Clinical Evaluation of a Wireless ECG Sensor System for Arrhythmia Diagnostic Purposes

Rune Fensli[1], **Torstein Gundersen**[2], **Tormod Snaprud**[2] and **Ole Hejlesen**[3]
[1)] University of Agder, Faculty of Engineering and Science, Grimstad, Norway
[2)] Sørlandet Hospital, HF, Medical Department, Arendal, Norway
[3)] Aalborg University, Department of Health Science and Technology, Denmark

E-mail: rune.fensli@uia.no

Short title: Clinical Evaluation of a Wireless ECG Sensor System

Abstract. In a clinical study, a novel wireless electrocardiogram (ECG) recorder has been evaluated with regard to its ability to perform arrhythmia diagnostics. As the ECG recorder will detect a "non-standard" ECG signal, it has been necessary to compare those signals to "standard" ECG recording signals in order to evaluate the arrhythmia detection ability of the new system. Simultaneous recording of ECG signals from both the new wireless ECG recorder and a conventional Holter recorder were compared by two independent cardiology specialists with regard to signal quality for performing arrhythmia diagnosis. In addition, calculated R-R intervals from the two systems were correlated. A total number of 16 patients participated in the study. It can be considered that recorded ECG signals obtained from the wireless ECG system had an acceptable quality for arrhythmia diagnosis. Some of the patients used the wireless sensor while doing physical sport activities, and the quality of the recorded ECG signals made it possible to perform arrhythmia diagnostics even under such conditions. Consequently, this makes possible improvements in correlating arrhythmias to physical activities.

Keywords: Evaluation studies, ambulatory electrocardiography, Holter monitoring, wireless ECG sensor, clinical trials

Fensli, R., Gundersen, T., Snaprud, T., & Hejlesen, O. (2013). Clinical evaluation of a wireless ECG sensor system for arrhythmia diagnostic purposes. Medical Engineering and Physics. doi: 10.1016/ j.medengphy.2013.03.002

1. Introduction

Disease management programs with ECG recording equipment (to be used by patients at home) and integrated telemedicine solutions are expected to become important in ensuring safety and cost-effectiveness in future health-care services [1, 2]. In recent years, several interesting projects have focused on developing new wireless ECG solutions. However, little information has been published on clinical results from this wireless technology. The Amon wrist watch system had a promising design, but a study with healthy volunteers showed unsatisfactory ECG signal quality [3]. The SmartVest system showed results from a variety of sensors including ECG, but has only been tested on healthy subjects for a 30-minute test during standing and walking [4].

Even though a wireless system can give valuable benefits for the patient with regard to mobility, a reliable and precise monitoring quality will be needed in order to use such equipment as a clinical diagnostic tool. Clinical experience also confirms the need for improvements in ECG recording equipment when the patient is performing physical activities, where artefact signals today represent a major obstacle.

A new wireless ECG system consisting of a wireless ECG sensor communicating by means of a hand-held receiver, intended for long-term arrhythmia detection, has been developed [5]. The new design of this "electronic electrode" uses only one ECG lead, which is in a different position compared to standard lead systems, which will thus record a "non-standard" ECG signal. A totally wireless solution eliminating the "cable spaghetti" can give continuous monitoring, while the patient's behaviour may be closer to his normal routines than when using existing technology [6]. Because there are no wires between the electrodes and the recording device, the patient will also be able to carry out physical activities, including athletic sport exercise.

There is a need for clinical evaluation of this newly developed wireless system, where a comparison with existing wearable ECG recorders is a requisite. There is, however, a lack of well-established methods to be used for clinical evaluation of wireless ECG recording systems. In this paper, we present results from a clinical study in which ECG signals from this novel wireless ECG recorder are compared to conventional Holter recordings with regard to quality and the capability of performing arrhythmia diagnostics. Recordings from the Holter system were used as a "golden standard," and evaluated by two independent cardiology specialists.

