




# Prevalence and incidence of osteoporotic vertebral fractures in community-dwelling European older adults: an observational analysis of the DO-HEALTH trial

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## Abstract

**Summary** We examined vertebral fracture (VF) prevalence, incidence, and treatment among 1488 older adults. VF prevalence and incidence were higher in women, older participants, and those with low bone density. In addition to VFs being underdiagnosed (only 20.7% of VFs clinically recognized), treatment rates were low, underscoring the need for improved screening and management.

**Purpose** To estimate prevalence and incidence of osteoporotic VFs and VF progressions overall and by sex, age, and bone status and to describe the proportion of participants with VFs in reporting osteoporosis (OP) medication use.

**Methods** This observational analysis of the DO-HEALTH trial, a three-year, randomized, controlled trial among community-dwelling adults age  $\geq 70$  years, includes a subsample of participants recruited at four study sites equipped with DXA machines. Prevalence and incidence rates (IR) of VFs and VF progressions were described overall and by subgroups of sex, age, and bone status. Incidence of VFs which were clinically recognized was also estimated. Further, we estimated the proportion of participants on OP medication.

**Results** A total of 1488 participants were included (mean age 74.9 years, 63.1% women, 77.0% had osteopenia or osteoporosis). One hundred forty-four (9.7%) participants had at least one radiographic VF at baseline and of those 19.4% participants reported OP medication use. Over the three-year follow-up, 50 participants sustained 58 new radiographic VFs (IR 1.4, 95% CI 1.1, 1.9). Of the 58 radiographic VFs, only 12 (20.7%) were clinically recognized. Furthermore, 31 participants sustained 35 VF progressions ( $N=157$ ; IR 7.7, 95% CI 5.5, 10.7). Prevalence and incidence were significantly higher in women, in older participants and those with osteopenia or osteoporosis compared to those with normal bone density.

**Conclusions** This study suggests a high prevalence and incidence of VFs in community-dwelling European older adults. Underdiagnosis may be even more prevalent than previously observed, and treatment rates were low.

**Keywords** DO-HEALTH trial · Osteoporosis · Vertebral fracture

## Introduction

Vertebral fractures (VFs) are the most common type of osteoporotic fractures [1–3]. Once a VF is sustained, the risk of subsequent fractures increases significantly, particularly in the first two years after the fracture: 40 to 60% of all recurrent fractures will occur within those first two years

[4]. VFs are associated with chronic pain, loss of height, kyphosis, reduced quality of life, and increased mortality [5–8]. The proportion of fracture-related deaths attributed to VFs was estimated at 53% for women and 65% for men [9].

Data on prevalence and incidence of VFs range considerably, based on study populations, geographic location, and the method of diagnosis [10, 11]. VFs can be asymptomatic or show non-specific symptoms at the time of fracture and therefore often do not come to clinical attention [12]. Prevalence of those that do come to clinical attention (hereinafter referred to as “clinically recognized VF” [13]) among European women and men age 50 years and older was estimated

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at 3.2% in the recently (2021) published scorecard for osteoporosis in Europe (SCOPE) [9]. In contrast, corresponding estimates in the same age group but based on radiographic diagnosis of VFs are approximately 12–14% [14, 15].

The same constraints as for prevalence data also apply to data on incident VFs; however, fewer data on incident VFs are available. A need for more data on incident VFs, particularly in men, has been identified [9, 13, 16]. Furthermore, few studies have assessed clinically recognized and radiographic VFs in the same population and thus allow an estimate of the extent of VF underdiagnosis [17, 18]. And those studies that provide such data are limited by using indirect estimates [2] or by including all types of vertebral deformities (e.g., degenerative) and not just osteoporotic fractures [17].

Based on the morbidity and high risk of subsequent fractures, identification and, if appropriate, treatment of VFs are critical. The proportion of individuals with osteoporosis (OP) at high risk for fracture, who would be eligible for but do not receive OP medication treatment is often described as the “treatment gap.” For osteoporosis in general, this treatment gap was estimated at 71% in SCOPE<sup>9</sup>. Given the underdiagnosis of VFs, it is likely that this gap may be even higher for VFs. Data on the treatment gap specific to VFs is limited but ranges from 42% for clinically recognized VFs in women in primary care settings [19] to 92% among men and women with a radiographic VF but previously undiagnosed with osteoporosis [20].

The aim of this study was to describe the prevalence and incidence of radiographic VFs overall and by sex, age, and bone status and to describe the proportion of participants with VFs reporting OP medication intake. For incident VFs, we describe radiographic and clinically recognized VFs and describe the incidence of existing VFs that progress in severity over the three-year follow-up. Moreover, we will describe treatment of incident clinically recognized VFs.

## Methods

### Study design and participants

The present study is an observational analysis using data from the DO-HEALTH trial, a three-year, randomized, double-blind, placebo-controlled trial [21, 22]. DO-HEALTH was a multi-center trial, including 2157 community-dwelling older adults from five European countries: Switzerland, Germany, Austria, France, and Portugal. Participants had to be age 70 years or older, free of major health conditions in the five years prior to enrollment (e.g., cancer, myocardial infarction, and stroke), and mobile enough to come to the study center. Exclusion criteria relevant to fracture risk were intake of active vitamin D metabolites, parathyroid hormone (e.g., teriparatide), calcitonin or intake of anti-convulsive medication, severe gait

impairment, acute fracture in the last six weeks (temporary exclusion), history of hypo- or hyperparathyroidism, diseases known to affect bone metabolism (e.g. Paget’s disease), and unwillingness to limit vitamin D intake to 800 IU/day and calcium intake to 500 mg/day. Participants were not selected based on low bone mass, osteoporosis, or fracture history. In order to recruit participants at increased risk of falling, DO-HEALTH specifically recruited 40% of participants with a history of falling within 12 months prior to enrollment at each study site. The full list of eligibility criteria has been published [21]. The present analysis includes 1488 participants recruited at four study sites equipped with DXA machines (Zurich, Berlin, Toulouse, Coimbra).

