

# Patient Characteristics and Disease Burden of Osteoporosis in Post-Menopausal Women at Increased Risk of Fracture in Germany

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## OBJECTIVES

- To describe, using real-world (claims) data, the characteristics (age, comorbidity, medication) of the female post-menopausal osteoporosis population with increased fracture risk, as defined by German Dachverband Osteologie (DVO) guidelines.<sup>1</sup>
- To estimate the imminent (1 year) fracture rates in women with post-menopausal osteoporosis.
- To estimate the economic burden, in terms of health resource utilization and cost, associated with the increased fracture risk, and to compare it to those who, while having post-menopausal osteoporosis, are not at an increased risk of fracture.

## BACKGROUND

- Individuals at increased risk of fracture can be identified by several tools such as FRAX or other combinations of risk factors. However, these tools provide the estimate of fracture risk over a lengthy (10 year) period of time.
- Identifying patients at imminent risk (those in whom fracture is likely to occur within 12–24 months) has clear value for prioritizing treatment strategies.
- The German DVO guidelines<sup>1</sup> provide a list of clinical and treatment-related risk factors to identify patients who are at increased risk of osteoporotic fracture (Box 1).
- This research was conducted to assess and confirm risk factors identified in the DVO guidelines using real-world data; and describe the level of imminent fracture risk within the increased risk group.

### Box 1. DVO guidelines for prophylaxis, diagnostics and treatment of osteoporosis in adult patients<sup>1</sup>

- Published in 2009 (updated 2014) by the umbrella organization of all medical associations in Germany, Austria and Switzerland that are related to treatment of bone diseases
- Based on a systematic review of the literature and a standardized evaluation and assessment procedure
- Cover epidemiology, diagnostic and treatment options, risk factors, and treatment recommendations
- Categorizes 3 different types of risk factors for fracture risk:
  - 12 general risk factors: eg. age, sex, previous vertebral fracture, smoking, underweight
  - 8 risks due to certain underlying concomitant diseases: eg. Cushing syndrome, primary hyperparathyroidism, epilepsy, Type 1 diabetes, bowel surgery, hyperthyroidism
  - 6 medication-induced risks: eg. anti-androgen therapy (in males), glitazones, aromatase inhibitors, oral glucocorticoids

## METHODS

### Study Design

- Observational study using retrospective German sick fund data (~5% of the population) for the years 2009–2011.
- The sample was defined based on 2010 data (baseline period) while the study investigational year was 2011.

### Patients

- Women aged ≥50 were defined to suffer from osteoporosis (OP) if they had an osteoporotic diagnostic code in the baseline period.
- Following DVO guidelines, osteoporotic women were considered to be at increased risk (IR) of fracture if they fulfilled any of the following conditions in the baseline period:
  - ≥1 prescription for an anti-resorptive/anabolic agent not associated to an alternative, non-OP indication or diagnosis (eg. Paget disease, malignancy)
  - a history of osteoporotic fracture (diagnostic code M80 and/or a diagnostic code for a fracture)
  - ≥1 clinical or treatment-related additional risk factor according to DVO guidelines.
- Osteoporotic women not meeting any of these criteria were considered non-increased risk (N-IR).

### Assessment of Fractures

- Incident fractures (regardless of etiology) were identified using ICD codes S22, S32, S42, S52, S72 and S82; outpatient diagnoses were used for S22, S32, S52 and S82, inpatient diagnoses were used for femur fractures (S72) as they would require hospital treatment.
- To avoid double-counting, a re-fracture of the same site required ≥6 months (outpatient) or ≥7 months (inpatient) between codes.
- The proportion of fractures attributable to osteoporosis was estimated using the approach suggested by Brecht and Schädlich,<sup>2</sup> in line with previous epidemiological studies.