2. Methods

2.1 Comparing ECG recordings from a variety of equipment

A mobile cardiac outpatient telemetry system with functionality similar to the new wireless system was tested by Joshi et al. However, they did not compare their detection accuracy to a Holter system, and instead only reported the clinical findings of arrhythmia events in the first 100 consecutive patients monitored [7]. In a study of determinants of diagnostic yield, Gula et al. used a cross-over design where patients were randomly selected for either a 48-hour Holter monitor or an external loop recorder, but they did not use those two systems simultaneously [8]. Hoefman et al. used a randomized clinical trial to evaluate the diagnostic yield of patient-activated loop recorders, but in this study the accuracy in the loop recorder itself was not evaluated [9].

Ariet et al. developed a computer program to examine serial changes in ECG wave forms intended to track changes after detection of acute myocardial infarction. In their study, serial ECG recordings were coded by an expert cardiologist. Those annotations were then used as a "golden standard" upon which the computer algorithms were validated for each pair of ECG sequences [10]. A similar approach was used by Shah and Rubin in their study of errors in the

computerized ECG interpretation, where two cardiology experts interpreted the tracings recorded [11].

Deery et al. compared a wireless system to a standard Holter monitor, seen as the "golden standard" in ambulatory ECG recordings, in which they defined several important parameters to be compared, like the Quality of Signal, Morphology, Rate, Accuracy, Mobility, Usability of Signal and Representation of Cardiac Events. The observations and comparisons were made by observing the signals directly on the monitor [12].

Christiansen et al. compared QT interval measurements on standard ECGs to those on Holter, where they simultaneously obtained ECG recordings from the two systems of the same complexes, using identical leads. For 14 patients, 100 ECG pairs were recorded, which gives seven pairs of recorded ECGs from each patient. The evaluation was performed by two observers blinded to pairing relationship [13].

Pandian et al. compared R-R intervals, QRS intervals and QT intervals in their evaluation of ECGs obtained from the wearable multi-parameter SmartVest[4].

In our study, we will use a combination of different methods, using a standard Holter recorder as the "golden standard", like Deery et al. [12]. In addition, according to the method used by Christiansen et al. [13], we will obtain several identical recordings from each patient for evaluation by two independent cardiology specialists. The cardiologists will be independent of each other (T. G. and T. S.), and they have not been involved in the development of the new wireless solution. We will also compare the accuracy in R-R interval detections, as this is an important parameter in arrhythmia detections, which was also used in the study by Pandian et al. [4]. The number of patients in our study is limited, but comparable to the study carried out by Christiansen et al. [13]. Combining the R-R interval comparison and a visual inspection method comparing the quality obtained by different parameters represents two different methods for this investigation; in order to give a better yield than evaluations based only on one single method.

2.2 Study design

The study design has an objectivistic approach, and according to Friedman and Wyatt, it has been performed as a correlational study not interfering in treatment procedures [14]. The clinical trial was designed such that the patients simultaneously had to wear both the conventional Holter system used at the hospital (Huntleigh, Medilog AR4, with the analyzing software program *Medilog Darwin v.1.5.11*) [15] and the new wireless ECG system (WPR Medical, Wireless ECG recorder with the analyzing software *WPR-Analyzer* v0.11) [16]. Those patients are defined as Group A.

In addition, patients with previous normal Holter recording were enrolled as a clinical follow-up, using only the wireless sensor; those patients are defined as Group B.

The study has been accepted by the Regional Ethical Committee in Norway as well as the hospital's ethical committee. In addition, permission to use the new technological equipment was obtained from The Directorate for Health and Social Affairs in Norway.

2.3 Participants

Patients referred for long-term ambulatory "Holter" arrhythmia procedures at the outpatient clinic at Sørlandet Hospital HF, Arendal, Norway, were asked to participate in the study. After signing the informed consent form, they participated in the study during their ordinary arrhythmia investigation.

