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ORIGINAL PAPER

Towards Improved Healthcare Performance: Examining Technological Possibilities and Patient Satisfaction with Wireless Body Area Networks

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Abstract This paper investigates the benefits of using less intrusive wireless technologies for heart monitoring. By replacing well established heart monitoring devices (i.e. Holter) with wireless ECG based Body Area Networks (BAN), improved healthcare performance can be achieved, reflected in (1) high quality ECG recordings during physical activities and (2) increased patient satisfaction. A small scale clinical trial was conducted to compare both technologies and the results illustrate that the wireless ECG monitor was able to detect ECG signals intended for arrhythmia diagnostics. Furthermore, from a patient's perspective, both technologies were evaluated using three dimensions, namely; hygienic aspects, physical activity, and skin reactions. Results demonstrate that the wireless ECG BAN showed better performance, especially regarding the hygienic aspects. It was also favourable for use during physical activities, and the signal quality of the wireless sensor system demonstrated good performance regarding signal noise and artefact disturbances. This paper concludes that wireless cardiac monitoring systems have significant benefits from a patient's perspective, and further clinical trials should be conducted to further evaluate the new ECG based BAN system, to identify the possibility of widespread adoption and utilisation of wireless technology for arrhythmia diagnostics.

Keywords Wireless BANs · Electrocardiography · Arrhythmia diagnostics · Patient satisfaction · Remote patient monitoring

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Introduction

Disease management programmes involving ECG home monitoring are expected to play a key role in the safety and cost effectiveness of future health-care services [1]. New wireless technologies open up possibilities for the monitoring of vital sign parameters using wearable biomedical sensors. The aim of using these technologies is to improve the quality of care/service, reduce the cost of caring for patients and facilitate home healthcare. This paper evaluates the performance of a new wireless ECG BAN technology against an existing wired technology, the Holter monitor (c.f. Fig. 1a). In the future we assume the wireless device can be utilised for early arrhythmia diagnostics e.g. arrhythmia control when adjusting a patient's medication. Our paper

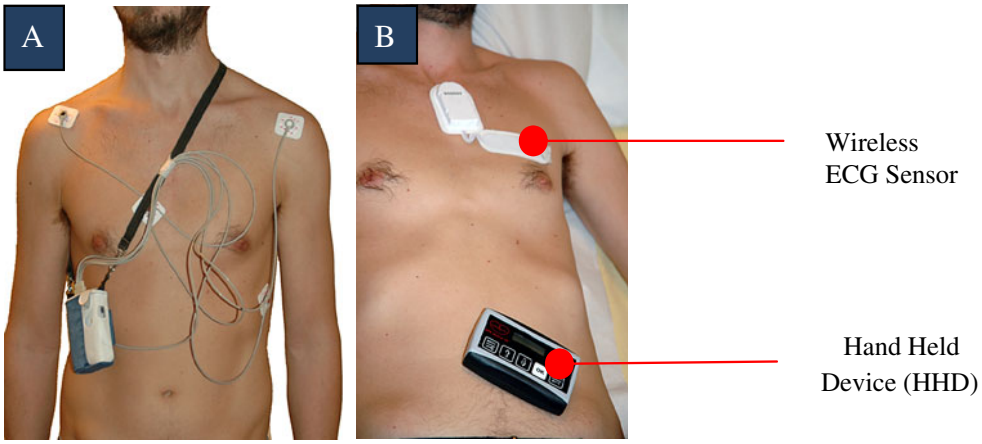

Fig. 1 Wired holter monitor (**a**) vs wireless ECG BAN (**b**) and corresponding HHD device shown on the patient

examines performance issues from the perspective of the signal quality of the ECG recordings from the ECG BAN, as well as patient satisfaction with wearing this device. It illustrates that wireless technologies in the area of cardiac monitoring have the potential to significantly improve patient care management. It concludes by discussing the issues which need to be addressed to enable wireless BAN technologies to be adopted for cardiac monitoring.

