Welcome!

FLS Bone Health ECHO® TeleECHO Clinic

We will be recording this TeleECHO Clinic for educational and quality improvement purposes.

By participating in this clinic you are consenting to be recorded.

- If you do not wish to be recorded, please email andrea.medeiros@nof.org at least one week prior to the TeleECHO Clinic you wish to attend.
- Please type in your name, location, and email address in the chat.

Some helpful tips:

- Please mute your microphone when not speaking
- Position webcam effectively
- Communicate clearly during clinic:
  - Speak clearly
  - Use chat function

Project ECHO's goal is to protect patient privacy

To help Project ECHO accomplish that goal, please only display or say information that doesn't identify a patient or that cannot be linked to a patient.

References:

For a complete list of protected information under HIPAA, please visit www.hipaa.com

Common HIPAA Identifier Slip-Ups and Easy Ways to Protect Patient Privacy

- 1st – **Names:** Please do not refer to a patient's *first/middle/last name* or use any *initials*, etc. Instead please use the *ECHO ID*.
- 2nd – **Locations:** Please do not identify a patient's *county, city or town*. Instead please use only the patient's *state* if you must or the *ECHO ID*.
- 3rd – **Dates:** Please do not use any dates (like *birthdates*, etc.) that are linked to a patient. Instead please use only the patient's *age* (unless > 89)
- 4th – **Employment:** Please do not identify a patient's *employer*, work *location* or *occupation*. Instead please use the *ECHO ID*.
- 5th – **Other Common Identifiers:** Do not identify patient's *family* members, *friends, co-workers, numbers, e-mails*, etc.

HYPERPARATHYROIDISM

Natalie E. Cusano, MD, MS
Associate Professor of Medicine | Zucker School of Medicine at Hofstra/Northwell
Director, Bone Metabolism Program | Lenox Hill Hospital
New York, NY

Disclosures

- Speaker (Honorarium): Shire Pharmaceuticals/Takeda, Alexion
- Consultant (Honorarium): Shire Pharmaceuticals/Takeda, Radius Pharmaceuticals
- Off-label use of estrogen, raloxifene and alendronate

Learning objectives

- Recognize the complications of primary hyperparathyroidism.
- Identify patients with primary hyperparathyroidism who are candidates for parathyroid surgery.
- Medically manage patients with primary hyperparathyroidism.

Outline

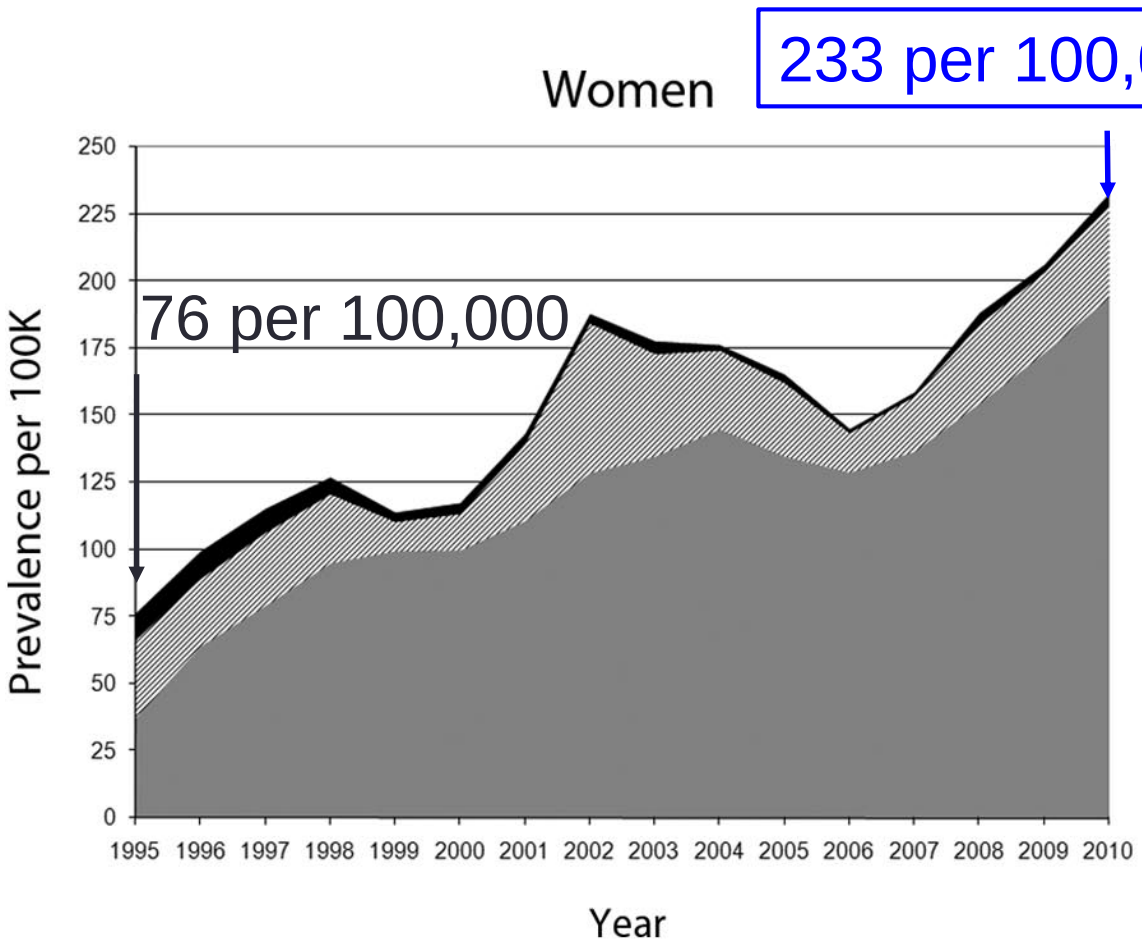
- Introduction
- Clinical presentation
- Guidelines
  - Screening and management
    - Bones
    - Kidney
    - Normocalcemic primary hyperparathyroidism
    - Medical therapy
    - Surgery

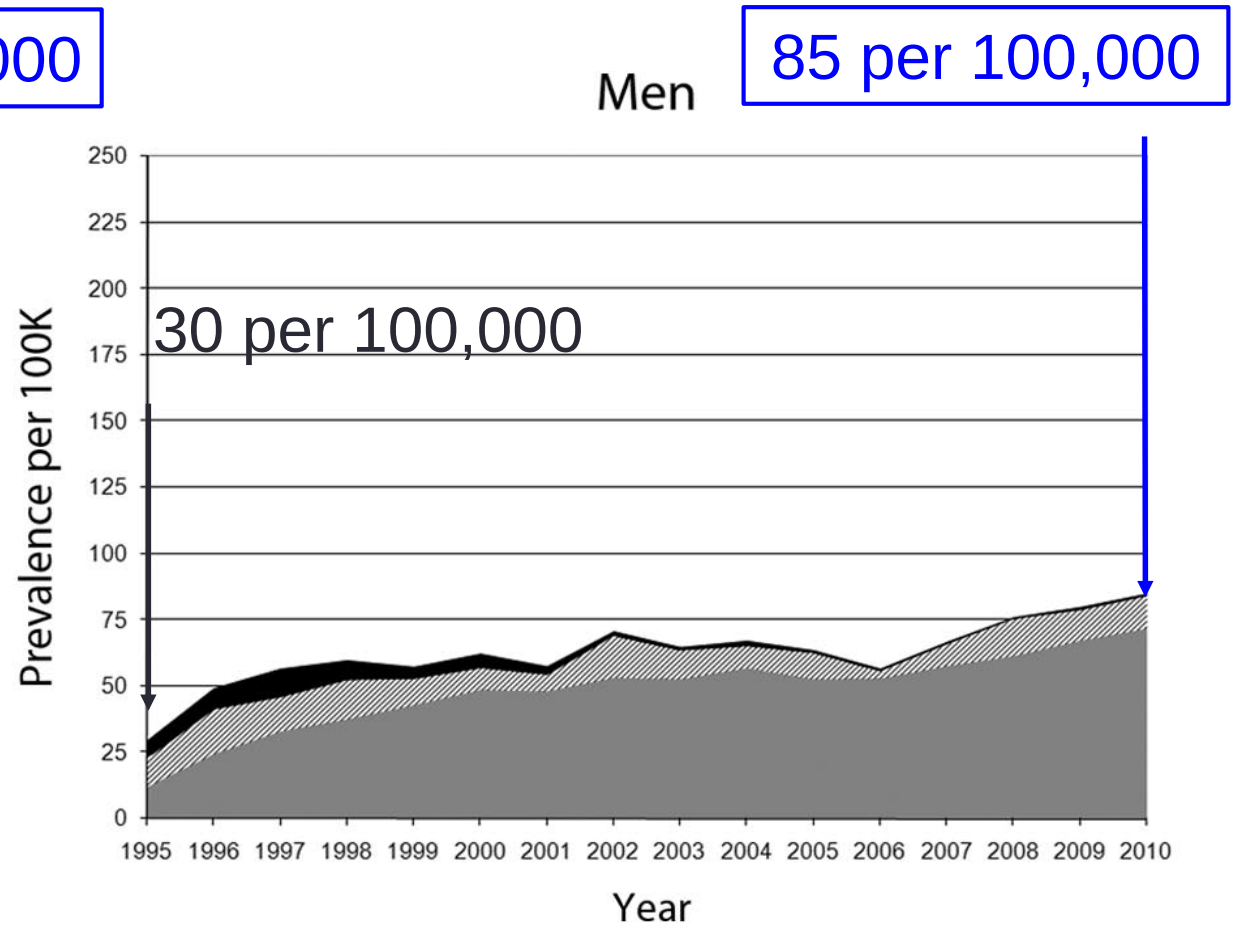
Primary hyperparathyroidism is common

- Parathyroid hormone (PTH) is made by the (usually) four parathyroid glands that sit on top of the thyroid
- Primary hyperparathyroidism (PHPT) is a disorder traditionally characterized by elevated levels of PTH and hypercalcemia
- PHPT is one of the most common endocrine disorders
  - Estimated prevalence 0.1-1% in postmenopausal women
  - Prevalence is about 3 times greater in women than men
  - More common with increasing age
- **PHPT is a common secondary cause of osteoporosis**

Wilhelm SM, et al. JAMA Surg 2016;151:959-68

The prevalence of PHPT in the US has tripled





Yeh MW, et al. J Clin Endocrinol Metab 2013;98:1122-28

Phenotypes of PHPT

Before 1970:

A disease of bones, stones, groans, and moans

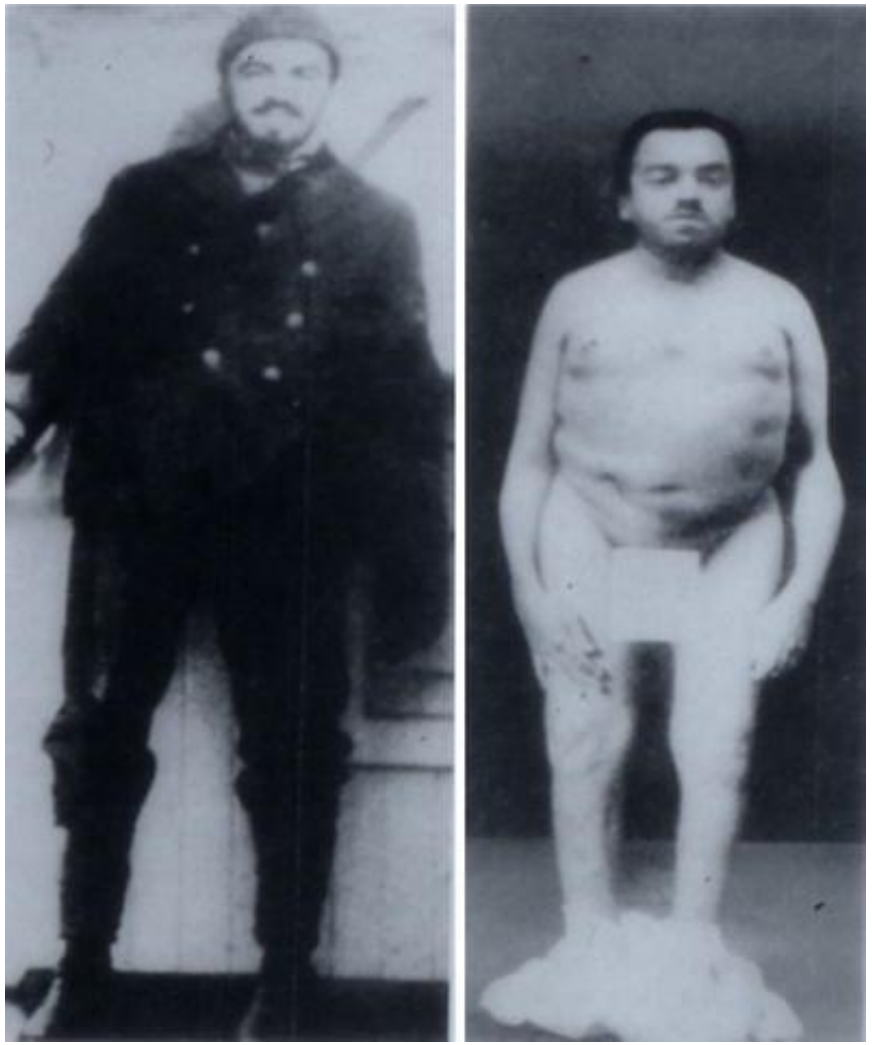
The early clinical picture of PHPT

1918

Zarnegar R and Clark OH. Clin Rev Bone Miner Metab 2007;5:81-88

The early clinical picture of PHPT

1918 1926



Zarnegar R and Clark OH. Clin Rev Bone Miner Metab 2007;5:81-88

Phenotypes of PHPT

Before 1970:

A disease of bones, stones, groans, and moans

After 1970:

A disease with primarily biochemical and densitometric signatures

The modern clinical profile of PHPT

	Cope[1] 1930-1965	Mallette[2] 1965-1974	Silverberg[3] 1984-1999	Walker[4] 2000-2014
Nephrolithiasis	57%	37%	17%	19%
Hypercalciuria	NR	40%	39%	17%
Overt skeletal disease	23%	14%	1.4%	0%
Asymptomatic	0.6%	22%	82%	81%

[1]Cope O. N Engl J Med 1966;274:1174-82; [2]Mallette LE, et al. Medicine (Baltimore) 1974;53:127-46; [3]Silverberg SJ, et al. N Engl J Med 1999;341:1249-55; [4]Walker MD, et al. Osteoporos Int 2015; 26:2837-43

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*More common if imaging performed for screening

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- 96 patients with PHPT without known history of nephrolithiasis
  - ➢Occult urolithiasis was detected in 21% of patients

Tay YD, et al. Endocr Res 2018 May;43:106-115

[1]Cope O. N Engl J Med 1966;274:1174-82; [2]Mallette LE, et al. Medicine (Baltimore) 1974;53:127-46; [3]Silverberg SJ, et al. N Engl J Med 1999;341:1249-55; [4]Walker MD, et al. Osteoporos Int 2015; 26:2837-43

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The biochemical signature of PHPT in the modern era

Index	1984-1991 N=121	2000-2014 N=100	p value	Normal range
Calcium (mg/dL)	10.6 ± 0.6	10.7 ± 0.6	0.14	8.4-10.2
PTH (pg/mL)	127 ± 69	85 ± 48	<0.0001	10-65
25-hydroxyvitamin D (ng/mL)	23 ± 10	29 ± 10	<0.0001	30-100
1,25-dihydroxyvitamin D (pg/mL)	57 ± 20	69 ± 24	0.002	15-60
Urinary calcium excretion (mg)	229 ± 119	250 ± 144	0.28	100-300

Silverberg SJ et al. N Engl J Med 1999; 341:1249-55
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None of the patients in the prior cohort were taking vitamin D supplements compared to 64% in the new cohort (median 800 IU daily)

Silverberg SJ et al. N Engl J Med 1999; 341:1249-55
Walker MD et al. Osteoporos Int 2015; 26:2837-43

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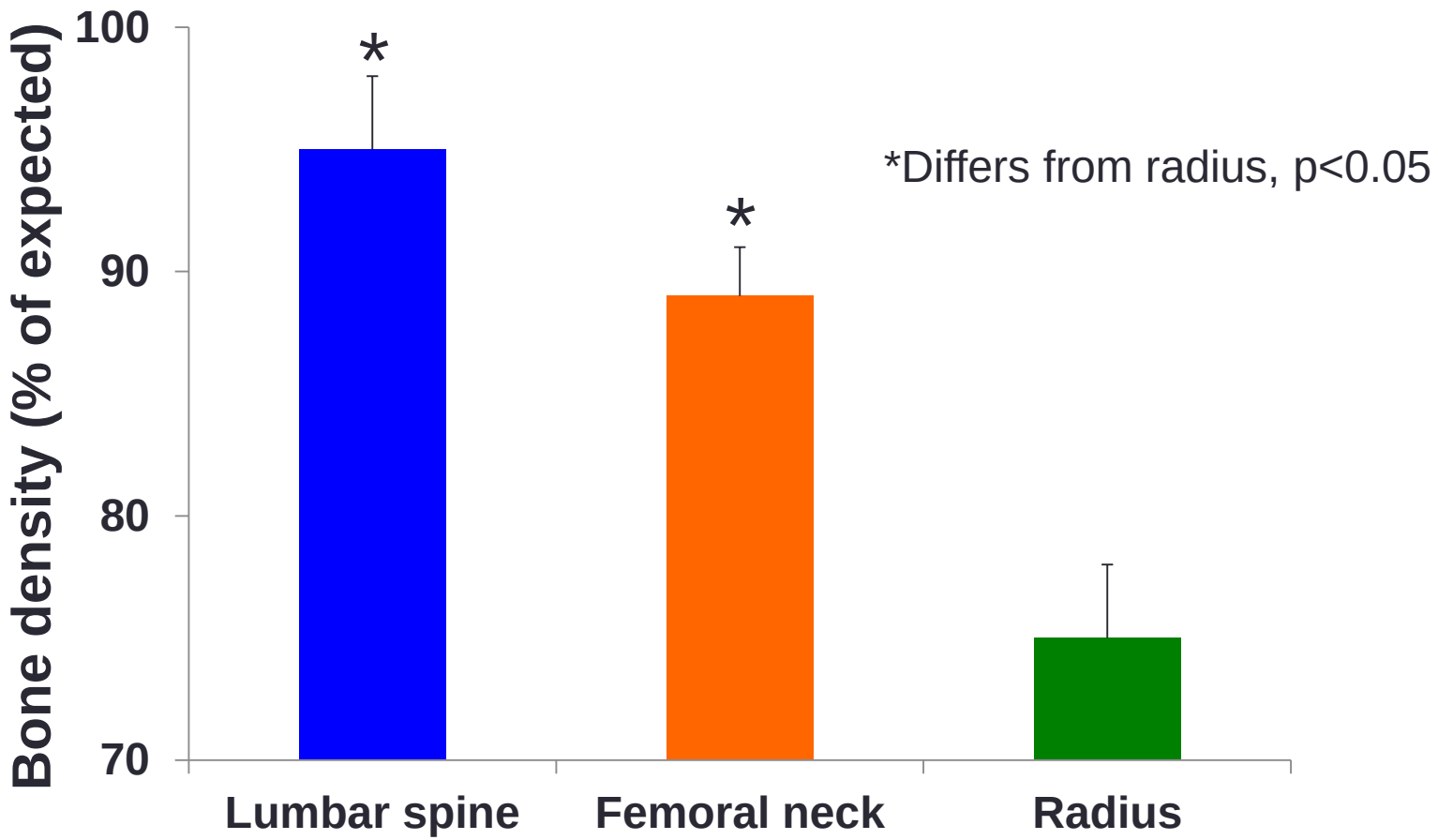
Primary hyperparathyroidism can be diagnosed with an "inappropriately normal" PTH concentration (>20 pg/mL)

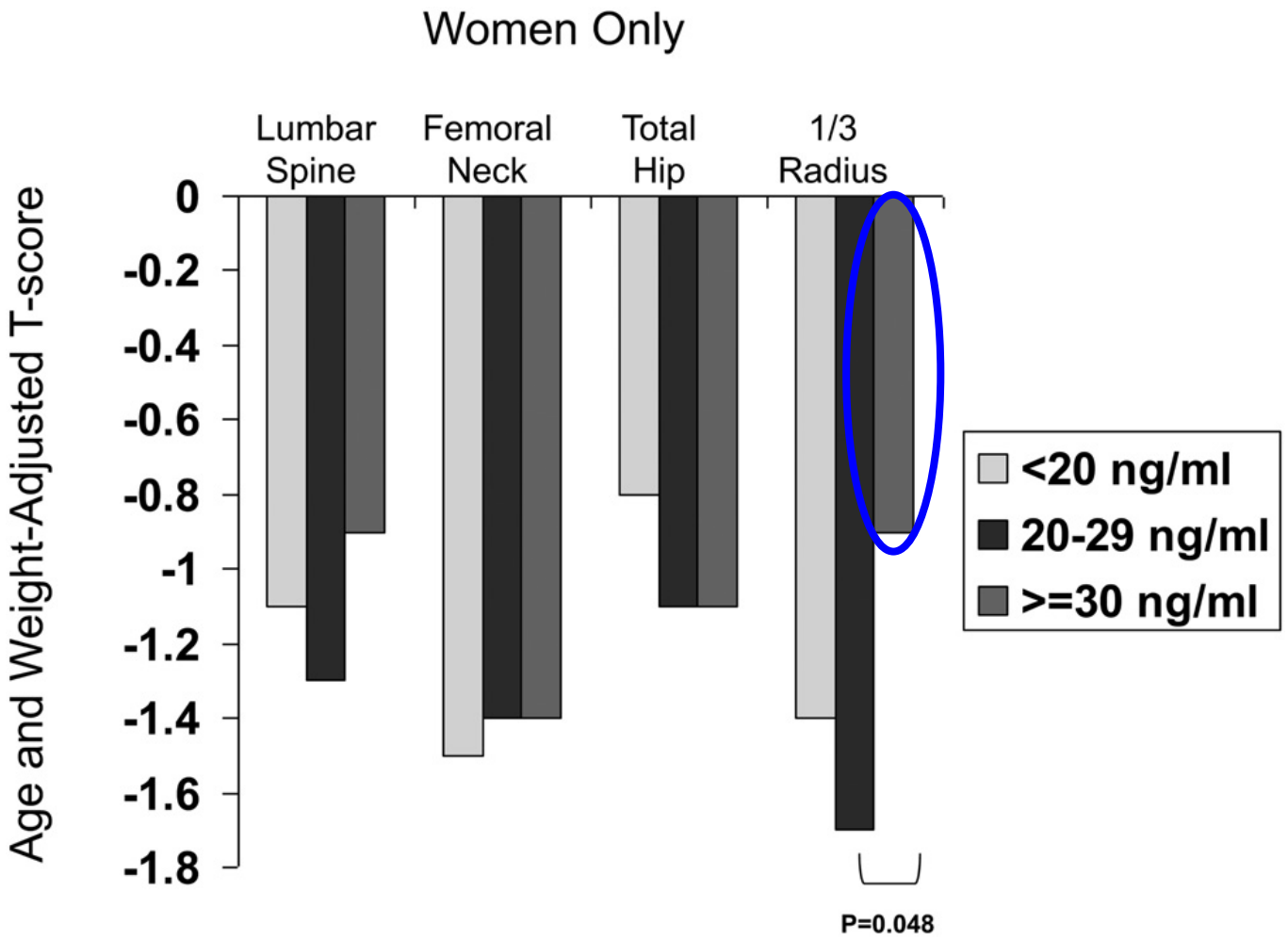
Silverberg SJ et al. N Engl J Med 1999; 341:1249-55
Walker MD et al. Osteoporos Int 2015; 26:2837-43

