and heavy works are risk factors of both KOA and VV. The association of the two diseases is variously assessed in the literature: prevalence of VV in KOA patients varies from 18 to 64% and prevalence of KOA in VV patients varies from 12 to 68%. This association is still questionable, as no case-controlled study is available.

Objectives To evaluate the possible association of the two diseases in a case-control study.

Methods Three hundred patients with KOA defined according to the ACR criteria (mean age $\pm$ SD: 66 years $\pm$ 10, 64% women) were age and sex-matched with 300 controls (subjects without any present or past knee pain + normal examination of their knees + normal AP x-rays of their knees on standing extended position: Kellgren-Lawrence stage 0). All classical risk factors were recorded (sports, trauma, heredity, works, meniscectomy, ?). In this epidemiological survey, VV were classified as followed: no VV (V0), simple venous varicosities with dull ache or pressure sensation in the legs which feel heavy after prolonged standing, (V1), or VV with complications (erythema, dermatitis, hyperpigmentation developed along the distal aspect of the leg, or skin ulcers) or which were operated (V2). This grading system was set up assuming that the diagnosis of VV at stage 1 is sometimes questionable, while VV at stage 2 is more accurate.

Results There were 95 and 74 V1 patients and 59 and 43 V2 patients in KOA and control groups respectively (Chi2 = 9.28; $p = 0.0097$). This increase of VV in KOA is also significant in women (chi2 = 9.498; $p = 0.0087$), but not in men ($p = 0.34$). As age, body mass index, hypertension, smoking, sports, carrying heavy loads are confounders in both diseases, a multiple logistic regression was performed. There was a relationship between VV and carrying heavy loads, leading to two separated analyses.

Abstract SAT0070 Table 1

	Varicose Veins	RR of Knee OA	CI 95%	P
Heavy loads (-)	V1	1.10	0.64–1.87	0.72
Heavy loads (-)	V2	1.46	0.79–2.70	0.23
Heavy loads (+)	V1	2.37	1.03–5.45	0.042
Heavy loads (+)	V2	3.58	0.16–11.04	0.027

Conclusion When there is no carrying of heavy loads, the RR of KOA is not significantly increased with the presence of VV, while it is when heavy load carriage is also present.

SAT0071 ROFECOXIB SHOWS CONSISTENT EFFICACY IN OA CLINICAL TRIALS, REGARDLESS OF SPECIFIC PATIENT DEMOGRAPHIC AND DISEASE FACTORS

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Background

Objectives Analyses were performed to demonstrate the generalizability of the efficacy of rofecoxib (MK-0966, VIOXXTM) in patients with different demographic or baseline disease characteristics, or with OA in nonsignal joints or multiple locations.

Methods Data were combined for patients with OA of the knee or hip receiving placebo, 12.5 or 25 mg rofecoxib once daily in three 6-week placebo controlled trials, the only trials to date

using all 3 treatments. Predefined analyses were performed after categorising patients according to baseline demographics (age, gender, height, weight BMI) and baseline disease characteristics (ARA functional class, joint tenderness, joint stiffness, WOMAC functional subscale, unilateral/bilateral joint involvement, number of joint groups involved). Three primary endpoints: Pain Walking on Flat Surface (WOMAC, 0–100 mm VAS), Patient Global Assessment of Response to Therapy (0 to 4 point Likert Scale), and Investigator Global Assessment of Disease Status (0 to 4 point Likert Scale) were analysed. Efficacy treating OA in patients with 1, 2, 3, or 4, joint groups (among interphalangeal/first carpal-metacarpal joint, spine, hip or knee) affected was analysed for four end points, Patient and Investigator Global Assessments of Response to Therapy and of Disease Status (which provided data on overall aspects of OA, regardless of affected joint). Treatment by factor interactions were tested by ANOVA.

