A systematic review of diagnostic criteria for psoriasis in adults and children: evidence from studies with a primary aim to develop or validate diagnostic criteria*

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Summary

Background The diagnosis of psoriasis in adults and children is made clinically, for both patient management and the selection of participants in research. Diagnostic criteria provide a structure for clinical assessment, which in turn helps standardize patient recruitment into clinical trials and case definitions in observational studies.

Objectives The aim of this systematic review was to identify and critically appraise the published studies to date that had a primary research aim to develop or validate diagnostic criteria for psoriasis.

Methods A search of Ovid MEDLINE and Ovid Embase was conducted in October 2016. The primary objective was to record the sensitivity and specificity of diagnostic criteria for psoriasis. Secondary objectives included diagnostic recommendations, applicability to children and study characteristics. Diagnostic accuracy studies were critically appraised for risk of bias using the QUADAS-2 tool.

Results Twenty-three studies met the inclusion criteria. None detailed clinical examination-based diagnostic criteria. The included criteria varied from genetic and molecular diagnostic models to skin imaging, histopathology, and questionnaire-based, computer-aided and traditional Chinese medicine criteria. High sensitivity and specificity (> 90%) were reported in many studies. However, the study authors often did not specify how the criteria would be used clinically or in research. This review identified studies with varying risk of bias, and due to each study developing separate criteria meta-analysis was not possible.

Conclusions Clinical examination-based diagnostic criteria are currently lacking for psoriasis. Future research could follow an international collaborative approach and employ study designs allowing high-quality diagnostic accuracy testing. Existing and newly developed criteria require validation.

What’s already known about this topic?

- Diagnostic criteria can aid both clinical diagnosis and support standardization in clinical trials and observational research.
- In routine dermatology practice, psoriasis is a clinical diagnosis, and the gold (reference) standard is a dermatologist’s diagnosis, supported where needed by histology.
- Diagnostic criteria are currently not widely used in clinical practice or in research about psoriasis.
The aim of this systematic review was to identify and critically appraise studies where the primary research aim was to develop or validate diagnostic criteria for psoriasis in adults or children. The review was designed to be broad and inclusive of all ages, types of psoriasis and types of diagnostic criteria. In this way, the review aimed to provide a comprehensive overview of the available evidence.

Psoriasis is an immune-mediated chronic inflammatory disease affecting the skin, joints or both. It is associated with both a genetic predisposition and environmental triggers. Onset may occur at any age, with an estimated prevalence of 1.0–8.5% in adults and up to 2.1% in children. Psoriasis is associated with systemic inflammation, although the risk of comorbidity and comorbidity-related mortality remains controversial.

In routine clinical practice, the diagnosis of psoriasis is made based on pattern recognition of clinical features, including the distribution, configuration and morphology of skin changes. The gold or reference standard is conventionally accepted to be a clinical diagnosis made by a qualified dermatologist, which may be supported, when required, by a skin biopsy. Unlike in other conditions such as Behçet disease, where clinical diagnostic criteria exist to aid the clinical assessment, and atopic dermatitis, where criteria are used in clinical research, diagnostic criteria are not widely used in the assessment of psoriasis.

Clinical diagnostic criteria not only support and provide a structure to clinical diagnosis, but also standardize recruitment into clinical trials and case definitions in observational studies. Studies that develop diagnostic criteria should follow the principles of high-quality diagnostic accuracy study design and reporting, and then go on to validate the criteria in the study or clinical population where they are intended to be used.

**Methods**

The protocol was registered on PROSPERO (http://www.crd.york.ac.uk/PROSPERO, record CRD42015032311), and the results have been reported according to the PRISMA checklist. The term ‘diagnostic criteria’ was interpreted to mean a group of diagnostic features that support a diagnosis of psoriasis.

Studies were included where the primary aim was to develop or validate diagnostic criteria for psoriasis. No restrictions were applied to study type, age of participants, language, type of psoriasis or type of diagnostic criteria developed. Studies were not required to include a comparator group. Review articles and studies focusing solely on psoriatic arthritis were excluded. Conference abstracts were excluded due to insufficient information; this was an alteration from the protocol.

The primary outcome was the sensitivity and specificity of diagnostic criteria for psoriasis. Secondary outcomes were as follows: recommendations on how to diagnose psoriasis, applicability of the diagnostic criteria to a paediatric population, study design and study population. The diagnosis of psoriasis can be more challenging in children, in part due to a different presentation compared to adults, and therefore this review assessed the applicability of diagnostic criteria to this specific population.