### Medical Resource Utilization and Cost

- Inpatient and outpatient costs were attributed to OP if there was an OP diagnostic code (M80, M81), one of the fracture codes listed above or a pre-specified treatment typically associated with OP or fractures (eg. fracture healing).
- For medication, a list of anti-resorptive/anabolic OP agents was defined which could directly be attributed to OP (patients taking these drugs for alternative indications were already excluded).
- Descriptive analyses on OP-related medical resource utilization, fracture frequency and osteoporosis related costs were performed.

Figure 1. Selection and identification of IR-group

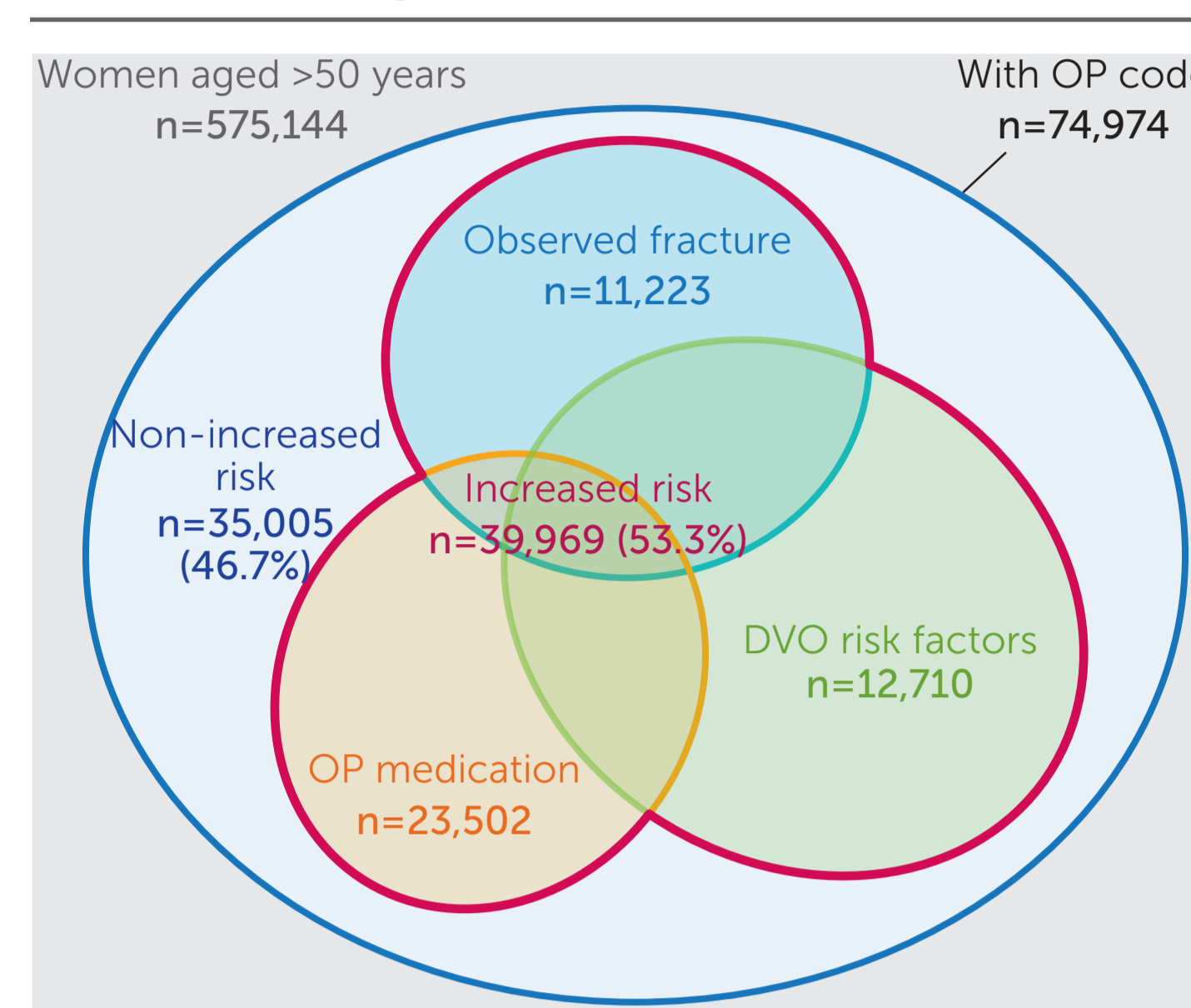


Figure 2. Incidence of all-cause and fragility fractures over 12 months by fracture site and risk group

