(715) Use of rizatriptan in the management of postdural puncture headache

Steven Mortazavi, MD[1], MaryJane Cerrone, RN, MSN[2], Robert Wertz, MD[2], Bruce Nicholson, MD[2], Robert Wilson, DO[2]; [1]Center for Pain Control, PC, Wyomissing PA; [2]Lehigh Valley Hospital, Allentown PA

Postdural puncture headache (PDPH) is a complication frequently accompanying spinal anesthesia, myelography, and diagnostic lumbar punctures. Although generally self-limited, some patients experience significant morbidity. Conservative therapies to reduce PDPH symptoms have relied upon hydration, bedrest, analgesics, and administration of vasoconstrictors, with caffeine benzoate being the most widely studied and accepted. The following study was undertaken to determine if rizatriptan, a cerebral vasoconstrictor approved for abortive treatment of migraine attacks would be helpful in the management of patients with PDPH referred for epidural blood patch (EBP) or reduce requirements for EBP. Ten adult subjects with symptoms of PDPH were randomly assigned to receive either placebo or rizatriptan benzoate 10 mg orally dissolvable tablets in a double-blinded fashion. Patients were permitted 3 doses per day for up to 96 hours. Upon completing the study, subjects were asked to assess their therapy as either effective or ineffective and requirements for EBP were recorded. Demographic variables, concomitant analgesic use and duration of symptoms were similar between groups. Treatment with rizatriptan did not reduce the symptoms of PDPH or the incidence of EBP compared with placebo. Although previous authors have reported benefit in PDPH patients with sumitriptan[1], a related 5-HT1 agonist, results from this study found that rizatriptan was not superior to placebo in reducing the symptoms of PDPH or reducing EBP requirements. Further study is needed before we can recommend rizatriptan as standard conservative therapy for patients with PDPH. References: 1. Connelly, N., et al., Sumatriptan in patients with postdural puncture headache. Soap Abstracts, 1999: p. A31. *The support of Merck for this project is gratefully acknowledged.*

C05 - Joint and Muscle Pain

(716) Adults with Ehlers-Danlos Syndrome (EDS): A description of chronic pain and quality of life indices

Trish Magyari, MS, CGC, Erin Pastovich, BS, Clair Francomano, MD, PhD; National Human Genome Research Institute, NIH, Bethesda MD

Ehlers-Danlos syndrome (EDS) comprises a spectrum of heritable connective tissue disorders caused by defects in collagen formation. Affected individuals typically display joint laxity and hypermobility, hyperextensible skin, and tissue fragility. Previous surveys of psychosocial functioning found that chronic pain, anxiety, depression, and anger are elevated in persons with EDS, with emotional reactions hypothesized to be closely tied to the chronic pain and medical complications of EDS. The incidence of chronic pain in persons with EDS is approximately 85%, with 25% of patients physically disabled by their pain. In order to more fully describe the impact of chronic pain on persons with EDS, 32 adults with EDS and chronic pain were evaluated using these measures: Brief Pain Inventory, SCL-90, SF-36, Ferrans and Powers Quality of Life Scale, Medical Symptom Checklist, Medication log. Usual pain and impairment in daily activities from pain is severe and significantly elevated over a population of cancer patients with pain (usual pain: $t=47.72$; $p< .005$; worst pain: $t=2.594$, $p< .01$; pain interference: $t=8.23$, $p< .005$; health and functioning: $t=5.81$, $p< .005$; family: $t=2.49$, $p <.01$). This is a group with severe chronic pain, increased medical symptomatology, and significantly demised quality of life.