The search was conducted in October 2016 in Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE 1946 to present, and Ovid Embase 1974–2015. A search strategy was developed with an information specialist (D.G.) using MeSH headings and free-text search terms around the keywords ‘diagnosis’, ‘criteria’ and ‘psoriasis’ (Appendix S1; see Supporting Information). Reference citations from included studies were searched for additional relevant papers.

Titles and abstracts of identified studies were independently screened by two authors according to the inclusion and exclusion criteria (E.B.T. and either R.C.P., S.R. or D.G.). Full-text papers were obtained for studies meeting the inclusion criteria. Two authors (E.B.T. and R.C.P.) independently assessed the eligibility of full-text papers. Study authors were contacted to clarify missing data from potentially eligible studies. Any disagreements on study eligibility were resolved through discussion or involvement of a third author (K.S.T.).

Data were independently extracted by two authors (E.B.T. and R.C.P.) using a standardized pro forma (Appendix S2; see Supporting Information). The pro forma was piloted on three studies and refined before independent extraction was initiated. Discrepancies between the two sets of data extraction were discussed and checked against the original manuscript.

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**What does this study add?**

- No clinical examination-based diagnostic criteria have been developed or validated for psoriasis in adults or children.
- Genetic, molecular, skin imaging, histopathology, questionnaire-based, computer-aided and traditional Chinese medicine diagnostic criteria have been developed for psoriasis, but their utility in clinical practice and research needs further exploration.
- Many of the included diagnostic accuracy studies had unclear or high risk of bias due to weaknesses in study design and study reporting.
For those studies not reported in English, data were extracted by an associate proficient in that language.

Diagnostic accuracy studies were individually critically appraised for risk of bias using QUADAS-2. The QUADAS-2 tool was specifically designed to assess the quality of studies included in systematic reviews of diagnostic accuracy. The tool assesses risk of bias across four domains, each guided by prompt questions. These domains were (i) patient selection: recruitment of consecutive patients or a random sample, case–control design avoided, inappropriate exclusions. (ii) Index test (diagnostic criteria): results interpreted without knowledge of the reference standard, use of a prespecified threshold. (iii) Reference standard (gold standard): results interpreted without knowledge of the index test, likely to classify psoriasis correctly. (iv) Flow of patients in the study: interval between index test and reference standard, complete verification, inclusion of all patients in the analysis. All studies, regardless of overall quality, were included in the data synthesis.

Paired forest plots and summary receiver operating characteristic curves were planned for studies that were clinically similar and suitable for meta-analysis. A narrative synthesis was planned for secondary outcomes.

Results

Within the 11 702 studies identified from the search strategy no clinical examination-based diagnostic criteria for psoriasis in adults or children were found. Only 23 studies met the inclusion criteria; they presented a broad range of diagnostic criteria including genetic, molecular, dermoscopy, confocal microscopy, histopathology, questionnaire-based, computer-aided and traditional Chinese medicine criteria (Table S1; see Supporting Information). Sixteen studies were of a case–control design, five studies were case series, one study was cross-sectional and one study was a Delphi consensus study. No studies developed diagnostic criteria specifically for children or validated diagnostic criteria specifically in a paediatric population.

Studies were excluded because they were duplicates (n = 4374), did not focus on psoriasis (n = 4266), did not mention diagnostic criteria for psoriasis (n = 2950), did not develop or validate diagnostic criteria (n = 34) or were review articles (n = 55). The search strategy was extensive and inclusive of many terms associated with diagnostic criteria and psoriasis. A large number of studies were therefore excluded at the screening stage. A PRISMA flow diagram of the included and excluded studies is presented in Figure 1.

The diagnostic criteria were summarized, including consideration of their utility, and the study quality is reported using the QUADAS-2 tool. With regards to the review’s primary outcome – the sensitivity and specificity of the diagnostic criteria – only 16 of the included studies investigated diagnostic accuracy, and of these studies only 13 provided these data. Figure 2 shows a scatter plot of the available sensitivity and specificity results of these 13 studies.

Meta-analysis was not appropriate due to the heterogeneity of the diagnostic criteria in terms of different study populations, experimental tests, and reference tests, and therefore a narrative review was undertaken.