The trial protocol was registered in the International Trials Registry (clinicaltrials.gov, registration ID: NCT01745263) and approved by regulatory agencies of all countries [21]. The approval for this observational analysis was obtained after trial completion from the ethics committee in Zurich (2024–01210).

### Assessment of vertebral fractures

Radiographic VFs were assessed using dual-energy X-ray absorptiometry (Lunar iDXA, GE Healthcare). Thoracolumbar spine scans were performed in the lateral decubitus position at each clinical visit (BL, 12, 24, and 36 months). Morphometric evaluation of anterior, mid, and posterior vertebral height from T4 to L4 was performed using the semi-automated enCORE vertebral fracture analysis (VFA) software (Version 13.60.033). Manual correction of measurement points was applied if necessary. A vertebra was considered deformed, if the anterior/posterior or mid/posterior height ratio was below 80%. Etiology of vertebral deformities was then classified as osteoporotic (low trauma), traumatic (high trauma), degenerative, or other (e.g., ankylosing spondylitis, hemivertebra) based on published radiological criteria, including reduction of anterior, medial and/or posterior height, height of the disk space, change in vertebral width, presence of spondylophytes, sclerotic endplates, and encroachment of the spinal canal [23]. For the present analysis, only deformities that were classified as osteoporotic were included. In addition, the grade of severity was classified using the Genant method as mild (grade 1, 20–25% height reduction), moderate (grade 2, 26–40% height reduction), and severe (grade 3, > 40% height reduction). A VF progression was defined as a progression in grade of severity (e.g., mild to moderate) or a progression in height loss leading to a change in deformity type (e.g., wedge to crush deformity). VF progressions were assessed in a subset of participants with a prevalent VF at baseline or those with an incident VF at year one or year two. All morphometric analyses of the scan images were performed by a single radiologist and DXA specialists (GA) at the study site in Berlin.

In addition to radiographic VFs, we assessed clinically recognized VFs, defined as those VFs that came to clinical attention and diagnosis. Incident clinically recognized VFs were self-reported by participants and assessed every three months (clinical visits at 12, 24, and 36 months and three-monthly phone calls between visits). All incident VF events were confirmed by X-ray reports or medical reports, and a detailed fracture questionnaire was completed. The questionnaire recorded cause of the fracture as well as health care utilization (e.g., doctor's visit and physiotherapy) and treatment (e.g., medications and surgery) related to the fracture [21].

### Assessment of osteoporosis (OP) treatment

Medication use was assessed by standardized questionnaires at each clinical visit and 3-monthly phone calls. For each medication, participants reported the following: brand name, generic name, dose, unit, interval (as needed or regularly), indication, and treatment duration. To minimize recall bias, participants were asked to bring their medication, medication packages, or a medication list (from the general practitioner) to the baseline visit. In addition, all participants completed a diary to improve recall. For the present study, OP medication is defined as antiresorptive medication, including bisphosphonates, denosumab, strontium ranelate, selective estrogen receptor modulators, and hormone therapy.

### Baseline demographic and health-related measures

Demographic and anthropometric information included age, sex, height, and body weight.

BMD and T-scores at the lumbar spine, femoral neck, and total hip were determined by DXA (Lunar iDXA, enCORE software, version 13.60.033) [24]. Classification of bone status into low bone mass (osteopenia) and osteoporosis was based on a T-score of  $-1.0$  to  $> -2.5$  and  $\leq -2.5$ , respectively, in at least one of the three regions of interest. Participants with a T-score  $> -1.0$  at all three regions were classified as normal BMD.

The comorbidity score was calculated based on the Self-Administered Comorbidity questionnaire, which assesses 12 common chronic diseases by three dimensions (presence, medication, limitation of activities). It has a range of 0 to 36 points, and lower scores indicate fewer comorbidities [25].

Dietary calcium intake was calculated from the Food Frequency Questionnaire [21], and calcium supplementation was assessed as part of the medication questionnaire described above.

Serum 25(OH)D levels were measured at the DSM Analytical Research Center, using HPLCMS/MS methodology. Vitamin D deficiency was defined as 25(OH)D serum levels  $< 20$  ng/mL.

### Statistical analysis

Baseline characteristics were described overall and by sex. Normally distributed continuous variables were presented as mean and standard deviation (SD) and non-normally distributed continuous variables as median and interquartile range (IQR). Data normality was assessed visually. Categorical variables were presented as frequencies and percentages. Sex differences were analyzed using Chi-square tests for categorical variables, *t*-tests for normally continuous distributed variables, and Wilcoxon rank-sum tests for non-normally distributed continuous variables.

At baseline, the number (count variable) and prevalence (binary, at least one VF) of radiographic VF were estimated overall and by sex, age group (70–74 and 75 + years), and bone status (normal, osteopenia, and osteoporosis). Sub-group analysis by country (Switzerland, Germany, France, and Portugal) were also conducted based on their relevance for future country-specific reports. Due to the small sample size, results by country are presented in the Supplementary Material of this manuscript. Differences in proportions between the groups were compared using Chi-square tests.

The proportion of participants reporting OP medication use at baseline was described overall and by sex, age, bone status, country, and among participants with prevalent VF at baseline.

