



# Hypothyroidism 2013

Joint AACE – AME Congress

Bari, Italy  
November 7-10, 2013



**Hossein Gharib, MD, MACP, MACE**

*Professor, Mayo Clinic College of Medicine*

*President, American Thyroid Association*

*Past President, American Association of Clinical Endocrinologists*

## Disclosure & Thanks

- **Nothing to disclose**
- **My sincere thanks for the invitation to participate at this meeting & speak to you today**

## ATA/AACE Guidelines

### **CLINICAL PRACTICE GUIDELINES FOR HYPOTHYROIDISM IN ADULTS: COSPONSORED BY THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND THE AMERICAN THYROID ASSOCIATION**

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and American Thyroid Association Taskforce on Hypothyroidism in Adults*

Thyroid 22:1200, 2012

## Subclinical Hypothyroidism

- A 34-year-old woman with BMI 30, fatigue and hyperlipidemia, is referred because a recent TSH is 5.6. Thyroid gland palpation is normal. Repeat TSH is 6.0, FT4 1.0 & TPOAb is positive

Do you Rx with T4?

Yes ~ No ~

- A 76-year-old woman has a screening serum TSH of 7.0 & FT4 1.2. Thyroid palpation is normal.

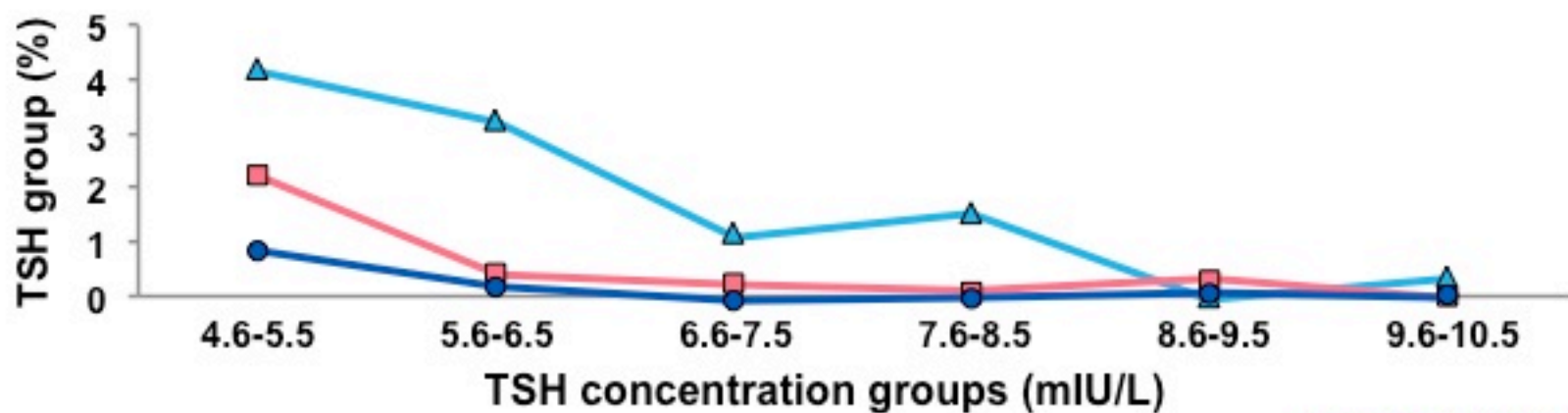
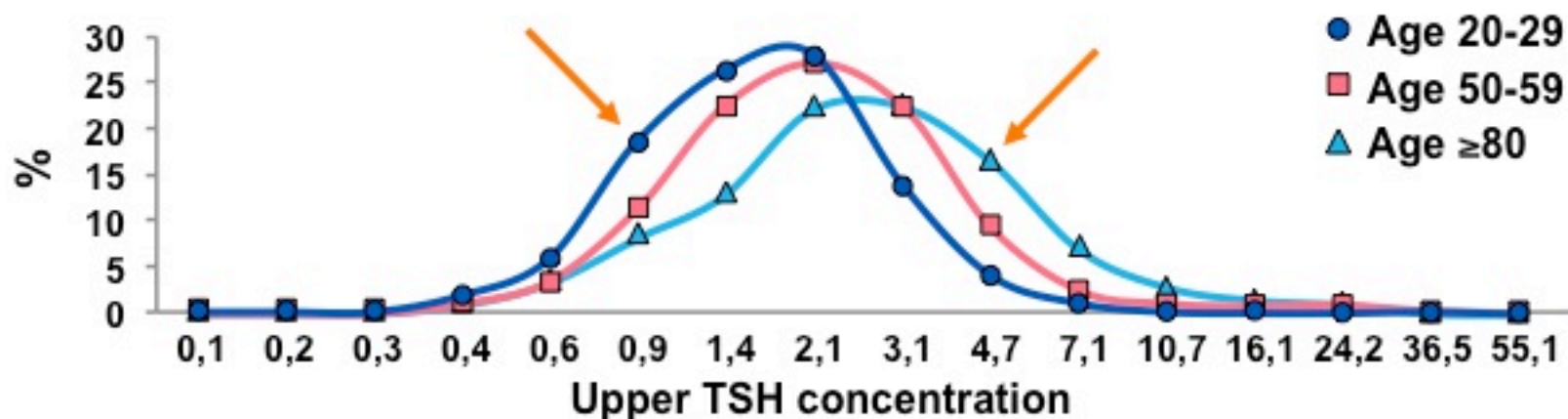
Do you Rx with T4?

Yes ~ No ~

## Normal Serum TSH

- A changing target & a matter of debate
- Lab *reference* range 0.5 to 5.0 mIU/L; lab *normal* range is 0.5-4.1
- Factors influencing TSH levels include age, ethnicity, I-intake and autoimmune disease

