OP0179 (2020)

USEFUL STUDY I: A MULTICENTRE LONGITUDINAL STUDY TO TEST WHETHER ULTRASOUND CAN IDENTIFY PATIENTS WITH MUSCULOSKELETAL SYMPTOMS OF LUPUS WITH BETTER RESPONSE TO THERAPY

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Background: In SLE, musculoskeletal manifestations impact on quality of life and trial outcomes. We previously showed that assessments based on joint swelling lack sensitivity, specificity and responsiveness compared to ultrasound (US).

Objectives: To determine clinical features predicting US synovitis and whether patients with US synovitis respond better to therapy

Methods: SLE patients were recruited if the referring physician deemed they had inflammatory pain warranting treatment. Swollen joints were not required. At baseline, physicians recorded features of inflammation, concurrent fibromyalgia and osteoarthritis. Stable doses of prednisolone (≤5mg/day), antimalarials or immunosuppressants were allowed. Participants received depomedrone 120mg IM then were assessed at 0, 2 and 6 weeks for 66/68 swollen and tender joint counts, BILAG-2004, SLEDAI-2K, physician global and MSK-VAS, inflammatory markers, patient pain and disease activity-VAS, HAQ-DI, LupusQoL, US of hands and wrists (blinded to patient and clinical assessor). An internal pilot determined the primary endpoint:(Early Morning stiffness-VAS (EMS-VAS) at 2 weeks (adjusted for baseline) between patients with US-synovitis (GS≥2 or PD≥1 in ≥1 joint) vs. normal US at baseline. 20% difference was considered clinically meaningful. Sensitivity analyses adjusted for prednisolone and immunosuppressants.

Results: 122/133 patients completed all visits. There was significant disagreement between clinical examination and US. 78/133 had US synovitis; 68% of these had ≥1 swollen joint. Of 66/133 patients with ≥ 1 swollen joint, 20% had normal US. US-synovitis was more likely with joint swelling, a symmetrical small joint distribution and active serology. Physician-determined EMS, other lupus features or prior response to therapy were not associated. Fibromyalgia or osteoarthritis did not reduce the probability of US synovitis.

In the full analysis set (n=133) there was no difference in EMS VAS at 2 weeks according to US synovial status at baseline (difference -8mm, 95% CI -19, 4mm, p=0.178). 32 patients had fibromyalgia. After excluding them, we found a statistically and clinically significantly better clinical response to depomedrone in patients with US-synovitis at baseline (baseline-adjusted EMS VAS at 2 weeks -12mm, 95% CI -24, 0mm, p=0.049). This difference was greater in the treatment-adjusted sensitivity analysis (-12.8 (95% CI -22, -3mm), p=0.007) and the per-protocol-adjusted sensitivity analysis (-14.8mm (95% CI -20.8, -8.8mm), p<0.001). Patient with US synovitis had higher rates of improvement in the MSK BILAG-2004 (56% vs. 26%, p=0.09) and SLEDAI-2K (37% vs. 15%, p=0.03).

Conclusion: In lupus arthritis, distribution and serology, but not other features, help identify US-synovitis. US-synovitis was independent of features of fibromyalgia, but fibromyalgia confounded assessment of clinical response. US should be used to select SLE arthritis patients for therapy and clinical trials, especially when there are inflammatory symptoms without swollen joints.

Acknowledgments: The Project was funded by Lupus-UK

Disclosure of Interests: Khaled Mahmoud: None declared, Ahmed Zayat: None declared, Md Yuzaiful Md Yusof: None declared, Katherine Dutton: None declared, Lee-Suan Teh: None declared, Chee-Seng Yee: None declared, David d'cruz Grant/research support from: GlaxoSmithKline, Nora Ng: None declared, David Isenberg Consultant of: Study Investigator and Consultant to Genentech, Coziana Ciurtin Grant/research support from: Pfizer, Consultant of: Roche, Modern Biosciences, Philip G Conaghan Consultant of: AbbVie, BMS, Eli Lilly, EMD Serono, Flexion Therapeutics, Galapagos, GSK, Novartis, Pfizer, Speakers bureau: AbbVie, Eli Lilly, Novartis, Pfizer, Paul Emery Grant/research support from: AbbVie, Bristol-Myers Squibb, Merck Sharp & Dohme, Pfizer, Roche (all paid to employer), Consultant of: AbbVie (consultant, clinical trials, advisor), Bristol-Myers Squibb (consultant, clinical trials, advisor), Lilly (clinical trials, advisor), Merck Sharp & Dohme (consultant, clinical trials, advisor), Novartis (consultant, clinical trials, advisor), Pfizer (consultant, clinical trials, advisor), Roche (consultant, clinical trials, advisor), Samsung (clinical trials, advisor), Sandoz (clinical trials, advisor), UCB (consultant, clinical trials, advisor), Christopher Edwards Grant/research support from: Abbvie, Biogen, Roche, Consultant of: Abbvie, Samsung, Speakers bureau: Abbvie, BMS, Biogen, Celgene, Fresenius, Gilead, Janssen, Lilly, Mundipharma, Pfizer, MSD, Novartis, Roche, Samsung, Sanofi, UCB, Elizabeth Hensor: None declared, Edward Vital Grant/research support from: AstraZeneca, Roche/Genentech, and Sandoz, Consultant of: AstraZeneca, GSK, Roche/Genentech, and Sandoz, Speakers bureau: Becton Dickinson and GSK

Citation: Ann Rheum Dis, volume 79, supplement 1, year 2020, page 111

Session: Diagnostics and imaging procedures *(Oral Presentations)*