DEVELOPMENT AND USE OF TOUCH-SCREEN COMPUTER-ASSISTED SELF INTERVIEWING IN PORTUGUESE PATIENTS WITH CHRONIC IMMUNE DISEASES: EVALUATION OF AN ELECTRONIC VERSION OF SF-36V2

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Abstract

Aim: The major purpose of this study was to evaluate alternative automated methods of collecting data on health related quality of life (HR-QoL). In order to achieve this, we developed a study with the following objectives: (1) to evaluated the feasibility of electronic version in patients with different chronic pathologies of the immune system using Short Form 36version2 (SF-36v2), (2) to evaluate the construct validity of SF-36v2 using the electronic data capture, and (3) to compare electronic version questionnaires with paper questionnaires in terms of patients´ acceptance, data quality, and reliability.
Methods: Out-patients with chronic immune diseases (HIV infection, lupus, scleroderma, rheumatoid arthritis, Behçet and Sjögren), were randomly selected to completed electronic and paper SF-36v2 (n=50) before consultation in Clinical Immunology Unit, in Hospital Santo António-Centro Hospitalar do Porto (CI-HGSA).
Results: There were very high correlations in SF-36v2 responses (p< .001) between the paper and electronic forms. Internal reliability coefficients (Cronbach's α) showed good internal consistency for all reported responses in either, computer and paper. There were no missing data in electronic version or paper. About 84% of the patients prefer to use the computer version in future.
Conclusion: The electronic HR-QoL assessment is technically possible and it can provide reliable and valid clinically significant information which can either be used in routine care appointments.

Keywords: SF-36v2; Electronic Data Capture; Quality of Life; Immune Chronic Diseases.

Introduction

Chronic dysfunction of the immune system, like immunodeficiency and self-immunity, can affect multiple organ systems and lead to increased mortality. However, with more effective treatment[1,2], chronic long-term morbidity and relapse are now the most significant aspects of such diseases. Improved survival with continuing morbidity highlights the need for accurate assessment of patients suffering from these diseases and their response to therapy[3].

Systematic health related quality of life (HR-QOL) assessment might facilitate patient management[4,5], detection of health problems[6,7] and communication between patients and physicians[8] without prolonging encounters. Nevertheless, patients' HR-QOL has rarely been systematically monitored on a regular basis, because there are several requirements to be achieved to optimally utilize this procedure in routine medical care: (1) data should be collected completely and accurately with little effort[9]; (2) data scoring and comparisons to previously collected information should be automated and take place during the office visit[10]; (3) results should be presented in a user-friendly format, for patients and physicians be able to easily understand and discuss them[11]; (4) results should be assigned to the respective electronic patient record[12] to allow easily monitoring and follow-up over time.

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Successful evaluation of disease status relies upon efficient information collection and management and the immediate availability of results. With continual improvement in technology, the development and implementation of electronic information systems aimed at addressing clinical problems is desirable and is becoming more common[11,13].

Thorough piloting of all procedures concerning complex interventions (such as the implementation of electronic questionnaires into routine care) is recommended before their effect can be studied within larger representative studies[14].

The aim of our study is to implement a tool for electronic HR-QOL assessment and evaluated, comparatively, the original paper methods and newly developed simple electronic system for SF-36v2 data capture, in the population of patients with disorders of the immune system followed in ambulatory CI-HGSA.

Methods

Procedure

The survey was conducted from May 2009 to July 2009. The sample under study was selected by convenience. During medical consultation, all patients followed in this service were approached and invited to participate in this research. The patients were informed of our intention to conduct the study and what it entailed, including the need to use a computer. All patients invited, have agreed to participate. Patient's written informed consent was obtained either for the electronic assessment and paper version. Each patient was asked either to complete the computerized version before and the paper version after their clinical consultation.

Study Population and Recruitman

Patients

The project enrolled 50 participants of both gender and was developed in the ambulatory CI--HGSA. This unit is dedicated to treatment of patients with diagnosis of immune system diseases, like systemic autoimmune diseases and primary and secondary (HIV) immunodeficiency's. As a criterion for inclusion of patients it was considered the diagnosis: infection with HIV or autoimmune disease.

A total of 50 participants completed version paper and digital form, 35 women and 15 men, with a mean age of 45.2 years with a SD = 15. 3. Regarding the marital status, 48.0 % (n = 24) the individuals are married, 28.0% (n = 14) are single 6.0% (n = 3) are window and 18.0% (n = 9) have other marital status. About 13.0% (n = 26) of the individuals are employed and 46% (n = 23) (dad less than five years of schooling. According to the diagnosis, 74% (n = 37) had autoimmune disease (24% of individuals have lupus, 6% have scleroderma, 34% have rheumatoid arthritis, 6% have Behçet, 4.0% have Sjögren) and 26% (n = 13) was infected by HIV. The mean disease duration is 7.0 years with a SD = 6.9 and the mean follow-up is 6.8 years with a SD=5.8. (Table I summarizes the main characteristics of the sample studied).

