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CME TEST

15 April 2012

What medications are safe and effective for aggressive behavior in patients with dementia?

Bottom line

Atypical antipsychotic agents (eg, aripiprazole, olanzapine, and risperidone) have been shown to improve some behavioral symptoms, including aggression, in patients with dementia, but also increase mortality compared with placebo. (SOR: A, based on consistent meta-analyses.) Haloperidol decreases aggression in patients with dementia but can cause somnolence, fatigue, and extrapyramidal symptoms. (SOR: A, based on a meta-analysis.) The selective serotonin reuptake inhibitors (SSRIs) citalopram and sertraline improve agitation and psychosis and have been suggested as a safer alternative to antipsychotic agents. (SOR: B, extrapolated from a meta-analysis.)

Evidence summary

Atypical antipsychotic agents

A meta-analysis of 37 controlled trials involving more than 5,000 elderly patients with dementia compared the effect of an atypical antipsychotic agent (risperidone, olanzapine, quetiapine, aripiprazole, ziprasidone, asenapine, iloperidone, paliperidone) with placebo, another active drug, or another atypical antipsychotic agent.1 Multiple medication dosages were used in the trials and the meta-analysis compared global outcome scores based on symptoms including psychosis, mood alteration, and aggression. No subanalysis was performed on aggression alone.

With a duration of follow-up from 6 to 26 weeks, small but statistically significant effect sizes (ES) were found for aripiprazole (ES 0.20; 95% CI, 0.04–0.35), olanzapine (ES 0.12; 95% CI, 0.00–0.25), and risperidone (ES 0.19; 95% CI, 0.00–0.38). (An effect size of 0.2 is considered small, 0.6 moderate, and 1.2 large.) Individual studies within the analysis suggested that higher doses of aripiprazole (10 mg/d) and risperidone (2 mg/d) were more effective than lower doses.1

However, atypical antipsychotic agents are not completely safe for elderly patients. Based on meta-analyses of safety data, the US Food and Drug Administration has issued a black box warning for atypical
antipsychotic agents, stating that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs are at an increased risk of death.\(^2\)\(^3\) (Editor’s note: Two HDAs in this issue of EBP further explore the risks of atypical antipsychotic agents.)

**Haloperidol**

A meta-analysis of 5 trials compared the effect of haloperidol (0.25–6 mg daily) with placebo in 856 patients with mild to severe dementia and agitation over 3 to 16 weeks.\(^4\) Three of 5 trials in this meta-analysis assessed aggression in a subset of 690 patients using 3 different assessment tools, demonstrating a benefit in patients treated with haloperidol. The authors noted symptom scores were typically 31% lower on Haldol than placebo (95% CI, –49% to –13%; \(P=.0006\)).

In pooled analysis of the data, adverse events related to use of haloperidol included extrapyramidal symptoms (OR 2.34; 95% CI, 1.25–4.38; NNH=6), somnolence (OR 4.20; 95% CI, 1.78–9.91; NNH=8), and fatigue (OR 5.39; 95% CI, 2.04–14.22; NNH=3).

**Antidepressants**

A meta-analysis of 9 trials including 692 patients looked at 4 studies comparing SSRIs with placebo, 3 studies comparing SSRIs with typical antipsychotics, 1 study comparing SSRIs with atypical antipsychotics, and 1 study comparing trazodone with haloperidol.\(^5\) The primary outcome was change in symptoms of agitation and psychosis on various neuropsychiatric symptom scales.

Sertraline (25–200 mg daily) and citalopram (10–30 mg daily) were associated with a “modest reduction” in symptoms of agitation and psychosis (Cohen Mansfield Agitation Inventory [CMAI] total score of –0.89 from baseline; 95% CI, –1.22 to –0.57; \(P<.001\)) over a 3- to 12-week period. For context, the CMAI involves rating 29 agitated behaviors on a scale of 1 to 7, where a 1 represents “never occurs” and a 7 represents a behavior that occurs “several times an hour.” There was no statistically significant difference in outcomes with SSRIs compared with typical or atypical antipsychotic agents. In addition, there was no difference in withdrawal rate due to adverse events with SSRIs compared with placebo or typical or atypical antipsychotics. SSRIs are known to be associated with serious side effects including gastrointestinal bleeding, hyponatremia, falls, and fractures.

**Recommendations from others**

In 2006, an expert geropsychiatry panel issued consensus guidelines for treating agitation and aggression in patients with dementia.\(^6\) The panel recommended using nonpharmacologic treatment initially. If nonpharmacologic treatment fails, then the panel stated that antipsychotic agents might be used with appropriate family consent and careful review of risks, benefits, and outcomes if the patients were not treated.

The American Psychiatry Association recommends the use of antipsychotic medications for treatment of agitation in patients with dementia at the lowest effective dose after considering the risks of not treating and side effect profiles, and discussing the risks and benefits with family members.\(^7\) Additionally, they recommend the use of serotonin reuptake inhibitors in patients with mild agitation or a history of an adverse reaction to antipsychotic medications.

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**REFERENCES**


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**Evidence-Based Practice**

**learning objectives**

1. To become knowledgeable about evidence-based solutions to commonly encountered clinical problems.
2. To understand how ground-breaking research is changing the practice of family medicine.
3. To become conversant with balanced appraisals of drugs that are marketed to physicians and consumers.
How do we know that?

Dear EBP Readers,

At EBP, we ask a lot of questions. In fact, most of our articles have questions as titles. But were you aware that there is a second question being asked in every article, one that is never stated but always implied? That all-important second question is, “How do we know that?”

Take for example a fairly simple clinical question, “What is the normal human body temperature?” Almost everywhere you look, from textbooks to old mercury thermometers, the answer seems to be 98.6°F (37.0°C). Simple enough. Now let us ask the second question, “How do we know that?”

