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Evidence-based algorithm for diagnosis and assessment in psoriatic arthritis: results by Italian DElphi in psoriatic Arthritis (IDEA)

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SUMMARY

Psoriatic arthritis (PsA) is a chronic inflammatory disease involving skin, peripheral joints, entheses, and axial skeleton. The disease is frequently associated with extrarticular manifestations (EAMs) and comorbidities.

In order to create a protocol for PsA diagnosis and global assessment of patients with an algorithm based on anamnestic, clinical, laboratory and imaging procedures, we established a DElphi study on a national scale, named Italian DElphi in psoriatic Arthritis (IDEA).

After a literature search, a Delphi poll, involving 52 rheumatologists, was performed. On the basis of the literature search, 202 potential items were identified.

The steering committee planned at least two Delphi rounds. In the first Delphi round, the experts judged each of the 202 items using a score ranging from 1 to 9 based on its increasing clinical relevance. The questions posed to experts were *How relevant is this procedure/observation/sign/symptom for assessment of a psoriatic arthritis patient?* Proposals of additional items, not included in the questionnaire, were also encouraged. The results of the poll were discussed by the Steering Committee, which evaluated the necessity for removing selected procedures or adding additional ones, according to criteria of clinical appropriateness and sustainability.

A total of 43 recommended diagnosis and assessment procedures, recognized as items, were derived by combination of the Delphi survey and two National Expert Meetings, and grouped in different areas. Favourable opinion was reached in 100% of cases for several aspects covering the following areas: medical (familial and personal) history, physical evaluation, imaging tool, second level laboratory tests, disease activity measurement and extrarticular manifestations. After performing PsA diagnosis, identification of specific disease activity scores and clinimetric approaches were suggested for assessing the different clinical subsets.

Further, results showed the need for investigation on the presence of several EAMs and risk factors.

In the context of any area, a rank was assigned for each item by Expert Committee members, in order to create the logical sequence of the algorithm. The final list of recommended diagnosis and assessment procedures, by the Delphi survey and the two National Expert Meetings, was also reported as an algorithm.

This study shows results obtained by the combination of a DElphi survey of a group of Italian rheumatologists and two National Expert Meetings, created with the aim of establishing a clinical procedure and algorithm for the diagnosis and the assessment of PsA patients.

In order to find accurate and practical diagnostic and assessment items in clinical practice, we have focused our attention on evaluating the different PsA domains. Hence, we conceived the IDEA algorithm in order to address PsA diagnosis and assessment in the context of daily clinical practice.

The IDEA algorithm might eventually lead to a multidimensional approach and could represent a useful and practical tool for addressing diagnosis and for assessing the disease appropriately.

However, the elaborated algorithm needs to be further investigated in daily practice, for evidencing and proving its eventual efficacy in detecting and staging PsA and its heterogeneous spectrum appropriately.

Key words: *Rheumatology; arthritis; psoriatic arthritis; psoriasis; comorbidities; diagnosis algorithm.*

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INTRODUCTION

Psoriatic arthritis (PsA) is a chronic inflammatory disease involving skin, peripheral joints, entheses, and axial skeleton. The disease is frequently associated with extrarticular manifestations (EAMs) and comorbidities (1). Diagnosis relies mainly on clinical evaluation and the CASPAR (ClASsification criteria for Psoriatic ARthritis) criteria are often used in epidemiological and research studies, having high specificity (98.7%) and sensitivity (91.4%) (2, 3).

Frequently, peripheral patterns overlap with axial involvement leading to different phenotypical combinations and frequency, in which dactylitis, enthesitis, low back pain, oligo and mono arthritis significantly characterize the disease (4-7). Cutaneous domain represents another aspect leading to wide phenotypical heterogeneity. Psoriasis generally occurs before articular manifestations; it can be contemporaneous with, or later than arthritis. Furthermore, the case of patients with arthritis and familiar psoriasis provides a PsA subset classified as *sine psoriasis* (8).

