CLINICAL PRACTICE GUIDELINE

Management of Thyroid Dysfunction during Pregnancy and Postpartum: An Endocrine Society Clinical Practice Guideline


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Objective: The objective is to provide clinical guidelines for the management of thyroid problems present during pregnancy and in the postpartum.

Participants: The Chair was selected by the Clinical Guidelines Subcommittee (CGS) of The Endocrine Society. The Chair requested participation by the Latin American Thyroid Society, the Asia and Oceania Thyroid Society, the American Thyroid Association, the European Thyroid Association, and the American Association of Clinical Endocrinologists, and each organization appointed a member to the task force. Two members of The Endocrine Society were also asked to participate. The group worked on the guidelines for 2 yr and held two meetings. There was no corporate funding, and no members received remuneration.

Evidence: Applicable published and peer-reviewed literature of the last two decades was reviewed, with a concentration on original investigations. The grading of evidence was done using the United States Preventive Services Task Force system and, where possible, the GRADE system.

Consensus Process: Consensus was achieved through conference calls, two group meetings, and exchange of many drafts by E-mail. The manuscript was reviewed concurrently by the Society’s CGS, Clinical Affairs Committee, members of The Endocrine Society, and members of each of the collaborating societies. Many valuable suggestions were received and incorporated into the final document. Each of the societies endorsed the guidelines.

Conclusions: Management of thyroid diseases during pregnancy requires special considerations because pregnancy induces major changes in thyroid function, and maternal thyroid disease can have adverse effects on the pregnancy and the fetus. Care requires coordination among several healthcare professionals. Avoiding maternal (and fetal) hypothyroidism is of major importance because of potential damage to fetal neural development, an increased incidence of miscarriage, and preterm delivery. Maternal hyperthyroidism and its treatment may be accompanied by coincident problems in fetal thyroid function. Autoimmune thyroid disease is associated with both increased rates of miscarriage, for which the appropriate medical response is uncertain at this time, and postpartum thyroiditis. Fine-needle aspiration cytology should be performed for dominant thyroid nodules discovered in pregnancy. Radioactive isotopes must be avoided during pregnancy and lactation. Universal screening of pregnant women for thyroid disease is not yet supported by adequate studies, but case finding targeted to specific groups of patients who are at increased risk is strongly supported. (J Clin Endocrinol Metab 92: S1–S47, 2007)

EXECUTIVE SUMMARY

OVER THE PAST 15 yr there has been a rapid expansion of knowledge regarding thyroid disease and pregnancy. These advances relate to the optimal management of pregnant women on levothyroxine therapy, the impact of iodine deficiency on the mother and developing fetus, the adverse effect of maternal hypothyroidism on mental develop-

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Abbreviations: ATD, Antithyroid drug; FNA, fine-needle aspiration; PPT, postpartum thyroiditis; RAI, radioactive iodine; TRAB, TSH-receptor antibodies; USI, universal salt iodization; USPSTF, United States Preventive Service Task Force.

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opment in their infants, the syndrome of postpartum thy-
roiditis (PPT), and its relation to permanent hypothyroidism.
Furthermore, a doubling of the miscarriage rate has been
reported in studies in antibody-positive euthyroid women,
and an increase in preterm delivery has been found in
women with subclinical hypothyroidism and/or thyroid
autoimmunity.

Given the rapidity of advances in this field, it is not sur-
prising that controversy surrounds optimal detection and
management of thyroid disease in the pregnant woman.
Thyroid disease during pregnancy has certain characteristics
that make writing guidelines more complicated than for
some other fields. This field is concerned with the manage-
ment of pregnant women who may have a variety of known
or undisclosed thyroid conditions, such as hypothyroidism
and hyperthyroidism, the presence of thyroid autoantibod-
ies, the presence of nodules, or unsatisfactory iodine nutri-
tion. Pregnancy may affect the course of these thyroid dis-
orders, and conversely, thyroid diseases may affect the
course of pregnancy. Moreover, thyroid disorders (and their
management) may affect both the pregnant woman and the
developing fetus. Finally, pregnant women may be under the
care of multiple health care professionals, including obstet-
ricians, nurse midwives, family practitioners, endocrinolo-
gists, and/or internists, making the development of guide-
lines all the more critical.