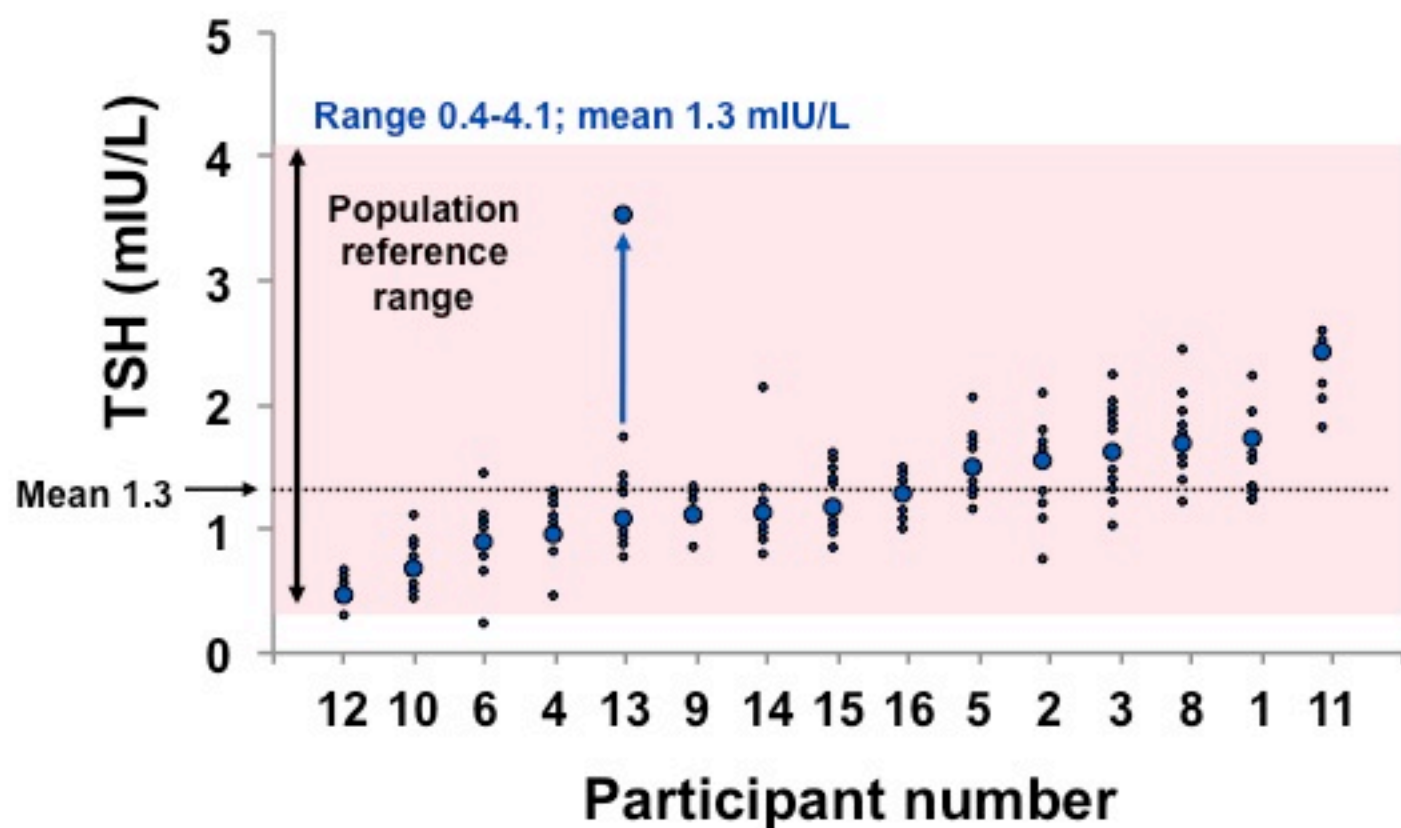
# Serum TSH and Age



JCEM 92:4575, 2007

# Serum TSH Variation in Normals

$\pm 0.5$  mIU/L Over 1 Year



Andersen S et al: JCEM 87:1068, 2002

## Subclinical Hypothyroidism

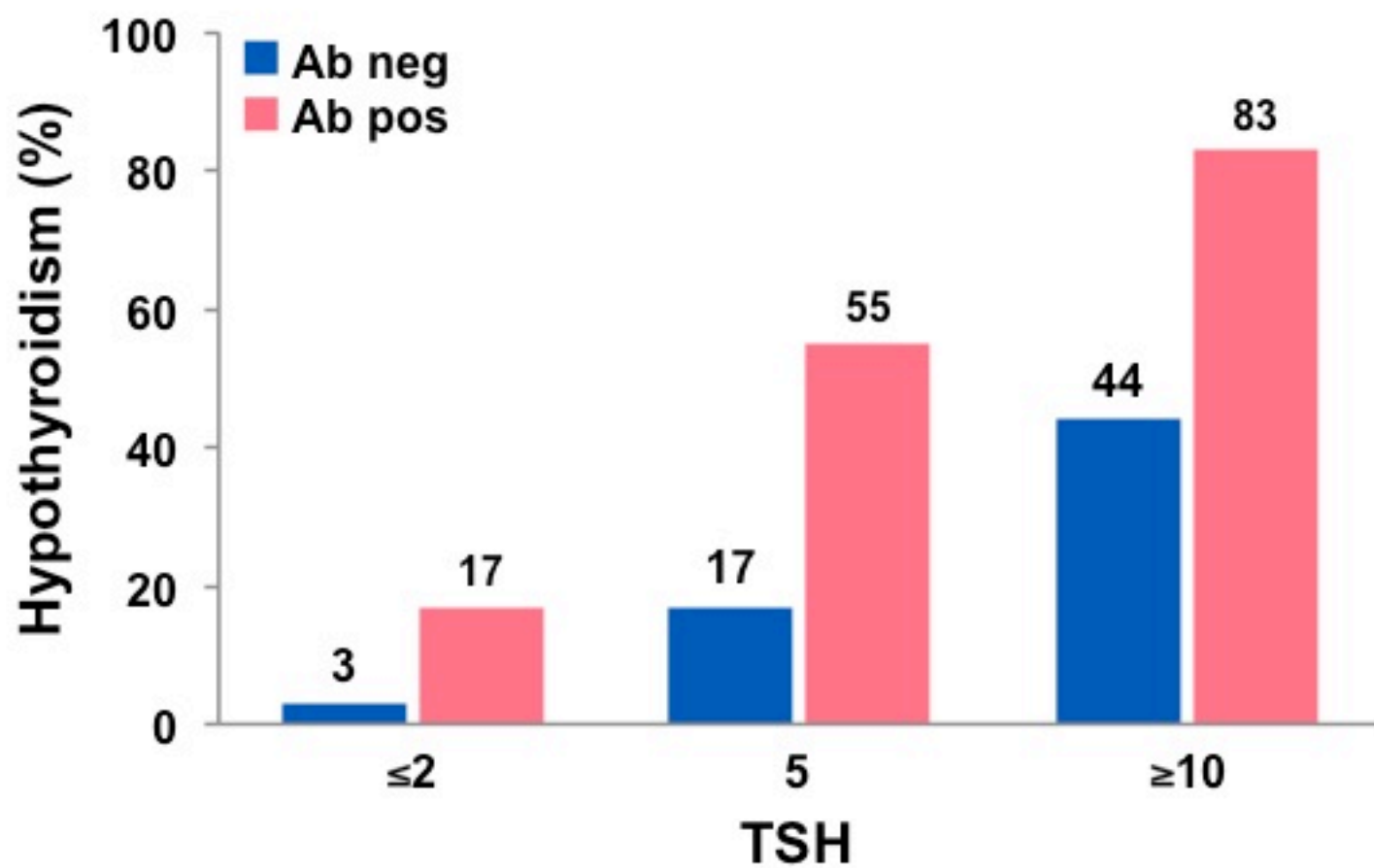
- **TSH  $\geq 5.0$  mIU/L with normal FT4**
- **In 80% of cases, TSH is between 5-10 mIU/L**
- **TPO antibodies (TPOAb), present in 60-80%, are more likely positive with higher TSH levels**
- **Sometimes referred to as "mild" or "early" hypothyroidism**



## Consequences of SCHypothyroidism

- **Progression to overt (symptomatic) hypothyroidism**
- **Symptoms include fatigue, mood & excess weight**
- **High serum cholesterol**
- **CV morbidity/mortality**

# Risk of Overt Hypothyroidism in a 60-Year-Old Woman

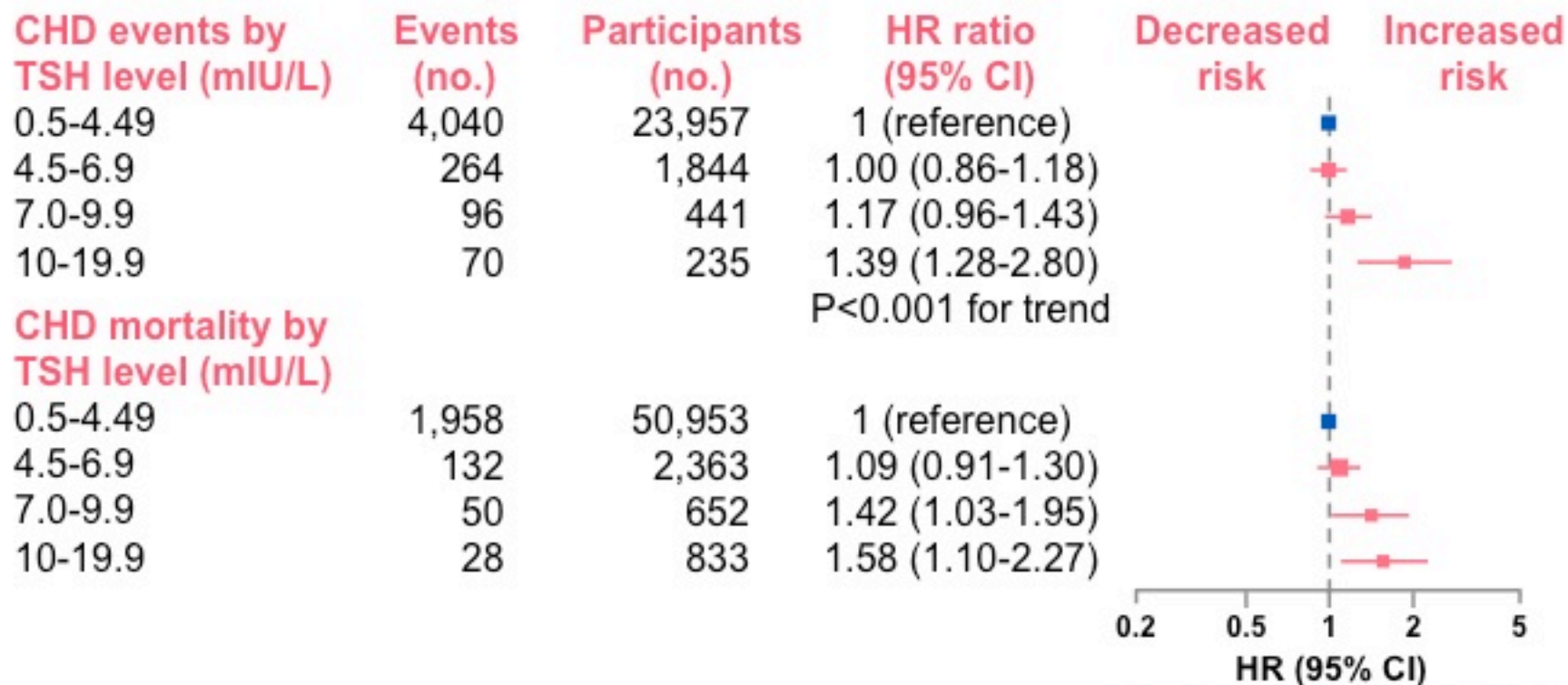


Vanderpump M et al, 2003

# CHD Events and Mortality

## Individual Patient Meta-Analysis from 7 Prospective Cohort Studies

Hazard ratios (HRs) for coronary heart disease (CHD) events, CHD mortality, and total mortality according to elevated (TSH) categories and subclinical hypothyroidism stratified by age vs euthyroidism



Rodondi et al: JAMA, 2010

# Incident Cardiovascular Disease in Subclinical Hypothyroidism

Prospective studies	Effect of SH on incident CHD	Comment
Whickham survey 1977	No	20 year F/U
Rotterdam study 2000	No	5 year F/U
<b>Atomic Bomb Survivors 2004</b>	<b>Yes</b>	<b>Middle aged men</b>
Leiden Plus 2004	No	Age >85
<b>Busselton study 2005 (Walsh)</b>	<b>Yes</b>	<b>Mean age 50</b>
Health Aging study 2005	No	Mean age 75; increased risk of CHF
Cardiovascular Health study 2006 (Cappola)	No	> age 65

## Subclinical Hypothyroidism

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Do you Rx with T4?

