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FRI0478

SUBCHONDRAL BONE SCLEROSIS ON COMPUTED TOMOGRAPHY - DOES IT HAVE ANY VALUE IN THE DIAGNOSIS OF INFLAMMATORY SACROILIITIS OR IS IT A NON-SPECIFIC FINDING?

O. Azmat¹, R.G. Lambert¹, Z. Jibri¹, W.P. Maksymowych². ¹Radiology; ²Medicine, University of Alberta, Edmonton, Canada

Background: Sclerosis in the sacroiliac joints (SIJ) on radiography and computed tomography (CT) is common but widely considered a non-specific finding of sacroillitis due to an association with degeneration and osteitis condensans ilii, despite little formal study. Availability of low dose radiation CT may lead to more widespread use for diagnostic evaluation.

Objectives: We standardized the definition of sclerosis on CT and then aimed to determine whether this lesion could be reliably detected and its diagnostic utility. Methods: 215 CT scans were obtained from patients with a history of low back pain. 107 patients had a clinical diagnosis of spondyloarthritis (SpA) and 108 patients were clinically proven not to have SpA. Groups were age and gender matched (140 males, 75 females, mean age was 45 years). Three musculoskeletal radiologists, blinded to patient demographics and diagnosis, scored the CTs after standardization of lesion definitions and calibration. Erosions, sclerosis, and ankylosis were graded by size and number of articular surfaces/ joints involved. Sclerosis was considered definite if located along the cartilaginous compartment, measured >5mm in all 3 planes, and present >5mm from the joint surface. Discrepant scores were arbitrated and inter-reader reliability calculated by intra-class correlation coefficient (ICC). Diagnostic utility of CT lesions was determined by calculating sensitivity and specificity for the clinical diagnosis and by logistic regression.

Results: ICC for sclerosis and erosion for each articular surface ranged from 0.65-0.76 and 0.71-0.78, respectively. ICC for ankylosis was 0.87-0.89. Sclerosis occurred in 87 (81%) cases with SpA and 25 (23%) controls. For a single articular surface the specificity for sacroiliitis ranged between 88-94%, for any two articular surfaces 95-100%, for all 4 articular surfaces 100%. Sensitivity ranged from 14% (4 articular surfaces) to 55% (either ilium). Erosion and ankylosis had a similar specificity range of 91-100% and 92-93%. The odds ratio was 4.9 for presence of definite sclerosis, and 12.6 for bilateral joint involvement. The odds ratio increased to 84.2 for bilateral erosion and 22.8 for bilateral ankylosis.

Conclusions: When sclerosis measures >5mm in three planes and is located >5mm from a joint perimeter, it has high specificity for sacroillitis, regardless of how many articular surfaces are involved, with similar specificity to erosion and ankylosis

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FRI0479 PREDICTORS OF LONG-TERM MODIFIED MINIMAL DISEASE ACTIVITY RESPONSE IN PERIPHERAL SPONDYLOARTHRITIS PATIENTS TREATED WITH ADALIMUMAB

<u>L.C. Coates</u> ¹, S. Abraham ², W. Tillett ³, P.J. Mease ⁴, S. Ramiro ⁵, T. Wu ⁶, X. Wang ⁶, A.L. Pangan ⁶, I.-H. Song ⁶. ¹ University of Leeds and Leeds Teaching Hospitals NHS Trust, Leeds; 2NIHR/Wellcome CRF, Imperial College Healthcare NHS Trust, London; 3 Royal National Hospital for Rheumatic Diseases and University of Bath, Bath, United Kingdom; ⁴Swedish Medical Center and University of Washington, Seattle, United States; ⁵Leiden University Medical Center, Leiden, Netherlands; 6 AbbVie Inc., N Chicago, United States

Background: There is a lack of validated outcome measures in non-psoriatic peripheral spondyloarthritis (pSpA). Therefore, a modified version of the minimal disease activity (mMDA)1 was developed and validated. Identification of factors that predict long-term mMDA response in pSpA patients (pts) can facilitate decisions regarding treatment initiation and maintenance.

Objectives: The purpose of this analysis was to determine predictors of long-term mMDA response following adalimumab (ADA) treatment in pSpA pts from the ABILITY-2 study.