METHODS

An international task force was created, under the auspices
of The Endocrine Society, to review the best evidence in the
field and develop evidence-based guidelines. Members of
the task force included representatives from The Endocrine
Society, American Thyroid Association, Association of
American Clinical Endocrinologists, European Thyroid As-
sociation, Asia and Oceania Thyroid Association, and the
Latin American Thyroid Society. The task force worked dur-
ing 2 yr to develop the guidelines, had multiple phone con-
versations, and two 2-d retreats. Upon completion of the
guidelines, they were reviewed and approved by all of the
participants.

Our committee undertook to review all material on these
topics published in English during the past two decades, or
earlier at the working group’s discretion. We concentrated on
original reports and largely excluded reviews from our re-
ferences. At present, with the exception of studies on iodide
supplementation, only two prospective, randomized inter-
vention trials have been published in this area. We are aware
of two large-scale prospective intervention trials that are
presently ongoing. Nevertheless, in the last 15 yr, many
high-quality studies have modified older dogmas and pro-
foundly changed the ways in which these patients are man-
aged. These studies are most often prospective or retrospec-
tive clinical evaluations of a particular patient population
and matched groups of control women. Such studies, when
carefully performed, adequately matched, and appropriately
interpreted, provide the bulk of the evidence presented
herein.

The committee evaluated recommendations and evidence
using the methodology of the United States Preventive Ser-
vice Task Force (USPSTF), in which treatments or medical
advice are referred to as a “service.” The USPSTF grades its
recommendations (level A, B, C, D, or I) on the basis of the
strength of evidence and magnitude of net benefit (benefits
minus harms), as follows.

A. The USPSTF strongly recommends that clinicians pro-
vide (the service) to eligible patients. The USPSTF found good
evidence that (the service) improves important health outcomes and
concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians provide (the
service) to eligible patients. The USPSTF found at least fair
evidence that (the service) improves important health outcomes and
concludes that benefits outweigh harms.

C. The USPSTF makes no recommendation for or against
routine provision of (the service). The USPSTF found at least fair
evidence that (the service) can improve health outcomes but
concludes that the balance of benefits and harms is too close to
justify a general recommendation.

D. The USPSTF recommends against routinely providing
(the service) to asymptomatic patients. The USPSTF found good
evidence that (the service) is ineffective or that harms out-
weigh benefits.

I. The USPSTF concludes that the evidence is insufficient
to recommend for or against routinely providing (the ser-
vice). Evidence that (the service) is effective is lacking, or poor
quality, or conflicting, and the balance of benefits and harms cannot
be determined.

The USPSTF grades the quality of the overall evidence for
a service on a three-point scale (good, fair, or poor), defined
as follows:

Good: Evidence includes consistent results from well de-
dsigned, well-conducted studies in representative populations
that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health
outcomes, but the strength of the evidence is limited by the
number, quality, or consistency of the individual studies,
generalizability to routine practice, or indirect nature of the
evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health
outcomes because of limited number or power of studies,
important flaws in their design or conduct, gaps in the chain
of evidence, or lack of information on important health
outcomes.

In addition to the USPSTF grading of recommendations,
we have also included the appropriate recommendation
level as indicated by the GRADE system. The value of an
evidence-based recommendation, using the GRADE system,
is scored from strong to moderate (1–2) and accompanied by
symbols indicating the value of the evidence: high (1, ○○○○
or ○○○○○), moderate (2, ○○○○), low (○○○), and very low
(○○). (There are no equivalents in the GRADE system for
the recommendation levels C, D, and I used in the USPSTF
system.)

