Usability of an innovative and interactive electronic system for collection of patient-reported data in axial spondyloarthritis: comparison with the traditional paper-administered format

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Abstract

Objective. To evaluate the validity, in terms of the patients’ acceptance, preference, feasibility and reliability of an innovative, interactive computerized system for collection of patient-reported outcome (PRO) data on axial SpA against the paper-and-pencil version.

Methods. Fifty-five patients with axial SpA completed both the touch screen and the paper-and-pencil set of questionnaires. A computerized touch-screen system, SPEAMonitor, was developed to capture PRO data. Variables recorded included demographic data, patient’s assessment of general health status, BASDAI, BASFI, BASMI and acute-phase reactant levels. In order to assess the patient’s acceptance of, preference for and feasibility of computer-based questionnaires, the participants filled in an additional questionnaire. The time taken to complete both formats was measured. In a further test-retest study, 25 patients were re-evaluated.

Results. The agreement between the paper-administered and computer touch-screen format of the BASFI, BASDAI questionnaires and the Ankylosing Spondylitis Disease Activity Scores was excellent. Intraclass correlation coefficients (ICCs) between data ranged from 0.90 to 0.96. Additionally the test-retest study showed a very good agreement between the scores for the two administrations (ICC ≥ 0.90). Age, computer experience and education level had no significant impact on the results. The computerized questionnaires were reported to be easier to use. The mean time spent completing the questionnaires on a touch screen was 5.1 min and on paper 7.9 min.

Conclusion. Our newly developed computer-assisted touch-screen questionnaires for PRO in axial SpA were well accepted by patients, with good data quality, reliability and score agreement.

Key words: axial spondyloarthritis, SPEAMonitor, patient-reported outcomes, touch screen, electronic data capture, self-administered questionnaires.

Introduction

SpA is a group of chronic inflammatory diseases that share certain genetic predisposing factors and clinical features [1]. Patients with predominantly axial SpA involvement have a progressive experience of inflammatory back pain with a reduction of physical functioning and health-related quality of life (HRQOL) over time [2]. Assessment of axial SpA is currently carried out through endpoints emphasizing disease activity, function and evaluation of spinal mobility [3, 4]. To measure these domains at present, there are three reliable, valid and sensitive-to-change instruments recommended by the Assessment of SpondyloArthritis international Society (ASAS) [4, 5]; the BASDAI [6], which measures disease activity; the BASFI [7] and the BASMI, which evaluates functional status and spinal and hip mobility, respectively.
[8]. More recently, a new composite disease activity score, the Ankylosing Spondylitis Disease Activity Score (ASDAS), has been developed by the ASAS to provide a composite measure that could reflect global disease activity in AS [9, 10].

Patient-reported outcome (PRO) data are playing an increasingly key role in the evaluation of symptoms, HRQOL and medication compliance monitoring. Most of these have been tested and validated by using paper-administered questionnaires, which can be associated with some practical disadvantages, such as difficulty in distributing questionnaires among patients and the collection of data. Moreover, it requires manual data computation, which is time consuming and can be a source of error [11, 12].

In the last few years the ongoing evolution of computer software and technology has greatly improved the ability to satisfy the clinical requirements of PRO assessment. The benefits of computerized collection of questionnaire data have been emphasized by several researchers [12–22].

The increasing importance of electronic PRO (ePRO) is evidenced by the US Food and Drug Administration’s (FDA) issuance in December 2009 of Guidance for Industry PRO Measures: Use in Medical Product Development to Support Labeling Claims (http://www.biomedsys.com/images/PDF/ePROguidance.pdf) and by the OMERACT group [23]. However, it has been suggested that investigators need to evaluate equivalence when PRO measures are transferred from paper to computer, because validation testing is required to ensure that the computerized version of the measurement is equivalent to the paper measurement [22; 23].

