Consensus on the Measurement Instruments to Evaluate the Effectiveness of Biological Treatment in Psoriatic Arthritis: MERECES Study

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PMS81

OBJECTIVE

- To reach consensus on the instruments used to evaluate the short-to-medium term effectiveness of biologics for psoriatic arthritis in routine clinical practice, specifically those which may support decision-making on treatment continuity.

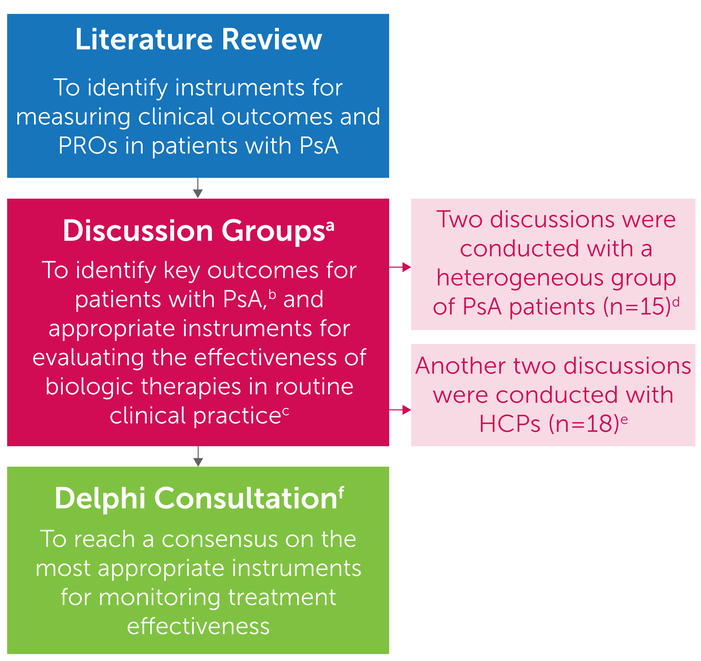
BACKGROUND

- The evaluation of health outcomes in patients with psoriatic arthritis (PsA) is hampered by the heterogeneous manifestations of the disease, and the lack of standard instruments to assess disease impact.
- Although further research is needed, evidence suggests that evaluation of patient-reported outcomes (PROs) in clinical practice may improve the care process (e.g. patient-professional and inter-professional communication, and clinical decision-making).[1]
- The GRAPPA-OMERACT group has established a core set of outcomes to be measured in PsA, including clinical outcomes and PROs,[2] and has defined a conceptual treatment target.[3] However, the instruments used to gauge treatment effectiveness have not been established.
- To address this gap, we sought to establish a consensus on the instruments used to evaluate the short-to-medium term effectiveness of biologics for the treatment of PsA in routine clinical practice.

