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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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.5715

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