Taking this information into account, the goal of this study was to evaluate the usability (in terms of patients’ acceptance, preference, feasibility and reliability) of an innovative, interactive electronic system for the collection of clinical data from patients with axial SpA. This type of innovation could benefit patients, clinicians and health care agencies by reducing errors, bias and redundancies, minimizing the time required to complete comprehensive assessments and improving documentation.

Methods

Patients

Patients with predominantly axial SpA [24] were invited to complete both the traditional paper-and-pencil format and the electronic touch-screen computerized version of the BASFI and BASDAI questionnaires and general health status numerical rating scale (NRS). In order to avoid an impact on the time taken, both modalities of questionnaires were administrated adopting a random procedure.

Patients <18 years of age and with a mental or physical disability were excluded from the study. Prior to proceeding with compilation of the electronic touch-screen computerized questionnaires, all patients received a brief information and training session to familiarize them with the electronic system. In addition, a real-time trained facilitator was available on the system to provide assistance if needed. In order to avoid any type of compilation bias, questionnaires were filled out in a separate, quiet room with a 60-min break between the two assessments and patients were unable to see their prior scores. The wording of the questions of the touch-screen computerized system was identical to that for the paper-and-pencil format. No information was supplied beforehand, but a readily available instructor was present to provide tutoring on demand. The questions and animations of the electronic system were presented in Italian.

To assess the patient’s acceptance of, preference for and feasibility of computer-based questionnaires, the participants filled out an additional questionnaire. The patient’s acceptance was established by asking the following questions: (i) ‘The touch-screen format combines cartoon, writing and voice. How did feel about that?’ and (ii) ‘The touch-screen format presents only one question at a time. How did you feel about that?’ There were three possible answers to these two questions: (a) ‘is informative/helpful’, (b) ‘is indifferent’ and (c) ‘is irritating’. Following the suggestions of Bischoff-Ferrari et al. [25], the patient’s preference was established by asking ‘Which version is preferable?’ There were three possible answers to this question: (a) ‘paper’, (b) ‘computer’ and (c) ‘no difference’. Finally, feasibility was evaluated by the time taken to complete the paper-administered format, which was recorded by a research assistant using a stopwatch, while the time taken to complete the touch-screen format was recorded by the software time registered on the computer. All subjects gave informed consent to participate in the study, which was performed according to the criteria of the Helsinki Declaration and approved by the local institutional research ethics committee (Comitato Etico dell’Azienda Sanitaria Unica Regionale di Ancona).

Key features of touch-screen tablet PC software and questionnaires

We developed a multimedia touch-screen tablet application, SPEAMonitor, according to the requirements for designing handheld computer systems for electronic collection of patient’s diary and questionnaire data [26, 27]. Technical details regarding the computer and software are described in the supplementary data available at Rheumatology Online.

The following are the key features of the SPEAMonitor that make it user friendly for subjects: (i) presentation of each question individually on one screen with both visual (cartoon) and auditory stimuli, (ii) voice and text synchronization, which allows subjects to follow the audio-visual playback with relative ease and (iii) replay buttons for the question stem and individual response options so that subjects may listen to these without repeating the entire question. The questions are answered by touching one of the 11 radio buttons of the NRS on the screen. This may be done with a pen or by hand (Fig. 1). The programme automatically goes ahead to the next question after receiving a response. It was not possible to leave a question unanswered. Each question had to be
completed before the computer continued to next screen. Questions included in the touch-screen tablet were strictly matched with the paper-format questions. The database (patient data) was stored on a web server and results were visualized on the website (http://www.speamonitor.net). The patients’ variables recorded in SPEAMonitor included the following information: demographic data, disease duration and the patient’s 11-number button NRS format for general health status (GH, 0–100), BASDAI and BASFI score [6, 7]. In addition, the SPEAMonitor comprises a database for data processing and storage of objective measures of spinal mobility, such as BASMI [8] and laboratory findings (ESR and CRP).

