FRI0395

PROGNOSIS OF TREATMENT OUTCOMES IN PATIENTS WITH ANKLE JOINT OSTEOCHONDRAL LESIONS AND DEFECTS

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Background: in most cases osteochondral lesions and defects (OHL) in the ankle joint are the consequences of trauma, and the results of their treatment depend on a number of factors. Some factors are directly related to the area of damage (depth, localization, size), others are connected to the patients age, presence of degenerative changes in the affected joint, comorbidities, body mass index (BMI), etc.

Objectives: to develop an effective system for predicting long-term outcomes in patients with ankle joint OHL.

Methods: 24 prognostic factors (age, gender, severity of injury, Charlson comorbidity index, BMI, OA stage, size of defect, localization of injury, degree of osteoporosis, contracture, instability, etc.) influence on the long-term (36 ± 4.5 months) treatment outcomes was analyzed by Bayesian probability analysis in 223 patients after ankle joint OHL. The prognostic coefficient (PC) was calculated by Wald sequential analysis for each prognostic factor and prognostic system was developed for prediction of high, medium or low probability of positive treatment result, which was determined as a functional joint outcome in AOFAS 75 - 100 points.

Results: the greatest predictive value for the positive result of OHL treatment had the following factors: age < 40 years (PC = 8.5); BMI < 25 kg/m² (PC = 7.0), time from trauma < 1 year (PC = 4.1); OA stage < II (PC = 7.2); size of OHL < 1.0 cm²; volume < 1.5 cm³ (PC = 8.0). The prognostic system is based on the calculating of total factors values for individual patients case in points (Σ PC). If Σ PC is less (-20) the probability of achieving a positive joint-saving result is absent; at Σ PC from (-20) to (+40) the probability is medium; and at Σ PC above (+40) probability is high. The accuracy of the prognostic assessment was retrospectively tested with a 95% confidence interval, the accuracy of predictive method – 84,17% (76,59-89,62)%.

Conclusion: the size and volume of osteochondral damage, BMI, age and time from trauma has the greatest predictive value for the determination of the long-term results of treatment in patients with ankle joint OHL; use of the developed prognostic method can be used as a basis for the clinical decision making in choosing different approaches in treatment.

Disclosure of Interests: None declared

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FRI0396

HOW DOES OSTEOARTHRITIS PAIN IMPACT FUNCTION, MOBILITY AND REQUIREMENT FOR HELP IN DAILY ACTIVITIES IN EUROPEAN PATIENTS?

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Background: Symptomatic osteoarthritis (OA) leads to functional limitations and loss of independence. OA management focuses on pain relief and preserving physical function using non-pharmacologic and pharmacologic therapy. Additionally, patients commonly manage OA pain by avoiding activities that exacerbate their pain. Informal care, i.e. assistance from an unpaid caregiver, plays a major role in the total care provided to patients with chronic diseases like OA.

Objectives: To evaluate how OA pain severity affects physical functioning and the subsequent need for assistance with mobility and daily activities in 5 EU countries: France, Germany, Italy, Spain and UK.

Methods: Data were drawn from the Adelphi OA Disease Specific Programme (2017-18), a point-in-time study of physicians and their OA patients. Patients rated their average pain intensity over the last week on a 0-10 scale (0 = no pain; 10 = worst possible pain) and were then categorised into mild (0-3), moderate (4-6) and severe (7-10) pain groups. Patients also provided an assessment of their physical function (0-10 WOMAC scale where higher scores indicated greater functional impairment), impact on mobility, whether caregiver assistance was required, daily activities requiring caregiver assistance and home modifications made due to their OA. Physicians also rated patients' functioning on

a 0 to 10 scale (0 = fully functional; 10 = completely impaired). Comparisons among pain severity groups were made using chi-squared tests and analysis of variance.

Results: The analysis included 1750 OA patients: 24% mild pain (n=413); 47% moderate pain (n=822); 29% severe pain (n=515). The patients were predominantly women (58%) and had a mean (SD) age of 65.6 (11.5).

Increased pain severity was associated with greater functional impairment scores as reported by patients (WOMAC scores: mild pain=2.1; moderate pain=4.1; severe pain=5.9) and physician-rated functional impairment (mild pain=3.5; moderate pain=4.3; severe pain=5.6). Mobility was impacted for 78% of patients with severe pain (vs. 41% mild; 63% moderate) and the need for a walking aid such as a walking stick or walking frame increased with worsening severity; wheelchair assistance was needed for 7% of severe patients (compared with <1% of mild or moderate patients). Furthermore, 31% of patients with severe pain reported having to modify their home due to their OA (vs. 11% mild; 18% moderate [p<0.001]), typically adapting their bathroom (23%) or fitting a stairlift (6%).

