis.

RESULTS

In this study, the age-wise distribution and mean age were similar between the aprepitant and control arms. Majority of patients in both groups were male (70% vs. 74%). The most prevalent malignancy in both arms was acute myeloid leukemia (AML) (30% vs. 35%), followed by acute lymphoblastic leukemia (ALL) (22% vs. 22%), hepatoblastoma (13% vs. 09%), neuroblastoma (04% vs. 09%), Wilms' tumor (04% vs. 13%), rhabdomyosarcoma (09% vs. 0%), acute promyelocytic leukemia (APML) (04% vs. 04%), Ewing sarcoma (04% vs. 04%), Hodgkin lymphoma (04% vs. 04%), and non-Hodgkin lymphoma (04% vs. 0%). According to distribution of 46 patients by chemotherapy, prior exposure to chemotherapy was similar in both arms. In the aprepitant arm, 65% of patients received multi-day chemotherapy compared to 78% in control arm, and difference was not statistically significant. Among 46 patients, 35 (76%) received HEC and 11 (24%) received MEC. The majority of patients received HEC (74% vs. 78%) in both arms. Single and multi-agent chemotherapy were similar in both arms. In this study, grading of vomiting between the aprepitant and control arms showed significant differences. In the acute phase, there was a statistically significant reduction in mild to moderate vomiting in the aprepitant arm compared to the control arm (p=0.01). No statistically

significant difference was observed between the aprepitant and control arms in vomiting during the delayed phase (p=0.184). In overall phase, which combined both acute and delayed phases, 35% of patients in aprepitant arm experienced mild to moderate vomiting compared to 74% in the control arm (p=0.027). This study revealed the proportion of patients achieving a complete response (CR). In acute phase, CR was observed in 82% of patients receiving aprepitant compared to 40% in the control arm (p=0.003), showing statistical significance. CR rates for aprepitant and the control arm during the delayed and overall phases were 65% vs. 40% (p=0.077) and 65% vs. 26% (p=0.008). respectively. In this current study, considering the distribution of patients achieving a complete response with HEC, the CR rate was higher in the aprepitant arm compared to the control arm across all phases, especially in the acute phase (p=0.024), demonstrating statistical significance. In evaluating patients achieving a complete response with MEC, CR rate was achieved significantly higher in the aprepitant arm compared to the control arm (p=0.015) in overall phase. Requirement for rescue medication for vomiting was higher in control arm compared to aprepitant arm in all phases, although difference did not reach statistical significance. No statistically significant differences in adverse effects were observed between the 2 arms in this study.

Table 1: General characteristics of participants, (n=46).

Characteristics		Aprepita	nt arm, (n=23)	Control ar	m, (n= 23)	P value
Characteristics		N	%	N	%	P value
Age (In years)						
5-12		14	60	16	70	
>12		9	40	7	30	0.536
Range (In years)		5.6-15		5.4-17		0.550
Mean \pm SD		10.29±3.	18	9.68±3.41		
Sex						
Female		7	30	06 (26)	26	0.743
Male		16	70	17 (74)	74	0.743
Primary diagnosis						
AML		7	30	8	35	_
ALL		5	22	5	22	0.868
APML		1	4	1	4	
Hepatoblastoma		3	13	2	9	
Wilms' tumor		1	4	3	13	
Neuroblastoma		1	4	2	9	
Rhabdomyosarcoma		2	9	0	0	
Ewing sarcoma		1	4	1	4	
Hodgkin lymphoma		1	4	1	4	_
Non-Hodgkin lymphoma		1	4	0	0	
Status regarding chemother	ару					
Prior exposure to chemotherap	ру	15	65	16	70	0.753
Chamatharany duration	Single day	8	35	5	22	0.326
Chemotherapy duration	Multiple days	15	65	18	78	
Emetogenic risk	HEC	17	74	18	78	0.73
Emetogenic risk	MEC	6	26	5	22	0.73
Chemotherapeutics agents	Single-agent	9	40	8	35	0.76
Chemotherapeutics agents	Multiple agents	14	60	15	65	0.76

Table 2: Antiemetic treatment regimen used in the study.

