[2007] [SAT0239] IMPROVED BLOOD PRESSURE CONTROL BUT SIMILAR EFFICACY WITH LUMIRACOXIB 100 MG OD COMPARED TO IBUPROFEN 600 MG TID IN HYPERTENSIVE PATIENTS WITH OSTEOARTHRITIS: RANDOMISED CONTROLLED TRIAL

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Background: Hypertension is a frequent concomitant disease of elderly osteoarthritis (OA) patients. In a recent US study of OA patients, increases in systolic blood pressure (SBP) of 1 to 5 mmHg were associated with 7,000-35,700 additional heart disease and stroke events over 1 year [1]. The previous TARGET study showed that lumiracoxib 400 mg od (4 x recommended dose for OA) has a more favourable BP profile in comparison with naproxen 500 mg bid or ibuprofen 800 mg tid [2].
Objectives: The primary objective was to test the hypothesis that lumiracoxib 100 mg od would have lower mean 24-hour ambulatory SBP compared to ibuprofen 600 mg tid in OA patients with controlled hypertension. The secondary objective was to compare the efficacy (pain and global disease activity) of lumiracoxib 100 mg od versus ibuprofen 600 mg tid.
Methods: This was a 4-week, multicentre, randomised, double-blind, double-dummy, parallel group study of ≥50 years old OA patients with hypertension controlled on stable drug treatment (office BP <140/90 mmHg). Eligible patients were randomised to either lumiracoxib 100 mg od or ibuprofen 600 mg tid in a 1:1 ratio. The primary endpoint was change from baseline at Week 4 in 24-hour mean ambulatory systolic BP (MASBP) in the intent-to-treat (ITT) population, and analysed using ANCOVA. Secondary endpoints included 24-hour mean ambulatory diastolic BP (MADBP), and change by at least one category in the respective Likert scales of patient's OA pain assessment in the target joint, patient's and physician's global assessments of disease activity at Week 4 (ITT population) was analysed using logistic regression.
Results: Of the 787 patients randomised (n=394 lumiracoxib, n=393 ibuprofen); 741 patients (94%) completed the study.
Change from baseline in 24-hour MASBP at Week 4 showed an estimated difference of 5 mmHg in favour of lumiracoxib (95% CI: -6.1,-3.8, p<0.001; [least square mean of -2.7 for Lumiracoxib; +2.2 for Ibuprofen]).
Similar results were obtained for 24-hour MADBP (estimated treatment difference: -2.0 mmHg [95% CI: -2.7,-1.3], p<0.001). Improvements in OA pain and in disease activity for lumiracoxib and ibuprofen were similar (table).
The proportion of patients with adverse events (AEs) were similar for lumiracoxib (22.6%) and ibuprofen (22.6%), and only six serious AEs were observed (n=1 lumiracoxib; n=5 ibuprofen).

Efficacy of Lumiracoxib 100 mg od compared to Ibuprofen 600 mg tid (ITT population)

	N	Improved n (%)	P-value
OA pain assessment in target joint			
Lumiracoxib 100 mg od	388	239 (61.6)	0.323
Ibuprofen 600 mg tid	381	223 (58.5)	
Patient's GA of disease activity			
Lumiracoxib 100 mg od	388	212 (54.6)	0.308*
Ibuprofen 600 mg tid	381	223 (58.5)	
Physician's GA of disease activity			
Lumiracoxib 100 mg od	387	236 (61.0)	0.472
Ibuprofen 600 mg tid	382	225 (58.9)	

*Fisher's exact test was used, global assessment (GA).

Conclusion: In osteoarthritis patients with hypertension, lumiracoxib 100 mg od resulted in a clinically significant lower mean 24-hour SBP compared to ibuprofen 600 mg tid.
Lumiracoxib 100 mg od and Ibuprofen 600 mg tid provided comparable improvement in symptoms of osteoarthritis.
References: 1. Singh G et al., J Rheumatol 2003;30(4):714
2. Farkouh ME et al., Lancet 2004;364:675

Osteoarthritis clinical aspects and treatment

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