



Daily POEMs
August 2008

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Methylnaltrexone effective for opioid-induced constipation in hospice patients

Clinical Question:

Is methylnaltrexone effective in the treatment of constipation in hospice patients taking opioids?

Bottom Line:

Methylnaltrexone (Relistor) is effective for the treatment of opioid-induced constipation in hospice patients. However, long-term safety is not known, so it should not be widely used for nonterminally ill patients until longer studies have been performed. ([LOE = 1b](#))

Reference:

[Thomas J, Karver S, Cooney GA, et al. Methylnaltrexone for opioid-induced constipation in advanced illness. N Engl J Med 2008; 358: 2332-2343.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry

Allocation:

Concealed

Setting:

Nursing home/extended care facility

Synopsis:

Opiates attach to mu-opioid receptors in the gut and cause constipation. Naltrexone is an opioid antagonist, but it causes central nervous system side effects. Methylnaltrexone is an opioid antagonist that crosses the blood-brain barrier to a much smaller degree. In this study, 133 hospice patients taking long-term moderate-dose to high-dose opioids were randomized to receive methylnaltrexone (42 patients received 0.15 mg/kg, 20 received 0.30 mg/kg) or matching placebo. All participants had a terminal illness but were expected to live at least 1 month, and all had been taking a stable regimen of laxatives and opioids for at least 3 days prior to enrollment. Patients were followed up for 2 weeks, then came the 3-month open label phase of the study. Groups were balanced at the start of the study except that the mean and median doses of opioids (150 mg vs 100 mg per day of oral morphine equivalent) were higher in the intervention group; analysis was by intention to treat. The mean age of participants was 71 years, 44% were male, and 58% had cancer as their primary diagnosis. The intervention was more effective than placebo across several outcomes, including percentage with a bowel movement within 4 hours of the initial dose (48% vs 15%; $P < .001$; number needed to treat [NNT] = 4), percentage with a bowel movement within 4 hours after at least 2 of the first 4 doses (52% vs 8%; $P < .001$; NNT = 3), and symptoms scores. Pain (17% vs 13%), flatulence (13% vs 7%), dizziness (8% vs 3%), nausea (11% vs 7%), and fever (8% vs 3%) occurred more often in the intervention group. There were no significant changes in the pain scores or withdrawal symptoms between the 2 groups.

PMID: 18509120

Delivered as Daily POEM: 2008-08-01

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Aloe vera gel effective for oral lichen planus

Clinical Question:

Is aloe vera effective for the treatment of oral lichen planus?

Bottom Line:

Aloe vera is an effective, inexpensive, and well-tolerated treatment for oral lichen planus. ([LOE = 1b](#))

Reference:

[Choonhakarn C, Busaracome P, Sripanidkulchai B, Sarakarn P. The efficacy of aloe vera gel in the treatment of oral lichen planus: a randomized controlled trial. Br J Dermatol 2008; 158: 573-577.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Government

Setting:

Outpatient (specialty)

Synopsis:

Oral lichen planus affects 1% to 2% of the population, and treatment options include corticosteroids, tacrolimus, and retinoids. In this study, 54 patients with erosive (83%) or ulcerative (17%) lesions were randomized to receive 70% aloe vera gel or matching vehicle. Aloe vera has antiinflammatory properties and may affect tumor necrosis factor levels. The mean age of participants was 52 years and approximately half were women; groups were balanced at the start of the study. It is not stated whether analysis was by intention to treat or per protocol, but since the numbers randomized and analyzed were the same it was probably by intention to treat. Primary outcomes were physician-assessed and patient-assessed symptom scores at 2, 4, 6, and 8 weeks. A good or complete clinical response was seen in 88% of patients receiving aloe vera compared with 4% receiving placebo ($P < .001$; number needed to treat [NNT] < 1). A good or complete response to pain was seen in 96% receiving aloe vera and 11% receiving placebo ($P < .001$; NNT < 1). There was mild stinging and itching in 2 patients which went away after 1 week of continued use.

PMID: 18093246

Delivered as Daily POEM: 2008-08-04

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Tetracyclines equally effective for acne vulgaris

Clinical Question:

What is the most effective way to use tetracyclines for the treatment of acne vulgaris?

Bottom Line:

There is no difference between tetracyclines regarding their efficacy in reducing lesion counts in acne. Although minocycline and doxycycline cost more, they require only once-daily dosing and may be better tolerated. There is no clear advantage to higher doses. ([LOE = 1a-](#))

Reference:

[Simonart T, Dramaix M, De Maertelaer V. Efficacy of tetracyclines in the treatment of acne vulgaris: a review. Br J Dermatol 2008;158:208-216.](#)

Study Design:

Meta-analysis (randomized controlled trials)

Funding:

Unknown/not stated

Setting:

Outpatient (any)

Synopsis:

Tetracyclines have antiinflammatory and antibacterial properties and are recommended for the treatment of moderate to severe acne vulgaris. In this systematic review, the authors identified clinical trials of tetracycline (48), minocycline (29), doxycycline (10), and lymescycline (7) and included a total of 57 studies after excluding for fewer than 6 patients, duplicate publication, combination therapies, recent antibiotic therapy, specific forms of acne, non-English language, and crossover studies. The authors focused on lesion count (inflammatory and noninflammatory) as the most objective and widely used outcome measure. Only 7 studies had more than 100 patients, only 22 were double-blinded and only used intention-to-treat analysis, and none lasted more than 24 weeks. Studies comparing different drugs found no consistent difference in the effect on inflammatory or noninflammatory lesion counts. There was no difference in efficacy over time, which might have happened if resistance had occurred. There was also no benefit to higher doses.

PMID: 17986300

Delivered as Daily POEM: 2008-08-05

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Rhythm control no better than rate control in AF + CHF

Clinical Question:

What is the best strategy for managing atrial fibrillation in patients with heart failure?

