Checklist

BEFORE the meeting

☐ Invite your participants
☐ Reserve a location
☐ Instruct your PL Journal Club participants to go to PharmacistsLetter.com to print their PARTICIPANT NOTES. Instruct them to search for the keyword “Journal Club” and tell them which month PL Journal Club you intend to use.
☐ Print your copy of PL Journal Club LEADER NOTES, which will be emailed to you from Pharmacist’s Letter
☐ Organize refreshments

DURING the meeting

☐ Announcements
   • Welcome and introductions
   • Pass around attendance sheet
   • Pass out any needed PL Journal Club PARTICIPANT NOTES
   • Announce next meeting time, location, and discussion leader

☐ Discuss any recommendations that you have made, or new information that you have learned or observed based on the discussion at the last PL Journal Club meeting

☐ Proceed to use your PL Journal Club LEADER NOTES to facilitate the PL Journal Club discussion
The following succinct analysis appeared in *Pharmacist’s Letter*.

**THYROID**

You’ll hear experts debate the pros and cons of treating subclinical hypothyroidism or hyperthyroidism.

There are good points on both sides.

Subclinical HYPothyroidism is associated with an increased risk of ischemic heart disease, cardiovascular events, and mortality.

About 5% of patients have subclinical hypothyroidism...with normal free T3 and T4 thyroid levels but elevated TSH of 4.5 to 10.

Preliminary evidence suggests that treating patients ages 40 to 70 might decrease cardiovascular risk...and usually isn’t harmful.

Consider treating patients with a persistent mildly elevated TSH if they are symptomatic or have positive thyroid peroxidase antibodies.

Be careful not to overtreat...too much levothyroxine increases the risk of bone loss, atrial fib, etc.

Subclinical HYPERthyroidism is associated with a higher risk of atrial fibrillation, coronary heart disease, and osteoporosis.

About 1% of patients fall into this category...with a normal free T3 and T4 levels but a low TSH below 0.45 mU/L.

These patients seem to have about a 20% higher mortality over an average of 10 years...especially if TSH is suppressed below 0.1 mU/L.

Consider treating if patients have a low TSH for 3 to 6 months...especially if it’s below 0.1 mU/L...and they are symptomatic, over 65, or at high risk for heart disease or osteoporosis.

Tell patients the value of your thyroid screening...especially those who are older or symptomatic. When you find a patient who will likely benefit from treatment, explain the pros and cons.

(For more on this topic, see PL Detail-Document #280618 at PharmacistsLetter.com.)


Discussion Questions

**Overview of current therapy**

1. What is known about subclinical hypothyroidism in the risk of cardiovascular events?

- Subclinical hypothyroidism is defined as an elevated TSH concentration with normal T3 and T4 levels. This condition is found in up to 10% of the adult population.
- Numerous studies have found an association between subclinical hypothyroidism and cardiovascular disease (CVD). This effect tends to be more pronounced in middle-aged adults compared with elderly patients. A study demonstrated subclinical hypothyroidism in patients over 85 was actually associated with improved survival compared with euthyroid patients.
- It is unclear whether treatment of subclinical hypothyroidism is associated with a reduction in CVD risk. However, a significant portion of patients with subclinical hypothyroidism are treated with thyroid supplementation.
- This study used a prospective cohort study design to evaluate the treatment of new onset subclinical hypothyroidism by examining a large primary care patient data set from the United Kingdom.
Analysis of new study

2. What type of study was this and how were the patients selected?

- Subjects were included if they received a first-ever serum TSH determination during calendar year 2001.
- Subclinical hypothyroidism was defined as TSH of 5.01–10.00 mIU/L and normal free thyroxine (T4).
- Subjects aged 40 to 70 were in the “younger” group; subjects > 70 comprised the “older” group.
- Subjects were followed until March 31, 2009. Subjects were censored once they developed ischemic heart disease, stroke, or died.
- Subjects were excluded if they had a history of ischemic heart disease or cerebrovascular disease. In addition, subjects were excluded if they had poor quality records.
- A variety of potentially confounding variables, that may influence cardiovascular risk, were noted.
- Levothyroxine use was identified through prescription records.
- Comparisons were made between the subjects receiving levothyroxine and those who were not.