The paper formats of the BASFI and BASDAI, in Italian and previously validated [28], were employed in this study. Spinal mobility was assessed by the physician by using the BASMI [8]. The ASAS has suggested using the BASMI as one of the measures of their core set for spinal mobility assessment in AS [29]. We adopted the recently proposed 11-grade definition of the BASMI (based on the 10-step definition) due to its greater responsiveness [30]. Its range is 0–10, with higher scores representing greater spinal mobility impairment. The clinimetric properties of these instruments have been shown to be adequate [28, 31–34]. Further, ASDAS composite indices can be calculated automatically by an electronic application and can be displayed by the rheumatologist after website synchronization.

Statistical analyses
Data recorded in a tablet PC were transferred through a wireless local area network to a computer and subsequently imported as an Excel file into MedCalc, version 11.1 for Windows XP, for analyses. Paper data were entered manually into the database. We chose to calculate and display both parametric and non-parametric statistics for all questionnaires because not all data met the requirements of being normally distributed and/or continuous. To check for significant systematic differences in test-retest administration, paired Student’s t-tests and intraclass correlation coefficients (ICCs) with 95% CIs for mean values were employed. An ICC >0.75 was considered relevant [35, 36]. After a 1-week interval patients were asked by the same data collector to repeat all of the touch-screen computerized outcome measures, without having access to any previous ratings. Because it was possible for a patient’s condition to change over a 1-week interval, a global rating-of-change questionnaire was concurrently administered to the subjects. This so-called transition questionnaire investigated the patient’s current health status compared with that when the first questionnaire was completed (Question: ‘Compared to when you completed the questionnaire regarding your health status a week ago, how is your health now?’). Possible response options were ‘much better’, ‘slightly better’, ‘no change’, ‘slightly worse’ or ‘much worse’. Subjects who reported no change were considered stable and those who reported a change were eliminated from this analysis. In this study test–retest reliability was analysed in a group of 25 patients who reported no change in their health. To assess reproducibility dichotomously, the smallest detectable difference (SDD) of each instrument on each scale was calculated (Table 1). The SDD is 1.96 S.D. of the difference between the scores, as well as a paired t-test and the ICC with 95% CI. We computed the SDD to assess agreement between scores of the touch-screen computer method and paper-and-pencil version. Agreement between scores was also illustrated by Bland–Altman plots, in which the difference between scores was plotted on the y-axis against the average of scores on the x-axis [37]. The Spearman correlation coefficient was used to assess associations between computer skills and differences between questionnaire versions. User preference, ease of use and patient characteristics were analysed using descriptive statistics. Patient characteristics of participants were compared using chi-square and Fisher’s exact tests. The level of statistical significance was set at <0.05 (two-sided).

Results
Patient acceptance, preference and feasibility
Of a total of 70 patients with axial SpA who were invited, 55 (45 males and 10 females) agreed to participate in the study. The patients’ ages ranged from 34 to 63 years (mean 51 years). Disease duration ranged from 3 to 14 years, with a mean of 6 years. With respect to their employment status and level of education, 47 of 55 patients (85.4%) were employed and 13 of 55 (23.6%) had only completed elementary school. The most common reasons for refusing to participate in the study were the following: difficulty in being available for the follow-up visit (n = 5), unavailability of a PC, inability to attend scheduled appointment (n = 2) and lack of computer experience (n = 2). When we asked subjects specifically about two features of the two formats, 50 of 55 (90%) of these thought that the combination of cartoon, writing and voice in the computer format was informative and helpful, 4 patients (7.2%) were undecided, and 1 patient (1.8%)
was irritated. Thirty-eight of 55 patients (69.1%) stated that it is informative and helpful for the computer format to present only one question at a time, while 16 patients (29.1%) had no preference and 1 patient (1.8%) was irritated. Moreover, 46 of 55 patients (83.4%) preferred the computer to the paper format, 2 patients (3.6%) were undecided and 7 patients (12.7%) had no preference. The mean time spent completing the questionnaires on a touch screen was 5.1 min (range 4.3–8.6 min) and on paper 7.9 min (range 5.8–9.9 min). The difference was slightly significant (Student’s t-test = 0.04). Also, despite the presence of an instructor during the trial, no patients required any tutoring related with the touch-screen versions of the questionnaires. Computer skills, age and/or education exerted no impact on differences between questionnaire versions; we found an unsystematic pattern of non-significant rho correlations ranging from 0.09 to 0.34 (P-values > 0.05).

