

Unmet needs in outcome measures of Psoriatic Arthritis: focus on axial radiographic and nail involvement

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Abstract. *Objectives:* This article reviews some unmet needs on the outcome measures in Psoriatic Arthritis (PsA). In particular, the radiological assessment of axial PsA and the assessment of nail involvement still remain problematic and this, in turn, could affect the best management. At present, the radiological assessment of spine has been evaluated by using scoring systems borrowed from Ankylosing Spondylitis (AS). In particular, the Bath Ankylosing Spondylitis Radiology Index (BASRI) and the modified Stoke Ankylosing Spondylitis Spine Score (m-SASSS) have been validated for the axial PsA and a new index for assessing the radiological axial involvement in PsA was also developed, called Psoriatic Arthritis Spondylitis Radiology Index (PASRI). Nail involvement has been evaluated by two different instruments: the Nail Psoriasis Severity Index (NAPSI) and its modified version (mNAPSI). Both are good instruments but only a few data are available on these instruments when adopted at a daily clinical practice level. (www.actabiomedica.it)

Key words: Psoriatic Arthritis, axial involvement, radiographic scoring methods, BASRI, m-SASSS, PASRI, NAPSI, mNAPSI.

Introduction

Psoriatic Arthritis (PsA) is a chronic inflammatory disease characterized by cutaneous (skin and nails) and articular/periarticular involvement (peripheral arthritis, enthesitis, dactylitis and spondylitis) (1). In the context of this multifaceted disease specific recommendations were made (2, 3) and during the OMERACT 8 a survey on outcome measures was carried out by GRAPPA (4). In particular, outcome measures of axial involvement for patients with PsA and nail involvement for patients with psoriasis seems to be the most relevant unmet needs since the definition and measurement of axial disease (5) and the role of objective measurements of nail psoriasis still remain problematic (6).

The present review was aimed to summarize the most recent studies on these two important domains in the context of the outcome measures of PsA.

A. The radiological Assessment of axial PsA

The combination of destructive changes with bone proliferation is the radiographic hallmark of PsA (7) and PsA patients with radiological axial changes and peripheral arthritic involvement may have more frequent and more severe joint lesions (8). Moreover, severity of radiological damage of peripheral and axial joints was most closely correlated with the scales of physical function (9).

Throughout the years, axial PsA has been defined in many ways, varying from an isolated unilateral grade 2 sacroiliitis to those criteria used for Ankylosing Spondylitis (AS) (10). Therefore the prevalence of axial PsA, depending on the criteria used, is very broad ranging from 25% (early disease and based only on clinical assessment) to 75% (late disease and sophisticated imaging). Axial PsA is usually less severe than that of AS and dissimilar in many respects (10).

Some radiographic features of axial PsA, such as asymmetrical sacroiliitis, non-marginal and asymmetrical syndesmophytes, paravertebral ossification, frequent involvement of cervical spine have been reported and they seem to be so characteristic as to be potentially helpful in diagnosing PsA and differentiating this condition from some cases of psoriasis with co-incident AS (11, 12). In fact, the non typical radiological pattern of axial PsA, compared to that classic observed in AS patients, was first described by McEwen (11) and later by Helliwell et al (12), where the two studies showed a radiological picture with some peculiarities. Indeed, for instance, the sacroiliac joint involvement was not so frequent and, mainly, was found as asymmetrical in axial PsA compared to AS. Other radiological finding distinguishing axial PsA to AS is the type of syndesmophytes. In fact, since the studies by McEwen (11) and later by Helliwell et al (12), non-marginal and asymmetrical syndesmophytes were found in patients with axial PsA, with a so called “chunky” shape, meaning a substantial structural difference to those “coarse” marginal and symmetrical ones observed in the classic AS. The radiological patterns of axial PsA, qualitatively might be completely different to that observed in AS patients. Even the distribution along the spine is not like AS, in which a progression of syndesmophytes from lumbar towards cervical is the rule, while a more random distribution is the most frequent finding in axial PsA. Indeed, sometimes the type of syndesmophytes occurring in axial PsA patients could be so “atypical” to be quite difficult in distinguishing from those occurring in AS, as well as those occurring in patients with osteoarthritis. With regards to this aspect, Baraliakos et al proposed a way to differentiate the main two radiological findings, namely syndesmophytes and spondylophytes, by using a 45° angle cut off on lateral views (13). In fact, the syndesmophytes grow in an angle of <45° to the vertebral edge, while spondylophytes grow in angle of >45° to the vertebral edge (13). This is a possible way to, approximately, split the inflammatory radiological findings from those truly degenerative, at spinal level.