The incidence rate (IR) of new radiographic VF and VF progressions over the three-year follow-up was estimated overall and by the subgroups listed above. IRs and 95% confidence intervals (CI) over the study period were estimated using negative binomial regression models. An offset of the logarithm of each participant's time (years) in the study was included in the models to account for exposure time. IR and 95% CI were also estimated and compared for each subgroup using the same approach described above.

For the subset of participants with incident clinically recognized VF, the proportion receiving osteoporosis treatment following the VF was estimated separately. Treatments were categorized into medications, physiotherapy, and/or surgery.

Statistical significance was set at *P* value of  $< 0.05$ , and reported *P* values are two sided. Statistical analyses were performed using SAS v9.4 (SAS Institute, Inc., Cary, NC, USA).

## Results

### Baseline characteristics

Baseline characteristics are presented overall and by sex (Table 1). Mean age was 74.9 years; 63.1% were women. The mean comorbidity score was 3.4, mean lumbar spine T-score  $-1.3$ , mean total hip T-score  $-1.1$ , 77.0% had

**Table 1** Baseline characteristics of study participants, overall, and by sex

|  | Overall (N = 1488) | Women (n = 939) | Men (n = 549) | P value <sup>a</sup> |
|--|--------------------|-----------------|---------------|----------------------|
| Age, mean (SD)   | 74.9 (4.4)         | 74.7 (4.4)      | 75.2 (4.3)    | 0.057                |
| Age categories   |                    |                 |               | 0.449                |
| 70–74 years, n (%)   | 851 (57.2)         | 544 (57.9)      | 307 (55.9)    |                      |
| ≥ 75 years, n (%)  | 637 (42.8)         | 395 (42.1)      | 242 (44.1)    |                      |
| BMI [kg/m <sup>2</sup> ], mean (SD) <sup>b</sup>           | 26.6 (4.3)         | 26.5 (4.7)      | 26.8 (3.5)    | 0.252                |
| Comorbidity score, mean (SD) <sup>c</sup>                  | 3.4 (3.2)          | 3.7 (3.3)       | 2.8 (2.8)     | < 0.0001             |
| Lumbar spine T-score, mean (SD) <sup>d</sup>               | − 1.3 (1.4)        | − 1.7 (1.3)     | − 0.6 (1.5)   | < 0.0001             |
| Femoral neck T-score, mean (SD) <sup>d</sup>               | − 1.4 (1.0)        | − 1.5 (1.0)     | − 1.3 (1.0)   | 0.002                |
| Total hip T-score, mean (SD) <sup>d</sup>                  | − 1.1 (1.1)        | − 1.3 (1.0)     | − 0.8 (1.1)   | < 0.0001             |
| Bone status <sup>e</sup> , n (%)                           |                    |                 |               | < 0.0001             |
| Normal   | 336 (23.0)         | 162 (17.6)      | 174 (32.2)    |                      |
| Osteopenia   | 792 (54.1)         | 507 (54.9)      | 285 (52.8)    |                      |
| Osteoporosis   | 335 (22.9)         | 254 (27.5)      | 81 (15.0)     |                      |
| OP medication intake, n (%) <sup>f</sup>                   | 186 (12.5)         | 182 (19.4)      | 4 (0.7)       | < 0.0001             |
| Fall history, n (%) <sup>g</sup>                           | 598 (40.2)         | 420 (44.7)      | 178 (32.4)    | < 0.0001             |
| 10-year history of low-trauma fracture, n (%) <sup>h</sup> | 182 (12.2)         | 155 (16.5)      | 27 (4.9)      | < 0.0001             |
| Daily dietary calcium intake [mg], mean (SD)               | 1445 (685)         | 1484 (720)      | 1378 (616)    | 0.004                |
| Calcium supplement use (≤ 500 mg/d), n (%)                 | 154 (10.4)         | 128 (13.6)      | 26 (4.7)      | < 0.0001             |
| Vitamin D deficiency (25(OH)D levels < 20 ng/mL), n (%)    | 646 (43.8)         | 381 (41.1)      | 265 (48.4)    | 0.006                |

BMI body mass index, DXA dual-energy X-ray absorptiometry, IU international units, SD standard deviation, mg milligramm, OP osteoporosis, d day, ng nanogram, mL milliliter

<sup>a</sup>P values are from Chi-tests for categorical variables, *t*-tests for normally continuous distributed variables, and Wilcoxon rank-sum tests for non-normally distributed continuous variables

<sup>b</sup>BMI was calculated as weight in kilograms divided by height in meters squared. Higher BMI values reflect overweight (≥ 25) and obesity (≥ 30)

<sup>c</sup>Comorbidity score: comorbidity was measured by the Self-Administered Comorbidity Questionnaire which assesses current medical comorbidities (12 comorbidities by three dimensions: presence, medication, and limitation of activities). It has a range of 0 to 36 points in which the lower scores are better

<sup>d</sup>T-score: assessed by DXA

<sup>e</sup>Bone status based on femoral neck T-score: normal > − 1.0, osteopenia − 1.0 to < 2.5 SD, osteoporosis ≤ − 2.5

<sup>f</sup>OP medication intake: intake of at least one of the following medications: bisphosphonate, hormone therapy, denosumab, and strontium ranelate

<sup>g</sup>Fall history: at least one fall in the 12 months prior to study enrollment

<sup>h</sup>Low-trauma fractures were defined as any fracture that occurred from minimal trauma, such as falling from standing height due to slipping or tripping, or vertebral fractures from coughing or sneezing. Fractures that resulted from high trauma, such as car accidents, were excluded

low bone mass (osteopenia) or osteoporosis, and 12.2% reported a history of low-trauma fracture in the 10 years prior to study enrollment. Additionally, mean dietary calcium intake was 1445 mg/day, and 43.8% were vitamin D deficient (25(OH)D levels < 20 ng/mL) at baseline. Women had more comorbidities, lower lumbar spine, femoral neck and total hip T-scores, and higher calcium intake. A greater proportion of women were reporting OP medication use, calcium supplements, reported a history of falls and fractures, and were vitamin D deficient. As outlined above, only osteoporotic VFs were included in the present analysis. Morphological vertebral deformities detected at baseline but excluded from the present study included degenerative changes in 35 (2.4%), traumatic

changes in 27 (1.8%), and other morphological changes (e.g., hemivertebrae) in five (0.3%) participants.