Agreement between touch-screen and paper scores and test–retest reliability

There was good comparability of touch-screen and paper scores (Table 1). There were no significant differences between mean touch-screen and paper-and-pencil scores for the BASFI and BASDAI (Student’s t-test significance = 0.92 and 0.25, respectively) and ICCs were 0.90 and 0.94, respectively. Based on mean ASDAS differences, there was no significant difference between the paper and the touch-screen version (Student’s t-test significance = 0.24 and 0.06, respectively). Agreement, assessed by the ICC, was excellent (ICC = 0.95 and 0.96, respectively). The difference between the two formats was plotted against the paper format as a gold standard to further illustrate the differences between formats by subscale in individuals. According to Bland–Altman analysis, there was no systematic error in the BASDAI and BASFI and in either of the ASDASs (Fig. 2). There was highly significant agreement between the paper and touch-screen measures (all P < 0.0001).

**Test–retest reliability**

The mean time between the two questionnaire administrations was 5 days (range 4–7 days). Coefficients of agreement between BASFI and BASDAI scores on the first and second administrations were excellent. All items showed very good agreement (ICC > 0.90; range 0.88–0.96).

**Discussion**

The overall aim of this study was to investigate validity in terms of patients’ acceptance, preference, feasibility and reliability of an innovative, interactive system for electronic collection of patient questionnaire data on axial SpA, namely SPEAMonitor.

The study showed that touch-screen self-assessment questionnaires at the rheumatology clinic are as reliable as paper-administered questionnaires. In general, the patients prefer the touch screen, and further advantages include a reduced need for staff assistance, no errors related to processing of paper versions and elimination of missing and/or incomplete data. The mean time required by the patient to complete the computerized questionnaire was also reduced.

Advances in interactive computer technology open opportunities for patients to be more involved in the planning, implementation and evaluation of their care. The escalating importance of ePRO is making it possible to deliver faster and more accurate medical information while simultaneously streamlining processes to expedite patient care. Tablet PCs are an important part of the technology hardware infrastructure.

A previous study assessed the validity of a tablet PC for completion of the BASDAI [38]. Good results were reported with a tablet PC [39] for completing items that are clinically relevant for patients with RA [Short Form 36 (SF-36)] [38, 39], the modified HAQ [39], the RA Disease Activity Index [39], the HAQ [38] and the Hannover Functional Questionnaire [38].

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**Table 1** Comparison of paper-administered and computer touch-screen format of the BASFI and BASDAI questionnaires and the ASDAS composite index

<table>
<thead>
<tr>
<th></th>
<th>Mean score</th>
<th>s.d.</th>
<th>Mean score difference</th>
<th>s.d. difference</th>
<th>Student’s paired t-test (P-value)</th>
<th>ICC</th>
<th>95% CI</th>
<th>SDD</th>
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<tbody>
<tr>
<td><strong>BASFI</strong></td>
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<td>Paper</td>
<td>3.49</td>
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<td>0.005</td>
<td>0.26</td>
<td>−0.10 (0.92)</td>
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<td>Touch screen</td>
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<td>Paper</td>
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<td>0.05</td>
<td>0.28</td>
<td>1.15</td>
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<td>Touch screen</td>
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<td><strong>ASDAS CRP</strong></td>
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<td>Paper</td>
<td>2.39</td>
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<td>0.04</td>
<td>0.20</td>
<td>1.19</td>
<td>0.24</td>
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<tr>
<td>Touch screen</td>
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<td><strong>ASDAS ESR</strong></td>
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<tr>
<td>Paper</td>
<td>2.11</td>
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<td>0.06</td>
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<td>2.01</td>
<td>0.06</td>
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<tr>
<td>Touch screen</td>
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The touch screen is self-explanatory. Many studies have found that use of a touch-screen system is feasible and preferable in comparison with paper versions of the questionnaires [38–41]. A previous study assessed the feasibility of a touch screen for self-administered patient questionnaires on first-time users and showed that only 3% of patients reported having a lot of difficulty using the touch screen, whereas 84% reported no difficulty [19, 42].