In addition, in recent years the increase of clinical studies have outlined how PsA can be associated with extrarticular manifestations, also alternatively recognized as comorbities (9-13). Among these, the most frequent are represented by uveitis (9), colitis (10), metabolic syndrome (MS) (11) and involvement of the cardiovascular system (12). Psychological aspects, such as depressive symptoms and anxiety, represent important correlates of health related quality of life (HRQoL) (13).

Hence, the new concept of psoriatic disease has identified this heterogeneous condition, abandoning the view of PsA as a merely articular and cutaneous mild inflammatory state (14).

However, once the patient has been diagnosed with PsA, the variable clinical spectrum can make the assessment of disease activity a challenge both for articular and cutaneous aspects and for systemic manifestations (15, 16).

In order to find accurate, reliable, and feasible activity measures useful in longitudinal cohorts, clinical trials, and clinical practice, the Group for Outcome Measures in Rheumatology (OMERACT), and for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), have focused their attention on refining and assessing the different PsA domains (16).

In particular, to assist the rheumatologist in the management of PsA, OMERACT Group proposed a core set of six core domains, represented by peripheral joint and skin activity, pain, patient global assessment (PGA), physical function, and HRQoL. In addition, spinal disease, dactylitis, enthesitis, fatigue, nail disease, radiography, and acute-phase indices were considered important domains (17).

GRAPPA group highlights that assessment of PsA patients requires full consideration of all major disease domains, including peripheral arthritis, axial disease, enthesitis, dactylitis, psoriasis, and nail disease. Further, the impact of PsA on pain, function, QoL, and structural damage needs to be assessed (18). In addition, a comprehensive assessment of other potential related conditions should be considered, including uveitis, inflammatory bowel disease (IBD), cardiovascular disease, obesity, MS, gout, diabetes mellitus (DM), liver disease, depressive and anxiety-symptoms (18-22).

In recent years, in psoriasis (23) and PsA (24-29), several studies have applied Delphi procedures (30, 31) for different aims, mainly focused on better diagnosis and assessment of these clinical conditions.

In particular, in 2015, in the context of psoriasis, Italian dermatologists performed a Delphi procedure involving 50 dedicated dermatological centres (23). This led to the definition of a multidimensional assessment algorithm for psoriasis diagnosis and assessment which was potentially useful for proving sensitivity sustainable in daily clinical practice, named PSOCUBE. It includes a three-dimensional table comprising 14 clinical examinations and history-recording items, 32 laboratory screenings and instrumental exams and 11 clinimetric scores (23).

In order to create PsA diagnosis and global

assessment protocol and an algorithm based on anamnestic, clinical, laboratory and imaging procedures, we established a Delphi study on a national scale, named Italian DElphi in psoriatic Arthritis (IDEA).

MATERIALS AND METHODS

As a first step, all the evaluations (patient anamnesis, clinical evaluation, laboratory tests, imaging procedures) considered useful for the diagnosis, and the domains for the assessment, were identified by an expert board dictating the items, through a literature search.

Subsequently, a Delphi poll involving 52 rheumatologists, representative of the Italian rheumatologic community and with expertise in current good clinical practice for PsA, was performed. We used a modified Delphi technique in which questionnaire rounds were followed by a well-structured meeting of the Steering Committee, to discuss and validate (by voting) the results.

Delphi questionnaire preparation

Articles published in indexed English language journals on randomized controlled clinical trials, meta-analysis, guidelines, reviews and observational studies dealing specifically with psoriatic arthritis and its comorbidities, were selected by the authors. The articles were identified by a MEDLINE, EMBASE, Cochrane Library, PubMed using the keywords *psoriatic arthritis* and/or *psoriasis*, matched with several keywords, relevant for every aspect of the diseases, including also the term comorbidities.

On the basis of the literature search, we identified a preliminary list of 202 potential items useful for assessment of PsA, subdivided in key domains necessary to assess and possibly to distinguish PsA from other rheumatic diseases. In particular the key domains were: musculoskeletal, dermatological, metabolic, cardiologic, psychiatric and quality of life related, gastroenterological, and ophthalmologic.

