EDITORIAL

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DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

THE EFFECTIVENESS AND SAFETY OF SINGLE US GUIDED INJECTION OF HYLASTAN SGL-80 IN PRIMARY HIP OSTEOARTHRITIS. PRELIMINARY DATA FROM A PROSPECTIVE OBSERVATIONAL STUDY

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Objective: To report preliminary data about the efficacy and safety of single intra-articular ultrasound guided injection of Hylastan SGL-80 in primary hip osteoarthritis of moderate severity. Materials and Methods: 20 patients (23 hip joints) were included. Each hip received single ultrasound guided injection of 4 ml Hylastan SGL-80 through a longitudinal antero-inferior approach. Hip examination, visual analogue scale (VAS), McGill Pain Questionnaire (McGill), Western Ontario McMaster Questionnaire (WOMAC), Lequesne Index, and tenderness scale were the main outcome measures for assessment of efficacy. Additionally both local and systemic side effect were screened through phone call 3 days after injection and regular follow up visits during the follow up duration: 1 month, 3 months, 6 months and 1 year post-injection. Results: 14 female (70%), 6 male patients (30%), mean age 68.4 years, mean Body Mass Index (BMI) 26.1 kg/m2, and average complaint duration 47.1 months. 23 hip joints were injected. Student-t test was used to compare baseline scales` values with those recorded after injection. 23 hips reached 1 month follow up, 22 reached 3 months, 17 reached 6 months, while 9 patients reached 1 year follow up. A significant improvement was shown at all time-points with ($p<0.01$) for all scales till T3, and continued till 1 year post-injection with ($p<0.01$) for WOMAC and ($p<0.05$) for McGill and Lequesne. The treatment was well tolerated by all patients without systemic adverse effects, only 2 hip joints reported mild localized pain that subsided spontaneously within 3 days post-injection. Conclusion: Our preliminary findings suggest that a single injection of Hylastan SGL-80 is safe and effective in patients with moderate primary hip osteoarthritis, and this effectiveness seems to be maintained over one year.

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CLINICAL AND SONOGRAPHIC ASSESSMENT OF THE EFFECTIVENESS OF COLLAGEN INJECTIONS GUNA MDs IN SHOULDER PERIARTHRITIS WITH BURSITIS

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The aim of this study was to evaluate the efficacy of collagen Injections GUNA MDs regarding pain and functioning of the shoulder in patients with periarthritis, subacromial subdeltoid bursitis (SASDB) and duration of symptoms up to 3 months. We studied 20 patients with painful shoulder and sonographic proved SASDB. We applied in the subacromial space a combination of GUNA MD-Shoulder and GUNA MD-Matrix in total course of treatment 8 weeks. Clinical assessment included demographic and clinical data, a visual analog scale (VAS) for pain (0-100), Likert scale, Shoulder Function Assessment (SFA) scale (0-70) and sonographic evaluation of the shoulder at baseline, 60 and 150 days. Evaluation of the efficacy according to the patient and the physician were performed. Results showed significant efficacy on pain which remained after the treatment. There was a statistically significant improvement of SFA index. 80% out of all patients gave a very good and good assessment of the efficacy, which coincided with the opinion of the physician. 80% out of all patients had reduction or lack of bursitis on second and on third visit which was sonographically proved. No adverse events were registered. In conclusion, collagen injections GUNA MDs significantly reduced pain and SASDB edema and increased functional activity of the shoulder, thereby increasing the quality of life.

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PAIN RELIEF AND FUNCTIONAL RECOVERY OVER A SIX-MONTH PERIOD AFTER INTRA-ARTICULAR INJECTION WITH SODIUM HYALURONATE (MW 1500 - 2000 KDA) IN OSTEOARTHRITIS OF THE KNEE

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The present study aimed to evaluate the effects of a single intra-articular injection of a high molecular weight (MW) (1500-2000 kDa) naturally linear hyaluronic acid (HA) in patients suffering from knee osteoarthritis (OA). One hundred and sixty-eight patients with mild to moderate OA of the knee were enrolled to receive one ultrasound-guided intra-articular (IA) injection of 4ml Sodium Hyaluronate (HyalOne®) and were followed up for 24 weeks. The primary efficacy outcome was the change from baseline to week 24 in patients' pain perception using a 100 mm visual analogue scale (VAS). Additional outcomes included the Western Ontario McMaster Universities Arthritis score (WOMAC) and Knee injury and Osteoarthritis Outcome Score (KOOS) assessed at 4, 12 and 24 weeks. The patients enrolled showed a significant improvement from baseline in all symptomatic outcome measures. Pain significantly decreased after treatment. VAS pain decreased from the baseline mean value of 77.7 mm (SD 8.8, range: 60-90) to the mean value of 13.8 mm (SD 4.9, range: 10-20) at week 24. The analysis of variance for repeated measures conducted on VAS, on each WOMAC subscale, on the total WOMAC score and on each KOOS subscale score showed a significant reduction in all scores at each study point (week 4, 12 and 24) ($p< 0.001$). Comparisons between week 4 and week 12 scores and week 12 and week 24 scores showed a significant and progressive improvement ($p< 0.05$, Wilcoxon test) during the study. The present study suggests that a single IA injection of linear high MW HA in patients suffering from knee OA is well tolerated and provides relief from pain. Benefit to knee function was confirmed by both the WOMAC and the KOOS scores. The patients' overall health status also improved as demonstrated by the high scores registered at the post-treatment KOOS Function in daily Living, Quality of Life and Function in Sport and Recreation subscales.

