〔一 般 論 文〕

先発医薬品と後発医薬品の安全性評価を目的としたコホート研究のレビュー

A Review of Cohort Studies Examining the Comparative Safety of Brand-Named Drugs and Generic Drugs

廣田（吉田）光恵[a, *b]，川俣 知己[c]，益山 光一[d]，村上 正泰[e]，白石 正[f]

Mitsue Hirota (Yoshida)[a, *b], Tomomi Kawamata[c], Kouichi Masuyama[d], Masayasu Murakami[e], Tadashi Shiraishi[f]

[a] 山形大学大学院医学系研究科医薬品医療機器評価学講座
[b] 総務省情報公開・個人情報保護審査会事務局
[c] 日本ジェネリック製薬協会
[d] 東京薬科大学薬学部薬事関係法規研究室
[e] 山形大学大学院医学系研究科生命環境医科学専攻医療政策学講座
[f] 山形大学医学部付属病院薬剤部

Received August 24, 2015
Accepted January 13, 2016

Summary：Using the JAPIC database *iyakuSearch*, we identified and analyzed cohort studies published from September 2007 to March 2013 that compared adverse event (AE) incidences between brand-name drugs and generic drugs.
We analyzed 26 studies comprising 9 journal articles and 17 conference papers. The studies were categorized according to data collection, sample size, evaluation measures (e.g., target AE), patient characteristics, and reported results. The statistical power (sensitivity) for each evaluation measure was also examined.
All 26 studies were retrospective analyses. Sample sizes ranged from 6 to 797 patients (median: 54.5 patients); however, the rationale for determining these sample sizes was not specified. Although 17 studies had compared patient characteristics, none incorporated these characteristics into their analyses. 8 studies included explanations for evaluation measure selection, and 13 studies used multiple measures (maximum: 27). Among the reported results, 11 studies found that generic drugs were less safe than brand-name drugs, while 13 studies noted no discernible difference; the remaining 2 studies reported poorer safety in brand-name drugs. 6 studies reported sensitivities of ≥ 0.8; for cases where the AE risk ratio of generic drugs was 1.5 times that of brand-name drugs, 3 studies reported sensitivities of ≥ 0.8.
In this review, we aimed to examine cohort studies that had compared the safety of brand-name drugs and generic drugs in Japan. Many studies had been conducted in exploratory purpose without adequate considerations to evaluation measures, sample size, and patient characteristics. As a result, we were unable to determine the overall comparative safety of brand-name drugs and generic drugs.

Key words：cohort study, adverse event incidences, generic drugs, statistical power (sensitivity)

要旨：2007 年 9 月から 2013 年 3 月に JAPIC の医薬品情報データベースから先発医薬品投与群と後発医薬品投与群の間で有害事象等の発生頻度を比較した研究報告を抽出し，その内容について検討した．
対象としたのは，論文 9 報，学会発表 17 報の合計 26 報であった．これらについて，データ収集の方法，症例数，評価項目（対象とした有害事象等），患者背景及び報告者の評価等について解析した．また，評価項目ごとに検出力を算出した．

* 〒100-0014 東京都千代田区永田町 1-11-39
永田町合同庁舎
TEL：03-5501-2878　FAX：03-3502-0165
E-mail：m.hirota@soumu.go.jp