

〔一般論文〕

FP療法を用いたシスプラチン後発品の安全性の検討

Assessment of the Safety of the Generic Drugs of Cisplatin
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Summary : The development of substitute generic drugs is encouraged to minimize the rising costs of prescription drugs. However, many physicians doubt the efficacy and safety of certain generic drugs. Therefore, to verify their safety, the incidence of adverse events should be investigated. Cisplatin (CDDP) plays a key role in chemotherapy regimens. Generic and brand-name drugs may differ in various clinical parameters. Therefore, the safety of generic CDDP has to be assessed. To compare the generic and brand-name drugs of CDDP, the incidence of adverse events, especially those involving renal function, was investigated in patients with esophageal cancer undergoing FP therapy.

The incidence of adverse effects such as increased serum creatinine and hiccups was significantly higher in the generic group. Concerning the clinical characteristics, however, the pre-therapy BUN level was significantly higher in the generic group. No significant differences were observed in the transition in median creatinine and median BUN between the brand-name and generic groups, or in the transition of creatinine clearance and eGFR. Thus, the higher incidence of renal impairment in the generic group was not caused by differences in drug properties. The frequencies of leukopenia and neutropenia were similar in the two groups. The adverse events attributed to reduction in, or discontinuation of, the second course of FP therapy were similar in the two groups.

In our study, there were no differences in the incidence of adverse events, especially those involving renal function, between the brand-name and generic groups. Therefore, the generic CDDP can be used as an alternative to the brand-name drug of CDDP.

Key words : generic drug, safety, cisplatin, FP therapy

要旨：わが国では年々医療費が増大しており、患者負担の軽減および医療保険財政の改善を目的として後発医薬品（以下、後発品）の利用が推進されている。しかし、後発品に対する臨床試験は行われていないことから有効性や安全性の問題が指摘されているため、後発品での安全性の確立には臨床効果や有害事象発現状況を調査する必要がある。シスプラチン（以下、CDDP）はがん治療レジメンのキードラッグ

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