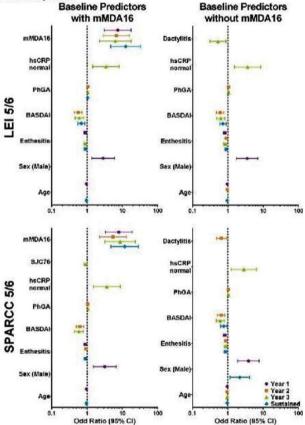
 $\textbf{Methods:} \ \textbf{ABILITY-2}^2 \ was \ a \ phase \ 3 \ randomized, \ double-blind \ trial \ evaluating \ the$ efficacy and safety of 40 mg ADA every other week versus placebo (PBO) over 12 weeks (wks) followed by open-label (OL) ADA for 144 wks in pts with pSpA. This post-hoc analysis included pts who received at least one dose of ADA during the PBO-controlled period or OL extension. The mMDA for pSpA was defined as achieving at least 5 out of the following 6 criteria: 1) TJC78 $\leq\!1;$ 2) SJC76 \leq 1; 3) pt pain visual analog scale (VAS) \leq 15 of 100 mm; 4) pt global activity

(PtGA) VAS <20 of 100 mm; 5) HAQ-DI <0.5; and 6) tender entheseal points 1 (Leeds Enthesitis Index [LEI] or Spondyloarthritis Research Consortium of Canada [SPARCC] Enthesitis Index). In this post hoc analysis, multiple logistic regression with stepwise variable selection was used to determine predictors of long-term (vrs 1-3) and sustained (defined as mMDA for at least 24 consecutive wks) mMDA responses. Variable selection of baseline (BL) pt demographics and disease characteristics were performed with and without mMDA response at wk 16 (mMDA16) as a candidate. In pts achieving mMDA at wk 16, ADA exposure ranged between 4 and 16 wks.

Results: In pSpA pts treated with ADA, mMDA (5/6 LEI or SPARCC) was achieved by almost 41%, 49%, and 50% of pts at vrs 1, 2, and 3, respectively and sustained mMDA response was achieved by 42% of pts. Regardless of mMDA definition, achieving mMDA response at wk 16 (up to 16 wks of ADA) was a robust positive predictor of attaining both long-term mMDA at yrs 1-3 and sustained mMDA (Figure). In the model examining the BL predictors (model without mMDA16), age, BL enthesitis and BL BASDAI scores were most commonly selected as negative predictors for achieving long-term and sustained mMDA. Other selected predictors included BL dactylitis, physician's global assessment, hsCRP, and male sex; however, these predictors were not consistently selected for all time points or sustained mMDA.

Conclusions: Early mMDA response is a stronger and more consistent predictor of long-term mMDA, whether at 1, 2, or 3 yrs or sustained over time, than BL

Figure Odds Ratio for Predictors of Long-term (years 1-3) and Sustained mMDA responses



Only variables selected by stepwise selection model are shown (model selected variables are

significant at P<.05)
mMDA16 = modified minimal disease activity response at week 16; LEI = Leeds enthesitis index; SPARCC = Spondyloarthrills Research Consortium of Canada enthesitis index; hocRP = high sensitivity C-reactive protein; PhGA = physician's global assessment of disease activity; BASDAI = Bath ankylosing spondylitis disease activity index; SJC76 = swollen joint count (76 ioints): CI = confidence interval

Abstract FRI0478 - Table 1

Single articular surface Any 2 articular surfaces All 4 articular surfaces Erosion of articular surface (s) involved Single articular surface

Sclerosis of articular surface (s) involved

Any 2 articular surfaces All 4 articular surfaces Ankylosis of articular surface (s) involved Single joint Both joints

Specificity (95% CI) Either ilium: 87% (82-91) - 91% (87-95) Either sacrum: 93% (89-96) - 94% (90 - 97) 96% (94–99) – 99% (98–100) 99% (8-100) Specificity (95% CI) Either ilium: 90% (85-94) Either sacrum: 94% (91-98) 96% (93–99) – 100% (100–100) 100% (100-100) Specificity (95% CI) 92% (88 - 95)

93% (89 - 96)

Sensitivity (95% CI) Either ilium: 46% (39-52) - 51% (44-58) Either sacrum: 19% (14–25) - 21% (16–26) 10% (6–14) - 41% (35–48) 14% (9 - 19) Sensitivity (95% CI) Either ilium: 77% (71-83) Either sacrum: 65% (58–72) 24% (18–31) – 67% (60–74) 38.1% (31-45) Sensitivity (95% CI) 60% (53-66) 58% (51-64)