SAT0254 PATIENT CHARACTERISTICS AND DISEASE MANAGEMENT OF RHEUMATOID ARTHRITIS AT BASELINE IN THE VIGOUR (VIOXX GI OUTCOMES RESEARCH) STUDY: EFFECTS OF DISEASE DURATION

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Background The VIGOUR Study was a large (n = 8076) randomised, double-blind, clinical trial comparing the GI safety of rofecoxib 50 mg. once daily to naproxen 500 mg twice daily. The median duration of follow-up was 9.0 months.

Objectives

Methods We examined demographics, disease status, disease impact, history of GI problems, and medication history for 3 subgroups based on disease duration: 0–2 years (N = 1498), >2–10 years (N = 3382), and >10 years (N = 3196).

Results Baseline demographic characteristics were quite comparable for the 3 groups. 76%, 78%, and 83% of the patients were female, with mean ages of 57, 58, and 59 years for 0–2, >2–10, and >10 years, respectively. The majority of patients were in ARA functional class II (0–2 years: 57%, 2–10 years: 55%, >10 years: 51%). 67% of the 0–2 year group were known to be seropositive compared with 74% and 75% in the other groups. The proportion of patients with erosions on hand x-rays varied by duration (44%, 60%, 71%), as did the percentage with rheumatoid nodules (16%, 30%, 43%).

The mean modified Health Assessment Questionnaire (mHAQ) scores (U. S. patients only) were 0.62, 0.57, and 0.61 on a scale of 0–3 with mean patient and investigator global scores of 2.0, 1.9, 2.0 and 1.9, 1.8, 1.9 on scales of 0–4. 56%, 50%, and 50% of the patients reported that they cut down their activities due to their RA for an average of 11, 10, and 10 days in the past 4 weeks. Patients reported that pain interfered with their normal work to a moderate extent (2.9, 2.8, and 2.9 on a scale from 1 (not at all) to 5 (extremely)).

The proportions of patients taking NSAIDs at baseline were similar (81%, 82%, 84%) as were the proportions taking corticosteroids (57%, 55%, 56%). At baseline, patients had taken an average of 2.0, 2.8, and 3.6 DMARDs with the following proportions having taken individual medications at some time: MTX: 57%, 74%, 77%; corticosteroids: 75%, 82%, 85%; hydroxychloroquine: 41%, 55%, 59%, injectable gold: 6%, 20%, 49%, sulfasalazine: 15%, 26%, 29%. 6%, 8%, and 9% of the patients reported a prior history of a GI ulcer or bleed at baseline, and 21%, 21%, and 20% reported dyspepsia within 14 days prior to baseline. 9%, 11%, and 14% had stopped an arthritis medication at some time due to abdominal pain. 45% of the 0–2 year group had changed their arthritis medication in the previous year; compared to 39% in the 2–10 year group, and 37% in the >10 year group.

Conclusion The VIGOUR cohort is useful for studying the relationship between disease duration and patient characteristics and treatment strategies. Despite having RA for <2 years, the early RA group demonstrates moderate levels of functional impairment comparable to the other groups as indicated by mHAQ and patient and investigator global scores. Patients in the early RA group also reported the greatest need to cut down their activities. The data on medication use reflect the general trends toward early use of single DMARDs and combination therapy, as well as a continuing reliance on corticosteroids. All groups

were comparable in their history of serious GI events and GI side effects.

SAT0255 REGIONAL VARIATION IN BASELINE PATIENT CHARACTERISTICS AND DISEASE MANAGEMENT OF RHEUMATOID ARTHRITIS PATIENTS IN THE VIGOUR (VIOXX GI OUTCOMES RESEARCH) STUDY

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Background The VIGOUR Study was a large (n = 8076) randomised, double-blind, clinical trial comparing the GI safety of rofecoxib 50 mg. once daily to naproxen 500 mg twice daily. The median duration of follow-up was 9.0 months.

Objectives To describe the baseline patient characteristics and prior drug treatment by geographic region, for one of the largest cohorts of RA patients ever studied.

Methods We examined demographic characteristics, disease status, history of GI problems, and medication history for subgroups of patients from Europe (EUR, N = 1051); Latin America (LA, N = 2746); and North America (NA, N = 3795).

Results Baseline demographic characteristics were fairly comparable across regions. Most patients were female: 79% in EUR, 88% in LA, and 74% in NA. The respective mean ages were 58, 56, and 60 years, with 23%, 18%, and 32% over age 65. The participants had mean disease duration of 11, 10, and 11 years, and the majority of patients were in ARA functional class II (54%, 56%, 53%). In EUR, 70% were known to be seropositive with 81% in LA and 68% in NA. The proportions of patients known to have erosions on hand x-rays varied across regions (86%, 73%, 45%), as did the percentage with rheumatoid nodules (25%, 23%, 43%). The mean patient global disease activity scores were 2.2, 2.0, and 1.9 on a scale of 0–4, and mean investigator global disease activity scores were 2.1, 1.8, and 1.9 on a scale of 0–4. While the proportions of patients taking NSAIDs at baseline were similar (87%, 84%, 81%), the proportion taking corticosteroids in LA (72%) was much higher than in EUR (52%) and NA (46%). At baseline, patients had taken an average of 3.4, 2.8, and 3.0 DMARDs with the following proportions having ever taken individual medications in EUR, LA, and NA respectively: MTX: 70%, 76%, 71%; corticosteroids: 81%, 88%, 79%; hydroxychloroquine: 43%, 62%, 51%, injectable gold: 49%, 21%, 29%, sulfasalazine: 56%, 15%, 21%. The newest DMARDs had been used by only a handful of patients in EUR and LA; in NA, 4% had used etanercept and 7% had used leflunomide. 7%, 7%, and 9% of the patients reported a prior history of a GI ulcer or bleed at baseline, and 17%, 24%, and 20% reported dyspepsia within 14 days prior to baseline. 12%, 10%, and 14% had stopped an arthritis medication at some time due to abdominal pain. 28% of the LA patients had changed their arthritis medication in the previous year; compared to 50% in EUR and 46% in NA.

Conclusion Because of its size, the VIGOUR cohort is useful for studying regional differences in patient characteristics and treatment strategies. While most measured patient characteristics are similar, differences in the proportions of seropositive patients and patients with erosions and nodules may reflect other differences in the medical characteristics of the populations. This cohort also highlights differences in treatment strategies across