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Validation of the electronic PASI application: establishing measurement equivalence

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Conflicts of Interest

FA has received travel expenses for attending AAD meetings from Janssen-Cilag Limited. FA has received lecture fees from Leo Pharmaceuticals.

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Despite its many shortcomings, the Psoriasis Area and Severity Index (PASI) remains the standard method worldwide for psoriasis assessment[1]. Several studies have implemented electronic versions without evidence of formal validation, raising the possibility of lack of equivalence with the paper counterpart[2]. This study aimed at comparing the conventional paper-based and a novel electronic application version of the PASI (Figure 1). International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines[3] were followed to assess rater preference and consistency of scores.

The study employed a randomized cross-over design using a within-subjects comparison of the two formats of the PASI. The study was conducted at the dermatology outpatient department, University Hospital of Wales, Cardiff, UK. Inclusion criteria were: patients aged 18 years or older with a clinical diagnosis of chronic plaque psoriasis from a dermatologist and the ability to read and understand English. Raters ranged from medical students to senior trainees and received standardised clinical training for PASI assessment to ensure uniformity of rating. The study power was 80%, with an expected intra-class correlation coefficient (ICC) of 0.9 ($\alpha = 0.05$), resulting in a target sample size of 44 patients.

All three raters showed high correlation in test scores (Pearson-correlation 0.949, $p<0.05$, $n=5$) demonstrating standardisation of the assessment criteria. Forty-four patients were recruited, mean age 45 years (SD ± 16, 59.1% male). The mean duration of chronic plaque psoriasis diagnosis was 19.2 years (SD ± 14.8, interquartile range, IQR, 8-30), with PASI severity ranging from 0.7 to 28.5. The ICC showed high concordance between the total PASI scores from paper and iPad

format (ICC = 0.993; 95% CI 0.988-0.996, Table 1). The median difference in PASI scores was also within the hypothesized difference of CC = 0.993 (p=0.72). The lower and higher limits of agreement were -1.4 and 1.4, respectively.

The PASI iPad® version demonstrated reduced inter-rater variability compared to the paper version (Pearson correlation 0.982 vs 0.949, number of patients assessed=5). There was no carryover effect demonstrated with scores (p=0.82) or time to completion (p=0.16) regardless of which format of the PASI was used first. The raters, using a stopwatch, took a median of 147 seconds (iPad®) versus 152 seconds (paper), not including calculation time (p=0.81). Raters reported that the iPad version was easier to use compared to the paper version due to the visual nature of the application allowing accurate assessment and calculation of severity scores, though suggestions were made to improve the user interface.

The future of medical practice is intricately anchored within the evolution of digital technology. There is high correlation, and thus equivalence, between the PASI iPad® and paper versions. The raters preferred the iPad version due to the visual nature of the scoring process and the reduced likelihood of calculation errors. The higher inter-rater reliability and the inherent advantages of electronic tools[4] further re-enforces the superiority of the digital format. The validated Psoriasis 360 application©, together with the previously validated DLQI[5] component, has the potential to be of considerable value to clinicians, researchers and patients.

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TABLES

Table 1 Equivalence analysis of paper and electronic PASI overall mean scores and mean completion time

	Paper	iPad®	ICC* (95% CI)	Difference (P – I)	Limits of agreement‡	
PASI scores (n=104)					lower	upper
Median (IQR)	5.7 (2.1-10.7)	5.8 (2.7-9.3)	0.993 (0.988 – 0.996)	0.0 (-0.3 – 0.4)†	-1.4	1.4
PASI times (mins:seconds)						
Median (IQR)	2:32 (01:55-03:07)	2:27 (01:54-03:00)	0.444 (0.148 – 0.665)	-00:10 (-00:31-00:40)†		

CI = confidence interval, ICC = intraclass correlation, IQR = interquartile range, SD = standard deviation
P-I = Paper - iPad®

* Hypothesizing coefficient of ≥ 0.9

† p value > 0.05 calculated by Wilcoxon Signed Rank test

‡ Limits of agreement calculated from Bland-Altman plots

Figures

Figure 1 Example screenshot from the PASI iPad App