Bottom Line:

Rhythm control is no better than rate control for patients with atrial fibrillation, even if they have left ventricular dysfunction. ([LOE = 1b](#))

Reference:

[Roy D, Talajic M, Nattel S, et al. for the Atrial Fibrillation and Congestive Heart Failure Investigators. Rhythm control versus rate control for atrial fibrillation and heart failure. N Engl J Med 2008; 358: 2667-2677.](#)

Study Design:

Randomized controlled trial (double-blinded)

Allocation:

Unconcealed

Setting:

Outpatient (any)

Synopsis:

Previous studies have consistently shown no benefit to rhythm control over rate control in patients with atrial fibrillation (AF), provided they were anticoagulated. This study looked at the important subset of patients with AF who also have left ventricular dysfunction. In this study, researchers recruited 1376 patients with a left ventricular ejection fraction of less than 35% and an episode of AF lasting at least 6 hours or requiring cardioversion within the past 6 months or an episode lasting at least 10 minutes within the past 6 months and a history of cardioversion. Patients with persistent AF for more than 12 months were excluded. Their mean age was 66 years and 82% were men. Groups were fairly well balanced at the start of the study -- although there were more men in the rate control group -- and analysis was by intention to treat. The study was not masked and allocation did not appear to have been concealed. Follow-up was good, with 94% of patients completing follow-up or dying, and a median follow-up of survivors of 47 months. Most patients in the rhythm control group were taking amiodarone, and 90% of patients received an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and 90% were anticoagulated. Crossovers occurred in both directions: 21% from rhythm to rate (for inability to maintain sinus rhythm) and 10% from rate to rhythm (for worsening heart failure). There was no difference in the rates of cardiovascular death (27% for rhythm vs 25% for rate control) or all-cause mortality (32% vs 33%).

PMID: 18565859

Delivered as Daily POEM: 2008-08-06

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Corticosteroids, selective use of antibiotics and NPPV for COPD exacerbations

Clinical Question:

What are the most effective treatments for acute exacerbations of chronic obstructive pulmonary disease?

Bottom Line:

Systemic corticosteroids for all patients, and antibiotics and noninvasive positive pressure ventilation (NPPV) for inpatients, reduce the likelihood of treatment failure in patients with an acute exacerbation of chronic obstructive pulmonary disease (COPD). ([LOE = 1a](#))

Reference:

[Quon BS, Gan WQ, Sin DD. Contemporary management of acute exacerbations of COPD: A systematic review and meta-analysis. Chest 2008;133:756-766.](#)

Study Design:

Meta-analysis (randomized controlled trials)

Funding:

Government

Setting:

Various (meta-analysis)

Synopsis:

This ambitious and well-executed study systematically reviewed the literature regarding corticosteroids, antibiotics, and NPPV for the treatment of acute exacerbations of COPD. The authors performed a careful review of the literature to identify randomized controlled trials to compare the above interventions with placebo or standard medical therapy. Only studies with a score on the 5-point Jadad quality scale of greater than or equal to 3 for antibiotics and steroids and greater than or equal to 2 for NPPV (because masking was not possible) were included. They identified 10 studies of corticosteroids with 959 patients; 11 studies of antibiotics with 1020 patients; and 14 studies of NPPV with 979 patients. Systemic corticosteroids reduced the likelihood of treatment failure (relative risk [RR] = 0.54; 95% CI, 0.41 - 0.71) and length of stay (RR = -1.4 days; -0.6 to -2.2 days). Eight of 11 studies of antibiotics were of inpatients, with a reduction in treatment failure rate (RR = 0.54; 0.32 - 0.92) and in-hospital mortality (RR = 0.22; 0.08 - 0.62). There was no evidence of benefit of antibiotics for outpatients; of 3 studies, 2 showed no benefit and 1 did not report results for treatment failure. NPPV reduced the need for intubation (RR = 0.35; 0.26-0.47) and in-hospital mortality (RR = 0.45; 0.3 - 0.66).

PMID: 18321904

Delivered as Daily POEM: 2008-08-07

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Fluoroquinolones = beta-lactam for acute bacterial sinusitis

Clinical Question:

Are fluoroquinolones more effective than beta-lactam antibiotics for acute bacterial sinusitis?

Bottom Line:

The authors found no benefit to fluoroquinolones over beta-lactams for acute bacterial rhinosinusitis (ABRS). The more important and relevant questions are whether we can distinguish ABRS from viral sinusitis (not very well) and whether antibiotics are needed at all (probably not for most patients). If you decide to prescribe an antibiotic because of severity of illness or duration of symptoms, a beta-lactam will work as well as a fluoroquinolone. ([LOE = 1a](#))

Reference:

[Karageorgopoulos DE, Giannopoulou KP, Grammatikos AP, Dimopoulos G, Falagas ME. Fluoroquinolones compared with beta-lactam antibiotics for the treatment of acute bacterial sinusitis: a meta-analysis of randomized controlled trials. CMAJ 2008;178:845-854.](#)

Study Design:

Meta-analysis (randomized controlled trials)

Funding:

Unknown/not stated

Allocation:

Uncertain

Setting:

Outpatient (any)

Synopsis:

The authors identified 11 studies that compared a fluoroquinolone with a beta-lactam for ABRS. Study quality was mixed: 5 studies were open label, 5 did not adequately describe randomization, 8 did not describe allocation concealment, and 4 did not describe patient withdrawals. The fluoroquinolones studied were moxifloxacin (4), levofloxacin (3), gatifloxacin (1), ciprofloxacin (2), and sparfloxacin (1). The most common comparison drugs were cefuroxime axetil (5 studies) and amoxicillin clavulanate (5 studies). The dose of the comparator drug was adequate; 8 studies required computed tomography or radiographic abnormalities for inclusion in addition to typical symptoms of ABRS. Using intention-to-treat analysis, there was no benefit to fluoroquinolones compared with beta-lactams regarding clinical success (odds ratio [OR] = 1.09; 95% CI, 0.85 - 1.39). If you included all "clinically evaluable" patients (ie, per protocol analysis) there was a slight benefit to fluoroquinolones (OR = 1.29; 1.03 - 1.63). Interestingly, the benefit was similar for nonrespiratory fluoroquinolones, which are supposed to have very limited activity against the bacteria that cause ABRS.

