Healthy Ageing 101 Presents:

How Best To Manage Your Bone Health To Enable Your Healthy Ageing: Part II

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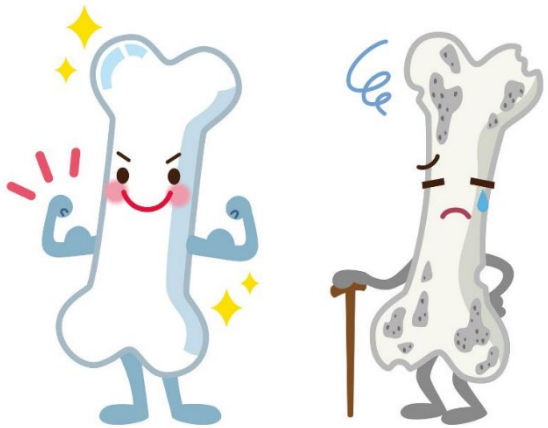
RTO ERO

Disclosures

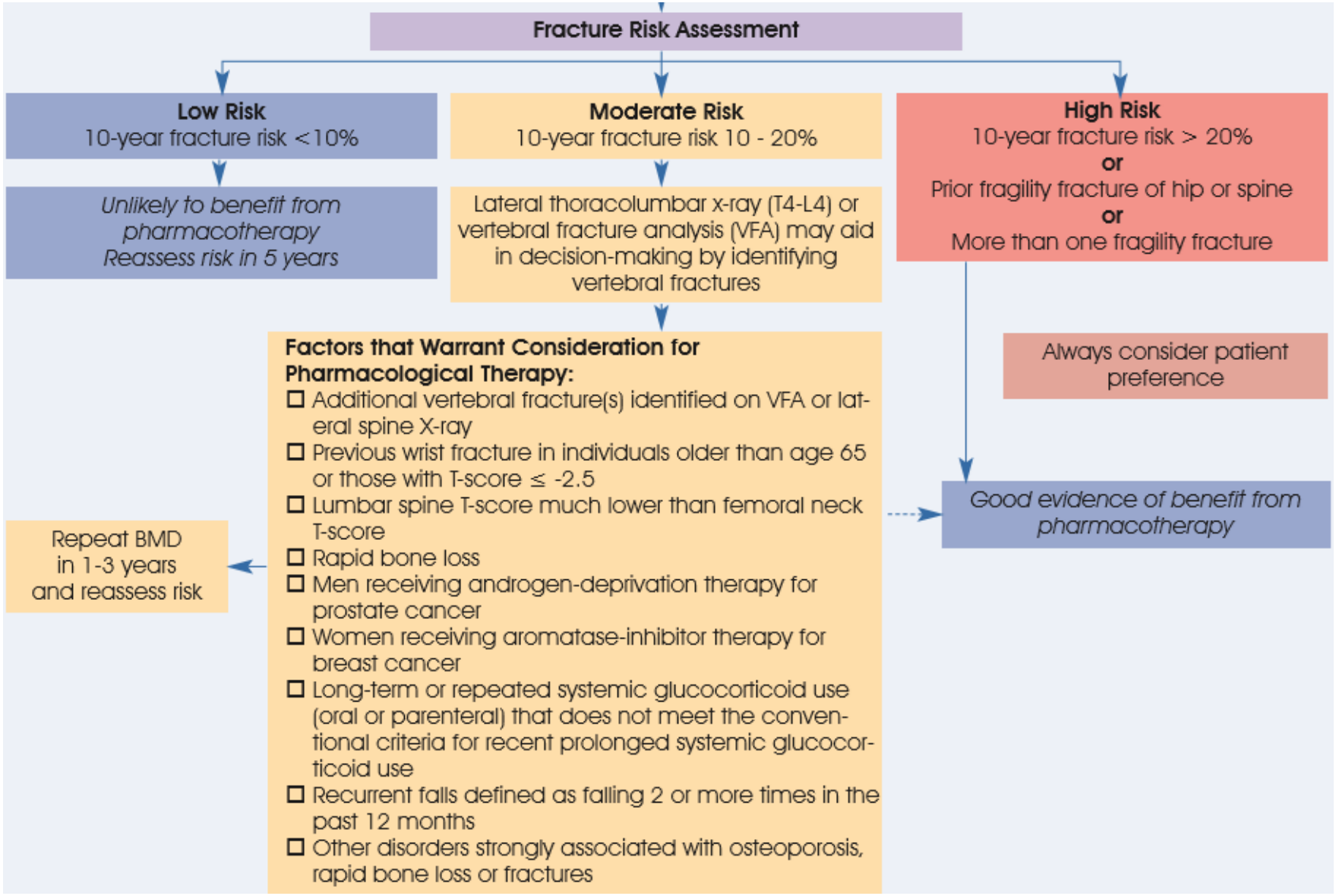
- No conflicts of interest to disclose

Objectives

- Re-visit indications for pharmacologic treatment of osteoporosis
- Understand current treatment options
- Discuss Atypical Femur Fractures and Osteonecrosis of the Jaw
- Review current approach to treatment duration and drug holidays



Review


Fracture Risk Assessment
Low Risk
10-year fracture risk <10%
Unlikely to benefit from pharmacotherapy
Reassess risk in 5 years
Moderate Risk
10-year fracture risk 10 - 20%
Lateral thoracolumbar x-ray (T4-L4) or vertebral fracture analysis (VFA) may aid in decision-making by identifying vertebral fractures
High Risk
10-year fracture risk > 20%
or
Prior fragility fracture of hip or spine
or
More than one fragility fracture
Always consider patient preference
Factors that Warrant Consideration for Pharmacological Therapy:
☐ Additional vertebral fracture(s) identified on VFA or lateral spine X-ray
☐ Previous wrist fracture in individuals older than age 65 or those with T-score ≤ -2.5
☐ Lumbar spine T-score much lower than femoral neck T-score
☐ Rapid bone loss
☐ Men receiving androgen-deprivation therapy for prostate cancer
☐ Women receiving aromatase-inhibitor therapy for breast cancer
☐ Long-term or repeated systemic glucocorticoid use (oral or parenteral) that does not meet the conventional criteria for recent prolonged systemic glucocorticoid use
☐ Recurrent falls defined as falling 2 or more times in the past 12 months
☐ Other disorders strongly associated with osteoporosis, rapid bone loss or fractures
Repeat BMD in 1-3 years and reassess risk
Good evidence of benefit from pharmacotherapy

Imminent Fracture Risk

The recency of your fracture matters!