3. What’s the difference between a cohort study and a case-control study?

- With a cohort study, the investigators identify a group of exposed patients and compare them with a group of nonexposed patients. Both groups are then followed forward in time and observed for the occurrence of disease.
- A problem with cohort studies is confounding. For example, those patients who take levothyroxine may have a (perhaps undefined) higher risk for the development of CVD. Put another way, patients who take levothyroxine may not be similar to those who do not take levothyroxine.
- In a case-control study, investigators identify patients who have already developed the condition of interest (in this case CVD). These patients are then compared with a group of controls who are similar in every way, but do not have the disease of interest.
- The investigators then compare the rates of exposure to the agent (in this case levothyroxine) in both cases and controls.
- Similar to cohort studies, case-control studies can be affected by confounding. Spurious associations may occur when appropriate controlling of confounders is not performed.
- Well-done cohort and case-control studies use statistical tests to adjust for confounding variables.
- Only randomization can fix these problems. However, with rare events that develop over long periods of time, prospective randomized controlled trials may not be practical. In these cases, cohort and case-control trials can provide quick results that, if taken in context, may reveal intriguing findings.

4. How were the outcomes evaluated?

- The incidence of CVD was compared between those who received levothyroxine with those who did not.
- The primary outcome was a composite of fatal and nonfatal ischemic heart disease.
- Secondary outcomes included cerebrovascular disease, and all-cause and cause-specific mortality.
- Potential confounders were also evaluated. These included age, baseline TSH, sex, smoking status, body mass index, blood pressure, total cholesterol, presence of diabetes, as well as social and economic factors.
- Cox proportional hazards models were used to calculate hazard ratios and 95% confidence intervals while adjusting for covariates.

5. How were the study groups defined?

- Treated and untreated patients in the younger and older age groups were of similar ages. In addition, they were similar in regards to most other demographic and clinical characteristics.
• However, there were several clinically (and statistically) significant differences in the treated and untreated groups. In the younger group, these included a higher proportion of women, a higher baseline TSH concentration, and a lower free T4 concentration in the treated group. In the older group, treated patients were more likely to be female, had higher BMIs, higher baseline TSH concentrations, and lower baseline free T4 concentrations.
• In those treated, the mean levothyroxine dose was 75 mcg per day.
• The median follow-up period was 7.6 years in the younger cohort and 5.2 years in the older group.

6. **What were the strengths and weaknesses of this trial?**

• The study was done with a large sample size and followed patients for an extended period of time.
• Because the study utilized diagnosis codes, coding errors are possible. However, it is unlikely that these errors would be applied preferentially in one group over another. Reliability of the data regarding CVD has been shown to be more than 90%.
• The authors acknowledge that missing data is possibly related to confounders (smoking, BMI, etc).

7. **What was the association between levothyroxine therapy and risk of CVD in patients with subclinical hypothyroidism?**

• 3093 younger patients and 1642 older patients completed the study.
• In the younger group, after adjusting for multiple variables, ischemic heart disease was reduced in the levothyroxine treated group (adjusted HR, 0.61; 95% CI, 0.39–0.95).
• All-cause mortality was also decreased (adjusted HR, 0.36; 95% CI, 0.19–0.66).
• Cerebrovascular disease was unchanged.
• Each month of treatment with levothyroxine reduced the risk for ischemic heart disease (HR, 0.989; 95% CI, 0.986–0.993).
• New atrial fibrillation was not associated with levothyroxine use.
• Levothyroxine use was not associated with a change in ischemic heart disease in the older group.
• Similarly all-cause mortality was not changed in those treated with levothyroxine.
• Again, in this group, atrial fibrillation was not associated with exposure to levothyroxine.
• Several different sensitivity analyses reinforced the results.

8. **Were the results expressed in terms we care about and can use?**

• Yes. In this cohort study, treatment of subclinical hypothyroidism in patients aged 40–70 years was associated with a reduction in CVD.
• These results do not prove cause and effect, but do suggest the need for a randomized controlled trial.