PMID: 18362380

Delivered as Daily POEM: 2008-08-08

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Pimecrolimus (Elidel) cream minimally effective for perioral dermatitis

Clinical Question:

Is 1% pimecrolimus cream (Elidel) safe and effective for treating perioral dermatitis?

Bottom Line:

Adults with perioral dermatitis clinically improve faster with 1% pimecrolimus cream (Elidel) compared with inactive placebo, but after 1 month there is no longer any significant difference in response rates between active and control therapy. In this study, the subgroup of patients with a history of topical corticosteroid use received significantly more benefit from pimecrolimus cream. ([LOE = 1b-](#))

Reference:

[Schwarz T, Kreiselmaier I, Bieber T, et al. A randomized, double-blind, vehicle-controlled study of 1% pimecrolimus cream in adult patients with perioral dermatitis. J Am Acad Dermatol 2008;59:34-40.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry

Allocation:

Uncertain

Setting:

Outpatient (specialty)

Synopsis:

Perioral dermatitis (POD) consists of erythematous papules or papulopustules occurring most often in young and middle-aged women. These investigators identified 124 adults meeting clinical criteria for perioral dermatitis with a severity score of 4 or higher at baseline on a previously validated POD Severity Index scoring tool (0 - 9, from none to worst, based on the amount of erythema, papules, and scaling). Eligible subjects randomly applied (uncertain allocation concealment) either active 1% pimecrolimus cream (Elidel) or matched placebo to the affected skin twice daily. Clinicians evaluating outcomes remained blind to treatment group assignment. Complete follow-up occurred for 90% of patients for 8 weeks. By intention-to-treat analysis, a greater than 50% reduction in POD Severity Index scores occurred for significantly more patients in the treatment group compared with control at day 8 (40% vs 11%, respectively). However, by day 29 there was no longer a statistically significant difference in the percentage of patients attaining a greater than 50% decrease in severity scores between the treatment and control group (65% vs 60%, respectively). Subjects with a history of topical corticosteroid use were significantly more likely to respond favorably to active treatment at day 29. Recurrence rates were similar in both treatment groups. Adverse events were mild and occurred similarly in both groups.

PMID: 18462835

Delivered as Daily POEM: 2008-08-11

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Bright light minimally improves cognitive function in elderly with dementia

Clinical Question:

Is bright light therapy and/or melatonin supplementation effective in improving cognitive and noncognitive function in elderly residents of group care facilities?

Bottom Line:

Bright light therapy (+1000 lux) minimally improves cognitive and noncognitive function in elderly residents of assisted living group facilities. Melatonin supplementation minimally improves sleep quality, but adversely affects daytime mood. The combination of bright light therapy and melatonin reduced the adverse effects of melatonin alone. Unfortunately neither bright light therapy, melatonin, nor the combination significantly reduced or delayed transfer to a nursing facility or overall mortality. ([LOE = 1b](#))

Reference:

[Riemersma-van der Lek RF, Swaab DF, Twisk J, Hol EM, Hoogendijk WJG, Van Someren EJW. Effect of bright light and melatonin on cognitive and noncognitive function in elderly residents of group care facilities. A randomized controlled trial. JAMA 2008;299:2642-55.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry + govt

Allocation:

Concealed

Setting:

Outpatient (any)

Synopsis:

Long-term stimulation of the circadian rhythm system with bright light and melatonin supplementation may reduce cognitive decline in the elderly. These investigators identified 189 residents of 12 assisted care facilities in the Netherlands, mean age 85.5 years. Most subjects (87%) met DSM IV criteria for probable Alzheimer dementia (63%), vascular dementia (11%), or other types of dementia (13%). By a 2 X 2 factorial design, patients in individual facilities randomly received (concealed allocation assignment) supplemental daily bright light (+1000 lux); bright light plus melatonin (2.5 mg at night, to all participants); regular light (+300 lux) plus melatonin; or regular light plus placebo. Bright lights remained on each day from approximately 9 AM to 6 PM. All caregivers and individuals assessing outcomes remained blind to randomization status and were unable to statistically correctly categorize facility light status. Complete follow-up occurred for all patients including death or transfer to a skilled nursing facility for 3.5 years. By intention-to-treat analysis, bright light therapy significantly reduced cognitive decline by 0.9 points on the 30-point Mini-Mental State Examination. It is uncertain whether this amount of change is clinically meaningful. By standard previously validated tools, bright light therapy also significantly but minimally improved depression scores and functional limitation ratings. Melatonin alone significantly shortened time taken to fall asleep (mean, -8.2 minutes) and increased sleep duration (mean, +27 minutes), but also increased withdrawn behavior and negative affect. However, the combination of melatonin and bright lights had no adverse effects. Unfortunately, but more clinically relevant, treatment group assignment had no significant association with frequency or timing of transfer to a skilled nursing facility or overall mortality.

PMID: 18544724

Delivered as Daily POEM: 2008-08-12

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St. John's wort not effective for treatment of ADHD

Clinical Question:

Is St. John's wort safe and effective in the treatment of ADHD?