Site of index fracture	Index fractures, n	2nd fractures at any site, n (%)	Median time (IQR) between index and 2nd fracture, days
Any	**115,776**	**20,629 (17.8%)**	**555** (236–955)
Hip	31,613	5,025 (15.9%)	**564** (267–952)
Wrist	17,859	3,160 (17.7%)	**582** (233–1,020)
Clavicle, ribs, or sternum	14,559	2,718 (18.7%)	**524** (219–927)
Humerus	13,237	2,507 (18.9%)	**566** (232–970)
Tibia, fibula, or knee	10,894	1,462 (13.4%)	**640** (297–1,023)
Pelvis	8,328	1,775 (21.3%)	**514** (203–896)
Vertebral	7,721	1,775 (23.0%)	**510** (215–899)
Radius or ulna	4,828	974 (20.2%)	**436** (69–939)
Multisite	3,735	752 (20.1%)	**581** (294–986)
Femur	3,002	481 (16.0%)	**562** (254–962)

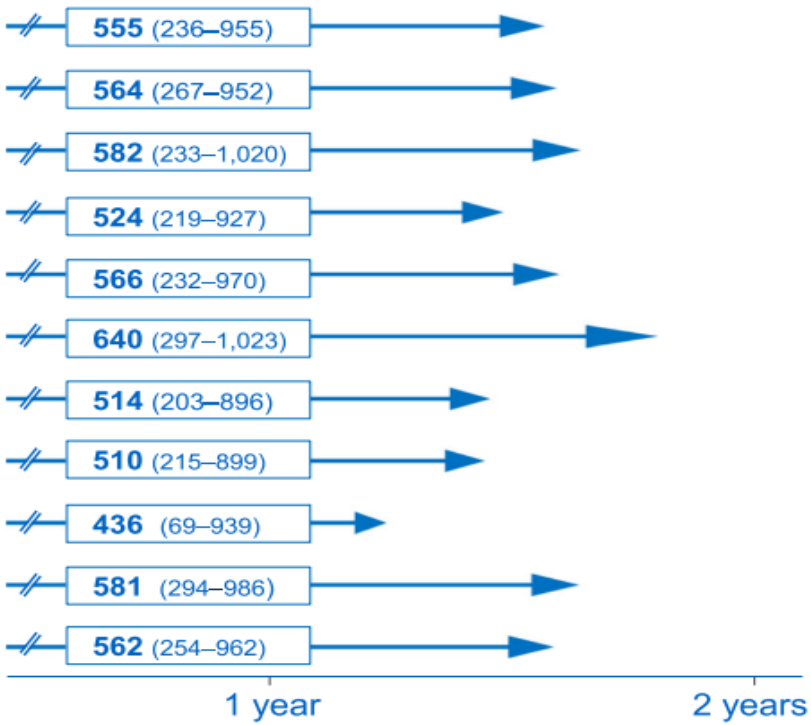


Fig. 1 Median time to second fragility fracture occurring at any site (by index fracture site). Number of index fractures, number and proportion of second fragility fractures at any site, and time to second fracture stratified by site of index fracture. Fracture sites are in descending order of number of index fractures. Abbreviations: IQR, interquartile range

Non-Pharmacologic Treatment

Lifestyle: Calcium

- Recommended daily intake is 1000-1200mg daily from all sources
- Calcium from diet is the preferred approach as it is the safest
- You can calculate your daily calcium intake using a calcium calculator tool (~300mg/dairy serving)
- If taking a supplement, 500-600mg of elemental calcium is generally sufficient

Lifestyle: Vitamin D

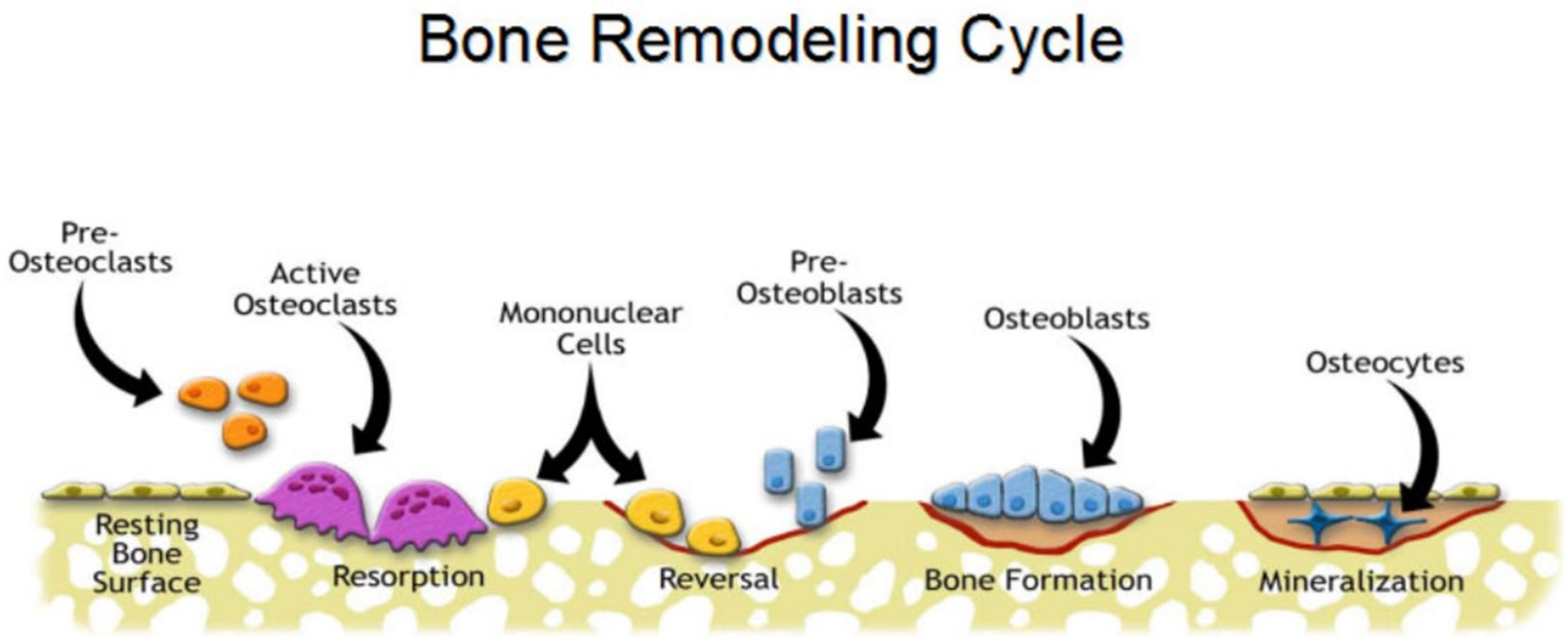
- Unlike calcium, it is difficult to get enough from food
- Older patients are particularly at risk for low Vitamin
- Level >75 nmol/l is considered normal
- 800-2000 IU daily for those older than 50
- Caution with regular intake of >4000 IU daily, no increased benefit on bone with high dose Vitamin D