Well, according to certain medical historians, the value comes to us from Carl Reinhold August Wunderlich, who published it in his 1868 book, Das Verhlten der Eigenwarme in Krankheiten.1 Dr. Wunderlich was no slouch. He analyzed more than 1 million axillary temperatures in 25,000 patients, using a state-of-the-art thermometer that had to equilibrate 15 to 20 minutes per reading. This means Dr. Wunderlich and his assistants spent up to 20,000,000 minutes up to their armpits in other people’s armpits. That, my friends, is 38 years spent watching a meniscus level. I hope they knew how to multitask.

Given this mountain of evidence, you would think that 98.6°F could be engraved in granite. Unfortunately, Dr. Wunderlich’s thermometers may not have been particularly accurate and arm pit thermometry has gone out of fashion. In the 1940s and again in the 1990s, other teams used other thermometers in other intimate places and got . . . surprise . . . other numbers.

One group of researchers using electronic thermometry took 700 oral readings in 148 healthy subjects and found a mean body temperature of only 98.2°F (36.8°C) with some daily variation.1 Of clinical interest, a temperature higher than 99.9°F (37.7°C) was considered a fever.

Now I am not about to tell anybody to go rewrite their medical textbook (although perhaps they should). But I hope that you agree our implied second question reveals some pretty interesting stuff. That is why we will keep asking it, even if we do not ask it out loud.

Regards,

Jon O. Neher, MD

Behavioral treatment as an alternative to alpha-blockers for men with overactive bladder


This RCT compared behavioral treatment and oxybutynin in 203 men with overactive bladder (OAB) who had no signs of outlet obstruction. All patients had a 4-week run-in period with an alpha-blocker. After the 4 weeks, those who continued to have symptoms (n=143) were randomized to receive either 4 behavioral therapy sessions (n=73) or oxybutynin (individually titrated doses starting at 10 mg up to 30 mg per day) (n=70). Both groups kept bladder diaries. At baseline, men in each group recorded about 11 voids per day.

Patients in the behavioral treatment group had a mean decrease of 2.2 voids per day (from 11.3 to 9.1) compared with those in the drug therapy group, who had a mean decrease of 2.0 voids per day (11.5 to 9.5; \( P \) value for equivalence=.006.) The behavioral treatment group had greater reductions in nocturia than the drug therapy group (2.2 to 1.5 voids vs 2.3 to 2.0 voids, respectively; \( P=.05 \)). However, the drug therapy group showed greater reductions in urgency symptoms compared with the behavioral treatment group (1.3 to 1.1 episodes vs 1.4 to 1.5 episodes, respectively; \( P=.05 \)). In both treatment groups, most patients were satisfied with their overall improvement, but those receiving oxybutynin reported significantly more side effects.

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**Bottom line:** Both behavioral treatment (bladder training) and oxybutynin can reduce the number of voids in men with OAB without bladder outlet obstruction. This finding is especially important for men who are unable to tolerate the medication’s side effects, usually dry mouth and constipation.

Behavioral therapy is, however, difficult to implement in a busy primary care setting. Its usefulness as an alternative to oxybutynin, therefore, depends on access and patient preferences.

**Article Reviewer and Summary Author:** Dionna Brown, MD
The University of Chicago, Department of Family Medicine, Chicago, IL

Questionable benefit of dietary supplements in older women


This cohort study used data from the Iowa Women’s Health Study to examine the relationship between dietary supplement use and mortality in postmenopausal women. In 1986, 38,772 white women ages 55–69 completed a self-administered questionnaire assessing food intake and supplement use; similar questionnaires were repeated in 1997 and 2004. Data regarding mortality were obtained from state and national registries. Mean follow-up time was 19 years. The analyses were adjusted for potential confounders including smoking, body mass index, diabetes mellitus, hormone replacement therapy, physical activity, and diet.

Multivitamin use was associated with an increased risk of mortality (NNH=42 over 19 years); copper use was also associated with increased mortality (NNH=5.6). Calcium use was associated with a decreased risk of mortality (NNT=26). Among shorter follow-up periods, there was also a dose-dependent increase in mortality with iron supplementation.

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**Bottom line:** This study calls into question the practice of recommending multivitamins and other supplements for white postmenopausal women. Calcium was the only supplement associated with decreased mortality, while all other supplements examined had either no association with mortality or were potentially harmful.

However, we question the validity of this study design. Although several important potential confounders were accounted for, many were not. For example, patients were not assessed for possible baseline vitamin deficiencies, and their reasons for supplement use were not taken into account.

**Article Reviewer and Summary Author:** Kate Kirley, MD
The University of Chicago, Department of Family Medicine, Chicago, IL
Musculoskeletal Health

How often can an osteoarthritic knee joint be safely injected?

Background
In addition to being an effective analgesic option, corticosteroid injection into an osteoarthritic knee is a relatively easy, fast, and well-reimbursed procedure for family physicians. A 2008 Society of Teachers of Family Medicine consensus statement therefore recommended that all family medicine residents should be able to independently perform a large joint injection. However, joint injection is not without risks, and debate has been ongoing as to the frequency with which an osteoarthritic knee may safely receive a corticosteroid injection (CSI).

Review of the evidence
Prolonged oral corticosteroid use can result in osteoporosis. To evaluate whether a CSI poses a similar risk, researchers divided 40 patients into 2 groups. Baseline levels of serum osteocalcin, a protein highly correlated with bone formation rate, were measured in all subjects. One group (baseline osteocalcin = 2.9±0.6 ng/mL) received an intraarticular injection of Xylocaine. The other group (baseline osteocalcin = 3.1±0.3 ng/mL) received an intraarticular injection of Xylocaine and triamcinolone acetonide.

After an initial dip to 1.5±0.2 ng/mL on day 1 after injection, osteocalcin levels in the Xylocaine plus triamcinolone group recovered to baseline by day 14 (2.9±0.4 ng/mL). The osteocalcin levels in the Xylocaine-only group did not vary significantly from baseline through day 14. These findings imply that bone formation normalizes within 2 weeks of a single CSI.