### Prevalence of radiographic vertebral fractures

Prevalence overall and by sex is presented in Table 2. One hundred forty-four (9.7%) participants had at least one prevalent VF at baseline. Of those 144 participants, 102 (70.8%) had a single, 27 (18.8%) had two, and 15 (10.4%) had three or more prevalent VF. A significantly higher prevalence of VFs was found in women compared to men (11.1% vs. 7.3%), in older compared to younger participants (13.2% vs. 7.1%) and in participants with osteoporosis compared to those with T-scores in the normal range (18.8% vs. 3.6%;

**Table 2** Prevalence of at least one VF at baseline overall and by subgroups of sex, age, and bone status

| Subgroup ( <i>n</i> participants) | Participants with $\geq 1$ VF, <i>n</i> (%) | Number of prevalent VF (range) | <i>P</i> value <sup>a</sup> | Participants with VF receiving meds, <i>n</i> (%) |
|-----------------------------------|---|--------------------------------|-----------------------------|---|
| <b>Overall</b> ( <i>n</i> = 1488) | 144 (9.7)                                   | 209 (0–6)                      | –                           | 28 (19.4)   |
| <b>Sex</b>                        |   |                                |                             |   |
| Women ( <i>n</i> = 939)           | 104 (11.1)                                  | 150 (0–6)                      | 0.02                        | 27 (28.8)   |
| Men ( <i>n</i> = 549)             | 40 (7.3)                                    | 59 (0–6)                       |                             | 1 (2.4)   |
| <b>Age group</b>                  |   |                                |                             |   |
| 70–74 years ( <i>n</i> = 851)     | 60 (7.1)                                    | 88 (0–6)                       | < 0.001                     | 13 (21.7)   |
| $\geq 75$ years ( <i>n</i> = 637) | 84 (13.2)                                   | 121 (0–5)                      |                             | 15 (17.9)   |
| <b>Bone status</b>                |   |                                |                             |   |
| Normal ( <i>n</i> = 336)          | 12 (3.6)                                    | 16 (0–3)                       | < 0.001                     | 1 (0.3)   |
| Osteopenia ( <i>n</i> = 792)      | 66 (8.3)                                    | 103 (0–6)                      |                             | 9 (1.1)   |
| Osteoporosis ( <i>n</i> = 335)    | 63 (18.8)                                   | 86 (0–3)                       |                             | 18 (5.4)  |

VF vertebral fracture(s), meds OP medications

<sup>a</sup>*P* values are from Chi-square tests

Table 2). Prevalence differed by country, with the highest prevalence in Switzerland (12.2%) and the lowest in Germany (5.2%; Supplemental Table 1).

Among participants with prevalent radiographic VFs and available lumbar spine and/or femoral neck and/or total hip BMD measures (*N* = 141), 63 (44.7%) had osteoporosis (T-score < − 2.5) and 66 (46.8%) had osteopenia (T-score  $\leq$  − 1.0 and > − 2.5) in at least one of the three measuring sites. The remaining 12 (8.5%) were categorized as normal BMD (T-score > − 1.0) in all three measuring sites.

### Incidence of new radiographic vertebral fractures

Over the three-year follow-up, 50 participants sustained 58 incident radiographic VFs (IR = 1.4, 95% CI 1.1, 1.9 per

100 person-years). Of those 50 participants, 42 (84%) had a single VF, and eight (16%) had two incident VFs. Results by subgroups are presented in Table 3. A significantly higher incidence of VFs was found in women compared to men (IR 1.8 vs. 0.9, *P* = 0.03), in older compared to younger participants (2.0 vs. 1.0, *P* = 0.02), and in participants with osteoporosis compared to those with T-scores in the normal range (2.4 vs. 0.7, *P* = 0.01). There were no significant differences in VF incidence between the four countries (Supplemental Table 2).

Of the 58 incident radiographic VFs, 12 (20.7%) were also clinically recognized. Among women, ten (22.2%) of 45 radiographic VFs were clinically recognized, while for men, two (15.4%) of 13 radiographic VFs were clinically recognized.

