

## Which postmenopausal women should be offered combined HRT?

### ■ EVIDENCE-BASED ANSWER

Recent studies have demonstrated a small but significant risk of adverse effects from combined hormone replacement therapy (HRT), including cardiovascular disease, thromboembolic disease, and breast cancer. Time-limited HRT will control intolerable menopausal symptoms and prevent risk of fractures in newly menopausal women. However, HRT achieves its maximum efficacy in 35 years, and the risk of adverse outcomes increases as time progresses. Women considering HRT, particularly those at higher risk for vascular disease and breast cancer, should be informed of the potential risks.

There is inadequate evidence to determine the extent of these risks in women who have had a hysterectomy and are taking unopposed estrogen (strength of recommendation: **A**, based on large randomized controlled trials).

### ■ EVIDENCE SUMMARY

The Women's Health Initiative (WHI),<sup>1</sup> the largest randomized trial of HRT, showed that long-term use of HRT poses more risks than benefits for healthy postmenopausal women. WHI studied the use of estrogen plus progestin for prevention of coronary heart disease in 16,608 postmenopausal women age 50–79 years. After 5 years of follow-up, this arm of the study was stopped because of the adverse effects of the intervention. The researchers found that HRT increases the risk of several events:

- coronary heart disease events (number needed to harm [NNH]=1428)
- invasive breast cancer (NNH=1250)
- stroke (NNH=1250)

- venous thromboembolic events (NNH=555)
- pulmonary embolism (NNH=1250).

An ongoing arm of WHI is studying estrogen alone in postmenopausal women who have had a hysterectomy.

The Heart and Estrogen/progestin Replacement Study (HERS)<sup>2</sup> examined the effects of HRT in postmenopausal women with coronary artery disease. HERS was a large randomized controlled trial of 2763 women with an average follow-up time of 4.1 years. It showed no statistically significant difference between the HRT (estrogen plus medroxyprogesterone) group compared with the placebo group in either the primary outcomes (nonfatal myocardial infarction or coronary heart disease death) or in the secondary outcomes (coronary revascularization, unstable angina, congestive heart failure, resuscitated cardiac arrest, stroke or transient ischemic attack, and peripheral arterial disease). The findings

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## What is a Clinical Inquiry?

Clinical Inquiries answer real questions that family physicians submit to the Family Practice Inquiries Network (FPIN), a national, not-for-profit consortium of family practice departments, residency programs, academic health sciences libraries, primary care practice-based research networks, and individuals with particular expertise.

Questions chosen for Clinical Inquiries are those considered most important, according to results of web-based voting by family physicians across the U.S.

Answers are developed by a specific method:

- First, extensive literature searches are conducted by medical librarians.
- Clinicians then review the evidence and write the answers, which are then peer reviewed.
- Finally, a practicing family physician writes a commentary.

of the WHI and HERS trials have been summarized in a recent meta-analysis done for the United States Preventive Services Task Force.<sup>3</sup>

Both the WHI and HERS trials demonstrated some benefits for HRT. WHI found a reduced risk of colorectal cancer (number needed to treat [NNT]=1667) and a decreased risk of any osteoporotic fracture (NNT=228). The HERS group found that HRT improved the quality of life of women with postmenopausal symptoms, particularly flushing.

Evidence indicates that women who take HRT for 3 years and then stop achieve as much protection from osteoporotic fractures as women who continue their HRT beyond 3 years.<sup>4</sup>

Continuing HRT beyond 5 years dramatically increases the risk of coronary heart disease, stroke, thromboembolic events, breast cancer, and cholecystitis.<sup>3</sup>

### ■ RECOMMENDATIONS FROM OTHERS

The American College of Obstetricians and Gynecologists has convened a multispecialty panel of experts to draft new recommendations for HRT in light of the WHI findings.

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### ■ CLINICAL COMMENTARY

The WHI and HERS trials demonstrated that long-term use of HRT (>5 years) incurs significantly more risks than benefits for a postmenopausal woman who has not undergone hysterectomy. However, these trials did not evaluate postmenopausal symptoms or quality of life as primary endpoints.

