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THE USE OF ELECTRONIC DIARIES IN RESPIRATORY STUDIES

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Background-Electronic diary cards have advantages over paper diaries for daily collection of data on lung function and symptoms in patients with respiratory disorders. The suitability of a pen-based electronic dairy (Apple MessagePad) for this purpose was assessed in a clinical trial setting.

Methods-Two studies were carried out in patients with chronic obstructive airways disease: 1. An open randomized two-period crossover study comparing electronic and paper diaries in 22 clinic outpatients aged 18-70. Data were collected for four weeks on each type of diary, and 2. An open study in 37 patients in general practice aged 13-80. Data were collected for four weeks on electronic diaries only.

Results--In Study 1, 59% of patients preferred the electronic diary and 18% preferred paper. Both paper and electronic diaries were found to be easy to use. There were fewer problematic data from the electronic diaries (0.24% of data points) compared with paper (5.6%), resulting in improved data reliability. There were more missing data, however, with electronic diaries (8.9% vs 0.2%; p = 0.0001) which probably relates to the fact that the electronic diary did not permit retrospective entry. Data handling procedures were greatly simplified for the electronic diaries. Problems occurred with battery life and power management. Study 2 confirmed the acceptability of electronic diaries in this patient group, and showed no battery problems using a later model of the hardware (MP 110).

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Conclusions-Pen-based electronic diaries are acceptable to patients, and offer major benefits in terms of data reliability and simplification of data handling.

Kev Words: Electronic diaries; Peak expiratory flow; Chronic obstructive airways disease

INTRODUCTION

DAILY DIARY CARDS have advantages over clinic assessments for monitoring severity of disease in chronic conditions such as asthma. Measurements are obtained repeatedly and fluctuations in the course of the illness can be followed. Regular assessments at home may reflect the patient's overall condition more accurately than intermittent out-patient review.

The method, however, has disadvantages, as patients may inadvertently enter data incorrectly, or may forget to enter data altogether and then attempt to make entries retrospectively (1).

An alternative approach which avoids many of these problems is to use electronic data collection. There is now a wide variety of electronic devices that are small enough to be taken home and used as electronic diaries by patients. Such devices can be programmed to record the date and time of entries, to allow only appropriate responses, and to remind patients to answer all questions. They can also greatly simplify data transfer and processing. Previous studies investigating electronic diaries have so far looked at small computers with conventional keyboards (2) or at custom-built devices using button presses (3).

More recently, devices using a pen for data input have become available. Small devices of this sort are referred to as personal digital assistants (PDAs). Making entries with a pen rather than a keyboard has potential advantages in that it may be a more natural method to use, especially for patients unfamiliar with computer technology.

Two studies have been carried out to assess the suitability of PDAs compared to paper in a clinical trial setting, evaluating acceptability to patients, measures of data quality, and ease of data handling. Study 1 was carried out on outpatients in a respiratory clinic. Study 2, carried out in general practice, assessed the suitability of the electronic diary in this patient population, and also addressed some technical issues arising from Study 1.

METHODS

The studies were set up specifically to assess the diaries, and involved no changes to the patients' normal medication. Patients gave written informed consent and the studies were approved by the local ethics committees. Custom software for the electronic diaries was developed using the Newton Toolkit (Apple Computer Inc.).

Study 1

This study was carried out at a respiratory clinic, and used a randomized two-period crossover design. Paper and electronic diaries were compared, each being filled in for a one-month period. Twenty-two outpatients, 13 male and nine female, aged 18-70 years (mean 45.3), with chronic obstructive airways disease completed the study. Seven had previously taken part in a clinical trial. The following items were recorded twice daily: peak expiratory flow measurements (best of three); inhaler use; and asthma symptoms on a four-point scale. Peak expiratory flow, using a Vitalograph Peak Flow Meter, was recorded on the electronic diary on a slider scale designed to resemble that on the meter (Figure 1). Data were entered by tapping with a special pen on the appropriate part of the

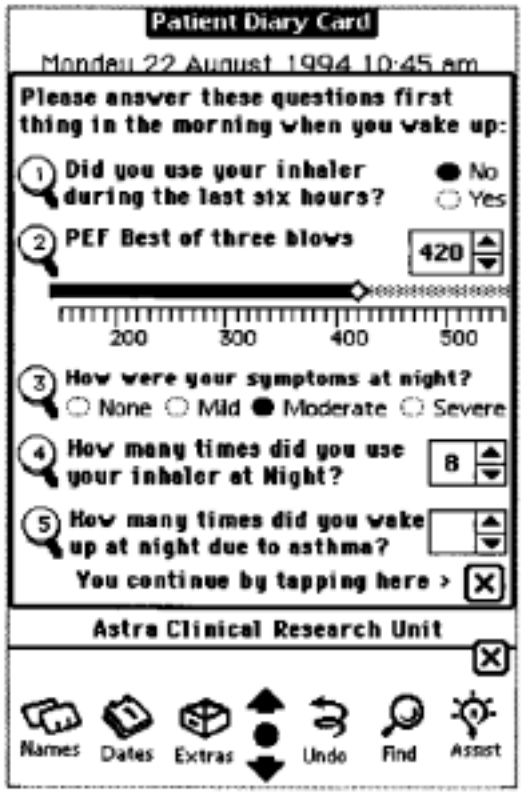

FIGURE 1. The main entry screen of the electronic diary. To enter peak expiratory flow rate, patients tapped the grey scale of Question 2 with a stylus to record the reading, which then appeared in the box at the right. The reading could be adjusted by tapping the up or down arrows

screen. The electronic diary permitted entries between 3:00 a.m and 3:00 p.m. and between 3:00 p.m. and 3:00 a.m. for morning and evening, respectively, and the date and time of all entries were recorded.