**How should the new findings change current therapy?**

9. **How are the patients studied similar to those you see?**

• Do you presently offer levothyroxine to your patients with subclinical hypothyroidism? How often do you confirm an elevated TSH with a free T4 determination? How often do you evaluate thyroid function in patients with lipid disorders?
• The subjects studied in these trials appeared to be fairly typical of the population cared for in most primary care practices. These trial cohorts were derived from primary care practices in the U.K.
10. Do the results force you to change your practice? How?

- Thoughtful management of patients with subclinical hypothyroidism is warranted in these results. Although preliminary, it should help to guide treatment until a randomized controlled trial is done.

**Apply the new findings to the following case**

MK is a 48-year-old female complaining of fatigue for the last 6 months. She has never had any significant medical issues. She does not smoke and uses alcohol once a month socially. She takes no OTC medications.

11. What are some important conditions to consider?

<table>
<thead>
<tr>
<th>Depression and anxiety</th>
<th>Hypothyroidism</th>
<th>Rheumatoid arthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>EBV infection</td>
<td>Drug abuse</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>Diabetes</td>
<td>Chronic fatigue syndrome</td>
</tr>
</tbody>
</table>

12. MK is obese and seems to be depressed but otherwise her history and physical is normal. A PHQ-9 scored 19 (moderately severe depression). She relates poor sleep quality and increased appetite. What labs would you consider?

- CBC, fasting glucose, sensitive TSH

13. Her CBC and fasting glucose are normal. Her TSH is elevated at 8 mIU/L. What now?

- Treat the depression – with moderately severe depression, medication is recommended.
  - With her fatigue, you consider an activating SSRI such as fluoxetine or an SNRI such as venlafaxine.
  - You also refer her for counseling to help prevent recurrences.
  - You arrange for follow-up in 2–3 weeks to check for side effects.
- Evaluate elevated TSH – order a full thyroid panel.

14. After 3 weeks, MK is tolerating her venlafaxine well. Her TSH remains elevated at 8.2 mIU/L while T4, free T4 index, and T3 uptake are normal. What are your diagnoses and plans?

- Depression – continue venlafaxine and follow up in a month. Plan to repeat the PHQ-9 at that time to determine progress. Continue counseling.
- Obesity – consider ordering a sleep study to determine if she is suffering from sleep apnea. Counsel on weight loss and consider referral to nutritionist.
- Subclinical hypothyroidism (SCH) – elevated TSH with a normal T4. You elect not to treat at this point to determine if her fatigue is due to her depression.

15. What are the potential benefits from treating SCH in this patient? Potential harms? Would you start MK on thyroid medication for SCH?

- Prevent progression to overt hypothyroidism – up to half of patients with SCH will develop overt hypothyroidism over the next 10–20 years.
- Prevention of CVD – some observational studies show an association of SCH with increased CVD risk. A 2010 meta-analysis shows a significant association of SCH with coronary heart disease (CHD), CHD death, hospitalization for angina, or coronary revascularization with TSH over 10 mIU/L. A 2012 retrospective cohort showed that treatment of SCH was associated with fewer ischemic heart disease events in patients between 40 and 70 with TSH between 5.01 and 10.0 mIU/L.
- Prevention of death – some observational studies have shown an increased risk of CVD and/or all-cause mortality with SCH.
- Hypothyroid symptoms – some patients with SCH have improvement in symptoms such as fatigue and constipation while on replacement thyroxine.
- Cost of medication and monitoring, perhaps lifelong
- Potential for overtreatment that may lead to angina or cardiac arrhythmias
- Potential lack of benefit for patients > 65
You’ll see more guidance on what to use to prevent migraines. Prophylaxis is appropriate if patients use acute meds more than 2 days a week...or their headaches decrease their quality of life.

Choose a therapy based on the patient’s other conditions, such as a beta-blocker for a patient with hypertension.

Beta-blockers can be helpful if patients can tolerate the possible fatigue and exercise intolerance. Use propranolol, metoprolol, or timolol for the ones with the best evidence...and give it at bedtime.

