Nationwide Chemotherapy Drug Shortages and the Impact on Patients with Gynecologic Malignancy at a Single Institution

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Background

The numerous drug shortages is a widespread topic within the medical field and has also recently become a popular topic in the mainstream media. The implications of chemotherapy drug shortages nationwide is profound, and has often required a change in patient treatment planning.[1-4]

Several underlying causes may contribute to these drug shortages, including manufacturing issues, quality issues, production discontinuation and delays, and shortages in receiving raw materials and components from suppliers.[1-4]

Objective

To assess the toxicities during chemotherapy regimen changes at our institution due to the nationwide drug shortages in patients with gynecologic malignancies.

Methods

Patients were identified from chemotherapy records during the period from August 1 to November 1, 2011 who required a change in chemotherapy regimen due to nationwide drug shortages of either liposomal doxorubicin or paclitaxel. Hematologic and renal toxicities were then graded on day of treatment and nadir during the original regimen and the new regimen using the Common Terminology Criteria for Adverse Events (CTCAE) v 4.0.

Results

Eight patients were identified who required a change in regimen. Six patients had uterine cancer (4 primary, 2 recurrent) and three had ovarian cancer (2 primary, 1 recurrent). Three patients necessitated a change based on shortages of liposomal doxorubicin, five were related to paclitaxel. In the liposomal doxorubicin patients, one was referred to radiation therapy for sandwich radiation. One patient was on combination with carboplatin and she was changed to paclitaxel and carboplatin for her final two cycles. One patient was eventually changed to single agent docetaxel after a treatment delay of waiting for liposomal doxorubicin to become available. In the patients affected by the shortage of paclitaxel, all five were initially on carboplatin and paclitaxel combinations. They were switched to docetaxel and carboplatin. Two patients were participating in GOG clinical trials.

Old Regimen: Paclitaxel

n=155

Grade	Percent
Grade 0	71.6%
Grade 1	18.7%
Grade 2	7.1%
Grade 3	1.9%
Grade 4	0.6%
Grade 5	0%

New Regimen: Docetaxel

n=153

Grade	Percent
Grade 0	62.7%
Grade 1	19.6%
Grade 2	11.1%
Grade 3	3.9%
Grade 4	2.6%
Grade 5	0%

Toxicities measured: WBC, ANC, Plts, Hgb, and Cr

2 patients on Docetaxel required GCF support

Results

Laboratory Evaluation

	WBC		ANC	
	Day 1	*Nadir*	*Day 1*	*Nadir*
Paclitaxel (#16 cycles)	6.49K	4.20K	5.43K	2.70K
Docetaxel (#13 cycles)	6.03K	5.80K	5.02K	3.47K*

* When removing the 2 patients with GCF support, the **Nadir ANC was 0.92K**

Conclusion

The change of regimen due to drug shortages has a significant impact on patients through treatment regimen and/or modality changes, treatment delays and increased toxicities. Drug substitution also will have an impact on the analysis of clinical trials in the future.

References

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