**Table 3** Incidence of VFs over the three-year follow-up overall and by subgroups of sex, age, and bone status

| Subgroup ( <i>n</i> participants) | Participants with $\geq 1$ VF, <i>n</i> (%) | Number of incident VF (range) | IR (95% CI) per 100 person-years <sup>a</sup> | <i>P</i> value <sup>b</sup> |
|-----------------------------------|---|-------------------------------|---|-----------------------------|
| <b>Overall</b> ( <i>n</i> = 1369) | 50 (3.7)                                    | 58 (0–2)                      | 1.4 (1.1, 1.9)                                | –                           |
| <b>Sex</b>                        |   |                               |   |                             |
| Women ( <i>n</i> = 861)           | 38 (4.1)                                    | 45 (0–2)                      | 1.8 (1.3, 2.5)                                | 0.03                        |
| Men ( <i>n</i> = 508)             | 12 (2.2)                                    | 13 (0–2)                      | 0.9 (0.5, 1.6)                                |                             |
| <b>Age group</b>                  |   |                               |   |                             |
| 70–74 years ( <i>n</i> = 786)     | 22 (2.8)                                    | 24 (0–2)                      | 1.0 (0.7, 1.6)                                | 0.02                        |
| $\geq 75$ years ( <i>n</i> = 583) | 28 (4.8)                                    | 34 (0–2)                      | 2.0 (1.3, 3.2)                                |                             |
| <b>Bone status</b>                |   |                               |   |                             |
| Normal ( <i>n</i> = 304)          | 6 (2.0)                                     | 6 (0–1)                       | 0.7 (0.3, 1.5)                                | ref                         |
| Osteopenia ( <i>n</i> = 738)      | 25 (3.4)                                    | 29 (0–2)                      | 1.3 (0.9, 2.0)                                | 0.15                        |
| Osteoporosis ( <i>n</i> = 314)    | 18 (5.7)                                    | 22 (0–2)                      | 2.4 (1.5, 3.9)                                | 0.01                        |

CI confidence interval, IR incidence rate, VF vertebral fracture(s)

<sup>a</sup>Adjusted for participants' follow-up time<sup>b</sup>*P* values are from negative binomial regression models



## Incident vertebral fracture progressions

There were 157 participants with prevalent VFs at baseline or incident VFs at 12 or 24 months who were included in the analyses of VF progressions. Of those, 31 participants sustained 35 VF progressions (IR = 7.7, 95% CI 5.5, 10.7) over the 3-year follow-up. Of those 31 participants, 28 (90.3%) had a single VF progression, two (6.5%) had two, and one (3.2%) had three VF progressions. The incidence did not differ in subgroups by sex and age (Table 4) or country (Supplemental Table 3). For bone status, models did not converge for the normal subgroup due to the small sample size (Table 4). Among the 31 participants with VF progression, 12 (38.7%) also had at least one new incident VF.

Of the 35 VF progressions, nine (25.7%) progressed from a mild to moderate severity grading, 24 (68.6%) progressed from moderate to severe, and two (5.7%) did not progress in the grade but progressed in height reduction from a biconcave to a crush deformity (Supplemental Table 4).

## Vertebral fracture location and severity

Of the 209 prevalent VFs at baseline, the majority occurred in the thoracolumbar junction with 19 (9.1%) in T11, 35 (16.7%) in T12, 45 (21.5%) in L1, and 18 (8.6%) in L2 (Fig. 1A, Supplemental Table 2). The severity of prevalent VFs was mild for 37 (17.7%), moderate for 85 (40.7%), and severe for 87 (41.6%), and the most prevalent type of VF was biconcave or concave ( $n = 187$ , 89.5%; Supplemental Table 6). The patterns in the subgroups of women and men align with the overall sample (Fig. 1A, Supplemental Table 5).

Similar to prevalent VFs, of the 58 incident VFs, the majority occurred in the thoracolumbar junction, with seven (12.1%) VFs each in T11, T12, and L1, and ten (17.2%) in L2 (Fig. 1B, Supplemental Table 7). The severity of incident VFs was mild in 11 (19.0%) cases, moderate in 29 (50.0%), and severe in 18 (31.0%), and the most frequent type of incident VFs was biconcave or concave ( $n = 47$ , 81.0%) (Supplemental Table 8). The pattern in the subgroups of women aligns with the overall sample; for men, the pattern is not as obvious, likely due to the small number of incident VFs (Fig. 1B, Supplemental Table 7, Supplemental Table 8). Similarly, for VF progression, the pattern is not as obvious; however, the greatest number of progressions was observed in L1 ( $n = 7$ , 20.0%) and L2 ( $n = 6$ , 17.1%; Fig. 1C, Supplemental Table 9).

## Medication treatment at baseline

Of the 144 participants with prevalent VFs at baseline, 28 (19.4%) reported OP medication use (Fig. 2). The types of medication included bisphosphonates ( $n = 22$ ), hormone therapy ( $n = 4$ ), strontium ranelate ( $n = 3$ ), and denosumab ( $n = 1$ ). Two of the participants were reporting bisphosphonate as well as hormone therapy use. The most commonly used bisphosphonates were ibandronate ( $n = 11$ ) and alendronate ( $n = 6$ ), whereas risedronate ( $n = 3$ ) and zoledronate ( $n = 2$ ) were used less frequently. Information on the type of bisphosphonates and hormone therapies is provided in Supplemental Table 10. Of the 28 participants reporting OP medication use, there were 27 women and one man (Fig. 2). The numbers of participants reporting OP medication use in each subgroup are shown in Table 2.

**Table 4** Incidence of VF progressions over the 3-year follow-up

| Subgroup ( $n$ participants) | Participants with $\geq 1$ VF progression, $n$ (%) | Number of VF progressions (range) | IR (95% CI) per 100 person-years <sup>a</sup> | $P$ value <sup>b</sup> |
|------------------------------|--|-----------------------------------|---|------------------------|
| <b>Overall</b> ( $n = 157$ ) | 31 (19.7)  | 35 (0–3)                          | 7.7 (5.5, 10.7)                               | –                      |
| <b>Sex</b>                   |  |                                   |   |                        |
| Women ( $n = 115$ )          | 23 (20.0)  | 25 (0–2)                          | 7.5 (5.0, 11.0)                               | 0.81                   |
| Men ( $n = 42$ )             | 8 (19.1)   | 10 (0–3)                          | 8.2 (4.0, 16.5)                               |                        |
| <b>Age group</b>             |  |                                   |   |                        |
| 70–74 years ( $n = 70$ )     | 13 (18.6)  | 16 (0–3)                          | 7.7 (4.5, 13.3)                               | 0.98                   |
| $\geq 75$ years ( $n = 87$ ) | 18 (20.7)  | 19 (0–2)                          | 7.7 (4.9, 12.0)                               |                        |
| <b>Bone status</b>           |  |                                   |   |                        |
| Normal ( $n = 16$ )          | 4 (25.0)   | 4 (0–1)                           | n/a <sup>c</sup>                              | n/a <sup>c</sup>       |
| Osteopenia ( $n = 74$ )      | 13 (17.6)  | 16 (0–3)                          | 7.4 (4.3, 12.8)                               |                        |
| Osteoporosis ( $n = 65$ )    | 13 (20.0)  | 14 (0–2)                          | 7.5 (4.4, 12.6)                               |                        |