Lifestyle: Exercise

- Exercise is very important to maintain strong and healthy bones. It can help maintain balance, and build muscle strength and also help prevent falls.
- Older adults should aim to exercise for 30 minutes per day.
- Strength Training, Balance Training, and Weight Bearing Aerobic Exercises, are all recommended for strong and healthy bones.
- Too Fit to Fracture series demonstrates some helpful exercises.

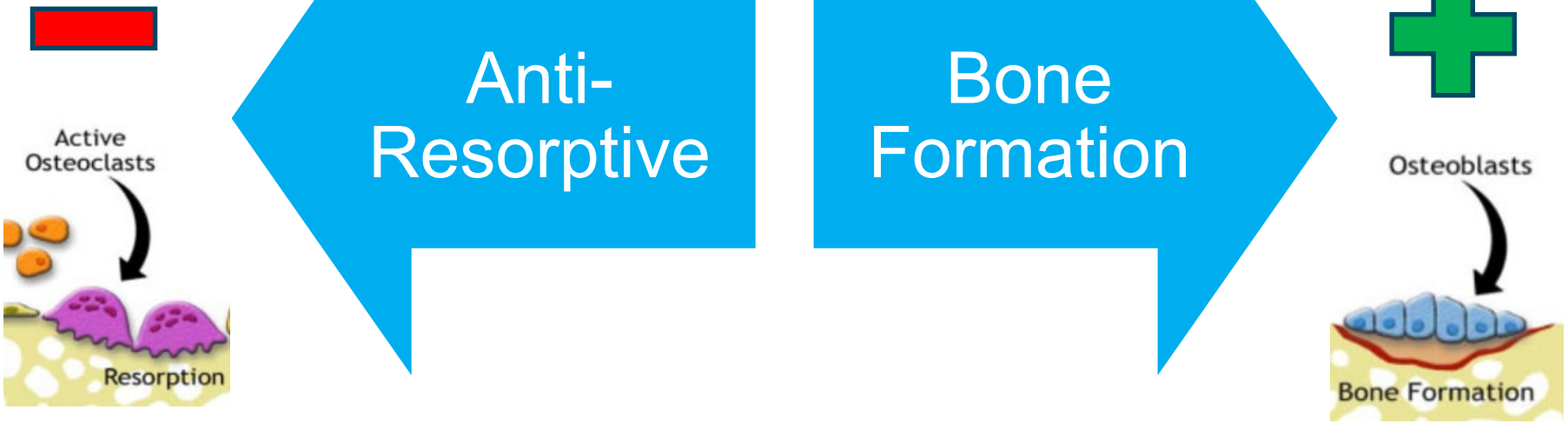
Pharmacologic Treatment

Bone is a dynamic tissue!



Baron R. Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism 6th ed.
Adapted from http://www.ns.umich.edu/Releases/2005/Feb05/img/bpme.jpg

Medications



Anti-Resorptive Treatments

Anti-Resorptive Treatments

- Typically 1st line due to ease of administration and cost-effectiveness
- Long term safety data

Bisphosphonates

- Mechanism: prevents osteoclasts from binding to bone
- Method/dose:
  - Oral
    - Risedronate (Actonel) 35mg weekly
    - Risedronate (Actonel) DR 35mg weekly
    - Risedronate (Actonel) 150mg monthly
    - Alendronate (Fosamax) 70mg weekly
  - IV
    - Zoledronic acid (Aclasta) 5mg yearly

Bisphosphonates

- Specific instructions for use (oral)
  - Empty stomach
  - 8oz of water
  - Upright for at least 30 mins
  - Separated from other medications
- Minor adverse effects
  - Dyspepsia
  - Diarrhea
  - Muscle aches
  - Infusion reaction with IV

Bisphosphonates

- Contraindications/Considerations
  - Esophageal disorders
  - eGFR <30 to 35
  - History of bariatric surgery or malabsorption
  - History of Atypical Femur Fracture (AFF) or Osteonecrosis of the Jaw (ONJ)

- Effective reduction in risk of hip and vertebral fractures by ~ 50%

Denosumab (Prolia)

- Mechanism: RANK ligand inhibitor
- Method/Dose: 60mg SC injection every 6 months
- Minor side effects: injection site reaction
- Contraindication: AFF, ONJ
  - Caution with low eGFR
  - Monitor for hypocalcemia

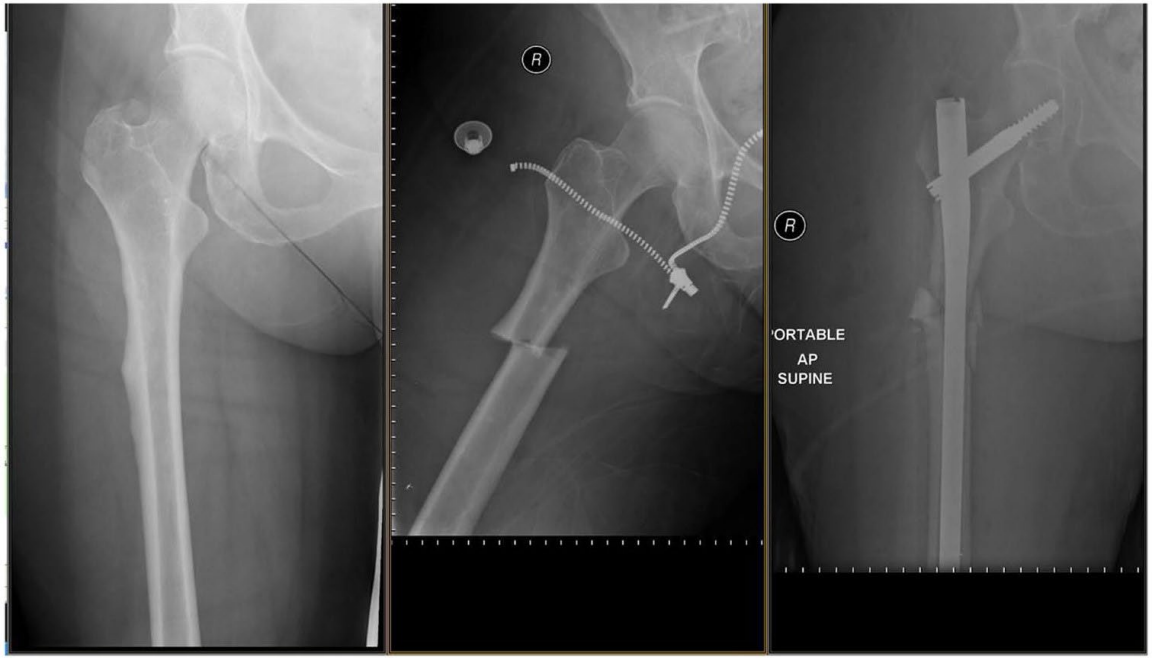
Denosumab (Prolia)