Divalproex or valproate (Depakote, etc) can cause drowsiness, nausea, and weight gain...and can be teratogenic.

Be sure to avoid it in pregnancy and counsel about contraception.

Topiramate (Topamax, etc) is popular because it can cause weight LOSS. But explain that it’s also teratogenic...and it can cause cognitive impairment and might make oral contraceptives less effective.

Amitriptyline is now second-line due to poor tolerability.

Consider it if the patient also has insomnia, anxiety, or depression.

Or try combining low doses of a tricyclic and beta-blocker...the combo can be more effective and better tolerated than either one alone.

Venlafaxine (Effexor XR, etc) is a new alternative to amitriptyline. Titrate to 150 mg/day.

Next, consider lisinopril, candesartan, cyproheptadine, or NSAIDs (naproxen, etc)...these have modest evidence for prevention.

But keep in mind that chronic NSAIDs can lead to rebound headaches.

Don’t rely on SSRIs, gabapentin, or calcium channel blockers... evidence of a benefit is unreliable or conflicting.

Avoid lamotrigine...explain that it’s NOT effective.

Triptans or NSAIDs can be used to prevent menstrual migraine.

Start the drug 2 days before menses and continue it for 5 to 7 days.

Or use an extended-cycle oral contraceptive if appropriate to prevent menstrual migraine.

Botox (botulinum toxin) results in 2 fewer headache days than placebo for patients with CHRONIC migraines...on 15 or more days/month.

But explain it hasn’t been shown to help less frequent migraines.

Butterbur, riboflavin, magnesium, or feverfew may help prevent migraines. Explain they’re likely safe if people want to try them.

For butterbur, recommend using a product with 15% petasin and isopetasin, such as Petadolex, 75 mg twice daily.

Encourage patients to identify and avoid triggers...skipping meals, stress, disrupted sleep, alcohol, wine, cheese, aspartame, etc.

Get our PL Special Report, Natural Medicines in the Clinical Management of Headache, for efficacy, safety, and dosing.

(For more on this topic, see PL Detail-Document #280620 at PharmacistsLetter.com.)
Discussion Questions

Background, scope, and purpose of the treatment guideline

1. What is already known about the prevention of migraine headache?

- Nearly 40% of migraineurs should receive preventive therapy; however only 3–13% receive it.
- The direct and indirect costs of migraine headaches reach more than $13 billion.
- Preventive therapy of migraine is indicated in patients who: 1) have ≥ 2 attacks per month producing disability of ≥ 3 days per month; 2) contraindication to or failure of acute treatments; 3) use of abortive medication > twice per week; 4) the presence of uncommon migraine conditions including hemiplegic migraine, migraine with prolonged aura, or migrainous infarction [Ann Intern Med 2002;137(10): 840-9].
- Antiepileptic medications, antidepressants, antihypertensives, and other products have been used as preventive therapies for migraine headache.
- This review article provided management strategies for the prevention of migraine headache.

2. What is the overall objective of the guideline or therapeutic review?

- This review was developed to systematically review new information on migraine prevention published since the last guideline. The article addresses the safety and efficacy of medications used to prevent migraine headaches.
- Over 40 references are provided.

3. What clinical question does the review address? What kinds of patients does it apply to? Are these patients similar to your patients?

- The guideline was developed to answer the following clinical question: For patients with migraine, which pharmacologic therapies are proven effective for prevention, as measured by reduced migraine attack frequency, reduced number of migraine days, or reduced attack severity?
- The guideline applies to all patients who qualify for preventive therapy.
- Most primary care practices will treat frequent migraineurs.

Evidence-based methodology

4. Was there a systematic strategy to find the studies that the review article is based upon?

- Yes. The authors state an explicit description of the analytic process. Briefly, computerized searches of biomedical databases were performed. Randomized controlled trials published between June 1999 and May 2007 were reviewed and included if they met specific criteria.
- Quality guidelines include detailed validity assessments of the articles included in the review. This generally includes statistical tests to determine if the results of the studies included are homogeneous and whether publication bias may be present. These tests were not included in this guideline.
- In this article, the authors provide a detailed analysis of the evidence with specific therapeutic outcomes.

