POEMs
Patient-Oriented Evidence that Matters

Each month, the POEMs editorial team reviews more than 80 journals of interest to primary care physicians, identifying the articles you have to know about to stay up to date. We call these articles POEMs (Patient-Oriented Evidence that Matters) because they deal with common primary care problems, report outcomes that matter to patients, and have the potential to change the way we practice. The 8 most important articles are critically appraised each month by a team of more than 50 reviewers who make a recommendation for clinical practice. The collected reviews of the POEMs are available on the Internet at http://jfp.msu.edu. Additional POEMs and other related evidence-based material are published in a monthly newsletter called Evidence-Based Practice, *available through subscription (1-201-782-5726; fax 1-201-391-2778) or via http://jfp.msu.edu/ebp.htm*

■ BEHAVIOR THERAPY FOR URGE INCONTINENCE IN OLDER WOMEN

Burgio KL, Locher JL, Goode PS, et al. Behavioral vs drug treatment for urinary urge incontinence in older women: a randomized controlled trial. JAMA 1998; 280:1955-2000.

Clinical question How effective is behavioral therapy in the treatment of urge incontinence in older women?

Background Urge incontinence is a common and costly condition affecting approximately 38% of older community-dwelling women. This condition can predispose patients to social isolation, depression, and other health problems. Pharmacologic intervention is the treatment of choice for urge incontinence. Some studies, however, have shown improvement in bladder control can be achieved through behavioral therapy.

Population studied The authors studied 197 older community-dwelling women (55 years or older) who had at least 2 episodes per week of urge incontinence in the previous 3 months.

Study design and validity This randomized controlled study was designed to compare the effects of behavior therapy with drug therapy or placebo in treating urge incontinence. Patients were given bladder diaries to document pretreatment frequency of incontinence. Inclusion criteria consisted of at least 2 accidents per week and urodynamic evidence of bladder dysfunction. Patients were excluded if they had a postvoid residual greater than 200 mL, continued leakage, uterine prolapse, unstable angina, decompensated congestive heart failure, arrhythmias, or impaired mental status (Mini-Mental State Examination score of <20).

All subjects were treated for a total of 8 weeks (4 clinic visits at 2-week intervals). Urine specimens were collected; anal sphincter pressures were measured using manometry; and all subjects completed an adverse-effect checklist. Subjects from the behavioral group were taught anorectal and pelvic muscle feedback skills and strategies to diminish urgency and urine loss. Subjects in the drug-intervention group were randomized in a double-blind fashion to either oxybutynin (Ditropan) in a minimum dosage of 2.5 mg per day titrated as necessary to a maximum dosage of 5.0 mg 3 times daily, or placebo. Bladder diaries were used to make dosage adjustments and to monitor progress and adverse effects.

Patients completed 2 weeks of posttreatment bladder diaries after interventions were done. Follow-up visits included a final urine specimen, adverse-effect checklist, cystometrogram, and patient satisfaction questionnaire. Subjects were asked to describe their progress, satisfaction with progress, and any perceived improvement.

Outcomes measured The primary outcome measured was reduction in frequency of incontinent episodes as derived from bladder diaries. Pretreatment and posttreatment frequencies of incontinence were used to calculate a percentage of reduction for each subject.

Results Frequency of incontinence was similar among the 3 groups before treatment. Behavioral therapy was significantly more effective than drug treatment (81% reduction in incontinence episodes vs 69%; $P = .04$; number needed to treat = 8.3), and both were more effective than placebo (39%). Patient-perceived improvement was also greatest for the behavioral therapy group (74% much better vs 51% and 27% for the drug-treatment and placebo groups, respectively). Only 14% of patients receiving biofeedback training as opposed to 75% in the drug and placebo groups wanted to change to another treatment.

Recommendations for clinical practice **Although biofeedback has traditionally been used in the treatment of stress incontinence, this study provides evidence of its safety and effectiveness in the treatment of urge and mixed urinary incontinence. This type of treatment requires a highly motivated patient with little cognitive impairment, thus limiting the number of older patients who could benefit. It is uncertain how long the effects**

of treatment will last, whether refresher courses will be necessary, and whether this treatment will be cost-effective and reimbursed by third-party payers (since behavioral intervention requires multiple teaching sessions conducted by a specialist in this field). It seems very reasonable to consider biofeedback training for motivated patients who prefer not to take medications for the long term or who are unable to tolerate them.