Table I. Sample characteristics according to demographic, socioeconomic and clinical variables (n = 50)

Characteristics	n	%
Gender		
Male	15	30
Female	35	70
Marital Status		
Married	24	48
Single	14	28
Window	3	6
Other	9	18
Education years		
0-4	27	54
5-12	15	30
>12	8	16
Diagnosis		
Rheumatoid arthritis	17	34
Behçet	3	6
HIV	13	26
Lupus	12	24
Scleroderma	3	6
Sjörgren	2	4
Employment Status		
Employed	13	26
Student	10	20
Retired	13	26
Unemployed	14	28
Age: X (SD)	45.2 (15.3)	–
Disease Duration: X (SD)	7.0 (6.9)	–
Follow Up Disease: X (SD)	6.8 (5.8)	–

X – Mean; SD – Standard Deviation

Instruments and Technical Procedures

QOL instruments

SF-36v2 was original designed as a generic indicator of health status for use in population surveys and evaluative studies of health policy, and more recently, is being used to complement disease-specific measures in clinical trials[15]. HR-QOL refers to functioning and well-being in physical, mental and social dimensions of life.

The SF-36 is the most frequently used multi-item HR-QOL instrument[16,17]. The SF-36 is composed of 8 multi-item scales (35 items) assessing physical function (10 items), role limitations due to physical health problems (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social function (2 items), role limitations due to emotional problems (3 items), emotional well-being (5 items)[16] and one single item dimension on health transition. This item, which asks about health change, is not included in the scale or summary scores. These eight scales can be aggregated into two summary measures: the Physical (bodily pain, general health, physical function and physical problems) and Mental (vitality, social function, mental health and emotional problems) Component Summary scores[18]. Both components were obtained from factor analysis of components key after the data has been subjected to orthogonal rotations[18].

Studies have suggested that electronic data–capture methods were preferred over traditional paper-and-pen methods by volunteers and patients[19,20]. Surveys conducted in patients with chronic diseases reported that the interactive computer programs were well accepted by the patients and provided reliable information[21,22].

Design of touch-screen questionnaire

The electronic interface was designed using a simple computer interface of an Access 97 form programmed with Visual Basic for Applications (Microsoft), the data being collected in underlying tables. The questions posed on the computer screen were phrased exactly the same way as those in the paper questionnaire and were presented in the same style (with the same words underlined and the same punctuation). The design of the interface (Figure 1) was such that the text was presented in large, easily read type and the buttons were large and easily navigable.

A computerized version of the SF-36v2 test was developed and a touch screen computer was set up

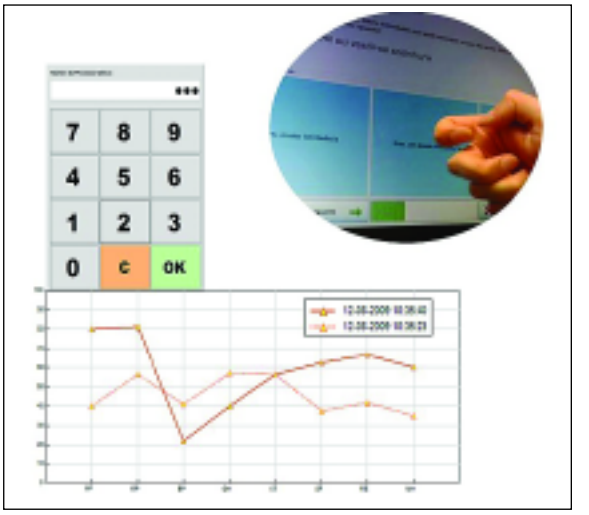

Figure 1. Screen showing graphical user interface for an electronic version.

in a relatively undisturbed area of the outpatient department. Questions were presented individually on the screen, and respondents entered their answers by touching the corresponding buttons on the screen. Questions were presented with the same instructions and in the same response as the originals. It was not possible to move on the next question without completing the previous one, but it was possible to go back and change previous responses. As this study involved a change to the normal routine of SF-36v2 data collection in Clinical Immunology Unit, we used unique identifiers for the patient. All patients invited to participate agreed to do so. Each patient was asked either to complete the computerized and paper version (or vice versa) before their clinical consultation.The median time between the two administrations was 1 hour. Each patient was assessed individually in a private room of the main patient reception area, thus maintaining patient confidentiality throughout the study and also reducing disruption to the normal functions of the clinic. The study initiated after obtaining Institutional Ethics Committee approval.

