Controversies in Osteoporosis Management

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Objectives

- Comprehensive Fracture Risk Assessment Requires Vertebral Imaging to Diagnose Compression Fractures
- Treating Osteoporosis to a Goal
- Who Should Be Offered a Medication Holiday and How should Patients on Holiday be Monitored?
- Teriparatide Treatment in Patients on Prior Potent Antiresorptive Therapy

Who Should Have Vertebral Imaging?

- NOF Clinicians Guide 2014 recommends screening xray or DXA based VFA in
  - women ≥70 and men ≥80
    - if T-Score -1 or lower (spine, total hip or fem neck)
  - women ≥65 and men ≥70
    - if T-Score -1.5 or lower (spine, total hip or fem neck)
  - younger individuals with risk factors:
    - Prospective height loss ≥0.8 in
    - Historical height loss ≥1.5 in
    - Fractures at age 50 and above
    - Longterm steroid treatment

Cosman et al OI Nov 2014

Which Patients should be Considered for Medication Holiday

- Patients Who Have Had No recent fractures
  - Including Baseline and Followup Vertebral Fracture Assessment for incident vertebral fractures
- Patients with Total BMD Above -2.5
- Patients who do not have Prevalent Vertebral fractures and Femoral Neck BMD ≤-2.5

Cosman et al JCEM 2014

Patients on Medication Holidays Must Be Monitored

- If medication withdrawal is recommended, patients must be monitored for
  - BMD loss
  - Occurrence of Fractures
  - Height Loss
  - New Medical Problems or Medications
  - Biochemical Marker Level Increases

Teriparatide After Prior Bisphosphonate Treatment

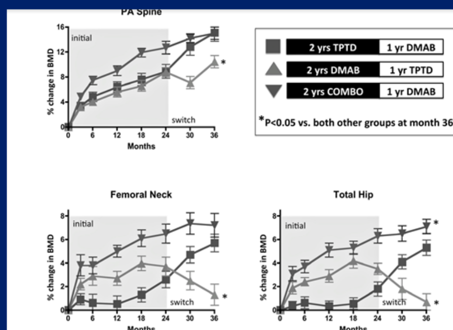
- ADD Vs. Switch Studies
  - Spine BMD may not be affected substantially when switching to teriparatide monotherapy compared to adding teriparatide to ongoing antiresorptive
  - Hip BMD routinely declines in Switch Studies over 6-12 months[1-3]
  - Hip BMD does not decline when TPTD is added to ongoing BP[4]

References
1.Ettinger JBMR 2004; 19(5):745–751
2.Miller, et al. JCEM 2008;93:3785–3793
3.Boonen, et al. JCEM 2008;93:852-860
4.Cosman, et al. NEJM 2005;353:566-75

Switch to Teriparatide in Patients Experienced on Prior Denosumab Treatment

- Patients randomized to Denosumab arm in DATA trial
  - After 2 years of Denosumab Alone, switched to Teriparatide

Leder et al ASBMR 2014



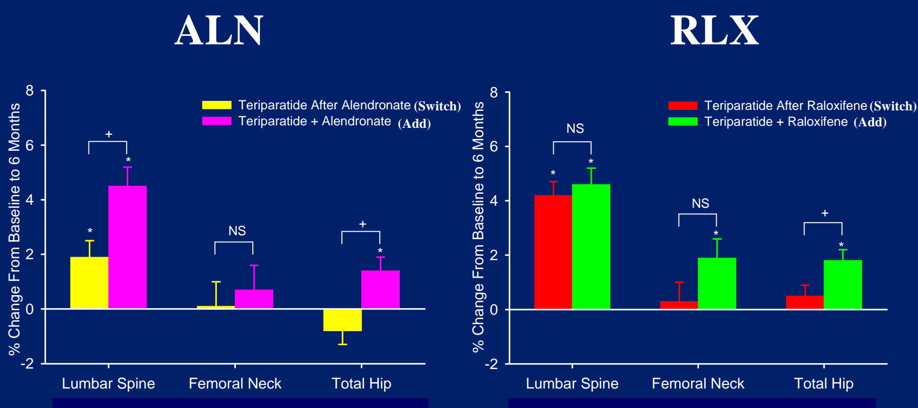
Teriparatide in Treatment Experienced: Monotherapy vs Combination Therapy

