

# Clinical Briefs in Primary Care™

The essential monthly primary care update

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## Oral Triptans in Acute Migraine Treatment

**Source:** Ferrari MD, et al. *Lancet*. 2001;358:1668-1675.

MIGRAINE IS A COMMONPLACE disorder that typically results in recurrent attacks of disabling headache. Triptans have become the foundation of abortive therapy for most migraneurs, yet little guidance is available to choose the most appropriate triptan from among the available, and soon to be available, agents. In this meta-analysis, Ferrari and colleagues reviewed data from 24,089 patients who had been included in double-blind, randomized, controlled clinical trials of oral triptans in migraine.

Sumatriptan (SUM) is the most widely used triptan, and hence serves as the most convenient and familiar comparator. Efficacy measures included response at 2 hours, pain free at 2 hours, recurrence within 24 hours, and sustained pain-free status (free of headache at 2 hours, without recurrence within 24 hours).

Eletriptan (ELE) demonstrated a higher placebo-subtracted 2-hour response rate and pain free at 2 hours rate than SUM, but frovatriptan (FRO) was slightly less efficacious than SUM for response at 2 hours. Sustained pain-free status was statistically significantly greater for rizatriptan (RIZ), ELE, and almotriptan (ALM). Placebo-subtracted adverse events rates were significantly lower for ALM.

As a group, all triptans demonstrate similar efficacy and adverse event profiles. Modest differences between agents might be helpful in initial product selection. ■

## Simvastatin, Niacin, and Antioxidant Vitamins for the Prevention of CAD

**Source:** Brown BG, et al. *N Engl J Med*. 2001;345:1583-1592.

IT HAS BEEN SUGGESTED THAT cardiovascular risk is separately and independently related to both changes in LDL and HDL. The oft-quoted relationship between lipid subfractions suggests that for each 1% reduction in LDL, one might achieve a 1-1.5% decline in cardiovascular end points, and that for each 1% increase in HDL a 2-4% reduction in cardiovascular end points. This study (n = 160) evaluated the hypothesis that for persons with existing coronary artery disease (CAD), lipid-altering and antioxidant treatments might provide independent and additive benefits. Inclusion criteria included established CAD plus a low HDL.

Treatments received by the subjects included simvastatin, slow-release niacin, and/or antioxidants (800 IU vitamin E, 1000 mg vitamin C, 25 mg beta carotene, 100 µg selenium daily). Patients were followed for 3 years, with end points of stenosis status and clinical cardiovascular events.

Risk of death from coronary causes, confirmed MI or stroke, or revascularization for worsening ischemia (the composite primary end point of the trial) was 90% lower in the simvastatin + niacin group than the placebo group. No statistically significant effects were shown for use of antioxidants. Brown and colleagues suggest that the combination of simvastatin and niacin may represent a major advance of traditional monotherapies, and that there is little to support the com-

monplace practice of antioxidant supplementation for CAD modulation. ■

## Decreased Rate of Coronary Restenosis After Lowering of Plasma Homocysteine Levels

**Source:** Schnyder G, et al. *N Engl J Med*. 2001;345:1593-1600.

THE POTENTIAL ETIOLOGIC relationship of homocysteine (HCST) to cardiovascular disease end points has generated much recent scrutiny. There has not been a major clinical trial indicating that homocysteine modification effects cardiovascular outcomes. Schnyder and colleagues examined the effect of folic acid-based treatment (FBT)—ie, 1 mg folic acid, 400 mcg vitamin B12, and 10 mg pyridoxine daily—upon post-coronary angioplasty patients (n = 205) administered over 6 months.

FBT produced a 35% reduction in homocysteine levels (from 11.1 to 7.2). Minimal luminal diameter was greater and degree of stenosis was less severe in FBT recipients.

FBT treatment produced an impressive halving of the rate of restenosis, and a comparably favorable reduction in the need for revascularization of the target lesion.