5. Were adverse effects and quality of life considered?

- Yes. Most recommendations included some discussion of adverse effects and therapeutic outcomes.
- Studies were not included if quality of life was the primary outcome.

6. Are all treatment options discussed? Is the guideline up-to-date? Is the guideline important?

- This is a comprehensive review of treatments related to migraine prevention up to May 2009.
• This review is important. The burden of migraine headache is substantial with a large economic impact as well. Disseminating evidence-based information related to the prevention of migraine headache is extremely valuable.

Ease of use and clarity of presentation

7. Are the recommendations easily identified? Are they specific and unambiguous?

• The review article is easy to read and is organized by therapeutic drug category and level of evidence.
• The review does emphasize the strengths and weaknesses of the evidence described.

8. What is needed to implement the recommendations? Are performance measures provided?

• The majority of the interventions recommended in the review article are relatively simple to implement.
• The costs of the various interventions are not included although the authors note that drug costs should be considered and may affect patient compliance with the regimen.
• Performance measures are not included (e.g. the desired percentage of patients achieving a clinically meaningful treatment outcome).

9. What are the different types of review articles and how do they differ in their usefulness?

• Practice guidelines may be simply a compilation of opinions or very detailed and rigorous and include very specific recommendations with levels of evidence (i.e. the Chest guidelines). Well-done practice guidelines are extremely useful for clinicians and provide comprehensive, detailed advice for the management of patients.
• Other types of reviews are considered a “summary review” and are designed to broadly paint the landscape associated with a therapeutic topic. Because they lack a systematic methodology, summary reviews have uncertain validity. Experts who base content on their opinions, rather than the entire evidence base, frequently write them. References may be selectively used and the literature review may be less than comprehensive. Finally, in order to apply the information to clinical practice, the reader may be required to verify certain references, which may be time consuming.
• Systematic reviews, including meta-analysis, are designed to answer very specific questions. In this setting, the authors evaluate the primary literature with strict criteria. Conclusions are supported with levels of evidence and a variety of statistical tests are applied to evaluate the heterogeneity of the results being combined. Systematic reviews of randomized controlled trials provide one of the highest levels of evidence to aid clinical decision-making.
• Committees working together to synthesize a body of literature to aid clinical care generally produce consensus statements. Unfortunately consensus statements vary widely in their quality and can be influenced by “the loudest voice in the room” (i.e. the opinion of one or two influential individuals). Because they often lack a systematic methodology, the usefulness of consensus statements varies widely.

10. What were the major recommendations from this evidence-based guideline?

• Valproate, topiramate, metoprolol, propranolol, timolol, and frovatriptan have the highest level of evidence associated with their use in migraine.
• Amitriptyline, venlafaxine, atenolol, nadolol, naratriptan, and zolmitriptan are probably effective.
• Calcium channel blockers have inadequate or incomplete data to support or refute their use.
• All these drugs may cause significant side effects; monitoring strategies are provided.
• Although the above summary statements are supported by randomized controlled trials, these studies are generally small and of short duration.

Editorial independence

11. Are potential conflicts of interest clearly stated?

• Financial disclosures and conflict of interest for the authors are included.
Apply the new findings to the following case

JD is a 28-year-old male with a severe headache that started about 3 hours ago in the morning. He has not had severe headaches in the past. This is the worst headache he has ever had. He has no other relevant history.

12. What is the first step in evaluating JD?

- The first step is a thorough history and physical exam. Laboratory testing and radiographic testing will be important as well.
- Urgent treatment of his pain is also important. Consider an emergency room if your office is not equipped to deal with these types of patients.

13. You suspect new onset migraine headaches. What aspects of the history and physical would be consistent with this diagnosis?