The survey

the steering committee planned at least two Delphi rounds. The consensus process was conducted via email. In the first Delphi round the experts judged each of the 202 items using a score ranging from 1 to 9 based on its increasing clinical relevance. The questions posed to experts was *How relevant is this procedure/observation/sign/symptom for assessment of a psoriatic arthritis patient?* Proposals of additional items, not included in the questionnaire, were also encouraged. Crucial to the final results were: speed of transmission, maintenance of respondent anonymity, and potential for rapid feedback.

The agreement was defined when a score was reached by at least 80% of the experts. The criteria for agreement and disagreement between experts were defined as follows:

1) *agreement* - when 80% of the panellists' ratings fall into one of the 3-bands in a scale from 1 to 9 (1-3; 4-6; 7-9);
2) *disagreement* - when 90% of the panellists' ratings fall instead into one of two extra-wide bands (1-6 or 4-9).

It means that if, to reach the 90% votes, we need to include two large intervals, the distribution is too skewed and not symmetrical. As such, it represents disagreement.

In the second round, participants were asked to rate again only the procedure that did not reach the optimal levels of agreement and disagreement.

The results of the poll were discussed by the Steering Committee, which evaluated the necessity for removing selected procedures or adding additional ones, according to criteria of clinical appropriateness and sustainability.

The final list, made of 43 items grouped in the previously agreed key domains, was discussed in a first 1-day National Expert Meeting in October 2014, involving 30 participants. Further, in this meeting it was decided to use the items to prepare an algorithm to assess the patient in daily clinical practice. In light of this, an additional round of the Delphi exercise was prepared to select through a priority level (high, medium, low) those items considered worthy of inclusion in the different steps of the flow-chart (laboratory data, history, physical exam, etc). The main steps of the study are reported in Figure 1.