A later study assessed cartilage health with repeated CSIs into an osteoarthritic knee. In a randomized double-blind trial, 68 subjects (40–80 years of age) received either a triamcinolone acetonide CSI or injections of saline every 3 months into an osteoarthritic knee. The authors measured the joint space width (JSW) of the medial compartment of the knees on weight-bearing x-ray at baseline and after 2 years (8 injections). At baseline the steroid group average JSW = 4.07±1.0 mm and the saline group average JSW = 3.93±0.91 mm.

After 2 years the steroid group average JSW = 4.02±1.20 mm and the saline group average JSW = 3.86±1.20 mm (P=.57, steroid vs saline at 2 years). At no time during the study were the differences between the average JSWs in the groups statistically significant. Thus, the authors concluded that CSI into an osteoarthritic knee at 3-month intervals does not pose a risk to knee cartilage.

Interestingly, 26 years earlier a retrospective study evaluated this concept in the extreme. Cases involving 65 knee joints affected with osteoarthritis (30) or rheumatoid arthritis (35) were reviewed. Each knee had been treated with repeated CSIs over 4 to 15 years. Except for 2 patients, the interval between CSIs was at least 4 weeks. Serial x-rays were evaluated by 2 independent assessors who graded arthritis progression on a scale of 0 to 4.

In all, 15 knees were rated a 0 (no progression, 3 of which had had >100 CSIs); 21 knees were rated a 1 (minimal progression, 6 of which had had >100 CSIs); 17 knees were rated a 2 (moderate progression, 4 of which had had >100 CSIs); and 10 knees were rated a 3 (marked progression, 3 of which had had >100 CSIs). Only 2 knees—both in the same patient—showed gross progression. This patient had received 82 and 85 injections over 7 years (about 12 per year).

As just 12 of 65 (18%) knees reviewed showed marked or gross progression, and considering that progression was not correlated with the number of CSIs given to a knee joint, the authors concluded that neither CSIs themselves nor their frequency of use inevitably promote arthritic progression.

Clinical considerations
No study demonstrates increased risk of osteoporosis with frequent CSI, and bench research suggests it is unlikely. In addition, solid prospective radiographic evidence suggests that CSI every 3 months—for up to 2 years—does not promote arthritic progression. Retrospective evidence suggests that CSI even monthly does not accelerate joint pathology.

Andrew W. Gottschalk, MD
Cleveland Clinic
Cleveland, OH

REFERENCES
What are the risks of using atypical antipsychotic drugs in treating patients with neuropsychiatric symptoms of dementia?

Evidenced-Based Answer
Severe adverse outcomes, including cerebrovascular events and death, have been observed in patients with dementia who are treated with atypical antipsychotic drugs (AAPDs) for neuropsychiatric symptoms. (SOR: A, based on systematic reviews.) Other adverse effects of AAPDs in this population include somnolence, abnormal gait, urinary retention or urinary tract infections, extrapyramidal symptoms, and decline in cognitive function. (SOR: A, based on systematic reviews.)

AAPDs carry a black box warning for an increased risk of death in patients with dementia-related psychosis. An unpublished meta-analysis conducted by the US Food and Drug Administration of 17 studies with 5,377 elderly patients with dementia found that use of AAPDs was associated with an increased risk of death compared with placebo (4.5% vs 2.6%, respectively; \( P \) value not provided). A published meta-analysis of 15 parallel-group, double-blind, placebo-controlled RCTs including 5,110 patients with various types of dementia showed an increased risk of death of a similar magnitude (3.5% vs 2.2% for placebo; \( P =.02; \text{NNH}=76 \)).

One of the included trials in the meta-analysis was a 12-week study of 345 nursing home patients with severe dementia of various types (Mini-Mental Status Exam=5.5) that drew particular attention to the increased risk of stroke associated with AAPDs. The risk of “severe” adverse events—defined as life-threatening, requiring hospitalization, or resulting in severe debilitation or incapacity—was 16.8% in patients on risperidone versus 8.8% in patients on placebo (\( P \) value not provided). Central vascular events were the most common serious adverse outcome, with 5 strokes and 1 transient ischemic attack all in the risperidone group.

Using the same data set used in meta-analysis above, authors delineated some of the less severe adverse effects of AAPDs. Somnolence was associated with aripiprazole, olanzapine, quetiapine, and risperidone (\( \text{NNH}=9 \) for all drugs combined), and was statistically significant for each individual medication. AAPDs were also associated with abnormal gait (\( \text{NNH}=13 \)), urinary retention or urinary tract infections (\( \text{NNH}=28 \)), and extrapyramidal side effects (\( \text{NNH}=25 \)). Extrapyramidal side effects were most commonly associated with risperidone (\( \text{NNH}=15 \)). Additionally, aripiprazole and risperidone were associated with decline in cognitive function measured by the 30-point MMSE (weighted mean difference 1.04 [95% CI, 0.33–2.35] and 0.69 [95% CI, 0.07–1.31], respectively).

Lindsey Elmore, PharmD
Samford U McWhorter School of Pharmacy
Birmingham, AL

Kevin Johnson, MD
New Hanover Regional Medical Center
Wilmington, NC

Can atypical antipsychotic agents be used safely in patients who are breastfeeding?

Evidence-based Answer
Olanzapine is considered compatible with breastfeeding due to both low concentrations in breast milk and lack of reported adverse effects. Clozapine should be avoided due to greater reported adverse effects in exposed infants. Aripiprazole, risperidone, quetiapine, and ziprasidone should be used with caution due to the lack of data concerning safety in this setting. (SOR: C, based on case series and expert opinion.)

A systematic review of 183 articles summarized data on psychotropic medication use during breastfeeding. Included studies needed to report infant exposure to a single psychotropic medication, data on the extent of infant exposure to the medication, and infant adverse effects. In total, 29 pharmacokinetic studies of 22 different antipsychotic drugs and their adverse effects in 146 mother-infant pairs met the inclusion criteria. The atypical antipsychotic agents clozapine, olanzapine, quetiapine, risperidone, and aripiprazole were included in the review. No comparison studies or randomized trials confirming safety were available.

