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Initial assessment of the early arthritis for psoriatic patients (EARP) diagnostic questionnaire in dermatology clinics in Australia, Korea and China

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ABSTRACT [Max 250 words. Current 250]

Objectives: To conduct initial assessment of the Early Arthritis for Psoriatic Patients (EARP) questionnaire for Australian, Korean and Chinese populations using translated and linguistically validated versions. To measure the proportion of patients with Psoriatic Arthritis (PsA) among patients with psoriasis who attended dermatology clinics.

Methods: Questionnaires were translated and culturally validated into Australian English, Korean and Chinese. A multicenter, observational, descriptive estimate of the proportion of patients with PsA among patients with psoriasis attending dermatology clinics in Australia, Korea and China was conducted. Initial assessments included evaluations of floor and ceiling effects, internal consistency (using Cronbach's alpha), test-retest reliability (using intraclass coefficient), and correlations between EARP score and rheumatology findings. If the initial EARP score was ≥ 3 , patients were assessed by a rheumatologist for PsA within 3-months of their re-test questionnaire.

Results: 250 patients participated. Translated EARP questionnaires showed satisfactory internal consistency and test-retest reliability. A potential floor effect was observed for the Chinese and Korean versions. Cronbach's alfa was 0.885 (Australian), 0.776 (Korean) and 0.789 (Chinese), indicating acceptable internal consistency. Intraclass correlation coefficients were 0.89 (Australian), 0.86 (Korean) and 0.87 (Chinese), indicating acceptable test-retest reliability. EARP summary scores had weak to moderate linear correlation with

the relevant PsA assessments. Overall, 32 (12.8%) patients were diagnosed with PsA based on Classification for Psoriatic Arthritis (CASPAR) score.

Conclusion: The Australian, Korean, and Chinese versions of the EARP questionnaire are suitable for the early detection of PsA symptoms in patients with psoriasis by dermatologists working in specialist dermatology clinics. **Trial registration:** NCT02470481.

Keywords: (up to 10) psoriatic arthritis, EARP, assessment, Australia, Korea, China

INTRODUCTION [MAX WORDS 3,500 exc abstract, tables, figures, acknowledgements, references and online only material. Current 3,237)

Psoriasis is a chronic inflammatory disease that mainly affects the skin, causing red raised plaque.¹ Up to 30% of patients with psoriasis will develop psoriatic arthritis, which manifests as fatigue, pain, stiffness and swelling of the joints, and may ultimately lead to joint destruction.¹ Typically patients with psoriasis first seek treatment for their skin condition, and then are referred to a rheumatologist as joint symptoms develop.² However, psoriatic arthritis (PsA) in patients with psoriasis is often overlooked. This may partially be because patients neglecting to tell their dermatologist about arthritis symptoms as they do not see the link between the skin symptoms and joint symptoms, because symptoms of PsA are in their early stages, or because inflammatory markers remain normal.² Unlike early rheumatoid arthritis (RA) where the majority of cases have anti-citrullinated protein autoantibodies, a specific marker is absent in early PsA. Therefore there is a greater reliance on clinical assessments in at risk groups. This has resulted in a search for reliable screening questionnaires. These all lead to delays in diagnosis of PsA. Delays in diagnosis of PsA can lead to irreversible joint damage, therefore early detection of PsA is important to prevent permanent disabilities.³

Given the potential benefits of treating PsA early, it is important to be able to identify patients with PsA among the patients who present at dermatology clinics for treatment of psoriasis. Several groups have developed screening tools for use in dermatology or general practice to ascertain those patients who might be at high risk for the development of PsA.⁴⁻⁹ More recently, a simple user friendly and easy to administer screening tool, the Early Arthritis for Psoriatic Patients (EARP) questionnaire was developed.² The EARP questionnaire is focused on early diagnosis of PsA and has a higher sensitivity than the Physical Activity Scale for the Elderly (PASE) and Psoriasis Epidemiology Screening Tool (PEST) questionnaires (albeit with low sensitivity).¹⁰ To date, the EARP questionnaire has been validated in Italian, Spanish, and Japanese.^{2, 11, 12} Cross-cultural validation of questionnaires

is required to ensure the questionnaire has semantic equivalence across cultures. In addition, validation in a real-world setting is important.