Yes ✓ No ~

- A 76-year-old woman has a screening serum TSH of 7.0 & FT4 1.2. Thyroid palpation is normal.

Do you Rx with T4?

Yes ~ No ✓

# Subclinical Hypothyroidism

## Recommendation 16

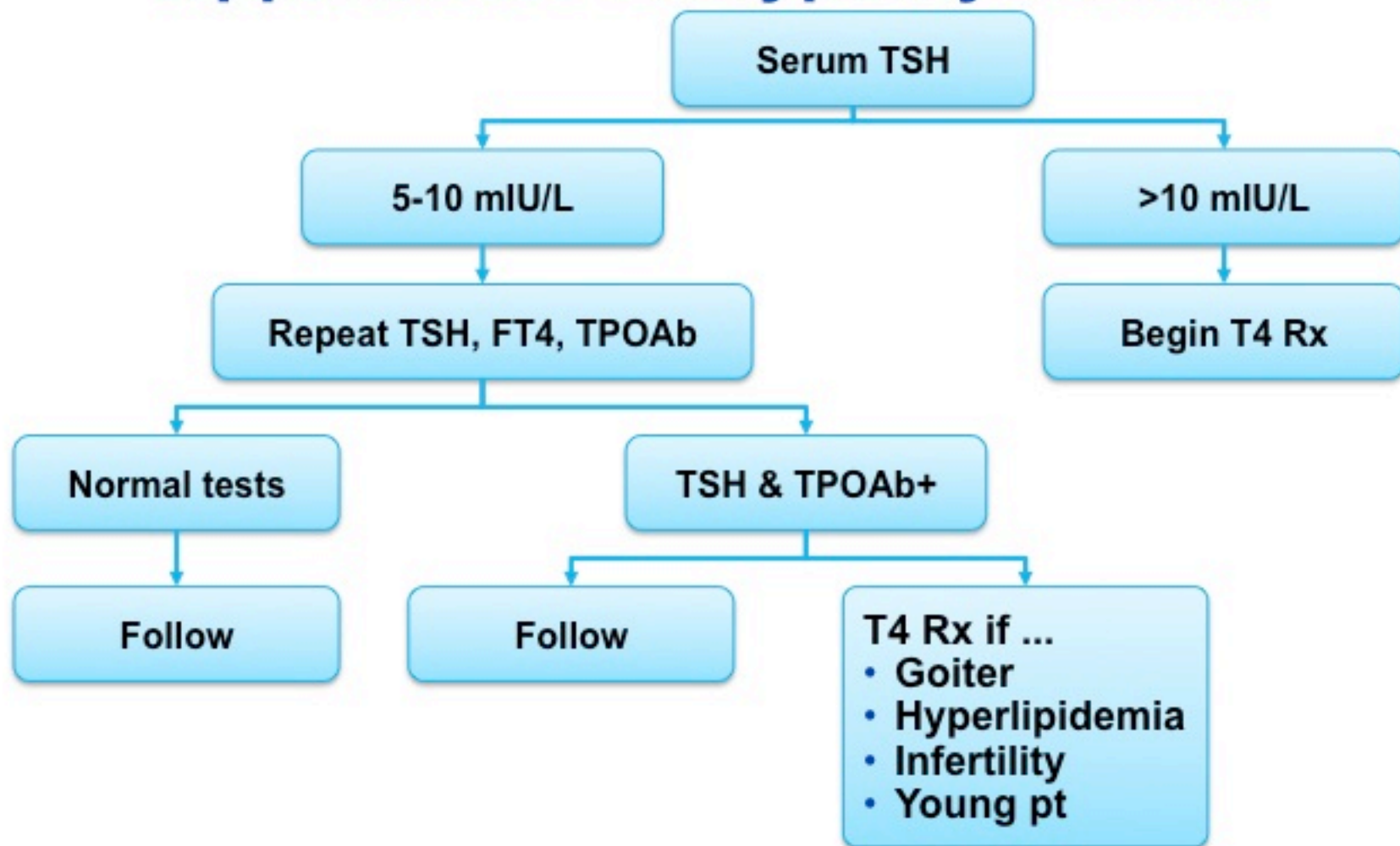
- **Treatment of TSH 5-10 mIU/L should be considered particularly if they have symptoms of hypothyroidism, positive TPOAb or atherosclerotic CV disease as risk factors**

# Subclinical Hypothyroidism

## Arguments against Rx

- **Impact on CV morbidity and mortality is unclear, especially in elderly**
- **Data on improved symptoms equivocal**
- **Benefits of improved cognitive outcomes unproven**
- **Complications of overtreatment**
- **Cost & inconvenience**

# Approach to SCHypothyroidism





## Screening for Thyroid Disease in Pregnancy

**A 24-year-old woman was just diagnosed with her first pregnancy. She enjoys good general health. There is no h/o thyroid disease.**

**Q: Should she have screening TSH?**

**Yes ~**

**No ~**

# What are the recommendations for TSH and T4 Screening in Pregnancy

- **Recommendation 20.1.1**  
**Universal screening is not recommended for patients who are pregnant or planning pregnancy**

# Screening for Thyroid Disease in Pregnancy

- Although the benefits of universal screening for thyroid dysfunction may not be justified at this time, aggressive case finding should be considered
  - Positive FHx thyroid disease
  - Goiter
  - Post TPO Ab
  - Symptoms
  - Type 1 DM
  - Miscarriage
  - Other autoimmune disease
  - Infertility
  - Morbid obesity
  - Age >30 years

## Screening for Thyroid Disease in Pregnancy

A 24-year-old woman was just diagnosed with her first pregnancy. She enjoys good general health. There is no h/o thyroid disease.

Q: Should she have screening TSH?