The supporting data for the full committee report follow
this executive summary. The supporting data consist of eight
subsections dealing in detail with specific maternal/fetal
thyroid problems. Each subsection provides the related back-
ground and evidence for recommendations. In the subsec-
tion reports, we have indicated specific bibliographic cita-
tions on which each recommendation is based, and for each
After delivery is not considered a danger (25). Pregnancy is not thought to adversely affect the course of thyroid malignancy (26–28). TSH suppression for known thyroid malignancy may be maintained during pregnancy with detectable TSH and with T₄ at the upper end of the range for normal pregnancy. Radioactive iodine (RAI) must not be administered during pregnancy or lactation.

Autoimmune thyroid disease is common in pregnancy. The presence of antibodies to thyroid peroxidase or thyroglobulin is associated with a significant increment in miscarriages (29, 30). One prospective study has reported that treatment with T₄ during pregnancy may reverse this risk (31). Additional studies on this important issue are needed.

PPT, a form of autoimmune thyroid disease closely related to Hashimoto's thyroiditis, is found in about 7% of women in the postpartum period (32). It causes hyperthyroidism and/or hypothyroidism that is usually transient (but often seriously symptomatic) (33, 34) and increases the risk of later permanent hypothyroidism (35, 36). Although depression may be a symptom of hypothyroidism in any setting, PPT per se has not been clearly linked to postpartum depression (37, 38).

A major unsettled question is the advisability of universal screening of pregnant women for thyroid disease, through TSH testing, and possibly antibody testing. The prevalence of overt thyroid disease in this population is 1%, and there is also a 2–3% prevalence of subclinical hypothyroidism and 10–15% antibody positivity (30, 39). As of this date, only one study has demonstrated that treatment of antibody positive euthyroid women with T₄ decreases the rate of miscarriage and preterm delivery (31). Thus, for now, the committee recommends targeted case finding during early pregnancy but anticipates that ongoing studies may alter this recommendation (40). Vaidya et al. (41) recently reported a study of screening by means of TSH, T₄, free T₄, and thyroid peroxidase antibodies in 1560 consecutive pregnant women. An important result was that screening only women considered high risk on the basis of a personal or family history of thyroid disease or a history of other autoimmune disease would have missed 30% of women with overt or subclinical hypothyroidism.

RECOMMENDATIONS

1. HYPOTHYROIDISM AND PREGNANCY: MATERNAL AND FETAL ASPECTS

1.1.1. Both maternal and fetal hypothyroidism are known to have serious adverse effects on the fetus. Therefore, maternal hypothyroidism should be avoided. USPSTF recommendation level is A; evidence is fair (GRADE 1⊕⊕⊕⊕). Targeted case finding is recommended at the first prenatal visit or at diagnosis of pregnancy (see Section 8, Screening for thyroid dysfunction during pregnancy). USPSTF recommendation level is B; evidence is fair (GRADE 2⊕⊕⊕○).

1.1.2. If hypothyroidism has been diagnosed before pregnancy, we recommend adjustment of the preconception T₄ dose to reach a TSH level not higher than 2.5 μU/ml before pregnancy. USPSTF recommendation level is I; evidence is poor (⊕⊕⊕○).

1.1.3. The T₄ dose usually needs to be incremented by 4–6
wk gestation and may require a 30–50% increase in dosage. USPSTF recommendation level is A; evidence is good (GRADE 1).

1.1.4. If overt hypothyroidism is diagnosed during pregnancy, thyroid function tests should be normalized as rapidly as possible. The T4 dosage should be titrated to rapidly reach and thereafter maintain serum TSH concentrations of less than 2.5 μU/ml in the first trimester (or 3 μU/ml in the second and third trimesters) or to trimester-specific normal TSH ranges. Thyroid function tests should be remeasured within 30–40 d. USPSTF recommendation level is A; evidence is good (GRADE 1).