The purpose of this study was to test the cross-cultural validity of the EARP questionnaire for use in Australian, Korean and Chinese populations using the translated and linguistically validated versions. As a secondary objective, we measured the proportion of patients with PsA among patients with psoriasis who attended dermatology clinics participating in this study in Australia, Korea and China.

METHODS

Translation and linguistic validation of EARP questionnaire

The EARP questionnaire underwent translation and cross-cultural equivalence testing by translating the original Italian version into UK English, then translating from UK English into Australian English, Korean or Chinese. The Australian English version underwent in-country review, while the Korean and Chinese versions underwent dual independent forward and backward translations by two native speakers of the target language and two native English speakers. For cognitive debriefing, the translation was then tested by five subjects for each of the target languages who were resident in the target country. Following completion, a series of questions were asked gauging the comprehension of the wording of the translation. The translated surveys were also reviewed by two clinicians in the target country (a dermatologist and a rheumatologist) who were experienced in working with patients with psoriasis. Any issues arising from this cognitive debriefing were returned to the translator of the target language who adjusted the translation as needed. These translated surveys were then used in the assessment phase of the study.

Study population

This multicenter and observational study was conducted at 6 sites (2 in Australia, 2 in China, and 2 in Korea). Eligible participants were men or women aged 18 to 65 years inclusive who had an established diagnosis of psoriasis based upon clinical evidence and documented medical history.¹³ The patient had to be able to read and write in the target language (Australian English, Korean or Mandarin). All participants signed a written informed consent form prior to their enrolment in the study. Patients were excluded if they had an established diagnosis of psoriatic arthritis (as we were wanting to test the questionnaire's ability to detect early PsA); had ever received treatment with a disease-modifying antirheumatic drug for arthritis or spondylitis; had ever received systemic treatment with a biologic disease-

modifying antirheumatic drug for psoriasis; had a history of employment or current employment within the healthcare industry; or participated in the translation and linguistic validation of the EARP questionnaire. Those with a previous history or current employment in the healthcare industry were excluded from this study to minimize any potential bias in response to the EARP questionnaire. The chosen study population was identical to that used in the original validation study conducted by Tinazzi and colleagues,² except that in some cases the patients were recruited from stand-alone dermatology practices rather than a co-located dermatology and rheumatology practice. The study protocol and support materials were reviewed and approved by the relevant institutional ethics committee at each participating center.

Overall study flow

Following screening, participants were trained on the completion of the survey instrument (translated EARP questionnaire) by study staff, and then asked to complete the survey instrument in the target language using a recall period of 12-months. Four weeks after the initial survey, participants underwent re-testing with the survey instrument in the target language, again the recall period was 12-months. After the re-test survey administration, participants who recorded an EARP score of 3 or higher *at their initial assessment* were referred to a rheumatologist for full assessment. They were also referred for X-rays of hands or feet and clinical laboratory testing of C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), uric acid, cyclic citrullinated peptide antibodies (anti-CCP), and human leucocyte antigen subtype B27 (HLA-B27) before visiting rheumatologists. Results from up to three months prior to the retest visit were accepted for all required laboratory tests, with the exception of HLA-B27, where the results of any test ever performed were accepted.

Within 3 months of the re-test visit, a rheumatologist assessed the referred participants. At this visit, the rheumatologist took a medical history, conducted a physical examination, and reviewed the results of X-rays and blood tests. The rheumatologic assessment included a modified nail psoriasis severity index (mNAPSI) assessment,¹⁴ dactylitis assessment including history of the previous 6-months, 66/68-joint count for swollen and tender joints,¹⁵ and enthesitis assessment using the Leeds Enthesitis Index (LEI).¹⁶ Psoriatic arthritis was diagnosed based on the Classification Criteria for Psoriatic Arthritis (CASPAR) score.¹⁷ The participant flow throughout the study is shown in Figure 1.

All aspects of treatment decisions and clinical management of patients was in accordance with clinical practice, or at the discretion of the treating physician.

Statistical analysis for the assessment of EARP questionnaire

The assessment dataset consisted of all patients who signed an informed consent form and met all eligibility criteria. Only patients that underwent a rheumatology assessment following an initial EARP score of 3 or higher were included in the correlation assessment.