Antiemetic regimen	Drugs			Day 1	Day 2	Day 3
		Weight >		125 mg	80 mg	80 mg
	Aprepitant PO	Weight 2		80 mg	80 mg	80 mg
		Weight 10	0-20 kg	80 mg	40 mg	40 mg
	Granisetron IV			40 μg/kg/ dose	NA	NA
Aprepitant regimen		HEC		3 mg/m ² / dose 6 hourly	NA	NA
	Dexamethasone IV/PO	MEC	BSA: ≤0.6/m ²	1 mg/m ² / dose 12 hourly	NA	NA
			BSA: ≥0.6/m ²	2 mg/m ² / dose 12 hourly	NA	NA
	Granisetron IV			40 μg/kg/ dose	NA	NA
Standard regimen	Dexamethasone IV/PO MEC	HEC		6 mg/m ² / dose 6 hourly	NA	NA
		MEC	BSA: ≤0.6/m ²	2 mg/m ² / dose 12 hourly	NA	NA
		WILC	BSA: ≥0.6/m ²	4 mg/m ² / dose 12 hourly	NA	NA

NA: Not applicable

Table 3: Distribution of patients according to vomiting.

Vomiting	Aprepitant a	rm, n=23	Control arm, n=23		P value
	N	%	N	%	r value
Acute phase					
Nil	19	83	9	40	
Mild	3	13	12	52	0.01
Moderate	1	4	2	8	0.01
Severe	0	0	0	0	
Delayed phase					
Nil	15	65	9	405	
Mild	7	31	11	47	0.184
Moderate	1	4	3	13	0.164
Severe	0	0	0	0	
Overall phase					
Nil	15	65	6	26	
Mild	7	31	14	61	0.027
Moderate	1	4	3	13	0.027
Severe	0	0	0	0	

Table 4: Distribution of patients achieving complete response.

Complete response	Aprepitant	Aprepitant arm, (n=23)		nrm, (n=23)	Davolaro
	N	%	N	%	P value
Acute phase					
Yes	19	82	9	40	0.003
No	4	18	14	60	0.003
Delayed phase					
Yes	15	65	9	40	0.077
No	8	35	14	60	0.077
Overall phase					
Yes	15	65	6	26	0.008
No	8	65	17	74	0.008

Table 5: Distribution of patients achieving complete response with HEC.

Complete response	Aprepita	Aprepitant arm, (n=17)		ol arm, (n=18)	Davolus
	N	%	N	%	P value
Acute phase					
Yes	13	76	07	39	0.024
No	04	24	11	61	0.024
Delayed phase					
Yes	10	59	08	44	0.394
No	07	41	10	56	0.394
Overall phase					
Yes	10	57	06	33	0.12
No	07	41	12	67	0.13

Table 6: Distribution of patients achieving complete response with MEC.

Complete response	Aprepita	Aprepitant arm, (n=06)		l arm, (n=05)	P value
	N	%	N	%	P value
Acute phase					
Yes	06	100	02	40	0.061
No	00	00	03	60	0.061
Delayed phase					
Yes	05	83	01	20	0.00
No	01	17	02	80	0.08
Overall phase					
Yes	05	83	00	00	0.015
No	01	17	05	100	0.015

Table 7: Distribution of patients requiring rescue medication.

Rescue medication	Aprepitant arm, (n=23)		Control arm, (n=23)		Davalara
Rescue illeulcation	N	%	N	%	P value
Acute phase					
Yes	3	13	8	35	0.084
No	20	87	15	65	0.084
Delayed phase					
Yes	6	26	10	43	0.216
No	17		13	57	0.210
Overall phase					
Yes	7	30	13	57	0.074
No	16	70	10	43	0.074

Table 8: Summary of associated adverse effects among participants.

