ΟΣΤΕΟΠΕΝΙΑ

ΚΩΝ/ΝΟΣ ΔΙΟΝ. ΣΤΑΘΟΠΟΥΛΟΣ M.D, PhD
ΟΡΘΟΠΑΙΔΙΚΟΣ ΧΕΙΡΟΥΡΓΟΣ
ΔΙΔΑΚΤΩΡ ΙΑΤΡΙΚΗΣ ΣΧΟΛΗΣ ΠΑΝΕΠΙΣΤΗΜΙΟΥ ΑΘΗΝΩΝ
ΕΠΙΣΤΗΜΟΝΙΚΟΣ ΣΥΝΕΡΓΑΤΗΣ ΙΑΤΡΙΚΗΣ ΣΧΟΛΗΣ ΕΚΠΑ

ΠΜΣ ΜΕΤΑΒΟΛΙΚΑ ΝΟΣΗΜΑΤΑ ΟΣΤΩΝ

Osteopenia: a key target for fracture prevention

Ian R Reid, Michael R McClung

Lancet Diabetes Endocrinol 2024; 12: 856–64

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- **ΠΡΟ ΤΟΥ 1987 : ΠΟΙΟΤΙΚΟΣ ΟΡΟΣ (ΑΠΛΗ ΑΚΤΙΝΟΓΡΑΦΙΑ)= “ΠΤΩΧΟ” ΟΣΤΟΥΝ= ΛΙΓΟΤΕΡΟ ΠΥΚΝΟ ΑΠΟ ΤΟ ΦΥΣΙΟΛΟΓΙΚΟ**
- **1987: ΕΙΣΑΓΩΓΗ ΜΕΤΡΗΣΗΣ ΟΣΤΙΚΗΣ ΠΥΚΝΟΤΗΤΑΣ ΜΕ ΤΗ ΜΕΘΟΔΟ DXA**
- **1994 (WHO): ΠΟΣΟΤΙΚΟΣ ΟΡΙΣΜΟΣ ΜΕ ΒΑΣΗ ΤΗ ΜΕΘΟΔΟ DXA = T-Score -1 SD ΩΣ -2,5 SD**
- **> 60% ΓΥΝΑΙΚΩΝ ΛΕΥΚΗΣ ΦΥΛΗΣ > 64χ**

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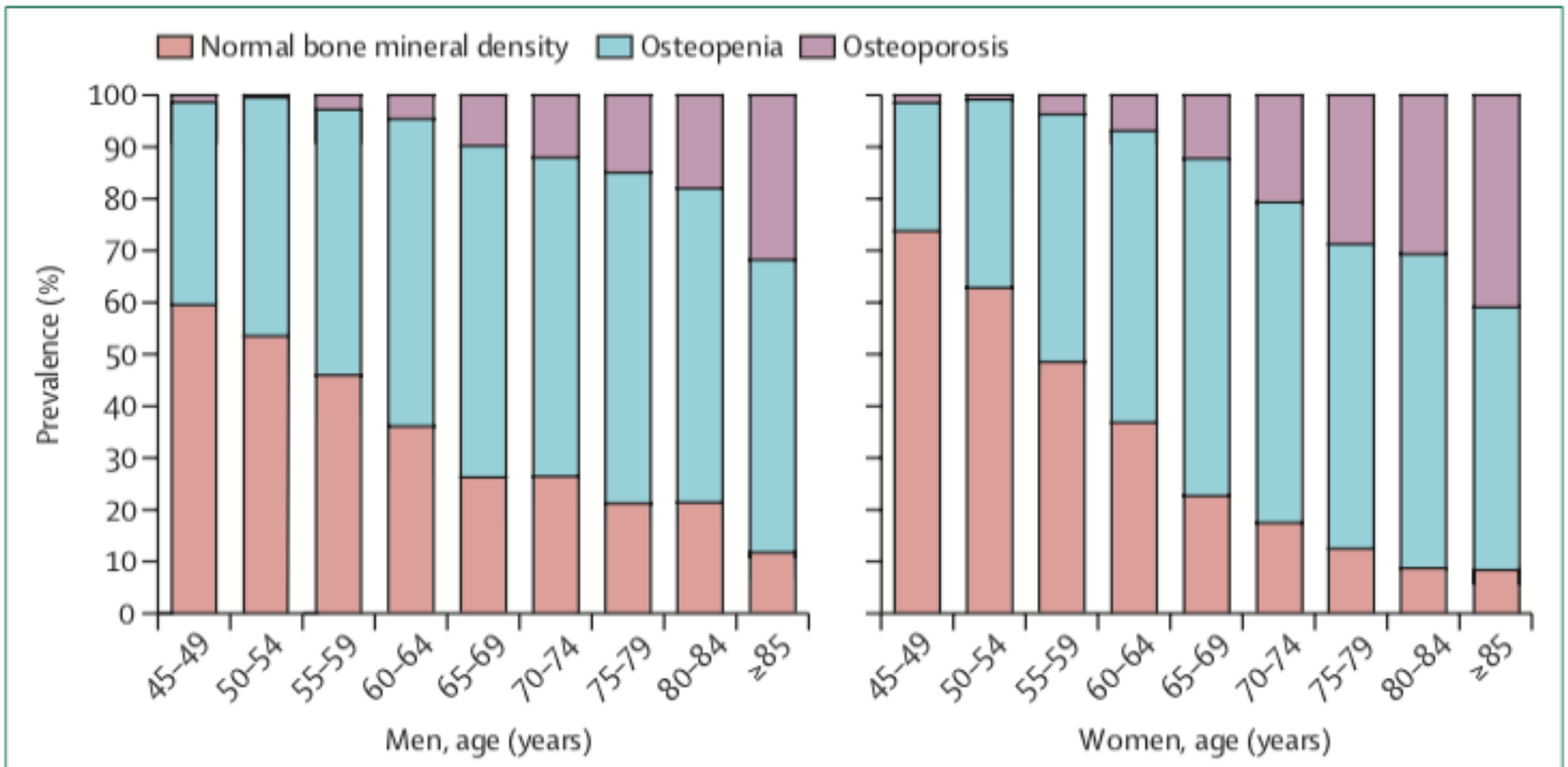

Figure 1: **Prevalence of osteoporosis and osteopenia in men and women by gender-specific T-scores in the Rotterdam Study**
Reproduced from Trajanoska et al,[5] by permission of Elsevier.

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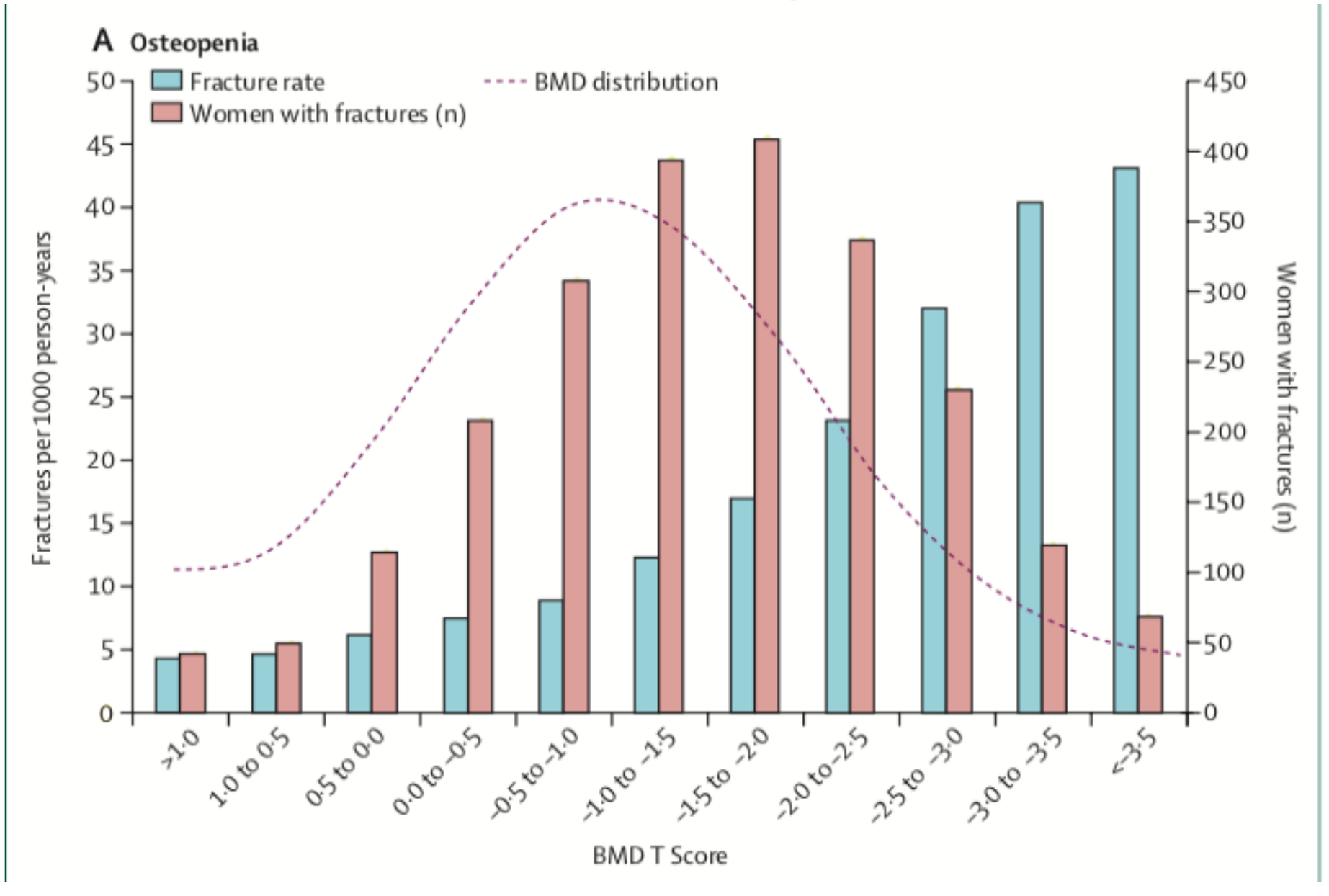
The NORA study provided a crucially important analysis of the relationship between BMD and fracture incidence.[7] Figure 2A shows that fracture rates climb steeply as BMD decreases from normal values to the osteoporotic range. However, because there are more women with osteopenia than with osteoporosis, the proportion of fractures was greater in the group with osteopenia (52%), than in the smaller group with osteoporosis (18%). For hip fractures, 26% occurred in osteoporotic women and 51% in those with osteopenia.



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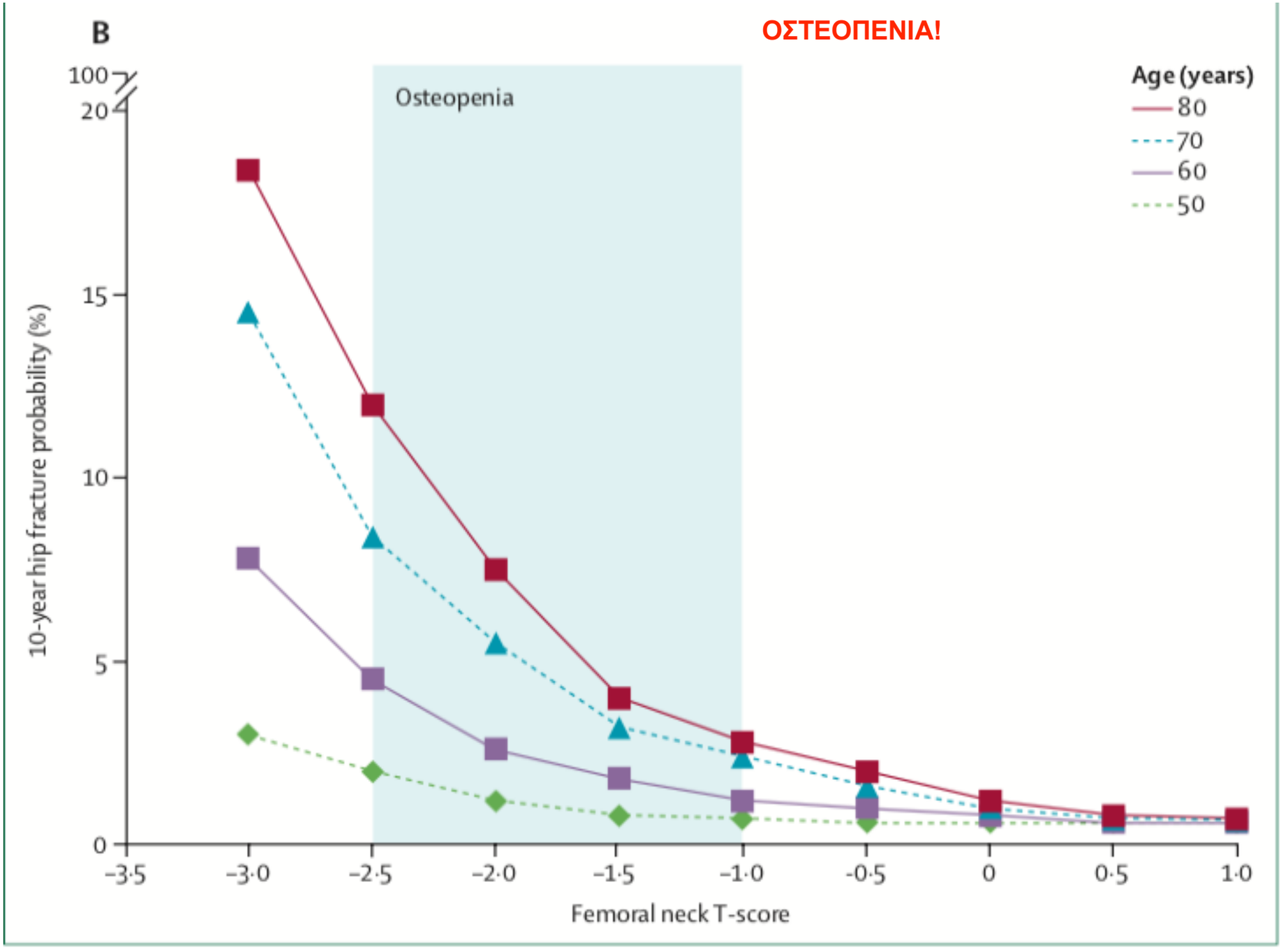
For any given T-score, the 10-year probability of hip fracture is much higher in older postmenopausal women than in younger postmenopausal women, so the range of risk among these women with osteopenia becomes 20-fold (from 0·6% to 12%).