METHODS

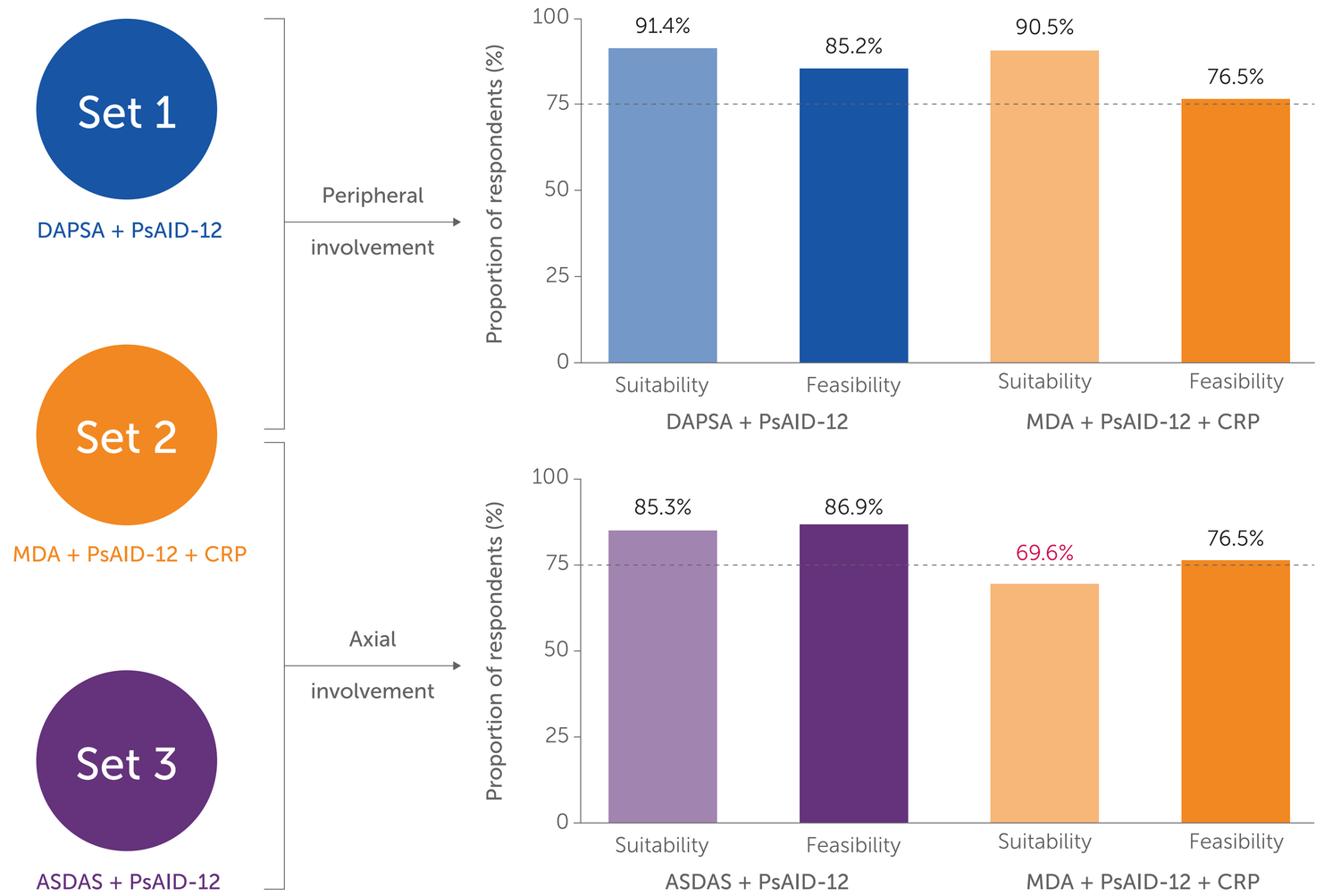
- This study was coordinated by a multidisciplinary scientific committee consisting of five experts: three rheumatologists, one psychologist with extensive experience in patient-reported outcome measures (PROMs), and one healthcare manager.
- The study comprised three phases: a literature review (including both Spanish and international publications), multiple discussion groups (involving both patients and HCPs from Spain), and a Delphi consensus (involving HCPs from Spain) **(Figure 1)**.
- The following method was used for the Delphi consensus **(Figure 1)**:
  - Based on the information gathered in the literature review and discussion groups, several sets of instruments were proposed.
  - Their suitability and feasibility for use in routine clinical practice were assessed on a 7-point Likert scale (1=completely disagree and 7=completely agree). Consensus was established when at least 75% of the respondents reached agreement (5–7 points) or disagreement (1–3 points). A similar cut-off for consensus has been used previously.[4]
  - The questionnaire was only completed by HCPs from Spain, and descriptive statistics were applied.
  - Delphi panelists were identified by the promoter and the scientific committee. A minimum of 2 years' professional experience was required.

Figure 1. MERECES study phases



[a]Prior to the discussion group, PROMs were pre-selected based on the availability of validated transcultural adaptations for Spanish PsA patients, and psychometric properties (i.e. consistency reliability, test-retest reliability, responsiveness and minimal important difference); [b]Reviewed by both patients and HCPs; [c]Reviewed and selected by HCPs; [d]Patients were selected by a patient association to achieve representativeness of age, gender, type of disease involvement, time from diagnosis, and time from treatment onset (20 patients were invited, but 15 accepted); [e]Including rheumatologists, dermatologists, hospital pharmacists, nurses, clinical psychologists and healthcare managers, who were selected by the promoter and the coordinating team according to their professional experience and interest in the project; [f]162 panelists were invited to participate in the Delphi consultation, 115 completed the first round, and 106 the second one. HCP: healthcare professional; PRO: patient-reported outcome; PROM: patient-reported outcome measure; PsA: psoriatic arthritis.