The relative infant dose exposure to medications in breast milk was calculated by taking the concentration of drug in breast milk (mg/mL) × 900 divided by the
weight-adjusted maternal daily dose (mg/kg). Olanzapine (14 mother-infant pairs) had a low percent relative infant dose exposure (<0.1%–0.4%). Olanzapine was listed as compatible with breastfeeding, generally defined as a relative infant dose exposure <10% with no known adverse effects. Clozapine (2 mother-infant pairs, 1.0%–1.1% relative infant dose exposure) was considered incompatible with breastfeeding because of reports of sedation and agranulocytosis.1

Aripiprazole (1 mother-infant pair, 0.8% dose exposure), quetiapine (8 mother-infant pairs, 0.1%–0.5% dose exposure), and risperidone (3 mother-infant pairs, 2.8%–4.7% dose exposure) were categorized “to be used with caution” because of the small number of mother-infant pairs studied, although there were no relevant adverse effects or evidence of drug accumulation.1

A case series reported mild mental and motor skill delay in 2 of 6 infants exposed to quetiapine. However, quetiapine was being used to augment another psychotropic medication.2 Only one case report has been published regarding ziprasidone during lactation; the infant showed no adverse effects and pharmacokinetic measures were not reported.3

Considerations when prescribing atypical antipsychotic agents should include the mother’s past experiences with various agents and the risks of not treating a psychiatric condition.

Jessica Battaglia, PharmD
Connie Kraus, PharmD
U of WI School of Pharmacy
Madison, WI

Should caffeine be restricted during pregnancy?

Evidence-Based Answer
Caffeine consumption <200 mg/d in pregnancy appears safe. (SOR: B, based on an RCT and cohort studies.) Older cohort studies suggest higher doses are associated with harmful effects.

A 2010 Cochrane review evaluated the effects of caffeine in pregnancy on fetal, neonatal, and maternal outcomes.1 Two studies met the inclusion criteria but only 1 study contributed data for the analysis. This study was a 2009 RCT that compared 1,207 pregnant women randomized to either decaffeinated or caffeinated coffee. No daily dosage of caffeine was specified.

Babies born to women in the caffeinated group averaged 20 g heavier than babies in the noncaffeinated group (3,539 vs 3,519 g, respectively), a difference that was not statistically significant (P=.48). The rates of preterm birth (RR 0.81; 95% CI, 0.48–1.37) and small for gestational age (RR 0.97; 95% CI, 0.51–1.6) in the 2 groups were not statistically significant. The conclusion of the study was that the evidence was insufficient to make a recommendation regarding caffeine usage during pregnancy.1

A 2008 prospective cohort study in Britain examined the effects of different amounts of caffeine use and fetal growth in 2,635 pregnant women between 18 and 45 years old and 8–12 weeks’ gestational age.2 Caffeine intake from various sources was quantified using questionnaires during each trimester. Caffeine use >200 mg/d averaged through pregnancy was associated with a greater chance of fetal growth restriction (OR 1.5; 95% CI, 1.1–2.1) compared with lesser amounts of caffeine intake. A 2008 population-based prospective cohort study in the United States examined the effect of maternal caffeine intake during pregnancy on the risk of miscarriage up to 20 weeks.3 The study consisted of 1,063 pregnant women, starting at approximately 8 weeks’ gestation, who were questioned about their caffeine intake. The average daily caffeine intake during pregnancy was categorized as 0, <200 mg/d, or ≥200 mg/d.

After controlling for potential confounders, patients consuming <200 mg/d caffeine were not at an increased risk of miscarriage (HR of miscarriage for consumption <200 mg/d was 1.4; 95% CI, 0.93–2.2). Risk of miscarriage was increased in patients consuming ≥200 mg/d (HR 2.2; 95% CI, 1.3–3.7).3
What is the best diet for improving long-term glycemic control in a patient with type 2 diabetes?

Evidence-Based Answer
A low-calorie diet resulting in maintenance of weight loss has been shown to reduce HbA1c for up to 4 years in overweight or obese patients with type 2 diabetes. (SOR: B, based on a single RCT.) Over a similar time frame, a low-calorie Mediterranean-style diet (low carbohydrate, high monounsaturated fat) reduces the need for medication compared with a caloric restriction diet relatively higher in carbohydrate and lower in fat. (SOR: B, based on a single RCT.)

Glycemic control reduces microvascular complications for patients with type 2 diabetes (DM). The American Diabetes Association (ADA) has consistently recommended weight loss for overweight patients with diabetes, based on evidence that weight loss improves glycemic control in the short term (<1 year).1

The Look AHEAD Trial showed weight loss improves glycemic control in the long term as well.2 In this study, 5,145 overweight or obese individuals with DM were randomized to either an intensive lifestyle intervention (ILI) group, with a goal of 7% maintained weight loss, or usual care. ILI participants were assigned a goal of 1,200–1,800 kcal/d, with less than 30% of calories from fat. Exercise, behavioral strategies, and frequent counseling sessions were also part of the 4-year intervention.

While differences between groups were greatest after the first year, at 4 years the ILI group maintained a mean loss of 4.7% of body weight compared with a loss of 1.1% body weight in the control group (P<.001). HbA1c declined an absolute 0.19% in the ILI group compared with 0.07% in the usual care group (P=.014).2 Follow-up was excellent (93%).