Results Data from 1501 patients were included. For patients taking 12.5 or 25 mg rofecoxib, treatment effects were generally consistent across subgroups categorised by demographic factors: age ($p = 0.08$), gender ($p = 0.06$), race ($p = 0.46$), prior therapy ($p = 0.19$), weight ($p = 0.10$), BMI ($p = 0.087$) or disease characteristics: baseline joint tenderness ($p = 0.17$), WOMAC functional subscale ($p = 0.52$) ARA functional class I, II, or III ($p = 0.49$), duration of OA ($p = 0.37$), or primary study joint ($p = 0.27$). Greater efficacy was seen in patients with study joint swelling; however, the difference from those without study joint swelling was not clinically meaningful. No significant interactions were observed among patients with unilateral/bilateral involvement or 1, 2, 3, or 4, joint groups affected.

Conclusion No specific factor predicted treatment effect in this study.

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SAT0072 CELECOXIB DOES NOT AFFECT INDEX JOINT X-RAYS IN OSTEOARTHRITIS (OA) PATIENTS WITH LONG TERM EXPOSURE

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Background Worsening of joint x-rays has been observed with nonsteroidal anti-inflammatory drug (NSAID) use.

Objectives The effect of celecoxib, a specific cyclooxygenase-2 inhibitor, on index joint (knee or hip) x-rays in patients with OA was determined during a long-term safety trial.

Methods X-rays were obtained from all patients prior to entry into a controlled clinical trial, prior to subsequent entry into the long-term safety trial, and at Month 12 or early termination visit of the long-term safety trial. Blinded x-rays were graded on a semiquantitative scale assessing multiple aspects of joint morphology.

Results Overall qualitative interpretation of the individual scores for hip and knee films indicated mild to moderate OA equivalent to an average Kellgren-Lawrence grade of between 2 and 3 at entry to the long-term safety trial. Data from 147 pairs of knee films were analysed prior to and after participation in the long-term safety trial (average duration of treatment, 1 year). Shift table analysis was not significant for any parameters of joint morphology (knee [medial and lateral] joint space narrowing, knee [medial and lateral] spurs, knee [medial and lateral]

sclerosis, and knee malalignment). Small mean changes over time were noted for these parameters, but all 95% confidence intervals (CI) overlapped 0. Data from 158 pairs of hip films were analysed prior to and after participation in the long-term safety trial (average duration of treatment, 1 year). Shift table analysis was significant for worsening of hip narrowing ($p = 0.029$) but not other parameters of joint morphology (hip cysts, hip spurs, and hip sclerosis). Mean change analysis demonstrated a change of 0.14 units/year in hip narrowing (95% CI 0.08–0.20), equivalent to a change of approximately 3% per year. Mean change analysis demonstrated a change of 0.04 units/year in hip cysts (95% CI 0.01–0.08), equivalent to a change of approximately 0.2% per year. These changes were not dose-dependent, and similar changes were noted prior to entry into the long-term safety trial.

Conclusion Celecoxib did not affect index joint x-rays in OA. Modest changes in hip narrowing noted were consistent with the natural history of the disorder.

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SAT0073 PATIENTS WITH KNEE OSTEOARTHRITIS TREATED BY HYLAN G-F 20 VERSUS USUAL TREATMENTS: A MEDICO-ECONOMIC, PROSPECTIVE, RANDOMISED LARGE SCALE TRIAL IN FRANCE, EFFICACY AND SAFETY OUTCOMES

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Background

Objectives To evaluate the efficacy and safety of Hylan G-F 20 over 9 months in the treatment of patients with knee osteoarthritis (OA).

Methods Patients with radiographically proven knee OA, pain on movement ³ 40 mm (VAS) and treated by at least two 10-day NSAIDs courses or by slow-acting anti-OA drugs within the previous 3 or 2 months respectively were enrolled by 81 centres (21 hospitals and 60 private rheumatologists). After stratification on known OA risk factors (patients? age, BMI,...), patients were centrally randomised in Synvisc (S) or in usual treatment (UT) groups. S-patients were treated by 3 intraarticular injections of Hylan GF 20 one week apart and encouraged to stop or spare any other OA treatments. If needed S-patients could be treated by Synvisc in both knees. Efficacy and safety data were collected at baseline, day 28, months 3, 6 and 9.

