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Running head – CONTEST Questionnaire to identify PsA in Primary Care

Title: Comparison of screening questionnaires to identify psoriatic arthritis in a primary care population: a cross sectional study

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**What's already known about this topic?**

- NICE guidance for management of psoriasis recommends annual screening for patients to identify psoriatic arthritis
- Many screening questionnaires are available but there is little evidence comparing them.
- A new screening questionnaire (CONTEST) was developed using the most discriminative items from existing questionnaires after the CONTEST study identified increasing positive predictive value with positivity on multiple questionnaires in secondary care.

**What does this study add?**

- This study confirms that the PEST and CONTEST questionnaires can be used to identify PsA in patients in primary care.
- It suggests that lower cut points on these questionnaires optimise sensitivity and specificity.

**Objective:** To test the proposed CONTEST questionnaire developed to identify patients with psoriasis who have undiagnosed psoriatic arthritis (PsA) and compare to the validated PEST questionnaire in a primary care setting.

**Methods:** A random sample of adult patients with psoriasis and no diagnosis of arthritis were identified from 5 GP surgeries in Yorkshire, UK. Consenting patients completed both questionnaires and were assessed by a dermatologist and rheumatologist. Diagnosis of PsA was made by the assessing rheumatologist. Receiver operator characteristic (ROC) curve analysis examined sensitivity and specificity of potential cut points.

**Results:** A total of 932 packs were sent to recruit 191 (20.5%) participants. Of these, 169 (88.5%) were confirmed to have current or previous psoriasis. Using physician diagnosis 17 (10.1%) were found to have previously undiagnosed PsA, 90 (53.3%) had another musculoskeletal complaint and 62 (36.7%) had no musculoskeletal problems.

Using ROC curve analysis, all of the questionnaires showed a significant ability to identify PsA. The area under the curve (AUC) for the CONTEST questionnaires was slightly higher than that of PEST (0.694 and 0.704 vs 0.652) but there was no significant difference identified. Examining the sensitivities and specificities for the different cut points, suggested that a PEST ≥2 would perform better in this dataset, and optimal scores for CONTEST and CONTESTjt were 3 and 4 respectively.

**Conclusions:** The accuracy of the questionnaires to identify PsA appeared similar with slightly higher AUC for the CONTEST questionnaires. Optimal cut points in this study appeared lower than previous studies.

Psoriatic arthritis (PsA) is an inflammatory arthritis associated with psoriasis. The majority of patients present with psoriasis prior to developing arthritis and many studies have identified that a proportion of patients under active follow up in primary care or secondary dermatology clinics for psoriasis have undiagnosed PsA [1]. Given this evidence, the National Institute for Health and Care Excellence (NICE) in the UK has recently recommended annual screening of all patients with psoriasis for PsA, including those only followed in primary care[2].

Many patient-reported screening questionnaires for PsA have been developed but they have not been widely adopted in clinical practice. The NICE guidance highlights that the optimal screening tool is not yet established, but given the data available has recommended the PEST questionnaire[2]. Given the lack of comparative studies, we undertook the CONTEST study to compare the performance of the PEST, PASE and TOPAS questionnaires in dermatology clinics in the UK[3]. The PEST questionnaire did seem to perform slightly better than the others, but given the relatively low specificity, we sought to create a new questionnaire incorporating the most discriminative items from each of the existing questionnaires. Three potential questionnaires were developed using different analyses[4]. They were then tested retrospectively in similar PsA screening datasets from Dublin and Utah. The weighted CONTEST questionnaire did not work well in the independent datasets, but the simple CONTEST score, which included the most discriminant items from the other questionnaires, and the CONTESTjt score, which was identical to CONTEST with the addition of a joint manikin, did suggest some advantage over PEST[4].

The aim of this study was to prospectively test the two candidate CONTEST questionnaires alongside the existing PEST questionnaire, this time in a primary care cohort, where a full spectrum of psoriasis disease activity can be identified.