During the period from November 2006 to March 2008, sixteen patients were enrolled in the study. The patients were instructed to carry out normal daily activities, as long as the equipment was no hindrance. The patients wearing only the wireless ECG recorder were encouraged to participate in athletic sport activities, and they were also allowed to take a shower while wearing the wireless sensor system.

A picture of the Holter recorder, which was used with five electrodes according to a standard five-lead system, can be seen to the left in fig.1. The wireless ECG sensor placed on the upper left part of the chest is shown in the middle of fig.1 with the corresponding hand-held receiver, which is also shown in a close-up picture to the right.

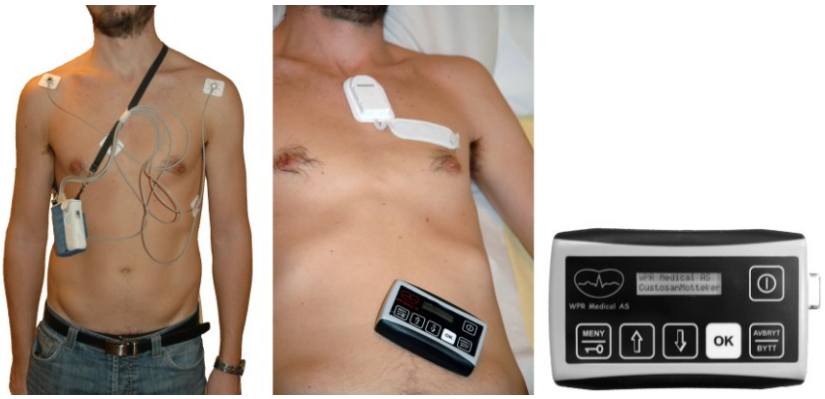

Figure 1. A picture of the Holter recorder with the cabled connections to the electrodes as used in the clinical trials (to the left), and the wireless ECG sensor placed on the chest (in the middle). A close-up photo of the hand-held receiver is shown to the right (different picture scales are used).

2.4 Technical system details

The Medilog AR4 recorder was used according to normal procedures at the hospital with a 48-hour recording time. In the setup of the system it was defined with a 3-channels recording, with a sampling rate of 256 Hz and 12 bit resolution. The WPR Wireless ECG system was defined with a 500 Hz sampling rate and 12 bit resolution. This system used a recording bandwidth from 0.05 Hz to 125 Hz. The wireless ECG sensor uses a 2.4 GHz single-chip radio solution for the wireless transfer of signals, with a recommended radio range of 3 meters between the wireless sensor (fastened to the chest) and the hand-held receiver device (which the patient has to carry in a pocket). If the patient moves away from the receiver, there might be data loss in the recorded data, which can be comparable to the situation where the Holter recorder loses contact with the skin on one electrode, as described by O'Donoghue et al. [17].

Both the Holter recorder system and the WPR Wireless ECG sensor system used a stand-alone PC with dedicated software to perform the arrhythmia diagnostic procedures. We used standard printout facilities to produce the recordings which were used in the visual comparisons. From those printouts, the R-R intervals were manually entered into an Excel spreadsheet to calculate the mean values and the standard deviations.

2.5 Methods for data acquisition and measurements

Because of the proprietary data formats of the signals recorded with the Holter system, the only available recordings for the evaluations were samples of the printout reports. Similar printouts were collected from the wireless ECG sensor system, from concurrent time sequences that corresponded to the Holter recordings, with a continuous series of one minute ECG recordings, in order to compare the recorded R-R intervals calculated from the two systems.

As the real-time clocks in the two systems were not accurately synchronized at the start-up of the recordings at the hospital's outpatient clinic, recordings displayed on the PC were manually inspected to find corresponding arrhythmia events from the two systems. This made synchronization in the time series possible, and the actual printout sequences showed the same series of heartbeats. The only exception is for patients numbers 04 and 07, who had a regular sinus rhythm where it was not possible to distinguish the exact matching beats from the two

systems. It was thus not possible to calculate the concurrent R-R intervals for those two patients. For those patients, the printouts were selected from nearly identical time series based on the two systems' real-time clock. For patients in Group B, four typical recordings were sampled in situations when arrhythmias were detected.

