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Original Article

Wireless Clinical Trial of Data Capture using a Personal Digital Assistant

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Abstract

Objective: Personal Digital Assistants (PDAs) have the potential to improve clinical trial data collection; however, most current PDA-based clinical data collection systems typically collect and store data in the offline mode, and then transfer the data to an operational database. The purpose of this study was to explore the usefulness of a wireless clinical data collection system for an irritable bowel syndrome trial compared with the traditional paper based data collection. **Methods:** We have developed a PDA-based data capture system for clinical trials, and tested it in a double-blind trial. Sixty four patients with irritable bowel syndrome were randomly selected and divided into a control group that used the standard paper report forms (CRF) and an intervention group that used the electronic report forms (e-CRF), daily for five weeks. There were 630 data sets consisting of six questions each, and thus 3,570 data points total were collected. **Results:** The response rate of the control group was significantly higher than that of the intervention group. However, the completeness of the response in the intervention group was higher and the number of input errors per person for the PDA group was lower than in the paper group. **Conclusion:** A PDA based electronic diary improved the response rate and decreased input errors in an IBS trial. We conclude that mobile devices can be very useful, especially when the proposed design and connectivity aspects have been taken into account. *(Journal of Korean Society of Medical Informatics 15-2, 235-244, 2009)*

Key words: Clinical Trials, Electronic Data Capture System, Handheld Computers, PDA (Personal Digital Assistants) Computer, Mobile Phone

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I. Introduction

Clinical trials are the most expensive and time consuming steps in drug development. In a paper-based clinical trial process, a Case Report Form (CRF), which is data collection form, typically has three or four copies per page, and the monitoring is typically done by hand at the investigative site comparing the CRF with source documents. The CRF data are later entered twice at a central location into a database. Information technology has been used to support clinical trials to have the most immediate and noticeable impact on drug development. Clinical trial technology that has been applied to improve clinical trial data collections is generally referred to as electronic data capture (EDC). The benefits of EDC include direct data entry at the investigator site leading to greater accuracy, fewer queries, decreased paper record storage, and timelier population of the study database[1]. Although increasing in pace, the conversion to EDC has been a slow progression[2]. A survey conducted in the year 2001 reported that only 5 percent of all new clinical trials made use of remote data entry for clinical trials, whereas the remaining 95 percent continued to use paper[3].

The internet allows transfer of clinical trial information and coordination of multiple clinical trial processes. Therefore, the Internet have increasingly been utilized in clinical trials[4)5)]. However, wired internet needs to connect the computer to the location where the Internet connection is available. Recently, mobile computing technology is proposed to improve information access, enhance workflow, and promote evidence-based practice to make informed and effective decisions at any place and any time. Mobile devices have been used in clinical trials for more than 16 years, utilizing different technologies. These devices have been used in different medical fields such as diabetes[6)7)], nutrition[8)], different surveys[9)]. The mobile technology capable of data capture or data entry becomes employed in clinical trials. The variety of applications in clinical trials ranges from electronic patient diaries[10-12)] to electronic case report forms (eCRFs)[13)14)].

Personal Digital Assistants (PDAs) are one the most popular mobile devices embedding mobile internet communication network. The PDAs offer portable and unobtrusive access to clinical data and relevant information at the point of care. They have been extensively tested and have shown mixed results as a data collection tool by physician users[15)16)] and patient users[17)] based on the application. The main advantage of PDA is to link a PDA to a central computer anytime and anyplace, whereas the wired systems are strained to the location where the connection exists. It enables to centralize study information and coordinate multiple trial processes in real time at a lower cost[18)]. In Korea, mobile internet subscribers exceeded 30 million, about 70% of the population by 2002[19)]. The mobile internet is generally used data communication network for everyday life such as mobile shopping, mobile banking, and mobile advertising in Korea. In spite of spreading mobile technology in Korea, data collection in clinical trial studies has still done on paper first and sometimes with electronic data entry taking place later. Furthermore, even few PDA-based clinical data collection systems typically collect and store data in offline mode, and then synchronize with the server by transferring to the operational database. Also, data review, data quality checks, and monitoring were performed manually and locally at the site. Real time data collection and transmit through mobile internet connection is still challenging area.

