

Study Summary

Title
Fracture Rates and Economic Outcomes in Patients with Osteoporosis Prescribed Risedronate Gastro-resistant Versus Other Oral Bisphosphonates: A Claims Data Analysis.

Study Sponsor
Theramex Ltd, 5th Floor, 50 Broadway, London, SW1H 0BL.

Status
Completed.

Objectives
To quantify and compare fracture rates among women with osteoporosis treated with risedronate GR versus other oral bisphosphonates. Health care resource utilisation (HCRU), health care costs (HCC), and medication persistence and adherence were also compared between the two treatment groups.

Study Type
Observational population-based retrospective study used claims data from the IBM® MarketScan® Commercial and Medicare Supplemental Databases (Q1 2009 to Q3 2019). The databases include de-identified patient-level claims and are compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Study Population

- Eligible participants were adult women with at least one medical claim with ≥ 1 diagnosis of osteoporosis and at least one prescription fill for an oral bisphosphonate (risedronate GR, alendronate, ibandronate, or immediate release risedronate).
- They had ≥ 6 months of continuous enrolment before the first bisphosphonate prescription (index date) and ≥ 2 years of follow-up after.
- Patients with Paget's disease or malignant neoplasms were excluded. After matching, 2,726 women were included in each cohort (risedronate GR vs. other oral bisphosphonates).

Methodology
The study used a retrospective observational design. Outcomes were compared between women with osteoporosis treated with risedronate GR (GR cohort) versus other oral bisphosphonates (other bisphosphonates cohort).

- For each patient, the date of the first observed prescription fills for an oral bisphosphonate was defined as the index date and the treatment initiated on that date as the index treatment.
- The 6-month period prior to the index date was defined as the baseline period.
- The observation period of patients spanned the period from the index date to the earliest of the data cutoff date or end of continuous eligibility.

Data analysis
The study used paired t-tests and McNemar tests for baseline comparisons after 1:1 matching. Fracture incidence and healthcare utilisation were analysed using generalised linear models with log link and negative binomial distribution, reporting (Incidence rate ratio IRRs with 95% CIs, p-values). Time to first fracture and treatment persistence were described using Kaplan–Meier (KM) curves, while between-group comparisons were assessed using the log-rank test. Healthcare costs were compared using non-parametric bootstrap resampling. Adherence was evaluated through the medication possession ratio (MPR).

Study Location
US Claims Database.

Ethics Approval
N/A.

Summary of Results
In total, 2,726 patients were selected in each cohort (median age: 60.0 years).

- The incidence of fractures was lower in the GR versus the other cohort for any fracture sites (incidence rate ratio, 95% CI: 0.83, 0.70–0.97) and spine fractures (0.71, 0.54–0.95), although the respective rate of medication discontinuation at 2 years was 80.5% and 74.4%.

- Time to first fracture was delayed for the GR cohort, reaching statistical significance after 36 months.
- The GR cohort incurred fewer hospitalisations (incidence rate per 1,000 patient-years: GR=106.74; other=124.20, $p<0.05$) translating into lower hospitalisation costs per patient per year (GR=\$3,611; other=\$4,603, $p<0.05$).

Conclusions

Patients prescribed risedronate GR versus other bisphosphonates had a lower incidence of fractures, which may be explained by the fact that the GR formulation is absorbed even when taken with food.

Limitations

- This retrospective study cannot establish causality; findings reflect associations only.
- The sample drawn from commercial and Medicare Supplemental claims may not represent the broader osteoporosis population, as patients were relatively young.
- Higher out-of-pocket costs for risedronate GR may introduce selection bias, and the database lacked clinical details needed to identify patients at elevated fracture risk.
- Diagnoses were based on administrative codes, which may reflect suspected rather than confirmed conditions and are subject to underreporting; spine fractures are often missed if they do not receive medical attention.
- Claims data indicate prescriptions filled, not actual medication use.
- Finally, reported healthcare costs likely underestimate true fracture-related costs, as they exclude payer administrative expenses, patient out-of-pocket spending, indirect costs, and intangible burdens.

Reference

The study results published in peer-reviewed journal: Thomasius, F., Palacios, S., Alam, A. et al. Fracture rates and economic outcomes in patients with osteoporosis prescribed risedronate gastro-resistant versus other oral bisphosphonates: a claims data analysis. *Osteoporos Int* 33, 217–228 (2022). <https://doi.org/10.1007/s00198-021-06108-w>