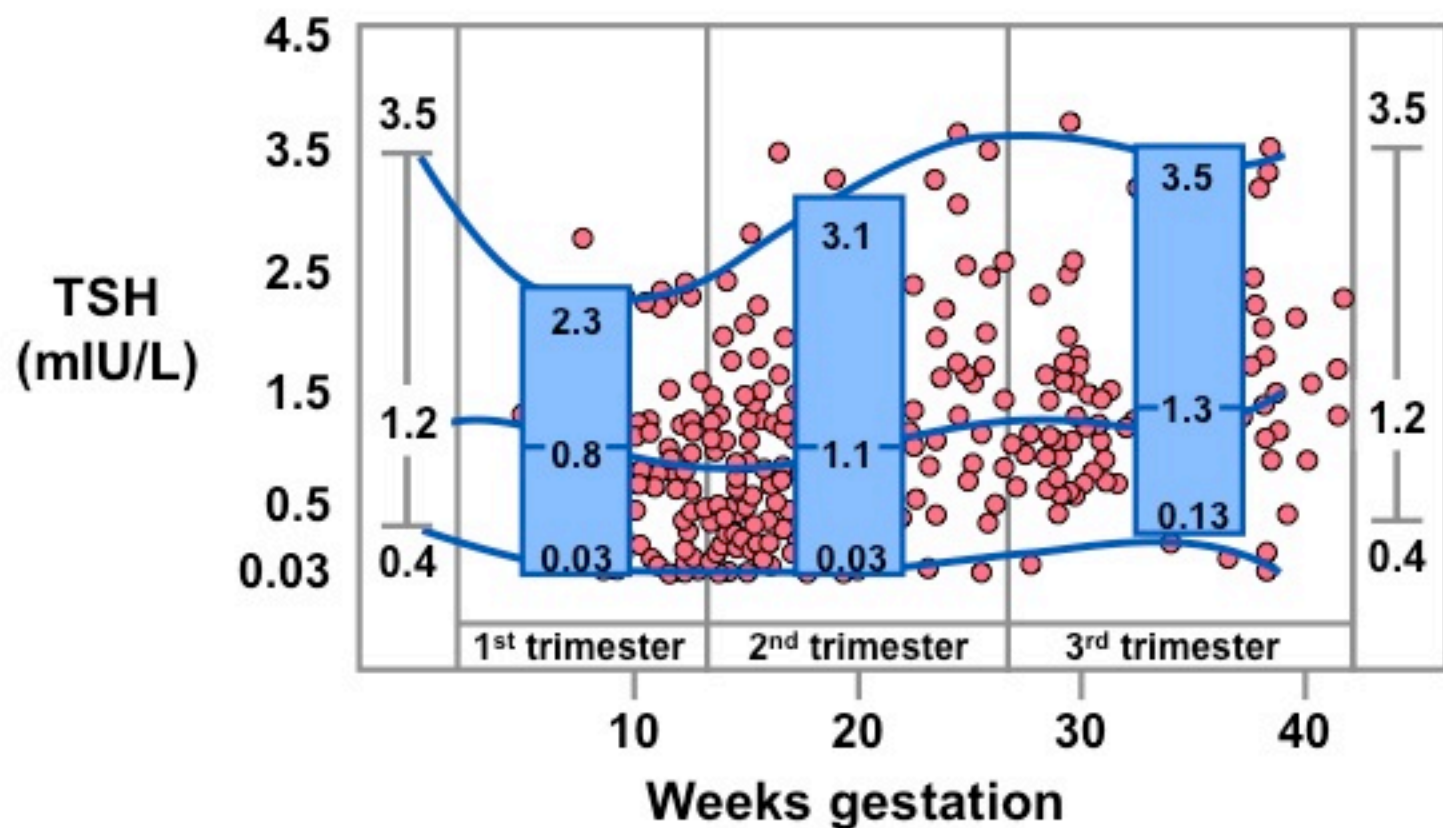
Yes ~

No ✓

Thyroid, 2012

# TSH Levels in Normal Pregnancies n=343

## Median and 95% TSH



Panesar NS et al: Ann Clin Biochem 32:329, 2001

## Serum TSH In Pregnancy

### Recommendation 14.2

- In pregnancy, the upper limit of normal range should be based on trimester-specific ranges for that laboratory. If trimester-specific reference ranges for TSH are not available in the lab, the following upper normal ranges are recommended:  
1<sup>st</sup> trimester, 2.5 mIU/L; 2<sup>nd</sup> trimester, 3.0 mIU/L; 3<sup>rd</sup> trimester, 3.5 mIU/L

## Pregnancy, TSH & LT4 Rx

A 26-year-old woman is planning pregnancy. She enjoys good health and has no thyroid disease. Thyroid gland is normal on palpation. Serum TSH is 4.3 mIU/L & FT4 1.0 ng/dL

Q: Should she be treated with LT4?

Yes



No

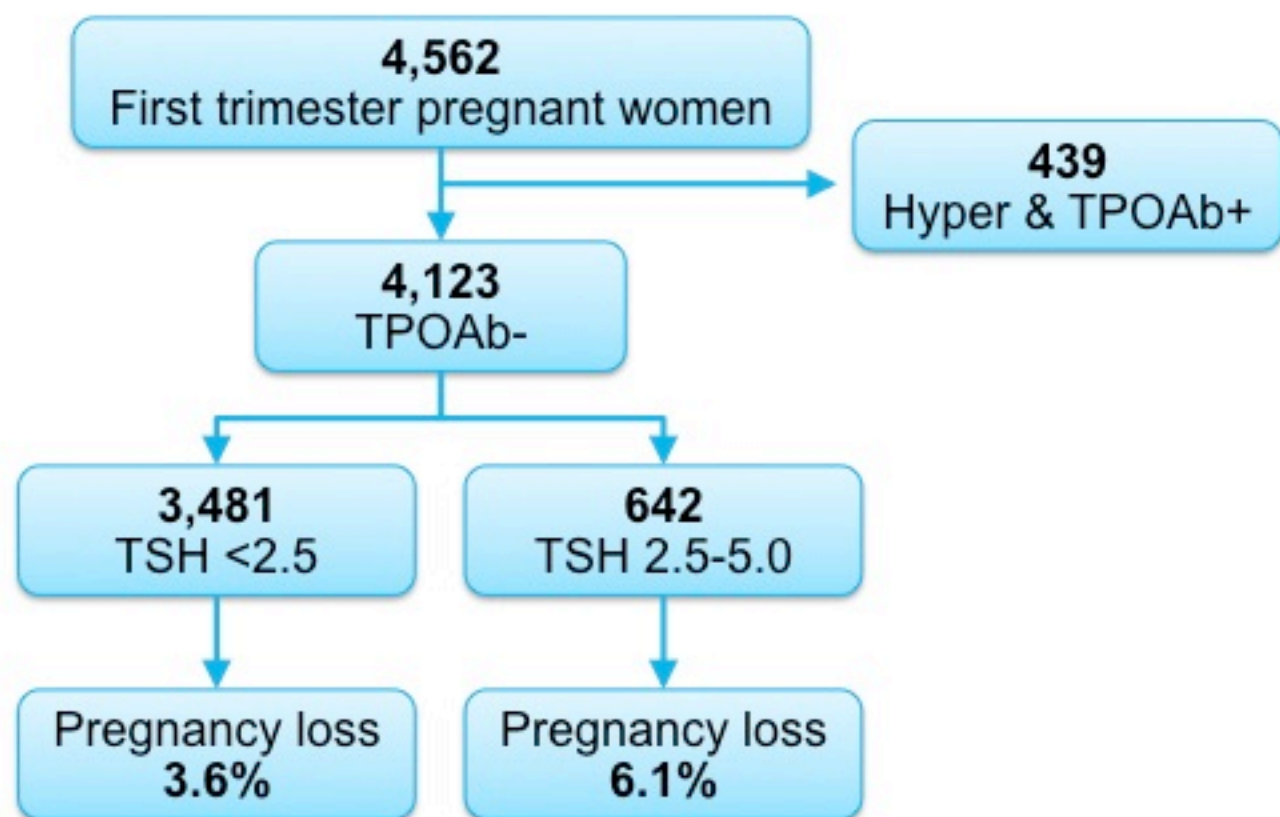


### Recommendation 19.1:

Rx with LT4 *should be considered* in women with TSH >2.5 in 1<sup>st</sup> trimester of pregnancy or planning pregnancy

Thyroid, 2012

# Increased Pregnancy Loss in TPOAb-Neg Women with TSH 2.5-5.0



**P=0.006**

Negro R et al: JCEM 95:E44-8, 2010



## Pregnancy, TSH & LT4 Rx

A 26-year-old woman is planning pregnancy. She is in good health. Thyroid gland is normal on palpation.

Serum TSH is 4.3 mIU/L; FT4 is 1.0 ng/dL; & TPOAb is positive

Q: Should she be treated with LT4?

Yes ✓

No ~

### Recommendation 19.3:

Women who are pregnant or plan pregnancy, **should be treated** with LT4 if TSH is  $>2.5$  & TPOAb positive

Thyroid, 2012

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Association between thyroid autoantibodies and miscarriage and preterm birth: meta-analysis of evidence

30 articles with 31 studies (19 cohort and 12 case-control) involving 12,126 women assessed the association between thyroid autoantibodies and miscarriage.

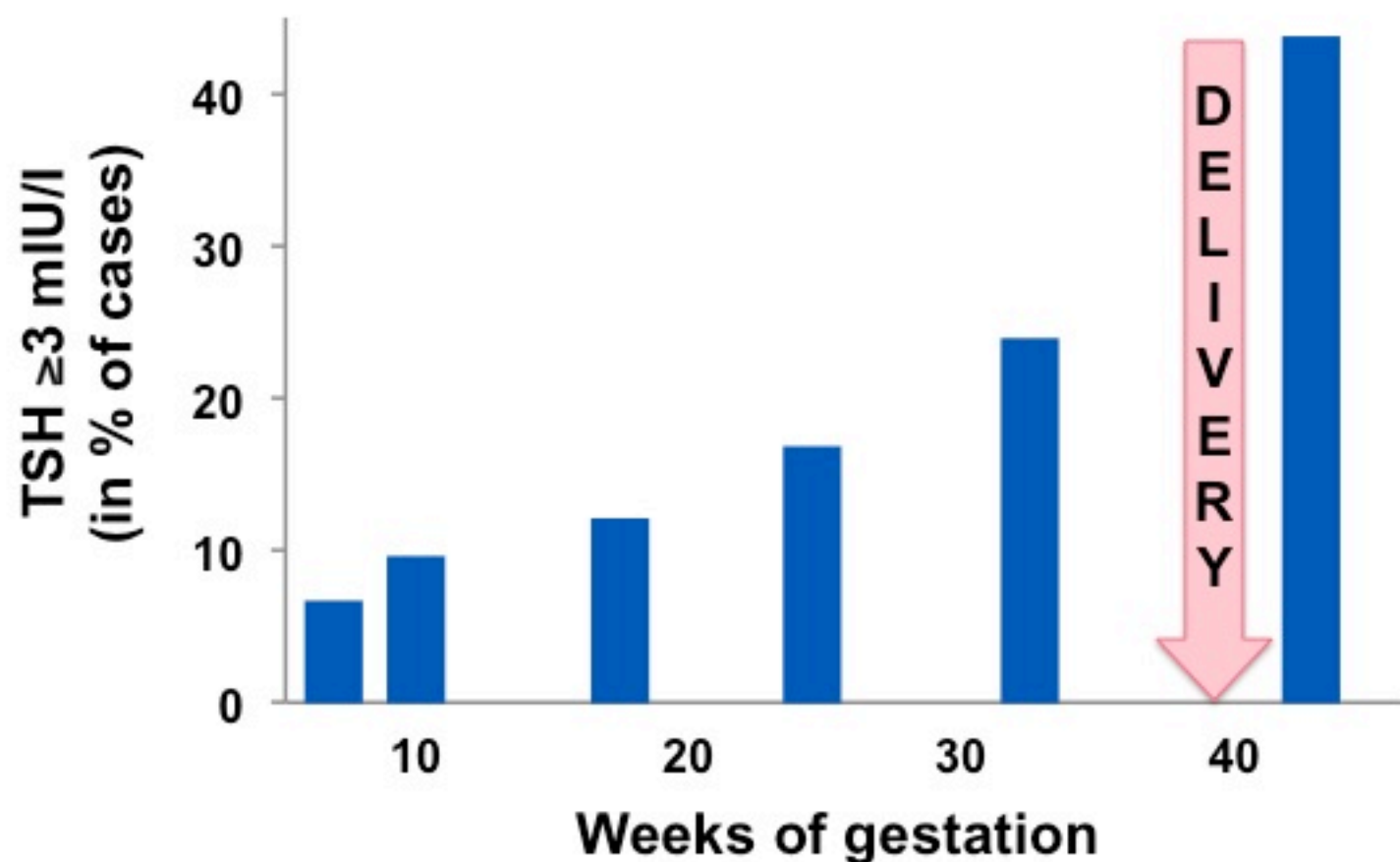
Cohort studies: OR 3.90 (95% confidence interval 2.48 to 6.12;  $P < 0.001$ ).