Most women experience postmenopausal symptoms for more than 1 year but have resolution of

symptoms within a few years after menopause. Since HRT remains the most effective therapy for hot flashes, short-term use of HRT (<5 years) may be offered to women experiencing postmenopausal symptoms.

Physicians may instruct women to attempt HRT discontinuation each year because the duration of symptoms can be variable. Discontinuation should be performed using gradual dose reductions to prevent rapid return of postmenopausal symptoms.

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## Is pneumococcal vaccine effective in nursing home patients?

### ■ EVIDENCE-BASED ANSWER

Evidence from clinical trials supports the use of pneumococcal polysaccharide vaccine for prevention of pneumonia in nursing home patients (strength of recommendation: **B**, based on randomized, nonblinded clinical trials).

Case-control studies have consistently shown the efficacy of pneumococcal vaccine in preventing invasive pneumococcal disease and bacteremia for

patients with chronic medical illnesses and the elderly, patients typically found in nursing home populations (SOR: **B**, based on consistent case-control studies).

### ■ EVIDENCE SUMMARY

Two clinical trials directly addressed the prevention of pneumonia in nursing home patients. A prospective, risk-stratified, randomized study of the 14-valent pneumococcal vaccine in 1686 patients living in hospices and nursing homes in France showed an absolute risk reduction (ARR) of 2.9% in the incidence of all-cause pneumonia, corresponding to a number needed to treat (NNT) of 35.<sup>1</sup> This study has 2 major limitations: the authors did not comment on whether the study was blinded, and 31% of patients were lost to follow-up.

A 6-year randomized clinical trial that studied the trivalent pneumococcal vaccine in preventing pneumonia in New York City Home (a nursing home) subjects showed an ARR=2.7% and NNT=37.<sup>2</sup> While this report also did not specify whether there was blinding, any bias introduced by absence of blinding is unlikely to account for the large effect size (relative risk reduction=0.56).

Nursing home residents may be especially vulnerable to acquiring pneumococcal infection due to advanced age, chronic illnesses, and their communal setting. The Centers for Disease Control and Prevention (CDC) has reported outbreaks of invasive pneumococcal disease in nursing homes where vaccination rates are low.<sup>3</sup> Pneumococcal bacteremia is seen in only 10%–20% of patients with pneumococcal pneumonia but confers a significant risk of death. Therefore, pneumococcal vaccination is indicated for patients  $\geq 65$  years or those with chronic medical conditions.

Case-control studies have consistently shown efficacy in preventing invasive pneumococcal disease. Farr and colleagues found efficacy of 70% (95% confidence interval [CI], 37%–86%) among 2 groups of patients: those  $\geq 2$  years of age with chronic disease or those  $\geq 65$  years.<sup>4</sup> A case-control study by Sims and colleagues also found the vaccine to have efficacy of 70% (95% CI, 37%–

86%) in preventing invasive pneumococcal disease in immunocompetent patients aged  $\geq 55$  years.<sup>5</sup>

### ■ RECOMMENDATIONS FROM OTHERS

The CDC Advisory Committee on Immunization Practices (ACIP) recommends pneumococcal vaccination of persons aged  $\geq 65$  years and those aged 2 to 64 who have chronic cardiovascular disease, chronic pulmonary disease, or diabetes mellitus (SOR: **A**).<sup>6</sup>

The ACIP also recommends the pneumococcal vaccine for persons aged 2 to 64 years who have alcoholism, chronic liver disease, or cerebrospinal fluid leaks (SOR: **B**).

The Canadian Task Force on Preventive Health Care endorses vaccination for immunocompetent patients  $\geq 55$  years residing in institutions (SOR: **A**).<sup>7</sup>

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### ■ CLINICAL COMMENTARY

The importance of pneumococcal vaccine for the elderly is well established. However, the vaccine is underused in long-term care settings, despite being indicated for most residents.

Patient confusion about the need for both influenza and pneumococcal vaccines, poor documentation of adult immunization status, poor availability of records from previous care facilities, and frequent changes in physician all contribute to low vaccination rates.

An optimal strategy to ensure high vaccination rates is to administer the pneumococcal vaccine to patients on admission to long-term care facilities. Patients who are uncertain about their vaccination status may safely receive the vaccine, as revaccination is relatively well tolerated.<sup>8</sup>

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## Does cranberry juice prevent or treat urinary tract infection?