- Effective fracture risk reduction
  - FREEDOM trial demonstrated reductions in vertebral (68%), hip (40%) and nonvertebral fracture risk (20%)
- Covered under Limited Use criteria for men and women
  - Treatment failure
  - Inability to take oral medications
- Important to not miss or delay doses or to stop suddenly due to decline in bone density, increase in bone resorption and risk of multiple vertebral fractures

Aren’t Anti-Resorptive Treatments Dangerous?

Rare but severe adverse effects

Atypical Femur Fractures (AFF)

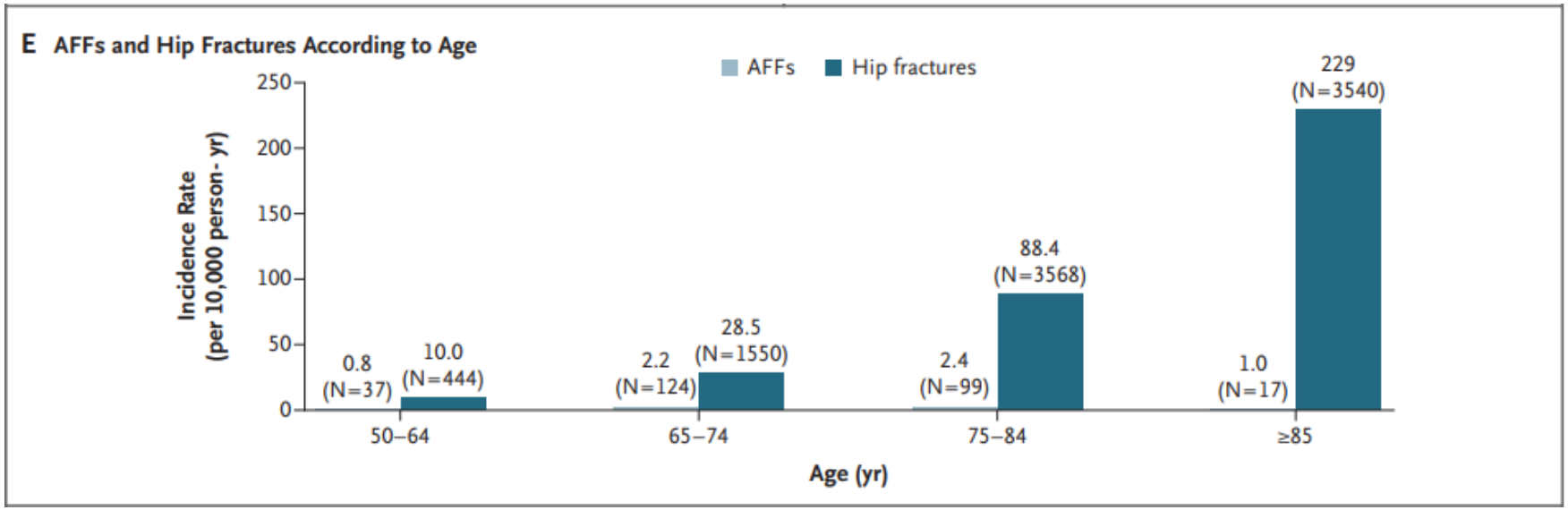


- Spectrum of presentations
- Defined by location, radiographic appearance and absence of trauma
- First associated with anti-resorptive meds in 2007 but can occur in absence of any treatment
- Prodromal pain in thigh or groin

Atypical Femur Fractures (AFF)

- <2 years of treatment: 1.8 cases per 100,000 person years
- ***8-10*** years of treatment: 113 cases per 100,000 person years
- 70% decrease in risk of atypical femur fracture after stopping
- Mitigate risk through regular screening for symptoms and appropriate medication use

Risk vs. Benefit Analysis



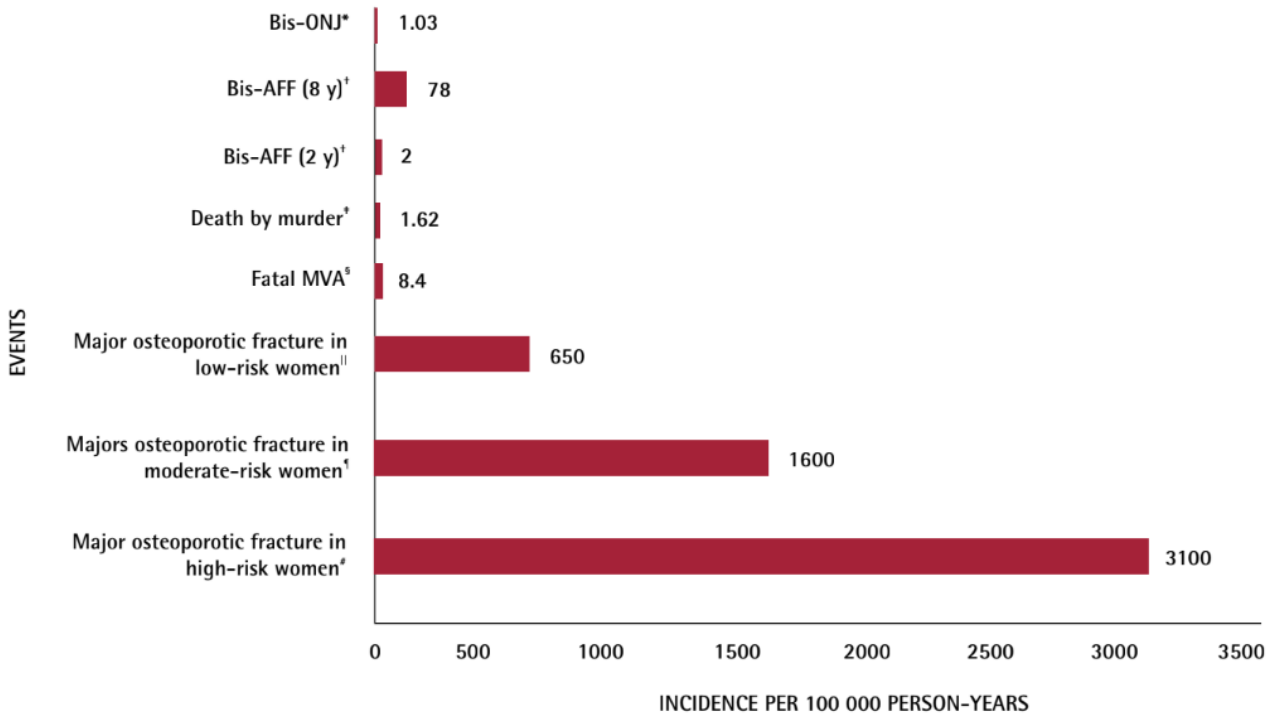
Black et al. N Engl J Med. 2020. 383(8):743-753

