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Price difference as a predictor of the selection between brand name and generic statins in Japan

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ABSTRACT

Objectives: This study aimed to explore the predictors of the selection between brand name drug (BR) and generic drug (GE) and to clarify the quantitative relationship about selection.
Methods: We identified "incident users" who dispensed statins between April 2008 and June 2011 in commercially databases consisted of dispensing claims databases (DCD) of out-of-hospital pharmacies and hospital claims databases (HCD) of in-house pharmacies in Japan. Predictors of the selection between BR and GE, including price difference (PD), the price of BR, their interaction and percent change of the price of GE relative to BR were explored by logistic regression using DCD and HCD separately.
Results: We extracted records of 670 patients who have opportunity for selection both BR and GE. Logistic regression analysis demonstrated that PD, the price of BR, interaction between them, and prescriber affiliation were factors significantly associated with the selection in the DCD; logit $(p) = 9.735 - 0.251 \times \mathrm{PD} - 0.071 \times$ the price of BR $+ 0.002 \times \mathrm{PD} \times$ the price of BR $- 1.816 \times$ affiliation $+ 0.220 \times$ gender $- 0.008 \times$ age $+ 0.038 \times$ monthly medical fee. PD was inversely proportional to BR choice in DCD and lead to the opposite result in HCD. Numerical simulation of selection revealed that the quantitative relationships heavily depend on situations.
Conclusions: PD and the price of BR are predictors of the selection between BR and GE interactively in out-of-hospital pharmacies, but not in in-house pharmacies of medical facilities. Results may support policies which increase the power of out-of-hospital pharmacies for selection.

1. Introduction

It is widely recognized by governments in developed countries that encouraging generic drugs (GEs) instead of brand name drugs (BRs), substitutable drugs with GE, is an appealing policy to reduce medical expenditures. The price of GEs is generally lower than that of BRs, acting as a prescribing incentive for medical facilities, prescribing physicians, pharmacists and patients. In fact, share of GEs prescribed is over 70% in the US and over 60% in the UK and Germany by quantity based [1–4], but share of GEs in Japan is around 40.0% in 2013 [5].

Several studies in western countries have shown a variety of effects of the entry of GEs [6–11], such as deliver competition [9], decreases in the average drug price in the market [6,10], increases in the price of BRs [7,8], and switching to other in-patent drugs in the same therapeutic class results in an increase of pharmaceutical expenditure [11]. However, encouraging GEs is expected to deliver significant savings to health insurers in general.

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Recently, the total health-care expenditure and medication cost of Japan amounts to 40 trillion yen. Ministry of Health, Labour and Welfare (MHLW) regards encouraging use of GEs as effective measures to control those expenditure [5], and several policies have been implemented since 2001 [12–14], including introduction of a new type prescription form of external prescription in April 2008. This form allow pharmacists in out-of-hospital pharmacies to dispense both BRs and GEs after obtaining patient consent, increasing flexibility in selection between BR and GE [12]. On the other hand, the prescription form of internal prescription did not changed, implying that internal prescription reflects physician's choice [12] (Fig. 1).

Several studies have investigated determinants of the use of GEs. Database studies in Switzerland and Norway revealed that price difference as well as price of BRs was associated with substitution of BRs for GEs [15,16]. In the database studies in Netherlands, Belgian and Australia, characteristics of patients such as acknowledgement of availability of GEs, age, sex, pharmacy status and drug categories showed effects on substitution of GEs [17–19]. A questionnaires study in Portugal also revealed an effect of communication with doctor and pharmacists [20]. However, these previous studies did not discriminate selection between BR and GE at the beginning of administration and in the settings of switching and prescription at in-house pharmacies in medical facilities and at out-of-hospital pharmacies. Moreover, data from Japan is limited particularly at a patient-level [14,21]

This study therefore aimed to explore predictors of the selection between BR and GE. To increase accuracy of the estimated quantitative relationships, we focused on BR and GE of statins rather than heterogeneous drug categories and adopted incident user design, in which patients with the first dispensing are identified and selected as study subjects rather than patients who switched to GE.

2. Methods

2.1. Study design

This is an analysis of a commercially available database of claims from employee's health insurance societies, acquired by the Japan Medical Data Center (JMDC) [22]. Dataset consists of dispensing claims data (DCD) containing information on all drugs in out-of-hospital pharmacies and hospital claims data (HCD) in pharmacies of medical facilities (in-house pharmacies), respectively. Those databases covers eight million claims of employee's health insurance societies and one million people, which account for 0.78% of the population of Japan, and the population is composed of large company (capitalized at five hundred million yen or more in Companies Act in Japan) workers with stable lifetime employment and included their dependent relatives. One advantage of using claims information as administrative data is that it is an almost complete collection of information on diagnostic procedures, treatment, and expenses.

2.2. Conceptual model

We initially identified potential predictors of the selection between BR and GE from interviews with pharmacists and data from previous studies [13,15,16,21,23–29] and created a conceptual model which represents selection between BR and GE (Fig. 1). The conceptual model includes potential predictors of the selection, selectors (patients, pharmacists, and physicians), place of selection, and results of selection. In this model, factors that could not be extracted as variables are indicated in gray shading. Selectors who have a choice BR and GE are indicated white-on-black.

The upper part of the conceptual model shows selection at out-of-hospital pharmacies and reflected in DCD. The lower part shows selection at in-house pharmacies in medical facilities and reflected in HCD. After the introduction of a new prescription form at 2008, in Japan [12], pharmacists at out-of-hospital pharmacies can select BR or GE after obtaining patient consent and physician sign-off to the substitution (drug substitution), but patients and pharmacists do not involved in prescription or selection of BR or GE at in-house pharmacies in medical facilities [12]. We assumed that price difference, the price of BR (medicine price of BR [e.g. "Mevalotin", for pravastatin] which was compared with GE [e.g. "Mevarich", for pravastatin] at the place of selection), gender or age, copayment for medical fee, and income were potential factors associated with selection by patients. The incentive of insurance reimbursement related to company business policy, the burden of stock inventory, as well as concern regarding GE product quality and availability could affect selection by the pharmacists. Out-of-hospital pharmacies are usually belonging to chains of pharmacies, because policies and concerns of their front office have a influence on stock, adoption, and selection of GE. Price gap between the reimbursement prices and the wholesale prices are considerable factor, however it is impossible to identify the individual wholesale prices. Prescriber affiliation, customary practice of prescription (including brand loyalty), sales promotions, clinical condition and preference of physicians were potential factors associated with selection by physicians [29]. Meanwhile, prescription form of internal prescription which directly reflects prescription of physicians was without any changes. Pharmacists of in-house pharmacies have no legal right to give an explanation about selecting BR or BR. Besides, previous studies demonstrated that little relationship between physicians' perceptions of patient cost burden and their perceptions of GEs [29].

2.3. Database

DCD included details of medicine dispensed by pharmacists at the out-of-hospital pharmacy, pharmacy identifier, patient information (age, gender, monthly all medical practice fee including initial visit fee, all prescribed drugs, examination, dispensing fee, administration fee, and all that), information on drug dispensed (HOT reference code [standard master for pharmaceutical products], brand name, specifications, GE classification, price, concomitant drug).