In response to these challenges, we have developed a wireless PDA application that patients can use both to evaluate their experience with a drug and to directly transmit their data to a database using a wireless internet connection. We used PDA instead of paper patient diaries in a randomized, placebo-controlled, double-blind irritable bowel syndrome (IBS) trial. IBS, a functional gastrointestinal disorder, rely exclusively on patients' self reports of their symptoms[20)].

The purpose of this study is to determine the im-

provement of speed, data accuracy and protocol compliance of PDA clinical data collection system comparing with traditional paper based data collection, which is popular way of current study, in the irritable bowel syndrome clinical trials study.

II. Materials and Methods

A randomized double-blind study was carried out to verify whether Remeron compared to placebo relieves irritable bowel syndrome (IBS). The study was approved by the Institutional Review Board of the hospital, and was designed as a double-blind clinical trial for efficacy of Remeron for IBS patients. Initially, sixty-four IBS patients from an 800-bed hospital signed informed consent forms. Subjects were required to visit one week before treatment for screening, to determine whether they met the inclusion criteria. Subjects took the actual medication or the placebo medication for four weeks and submitted a questionnaire each week. Patients visited the site each week during the one week of screening period and at weeks 2, 3, 4, 5, and 6 of the treatment period (Fig. 1). The study was conducted from Nov. 2001 to Apr. 2003.

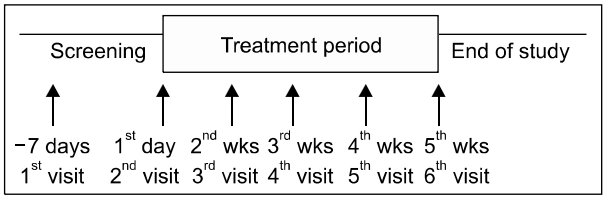

Figure 1. Study design for paper and PDA

The sixty four patients, who agreed to participate in the IBS clinical trial for the Remeron, were self-selected to either the experimental (PDA data entry) group or the control (standard paper data entry) group, according to their preference. Subjects of both control group and intervention group are asked to complete the questionnaires consisting of 6 check lists everyday as suggested in Table 1.

Research coordinators gained the informed consent and enter patients' basic information into the system at the beginning. Both forms are completed once daily at home for five weeks.

Table 1. Question items for the study

No	Category	Measurement frequency	Question items	Severity
1	Abdominal discomfort or abdominal pain	Daily	How severe do you feel abdominal discomfort or abdominal pain today?	0=None 1=Mild 2=Moderate 3=Severe
2	Abdominal distension	Daily	How severe do you feel abdominal distension today?	0=None 1=Mild 2=Moderate 3=Severe
3	Defecation	Daily	Did you defecate today?	0=No 1=Yes
5	Stool frequency	Daily	How frequently do you defecate?	0=None 1=One 2=Two 3=More than 3 times
4	Hard or lumpy stools	Daily	Do you feel hard or lumpy stools after defecating? Do you feel incomplete rectal evacuation after a bowel movement? Do you feel defecation frequently?	0=No 1=Yes
6	Stool form	Daily	How would you describe your stools?	0=Hard 1=Solid 2=Watery

The eighteen subjects in the control group are requested to fill in the questionnaires daily on the paper CRFs for one week and bring the completed papers to next planned visit.

On the other hand, the eighteen subjects in the intervention group are requested to answer questionnaires on the PDA till two o'clock of the next day of taking medication everyday and transmit data to the server through wireless internet.

This result in 630 data sets consisting of six questionnaires each, and 3,570 data points total. The intervention group subjects complete the six items on the PDA and transfer the complete data it by two o'clock each day using wireless internet. The control group subjects were asked to fill out the paper daily, and submit seven paper CRFs each week at their planned visits. Then, a coordinator entered their data into a web application later.