Η ΗΛΙΚΙΑ ΕΙΝΑΙ ΠΟΛΥ ΣΗΜΑΝΤΙΚΟΣ ΠΑΡΑΓΟΝΤΑΣ ΓΙΑ ΤΟΝ ΚΑΤΑΓΜΑΤΙΚΟ ΚΙΝΔΥΝΟ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΟΣΤΕΟΠΕΝΙΑ!



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- **ΙΣΤΟΡΙΚΟ ΠΡΟΗΓΟΥΜΕΝΩΝ ΚΑΤΑΓΜΑΤΩΝ (ΕΙΔΙΚΑ ΠΡΟΣΦΑΤΑ <2 ΕΤΗ ΚΑΙ ΠΟΛΛΑΠΛΑ)**
- **ΦΥΛΟ**
- **ΕΘΝΙΚΟΤΗΤΑ**
- **ΙΣΤΟΡΙΚΟ ΠΤΩΣΕΩΝ**
- **ΚΛΙΝΙΚΟΙ ΠΑΡΑΓΟΝΤΕΣ ΚΙΝΔΥΝΟΥ (Ρ.Α., ΛΗΨΗ ΚΟΡΤΙΖΟΝΗΣ κ.α.)**

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	Age, years	Weight, kg	Height, cm	Previous fracture	T-score	Country	10-year risk (%)	
							Major osteoporotic fracture	Hip
Female	55	60	165	No	–1·2	USA*	5·7%	0·4%
Female†	75	60	165	Yes	–2·2	USA*	60%	45%
Female	75	60	165	Yes	–2·2	USA*	20%	5·6%
Female	75	60	165	Yes	–2·2	USA‡	9·2%	2·5%
Female	75	60	165	Yes	–2·2	USA§	12%	3·3%
Male	75	70	175	Yes	–2·2	USA*	14%	5·6%
Female	75	60	165	Yes	–2·2	Colombia¶	6·3%	2%
Female	75	60	165	Yes	–2·2	China¶	7·6%	2·8%
Female	75	60	165	Yes	–2·2	Japan¶	21%	4·8%
Female	75	60	165	Yes	–2·2	New Zealand¶	15%	5%
Female	75	60	165	Yes	–2·2	Denmark¶	29%	9·2%
Female	75	60	165	Yes	–2·2	UK¶	18%	5%

10-year risk given to two significant figures. *White ethnicity. †Parental history of hip fracture, rheumatoid arthritis, and history of glucocorticoid use. ‡Black ethnicity. §Asian ethnicity. ¶Ethnicity not specified.

Table 1: **Fracture risks by the Fracture Risk Assessment tool in a range of individuals with osteopenia**

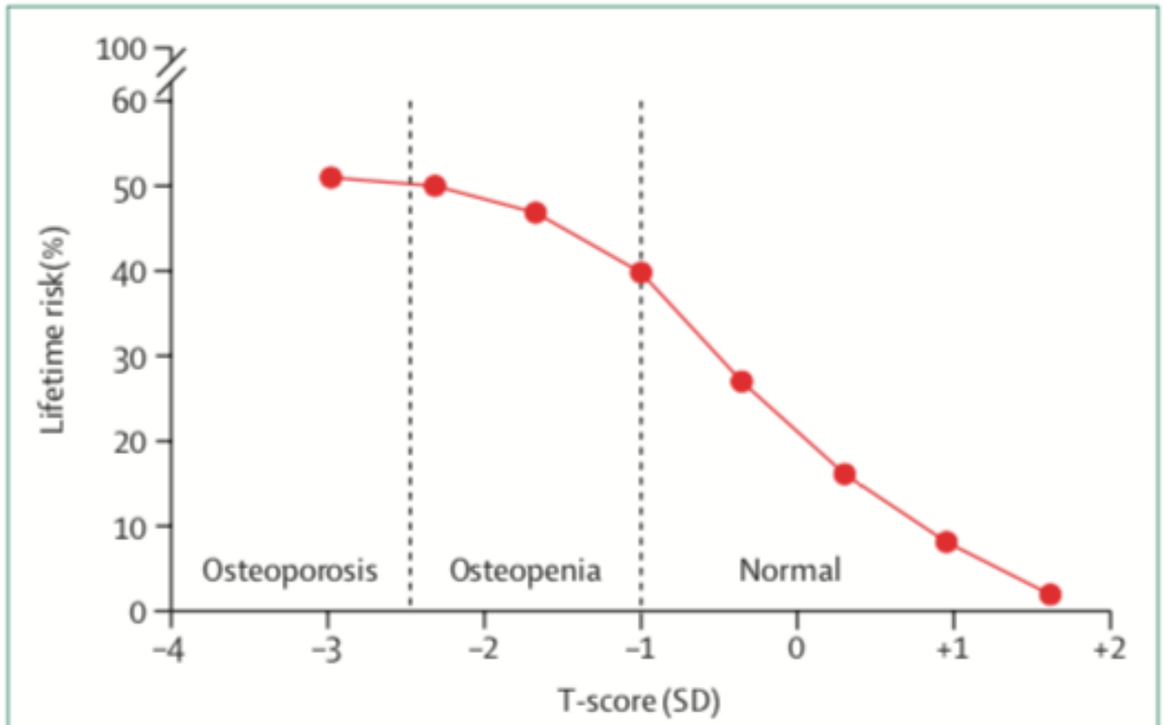

Figure 3: **Remaining lifetime risk of hip fracture in women aged 50 years, according to bone mineral density or T-score at the hip**
Reproduced from Kanis,[15] by permission of Elsevier.

Is fracture prevention possible in osteopenia?

- ΠΟΛΥΑΡΙΘΜΕΣ ΜΕΛΕΤΕΣ ΓΙΑ ΤΗ ΔΡΑΣΗ ΦΑΡΜΑΚΩΝ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΟΣΤΕΟΠΕΝΙΑ ΑΝ ΚΑΙ ΣΕ ΟΡΙΣΜΕΝΕΣ ΠΕΡΙΠΤΩΣΕΙΣ ΜΕΡΙΚΟΙ ΑΣΘΕΝΕΙΣ ΕΙΧΑΝ ΠΡΟΗΓΟΥΜΕΝΟ ΣΠΟΝΔΥΛΙΚΟ ΚΑΤΑΓΜΑ Ή T-score ≤–2·5 ΣΕ ΑΛΛΗ ΣΚΕΛΕΤΙΚΗ ΘΕΣΗ ΜΕΤΡΗΣΗΣ

- ΓΙΑ ΑΛΕΝΔΡΟΝΑΤΗ (Cummings JAMA 1998) ΚΑΙ ΡΙΣΕΔΡΟΝΑΤΗ (Mc Clung NEJM 2001), ΜΕΛΕΤΕΣ ΥΠΟΠΛΗΘΥΣΜΩΝ ΔΕΝ ΕΔΕΙΞΑΝ ΕΛΑΤΤΩΣΗ ΕΠΙΠΤΩΣΗΣ ΜΗ ΣΠΟΝΔΥΛΙΚΩΝ ΚΑΤΑΓΜΑΤΩΝ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΑΠΛΗ ΟΣΤΕΟΠΕΝΙΑ.

- ΜΕΛΕΤΗ ΜΕ ΑΛΕΝΔΡΟΝΑΤΗ ΕΔΕΙΞΕ ΕΛΑΤΤΩΣΗ ΕΠΙΠΤΩΣΗΣ ΣΠΟΝΔΥΛΙΚΩΝ ΚΑΤΑΓΜΑΤΩΝ (Quandt Mayo Clin Proceed 2005)

- ΜΕΛΕΤΗ ΜΕ ΡΙΣΕΔΡΟΝΑΤΗ ΕΔΕΙΞΕ ΕΛΑΤΤΩΣΗ ΚΑΤΑΓΜΑΤΩΝ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΟΣΤΕΟΠΕΝΙΑ ΧΩΡΙΣ ΠΡΟΗΓΟΥΜΕΝΟ ΣΠΟΝΔΥΛΙΚΟ ΚΑΤΑΓΜΑ (Siris Osteoporos Int 2008)

- Denosumab phase 3 trial: Η ΕΛΑΤΤΩΣΗ ΕΠΙΠΤΩΣΗΣ ΣΠΟΝΔΥΛΙΚΩΝ ΚΑΤΑΓΜΑΤΩΝ ΗΤΑΝ ΑΝΕΞΑΡΤΗΤΗ ΑΡΧΙΚΗΣ BMD, ΑΛΛΑ ΓΙΑ ΤΑ ΜΗ ΣΠΟΝΔΥΛΙΚΑ ΚΑΤΑΓΜΑΤΑ ΕΠΙΔΡΑΣΗ ΑΠΟΔΕΙΧΘΗΚΕ ΜΟΝΟ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ T-score<–2·5 ΣΤΟΝ ΑΥΧΕΝΑ (post-hoc analyses were probably underpowered)

- Post-hoc analyses, strontium ranelate/ raloxifene ΕΛΑΤΤΩΣΗ ΣΠΟΝΔΥΛΙΚΩΝ ΚΑΤΑΓΜΑΤΩΝ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΟΣΤΕΟΠΕΝΙΑ ΣΤΗ ΣΠΟΝΔΥΛΙΚΗ ΣΤΗΛΗ ΚΑΙ ΤΟ ΙΣΧΙΟ ΑΝΤΙΣΤΟΙΧΑ ΑΝ ΚΑΙ ΟΙ ΑΣΘΕΝΕΙΣ ΑΥΤΟΙ ΜΠΟΡΕΙ ΝΑ ΕΙΧΑΝ ΟΣΤΕΟΠΟΡΩΣΗ ΜΕ ΑΛΛΑ ΚΡΙΤΗΡΙΑ

- **ΜΙΑ ΜΕΤΑ-ΑΝΑΛΥΣΗ ΤΟΥ 2024 ΑΣΘΕΝΩΝ ΑΠΟ 25 trials (103086 patients) ΚΑΤΕΔΕΙΞΕ ΟΤΙ ΤΑ ΦΑΡΜΑΚΑ ΕΛΑΤΤΩΣΑΝ ΤΟΝ ΚΙΝΔΥΝΟ ΚΑΤΑΓΜΑΤΩΝ ΑΝΕΞΑΡΤΗΤΑ ΑΠΟ ΤΗΝ ΑΡΧΙΚΗ BMD ΣΤΟΝ ΑΥΧΕΝΑ ΤΟΥ ΜΗΡΙΑΙΟΥ, ΑΛΛΑ ΤΑ ΑΠΟΤΕΛΕΣΜΑΤΑ ΗΤΑΝ ΜΕΓΑΛΥΤΕΡΑ ΚΑΙ ΠΕΡΙΣΣΟΤΕΡΟ ΣΤΑΤΙΣΤΙΚΑ ΣΗΜΑΝΤΙΚΑ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΧΑΜΗΛΟΤΕΡΕΣ ΤΙΜΕΣ BMD ΚΑΙ ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΟΣΤΕΟΠΕΝΙΑ ΚΑΙ ΠΡΟΗΓΟΥΜΕΝΑ ΣΠΟΝΔΥΛΙΚΑ ΚΑΤΑΓΜΑΤΑ (Schini JBMR 2024)**

Journal of Bone and Mineral Research, 2024, **39**, 867–876
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Advance access publication: May 1, 2024
Research Article

Pre-treatment bone mineral density and the benefit of pharmacologic treatment on fracture risk and BMD change: analysis from the FNIH-ASBMR SABRE project

Marian Schini[1,*], Tatiane Vilaca[1], Li-Yung Lui[2], Susan K. Ewing[3], Austin Thompson[3], Eric Vittinghoff[3], Douglas C. Bauer[3,4], Mary L. Bouxsein[5], Dennis M. Black[3], Richard Eastell[1]

Table 1. Baseline FN BMD T-score status by trial in SABRE study.

Trial	Drug class	Study drug	N (%) in FN BMD T-score > −2.5	N (%) in FN BMD T-score ≤ −2.5
ALN Phase 3[22]	Bisphosphonate	Alendronate	608 (68.4%)	281 (31.6%)
FIT I[23]	Bisphosphonate	Alendronate	1133 (55.9%)	893 (44.1%)
FIT II[7]	Bisphosphonate	Alendronate	3239 (73.1%)	1191 (26.9%)
FOSIT[24]	Bisphosphonate	Alendronate	1381 (76.0%)	436 (24.0%)
MENs[25]	Bisphosphonate	Alendronate	174 (72.2%)	67 (27.8%)
CLODRONATE[26]	Bisphosphonate	Clodronate	4008 (77.5%)	1165 (22.5%)
BONE[8]	Bisphosphonate	Ibandronate	2040 (70.4%)	856 (29.6%)
IBAN IV[27]	Bisphosphonate	Ibandronate (intravenous)	1966 (69.6%)	860 (30.4%)
HIP[28]	Bisphosphonate	Risedronate	545 (31.7%)	1173 (68.3%)
VERT-MN[29]	Bisphosphonate	Risedronate	409 (52.3%)	373 (47.7%)
VERT-NA[30]	Bisphosphonate	Risedronate	971 (61.4%)	611 (38.6%)
HORIZON PFT[31]	Bisphosphonate	Zoledronate (intravenous)	2643 (34.3%)	5053 (65.7%)
HORIZON RFT[32]	Bisphosphonate	Zoledronate (intravenous)	976 (52.3%)	891 (47.7%)
LOFT[33]	Cathepsin K inhibitor	Odanacatib	4719 (30.7%)	10 635 (69.3%)
ACTIVE[34]	Anabolic	Abaloparatide	1168 (71.1%)	474 (28.9%)
TOP[35]	Anabolic	PTH (1-84)	1637 (64.7%)	894 (35.3%)
FPT[14]	Anabolic	Teriparatide	949 (61.2%)	602 (38.8%)
FRAME[36]	Anabolic	Romosozumab (subcutaneous)	799 (11.1%)	6380 (88.9%)
WHI-E[37]	Hormone therapy	Estrogen	865 (92.6%)	69 (7.4%)
WHI-EP[38]	Hormone therapy	Estrogen and progestin	940 (91.8%)	84 (8.2%)
FREEDOM[39]	RANKL inhibitor	Denosumab (subcutaneous)	5210 (67.1%)	2559 (32.9%)
GENERATIONS[40]	SERMs	Arzoxifene	7555 (81.0%)	1773 (19.0%)
BZA[41]	SERMs	Bazedoxifene	4582 (81.3%)	1054 (18.7%)
PEARL[42]	SERMs	Lasofoxifene	5696 (66.7%)	2845 (33.3%)
MORE[43]	SERMs	Raloxifene	5074 (66.3%)	2580 (33.7%)

Journal of Bone and Mineral Research, 2024, **39**, 867–876
https://doi.org/10.1093/jbmr/zjae068
Advance access publication: May 1, 2024
Research Article

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Marian Schini[1,*], Tatiane Vilaca[1], Li-Yung Lui[2], Susan K. Ewing[3], Austin Thompson[3], Eric Vittinghoff[3], Douglas C. Bauer[3,4], Mary L. Bouxsein[5], Dennis M. Black[3], Richard Eastell[1]

Table 2. Baseline characteristics (mean ± SD, or %) by baseline FN BMD T-score status.