The need for assistance from a caregiver to help with daily activities was associated with an increase in patients' pain (9% mild; 20% moderate; 42% severe [p<0.001]). For most patients this was an immediate family member, however, the proportion of patients paying for professional care also increased with severity (1% mild; 2% moderate; 7% severe). Taking the patient to work or doctor's appointments; help with shopping; preparing/cooking meals and help with travelling out of the home were most frequently reported activities needing caregiver assistance.

Conclusion: In this study of European patients, increased pain severity was associated with greater functional impairment and impact on mobility as expected; however, this study highlights the substantial need for assistance with daily activities as well as modifications to the home. The unseen costs to the patient with moderate to severe OA pain are significant.

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FRI0397

THE IMPACT OF OSTEOARTHRITIS DISEASE SEVERITY ON HEALTHCARE RESOURCE USE: ANALYSIS OF REAL-WORLD EUROPEAN DATA

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Background: Osteoarthritis (OA) is a chronic joint disease associated with pain and impaired activity. With increasing obesity trends and an ageing population, the prevalence of OA is expected to rise in the future. This represents an increasing societal problem which will lead to an increased burden on healthcare services.

Objectives: To understand the pattern of healthcare resource utilisation (HCRU) across France, Germany, Italy, Spain and the UK, as OA disease severity increases.

Methods: Data were drawn from the Adelphi OA Disease Specific Programme (2017-18), a point-in-time study of physicians and their OA patients. OA disease severity was reported by physicians, who categorised patients' OA severity as mild, moderate or severe. Patients were excluded from the analyses if they suffered from back and neck OA only, and shoulder OA that had not been diagnosed by X-ray. Physicians provided information, on a patient record form, about OA-related visits to healthcare professionals (HCPs), tests/scans conducted, emergency room (ER) visits and surgeries. Statistical comparisons among disease severity groups were made by analysis of variance and chi-squared tests.

Results: The study included 489 physicians (primary care physicians, rheumatologists, orthopaedists) reporting on 3596 of their patients with OA: 24% mild (n=874), 53% moderate (n=1904) and 23% severe (n=818). Over the last 12

months, the mean number of consultations with HCPs increased with disease severity (3.7 mild, 4.2 moderate and 5.7 severe [<0.001]). This pattern was also observed in relation to the mean number of tests/scans conducted in the last 12 months (6.9 mild, 7.9 moderate and 9.3 severe [<0.001]). More than a quarter of severe patients visited the ER in the last 12 months (26% vs. 4% mild; 9% moderate [<0.001]) and visits to hospital increased with disease severity (Table 1). The proportion of patients that have had a surgery due to their OA rose with worsening disease severity (11%, 13% and 27% for mild, moderate and severe, respectively [<0.001]).

Table 1. Physician-reported healthcare burden by OA disease severity

	Mild (n=874)	Moderate (n=1904)	Severe (n=818)
Number of patient visits to ER in the last 12 months, mean (SD)	0.1 (0.4)	0.1 (0.6)	0.5 (1.0)
Patients with ≥ 1 emergency visit in the last 12 months, n (%)	13 (1.5)	43 (2.3)	79 (9.7)
Patients with ≥ 1 hospitalisation in the last 12 months, n (%)	11 (0.1)	9 (0.5)	26 (3.2)
Number of patient outpatient hospital visits in the last 12 months, mean (SD)	0.5 (1.4)	0.6 (1.1)	1.2 (1.4)

Conclusion: This real-world data demonstrated an increase in visits to HCPs, monitoring tests and scans, hospitalisations, ER visits and surgery as OA disease severity worsened.

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FRI0398

COMPARISON OF THE EFFICACY AND SAFETY OF TWO HYALURONIC ACIDS IN THE TREATMENT OF KNEE OSTEOARTHRITIS

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Background: Several viscosupplement treatments are available to patients suffering from osteoarthritis (OA) but few comparative clinical trials have been conducted.

Objectives: The primary objective of the study was to demonstrate at 24 weeks the non-inferiority of on hyaluronic acid over a second one in terms of efficacy (pain relief) in knee OA patients (Kellgren and Lawrence radiologic stage II or III) with whom oral treatment had failed.

Methods: This was a prospective, multicenter, comparative, randomized, double-blinded study (one independent physician evaluator—one physician injector), comparing two viscosupplements: one containing a solution of hyaluronic acid (SYNOLIS VA® 80mg hyaluronic acid and 160mg sorbitol – Group HA1) and the other containing one of Hylan (SYNVISCO ONE® 48mg Hylane GF-20 – Group HA2) over a period of 24 weeks. At inclusion, the average VAS Pain (1-100) was 62.5. The patients were randomized in 2 parallel groups at D0 and followed until D168. They received an injection of either HA1 or HA2. Efficacy was primarily assessed using the WOMAC Pain index (daily assessed by the patient during seven days following the injection, and then at D14). During the follow up visits (D28-D84-D168) WOMAC pain, stiffness and function scores were assessed as secondary objectives. At D168, efficacy and satisfaction were also evaluated by the evaluator and by the patient using Likert scale (7 points). Moreover, the number of responders strict each group was evaluated according to the OMER-ACT-OARS criteria. According to methodology guidelines, the per protocol (PP) population has been used as primary analysis. The PP population included all patients from the intention to treat (ITT) population who completed the study without any major protocol violation.

