THE EVALUATION OF THE OFF-LABEL USE OF ANTICANCER DRUGS IN KOREA

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Aim: Using off-label anticancer drugs unapproved indications has some concerns about its efficacy and toxicity. With some clinical needs, off-label medication has been common in oncology. HIRA (Health Insurance Review & Assessment Service) has a process for controlling the use of off-label anticancer drugs in Korea. HIRA has permitted only for off-label uses for which there is adequate evidence with the efficacy, toxicity, and cost effectiveness. We have approved the off-label uses in 69 hospitals, and 203 regimens since 2006. The aim of this study was to evaluate the clinical benefits for the most widely used off-label anticancer drugs in Korea.

Methods: We evaluated 11 off-label regimens that over 3 years from the date of the initial approved, and 100 or more cases of cumulative cases. This retrospective multicenter study included 3,756 patients 49 hospitals. From Sep. 2010 to Jul. 2011 (3 regimens), and Aug. 2013 to Feb. 2014 (8 regimens), researchers visited and reviewed all the hospital medical records, respectively. Oncology specialists analyzed the efficacy and toxicities; response rate, PFS, overall survival, side effect, and cessation of treatment due to toxicity. We also compared each regimen with the alternative regimens approved by KFDA.

Results: Through the results of this study, the 8 regimens showed the sufficient efficacy and low toxicity; "<neo-adjuvant> AC → T" 3 weekly for breast cancer (n = 851), "TIP" for cervical cancer (n = 125), "S-1 ± cisplatin" 3 weekly for gastric cancer (n = 1372), and "TCD" for multiple myeloma, etc. These regimens were determined to keep their use. With a low level of evidence for the efficacy and cost-effectiveness, 3 regimen were restricted their use. The 1 regimen(TACE<cisplatin + epirubicin> + IV<;5-FU>)’s copayment rate was adjusted 5% to 100%. We determined to discontinue the 3 regimens.

Conclusions: In this study, many of these off-label medications showed having clinical benefits. Under controlling, off-label use of anticancer drugs might be useful. The use of off-label medication is restricted by government in many countries. We think this process and evaluation program would be a good model for the other countries.

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