(2.16) mm). The reduction was statistically different versus placebo for both doses (400 mg $p < 0.0001$; 95% CI, (-19.95 to -6.04) and 200 mg $p = 0.0008$; 95% CI, (-17.64 to -4.12). There was no effect on the WOMAC subscale of pain.

Conclusion: Rubus idaeus leaf extract, even at the low dose of 200 mg, was effective to relieve pain at short-term in-patient with knee OA. As Rubus idaeus leaf extract is well tolerated, it could be an alternative to nonsteroidal anti-inflammatory drugs and paracetamol to relieve knee joint pain in OA patients.

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POS0282

EVALUATION OF A NEW HYALURONATE FORMULATION ONE YEAR AFTER SINGLE INJECTION TO PATIENTS WITH SYMPTOMATIC KNEE OSTEOARTHRITIS (SOYA STUDY)

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Background: Osteoarthritis (OA) is a leading cause of chronic pain and disability, and its prevalence is expected to increase worldwide (1) being the knee the most affected joint, especially in older adults. Intra-articular hyaluronic acid (HA) could be of particular benefit in OA patients with co-morbidities, and in case of inadequate response to other pharmacological treatments (2). HA has been generally administered in cycles of 3-5 injections, however, due to the pressure on public health systems, the trend is to reduce the number of injections maintaining the duration of effects as longer as possible.

Objectives: To assess the effectiveness and safety of a new formulation of HA, up to one year after one single injection to patients in the SOYA (Symptomatic Osteoarthritis One Year Assessment) study.

Methods: Patients with Kellgren-Lawrence (KL) grade 2-3 and Visual Analogue Scale (VAS) pain ≥ 40 - ≤ 80 mm were prospectively included to receive a single injection of MPS-HA2%. At 6m a second injection could be offered to selected patients. Primary outcome was reduction of VAS pain in the target knee. VAS for joint pain and WOMAC were recorded at 6 and 12m; Minimally Clinical Important Improvement MCII ($\geq 20\%$ relative change for VAS pain) and patient and investigator assessments (PGA, IGA) (Likert scale 0-4 points) were also estimated. Adverse events were recorded for safety assessment.

Results: One hundred and one patients (mean age 68 years, 74% female and 78% with overweight) were included. Mean pain at baseline in the target knee was 63.57 mm and 57% were grade 3 KL with a mean evolution of 7.5 years. Table 1 shows the improvement in VAS and WOMAC scores at 6 and 12 months in the mITT population. Similar results were obtained in PP population.

Table 1. Changes in VAS and WOMAC scores, expressed as mean values

SCORE	Baseline		6 months		12 months	
	value	value	% variation (95% CI)	value	% variation (95% CI)	
VAS pain	63.57	37.59	-39.74* (-49.23; -30.25)	38.37	-37.67* (-47.82; -27.52)	
WOMAC						
total	50.19	31.88	-37.96* (-46.83; -29.09)	31.65	-36.47* (-46.20; -26.73)	
pain	49.37	32.01	-32.92* (-43.37; -22.46)	31.08	-32.07* (-43.19; -20.95)	
stiffness	49.12	28.35	-35.24** (-53.22; -17.23)	28.71	-34.08* (-49.30; 18.86)	
function	52.07	35.30	-33.95* (-43.49; -24.40)	35.15	-32.71* (-42.80; -22.62)	

*p-value: 0.0001; **p-value: 0.0002. Student test

The MCII was achieved by 66.3% of patients at 6m and 62.2% at 12m. Regarding PGA mean score was 2.44 at baseline, 1.35 at 6m and 1.46 at 12m (Wilcoxon, p -value < 0.05). As for the IGA mean score was 2.29 at baseline, 1.06 at 6m and 1.48 at 12m (Wilcoxon, p -value < 0.05).

Fourteen patients received a second injection at 6m and 50% of them achieved at 12m a significant and clinically relevant improvement compared to baseline, above the 20% established for the MCII.

In total, 12 adverse events (8 patients) were reported, all of them local, non-serious, and of mild-moderate intensity.

Conclusion: Viscosupplementation with a single intra-articular injection of MPS-HA2% has proven to be effective and well tolerated up to 12 months after treatment. The re-infiltration of the joint in appropriate cases has proven to be effective in a significant number of patients. The acceptability of the treatment by the patient was optimal.

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POS0283

TREATMENT PATTERNS AND CLINICAL CHARACTERISTICS OF PATIENTS WITH OSTEOARTHRITIS OF THE HIP AND/OR KNEE TREATED WITH TRADITIONAL NSAIDS VS COX-2S: A REAL-WORLD STUDY OF COMMERCIALY-INSURED PATIENTS

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Background: The 2019 American College of Rheumatology (ACR) guidelines strongly recommend oral nonsteroidal anti-inflammatory drugs (NSAIDs) for management of hip and knee osteoarthritis (OA) and strongly recommend topical NSAIDs for knee OA. There are, however, important safety considerations with NSAIDs in terms of increased rates of gastrointestinal, cardiovascular, and renal events. Given these risks, it is important to understand the characteristics and drug utilization of the patients who start treatment on these different treatments (i.e., traditional NSAIDs [tNSAIDs] and cyclooxygenase-2 inhibitors [COX-2s]).

Objectives: The goal of this research was to describe and compare baseline characteristics of commercially-insured patients diagnosed with OA of the hip and/or knee who started treatment on different types of NSAIDs (i.e., oral tNSAIDs, topical tNSAIDs, and COX-2s).

Methods: The Optum Healthcare Solutions, Inc. claims database (1/2012-3/2017) was used to identify patients ≥ 18 years old, with ≥ 2 diagnoses of hip and/or knee OA, and ≥ 90 days supply of oral tNSAIDs, topical tNSAIDs, or COX-2s during the one-year follow up period. The index date was defined as the first prescription after the first OA diagnosis. Patients were assigned to cohorts based on the type of NSAID prescribed on index date. Patients were required to be continuously-enrolled six months before (baseline period) and 36 months after (follow-up period) the index date. Demographic and clinical characteristics including age, sex, comorbidities, and healthcare resource use (HRU) were summarized during baseline. Drug utilization characteristics including days supply and number of prescriptions for the different NSAIDs types were summarized during follow-up period.

Results: Data for 23,796 patients were analyzed: 18,100 patients received oral tNSAIDs, 4,825 received COX-2s, and 871 topical tNSAIDs. Patients who initiated treatment on oral tNSAIDs were the youngest (mean age of 60.6 vs. 64.6 for COX-2s and 65.0 for topical tNSAIDs) and topical tNSAIDs had the highest proportion of female patients (71% vs. 62% for oral tNSAIDs and 63% for COX-2s). The topical tNSAIDs cohort had the highest presence of chronic kidney disease (2.6% vs. 1.0% and 1.5% for oral tNSAIDs and COX-2s, respectively) and congestive heart failure (2.5% vs. 0.8% and 1.7% for oral tNSAIDs and COX-2s, respectively) at baseline. In terms of HRU during baseline, topical