Adverse events	Aprepit	Aprepitant arm, (n=23)		ol arm, (n=23)	Develop	
	N	%	N	%	P value	
Clinical findings					-	
Anorexia	11	43	9	35	0.552	
Fever	7	30	8	35	0.753	
Headache	3	13	2	9	0.636	
Fatigue	3	13	2	9	0.636	
Abdominal discomfort	3	13	1	4	0.295	
Diarrhoea	3	13	1	4	0.295	
Hiccups	2	9	1	4	0.55	
Laboratory findings						
Neutropenia	10	43	9	40	0.756	
Anemia	6	26	5	32	0.73	
Thrombocytopenia	7	30	8	35	0.753	
Hypertransaminasemia	2	9	1	4	0.55	
Hypokalaemia	2	9	2	9	1	

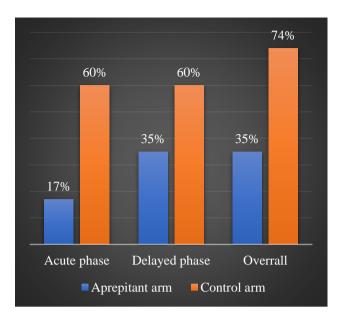


Figure 1: Distribution of patients experiencing vomiting episodes.

DISCUSSION

This study aimed to evaluate the effectiveness of aprepitant as an add-on therapy for the prevention of CINV in children. In this study, the complete response rates for the aprepitant versus control arm during the acute phase and overall phase were 82% vs. 40% (p=0.003) and 65% vs. 26 % (p=0.008), respectively. Bakshi et al found that the complete response rate was significantly higher in the acute phase when patients received aprepitant as a component of triple antiemetic therapy and Giagnuolo et al also demonstrated a greater proportion of patients achieving complete response with aprepitant in the acute phase in a cohort of 32 children and adolescent patients with Hodgkin lymphoma, who received MEC or HEC protocol. 10,13 The present study also shows a higher percentage of patients achieved CR in the delayed phase though statistically not significant (65% vs 40%, p=0.077). This might be due to the smaller sample size or heterogeneous patients receiving different single-day or multi-day chemotherapy protocols. In the present study, mild to moderate vomiting was lower in the Aprepitant arm as compared to the control arm in all phases. Kang et al also showed that Aprepitant reduced the incidence of mild to moderate vomiting in the acute and delayed phases. 14 Bakshi et al reported a significant number of patients experiencing severe vomiting in their study. 10 However, no patients in our study experienced severe vomiting. For patients with MEC, the CR rate was higher in the Aprepitant arm compared to the control arm during all phases, especially in the overall phase. Felix-Ukwu et al also found that the addition of aprepitant significantly improved the control of emesis in patients with MEC. 15 In our patients receiving HEC, the CR rate was higher in the Aprepitant arm during all phases, especially in the acute phase. When compared with MEC, the CR rate was relatively lower in the overall and

delayed phases in patients with HEC. A similar finding was also observed by Kang et al who showed that the CR rate was relatively lower in patients who received very high emetogenic chemotherapy in the overall and delayed phases. 16 Though not statistically significant, the requirement for rescue medication for vomiting in all phases was lower in the aprepitant arm. In the overall phase, 30% of patients in the Aprepitant arm and 57% of patients in the control arm required rescue medication. Kang et al found that the requirement for rescue medication was higher in the control arm than in the aprepitant arm. 14 The requirement for rescue medication for vomiting was higher in patients receiving HEC compared to patients receiving MEC in the overall phase. The most frequently used rescue medications were ondansetron, granisetron, and dexamethasone. Bakshi et al also used ondansetron and/or dexamethasone as rescue agents for vomiting.10 In this study, no significant differences in adverse effects were observed between the aprepitant and control arms during the study period. The overall pattern of clinical and laboratory adverse effects observed was often very similar to those reported in the control arm of the study, possibly resulting from the administration of concurrent chemotherapeutic drugs or other antiemetic agents. Kang et al, Bakshi et al and Felix-Ukwu et al also did not find any major drug-related adverse effects in patients receiving aprepitant. 10,14,15 The present study suggests that Aprepitant can decrease the chance of CINV in children receiving emetogenic chemotherapy, thereby improving patients' health-related quality of life. The limitations of the study were small sample size, heterogeneity of the patients receiving the different chemotherapy protocols, and adverse effects were not directly supervised and depended on selfreported by patients, parents, or guardians which may have led to under-reporting of adverse effects related to the aprepitant.

CONCLUSION

Based on the findings of this study, it can be concluded that the addition of aprepitant as an add-on therapy to the standard antiemetic regimen is effective and safe in preventing CINV in pediatric patients receiving MEC and HEC at all phases, especially in the acute phase.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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