THE ARTHRITIS COMPONENT OF THE SLEDAI SHOULD ONLY BE SCORED IF THERE IS JOINT SWELLING

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Background: SLE disease activity tools do not optimally define disease activity and response. The SLEDAI arthritis item is common, and sufficient to define SRI response. Lupus patients with arthralgia often have no swelling. Glossary definitions of arthritis in different versions of the SLEDAI have included: swelling, swelling between visits, effusion, tenderness, warmth and erythema. MSK ultrasound in SLE can identify synovitis without swelling, ultrasound synovitis is associated with worse symptoms and serology, predicts response to therapy, and is more responsive to therapy than clinical variables.

Objectives: To validate different glossary definitions for SLEDAI arthritis using musculoskeletal ultrasound.

Methods: We analysed baseline data from a multicentre longitudinal study. Physicians scored SLEDAI-2K in 133 patients with joint pain that was considered inflammatory, but not necessarily swelling. Stable immunosuppressants and prednisolone <=5mg were permitted. If the arthritis criterion was scored, we asked physicians to report which glossary features drove their decision. Musculoskeletal ultrasound of hands and wrists was performed on the same day, blinded to clinical findings. We defined abnormal grey-scale in joints as 1 joint with GS>=2, and in tendons as >=1 tendon with GS >=1, and abnormal power Doppler as >=1 joint or tendon with PD >=1.

Results: 78/133 patients had arthritis scored on SLEDAI-2K. In 21/78, swelling was not a reason for that decision. These 21 patients had either tenderness (16/21), swelling reported between visits (4/21) or both of these (1/21). No patient was scored for warmth, erythema or effusion alone. Comparison of SLEDAI definitions and ultrasound is shown in Table 1. Of 57 patients with SLEDAI arthritis scored due to swelling, 90% had an abnormal ultrasound. The positive predictive value was 89% (95% CI 79 – 94). Of 21 patients with SLEDAI arthritis scored without swelling, 48% had an abnormal ultrasound. The positive predictive value was 48% (95% CI 31 – 67). There was no substantive difference in clinical and serological variables comparing patients with SLEDAI arthritis without swelling and patients without SLEDAI arthritis. In contrast, patients with SLEDAI arthritis with swelling had worse ESR (p=0.0003), Physician MSK disease activity VAS (p<0.001) and patient EMS VAS (p=0.0019) and IgG (p=0.0625) compared to the other two groups.

Conclusion: Although ultrasound proven synovitis in the absence of swelling is not uncommon, it is not reliably identified using other signs or symptoms. The arthritis item of the SLEDAI was likely to be associated with ultrasound synovitis if scored because of swelling, but not if scored because of tenderness or swelling between visits. Our results support raising the threshold criteria for arthritis so that it should only be scored when there is joint swelling. Previous clinical trial datasets could be re-analysed excluding SLEDAI arthritis scores not confirmed by a swollen joint count greater than one.
### Ultrasound Abnormalities at Baseline

<table>
<thead>
<tr>
<th></th>
<th>GS joints n/N (%)</th>
<th>PD joints n/N (%)</th>
<th>GS tendons n/N (%)</th>
<th>PD tendons n/N (%)</th>
<th>Any abnormality n/N (%)</th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
<th>PPV % (95% CI)</th>
<th>NPV % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All patients</strong> (n=133)</td>
<td>77/133 (58)</td>
<td>33/133 (25)</td>
<td>36/133 (27)</td>
<td>27/106 (20)</td>
<td>83/133 (62)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>MSK SLEDAI = No</strong> (n=55)</td>
<td>20/55 (36)</td>
<td>2/55 (4)</td>
<td>9/55 (16)</td>
<td>3/55 (6)</td>
<td>22/55 (40)</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td><strong>MSK SLEDAI = Yes</strong> (n=78)</td>
<td>57/78 (73)</td>
<td>31/78 (40)</td>
<td>27/78 (35)</td>
<td>24/78 (31)</td>
<td>61/78 (78)</td>
<td>73 (62, 82)</td>
<td>66 (51, 78)</td>
<td>78 (70, 84)</td>
<td>60 (49, 69)</td>
</tr>
<tr>
<td><strong>- Due to swelling</strong> (n=57)</td>
<td>48/57 (84)</td>
<td>28/57 (49)</td>
<td>21/57 (37)</td>
<td>19/57 (33)</td>
<td>51/57 (90)</td>
<td>61 (50, 71)</td>
<td>88 (75, 95)</td>
<td>89 (79, 94)</td>
<td>57 (50, 64)</td>
</tr>
<tr>
<td><strong>- Without swelling</strong> (n=21)</td>
<td>9/21 (43)</td>
<td>3/21 (14)</td>
<td>6/21 (29)</td>
<td>5/21 (24)</td>
<td>10/21 (48)</td>
<td>31 (16, 50)</td>
<td>75 (60, 87)</td>
<td>48 (31, 67)</td>
<td>60 (45, 68)</td>
</tr>
</tbody>
</table>

**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: None declared, Nora Ng: None declared, David Isenberg: None declared, Coziana Ciurtin: None declared, Philip G Conaghan: None declared, Paul Emery: None declared, Christopher John Edwards Shareholder of: Research grant support from; Abbvie, Biogen, Pfizer, Consultant of: Personal fee from; Abbvie, BMS, Biogen, Celgene, Celltrion, Fresenius, Gilead, GSK, Janssen, Lilly, Mundipharma, Pfizer, MSD, Novartis, Roche, Samsung, Sanofi, UCB, Grant/research support from: Research grant support from; Abbvie, Biogen, Pfizer, Elizabeth Hensor: None declared, Edward Vital: Speakers bureau: AstraZeneca, Genentech, Aurinia, Lilly, Modus, Consultant of: AstraZeneca, Genentech, Aurinia, Lilly, Modus, Grant/research support from: Sandoz, AstraZeneca,

**Citation:** Ann Rheum Dis, volume 80, supplement 1, year 2021, page 625

**Session:** SLE, Sjögren’s and APS - clinical aspects (other than treatment) *(POSTERS only)*