Measurement instruments for the effectiveness of the PDAs in collecting clinical trial data were developed in consultation with the co-authors of clinical side,: a) response rate; b) completeness of data; c) the number of input errors; and d) protocol compliance. Response rate measured the extent to which they used the e-CRFs during the treatment period. Response completeness was measured whether the subjects answered all data items completely. Matthew et al. also proposed completeness of data to evaluate data quality for PDA data collection[21]. A chi-square test was conducted to compare response rates and response completeness between the two groups. Additionally, the Mantel-Haenszel chi-square test was applied to identify the influence of data collection methods on response completeness controlling demographic variables. Finally, the number of input errors and protocol compliance were measured.

Protocol compliance means that both groups should enter their medication intakes during five weeks at five measurement periods on a paper or a PDA form. Subjects usually report that they fill out the survey form following the protocol. However, subjects usually forget to write down the form at the exact time. This study compared the reported compliance and actual compliance.

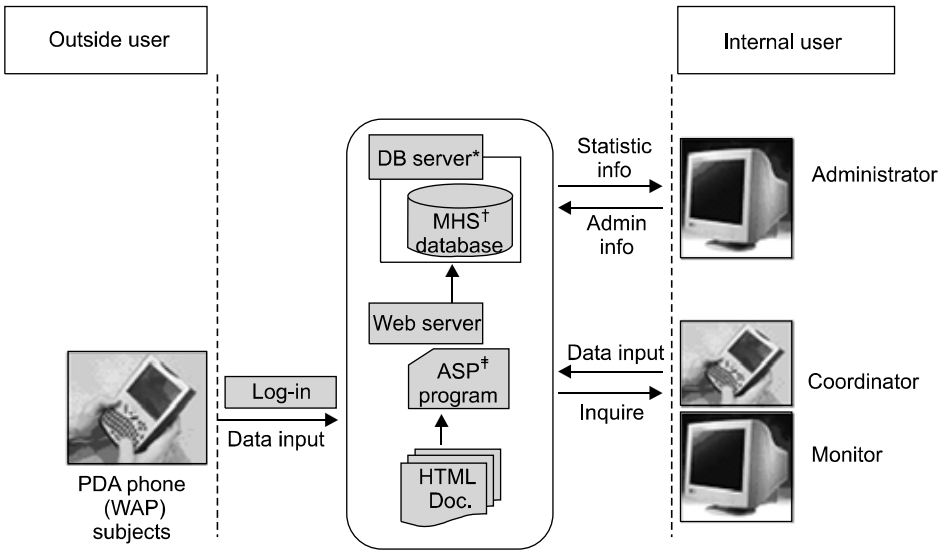

Figure 2. Data flow for PDA clinical data collection system
* DB: Database
† MHS: Message handling system
‡ ASP: Active server page

1. System architecture

Our data collection system is comprised of two components: a) a web application for internal users and subjects; and b) PDA application composed of an administrator module and a subject module Web application (Fig. 2).

The web application was developed with Active Server Page (ASP) and Javascript. MS SQL Server was used as database. The web application was divided by two parts by the types of users: such as administrators or coordinators, and subjects. Application for internal users has Active Sync 3.1 program to synchronize the PDA application with the desktop application. Authenticated users can then update and edit data through any web browser, which permits a reliable and wireless internet access.

Coordinators can enroll eligible subjects and check the entered data, add new subjects, modify and review information for registered subjects, and review the status of the current study. They are also able to enter and revise demographic information and make inquiries about all entered information through PDAs or desktop. Administrators are able to enter and manage patient information and assign appropriate privilege to study personnel, thus allowing management of subjects and information. They can also check for redundant identification when new subjects are added. By clicking the detail button on the subject list, a graph and table with data analysis pop up on the screen.

The Cesscon LUXian 2500 model of PDAs, installing Microsoft CE operating systems, are distributed to eligible subjects at free of charge. Subjects can gain access into the PDA CDCS through the phone number assigned by the wireless provider and enter the IP address of the gateway server. PDA software allows for only a single patient's data to be collected at any one time. Once the PDA has been synchronized with the personal computer, the patient self-reported data are purged from the unit. These features ensure that only the current user's data are stored on the PDA and that the data are only accessible to the coordinators and monitors.