	FN BMD T-score		
	>−2.5 (N = 59 287)	**≤ −2.5 (N = 43 799)**	***P*-value**
Age (yr)	68.5 ± 7.2	71.6 ± 6.7	<.0001
Female (%)	99.3	99.4	.008
BMI (kg/m^2)	26.6 ± 4.3 *(n = 59 070)*	24.5 ± 4.2 *(n = 43 653)*	<.0001
Prevalent vertebral fracture (%)	39.8 *(n = 54 771)*	39.4 *(n = 41 844)*	.18
History of non-vertebral fracture (%)	32.1 *(n = 21 453)*	35.2 *(n = 15 415)*	<.0001
TH BMD T-score	−1.49 ± 0.78 *(n = 54 392)*	−2.60 ± 0.60 *(n = 40 106)*	<.0001
FN BMD T-score	−1.80 ± 0.59 *(n = 59 287)*	−2.91 ± 0.34 *(n = 43 799)*	<0.0001
LS BMD T-score	−2.38 ± 1.11 *(n = 51 323)*	−2.96 ± 1.08 *(n = 35 912)*	<0.0001

Abbreviation: n, number of participants with data.

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Treatment efficacy was greater in the T-score ≤ −2.5 subgroup than the > −2.5 subgroup for all 5 fracture types (eg, reduction of 53% vs 48% for vertebral, 25% vs 19% for all clinical), but **only the all-fracture outcome reached conventional levels of statistical significance (reduction of 35% vs 26%, *P*-value for interaction = .001).**

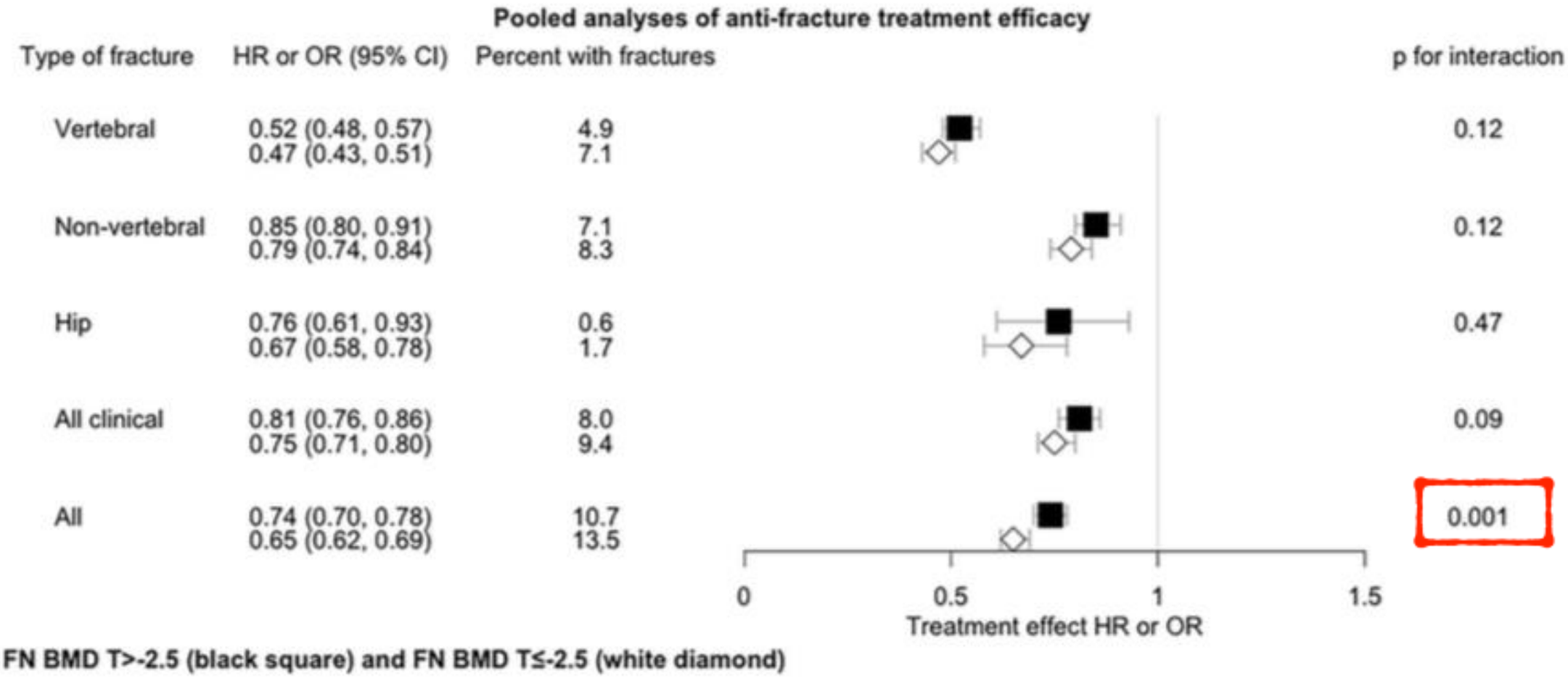

Figure 1. Pooled analyses of anti-fracture treatment efficacy by baseline FN BMD T-score status across all studies. All results are adjusted for trial. 2-way interaction: Treatment * T-score status. Abbreviations: HR, hazard ratio; OR, odds ratio.

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Combined set of 13 trials evaluating bisphosphonate treatments.

Once again, the fracture risk reduction was greater in those with T-score ≤ −2.5 for all-fracture outcomes, but only the all-fracture outcome reached statistical significance (*P*-value for interaction = .005).

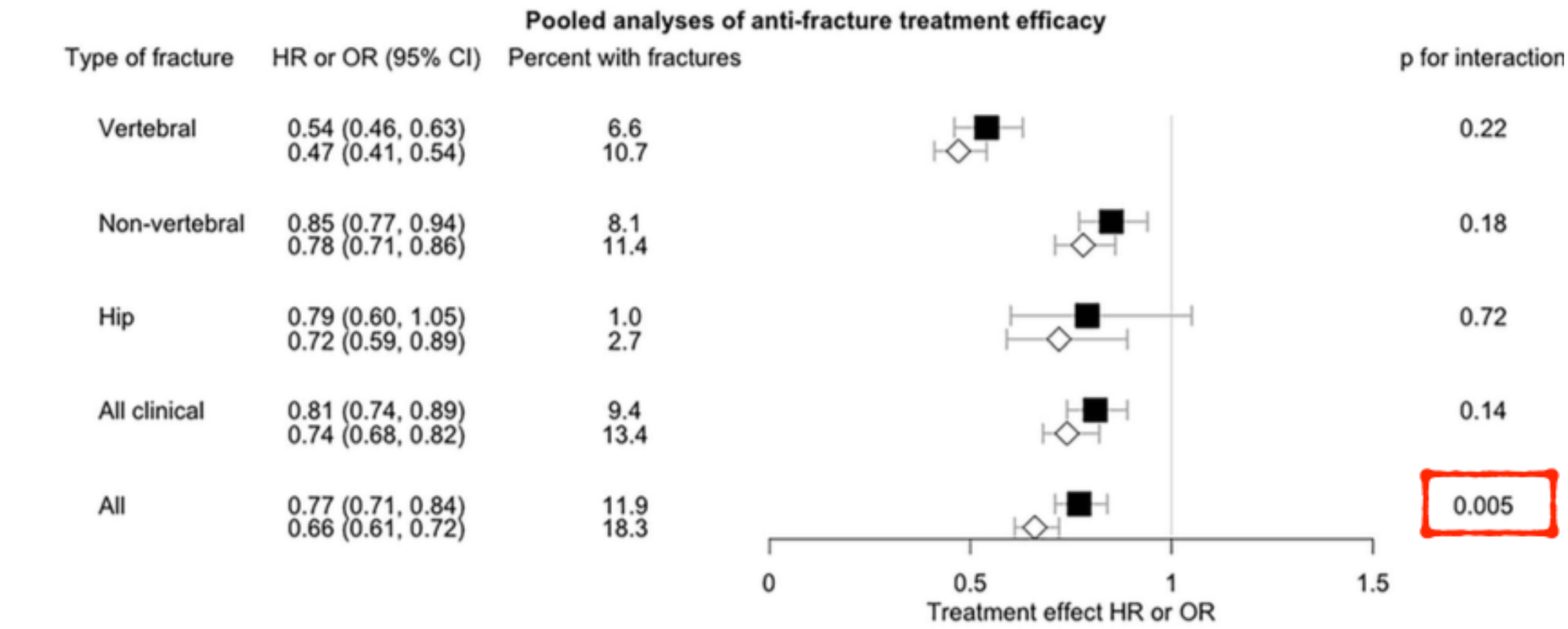

Figure 2. Pooled analyses of anti-fracture treatment efficacy by baseline FN BMD T-score status across 13 bisphosphonate trials. All results are adju for trial. 2-way interaction: Treatment * T-score status. Abbreviations: HR, hazard ratio; OR, odds ratio.

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The number of participants included in each FN BMD T-score quintile for each study is shown in Table S5, and the baseline characteristics by T-score quintiles are provided in Table S6. In general, there was a linear relationship between quintiles, age, and BMI: the lower the T-score, the lower the BMI, and the older the age.

There was a treatment-related reduction in fracture risk within each quintile for each fracture type assessed, generally more pronounced in lower T-score quintile.There was no significant interaction between treatment and BMD quintile for the hip fracture outcome, but the number of hip fractures was small (eg, $n = 82$ at Q5). Interactions were significant for the other 4 fracture outcomes (P-value for interaction ≤.03).

The CI for the highest T-score quintile crossed 1.0 for the non-vertebral and all clinical fractures outcomes, suggesting that antiosteoporotic medications might not be effective against these fracture types among those with higher BMD

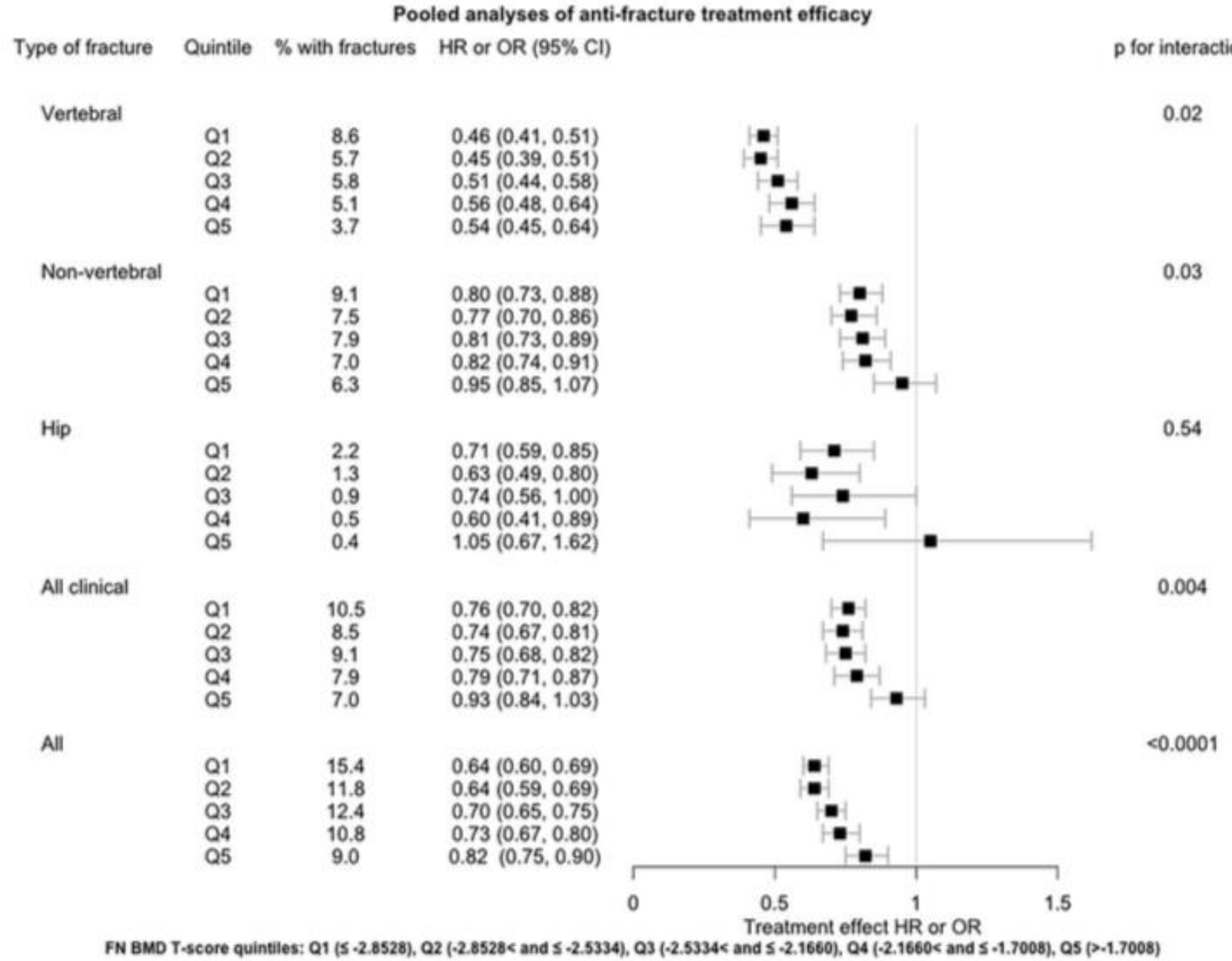

Figure 3. Pooled analyses of anti-fracture treatment efficacy by baseline FN BMD T-score quintiles across 25 trials.