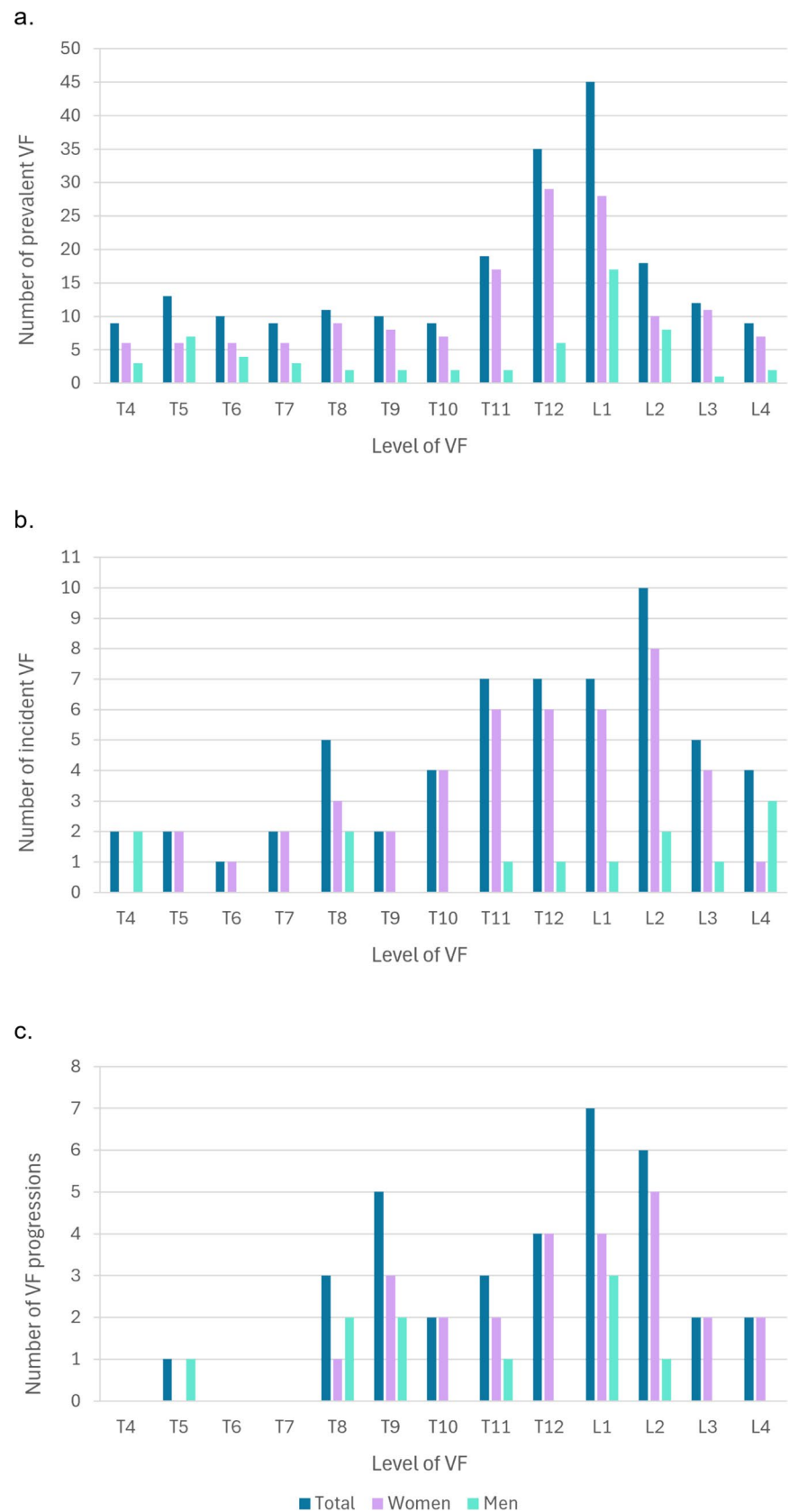
IR incidence rate, VF vertebral fracture

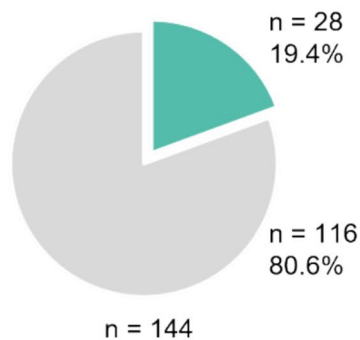
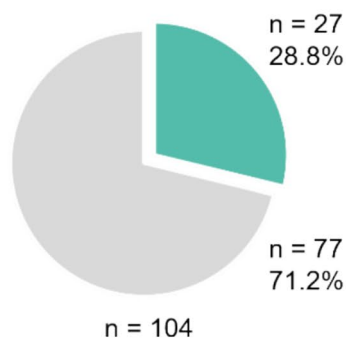
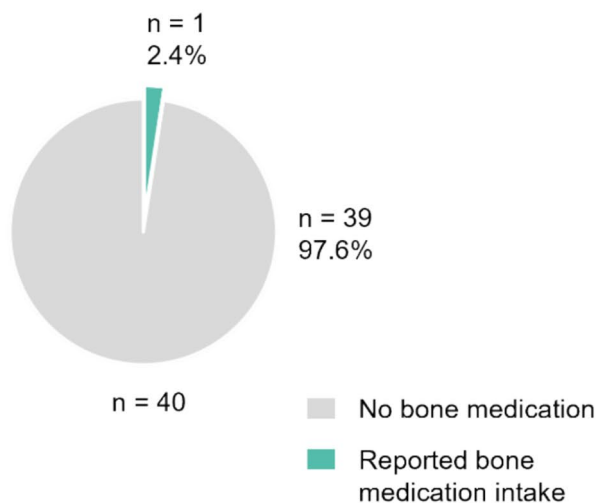
<sup>a</sup>Adjusted for participants' follow-up time

