Research Paper ■

Handheld vs. Laptop Computers for Electronic Data Collection in Clinical Research: A Crossover Randomized Trial

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Abstract **Objective:** To compare users' speed, number of entry errors and satisfaction in using two current devices for electronic data collection in clinical research: handheld and laptop computers.

Design: The authors performed a randomized cross-over trial using 160 different paper-based questionnaires and representing altogether 45,440 variables. Four data coders were instructed to record, according to a random predefined and equally balanced sequence, the content of these questionnaires either on a laptop or on a handheld computer. Instructions on the kind of device to be used were provided to data-coders in individual sealed and opaque envelopes. Study conditions were controlled and the data entry process performed in a quiet environment.

Measurements: The authors compared the duration of the data recording process, the number of errors and users' satisfaction with the two devices. The authors divided errors into two separate categories, typing and missing data errors. The original paper-based questionnaire was used as a gold-standard.

Results: The overall duration of the recording process was significantly reduced (2.0 versus 3.3 min) when data were recorded on the laptop computer ($p < 0.001$). Data accuracy also improved. There were 5.8 typing errors per 1,000 entries with the laptop compared to 8.4 per 1,000 with the handheld computer ($p < 0.001$). The difference was even more important for missing data which decreased from 22.8 to 2.9 per 1,000 entries when a laptop was used ($p < 0.001$). Users found the laptop easier, faster and more satisfying to use than the handheld computer.

Conclusions: Despite the increasing use of handheld computers for electronic data collection in clinical research, these devices should be used with caution. They double the duration of the data entry process and significantly increase the risk of typing errors and missing data. This may become a particularly crucial issue in studies where these devices are provided to patients or healthcare workers, unfamiliar with Computer Technologies, for self-reporting or research data collection processes.

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Introduction

Large amounts of data are collected, stored and processed in clinical research. With computer technologies, this information can be captured directly in an electronic format, increasingly replacing paper-based data records.[1,2] Electronic data offer the advantages of improved data quality and consistency through the use of automated validation procedures and data range checks. They can integrate different kind of formats (images, texts, physiological signals) which can easily be transferred over long distances through wireless networks. Recent advances in hardware and software technologies allow such data to be collected on increasingly smaller portable devices such as laptops and handheld computers. This is particularly convenient for studies performed at patients' bedside, or in practice or home environments. It is currently unknown which of the two devices is the best for electronic data collection in clinical research. This cross-over randomized controlled trial assesses users' accuracy, efficacy and satisfaction in using the two devices.

Background

Handheld computing devices such as personal digital assistants (PDA) and Smartphones are used by more than 50% of physicians in OECD countries[3,4] and by 75% of United States residents.[5] Their extended functionalities associated with easy touch input on display screens or miniature keyboards make them very popular in busy clinical and academic environments. Handheld computers are used to access med-

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ical literature, display electronic pharmacopeias, track patients, or prescribe drugs.[6] In classrooms, they are used to download lecture materials, images or multimedia files, and as polling tools.[7–11] As researchers are progressively turning to electronic data collection methods, handhelds are increasingly used in clinical research to record and process data. They are particularly convenient for field studies and self-reporting data collection processes. Gupta et al. report the use of handheld computers to perform a survey on more than 99,598 tobacco users in Mumbai, India.[12] The device was found to be a particularly convenient tool to collect data directly in the study field of a densely populated city. Lal et al. used handheld computers for data collection in burn patients.[13] Handheld computers were found to be 23% faster and 58% more accurate than paper and pencil recording. Their multiple functionalities associated with user-friendly touch screen technologies make them a particularly attractive alternative to paper-based diaries or questionnaires for patients' self reporting use, particularly children and young adults[14–16] the electronic format of handheld computers allows the capture and recording not only of text data but also of virtual electrocardiograms, electrochemical data and photographs. These can be encrypted and transmitted to a central database management system through a wireless connection to a local area network (LAN) or the Internet.[17–19] Since 2000, more than 40,000 handhelds have been sold in 48 countries for use in clinical trials.[17]

