Removing the Practice Standard of Bleomycin Test Dosing and the Impact On Patient Safety

Jennifer Collier, Pharm.D., BCPS, BCOP, Laura Cotiguala, Pharm.D., Meredith Wills, Pharm.D.
Oncology Team, Pharmacy Department, Saint Luke's Health System, Kansas City MO

Background

Bleomycin reactions include hypotension, confusion, fever, chills and wheezing. Historically, the risk of hypersensitivity reaction appeared highest in lymphoma patients particularly after the first or second dose.

Package labeling recommends patients receive a test dose prior to the first two doses.

The last published case report of a bleomycin hypersensitivity reaction occurred in 1989.

Literature suggests reactions occur independent from the size of the bleomycin dose and number of bleomycin doses the patient previously received. Reactions have occurred minutes to days after the bleomycin dose was infused.

Drug contamination may have lead to these reactions.

Chemotherapy pre-medications (steroids, diphenhydramine, acetaminophen) may mask reactions.

Saint Luke's Health System (SLHS) oncology pharmacists and physicians concluded that the bleomycin test dose has low sensitivity as a screening measure for patients at risk of developing a hypersensitivity reaction with bleomycin. Bleomycin test doses have been removed from order sets.

Study Design and Purpose

This was a retrospective study that reviewed data from January 8th 2014 through mid April of 2016. Data was collected from the electronic medical record of both the EPIC and HMM databases.

The purpose of this study is to evaluate the patient safety implications after eliminating the requirement of bleomycin test doses at Saint Luke's Hospital.

Study Population

Inclusion Criteria:

Age of 18 years or older that received bleomycin infusion as documented on the medication administration record

Exclusion Criteria:

Patients who received bleomycin for venous sclerotherapy

Study Objectives

Primary Objective:

Evaluate safety by measuring the percentage of patients who experienced a hypersensitivity reaction before and after the requirement of bleomycin test doses was removed from the order sets.

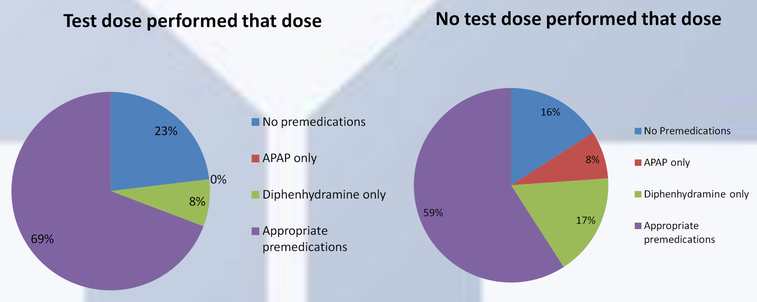
Secondary Objective:

Define the percentage of patients receiving appropriate pre-medication with acetaminophen and diphenhydramine.

Demographics / Data

	Total	Test dose	NO test dose	P- Value
Doses	101	50	51	
Number of patients	19	10	9	
Female	36 (35.6%)	12 (24.0%)	24 (47.1%)	
Male	65 (64.4%)	38 (76.0%)	27 (52.9%)	0.015
Average age(yr)	36.0 ± 15.1	36.8 ± 11.3	35.1 ± 18.1	0.577
Average dose #	4.9 ± 3.3	4.9 ± 3.4	5.0 ± 3.1	0.902
Indication:				
Germ-cell	4 (4.0%)	3 (6.0%)	1 (2.0%)	
Hodgkins	52 (51.5%)	17 (34.0%)	35 (68.6%)	
Ovarian	5 (5.0%)	5 (10.0%)	0 (0.0%)	<0.001
Teratoma	3 (3.0%)	3 (6.0%)	0 (0.0%)	
Testicular	37 (36.6%)	22 (44.0%)	15 (29.4%)	
Reactions	0	0	0	N/A

Pre-medication adherence



Study Limitations

Limited sample size

Retrospective review

Conclusions

The removal of the bleomycin test dosing did not result in a higher incidence of hypersensitivity reactions

We will continue the practice of not requiring bleomycin test doses to be performed prior to any doses of bleomycin

Work needs to be done to educate providers on appropriate pre-medication practices

Further research needs to be done to continue to validate these results

Authors' Disclosures and References

The authors have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter.

References available by request