The floor and ceiling effect (the artificial lower and upper limit) of the EARP questionnaire, which is indicated by large proportions of patients with minimum or maximum values, were estimated with the cut-off as percentage of minimum and maximum values of 20% or more. The internal consistency of the EARP questionnaire was measured by Cronbach's coefficient alpha and test-retest reliability was estimated by using intraclass correlation coefficient (ICC). The correlation between the EARP score and the rheumatology assessment of questionnaire was tested using Pearson correlation coefficients.

The proportion of patients diagnosed with PsA based on CASPAR score was calculated for each target population. Physical examination results, mNAPSI results, clinical laboratory evaluations, dactylitis scores, interpretations of radiographic assessment, total tender and swollen counts, and LEI scores were summarized using descriptive statistics including floor and ceiling effect.

RESULTS

Translation and linguistic validation of EARP questionnaire

Translation and linguistic validation was satisfactory for all target languages. In all cases, complex terminology was clarified, such as 'Achilles tendon' and 'anti-inflammatory drugs'. All three translations to the target languages were considered appropriate, and culturally and linguistically valid.

Demographics and flow of participants

A total of 250 participants were enrolled, 50 Australian, 100 Korean and 100 Chinese (Figure 1). Participant demographics are provided in Table 1. There were 151 (60.4%) men, and the number of participants across 3 age groups; 18-35 (87, 34.8%), 36-50 (83, 33.2%), and 51-65 (80, 32.0%) years was similar. Across the three countries, participants were generally well matched with the exception of race. Most participants were Asian (201, 80.4%).

All participants (n=250) answered the initial EARP questionnaire, and 227/250 (91%) repeated the questionnaire after 4 ± 1 weeks. Of the 250 participants, 71 (28%) scored three or more on the initial EARP questionnaire and were referred for rheumatological

assessment, and 59 attended the rheumatology assessment. Twelve patients (2 Australian, 8 Korean, and 2 Chinese) withdrew early from the study.

Assessing the EARP questionnaire

Floor and ceiling effect: In Australian participants, the median EARP score was 5 (range 0 to 10) at baseline and 6 (0 to 10) at follow-up. In Korean and Chinese, respectively, median scores of 1 (0 to 8) and 0 (0 to 7) were reported at baseline and similar score of 1 (0 to 9) and 0 (0 to 6) at follow-up. With the cut-off as percentage of minimum values $\geq 20\%$, no floor effect was observed for the Australian population at baseline and follow-up (14.0% and 19.1%, respectively). However, more than 20% of Korean and Chinese patients reported minimum values at both baseline (49.0% and 70.0%, respectively) and follow-up (44.2% and 73.7%, respectively). No ceiling effect was observed at baseline or follow-up for any of the populations. In particular, Australians tended to report greater joint pain (74% of patients) compared to those from China (23%) or Korea (54%). They also reported more swelling in their wrists or fingers (66%) compared to China (15.2%) and Korea (45%). The distribution of individual item scores for each country are shown in **Supplementary Table 1**.

Internal consistency: All survey instruments showed acceptable internal reliability (Cronbach's $\alpha \geq 0.70$).¹⁸ Cronbach's α was 0.885 for Australian, 0.776 for Korean and 0.789 for Chinese EARP total scores. Overall the standardized Cronbach's α was 0.872.

Test-retest reliability: Thirty-seven Australian, 63 Korean, and 83 Chinese patients were included in the analysis. The overall ICC for 183 patients was 0.92 (95% CI: 0.89 to 0.94). All populations recorded an ICC greater than 0.8: Australian (0.89 [95% CI: 0.80 to 0.94]), Korean (0.86 [95% CI: 0.78 to 0.91]), and Chinese (0.87 [95% CI: 0.81 to 0.91]), indicating the translated EARP questionnaires show high test-retest reliability.

Correlation between total EARP questionnaire score and the rheumatology

assessment: Pearson's correlation coefficient was calculated by correlating the total EARP question score for each target population with the relevant PsA assessments collected by the rheumatologist (Table 2). The EARP summary scores for Australian patients showed a moderate linear correlation with total swollen joints assessment. The EARP summary scores for Korean patients showed a moderate positive linear correlation with total tender joint assessments and LEI summary scores. The EARP summary scores for Chinese patients showed a strong negative linear correlation with dactylitis history and assessment summary score. All other correlation scores were <0.4 (Table 2), indicating the lack of strong

correlation between the EARP summary scores and the relevant PsA assessments. Correlations for individual item scores were conducted (**Supplementary Table 2**), however, no consistent strong correlation was observed between the score of any EARP question and the relevant PsA assessment in the 3 populations.