The densitometric signature of PHPT in the modern era



Silverberg SJ, et al. J Bone Miner Res 1989;4:283-91

The densitometric signature of PHPT in the modern era -2-



Walker MD et al. Osteoporos Int 2015; 26:2837-43

Management of **asymptomatic** PHPT

- Who needs surgery?
- Who doesn't need surgery?

Even though patients may not meet any specific criteria for surgery, parathyroidectomy is not inappropriate, as long as there are no medical contraindications

Management of **asymptomatic** PHPT

- Who needs surgery?
- Who doesn't need surgery?

- First International Workshop,1990
- Second International Workshop, 2002
- Third International Workshop, 2008
- Fourth International Workshop, 2013

- American Association of Endocrine Surgeons, 2016

Guidelines overview

- Biochemical presentation
- Diagnostics
- Clinical presentations
- Natural history
- Densitometric features
- Other skeletal features
- Non-traditional features
- Pharmacological approaches
- Localization and surgical approaches

Bilezikian JP, et al. J Clin Endocrinol Metab 2014;3561-9
Eastell R, et al, J Clin Endocrinol Metab 2014;99:3570-9
Silverberg SJ, et al. J Clin Endocrinol Metab 2014;99:3580-94
Udelsman R, et al. J Clin Endocrinol Metab 2014;99:3595-606
Marcocci C, et al. J Clin Endocrinol Metab 2014;99:3607-18

Wilhelm SM, et al. JAMA Surg 2016;151:959-68

Outline

- Introduction
- Clinical presentation
- Guidelines
  - Screening and management
    - Bones
    - Kidney
    - Normocalcemic primary hyperparathyroidism
    - Medical therapy
    - Surgery

Surgical guidelines for asymptomatic PHPT

Index	Third workshop (2008)	Fourth workshop (2013)
Age	<50 years	<50 years
Serum calcium	>1.0 mg/dL above normal	>1.0 mg/dL above normal

Recommendation 3-2: Parathyroidectomy is indicated when the serum calcium level is greater than 1 mg/dL above normal, regardless of whether objective symptoms are present or absent (strong recommendation; low-quality evidence)

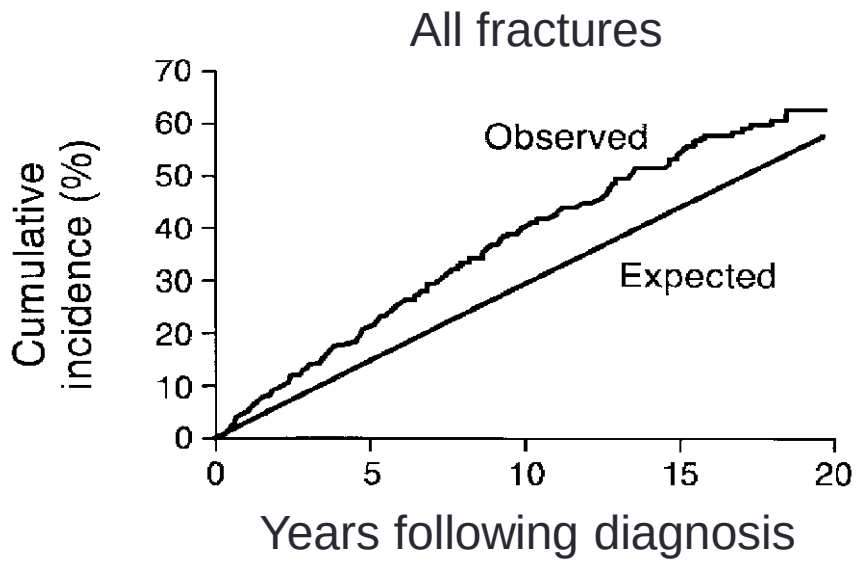
Recommendation 3-5: Parathyroidectomy is indicated when PHPT is diagnosed at 50 years or younger regardless of whether objective or subjective features are present or absent (strong recommendation; moderate-quality evidence)

Fracture risk in PHPT

- Bone density and bone biopsy data show decreased cortical bone but preservation of the trabecular skeleton[1-3]
- Fracture risk may be expected to be
  - ↓ at vertebral sites
  - ↑ at nonvertebral sites

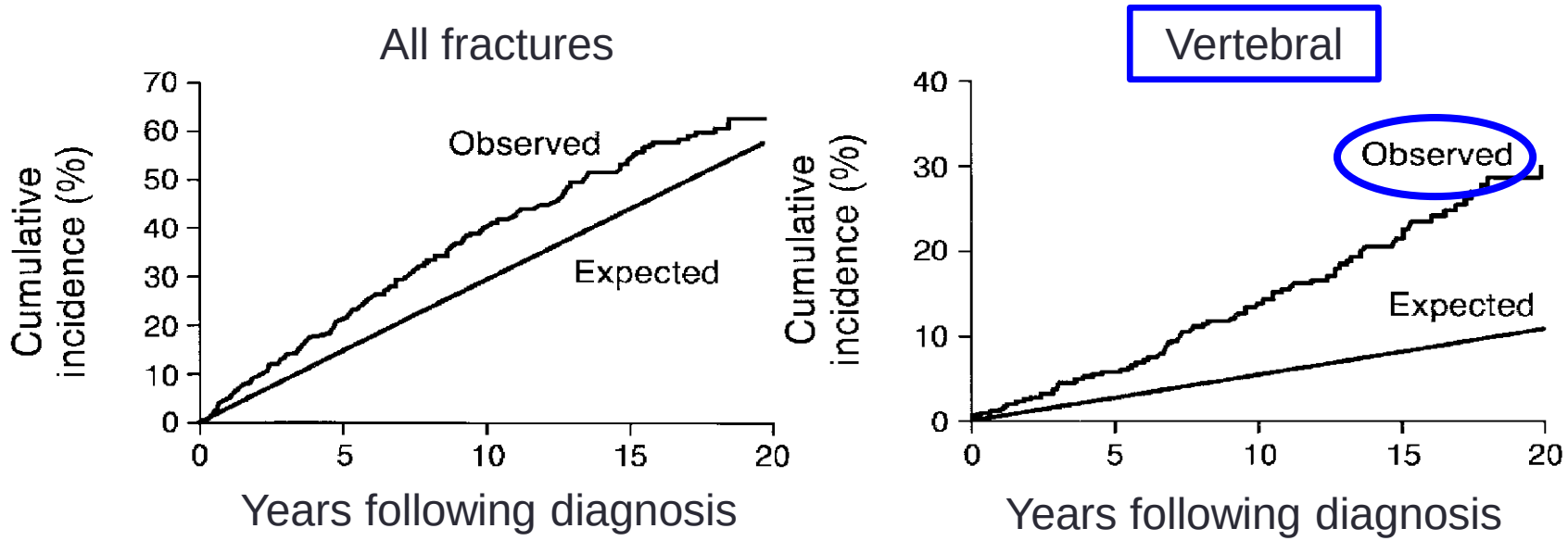
[1]Silverberg SJ et al. J Bone Miner Res 1989;4:283-91
[2]Parisien M, et al. J Clin Endocrinol Metab 1990;70:930-8
[3]Dempster DW, et al. Bone 2007;41:19-24

Fracture risk in PHPT -2-



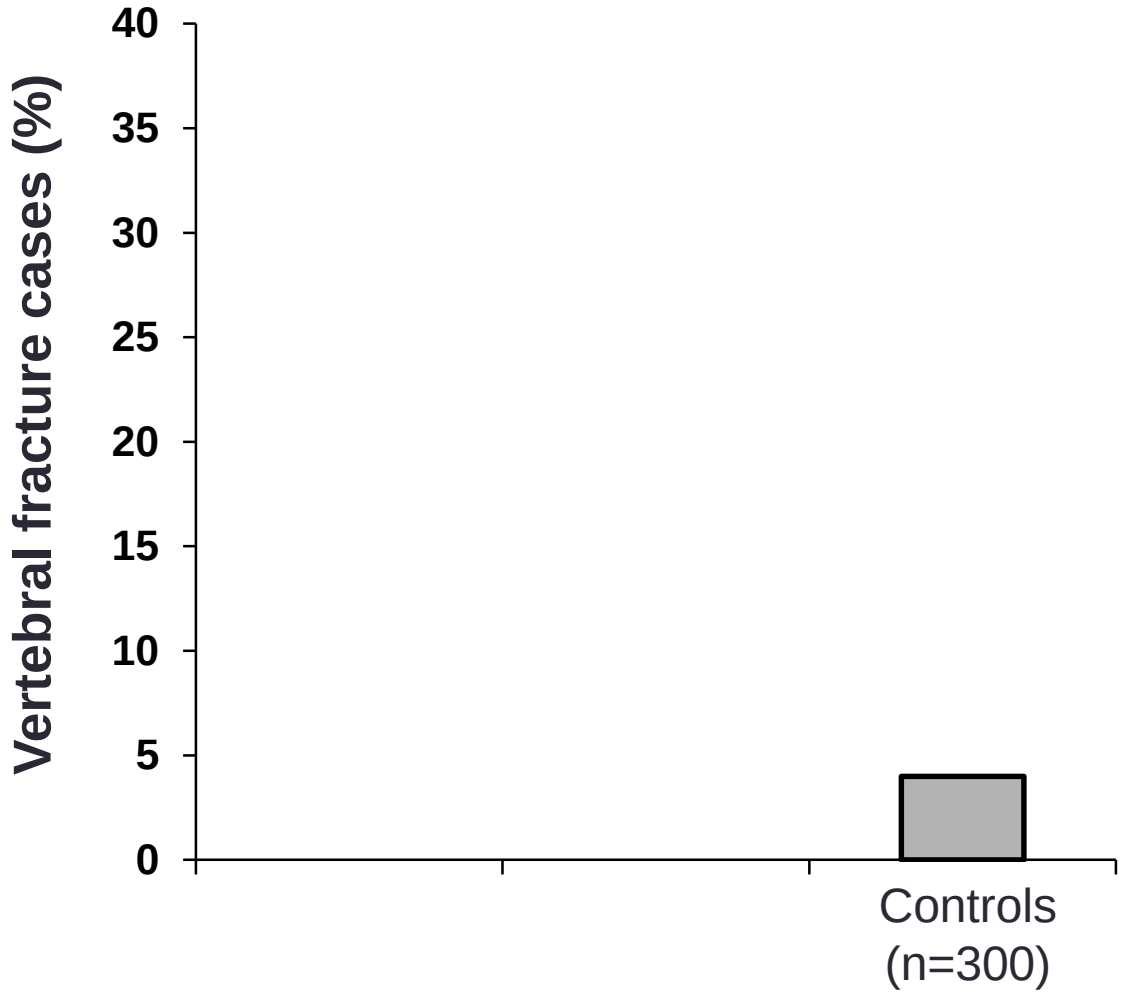
Khosla S et al, J Bone Miner Res 1999;14:1700-7

