SAT0115 EFFICACY OF CELECOXIB IN PATIENTS WITH ACUTE SHOULDER PAIN: RANDOMISED DOUBLE-BLIND COMPARISON WITH NAPROXEN

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10.1136/annrheumdis-2001.511

Background

Objectives To evaluate and compare the efficacy of 14-day dosing with celecoxib 200 mg BID and naproxen 500 mg BID in patients with acute shoulder pain.

Methods Patients with pain onset within the previous 14 days and pain intensity of ≥ 40 mm on a 100-mm VAS were randomly assigned to enter one of two parallel groups of a double-blind controlled, multicenter study. The primary assessment was pain at rest.

Results The primary ITT analysis was conducted in 202 randomised and treated patients, 99 in the celecoxib group and 103 in the naproxen group. Baseline characteristics were similar (47 ± 12 years of age; mean duration of acute episode, 5.6 ± 5.1 days). At 14 days, the mean ($\pm$ SE) decrease in pain at rest was not statistically significantly different between the two groups. According to the limits of 95% CI of the difference between groups, celecoxib seemed to be at least as effective as naproxen. Fewer patients experienced epigastric pain with celecoxib (7 patients vs 14 with naproxen). This adverse event led to treatment discontinuation in 2 patients receiving celecoxib and 5 receiving naproxen. One patient with a history of ulcer had duodenitis (Hp positive) in the celecoxib group.

Abstract SAT0115 Table 1

	Changes from Baseline Celecoxib	Changes from Baseline Naproxen	Difference Between Groups
Pain at rest (VAS 0–100 mm)	-47.9 ($\pm$ 2.5)	-42.3 ($\pm$ 2.5)	-5.6, p = 0.1167 (95% CI [-12.5, +1.4])

Conclusion This study provides data in favour of the use of celecoxib, which is probably at least as effective as naproxen in acute shoulder pain. Observed upper GI events rates in this study of limited sample size do not permit drawing conclusions in terms of improved GI safety, which has previously been shown in larger randomised controlled trials.

Sponsored by Pharmacia Corporation and Pfizer, Inc.

SAT0116 EFFICACY OF CELECOXIB VS IBUPROFEN AND NAPROXEN IN THE TREATMENT OF ANKLE SPRAIN

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10.1136/annrheumdis-2001.512

Background Ankle sprain is a common acute soft-tissue injury that often results in swelling, pain, inflammation, and ecchymosis.

Objectives We hypothesised that celecoxib, a COX-2 specific inhibitor, would be as effective as conventional NSAIDs and better than placebo in the treatment of ankle sprain.

Methods Two separate multicenter, randomised, double-blind studies were conducted: (1) celecoxib 400 mg/d (n = 147) vs ibuprofen 2400 mg/d (n = 155) or placebo (n = 141) over 10 days, and (2) celecoxib 400 mg/d (n = 198) vs naproxen 1000 mg/d (n = 198) over 8 days. Patients had grade 1 or 2 ankle sprains and moderate-to-severe pain on weight bearing [≥ 45 mm, 100-mm VAS] at baseline.

Results Most patients were male (60% and 67% for ibuprofen and naproxen comparator studies, respectively); mean ages were 31 and 30 years for ibuprofen and naproxen comparator studies, respectively. The first study dose was taken within 48 h after the injury occurred (mean duration: 25.6 and 23.2 hrs for ibuprofen and naproxen comparator studies, respectively). Covariate-adjusted analyses of the primary endpoints (Patient's Global Assessment of Ankle Injury responder rate, and Patient's Assessment of Ankle Pain VAS on weight-bearing) demonstrated that celecoxib was significantly more effective than placebo and as effective as ibuprofen and naproxen in improving the signs and symptoms of ankle sprain. Median times to return to normal function/activity or to improve function by at least 2 grades (5-pt scale) were 5 days for celecoxib-, 6 days for ibuprofen-, and 8 days for placebo-treated patients (celecoxib vs placebo, p = 0.001) in the ibuprofen comparator study and 5 days for both groups in the naproxen comparator study.

Abstract SAT0116 Table 1

	Responder Rates [n (%)] on Patient's Global Assessment of Ankle Injury *			Patient's Ankle Pain (VAS), mm**		
	Celecoxib	Ibuprofen	Placebo	Celecoxib	Ibuprofen	Placebo
Baseline [§]	..	..	..	68.5 (14.1)	68.2 (14.8) (12.1)	71.3 (12.1)
Day 4	99 (67%) [†]	110 (71%)	77 (55%)	35.3 (1.6) [†]	36.6 (1.6) (1.6)	42.4 (1.6)
Day 8	121 (82%) [†]	126 (81%)	101 (72%)	23.3 (1.8) [†]	24.3 (1.8) (1.8)	31.2 (1.8)
Day 11	133 (90%) [†]	142 (92%)	124 (88%)	15.6 (1.8) [†]	15.7 (1.8) (1.8)	19.9 (1.8)
	Celecoxib	Naproxen	Placebo	Celecoxib	Naproxen	Placebo
Baseline	..	..	..	67.6 (14.5)	67.5 (13.1)	..
Day 4	139 (71%) [‡]	142 (72%)	..	31.9 (2.0) [†]	29.0 (1.9)	..
Day 8	175 (89%) [‡]	178 (90%)	..	15.0 (1.7) [†]	15.3 (1.7)	..

*Improved by ≥ 1 grade on 5-pt scale from 1 (very good) to 5 (very poor); **covariate-adjusted; [†]celecoxib not inferior to ibuprofen or naproxen based on 95% CI; [‡]p ≥ 0.51 ; [§]VAS score = Mean (SD).

Conclusion Celecoxib is as effective as the maximum recommended dose of ibuprofen and naproxen for pain and superior to placebo in treating ankle sprains. Celecoxib, with its platelet-function-sparing properties, may offer an advantage over ibuprofen and naproxen in managing ankle sprain injuries.

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