The remainder of this paper is structured as follows. The literature in the area is reviewed and concludes that if wireless technologies are to be adopted by medical practitioners, such devices must be proven to be as reliable as the widely used Holter monitor. Furthermore, it reveals a lack of research focusing on a patient's perception of these devices. It outlines the objective of this study which is "to determine the way in which wireless ECG BAN recording technologies can be used by medical practitioners as an arrhythmia diagnostic tool, and to evaluate the patient satisfaction of using wireless ECG based BANs".

The paper proceeds by documenting the three stage research approach adopted for this study and presents the initial findings. The paper concludes by highlighting key issues associated with remote patient monitoring and further research directions.

Literature

The application of wireless technologies in a healthcare context is not new [c.f. [2–9]. In particular, the adoption and utilisation of these wireless technologies is growing rapidly as hospitals and medical equipment firms realise the benefits which can be delivered [10, 11]. As the safety and reliability of these systems improves, hospitals are now more willing to adopt wireless solutions [11]. Researchers [10, 11] also note that devices for the treatment of chronic health conditions represent an opportunity to empower patient's to control their treatment. They argue that patient care is improved by the less intrusive nature of wireless technology and when implemented, a wireless solution should reduce the impact of treatment on the lifestyle of the patient and improve their health outcomes in the long term.

With new technologies continuously being investigated in terms of their applicability to healthcare, it is important to investigate if healthcare performance improves as a result of utilising these technologies. In healthcare, performance has primarily been investigated in terms of how technology facilitates performance improvements in administrative tasks [12]. However, research is limited on the adoption of new technologies by medical practitioners for diagnostic purposes and the resulting performance implications [11]. Furthermore, the investigation of patient issues in relation to new technologies is an area devoid of study with the issues faced by patients not being explored. We argue that such research would provide insights into why particular technological innovations are not widely adopted and utilised by medical practitioners in their day to day activities.

Technology constraints

In the area of cardiac monitoring, Holter monitors have long been used for the detection of arrhythmia situations [13], and those wearable monitors are used at out-patients' clinics for cardiac monitoring to diagnose arrhythmias because of their accuracy and reliability in relation to:

1. The quality in the ECG signal,
2. The accuracy of the R-wave detections, and
3. The arrhythmia detection performance.

Their performance in relation to these criteria is key in explaining why they are the industry standard and used the world over by medical practitioners for cardiac monitoring. However, the Holter monitor can be characterised as having

Table 1 Performance issues with the Holter monitor

Patient	Medical practitioner
Stigmatisation	Less reaction time due to lack of real-time data
A lack of timely intervention	Manual retrieval of data (time consuming)
Lack of mobility	
A large number of visits and a large percentage of time spent at hospital	

a number of performance issues, which are summarised in Table 1. Its limitations include [14, 15]:

1. Its restricted recording time due to a limited storage capacity,
2. A large amount of wires connecting the device to the patient, and
3. A lack of real-time data.

From a general practitioner's perspective, the biggest disadvantage of using the Holter technology is that the data is not real-time which in a medical context makes the possibility of instant diagnosis impossible. It may be a number of days before a medical prognosis is made, which in certain instances may be fatal [15]. Correct diagnosis will normally be given by a cardiology specialist, and the possibilities for a general practitioner to use a Holter as a quick diagnostic procedure is thus limited.

From a patient's perspective, there are also shortcomings with the Holter Monitor. Firstly, it is large and heavy [14] with patients required to wear it for a minimum of 24 hours and in many cases for a period of up to 1 week, depending on the specific medical condition of the patient. A patient's mobility is severely hampered when wearing a Holter monitor [14]. For instance, a patient can't take a shower or bath while attached to the monitor [13], as this will destroy the electronics in the recording device. Difficulties can also arise with sensors becoming unattached due to patient movement [16, 17], which will give artefact disturbances to the recorded signals. Furthermore, there is also a large amount of 'stigmatisation' [18] associated with wearing the device. To summarise, in terms of the Holter monitor, there are performance issues from both the general practitioner and patient perspectives.

Such limitations have resulted in researchers exploring how other technologies can facilitate cardiac monitoring, for example wristwatch technology [4], mobile phones [19] and Bluetooth technology [20]. Yet, in all cases, the performance issues, in relation to the diagnostic performance of these devices result in the majority of general practitioners not willing to adopt these technologies. Yet the issues (outlined in Table 1) with the incumbent Holter monitor technology still remain, predominately based on a wired non real-time connection to the patient [c.f. [21].