Fracture risk in PHPT -2-



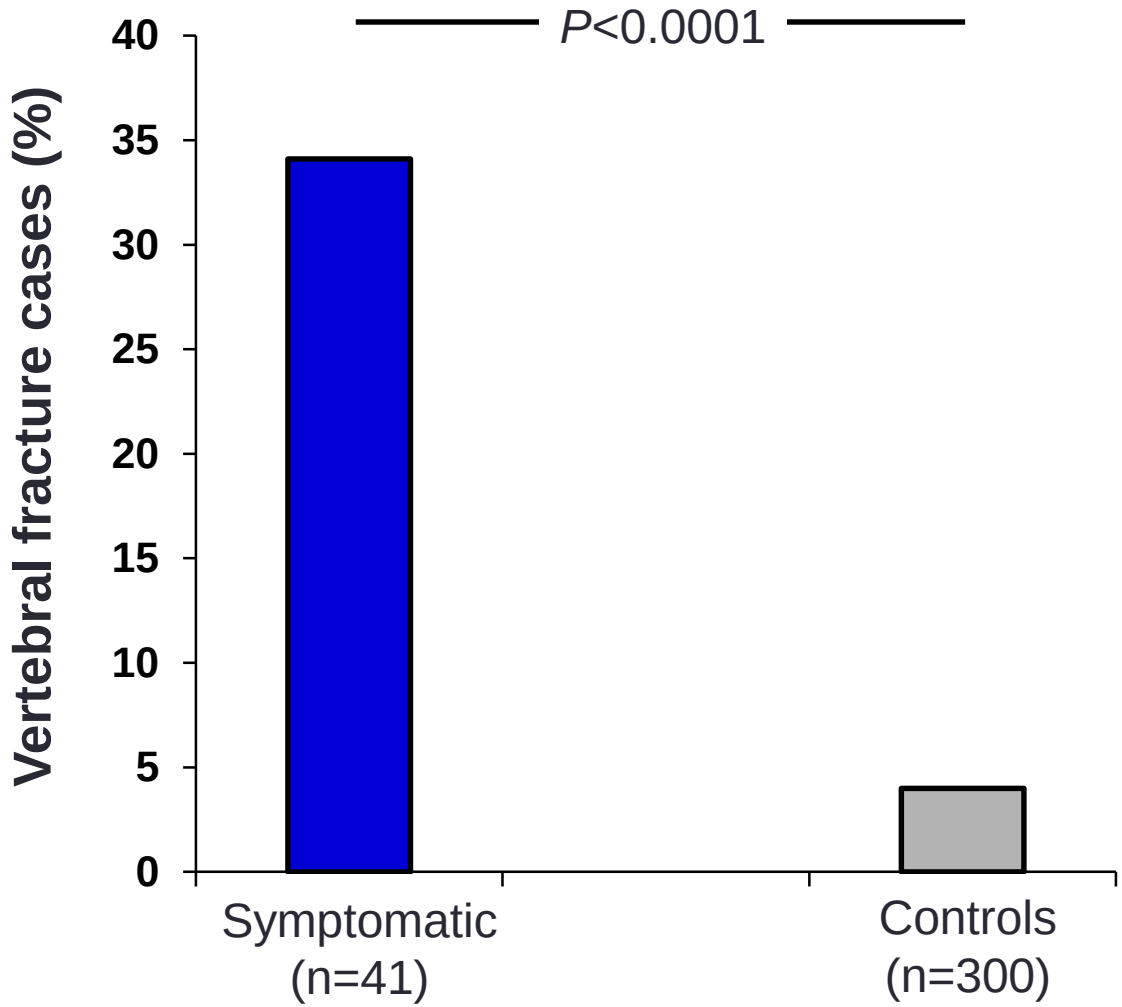
Khosla S et al, J Bone Miner Res 1999;14:1700-7

Fracture risk in PHPT -3-



Vignali E, et al. J Clin Endocrinol Metab 2009;94:2306-12

Fracture risk in PHPT -3-



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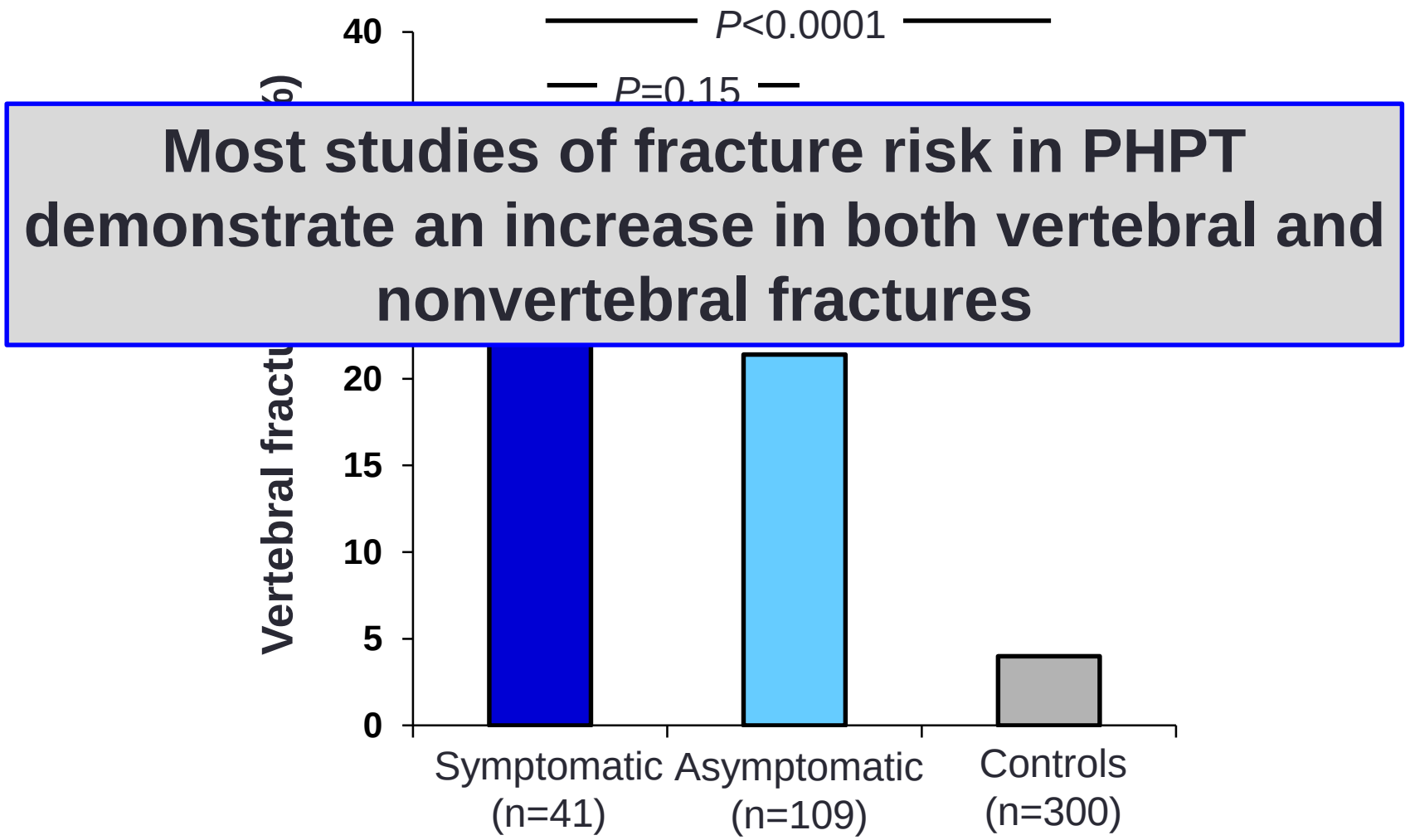
Fracture risk in PHPT -3-

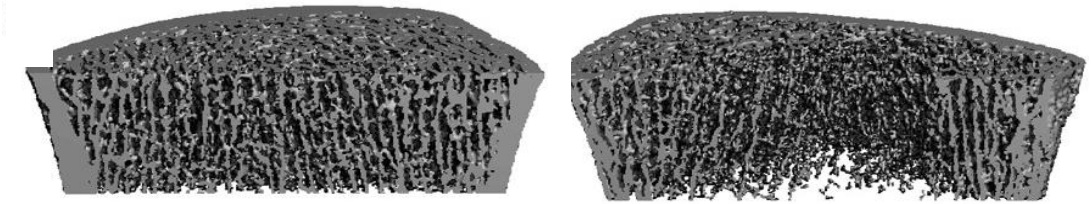


Most studies of fracture risk in PHPT demonstrate an increase in both vertebral and nonvertebral fractures

Vignali E, et al. J Clin Endocrinol Metab 2009;94:2306-12

Trabecular bone is also affected in asymptomatic PHPT

- High-resolution peripheral quantitative computed tomography (HRpQCT) is a non-invasive methodology to determine bone quality
- Using HRpQCT, two groups have demonstrated abnormalities in both cortical and trabecular bone in women with PHPT

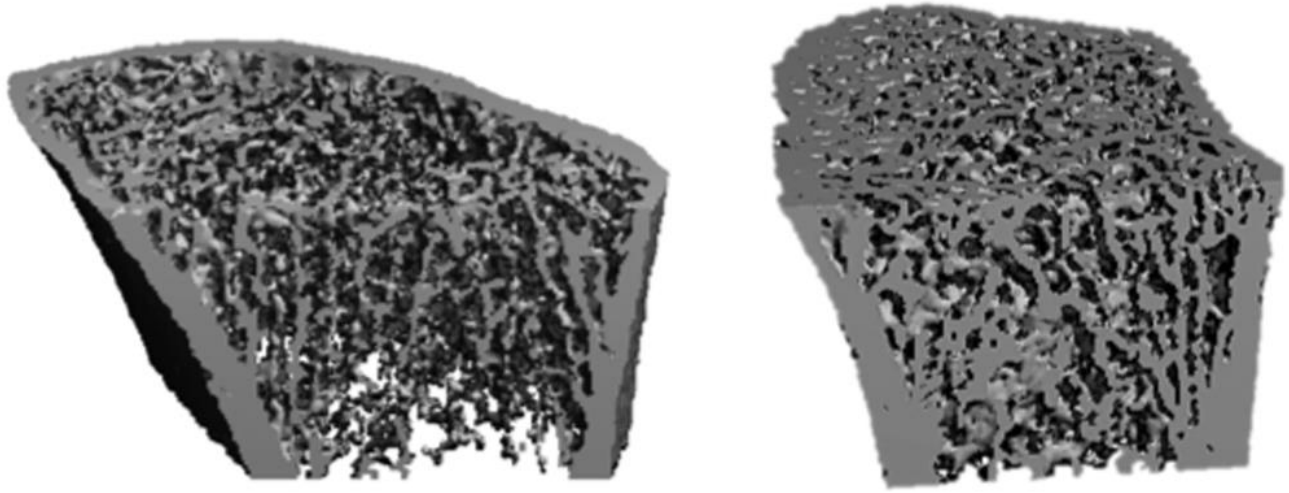


Normal Osteoporotic

XtremeCT

Hansen S, et al. J Bone Miner Res 2010;25:1941-7
Stein EM, Silva BC, Cusano NE, et al. J Bone Miner Res 2013;28:1029-40

