While the study design and differences in sample sizes does not allow formal comparisons between the double- and single blinded groups, the exploratory comparator, Voltaren QID, did not reach statistically significant differences to placebo or AMZ001 in any of the endpoints, in neither the ITT nor the subgroup analyses. The safety and tolerability of AMZ001 was favorable, as the frequency of AEs leading to discontinuation of treatment was similarly low (ranging between 2.8 % to 6.6 %) between AMZ001 once or twice daily and placebo or Voltaren Gel 1%. The most common treatment-emergent AEs were application site dryness, and application site erythema. No serious adverse events were reported during the trial.

Conclusion: AMZ001, a novel topical diclofenac formulation, either once or twice daily was efficacious in the treatment of knee OA pain with a good tolerability and safety profile, suggesting AMZ001 may be a promising alternative to existing pain-relieving treatments in knee OA.

References: NA

Disclosure of Interests: Asger Bihlet Shareholder of: Nordic Bioscience, Consultant of: Amzell BV, Medivir AB, Xintela AB, Merck KGaA, Employee of: Nordic Bioscience, Inger Byrjalsen Employee of: Nordic Bioscience, Henning Bay Nielsen: None declared, Jeppe Andersen Shareholder of: Minor shareholder of Nordic Bioscience, Consultant of: Medivir AB, Xintela AB, Employee of: Nordic Bioscience, Laetitia Delpy Employee of: Amzell BV, Caroline Derne Employee of: Amzell BV, Dario Carrara Employee of: Amzell BV

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AB0857 A NEW BIOPSYCHOSOCIAL QUESTIONNAIRE FOR PATIENTS WITH KNEE OSTEOARTHRITIS

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Background: OA is a problem that cartilage damage occurs, which leads to stiffness in the joint, pain and functional limitations (1). This problem can also cause psychosocial impact like other chronic diseases (2). As with other rheumatic diseases, this complex picture of inflammation required biopsychosocial approaches and measurement methods for knee OA.

Objectives: This study was planned to investigate the validity and reliability of a new biopsychosocial questionnaire which is named Cognitive Exercise Therapy Approach Biopsychosocial Questionnaire (BETY-BQ) in individuals with knee osteoarthritis (OA).

Methods: The study included 150 individuals who diagnosed knee osteoarthritis at stage 1 or 2 according to the Kellgren-Lawrence scale. For determining daily living activities; Health Assessment Questionnaire (HAQ), for quality of life Short Form-36 (SF-36) Quality of Life Scale, for anxiety and depression levels; Hospital Anxiety and Depression Scale (HADS), for severity of disease Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and for biopsychosocial evaluation BETY-BQ were used.

Results: The correlation between BETY-BQ and other scales was examined by Spearman correlation analysis ($r=-0.252, 0.633, p<0.05$). Cronbach's alpha coefficient and item-total correlation were used as reliability methods. Cronbach's alpha coefficient was examined for the internal consistency of the scale and was found to be 0.887 for the first evaluation, 0.917 for measurements after 1 week and 0.843 for measurements after 3 months. Item total correlation, which was another indicator of reliability, ranged from 0.632 to 0.854 ($p<0.05$).

Table 1. Correlation coefficients between all questionnaires and Cognitive Exercise Therapy Approach Biopsychosocial Questionnaire (BETY-BQ).

Spearman Correlation Analysis	Cognitive Exercise Therapy Approach Biopsychosocial Questionnaire (BETY-BQ)	
	r	p
WOMAC-Pain	0,473	<0,001
WOMAC-Stiffness	0,458	<0,001
WOMAC-Physical Function	0,514	<0,001
WOMAC-Total Score	0,553	<0,001
hospital anxiety and depression scale- anxiety	0,615	<0,001
hospital anxiety and depression scale-depression	0,252	0,002*
Health Assessment Questionnaire	0,633	<0,001
Short Form-36 Role limitations due to physical health	-0,440	<0,001
Short Form-36 Role limitations due to emotional problems	-0,357	<0,001
Short Form-36 Physical functioning	-0,469	<0,001
Short Form-36 Social functioning	-0,355	<0,001
Short Form-36 Pain	-0,487	<0,001
Short Form-36 General Health	-0,513	<0,001
Short Form-36 Emotional well-being	-0,508	<0,001
Short Form-36 Energy/fatigue	-0,453	<0,001

Conclusion: As a result of our study, it was concluded that BETY-BQ is a valid and reliable biopsychosocial questionnaire in individuals with knee OA diagnosis. This result showed that BETY-BQ can be used in clinics to evaluate biopsychosocial involvement in patients with knee OA.

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AB0858 TREATMENT ALGORITHM FOR ANKLE OSTEOCHONDRAL LESIONS AND DEFECTS

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Background: traumatic ankle joint osteochondral lesions and defects (OHL) is frequent cause of OA, chronic pain and loss of joint function; results of traditional treatment strategy are often unsatisfying

Objectives: to develop treatment algorithm for OHL based on evaluation of previously determined main prognostic factors.

Methods: the analysis of long-term (36 ± 4.5 months) treatment results of 239 patients after traumatic ankle joint OHL revealed the following factors with the greatest predictive value (defined by PC – prognostic coefficient) for good result of treatment (defined as AOFAS function score 75-100 points): age < 40 years ($PC = 8.5$); size of OHL $\leq 1.0\text{cm}^2$; volume $\leq 1.5\text{cm}^3$ ($PC = 8.0$); osteoarthritis stage $\leq II$ ($PC = 7.2$). Based on these factors, a step-by-step, discrete and alternative algorithm for the choice of treatment tactics was created. The algorithm includes use of arthroscopic or open debridement, abrasive chondroplasty, bone marrow regeneration stimulation (microfracturing or tunneling), mosaic osteochondroplasty, arthroplasty or arthrodesis, the use of cellular regenerative technologies (bone marrow cells, platelet riched plasma), and others. Patients of older age with advanced OA need complex, step up approach, surgical treatment combined with regenerative cell technologies. The effectiveness of the differentiated approach to treatment was studied in 72 patients with OHL (main group) in comparing to 72 patients in whom traditional treatment approaches were used, based on the stage of injury according to the Berndt & Hardy classification (comparison group).

Results: compared to the traditional approach, the developed algorithm and treatment system allowed to half terms of hospitalization, to reduce the intensity of pain syndrome (by NRS) and increase the functional activity (by AOFAS) by 25%. In 3 years after trauma good/excellent results of treatment demonstrated 86% patients of main group and 32,2% of patients from comparing group ($p<0.05$).

Conclusion: implementation of the developed treatment algorithm increases the number of good and excellent long-term results by 2.6 times and reduces the number of complications and unsatisfactory results by 4.9 times.

Disclosure of Interests: None declared

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AB0859 IMPROVEMENTS IN PHYSICAL FUNCTION IN PATIENTS WITH OSTEOARTHRITIS RECEIVING SUBCUTANEOUS TANEZUMAB IN 3 RANDOMIZED CONTROLLED TRIALS

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Background: Tanezumab, a monoclonal antibody against nerve growth factor, is in development for the treatment of the signs and symptoms of osteoarthritis (OA).

Objectives: To assess the improvement in physical function following treatment with subcutaneous (SC) tanezumab in three Phase 3 OA studies.

Methods: All three randomized, double-blind, controlled studies enrolled patients (pts) with radiographically-confirmed OA of the hip or knee, who had inadequate response or could not tolerate standard of care analgesics. Study 1 was a dose-titration study (NCT02697773), where pts received two SC doses of: placebo at baseline/week (wk) 8; tanezumab 2.5mg at baseline/wk 8; or