Methods

In order to perform continuous ambulatory ECG recordings, a new wireless ECG based BAN was developed, and Fig. 2 shows a photograph of the ECG BAN prototype which incorporates analog amplification circuits, a radio transmitter and a battery. The unit is disposable with an adhesive surface underneath the ECG patch; thus it is uncomplicated to use and can easily be applied to a patient's chest. A very strong single ECG patch is used as opposed to the traditional multi-patch Holter monitor (c.f. Fig. 1). The patch is positioned at the upper left part of the chest. The Holter recorder was used according to normal procedure at the hospital with five electrodes in a standard five-lead system [22].

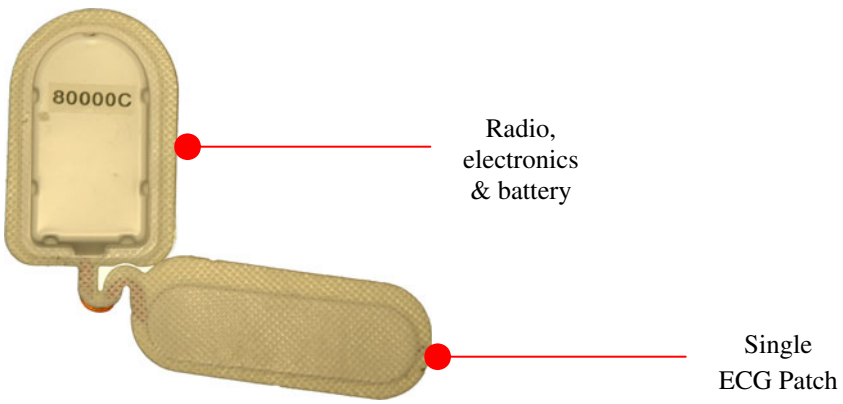

Fig. 2 ECG BAN prototype used in the clinical trials. c.f. Fig. 1b (attached to patient)

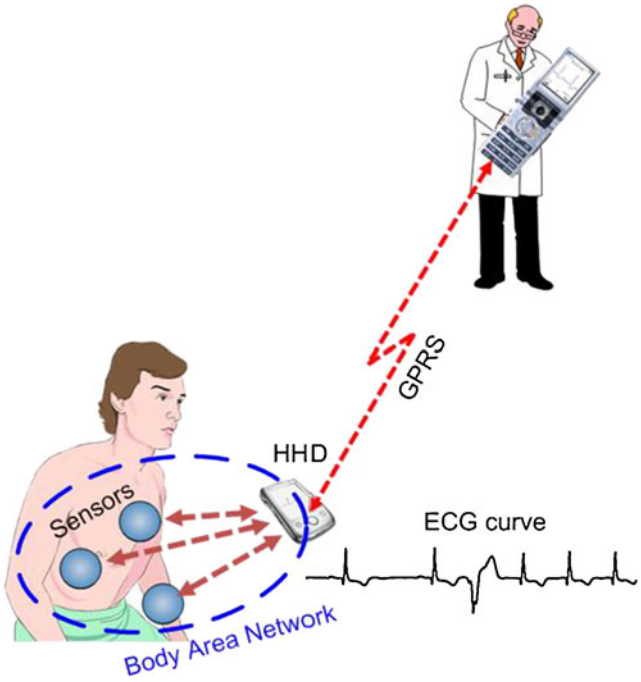

Fig. 3 Several wireless sensors can communicate with a wearable hand held device (HHD) forming a Body Area Network which can act as a gateway to transmit the actual ECG signal to the doctor by use of mobile phone data transmissions e.g. GPRS

The ECG based BAN measures one ECG signal and continuously transmits the signal to a Wireless Handheld Device (HHD). The ECG BAN device facilitates secure communication to the HHD as a common gateway to transmit the actual recordings to a designated doctor (illustrated in Fig. 3). The wireless ECG BAN solution was developed by WPR Medical, Arendal, Norway [23].

