Methods 1082 patients meeting entry criteria for OA, responsive to NSAIDs, were randomised 3:3:1 to treatment with rofecoxib 25 mg qd (n = 471), celecoxib 200 mg qd (n = 460) or placebo (n = 151). Efficacy was assessed over the first 6 days of therapy and at weeks 2, 4, and 6 by WOMAC questionnaire and patient global assessment of response to therapy (PGART).

Results Demographics were well balanced. Significantly more patients on placebo discontinued prematurely compared to both active groups ($p < 0.001$) mainly due to lack of efficacy. Rofecoxib provided statistically superior relief of night pain ($p = 0.023$), morning stiffness ($p = 0.002$), rest pain ($p = 0.023$), and walking pain ($p = 0.005$) compared to celecoxib. Rofecoxib was significantly superior to celecoxib on all WOMAC subscales, including pain ($p = 0.008$), stiffness ($p = 0.001$) and physical function ($p = 0.01$). Rofecoxib was superior to celecoxib in % of patients with good or excellent PGART over 6 weeks ($p = 0.014$) and provided quicker onset of efficacy as assessed by time to first report of good or excellent response ($p < 0.001$). Both active groups were superior to placebo on efficacy endpoints. Incidence of clinical AEs, drug related AEs, serious AEs, and discontinuations due to AEs was similar between active groups.

Conclusion In this study, once daily doses of rofecoxib provided superior relief of pain and other related symptoms in OA compared to celecoxib and placebo. All treatments were generally well tolerated.

SAT0090 CORRELATION BETWEEN PROXIMAL FEMUR BONE MINERAL DENSITY AND HIP OSTEOARTHRITIS: PRELIMINARY DATA

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10.1136/annrheumdis-2001.466

Background Osteoarthritis (OA) is a very frequent disease in postmenopausal women. The question whether high bone mineral density (BMD) plays a role in the development of this disease is under investigation.

Objectives Here we report the preliminary data of a study aimed at investigating the relationship between the BMD of healthy women and women with OA of the hip.

Methods Exclusion criteria included all diseases and drugs known to cause BMD loss. Till now 136 age matched women have entered the study: 46 with OA (mean age 65.76, SD 8.07) and 92 healthy individuals (mean age 65.60, SD 8.12). All subjects underwent Dual Energy X-ray Absorptiometry (DEXA-XR 36 Norland) measurements of the femoral neck, trochanter, Ward's and the lumbar spine (L2-L4). Age, age of menopause, height and weight were also collected. Data were analysed using the Anova test to compare groups. The ability of selected parameters to discriminate the two groups of patients was tested by logistic regression.

Results Weight ($p = 0.003$) and femoral neck BMD ($p = 0.045$) were significantly higher in women with OA than in healthy women. None of the other variables were significantly different in the two groups. At the logistic regression both age corrected

weight (OR: 1.05; 95% CI: 1.01–1.09) and age corrected femoral neck BMD (OR: 1.01; 95% CI: 1.00–1.03) were able to significantly discriminate the two groups of women. Both variables correctly classified 13.04% of OA while 93.48% of healthy women were correctly classified by the variable weight and 97.83% the femoral neck BMD.

Conclusion Our data suggest that the body weight and femoral neck BMD are the main risk factors for OA of the hip. The fact that at the trochanter and at the Ward's (where BMD measurement does not discriminate between the two groups) the cortical component of bone is lower than at the femoral neck should indicate that high cortical bone density is a marker of OA.

SAT0091 EFFECTS OF JOINT LAVAGE AND HYALURONIC ACID INFILTRATION IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE

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10.1136/annrheumdis-2001.466

Background Infiltration with hyaluronic acid (HA) and joint lavage (JL) have recently been proposed as local treatments for osteoarthritis of the knee. Joint lavage is a therapeutic treatment involving passing cold sterile 0.9% saline through the knee joint in order to have the liquid reach the inside of the joint capsule.

Objectives To evaluate the efficacy of joint lavage and intraarticular infiltration with hyaluronic acid, alone and in combination (JLHA), as symptomatic treatments for knee osteoarthritis.

Methods An overall 37 patients (8 males and 29 females) aged 43–85 years with knee osteoarthritis of radiological grade II on the Kellgren scale were randomly classified into three therapeutic groups, namely: JL (n = 14), HA (n = 10) and JLHA (n = 13). The patients in group JL received joint lavage, on day 0 only; those in group JLHA were subjected to joint lavage on day 0 and to infiltration on days 0, 7, 14, 21 and 28. Outcome measures evaluated at baseline, at days 7 and 30 included severity of pain (VAS), Global status (VAS) and Lequesne's functional index.

Results The results of the Global Status difference from baseline are summarised in the following Table 1:

Abstract SAT0091 Table 1

	Assessment at week Differential Global Status (significance level)	Assessment at month Differential Global Status (significance level)
JL vs HA	-5.14 vs -3.10 ($p = 0.03$)	-5.07 vs -2.80 ($p = 0.02$)
HA vs JLHA	-3.10 vs -5.38 ($p = 0.01$)	-2.80 vs -5.76 ($p = 0.02$)
JL vs JLHA	-5.14 vs -5.38 ($p = 0.59$)	-5.07 vs -5.76 ($p = 0.36$)

Conclusion Our results suggest significant differences between the tested treatments, joint lavage alone and followed by infiltration with the hyaluronic acid is more effective than local infiltration with hyaluronic acid alone.