1.1.5. Women with thyroid autoimmunity who are euthyroid in the early stages of pregnancy are at risk of developing hypothyroidism and should be monitored for elevation of TSH above the normal range. USPSTF recommendation level is A; evidence is good (GRADE 1).

1.1.6. Subclinical hypothyroidism (serum TSH concentration above the upper limit of the reference range with a normal free T4) has been shown to be associated with an adverse outcome for both the mother and offspring. T4 treatment has been shown to improve obstetrical outcome but has not been proved to modify long-term neurological development in the offspring. However, given that the potential benefits outweigh the potential risks, the panel recommends T4 replacement in women with subclinical hypothyroidism. For obstetrical outcome, USPSTF recommendation level is B; evidence is fair (GRADE 1).

1.1.7. After delivery, most hypothyroid women need a decrease in the T4 dosage they received during pregnancy. USPSTF recommendation level is A; evidence is good (GRADE 1).

2. MANAGEMENT OF MATERNAL HYPERTHYROIDISM: MATERNAL (A) AND FETAL (B) ASPECTS

2.1.a.1. If a subnormal serum TSH concentration is detected during gestation, hypothyroidism must be distinguished from both normal physiology during pregnancy and hyperemesis gravidarum because of the adverse effects of overt hyperthyroidism on the mother and fetus. Differentiation of Graves’ disease from gestational thyrotoxicosis is supported by evidence of autoimmunity, a goiter, and presence of TRAb. USPSTF recommendation level is A; evidence is good (GRADE 1).

2.1.a.2. For overt hyperthyroidism due to Graves’ disease or hyperfunctioning thyroid nodules, ATD therapy should be either initiated (for those with new diagnoses) or adjusted (for those with a prior history) to maintain the maternal thyroid hormone levels for free T4 in the upper nonpregnant reference range. USPSTF recommendation level is A; evidence is good (GRADE 1).

2.1.a.3. Because available evidence suggests methimazole may be associated with congenital anomalies, propylthiouracil should be used as a first-line drug, if available, especially during first-trimester organogenesis. Methimazole may be prescribed if propylthiouracil is not available or if a patient cannot tolerate or has an adverse response to propylthiouracil. USPSTF recommendation level is B; evidence is fair (GRADE 1).

2.1.a.4. Subtotal thyroidectomy may be indicated during pregnancy as therapy for maternal Graves’ disease if 1) a patient has a severe adverse reaction to ATD therapy, 2) persistently high doses of ATD are required, or 3) a patient is not adherent to ATD therapy and has uncontrolled hyperthyroidism. The optimal timing of surgery is in the second trimester. USPSTF recommendation level is I; evidence is poor (GRADE 1).

2.1.a.5. There is no evidence that treatment of subclinical hyperthyroidism improves pregnancy outcome, and treatment could potentially adversely affect fetal outcome. USPSTF recommendation level is I; evidence is poor (GRADE 1).

2.1.b.1 TRAb (either TSH receptor-stimulating or -binding antibodies) freely cross the placenta and can stimulate the fetal thyroid. These antibodies should be measured before pregnancy or by the end of the second trimester in mothers with current Graves’ disease, with a history of Graves’ disease and treatment with 131I or thyroidectomy, or with a previous neonate with Graves’ disease. Women who have a negative TRAb and do not require ATD have a very low risk of fetal or neonatal thyroid dysfunction. USPSTF recommendation level is B; evidence is fair (GRADE 1).

2.1.b.2. 131I should not be given to a woman who is or may be pregnant. If inadvertently treated, the patient should be promptly informed of the radiation danger to the fetus, including thyroid destruction if treated after the 12th week of gestation. USPSTF recommendation level is A; evidence is good (GRADE 1). There are no data for or against recommending termination of pregnancy after 131I exposure. USPSTF recommendation level is I; evidence is poor (GRADE 1).