In addition, we sought to retrospectively identify any potential clinical risk factors that may aid the identification of PsA in primary care patients with psoriasis.

Methods

Patients with psoriasis were identified from five primary care practices across Yorkshire with varied socioeconomic backgrounds. The practices varied in size (table 1) and 4/5 did not have any specialist interest general practitioners in either dermatology or rheumatology. One practice (practice C) has two general practitioners with an interest in dermatology, but none who specialise in rheumatology. Each practice performed a database search to identify potential subjects. Patients were eligible for participation if they were aged 18 years or over, had a diagnostic label of psoriasis (by Read code M161, x506Y, M16Y) but did not have a coexistent diagnosis of psoriatic arthritis (Read code M160), ankylosing spondylitis (Read code N100) or rheumatoid arthritis (Read code N040). A random sample from each practice was taken from those meeting inclusion criteria on the practice's database using random number tables to select participants. Information about the study was posted to those patients. Patients were asked to return a reply slip if they were willing to attend one study visit at their general practitioner's (GP) surgery for assessment by a dermatologist and a rheumatologist. Clinics were held in the evening to aid attendance.

At the study visit, following informed consent, patients were asked to complete a questionnaire booklet including the PEST[5] and CONTEST questionnaires[4], PsA quality of life (PsAQoL)[6], dermatology life quality index (DLQI)[7] and health assessment questionnaire (HAQ)[8]. They were then reviewed independently by a dermatologist (LS) and a rheumatologist (LCC, ARM or PSH). Dermatology assessment included type and areas of involvement of psoriasis, psoriasis area and severity index (PASI)[9], body surface area (BSA) and modified nail psoriasis severity index (mNAPSI)[10]. Rheumatology assessment included entheseal tenderness (at sites covered by the Leeds enthesitis index[11], Maastricht ankylosing spondylitis enthesitis score[12] and SPARCC score)[13], dactylitic digit count, 68 tender and 66 swollen joint counts. The Classification of PsA (CASPAR) criteria[14] were applied but diagnosis was made by the assessing rheumatologist. Study physicians did not have

access to GP records and no specific serological or imaging investigations (as part of the CASPAR criteria) were performed.

Statistics

Receiver operator characteristic (ROC) curve analysis was used to assess the PEST and CONTEST questionnaires using physician diagnosis as the gold standard. Sensitivity and specificity of potential cut points were examined.

The study was powered to allow novel assessment of the sensitivity and specificity of the CONTEST questionnaire in a primary care population. The sensitivity and specificity of the CONTEST questionnaire in the development cohort were 0.82 and 0.52 respectively. To confirm the sensitivity and specificity in this new primary care population with a minimum accuracy of 10% and a confidence level of 95% assuming a prevalence of 0.3, the minimum number required for the total sample size was 191[15].

The Chi-square test of independence and Fisher's Exact test were used to assess the relationship between specific anatomical sites of psoriasis (nails, gluteal cleft, scalp and retro-auricular areas) and the presence or absence of PsA. An independent two-sample Mann Whitney U-test was used to assess the difference in psoriasis severity between those with and without PsA. Missing data were excluded. All analyses were performed using IBM SPSS Statistics (version 21.0).

Results

A total of 932 packs were sent out from the 5 GP practices to recruit 191 (20.5%) participants who agreed to attend for assessment. Response rates varied from 14.7% to 30.6% depending on the practice. Of the 191, 169 (88.5%) patients had current or previous psoriasis, with the remaining 22 being misdiagnosed or coded incorrectly. Table 1 lists the population size of each practice, the proportion of patients coded as psoriasis and PsA.

The demographics of the 169 participants with psoriasis are shown in table 2. The majority had active psoriasis, but psoriasis severity was generally mild or moderate, with a median PASI score of 2.6 (1.1-5.4). Only 12 patients had a PASI score of ≥10 and referrals to secondary care were recommended where appropriate. In terms of therapy, 83 patients were currently using at least one topical therapy, two were undergoing NBUVB phototherapy and two were receiving oral treatment (actiretin/methotrexate).