SAT0092 SUCCESS-1 IN OSTEOARTHRITIS (OA) TRIAL: CELECOXIB DEMONSTRATES SIGNIFICANTLY LOWER HEPATIC TOXICITY THAN DICLOFENAC IN THE TREATMENT OF OSTEOARTHRITIS

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10.1136/annrheumdis-2001.467

Background Significant elevations of liver enzymes have been reported in patients taking NSAIDs. Among all NSAIDs, diclofenac and aspirin have been associated with the highest rates of liver toxicity. In previous trials with patients in the US and Canada treated for osteoarthritis (OA), the incidence of hepatic adverse events in patients receiving celecoxib 200 or 400 mg per day was similar to placebo and significantly lower than the incidence for patients receiving diclofenac 100 or 150 mg per day.

Objectives We compared the hepatic tolerability of celecoxib and the most commonly used regimen of diclofenac in the treatment of OA of the knee, hip, or hand in 13,274 patients enrolled in SUCCESS-1, a multinational, double-blind, randomised trial.

Methods In the SUCCESS-1 in OA trial, patients with OA from Europe and South Africa, Asia, Latin America, and the US and Canada were evaluated for 12 weeks using fixed dosages of celecoxib 200 mg per day, celecoxib 400 mg per day, or diclofenac 100 mg per day. Patients with pretreatment ALT or AST $\geq$ 3x ULN were excluded. Laboratory tests were obtained at pretreatment and at the final visits.

Results Overall, patients were mostly female (78%), and had a mean age of 62 ($\pm$ 10.4) years. Previous daily diclofenac use was comparable (p = 0.57). Clinically meaningful elevations ($\geq$ 3x ULN) in ALT and AST were significantly more frequent in the diclofenac- vs celecoxib-treated patients (p < 0.001) at 12 weeks. In parallel, physician-reported hepatic adverse events, including hepatic dysfunction and increases from pretreatment ALT and AST, were significantly more frequent in patients treated with diclofenac (p < 0.01).

Abstract SAT0092 Table 1

	Celecoxib 200 mg/d	Celecoxib 400 mg/d	Diclofenac 100 mg/d
Laboratory value elevation	n = 2988	n = 2948	n = 2998
AST $\geq$ 3x ULN at final visit	1 (<0.1%)	3 (0.1%)	20 (0.7%)*
ALT $\geq$ 3x ULN at final visit	6 (0.2%)	6 (0.2%)	45 (1.5%)*
Adverse events, incidence			
AST increased from pretreatment	11 (0.3%)	13 (0.4%)	31 (0.9%)
ALT increased from pretreatment	20 (0.6%)	15 (0.4%)	58 (1.7%)*

ULN: upper limit of normal; diclofenac vs celecoxib 200 or 400 mg/d: * p < 0.01.

Conclusion Celecoxib, with its greater hepatic tolerability than the most commonly prescribed regimen of diclofenac, offers a clinical advantage over diclofenac in the management of OA patients.

Sponsored by Pharmacia Corporation and Pfizer Inc.

SAT0093 SUCCESS-1 IN OSTEOARTHRITIS: CELECOXIB DEMONSTRATES SIMILAR EFFICACY TO THE CONVENTIONAL NSAIDS, DICLOFENAC AND NAPROXEN, IN PATIENTS WITH OSTEOARTHRITIS TREATED IN 39 COUNTRIES IN 6 CONTINENTS

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10.1136/annrheumdis-2001.468

Background The SUCCESS-1 trial is the largest controlled study comparing celecoxib and NSAIDs. This long-term trial was intended to closely parallel clinical practice in a variety of world-wide settings to assess the overall efficacy, tolerability, and safety of celecoxib and NSAIDs with a large group of diverse physicians.

Objectives This study compared the efficacy, safety, and tolerability of celecoxib 200 and 400 mg per day and the most commonly prescribed NSAIDs in 39 countries in the treatment of the signs and symptoms of osteoarthritis (OA) of the knee, hip, and hand.

Methods The SUCCESS-1 in OA trial is a large double-blind, randomised study conducted in patients from 1,142 centres in Europe and South Africa, Asia, Latin America, and the US and Canada. Patients were treated for 12 weeks using celecoxib (200 or 400 mg/d) and the most common regimens of NSAIDs (naproxen 1000 mg/d in US and Canada and diclofenac 100 mg/d in all other countries). Assessments of arthritis efficacy were performed by country or region. Safety and tolerability were assessed globally.

Results Of the 13,194 intent-to-treat patients, the mean age was 62 years, and the majority were female (76%) and caucasian (80%). Patients in each group had comparable baseline aspirin use and history of upper GI bleeding. Arthritis assessments were based on mean changes in baseline arthritis pain by VAS and night pain at week 12. Data is presented from European countries/regions. No significant differences between celecoxib 200 mg/day and celecoxib 400 mg/day compared to diclofenac 100 mg/day were observed. In addition, celecoxib 200 mg/day and 400 mg/day were similar in efficacy. Comparable efficacy between celecoxib and NSAIDs was also demonstrated in other countries/regions that participated in the study.

Abstract SAT0093 Table 1

	Patient's Assessment of Arthritis Pain VAS, mean change, mm?	Patient's Assessment of Night Pain, mean change?		
EFFICACY	Celecoxib 200 mg/ day*	Diclofenac 100 mg/day	Celecoxib 200 mg/ day*	Diclofenac 100 mg/day
Central	-22.1	-20.4	-0.73	-0.69
Europe				
Germany	-28.3	-25.7	-0.89	-0.67
Italy	-17.6	-20.6	-0.50	-0.54
Nordic	-13.4	-14.2	-0.36	-0.38
regions				
Spain/ Portugal	-18.4	-21.0	-0.68	-0.66
UK/Ireland	-10.9	-11.9	-0.33	-0.38

?Scale: 0 = no pain to 100 = most severe pain; ?5 pt scale: 1 = very good to 5 = very poor; * p > 0.18.