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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 of generic (apo-alendronate) and proprietary alendronate (Fosamax).

*Apotex Inc, Toronto, Ontario, Canada.

†Merck Sharp & Dohme Corp., Pavia, Italy.

Research design and methods:

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 than those on proprietary alendronate. Therefore, the switch from proprietary alendronate to the generic forms should not only consider the cost of the products but must also ensure that the generic and proprietary alendronate are equivalent in all aspects of efficacy and safety.

Keywords::

Alendronate Generic Medication adherence Proprietary Side-effect

Transparency

Declaration of funding

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Declaration of financial/other relationships

The authors declare that they have no competing interests. CMRO peer reviewers on this manuscript have no relevant financial relationships to disclose.

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Notes

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