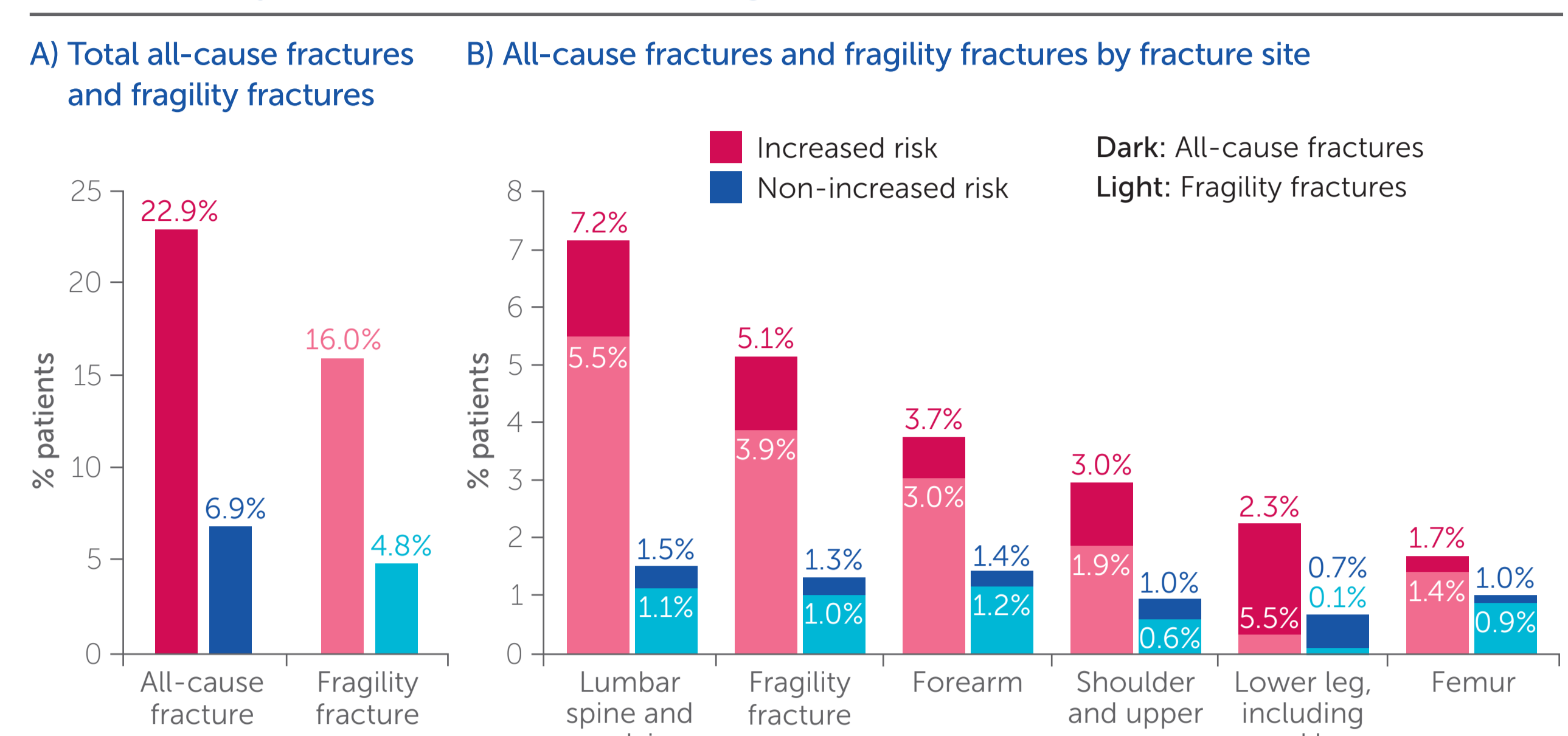


Figure 3. Comorbidities in baseline period by risk group

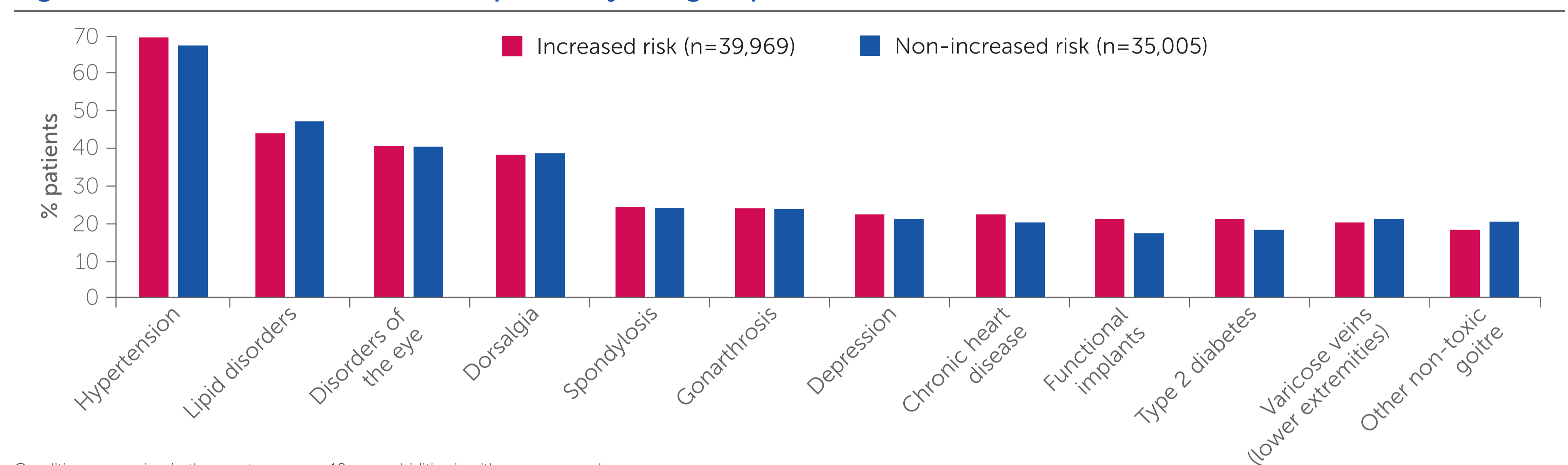


Figure 4. Prescription of osteoporosis-related medication by risk group

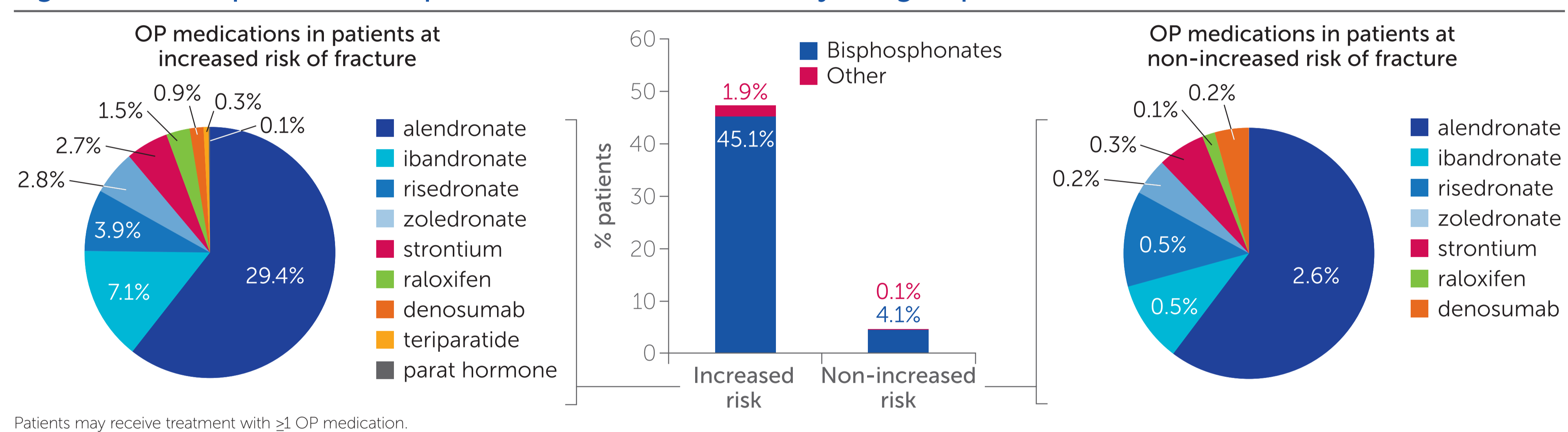


Table 1. Cost of treatment for osteoporosis (medication, hospitalization, outpatient treatment) by risk group (€)

	IR group				N-IR group			
	Mean	Median	SD	IQR	Mean	Median	SD	IQR
Inpatient cost	846.0	0.0	3,058.2	0.0	345.3	0.0	1,935.7	0.0
Outpatient cost	276.4	224.0	265.6	265.7	220.0	183.2	209.3	193.0
Medication	206.7	53.8	597.5	234.0	12.8	0.0	113.6	0.0
Total OP cost	1,405	435	3,193	622	640	225	2,110	237

IQR: inter-quartile range; SD: standard deviation.

## RESULTS

- Among 74,974 women who were diagnosed or treated for OP, 39,969 (53.3%) were identified as being at increased risk for fracture (Figure 1).
- Women with IR had a mean age of 75.2 (SD 9.5) years and were only slightly older than N-IR women (74.0, SD 10.1 years).
- The most frequent comorbidities in IR patients were hypertension (70%) and lipid disorders (44%) (Figure 3).