A 4-year RCT found benefit from a low-calorie Mediterranean-style diet for glycemic control. This RCT randomized 215 overweight people with newly diagnosed diabetes to either a Mediterranean-style or low-fat diet, both equally low in calories (1,500 calories per day for women, 1,800 calories per day for men).3 The Mediterranean diet contained 30–50 g olive oil daily with no less than 30% of calories from fat and no more than 50% from carbohydrates; the low-fat group had no more than 30% of calories from fat. The endpoint was need for antihyperglycemic drug therapy. At 4 years, 70% of the low-fat diet group but only 44% of the Mediterranean-style diet group required antihyperglycemic therapy (absolute risk reduction 26%; 95% CI, 31%–20%; P<.001; NNT=4). Weight loss was not significantly different between groups at 4 years (3.8 kg for Mediterranean diet group vs 3.2 kg for low-fat diet group), but HbA1c was significantly lower in the Mediterranean diet group than in the low-fat diet group (mean absolute difference −0.9% vs −0.5%, respectively; difference −0.4; 95% CI, −0.09 to −0.1).3 Studies of other lower carbohydrate diets for glycemic control have been shorter and have yielded mixed results.

To date, the ADA does not endorse any particular macronutrient allocation for glycemic control.4

Marcy Oppenheimer, MD
William Gallagher, MD
Georgetown/Providence FMR
Washington, DC


What is the best way to diagnose postconcussion syndrome?

Evidence-Based Answer
The prevalence of postconcussion syndrome (PCS) is higher using the International Classification of Diseases, 10th edition (ICD-10) diagnostic criteria than using the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria. (SOR: B, based on a cohort study.) Symptom number and severity reported by patients is increased using structured evaluation instruments compared with open-ended interviews. (SOR: B, based on a cohort study.)

A prospective cohort study compared the prevalence of PCS with ICD-10 versus DSM-IV diagnostic criteria in 178 adults (71% men; mean age, 33 years) with mild traumatic brain injury (mTBI) and 104 adults (70% men; mean age, 35 years) with extracranial trauma.1 A structured interview evaluated whether DSM-IV and ICD-10 threshold criteria for PCS were met. No independent reference standard was used.
PCS prevalence was 64% with ICD-10 criteria versus 11% with DSM-IV criteria. Patients with mTBI fulfilled PCS criteria more often than patients with extracranial trauma using both the DSM-IV (OR 1.66; 95% CI, 0.69–3.64) and the ICD-10 (OR 2.15; 95% CI, 1.07–4.33) criteria. Brain-injured patients with intracranial abnormalities on CT had no greater prevalence of PCS either by DSM-IV (OR 1.62; 95% CI, 0.58–4.55) or ICD-10 criteria (OR 0.82; 95% CI, 0.32–2.13).¹

Another prospective study evaluated the utility of a bedside emergency department (ED) screen for the prediction of PCS 3 months after mTBI.² One hundred patients (78% men; mean age, 34 years) were compared with 2 control groups—a “minor non-head injury group” (n=100; 77% men; mean age, 32 years) and an “uninjured group” (n=100; 78% men; mean age, 34 years). Brief evaluation of neuropsychological function (immediate and delayed memory for 5 words), postural instability, and visual analog scale of acute headache were obtained in the ED. Telephone follow-up at 3 months was performed using the Rivermead Post-Concussion Symptoms Questionnaire as the reference standard.

Bedside screening for immediate and delayed word recall and headache severity provided 80% sensitivity and 76% specificity (positive likelihood ratio 3.3; negative likelihood ratio, 0.26) for prediction of PCS at 3 months postinjury.²

A cohort study of 61 patients (57% men; mean age, 40 years) referred to a concussion clinic after mTBI compared spontaneous symptom reporting with open-ended interview to their symptom endorsement using a standardized questionnaire (British Columbia Post-concussion Symptom Inventory [BC-PSI]).³ Using the BC-PSI, patients reported more symptoms than spontaneously reported with the open-ended interview (9.1 vs 3.3, respectively; P<.001) and were more likely to characterize these symptoms as moderate or severe.

Darrell R. Over, MD, MSc
Daniel Patrick Hardin, MD
U of AR for Medical Sciences AHEC, South Central FMRP
Pine Bluff, AR

Evidence-Based Answer

How can you best differentiate gout from cellulitis when aspiration of the joint is not possible?

Evidence-Based Answer

Physical examination using a diagnostic decision rule has moderate positive and negative predictive value for recognition of gout. (SOR: B, based on an exploratory cohort study.) The monosodium urate (MSU) crystals of tophaceous gout are detectable by ultrasound (US), which is more sensitive than X-ray evaluation. (SOR: B, based on cohort studies.)

A prospective diagnostic study of 328 patients (mean age, 58 years; 80% men) with monoarticular arthritis sought to develop a clinical prediction model for the diagnosis of acute gouty arthritis in primary care.¹ The gold standard for gout was the identification of MSU crystals in joint fluid. A model was developed that scored 1 point for each of 7 variables (male sex, previous patient-reported arthritis attack, onset within 1 day, first metatarsophalangeal joint involvement, joint redness, hypertension or ≥1 cardiovascular disease risk factor, and serum uric acid >5.88 mg/dL).

A score of ≤4 ruled out gout in 98% of patients. The area under the receiver operating characteristic curve for this diagnostic rule was 0.85 (95% CI, 0.81–0.90).¹

A retrospective study compared US images of 37 joints in 23 patients (mean age, 60 years; 74% men) with MSU crystal-proven gout to US images of 33 joints in 23 patients (mean age, 52 years; 35% men) with rheumatic conditions other than gout.² US features of gouty joints were (i) a hyperechoic irregular band overlying the superficial margin of the articular cartilage (in 92% of gouty vs none of the control joints); (ii) nonhomogenous hypoechoic-to-hyperechoic material surrounded by an anechoic rim representing tophaceous material (in 100% of gouty vs none of the control joints); and (iii) erosions adjacent to tophaceous deposits (in 65% metatarsophalangeal and 25% metacarpophalangeal gouty joints vs none of the control joints). No data reporting the sensitivity or specificity for gout diagnosis of using combinations of US features were reported.