Genetic and molecular diagnostic criteria

Six studies reported genetic and two studies reported molecular diagnostic criteria (Table S1; see Supporting Information). These studies aimed to identify a combination of genetic or molecular markers that could best predict psoriasis. Seven studies were of a case–control design and one was a cross-sectional study. Sensitivity and specificity results of the criteria were presented or available on request for five studies; the sensitivity values ranged from 65·6% to 98% and specificity from 58·2% to 100%. Diagnostic accuracy results were often reported as area under the curve, and three studies reported a value ≥0·7. Six studies undertook validation testing of their developed criteria; this was conducted in a separate cohort, but no studies reported validation in their intended population.

Domain 1 (patient selection) was scored as having high risk of bias in six studies, while the remaining three domains nearly all scored low or unclear risk of bias in the seven diagnostic accuracy studies (Fig. 3). The low scores reflect that the index test was interpreted separately from the reference standard, and the flow of patients through each study minimized bias. However, the reference standard was detailed in only one study.

Across the eight studies, the study authors proposed that their research might: (i) improve the efficiency and/or accuracy of diagnosis including screening individuals at high risk for psoriasis; (ii) improve disease outcomes; (iii) aid further understanding of pathogenesis and (iv) aid the development of personalized medicine and new treatments. The authors of two studies proposed that these genetic criteria would, in time, translate into routine clinical practice.

We conclude that the research and clinical utility of these genetic and molecular criteria for the diagnosis of psoriasis require further exploration, and new validation studies are needed. The cost of the laboratory investigations and training required to undertake a skin biopsy for genetic testing are likely to be barriers to adoption. The effect of the anatomical distribution of psoriasis on the predictive ability of these criteria is also unknown.

Skin imaging diagnostic criteria

Four studies reported dermoscopic or videodermoscopic diagnostic criteria, two studies reported reflective confocal microscopy (RCM) criteria and one study reported high-definition optical confocal tomography (Table S1; see Supporting Information). All seven studies were of a case–control study design, and five studies assessed the diagnostic
accuracy of the proposed criteria in distinguishing psoriasis from other inflammatory skin diseases and skin cancer.

The different dermoscopic criteria studies reported variable sensitivity (45–98%), but high specificity (88–99.5%) for diagnosing psoriasis.27–29 Koller et al.26 reported high sensitivity (89%–1%) and specificity (95–4%) for the RCM criteria tested, and Munro microabscesses on RCM achieved both high sensitivity and specificity (90% and 96–4%, respectively).31 The Videodermoscopy Scalp Psoriasis Severity Index criteria had poor interobserver reproducibility; only 68% of dermatologists recognized ≥13 images.30 None of the imaging studies included testing the diagnostic criteria in a validation cohort.

The risk of bias was highly variable across the five diagnostic accuracy studies (Fig. 3). These scores reflect not only the study quality but also the quality of study reporting; for example the details reported by Liu et al.28 and Zhong et al.31 were brief and therefore many of the domains were scored as unclear. Lallas et al.27 and Koller et al.26 achieved a low risk-of-bias score in three out of four domains, demonstrating both a strong study design and detailed reporting.

The authors of the seven skin imaging studies proposed that the developed criteria might: (i) assist clinical diagnosis, reducing the need for skin biopsy;25,29,31 (ii) help identify an optimal site to biopsy;26 (iii) enable response to treatment and side-effect monitoring27 and (iv) help to identify patients requiring screening for psoriatic arthritis.30 One group of authors highlighted that the feasibility of applying imaging criteria in clinical practice requires further evaluation.27 The authors of one study suggested that the criteria could be adopted as an outcome tool in clinical trials.30

We conclude that further discussion about the clinical and research utility of imaging criteria in the diagnosis of psoriasis...
is needed, including validation of their diagnostic accuracy in the proposed setting and population. The implementation of imaging criteria research is likely to be restricted to the specialist setting due to the availability of equipment and trained professionals. Dermoscopy is already widely practised among dermatologists for the assessment of skin cancer, and therefore further training could extend existing skills to inflammatory lesions. However, the availability of confocal microscopy is limited to specialist research centres. Further studies are also needed to guide lesion selection, as it is not clear whether the performance of the criteria varies when plaques at different anatomical sites are assessed.

**Histopathological diagnostic criteria**

Four studies have contributed to the development of histopathological criteria, focusing on clinical situations where diagnosing psoriasis is recognized as challenging, namely isolated scalp psoriasis, isolated nail psoriasis and erythroderma (Table S1; see Supporting Information). Three studies were case series and one was of a case–control design and provided diagnostic accuracy data. None included a validation cohort. Park et al. reported poor sensitivity (33%) and good specificity (90%) of $>5.75$ mitotic features in one high-power field for the diagnosis of psoriasis. Minimal study details were provided and therefore the risk of bias was high or unclear across the four domains evaluated (Fig. 3). The study was strengthened by assessment of histological samples by three independent histopathologists, but no intraobserver data were provided.