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Abstract

Some osteoporosis drug trials have suggested that treatment is more effective in those with low BMD measured by DXA. This study used data from a large set of randomized controlled trials (RCTs) to determine whether the anti-fracture efficacy of treatments differs according to baseline BMD. We used individual patient data from 25 RCTs (103 086 subjects) of osteoporosis medications collected as part of the FNIH-ASBMR SABRE project. Participants were stratified into FN BMD T-score subgroups (≤−2.5, > −2.5). We used Cox proportional hazard regression to estimate treatment effect for clinical fracture outcomes and logistic regression for the radiographic vertebral fracture outcome. We also performed analyses based on BMD quintiles. Overall, 42% had a FN BMD T-score ≤ −2.5. Treatment with anti-osteoporosis drugs led to significant reductions in fractures in both T-score ≤ −2.5 and > −2.5 subgroups. Compared to those with FN BMD T-score > −2.5, the risk reduction for each fracture outcome was greater in those with T-score ≤ −2.5, but only the all-fracture outcome reached statistical significance (interaction P = .001). Results were similar when limited to bisphosphonate trials. In the quintile analysis, there was significant anti-fracture efficacy across all quintiles for vertebral fractures and with greater effects on fracture risk reduction for non-vertebral, all, and all clinical fractures in the lower BMD quintiles (all interaction P ≤ .03). **In summary, anti-osteoporotic medications reduced the risk of fractures regardless of baseline BMD. Significant fracture risk reduction with treatment for 4 of the 5 fracture endpoints was seen in participants with T-scores above −2.5, though effects tended to be larger and more significant in those with baseline T-scores <−2.5.**

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- **ΔΥΟ ΟΜΑΔΕΣ: 5mg IV Zolendronate vs Placebo (Normal Saline) ΚΑΘΕ 18 ΜΗΝΕΣ**
- **ΑΡΧΙΚΗ ΜΕΛΕΤΗ ΟΛΟΚΛΗΡΩΘΗΚΕ ΣΕ 6 ΕΤΗ (4 ΕΓΧΥΣΕΙΣ)**
- **ΕΠΕΚΤΑΣΗ ΤΗΣ ΜΕΛΕΤΗΣ ΓΙΑ 4 ΑΚΟΜΑ ΕΤΗ (ΜΟΝΟ ΠΑΡΑΤΗΡΗΣΗ, ΟΧΙ ΛΗΨΗ ΦΑΡΜΑΚΩΝ ΟΠ> 6 ΜΗΝΕΣ ΑΠΟ 6ο ΩΣ 10ο ΕΤΟΣ)**
- **ΒΑΣΙΚΟ ΚΑΤΑΛΗΚΤΗΡΙΟ ΣΗΜΕΙΟ Η BMD ΟΛΙΚΟΥ ΙΣΧΙΟΥ (ΣΕ 50 ΑΤΟΜΑ ΕΛΕΓΧΟΣ ΒΙΟΧΗΜ. ΔΕΙΚΤΩΝ)**
- **ΑΝΑΦΟΡΑ ΚΑΤΑΓΜΑΤΩΝ ΑΠΟ ΤΟΥΣ ΑΣΘΕΝΕΙΣ ΚΑΙ ΑΚΤΙΝΟΛΟΓΙΚΗ ΕΠΙΒΕΒΑΙΩΣΗ (+ ΕΡΩΤΗΣΕΙΣ ΓΙΑ ΚΑΡΔΙΑΓΓΕΙΑΚΑ ΚΑΙ ΟΔΟΝΤΙΑΤΡΙΚΕΣ ΕΠΕΜΒΑΣΕΙΣ/ΣΥΜΒΑΝΤΑ)**

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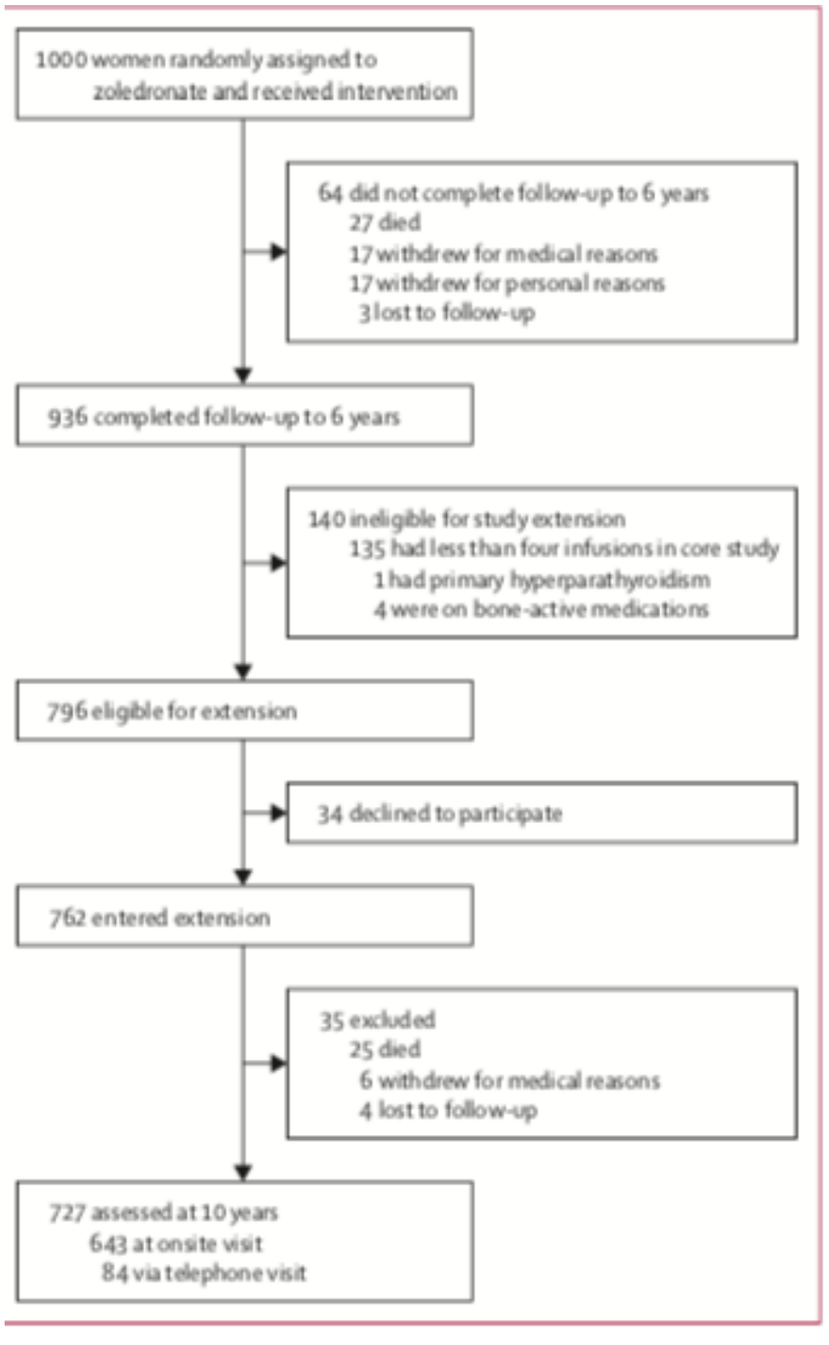

	Original zoledronate cohort at trial baseline (n=1000)	Extension cohort at trial baseline (n=762)	Extension cohort at extension baseline (ie, year 6; n=762)
Age, years	71 (5)	71 (5)	77 (5)
Ethnicity			
European	954 (95%)	739 (97%)	739 (97%)
Māori	17 (2%)	5 (1%)	5 (1%)
Pacific	7 (1%)	3 (<1%)	3 (<1%)
East Asian	15 (2%)	11 (1%)	11 (1%)
Indian	5 (1%)	2 (<1%)	2 (<1%)
Other	2 (<1%)	2 (<1%)	2 (<1%)
Height, cm	160·7 (5·8)	160·8 (5·8)	160·1 (5·8)
Weight, kg	69·1 (12·5)	69·0 (12·0)	67·9 (12·4)
Prevalent non-vertebral fracture*	237 (24%)	192 (25%)	255 (33%)
Prevalent vertebral fracture†	137 (14%)	101 (13%)	120 (16%)
Bone density T-scores			
Lumbar spine	−0·91 (1·12)	−0·94 (1·12)	−0·33 (1·24)
Total hip	−1·27 (0·59)	−1·26 (0·58)	−0·99 (0·63)
Total body	−0·81 (0·86)	−0·84 (0·86)	−0·55 (0·87)
Current smokers	23 (2%)	12 (2%)	12 (2%)
FRAX 10-year risk of major osteoporotic fracture, %	12 (9–16)	12 (9–16)	13 (10–17)

Data are mean (SD), n (%), or median (IQR). *Fracture occurring after age 45 years, excluding fractures of the skull, face, mandible, hands, and feet. †Genant grade 2 or 3.

Table 1: **Baseline characteristics of women enrolled in the study extension, with trial baseline data from original zoledronate group for comparison**

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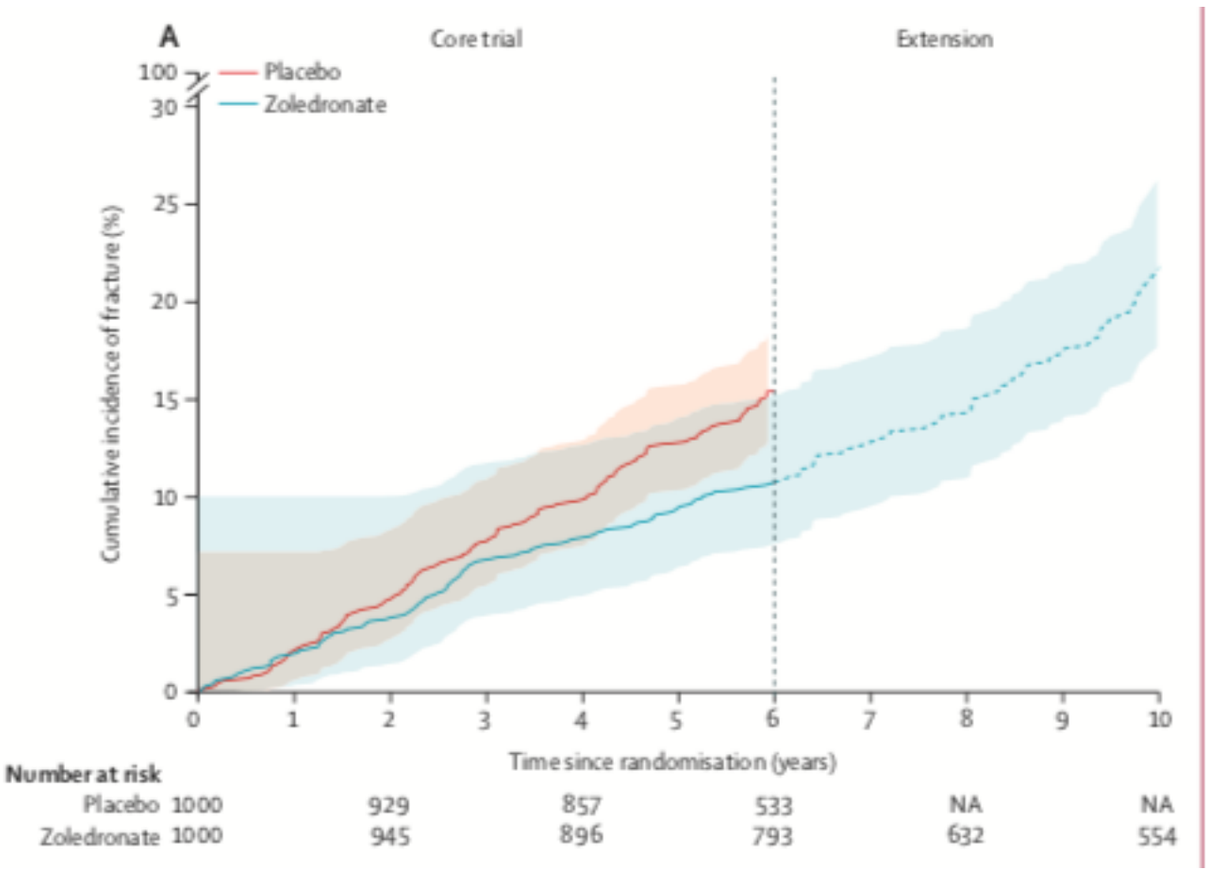