### ■ EVIDENCE-BASED ANSWER

Cranberry juice (200 mL daily to 250 mL 3 times daily) or cranberry concentrate tablets (at least 1:30 parts concentrated juice twice daily) reduce recurrent, symptomatic urinary tract infection (UTI) in women by 12% to 20% (absolute risk reduction [ARR]) compared with placebo (number needed to treat [NNT]=58) (strength of recommendation: A). There is no conclusive evidence that cranberry juice effectively treats UTI (SOR: D).

### ■ EVIDENCE SUMMARY

A Cochrane review found only a small number of poor-quality trials, providing insufficient support to recommend cranberry juice to prevent UTI.<sup>1</sup> However, 2 recent randomized studies, not included in the Cochrane review, found that women taking cranberry juice have fewer symptomatic UTIs.

In women with prior *Escherichia coli* UTI, 50 mL of cranberry-lingonberry juice concentrate daily for 6 months reduced the recurrence of symptomatic UTI from 36% in the control group to 16% in the treated group (NNT=5).<sup>2</sup>

In a placebo-controlled randomized trial, women with prior UTI who took 1 tablet of concentrated cranberry juice (at least 1:30 parts concentrated juice) twice daily (n=50) or drank 250 mL of pure unsweetened cranberry juice 3 times a day for 12 months (n=50) reduced their incidence of symptomatic UTI.<sup>3</sup> Women who drank the juice had an ARR of 12% (32% symptomatic UTI on placebo group, 20% in cranberry juice group, NNT=8.3) over 1 year. Use of cranberry juice tablets produced an ARR of 14% (32% symptomatic UTI in placebo group; 18% in cranberry tablet group, NNT=7.1). Self-reported compliance was 75% to 90% in the juice group and 90% in the tablet group.

No dose-response studies have been done to determine the optimal volume of juice or number of tablets needed to prevent infection. Studies have used between 200 mL once a day to 250 mL 3 times a day of the juice or 1 cranberry tablet taken twice daily. The subject dropout rate was as high as 34% in one study using juice,<sup>4</sup> implying that cranberry juice—which is acidic and astringent at full strength—may not be acceptable to many patients as a prophylactic therapy over a long period. The 1-month compliance rate of patients taking cranberry tablets was between 88% and 100%, suggesting that this form of cranberry may improve compliance.

The cost of cranberry juice and cranberry tablets was estimated at \$1400 and \$624 per year, respectively.<sup>3</sup> This must be balanced

against the cost of treating symptomatic UTIs. No randomized trials have tested the more readily available and palatable cranberry juice cocktail—which is mixed with water, a sweetener, and vitamin C—to prevent recurrent UTI.

Cranberry juice does not inhibit bacterial growth and will not sterilize the urinary tract. Also, cranberry juice does not prevent or treat UTI by changing the pH of the urine. Rather, the suspected mechanism of action is that proanthocyanidins contained in cranberry juice prevent bacterial adherence to uroepithelial cells, thus reducing the development of UTI.<sup>5</sup> Cranberry juice has been shown to reduce uroepithelial cell adherence by bacteria resistant to trimethoprim-sulfamethoxazole.<sup>6</sup>

#### ■ RECOMMENDATIONS FROM OTHERS

No national practice guidelines have recommended cranberry juice as a preventive strategy for recurrent UTI but, anecdotally, patients are often advised to try cranberry juice to prevent UTI.

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#### ■ CLINICAL COMMENTARY

The protective value of cranberry juice against UTI bacteria is supported by a significant body of data from in vitro studies. The published studies examining the clinical use of cranberry juice for UTI prevention suffer from a number of flaws, including small sample size, poor design, lack of randomization, lack of placebo control, heterogeneous endpoints, and a focus on the geriatric population. Even the best of these studies suffers from a major defect: failure to use commonly available cranberry juice cocktail as the experimental intervention.

Despite these flaws, the weight of the clinical evidence suggests that cranberry juice is an effective intervention for the prevention of

### Patients may not tolerate full-strength cranberry juice—which is acidic and astringent—over a long period

UTIs—especially in high-risk populations. Unfortunately, cranberry juice is expensive and its taste is displeasing to some, thus limiting its usefulness. Cranberry capsules/tablets offer a reasonable alternative, but their composition varies greatly by manufacturer, and patient compliance may be poor.