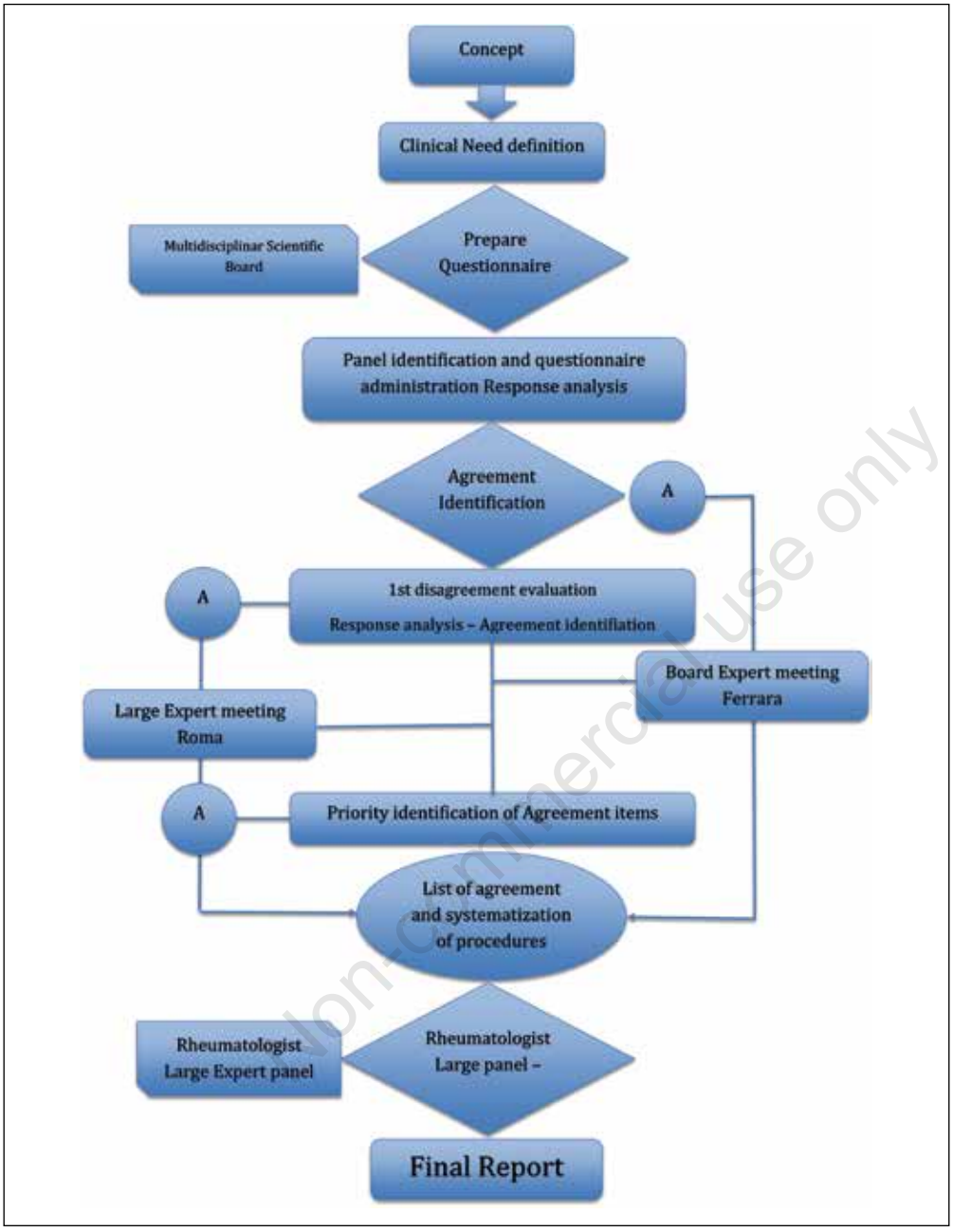

Figure 1 - Main steps of the Italian Delphi in Psoriatic Arthritis (IDEA) project.

Calculations were performed using the Office 2007 software package.

RESULTS

A total of 43 recommended diagnosis and assessment procedures, recognized as items, were derived by a combination of the Delphi survey and two National Expert Meetings, and grouped in different areas including medical (familial and personal) history, physical evaluation, imaging tool, second level laboratory tests, disease activity measurement and extrarticular manifestations (Table I). For each of these, the frequency of high, middle and low priorities are also reported.

A first level laboratory tests area was also

Table I - The 43 recommended diagnostic and assessment procedures, recognized as items, derived by combination of the DElphi survey and two National Expert Meetings, and grouped in different areas including medical (familial and personal) history, physical evaluation, imaging tool, second level laboratory tests, disease activity measurement and extrarticular manifestations.

Area	Item
1st level laboratory tests	Cellular blood count (CBC)
1st level laboratory tests	Creatinine
1st level laboratory tests	ALT/GPT
1st level laboratory tests	ESR
1st level laboratory tests	CRP
1st level laboratory tests	Urinalysis
Medical history	Diagnosis of psoriasis and/or psoriatic onychopathy
Medical history	Psoriasis in 1st and 2nd degree relatives
Medical history	Site and symptoms characteristics (pain and/or swelling and/or stiffness)
Medical history	Symptoms duration
Medical history	Arthritis and/or spondylitis familiarity
Family medical history	Personal or familiar hystory of inflammatory bowel disease
Physical evaluation	Site and number of swollen joints
Physical evaluation	Site and number of tender joints
Physical evaluation	Insertional pain in enthesitis sites
Physical evaluation	In case of axial disease pattern, clinimetric evaluation of the spine (tragus-to-wall distance, lateral bending, Schober's test, cervical spine rotation, inter-malleolar distance)
Physical evaluation	Presence of psoriasis and/or onychopathy
Imaging	X-ray of the involved joints
Imaging	US of the involved joints and enthesis
Imaging	MRI of the sacroiliac joints
2nd level laboratory tests	CRP
2nd level laboratory tests	HLA-B27 (only if axial and/or enthesis symptoms)
2nd level laboratory tests	ACPA + Rheumatoid factor
2nd level laboratory tests	Uricaemia
Involved sites	Pattern of localization of disease symptoms
Disease activity measurement	Number of tender joints (TJ 68) and swollen joints (SJ 66)
Disease activity measurement	LEI (0 - 6)
Disease activity measurement	Pain VAS (0 - 10)
Disease activity measurement	BASDAI
Disease activity measurement	BASFI
Disease activity measurement	PGA (0 - 10)
Disease activity measurement	HAQ
Comorbidities	Cardiovascular events, hypertension, diabetes, obesity, dyslipidemia ed hyperuricemia
Comorbidities	General visit (heart, lung, abdomen, skin and annexes)
Comorbidities	Sending the specialist areas of expertise must be selective and based on patient characteristics
Ocular comorbidity	Active uveitis and relapses number