While the HHD receives and analyses the ECG signal, if an abnormal cardiac signal is encountered, the HHD device will start transmitting the recorded ECG signal to the cardiology specialist at the hospital. In a hospital or private alarm centre, the alarm will be raised by the operating personnel and the system can display the actual recorded ECG signals received from the patient. However, as it is in the early stage of development, this automatic transmission functionality was not incorporated into the prototype used in our study.

The objective of this research is "to determine the way in which wireless ECG BAN recording technologies can be used by medical practitioners as an arrhythmia diagnostic tool, and to evaluate the patient satisfaction of using wireless ECG based BANs". A three stage approach was adopted to operationalise this study and meet its objective.

Stages one and two took place in the cardiac out-patient clinic at Sørlandet Hospital, Arendal, Norway. The performance of both technologies (the Holter monitor and the wireless ECG BAN) was compared with the purpose being to assess the performance in terms of ECG signal quality and patient satisfaction. This clinical trial was designed with patients wearing both the conventional Holter monitor and the wireless ECG BAN technology at the same time for 1 day. Thus, simultaneous recordings made by the two devices could be compared and correlated. Patients referred to long term ambulatory (Holter) procedures at the outpatient cardiology clinic at Sørlandet Hospital, Arendal, Norway were asked to participate in the clinical trial. After signing the informed consent form, they participated in the study during their arrhythmia investigation. The inclusion criteria was patients with suspected arrhythmia and the exclusion criteria was patients with dementia who were not able to handle the equipment. Eleven patients signed up for the clinical trial which took place between November 2006 and May 2007. In addition, a reference group (those who were examined using only the Holter monitor) of 25 patients were recruited to study patients' experiences in relation to using the Holter monitor during a "normal" arrhythmia investigation procedure. A Sensor Acceptance Model [18] was utilised to assess patient satisfaction, and the patients had to fill in a detailed questionnaire. This model assesses patient's satisfaction in relation to anxiety, skin reaction, equipment, hygienic aspects and ease in conducting physical activity. Patient's characteristics are presented in Table 2.

As a follow on (stage three), the wireless equipment was made available to a general practitioners office. This facilitated the testing of a decentralised medical expert diagnostic service. General practitioners at two health centres in Arendal, Norway were educated to apply the wireless ECG BAN to the patient's chest and use this technology as a decentralised arrhythmia diagnostic solution. The rationale for this trial was an attempt to perform this medical diagnostic procedure in closer proximity to the patient's natural surroundings and to reduce the number of visits to cardiologists which are located in centralised care units in Norway. The procedure in selecting the patients was the same as that used in the hospital stage of the clinical trial, and the patients only had to wear the wireless ECG system for 3 days. The wireless ECG BAN used in this study stored the recorded ECG signals in an internal memory chip. This chip was sent to the cardiology specialists at Sørlandet Hospital in Arendal Norway, in

Table 2 Patient characteristics (n=36)

Group	Number	Gender (male/female)	Age		
			Mean (SD)	Min	Max
Wireless	11	6/5	40.2 (19.4)	11	67
Reference (Holter)	25	7/18	56.4 (13.2)	36	77

order for the cardiology specialists to evaluate the recordings in a similar way as the traditional Holter.

It was essential to evaluate whether the wireless ECG BAN could be used in everyday life situations, and it was assumed that recorded signals could give higher diagnostic yield compared to situations where the patient is restricted or limited in their physical activities. The primary goal of developing a wireless ECG BAN was to find ways of monitoring the everyday life of the patient as closely as possible.

During following up interviews carried out in the patient's home, patients were asked about their experience with ECG BAN and how they managed this technology. We tried to identify important factors for the patient's acceptance of the wireless ECG BAN and to evaluate to what degree the patient accepts it [24]. This was a phenomenological study based on Giorgi's theory [25], therefore, the methods used for the patient's acceptance include a combination of quantitative and qualitative data gathered using the sensor acceptance model and phenomenological interviews.

The study has been accepted by the Regional Ethical Committee as well as the hospital's Ethical Committee, and permission with respect to data privacy requirements was given by the Norwegian Social Science Data Services on behalf of The Norwegian Data Inspectorate. The permission to use the developed prototype in a clinical study was given by the Directorate for Health and Social Affairs in Norway, as this equipment does not yet have a CE conformance declaration.

