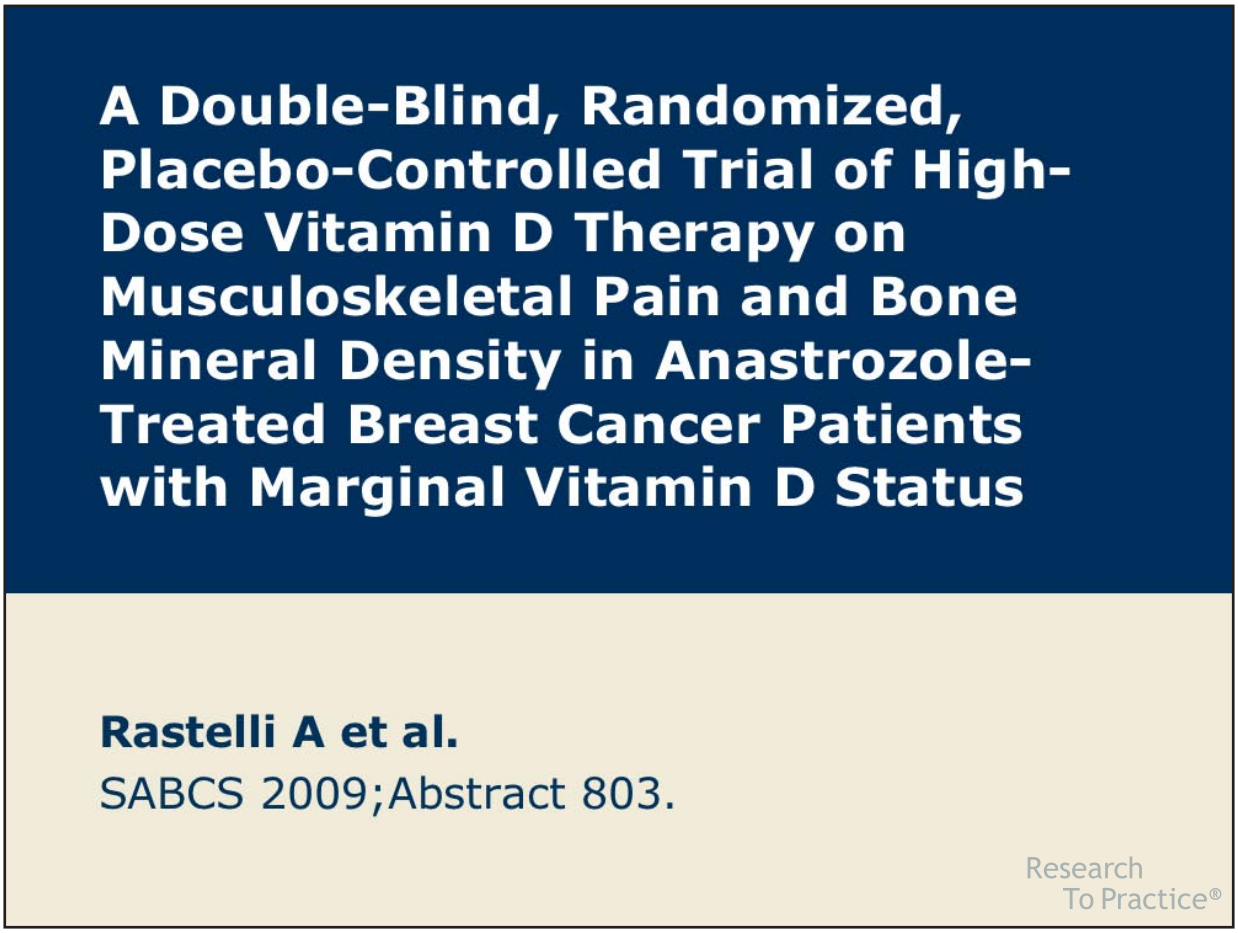
Effect of High-Dose Vitamin D Therapy on Bone Mineral Density and Anastrozole-Induced Musculoskeletal Pain

Presentation discussed in this issue:

Rastelli AL et al. **A double-blind, randomized, placebo-controlled trial of high dose vitamin D therapy on musculoskeletal pain and bone mineral density in anastrozole-treated breast cancer patients with marginal vitamin D status.** San Antonio Breast Cancer Symposium 2009;**Abstract 803**.