An increasing interest in the assessment and definition of the axial PsA with a particular attention to the radiological evaluation has been found in the last

5 years. However, the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) carried out during OMERACT 8 a survey on outcome measures. In particular, the role of spinal involvement was dealt in patients with psoriasis and PsA, and it was deemed a common and important problem (4). Therefore, the assessment of spine was considered as recommended but not mandatory for Randomized Controlled Trials (RCT) or for Longitudinal Observational Study (LOS); it was allocated in the so called “outer core” (14). This was the result of breakout groups and based on the paucity of validated instruments for some of the domains (14). Research agenda of GRAPPA considered the development of instruments tailored for PsA or, alternatively, the validation of previous ones already developed for other diseases, such as AS.

With regards to the radiological assessment, no specific instruments to assess the axial PsA were developed and validated. The idea was to obtain instruments to provide information on disease evolution and outcome either at level of individual patient or clinical trials. The main instruments to assess the axial radiological involvement were initially considered those validated for AS: the Bath Ankylosing Spondylitis Radiology Index (BASRI) (15), the modified Stoke Ankylosing Spondylitis Spine Score (m-SASSS) (16). These instruments were then validated for the axial PsA, showing that they are valid instruments but both scores did not encompass any radiological features of PsA (17). A new index called PASRI (Psoriatic Arthritis Spondylitis Radiology Index) was later developed, tailored for the axial PsA (18) (table 1).

The validation study of BASRI and mSASSS confirmed some previous data (17). For instance, an axial involvement at the cervical and lumbar spine without sacroiliac involvement was observed in 7/71 patients by BASRI (9.8%) and in 3/70 by m-SASSS (4.28%) (17), and this confirmed some previous results (11, 12). This aspect, in turn, could suggest a different pathophysiology of PsA compared to AS, supporting the concept that among the seronegative spondyloarthritis some identities should be considered separately but under the same umbrella.

Another aspect, very common to observe in clin-

Table 1. Characteristics of the radiological scores used for axial PsA

	Bath Ankylosing Spondylitis Radiology Index (BASRI)-spine	Modified Stoke Ankylosing Spondylitis Spine Score (m-SASSS)	Psoriatic arthritis spondylitis radiology index (PASRI)
Sacroiliac joint	New York grading (2-4) of SI joint disease 2 = minimal disease, 3 = moderate disease 4 = severe disease	New York grading (0-4) of SI joint disease 0 = no disease, 1 = suspicious for disease, 2 = minimal disease, 3 = moderate disease 4 = severe disease	New York grading (0-4) of SI joint disease 0 = no disease, 1 = suspicious for disease, 2 = minimal disease, 3 = moderate disease 4 = severe disease score each sacroiliac joint individually and sum the score
	Score: range 2-4	• Total score: range 0-4	score range: 0-8
Lumbar spine	Antero-Posterior and lateral views (score the lower border of T12 to the upper border of S1) the view with the highest score is taken 0= normal (no change) 1=suspicious (focal joint space narrowing) 2= mild (any number of erosions, squaring, or sclerosis, with or without syndesmophytes, on ≤ 2 vertebrae) 3= moderate (syndesmophytes on ≥ 3 vertebrae, with or without fusion involving 2 vertebrae) 4= severe (fusion involving ≥ 3 vertebrae)	Lateral view: the anterior site (score from the lower border of T12 to the upper border of S1) 0 normal, 1 erosion, sclerosis, squaring; 2 syndesmophyte non-bridging; 3 bridging syndesmophyte)	Antero-Posterior and lateral views (score from the lower border of T12 to the upper border of S1) 0 normal, 1 erosion, sclerosis, squaring; 2 syndesmophyte non-bridging; 3 bridging syndesmophyte)
	score range 0-4	score range 0-36	score range 0-36
Cervical spine	Lateral view (score the lower border of C2 to the upper border of C7) 0= normal (no change) 1=suspicious (focal joint space narrowing) 2= mild (any number of erosions, squaring, or sclerosis, with or without syndesmophytes, on ≤ 2 vertebrae) 3= moderate (syndesmophytes on ≥ 3 vertebrae, with or without fusion involving 2 vertebrae) 4= severe (fusion involving ≥ 3 vertebrae)	Lateral view: the anterior site (score from the lower border of C2 to the upper border of T1) 0 normal, 1 erosion, sclerosis, squaring; 2 syndesmophyte non-bridging; 3 bridging syndesmophyte	Lateral views (score from the lower border of C2 to the upper border of C6) 0 normal, 1 erosion, sclerosis, squaring; 2 syndesmophyte non-bridging; 3 bridging syndesmophyte add 1 point for every level fused posteriorly (C2/C3, C3/C4, C4/C5, C5/C6)
	score range 0-4	score range 0-36	score range 0-28
Total score	• Range: 2-12	• Range: 0-72	• Range: 0-72

ical practice, is the frequent involvement of the zygo-apophyseal joints, with a tendency in some patients to be the only anatomical area of the vertebra to be involved. The radiological scoring systems developed and validated for AS do not take into account the posterior elements of the spine. In our study, for instance, 22/77 patients (28%) showed a fusion of the zygo-apophyseal joints at the cervical spine and this radiological finding was not considered by BASRI and m-SASSS (17). In fact BASRI, per se, only contemplates any fusion (posteriorly or anteriorly) of the spine which, in turn, allows the reader to identify the severity of the radiological progression without specifying the anatomical site.

