knee arthroplasty (TKA) and undergo surgery at a later stage of the disease than men, which could lead to worse postoperative outcomes (1). These differences have been attributed to differences in the interpretation of symptoms between men and women (2), yet little is known about expectations of the postoperative outcomes of TKA.

Objectives: To compare the duration of symptoms before TKA and the preoperative expectations of postoperative outcomes of TKA between men and woman.

Methods: Preoperative data from a multicenter cohort study on outcomes of primary TKA were used. Preoperatively, patients were asked to indicate the duration of symptoms to TKA (<1 year, 1-5 years, 5-10 years and >10 years). The Hospital for Special Surgery (HSS) Knee Replacement Expectations Survey was used to obtain information on expectations regarding postoperative pain relief, mobility and daily activities and improvement of quality of life (score range 0-100), with lower scores indicating higher expectations. In addition, the Knee injury and Osteoarthritis Outcome Score (KOOS), pain (Numeric Rating Scale, NRS), comorbidities and work-status were gathered. Differences between men and women regarding the duration of symptoms and preoperative expectations were examined by the means of the Chi-Square test and independent t-test and difference with the 95% Confidence Interval (CI) respectively.

Results: A total of 1543 patients, 556 men (mean age 71 (SD 8), 32.3% paid employment) and 987 women (mean age 71 (SD 9), 20.3% paid employment) were included. Women had more pain preoperatively than men, 5.3 (SD 3) versus 4.3 (SD 3) at rest and 7.1 (SD 2) versus 6.2 (SD 3) during activity, respectively. Furthermore, men scored better on each KOOS subscale compared to women. Overall the duration of symptoms was longer in men than women: <1 year: 11.3% versus 9.6%, 1-5 years: 38.8% versus 49.7%, 5-10 years: 18.3% versus 20.0% and > 10 years: 31.5% versus 20.7%. Finally, women had significantly higher expectations of postoperative TKA outcomes than men, 67.4 (SD 19) and 70.2 (SD 19), respectively (Mean Difference; 2.79, 95% CI 0.84-4.75).

Conclusion: Preoperatively, men reported a longer duration of symptoms and had lower expectations of TKA outcomes than women. However, men seemed to perceive less symptoms and restrictions in daily activities despite a longer duration of symptoms.

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AB0799

ART- QUALIVIE: ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS WITH KNEE OSTEOARTHRITIS SIX MONTHS AFTER TREATMENT WITH THREE INTRA-ARTICULAR INJECTIONS OF ARTHRUM H 2%

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Background: Knee osteoarthritis (KOA) is a chronic condition affecting mainly the elderly and considered as the leading cause of disability after cardiovascular disease. KOA is characterized by functional discomfort and deformities, leading to a deterioration in the quality of life (QoL) of patients.

Objectives: The main objective was to demonstrate that 3 intra-articular injections of ARTHRUM H 2% improves the physical QoL of patients over a 6-month period.

Methods: A French observational, prospective, multi-centre study was conducted between 02/2016 and 07/2017 in patients over 40 suffering from Kellgren and Lawrence (KL) grade I, II or III primary KOA and treated with 3 intra-articular injections of ARTHRUM H 2%. The variables included a questionnaire completed by a physician and the validated 12 items Short Form Health Survey (SF-12), completed by patients at baseline (right before the injections), and then at 90 and 180 days. The primary endpoint was the change in physical summary score from baseline

to 180 days (paired Student t-tests). Logistic regression analyses were used to identify the main drivers of significant increase of physical summary score, adjusted for sociodemographic and health covariates.

Results: Of the 134 patients treated with ARTHRUM H 2% included in the study, 115 were evaluable for the primary outcome (non-exploitable data for 19 patients).

The baseline characteristics of the analysable population were as follows: mean age of 66.4 years (± 10.7); majority female (66.4%); mean BMI of 28.7 (± 5.3) kg/m² (43.3% overweight and 35.1% obese); KL grade KOA grade: I 13.6%, II 40.2%, III 46.2%; localization: uni-compartmental 53.0% (78.6% medial, 15.7% lateral, 5.7% patellofemoral), bi-compartmental 40.2% and tri-compartmental 6.8%. Regarding management history, respectively 6.7% and 44.8% of patients had previously received physical therapy or rehabilitation, and a visco-supplementation (2.2 treatments on average). Comorbidities observed in 73.9% of patients were metabolic-related in 54.5%, cardiovascular-related in 46.3%, gastrointestinal-related in 20.9%, and neurological-related in 8%.

A clinically and statistically significant improvement in the QoL of patients was observed with an increase from 40.0 at baseline to 44.8 at 6 months ($p < 0.001$). A significant improvement was achieved during the 3 months following visco-supplementation (D0: 40.0 vs. D90: 44.8) and maintained from three to 6 months from baseline (D90: 44.8 vs. D180: 44.9).

The factors significantly associated with an improvement in QoL were: grade III KOA (OR=5.254, $p=0.032$), grade II KOA (OR=3.507, $p=0.100$), lateral femorotibial osteoarthritis (OR=3.175, $p=0.029$) and a single history of visco-supplementation (OR=2.936, $p=0.044$).

Conclusion: ART-QUALIVIE is a French study providing real-world data on the evolution of QoL of visco-supplemented KOA patients. It has demonstrated the positive impact of ARTHRUM H 2% on the QoL of patients over the 3 months following injections maintained until 6 months after treatment.