Clinical characteristics of participants referred for rheumatological assessment

The clinical characteristics of patients referred for rheumatological assessment are presented in Table 3. Although 71 patients had EARP scores over 3, only 59 underwent rheumatological assessment as they withdrew early (lost to follow up or withdrew consent) from the study (Australia n=2, Korea n=8, China n=2). Of them, nail involvement, dactylitis, and enthesitis were found in 33/59 (non-zero NAPSI score), 7/59, and 30/59 participants, respectively. Nail involvement was more common in Australian patients. Dactylitis scores were consistent with an absence of finger or toe tenderness in most patients. One patient had a total dactylitis score of 30 (the maximum score), which was consistent with the physical examination. Few radiographic abnormalities were observed, and there were low median numbers of swollen and tender joints. Severe enthesitis (LEI $\geq$ 4) was observed in 9/59 and was more common in Australian patients (n=6). Finally, 32 (13% of the study population) were diagnosed with PsA based on CASPAR criteria: 18 (36%) Australians, 8 (8%) Koreans and 6 (6%) Chinese (Figure 2).

DISCUSSION

The Australian, Korean, and Chinese versions of the EARP questionnaire are suitable for the early detection of patients with PsA by dermatologists working in specialist dermatology clinics. The EARP questionnaire has previously been validated for use in Italian, Spanish and Japanese populations.^{2, 11, 12} In the Italian and Japanese versions, a score of 3 or more was suggested as a cut-off value to identify PsA, while in the Spanish version a score of 4 or more was proposed.^{2, 11, 12} In our versions, a score of 3 or more was used, in line with the original questionnaire and receiver-operator curve analysis.² In the Australian population, none of the patients with an EARP score of 3 or 4 were diagnosed with PsA based on CASPAR criteria, in contrast to the Korean and Chinese populations. The false positive rate was higher than in the originally reported 22.3% for the overall population. Of the patients with an initial EARP score of 3 or higher, 11/29 (38%) Australian, 25/33 (75%) Korean, and 3/9 (33%) Chinese patients were not subsequently diagnosed with PsA. A false negative rate could not be calculated as participants with EARP scores of zero to two were not referred for rheumatological assessment. Previously, the false negative rate associated with the EARP questionnaire was reported as 3.5%.²

It is well recognized that patients with psoriasis may have painless dactylitis or joint swelling, or imaging features of PsA despite no history of joint symptoms. Screening questionnaires, including the EARP, although not perfect, are designed to facilitate Dermatologists in the recognition of early PsA, and the questions deal mostly with joint symptoms. The questionnaire ensures that patients have their musculoskeletal symptoms assessed (including their pain). It is unusual for patients to present with significant dactylitis in the absence of pain. In the original validation using 386 patients, none of the 14 incident PsA patient presented with dactylitis.² From a practical perspective, around a third of patients with psoriasis have positive screening questionnaires and given how common psoriasis is, it would be impossible to have all cases evaluated by an expert Rheumatologist. Therefore, the EARP and other questionnaires are predominantly used to facilitate the recognition of PsA in symptomatic psoriasis cases. Accordingly, we used this real-world Dermatology clinic strategy and did not evaluate cases that failed to reach the cut off.

In this study, the EARP questionnaire was translated based on the systematic translation process presented in the previous studies, that consists of forward and backward translation, reconciliation, cognitive debriefing, feedback, and final proof-reading.¹⁹ The purpose of systematic translation was to preserve the validity of the questionnaire itself and to maintain conceptual identity with the original text. The translated EARP questionnaires in Australian English, Chinese, and Korean showed similar internal consistency to the previous reports (Cronbach's alpha 0.83 in the original Italian study and 0.776 in the Spanish study). Test-retest reliability was also satisfactory, indicating the questionnaires have stability over time. Thus, the translated EARP questionnaires could be applied to patients using the target languages with good reliability.