The electronic case report form for PDA was designed for this study as Figure 3. The subjects are requested to enter their data everyday about perceived changes in their specific symptoms from 12 till at least 2 o'clock during the treatment period as shown in Figure 1. Once they complete answers, and then send data into the central server through mobile internet connection. Figure 3 shows the log-in screen and input

Table 2. Reason for withdrawal of participants

Reason	Withdrawals
Improved health condition	2
Study protocol violation	3
Fail to track patients	13
Administrative problems	5
Past disease history	5
Total	28

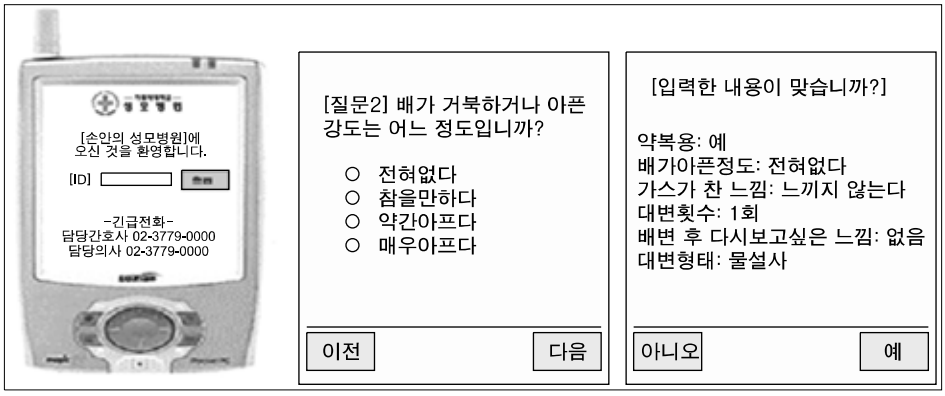

Figure 3. Log-in screen and questionnaire screen for PDA

screen for the PDA application.

III. Results

Sixty four patients initially enrolled to participate, but twenty eight patients withdrew for the following reasons suggested by Table 2.

1. Demographic characteristics

The sample for this study consisted of 18 patients (50%) for control and 18 patients (50%) for intervention; 19 (53%) were women, and 17 (47%) were men. The mean age for the control group ranged from 52.5 +/− 12.3 and 35.6 +/− 10.4 for the intervention group.

The demographic characteristics of the participants are summarized in Table 1. The two groups did not have any significant demographic differences, except age. Age between the two groups shows statistically significant difference. The age of the control group was much higher than the intervention group (p<0.0001). These significant age differences can make selection bias. To control selection bias, patients in the common age range should be retested. The common age range is 40 to 45 years. However, there are only four patients in the intervention group and five patients in the control group within this age range. Thus, additional analysis cannot be conducted because the sample size is too small. And, disease duration of control group and intervention group is 4.1 and 6.2 year respectively. However, it doesn't show statistical difference (Table 3).

Table 3. Demographic characteristics of patients

Variables		Control	Intervention	χ^2	p
Sex	Male (N=19)	8 (44%)	11 (61%)	1.01	0.3166
	Female (N=17)	10 (56%)	7 (39%)		
Age (Average)		52.5±12.3	35.6±10.4	4.46	0.0001
Disease duration		4.1±3.3	6.2±9.4	0.90	0.3782

2. Response rate

Both groups need to submit results for five weeks, totaling 630 submissions per group. Out of 630 expected submissions, the response rate for the control group was 94.4 percent (595 submissions), whereas the e-CRF response rate for the intervention group was 77.3 percent (487 submissions). Thus, the response rate for the control group was higher than that for the intervention group (p<0.0001) (Table 4)

3. Response completeness

Response completeness measures whether or not patients submitted complete data elements on paper CRFs or e-CRFs. Since 595 CRF from the control group are submitted, the 3,570 items are supposed to be completed. Out of 3,570 items on paper CRFs, 3,409 items are complete and 161 items are incomplete. By contrast, out of 2,922 items, the patients of the intervention group are supposed to submit, 2894 items are complete and 28 items are incomplete data items. Thus, the response completeness of the intervention group is higher than that of the control group (p<0.0001) (Table 5).