The decision to use cranberry juice should be left to the patient and her clinician.

Given the evidence, cranberry juice is best suited for secondary prevention of recurrent UTI. Patients with recurrent UTI who are being considered for antibiotic prophylaxis and are willing to drink the juice are ideal candidates. Although the studies have yet to establish an ideal dose, 3 glasses a day should be sufficient.

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## Are drug therapies effective in treating Bell's palsy?

- Photocopy for your patients "Bell's palsy" on page 160.

### ■ EVIDENCE-BASED ANSWER

Early use of corticosteroid therapy results in less autonomic synkinesis and possibly improved rates of recovery in adults (strength of recommendation: **C**); there is no proven benefit in children (SOR: **B**).

Adding acyclovir (Zovirax) to prednisone therapy may improve recovery rates compared with prednisone alone (SOR: **C**).

The results of 1 nonblinded study indicate that intramuscular methylcobalamin (vitamin B<sub>12</sub>) used alone or in combination with prednisone may shorten time to recovery (SOR: **C**).

### ■ EVIDENCE SUMMARY

Bell's palsy is a lower motor neuron disease of the facial nerve characterized by a transient paralysis. Healing is occasionally incomplete, resulting in residual nerve dysfunction, including partial palsy and motor synkinesis (involuntary movement accompanying a voluntary one) and autonomic synkinesis (involuntary lacrimation after a voluntary muscle movement). Bell's palsy is associated with significant edema and

ischemia of the facial nerve as it passes through its bony canal.

Herpes simplex reactivation has been shown to be associated with a large proportion of cases.

Corticosteroids are the most studied form of therapy for Bell's palsy (**Table**). Early work in England culminated in 1971 with a well-performed study demonstrating lower rates of incomplete recovery with prednisolone compared with corticotrophin.<sup>1</sup> A potentially definitive randomized controlled trial in 1970 was stopped prematurely because of investigators' subjective impression that prednisone markedly reduced postauricular pain.<sup>2</sup> Subsequently, the highest-quality study had few patients (n=51) and reported no difference in outcomes between patients receiving 10 days of oral prednisone plus vitamins and those receiving vitamins alone.<sup>3</sup>

One open randomized controlled trial demonstrated shorter mean recovery times with intramuscular methylcobalamin (1.95 weeks) and methylcobalamin plus prednisone (2.0 weeks) compared with prednisone alone (9.6 weeks).<sup>4</sup> Another trial of 239 patients showed improved rates of autonomic synkinesis after treatment with 16 days of prednisone compared with placebo.<sup>5</sup>

A randomized, controlled trial of children 2 to 6 years of age found no significant differences in short-term recovery after treatment with methylprednisolone compared with untreated controls.<sup>6</sup> Eventually, all these children recovered normal

**TABLE**

### Therapies for Bell's palsy

Drug	Dosage	SOR
Prednisone (adults only)	Total from 410 mg over 10 days, to 760 mg over 16 days (tapering doses)	C
Acyclovir	400 mg 5x/d for 10 days	C
Methylcobalamin	500 (g IM 3x/wk until full recovery, or for 8 weeks	C

SOR, Strength of recommendation

facial nerve function within 12 months.

Two randomized controlled trials have assessed the efficacy of acyclovir for treatment of Bell's palsy. One trial compared prednisone with acyclovir and found patients treated with prednisone had better complete recovery rates, 93.6% versus 77.7% (absolute risk reduction [ARR]=15.9%, 95% confidence interval [CI]=2.8%–29%), number needed to treat [NNT]=7).<sup>7</sup>

Another study demonstrated that the combination of prednisone and acyclovir had greater complete recovery rates compared with prednisone alone (92% vs. 76%, ARR=16%, 95% CI=1.7%–30.3%, NNT=7).<sup>8</sup>

Overall, the data suggest corticosteroid therapy may provide a small clinical benefit in adult patients with Bell's palsy. In many of these studies, patients who had contraindications to steroid therapy (peptic ulcer disease, uncontrolled diabetes, hypertension, or immunosuppression) were excluded.