Osteonecrosis of the Jaw

- First reported by dental surgeons in 2003
- 1 in 10,000 to 1 in 100,000 patient-years
- Risk factors
  - Dental trauma
  - Periodontal disease
  - High doses of anti-resorptive treatments (cancer treatment)
  - Steroids
  - Diabetes
  - Smoking
- Risk reduction through close coordination with dental care

Risk in Context

Figure 1. Risks of major osteoporotic fracture and other rare events



Bis-AFF—bisphosphonate-associated atypical subtrochanteric and diaphyseal femur fracture, Bis-ONJ—bisphosphonate-associated osteonecrosis of the jaw, BMD—bone mineral density, FN—femoral neck, FRAX—Fracture Risk Assessment Tool, MVA—motor vehicle accident.

*Data from Khan et al[33] (Canadian data).

†Data from Dell et al[38] (American data).

‡Data from Statistics Canada[77] (Canadian data).

§Data from Transport Canada[78] (Canadian data).

||The 10-year risk of major osteoporotic fracture in a low-risk woman by Canadian FRAX (65-year-old woman, weighing 60 kg with a height of 168 cm; BMD FN T-score -1.2).

¶The 10-year risk of major osteoporotic fracture in a moderate-risk woman by Canadian FRAX (65-year-old woman weighing 60 kg with a height of 168 cm; parent hip fracture history; BMD FN T-score -2.0).

#The10-year risk of major osteoporotic fracture in a high-risk woman by Canadian FRAX (65-year-old woman weighing 60 kg with a height of 168 cm; parent hip fracture history; previous fracture; BMD FN T-score -2.6).

Brown et al. Can Fam Physician. 2014: (4):324-33

Bone Formation Treatments

Bone Formation Agents

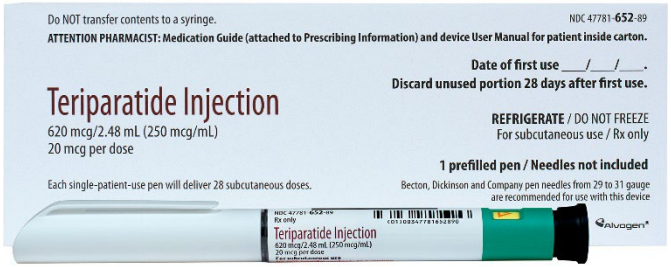
- Recommended for those at ***very*** high risk of fracture
  - Very low T-score <-3.0
  - Major osteoporotic fracture risk of >30% or Hip fracture risk of >4.5%
  - Multiple fragility fractures, recent fracture
  - Failure of other treatments

- Greater fracture risk reduction for those with severe osteoporosis
  - VERO TRIAL: Teriparatide vs. Risedronate
  - ARCH STUDY: Romosozumab + Alendronate vs. Alendronate alone

- More effective when used before anti-resorptive agents

Teriparatide (Forteo, Osnuvo)

- Mechanism: Recombinant human parathyroid hormone
- Method/dose: 20mcg daily SC injection x 18-24 months
- Contraindications:
  - previous cancer or risk of osteosarcoma
  - history of radiation treatment
  - hypercalcemia/hyperparathyroidism



Teriparatide

- Reduces risk of vertebral fractures (65%) and non-vertebral fractures (~50%)
- $$$ but covered for patients with AFF or ONJ
- 2 step medication sequence

Teriparatide x 24 months → Bisphosphonate Or Prolia

Romosozumab (Evenity)

- Mechanism: Sclerostin inhibitor, approved in Canada for use in postmenopausal women since 2019
  - Bone formation and decreases bone resorption (dual activity)
- Method/Dose: 210mg SC injection monthly x 12 months
- Fracture risk reduction
  - 73% relative risk reduction in vertebral fractures (FRAME study)
  - 48% lower risk of new vertebral fractures, 27% lower risk of clinical fractures, 38% lower risk of hip fractures compared with Alendronate (ARCH study)

Romosozumab

- Contraindications:
  - recent myocardial infarction or stroke
  - multiple risk factors for major cardiovascular event (ARCH study)
- $$$
- 2 step medication sequence