In another study that included 196 patients, 92% found a touch screen easy to use [43]. Greenwood et al. [44] demonstrated that the use of touch-screen computer questionnaires in patients with RA is a feasible way of overcoming many practical issues that limit the collection and utilization of outcome data in routine rheumatology practice. Wilson et al. [45] and Taenzer et al. [46] reported that the time to complete an automated assessment that minimized the need for keyboard skills in patients being treated for hypertension was related to age, but to no other demographic factors such as gender, education or previous computer use. In contrast, our findings suggested that the amount of time required to complete the SPEAMonitor was not different based on age or on any of the demographic variables that we studied. A lack of correlation between previous computer experience and differences among questionnaires has also been reported by Harlin et al. [47], in which the use of touch-screen questionnaires was reported as less stressful and requiring less or no help from staff to understand how to use them, and Gudbergsen et al. [48] also compared data based on a touch-screen system to data based on traditional paper versions of questionnaires used to examine PRO in knee osteoarthritis. This may be due to only receiving one question at a time, thereby avoiding problems created by interruptions [49].

Our study has demonstrated that agreement between touch-screen and paper questionnaire scores on the

Agreement between scores obtained by the touch-screen and paper versions for BASDAI (1.96 s.d. limits of agreement, –0.59 to 0.51; mean difference –0.04), BASFI (1.96 s.d. limits of agreement, –0.53 to 0.52; mean difference –0.01), ASDAS ESR (1.96 s.d. limits of agreement, –0.30 to 0.22; mean difference –0.04) and ASDAS CRP (1.96 s.d. limits of agreement, –0.31 to 0.21; mean difference –0.06).

Fig. 2 Bland–Altman analysis of BASDAI, BASFI and ASDAS scores.
individual patient level was also generally excellent. The data were confirmed by a Bland-Altman plot, which showed higher mean values, with differences progressing toward zero. This overall difference may be due to the fact that questions addressing easy tasks are presented at the beginning of the questionnaire and patients tend to continue answering the progressively more difficult questions at the same level when viewing all questions simultaneously in the paper version. We found the SDD to be closer to those reported in studies on paper forms [39]. This indicates that the instruments themselves rather than the different devices (paper or computer) comprise the main source of measurement error. Also, the test–retest study showed excellent agreement between scores for the two administrations.

Reliability has also been demonstrated for touch-screen questionnaires in rheumatology. Self-explanatory touch screens based on the nationwide Danish DANBIO [50] open-source system generates valid results in patients with AS and RA on completion of BASDAI, BASFI, HAQ and visual analogue scale (VAS) scores for pain, fatigue and global health when compared with the traditional paper form. Other researchers confirm these observations in studies comparing paper with touch-screen versions for Bath AS questionnaires and the Quebec Scale [51] for the Quality of Life Reflux and Dyspepsia questionnaire [52], the Western Ontario and McMaster Universities Osteoarthritis Index [26, 53], the RAQol and VAS [44], the McGill Pain Index and Pain Disability Index [54, 55], the HAQ [56], the Physical Activity Scale or pain DETECT questionnaire [48], utility scales such as the EQ-5D and Health Utilities Index (HUI2 and HUI3) [57] and for other generic HRQOL questionnaires [58] and the Quality of Care questionnaire [57, 59]. Schaeren et al. [60] validated the North American Spine Society (NASS) outcome assessment instrument for the lumbar spine in a computerized touch-screen format and found that the latter is comparable to the paper form and may improve follow-up in clinical practice and research by meeting patients’ preferences and minimizing administrative work.