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AB0800

ESTABLISHMENT OF TECHNICAL PERFORMANCE CRITERIA AND REFERENCE INTERVALS FOR OSTEOARTHRITIS-RELATED SOLUBLE BIOMARKERS: THE APPROACH CONSORTIUM

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Background: Disease modifying therapy of osteoarthritis (OA) represents an unmet clinical need, and appropriate outcome measures are required that can robustly identify patients with different OA phenotypes who may benefit from specific and more targeted therapies. APPROACH is an exploratory, 5-centre, 2-year prospective follow-up European cohort study. It entails extensive clinical, imaging, biomechanical and biochemical parameters, in a cohort recruited using machine learning models based on retrospective patient data to display a high likelihood of radiographic joint space width loss, MRI changes and/or knee pain over the course of the study. Biochemical markers (biomarkers) can be used to understand

pathogenesis, drug mode of action and as prognostic tools, as well as finding the right treatment for the right patients.

Objectives: Different biomarkers were selected to be measured in APPROACH patient samples for prospective predictive and prognostic analyses. Here we describe the biological rational, reference ranges and technical performance of the selected biomarker.

Methods: The APPROACH cohort includes 300 OA patients recruited based on the APPROACH enrichment model (www.approach.eu), in the period from 2017 and 2019. Serum and urine will be collected at baseline, 6, 12 and 24 months, as well as pain, radiographic and MRI assessments.

Results: Eighteen exploratory and technically validated biomarkers reflecting joint tissue (i.e. cartilage, bone, synovium) turnover were chosen based on following characteristics; i) has shown association with OA pathogenesis (published data such as OAI¹); ii) has shown diagnostic or prognostic potential ²; iii) GLP or GMP certified assay production with acceptable technical performance (e.g. precision and linearity data, table); iv) readily availability of the kits from consortium partner or from third party vendor. The markers will be tested asking following research questions: Can the markers alone or in combination subgroup patients into different phenotypes which display different progression rates, or with different pain and radiographic profiles. Also, we will test whether a change in markers are correlated with change in the clinical assessments scores. Results from these analyses may provide insight to the potential usage of the biomarkers in drug development.

Biomarker	Description	Analysis method	Reported donor range in Serum and Urine (n=30)	Technical performance with in the dynamic range of the assay ▪ Precision (intra/inter-assay CV %) ▪ Serum/urine linearity within the measurement range (relative error %)
S-ARG5-aggrecan ³	Aggrecan degradation	Electro-chemiluminescence	0.010 – 0.200 pmol/mL	2.8% (mean)/10% (max) -15.3 to 21.4%
		Chemiluminescence	132 – 1844 U/mL ^b	<3.1% / <15.2 (max) -10.1 to 4.9 %
S-C1M ⁴	Type I collagen degradation	Colorimetric	28.7 – 66.8 ng/mL	<17.7% / <11.6 % (max) -7.8 to 2.4 %
S-C2M ⁵	Type II collagen degradation	Colorimetric	0.162 – 0.938 ng/mL	<17.7% / <11.6 % (max) -8.8 to 15.4 %
S-C3M ⁴	Type III collagen degradation	Colorimetric	13.1 – 31.1 ng/mL	<13.5% / <14.5 % (max) -9.5 to 12.8%
S-C-Colneo (C10C) ⁶	Type X collagen degradation	Colorimetric	600 – 1800 umol/L	<7.6% / <11.6 % (max) -9.4 to 9.5%
S-Coll2-1 ⁷	Type II collagen degradation	Colorimetric	160 – 224 nmol/L	<9% / <20% (max) -6.2 to 8.6%
S-Coll2-1-NO2 ⁷	Nitrated form of coll2-1	Colorimetric	ND ^a	<12% / <13% (max) -10.3 % to 9.4 %
S-COMP ¹	Cartilage oligomeric protein	Colorimetric	ND ^a	ND ^a
S-CRPM ⁵	C-reactive protein degradation	Colorimetric	4.4 – 11.7 ng/ml	<11.1 / <20.8 % (max) -12.2 to 8.6 %
S-CTX-I ¹	Type I Collagen C-terminal Telopeptide (cross-linked)	Chemiluminescence	16 – 1008 pg/mL	ND ^a
S-F3F ⁸	Fibulin-3	Colorimetric	ND ^a	<10%/<11% -13.4 to 12.5%
S-HA ¹	Hyaluronan	Colorimetric	20 – 196 ng/mL	<7.2 / <16.2 % (max) -5.8 to 7.6 %
S-hsCRP ¹	High sensitive C-reactive protein	Chemiluminescence (automatic)	ND ^a	<5 / <5 % (max) ≤20%
S-hsPRO-C2 ⁹	Type IIB Collagen synthesis	Electro-chemiluminescence	1.1 – 4.9 ng/mL	<15.9 / <13.3 % -15.1 to 12.2%
S-NMID ¹	Osteocalcin	Chemiluminescence (automatic)	11 – 46 ng/mL	<2.8 / <4.6 % (max) -4.0 to 8.1 %
S-PIIANP ¹	Type IIA Collagen Synthesis	Colorimetric	1236 – 4475 ng/mL	<10.8 / <16.6 % (max) -8.0 to 19.8 %
U-ALPHACTX-I ¹	Type I Collagen C-terminal Telopeptide	Colorimetric	ND ^a	<3.4/ <6.0 % ≤20%
U-CTX-II ¹	Type II Collagen C-terminal Telopeptide	Colorimetric	ND ^a	<7.8 / <12.2 % -12.3 to 7.4 %

^a ND; not determined by the consortium members, but reference can be found elsewhere. ^b U; units, ADAMTSS cleavage units, corresponding. S- and U-; Serum and Urinary

Conclusion: The APPROACH consortium is the first European study that attempts to establish robust technical performance criteria and reference intervals for osteoarthritis-related soluble biomarkers in an effort to develop biomarker panels that can identify patients with different OA phenotypes.

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