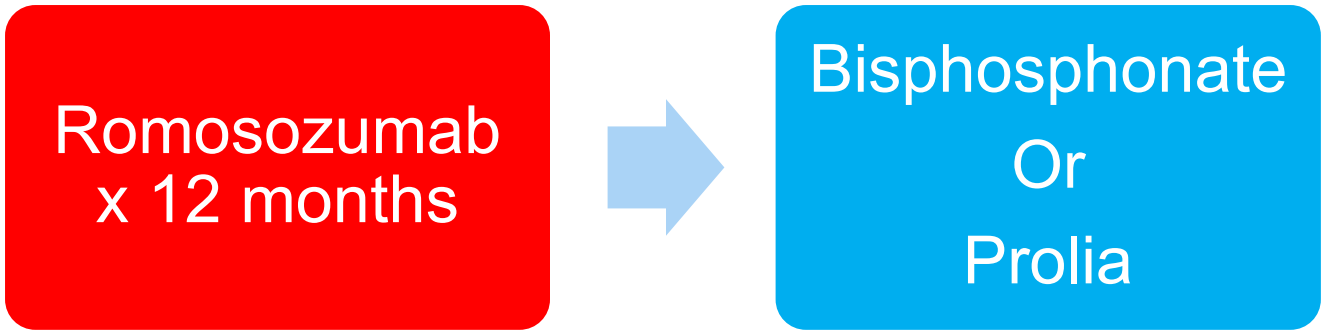


Table 10: CADTH Cost Comparison Table for the Treatment of Osteoporosis

Treatment	Strength	Form	Price	Recommended dosage	Daily cost ($)	Annual cost ($)
Romosozumab (Evenity)	105 mg/1.17 mL	Single-use pre-filled syringe 1.17 mL	328.3900[a]	210 mg, every month	21.59	7,881
RANK ligand inhibitor						
Denosumab (Prolia)	60 mg/mL	Single-use pre-filled syringe 1 mL	395.7800	60 mg, every 6 months	2.17	792
Bisphosphonates						
Alendronate (Fosamax, generics)	10 mg 70 mg	Tablet	0.4987 2.1014	10 mg daily or 70 mg weekly	0.30	109
Alendronate / cholecalciferol (Fosavance, generics)	70 mg/70 mcg 70 mg/140 mcg	Tablet	2.4348 1.2174	70 mg weekly	0.17	63
Risedronate (Actonel, generics)	35 mg 150 mg	Tablet	1.9787 11.1875	35 mg weekly	0.28	103
Risedronate (Actonel)	35 mg	Delayed release tablet	11.8653	35 mg weekly	1.69	617
Zoledronic acid (Aclasta, generics)	5 mg/100 mL	IV infusion 100 mL	335.4000	5 mg annually	0.92	335
Parathyroid hormone analogue						
Teriparatide (Forteo, generic)	250 mcg/mL	Pre-filled pen 3 mL (37.5 doses) 2.4 mL (30 doses)	800.7934[b]	20 mcg daily[c]	28.60	10,439
Selective estrogen receptor modulator						
Raloxifene HCl (Evista, generics)	60 mg	Tablet	1.0268	60 mg daily	1.03	375

Note: All prices are from the Ontario Drug Benefit Formulary (accessed June 2021), unless otherwise indicated, and do not include dispensing fees.

[a]Sponsor's submitted price: 1 package contains 2 syringes (i.e., 210 mg) — $656.7800.

[b]Price from Delta PA accessed March 2021.[12]

[c]One pen lasts for 28 days.

Other

Raloxifene

- Selective Estrogen Receptor Modulator—pro-estrogenic effect in bone
- Risk reduction of invasive breast cancer
- Dose: 60mg tablet daily
- Not 1st line
- Demonstrates reduction in vertebral fractures (30-35%) but not non-vertebral or hip fractures
- Serious risk of VTE

HRT

- Not 1st line for most individuals
- Can be 1st line for postmenopausal women <60 with concurrent menopausal symptoms
- Increased risks with prolonged use and need to consider individual risk of breast and ovarian cancer and risk of thromboembolism

Bottom Line

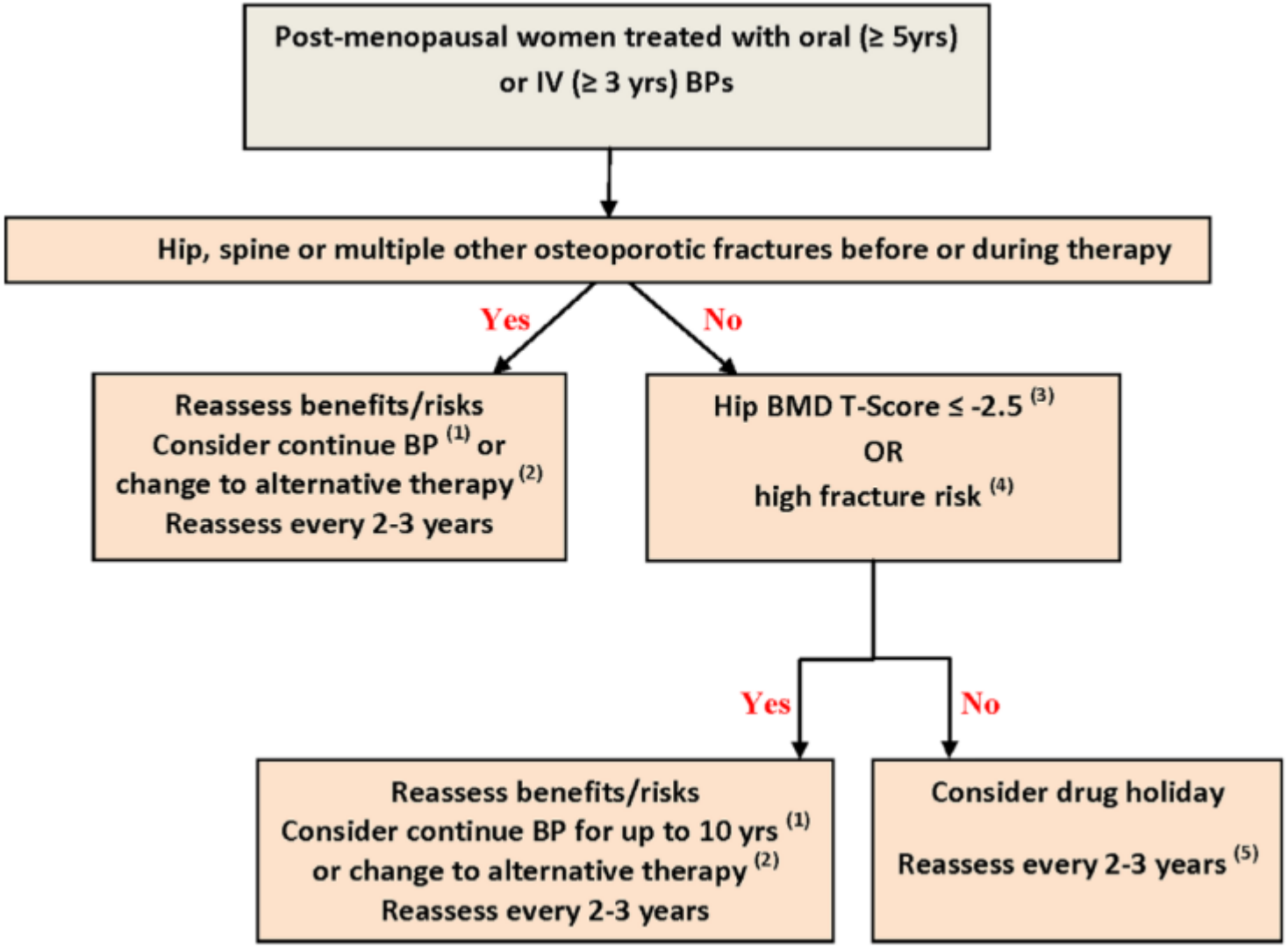
- Anti-resorptive treatment options (bisphosphonates, Prolia) are usually 1st line treatments for most individuals and are effective in reducing fracture risk
- If logistics and cost are not barriers, bone formation agents are effective medications for those at highest risk
- Bone formation agents must always be followed by anti-resorptive treatment