A prospective study compared the accuracy of imaging with X-ray and US for the diagnosis of gout in 105 consecutive patients (mean age, 59 years; 88% men).³ All images were independently reviewed by

2 radiologists and thereafter consensus opinion was obtained. The reference standard was microscopy of aspirates. Fifty-five patients had a definitive diagnosis of gout (102 involved sites), 31 patients were diagnosed with another rheumatic condition (59 involved sites), and a definitive diagnosis could not be established in 19 patients who were excluded.

X-ray criteria for gout included (i) soft-tissue opacifications with densities between soft tissue and bone; (ii) articular and periarticular bone erosions; and (iii) osteophytes at the margins of opacifications or erosions.

US criteria for gout included (i) bright stippled foci; (ii) hyperechoic soft-tissue areas; (iii) hypoechoic streaks between and around hyperechoic areas; (iv) hypervascularization on color Doppler US; and (v) articular and periarticular bone erosions. For detecting gouty joints, X-ray demonstrated a sensitivity of 31% (32/102) and a specificity of 93% (55/59) (positive likelihood ratio [LR+] 4.43; negative likelihood ratio [LR–] 0.74). US showed a sensitivity of 96% (98/102) and a specificity of 73% (43/59) for detecting gouty joints (LR+ 3.56; LR– 0.05).

Darrell R. Over, MD, MSc
Alexander Tyler, MD
U of AR for Medical Sciences AHEC, South Central FMRP
Pine Bluff, AR


What is the sensitivity and specificity of skin scraping in the office to detect scabies?

Evidence-Based Answer
The sensitivity of skin scraping in the office to detect scabies is typically low (<50%), but may be as high as 90% with a skilled sampling. (SOR: C, based on expert opinion and 1 study designed to answer a different question.) The specificity is theoretically 100%, although it is possible for non-scabies material in a sample to be misidentified as a mite or an egg.

A positive skin scraping is pathognomonic for scabies. However, currently no test completely rules out scabies. History and physical examination alone are sometimes sufficient. In a study from one part of Africa, where scabies is estimated to be as prevalent as 13%, a diagnosis based on a history of diffuse itching and visible lesions, associated with either lesions in 2 areas classic for scabies or another family member with itching, was reported to be 100% sensitive and 97% specific.1

However, skin scrapings in the office may be obtained to try to confirm the presence of scabies. According to the experience of 1 widely quoted expert,3 the sensitivity of skin scrapings is less than 50%.

A prospective study evaluated the effectiveness of a handheld dermoscope for the diagnosis of scabies.4 In this study, 245 patients with signs or symptoms of scabies were tested with both skin scraping and dermoscopy. The skin scrapings were obtained by 3 parasitologists, each with more than 5 years of experience doing such scrapings. Only 12 patients of 124 who were ultimately determined to have scabies were missed by the initial skin scraping procedure, yielding a 90% sensitivity for the skin scrapings.

Jennifer B. Griffiths, MD
Medical College of Wisconsin
Columbia St. Mary’s FMRP
Milwaukee, WI

Abnormal Pap smear in pregnancy

Effects of pregnancy on colposcopic findings
- Pregnancy triggers active squamous metaplasia, exaggerating acetowhite changes in response to acetic acid
- Gland openings become more prominent with acetowhite outline, mimicking cervical cancer
- Stromal edema, increased vascularity, stromal hypertrophy
  - Cause marked enlargement of the cervix
- Eversion exposes upper extent of lesions (first or second trimester) – make colposcopy satisfactory more often
- Grading more difficult than in the nonpregnant patients
- Decidual changes can be confusing – may have features consistent with invasive cancer
- Goal of colposcopy in pregnancy is to rule out invasive cancer. This requires biopsy if you suspect high-grade squamous intraepithelial lesion or worse; an experienced colposcopist may elect to omit biopsies of low-grade–appearing lesions, especially if the cervical cytology is low grade (due to risk of bleeding from hypervascular cervix)
- After first trimester, colposcopy best performed by skilled, experienced colposcopist
- Never perform endocervical curettage during pregnancy – risk of inducing abortion

Postpartum evaluation
- Likelihood of disease progression during pregnancy small; regression more likely (12%–70%)
- Controversial whether severity of disease and route of delivery influence postpartum persistence

Mitral regurgitation (MR)
Second most common valvular pathology, and most common valvular insufficiency.
- “Organic” MR: primary abnormalities in the mitral valve leaflets, annulus, or tensor apparatus
- “Functional” MR: secondary to left ventricular dilatation, damage, or remodeling
- “Ischemic” MR: functional MR secondary to ischemic cardiomyopathy

Risk factors
- Mitral valve prolapse: Number 1 risk factor for MR in developed world
- Rheumatic fever: Number 1 risk factor worldwide
- The ergot derivative dopamine agonists pergolide and cabergoline when used in high doses

Morbidity/mortality
- Severe MR associated with progressive deterioration
  - 5-year mortality of 22%, 5-year cardiac morbidity/mortality of 33%
  - In MR secondary to mitral valve prolapse, 90% of initially asymptomatic patients die or receive surgical intervention within 10 years
  - Annual cardiac event rate up to 10% to 11%
- Increased risk of sudden cardiac death, up to 0.8% annually

Long-term care
- Mild or moderate MR requires close follow-up, not surgery
- Surgery is recommended for patients who develop severe MR and have either signs of left ventricular dysfunction or an easily repaired valve
- Repair superior to replacement
- No medications proven to be beneficial or disease-modifying in isolated organic MR

Authors: James Monaco, MD, and Michael P. Flanagan, MD, Penn State Hershey Medical Center, Hershey, PA
Editor: Juan Jan Qiu, MD, Penn State Hershey Medical Center, Hershey, PA

To review complete topic monographs, visit www fpin org/ebpemedref

Author: Ana May Magdalen P. Manuel, MD, United Hospital Center, Bridgeport, WV
Editor: Robert Marshall, MD, MPH, MISM, CMIO, Madigan Army Medical Center, Tacoma, WA
Is motivational interviewing effective for hypertension?