Bottom Line:

This study found no difference between St. John's wort and placebo in the treatment of children and adolescents with attention deficit/hyperactivity disorder (ADHD). ([LOE = 1b](#))

Reference:

[Weber W, Vander Stoep A, McCarty RL, Weiss NS, Biederman J, McClellan J. Hypericum perforatum \(St. John's Wort\) for attention-deficit/hyperactivity disorder in children and adolescents. A randomized controlled trial. JAMA 2008;299:2633-41.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry + govt

Allocation:

Concealed

Setting:

Outpatient (specialty)

Synopsis:

Complementary or alternative medicine is frequently used by parents for their children with attention-deficit/hyperactivity disorder (ADHD). These investigators identified 54 children, aged 6 to 17 years, meeting DSM IV criteria for ADHD. Eligible subjects who did not significantly improve after a 1-week placebo run-in phase randomly received (concealed allocation assignment) Hypericum perforatum (St. John's wort) standardized to 0.3% hypericin (300 mg 3 times daily) or matched placebo. Changes in ADHD symptoms were measured using previously validated improvement scales. One investigator, blinded to treatment group assignment, administered the symptom scoring tools to parents at baseline and weeks 1, 2, 4, and 8. Complete follow-up occurred for all but one subject at 8 weeks. Using both intention-to-treat and per-protocol (including only medication-compliant subjects) analysis, no significant differences were found in the change in rating scale scores from baseline to week 8 between the 2 treatment groups. Approximately half of the parents, children, and clinicians correctly identified individual medication status. Adverse effects were also similarly reported in both groups. The study was 80% powered to detect an 8-point difference on a 54-point scale between the two groups.

PMID: 18544723

Delivered as Daily POEM: 2008-08-13

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Pharmacist-assisted Web-based care improves hypertension control

Clinical Question:

Can a pharmacist-assisted Web-based care program improve hypertension control?

Bottom Line:

A pharmacist-assisted management program including home blood pressure monitoring and regular web site communication resulted in a higher rate of adequate blood pressure control in hypertensive adults than usual office-based care or home blood pressure monitoring and web site communication alone. ([LOE = 1b](#))

Reference:

[Green BB, Cook AJ, Ralston JD, et al. Effectiveness of home blood pressure monitoring, Web communication, and pharmacist care on hypertension control. A randomized controlled trial. JAMA 2008;299:2857-67.](#)

Study Design:

Randomized controlled trial (single-blinded)

Funding:

Government

Allocation:

Concealed

Setting:

Outpatient (any)

Synopsis:

Effective efforts to improve blood pressure (BP) control in hypertensive patients are urgently needed. These investigators identified 778 adults, aged 25 to 75 years, with Internet access and uncontrolled hypertension (systolic pressure from 141 to 199 mm Hg and/or diastolic pressure from 91 to 109 mm Hg) and no other coexisting serious disease. Eligible subjects were randomly assigned (concealed allocation) to either usual care with their individual clinician; home BP monitoring and web site training; or home BP monitoring and Web site training plus pharmacist-assisted care management. Web site access and training included usual care plus e-mail communication with individual clinicians, medication refills, lab information, and patient education tools. Pharmacist-assisted care consisted of active individual-based, online medication adjustment using nationally accepted hypertension guidelines. Individuals assessing outcomes remained blind to treatment group assignment. Complete follow-up occurred for 94% of patients at 12 months and all analyses were by intention-to-treat. Adequate BP control (< 140/90 mm Hg) occurred significantly more often in the home BP monitoring/Web site training plus pharmacist-assisted care group compared to the home BP monitoring/web site training and usual care groups (56% vs. 36%, 31%, respectively; NNT = 5, range 3-7). There was no significant difference in the rate of adequate BP control between the usual care and home BP monitoring/Web site training group.

PMID: 18577730

Delivered as Daily POEM: 2008-08-14

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Intensive control of blood sugar (HbA1c < 7.0%) in DM2 may be harmful (ACCORD)

Clinical Question:

Does intensive control of blood sugar (HbA1c < 7.0%) improve outcomes in adults with type 2 diabetes?

Bottom Line:

Intensive control of blood glucose levels in type 2 diabetics (glycated hemoglobin level < 7.0%) may reduce the incidence of disease-oriented outcomes, but multiple studies have failed to demonstrate any significant reduction in the incidence of adverse patient-oriented outcomes. In this study, intensive control actually increased the incidence of all-cause mortality. Metformin significantly reduces the risk of both major macrovascular events and all-cause mortality and should remain the treatment of choice for lowering blood sugar in type 2 diabetics. There is no evidence that significantly demonstrates improved patient-oriented outcomes for any other diabetic drug classes, including insulin. ([LOE = 1b](#))

Reference:

[Gerstein HC, Miller ME, Byington RP, for the Action to Control Cardiovascular Risk in Diabetes \(ACCORD\) Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358:2545-59.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Foundation

Allocation:

Uncertain

Setting:

Outpatient (specialty)

Synopsis:

Previous studies of type 2 diabetes have not reported any significant patient-oriented benefits for intensive control of blood glucose levels, regardless of treatment modality (Shaughnessy AF, Slawson DC. BMJ 2003;327:1-7). The present investigators identified 10,251 adults, aged 40 to 79 years, with type 2 diabetes and a median glycated hemoglobin level (HbA1c) of 8.1%. Eligible subjects randomly received (uncertain allocation concealment) either intensive therapy (targeted HbA1c < 6.0%) or standard therapy (HbA1c from 7.0% to 7.9%). Treatment regimens were individualized by standard diabetic medications at the discretion of patients and their clinicians. Complete follow-up occurred for 99% of subjects for a mean of 3.5 years. The individuals who measured all outcomes remained blind to treatment group assignment. By intention-to-treat analysis, at 1 year HbA1c levels were significantly lower in the intensive-therapy group compared with the standard therapy group (6.4% vs 7.5%, respectively). Lower HbA1c levels in the intensive-therapy group were associated with higher medication use from all diabetic drug groups. However, as a result of an increase in all-cause mortality in the intensive-therapy group compared with standard therapy (257 vs 203 deaths, respectively), the study was discontinued. Subjects in the intensive-therapy group also had a significantly increased rate of hypoglycemia, weight gain, and fluid retention. Another study published in the same journal issue (The ADVANCE Collaborative Group. N Engl J Med 2008;358:2560-72) also evaluated the benefit of intensive-control (HbA1c of 6.5% or less) compared to standard therapy (HbA1c from 7.0% to 7.9%) in 11,140 adults with type 2 diabetes. Although intensive-control significantly reduced the incidence of disease-oriented microvascular events (primarily nephropathy), intensive control did not significantly reduce any patient-oriented major macrovascular events (including death from cardiovascular causes or all-cause mortality). Severe hypoglycemia was again significantly more common in the intensive-control group.

