AB0741 PSORIATIC ARTHRITIS QUALITY OF LIFE QUESTIONNAIRE: TRANSLATION, CULTURAL ADAPTATION AND VALIDATION INTO PORTUGUESE LANGUAGE

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Background: Psoriatic Arthritis (PsA) has a strong negative impact in the quality of life of patients, through pain, stiffness, functional disability, deformity and a variety of other dimensions. The Psoriatic Arthritis Quality of Life (PsAQoL) questionnaire is a disease-specific instrument developed to measure quality of life in patients with PsA.

Objectives: The aims of this study were to culturally adapt the questionnaire for Portugal, and evaluate its reliability and validity in patients with PsA.

Methods: The original UK English version of PsAQoL was translated into Portuguese by a bilingual translation panel. An independent lay panel reviewed the instrument's item phrasing to ensure appropriateness in colloquial European Portuguese. Structured cognitive debriefing interviews were conducted with ten PsA patients to assess the acceptability, the understanding and the redundancy or ambiguity of the questionnaire. The Portuguese PsAQoL was subsequently applied to PsA patients followed at the Rheumatology Department of Centro Hospitalar do Baixo Vouga, E.P.E. To assess reproducibility, thirty patients with PsA completed the Portuguese PsAQoL on two occasions, two weeks apart. A larger sample was recruited to determine internal consistency and construct validity. Descriptive statistical analysis was used to characterize the data. The Nottingham Health Profile (NHP) was used as a comparator instrument.

Results: Translation and adaptation were successful. The validation sample included 104 patients, 67% of whom were men. Their median age was 50.2 (SD=12.1) years and most were married. Cronbach's alpha for the Portuguese version of the PsAQoL was 0.91 and the test-retest reliability was 0.92, indicating that the measure has good internal consistency and produces low random measurement error. The PsAQoL could distinguish between groups of patients defined by self-reported general health status, self-reported severity of PsA and flare of arthritis. Duration of arthritis did not influence PsAQoL scores. There was a positive correlation between the total score of APsQoL and each of the dimensions of the NHP.

Conclusions: The Portuguese version on the PsAQoL was found to be relevant, understandable and easy to complete, reliable and valid. It should be considered for use in clinical practice and research settings to asses PsA-specific QoL.

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AB0742 ULTRASONOGRAPHY OF THE NAIL UNIT IN PSORIASIS AND PSORIATIC ARTHRITIS: A QUALITATIVE AND QUANTITATIVE ANALYSIS

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Background: the nail unit is a shared topic of interest both for dermatologist and rheumatologist [1]. It is easy to study using imaging techniques such as ultrasonography. The nail was considered one of the possible target of assessment for the disease, especially when ultrasonography is performed. Ultrasound imaging of nails is a quite new technique, available since high frequencies probes were introduced in musculoskeletal examination and nail was considered one of the possible target for assessing the disease and defining its prognosis [2,3].

Objectives: to evaluate the presence of the nail involvement and subclinical alterations using ultrasonography in psoriasis and psoriatic arthritis.

Methods: the study sample included 82 patients affected by psoriasis and/or psoriatic arthritis and 50 healthy controls (HC). The patients were consecutively enrolled during their routine visit in the outpatient clinic and they performed clinical and ultrasonographic evaluation of the nail. Activity indexes (DAPSA, PASI, NAPSI) and other clinimetric parameters were considered.

Results: multivariate analysis of variance (mANOVA) was performed between groups and the nail plate and nail bed thickness, PASI, NAPSI, age and BMI were considered (table 1). Post hoc analysis underlined the differences between groups, in particular between healthy and affected. The lesions for nail plate and nail bed in the PASI score were analyzed using Pearson's chi square test and, secondary, odd ratios for significant results were calculated. Nail plate thickness and nail bed thickness were correlated with PASI, NAPSI, BMI and DAPSA. ROC curves were calculated obtaining also quantitative cut offs for nail plate and nail bed thickness in the affected vs healthy ones.