A Mantel-Haenszel chi square test was performed to identify the influence of data collection methods on response completeness controlling demographic variables.

Table 4. Response rate Unit : N (%)

Response	Control (N=630)*	Intervention (N=630)*	χ^2	p
Yes	595 (94.4%)	487 (77.3%)	76.31	0.0001
No	35 (5.6%)	143 (22.7%)	76.31	0.0001

* 18 subjects×35 days (5 wks)

Table 5. Response completeness Unit : N (%)

Completeness	Control (N=3,570)*	Intervention (N=2,922)†	χ^2	p
Complete	3,409 (95.5%)	2,894 (99.0%)	71.71	0.0001
Incomplete	161 (4.5%)	28 (1.0%)	71.71	0.0001

* 595 response×6 items
† 487 response×6 items

Table 6. Mantel-Haenszel test of response completeness controlling sex, age, and disease duration

	Variables	Response	Group N (%)		χ^2	*p*
			Control (N=3,409)	Intervention (N=2,894)		
Sex	Male	Yes	1,577 (96.6)	1,811 (98.9)	63.42	0.0001
		No	55 (3.4)	19 (1.1)		
	Female	Yes	1,832 (94.5)	1,083 (99.2)		
		No	106 (5.5)	9 (0.8)		
Age	Below 40	Yes	548 (97.2)	2,084 (98.9)	38.24	0.0001
		No	16 (2.8)	22 (1.1)		
	Over 40	Yes	2,861 (95.2)	810 (99.3)		
		No	145 (4.8)	6 (0.7)		
Disease duration	Less than 2 years	Yes	1,929 (96.5)	1,317 (99.3)	77.36	0.0001
		No	69 (3.5)	9 (0.7)		
	More than 2 years	Yes	1,480 (94.2)	1,577 (98.8)		
		No	92 (5.8)	19 (1.2)		

Female has higher completeness than male in the control group while male has higher completeness in the intervention group (63.42, p=0.0001). In addition, over 40 group has better completeness in the control group while below 40s has better completeness in the PDA group (38.24, p=0.0001). Below 40s Male rather than over 40s female, whose disease duration is over 2 yrs, fells comfortable to enter clinical study data with PDAs (77.36, p=0.001) (Table 6). This result shows Sex, Age and disease duration has significant relationship with the use of PDA for data collection.

4. Input error

In the control group, 11 subjects committed 78 cases of input error, whereas in the intervention group, 14 subjects committed 52 cases of input error. Additionally, the characteristics of the errors were different across the two groups. The major errors in the control group were duplicate answers in a question. By contrast, the errors in the intervention group were functional errors, like pushing the wrong button or the same button twice causing unwanted double entry in a day. As subjects become proficient with the PDA, errors are expected to decrease. Nonetheless, the input error per person for the PDA group (4 cases) was lower than that for the paper group (7 cases) (Table 7).

Table 7. The profile of input errors

	Control	Intervention
No. of input errors	78 (2.3%) Total case: 3,331	52 (1.8%) Total case: 2,832
No. of subjects that enter wrong data	11 (61.1%) Total subjects: 18	14 (77.8%) Total subjects: 18
Input error per a subject	7	4

Table 8. The difference between reported compliance and actual compliance

	Control	Intervention
1-2 weeks (N=252)		
Complete (case)	240	212
Incomplete (case)	12	40
Reported compliance*	95.2%	84.1%
Actual compliance†	73.4%	84.1%
3-4 weeks (N=252)		
Complete (case)	237	198
Incomplete (case)	15	54
Reported compliance	94.4%	78.6%
Actual compliance	67.2%	78.6%

* Response rate of the case report forms reported to be completed by the study subjects

† Response rate of the case report forms actually completed by the study subjects

5. Protocol compliance

Protocol compliance means that both groups should enter their medication intakes during five weeks at five measurement periods on a paper or a PDA form. 95.2% of the control group reported that they answered the

questionnaires according to the direction during first through second weeks, however, only 73.4% followed up the direction correctly. On the other hand, since PDA group transmit data as soon as items are answered, reported and actual response rate are identical as 84.1%. The compliance rate for 1-2 weeks of the intervention group is higher than the control group (Table 8).