Results

This section outlines the findings of the three stages in this study.

Stage 1: Evaluation of ECG recordings: Holter vs. wireless ECG BAN

If wireless technologies are to be adopted by general practitioners to assess cardiac arrhythmias, such devices must be proven to be at least as reliable, if not better, than the existing Holter technology. Printouts were collected from the wireless ECG BAN and corresponding time sequences of the Holter recordings. An example of an actual recording is presented in Fig. 4, where the three upper curves are from the Holter recorder while the lowest curve is from the wireless ECG BAN. The QRS complexes from the Holter and Wireless ECG BAN produce comparable results. Each system detects the R-wave and prints the R–R interval in milliseconds (shown as digits on the top). In addition, the annotations for each R-wave describes whether this was detected as a normal beat (*N*), a supraventricular extra systoles (*S*) or a ventricular extra systoles (*V*).

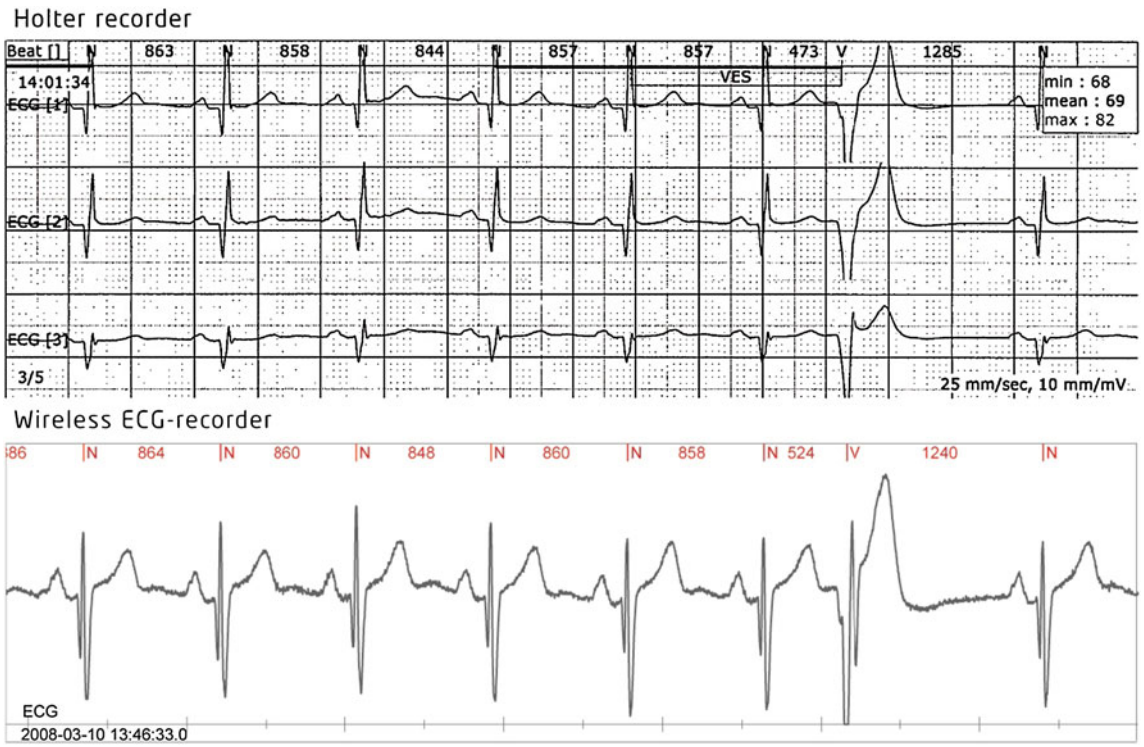

Fig. 4 Printouts from a three-lead Holter (*at the top*) and the one-lead wireless ECG BAN (*underneath*)