2.1.b.3. In women with elevated TRAb or in women treated with ATD, fetal ultrasound should be performed to look for evidence of fetal thyroid dysfunction that could include growth restriction, hydrops, presence of goiter, or cardiac failure. USPSTF recommendation level is B; evidence is fair (GRADE 2).

2.1.b.4. Umbilical blood sampling should be considered only if the diagnosis of fetal thyroid disease is not reasonably certain from the clinical data and if the information gained would change the treatment. USPSTF recommendation level is B; evidence is fair (GRADE 1).

2.1.b.5. All newborns of mothers with Graves’ disease should be evaluated for thyroid dysfunction and treated if necessary. USPSTF recommendation level is B; evidence is fair (GRADE 2).

3. GESTATIONAL HYPEREMESIS AND HYPERTHYROIDISM

3.1. Thyroid function tests should be measured in all patients with hyperemesis gravidarum (5% weight loss, dehydration, and ketonuria) USPSTF recommendation level is B; evidence is poor (GRADE 2).

3.2. Few women with hyperemesis gravidarum will require ATD treatment. USPSTF recommendation level is A; evidence is good (GRADE 1). Overt hyperthyroidism believed due to coincident Graves’ disease should be treated with ATD. USPSTF recommendation level is B; evidence is
clearly elevated thyroid hormone levels (free T$_4$ above the reference range or total T$_4$ > 150% of top normal pregnancy value and TSH < 0.1 μU/ml) and evidence of hyperthyroidism may require treatment as long as clinically necessary. USPSTF recommendation level is I; evidence is poor (GRADE 1E).

4. AUTOIMMUNE THYROID DISEASE AND MISCARRIAGE

4.1. Although a positive association exists between the presence of thyroid antibodies and pregnancy loss, universal screening for antithyroid antibodies and possible treatment cannot be recommended at this time. As of this date, only one adequately designed intervention trial has demonstrated a decrease in the miscarriage rate in thyroid antibody-positive euthyroid women. USPSTF recommendation level is C; evidence is fair (GRADE 2E).

5. THYROID NODULES AND CANCER

5.1. Fine-needle aspiration (FNA) cytology should be performed for thyroid nodules larger than 1 cm discovered in pregnancy. Ultrasound-guided FNA may have an advantage for minimizing inadequate sampling. USPSTF recommendation level is B; evidence is fair (GRADE 1E).

5.2. When nodules are discovered in the first or early second trimester to be malignant on cytopathological analysis or exhibit rapid growth, pregnancy should not be interrupted, but surgery should be offered in the second trimester before fetal viability. Women found to have cytology indicative of papillary cancer or follicular neoplasm without evidence of advanced disease who prefer to wait until the postpartum period for definitive surgery may be reassured that most well differentiated thyroid cancers are slow growing and that surgical treatment soon after delivery is unlikely to adversely affect prognosis. USPSTF recommendation level is B; evidence is fair (GRADE 1E).

5.3. It is appropriate to administer thyroid hormone to achieve a suppressed but detectable TSH in pregnant women with a previously treated thyroid cancer or an FNA positive for or suspicious for cancer and those who elect to delay surgical treatment until postpartum. High-risk patients may benefit from a greater degree of TSH suppression compared with low-risk patients. The free T$_4$ or total T$_4$ levels should ideally not be increased above the normal range for pregnancy. USPSTF recommendation level is I; evidence is poor (GRADE 1E).

5.4. RAI administration with $^{131}$I should not be given to women who are breastfeeding. USPSTF recommendation level is B; evidence is fair (GRADE 1E). Furthermore, pregnancy should be avoided for 6 months to 1 yr in women with thyroid cancer who receive therapeutic RAI doses to ensure stability of thyroid function and confirm remission of thyroid cancer. USPSTF recommendation level is B; evidence is fair (GRADE 1E).

