

to APR30 or APR20 at Week 16 (early escape) or Week 24. Double-blind APR treatment continued to Week 52; patients could continue APR during an open-label, long-term treatment phase for up to 5 years treatment. Visits in years 2, 3, and 4 were scheduled at 13-week intervals. Safety was assessed at each visit throughout the study, and results are summarized here by exposure.

Results: A total of 1493 patients were randomized and received ≥ 1 dose of study medication (PBO: n=495; APR30: n=497; APR20: n=501). At the 4-year data cut, the numbers of patients receiving APR30 and APR20 in each exposure period were 1441 in Weeks 0 to ≤ 52 , 1028 in Weeks >52 to ≤ 104 , 865 in Weeks >104 to ≤ 156 , and 767 in Weeks >156 to ≤ 208 . During the 0- to ≤ 52 -week APR-exposure period, adverse events (AEs) occurring in $\geq 5\%$ of APR30-exposed patients were diarrhea, nausea, headache, upper respiratory tract infection, and nasopharyngitis (Table). Most diarrhea and nausea AEs were reported within the first 2 weeks of treatment and usually resolved within 4 weeks; the frequency of gastrointestinal AEs decreased with longer APR30 exposure, and the frequency of other common AEs either decreased or remained stable with prolonged exposure (Table). Most AEs were mild/moderate in severity. During Weeks >156 to ≤ 208 of APR exposure, the discontinuation rate due to AEs was 1.7% with APR30, and the rate of serious AEs (SAEs) was 7.0%, consistent with earlier periods; most SAEs occurred in 1 patient each. Rates were very low for major cardiac events, malignant neoplasms, and serious opportunistic infections, comparable to the first year of treatment. Rates of depression remained very low in Weeks >156 to ≤ 208 . Marked laboratory abnormalities were infrequent, and most returned to baseline with continued treatment.

Conclusions: APR30 demonstrated a favorable safety profile and was well tolerated for up to 208 weeks, marked by the lack of accumulation of immunosuppression or need for specific laboratory monitoring. The incidence of AEs remained stable or decreased with long-term exposure to APR30.

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AB0786 SYSTEMATIC REVIEW OF MEASUREMENT PROPERTIES OF PATIENT REPORTED OUTCOME MEASURES IN PSORIATIC ARTHRITIS: A GRAPPA-OMERACT INITIATIVE

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Background: An updated psoriatic arthritis (PsA) core domain set (COS) for randomized controlled trials (RCTs) was endorsed at the Outcome Measures in Rheumatology (OMERACT) meeting in 2016 and reflects the patient and physician perspectives.[1]

Objectives: To synthesise the evidence on measurement properties of Patient Reported Outcome Measures (PROMs) in PsA in order to contribute to the development of a PsA core outcome measurement set (COMS) for RCTs adhering to the OMERACT filter 2.0 Framework.[2]

Methods: A systematic literature search was performed in EMBASE, MEDLINE and PsycINFO to identify studies published in English on PROM measurement properties in PsA. Two independent reviewers rated the quality of studies according to Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines.[3] extracted data on measurement properties and performed a qualitative evidence synthesis.

Results: Of 4703 identified references, 162 were read in full-text and 44 included in the systematic review (SR). Thirty-nine instruments, consisting of one or more scales, were analysed. PROMs measuring core set domains with at

least fair quality evidence for good validity and reliability (and without evidence for inadequate measurement properties) were: Stockerau Activity Score for PsA (German) for the *Musculoskeletal Disease Activity* domain; the Psoriatic Symptom Inventory for *Skin Disease Activity*; the 36-Item Short Form Health Survey Physical Function scale and to a lesser extent the Health Assessment Questionnaire Disability Index and Bath Ankylosing Spondylitis Functional Index for *Physical Function*; the Psoriatic Arthritis Quality of Life Questionnaire, the Psoriatic Arthritis Impact of Disease questionnaire and VITACORA-19 (Spanish) for *Health related Quality of Life/Life Impact*; the Functional Assessment of Chronic Illness Therapy-Fatigue Scale for *Fatigue*, and the Social Role Participation Questionnaire for *Participation*. Evidence for content validity was lacking for most of these PROMs.

Conclusions: At least one PROM with some evidence for good validity and reliability was available for five out of eight inner circle domains of the PsA COS. Lack of content validity evidence constitutes a critical barrier for application to the PsA COS per the OMERACT Filter 2.0 Instrument Selection Algorithm [2]. This SR serves as a guide for additional research to increase knowledge of PROM measurement properties in PsA followed by stakeholder consensus for developing a PsA COMS.

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AB0787 STUDY OF SERUM SCLEROSTIN LEVELS IN ASSOCIATION TO ENTESIAL ULTRASONOGRAPHY IN EGYPTIAN PSORIATIC ARTHRITIS PATIENTS

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Background: Psoriatic arthritis (PsA) is characterized by focal bone erosions and new bone formation, suggesting an uncoupling of osteoblast-osteoclast homeostasis [1]. Serum sclerostin is a protein inhibitor of wnt signaling pathway of bone formation implicated in the suppression of bone repair in inflammatory arthritis. The role of sclerostin in osteoimmunology and inflammatory arthritides is still controversial [2].

Objectives: This study aimed at measuring serum sclerostin in psoriatic arthritis men and to correlate its levels with disease activity scores, ultrasonographic findings and bone mineral density in those patients

Methods: This study included 30 male patients diagnosed with Psoriatic arthritis (PsA), 15 healthy age and sex matched volunteers as control group. Patients disease activity index measured. Clinical assessment by Leeds enthesitis Index (LEI) [3]. Spinal manifestations scored according to Bath Ankylosing Spondylitis Activity Index [4]. Serum sclerostin measured using enzyme linked immunosorbent assay. Ultrasonography of enthesitis at Leeds enthesitis sites [5] and dual energy x-ray absorbiometry (DEXA) at the lumbar spine.

Results: The study included 30 PsA male patients with a mean age of 43.33±8.33 mean, body mass index (BMI) of 26.87±2.63 and 15 healthy age and sex matched

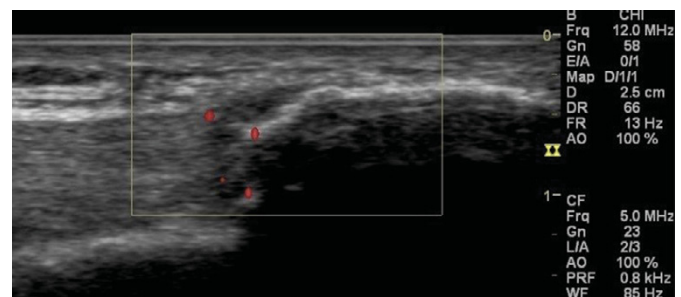


Figure 1. Ultrasonographic longitudinal scan of the tendoachillis showing hypoechoic area of edema & power Doppler signal at insertion.