International Journal of Gerontology 13 (2019) 105
https://doi.org/10.6890/IJGE.201906_13(2).EC

International Journal of Gerontology

journal homepage: http://www.sgecm.org.tw/ijge/

Editorial Comment

"Real World" Difference in Effectiveness between Brand-Name and Generic Drugs – Real? or Fantasy?

In Taiwan, many hospitals replace lots of off-patent brand-name drugs with generic ones, considering the national reimbursement policy and overall operation cost of the hospital. The major problem of this switch is the "real-world" equivalence of effectiveness between brand-name and generic drugs. Before marketing, generic drugs always have been tested and claimed to have the same bioavailability and bioequivalence with the brand-name drugs. However, the "real world" responses may be quite different from what generic pharmatheutical companies claimed. "Real patients" are always quite distinct from the tested participants for the proof of equivalence who are relatively young, healthy and highly selected. Although in Taiwan the efficacy and safety of these generic drugs are often questioned by clinicians, and several hospitals even deliberately reserve certain brand-name drugs for life-threatening disease (e.g., clopidogrel for acute myocardial infarction), only very few studies have been focused on this important issue.

Although the best way to clearly elucidate this issue is a randomized clinical trial (RCT), it is too costly for a generic company to conduct only for a proof of clinical equivalence. A post-marketing registry or a retrospective medical record analysis may be a more feasible and cost-effective survey to observe whether a generic drug is as clinically effective and safe as its brand-name counterpart. However, a post-marketing registry or medical record analysis has its own drawbacks and limitations, such as uncontrolled co-morbid diseases, co-administered drugs, unscheduled and unstandardized visits and laboratory tests, etc., just to name a few. Be that as it may, they are still currently the best feasible way to understand "real world" difference between a brand-name drug and the corresponding generic drug.

In this issue of International Journal of Gerontology, Chen, et al.[1] have surveyed if there would be substantial differences in terms of HbA1c levels and dosage between brand-name and generic glimepiride after the systemic switch at a medical center. In the electronic medical record analysis, they divided all patients with their brand-name glimepiride switched to the generic drug into two groups according to whether the dosage or related hypoglycemics were changed after the switch. Interestingly, they found that up to 87.2% of patients were in the group that changed their medication, and that in this group, the prescribed daily dose (PDD)/defined daily dose (DDD) ratio[2] was significantly higher after the switch, though the HbA1c levels were comparable before and after the switch. This phenomenon has drawn our attention that the generic glimepiride may be not as clinically effective as the brand-name drug in the real-world practice. All switches from brand-name to generic drugs need to be closely monitored and adjusted afterward, particularly for the drugs that fluctuation of their effectiveness may be life threatening.

References

1. Chen CF, Ting HW, Yang CZ, et al. Effectiveness of brand-name and generic versions of glimepiride for diabetes mellitus care: Experience at a medical center in Taiwan. *Int J Gerontol* 2019;13:116–120
2. Grimmsmann T, Himmel W. Discrepancies between prescribed and defined daily doses: A matter of patients or drug classes? *Eur J Clin Pharmacol* 2011;67:847–854.

Yih-Jer Wu, MD, PhD
Cardiovascular Center, Department of Internal Medicine, and Department of Medical Education, MacKay Memorial Hospital

Department of Medicine, Mackay Medical College