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■ ASPIRIN AND THE RISK OF HEMORRHAGIC STROKE

Clinical question What is the risk of hemorrhagic stroke associated with aspirin treatment?

Background Aspirin is widely used to reduce the risk of myocardial infarction and ischemic stroke. While several studies have shown an increase in the risk of hemorrhagic stroke among aspirin users, none had sufficient statistical power to provide definitive results.

Population studied Trials from North America, Europe, the United Kingdom, and Australia were included in this meta-analysis. Patients were predominantly men (86%) and white (99%), with an average age of 59 years. Fourteen of the 16 trials included only patients with preexisting cardiovascular or cerebrovascular disease. The 2 remaining trials, which studied healthy white men, included as many participants as the other 14 trials combined.

Study design and validity This study was a meta-analysis, combining patient data from randomized controlled trials in which participants were treated with aspirin, a placebo, or nothing. Patients in the treatment groups of these trials took only aspirin or placebo for at least 1 month. Sixteen trials with 55,462 participants were included in this meta-analysis. The mean dose of aspirin was 273 mg per day (range = 75 - 1500 mg/day) and the mean duration of treatment was 37 months. A total of 108 hemorrhagic stroke cases occurred in 13 of the 16 trials. No hemorrhagic strokes were reported in the 3 remaining trials. Information on country of origin, sample size, duration of study, study design, aspirin dosage, participant characteristics, and outcomes was independently abstracted by 2 of the authors using a standardized protocol.

Numerous trials have compared aspirin treatment with treatments using other antiplatelet or anticoagulant medications, and others have studied a combination of aspirin therapy with one of these medications compared with a control. By choosing to include only studies that met the above criteria, the authors were able to isolate the effect of aspirin on the risk of hemorrhagic stroke. In addition, the combination of randomized studies and meta-analysis techniques allowed the authors to find differences with enough statistical strength to provide definitive results regarding that risk, something that had not been possible with the individual trials.

Outcomes measured The primary outcome was the likelihood of different types of stroke during treatment. In addition, the authors assessed the overall likelihood of stroke and myocardial infarction, cardiovascular disease mortality, and all-cause mortality that occurred during treatment.

Results The total number of strokes was reduced by 31 events per 10,000 persons (95% confidence interval [CI], 5 - 57; $P = .02$). A total of 322 people had to be treated for 1 to benefit (number needed to treat [NNT] = 322). Aspirin use was associated with an increase in the absolute risk of hemorrhagic stroke of 12 events per 10,000 persons (95% CI, 5 - 20; $P < .001$; number needed to harm [NNH] = 833). However, aspirin reduced the likelihood of ischemic stroke by 39 events per 10,000 persons (95% CI, 17 - 61; $P < .001$; NNT = 256). Neither patient characteristics nor study design influenced the absolute risk.

Overall, aspirin use reduced all-cause mortality by 120 per 10,000 persons (95% CI, 77 - 162; $P < .001$; NNT = 83). Cardiovascular deaths were decreased by 97 per 10,000 (95% CI, 59 - 135; $P < .001$; NNT = 103). The incidence of myocardial infarction was reduced by 137 events per 10,000 persons (95% CI, 107 - 167; $P < .001$; NNT = 73), and fatal myocardial infarction rates were reduced by 37 events per 10,000 persons (95% CI, 16 - 55; $P < .001$, NNT = 270).

Recommendations for clinical practice This meta-analysis quantifies the risk of hemorrhagic stroke associated with aspirin therapy. The NNH of patients treated with aspirin to have 1 event of hemorrhagic stroke is 833. Although this is not an insignificant number considering the potentially catastrophic implications of hemorrhagic stroke, it is much higher than the NNT with aspirin to prevent the complications of cardiovascular disease. Therefore, for patients for whom aspirin is being prescribed for secondary prevention or for those with multiple risk factors, the benefits of aspirin therapy outweigh the risks. For low-risk individuals, including men and women younger than 50 years without evidence of heart disease, aspirin