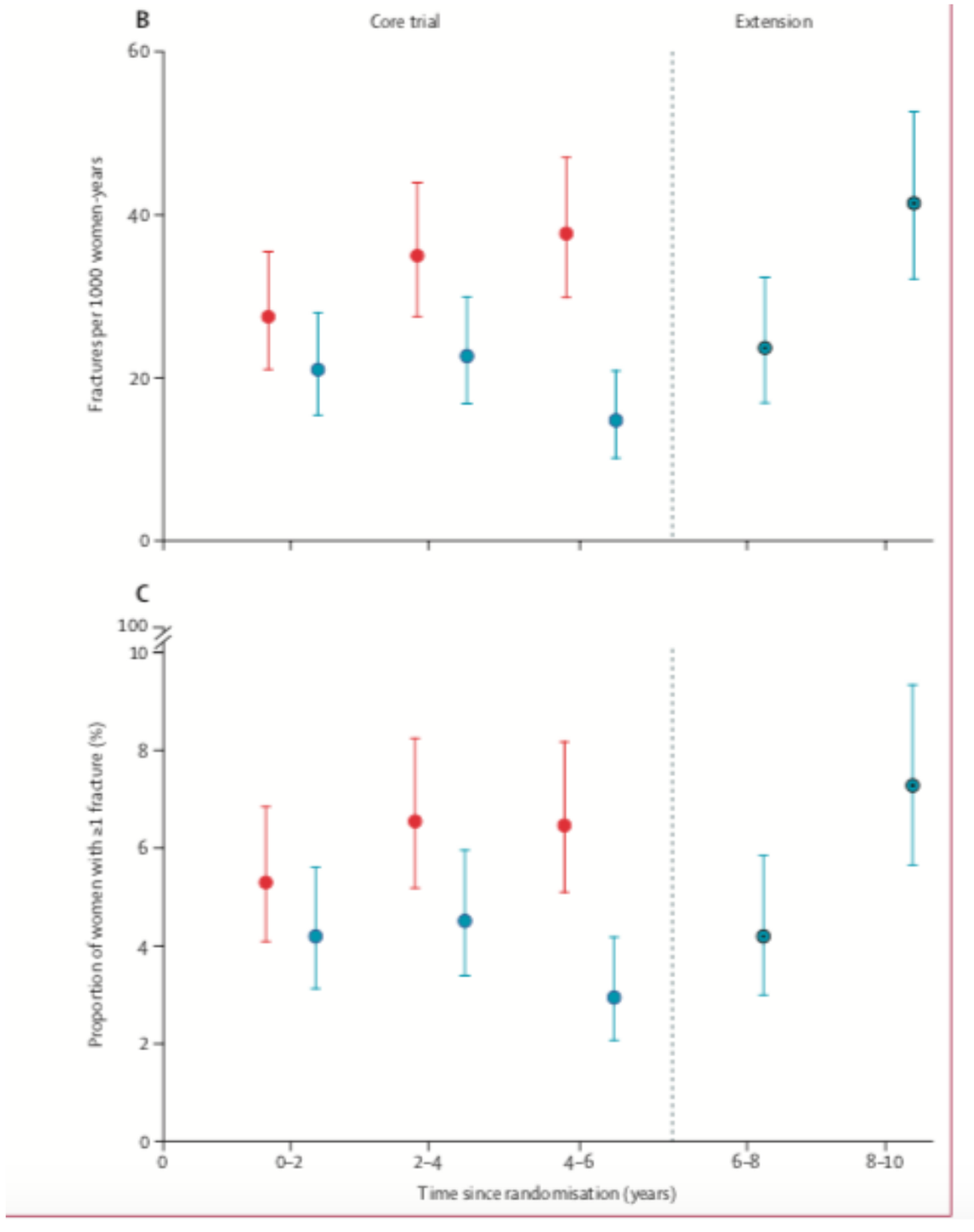

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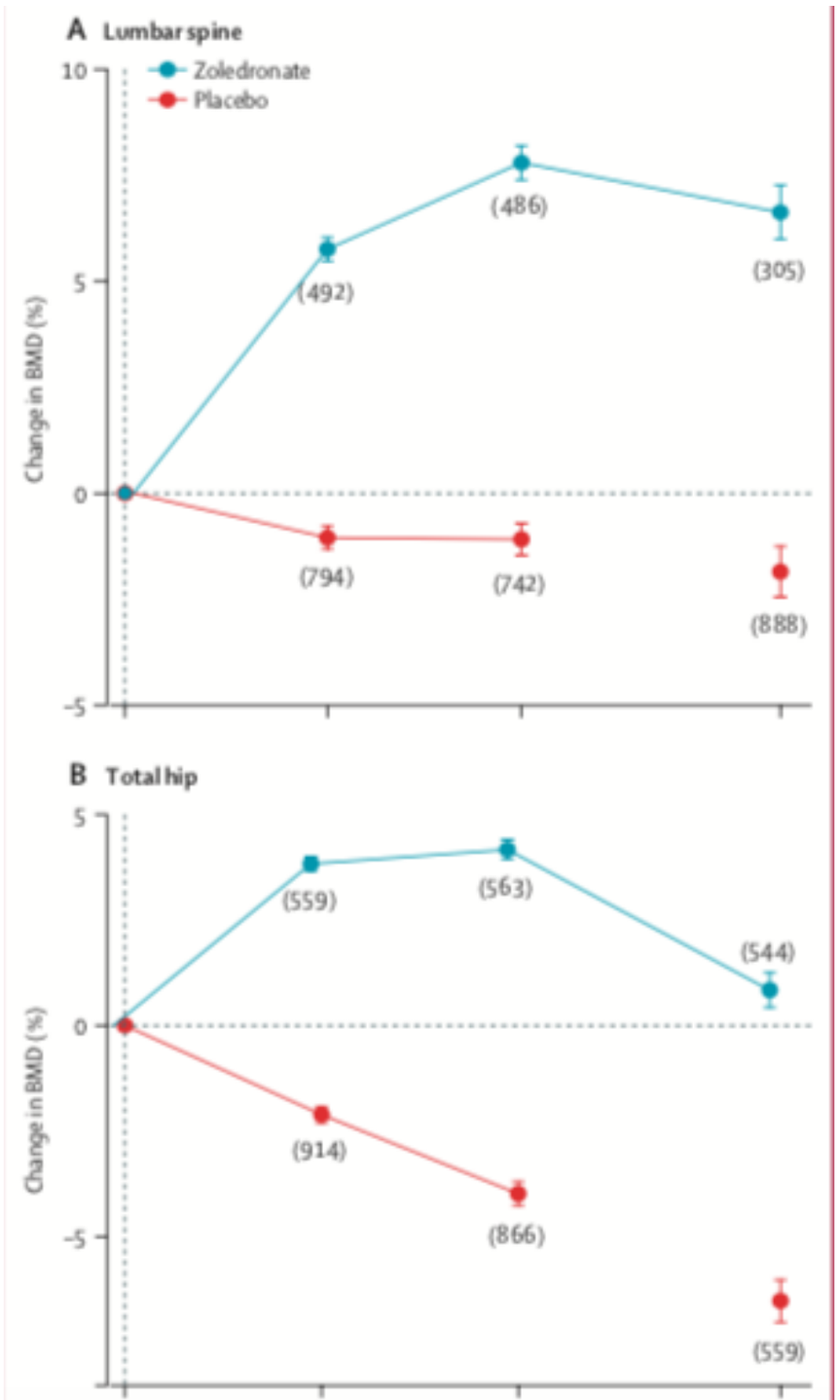
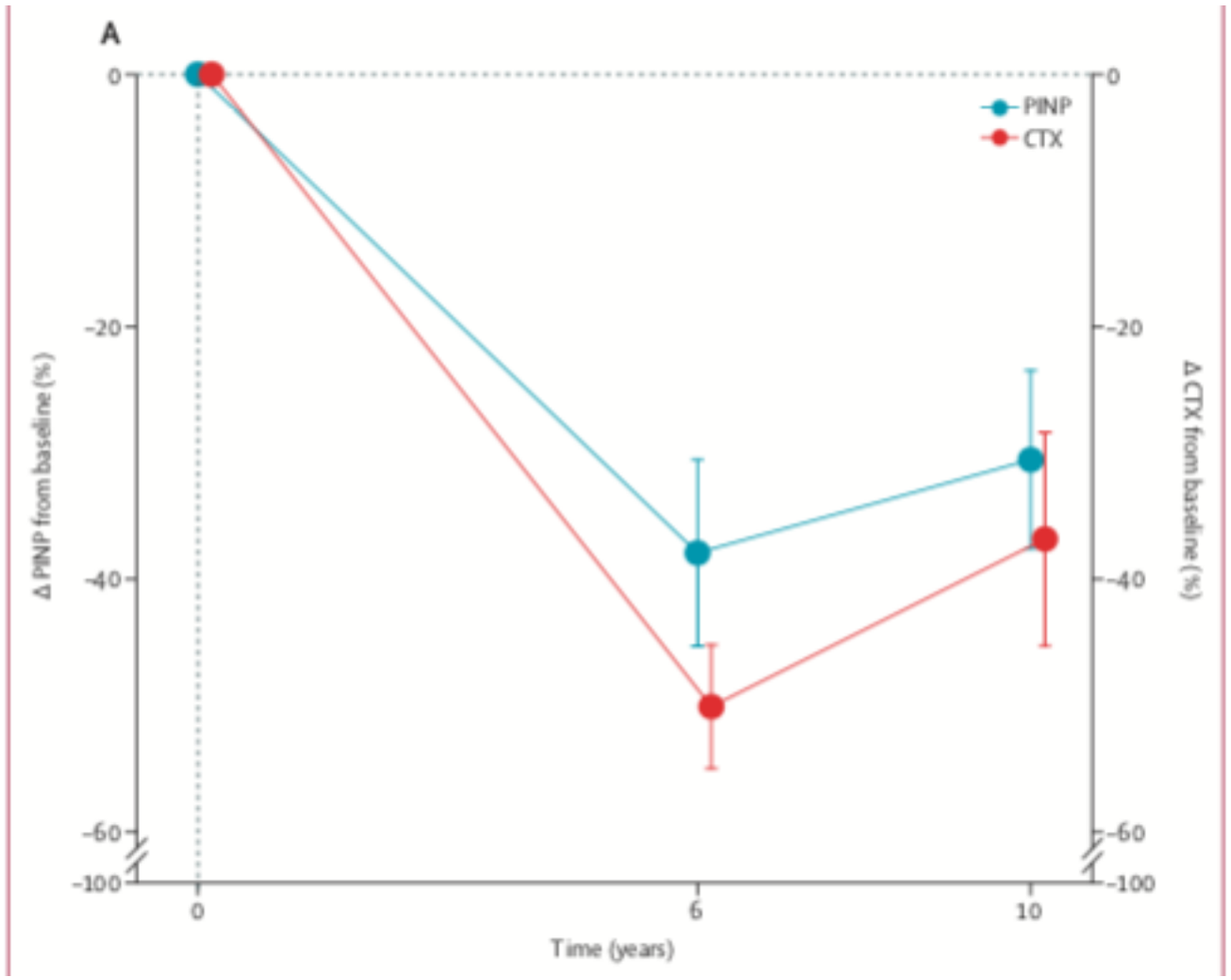


for total hip and total body. **At 10 years, BMD was higher at all sites in the zoledronate group than the extrapolated values from the placebo group (p<0·0001).At the end of the core trial (6 years), lumbar spine BMD was 7·8% higher than at baseline, and it remained 6·6% higher than at baseline at year 10 (p=0·55 for change from years 6 to 10).**

For total hip, BMD was 4·2% higher than at baseline at 6 years, decreasing to 0·8% higher than at baseline at year 10, which was significantly higher than at baseline (p=0·0003) but significantly lower than at 6 years (p<0·0001).



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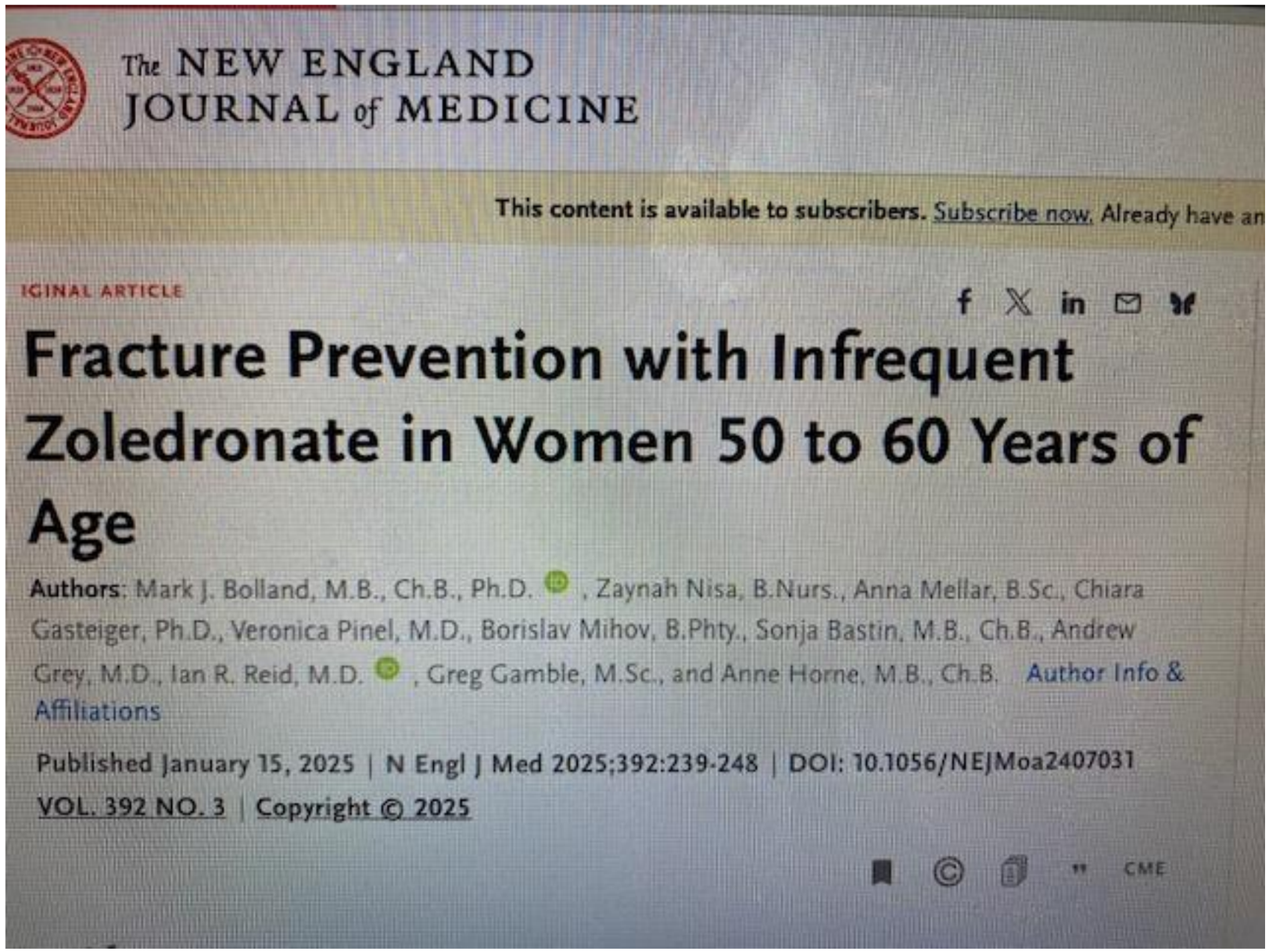
	Study extension			Events per 1000 woman-years (95% CI) in the core trial placebo group	Events per 1000 woman-years (95% CI) in the core trial zoledronate group
	Number of events	Women with ≥1 event (n=762)	Events per 1000 woman-years (95% CI)		
Death	25	25 (3%)	7·7 (5·1–11·3)	7·0 (5·4–9·4)	4·5 (3·0–6·6)
Myocardial infarction	12	12 (2%)	3·7 (2·0–6·3)	7·3 (5·3–9·8)	4·2 (2·7–6·2)
Composite of vascular events*	40	37 (5%)	12·4 (9·0–16·7)	16·6 (13·5–20·3)	12·0 (9·3–15·1)
Cancer†	62	50 (7%)	19·2 (14·8–24·4)	21·5 (18·0–25·6)	14·7 (11·7–18·1)
Lower tract respiratory infection or pneumonia	26	24 (3%)	8·1 (5·4–11·6)	15·9 (12·9–19·5)	11·6 (9·0–14·7)
Osteonecrosis of the jaw	0	0	NA	NA	NA
Atypical femoral fracture	0	0	NA	NA	NA

NA=not applicable. *Sudden death or death due to myocardial infarction, coronary revascularisation, or stroke. †Excluding non-melanoma skin cancers.