History
- Recurrent attacks
- Prodrome – 24 to 48 hours before headache. Include euphoria, depression, irritability, neck stiffness, increased yawning.
- Aura – occurs in about 25% of patients. Focal neurologic symptoms such as visual changes or even sensory, verbal, or motor disturbances. Classic aura is visual and begins as a bright spot, which progresses to geometric shapes or zigzagging lines.
- Headache – usually unilateral, throbbing, nausea and vomiting, photo/phonophobia, lasts 4 hours to several days
- Postdrome – Feel drained or exhausted and pain can recur with sudden head movements
- Precipitating factors include, but are not limited to emotional stress, menses, not eating, weather changes, disturbed sleep, odors, alcohol.
- Physical – typically normal
- Cutaneous allodynia – perception of pain with benign stimulation of normal skin

14. What tests would you order for JD?

- As the patient is complaining of the worst headache of his life, a noncontrast CT is indicated to rule out subarachnoid hemorrhage. JD’s CT scan is normal.
- No other labs are recommended for initial evaluation of a migraine headache. Labs should be ordered based on findings of the history and physical exam.

15. What acute treatment would you recommend? What about preventative therapy?

- For a moderate to severe migraine headache, a triptan is a good initial choice.
- No triptan is more effective than another. Choose based on side effects and delivery routes.
  - Sumatriptan offers the most delivery options.
  - Rizatriptan has the fastest onset of action.
  - Almotriptan has fewer side effects than sumatriptan.
- In the emergency room setting, consider:
  - IV metoclopramide 10 mg or prochlorperazaine 10 mg with 12.5 to 20 mg of diphenhydramine (to prevent dystonic reactions)
  - IV dihydroergotamine (DHE 45) with metoclopramide 10 mg for severe intractable migraine
- Oral agents may not be effective due to poor absorption from gastric stasis.
- In addition, IV or IM dexamethasone 10–25 mg reduces the risk of early headache recurrence.
References

THYROID


Additional Pharmacist’s Letter Resources available at PharmacistsLetter.com
PL Detail-Document, Should subclinical hypothyroidism or hyperthyroidism be treated? Pharmacist’s Letter/Prescriber’s Letter. June 2012.

MIGRAINE


Additional Pharmacist’s Letter Resources available at PharmacistsLetter.com
Drugs used to prevent migraine headaches. Pharmacist’s Letter/Prescriber’s Letter 2011;27(3):270308.
Welcome to PL Journal Club

PL Journal Club gives you insights and guides you to the discoveries that Pharmacist’s Letter researchers and editors uncover. Each month we analyze many new studies and help you discover the answers to the hard questions. “What are the real advantages and disadvantages of new therapies?” “How do they compare with other options?” “What do pharmacists and prescribers need to know?” We look beyond the headlines and promotional materials to interpret the clinical studies and data. Sometimes the marketing spin doesn’t stand up to scrutiny. Sometimes studies do not really prove what they are reported to prove. PL Journal Club helps guide you to the truth and how to apply new findings to patient care.

PL Journal Club builds on Pharmacist’s Letter to provide you with background for your own journal club discussions. We won’t bring up every possible question, but you can…in your own group meetings. If a question comes up, go to PharmacistLetter.com to find more background. As a PL Journal Club participant, you get access to all of Pharmacist’s Letter. Feel free to call or email us with suggestions or if we can be of assistance...209-472-2240 or PLJournalClub@pletter.com.

Instructions

Go to PharmacistLetter.com to get the PL Journal Club PARTICIPANT NOTES. Use the search function to look for “Journal Club.” You’ll also get great background materials, including Pharmacist’s Letter and PL Detail-Documents. PL Journal Club functions like a typical group meeting, except that it is organized for you with the expert analysis of important new studies done by the large Pharmacist’s Letter research and editorial staff. Let the questions serve as a springboard for your discussions. Let your own patient cases shape the discussion. Each month PL Journal Club gives you two topics that are also covered in Pharmacist's Letter. Your group might discuss only one or both topics. You’ll also find a library of previous PL Journal Clubs online for your use.

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AFTER the meeting

☐ File your attendance rosters

☐ Note the next *PL Journal Club* meeting

☐ Send email invitations and reminders to participants

NOTES

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