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Physical evaluation	Dactylitis (sites and numbers)
Gastroenteric comorbidity	Personal or family history of IBD
Dermatologic comorbidity	PASI
Psycological comorbidity & QoL	Presence/absence fybromyalgia
Psycological comorbidity & QoL	Performing of PsAID-12 test is recommended
Dismetabolic comorbidity	Metabolic syndrome
Dismetabolic comorbidity	Obesity

ALT/GPT, alanine serum transaminases; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; US, ultrasound; MRI, magnetic resonance imaginf; ACPA, anti-citrullinated protein antibodies; LEI, Leeds enthesitis index; VAS, visual analogic scale pain; BASDAI, bath ankylosing spondylitis disease activity index; BASFI, bath ankylosing spondylitis functional index; PGA, patient global assessment; HAQ, health assessment questionnaire; IBD, inflammatory bowel disease; PASI, psoriasis area severity index; PsAID-12, psoriatic arthritis impact of disease questionnaire; QoL, quality of life.

added by expert committee members as described successively.

Anamnestic data

In the anamnestic phase, for each patient suspected of PsA, useful investigations were represented by diagnosis of psoriasis and/or psoriatic onychopathy in personal history (favorable opinion in 100% of cases with high priority in 100%) and of psoriasis in 1st and 2nd degree relatives (favorable opinion in 100% of cases with high and middle priority respectively, in 92.6% and 7.4%).

Other important anamnestic aspects for PsA diagnosis were considered familial history for arthritis and spondylitis (favorable opinion in 96% of cases with high, middle and low priority respectively in 37%, 51.9% and 11.1%), site and pattern of articular involvement (pain, swelling and stiffness) (favorable opinion in 89% of cases with high and middle priority respectively, in 88.9% and 11.1%) and disease duration (favorable opinion in 100% of cases with high, middle and low priority respectively, in 59.3%, 33.3 and 7.4%).

Physical evaluation

In the context of physical examination, favourable opinion was reached in 100% of cases for the following items: swollen joints count (SJC) (high and middle priority respectively in 85.2% and 14.8%); tender joints count (TJC) (high, middle and low priority respectively in 85.2%, 11.1% and 3.7%); tender entheseal sites (high and middle priority respectively in 88.9% and 11.1%); dactylitis (sites and numbers) (high and middle priority respectively in 96.3% and 3.7%); clinimetric evaluation of the spine (tragus-to-wall distance, lateral bending, Schober's test, cervical spine rotation, inter-malleolar distance) (high, middle and low priority respectively in 63%, 33.3% and 3.7%); presence of psoriasis and/or onychopathy (high, middle and low priority respectively in 92.6%, 3.7% and 3.7%).

Imaging tools

Favorable opinion was reached in 100% of cases for the following imaging items: X-ray of the involved joints (high and middle priority respectively, in 80% and 20%); US of the involved joints and enthesis (high and middle priority respectively in 74.1% and 25.9%) (high and middle priority respectively in 85.2% and 14.8%); magnetic resonance imaging (MRI) of the sacroiliac joints in presence of inflammatory back pain (high and middle priority respectively in 88.9% and 11.1%).