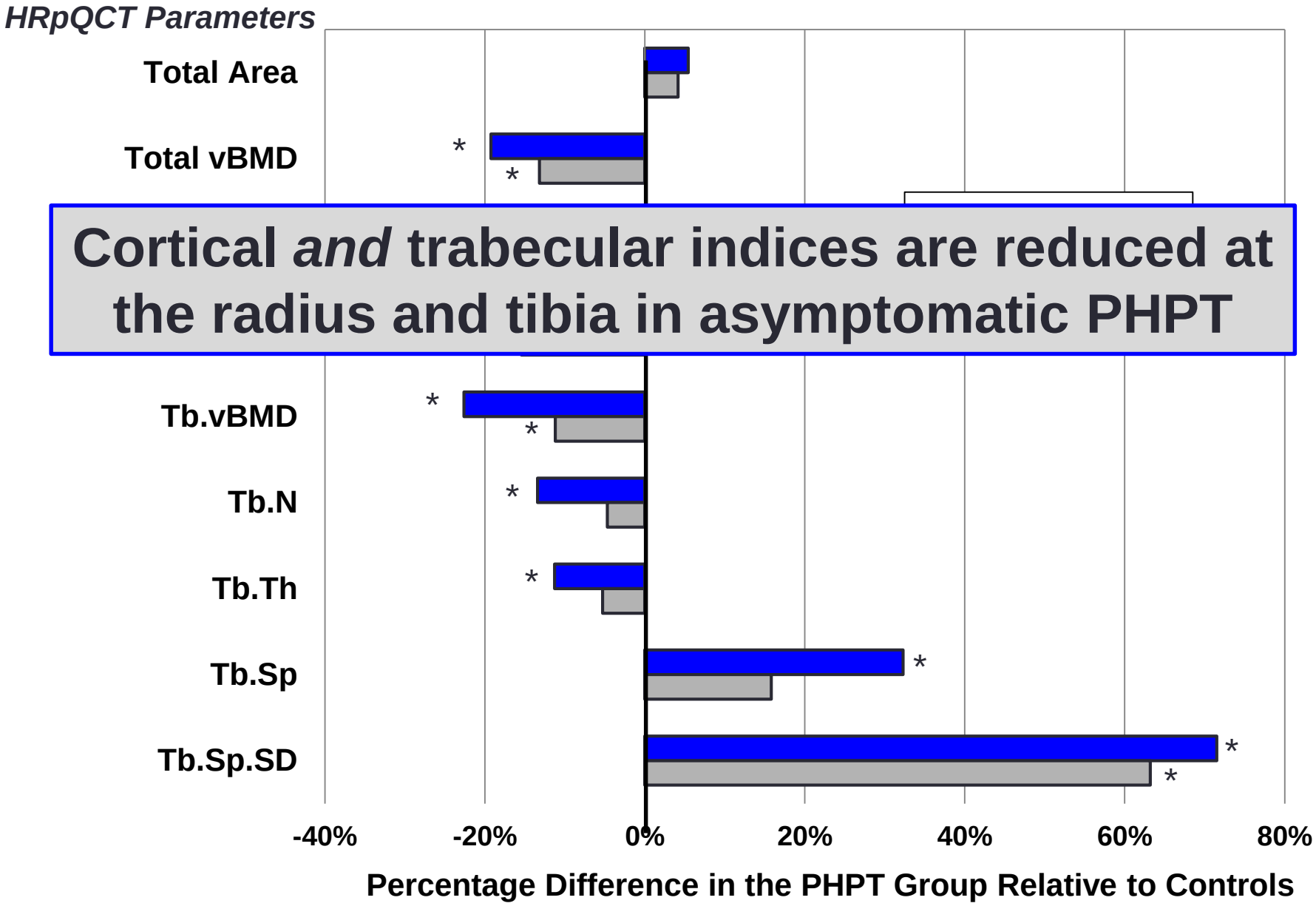
Microstructure is abnormal in asymptomatic PHPT



PHPT Matched control

Stein EM, Silva BC, et al. J Bone Miner Res 2013;28:1029-40

Microstructure is abnormal in asymptomatic PHPT



Cortical *and* trabecular indices are reduced at the radius and tibia in asymptomatic PHPT

Stein EM, Silva BC, et al. J Bone Miner Res 2013;28:1029-40

Surgical guidelines for asymptomatic PHPT

Index	Third workshop (2008)	Fourth workshop (2013)
Age	<50 years	<50 years
Serum calcium	>1.0 mg/dL above normal	>1.0 mg/dL above normal
Skeletal	• T-score <-2.5 at any site • Clinical fragility fracture	• T-score <-2.5 at any site • Clinical fragility fracture ➢ Vertebral fracture by vertebral fracture assessment (VFA), X-ray, CT or MRI

Recommendation 3-4: Parathyroidectomy is indicated in patients with PHPT and osteoporosis, fragility fracture, or evidence of vertebral compression fracture on spine imaging (strong recommendation; high-quality evidence)

Surgical guidelines for asymptomatic PHPT

Index	Third workshop (2008)	Fourth workshop (2013)
Age	<50 years	<50 years
Serum calcium	>1.0 mg/dL above normal	>1.0 mg/dL above normal
Skeletal	• T-score <-2.5 at any site • Clinical fragility fracture	• T-score <-2.5 at any site • Clinical fragility fracture ➢ Vertebral fracture by VFA, X-ray, CT or MRI
Renal	Creatinine clearance <60 cc/min [24-hour urine not recommended]	• eGFR <60 cc/min ➢ Kidney stone by X-ray, CT, or US ➢ Urinary calcium >400 mg + other urinary indices of increased stone risk

Recommendation 3-3: Parathyroidectomy is indicated for objective evidence of renal involvement, including silent nephrolithiasis on renal imaging, nephrocalcinosis, hypercalciuria (24-hour urine calcium level >400 mg/dL) with increased stone risk, or impaired renal function (glomerular filtration rate <60 mL/min) (weak recommendation; low-quality evidence)

Recommendations: Calcium and vitamin D intake

Nutritional elements

- Calcium intake should follow national guidelines
- 25-hydroxyvitamin D levels >20 ng/mL (>50 nmol/L) using initial doses of 600-1000 IU daily
- Monitor serum and urine calcium with vitamin D repletion

Recommendation 5-1: Most patients with PHPT should follow Institute of Medicine guidelines for calcium intake (strong recommendation; moderate quality evidence

Recommendation 5-2: Prior to parathyroidectomy, patients with PHPT who are vitamin D deficient can safely begin vitamin D supplementation (weak recommendation; low quality evidence)

Phenotypes of PHPT

Before 1970:

A disease of bones, stones, groans, and moans

After 1970:
A disease with primarily biochemical and densitometric signatures

After 2000:
A disease that may present at first with a more subtle biochemical signature – elevated PTH levels with normal serum calcium

Diagnostic features of normocalcemic PHPT

- Elevated PTH
- Normal albumin-adjusted serum calcium
- Normal ionized calcium
- Corrected and ionized calcium *ALWAYS NORMAL*

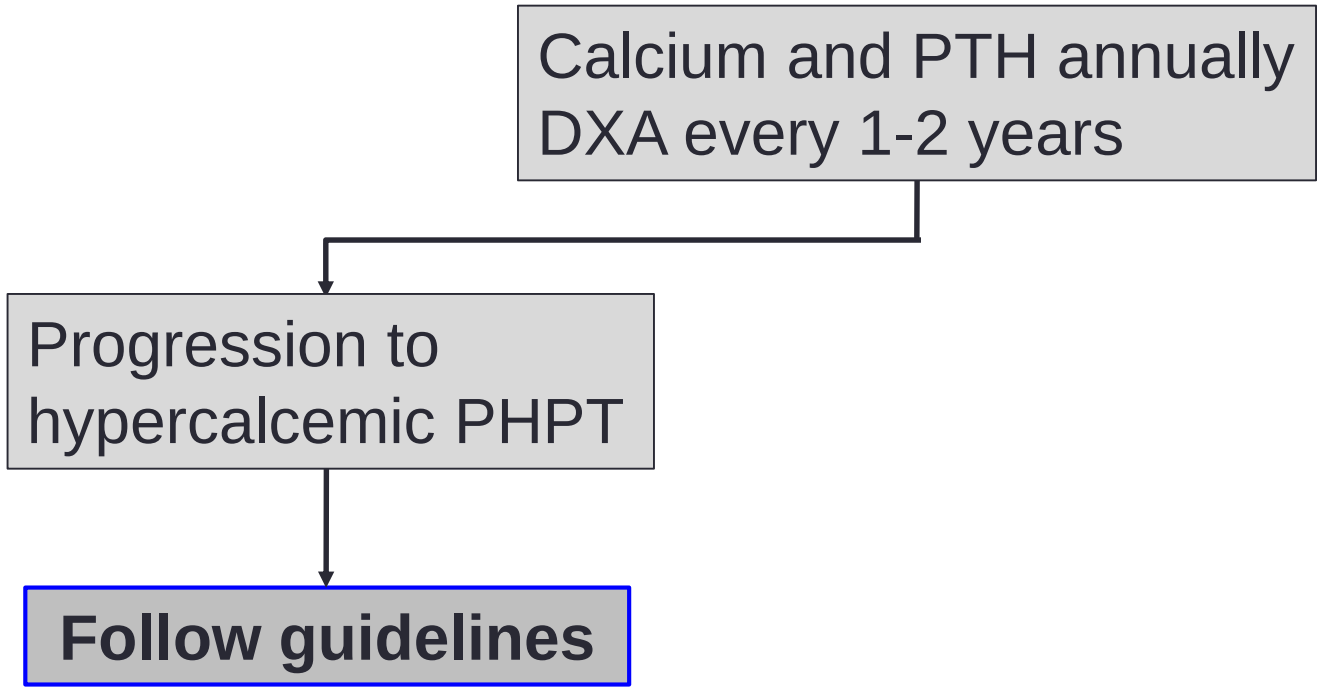
Cusano NE, et al. J Clin Densitom 2013;16:33-9
Eastell R et al, J Clin Endocrinol Metab 2014;99:3570-9

Exclude secondary hyperparathyroidism

- Vitamin D deficiency
  - Minimal goal level should be 20 ng/mL (50 nmol/L) but desirable >30 ng/mL (>75 nmol/L)
- Renal insufficiency
  - eGFR <60 cc/min
- Medications
  - Thiazide or loop diuretics, lithium, bisphosphonates, denosumab
- Hypercalciuria
- Malabsorption