The prevalence of PsA within our cohort of 169 patients with confirmed current or previous psoriasis was 10.1% (n=17). In our sample all 17 cases identified were new diagnoses. Using the prevalence of new PsA within our cohort and the prevalence of psoriasis misdiagnosis, corrected prevalence figures for psoriasis and PsA across the 5 GP practices are shown in table 1. The estimated prevalence figure suggest that around a half of PsA patients in primary care are undiagnosed (140/283=49.5%). Overall, the estimated prevalence of psoriatic arthritis in patients with psoriasis was 18.1% (95% CI: 16.2 – 20.1%).

Alternative musculoskeletal (MSK) diagnoses were made in a further 90 patients with psoriasis, namely osteoarthritis and mechanical joint pain (74 patients), tendinopathy (7 patients), gout (2 patients), fibromyalgia (2 patients), palindromic arthritis (1 patient), Morton's metatarsalgia (1 patient) and joint hypermobility (1 patient). Demographics for the cohort divided into three groups: PsA, alternative MSK diagnoses and no MSK diagnosis are shown in table 2.

Using ROC curve analysis, all of the screening questionnaires showed a significant ability to identify PsA. The area under the curve (AUC) for the CONTEST and CONTESTjt questionnaires was slightly higher than that of PEST (see figure 1) but there was no significant difference between any of the questionnaires. Examining the sensitivities and specificities for the different cut points, suggested that a PEST score of ≥2 would perform better in this dataset, and optimal scores for CONTEST and CONTESTjt seemed to be 3 and 4 respectively.

Using the validated cut-off of 3 for the PEST questionnaire, there were 8 patients with false negative results. The majority of these patients with PsA reported presence of swollen joints (7/8) but most of the other features (enthesitis, nail disease and dactylitis) were only reported by one patient each leading to a score of 2 for most of the patients. Five patients had axial involvement of whom two had pure axial involvement. Both of these had a PEST score of 2, whilst only one of them was identified by the CONTEST questionnaire despite specific questions on spinal pain.

In contrast there were 50 patients with false positive results. The majority of these had other MSK diagnoses (41/50) with most of these having OA or mechanical joint pain (n=33). Again most patients reported swollen joints (48/50), with high proportions also reporting being told they had arthritis (n=35), nail psoriasis (n=28), heel pain (n=35) and a swollen and painful finger or toe (n=39). In this group of 50 false positive patients, the HAQ and PsAQOL scores were similar to the PsA cohort (median HAQ 0.25, IQR 0.0, 0.75, median PsAQOL 5.0, IQR 0.0, 12.0) suggesting a significant burden of MSK disease on their function and quality of life.

Looking at other potential clinical predictors of PsA, in terms of psoriasis distribution, a numerically higher proportion of patients with PsA had nail psoriasis and retro-auricular psoriasis, but this did not reach significance due to small numbers (p=0.207). Chi-square and Fisher's Exact tests were performed to examine any predictors of PsA, but due to the small number of cases, all failed to reach significance. No correlation between PASI score and presence of PsA was found in this small cohort using the Mann Whitney U-test.

## Discussion

This study demonstrates the significant ability of the PEST and both CONTEST screening questionnaires to identify PsA in a primary care population. The PEST was originally developed and tested in such a population before being validated in dermatology clinics. However, the CONTEST questionnaires had only been tested in secondary care dermatology populations prior to this study.

There was no significant difference between the three questionnaires in their ability to identify PsA, but a much larger study would be needed to identify a significant difference in the questionnaires' sensitivity and specificity.