Of interest to our assessment were the differences in floor and ceiling effects observed in our populations. The Chinese and Korean language questionnaires indicated a potential floor effect based on the high percentage of minimum scores (that is, there was a skewed distribution of the scores, with a high percentage of minimum scores observed in these populations). Whether there were cultural differences in responses to the questionnaire and difficulties in translation, or whether there were true differences in the PsA disease experienced in Korean and Chinese patients compared to Australian patients is not clear. We may assume the cultural difference and difficulties in translation very cautiously, considering together with the finding that some patients with high EARP score were not diagnosed with PsA in Korea while only patients with low EARP score were not diagnosed in Australia. However, consistent floor effect observed at both baseline and retest visit implies that the patients enrolled in China and Korea had a lower occurrence of PsA. Further, this

skewing of the data in the Chinese and Korean populations may help to explain the lower estimates of reproducibility observed for these populations.

The EARP summary scores had weak to moderate linear correlation with the relevant PsA assessments. This is partially because we targeted patients with undiagnosed PsA in this study and thus most of the patients referred to rheumatologists had early PsA or no PsA. In addition, the difference in the performance of EARP may be due to the different pattern of psoriatic arthritis between countries. EARP identifies patients with active arthritis, with Achilles tendinitis and dactylitis. Among the patients referred for rheumatologic assessment in this study, the number of swollen joints and even LEI score were generally higher in Australian than in Korean and Chinese, that was consistent with the previous study reporting that spondyloarthritis is most common and dactylitis and enthesitis are less common in Korea.²⁰ In the EARP questionnaire, only one question asks about back pain.

Our study found low proportions of patients diagnosed with PsA based on CASPAR criteria amongst Korean (8%) and Chinese (6%) patients compared to Australian (36%) patients with psoriasis. There is wide variation in the reported prevalence of psoriasis in different countries.^{21, 22} Previous studies have reported the prevalence of psoriasis to be 2.6% in Australia²¹ and 0.4% in China.²¹ Among those with psoriasis, between 6 and 42% of Caucasian patients are reported to have psoriatic arthritis, while the proportion of Asian people with PsA appears to be lower (between 1 and 9%).^{20, 22} This is consistent with our findings. The reasons for these differences remain unclear but may be due to differences in genetics between the populations. PsA in Caucasian patients was reported to be associated with HLA-B16, -B17, -B27, and Cw6, however, HLA-B27 was not associated with PsA in Korean patients.²² Alternately, it may reflect the difference in the prevalence of obesity between the three countries, the Australian prevalence being almost double that in Korea and China.²³ Obesity has been linked to an increase in inflammatory cytokines IL-6 and TNF α , leading to a pro-inflammatory state.²⁴ It is postulated that obesity-related systemic inflammation may become localized at the joints or entheses, particularly in PsA.²⁴ It is unlikely that the difference in prevalence is due to differences in awareness of PsA in the Asian population.

Despite the differences in proportion of patients diagnosed with PsA between countries, detection of undiagnosed PsA is likely to prevent irreversible joint damage. In addition, early diagnosis and management of PsA can reduce the medical burden of patients since PsA is associated with obesity, hypertension, type 2 diabetes, the metabolic syndrome, and an increased risk of cardiovascular events.²⁵

This study was not powered to assess the epidemiology of psoriasis or PsA, and therefore the proportion of patients presenting with psoriasis that are diagnosed with PsA may not be generalizable. Further, patients attending specialist clinics may not be representative of patients presenting with psoriasis. We excluded patients who had ever been prescribed a biologic agent. However, EARP and other screening questionnaires are designed to be used annually for all patients with PsA regardless of prior treatment. The highest risk of developing PsA is during the first 10 years when many patients are receiving treatment (including biologic treatment) for psoriasis. Since treatment may mask the symptoms of PsA, it is more difficult to diagnose in these patients. By excluding these patients the questionnaire may appear more effective than in a real world setting. Additionally, in the real world, patients who are negative for PsA on the screening questionnaire are not referred to a rheumatologist. Without this data it is not possible to assess the sensitivity or specificity of the questionnaire or make comparison to other validation studies. This is a major limitation. Further, other studies have reported very low sensitivity with PEST, PASE and ToPAS assessments in patients with psoriasis attending dermatology clinics.²⁶ Finally, full psychometric testing has not been conducted, due to the limited sample size. A study with a larger number of patients that includes a full validation including an assessment of construct validity is warranted.