All these intriguing and, to some extent, contradictory aspects could drive the researcher to arise at least two main questions: a) what PsA patient should be evaluated, radiologically, for axial involvement?; b) how should the evaluation be performed?. To address the first question, few studies were carried out. In a study we evaluated PsA patients with established disease and axial disease. Inclusion criteria were the presence of clinical spinal involvement (inflammatory back pain according to Calin criteria) and/or radiological axial involvement (17). More recently, Chandran et al evaluated PsA patients with grade 2 sacroiliitis or greater, inflammatory back pain and/or restricted spinal mobility (19). In both studies the inclusion criteria were associated with the presence of symptoms, functional impairment and structural damage at spinal joints, meaning an established stage of the natural course of the disease and, in turn, meaning that an early stage or even on occult stage of the disease (20) is quite difficult to identify with the present radiological scoring systems instruments.

To address the second point, different approaches were carried out. In our study, we evaluated the X-rays of PsA patients by using the BASRI and m-SASSS, trying to validate these two instruments for the axial PsA (17). The study showed, in a group of 77 patients with established disease and an axial involvement, that the two radiological scores were found to be valid and feasible instruments. Both instruments were easy to use and took little time to complete, both had good test-retest reliability and both showed modest but significant correlations with anthropometric

measures of spinal involvement in this disease. Noteworthy, our results have been obtained from real clinical practice. However, in terms of weakness of these two scores in detecting radiologically the axial PsA, we found that BASRI assumes at least grade 2 sacroiliitis and in many axial PsA patients a spinal involvement without a sacroiliac joint involvement is possible. Again, m-SASSS, is characterized by frequently missing data and it takes longer to be performed, being not very practical in daily clinical practice. Finally, both BASRI and m-SASSS do not take into account in their scores the zygo-apophyseal joints. In other words, both scores do not encompass some radiological features of axial PsA. Therefore the attempt to design a radiological score tailored for axial PsA was made and a new index called PASRI (Psoriatic Arthritis Spondylitis Radiology Index) was developed in a group of 73 patients with established PsA and axial involvement (18). The new index showed to be capable of encompassing a greater range of the spinal radiological features of PsA, to be a valid instrument with a good correlation with anthropometric measures and patient reported outcome measures. Finally, the PASRI had the advantage over the existing instruments (i.e. BASRI and m-SASSS) for the capacity in detecting the posterior axial involvement (18). Following these studies, other groups reported some results on the radiological involvement of axial PsA. In particular, Chandran et al (19) tried to assess the sensitivity to change of radiographic scoring instruments in axial PsA. The study was designed to test BASRI spine, m-SASSS, another score called Radiographic Ankylosing Spondylitis Spinal Score (RASSS) and PASRI, in a group of PsA patients with axial involvement, defined as grade 2 sacroiliitis or greater, inflammatory back pain, and/or restricted spinal mobility). The X-rays, 2 time points (at least 2 years apart) were read by 3 rheumatologists, and the assessment by an independent readers represented the true change (gold standard). The main results showed that the 3 scoring instruments had a moderate sensitivity to change but with high specificity to detect the true changes. All measures performed equally well in detecting change (19).

Finally, the GRAPPA group recently summarized some of these studies in a report, giving also an

overview of the recent studies on PsA developed in Italy (21).

B. The assessment of nail in PsA

During the OMERACT 8 a survey on outcome measures was carried out by GRAPPA. In particular, the role of nail involvement was dealt by patients with psoriasis and PsA, and it was deemed as a common and important problem (4).