Treatment Durations and Drug Holidays

Drug Holidays

- A drug holiday is an intentional pause in treatment
- Rationale for drug holidays is to ensure safe medication use
- Concept applies primarily to bisphosphonates due to mechanism of action

Drug Holidays: Bisphosphonates



Adler et al. J Bone Miner Res. 2016: (1):16-35

Drug Holidays: Bisphosphonates

Moderate Risk

Drug holiday after 5 years of oral bisphosphonate

Drug holiday after 3 doses of IV bisphosphonate

High Risk Option A

Treat for 5-10 years and consider short drug holiday

Reassess 1-2 years

High Risk Option B

- Treat for 5-10 years and switch to bone formation agent
- Teriparatide x 24 months
- Romosozumab x 12 months

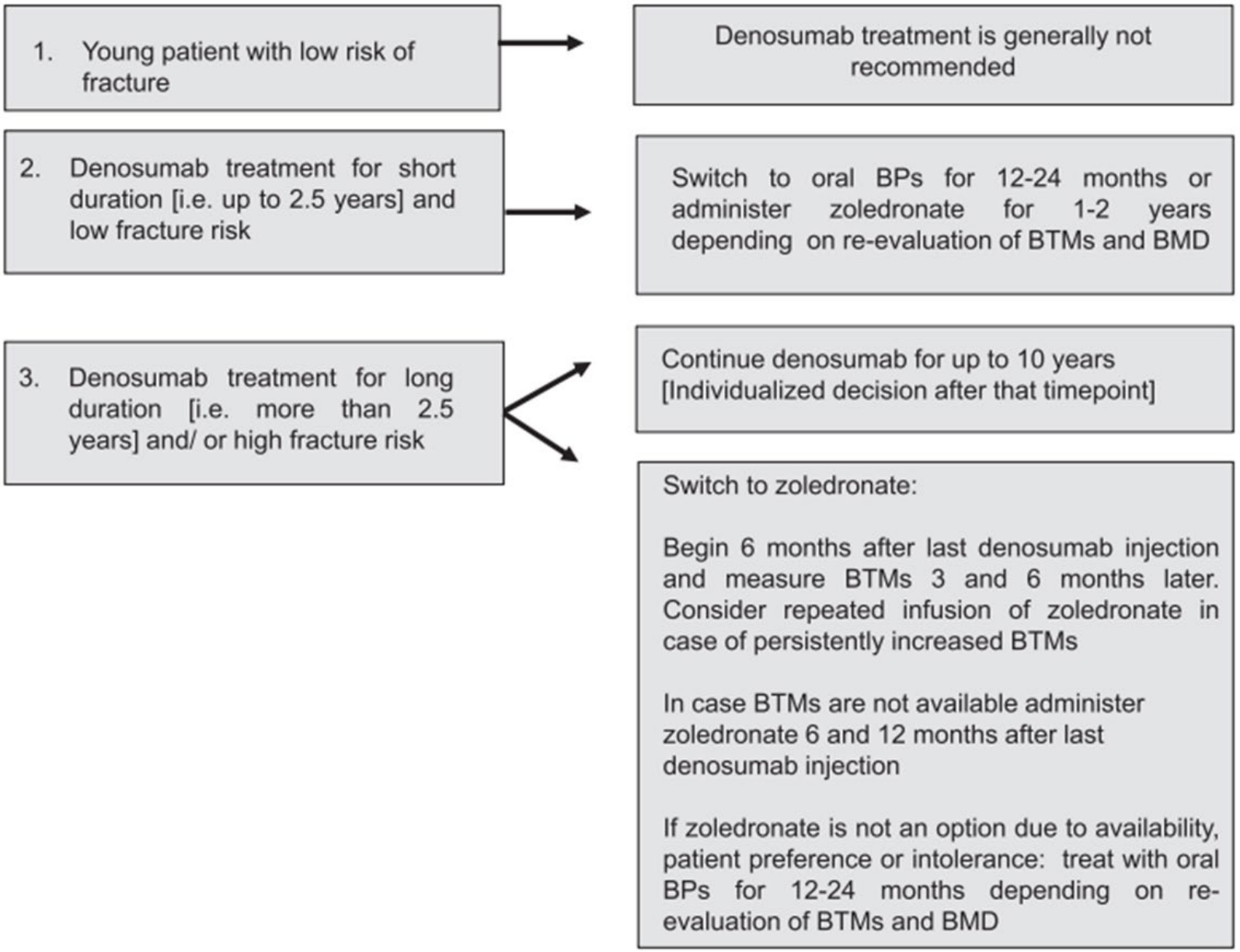
Resume anti-resorptive treatment after bone formation treatment

Drug Holidays and Prolia?

- The traditional concept of a drug holiday cannot be applied to Prolia as there is no lasting protection

- If stopping Prolia, this needs to be coordinated with your doctor or a bone health specialist to reduce the risks of stopping therapy

Discontinuing Denosumab (Prolia)



10 years of denosumab treatment in postmenopausal women with osteoporosis: results from the phase 3 randomised FREEDOM trial and open-label extension

Henry G Bone, Rachel B Wagman, Maria L Brandi, Jacques P Brown, Roland Chapurlat, Steven R Cummings, Edward Czerwiński, Astrid Fahrleitner-Pammer, David L Kendler, Kurt Lippuner, Jean-Yves Reginster, Christian Roux, Jorge Malouf, Michelle N Bradley, Nadia S Daizadeh, Andrea Wang, Paula Dakin, Nicola Pannacciulli, David W Dempster, Socrates Papapoulos