Table 2: **Prespecified adverse events**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IGINAL ARTICLE

Fracture Prevention with Infrequent Zoledronate in Women 50 to 60 Years of Age

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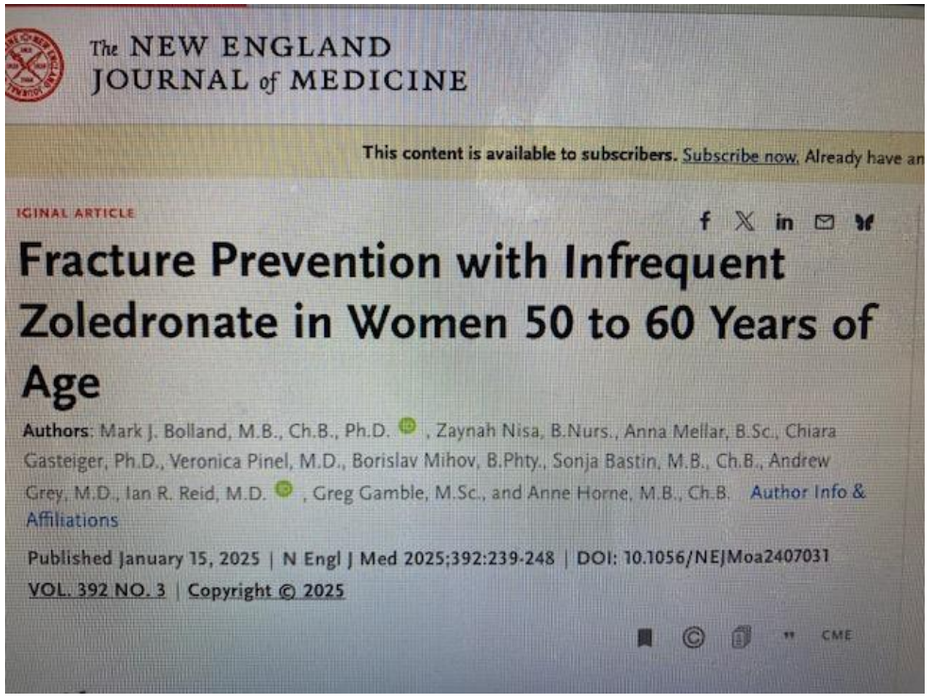
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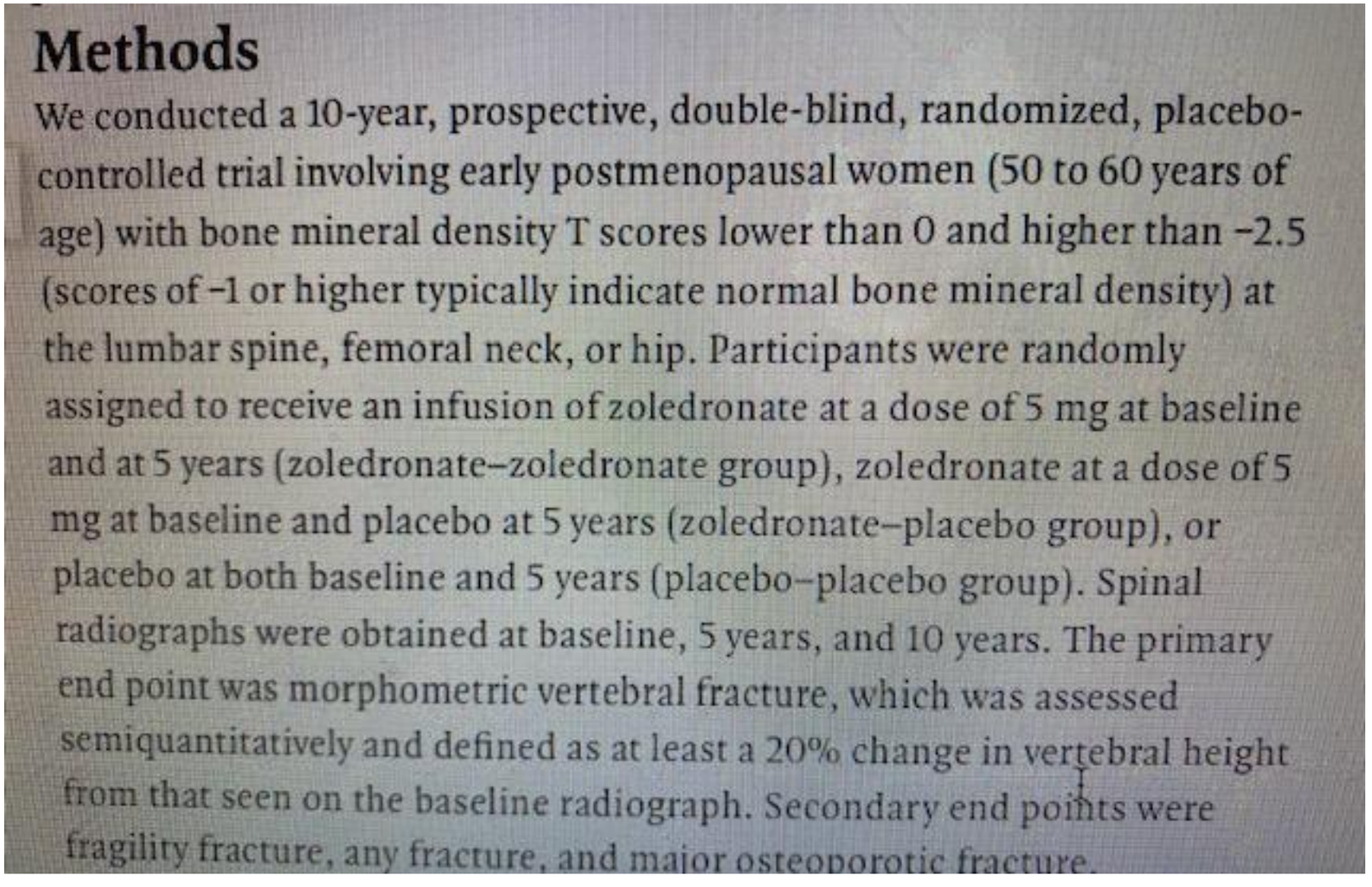
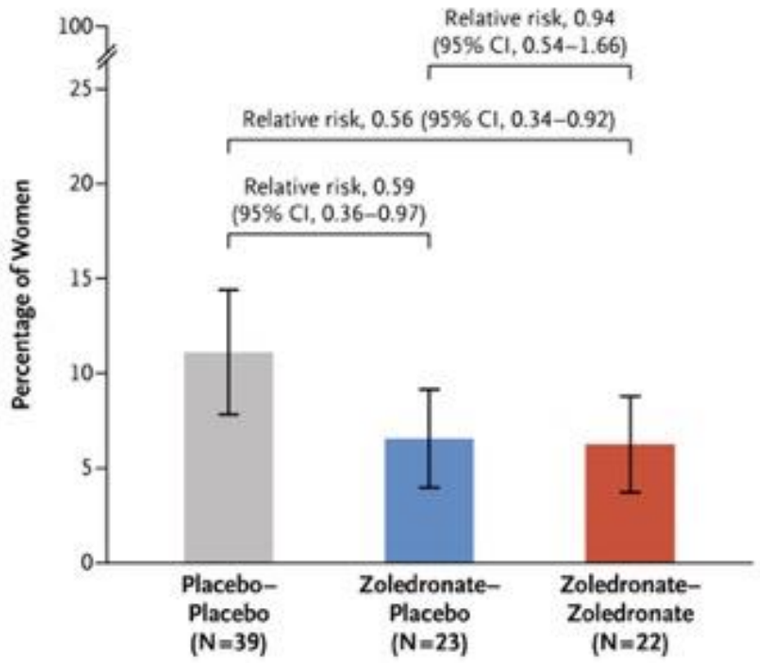


Methods

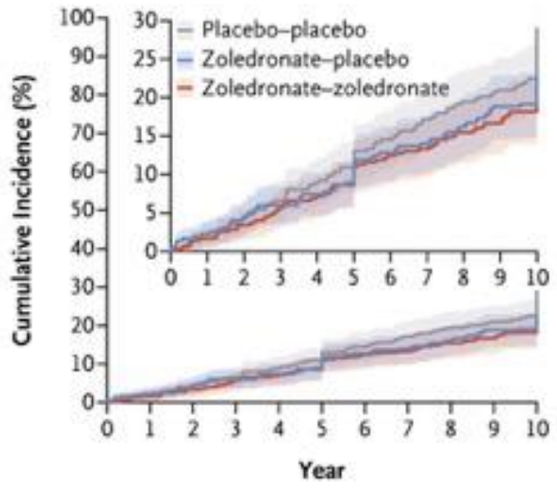
We conducted a 10-year, prospective, double-blind, randomized, placebo-controlled trial involving early postmenopausal women (50 to 60 years of age) with bone mineral density T scores lower than 0 and higher than −2.5 (scores of −1 or higher typically indicate normal bone mineral density) at the lumbar spine, femoral neck, or hip. Participants were randomly assigned to receive an infusion of zoledronate at a dose of 5 mg at baseline and at 5 years (zoledronate–zoledronate group), zoledronate at a dose of 5 mg at baseline and placebo at 5 years (zoledronate–placebo group), or placebo at both baseline and 5 years (placebo–placebo group). Spinal radiographs were obtained at baseline, 5 years, and 10 years. The primary end point was morphometric vertebral fracture, which was assessed semiquantitatively and defined as at least a 20% change in vertebral height from that seen on the baseline radiograph. Secondary end points were fragility fracture, any fracture, and major osteoporotic fracture.

A Risk of Morphometric Vertebral Fracture



B Fragility Fracture

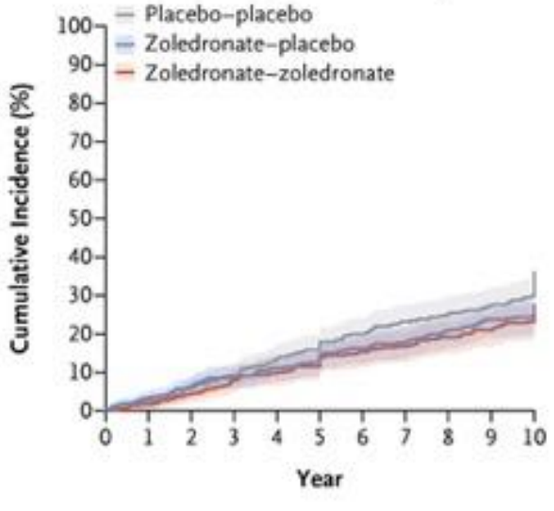
Zoledronate–zoledronate vs. placebo–placebo hazard ratio, 0.69 (95% CI, 0.51–0.94)
Zoledronate–placebo vs. placebo–placebo hazard ratio, 0.77 (95% CI, 0.57–1.04)
Zoledronate–zoledronate vs. zoledronate–placebo hazard ratio, 0.91 (95% CI, 0.66–1.25)



No. at Risk											
Placebo–placebo	351	342	332	323	314	304	291	281	273	267	258
Zoledronate–placebo	351	342	332	324	316	306	292	287	278	266	260
Zoledronate–Zoledronate	352	344	336	327	319	313	297	291	281	274	267

C Any Fracture

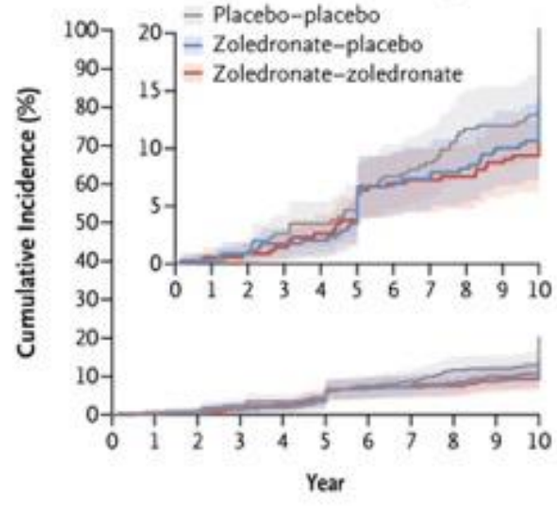
Zoledronate–zoledronate vs. placebo–placebo hazard ratio, 0.66 (95% CI, 0.50–0.87)
Zoledronate–placebo vs. placebo–placebo hazard ratio, 0.74 (95% CI, 0.57–0.97)
Zoledronate–zoledronate vs. zoledronate–placebo hazard ratio, 0.91 (95% CI, 0.68–1.22)



No. at Risk											
Placebo–placebo	351	341	326	314	298	287	272	260	253	245	235
Zoledronate–placebo	351	339	325	314	303	293	280	274	263	250	242
Zoledronate–Zoledronate	352	344	333	319	309	303	287	279	268	259	250