Second level laboratory tests

In the context of laboratory evaluation, favourable opinion was reached in 100% of cases for the following items: HLA-B27 in patients with axial and entheseal involvement (high, middle and low priority respectively in 44.4%, 51.9% and 3.7%); C-RP (high, and middle priority respectively in 73.1%, and 26.9%); uricaemia (high, mid-

dle and low priority respectively in 29.6%, 55.6% and 14.8%).
It was suggested that anti-citrullinated protein antibodies (ACPA) and rheumatoid factor (RF) should be evaluated in case of differential diagnosis with rheumatoid arthritis (RA) (high, middle and low priority respectively in 37%, 48.1% and 14.8%).

Clinimetric approach
Favourable opinion was reached in 100% of cases for the following clinimetric items: 68-TJC and 66-SJC (for both, high and middle priority respectively in 92.6% and 7.4% of cases); Bath ankylosing spondylitis disease activity index (BASDAI) (high and middle priority respectively in 81.5% and 18.5%); Bath ankylosing spondylitis functional index (BASFI), health assessment questionnaire (HAQ) and visual analogic scale (VAS)-pain (for all, high and middle priority respectively in 63% and 37%); Leeds enthesitis index (LEI) (0-6) (high, middle and low priority respectively in 37%, 51% and 11.1%); PGA (0-10) (high, middle and low priority respectively in 55.6%, 40.7%, and 3.7% of cases).

Psoriatic arthritis classification
After performing PsA diagnosis, identification of clinical subsets, specific disease activity scores and clinimetric approach were suggested for assessing the disease.
Among these, the most important were considered to be BASDAI, BASFI, HAQ, VAS and PGA in axial pattern; 68-TJC, 66-SJC, HAQ, VAS, PGA in peripheral pattern; LEI (0-6), HAQ, VAS, PGA in enthesitis; HAQ, VAS, and PGA in dactylitis.

Extrarticular manifestations
After performing PsA diagnosis, identification of associated extrarticular manifestations was considered of relevance as result of the study. In particular, the results showed the need for investigation on the presence of several extrarticular manifestations and risk factors.
In particular, in the anamnestic phase, the results evidenced the need to focus on cardiovascular events, systolic and/or diastolic hypertension, DM, obesity, dyslipidaemia and hyperuricemia (favorable opinion in 100% of cases with high and middle priority in 74.1% and 25.9%).
The presence of high psoriasis area severity index (PASI), MS, obesity, uveitis or recurrence of uveitis, personal and/or familial history of IBD, psychological comorbidity and low QoL tested by the psoriatic arthritis impact of disease questionnaire, represented important tools for addressing the patient towards the specialist area of expertise (favorable opinion in 100% of cases with high, middle and low priority respectively in 55.6%, 37%, and 7.4%).
At the first patient interview, expert committee members recommended performing first level laboratory tests such as cellular blood count (CBC), serum creatinine, aspartate and alanine serum transaminases (AST and ALT), erythrocyte sedimentation rate (ESR), and urinalysis. These were included in the first level laboratory tests area.
In the context of each area, a rank was assigned for each item by Expert Committee members, in order to create the logical sequence for the algorithm.
The final list of recommended diagnosis and assessment procedures, by the Delphi survey and the two National Expert Meetings, is shown in Table I and as an algorithm in Figure 2.

DISCUSSION

This study shows results obtained by the combination of a Delphi survey of a group of Italian rheumatologists and two National Expert Meetings, created with the aim of establishing a clinical procedure and algorithm for the diagnosis and the assessment of PsA patients.
In PsA, due to the absence of recent diagnostic criteria and of well-defined indices assessing the heterogeneity of the condition, both diagnosis and assessment need of be deeply investigated. Reduction of PsA severity, improvement of QoL and psychosocial components are mainly related to early diagnosis and appropriate assessment with prompt therapeutic intervention (32-34).

