

## LOW DOSE CALCIUM AND VITAMIN D INEFFECTIVE IN PRIMARY PREVENTION OF FRACTURES IN POST- MENOPAUSAL WOMEN WITHOUT OSTEOPOROSIS<sup>1</sup>

STRENGTH OF EVIDENCE: MODERATE ⊕ ⊕ ⊕ ○

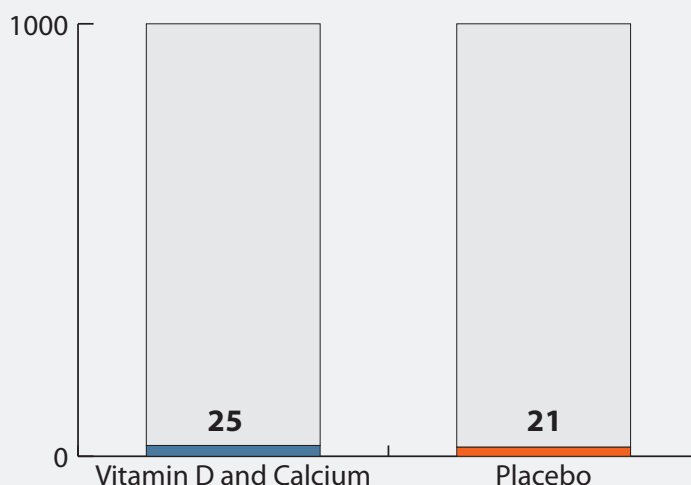
### Why is this important?

Approximately 56 -60% of women  $\geq 60$  years take supplemental vitamin D and/or calcium for primary prevention of fractures. 1.5 million osteoporotic fractures occur annually in the US. Nearly half of all women  $\geq 50$  years will suffer an osteoporotic fracture in their lifetime. Fractures are associated with chronic pain, disability, decreased quality of life and institutionalization.

### Facts:

- United States Preventive Services Task Force (USPSTF) commissioned 2 systematic reviews and 1 meta-analysis to assess supplementation of Vitamin D +/- calcium on bone health among community dwelling (noninstitutionalized) adults without osteoporosis.
- **Daily doses of  $\leq 400$  IU Vitamin D<sub>3</sub> with  $\leq 1000$  mg of calcium did not prevent fractures in postmenopausal women without osteoporosis (6 trials, N= 43,549).**
- **There was insufficient data to assess Vitamin D and calcium supplementation for fracture prevention in men and premenopausal women.**
- **Compared to placebo, Vitamin D and calcium treatment led to 4 episodes of nephrolithiasis per 1000 patient over 7 years (1 trial, women only).**

### Rate of Nephrolithiasis at 7 years, per 1000 patients<sup>3</sup>



### Harms and concerns:

- There was limited information about harm, however the largest trial<sup>3</sup> noted an increased risk for nephrolithiasis over 7 years.
- The majority of trial participants were white, though the risk for fractures in nonwhite women is lower.
- Most, but not all trials used Vitamin D<sub>3</sub> and the type of calcium supplement varied extensively.
- Although low dose of Vitamin D and calcium showed no benefit, there was insufficient data about the benefits or harms of higher doses.

## THE BOTTOM LINE

**Daily supplementation with  $\leq 400$  IU of Vitamin D<sub>3</sub> and  $\leq 1000$  mg calcium in community dwelling postmenopausal women is not recommended for primary prevention of fractures. The benefits and harms of larger doses and use in premenopausal women or in men is not known.**

## Strength of Evidence

(Adapted from Guyatt G BMJ, 26 April 2008)

This refers to the degree to which the findings of this study are likely to be free of bias.

⊕ ⊕ ⊕ ⊕	High
⊕ ⊕ ⊕ ○	Moderate
⊕ ⊕ ○ ○	Low
⊕ ○ ○ ○	Very low

## Tips for Discussion of Results with Patients

- Low daily doses of Vitamin D<sub>3</sub> ( $\leq 400$  IU) and calcium ( $\leq 1000$  mg) did not provide a benefit against fractures for community dwelling postmenopausal women without osteoporosis, and there was an increased risk of forming kidney stones.
- The USPSTF recommendations only apply to the low daily doses of Vitamin D<sub>3</sub> and calcium.
  - It is uncertain if Vitamin D and Calcium at higher doses offer a benefit
  - It is uncertain if Vitamin D and Calcium benefits premenopausal women, or men
  - Recommendations do not address falls or cancer prevention
- Discussions about starting or continuing vitamin D and calcium should include consideration of the patient's individual baseline risk for fracture and renal stones.

## References

1. Moyer et al. Vitamin D and calcium supplementation to prevent fractures in adults: US Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 2013;158:691-696.
2. Chung et al. Vitamin D with or without calcium supplementation for prevention of cancer and fractures: an updated meta-analysis for the US Preventive Services Task Force. *Ann Intern Med*. 2011;155:827-838.
3. Jackson et al. Women's Health Initiative Investigators. Calcium plus vitamin D supplementation and the risk of fractures. *N Engl J Med*. 2006;354:669-83.

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The Bottom Line summaries reflect the expertise and opinions of the SGIM EBM Task Force as of the date of release of this summary.



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