AB0855

THE "HORSE SADDLE" SIGN: A NEW ULTRASOUND SIGN FOR OSTEOARTHRITIS

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Background: Hand Osteoarthritis is one of the most prevalent rheumatic diseases that can give early visible findings by ultrasound where synovial hypertrophy, effusion, osteophytes and articular cartilage decrease stand out. However, these findings, although sensitive, may not be very specific since they are also observed in inflammatory arthritis. Throughout our clinical practice in osteoarthritis, we have seen, over repeated examinations, an specific morphological change of bone not previously described in the literature. It is a bone extension in the head of the phalanx of the finger joints that causes a deformity that we have called "horse saddle" and that is typically located in the proximal and distal interphalangeal joints of the fingers. This sign can be seen in the longitudinal exploration of the palm of the hand by grayscale ultrasound. This sign that we have not found specifically described in the literature reviewed to date is considered to be useful for the diagnosis of osteoarthritis.

Objectives: To Assess the sensitivity and specificity of the "horse saddle" sign in the diagnosis of osteoarthritis.

Methods: An exploratory clinical comparative cross-sectional study where an ultrasound of the hands and comparative radiographs in PA view were performed on patients with osteoarthritis, inflammatory arthritis and healthy patients seen in the Rheumatology clinic of the Vall de Hebron Hospital. Age, sex and time of evolution of the disease were collected as clinical variables. The MCP, PIP and DIP joints from the second to the fifth finger of both hands were viewed with grayscale in longitudinal and transverse plane of both the dorsal and palmar face, assessing for osteophytes, synovitis and the horse saddle sign. A General Electric Logiq S8 machine was used with an 8-13 MHz linear probe. All patients signed an informed consent and approval was obtained from the hospital ethics committee. The statistical analysis was carried out with Stata 15.1.

Results: A total of 38 patients with osteoarthritis, 20 patients with inflammatory arthritis (8 psoriatic, 9 RA, 1 LES, 1 PMR and 1 Sjögren) and 2 healthy patients were assessed. It was found that the horse saddle sign had a sensitivity of 66.7% and specificity of 86.4% in osteoarthritis showing a p-value of 0.052 by means of the chi-square test. 87% of patients with the horse saddle sign had osteoarthritis and only in 2 patients with RA and in the patient with LES. In contrast for osteophytes a sensitivity of 100% was observed with a specificity of 45.45% (p of 0.001) and for synovitis a sensitivity of 53.3% and specificity of 77.27% was observed with p of 0.039.

Conclusion: The horse saddle sign is an ultrasound sign with good sensitivity and specificity for the diagnosis of hand osteoarthritis comparable to other classic ultrasound signs such as osteophytes and synovitis.

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AB0856

A PLACEBO-CONTROLLED, DOUBLE-BLIND, RANDOMIZED, TRIAL OF AMZ001 – A NOVEL DICLOFENAC SODIUM 3.06% GEL – FOR THE TREATMENT OF KNEE OSTEOARTHRITIS SYMPTOMS

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Background: Development of improved topical treatments of painful joints is warranted. A novel diclofenac sodium gel formulation, AMZ001, has been developed with the purpose of improving 1) The onset and duration of pain relief, and 2) The ease of use by reducing the required daily frequency of gel application. Previous trials in human subjects have confirmed improved permeability of a reduced volume of AMZ001 gel as compared to approved diclofenac topical products with a comparable safety and tolerability profile, supporting trials to evaluate the efficacy and safety of AMZ001 in painful joint conditions.

Objectives: The current abstract reports the main results of a randomized trial of AMZ001 once or twice daily application versus placebo in symptomatic knee osteoarthritis.

Methods: The trial was a placebo-controlled, parallel group, double-blind, randomized trial to evaluate the efficacy and safety of AMZ001 or placebo in subjects with knee osteoarthritis. The main inclusion criteria were Kellgren-Lawrence radiographic severity of 1-3, and pain ≥ 40 and ≤ 90 out of 100 using the WOMAC pain subscale (5 questions) at the time of screening. The subjects were randomized to apply AMZ001 gel once (QD) or twice (BID) daily or placebo twice daily per OA knee for a period of 28 days, or to apply Voltaren® Gel 1 % four times daily (QID) in a single-blind fashion for exploratory comparison. The primary endpoint was change from baseline at week 4 in WOMAC pain (5 questions). The main secondary endpoints included WOMAC subscales, Patient Global Assessment (PGA) and quality of life using the EQ-5D. In addition to the main analysis, a post-hoc subgroup analysis of subjects meeting the pain criterion at both screening and baseline was performed.

Results: A total of 444 subjects were randomized. The main baseline characteristics were well balanced between treatment groups.

AMZ001 QD and BID led to statistically significant reductions in pain compared to baseline with an estimated difference (95% CI) normalized to 0-100 at week 4 of -27.33 (-30.50, -24.17), and -26.49 (-29.60, -23.38), respectively. Reduction in pain at week 4 was statistically significantly superior to placebo for AMZ001 QD (p=0.04), and borderline significant for AMZ001 BID (p<0.10) as shown in Figure 1.

WOMAC pain change from baseline

Both AMZ001 QD and BID led to statistically significant improvements in PGA at week 4 compared to placebo (p<0.05 for both), and AMZ001 BID led to significantly improved quality of life (p<0.05) compared to placebo. There were no statistically significant differences between AMZ001 QD or BID in any of the endpoints. In the post-hoc analysis of subjects meeting the pain criterion at both screening and baseline the differentiation to placebo was strengthened for all efficacy endpoints, as shown in Figure 2.

Main endpoints Subgroup of WOMAC ≥ 40 of 100 at baseline

¹ Negative values indicate improvement

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

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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