Data quality is a crucial factor in clinical research. An increasing number of treatments, diagnostic strategies, or clinical guidelines are based on evidence, the best of which comes from randomized trials.[20] Time and its financial correlates is also increasingly of essence in such trials. If the collected data are inaccurate or missing, conclusions will be biased and the scientific evidence subsequently misleading. There are many examples of publication retractions due to data management errors.[21] Consequences can be serious as even retracted articles are still cited and misleading results still used to guide clinical practice.[22]

Despite the above-cited advantages, some authors suggest that the use of handhelds could negatively impact data quality. The small screen size along with the peculiarities of text entry on handhelds (character recognition or on-screen keyboards) could make the data entry process slower and more prone to errors than other electronic data collection tools such as desktop or laptop computers.[23,24] As laptops are becoming increasingly cheaper and handier, these devices represent an alternative to handheld computers for electronic data collection in research. Laptops are portable devices, usable in a natural environment, which also have wireless network facilities allowing data to be transferred quickly and efficiently over long distances.

Research Question and Objectives

It is currently unknown which of the two portable devices (laptop or handheld computer) is the fastest, most accurate, and has the preference of users. The purpose of this randomized cross-over trial was to compare users' speed, number of entry errors, and satisfaction in using the two different devices.

Methods

Participants

Following University Hospitals Human Research and Ethics Committee's exemption, we recruited through web advertisement at the Hospital and University of Geneva four study volunteers. Participants needed to have at least 1 year regular data recording and typing experience with a laptop or desktop computer. They also needed to be reasonably familiar with handheld computers and have a good general knowledge of information technologies. We excluded participants aged over 55 years or who had uncorrected visual impairments.

Laptop and Handheld Interface Design

We used a common commercially available laptop, the Dell® latitude 860 (Dell, Inc). The data base interface we used was the program EpiData (version 2.1 EpiData Association, Odense-DK). This program is widely used as it is freely available on the Internet and offers all the usual features of commercial databases (data entry forms, input masks, validation rules, automatic filters) to ensure data consistency and completeness.

For the handheld computer, we chose the Palm®-tungsten E_2 (PalmSource, Inc, Sunnyvale, CA), also widely available on the market. Because there is no version of EpiData for handheld computers (Palm OS or Pocket PC, we used HanDBase professional® (version 3.0, DDH-softwares, Inc-Wellington, FL) a commercial database package for Palm Pilot handhelds. This system is characterized by its flexibility and interoperability. Data collected on a handheld computer can be synchronized to a desktop computer and transformed into a CSV (Comma Separated Values), Access-Microsoft or Stata tables. The HanDBase professional® package also allows the implementation of a number of filters, pull-down menus and authorized values. Forms with buttons, checkboxes, pop-up lists and automated date and number entry can be used to enter data.

For both devices, we developed a form that was graphically as close as possible to the layout of the written questionnaire (see Figures 1 and 2). For the PDA, we designed low-level dialogue boxes to minimize the risk of text overload, a critical issue for 3-inch PDA screens. We used tabbing sequences as much as possible and options set within windows integrated within dialogue boxes. We also standardized controls and position buttons in a logical sequence, as close as possible to the initial written questionnaire. This contributed to making the handheld a flexible and user-friendly device.

Prior to the study, the overall data collection procedure was pilot tested by one of the coauthors (DH) on 126 paper-based questionnaires, randomly allocated to be recorded on the Palm®-Tungsten E_2 handheld or on the Dell® latitude 860 laptop. The handheld data entry form and the computer-user screen interface were then finalized, taking into account minor problems identified in the pilot. The pilot study also allowed the measurement of errors for future sample size calculation and the estimation of the training required for users to become familiar with the data entry process on both devices.

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