PMID: 18539917

Delivered as Daily POEM: 2008-08-15

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After 15 years, 50% of patients with optic neuritis developed MS (ONTT)

Clinical Question:

How many patients with optic neuritis will develop multiple sclerosis?

Bottom Line:

After 15 years of follow up, 50% of patients with optic neuritis went on to develop multiple sclerosis (MS). Patients with 1 or more white matter lesions on magnetic resonance imaging (MRI) have the greatest risk of developing MS. (LOE = 1b-)

Reference:

[Optic Neuritis Study Group. Multiple sclerosis risk after optic neuritis: final optic neuritis treatment trial follow-up. Arch Neurol 2008;65:727-732.](#)

Study Design:

Cohort (prospective)

Funding:

Government

Setting:

Outpatient (specialty)

Synopsis:

The Optic Neuritis Treatment Trial was a randomized controlled trial of steroids versus placebo in 389 adult patients without MS who had acute unilateral optic neuritis. The authors used standard criteria for the diagnosis of MS. In addition to the original episode of optic neuritis, a patient had to have a second new neurologic deficit attributable to central nervous system demyelination lasting at least 24 hours and separated by at least 4 weeks from the initial event. Recurrent episodes of optic neuritis did not count in the diagnostic criteria for MS. At the beginning of the study, each patient underwent a standardized assessment that included MRI of the brain. Most of the patients were white (85%) and female (77%) with an average age of 39 years. After 15 years, 50% of the patients (95% CI, 44% - 56%) developed MS, most in the first 5 years. The risk of developing MS was highly correlated to the number of lesions found on the initial MRI. Twenty five percent of patients with no lesions developed MS (18% - 32%), while 72% of those with at least 1 lesion developed MS (63% - 81%). Although the researchers used statistical methods that take into account the patients who dropped out, a significant limitation of the study is that after 15 years, the researchers could only account for 142 of the original 389 patients.

PMID: 18541792

Delivered as Daily POEM: 2008-08-18

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Oral prednisolone is equal to naproxen in acute gout

Clinical Question:

Do oral prednisolone and naproxen have similar effectiveness in the initial treatment of patients with acute gout?

Bottom Line:

Oral prednisolone and naproxen are equivalent in treating acute gout. ([LOE = 1b](#))

Reference:

[Janssens HJ, Janssen M, van de Lisdonk EH, van Riel PL, van Weel C. Use of oral prednisolone or naproxen for the treatment of gout arthritis: a double-blind, randomised equivalence trial. Lancet 2008;371:1854-1860.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Foundation

Allocation:

Concealed

Setting:

Outpatient (primary care)

Synopsis:

Colchicine, long the gold standard in treating acute gout, has a narrow therapeutic window and cannot be used in patients with kidney failure. Nonsteroidal antiinflammatory drugs (NSAIDs) have been used more frequently in recent years, but their gastrointestinal toxicity, especially in the elderly, is problematic. Oral steroids are an attractive potential alternative since the short-term side effects are fairly mild. These researchers designed this study to see if oral prednisolone and naproxen were equivalent in treating patients with acute gout. Primary care physicians in the Netherlands were asked to refer any patient with acute monoarthritis to the study, even if gout was not the likely diagnosis. Within 1 day of referral, the patients had the joint fluid aspirated and evaluated for monosodium urate crystals. The authors excluded patients with unstable medical conditions, chronic rheumatic diseases, and upper gastrointestinal disorders. Patients were not allowed to use NSAIDs, colchicine, or other analgesics within 24 hours of enrollment or during the follow-up period. The patients were randomly assigned to receive prednisolone 35 mg once daily plus look-alike naproxen placebo twice daily (n = 60) or 500 mg naproxen twice daily plus look-alike prednisolone placebo once daily (n = 60). The researchers evaluated the patients for up to 3 weeks after enrollment. They analyzed the data by intention to treat. The study was designed to be powerful enough to detect moderate differences in pain (30 mm on a 100-mm scale). Only one patient in each group had incomplete data. Although both treatment groups had significant pain relief from baseline to follow-up, there was no significant difference in pain improvement or impairment between the 2 groups. Approximately two thirds of patients in each group reported no treatment side effects. The rate of side effects was identical in each group for: gastric or abdominal pain (15%); itching or dizziness (7%); and dyspnea or palpitations (5%). Approximately 20% in each group experienced "other side effects." By 3 weeks, all patients reported complete relief from the initial attack and no patients had a recurrence.

PMID: 18514729

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Perioperative metoprolol: fewer CV events and MIs, more deaths and strokes (POISE)

Clinical Question:

Is metoprolol effective in preventing bad outcomes in high-risk patients undergoing noncardiac surgery?

Bottom Line:

In this large, well-conducted study, the perioperative use of extended-release metoprolol was a mixed bag: it produced fewer major cardiovascular events but more deaths and more strokes. Other studies have found perioperative beta-blockers beneficial. However, they used different beta blockers, were smaller or had methodologic limitations. Pooled data from prior trials were less enthusiastic about the benefits and reported an increased risk of hypotension and bradycardia. (LOE = 1b)

Reference:

[POISE Study Group, Devereaux PJ, Yang H, Yusuf S, et al. Effects of extended-release metoprolol succinate in patients undergoing non-cardiac surgery \(POISE trial\): a randomised controlled trial. Lancet 2008;371:1839-1847.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry + govt

Allocation:

Concealed

Setting:

Inpatient (any location) with outpatient follow-up

Synopsis:

High-risk patients older than 45 years undergoing noncardiac surgery were randomly assigned (concealed allocation) to receive extended-release metoprolol (n = 4174) or placebo (n = 4177) perioperatively. The researchers used the following criteria to identify high-risk patients: coronary artery disease; peripheral vascular disease; stroke; hospitalization for congestive heart failure in the previous 3 years; major vascular surgery; and having any 3 of the 7 following risk criteria: intrathoracic or intraperitoneal surgery; congestive heart failure; transient ischemic attacks; diabetes; a serum creatinine level higher than 175 micromol/L (2.3 mg/dL); 70 years or older; and urgent or emergency surgery. The patients took 100 mg metoprolol or placebo 2 hours to 4 hours before surgery and a second dose 6 hours after surgery. For the subsequent 30 days, the patients took 200 mg daily. The main outcome, a composite of cardiovascular death plus nonfatal myocardial infarction plus nonfatal cardiac arrest, was evaluated 30 days after surgery by clinicians who were unaware of which treatment the patients received. The researchers used intention-to-treat analysis to assess the outcomes and had follow-up results for 99.8% of patients. Patients receiving metoprolol had a lower rate of the combined endpoint than patients receiving placebo (5.8% vs 6.9%; number needed to treat [NNT] = 92; 95% CI, 47 - 2135). Additionally, patients receiving metoprolol had fewer myocardial infarctions (4.2% vs 5.7%; NNT = 67; 41 - 175), but more deaths (3.1% vs 2.3%; number needed to treat to harm [NNTH] = 131; 68 - 1407) and more strokes (1% vs 0.5%; NNTH = 190; 110 - 605).

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Smoking is bad for your health

Clinical Question:

What is the risk of death among smokers compared with nonsmokers?

Bottom Line:

Cigarettes rob 5 to 10 years of life from smokers. Get a copy of this paper because it has several tables that might be useful to help motivate patients to quit smoking. An earlier paper by this team also has useful tables that can be found at <http://www.aafp.org/afp/20070315/poc.html>. (LOE = 2c)

Reference:

[Woloshin S, Schwartz LM, Welch HG. The risk of death by age, sex, and smoking status in the United States: putting health risks in context. J Natl Cancer Inst 2008;100:845-853.](#)

Study Design:

Other

Funding:

Government

Setting:

Population-based

Synopsis:

This team mined several databases, including the United States Census Bureau data, a national death registry, and the National Health Interview Survey. They calculated the age-specific and sex-specific death rates for the general population and also for citizens who never smoked, former smokers, and current smokers. Since concerns have been raised about the accuracy of these databases, the authors performed sensitivity analyses to determine how robust the data are. From all this, they generated simple charts comparing the risk of death from various causes for men and women, smokers and nonsmokers, all grouped in 5-year age increments. In general, men die 10 years earlier than women. Smoking adds 5 years to 10 years to a person's age. The authors point out the paradox of looking at relative risk of cause-specific death. The average smoker will die earlier than a nonsmoker and more likely from heart disease, lung cancer, and so forth. On the other hand, nonsmokers at age 75 have a greater chance of dying from prostate cancer, not associated with smoking. But this is due to the number of men who have already kicked off from other causes at earlier ages and NOT because smoking protects against prostate cancer.

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Motor cortex stimulation may improve chronic pain

Clinical Question:

Does motor cortex stimulation improve chronic pain?

Bottom Line:

The reporting of this systematic review limits the conclusions, but it appears that motor cortex stimulation decreases pain in patients with chronic pain. The inclusion of lower-quality studies and the incomplete reporting makes it difficult to determine if the improvement is clinically important. (LOE = 2a-)

Reference:

Lima MC, Fregni F. Motor cortex stimulation for chronic pain: systematic review and meta-analysis of the literature. Neurology 2008;10;70:2329-2337.

Study Design:

Meta-analysis (randomized controlled trials)

Funding:

Government

Setting:

Various (meta-analysis)

Synopsis:

The authors searched several databases for prospective studies that evaluated the effectiveness of motor cortex stimulation in patients with chronic pain. Additionally, the authors tried to find unpublished studies. The authors don't describe independent selection of the included studies, assessing study quality, or data extraction. They included 22 studies (327 patients) of invasive brain stimulation and 11 studies (274 patients) of noninvasive stimulation. In other words, these were all small studies. Some of the studies were open-label trials, a design that tends to make the intervention look better. The authors report that pain was significantly reduced by 9.4% using a visual analog scale. They also provide a great deal of data about the proportion of responders in the various studies, but fail to define what constitutes a response. They also fail to report the response rate in the control groups. The response rate is greater in the invasive studies than in the noninvasive studies, but since we don't know the control rate, we don't know how much better these interventions really are.

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Gestational diabetes screening: Insufficient evidence of benefit

Clinical Question:

Should pregnant women without known diabetes be screened for diabetes during their pregnancy?

Bottom Line:

Reaffirming their conclusions from 2003, the United States Preventive Services Task Force finds insufficient evidence to support routine screening for gestational diabetes. Treatment may improve some maternal and neonatal outcomes, though. Considering the number of women screened each year, the quantity of data to support this practice is appallingly low. ([LOE = 5](#))

Reference:

[U.S. Preventive Services Task Force. Screening for gestational diabetes mellitus: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008;148:759-765.](#)

Study Design:

Practice guideline

Funding:

Government

Setting:

Various (guideline)

Synopsis:

This guideline is based on a systematic review of four databases, updating the evidence report generated in 2003. They found no randomized controlled trials evaluating the effect of screening for diabetes. They were unable to find any studies evaluating the sensitivity or specificity of screening for gestational diabetes at any point during pregnancy. They state, though, in their recommendation, that most women who test positive actually will not have gestational diabetes. Two studies have evaluated treatment of gestational diabetes; one found a decrease in serious neonatal complications and less preeclampsia in treated women; the second study reduced macrosomia but not perinatal death. Both studies were done before current levels of treatment and monitoring were available. Three studies have addressed the psychological effect and burden of screening; these small studies found no difference in mood and only a short-term increase in anxiety. The American Diabetes Association, American College of Obstetricians and Gynecologists, and the World Health Organization recommend screening for most pregnant women. The UK's National Institute for Clinical Excellence recommends targeted screening of women with risk factors for gestational diabetes.

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NICE guidelines for diabetes mellitus, type 2

Clinical Question:

What does the National Institute of Clinical Effectiveness (NICE) recommend regarding the treatment of patients with type 2 diabetes?