Interestingly the optimal cut points of all of the questionnaires seem to be lower in this cohort with a PEST score of ≥2 being more accurate in differentiating PsA. The population in this study is drawn from primary care, in comparison to our previous study CONTEST which was recruited from dermatology outpatient clinics. However the PEST was originally developed in a primary care setting and yet the cut point of ≥3 was defined in this study. Although the PEST questionnaire does not contain specific questions on spinal pain it may, for other reasons, identify patients with pure axial disease. In this study only two patients had axial disease and both of these scored '2' on this instrument. Conversely, although the CONTEST instrument contains at least two questions on spinal pain, it still failed to 'capture' both patients with pure axial disease even with the lower cut-off suggested by this study.

A high proportion of the false positive patients who had OA or other MSK complaints reported typical symptoms of PsA on these screening questionnaires, including answering positive to the 'dactylitis' question. This suggests that rewording of this question may be needed. A significant number of patients without PsA also identified poor function or quality of life on the HAQ and PsAQOL questionnaires. The HAQ is a generic functional questionnaire and would be expected to be high in patients with significant limitations due to the other MSK complaints. The PsAQOL, whilst developed specifically for PsA, may be relevant to patients with chronic psoriasis or other musculoskeletal disorders, in particular those questions relating to tiredness, depression or lifestyle limitation.

The prevalence of psoriasis and PsA in our cohort is in keeping with published population estimates. Around 10% of the patients with psoriasis had previously been diagnosed (and coded) with PsA and an additional 10% were found to have PsA on examination. This overall 18.1% prevalence of PsA is

slightly lower than the 30% reported in large secondary care cohorts[16]. Interestingly a recent meta-analysis found an overall prevalence of 15.5% which is more inkeeping with our results[17]. Our estimate of 18.1% is also likely to be an overestimate as people with musculoskeletal symptoms are presumably more likely to respond and attend for examination creating a selection bias.

There was a misdiagnosis rate for psoriasis of around 10% in our sample. Alternative diagnoses included seborrhoeic dermatitis, eczema, actinic keratosis and ichthyosis vulgaris. Conversely, there are also likely to be some patients within these practices who have psoriasis but have not been coded as such perhaps because they have never consulted their doctor or because they have not had the correct diagnosis made by their general practitioner. This has also previously been suggested to be around 10%. Our study did not assess any patients not coded as having psoriasis and therefore this number cannot be confirmed.

No clinical predictors of PsA were identified in this cohort. However, the study was powered to assess the performance of the screening questionnaires rather than to look at PsA predictors. Our assumption is that the relatively small number of patients with PsA (n=17) meant that any differences seen were non-significant.

There remains the problem of low specificity with these instruments and the new CONTEST tools do not really improve on this. Psoriatic arthritis is an heterogeneous disease and developing a questionnaire to precisely identify cases, while excluding other causes of musculoskeletal pain, seems problematic. Perhaps the existing tools cannot be improved upon and the deficiencies accepted and acknowledged. The other cases of musculoskeletal pain clearly are having an impact on the patient and perhaps need review by a rheumatologist just as much as those with PsA. If the primary care physician, or dermatologist, were to use the instruments as a screening tool and make further clinical assessment prior to referral it is likely that the more appropriate cases would be referred to a rheumatology specialist. In this regard, further educational activities, such as those promoted by GRAPPA[18], will be of benefit.

In summary, this study demonstrates the significant ability of the screening questionnaires to identify PsA in a primary care population but no significant improvement in performance has been shown by the new instruments. Low specificity remains a problem for these tools in clinical practice but the use of these questionnaires to screen for musculoskeletal disorders in patients with psoriasis should continue. Inappropriate referrals to rheumatology can be minimised by a brief clinical assessment prior to referral and the use of these screening questionnaires will help identify cases of psoriatic arthritis that currently remain undiagnosed.

