ASSESSING THE EQUIVALENCE OF ELECTRONIC AND PAPER DATA COLLECTION OF BRIEF PAIN INVENTORY (BPI) DATA IN RHEUMATOID ARTHRITIS

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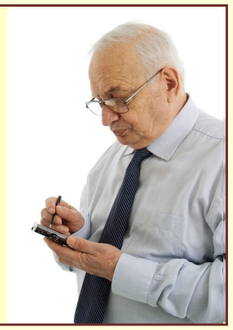
Electronic Patient-Reported Outcomes (ePRO)

- Improved, documented compliance with protocol
- Time-stamping helps ensure data integrity
- Rapid review of results
- Acceptable to patients – often preferred to paper



Migration

When an instrument has been migrated from a validated paper version to ePRO, it is necessary to review the changes and assess their implications for data equivalence.

Brief Pain Inventory (BPI)

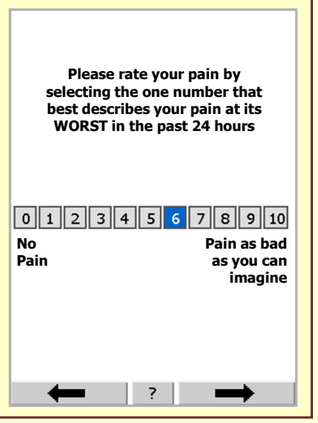
The BPI has four questions rating pain (worst, least, average over the past 24h, and pain right now); a question on pain relief; and seven questions asking about how much pain has interfered with general and specific abilities. All questions except pain relief are rated on a 0-10 numeric rating scale. Here is the question on worst pain

2. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10

No Pain — Pain as bad as you can imagine

When migrating to a device with a small screen, such as a personal digital assistant (PDA), it is necessary to present the questions one per screen. There is considerable evidence from equivalence studies indicating that the change to presenting a single question at a time does not in general affect the data collected (see e.g. Gwaltney et al., 2008). The ePRO implementation of the Worst Pain question on the PDA is shown on the right. The patient taps on the desired choice, which highlights, and then taps => to move to the next question.



The Study

Forty-three patients (12 male, 31 female) with a diagnosis of rheumatoid arthritis took part in the study. They were aged between 32 and 83 years, with 25 (58%) being under 60, and 18 (42%) being 60 or over (median age 57). Patients were excluded if they had any condition other than RA likely to cause pain or fatigue, to affect quality of life, or to impair functioning. They took part in a two-period within-subjects design comparing electronic (E) and paper (P) modes. Patients took part in a single session in which they completed a set of scales, including BPI, in the first mode, then in the second mode, with an interval of 45 min in between. Half the patients completed E then P, half P then E, in randomised order. Electronic assessments were carried out on a Palm TX (screen size 75 X 55 mm). Patients also completed a final questionnaire which included questions on acceptability of the questionnaires and mode preference.

A composite index was calculated as the mean of the four BPI pain items (worst, least, average, and pain now). Agreement between modes was assessed using the intraclass correlation coefficient (ICC) exact agreement form (2,1 as defined by Shrout and Fleiss, 1979) and mean differences, for the composite index and for individual items.

Results

Data for the agreement between E and P are shown in the Table. The E-P differences rescaled as effect sizes (ES) are shown in the Figure. All ICCs were at least 0.75, the a priori criterion for excellent agreement (Gwaltney et al., 2008). All mean differences were less than an ES of ± 0.2, and confidence intervals were completely contained within a range of ES of ± 0.4. Bland-Altman plots are shown for two BPI items in Figures 2 and 3.

All patients found both modes acceptable. More patients preferred E (53%) than preferred P (14%) and this was true for the older patients and those less familiar with technology as well as for the younger.

Discussion

The values for ICC found here are in the same range or higher than those seen for paper-paper retest reliability. For example, Daut et al (1983) reported retest correlations of 0.93 for worst pain and 0.59 for pain now over a one-week period, while Williams et al. (2006) reported ICCs of 0.81 for a composite interference score and 0.65 for sleep, also over a one-week period.

Bland-Altman plots did not indicate any problems with scale equivalence. Variability of scores was lower closer to zero for the composite index.

A number of previous studies have shown that ePRO scales are acceptable to patients, who often prefer them to paper. Previous work has also shown that acceptability and preferences are similar in older patients and those who are not familiar with computers (see e.g. Drummond et al., 1995; Ring et al., 2008).

Agreement between paper and electronic assessments

Item or Subscale	N	Paper Mean	Paper S.D.	Electronic Mean	Electronic S.D.	ICC
Composite Index	42	3.55	2.03	3.74	2.056	0.931
Worst Pain	42	4.45	2.44	4.41	2.36	0.873
Least Pain	42	2.69	2.04	3.07	2.13	0.793
Average Pain	42	3.83	2.06	4.05	2.15	0.816
Pain Now	42	3.24	2.17	3.45	2.35	0.912
Pain Relief (%)	42	57.9	29.1	57.1	28.7	0.932
Activity	42	4.14	2.94	3.98	3.06	0.871
Mood	42	3.33	3.01	3.14	2.88	0.890
Walking	42	4.52	3.02	4.17	2.86	0.767
Work	42	4.60	3.08	4.24	3.05	0.803
Relations	42	2.64	2.80	2.95	2.89	0.791
Sleep	42	3.76	3.05	3.76	3.43	0.873
Enjoyment	42	3.45	3.08	3.14	3.17	0.837

Figure 1

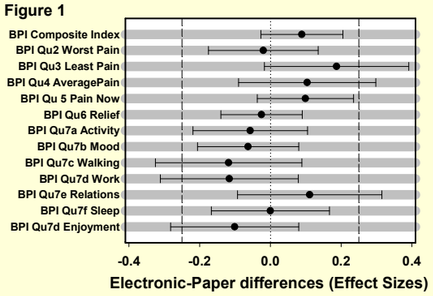


Figure 2: BPI Composite Index

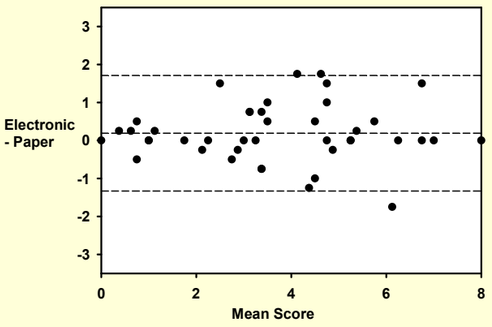
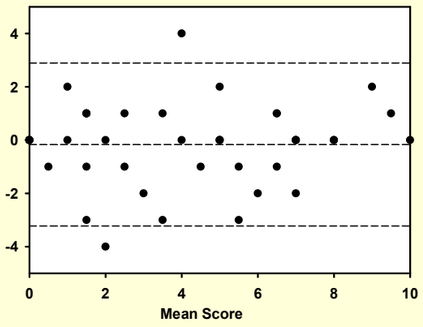


Figure 3: BPI Interference with Activity



Conclusion

These results support the validity of the PDA version of the BPI, and confirm that the electronic version is suitable for use in a wide range of patients

References

Daut et al. (1983) Pain 17:197
Drummond et al. (1995) Quality of Life Research 4:21
Gwaltney CJ et al. (2008) Value in Health 11:322
Ring et al. (2008) The Patient 1:105
Shrout & Fleiss (1979) Psychol. Bull 86: 420
Williams et al. (2006) J Pain Sym Man 31:48

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