Administration of moderate supplementation with folic acid, vitamin B12, and pyridoxine is inexpensive and well tolerated. Schnyder et al suggest that such treatment should be considered “adjunctive therapy” after coronary angioplasty. Though folate is

likely to be the most prominently involved constituent, it is possible that pyridoxine and/or vitamin B12 also exert effects. ■

## Identification and Fracture Outcomes of Undiagnosed Low BMD in Postmenopausal Women

**Source:** Siris ES, et al. *JAMA*. 2001; 286:2815-2822.

**B**ONE MINERAL DENSITY (BMD) MEASUREMENT by dual-energy x-ray absorptiometry (DEXA) is currently the gold standard for identification of osteoporosis (OSPS) and osteopenia (OSPN). Measuring BMD at the hip and spine is expensive, and often not covered as a screening test for young women, many of whom may be suffering silent, but substantial, loss of bone. This report shares results from the National Osteoporosis Risk Assessment, which examined 200,160 ambulatory women older than age 50 who had no prior history of reduced BMD. BMD was obtained using a portable peripheral

BMD assessment device that measures at the heel, finger, or forearm. Historical data obtained from the population of women included risk factors for osteoporosis; all women were postmenopausal.

Almost 40% of these women had OSPN, and 7.2% had OSPS (WHO criteria). Risk factors for reduced BMD were determined to be concordant with those already established in traditional literature: family history, age, ethnicity, smoking, use of glucocorticoids, lack of exercise, and low body mass.

That peripheral measurement of BMD is a functional method substantiated by the 4-fold increased rate of fractures subsequently found in women with peripheral DEXA-determined OSPS when compared with normal BMD women. This study is the largest ever conducted in United States, and adds substantially to our body of knowledge about minority women, since 18,000 of the population were minority women. Though the relative risk of OSPS and OSPN among African-American women was less than others, the fact that 32% had OSPN and 4% had OSPS mandates renewed clinician awareness of low BMD disorders in minorities. ■

## Comparison of Cefuroxime With or Without Intranasal Fluticasone for the Treatment of Rhinosinusitis

**Source:** Dolor RJ, et al. *JAMA*. 2001;286:3097-3105.

**T**HE USE OF INTRANASAL STEROIDS (INS) is appropriate foundation therapy for many patients with allergic rhinitis. Since INS produce reduction in inflammation and edema of the nasal mucosa and turbinates, it is plausible that they might enhance drainage and function of sinuses involved with acute rhinosinusitis (ARS). To determine whether INS enhances recovery from ARS, Dolor and colleagues performed a double-blind, randomized, placebo-controlled study comparing cefuroxime axetil alone (250 mg b.i.d.) with cefuroxime plus intranasal fluticasone (2 puffs, 100 µg/puff QD); all patients in both

groups also received xylometazoline, a nasal decongestant. The diagnosis of sinusitis was confirmed by radiography as well as symptom criteria as established by the Task Force on Rhinosinusitis of the American Academy of Otolaryngology-Head and Neck Surgery.

Use of fluticasone resulted in both a higher proportion of clinical success and a more rapid time to clinical success, when compared with cefuroxime alone. The number needed to treat (NNT) with fluticasone to gain 1 additional cure was 6 patients.

Dolor et al conclude that fluticasone is beneficial when added to background antibiotic and decongestant therapy for ARS. ■

## Lack of Clinical Significance of Early Ischemic Changes on CT in Acute Stroke

**Source:** Patel SC, et al. *JAMA*. 2001; 286:2830-2838.

**I**T HAS BEEN RECOMMENDED, LARGELY based upon the National Institute of Neurological Disorders and Stroke (NINDS) study, that patients presenting within 3 hours of stroke onset be considered for thrombolytic therapy with recombinant tissue plasminogen activator (rt-PA). In order to exclude stroke patients with cerebral hemorrhage as the cause of their acute stroke, baseline head CT is recommended. Although CT is highly effectively in ruling out hemorrhage, the subgroup of patients with edema or mass effect on CT has demonstrated in some studies a worsened risk of hemorrhage subsequent to rt-PA. Overall, despite this finding, nonhemorrhagic patients with edema or mass effect on CT who receive rt-PA still fared better than those who did not. Patel and colleagues analyzed CT early ischemic changes which have been brought to light since the NINDS by re-examining CT scans obtained in that study, and trying to determine if such changes are associated with response to rt-PA, clinical outcome, or development of post-rt-PA hemorrhage.

CT scans were evaluated in 616 patients. Early ischemic changes were not associated with any alteration in response to rt-PA, clinical outcome, or subsequent hemorrhage. Patel et al conclude that early ischemic changes do not add substantial impact to the criteria currently used for treatment decisions. ■

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