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Presentation type (s):	Poster

Comparative effectiveness of alendronate and raloxifene in reducing the risk of hip fracture in women with osteoporosis

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Abstract

We conducted a retrospective database study investigating patients who initiated alendronate or raloxifene. The primary outcome was comparison of hip and vertebral fracture incidences during each respective treatment period. And, the comparison of adverse effects involved in anti-osteoporosis medications was conducted as a secondary outcome. Data were extracted from 8 clinical datasets using the open-source OHDSI CohortMethod package. In the intent-to-treat analysis, 425,298 women over 45 years old initiating alendronate or raloxifene were included and 371,784 alendronate patients were matched with 53,514 raloxifene patients. No difference in hip fracture incidence between two groups was identified (HR 1.04, 95% CI: 0.94-1.15), and higher incidence of vertebral fracture in alendronate group was determined than that of raloxifene group (HR 1.07, 95% CI: 1.01-1.14). In terms of adverse outcomes, higher incidence of atypical femoral fracture in alendronate group was identified. In conclusion, raloxifene has a similar preventive effect of hip fracture and lower incidence of vertebral and atypical femoral fracture compared to alendronate, and raloxifene is one of the recommendable options for treatment of osteoporosis and preventing the osteoporotic fractures.

Introduction

Osteoporosis is a chronic, progressive disorder in which bone resorption exceeds formation, resulting in decreased bone mass and deterioration of the microarchitecture, with consequent decreased bone strength and increased

susceptibility to fracture.[1] Approved and popularized therapies for osteoporosis include alendronate(bisphosphonate), calcitonin, raloxifene(SERM), and teriparatide. The alendronate and raloxifene are known to be the most frequently prescribed anti-osteoporosis medication. Until now, a definitive study comparing the effectiveness of alendronate and raloxifene was limited and the effectiveness has controversies according to the study. Therefore, we conducted a retrospective database study investigating patients who initiated alendronate or raloxifene. The primary outcome was comparison of hip and vertebral fracture incidences during each respective treatment period. And, the comparison of adverse effects involved in anti-osteoporosis medications was conducted as a secondary outcome.

Methods

We conducted a new-user cohort study comparing first-time users of alendronate with first-time users of raloxifene using the open-source OHDSI CohortMethod package.[2] Only women over 45 years were included who had an exposure to alendronate or raloxifene as well as a diagnosis of osteoporosis in the year prior to treatment initiation. In five independent analyses, patient records were assessed for the five outcomes of interest: occurrence of osteoporotic hip fractures, vertebral fractures, atypical femoral fracture(AFF), osteonecrosis of the jaw(ONJ), and esophageal cancer. Cox proportional hazard models were used to assess the hazard ratios (HR) between the two exposure cohorts.

Results

In the intent-to-treat analysis, 425,298 women over 45 years old initiating alendronate or raloxifene were included and 371,784 alendronate patients were matched with 53,514 raloxifene patients. The incidence of hip fracture was 2.87% in alendronate group, and 2.54% in raloxifene group. The summary hazard ratio of hip fracture for intent-to-treat analysis was 1.04 (95% CI: 0.94-1.15). The vertebral fracture incidences were 3.18% in alendronate group and 2.82% in raloxifene group, showed higher incidence in alendronate group than that of raloxifene group (HR 1.07, 95% CI: 1.01-1.14). In terms of AFFs, 1548 AFFs were identified in alendronate group and 138 AFFs was found in raloxifene group. Result yielded a statistically significant higher rate of AFF in alendronate compared with raloxifene (HR 1.51, 95%: 1.23-1.85). The incidences of esophageal cancer and ONJ in alendronate group were 0.08% and 0.04% respectively. In raloxifene group, the incidences were 0.08% of esophageal cancer and 0.03% of ONJ.

Conclusion

Raloxifene has a similar preventive effect of hip fracture and lower incidence of vertebral and atypical femoral fracture compared to alendronate, and raloxifene is one of the recommendable options for treatment of osteoporosis and preventing the osteoporotic fractures.

Reference

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