Analyses

Reliability

We compared the answers reported on the paper form *vs* the electronic version using split-half. The internal reliability of the SF-36v2 scales scores was measured using Cronbach's alpha coefficient. A Cronbach's alpha value of .70 or higher was gene-

rally considered to be satisfactory to demonstrate internal consistency[23].

PATIENT'S PREFERENCE

Patient's preferences for the two versions of SF-36v2 were recorded. This included their opinions on the ease of use and clarity of the layout. We asked the patients which system they prefer to use and which one they would like to see adopted for future use.

RESULTS

Paper and Stencil VS Digital Data Analysis

RELIABILITY

Internal consistency coefficients (Cronbach's α and split-half reliability) showed that all reported responses had good to excellent internal consistency for both the digital and the paper form, which were very similar to those reported for each SF-36 dimension. Cronbach's α ranged from .627 to .954 (paper and pencil version) and .647 to .939 (digital version). The split-half reliability coefficient ranged .627 to .956 (paper and pencil version) to .647 to .950 (digital version) (Table II).

VALIDITY

1. Factor Analysis

Eight factors were created with a cumulative variance proportion of 76.345% to paper and pencil version, and 74.733% to digital version. The dimensions were in accordance with the theoretical construction of SF-36v2.

2. Convergent validity

Spearman correlation analysis showed that the correlations between the dimensions and items inside were higher than those between the dimensions and items outside (Table II).

Test-retest reliability Digital and paper Data Analysis

The responses given to any on the facets of the SF-36v2 by all patients when they used the electronic system or the standard paper questionnaires are related. Correlations ranged from r = .711 (VT) to r = .892 (MH) for the whole patient group (Table III). These were all highly significant ($p < .001$).

PATIENT PREFERENCE

Of the 50 patients tested on the computer, all were

Table II. Paper and pencil data vs digital data: Reliability and Validity Analysis (n=50)

		RELIABILITY					CORRELATION			
		Paper and pencil data			Digital data		Paper and pencil data		Digital data	
Dimension	Item Amount	Split-half reliability	Cronbach's alfa	Split-half reliability	Cronbach's alfa	Correlations between dimensions and items inside	Correlations between dimensions and items outside	Correlations between dimensions and items inside	Correlations between dimensions and items outside
Physical Function	10	0,956	0,894	0,944	0,903	0,466 - 0,826	0,031 - 0,717	0,531 - 0,841	0,004 - 0,598
Physical Problems	4	0,930	0,936	0,950	0,901	0,850 - 0,953	0,127 - 0,659	0,826 - 0,908	0,122 - 0,698
Bodily Pain	2	0,862	0,862	0,887	0,887	0,929 - 0,941	0,122 - 0,669	0,922 - 0,949	0,030 - 0,647
General Health	5	0,709	0,792	0,647	0,708	0,552 - 0,803	0,082 - 0,480	0,430 - 0,832	0,045 - 0,551
Vitality	4	0,857	0,733	0,822	0,713	0,654 - 0,815	0,212 - 0,698	0,624 - 0,786	0,008 - 0,549
Social Function	2	0,627	0,627	0,647	0,647	0,819 - 0,867	0,084 - 0,727	0,854 - 0,873	0,113 - 0,772
Emotional Problems	3	0,863	0,954	0,852	0,939	0,940 - 0,963	0,034 - 0,642	0,920 - 0,964	0,054 - 0,638
Mental Health	5	0,900	0,924	0,838	0,895	0,816 - 0,919	0,016 - 0,671	0,763 - 0,875	0,070 - 0,689

Table III. Test-Retest reliability digital and paper data analysis (*n*=50)

Paired samples correlations

		N	Correlation	Sig.
Pair 1	Physical Function (digital data) & Physical Function (paper and pencil)	50	,831	,0001
Pair 2	Physical problems (digital data) & Physical problems (paper and pencil)	50	,828	,0001
Pair 3	Body Pain (digital data) & Body Pain (paper and pencil)	50	,857	,0001
Pair 4	General Health (digital data) & General Health (paper and pencil)	50	,889	,0001
Pair 5	Vitality (digital data) & Vitality (paper and pencil)	50	,711	,0001
Pair 6	Social Function (digital data) & Social Function (paper and pencil)	50	,809	,0001
Pair 7	Emotional Problems (digital data) & Emotional problems (paper and pencil)	50	,829	,0001
Pair 8	Mental Health (digital data) & Mental Health (paper and pencil)	50	,892	,0001

very keen to complete the task; no-one refuse to finish the paper or computer test. Eighty four per cent, 42 of patients preferred the computerized version to the paper version. When asked their preferences for adoption of these systems in future, the same 84% ($n = 42$) requested the computerized version. Nevertheless, participants did not skip a question. Although results could be immediately printed out we did not take advantage of this option in this pilot study.