Results: 202 patients were randomized (ITT population, 96 in the HA1 group and 106 in the HA2 group). Baseline demographic data for the PP population at the time of randomization by treatment group. Patients were predominantly female (66%). The median age of the whole population was 65 years and the median body mass index of 27.4 kg/m². No statistically significant differences between the two treatment groups were observed for any demographic criteria. At D168, 197 presented no protocol violations (94 in the HA1 group and 103 in the HA2 group). This population had a decrease on the overall score of the WOMAC Pain at -29.2 +/- 24.1 (SD) in the HA1 group and -31.6 +/- 25.5 (SD) in the HA2 group confirming the non-inferiority ($P = 0.57$ for the difference between groups). Regarding the secondary endpoints, no significant difference has been observed at D14, D28, D84, D168, in the PP population for all the outcome except stiffness at D28. There was also no difference between the responders rate in two groups (79 % for HA1 and 77% for HA2). In terms of safety, both products were well tolerated. No case of allergy or infection in the course of the injection was reported. Serious adverse events have been reported by 4 patients in HA1 group and 3 in HA2 group.

Conclusion: In this study, we confirmed the non-inferiority of HA1 compared with HA2 in terms of both efficacy and safety.

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FRI0399

COLCHICINE IS NOT EFFECTIVE FOR REDUCING OSTEOARTHRITIC HAND PAIN COMPARED TO PLACEBO: A RANDOMISED, PLACEBO-CONTROLLED TRIAL (COLAH)

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Background: Current pharmacotherapies to treat or prevent hand osteoarthritis are limited. Colchicine, an anti-inflammatory agent effective at reducing joint pain and swelling in gouty arthritis, may offer relief in hand osteoarthritis, though this has not been investigated before.¹

Objectives: To investigate the efficacy of colchicine compared to placebo on VAS pain scores over 12 weeks in adults with hand osteoarthritis in a randomised, double-blind controlled trial.

Methods: 64 community-dwelling adults with hand osteoarthritis (American College of Rheumatology criteria)² (54 females, 48-79 years) were randomised 1:1 to colchicine (0.5mg twice daily) or placebo for 12 weeks. VAS pain scores (worst affected hand) were obtained at baseline and weeks 6, 12, and after treatment withdrawal at week 16. Secondary outcome measures included grip strength, C-reactive protein (CRP) and tender and swollen joint count (TSJC). Grip strength, TSJC and CRP were obtained at baseline and week 12. Intention-to-treat analyses, adjusted for age and gender, were performed using constrained longitudinal data analysis models in Stata v16.³ This study is registered with the Australia New Zealand Clinical Trials Registry, ACTRN12617001524381.

Results: 58 participants completed the study (N=27 colchicine, N=31 placebo, withdrawal rate 9%). Mean (S.D.) VAS score of the affected hand at baseline was 71.4 (14.5) mm in the placebo and 65.4 (15.0) mm in the colchicine group ($p = 0.11$). VAS scores improved during treatment, but were comparable between groups at week 6, 12 and 16 (Table 1). There were no differences between groups at week 12 for CRP, TSJC or grip strength (Table 1). Adverse events related to study medications included nausea (n=4), diarrhoea (n=9), vomiting (n=3), bloating (n=1) and reflux (n=1).

Table 1. COLAH study primary and secondary outcomes, from constrained longitudinal data analysis model

Outcome	Timepoint	Colchicine (SE)	Placebo (SE)	Colchicine-Placebo (95% CI)	p-value
VAS Pain (mm)	6 weeks	53.5 (4.5)	53.9 (4.6)	-0.4 (-12.3, 13.1)	0.95
	12 weeks	57.1 (4.4)	48.4 (4.6)	8.7 (-21.2, 3.9)	0.18
	16 weeks	62.0 (4.3)	61.6 (3.7)	-0.4 (-11.4, 10.5)	0.94
TSJC (0-20)	12 weeks	5.6 (0.7)	3.8 (0.7)	1.8 (-4.1, 0.5)	0.13
Grip strength (kg)	12 weeks	14.4 (0.8)	15.3 (0.8)	-0.9 (-0.2, 2.0)	0.10
CRP (mg/L)	12 weeks	4.5 (1.4)	4.0 (1.3)	0.5 (-3.8, 2.9)	0.77