Results Out of 518 patients randomised, 506 (253 per group) were treated and evaluable. Demographic data (mean age = 66/66 years, female = 67/68%, BMI = 28/28 kg/m², bilateral knee OA = 72/76% in S vs UT groups respectively) were comparable at baseline. Forty-five S-patients (18%) were treated in both knees.

S-patients showed a better improvement than UT-patients regarding all primary and secondary efficacy outcomes. More especially, mean (SD) changes in S-group versus UT-group were ?3.6 (4.1) vs ?1.6 (4.0) for Lequesne Index, ? 20.1 (19.3) vs ? 8.2 (20.5) mm for WOMAC total score and ? 37.4 (22.3) vs ? 24.4 (24.0) mm for pain on movement. Therefore additional improvements ($p = 0.0001$) were observed in S-group for Lequesne Index (+ 18.7%), WOMAC total (+ 24.4%), and pain on movement (+ 21.1%).

In S-group, global efficacy was assessed as good/satisfactory by 74% of patients and by 76% of investigators versus 51% and 48% respectively in UT-group, $p < 0.0001$.

Transient local adverse events (pain, swelling) after Synvisc injections were reported in 11.8% of injections. Gastrointestinal adverse events related to OA treatment were less frequently reported in S-patients (3.5%) as compared to UT-patients (11.9%) ($p < 0.001$).

Conclusion This large-scale study confirms the efficacy and safety of viscosupplementation by Synvisc in knee OA over a 9-month follow-up.

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SAT0074 PATIENTS WITH KNEE OSTEOARTHRITIS TREATED BY HYLAN G-F 20 VERSUS USUAL TREATMENTS: A MEDICO-ECONOMIC, PROSPECTIVE, RANDOMISED LARGE SCALE TRIAL IN FRANCE, MEDICO-ECONOMIC OUTCOMES

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Background

Objectives To evaluate the medico-economic benefits of Hylan G-F 20 over 9 months in the treatment of patients suffering from knee osteoarthritis (OA).

Methods Patients with radiographically proven knee OA, pain on movement ³ 40 mm (VAS) and treated by at least two 10-day NSAIDs courses or by slow-acting anti-OA drugs within the previous 3 or 2 months respectively were enrolled by 81 centres (21 hospitals and 60 private rheumatologists). After stratification on known OA risk factors (patients? age, BMI,...), patients were centrally randomised in Synvisc (S) or in usual treatment (UT) groups. S-patients were treated by 3 intraarticular injections of Hylan GF 20 one week apart and encouraged to stop or spare any other OA treatments. If needed S-patients could be treated by Synvisc in both knees. Primary outcome was difference in specific knee-OA cost (visits, exams, hospitalisations, treatments and adverse event treatment/prevention related to OA treatments) divided by difference in AUC mean change of Lequesne index between groups. Data were collected at baseline, day 28, months 3, 6 and 9.

Results Out of 518 patients randomised, 506 (253 per group) were treated and evaluable. Both groups were comparable at baseline. Forty-five S-patients (18%) were treated in both knees. Cost per patient was analysed over 9 months in social security perspective (year 1998 value). All direct and indirect costs were decreased in S-group compared to UT-group (medications ? 40%, non-drug treatments ? 19%, hospitalisation ? 5%, exams ? 2%, seak-leave ? 15%) with the only exception of physician visits cost (+ 33%) due to Synvisc injection procedure.

Specific OA total costs (including Synvisc) were 829.12 Euros in S-group and 821.34 Euros in UT-group. Synvisc cost in social security perspective (year 2000 value) is 99.09 Euros per treatment.

AUC mean change in Lequesne Index was 7.9 points in S-group vs 9.9 in UT-group ($p < 0.0001$). All together the cost/efficacy ratio (including Synvisc cost) was 7.78 Euros for a 2-