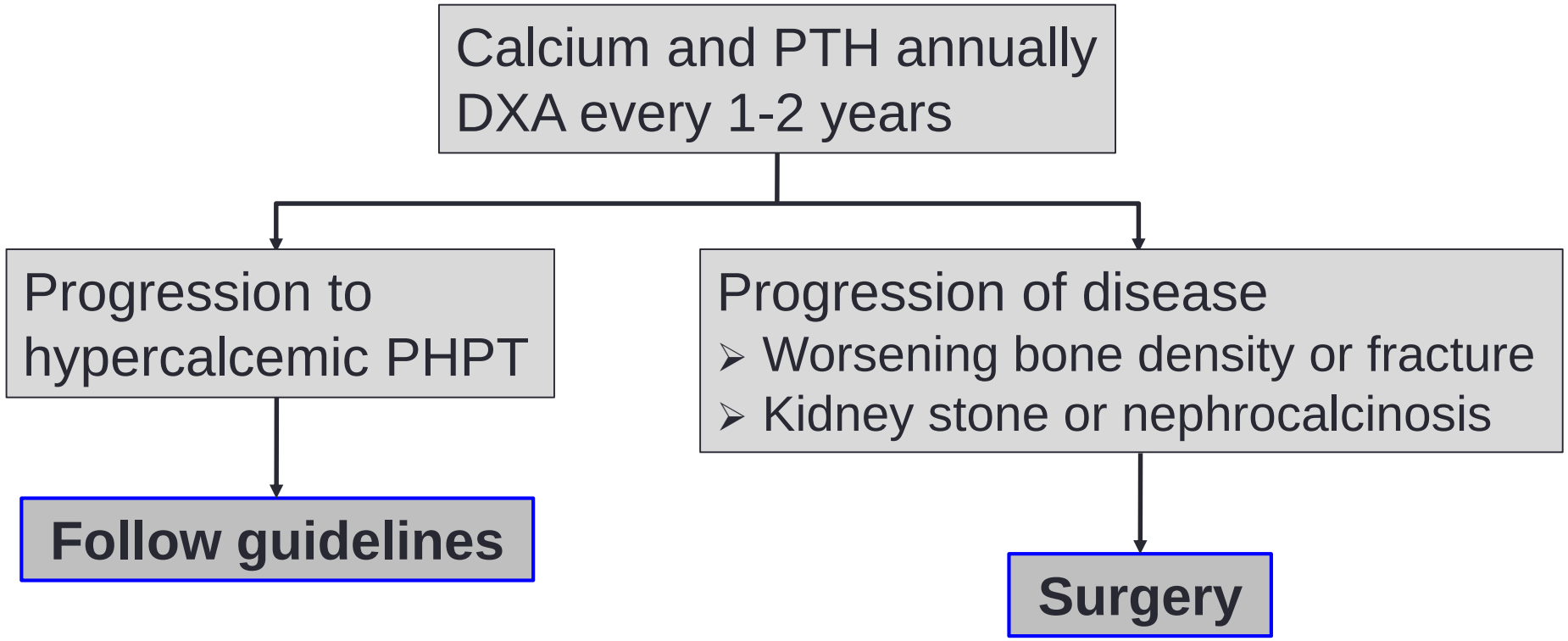
Eastell R et al, J Clin Endocrinol Metab 2014;99:3570-9

Management of asymptomatic normocalcemic PHPT



Bilezikian JP, et al. J Clin Endocrinol Metab 2014;99:3561-9

Management of asymptomatic normocalcemic PHPT



Bilezikian JP, et al. J Clin Endocrinol Metab 2014;99:3561-9

Management of normocalcemic PHPT

- Bone density in patients with normocalcemic PHPT increases with alendronate treatment[1]
- Imaging studies less likely to localize a parathyroid lesion[2,3]
- Higher percentage of multiglandular disease in normocalcemic versus hypercalcemic PHPT
  - 13 vs 7%; $p<0.05$[2]
  - 45 vs 9%; OR 8.17 (95% CI 4.49-14.83)[3]
- Patients with normocalcemic disease have similar improvements in bone density as hypercalcemic patients following parathyroid surgery[4,5]

[1]Cesareo R, et al. Osteoporos Int 2015;26:1295-1302; [2]Šiprová H, et al. Endocr Pract. 2016;22:294-301; [3]Lim JY, et al. Surgery 2017;161:70-77; [4]Koumakis E, et al. J Clin Endocrinol Metab 2013;98:3213-3220; [5]Traini E, et al. Langenbecks Arch Surg 2018;403:317-323

Medical management of PHPT

- Observation
- Pharmacological approaches

Marcocci C, et al. J Clin Endocrinol Metab 2014;99:3607-18

15-year natural history without surgery

Index	Baseline	5 years	10 years	13 years	15 years
Calcium	10.5 ± 0.1	10.7 ± 0.1	10.8 ± 0.2	11.0 ± 0.2	11.1 ± 0.2
PTH	122 ± 10	119 ± 12	123 ± 14	124 ± 16	121 ± 18
25-hydroxyvitamin D	21 ± 1	22 ± 2	22 ± 3	21 ± 3	20 ± 4
1,25-dihydroxyvitamin D	50 ± 2	58 ± 3	54 ± 6	40 ± 5	48 ± 7
Urine calcium	238 ± 19	215 ± 23	185 ± 32	247 ± 36	202 ± 36

Rubin MR, et al. J Clin Endocrinol Metab 2008;93:3462-70

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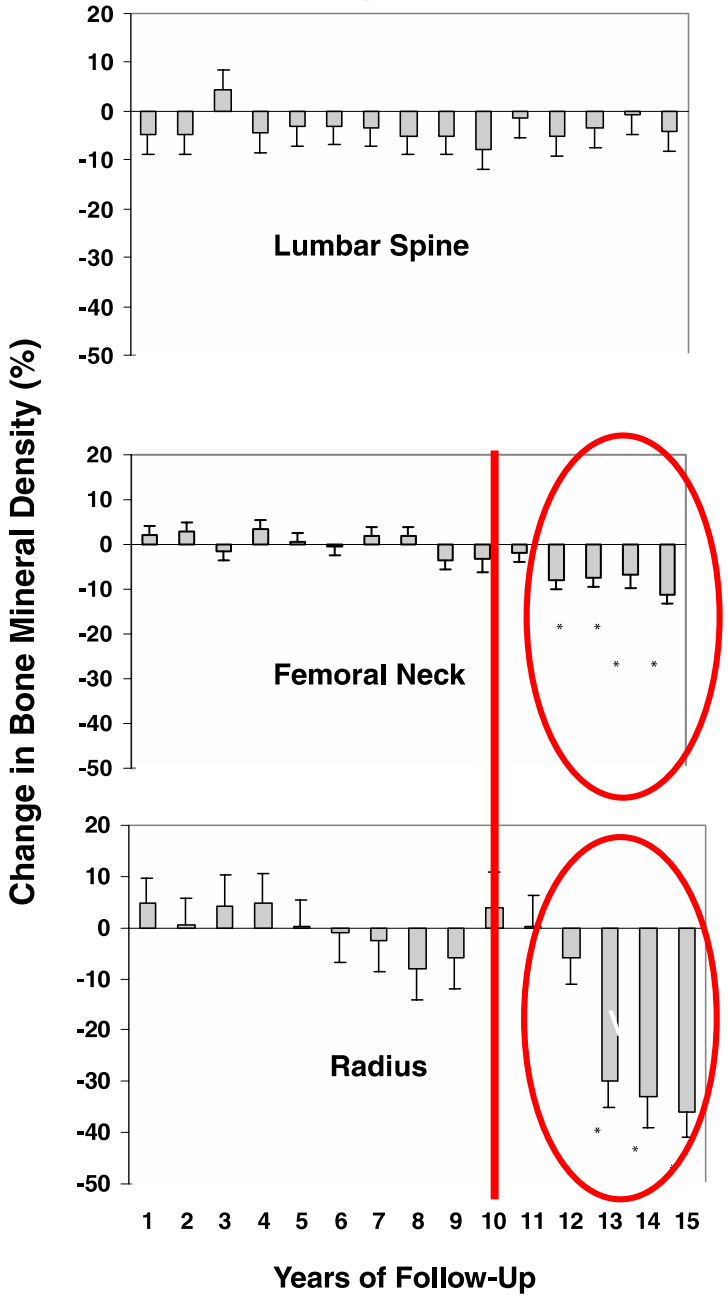
15-year natural history without surgery -2-



Rubin MR, et al. J Clin Endocrinol Metab 2008;93:3462-70

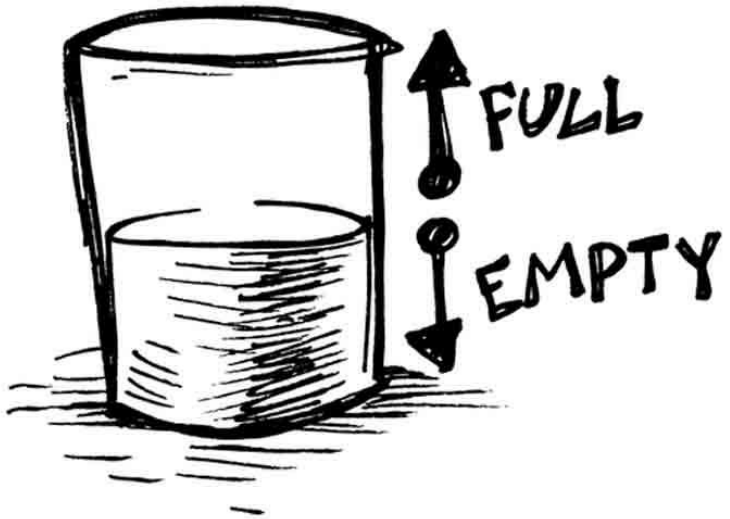
15-year natural history without surgery -3-

37% of patient developed one or more indications for surgery during 15 years of monitoring (nephrolithiasis, hypercalcemia, or reduced bone mineral density)

Rubin MR, et al. J Clin Endocrinol Metab 2008;93:3462-70

15-year natural history without surgery -3-

63% of patients did not develop an indication for surgery during 15 years of monitoring (nephrolithiasis, hypercalcemia, or reduced bone mineral density)



Pharmacologic approaches to PHPT

- When?
  - Surgery is indicated but medically contraindicated or patient declines
- Which agent?
  - The surgical indication can be ameliorated by the drug (e.g., severe hypercalcemia, reduced bone density)
  - Cinacalcet is the only approved agent for therapy of hypercalcemia in the US and EU
  - Other agents that have been studied include: estrogen, raloxifene, alendronate

Pharmacologic approaches to PHPT

Agent	Serum calcium	PTH	Bone density	
Estrogen[1]	↔	↔	↔	
Raloxifene[2]	↓	↔	↔	
Alendronate[3]	↔	↔	↑↑↑	**Fracture data lacking**
Cinacalcet*[4]	↓↓↓	↓	↔	
Cinacalcet + Alendronate[5]	↓↓↓	↓	↑↑↑	**Fracture data lacking**

*The only agent approved for PHPT in the US and EU

[1]Grey et al., 1996; [2]Rubin et al., 2005; [3]Khan et al., 2004; [4]Peacock et al., 2005, 2009; [5]Faggiano et al., 2011