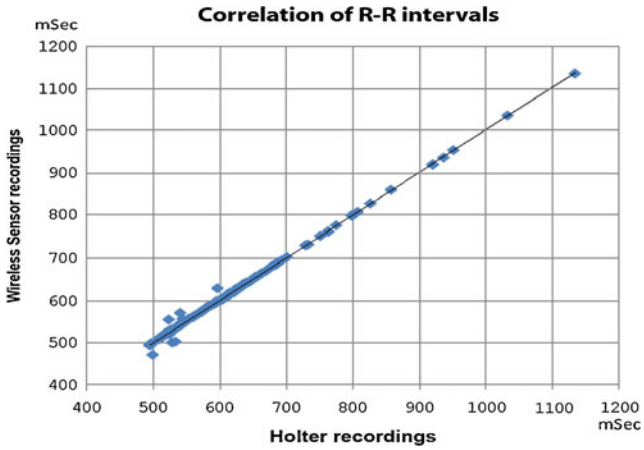

Fig. 5 Correlation plot with the actual R–R intervals given in milliseconds, and with results from the Holter recorder on the *X-axis* and from the wireless ECG BAN on the *Y-axis*. Number of R–R intervals in the continuous sequence was 131, and showed a strong correlation (r=0.998, p<0.005)

A comparison of R–R intervals

As it is essential in correct detection of arrhythmia situations that the monitoring device shows a precise interpretation of the R-wave within the QRS complex in the ECG recordings, a correlation analysis method was used to compare the actual recordings. On the recorded ECG curve printouts, the actual interval between two R-waves, are given at the top of the curves in milliseconds.

By comparing a time sequence for exactly the same heartbeats recorded by two different devices, it is possible to calculate Pearson's r correlation coefficient. A correlation plot for a single patient is presented in Fig. 5, showing a strong correlation (r=0.998, n=131, p<0.0005). Similar correlations were calculated from another five patients where it was possible to identify exactly the corresponding time series of heart beats from the two devices, showing good correlations with r>0.998 for all the sequences. The correlation analysis method of Bland and Altman [26] have also been performed by calculating the difference of the mean and the bias defined by the mean difference and the standard deviation of the difference. It was found that a deviation between the two systems within the range of −6 to +7 ms, which corresponds to ±1% of the mean R–R interval, can be considered as near identical for any practical purpose.

In order to assess the quality of the results originating from the wireless ECG BAN against the Holter monitor, two independent and experienced cardiologists reviewed the results from both approaches. The recording quality of an ECG may vary (as a result of patients' movement and physical activity), and a total of 103 recorded ECG sequences of 30 seconds duration were evaluated. The cardiologists gave their scores evaluating the quality of the recording curve regarding its usefulness in arrhythmia diagnosis in terms of whether they would be able to give a valid interpretation of the recorded ECG sequence, using a five-point Likert scale (5—very good, 4—good, 3—acceptable. 2—poor, 1—not acceptable). Comparisons of scores from the two systems are given in Table 3.

The cardiologists' evaluations showed that the differences between the two recording devices were small and not statistically significant (p=0.2). Analysis revealed that the Holter monitor was more exact for precise arrhythmia annotations, while the wireless system in some instances did not give correct annotation for the extra systoles (*S* or *V*).

During patients' physical activities, the signal quality of the wireless ECG BAN demonstrated good performance and adequate ECG recordings in relation to signal noise and artefact disturbances.

In some of the wireless recordings the P-wave amplitude was relatively low; however, in all sequences it was possible for a cardiologist to make a correct interpretation of the arrhythmias detected. The cardiologists believed the reason for the low P-wave amplitude was the actual position of the patch on the chest, and if the patch was placed at the upper left part of the chest (above the left breast), the quality of the P-waves would be improved.

It is therefore reasonable to conclude that the differences between the two recordings, with regard to their ability to perform arrhythmia diagnostics, were minor and that the evaluations of the ECG signals obtained with the wireless ECG BAN device showed promising levels of recording quality for the purposes of arrhythmia diagnosis.