	Placebo			Combined denosumab groups									
	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Number of participants	3883	3687	3454	6085	5787	5452	4099	3890	3582	3261	1743	1585	1451
All adverse events	189·5	156·3	132·8	165·3	137·8	124·6	129·9	110·9	110·0	108·4	107·6	109·5	95·9
Infections	38·6	33·9	31·7	35·1	30·3	29·5	29·1	26·0	27·2	26·5	27·0	27·0	23·0
Malignancies	1·8	1·6	1·5	1·9	1·5	2·2	2·3	2·4	2·2	2·7	1·7	2·6	1·6
Eczema	0·8	0·5	0·6	1·4	1·1	1·0	1·1	1·2	0·9	0·7	0·8	0·9	1·3
Hypocalcaemia	<0·1	0	<0·1	<0·1	<0·1	0	<0·1	0·1	0	<0·1	<0·1	0	0·1
Pancreatitis	<0·1	<0·1	0	<0·1	<0·1	<0·1	0	<0·1	0·1	<0·1	0·1	<0·1	0
Serious adverse events	11·7	11·9	10·8	12·0	11·5	12·3	11·5	12·9	12·6	14·4	11·5	13·1	12·3
Infections	1·1	1·4	1·4	1·5	1·6	1·4	1·4	1·3	1·9	2·3	1·2	1·5	2·6
Cellulitis or erysipelas	0	0	<0·1	<0·1	<0·1	0·2	<0·1	<0·1	0·1	<0·1	0·2	<0·1	0·1
Fatal adverse events	0·8	0·8	1·0	0·7	0·6	0·7	0·5	0·8	0·9	1·5	0·7	1·0	0·9
Osteonecrosis of the jaw	0	0	0	0	<0·1	0	<0·1	0	0·2	<0·1	0	<0·1	<0·1
Atypical femoral fracture	0	0	0	0	0	<0·1	0	0	0	<0·1	0	0	0

Analyses were based on the original randomised treatment groups in FREEDOM. Data include all participants who received at least one dose of investigational product in FREEDOM or the extension. Placebo data are for all participants who received at least one dose of placebo during FREEDOM. Denosumab data are for all participants who received at least one dose of denosumab during FREEDOM or the extension. Data are shown for each year of exposure; thus a long-term participant could have up to 10 years of exposure and a crossover participant could have up to 7 years of exposure to denosumab. All adverse and serious adverse events were coded using Medical Dictionary for Regulatory Activities version 13.0.

Table 2: **Yearly exposure-adjusted participant incidence of adverse events per 100 participant-years of follow-up for placebo and for the combined FREEDOM, long-term, and crossover denosumab participants, up to 10 years**

Areas for Shared Decision Making

- Drug Holidays in patients with high fracture risk
- Decisions to discontinue Prolia
- Romosozumab and cardiovascular risk
- Sequencing of treatments

Take Home Points

1. For high risk individuals, benefits in pharmacologic treatment outweigh risks
2. If cost is not a barrier, bone formation agents should be considered for those with very high fracture risk
3. Treatment > No treatment
4. Treatment decisions should always be individualized based on clinical picture, values and goals

Thank you for your time

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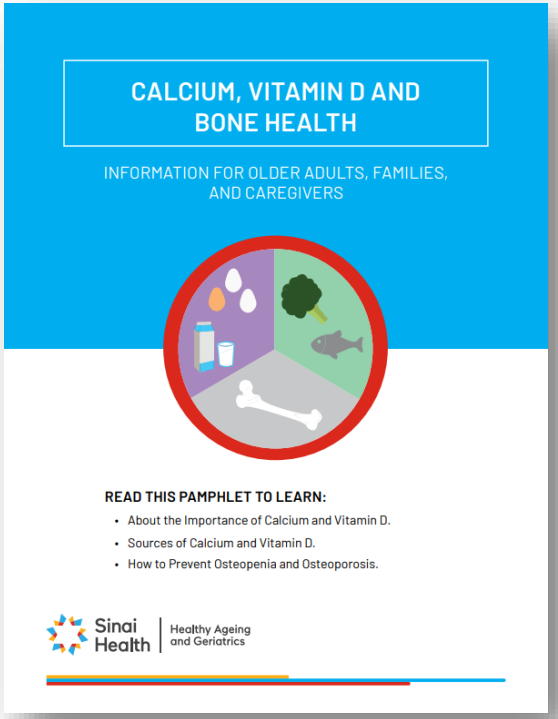
- Khan Aliya et al. Guideline No. 422g: Menopause and Osteoporosis, SOCG Clinical Practice Guideline, J Obstet Gynaecol Can 2022; 44(5): 527-536

Additional Resources

https://sinaigeriatrics.ca/healtheducation/

Find more information in “Calcium, Vitamin D and Bone Health” available on our website

https://sinaigeriatrics.ca/patient-resources/calcium-vitamin-d-and-bone-health/



Additional Resources

https://www.ontario.ca/page/health-care-ontario

Seniors' INFOline at 1-888-910-1999

Osteoporosis Canada
https://osteoporosis.ca/

Osteoporosis Line (Toll Free)
English: 1-800-463-6842
French: 1-800-977-1778

IOF
International Osteoporosis Foundation | IOF

Bone Fit
Looking for A Bone Fit™ Trained Professional?

Additional Resources

Physical Activity Guidelines
https://csepguidelines.ca/

Healthy Eating: Variety and Balance
www.dietitians.ca

Canada's Food Guide
https://www.unlockfood.ca/en/Articles/Bone-Health

Exercise and Falls Prevention Programs
https://www.ontario.ca/page/exercise-and-falls-prevention-programs

Questions? (Submit through Q&A)

Stay Connected With Us

https://sinaigeriatrics.ca/healtheducation/

Website:

https://sinaigeriatrics.ca

Twitter:

@SinaiGeriatrics

LinkedIn:

Healthy Ageing and Geriatrics Program (Sinai Health and University Health Network)

RTO ERO

Sinai Health | Healthy Ageing and Geriatrics

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

Upcoming Healthy Ageing 101 Schedule

October 17, 2023 12-1pm EST
Delirium and Older Adults: What You Need to Know
Speaker: **Dr. Don Melady** (Family Physician and Professor, University of Toronto)

The rest of the schedule will be communicated

https://sinaigeriatrics.ca/healthy-ageing101/

Sinai Health | Healthy Ageing and Geriatrics

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

Toronto Geriatrics Update Course

Friday November 10th, 8:40 AM – 3:30 PM EST

Hosted Virtually via ZOOM

4 Lectures + 4 Workshops

Eligible for CFPC Mainpro+ credits

Registration is Open !!!

www.sinaigeriatrics.ca/events