Slides from a presentation at SABCS 2009



Introduction

- Musculoskeletal (MS) pain and bone loss are known adverse effects of aromatase inhibitors.
- A high prevalence of vitamin D deficiency/insufficiency has been previously reported in patients with breast cancer complaining of MS pain (SABCS 2004:Abstract 443).
- Anecdotal evidence suggests that MS pain induced by aromatase inhibitors can be relieved by weekly supplementation with high doses of vitamin D.
- **Current study objectives:**
  - Assess if high-dose vitamin D (HDD) supplementation improves anastrozole-induced musculoskeletal symptoms.
  - Assess if vitamin D supplementation may favorably impact the bone mineral density (BMD) of patients on anastrozole.

Rastelli A et al. SABCS 2009;Abstract 803.

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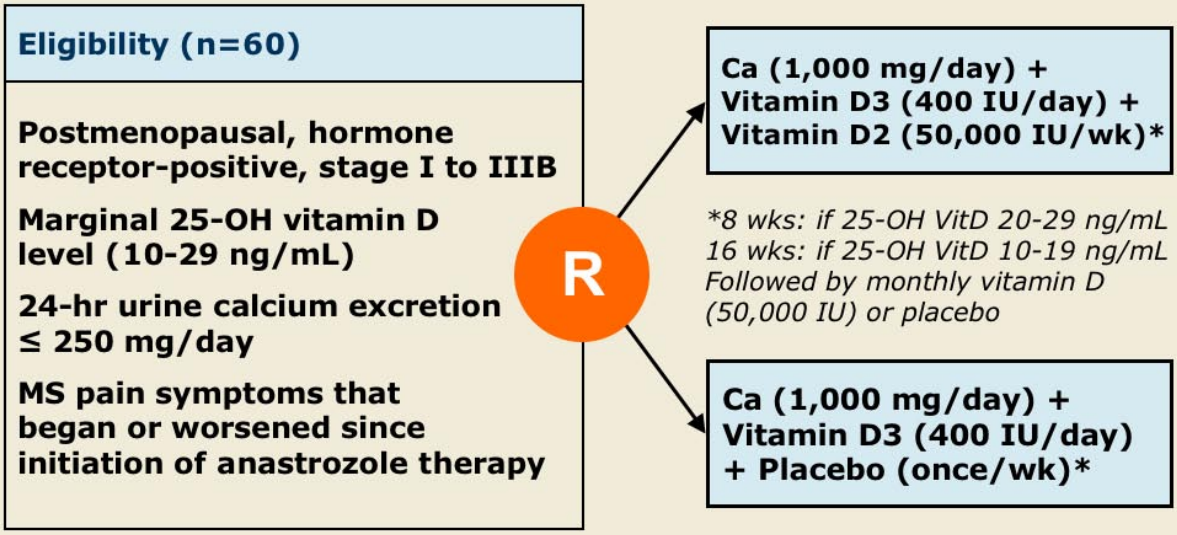
Trial Design



Pain and impairment evaluated: baseline, 2, 4, and 6 mos
Femoral/Neck BMD evaluated: baseline and 6 mos

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Participants in Each Arm at Each Time Point

	High-dose Vitamin D	Placebo
Number of patients randomized	30	30
Number of discontinuations over 6 mos*	9	4
Number of patients completing 2 mos	28	29
Number of patients completing 4 mos	22	28
Number of patients completing 6 mos	21	26

**Reasons for discontinuation include: continued muscle pain, high serum or urinary calcium, or development of adverse event (Placebo arm: 1 diarrhea, 1 non-treatment related arterial thrombosis).*

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Effect of High-Dose Vitamin D on Pain and BMD

- At 2 months, patients receiving HDD reported lower scores on pain-related questions on BPI (p=0.009) and FIQ surveys (p=0.01).
- A trend for improved scores for walking and climbing steps on the Health Assessment Questionnaire (HAQ) was reported in patients administered HDD (at 2 mos, p=0.04).
- Preliminary BMD analysis data demonstrated higher femoral/neck values in the HDD group (p=0.05).
  - HDD group, % change (0 - 6 mos): 0.54 ± 0.71
  - Placebo group, % change (0 - 6 mos): -1.43 ± 0.66

Rastelli A et al. SABCS 2009;Abstract 803.

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Conclusions

- High-dose vitamin D may significantly improve anastrozole-induced MS pain.
  - The beneficial effect of high-dose vitamin D appears to end once vitamin D is supplemented monthly instead of weekly (data not shown).
- Femoral/Neck BMD appears to be maintained at 6 mos in patients administered high-dose vitamin D supplementation.
- High-dose vitamin D was well tolerated and did not cause toxicity.
- Larger studies will be needed to confirm the pilot data presented in this study.

Rastelli A et al. SABCS 2009;Abstract 803.

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