The authors of the four histopathology studies provided few details on the potential application of the proposed diagnostic criteria, except stating that they would assist clinical diagnosis. We conclude that the clinical and research utility of histopathological criteria is poorly explored, especially considering that histology was often part of the inclusion criteria for many studies within this review. A skin biopsy is a small but invasive procedure, incurs costs and is not widely available outside the specialist setting. These factors are likely to limit the adoption of histological criteria outside dermatology clinics and within clinical trials. Clinically, histological criteria may be of greatest benefit in those with indeterminate skin changes. The criteria proposed are for specific anatomical sites, and therefore it is unknown whether these findings are applicable to other body sites.

**Computer-aided diagnostic criteria**

Two case–control studies developed computer-aided diagnostic criteria and reported high diagnostic accuracy (sensitivity and specificity 100%, 5-7 errors per 100 cases) (Table S1;
Neither included a validation group. The risk of bias across the four domains varied between the two studies, reflecting the specific details reported in West and West on the reference test and index test (Fig. 3).36,37 Both sets of authors proposed that their criteria would be used in the clinical setting, although they differed on whether the computer-aided tool would augment or replace current diagnostics. We propose that further discussion of clinical and research utility is needed, as well as validation studies. The performance of the criteria when psoriasis affects specific body areas is unknown.

Questionnaire-based diagnostic criteria

Dominguez et al. developed a self-administered screening questionnaire for the diagnosis of psoriasis.38 In this case–control study the questionnaire achieved high diagnostic accuracy, with sensitivity 98% and specificity 95%. However, the performance of the questionnaire relied heavily on question number three, ‘I have been diagnosed with psoriasis by a dermatologist’ (sensitivity 93%, specificity 98%), and removal of this question led the sensitivity and specificity to fall to 35% and 50%, respectively.38

The risk-of-bias assessment was variable across the four domains. In particular, the quality of the study was limited by lack of clarity as to whether the index test (questionnaire) was separated from the reference standard (dermatologist’s diagnosis; Fig. 3).

Fig 3. Risk-of-bias assessment using the QUADAS-2 diagnostic accuracy critical appraisal tool. (a) Graph showing the percentages of studies with a low, high or unclear risk of bias for each of the four domains. (b) Table showing the risk of bias for each domain for individual studies. Sixteen of the 23 studies in the review were critically appraised using QUADAS-2 as these are the diagnostic accuracy studies.
suitable for large and population-based studies. It is not clear what impact limited psoriasis or psoriasis affecting only certain body sites may have on the questionnaire’s diagnostic ability.

**Traditional Chinese medicine diagnostic criteria**

In a Delphi consensus study, Yang et al.\(^4^9\) aimed to develop a checklist for the effects of traditional Chinese medicine on symptoms and signs of psoriasis. The study did not assess diagnostic accuracy, but within the consensus study there was good intraobserver but poor interobserver agreement.

The study authors proposed that the criteria may aid the diagnosis and classification of psoriasis in clinical practice and research,\(^3^9\) but no further details were provided. We conclude that further discussion about the criteria’s utility is needed, along with testing of the diagnostic performance. No reference was made to psoriasis affecting specific body areas. It is likely that the usefulness of these criteria will be limited mostly to settings practising traditional Chinese medicine.

**Discussion**

This systematic review identified 23 studies that reported diagnostic criteria for psoriasis, but it is surprising that no clinical examination-based diagnostic criteria have been developed or tested. The questionnaire-based criteria by Dominguez et al.\(^3^8\) were the closest in type to clinical diagnostic criteria, but relied on patient confirmation of a dermatologist’s diagnosis. Validation was frequently performed within studies developing genetic and molecular criteria, but no studies validated their criteria in the setting and population in which they were intended to be used. Due to the heterogeneity of diagnostic criteria included in this review it was not possible to compare their diagnostic accuracy. Nevertheless, high sensitivity and specificity (>90%) were reported in many studies.

The majority of the included studies were limited by their case–control design, which is likely to overestimate the diagnostic accuracy of a test or tool.\(^4^1,^4^2\) There was also significant variation in study reporting, with frequent or high risk of bias in domains where details were limited or missing about the study population, reference standard or flow of patients in the study.\(^1^6\) Nearly all diagnostic accuracy studies were undertaken on a selected population using a case–control study design, and therefore QUADAS-2 domain 1 (patient selection) was rated as high risk of bias in all critically appraised studies.