Summary
Motivational interviewing, delivered individually or in groups, may produce small changes in systolic and diastolic blood pressure. One study indicated the mediating factor may be improved medication adherence.

The evidence
Motivational interviewing has been shown to be beneficial in preventing and managing a number of chronic medical diseases. Motivational interviewing is easily applied in medical settings because the technique can be adapted to standard 15- to 20-minute office visits.1,2

A systematic review and meta-analysis of 72 high-quality RCTs (total number of patients not given) examined motivational interviewing used for a broad range of health indicators and diseases. Most of the studies (74%) showed benefits of motivational interviewing for various biomedical diseases and health indicators. Motivational interviewing was associated with a significant decrease in systolic blood pressure, with a reduction of 4.22 mmHg (n=316; 95% CI, 0.23–8.99; P=.038).3

A later study of 190 adult African American patients with hypertension compared the effects of usual care versus motivational interviewing on blood pressure control and medication adherence.4 Patients were taking at least 1 antihypertensive medication and were randomly assigned to either the usual care or motivational interviewing group. The motivational interviewing group received usual care plus 30 to 40 minutes of motivational interviewing interventions at sessions at 3, 6, 9, and 12 months.

Over 12 months, systolic blood pressure decreased 5.1 mmHg with usual care and 11.2 mmHg with motivational interviewing (not significantly different). The diastolic pressures dropped 3.5 and 4.9 mmHg, respectively (again, not significantly different). However, medication adherence rates were higher with motivational interviewing: 57% of the patients in the motivational interviewing group adhered to their medication regimen versus 47% in the usual care group (P=.027).4

A recent quasiexperimental study examined the effects of group motivational interviewing on blood pressure in patients diagnosed with hypertension.5 Participants were selected from a metabolic screening project who had hypertension and met other inclusion criteria for either an experimental (pretest, posttest) or control group. Each group contained 40 patients. The experimental group received eight 2-hour sessions over 4 weeks—3 of lifestyle modifications and 5 of motivational interviewing. The control group received six 45- to 60-minute sessions in lifestyle modifications. Systolic and diastolic blood pressure was measured preintervention, postintervention, and at a 16-week follow-up.

The control group had mean pre- and postsystolic blood pressures of 135 and 129 mmHg, and diastolic blood pressures of 86 and 83 mmHg. The motivational interviewing group showed a greater reduction in systolic blood pressure, from 135 to 127 mmHg (P=.01), and in diastolic blood pressure, from 86 to 82 mmHg (P=.05), compared with the control group. There was no significant decrease in systolic blood pressure between the 2 groups at follow-up, but the significant difference in diastolic blood pressure did persist at follow-up. Limitations of the study included limited sampling range and a short follow-up period.4

Overall, motivational interviewing appears promising in improving some outcomes for patients with hypertension, although more research is needed regarding the methods of motivational interviewing that prove most efficient.

Verena Roberts, PhD
Denver Health, General Internal Medicine
Denver, CO

Laurie C. Ivey, PsyD
Swedish FMR
Littleton, CO

REFERENCES
Are there any risks to a water birth?

**Bottom line**

Despite reports in the literature of anecdotal adverse outcomes, water birth has not been shown in RCTs or observational studies to increase maternal or neonatal morbidity or mortality. However, research looking specifically at the second stage of labor in water is limited and would need to be undertaken to more thoroughly evaluate the risks.

**Evidence summary**

Benefits of immersion, such as reduced duration of the first stage of labor and decreased use of epidural anesthesia, have been demonstrated in RCTs.

A theoretical maternal risk that has been discussed but not reported in the literature is water embolism. Potential neonatal complications include metabolic disturbance from hyperthermia, waterborne infections (ie, *Pseudomonas*), fresh water drowning, hyponatremia, cord rupture with hemorrhage, hypoxic ischemic encephalopathy, and death. Neonates with these complications have been documented in case reports, case series, retrospective reviews, and mailed surveys. None of these potential adverse outcomes were trends found in randomized adequately controlled trials.

A 2011 Cochrane review of 12 RCTs found no difference between water and nonwater immersion during the first stage of labor for the following measures: maternal infection (risk ratio [RR] 0.99; 95% CI, 0.50–1.96; 5 trials; N=1,295); oxytocin augmentation (RR 0.64; 95% CI, 0.32–1.28; 5 trials; N=1,834); second-degree perineal laceration (RR 0.94; 95% CI, 0.74–1.20; 5 trials; N=1,286); third- or fourth-degree perineal laceration (RR 1.37; 95% CI, 0.86–2.17; 5 trials; N=2,401); assisted vaginal deliveries (RR 0.86; 95% CI, 0.71–1.05; 7 trials; N=2,628); cesarean sections (RR 1.21; 95% CI, 0.87–1.68; 8 trials; N=2,712); neonatal infection (RR 2.00; 95% CI, 0.50–7.94; 5 trials; N=1,295); 5-minute Apgar score <7 (RR 1.58; 95% CI, 0.63–3.93; 5 trials; N=1,834); and neonatal intensive care unit admissions (RR 1.06; 95% CI, 0.71–1.57; 3 trials; N=1,571).

One trial showed increased satisfaction of women with their birth experience (RR 0.24; 95% CI, 0.07–0.80; N=120). Only 3 trials specifically evaluated immersion of water during the second stage of labor, the results of which did not differ from those listed above.

However, outcomes were not analyzed according to use of water during the first versus the second stage, and rates of maternal infection and labor augmentation were not reported. No trials evaluated the third stage of labor in water.

Other non-RCTs have reported similar results. In a retrospective surveillance study of 4,032 water births, no deaths were attributable to water birth; 2 neonates were admitted for water aspiration. Overall, perinatal mortality was not significantly higher among babies delivered in water than those born in air.

A European controlled prospective observational study (nonrandomized) of 513 women reported a slightly increased incidence of neonatal conjunctivitis in those born in water, but otherwise no significant differences were noted between the groups for neonatal or maternal infection, or morbidity.