Recommendations: Pharmacologic management

- For the control of hypercalcemia, cinacalcet is the treatment of choice
- To improve BMD, bisphosphonate therapy is recommended
  - The best evidence is for the use of alendronate
- To reduce the serum calcium and improve BMD, combination therapy with both agents is reasonable, but strong evidence for efficacy is lacking

* Recommendation 3-12: Operative management is more effective and cost-effective than either long-term observation or pharmacologic therapy (strong recommendation; moderate quality evidence)

Surgical management of PHPT

- Surgical approaches include minimally invasive parathyroidectomy with intraoperative PTH and full exploration
  - In the modern era, MIP with iPTH has helped achieve cure rates of 97-99%

"The most important preoperative localization challenge in PHPT is to locate the parathyroid surgeon!" – John Doppman, 1975

Udelsman R, et al. J Clin Endocrinol Metab 2014;99:3595-606

Following successful parathyroid surgery…

- Serum calcium
- PTH
- 25-hydroxy- and 1,25-dihydroxyvitamin D
- Urine calcium
- Risk of nephrolithiasis
- Bone markers (resorption and formation)
- Bone density
- Bone microarchitecture

→***Normalize or return towards normal***

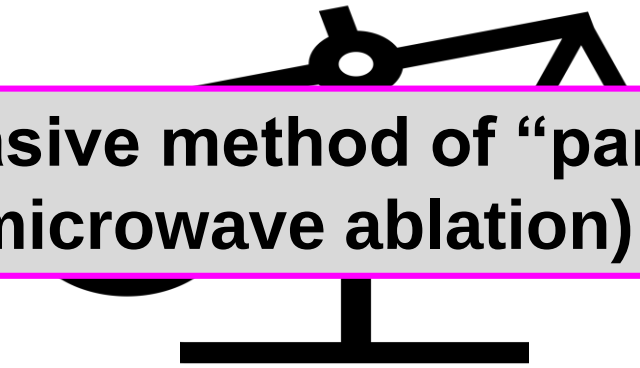
Are the scales tipping toward surgery?

Surgery

- 15-year natural history
- Vitamin D deficiency
- Neurocognitive data?
- Cardiovascular data?
- Cortical and trabecular abnormalities and improvement following surgery
- Better imaging techniques
- Improvements in surgical technique
- Patient preference

Medical management

- 15-year natural history
- Use of vitamin D
- Medical alternatives
- Patient preference



Would a noninvasive method of “parathyroidectomy” (ultrasound guided microwave ablation) further tip the scale?

Both options are important to consider in each patient

Key Points

- Guidelines for parathyroid surgery have been revised consistent with the latest new information
- Non-surgical management may be appropriate for individuals who do not meet surgical criteria or if there are contraindications to surgery
- Surgery may also be appropriate for individuals who do not meet surgical criteria, if there are no medical contraindications

Acknowledgements

- Dr. John Bilezikian

THANK YOU

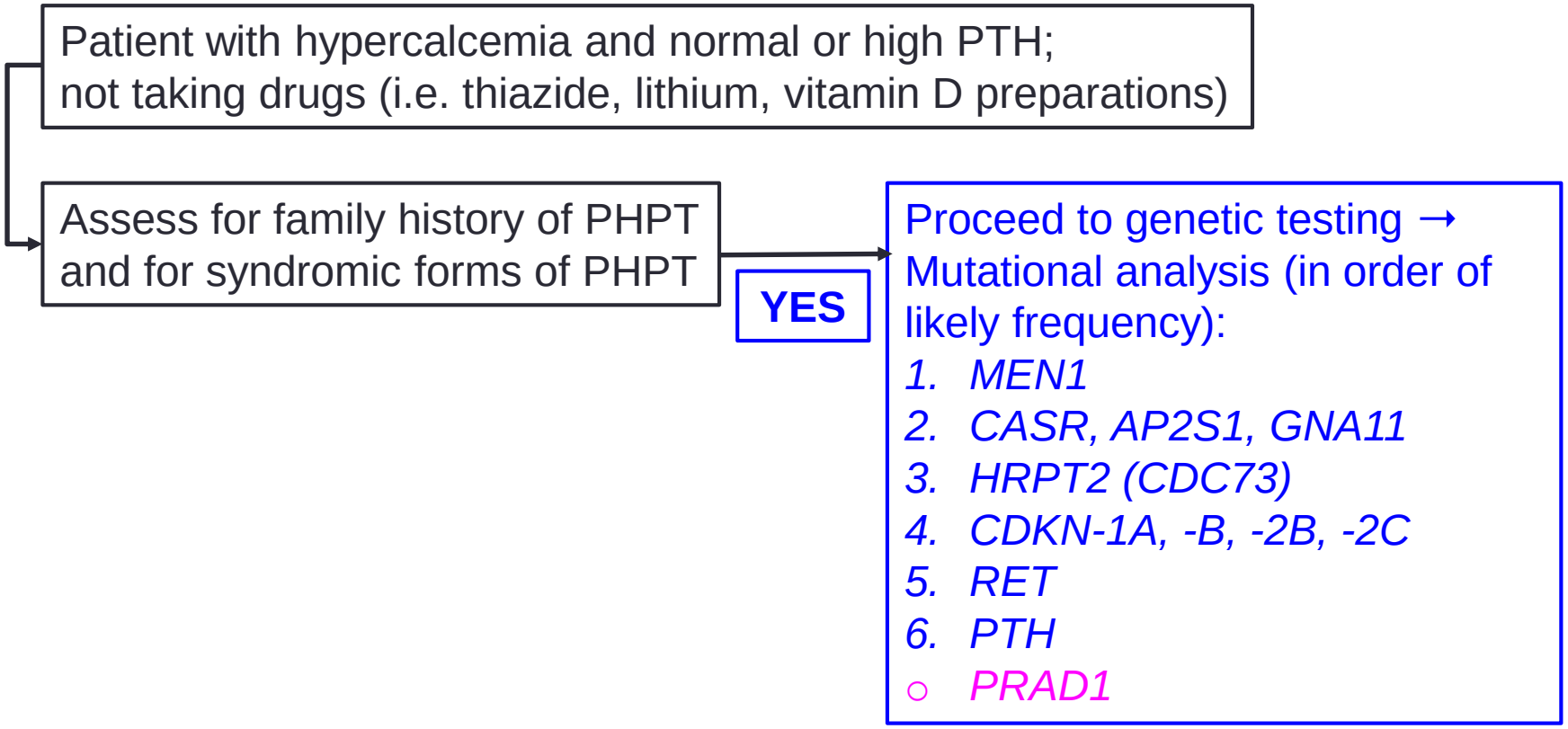
Differential diagnosis

If low PTH, exclude biotin supplements

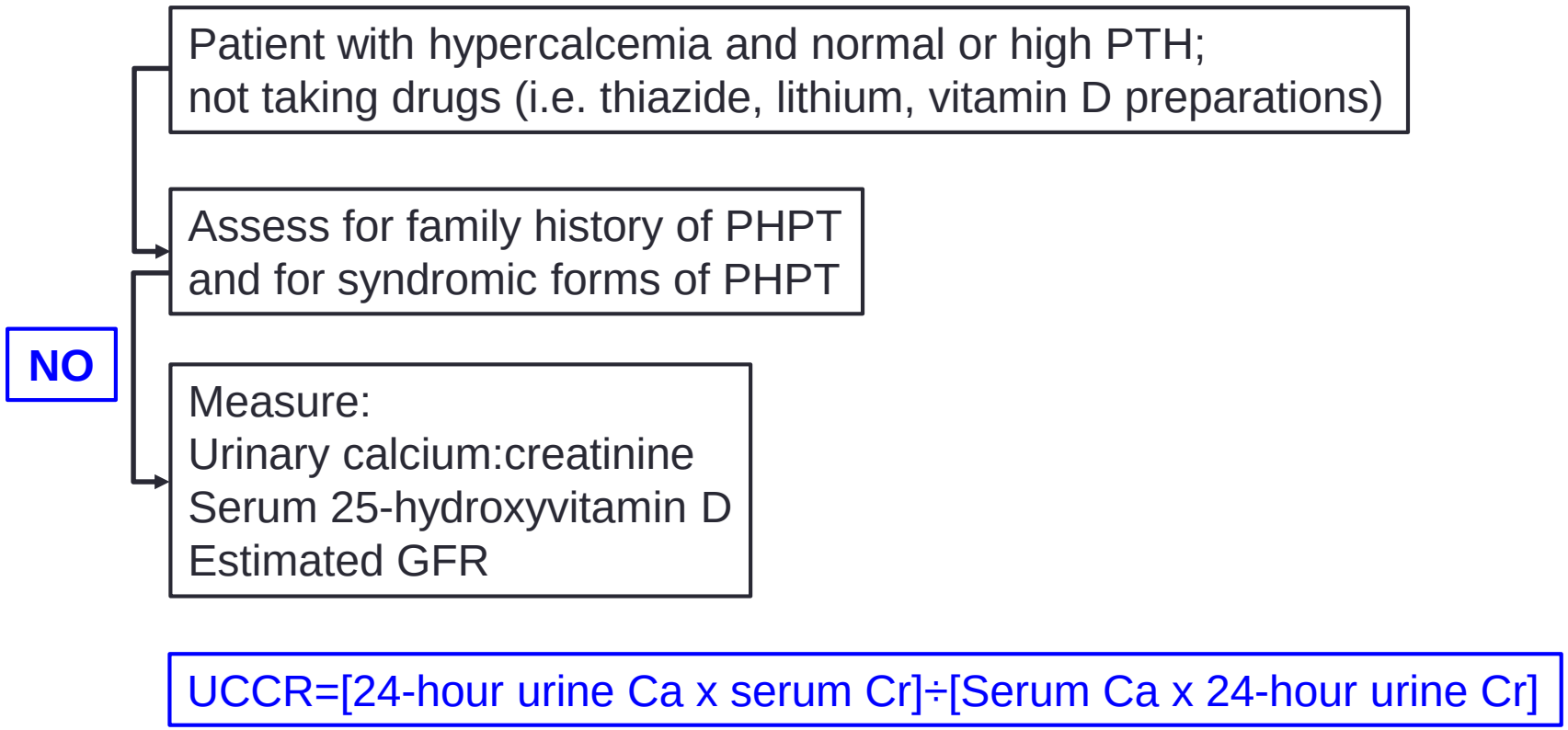
Patient with hypercalcemia and normal or high PTH;
not taking drugs (i.e. thiazide, lithium, vitamin D preparations)

Eastell R et al, J Clin Endocrinol Metab 2014;99:3570-9
Wangrey A, et al. Endocr Pract 2013;19:451-5