D Major Osteoporotic Fracture

Zoledronate–zoledronate vs. placebo–placebo hazard ratio, 0.58 (95% CI, 0.39–0.85)
Zoledronate–placebo vs. placebo–placebo hazard ratio, 0.69 (95% CI, 0.48–1.00)
Zoledronate–zoledronate vs. zoledronate–placebo hazard ratio, 0.84 (95% CI, 0.55–1.28)



No. at Risk											
Placebo–placebo	351	349	343	337	333	325	314	309	299	297	289
Zoledronate–placebo	351	349	345	339	335	325	313	309	305	296	289
Zoledronate–Zoledronate	352	348	345	342	335	330	316	312	308	301	297

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IGINAL ARTICLE

Fracture Prevention with Infrequent Zoledronate in Women 50 to 60 Years of Age

Authors: Mark J. Bolland, M.B., Ch.B., Ph.D. , Zaynah Nisa, B.Nurs., Anna Mellar, B.Sc., Chiara Gasteiger, Ph.D., Veronica Pinel, M.D., Borislav Mihov, B.Phty., Sonja Bastin, M.B., Ch.B., Andrew Grey, M.D., Ian R. Reid, M.D. , Greg Gamble, M.Sc., and Anne Horne, M.B., Ch.B. Author Info & Affiliations

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VOL. 392 NO. 3 | Copyright © 2025

CME

Results

Of 1054 women with a mean age of 56.0 years at baseline, 1003 (95.2%) completed 10 years of follow-up. A new morphometric fracture occurred in 22 women (6.3%) in the zoledronate–zoledronate group, in 23 women (6.6%) in the zoledronate–placebo group, and in 39 women (11.1%) in the placebo–placebo group (relative risk, zoledronate–zoledronate vs. placebo–placebo, 0.56 [95% confidence interval {CI}, 0.34 to 0.92; P=0.04]; and zoledronate–placebo vs. placebo–placebo, 0.59 [95% CI, 0.36 to 0.97; P=0.08]). The relative risk of fragility fracture, any fracture, and major osteoporotic fracture was 0.72 (95% CI, 0.55 to 0.93), 0.70 (95% CI, 0.56 to 0.88), and 0.60 (95% CI, 0.42 to 0.86), respectively, when zoledronate–zoledronate was compared with placebo–placebo and 0.79 (95% CI, 0.61 to 1.02), 0.77 (95% CI, 0.62 to 0.97), and 0.71 (95% CI, 0.51 to 0.99), respectively, when zoledronate–placebo was compared with placebo–placebo.

Download a PDF of the Plain Language Summary.

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[c] Department of Orthopedics & Rehabilitation, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin

- **ΠΕΡΙΠΡΟΘΕΤΙΚΑ ΚΑΤΑΓΜΑΤΑ ΜΕΤΑ ΑΠΟ ΟΛΙΚΗ ΑΡΘΡΟΠΛΑΣΤΙΚΗ ΙΣΧΙΟΥ=↑↑ ΝΟΣΗΡΟΤΗΤΑ ΚΑΙ ΘΝΗΣΙΜΟΤΗΤΑ, ΔΙΑΡΚΩΣ ΑΥΞΑΝΟΜΕΝΗ ΕΠΙΠΤΩΣΗ ΕΙΔΙΚΑ ΣΕ ΗΛΙΚΙΩΜΕΝΟΥΣ (4-7%), ΥΨΗΛΟΤΕΡΑ ΠΟΣΟΣΤΑ ΣΕ ΑΡΘΡΟΠΛΑΣΤΙΚΕΣ ΧΩΡΙΣ ΧΡΗΣΗ ΤΣΙΜΕΝΤΟΥ ΚΑΙ ΣΕ ΗΔΗ ΑΝΑΘΕΩΡΗΜΕΝΕΣ ΑΡΘΡΟΠΛΑΣΤΙΚΕΣ**

- **ΑΝΑΓΝΩΡΙΣΗ 171 ΑΝΔΡΩΝ ΚΑΙ ΓΥΝΑΙΚΩΝ ΣΤΟΥΣ ΟΠΟΙΟΥΣ ΧΡΗΣΙΜΟΠΟΙΗΘΗΚΕ ΠΡΟΘΕΣΗ ΓΙΑ ΠΕΡΙΠΡΟΘΕΤΙΚΑ ΚΑΤΑΓΜΑΤΑ VANCOUVER B2, B3 ΤΑ ΕΤΗ 2000-2018 (ΑΠΟΚΛΕΙΣΜΟΣ ΑΣΘΕΝΩΝ ΓΙΑ ΤΟΥΣ ΟΠΟΙΟΥΣ ΤΟ ΥΛΙΚΟ ΧΡΗΣΙΜΟΠΟΙΗΙΗΚΕ ΓΙΑ ΑΛΛΗ ΑΙΤΙΑ)**

- **ΠΡΟΣΒΑΣΗ ΣΤΑ ΣΤΟΙΧΕΙΑ ΑΥΤΩΝ ΤΩΝ ΑΣΘΕΝΩΝ ΑΠΟ ΗΛΕΚΤΡΟΝΙΚΗ ΤΡΑΠΕΖΑ ΠΛΗΡΟΦΟΡΙΩΝ ΑΝΑΔΡΟΜΙΚΑ**

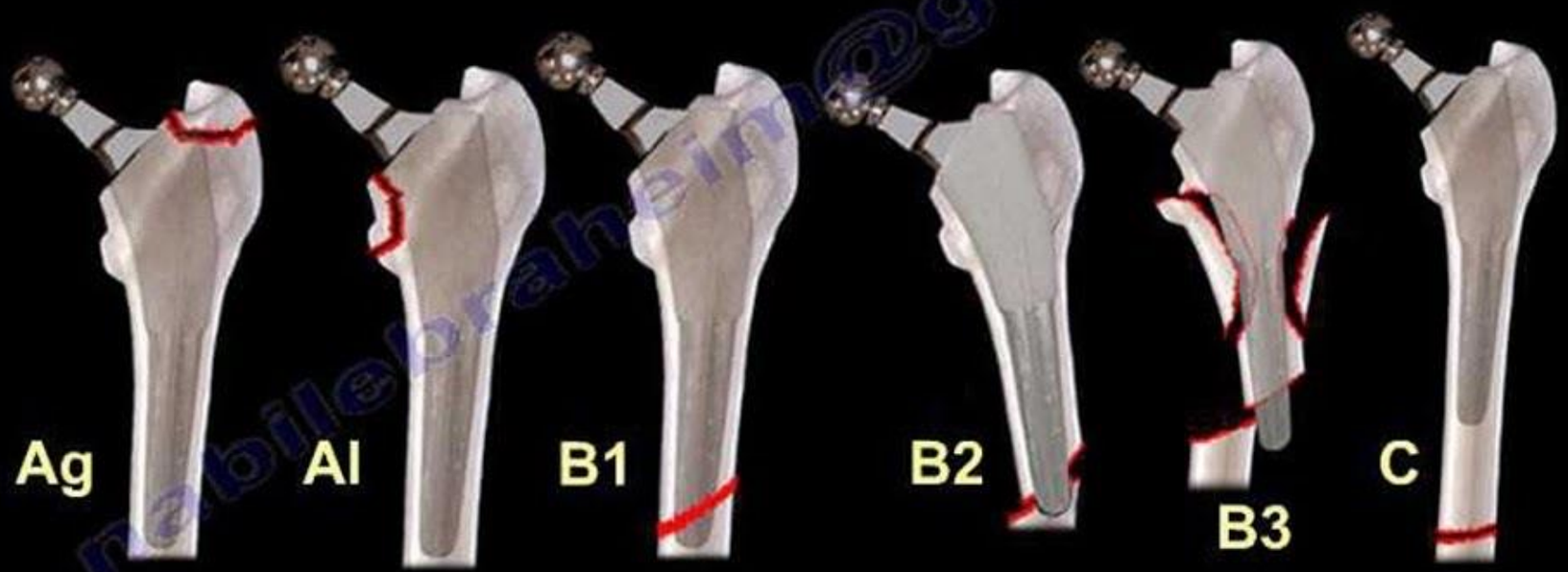
- **ΣΤΟΙΧΕΙΑ ΓΙΑ ΤΑ ΜΗΡΙΑΙΑ ΟΣΤΑ ΜΕ ΒΑΣΗ ΤΗΝ ΤΑΞΙΝΟΜΗΣΗ DORR**

- **ΟΣΤΕΟΠΟΡΩΤΙΚΑ ΘΕΩΡΗΘΗΚΑΝ ΤΑ ΚΑΤΑΓΜΑΤΑ ΜΕΤΑ ΑΠΟ ΠΤΩΣΗ ΑΠΟ ΤΟ ΥΨΟΣ ΣΩΜΑΤΟΣ**

- **ΕΞΕΤΑΣΗ ΩΣ ΠΡΟΣ BMD (ΟΣΤΕΟΠΕΝΙΑ/ΟΣΤΕΟΠΟΡΩΣΗ) ΚΑΙ ΑΛΛΕΣ ΠΑΡΑΜΕΤΡΟΥΣ**

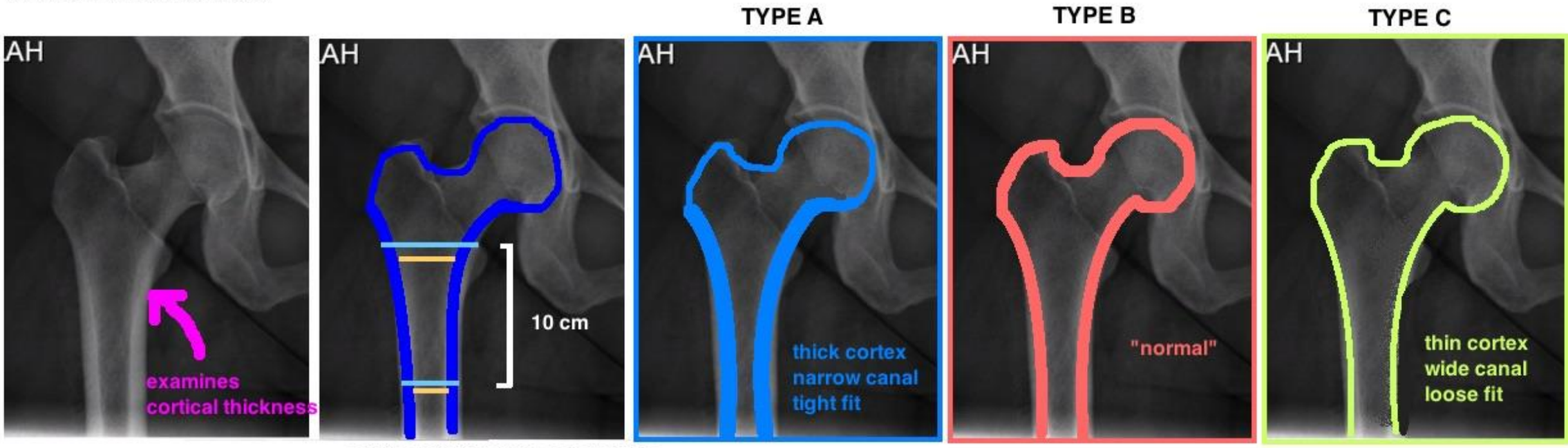
Periprosthetic Femur Fracture

Vancouver Classification of Postoperative Periprosthetic Femur Fractures



Masri BA. Meek RM. Duncan CP. Periprosthetic fractures evaluation and treatment. Clin Orthop Relat Res. 2004;420: 80 - 95.

DORR CLASSIFICATION



= cortical width minus canal width
(@ 10 cm below lesser)

divided by...

cortical width minus canal width
(@ lesser)

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[a] Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota
[b] Department of Endocrinology, Mayo Clinic, Rochester, Minnesota
[c] Department of Orthopedics & Rehabilitation, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin

Table 1
Demographic and Operative Factors.

Characteristic	Overall, Number or Percent	Patients Who Have Fragility Fractures, Number or Percent
No. of hips	171	160
Age at Surgery (y)		
Mean (Standard Deviation)	75 (13)	75 (12)
Range	35 to 94	38 to 94
Sex (no. [%])		
Men	85 (50)	84 (53)
Women	86 (50)	76 (48)
Body Mass Index (kg/m^2)		
Mean (Standard Deviation)	29 (8)	29 (12)
Range	17 to 60	17 to 60
Vancouver Classification (no. [%])		
B2	109 (64)	100 (63)
B3	62 (36)	60 (38)
Dorr Classification (no. [%])		
A	0 (0)	0 (0)
B	97 (57)	88 (55)
C	74 (43)	72 (45)

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[c] Department of Orthope

Conclusions

In conclusion, fragility fractures were often missed as osteoporosis-defining events after periprosthetic femur fractures. The use of age-appropriate BMD testing and fracture risk assessment tools in TJA patients was severely lacking. Pharmacotherapy use after fractures was also uncommon and may be an opportunity for improved care. There remain major gaps in the screening, diagnosis, and treatment of systemic osteoporosis and osteopenia after periprosthetic femur fractures. Like nonarthroplasty fragility fractures, a systematic approach is needed after periprosthetic femur fractures.

Table 2
Prevalence of Systemic Osteoporosis and Osteopenia Diagnosis, Screening, Medication, and Supplementation Before and After Fracture.

Category	Before Fracture			After Fracture			*P* Value
	Prevalence (%)	95% CI	Median Years before Fracture	Prevalence (%)	95% CI	Median Days after Fracture	
Diagnosis							
Osteoporosis	20	(14 to 26)	3.1	39	(32 to 46)	42	<.001
Osteopenia	13	(8 to 18)	4.5	24	(18 to 30)	292	<.001
Osteoporosis or Osteopenia	24	(18 to 30%	3.2	44	(37 to 52)	83	<.001
Screening							
Fracture Risk Assessment Tool	0	(0 to 0)	n/a	2	(0 to 4)	495	n/a
Bone Mineral Density Testing	21	(15 to 27)	6.2	22	(15 to 28)	334	0.88
Endocrinology Consult	6	(3 to 10)	4.9	25	(18 to 31)	59	<.001
Medication							
Any Medical Treatment	26	(19 to 32)		29	(22 to 35)		0.40
Bisphosphonate	19	(13 to 25)		25	(19 to 32)		0.08
Anabolic/antiresorptive	1	(0 to 3)		5	(2 to 9)		0.008
Estrogens (women only)	24	(15 to 33)		14	(7 to 22)		0.06
Calcitonin	2	(0 to 4)		5	(2 to 9)		0.034
Other Medications (females only)	5	(0 to 9)		4	(0 to 7)		0.56
Supplementation							
Any Supplement	13	(8 to 18)		40	(33 to 48)		<.001
Calcium	4	(1 to 7)		18	(12 to 24)		<.001
Vitamin D3	12	(7 to 17)		37	(30 to 45)		<.001

McNemar tests were used to analyze differences in prevalences before and after fracture along with calculated 95% binomial confidence intervals. The median days after fracture are reported only for patients with a diagnosis or workup first occurring after fracture. The *P* value for Fracture Risk Assessment Tool was not able to be calculated due to no patients having had this before fracture. Prevalences for estrogens and other medications only considered female patients. Other medications included raloxifene, bazedoxifene, lasofoxifene, and tibolone.
CI, confidence interval; n/a = not applicable.