The number of missing and problematic data points were compared for the two types of diary. Problematic data points were defined as those requiring some intervention such as editing or query resolution. Statistical analysis used an arcsine transformation followed by the standard parametric method for a two-period crossover design (4,5). At the end of the study patients filled in a paper questionnaire concerning attitudes to technology in general and the diaries in particular. Preferences for paper or electronic diaries were recorded, and ease of use of the two methods of data entry were assessed on a five-point scale ranging from "Very easy to use" to "Very difficult to use."

Study 2

This study was carried out in general practice, and used a later version of the Apple MessagePad, the MP110, which differs from the original version in having larger batteries and improved power management software. The study used only electronic diaries.

Thirty-seven patients suffering from chronic obstructive airways disease took part. They consisted of 15 males and 22 females, and were aged 13-80 years (mean 37.6).

Fifteen patients were issued MessagePads with rechargeable batteries (Apple Computer) and 22 with dry cells (Ever Ready Silver Seal). They filled in the electronic diary for four weeks as in Study 1. At the end of the study a survey questionnaire was filled in.

RESULTS AND DISCUSSION

Study 1

The acceptability of the two types of diary, as assessed by the surveys, is shown in Figures 2 and 3. The majority of patients (59%) preferred the electronic diary to paper, while 18% preferred paper, and 23% expressed no

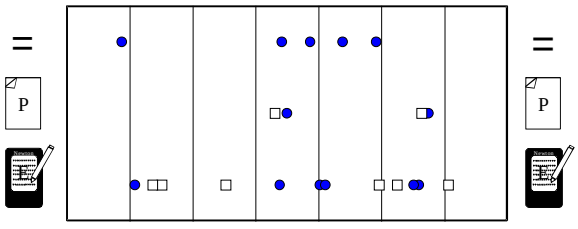

FIGURE 2. Patient preferences plotted against age for Study One. E: preference for electronic diary; P: preference for paper diary; =: no preference. Each dot corresponds to one patient. Closed circles: Males; Open squares: Females.

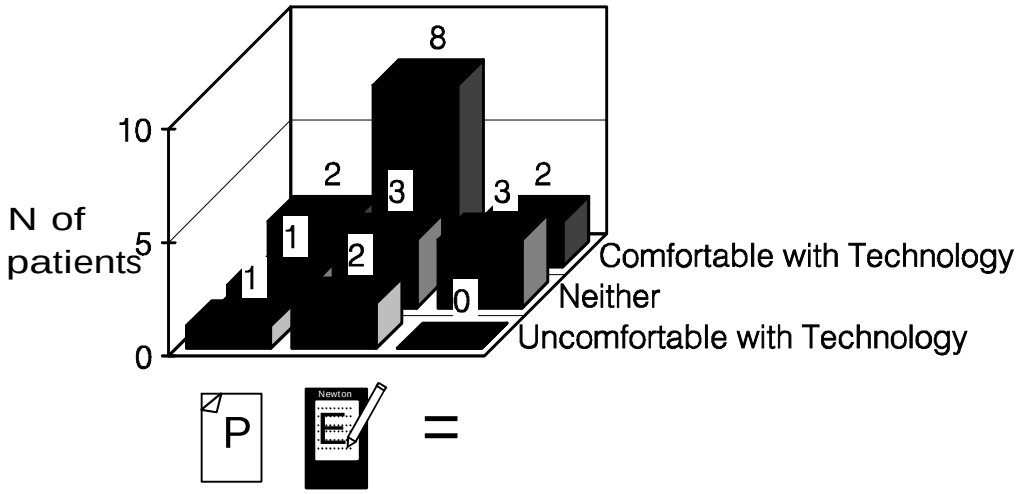

FIGURE 3. Patient preference plotted against comfort with technology for Study 1.

preference. Neither age, gender, nor familiarity or comfort with technology had any marked association with preference. All patients found both types of diary either "very easy" or "easy" to use. These data are very similar to those found for pen-based questionnaires by Drummond et al. (6).

The results relating to data quality are shown in Table 1. It can be seen that the amount of missing data is greater for electronic data, while the amount of problematic data is greater for paper.

The rate of missing data is very low for the paper diaries. This immediately raises the suspicion that data were being filled in retrospectively. In agreement with this, the rate of missing data for the electronic diary, which did not permit retrospective entry, was much higher.