Many opportunities exist for the use of validated computerized versions of questionnaires. These include internet clinical and research applications and the rapidly growing field of telemedicine. Electronic pain assessment has recently been incorporated into an internet-based clinical trial for OA of the knee [61] and possesses potential benefits for pain assessment in telemedicine interventions such as self-regulation training for chronic pain [62]. Similar experiences of internet-based platforms are currently being utilized at our rheumatology centre for telemonitoring patients with fibromyalgia (http://www.fibromialgiamonitor.net/) and RA (http://www.armonitor.net/telemonitoraggio/).

Although internet-based systems provide an appealing medium for the communication of health-related information, due its ease of use and growing popularity, they can be systematically vulnerable to certain types of security threats. Our electronic system protects the patients’ data using a security system that is adequately encrypted. It ensures confidentiality, integrity and accountability of the patients’ data.

Despite the advantages of computerized questionnaires, we recognize that there are limitations to this study. First, the small sample size may have limited our ability to demonstrate the equivalence of the mean scores obtained using computerized or paper administration. Second, the majority of study participants were computer literate, thus we cannot confirm whether or not all patients can use this kind of computer technology, so the generalizability of our findings to other PRO instruments requires further investigation. Third, there was a relatively short 60-min washout period between administration of the computer and paper versions. This may have allowed a memory effect to contribute to agreement between the methods of administration. However, the subjects did not have access to their scores from the first test when completing the second one and four tests were administered in each version with a total of 38 questions. Thus we thought it unlikely that the subjects would recall their scores from the first test. Fourth, direct and indirect costs of the electronic system were not estimated, which could give more detailed information; however, this will be the object of the next prospective phase of the project. Another potential limitation of this study could be related to the technical aspects. For example, computer experience and skills are fundamental for accurate use of the electronic system. However, our recent previous experience with patients with RA demonstrated that there were not significant differences in terms of the time taken between older and younger people.

Further, recall bias was reduced by organizing various activities, such as visiting the physician during the interval. Our results are very similar to a test–retest study with a 5- to 7-day interval [39], thus we believe that recall bias is of limited significance in the present study.

Conclusion

In conclusion, computer touch-screen questionnaires were well accepted by patients with axial SpA, with good data quality, reliability and score agreement. The SPEAMonitor can be helpful to rheumatology nurses and physicians in assessing, collecting and evaluating their patients’ activity and functional scores in busy clinical practices.

Rheumatology key messages

- The SPEAMonitor is feasible and well accepted by patients with axial SpA.
- The SPEAMonitor is the computerized equivalent of the paper version of the questionnaire.
- The SPEAMonitor can be helpful to rheumatology nurses and physicians in assessing, collecting and evaluating axial SpA patients.

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Disclosure statement: F.S. has attended advisory board meetings for Bristol-Myers Squibb, Abbott Immunology, Wyeth Lederle and Pfizer and has received research support from Bristol-Myers Squibb. W.G. has received board membership, consultancy and lecture fees from Bristol-Myers Squibb, Abbott Immunology, AbbVie, UCB, Menarini, MSD/Schering Plough and Pfizer/Wyeth. M.G. has attended advisory board meetings, scientific consultations and has obtained speaking fees from Abbott Immunology, UCB Pharma, Esaote and Bristol-Myers Squibb. A.C. has attended advisory board meetings and has obtained speaking fees for Bristol-Myers Squibb. The other author has declared no conflicts of interest.

Supplementary data

Supplementary data are available at Rheumatology Online.

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