<sup>b</sup> $P$  values are from negative binomial regression models

<sup>c</sup>Models did not converge

**Fig. 1** Number of VF at each level from T4-L4. **a** Prevalent VF at baseline (209 VF among 1488 participants). **b** Incident VF over the three-year follow-up (58 VF among 1369 participants). **c** VF progressions over the three-year follow-up (35 VF progressions among 157 participants)



**a. Overall****b. Women****c. Men**

**Fig. 2** Participants with prevalent VFs reporting OP medication use at baseline, overall (a) and for women (b) and men (c)

Of the 144 participants with prevalent VFs, 122 (84.7%) had at least one moderate or severe (grade 2 or 3) prevalent VFs, and of those 122, 25 (20.5%) participants reported OP medication use. Among the remaining 22 participants with mild VFs, three (13.6%) reported OP medication use.

### Medication treatment of over the three-year follow-up

Five of the 12 participants with incident clinically recognized VFs received no treatment for the fracture, and none of them reported OP medication use at the time of fracture. Three out of 12 participants reported OP medication use: of those, one participant had already been receiving denosumab at the time of VF and continued the medication after fracture. For the other two participants, alendronate was initiated following the fracture. The remaining four participants were treated with vertebroplasty ( $n = 2$ ), vertebroplasty plus physiotherapy ( $n = 1$ ), or physiotherapy only ( $n = 1$ ). None of these four participants reported OP medication use prior to or after sustaining the VF.

Of the 1369 participants with follow-up data, 160 (11.7%) already reported OP medication use at baseline, whereas 75 (5.5%) initiated OP medication treatment during the follow-up period.

### Discussion

This three-year observational study describes the prevalence and incidence of osteoporotic VFs and VF progressions as well as OP medication use among 1488 generally healthy, community-dwelling older adults, recruited at four out of seven DO-HEALTH study centers. Prevalence of at least one VF at baseline was 9.7%. Among participants with a prevalent VF at baseline, 19.4% reported OP medication use. Over the three-year follow-up, 3.7% of participants sustained at least one new osteoporotic VF, and among those with prevalent VFs, 19.7% sustained a progression in at least one VF. Out of all incident radiographic VF, 20.7% were also clinically recognized. Prevalence and incidence were higher in women, older participants, and those with osteoporosis. Differences between countries were found for prevalent VFs but not for incident VFs or VF progressions.

Prevalence of osteoporotic VFs reported in the literature varies considerably. In a systematic review from 2017, overall prevalence of radiographic VFs ranged from 7.3 to 18% in Europe and from 7.3 to 27% worldwide [11]. In general, the prevalence observed in DO-HEALTH is lower compared to other European studies. For example, in the European Prospective Osteoporosis Study (EPOS), which included men and women aged 50–79 years (mean 64 years,  $N = 6788$ )



from 19 European countries, overall prevalence was 12.5%, compared to 9.4% in DO-HEALTH [26]. For sex-specific prevalence, a similar picture emerges: a wide range across countries and a somewhat lower prevalence in DO-HEALTH compared to other European countries [11, 26]. The differences in prevalence between studies can be attributed to differences in the methods of VF assessment, differences in (socio-)demographic factors (e.g., age), and the selection of generally healthy participants in DO-HEALTH.

Similar as for prevalence, incidence data reported in the literature vary. The Rotterdam study included 3469 men and women who were followed over a period of 6.3 years on average [27]. The incidence in participants 75 years and older was 2.0/100 person-years for women and 0.9 for men, which is comparable to our data (1.8/100 person-years for women and 0.9 for men). In the European Prospective Osteoporosis Study (mean follow-up of 3.8 years), the incidence was slightly higher for women with 2.0/100 person-years in the age group 70–74 years and 2.6 for the age group 75–79 years. For men, the corresponding incidence was 0.8 and 1.5, respectively [26]. Of note, EPOS also used a combination of morphological and quantitative VF assessment, as we did in DO-HEALTH. This is relevant, as in addition to differences between study populations and follow-up duration, the VF assessment method may contribute significantly to the heterogeneity in published prevalence and incidence data. Morphological assessment is used frequently and has several advantages. It is semi-automated, reproducible, and relatively fast [28]. The advantage of adding the qualitative approach is that alteration in vertebral morphology unrelated to osteoporosis (e.g., osteoarthritis and high trauma) can be excluded [23, 26].

The higher prevalence and incidence of VFs with increasing age observed in the present study have been well documented in population-based studies [10, 26, 27]. Similarly, the higher prevalence of VFs in women compared to men [15, 26, 27] and in participants with osteoporosis compared to individuals with normal bone status [13] align with the published literature.