Figure 2. Consensus on the suitability and feasibility of the proposed instrument sets for patients with peripheral and axial involvement



The suitability and feasibility of each set of instruments for use in routine clinical practice were assessed on a 7-point Likert scale (1=completely disagree and 7=completely agree). Consensus was established when at least 75% of respondents reached agreement (5–7 points) for each criterion (dotted line). ASDAS: ankylosing spondylitis disease activity score; CRP: C-reactive protein; DAPSA: disease activity in PsA; MDA: minimal disease activity; PsAID-12: PsA impact of disease.

RESULTS

Literature Review

- A total of 87 instruments were identified in 138 reviewed publications, none of which assessed the 8 domains previously established by the GRAPPA-OMERACT group.
- This finding underlined the need to standardise the instruments used to monitor patients with PsA.

Patient Discussion Groups

- Impairment of physical and emotional well-being was considered the most important aspect for patients.
- In addition, patients considered the use of PROMs to be important, and were generally willing to use these instruments themselves.

HCP Discussion Groups

- During the discussion group, HCPs agreed to select the PsA Impact of Disease (PsAID-12) as the most suitable PROM due to its reliability, feasibility and capacity to assess most of the domains proposed by the GRAPPA-OMERACT group.
- Three sets of instruments to assess clinical outcomes and PROs were proposed based on their suitability and feasibility for use in routine clinical practice:
  - Set 1: Disease Activity in PsA (DAPSA) + PsAID-12;
  - Set 2: Minimal Disease Activity (MDA) + PsAID-12 + C-reactive protein;
  - Set 3: Ankylosing Spondylitis Disease Activity Score (ASDAS) + PsAID-12.
- All sets include a composite index and a PROM, and cover the core outcomes established by the GRAPPA-OMERACT group.
- Sets 1 and 2 were proposed for patients with peripheral involvement, and 2 and 3 for those with axial involvement.

Delphi Consultation

- One hundred and fifteen HCPs from Spain completed the questionnaire. Sociodemographic characteristics of the participants are described in **Table 1**.
- In patients with peripheral involvement, consensus was reached on the use of either DAPSA + PsAID-12 (Agreement on suitability [S]: 91.4%; Agreement on feasibility [F]: 85.2%), or MDA + PsAID-12 + C-reactive protein (S: 90.5%; F: 76.5%).
- In patients with axial involvement, consensus was reached on the use of ASDAS + PsAID-12 (S: 85.3%; F: 86.9%) **(Figure 2)**.

Table 1. Sociodemographic characteristics of Delphi panelists (n=115)

Characteristic, mean (SD) unless otherwise specified	
Age (years)	48 (8.3)
Male, n (%)	60 (52.2)
Specialty, n (%)	
Rheumatologists	87 (75.7)
Dermatologists	18 (15.7)
Others[a]	10 (8.6)
Experience (years)	21.7 (19.3)
Patients attended per month	311.6 (136.5)
Patients with PsA (%)	22.7 (20.9)
Membership in multidisciplinary PsA monograph working group (%)	44.3

[a]Nurses, hospital pharmacists, clinical psychologists and healthcare managers who participated in the discussion groups were invited to participate in the Delphi consensus alongside rheumatologists and dermatologists (n=10 agreed). Most of the rheumatologists and dermatologists involved in the Delphi consensus were not involved in the discussion groups. PsA: psoriatic arthritis; SD: standard deviation.

CONCLUSIONS

- In this study, a multidisciplinary consensus among HCPs has been reached on the most appropriate sets of instruments, including clinical and patient-reported outcome measures, to assess the effectiveness of biologic therapies in patients with PsA in the Spanish setting.
- Further research is needed to define therapeutic success using these instruments.

References: **1.** Desomer A. *et al.* KCE Reports 303 2018; D/2018/10.273/40; **2.** Orbai A-M. *et al.* Ann Rheum Dis 2017;76:673–80; **3.** Coates LC. *et al.* Arthritis Rheumatol 2018;70:345–55; **4.** Blade J. *et al.* BMJ Open 2018;8:e018850.

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