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Table 1: The proportion and prevalence of patients in each practice diagnosed with psoriasis and/or psoriatic arthritis according to Read code

| Practice | A | B | C | D | E | Total |
|---|---|---|---|---|---|---|
| Practice List Size | 2908 | 13300 | 19850 | 10102 | 9768 | 55928 |
| Patients coded PsO (n) | 118 | 360 | 433 | 450 | 313 | 1674 |
| Patients coded PsA and PsO (n) | 8 | 12 | 16 | 14 | 18 | 68 |
| Patients coded PsA alone (n) | 2 | 28 | 36 | 2 | 7 | 75 |
| Total coded PsA (n) | 10 | 40 | 52 | 16 | 25 | 143 |
| Patients seen in study (n) | 33 | 16 | 64 | 56 | 22 | 191 |
| New PsA diagnosed (n) | 3 | 1 | 4 | 7 | 2 | 17 |
| PsO misdiagnosis (n) | 4 | 2 | 7 | 6 | 3 | 22 |
| Misdiagnosis rate of PsO (%) | 12.1 | 12.5 | 10.9 | 10.7 | 13.6 | 11.5 |
| *Corrected likely patients with PsO (n) | 105 | 320 | 391 | 404 | 274 | 1494 |
| Corrected prevalence of PsO (%) | 3.61 | 2.41 | 1.97 | 3.99 | 2.80 | 2.67 |
| Estimated PsA in PsO patients not seen (n) | 7 | 19 | 20 | 47 | 24 | 117 |
| Total actual and predicted PsA (n) | 20 | 60 | 76 | 70 | 51 | 277 |
| Estimated PsA prevalence in those with PsO (%) | 18.9 | 18.1 | 19.4 | 17.4 | 18.7 | 18.5 |

**PsO=psoriasis, PsA=psoriatic arthritis**

*** given the high frequency of patients coded with PsA and not PsO it was assumed that this was a coding error. Patients coded as PsA only were added to the presumed number of PsO cases.**

Table 2 – Demographics of the study participants with PsA, other MSK problems, no MSK symptoms and the total population

| Parameter | Psoriasis N=169 | Psoriatic Arthritis N=17 | Alternative MSK diagnosis n=90 | No MSK diagnosis n=62 |
|---|---|---|---|---|
| Male sex, n (%) | 83 (49.1) | 8 (47.0) | 41 (45.6) | 34 (54.8) |
| Age (years), median (IQR) | 61.0 (48.0, 68.0) | 52 (47.5, 62.5) | 61 (50, 69) | 62 (46.8, 68.3) |
| Psoriasis duration (years) | 28.0 (14.0, 39.5) | 30.0 (19.5, 43.0) | 30.5 (13.3, 43.0) | 25.0 (12.5, 37.0) |
| Active psoriasis | 144 (85.2) | 12 (70.6) | 75 (83.3) | 57 (91.9) |
| Psoriasis subtype | | | | |
| Chronic plaque | 114 (79.2) | 10 (83.3) | 58 (77.3) | 46 (80.7) |
| Small plaque | 13 (9) | 0 | 6 (8.0) | 7 (12.3) |
| Guttate | 2 (1.4) | 0 | 0 (0) | 2 (3.5) |
| Palmoplantar | 4 (2.8) | 1 (8.3) | 2 (2.7) | 1 (1.8) |
| BSA, median (IQR) | 3 (3, 5) | 5 (0, 5) | 3.0 (2.0, 5.0) | 5.0 (3.0, 5.0) |
| PASI, median (IQR) | 2.6 (1.1, 5.4) | 2.5 (0, 5.5) | 1.8 (1.0, 3.6) | 3.6 (1.3, 5.9) |
| PASI≥10, n (%) | 12 (8.3) | 1 (8.3) | 6 (8.0) | 5 (8.8) |
| Site of psoriasis involvement | | | | |
| Scalp | 79 (54.9) | 8 (66.7) | 41 (54.7) | 30 (52.6) |
| Retroauricular | 38 (26.4) | 6 (50) | 13 (17.3) | 19 (33.3) |
| Gluteal cleft | 22 (15.3) | 2 (16.7) | 11 (14.7) | 9 (15.8) |
| Nail | 39 (23.1) | 6 (50) | 18 (24.0) | 14 (24.6) |