Nail lesions are very common and help distinguish between patients who have PsA and those who have rheumatoid arthritis (22). Nail lesions occur in about 40–45% of patients with psoriasis uncomplicated by arthritis and about 87% of patients with PsA (23). The Nail Psoriasis Severity Index (NAPSI) is a numeric, reproducible, objective, simple scale for evaluation of nail bed psoriasis and nail matrix psoriasis. According to Rich and colleagues (24), the nail was divided by imaginary horizontal and longitudinal lines into quadrants. Each nail was given a score for nail bed psoriasis (0–4) and nail matrix psoriasis (0–4) depending on the presence of any of the features of nail psoriasis in that quadrant. In each quadrant of the nail, nail matrix psoriasis was evaluated by the presence of any of the nail matrix features (pitting, leukonychia, red spots in the lunula, crumbling): 0 for none, 1 if present in 1 quadrant of the nail, 2 if present in 2 quadrants of the nail, 3 if present in 3 quadrants of the nail, and 4 if present in 4 quadrants of the nail. Nail bed psoriasis was evaluated by the presence of any of the nail bed features (onycholysis, splinter hemorrhages, subungual hyperkeratosis, “oil drop” (salmon patch dyschroma): 0 for none, 1 for 1 quadrant only, 2 for 2 quadrants, 3 for 3 quadrants, and 4 for 4 quadrants. 3. Each nail is given a matrix score and a nail bed score, the total of which is the score for that nail (0–8).

The NAPSI was useful during clinical trials for evaluating response to treatment of psoriatic nails (24). Cassell and colleagues validated a modified version of NAPSI (mNAPSI), also showing that the modified instrument had good correlation with both physicians and patients global assessment, enhancing the face validity and feasibility of this tool. Indeed, mNAPSI has been found to be more sensitive than NAPSI and ideal for clinical trials (25).

In 2009, a study was aimed to determine whether assessment of the skin and joints in patients with PsA by rheumatologists and dermatologists was reproducible. An excellent agreement was obtained (ICC >0.80) among expert dermatologists and rheumatologists on the mNAPSI, whereas the agreement for other parameters was moderate or fair (26).

Although mNAPSI showed excellent inter-rater reliability (25), it has not been determined whether the assessments of NAPSI or mNAPSI is reliable in real life by rheumatologists that are not involved in clinical trials. Nevertheless the NAPSI was found easy to use in daily clinical practice, in dermatological settings (24).

Recently an open 24-week, prospective cohort study in adult psoriatic patient measured the efficacy of three TNF- α antagonist by means of the NAPSI score (27).

On the other hand no studies were carried out in assessing the reliability of NAPSI in rheumatology settings. Therefore, a study on a rheumatologist assessment of nail disease activity in PsA patients was designed and its purpose was to determine the agreement and reliability of NAPSI in the assessment of nail involvement in patients with PsA when performed by rheumatologists without any experience with this instrument (6). The result obtained showed that one-third of non trained-rheumatologists for NAPSI agreed with the score of the expert rheumatologists. The inter-reader reliability was high but intra-reader reliability showed a variable agreement in patients suggesting that the different pattern of nail lesions could affect the reliability of NAPSI. Thus, NAPSI seemed to be a poor reliable instrument to assess the nail involvement by non-trained rheumatologists in clinical practice (6). Finally, either NAPSI or mNAPSI could be quite “uncomfortable and time consuming” for rheumatologists in their daily clinical practice, while mNAPSI could be good for clinical trials as well as it seems to have good correlation with both physician and patient global assessment of psoriatic nail activity (28).

Finally, in 2004, a simple physician global score for nails was proposed during a study aimed to examine the relationship between the severity of nail disease and characteristics of PsA (29).

Conclusion

PsA has a variable clinical course: some patients have mild disease that can be responsive to therapeutic intervention, while some others are refractory to several treatments and potentially associated with functional disability and poor quality of life (30).

The axial PsA, radiologically defined, still remains an unmet need. The main results on the radiological assessment of axial PsA are summarised as follows: a) the definition of axial PsA, per se, still remains to be defined; b) few studies tried to assess the validity and feasibility of instruments already validated for AS and borrowed for the axial PsA, showing to be valid and feasible; c) a new radiological scoring system, called PASRI, and tailored to detect some specific radiological features of axial PsA has been recently validated; d) few studies aimed to assess the sensitivity to change of the instruments; e) further multi-centre studies are required to confirm these previous results.

Similarly, the measurement of nail involvement in PsA still remains problematic. In fact there are objective measurements of clinical improvement or worsening of nail psoriasis, and they are of great value in guiding medical therapy and standardizing clinical trials. At present, the two instruments developed are good instruments for research and clinical trials, rather than the feasibility in clinical practice. This is in keeping with similar results obtained, i.e., in measuring joint counts that showed poor inter-reader reliability (31). Therefore, the use of NAPSRI in real-life requires a further analysis of intra-reader reliability and the sensitivity to change of this instrument. Another issue is the development of an educational training programme using NAPSRI in rheumatological settings.

In conclusion, even with some similarities and some differences, the radiological assessment of axial PsA and the evaluation of nail involvement are two important and distinctive aspects of the outcome measures of an intriguing disease.

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