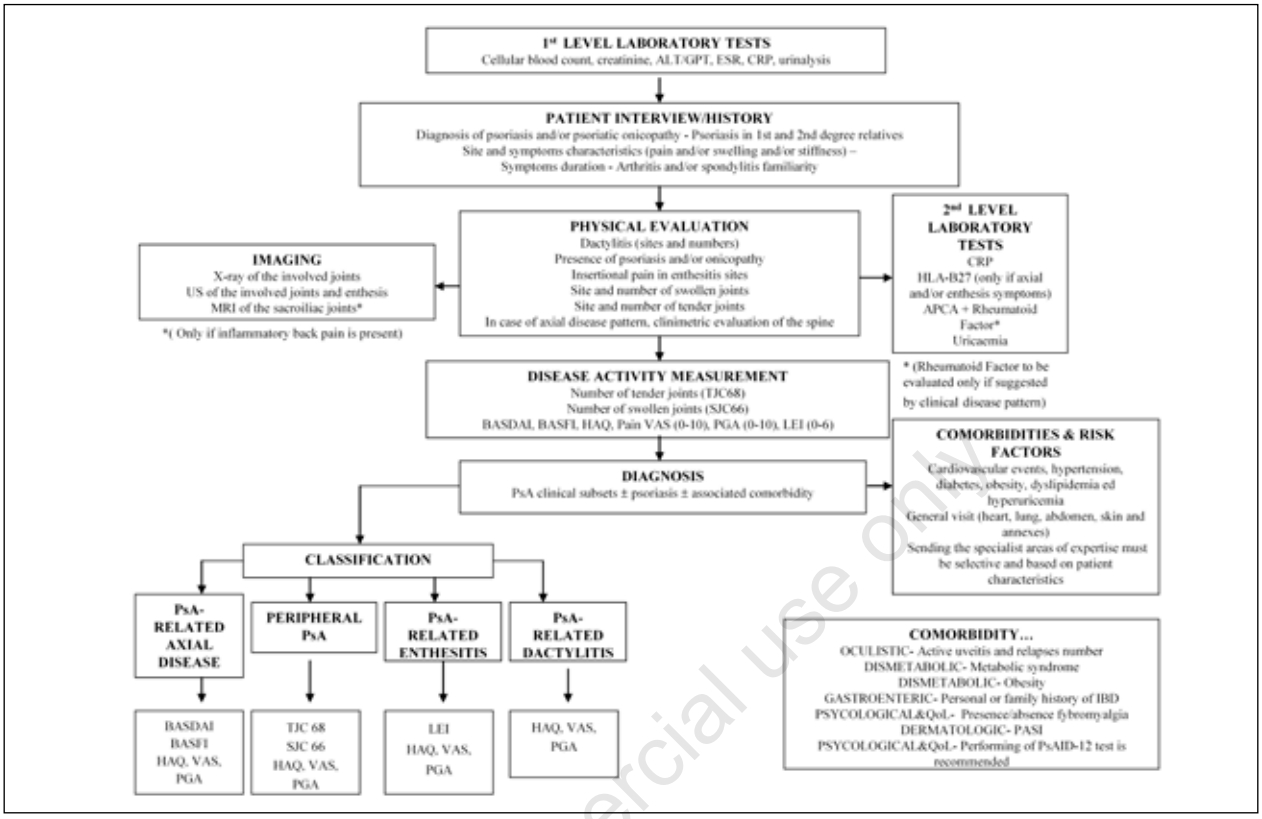

Figure 2 - Italian DElphi in Psoriatic Arthritis (IDEA) algorithm reporting the final list of recommended diagnosis and assessment procedures, by the Delphi survey and the two National Expert Meetings.

The final goal in PsA therapy is to inhibit structural radiological damage, induce clinical remission, and improve patients' QoL, as defined by GRAPPA and the European League Against Rheumatism in the European League Against Rheumatism (EULAR) recommendations (19, 35-38).

Hence, we have hypothesised a Delphi study for establishing a consensus from a large group of rheumatologists with the aim of improving PsA early diagnosis and assessing the disease and its heterogeneous aspects.