Stage 2: Patient satisfaction: Holter vs. wireless

As in the medical practitioner's case, the performance of the new wireless ECG BAN device is compared to the existing Holter monitor in order to determine the patients' satisfaction with both technologies. Patients' perspectives

Table 3 Independent cardiologists' evaluation of the usefulness in arrhythmia diagnostics for the two systems; the Holter recorder and the wireless ECG BAN, where a total number of 103 ECG sequences were evaluated

Evaluator factor	Total score			Holter			Wireless		
	N	Mean	SD	*N*	Mean	SD	*N*	Mean	SD
Usefulness in arrhythmia	103	3.45	0.98	44	3.60	1.00	59	3.34	0.96

Table 4 Results from the questionnaires, mean (SD) for the three dimensions calculated

Dimensions	Wireless sensor (n=11)	Reference group (n=25)
Hygienic aspects	8.6 (1.6)	6.6 (2.9)*
Physical activity	9.2 (0.8)	8.0 (2.8)
Skin reactions	6.3 (2.5)	8.6 (2.4)*

A high score for the dimension Anxiety indicate the patient shows a low degree of anxiety.

*$p<0.05$ significant difference

on both technologies were evaluated using the following dimensions: *hygienic aspects*, *physical activity*, and *skin reactions*. Scores were given using an 11-point semantic differential scale, where the patients evaluated their experience of using the wireless device and the Holter monitor. The performance of the Holter and wireless ECG BAN across the various patient satisfaction dimensions is summarised in Table 4.

The Holter monitor performed better in terms of skin reaction ($p<0.05$). This can be explained by a larger medical patch for the wireless sensor compared to the normal multi-patch ECG electrodes employed by the Holter. In terms of hygienic aspects, there was a significant difference between the 2 systems, with a significantly higher score for the wireless ECG BAN ($p<0.05$).

The hygienic aspects focused on tasks related to the patient's ability to have a bath/shower and to use the equipment during the night while sleeping. The survey showed a significant difference between the two devices ($p<0.05$), with the wireless ECG BAN being preferable. With the wireless ECG BAN, the patients had the possibility to have a shower, in contrast to the Holter system. Furthermore, the wireless ECG BAN was less heavy and cable free.

In seeking to understand patients' satisfaction with both technologies, a series of interviews were conducted. One patient complained about the Holter recorder and stated that he had a feeling of "being a living medical instrument" because of all the cables he had to wear. With regard to the wireless ECG BAN, he stated "the wireless sensor was comfortable to wear and most of the time I forgot I was wearing it". He said that after a while the ECG BAN became "a part of me". In terms of mobility, a number of patients expressed the advantage of performing physical exercise while monitored.

The patients reported they were able to participate in football games, outdoor jogging, aerobics and similar activities. This represents a clear advantage of the wireless ECG BAN giving the patients a much greater possibility of carrying out the activities of daily living (ADL) without any obstacles.

Stage 3: Decentralisation to the general practitioner's office

To evaluate the wireless ECG BAN as part of a decentralised initiative for cardiac monitoring (proximity of patient to GP), it was made available at a GP's office. For this stage of the study, a trained nurse applied the ECG BAN to the patient's chest, and instructed the patient on how to use the device and perform overnight charging of the HHD. After a predetermined time, normally 3 days, the patient had to return the equipment to the GP's office. The internal memory storage chip in the HHD was then manually transferred to the cardiologist at the hospital, to facilitate arrhythmia analysis. The GP subsequently received a report from the cardiologist which facilitated diagnosis and treatment of the patients by the GP without the need for them to travel a large distance in order to attend the cardiologist's clinic. Five patients participated in this aspect of the study in the period from May to June 2008. In evaluating this part of the clinical trial, the researchers focused on the patients experiences with the wireless ECG BAN. During phenomenological interviews the researchers documented patients' experience in using this device. Analysis from these interviews provided key insights on patient's performance, in relation to physical, psychological and social dimensions (c.f. Table 5).

As presented in Table 5, the wireless ECG BAN made it possible to participate in physical exercise; this was positively evaluated by the patients. Patients reported that management of the sensor was easy and unproblematic;

Table 5 Patient performance indicators for decentralised solution (home healthcare)

Performance indicator	Patient insights
Physical dimension	Ability to conduct normal daily activities e.g. shopping, walking etc without thinking about wearing the sensor.
	Patients reported that intensive physical activities were also possible.
Psychological dimension	Reduction of anxiety both for the patient and spouse/partner.
	Feeling of safety increased.
Social dimension	Ability to function in normal social situations.
	They went to town, went shopping and participated in meetings.

however, they wanted a visual display to indicate the sensor system was working properly. With the wireless ECG BAN available at their local GPs office, patients felt that quality of care given by the GP was improved. Therefore in summarising the wireless technology from a patient's perspective (both at the hospital and home trials), four issues were noted:

1. Stigmatisation
    - Some patients wish to hide a cardiac monitor from the general public. Our analysis revealed that this was a problem with the Holter monitor, however stigmatisation was not an issue with the wireless ECG BAN. The equipment is not a hindrance to the patients' activities of daily living (ADL), including physical sport activities. It enables the recording of cardiac arrhythmias under more strenuous physical conditions, which are very difficult to capture with the Holter monitor due to noise and artefact disturbances during activity.
2. Need for feedback from the system
    - Some of the patients were concerned about not receiving any feedback from the recording system; whether it was operating as normal or not. A display on the hand-held device indicating proper system functions is recommended so the patient can be sure that the wireless ECG BAN is functioning correctly.
3. Need for feedback from health personnel
    - Some patients reported that they wanted quick reaction and feedback from their medical practitioner regarding their arrhythmia diagnosis. Quick feedback from the hospital/doctor to the patients regarding findings will be dependant on the routines at the hospital and the GP's office.
4. Patients expressed confidence when using the wireless ECG BAN
    - The wireless technology is easy to use.
    - The patients felt no discomfort wearing the wireless ECG BAN.
    - Reduced waiting time for treatment through a decentralised cardiac monitoring model.

Discussion

This investigation showed that there are advantages associated with wireless cardiac monitoring. The wireless ECG BAN illustrated significant benefits for the patients, especially regarding the hygienic aspects; probably because the patient's ability to have a shower and to use the equipment during the night while sleeping with little or no discomfort; "no cable spaghetti".

However, in this small scale study only a limited number of patients have been included, thus limiting the generalisability of the results. The patient's age in the reference group was significantly higher than in the wireless group ($p<0.05$). In the reference group, the majority of patients were older females; this can represent a bias especially in the evaluation of user acceptance as many of them would not have a physically active lifestyle necessitating an easy to wear sensor system.

As part of this study, a total of 103 ECG sequences were compared by two independent cardiologists, and this sample is too small to give calculations of validity and reliability, and thus we can only give some tentative indications of the wireless ECG BAN's performance. The number of arrhythmic episodes was also limited, and the ability of the wireless ECG BAN to detect significant arrhythmias must be tested in larger studies. Specifically, it will be important to detect significant P-wave amplitudes as the timing from the P-wave to the R-wave is important for arrhythmia diagnostics. In this study, we have discovered differences in the P-wave amplitude recorded, indicating the actual position of the patch on the patient's chest is a critical factor. We also discovered that the signal quality from the wireless ECG BAN during the patients' physical activity showed acceptable quality regarding low signal noise and limited artefact disturbances.

Conclusion and further research

This paper discussed the performance issues associated with two devices which can be utilised for cardiac monitoring. It illustrates that by utilising wireless technology, healthcare performance, especially from a patient's perspective, can be improved and that the quality of results recorded with the wireless ECG BAN is high. Therefore, it can be concluded that wireless cardiac monitoring systems may provide significant opportunities for improved healthcare from a patient's perspective. However, this pilot study was the first initial step in evaluating the wireless ECG BAN technology and further clinical studies are required.

For the evaluation of patient acceptance, a triangulation of methods was used. In this clinical trial the number of patients was limited, but some interesting aspects have been discovered in relation to integration into the patients' everyday life. Further investigation in this area is required. Specifically, a patient's ability to participate in physical activities while still being monitored for arrhythmia occurrences are of special importance.

In extending this research, the authors are focusing on four distinct, yet interrelated areas:

- Further developing hardware and software necessary to support the wireless ECG BAN architecture.
- Conducting a large scale clinical trial evaluating the results from the wireless ECG BAN.
- Exploring possibilities of business re-engineering of healthcare services and information flows between the cardiologist and the GP.
- Investigating the implications for general practitioners and healthcare providers of adopting this wireless ECG BAN, specifically focusing on a quality, efficiency and cost (QEC) analysis.

Overall, such research will provide us with further insights in relation to the potential for wireless ECG based BANs to complement and in the future replace the traditional Holter monitors for cardiac arrhythmias.

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