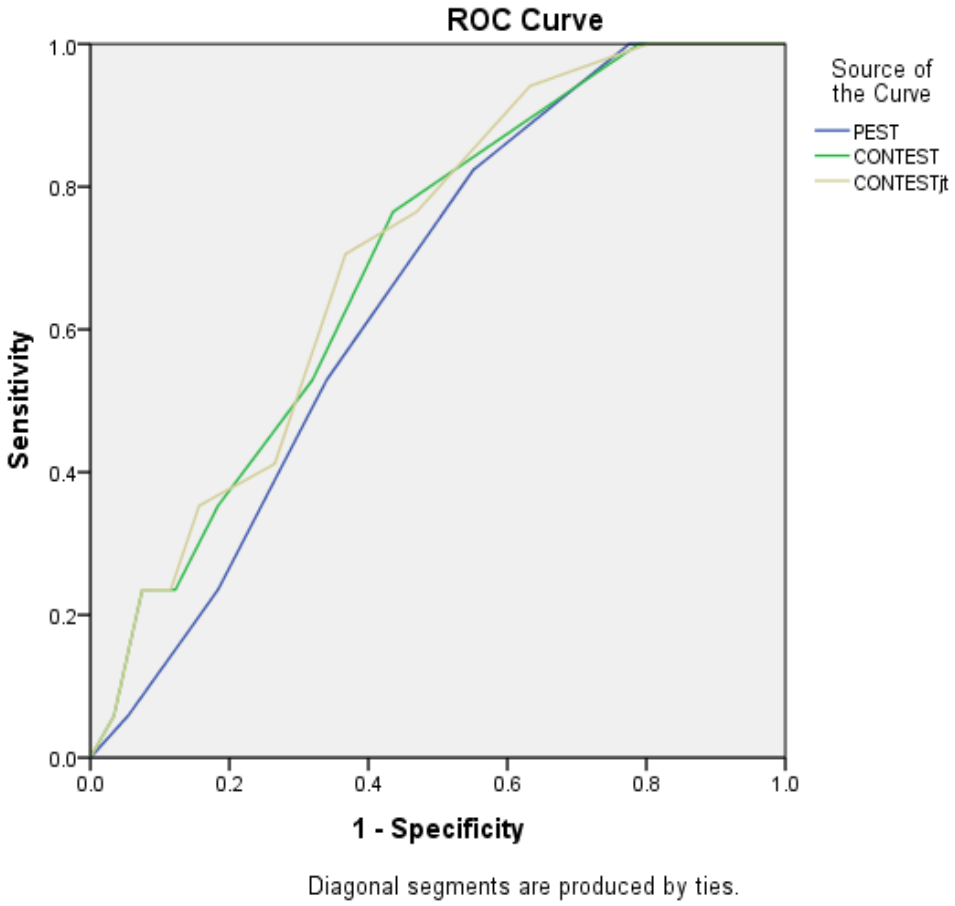
| | | | | |
|---|---|---|---|---|
| Active nail disease, n (%) | 39 (23.1) | 6 (35.3) | 19 (21.1) | 14 (22.6) |
| mNAPSI score (condition present), median (IQR) | 16.0 (8.0, 28.0) | 16 (11.0, 23.3) | 17.0 (10.0, 35.0) | 12.5 (8.0, 34.3) |
| Cutaneous symptoms | 100 (69.4) | 10 (83.3) | 50 (66.7) | 40 (70.2) |
| Itching | 86 (59.7) | 9 (75) | 41 (54.7) | 36 (63.2) |
| Soreness | 43 (29.9) | 5 (41.7) | 19 (25.3) | 19 (33.3) |
| Pain | 6 (4.2) | 1 (8.3) | 4 (5.3) | 1 (1.8) |
| Physician diagnosis PsA, n (%) | 17 (10.1) | 17 (100) | 0 (0) | 0 (0) |
| CASPAR criteria met (score ≥3), n (%) | 10 (5.9) | 8 (47.1) | 2 (2.2) | 0 (0) |
| CASPAR score ≥2, n (%) | 18 (10.6) | 14 (82.3) | 4 (4.4) | 0 (0) |
| PsA pattern, n (%) of patients | | | | |
| Polyarthritis (≥5 joints) | | 3 (17.6) | | |
| Oligoarthritis (<5 joints) | | 11 (64.7) | | |
| DIP disease | | 0 (0) | | |
| Axial involvement | | 5 (29.4) | | |
| Entheseal only | | 1 (5.9) | | |
| Arthritis mutilans | | 0 (0) | | |
| Number of swollen joints (0-66), median (IQR) | 0 (0, 0) | 1 (0, 2.5) | 0 (0, 0) | 0 (0, 0) |
| Number of tender joints (0-68), median (IQR) | 0 (0, 2) | 1 (0.5, 3.5) | 1 (0, 4) | 0 (0, 0) |
| Active enthesitis, n (%) | 61 (36.1) | 7 (41.2) | 41 (45.6) | 13 (21.0) |
| Enthesitis score (condition at baseline), median (IQR) | 2.0 (1.0, 4.5) | 1.0 (1.0, 6.0) | 3.0 (1.0, 5.0) | 2.0 (1.0, 2.5) |
| Active dactylitis, n (%) | 1 (0.6) | 1 (5.9) | 0 (0) | 0 (0) |