Some, but not all, of the missing data for the electronic diary can be attributed to technical problems with the MessagePad which involved five patients, one of whom withdrew from the study. Batteries ran flat sooner than expected, leading to the application terminating, due to apparent problems in the power management software. After allowing for this problem, the estimated rate of residual missing data for electronic diaries is about 5% of data points.

If the higher rate of missing data for the electronic diary indicates that data which should be missing on paper have been filled in after the event, this could be reflected in the data themselves. Therefore, individual patient data were inspected for evidence of problems.

TABLE 1
Incidence of missing and problematic data in the electronic and paper diaries for Study 1. Numbers of data points in the various categories are given, together with percentages in brackets

	Paper	Electronic	Statistical Significance
Correct	1153 (94.2%)	1112 (90.85%)	
Missing	2 (0.16%)	109 (8.91%)	p = 0.0001
Problematic	69 (5.64%)	3 (0.24%)	p=0.19
Combined Missing + Problematic	71 (5.80%)	112 (9.14%)	p = 0.155
Total	1224	1224	

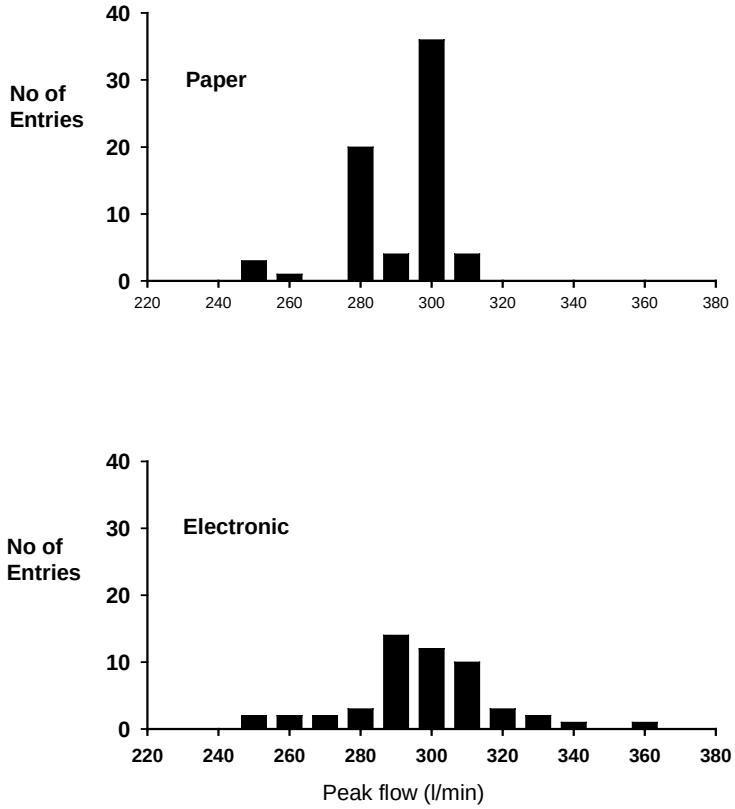

FIGURE 4. Distribution of recorded values for expiratory flow (1/min) for one patient in Study 1 . Top: paper diary; Bottom: electronic diary.

The results from one patient are illustrated in Figure 4 (also see reference 7). Over 80% of the entries for peak expiratory' flow for this patient had one of two values 280 or 300- indicating that these data are largely suspect. By contrast, the data on the electronic diary for the same patient were much more smoothly distributed, suggesting that the data had been recorded correctly. It should be pointed out that this patient is an extreme example. Several other patients showed similar patterns, however, and no patient showed obviously poorer data for electronic than paper diaries, suggesting that important gains in data quality can be obtained using electronic diaries.

In the area of data handling, the electronic diary eliminated the need for editing, and data entry became an automated process, with no need for any manual keying of data. This reduced the total time required for data handling by over 80%. Problematic data were also greatly reduced, and the date and time-stamping ensured that all records were entered at a known time.

Study 2

Results from the survey showed that 36 of the 37 patients found the electronic diary "very easy to use," and were comfortable with it. One patient found the diary difficult to use, and this related to a software problem which caused the diary to "freeze." Two other patients reported problems, one with software which allowed two entries of the same data, the other with the wording of one of the questions.

The two software problems were traced to the handling of the transition between time windows when the diary is switched off. This has been resolved in a later version of the software.

The proportion of complete data points was 85.1% (morning entries: 84.2%; evening entries: 86.1%). The lower rate of completion than in Study 1 may be associated with the fact that patients attending outpatient clinics suffer from more severe conditions, and may thus be more conscientious in their approach to treatment management than those treated in general practice. The rate of completion is, however, sufficient for a reliable estimate of the course of the disease to be obtained for most patients.

Both types of battery proved adequate for the four-week study period-in no case did levels go down sufficiently to produce a "battery low" warning, and no replacement or recharging of batteries was necessary. The problems with earlier models of the MessagePad thus appear to have been re-solved.

In conclusion, electronic diaries are very acceptable to patients in clinical trials in both clinic and general practice settings. They offer advantages over conventional paper diaries in terms both of easier and faster data handling and of the quality of the data obtained.

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