- Objective: To compare the effect of Adding vs Switching to TPTD in women on prior aln or rlx in a randomized trial
- Subjects: Postmenopausal women ≥ 50 years of age on weekly aln (n=102) or daily rlx (n=96) for ≥ 18 months
  - Average treatment duration >4 years
  - Mean age 68
- Protocol: Randomize to
  - Continue Aln/Rlx and ADD TPTD (Combination Therapy)
  - Stop Aln/Rlx and SWITCH to TPTD (Monotherapy)

Cosman F, et al; JCEM 2009; 94: 3772–3780.

Teriparatide in Treatment Experienced Switch vs Add: BMD At 6 Months

ALN **RLX**

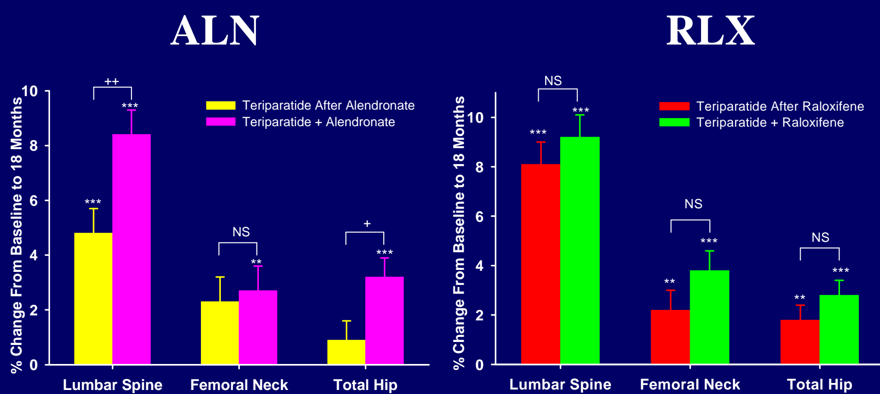


*P<0.05 within group from baseline
+P<0.05 between treatment groups within each treatment stratum

Cosman F, et al; JCEM 2009; 94: 3772–3780

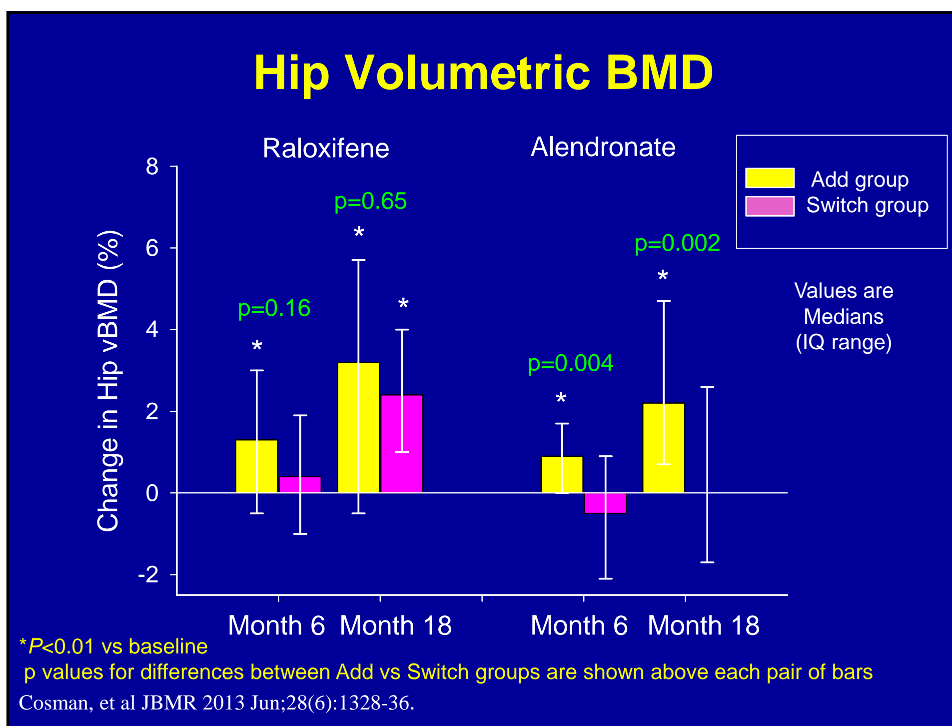
Teriparatide in Treatment Experienced Switch vs Add: BMD At 18 Months