Case control studies: OR 1.80 (1.25 to 2.60;  $P = 0.002$ ).

There was a significant doubling in the odds of preterm birth with the presence of thyroid autoantibodies (2.07, 1.17 to 3.68;  $P = 0.01$ ).

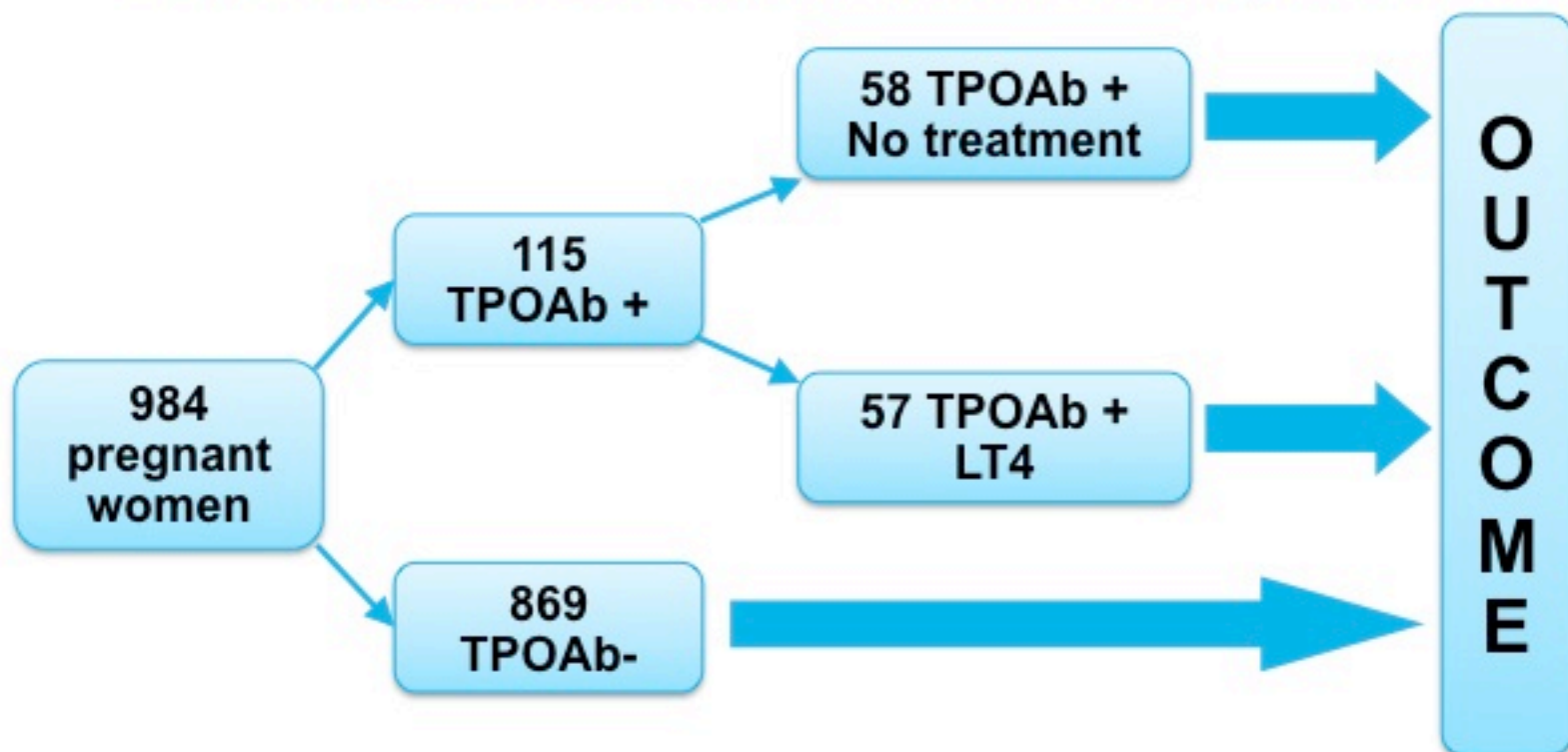
Conclusion: The presence of maternal thyroid autoantibodies is strongly associated with miscarriage and preterm delivery. There is evidence that treatment with levothyroxine can attenuate the risks.

# TSH Changes in TPOAb (+) Pregnancy Women During Gestation



Vanderpump M et al, 2003

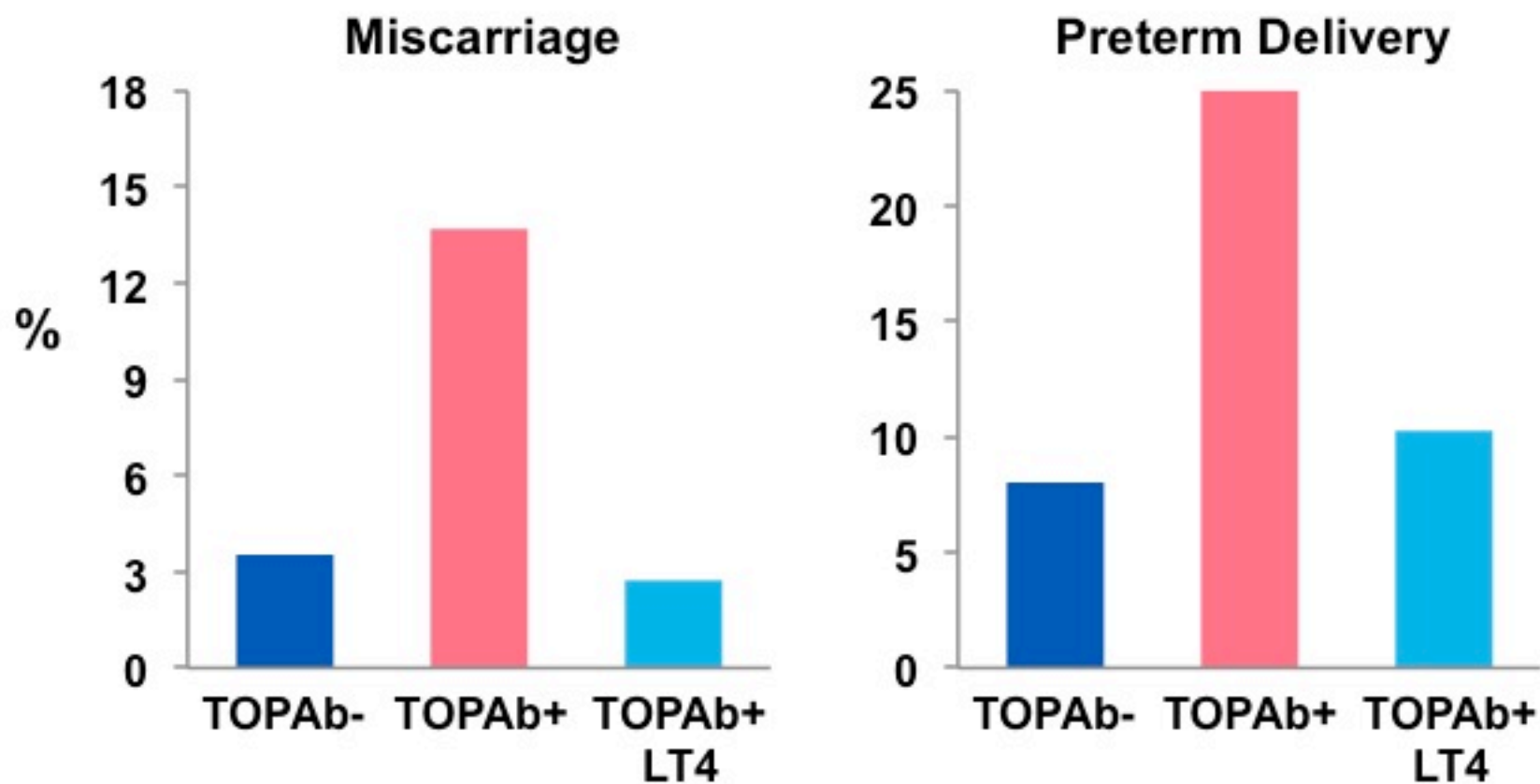
# Treatment with LT4 in Pregnant Women with TAI: Effects on Obstetrical Complications