In third through fourth weeks, 94.4% of the control group reported to follow up the diction, however only 67.2 % actually answered correctly, Thus, the protocol compliance rate for 3-4 weeks of the intervention group is also higher than the control group as 78.6% (Table 8).

IV. Discussion

This study addresses whether wireless PDA technology can reduce clinical data input error and improve response rate, data quality and protocol compliance.

Average age choosing PDA group is much lower than non-PDA group. Higher preference for PDA of younger generation is likely due to their equal familiarity with mobile phone. As mobile phones continue to become integrated into their daily lives, mobile EDC preference among patients may continue to grow.

In spite of participants' preference, the response rate was lower than paper group. We assume that current PDA technology is not stable and reliable to use for clinical trials yet based on our supplementary survey. The survey regarding the PDA usage shows that few users become disgruntled and complained some difficulties of PDA data entry. Out of 21 respondents, 66% of them showed the difficulty of PDA usages, and 33% had unstable internet access. To apply PDA for clinical data collection, these technical issues should be resolved soon.

Our finding also supports previous literature reporting that PDA can enhance completeness of data collection[21]. Lower number of the missed items was found in the PDA collection compared with paper method. This increased data collection has a direct beneficial impact on the quality of data collected.

Regarding to input errors, PDA is supposed to have error free data collection compared with paper. However, PDA collection still has input errors. The errors were functional errors, like pushing the wrong button or the same button twice. Therefore, predesigned functions alerting users before developing e-CRF application will be able to reduce possible errors. Electronic data entry will not result in error-free data collection without built in check functions. Minimizing the data entry errors that result from extra data entry steps will streamline the data clean-up stage of clinical trials.

In spite of few errors, the quality of data in PDA is improved in comparison to paper group because the data are more complete, have fewer errors, and there are fewer protocol violations like other studies[14)22-24)]. Thus, data editing, retyping, proofreading, and the process of clarification can be eliminated, and irrelevant questions can be omitted.

Also, protocol compliance was comparably improved. Significant retrospective entries were made in the control group. Poor diary completion may result from having unreasonable expectations of patients and giving incomplete instructions. Electronic, time coded diaries could ensure better quality of records.

Selection bias can occur because the intervention group is self-selected according to their preference. In addition, recruitment only included patients treated by an investigator in large hospital. This sampling method limits the degree of generalization of our results and may not reflect outcomes in other setting. Additional attempt to control potential impact of selection bias should be made in this type of research. Also, this study should be replicated using a larger number of subjects from various clinical trial studies in future.

This study shows advantages and some weakness of wireless PDA technology applying for clinical trials. Our results showed input errors are significantly re-

duced but PDA based data collection cannot improve response rate. PDAs with wireless internet capabilities have the potential to improve clinical trial data collection and management, and thus, to expedite the development of important new drugs. In spite of various overseas researches in the area of electronic diary, PDA has not been used in clinical trial yet in Korea. However, wide adoption of PDA technology is expected with better designed PDA hardware and software applications, faster internet access, improved battery life, seamless integration of PDA technology with hospital information systems, and satisfactory security measures. Herein, we described some barriers and benefits based on our experience to collect clinical trial data. We desire it will give you some idea on how to successfully implement PDA based data capture system in your organization. The results of this study confirm the feasibility and adaptability of the data capture through PDA administered questionnaires. Analysis of data completeness, response rate, and protocol compliance suggest that the IBS questionnaires can be maintained under PDA application.

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