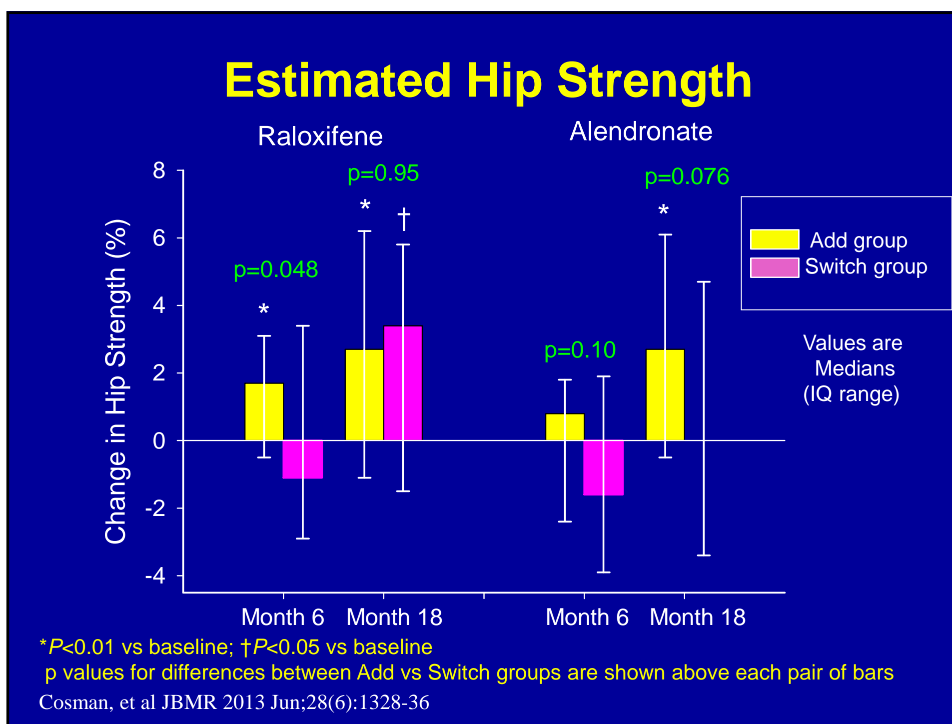
ALN **RLX**



***$P < 0.001$, **$P < 0.01$ within group from baseline
++$P < 0.01$, +$P < 0.05$ between treatment groups within each treatment stratum

Cosman F, et al; JCEM 2009; 94: 3772–3780


Hip Volumetric BMD
Raloxifene
Alendronate
Add group
Switch group
Values are Medians (IQ range)
Change in Hip vBMD (%)
p=0.16
p=0.65
p=0.004
p=0.002
Month 6
Month 18
Month 6
Month 18
*P<0.01 vs baseline
p values for differences between Add vs Switch groups are shown above each pair of bars
Cosman, et al JBMR 2013 Jun;28(6):1328-36.


Estimated Hip Strength
Raloxifene
Alendronate
Add group
Switch group
Values are Medians (IQ range)
Change in Hip Strength (%)
p=0.048
p=0.95
p=0.10
p=0.076
Month 6
Month 18
Month 6
Month 18
*P<0.01 vs baseline; †P<0.05 vs baseline
p values for differences between Add vs Switch groups are shown above each pair of bars
Cosman, et al JBMR 2013 Jun;28(6):1328-36