Consistent with previous studies, we observed the greatest number of prevalent and incident VFs in T11 to L2, in the region of the thoracolumbar junction [29–31]. It is defined as the transitional zone between the rigid thoracic and more mobile lumbar spine and between thoracic kyphosis and lumbar lordosis. These mechanical and anatomical properties make this region of the spine particularly vulnerable for injuries [32].

Few studies have examined the proportion of radiographic VFs that are also clinically diagnosed. The Rochester cohort [2] and the Multicenter Study of Osteoporotic Fractures [7] are the earliest studies and estimated that approximately one in four to one in three VFs are clinically diagnosed. These two studies are still highly cited,

although more recent studies report lower proportions in women (22.6%) [17] and particularly in men (13.5%) [18]. Our findings align with these more recent studies (women 22.2%; men 15.4%). The higher estimates reported in the earlier studies may partly be related to methodological concerns, such as using retrospective data, lack of standardized assessment criteria, and inclusion of vertebral deformities other than fractures. While our estimates are based on a relatively small sample size, we also like to highlight that this is the first study including prospective data on radiographic and clinically recognized VFs that focuses solely on osteoporotic VFs and excluding other types of vertebral deformities. More importantly, based on newer evidence, underdiagnosis of VFs may have been underestimated in the widely cited earlier studies.

Current European guidelines on osteoporosis treatment initiation are based on assessment of fracture risk [33–35]. According to those guidelines, having sustained a major osteoporotic fracture (including a VF) puts an individual at high risk for subsequent fractures and qualifies for osteoporosis medication treatment, independent of other risk factors [33, 34]. All participants with prevalent VFs at baseline in this study fall into that category; however, only 19.4% of them were reporting OP medication use, while 80.6% were untreated. There is some debate, whether mild VFs (grade 1) should be included in the fracture risk assessment and osteoporosis treatment decision, especially due to challenges of their detection [36]. In the present study, the proportion of participants receiving treatment was 20.5% in participants with moderate and/or severe VFs and 19.8% if all severity categories of VFs were considered. The proportion of participants without treatment (treatment gap) is somewhat higher compared to the treatment gap of 71% across 29 European countries reported in SCOPE [9]. While SCOPE only considered clinically recognized VFs, we included any radiographic VF, which may explain the somewhat lower treatment rate.

One important finding to shed light on in the present study is the very low proportion of men reporting the use of OP medications. Only one out of 40 men with prevalent VFs reported OP medication use at baseline. Furthermore, neither of the two men who reported a clinically recognized VF over the three-year follow-up reported the use of OP medications. The proportion of men (2.4%) reporting OP medication use at baseline is somewhat lower compared to the literature. For example, in the Canada Multicenter Osteoporosis Study, 10% received medication treatment, while 90% of men with fragility fractures were untreated [37]. A similar treatment proportion of one in ten men was reported in the Australian branch of the International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS) [38]. As highlighted by previous reviews, the burden of osteoporosis in males is substantial, including higher morbidity and

mortality compared to women [39]. However, male osteoporosis is significantly underdiagnosed and undertreated. Greater awareness and screening efforts are thus needed to improve patient care.

While several studies have examined the risk of subsequent osteoporotic fractures, less is known about the progression of existing VFs. In a study among Chinese women (mean age 75.7 years,  $N = 1533$ ), 8.0% of grade 1 (mild) and 10% of grade 2 (moderate) severity VFs progressed over the four-year follow-up [40]. Another cohort study of Japanese older adults (mean age 70.1 years,  $N = 224$ ) reported progressions in vertebral deformities in 13.4% of prevalent fractures over a four-year follow-up period [41]. The proportion of participants with at least one VF progression in DO-HEALTH over the three-year follow-up was somewhat higher (19.7%). In contrast to the results for prevalent and incident new VFs, we did not observe any differences in the subgroups by sex and age for VF progressions. The reason for this observation remains unclear, and further studies examining VF progressions are warranted.

Given the association between higher VF grading (severity) and worse clinical outcomes (e.g., severe kyphosis [42] and back pain [43]), identification and prevention of VF progressions are equally important as preventing new fractures.

We acknowledge some limitations to our work. First, this is not a population-based study. The DO-HEALTH participants volunteered to be part of the trial and do not represent the general population. Generalizability of our findings may thus be limited. Second, there is no consensus on diagnosis of VFs which makes comparison to the available literature challenging. However, the combination of morphological and qualitative assessment used in the present study can be seen as a strength, as it excludes morphological changes unrelated to osteoporosis. Third, volunteers who were taking the osteoanabolic OP medication parathyroid hormone were excluded from the DO-HEALTH trial. And last, we did not report past medication intake, and it cannot be excluded that some participants took OP medications for a period of time prior to enrollment.

In summary, this observational study confirms a high prevalence and incidence of VFs in community-dwelling European older adults. Underdiagnosis of VF may be even more prevalent than previously stated, affecting one in six VFs in men and one in four VFs in women. Similarly, the proportion of participants reporting treatment for osteoporotic VFs is low, particularly in men. And last, this study provides novel descriptive data on VF progressions, which have received little attention so far.

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## Declarations

**Conflict of interest** HAB-F reports as the PI of the DO-HEALTH trial, grants from the European Commission, (grant agreement no. 278588) from the University of Zurich, from NESTEC, from PFIZER Consumer Healthcare, from Streuli Pharma, plus non-financial support from DSM Nutritional Products and from Roche Diagnostics. Furthermore, HAB-F reports speaker fees from Wild, Pfizer, Vifor, Mylan, Roche Diagnostics, and independent and investigator initiated grants from Pfizer and from Vifor, outside the submitted work. AA, MK-F, CG, GA, GF, RT, RWK, JAPD, RR, GAW, AE, and BD-H declare no conflicts of interest.

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