Table 1. patient groups and ANOVA results

	HC N=50 (M/F 22/28)	PSOs N=31 (M/F 22/9)	PsAs) N=51 (M/F 26/25)
	Mean ± SD	Mean ± SD	Mean ± SD
Eta	48.44±13.95	48.22±14.7	50.92±13.9
BMI	24.61±3.92	28.61±4.95*	28.64±5.84*
Thickness NAIL PLATE	0.051±0.006	0.063±0.011*	0.065±0.014+
Thickness NAIL BED	0.22±0.02	0.25±0.05*	0.25±0.04*

Conclusions: the application of ultrasonography is of potential advantages supported by the data of this study and strengthens the information available in literature, also adding quantitative parameters for the ultrasonography of the nail.

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AB0743 LOW RATES OF MAJOR ADVERSE CARDIAC EVENTS, MALIGNANCIES, AND SERIOUS INFECTIONS IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS TREATED WITH APREMILAST FOR ≥156 WEEKS: POOLED ANALYSIS FROM THE ESTEEM AND PALACE 1-3 PHASE 3 TRIALS

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Background: Apremilast (APR), an oral PDE4 inhibitor, was effective in phase 3, randomized, placebo (PBO)-controlled trials assessing treatment of moderate to severe plaque psoriasis (ESTEEM 1 and 2) and psoriatic arthritis (PsA; PALACE 1–3).

Objectives: We report incidence of MACE, malignancies, and serious infections (SIs; opportunistic and non-opportunistic) in pts receiving APR 30 mg BID (APR30) for ≥156 wks in a pooled analysis of these studies.

Methods: Incidence rates and exposure-adjusted incidence rates (EAIR)/100 pt-yrs of MACE, malignancies, SIs, and serious opportunistic infections (SOIs) are reported for 0 to 16 wks, 0 to ≤52 wks, and the APR-exposure period (0 to ≥156 wks) for pts receiving APR30 any time during the studies, through February 2015; ~30% (n=575) of pts received >3 yrs (>156 wks) of APR exposure.

Results: 2,242 pts were included in the safety analysis for 0 to 16 wks (PBO n=913, pt-yrs exposure [py]=260.2; APR30 n=1,329, py=377.8); 1,905 pts received APR30 during the APR-exposure period, representing 3,527.5 py; exposure during 0 to ≤52 wks was 1,524.5 py. At baseline 64.2% of PsA pts (PALACE 1–3) in the APR30 group were receiving concomitant DMARDs (including methotrexate). Incidence of MACE with APR30 was low and comparable to PBO during 0 to 16 wks. During 0 to ≤52 wks and the APR-exposure period, incidence of MACE (EAIR/100 pt-yrs) remained low (Table). Incidence rates (EAIR/100 pt-yrs) of hematologic malignancies, non-melanoma skin cancers, and solid tumors were similar with PBO (0.0, 1.2, 0.4) and APR30 (0.0, 1.3, 0.3) during 0 to 16 wks; incidence rates remained low during 0 to ≤52 wks and the APR-exposure period (Table). During 0 to 16 wks, the overall rate of infections (serious and non-serious) was low and comparable between pts receiving PBO (20.6%) and APR30 (24.8%). The overall rate of infections (serious and non-serious) was 42% during 0 to ≤52 wks and comparable to rates during the PBO-controlled period (0 to 16 wks); the majority of reported infections (URTI, nasopharyngitis, sinusitis) were not serious. During the PBO-controlled period (0 to 16 wks), rates of SIs with APR30 were low and comparable to PBO; no SOIs were reported. During 0 to ≤52 wks, the overall rate of SIs was low (0.6%; EAIR/100 pt-yrs: 0.7). The rate of SIs remained low (1.8%; EAIR/100 pt-yrs: 1.0) during the long-term cumulative APR-exposure period (0 to ≥156 wks) (Table). No clustering of any particular event was noted with respect to SIs; most events occurred in only 1 pt. No clinical reactivation of tuberculosis was reported with long-term APR30 exposure (0 to ≥156 wks). The rate of marked hematologic abnormalities remained low with long-term APR exposure.