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INTRA-ARTICULAR METHOTREXATE: CLINICAL AND POWER DOPPLER ULTRASONOGRAPHY STUDY IN RHEUMATOID KNEE SYNOVITIS.

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Background: The effects of intra-articular methotrexate (I/A MTX) in knee synovitis in rheumatoid arthritis have been previously evaluated with inconstant results. Ultrasonography (US) has been little studied in I/A MTX. Objectives: To test the efficacy of I/A MTX in rheumatoid arthritis patients with knee synovitis resistant to systemic methotrexate and other disease modifying antirheumatic drugs (DMARDS). Methods: 10 mg of methotrexate was injected every week for 8 weeks intra-articularly in 41 knees in 29 consecutive RA patients with one or both knees arthritis resistant to systemic DMARDS including methotrexate and other joints in clinical remission. Clinical evaluation includes visual analogue scale (VAS) and Global index of knee arthritis (GIKA). Evaluation was done before the 1st injection (W0), before the 6th injection (W5), one week after the last injection (W8), 12 weeks later (W20) and 24 weeks after the last injection (W32). On the same days Power Doppler US was done. Synovial thickness in suprapatellar region was measured. The intra-articular power Doppler signal was graded on a semi quantitative scale from 0 to 3 during the US examination. Results: There was significant reduction in VAS (mean value± SD) between W0 (7.84±1.16) and W8 (1.17± 0.77) p< 0.001, W0 and W20 (2.56 ± 1.02) p< 0.001 and between W0 and W32 (3.16 ±0.72) p< 0.01, GIKA reduced significantly between W0 (8.26 ± 1.2) and W8 (2.58± 0.92) p< 0.001, W0 and W20 (2.53± 1.05) p< 0.001 and between W0 and W32 (2.04± 0.95) p< 0.01. Gray US showed that synovial thickness was reduced significantly between W0 (7.09 ±1.33 mm) and W8 (3.45 ± 0.87 mm) p< 0.001, between W0 and W20 (3.67± 0.80 mm) p< 0.001 and between W0 and W32 (4.01± 0.80) p< 0.01. There was insignificant increase in VAS, KJAI and synovial thickness between (W8 and W20) and between (W8 and W 32). Power Doppler signals reduced significantly between (W0 and W5, W8, W20 and W32) p< 0.001 while between W5 and W8 the significance level was p<0.05. Conclusions: Repeated I/A MTX resulted in a decrease in degree of knee synovitis both clinically and by power Doppler US. While the clinical effects and the decrease in synovial thickness by gray US continue after 6 months, power Doppler signals tends to increase after 6 months. To the best of our knowledge this the first study to detect the effect of I/A MTX by power Doppler US.

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IMPLICATION OF MAST CELLS AND CYTOKINES IN MUSCULAR TISSUE DEMAGE

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Cytokines are important mediators, not only for the communication of immune cells but also for epithelial cells, mesanchymal cells, muscle cells and others. They contribute to pathophysiological events including tissue fibrosis and autoimmune diseases. It is well known that proinflammatory cytokines are mediators of muscle wasting in many diseases, with progressive loss of muscle mass, injured tissues, and fibrosis. Mast cells derive from bone marrow, matured under the influence of various cytokines such as stem cell factor (SCF). Stimulation of mast cells leads to NF-KB and AP-1 and cytokine production. In addition, they generate prostaglandins and leukotrines in the *de novo* synthesis which contribute to the inflammatory process. Mast cells are present in fibrotic tissues and they are implicated in remodeling and inflammation by producing fibrinogenic mediators including histamine, specific protease, tryptase, chymase, cytokines and growth factors. Mast cells act in two different manners, one protective and one reparative. These two systems of action work in harmony, based on a balance of a complex cytokine activity. In this review we report for the first time the implication of mast cells and cytokines in muscular tissue damage.

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