LT4: 0.5  $\mu\text{g}/\text{kg}\cdot\text{d}$  TSH <1.0 mIU/l  
0.75  $\mu\text{g}/\text{kg}\cdot\text{d}$  TSH 1.0-2.0 mIU/l  
1  $\mu\text{g}/\text{kg}\cdot\text{d}$  for TSH >2.0 mIU/l or  
TPOAb >1,500 kIU/L

Negro R et al: JCEM 91:2587-2591, 2006

## Treatment with LT4 in Pregnant Women with TAI: Effects on Obstetrical Complications



Negro R et al: JCEM 91:2587-2591, 2006

## Recommendations for TPOAb Screening in Pregnancy

- **There is insufficient evidence to recommend for or against screening for thyroid antibodies in the first trimester of pregnancy, or treating TPOAb+ euthyroid women with LT4 to prevent preterm delivery**
- **Women with TAI (TPOAb pos) who are euthyroid in the early stages of pregnancy are at risk for developing hypothyroidism, and should be monitored carefully**

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## MATERNAL THYROID DEFICIENCY DURING PREGNANCY AND SUBSEQUENT NEUROPSYCHOLOGICAL DEVELOPMENT OF THE CHILD

JAMES E. HADDOW, M.D., GLENN E. PALOMAKI, B.S., WALTER C. ALLAN, M.D., JOSEPHINE R. WILLIAMS,  
GEORGE J. KNIGHT, PH.D., JUNE GAGNON, M.A., CHERYL E. O'HEIR, M.ED., ED.S., MARVIN L. MITCHELL, M.D.,  
ROSALIE J. HERMOS, M.P.H., SUSAN E. WAISBREN, PH.D., JAMES D. FAIX, M.D., AND ROBERT Z. KLEIN, M.D.

*The* **NEW ENGLAND**  
**JOURNAL** *of* **MEDICINE**

ESTABLISHED IN 1812

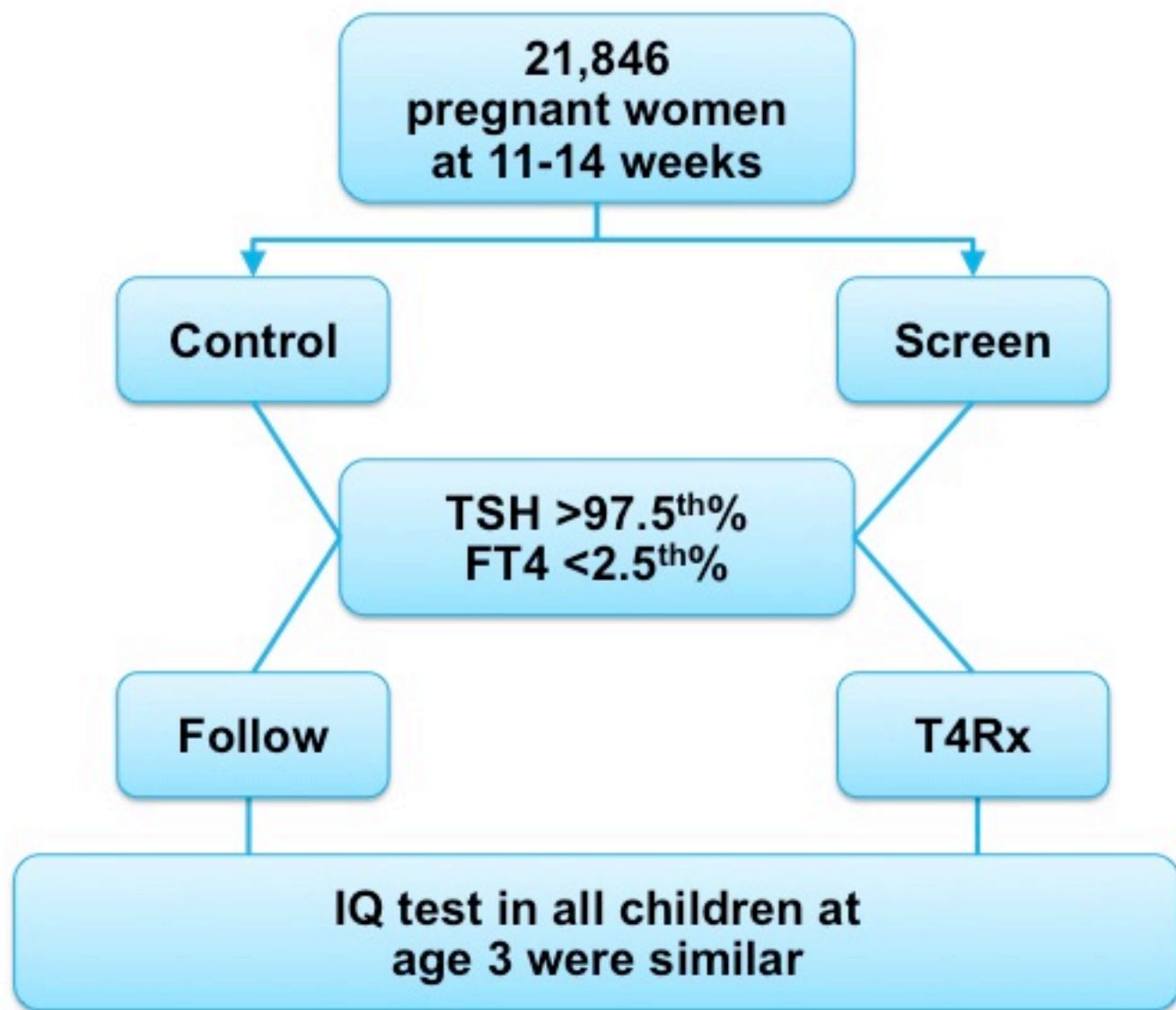
FEBRUARY 9, 2012

VOL. 366 NO. 6

**Antenatal Thyroid Screening and Childhood  
Cognitive Function**

John H. Lazarus, M.D., Jonathan P. Bestwick, M.Sc., Sue Channon, D.Clin.Psych., Ruth Paradice, Ph.D.,  
Aldo Maina, M.D., Rhian Rees, M.Sc., Elisabetta Chiusano, M.Psy., Rhys John, Ph.D.,  
Varvara Guaraldo, M.S.Chem., Lynne M. George, H.N.C., Marco Perona, M.S.Chem., Daniela Dall'Amico, M.D.,  
Arthur B. Parkes, Ph.D., Mohammed Joomun, M.Sc., and Nicholas J. Wald, F.R.S.





Lazarus et al: N Engl J Med 366:493, 2012

## Thyroid Hormone Therapy

- **Up to 3% of population in Western Countries is on thyroid hormone Rx (JCEM 89:3879, 2004)**
- **Replacement Rx is for hypothyroidism: Keep TSH normal**
- **LT4 dose requirement is less for primary hypothyroidism compared to central hypo-, postop- or post<sup>131</sup>I hypothyroidism**
- **Generic LT4 is in common use nowadays**

# Primary Hypothyroidism

- A 50-year-old woman complains of recent wt gain, fatigue, sleepiness and cold intolerance; one sister has Graves' disease and another hypothyroidism

## Tests

- TSH 62.0 mIU/L
- FT4 0.2 ng/dL
- TPOAb 560 (<9)



# Hypothyroidism

- **What is the most likely cause of hypothyroidism in this patient?**
- **When is TPO measurement useful?**
- **How do you select LT4 dose?**