6. IODINE NUTRITION DURING PREGNANCY

6.1. Women of childbearing age should have an average iodine intake of 150 μg/d. During pregnancy and breastfeeding, women should increase their daily iodine intake to 250 μg on average. USPSTF recommendation level is A; evidence is good (GRADE 1E).

6.2. Iodine intake during pregnancy and breastfeeding should not exceed twice the daily recommended nutritional intake for iodine, i.e. 500 μg iodine per day. USPSTF recommendation level is I; evidence is poor (GRADE 1E).

6.3. To assess the adequacy of the iodine intake during pregnancy in a population, urinary iodine concentration should be measured in a cohort of the population. Urinary iodine concentration should ideally range between 150 and 250 μg/liter. USPSTF recommendation level is A; evidence is good (GRADE 1E).

6.4. To reach the daily recommended nutrient intake for iodine, multiple means must be considered, tailored to the iodine intake level in a given population. Different situations must therefore be distinguished: 1) countries with iodine sufficiency and/or with a well established universal salt iodization (USI) program, 2) countries without a USI program or an established USI program where the coverage is known to be only partial, and finally 3) remote areas with no accessible USI program and difficult socioeconomic conditions. USPSTF recommendation level is A; evidence is good (GRADE 1E).

7. POSTPARTUM THYROIDITIS

7.1. There are insufficient data to recommend screening of all women for PPT. USPSTF recommendation level is I; evidence is poor (GRADE 1E).

7.2. Women known to be thyroid peroxidase antibody positive should have a TSH performed at 3 and 6 months postpartum USPSTF recommendation level is A; evidence is good (GRADE 1E).

7.3. The prevalence of PPT in women with type 1 diabetes is 3-fold greater than in the general population. Postpartum screening (TSH determination) is recommended for women with type 1 diabetes mellitus at 3 and 6 months postpartum. USPSTF recommendation level is B; evidence is fair (GRADE 1E).

7.4. Women with a history of PPT have a markedly increased risk of developing permanent primary hypothyroidism in the 5- to 10-yr period after the episode of PPT. An annual TSH level should be performed in these women. USPSTF recommendation level is A; evidence is good (GRADE 1E).

7.5. Asymptomatic women with PPT who have a TSH above the reference range but less than 10 μU/ml and who are not planning a subsequent pregnancy do not necessarily require intervention but should, if untreated, be remonitored in 4–8 wk. Symptomatic women and women with a TSH above normal and who are attempting pregnancy should be treated with levothyroxine. USPSTF recommendation level is B; evidence is fair (GRADE 1E).

7.6. There is insufficient evidence to conclude whether an association exists between postpartum depression and either PPT or thyroid antibody positivity (in women who did not develop PPT). USPSTF recommendation level is I; evidence is poor (GRADE 1E).

However, because hypothyroidism is a potentially revers-
ible cause of depression, women with postpartum depression should be screened for hypothyroidism and appropriately treated. USPSTF recommendation level is B; evidence is fair (GRADE 2B).

8. SCREENING FOR THYROID DYSFUNCTION DURING PREGNANCY

Although the benefits of universal screening for thyroid dysfunction (primarily hypothyroidism) may not be justified by the current evidence (presented above), we recommend case finding among the following groups of women at high risk for thyroid disease by measurement of TSH:

1. Women with a history of hyperthyroid or hypothyroid disease, PPT, or thyroid lobectomy.
2. Women with a family history of thyroid disease.
3. Women with a goiter.
4. Women with thyroid antibodies (when known).
5. Women with symptoms or clinical signs suggestive of thyroid underfunction or overfunction, including anemia, elevated cholesterol, and hyponatremia.
7. Women with other autoimmune disorders.
8. Women with infertility who should have screening with TSH as part of their infertility work-up.
9. Women with previous therapeutic head or neck irradiation.
10. Women with a history of miscarriage or preterm delivery. USPSTF recommendation level is B; evidence is fair (GRADE 1B).

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