C06 - Low Back Pain

(717) High dose intravenous pamidronate as adjuvant therapy for chronic spinal pain

Maria Gillego, MSN, Marco Pappagallo, MD; Mt Sinai-NYU, New York NY

The aim of this study was to explore the usefulness of intravenous (IV) pamidronate in the management of non-cancer spinal pain. Oral biphosphonates are used in the treatment of osteoporosis. They are poorly absorbed and often cause upper gastrointestinal toxicity. IV pamidronate therapy has been utilized for bone pain secondary to cancer. Biphosphonates appear to block osteoclastic and macrophagic activity. In an open-label study, patients with chronic spinal pain received pamidronate over a four-hour infusion (1.5 mg/Kg) for three consecutive days. All patients were on combination therapies of anti-inflammatory and opioid medications. Patients were screened for hypocalcemia, cardiac, hepatic, or renal impairment. Assessments of spinal pain using a numerical scale (0=no pain; 10=worst pain were performed at baseline and at monthly follow-up visits. Patients were also assessed for pain relief (PR) using a verbal percent scale (0%=no relief; 100%=total relief). Bone density studies of spine were obtained at baseline and at 3 months. Patients were: 1) a 76y/o male with scoliosis, spondylosis, and osteoporosis; 2) a 60y/o male with L2-3 retrolisthesis and osteoporosis; 3) a 66y/o female with thoracic hemangioma and osteoporosis; 4) a 53y/o female with lumbar spondylosis and osteoporosis; and 5) a 58y/o female with spondylosis and osteoporosis. Patient (Pt)#1 reported 90%PR at 2 months follow-up. Pt#2 reported 70%PR, pt#3 and pt#4 50%PR, and pt#5 60%PR at 2 months follow-up. Two of the patients were able to discontinue chronic opioid therapy. The patients reported no adverse events while receiving the infusions. All 5 patients reported myalgias on the second infusion day that responded well to anti-inflammatory agents. Two patients reported a self-limiting cutaneous reaction diagnosed as aseptic chemical phlebitis. All patients showed an increase in their bone density. Preliminary observations suggest that high dose pamidronate may be an important adjuvant therapy for a variety of spinal painful conditions.

(718) Rofecoxib in the Treatment of Chronic Low Back Pain in Two Multicenter Trials

Nathaniel Katz, MD[1], Kristine E. Johnson[2], David A. Krupa[2], William D. Ju, MD[2], David G. Borenstein, MD[3]; [1]Brigham and Women's Hospital, Boston MA; [2]Merck & Co., Inc.; [3]George Washington University Medical Center

The objective of this study was to evaluate the efficacy and safety of rofecoxib in the treatment of chronic low back pain (CLBP). The studies were replicate, randomized, double-blind, placebo-controlled, parallel group, 4-week, multicenter studies enrolling individuals with CLBP (Quebec Task Force on Spinal Disorders Class 1 and 2) who were routine users of analgesic medications. Patients meeting pain worsening (flare) criteria upon discontinuation of prestudy analgesics were randomized to rofecoxib 25-mg (n=233), rofecoxib 50-mg (n=229), or placebo (n=228), administered orally once daily. Both protocols provide replicate evidence of statistically significant drug effects across the majority of efficacy parameters. To provide the best estimates of therapeutic effect, the efficacy endpoint data have been combined. Patient baseline characteristics were similar across both studies and in all treatment groups (mean age 53.4 years, 62.3% female, mean duration of back pain 12.1 years, prestudy analgesics: NSAID 82.8%, non-NSAID 17.2%). Rofecoxib at both doses was superior to placebo as assessed by the Low Back Pain Intensity Scale (0- to 100-mm VAS), the prespecified primary endpoint. The least square mean difference from placebo was -13.50 mm and -13.81 mm for the rofecoxib 25-mg and 50-mg dose levels, respectively ($p<0.001$). Both rofecoxib regimens were statistically significantly superior to placebo in prespecified secondary and other endpoints including: Bothersomeness Scale, Roland Morris Disability Questionnaire, Patient and Investigator Global Assessment of Response to Therapy, Patient Global Assessment of Disease Status, SF-12 Health Survey (Physical Component), Rescue Acetaminophen Use, and Relief from Starting Pain by bedtime after the first morning dose ($p<0.001$ for all comparisons). For all endpoints, the 25-mg and 50-mg doses were not statistically different from each other, and both rofecoxib regimens were generally well tolerated. Rofecoxib administered once daily reduced CLBP compared to placebo and was well tolerated. The 25-mg and 50-mg rofecoxib regimens demonstrated comparable efficacy.