| | | | | |
|---|---|---|---|---|
| Dactylitis score (condition at baseline), median (IQR) | 1 | 1 | n/a | n/a |
| DLQI, median (IQR)[$] | 2.0 (1.0, 5.0) | 3.0 (1.5, 4.3) | 2.0 (1.0, 5.0) | 2.0 (1.0, 5.0) |
| HAQ score, median (IQR)[#] | 0.0 (0.0, 0.4) | 0.4 (0.0, 0.6) | 0.0 (0.0, 0.5) | 0.0 (0.0, 0.0) |
| PsAQOL, median (IQR)[&] | 1.0 (0.0, 7.0) | 5.0 (0.0, 12.0) | 2.0 (0.0, 9.0) | 0.0 (0.0, 3.0) |
| PEST, median (IQR)* | 2.0 (1.0, 3.0) | 2.5 (1.8, 4.0) | 2.0 (1.0, 4.0) | 1.0 (0.0, 2.0) |
| CONTEST, median (IQR)* | 2.0 (1.0, 4.0) | 4.0 (2.8, 5.5) | 3.0 (1.0, 4.0) | 1.0 (0.0, 3.0) |
| CONTESTjt, median (IQR)* | 2.0 (1.0, 5.0) | 4.0 (3.5, 6.5) | 3.0 (1.0, 5.0) | 1.0 (0.0, 3.0) |

[$]missing data in 10 participants, [#]missing data in 3 participants, [&]missing data in 18 participants,

*missing data in 5 participants

Figure 1 – Receiver operator characteristic curve analysis for the PEST, CONTEST and CONTESTjt questionnaires on 164 participants with psoriasis and no missing data (n=5 missing questionnaire data)




| Test | Score | AUC | Sensitivity | Specificity |
|---|---|---|---|---|
| PEST | 2 | 0.652 | 0.824 | 0.449 |
| | 3 | 0.652 | 0.529 | 0.660 |
| | 4 | 0.652 | 0.235 | 0.816 |
| CONTEST | 2 | 0.694 | 0.882 | 0.388 |
| | 3 | 0.694 | 0.765 | 0.565 |
| | 4 | 0.694 | 0.529 | 0.680 |
| | 5 | 0.694 | 0.353 | 0.816 |

| | | | | |
|---|---|---|---|---|
| CONTESTjt | 2 | 0.704 | 0.941 | 0.337 |
| | 3 | 0.704 | 0.765 | 0.531 |
| | 4 | 0.704 | 0.706 | 0.633 |
| | 5 | 0.704 | 0.412 | 0.735 |
| | 6 | 0.704 | 0.353 | 0.844 |