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Osteoporosis: Original Article

The effect of mandatory generic substitution on the safety of alendronate and patients' adherence

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Abstract

Objective:

Generic medicines are often used in public hospitals. However, data on the quality of generic alendronate, its efficacy, side-effects and medication adherence in clinical practice is scarce. Therefore, this study aimed to compare the side-effects and

medication adherence in patients with osteoporosis treated with alendronate (Fosamax®).

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This prospective study involved two groups of patients: (1) postmenopausal osteoporotic women prescribed once-weekly Fosamax (proprietary group) but were switched to apo-alendronate after 2 years ('switched over' group); and (2) patients initiated with once-weekly apo-alendronate (generic group). Participants were recruited from the Osteoporosis Clinic of a tertiary hospital. Data were collected through interviews.

Main outcome measures:

Side-effects and medication adherence.

Results:

A total of 131 participants were recruited: proprietary group = 64 and generic group = 67. An intergroup and a within-group comparison were made. Side-effects were reported by 6 (9.4%), 30 (44.8%) and 12 (18.8%) participants in the proprietary, generic and 'switched over' groups, respectively. Participants who were on generic alendronate were at a significantly higher risk of experiencing side-effects compared to those who were taking proprietary alendronate [odds ratio (OR):7.84 (95% CI: 2.98–20.65), $p < 0.001$]. However, no significant statistical difference was found between the 'switched over' and the proprietary group [OR: 2.23 (95% CI: 0.78–6.37), $p = 0.127$]. Four out of 12 (33.3%) patients who experienced side-effects immediately after switching to generic alendronate discontinued generic alendronate due to intolerable gastrointestinal side-effects. There was no difference in medication adherence to generic or proprietary alendronate.

Conclusions:

Medication adherence to both generic and proprietary alendronate appeared similar although patients who were taking generic alendronate* were significantly more likely to experience side-effects. The switch from proprietary to generic alendronate at the cost of the production of generic alendronate are

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Q Keyword

Transparency

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Notes

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