Overall, the studies often poorly described the clinical and research utility of their proposed criteria, or future research required to validate and implement them. Studies focused, where detailed, on plaque psoriasis, and the diagnostic performance of the criteria across a variety of body areas is unknown.

The benefits of diagnostic criteria in supporting improved clinical diagnosis, research studies and systematic reviews are widely reported.\(^9,^4^3,^4^4\) However, diagnostic criteria have been developed for only a small number of diseases in dermatology.

In eczema, Brenninkmeijer et al.\(^1^2\) summarized and assessed the validity of six examination-based diagnostic criteria, developed mostly for research purposes. These criteria achieved varied diagnostic accuracy, and Brenninkmeijer et al. commented that the methodological quality in both the conduct and reporting of the eczema studies differed substantially; this was a similar finding to ours on the diagnostic criteria for psoriasis. In Behçet disease, Davatchi et al.\(^4^5\) appraised 17 sets of examination-based diagnostic criteria that were developed to aid clinical diagnosis. Two internationally developed sets of diagnostic criteria for Behçet disease were found to be the best-performing criteria. The review emphasized that further validation studies in different countries were required, as well as the need to accept that the clinical picture of a disease may change over time.\(^3^5\) These are both concepts that need to be considered when developing diagnostic criteria for psoriasis.

Diagnostic criteria have also been proposed for a small number of other dermatological conditions, primarily those with extracutaneous involvement and those requiring multiprofessional input. Examples are mucous membrane pemphigoid, PHACE syndrome (posterior fossa, haemangioma, arterial lesions, cardiac abnormalities, eye abnormalities) and erosive lichen planus.\(^4^6–^4^8\)

Diagnostic criteria in dermatology aim to support, not replace, clinical diagnosis, especially in the specialist setting, where the reference standard is a dermatologist’s diagnosis. In this review many of the criteria identified were ‘test based’. The utility of skin imaging or histopathological diagnostic criteria alone may be limited, as they are unlikely to be used without a clinical assessment. However, they are likely to be useful adjuvants to clinical diagnosis, for example in cases of clinical diagnostic uncertainty where dermoscopic followed by histopathological diagnostic criteria may be applied. At present, it is more difficult to recognize how genetic or molecular diagnostic criteria would be used in routine clinical practice.

Most studies in this review, where stated, included an adult secondary-care population, and therefore the findings of this review would be difficult to translate to children or a community setting, where the diagnostic challenges are different.

The implications for patients of not receiving an accurate psoriasis diagnosis (false negatives) include a delay in initiating effective treatment and monitoring for comorbidities. Incorrectly identifying patients with psoriasis (false positives) may result in inappropriate treatment for their skin condition and the possible anxiety of being labelled with a potentially lifelong skin condition.

Only the questionnaire-based diagnostic criteria were specifically developed for research purposes.\(^3^8\) However, the diagnostic accuracy of this tool in the community setting has not yet been assessed in a validation study. Genetic and molecular diagnostic criteria may play an important role in future genoepidemiological studies, developing biobanks and stratifying patients according to disease. However, further work is...
needed to improve the diagnostic accuracy of such criteria and validate them.

The diagnostic criteria identified in this review are currently not suitable to standardize psoriasis disease definition in clinical trials and observational studies, confirming an important gap in the available literature.

To the authors’ knowledge this review is the first to collate and appraise available studies that have developed and/or validated diagnostic criteria for psoriasis. The search strategy was designed to be comprehensive and was supported by an information specialist. Diagnostic accuracy studies were critically appraised using the validated QUADAS-2 tool. As the literature in this area was anticipated to be limited, a broad definition of diagnostic criteria was applied. Therefore, the types of diagnostic criteria included in this review are diverse and meta-analysis was not possible.

In conclusion, at present there are no available clinical examination-based diagnostic criteria for psoriasis to support clinical diagnosis and standardization of disease definition in research studies. A number of criteria based on different diagnostic methods have been developed, but their clinical and research utility is unclear. There is a need for these proposed criteria to be validated in the populations and settings where they are intended to be used. To date, studies have focused on the adult population. Work to develop clinical examination-based diagnostic criteria should be undertaken with an international collaborative approach, considering the type and extent of psoriasis, and with the aim to minimize the risk of bias in the study design and to validate the criteria in the target population. Such work should carefully consider the diagnostic challenges of psoriasis affecting particular sites and ages.

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