If no contraindications to steroids exist, it is reasonable to initiate treatment with corticosteroids for an adult patient with new-onset Bell's palsy. Most studies have started patients on steroids within 10 days of onset of symptoms.

### ■ RECOMMENDATIONS FROM OTHERS

A practice parameter from the American Academy of Neurology states that steroids are safe and probably effective (SOR: **B**), whereas acyclovir is safe and possibly effective (SOR: **C**).<sup>9</sup> Systematic reviews from the Cochrane Database report that available evidence from randomized controlled trials does not show significant benefit from treating Bell's palsy with corticosteroids and that clinical trials on acyclovir are inconclusive and therefore cannot be used to make recommendations regarding its use.<sup>10,11</sup>

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### ■ CLINICAL COMMENTARY

My practice of neurology began before the era of corticosteroid treatment for Bell's palsy. Despite the lack of convincing evidenced-based data, it is my clinical impression that there are far fewer patients today with incompletely resolved Bell's palsy than before the widespread use of steroids. Permanent facial deformities seemed more common back then. Therefore, in the absence of harmful effects, I will continue treating with steroids.

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From the Office of Dr. \_\_\_\_\_

## Bell's palsy

### What is Bell's palsy?

Weakness and slumping on one side of the face are common features of this condition in which the *nerve controlling the face* has been injured.

Other symptoms are:

- Inability to move affected side of the face
- Drooping mouth, unblinking eye
- Numbness
- Twitching of facial muscles
- Taste disturbance
- Increased sensitivity to sound.

Symptoms usually start suddenly. Pain behind the ear may be felt hours to days before other symptoms appear. People between ages 30 and 60 years are most likely to be affected, but this disorder can happen at any age.

Any sudden weakness of the face also suggests the possibility of stroke—a serious emergency. You should contact your physician immediately.

### Possible causes

The most common cause of Bell's palsy is an infection of the facial nerve by the herpes simplex virus. Your doctor will also ask about possible recent trauma to the face and will check for swelling of facial tissues or a mass pressing on the facial nerve.

### What to expect

In many cases, the symptoms of Bell's palsy go away in about 3 weeks without treatment, and the face regains its normal appearance. A good sign that this will happen is if the weakness or other symptoms begin to resolve after 1 week.

In other cases, symptoms may take several months to disappear. Lasting effects are possible, though rare.

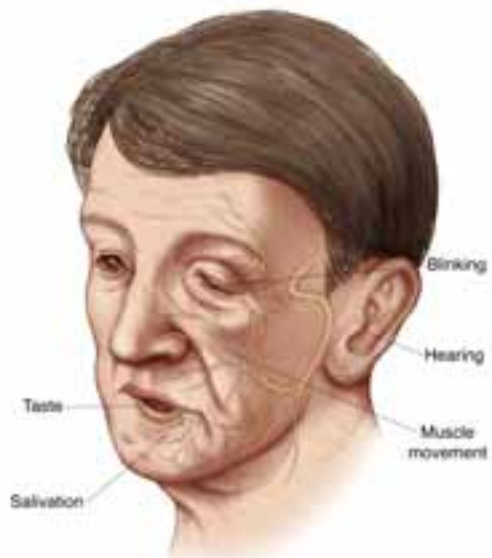


ILLUSTRATION BY STEVE OH

*In Bell's palsy, one side of the face becomes paralyzed due to an injury to the facial nerve, which controls facial muscles, tearing, and blinking.*

### Treatments your doctor may prescribe

If a viral infection is the likely cause of your symptoms, your doctor may have you take acyclovir (Zovirax), famciclovir (Famvir), or another **antiviral medication** to speed your recovery. These antiviral medications are taken as pills, usually a few times a day for 10 days.

A **steroid** (prednisone, for example) may also help to reduce swelling that could be pressing on the facial nerve. This medication is also administered as a pill over 1 to 2 weeks.

If you cannot blink, and dryness of the eye is one of your symptoms, your doctor will ask you to use moisturizing eye drops to protect the eye from damage while you recover.

The variety of different symptoms you are experiencing is due to the fact the facial nerve controls normal functions from your forehead to your chin—including tearing, taste, muscle movement, and blinking.

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