Discussion

For many years, paper questionnaires have been the rule. When information is simple and requires little post-translation, this may be adequate. However, in the case of assessments used for monitoring chronic diseases, which would benefit from immediate feedback and the ability to monitor change against previous responses, this is not feasible solely with paper forms.

With the burgeoning developments in information technology, simple and effective yet highly specialized electronic data capture systems can be easily developed and implemented with the intention of improving practices[24,25].

The literature review showed a very high correlation in SF-36 responses ($p<0.001$) between the paper and electronic forms. Internal reliability coefficients (Cronbach's alpha) showed good internal consistency for all reported responses in either computer or paper forms[26]. Electronic methods of data collection (QOL recorders[21] and interactive computer programs) look promising for implementation in clinical practice.

These studies suggest that ease of use and acceptance by patients with immunological chronic diseases present no barrier to use of digital version questionnaires in Clinical Immunology and digital version questionnaires need take no longer to complete than the equivalent paper and pencil version.

It was developed a system which allows effective collection of SF-36v2 data from patients with little or no intervention by the clinical or nursing staff. This circumvents the need to transpose the information from the paper questionnaires which the patient has previously completed. This facilitates the information-gathering process and reduces the delay in monitoring the changes in patient responses, and the information becomes available to the clinician immediately.

The results of this study suggest the electronic assessment of HR-QOL data is technically feasible in general practice, it is welcomed by patients and can provide clinically significant information and indicators to marked HR-QOL impairments, which can be useful for clinical or research purposes. We have developed a simple electronic graphical (Figure 1) user interface for the SF-36v2, prepared in line with guidelines for such design[27,28].

Although this was an initial version tested for usability, we tried to incorporate into the design aspects which we thought would be helpful to patients hindered by the limitations of conditions such as HIV infection, lupus, scleroderma, rheumatoid arthritis, Behçet and Sjögren. This included large, easy-to-read text, easy navigable interfaces and large, simple-to-use buttons for them to record their responses.

The computerized version of the SF-36v2 was well accepted by patients, the majority preferring it to the paper version. With better design of the

computerized SF-36v2, it may be possible to introduce a system which is acceptable to all patients.

Internal consistency coefficients (Cronbach's α and Spearman's correlation) showed that all reported responses had good to excellent internal consistency for both the computer and paper form, which were very similar to those previously reported for each SF-36v2. Cronbach's α was high for the touch-screen score and for the paper score, demonstrating that the touch-screen version had a high level of internal consistency. There was good comparability of the touch-screen and paper SF-36v2.

The literature shows as hypothesized, the routine collection and dissemination of HR-QOL – related information in the outpatient with chronic disease resulted in a significant increase in the frequency with which HR-QOL issues were discussed. Like other study[29] we demonstrated that the use of touch screen questionnaires is a feasible way of data collection in chronic immune diseases. Application of interactive computer systems in practice daily routine may be the provision of health information.

With the use of electronic questionnaires, some of the problems with the process of data entry may be overcome[30]. Results can be compiled automatically in a database and can be immediately available for use in clinical practice health services outcome studies, and clinical trials. A major advantage of the computerized questionnaires is the ability to collect good quality data without missing or problematic responses.

Conclusion

The integration of electronic HR-QOL assessment into general practice brings it the prospect of reciprocal transfer of knowledge from patient rated outcomes research into clinical practice and from clinical practice to research. Combining such HR-QOL data with information from electronic patient records would provide a basis for scientific analyses of associations between HRQoL and patients' characteristics, disease and treatment.

The availability of HR-QOL score immediately during the consultation could contribute to patient centered care, help to focus the patient-physician consultation, supporting the definition of therapeutic goals as well as the evaluation of their achievement, and provides standardized data, which can be compared intra- and inter- individually.

In this pilot study we have demonstrated that the use of touch-screen digital questionnaires in the clinic is a feasible way of overcoming many practical issues that currently limit the collection and utilization of outcome data in routine immunology practice. Touch-screen questionnaires can produce comparable results to paper, eliminate the need for data entry, afford immediate access to results and to be a highly acceptable and in many cases a preferable option to paper and pencil version.

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