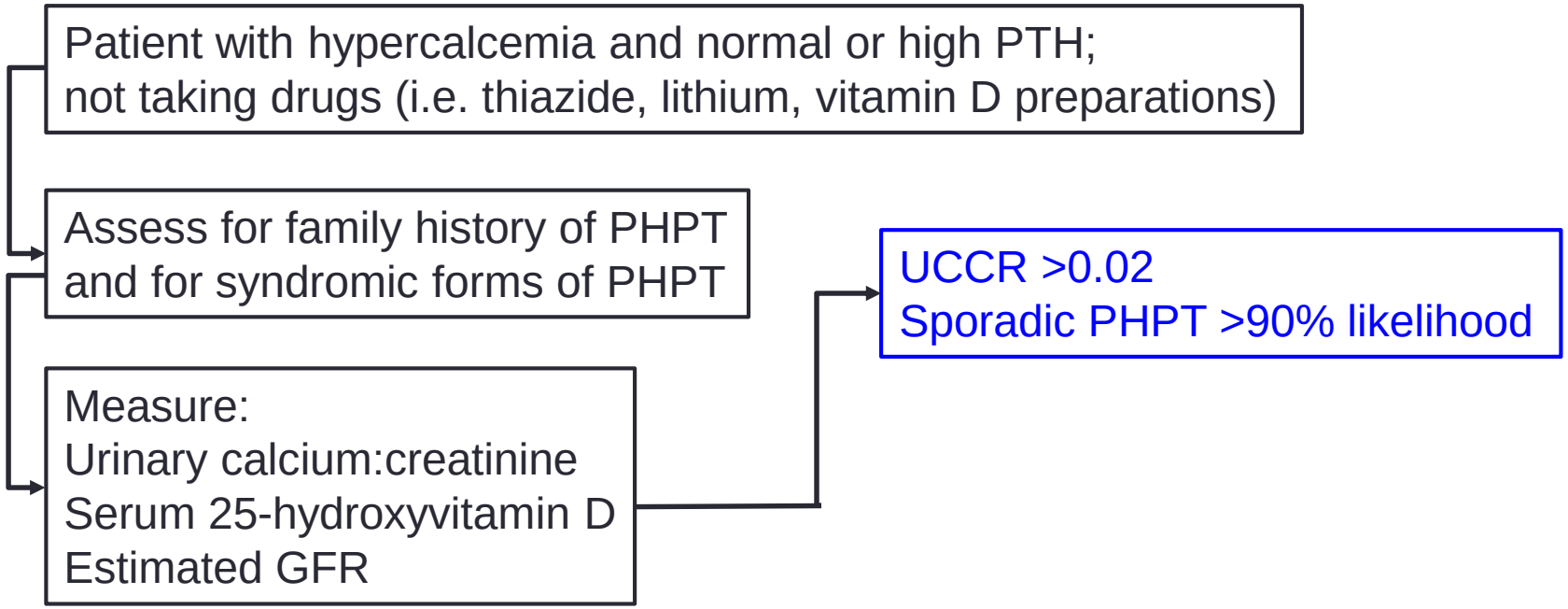
Differential diagnosis



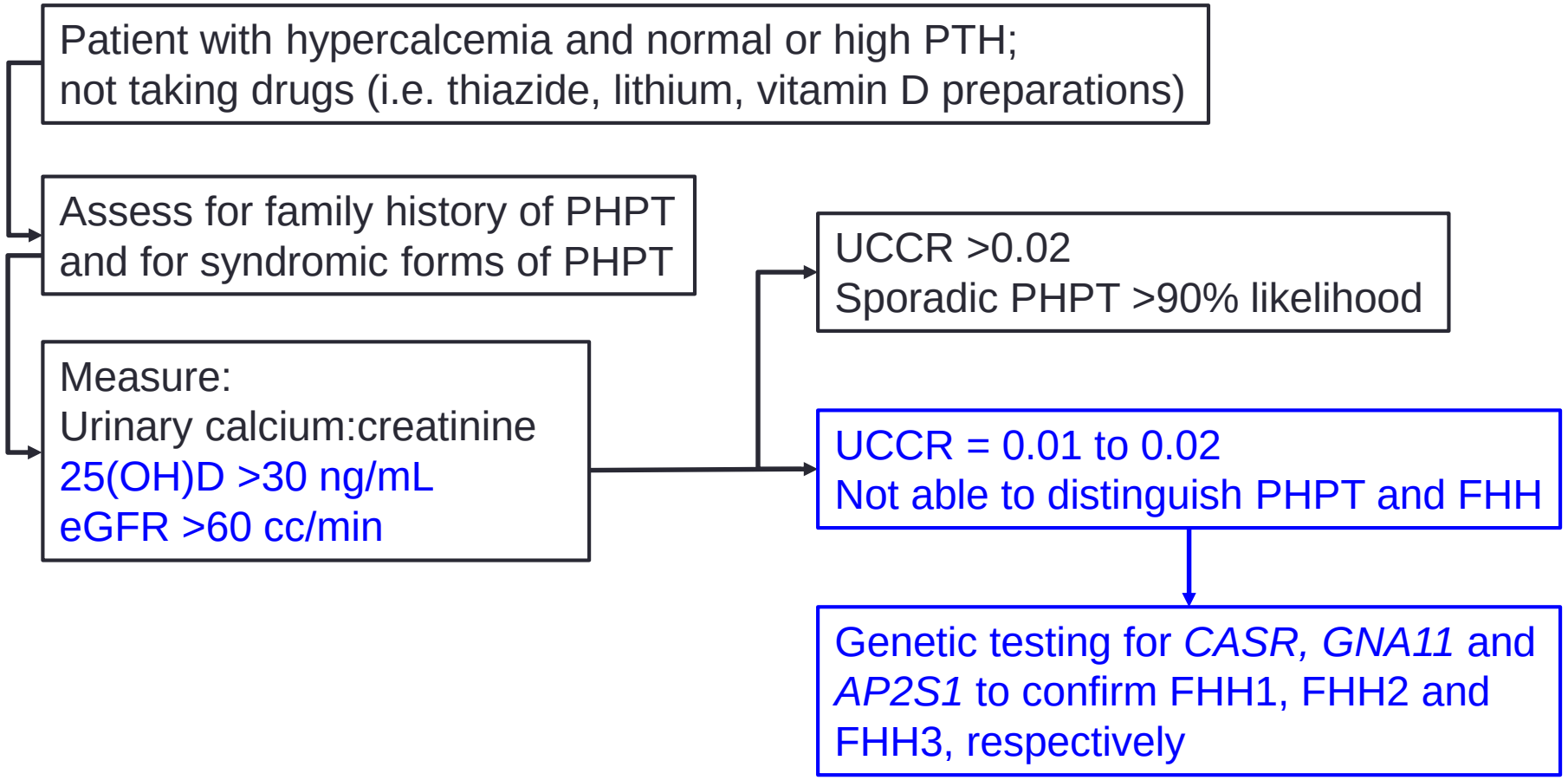
Differential diagnosis



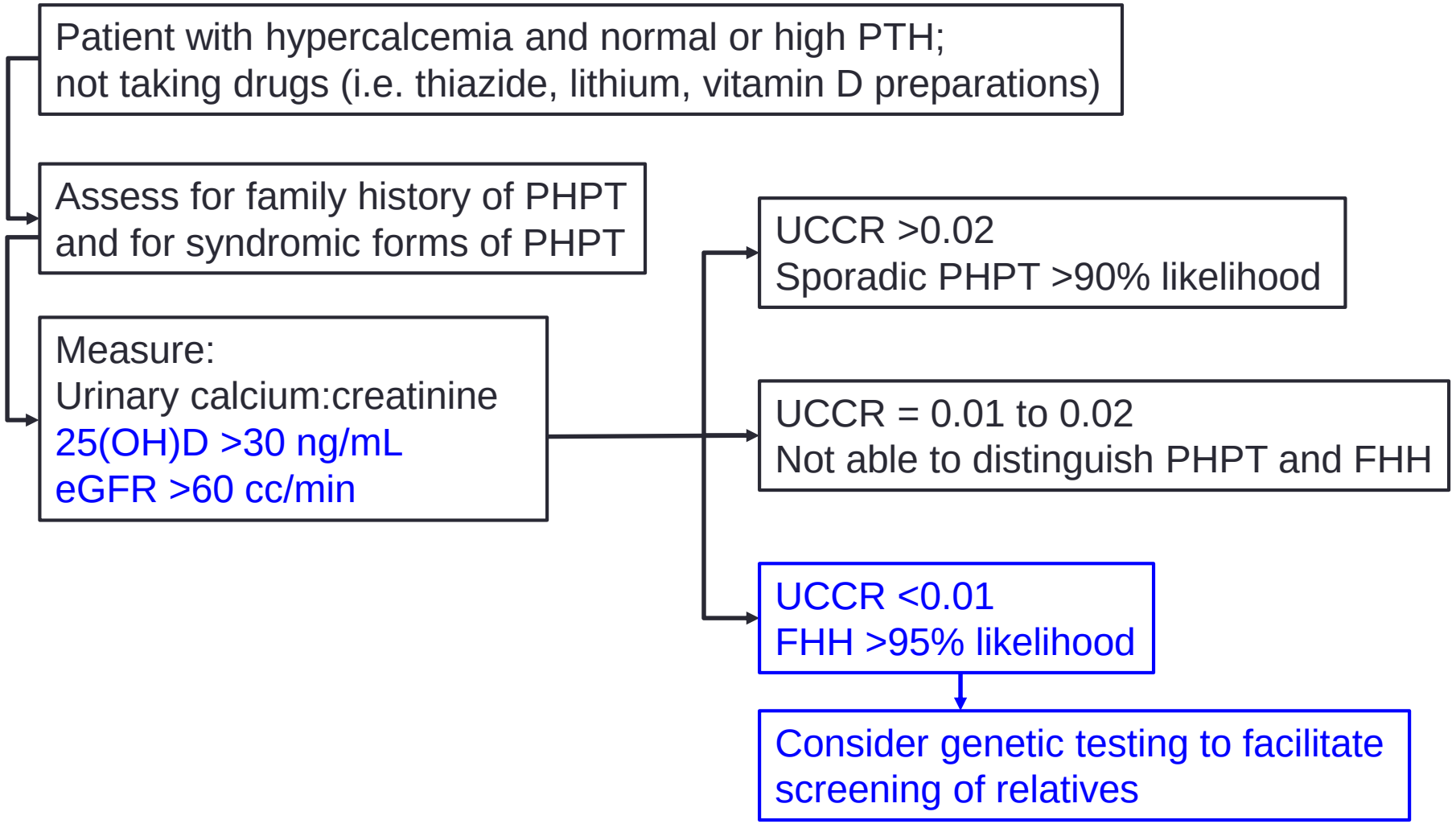
Differential diagnosis



Differential diagnosis



Differential diagnosis



Monitoring guidelines for asymptomatic PHPT

Index	Third workshop (2008)	Fourth workshop (2013)
Serum calcium	Annually	Annually
Skeletal	DXA: Every 1-2 years	• DXA: Every 1-2 years • Imaging if clinically indicated
Renal	Annual monitoring of creatinine clearance	• Annual monitoring of eGFR • Stone risk profile or abdominal imaging if clinically indicated

Indications for surgery during monitoring

Index	Fourth workshop (2013)
Serum calcium	>1 mg/dL above the normal limit
Skeletal	• T-score <-2.5 at lumbar spine, total hip, femoral neck, or distal 1/3 radius; or a significant reduction in BMD* • Vertebral fracture by X-ray, CT, MRI or VFA
Renal	• eGFR <60 cc/min • Clinical development of a kidney stone or by imaging (X-ray, ultrasound, or CT)

*A significant change is defined by a reduction that is greater than the least significant change (LSC) as defined by the International Society for Clinical Densitometry. If the reduction is > LSC of the measurement to a T-score that is <-2.5 then, surgery is recommended. If the patient demonstrates a progressive reduction in BMD that exceeds the LSC at any site and is between -2.0 and -2.5, the physician may opt to recommend surgery even though guidelines have not been strictly met.