CONCLUSION

The Australian, Korean, and Chinese versions of the EARP questionnaire are suitable for the early detection of patients with PsA by dermatologists working in specialist dermatology clinics. Furthermore, this study suggests lower frequency of PsA in Korean and Chinese patients with psoriasis than Australian patients. Further research is required to evaluate the EARP questionnaire in a more generalized setting, to explore the effects of psychology (depression and anxiety), and the cultural differences upon the EARP scores.

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FIGURE LEGENDS

Figure 1: Participant flow in the study

Note: While 45 Australian, 84 Korean and 98 Chinese attended for a follow-up visit for retest, only 37, 63 and 83, respectively had two assessments of EARP, and therefore, only these patients were included in the Test-Retest analysis.

Figure 2: Number of patients diagnosed with psoriatic arthritis by EARP score and country (for EARP scores of 3 or higher). Note that only patients with EARP scores of 3 or more were assessed by a rheumatologist.

TABLES

Table 1: Participant demographics

	Overall	By Country			
		Australian	Korean	Chinese	P-value
Number of subjects	250	50	100	100	
Age at screening (years), mean (SD)	42.6 (13.14)	44.1 (13.29)	43.4 (13.75)	41.0 (12.39)	0.30
Age groups (years), n(%)					0.06
18 – 35	87 (35%)	13 (26%)	33 (33%)	41 (41%)	
36 – 50	83 (33%)	20 (40%)	27 (27%)	36 (36%)	
51 – 65	80 (32%)	17 (34%)	40 (40%)	23 (23%)	
Sex					0.13
Female	99 (40%)	22 (44%)	45 (45%)	32 (32%)	
Male	151 (60%)	28 (56%)	55 (55%)	68 (68%)	

	Overall	By Country			P-value
		Australian	Korean	Chinese	
Race, n(%)					<0.001
White	37 (15%)	37 (74%)	-	-	
Asian	201 (80%)	1 (2%)	100 (100%)	100 (100%)	
Not reported	12 (5%)	12 (24%)	-	-	

Table 2: Convergent / discriminant validity by country – per EARP summary score

Country	Pearson correlation coefficient			
	Total tender joint assessment	Total swollen joint assessment	Dactylitis history and assessment summary score	LEI summary score
Australian (n =27)	0.24	0.47	0.11	0.33

Korean (n =25)	0.43	-0.13	*	0.46
Chinese (n =7)	0.36	0.34	-0.67	-0.34

* All dactylitis scores were 0 for Korean subjects, thus the correlation coefficient cannot be calculated.

Table 3: Clinical characteristics of patients sent for rheumatological assessment

	Australian (n=27)	Korean (n=25)	Chinese (n=7)	Overall (n=59)
Age, years, mean (SD)	46.2 (14.4)	45.9 (13.4)	45.7 (14.9)	46.0 (13.8)
Sex, n (%)				
Female	14 (51.9%)	17 (68.0%)	4 (57.1%)	35 (59.3%)
Male	13 (48.2%)	8 (32.0%)	3 (42.9%)	24 (40.7%)
*mNAPSI, median (min, max)	6.0 (0, 29)	1.0 (0, 49)	0.0 (0, 29)	2.0 (0, 49)
Dactylitis assessment score, median (min, max)	0.0 (0, 30)	0.0 (0, 0)	0.0 (0, 3)	0.0 (0, 30)
Clinically significant abnormalities on radiographs, n (%)	1 (3%)	0 (0%)	1 (11%)	2 (3%)
68-joint count for tenderness, median (min, max)	2 (0, 22)	0 (0, 68)	3 (0,14)	0.5 (0, 68)
66-joint count for swelling, median (min, max)	1 (0, 21)	0 (0, 1)	1 (0,3)	0 (0, 21)
LEI, median (min, max)	2.0 (0, 6)	0.0 (0, 4)	0.0 (0, 3)	1.0 (0, 6)

LEI: Leeds Ethesitis Index; mNAPSI: modified nail psoriasis severity index; SD: standard deviation

Australia

Korea

China

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Title:

Initial assessment of the early arthritis for psoriatic patients diagnostic questionnaire in dermatology clinics in Australia, Korea and China

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