- There was little difference in frequency and rank order of comorbidities between IR and N-IR patients.
- Approximately half (46.6%) of the IR patients received an OP medication compared to 4.1% in the N-IR group (Figure 4).
- Of those receiving OP treatment:
  - 96.7% received oral bisphosphonates in the IR group.
  - Nearly 100% received oral bisphosphonates in the N-IR group (Figure 4).
- Incident fracture events were frequently observed in IR patients, the most frequent being vertebral fractures (Figure 2).
- After applying the algorithm of Brecht and Schädlich for the estimation of fractures attributable to OP, the incidence of fractures remained high in IR patients (16 events per 100 patients) (Figure 2).
- The higher prescription of OP drugs and the higher OP-related utilization and fracture rates in IR patients translated into substantial differences in OP-related healthcare cost (Table 1):
  - IR patients had higher mean medical expenses related to OP care.
  - Most of the cost was related to taking care of fractures in the inpatient setting.

## Limitations

- For the interpretation of these results the general limitations of a claims data based analysis apply:
  - Partial clinical and diagnostic information
  - Contains only information on services that are relevant for reimbursement
  - Coding of claims may underlie incentives for reporting

## CONCLUSIONS

- Approximately half of the OP population met increased risk definition criteria, yet despite being at increased risk of fracture less than half were receiving an approved therapy for OP.
- The German DVO guidelines/criteria identify patients at a considerable risk of having an imminent fracture (ie. a fracture that would occur in the next 12 months).
- Increased risk of fracture was confirmed to be associated with greater burden on the healthcare systems and increased related health care costs. The higher disease burden and costs were not attributable to comorbid conditions, which were similar between those at increased risk and those not.

## References

- Dachverband Osteologie e.V. Osteologie 2009;18:304–328.
- Brecht J and Schädlich P. HEPAC 2000;1:26–32.

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