# 橋本 徹

Hashimoto-Dōri

橋本 策

1881-1934



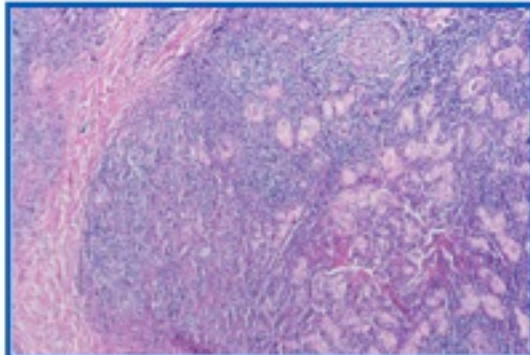
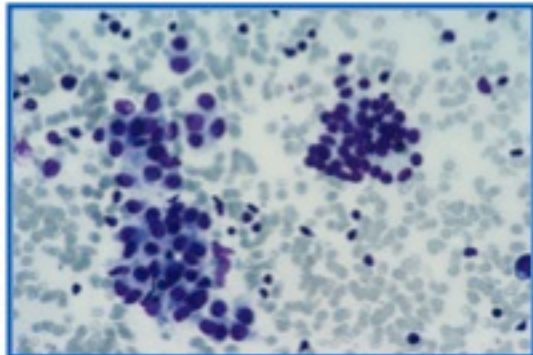
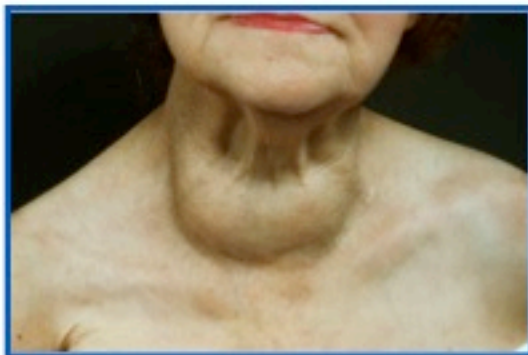
橋本 策は、現阿山郡西柘植（つげ）村（現伊賀町）生まれ。医学部の前身、京都帝国大学福岡医科大学の第1回生として1907年に卒業。外科学第一講座（三宅速教授）在局中にリンパ球を豊富に含む特異な甲状腺腫に着目。1912年ドイツの外科学雑誌に論文を発表。ドイツ留学ののち帰郷して医業を継いだが発見した自己免疫の独立性が認められ、さらに自己免疫という概念の登場とともに自己免疫疾患となった「橋本病」にその名を残した。

Hakaru Hashimoto was born at Iga town in Mie prefecture. He graduated from Kyushu University in 1907. In his career at

**Hakaru Hashimoto**  
**1881-1934**

# Hypothyroidism

- Hashimoto thyroiditis is the most common cause
- 95% of pt are women
- Goiter is nontender, diffuse, firm (rubbery) and bosselated
- Additional helpful tests include TPOAb, FNA, & US



## Thyroid Peroxidase Antibody (TPOAb)

- **Sensitive test for detecting thyroid autoimmune disease (TAID)**
- **Order in pt with subclinical hypothyroidism**
- **Order when TAID is suspected in pt with nodular thyroid**
- **Consider in woman with recurrent miscarriage**

## Levothyroxine (LT4) Therapy

- **Average daily dose is about 100 mcg**
- **Initial dose is influenced by severity & duration of hypothyroidism, as well as presence of CAD**
- **Obesity ( $\uparrow$  BMI) increases requirement**
- **Replacement therapy (TSH 0.3-3.0) is life-long treatment**





## LT4 Rx

### Recommendation 13

- Pt treated for hypothyroidism should have TSH measurement at 4-8 wk

### Recommendation 22.8

- When initiating Rx in pt older than 50-60 yr, without CAD, LT4 dose of 50 mcg daily should be considered

### Recommendation 23

- LT4 should be taken 30-60 min before breakfast or 4 hr after pm meal

# Target TSH

## Recommendation 17

- **In pt with hypothyroidism who are not pregnant, the target should be the normal range of a sensitive TSH assay**

## Hypothyroidism With Low TSH

A 52-year-old man reports fatigue, lethargy, 5 lb wt gain and decreased libido. Thyroid is small on exam. Serum TSH is 2.0 (0.5-5.0) & FT4 0.5 (0.8-1.8)

**Q:** Differential diagnosis?  
Additional tests?

**Causes:** Pituitary/hypothalamic tumor  
lymphocytic hypophysitis  
Sheehan's syndrome  
surgery  
radiation

# Hypothyroidism With Low TSH

## Additional test

- Serum T3 55 ng/dL
- Serum cortisol 2.1 ng/dL
- Serum testosterone 60 ng/dL
- LH/FSH ↓
- Prolactin normal

## Imaging

- Head MR showed on 2 cm smaller mass

## Rx

- Placed on T4, testosterone & prednisone
- Pituitary surgery

# Central Hypothyroidism

## Recommendation 12

- In patient with central hypothyroidism, assessment of FT4 or FTI, not TSH, should be done to Dx & Rx hypothyroidism

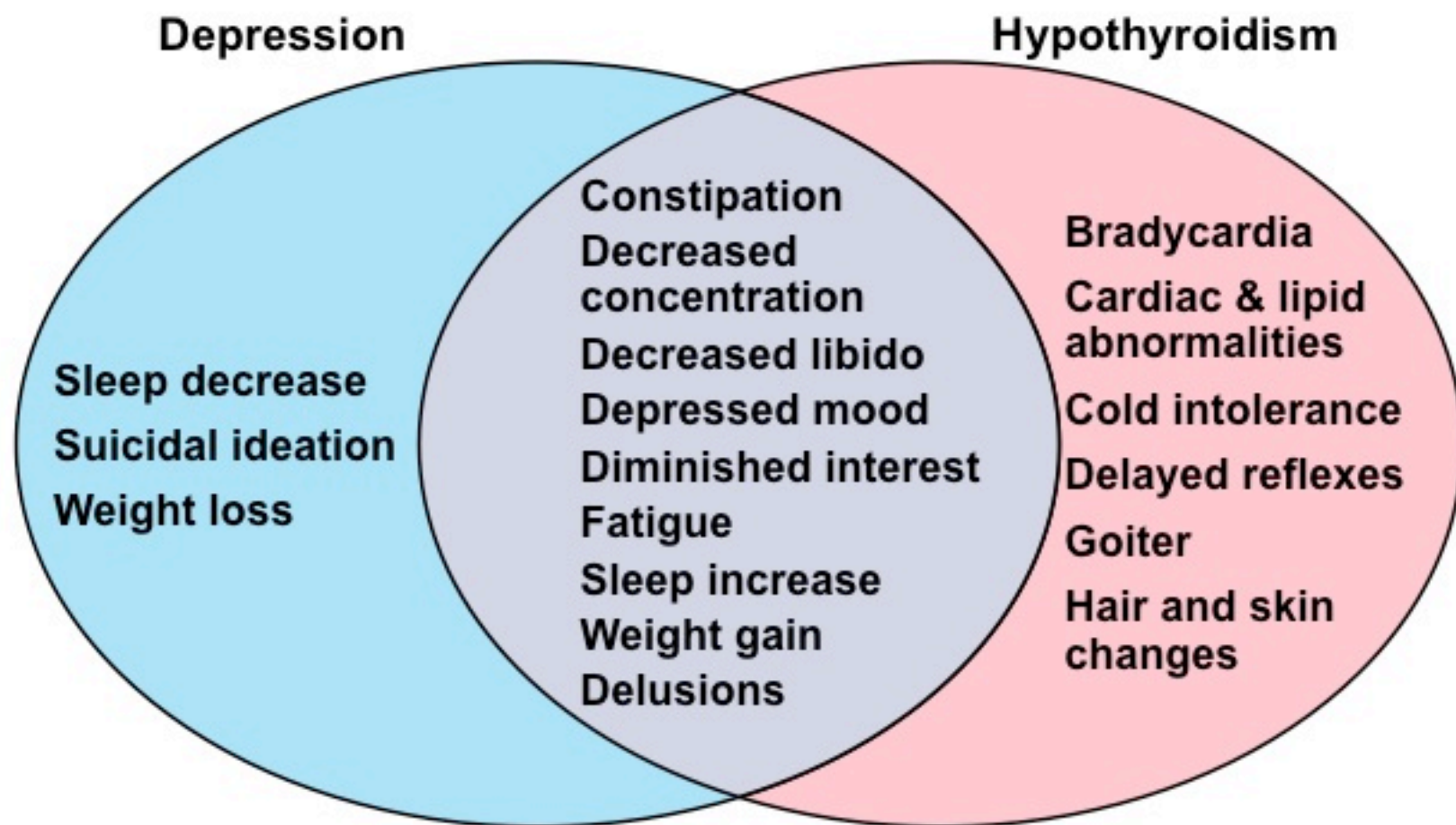
## Symptomatic Hypothyroidism With Normal TSH

- A 42-year-old nurse complains of fatigue, cold intolerance, constipation and depression
- She has been on T4 for 12 years since  $^{131}\text{I}$  Rx for hyperthyroidism
- Exam is normal; serum TSH is 3.6 mIU/L (0.5-5.0) & FT4 1.3 ng/dL (0.8-1.8)

## Why Some Patients With Hypothyroidism Continue to Complain Despite Normal TFTs?

- **Non-thyroid causes**
- **T4 dose inadequate**
- **Need for combination T4 plus T3**
- **Other explanations**

# Common Features of Hypothyroidism and Depression



Nemeroff CB: J Clin Psychiatry 50 (Suppl:13-20), 1989



## Possible Other Causes

- **Obesity**
- **Sleep disorder**
- **Stress**
- **Depression**
- **Menopause**
- **Iron or vit D deficiency**

## Small Changes in Thyroxine Dosage Do Not Produce Measurable Changes in Hypothyroid Symptoms, Well-Being, or Quality of Life: Results of a Double-Blind, Randomized Clinical Trial

John P. Walsh, Lynley C. Ward, Valerie Burke, Chotoo I. Bhagat, Lauren Shiels, David Henley, Melissa J. Gillett, Rhonda Gilbert, Melissa Tanner, and Bronwyn G. A. Stuckey

Background: The optimal TSH target range for the treatment of primary hypothyroidism is controversial.

