A Retrospective Chart Review of Hypersensitivity and Infusion-Site Adverse Events Associated With Fosaprepitant IV in Patients Receiving Anthracycline and Cyclophosphamide (AC)–Based Chemotherapy

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INTRODUCTION

- The consensus guideline–recommended regimen for chemotherapy-induced nausea and vomiting (CINV) following highly emetogenic chemotherapy (HEC) (eg, AC) and some moderately emetogenic chemotherapies is a
  - Neurokinin 1 (NK-1) receptor antagonist (RA) + 5-hydroxytryptamine type 3 (5-HT_3) RA + dexamethasone[1-3]
- Aprepitant and its IV prodrug, fosaprepitant, are the most widely used NK-1 RAs[4]
- Polysorbate 80, a surfactant for solubilizing fosaprepitant, has been associated with systemic hypersensitivity and infusion-site adverse events (ISAEs)[5]
- ISAE incidence is likely underestimated; however, ISAEs have been reported in up to 29%-42% of patients and appear to be associated with the use of peripheral lines and anthracyclines[6,7]

OBJECTIVE

- To identify the incidence of ISAEs and systemic reactions associated with fosaprepitant IV in patients receiving AC-based chemotherapy regimens via a peripheral line

METHODS

- Patient medical records (documented codes, nursing notes/codes, physician notes) were evaluated from 14 US sites
- Eligible men and women
  - Were 18-80 years of age
  - Had ECOG performance status 0-1
  - Were receiving doxorubicin (≥ 60 mg/m^2) + cyclophosphamide (≥ 600 mg/m^2) via peripheral IV line
  - Were receiving a 3-drug antiemetic regimen including fosaprepitant IV
- ISAE and systemic reaction incidences were collected over multiple cycles

REFERENCES

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RESULTS

- Of 127 charts reviewed, 35 (28%) reported an ISAE and/or systemic reaction during or following infusion of the antiemetics and chemotherapy
- In 32 patients with ISAEs, 137 individual ISAEs were documented over multiple chemotherapy cycles (range, 0-90/cycle)
- Most common ISAEs were erythema, pain, and swelling (**Table 1**)

Table 1. Summary of ISAEs by Cycle

Unique Patients	26	15	1	2	0	
	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	TOTAL Incidence per Reaction
Erythema at site	24	10	0	1	0	35
Pain at site	24	9	0	1	0	34
Swelling at site	18	6	0	1	0	25
Vein discoloration at site	8	5	1	2	0	16
Venous engorgement, hardening or induration	4	3	0	1	0	8
Superficial thrombosis at site	2	2	0	1	0	5
Infusion-site hives	4	0	0	0	0	4
Extravasation at site	2	2	0	0	0	4
Superficial thrombophlebitis at site	1	1	0	1	0	3
Thrombosis at site	3	0	0	0	0	3
Deep venous thrombosis	0	0	0	0	0	0
Other	0	0	0	0	0	0
TOTAL incidence per cycle	90	38	1	8	0	

- In 16 patients with systemic reactions,
  - 50 individual reactions were documented over multiple cycles (range, 0-36/cycle)
  - Most common were edema/swelling, erythema, and dermatitis (**Table 2**)

Table 2. Summary of Systemic Reactions by Cycle

Unique Patients	14	6	3	0	0	
	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	TOTAL Incidence per Reaction
Edema/swelling	9	1	0	0	0	10
Erythema	6	2	2	0	0	10
Dermatitis	6	3	0	0	0	9
Rash	6	0	0	0	0	6
Flushing	2	1	2	0	0	5
Dyspnea	2	0	0	0	0	2
Bronchospasm/shortness of breath	2	0	0	0	0	2
Other	1	0	1	0	0	2
Hypotension/hypertension	0	1	0	0	0	1
Chills/fever	1	0	0	0	0	1
Coughing	0	1	0	0	0	1
Vomiting at time of infusion	1	0	0	0	0	1
Anaphylaxis	0	0	0	0	0	0
Pneumonitis	0	0	0	0	0	0
TOTAL incidence per cycle	36	9	5	0	0	

CONCLUSIONS

- Patients receiving fosaprepitant IV and AC chemotherapy via peripheral line are at risk for hypersensitivity reactions and ISAEs
- An IV polysorbate 80–free NK-1 RA could reduce systemic hypersensitivity and ISAE incidence in this setting

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