The Pros and Cons when Generic Antineoplastic Agents are Introduced into Clinical Practice

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Abstract：The use of generic drugs is recommended to curb escalating drug expenditures. Antineoplastic agents are generally expensive and they have been increasingly used to treat solid tumors as well as hematological malignancies. Switching from brand-name to generic antineoplastic agents is very economical. However, there is a great concern in regard to whether generic drugs are as active and safe as brand-name agents. In this article, we discuss the problems associated with generic drug substitution for antineoplastic agents. The safety and effectiveness of the original brand-name drugs has been well investigated by clinical trials. On the contrary, only bioequivalence tests, i.e. quantity and purity analysis of an active ingredient, dissolution tests, and stability tests, are necessary for generic drugs to be marketed. The bioavailability of oral agents is studied to evaluate the similarity between brand-name drugs and generic formulations, but no such analysis is required for parenteral drugs. Since the most of antineoplastic drugs are used intravenously, it is of note that no *in vivo* testing must be performed for generic drugs to be approved. The interview form described the expected response, side effects and drug interaction with other agents based on the clinical trials is available for the brand-name drugs, but not for most generic drugs. Generic drug companies are generally small and only a small number of medical representatives (MR) are available, even though they must deal with many generic drugs. It is conceivable that the number of MRs is not sufficient to provide new drug information when needed. In treating cancer patients with chemotherapeutic agents, the use of less effective and more toxic generic drugs will thus influence the patient survival and treatment-related toxicity. When we consider introducing generic substitution, it is important for ourselves to thoroughly evaluate not only the cost but also the activity and safety of the generic drugs. After substitution, the treatment responses and side effects should also be carefully monitored and validate whether the generic drugs are actually safe and effective for the patients.

Key words：**Generic drug, Brand-name drug, Antineoplastic agent**