Bottom Line:

The British NICE guidelines suggest good blood pressure control, metformin as initial treatment, daily aspirin, and statin treatment for most patients with type 2 diabetes (regardless of initial cholesterol level). These guidelines differ from the American Diabetes Association guidelines in that they are much more patient-centered and much less aggressive in their pursuit of sustained lower glucose levels. ([LOE = 5](#))

Reference:

[Home P, Mant J, Diaz J, Turner C, on behalf of the Guideline Development Group. Management of type 2 diabetes: updated NICE guidance. BMJ 2008;336:1306-8.](#)

Study Design:

Practice guideline

Funding:

Government

Setting:

Various (guideline)

Synopsis:

The NICE guidelines are derived from systematic reviews, supplemented, when minimal evidence is available, with recommendations based on expert opinion. Moving toward a more patient-centered approach that has not caught on in the U.S., the organization recommends involving patients in setting targets for their individual A1c levels, blood pressure, and lipid levels. Based on moderate evidence and expert opinion, the guidelines recommend structured education based on the needs of the individual, delivered by trained educators. Nutrition advice should be offered as well. They suggest home (self) glucose monitoring only as an aid to education, with continual reassessment of its need for an individual. Other recommendations: 1) Blood pressure control should be addressed in patients with a confirmed blood pressure of $>140/80$ mmHg or $>130/80$ mmHg with organ changes (high to moderate evidence). 2) Metformin should be first line treatment in most patients, following a trial of lifestyle changes and education (high quality evidence). 3) All patients with diabetes over the age of 50 years should receive daily aspirin, and younger patients with risk for cardiovascular disease (Moderate quality evidence). 4) Start statin treatment in most people at least 40 years old and in younger people with cardiovascular risk. Increase the dose to maintain a cholesterol less than 155 mg/dl (4.0 mmol/l) or low density lipoprotein <77 mg/dl (2.0 mmol/l). Based on high quality evidence. 5) Monitor albumin secretion, visual acuity, and neuropathic symptoms (expert opinion to high quality evidence).

PMID: 3081394

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NICE guidelines for lipid lowering

Clinical Question:

What does the British National Institute of Clinical Effectiveness (NICE) recommend regarding the treatment of patients at risk for cardiovascular disease and elevated lipid levels?

Bottom Line:

It's the baseline risk, not the baseline lipid levels, that is of primary importance when making decisions about lipid lowering treatment, according to NICE. For patients with elevated lipids but without heart disease, the guidelines suggest initiating treatment only if patients have a 10-year risk of 20%. A calculator is available to calculate this risk in Essential Evidence Plus. For this primary prevention, they suggest a hands-off approach of treating with simvastatin 40 mg daily and not checking follow-up cholesterol. For patients with heart disease, they suggest starting with the same dose but checking response and increasing the dose when necessary. They apply these guidelines to men and women, though cholesterol treatment in women has not been shown to decrease mortality. (LOE = 5)

Reference:

Cooper A, O'Flynn N. Risk assessment and lipid modification for primary and secondary prevention of cardiovascular disease: summary of NICE guidance. BMJ 2008;336:1246-1248.

Study Design:

Practice guideline

Funding:

Government

Setting:

Various (guideline)

Synopsis:

The British NICE guidelines are derived from systematic reviews, supplemented, when minimal evidence is available, with recommendations based on expert opinion. These guidelines move away from "if cholesterol is high, lower it" to a more nuanced approach, focusing on patients' risk for CV disease. This approach makes sense, given that most people would not qualify for the studies that have been conducted on cholesterol-lowering drugs (Arch Intern Med 2001;161:949-54). For patients without pre-existing heart disease, the guidelines emphasize establishing their 10 year risk using a calculator based on the Framingham data (see Essential Evidence Plus) and treating only patients with a risk level of at least 20%. Adding their own spin to this risk calculation, they suggest increasing the risk estimate by 1.5 if the patient has one first-degree relative with premature heart disease, and doubling it if they have two first-degree relatives with premature heart disease. In a much more hands-off approach, the guidelines suggest treating patients meeting with this criteria with simvastatin 40 mg and -- ! -- not checking response to therapy or increasing the dose. Adopting this approach will require quite a culture change in the U.S. For secondary prevention in patients with pre-existing heart disease, the guidelines suggest starting with simvastatin 40 mg daily and increasing the dose if the patient's total cholesterol does not decrease to < 155 mg/dl (4.0 mmol/l) or low density lipoprotein < 77 mg/dl (2.0 mmol/l). The guidelines suggest these approaches for men and women, even though cholesterol lowering has not been shown to decrease mortality in women (JAMA. 2004;291:2243-2252, Lancet 2007; 369: 168-169).

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Pioglitazone does not increase cardiovascular events (PROactive)

Clinical Question:

What is the effect of pioglitazone (Actos) on the likelihood of cardiovascular events in patients with diabetes at high risk?

Bottom Line:

Pioglitazone (Actos), unlike its chemical cousin rosiglitazone (Avandia), does not seem to increase the likelihood of cardiovascular events (N Engl J Med. 2007;356:2457-2471). The researchers conducting this study stretched -- and broke -- the scientific method when claiming benefit, but any claims of benefit are specious. ([LOE = 1a-](#))

Reference:

[Wilcox R, Kupger S, Erdmann E, for the PROactive study investigators. Effects of pioglitazone on major adverse cardiovascular events in high-risk patients with type 2 diabetes: Results from PROspective pioglitAzone Clinical Trial in macro Vascular Events \(PROactive 10\). Am Heart J 2008;155:712-7.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Industry

Allocation:

Concealed

Setting:

Outpatient (specialty)

Synopsis:

To study the effect of pioglitazone on cardiovascular events, these European researchers enrolled 5,238 high-risk patients with diabetes for an average 9.5 years. Most of the patients (75%) had hypertension, half had myocardial infarction in their history, and 19% had experienced a stroke. In addition to their aggressive treatment for all of these risk factors, patients were randomized (allocation concealed) to receive either placebo or pioglitazone, force-titrated to 45 mg/day, for 3 years. Over this time period, approximately 11% of patients experienced at least one of the three events that made up the composite outcome evaluated in this report: cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke. The researchers report a statistically significant difference between treatment and placebo, though their statistical analysis was suspect and likely improper. Despite having several analyses, they did not adjust the p-value for multiple comparisons. Also, none of the outcomes, when assessed individually, were statistically lower in the treated group. For a composite outcome to be considered valid, at least one of the individual outcomes should be statistically significant. An even greater threat to the validity of this study is that the overall goal of the PROactive study was to evaluate the effect of pioglitazone on a different composite outcome, all-cause mortality, nonfatal myocardial infarction, stroke, acute coronary syndrome, endovascular or surgical intervention in the coronary or leg arteries, and amputation above the ankle. There was no difference with therapy on this outcome (Lancet 2005;366:1279-89). Researchers cannot slice-and-dice their data so that they find a significant difference.

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Antibiotic prophylaxis promising for anal sphincter repair

Clinical Question:

Does antibiotic prophylaxis reduce the rate of wound infections when given at the time of anal sphincter repair after vaginal delivery?

Bottom Line:

For women with a third-degree or fourth-degree perineal laceration during vaginal childbirth a single dose of a second-generation cephalosporin administered at the time of anal sphincter repair probably reduces the risk for wound infections. Although further studies are needed, this evidence is sufficient to consider the use of prophylactic antibiotics. (LOE = 2b)

Reference:

[Duggal N, Mercado C, Daniels K, Bujor A, Caughey AB, El-Sayed YY. Antibiotic prophylaxis for prevention of postpartum perineal wound complications. Obstet Gynecol 2008;111:1268-1273.](#)

Study Design:

Randomized controlled trial (double-blinded)

Funding:

Unknown/not stated

Allocation:

Concealed

Setting:

Inpatient (ward only)

Synopsis:

Women who had third-degree or fourth-degree perineal lacerations at the time of vaginal birth were enrolled in this randomized double-blind controlled trial. Exclusions included being younger than 18 years, group B streptococcus positive, HIV positive, having chorioamnionitis, history of inflammatory bowel disease, or already taking antibiotics. Treatment consisted of a single dose of cefotetan or cefoxitin, 1 g intravenously, or clindamycin 900 mg intravenously if allergic to penicillin, or placebo. The study was conducted at 2 hospitals with differing pharmacy formularies, which dictated the choice of cephalosporins at each. Outcome was assessed at 2 weeks by perineal examination by one of the investigators. The study was planned for an enrollment of 310 women, but the analysis was conducted after 3 years with 147 patients enrolled, of whom 107 attended the evaluation at 2 weeks postpartum. Follow-up information was obtained by medical record review of the postpartum visit for an additional 21 patients, none of whom had documentation of wound complications. Thus, the primary analysis included 128 patients. There were wound infections in 4 of 55 (7%) women who received antibiotics and 14 of 73 (17%) women who did not ($P = .07$).

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Maternal obesity associated with neural tube defects

Clinical Question:

Is maternal obesity associated with an increased risk for neural tube defects in offspring?

Bottom Line:

There is an association between maternal obesity and neural tube defects in their children with a dose-response gradient (increasing risk with increasing body mass index) that persists after adjustment for known confounders. Intervention studies are needed. ([LOE = 1a-](#))

Reference:

[Rasmussen SA, Chu SY, Kim SY, Schmid CH, Lau J. Maternal obesity and risk of neural tube defects: a metaanalysis. Am J Obstet Gynecol 2008;198:611-619.](#)

Study Design:

Meta-analysis (other)

Funding:

Government

Setting:

Various (meta-analysis)

Synopsis:

Observational studies regarding the association between neural tube defects and maternal obesity have had inconsistent results. These authors conducted a meta-analysis of the published literature to synthesize the evidence. They identified 12 cohort and case-control studies that met their inclusion criteria of reporting obesity measures before pregnancy weight gain, had comparison group of normal weight women, and reported the outcome of neural tube defects. All but 2 studies were conducted in the United States. Neural tube defects were defined as spina bifida, anencephaly, encephalocele, craniorachischis, or iniencephaly. The authors calculated unadjusted odds ratios of 1.22 (95% CI, 0.99-1.49), 1.70 (1.34-2.15), and 3.11 (1.75-5.46), among overweight, obese, and severely obese women. Adjustments to account for other variables did not meaningfully change the results.

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Doula support decreases cesarean rate

Clinical Question:

Does the support of a doula decrease cesarean delivery rate for nulliparous women in labor with a male partner present?

Bottom Line:

The support of a doula in labor reduces the risk of cesarean delivery for nulliparous women laboring with a male partner present. ([LOE = 2b](#))

Reference:

[McGrath SK, Kennell JH. A randomized controlled trial of continuous labor support for middle-class couples: Effect on cesarean delivery rates. Birth 2008; 35:92-97.](#)

Study Design:

Randomized controlled trial (nonblinded)

Funding:

Government

Allocation:

Concealed

Setting:

Inpatient (ward only)

Synopsis:

Previous randomized controlled trials have demonstrated reductions in cesarean rates and improved obstetrical outcomes for low-income women laboring without the support of family members. This study included laboring nulliparous middle-income or upper-income women accompanied by their male partners. Obstetric care was provided by private obstetricians working in a university hospital labor and delivery unit. Four hundred twenty women were enrolled and randomly assigned to have the support of a doula or no support of a doula. There were 10 doulas ranging in age from 24 years to 44 years. In addition to direct support of the women, doulas assisted the partners in their efforts to be supportive. The cesarean delivery rate was 13% in the doula group and 25% among the control group (number needed to treat [NNT] = 9; 95% CI, 5-25). For women undergoing induction of labor the rates were 13% vs 59% (NNT = 2, 1.5-7). The doula group also had a lower rate of epidural analgesia: 65% vs 76% (NNT = 9; 5-40).

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