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- **94% ΚΑΤΑΓΜΑΤΩΝ ΜΕΤΑ ΑΠΟ ΠΤΩΣΗ ΑΠΟ ΤΟ ΥΨΟΣ ΤΟΥ ΣΩΜΑΤΟΣ (=ΟΣΤΕΟΠΟΡΩΤΙΚΑ) ΑΛΛΑ ΜΟΝΟ 39% ΤΩΝ ΑΣΘΕΝΩΝ ΕΙΧΑΝ ΤΕΚΜΗΡΙΩΜΕΝΗ ΔΙΑΓΝΩΣΗ ΟΠ ΜΕΤΑ ΤΟ ΚΑΤΑΓΜΑ (ΥΠΟΔΙΑΓΝΩΣΗ>50%)**

- **ΥΠΟΔΙΑΓΝΩΣΗ ΟΣΤΕΟΠΟΡΩΣΗΣ ΣΕ ΑΣΘΕΝΕΙΣ ΠΟΥ ΠΡΟΚΕΙΤΑΙ ΝΑ ΥΠΟΒΛΗΘΟΥΝ ΣΕ ΟΛΙΚΗ ΑΡΘΡΟΠΛΑΣΤΙΚΗ ΑΛΛΑ ΚΑΙ ΜΕΤΑ ΤΗΝ ΑΡΘΡΟΠΛΑΣΤΙΚΗ = ΧΑΜΕΝΕΣ ΕΥΚΑΙΡΙΕΣ ΠΡΟΛΗΨΗΣ ΚΑΤΑΓΜΑΤΩΝ!**

- **ΜΟΝΟ ΤΟ 16% ΤΩΝ ΑΣΘΕΝΩΝ ΜΕΤΑ ΑΠΟ ΤΟ ΠΕΡΙΠΡΟΘΕΤΙΚΟ ΚΑΤΑΓΜΑ ΕΞΕΤΑΣΤΗΚΑΝ ΓΙΑ ΟΠ**

- **ΑΠΟ ΤΟ 39% ΤΩΝ ΑΣΘΕΝΩΝ ΠΟΥ ΔΙΑΓΝΩΣΤΗΚΑΝ ΜΕ ΟΠ ΚΑΤΑ ΤΗΝ ΕΠΑΝΕΞΕΤΑΣΗ ΜΟΝΟ ΤΟ 25% ΕΛΑΒΕ ΑΓΩΓΗ ΜΕ ΔΙΦΩΣΦΟΝΙΚΑ**

- **ΣΗΜΑΝΤΙΚΟ ΚΕΝΟ ΣΤΗ ΔΙΑΓΝΩΣΗ ΚΑΙ ΘΕΡΑΠΕΙΑ ΑΥΤΩΝ ΤΩΝ ΑΣΘΕΝΩΝ!**

Journal of Bone and Mineral Research, 2024, **39**, 1393–1405
https://doi.org/10.1093/jbmr/zjae119
Advance access publication: July 29, 2024
Review

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Felicia Cosman[1,*], E. Michael Lewiecki[2], Richard Eastell[3], Peter R. Ebeling[4], Suzanne Jan De Beur[5], Bente Langdahl[6,7], Yumie Rhee[8], Ghada El-Hajj Fuleihan[9], Douglas P. Kiel[10,11], John T. Schousboe[12,13], Joao Lindolfo Borges[14], Angela M. Cheung[15,16], Adolfo Diez-Perez[17], Peyman Hadji[18], Sakae Tanaka[19], Friederike Thomasius[20], Weibo Xia[21], Steven R. Cummings[22]

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- **ΟΙ ΣΤΟΧΟΙ ΤΗΣ ΘΕΡΑΠΕΙΑΣ (Treatment targets) ΠΡΕΠΕΙ ΝΑ ΕΙΝΑΙ ΕΞΑΤΟΜΙΚΕΥΜΕΝΟΙ ΚΑΙ ΒΑΣΙΣΜΕΝΟΙ ΣΤΗΝ ΕΙΔΙΚΗ ΕΝΔΕΙΞΗ ΓΙΑ ΕΝΑΡΞΗ ΘΕΡΑΠΕΙΑΣ, π.χ ΠΡΟΣΦΑΤΟ ΚΑΤΑΓΜΑ, ΑΡΙΘΜΟΣ ΚΑΙ ΕΙΔΟΣ ΠΡΟΗΓΟΥΜΕΝΩΝ ΚΑΤΑΓΜΑΤΩΝ, ΒΑΡΥΤΗΤΑ ΠΡΟΗΓΟΥΜΕΝΩΝ ΣΠΟΝΔΥΛΙΚΩΝ ΚΑΤΑΓΜΑΤΩΝ, BMD ΣΤΟ ΟΛΙΚΟ ΙΣΧΙΟ, ΑΥΧΕΝΑ ΜΗΡΙΑΙΟΥ, ΣΣ, ΗΛΙΚΙΑ Ή ΑΛΛΟΙ ΣΟΒΑΡΟΙ ΠΑΡΑΓΟΝΤΕΣ ΚΙΝΔΥΝΟΥ ΓΙΑ ΚΑΤΑΓΜΑ**

- **ΣΕ ΑΣΘΕΝΕΙΣ ΜΕ ΑΡΧΙΚΟ T-score > −2.5 (ΟΣΤΕΟΠΕΝΙΑ): ΑΝ ΕΙΝΑΙ ΥΨΗΛΟΥ ΚΙΝΔΥΝΟΥ ΓΙΑ ΚΑΤΑΓΜΑ (ΙΣΤΟΡΙΚΟ ΠΡΟΗΓΟΥΜΕΝΩΝ ΚΑΤΑΓΜΑΤΩΝ Ή ΠΑΘΗΣΕΙΣ ΠΟΥ ΣΥΣΧΕΤΙΖΟΝΤΑΙ ΜΕ ΚΑΤΑΓΜΑΤΑ) Η ΑΥΞΗΣΗ ΤΗΣ BMD ΘΕΩΡΕΙΤΑΙ ΣΤΟΧΟΣ ΓΙΑ ΤΗΝ ΕΛΑΤΤΩΣΗ ΤΟΥ ΚΑΤΑΓΜΑΤΙΚΟΥ ΚΙΝΔΥΝΟΥ ΚΑΙ ΟΣΟ ΜΕΓΑΛΥΤΕΡΗ Η ΑΥΞΗΣΗ ΤΟΣΟ ΜΙΚΡΟΤΕΡΟΣ Ο ΚΙΝΔΥΝΟΣ**

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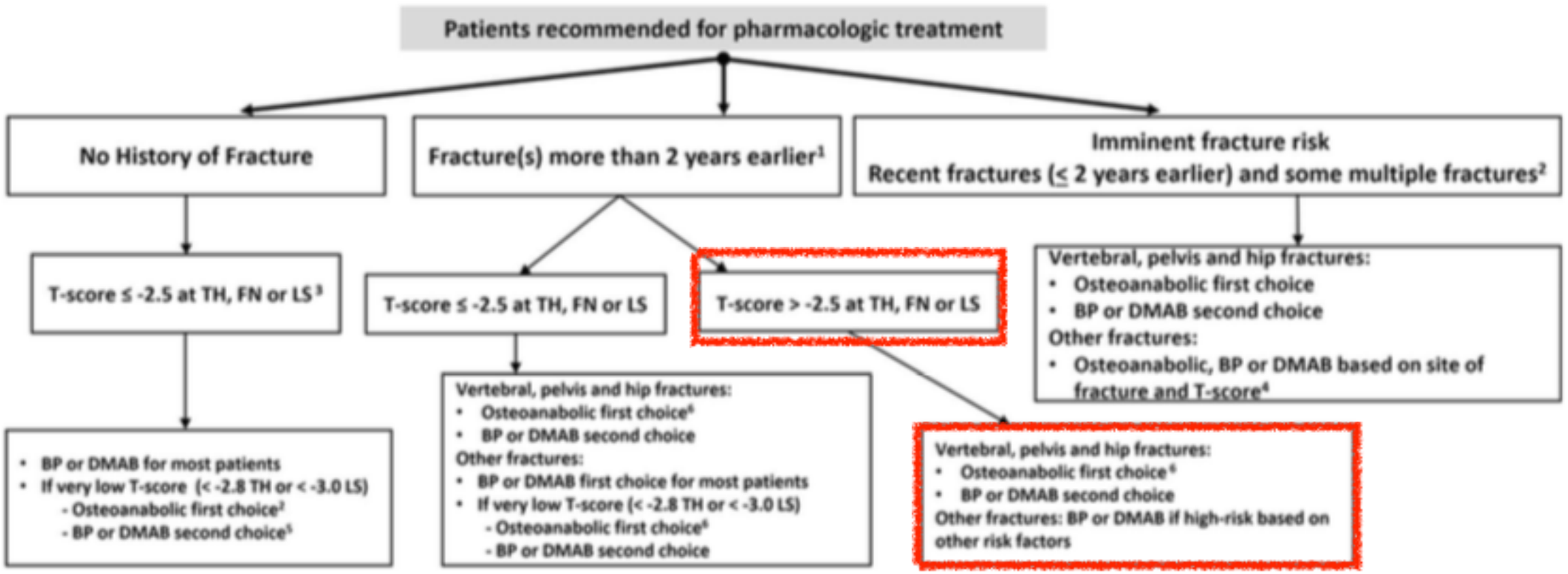
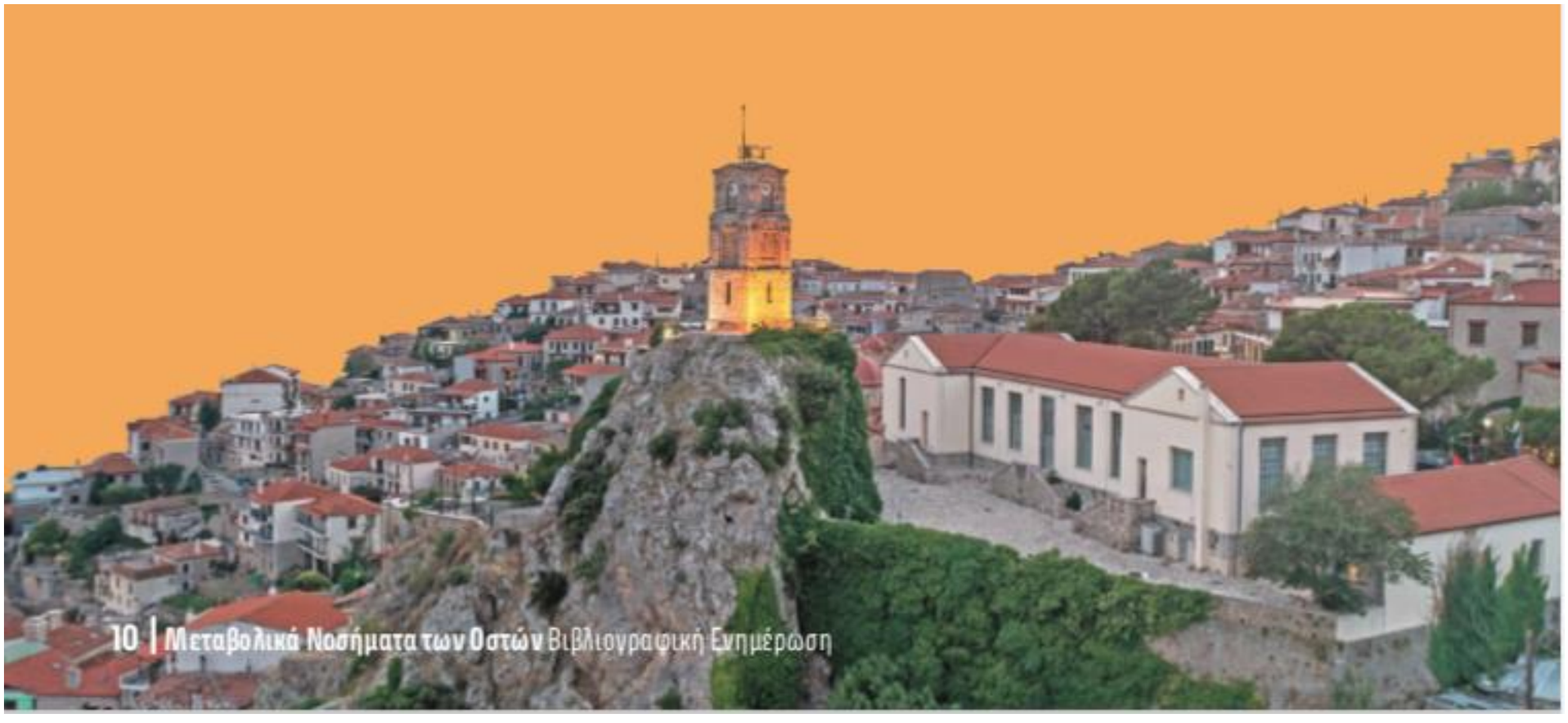
Treatment Targets:

- For imminent risk patients, maximal rapid reduction in fracture risk
- For patients with T-score ≤ -2.5, minimal target is to increase T-score to > -2.5, higher for patients with fracture history, or other major risk factors
- For patients with T-score > -2.5, increase TH T-score by 0.2 (3%) and LS by 0.5 (6%)



ΕΥΧΑΡΙΣΤΩ!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