**Recommendation**

The British Royal College of Obstetricians and Gynaecologists states that only healthy women with uncomplicated term pregnancies should be allowed to undergo water birth; ACOG has no formal guidelines.

Providers and patients should be informed of potential, though small, risks. Women should be carefully screened, birth attendants should be properly trained, and institutions providing water birth should follow rigorous standards. If these precautions are taken, no systematic evidence suggests harm from water birth, but a well-designed, carefully controlled RCT of immersion during the second stage of labor is needed to investigate theoretical concerns of increased risk.

Elizabeth Kvach, MD, MA
A. Ildiko Martonffy, MD
U of WI School of Medicine and Public Health
Madison, WI

**REFERENCES**

What is the appropriate duration of drug interruption for patients taking dabigatran who need an invasive procedure?

**Bottom line**
Before invasive surgery, dabigatran should be discontinued for a minimum of 24 hours in patients with a creatinine clearance >50 mL/min. This should be extended up to 5 days in patients with lower creatinine clearance and for procedures with a high bleeding risk. Because of its rapid onset of action, resumption of dabigatran postoperatively should be guided by an assessment of bleeding risk. (SOR: C, based on expert opinion and consensus guidelines.)

**Evidence summary**
A pharmaceutical industry–sponsored, open-label, parallel-group study investigated the influence of renal impairment on the pharmacokinetics of dabigatran etexilate in 23 subjects between 18 and 75 years of age. Subjects were stratified into groups based on calculated creatinine clearance (CrCl). Subjects received a single 150-mg dose orally of dabigatran. Dabigatran was absorbed rapidly, with a maximum concentration at 2–2.5 hours in all subjects.

In patients with normal renal function (CrCl >80 mL/min) renal clearance was largely complete in 24 hours, but in patients with severe renal impairment (CrCl ≤30 mL/min) complete clearance was delayed up to 96 hours.

The investigators who conducted the trial above authored a narrative review recommending that patients with normal renal function (CrCl >80 mL/min) or mild impairment (CrCl >50 and ≤80 mL/min), discontinue dabigatran etexilate 24 hours before surgeries with a standard risk of bleeding or 2–4 days before surgeries with high bleeding risk (neurosurgery, cardiovascular surgery, abdominal surgery, or use of spinal anesthesia) or in patients with high risk of bleeding (elderly, comorbid conditions, or use of antiplatelet therapy). For patients with moderate impairment (CrCl >30 and ≤50 mL/min), they recommended dabigatran be discontinued for at least 48 hours before procedures with standard bleeding risk or 4 days before procedures with high bleeding risk. For patients with severe renal impairment (CrCl <30 mL/min), dabigatran should be discontinued 2–5 days for standard bleeding risk or >5 days for high bleeding risk surgeries.

The South Australian Department of Health, in a consensus guideline, also recommended using caution when resuming dabigatran within the first 48–72 hours after procedures with a high risk of bleeding. They also recommend that patients with severe kidney impairment (CrCl <30 mL/min) should not resume use of dabigatran.

— Jon O. Neher, MD

**REFERENCES**
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1. Which of the following statements most accurately describes the risks associated with atypical antipsychotics for the treatment of neuropsychiatric symptoms of dementia?
   a. Patients have an increased risk of spastic bladder symptoms
   b. Patients may experience somnolence, extrapyramidal symptoms, or more serious adverse effects such as stroke or death
   c. Patients are more likely to die from heart attack, and each atypical antipsychotic has high-quality evidence to support this link
   d. Each atypical antipsychotic has the same risk of adverse effects, and all of the effects can be considered class effects

2. For a patient using dabigatran whose creatinine clearance is 80 mL/min and who needs to undergo neurosurgery, how long before the procedure should dabigatran be discontinued?
   a. 2–4 days
   b. 12 hours
   c. >5 days
   d. There is no need to discontinue dabigatran

3. According to the best evidence available at this time, water birth:
   a. Has been shown to cause fetal tachycardia due to maternal temperature elevation during labor
   b. Has not been shown in randomized controlled trials or observational studies to increase maternal or neonatal morbidity or mortality
   c. Is associated with increased rates of admission to the special care nursery, but is not associated with increased neonatal mortality
   d. Should not be recommended due to proven risks to the mother

4. Which of the following medications has been shown to reduce aggression scores in elderly patients with dementia?
   a. Mirtazapine
   b. Risperidone
   c. Trazodone
   d. Alprazolam

5. In discussing dietary options with patients with type 2 diabetes mellitus, it is important to mention that
   a. Sustained weight loss is associated with lower HbA1c levels
   b. A Mediterranean-style diet is associated with higher HbA1c levels than a low-fat diet
   c. A Mediterranean-style diet is associated with a need for more medication than a low-fat diet
   d. The beneficial effect of diet on HbA1c levels disappears after about a year

6. In older cohort studies, maternal caffeine consumption of more than 200 mg/d during pregnancy was associated with:
   a. Cerebral palsy and gross motor delay
   b. Neonatal jaundice
   c. Miscarriage and impaired fetal growth
   d. Placental abruption

7. Which of the following statements is FALSE about the diagnosis and treatment of scabies?
   a. If a skin scraping is negative, you can be sure the patient does not have scabies
   b. If a skin scraping is positive, you can be sure the patient has scabies
   c. In some settings, it is appropriate to treat for scabies based on history and examination findings alone
   d. The utility of skin scrapings depends on the experience of the clinician

8. According to recent studies, motivational interviewing used with patients who have hypertension has helped:
   a. Reduce systolic pressure
   b. Reduce diastolic pressure
   c. Reduce both systolic and diastolic pressure
   d. None of the above

Answer key: 1. b; 2. a; 3. b; 4. a; 5. a; 6. c; 7. a; 8. c

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**Friday, April 27, 2012 @ 2:45pm**
Using PURLs in Your Institution

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