Forty-three recommended items reaching high frequency of favourable opinion in this study included both diagnostic and assessment procedures. Items were then grouped in different areas covering medical (familial and personal) history, physical evaluation, imaging, second level laboratory tests, disease activity measurement and extrarticular manifestations (ocular, gastrointestinal, dermatological, psychological, and dismetabolic manifestations). A first level laboratory tests area was also added by expert committee members.

In particular, the results of the study showed that diagnosis of psoriasis and/or psoriatic onychopathy in personal history, psoriasis in 1st and 2nd degree relatives, familiar history for arthritis and spondylitis, articular site and pattern, and disease duration represented the most important anamnestic items. In the context of physical evaluation, the most important items were represented by dactylitis (sites and numbers), presence of psoriasis and/or onychopathy, tender entheseal sites, SJC and TJC, clinimetric evaluation of the spine (tragus-to-wall distance, lateral bending, Schober's test, cervical spine rotation, inter-malleolar distance). Articular X-rays, US of the involved joints and enthesis and MRIs of the sacroiliac joints in presence of inflammatory back pain provided the most important imaging findings.

The following key laboratory findings were suggested: C-RP, HLA-B27 in patients with axial and entheseal involvement, and uricaemia. ACPA and RF were considered important in the differential diagnosis with RA. Further, first level laboratory tests such as CBC, serum creatinine, AST and ALT, ESR, and urinalysis were recommended by expert committee members, to be performed at the first patient interview.

With regard to the clinimetric approach, the most important items were represented by 68-TJC and 66-SJC, BASDAI, BASFI, HAQ, VAS-pain, LEI (0-6), and PGA (0-10).

In addition, expert committee members recommended the calculation of the DAPSA score (39). Disease activity index for psoriatic arthritis (DAPSA) is a disease-specific validated and feasible tool for PsA assessment. Recently, DAPSA has been considered as reference tool for defining remission or low disease activity within the first recommendation of the latest EULAR recommendations on PsA (38).

Anamnestic investigation on the presence of cardiovascular events, systolic and/or diastolic hypertension, DM, obesity, and dyslipidemia were suggested as important findings for the assessment of the disease.

Among extrarticular manifestations, the presence of high PASI, MS, obesity, uveitis or recurrent uveitis, personal and/or familial history of IBD, and psychological aspects needed to be evaluated.

In order to find accurate and practical diagnostic and assessment items in clinical practice, we have focused our attention on evaluating the different PsA domains. Hence, we conceived the IDEA algorithm in order to address PsA diagnosis and assessment in the context of daily clinical practice.

In accordance with OMERACT (17) and GRAPPA groups (18-22), this study revealed the need to assess PsA with full consideration of all major disease domains, including peripheral arthritis, axial disease, enthesitis, dactylitis, and psoriasis, both in anamnestic and clinical evaluation.

In particular, in this study, the presence of arthritis, dactylitis, enthesitis and axial involvement in the context of psoriasis and/or its familiarity are confirmed as the main clinical items useful in addressing the diagnosis. Peculiar MRI and US imaging findings of involved articular and entheseal districts, evaluation of C-RP and HLA-B27 positivity in case of axial involvement emerged as important elements for addressing the diagnosis and assessing the disease. RF and ACPA seronegativity represent useful findings for excluding RA. Further, in accordance with GRAPPA recommendations (18-22), this study confirms that rheumatologists should be also aware of differing extrarticular conditions, which require expert consultation to guarantee prompt global assessment.

CONCLUSIONS

In conclusion, the IDEA algorithm could represent a useful and practical tool for addressing the diagnosis and for assessing appropriately the disease. In addition, this algorithm might eventually lead to a multidimensional approach in which rheumatologists have to consider not only articular and cutaneous aspects, but also systemic aspects.

However, the elaborated algorithm needs to be further investigated in daily practice, for evidencing and for proving its eventual efficacy in detecting and staging appropriately PsA and its heterogeneous spectrum.

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