Design: We conducted a double-blind, randomized clinical trial with a crossover design.

Setting: The study was conducted in a tertiary care hospital.

Patients: Fifty-six patients with primary hypothyroidism were randomized to receive 3 T4 doses of 1.0, 1.5, or 2.0 times the current T4 dose.

Measurements and Main Results: Mean serum TSH levels were 2.8 ± 0.4 mU/L, 1.0 ± 0.2 mU/L, and 0.3 ± 0.1 mU/L for the 3 treatments, respectively. There were no significant treatment effects on any of the instruments of well-being, symptoms, quality of life, cognitive function, or treatment preference.

Conclusions: Small changes in T4 dosage do not produce measurable changes in hypothyroid symptoms, well-being, or quality of life, as measured by validated instruments.

These data do not support the suggestion that the target TSH range for the treatment of primary hypothyroidism should differ from the general laboratory range. *J Clin Endocrinol Metab* 91:2624-2630, 2006

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- 56 hypothyroid patients on T4
- Randomized to receive 3 T4 doses & outcomes measured
- Mean serum TSH levels were:  $2.8 \pm 0.4$  mU/L,  $1.0 \pm 0.2$  mU/L, and  $0.3 \pm 0.1$  mU/L for the 3 treatments
- There were no significant treatment effects on any of the instruments of well-being, symptoms, quality of life, cognitive function, or treatment preference

## Thyroxine-Triiodothyronine Combination Therapy Versus Thyroxine Monotherapy for Clinical Hypothyroidism: Meta-Analysis of Randomized Controlled Trials

Simona Grozinsky-Glasberg, Abigail Fraser, Ethan Nahshoni, Abraham Weizman, and Leonard Leibovici

- Meta-analysis of 11 studies and 1,216 patients
- Randomized trials comparing T4 & T3 to T4 therapy
- End points included bodily pain, depression anxiety, fatigue, QOL, B wt, and lipid profiles
- Adverse effects were similar
- No difference between T4 & T3 vs T4 therapy
- T4 monotherapy should remain the Rx of choice for hypothyroidism

JCEM 89:2099, 2004

# LT4 Rx in Hypothyroidism

## Recommendation 22.1

- Pt with hypothyroidism should be treated with LT4 monotherapy

## Recommendation 22.2

- The evidence does not support using LT4 and LT3 combinations to treat hypothyroidism

## Recommendation 22.4

- There is no evidence to support using DTE in preference to LT4 monotherapy in hypothyroidism, therefore DTE should not be used

# Results of Randomized, Controlled Trials of T4+T3 vs T4 Alone

Study (yr)	Outcome	Pt preference
Bunevicius et al, 1999	T4 + T3 > T4	T4 + T3 > T4
Walsh et al, 2002	No difference	No difference
Escobar-Morreale et al, 2005	No difference	T4 + T3 > T4
Appelhof et al, 2005	No difference	T4 + T3 > T4

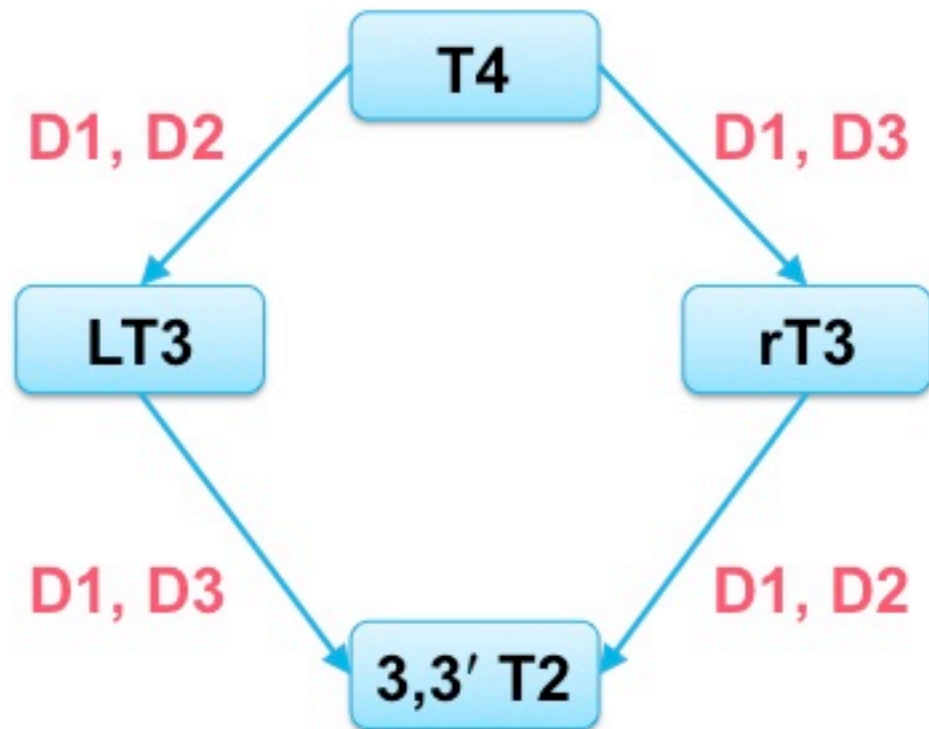
\*Review of Endo 2:32, 2008

## Combination T4 & T3 Therapy

- 70 pt, age 18-65 yr
- RCT using Dessicated Thyroid Extract (DTE) vs LT4 treatment in hypothyroidism
- DTE did not result in significant QOL improvement but did cause moderate weight loss
- Combination T4 + T3 is safe but not better than LT4

Hoang TD et al: JCEM 98:1982, 2013

# Thyroid Hormone Metabolism



T4 = Thyroxine

T3 = Triiodothyronine

D = Deiodinase

D1 = liver, kidney, thyroid

D2 = CNS, pituitary

D3 = brain, placenta

## Why LT4 Monotherapy May Not be Enough?

- **Type 2 deiodinase (Dio2) controls T4 → T3**
- **Dio2 polymorphism could influence T3 level in brain and mood**
- **Increasing LT4 levels result in ↓ Dio2 and ↓ T3**
- **Some patients on T4 Rx do not feel normal because of ↓ T3 level in brain**

Panicker V et al: JCEM 94:1623, 2009



## Elevated TSH in LT4 Therapy

**A 50-year-old biology teacher reports recent fatigue, lethargy and decreased libido; has been on LT4 for hypothyroidism for 20 years. Last yr TSH was 2.2; current TSH 11.7 mIU/L with FT4 0.7 ng/dL. He is on 15 other drugs and supplements**

**Q: Cause of ↑ TSH?**

## Drug-Induced Abnormal TSH

↑ TSH due to ↓ GI absorption of T4

- Aluminum hydroxide
- Calcium
- Carafate
- Ferrous sulfate
- Lovastatin

## Drug-Induced Abnormal TSH

↑ TSH due to ↑ T4 metabolism

- Dilantin
- Phenobarbital
- Rifampin
- Tegretol

## Drug-Induced Abnormal TSH

Drug	Hypo-/hyper-	Mechanism
Bexarotene	Y/N	Central
Lithium	Y/?Y	Autoimmune
Amiodarone	Y/Y	Iodine
Interferon	Y/Y	Autoimmune
Sunitinib	Y/N	?

## Conclusions (1)

- **Subclinical hypothyroidism in the young pt should be treated with LT4**
- **Aggressive case finding rather than routine screening is recommended in pregnancy**
- **Normal serum TSH is  $\leq 2.5$  in early &  $\leq 3.5$  in late pregnancy**
- **Commonest cause of hypothyroidism is Hashimoto thyroiditis**

## Conclusions (2)

- **Use FT4 or FTI, rather than TSH, to Dx & Rx central hypothyroidism**
- **LT4 monotherapy is recommended for most pt with hypothyroid**
- **Deiodinase polymorphism is one explanation for hypothyroid pt being unhappy with T4 Rx**
- **Consider interfering drugs when TSH is abnormal in established, hypothyroid pt**



# Thank You



# Thyroid Hormone Therapy

OSU Internal Medicine Grand Rounds

Columbus  
November 14, 2013



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