All printout sequences show beat annotations and calculated R-R intervals from the recording systems' analyzing software. An example of the actual recordings is shown in fig.2, with two snapshots of a 7-second duration time series recorded from patient ID 08. At the top is shown the Holter recording, and at the bottom the concurrent signals obtained from the wireless ECG recorder. The recordings from the wireless sensor system had some signal noise (of 40 Hz) due to an unfortunate construction in the power system, which can be seen as small disturbances in the recordings.

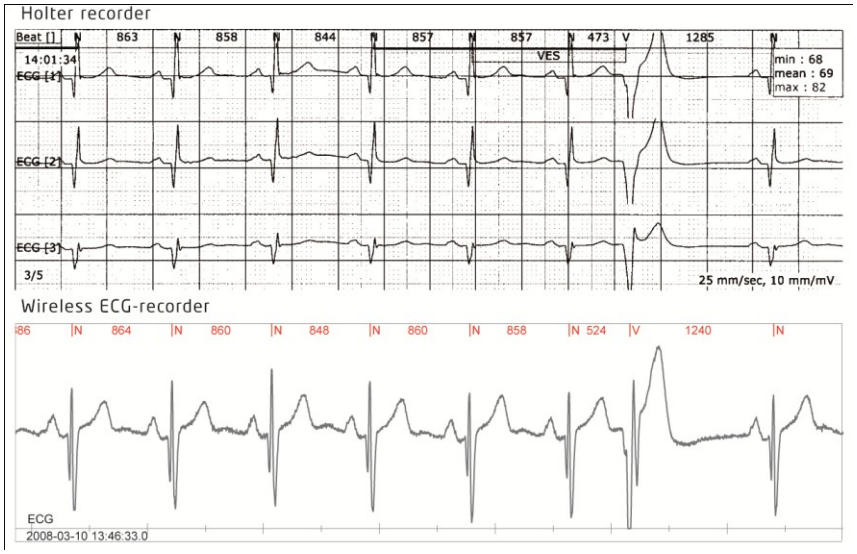

Figure 2. Two snapshots of 7-second time-series of concurrent ECG recordings from the Holter recorder (at the top), and from the wireless ECG recorder (at the bottom). The recordings are from patient ID 08.

Because of variances in the recording quality due to patients' movements and physical activity during the day, a total of 4 to 10 different printouts, each of 30 seconds' recording time, were made for each patient at different times of the day. Recorded samples were chosen from a typical time series where the Holter recorder detected arrhythmia episodes. Time series which were manually rejected during the analyzing procedure of the Holter recordings because of substantial disturbances of artefacts were not selected. Similarly, time series from the wireless recorder were not selected if the sensor had unacceptable skin contact.

All printouts were made anonymous and given only a random record number, in order to perform a visual blind test with regard to the pairing relation from the two systems. However, because of the three-lead recording in the Holter system, and the one-lead recording in the wireless system, the recordings from the two systems were not blinded.

2.6 Data analyzing methods

a) Comparing the R-R intervals

A calculation of correlation between the two systems with regard to R-R intervals will give an indication of the accuracy of the new wireless system. The correlation analysis method of Bland and Altman has been performed by calculating the difference of the mean and the bias defined by the mean difference ($\bar{d}$) and the standard deviation of the difference (s). These "limits of

agreement" are given within $\bar{d} \pm 2s$ (confidence interval of 95%), and it is necessary to evaluate whether these differences are within acceptable clinical limits [18]. We have calculated those correlations for the six patients for whom it was possible to define the concurrent time series.

b) Visual comparison of recorded ECG curves
We have chosen a visual test of the recorded printouts, performed by two independent and experienced cardiologists, as a suitable comparison. For each recorded sequence of ECG curves identified by a random number, the cardiologists had to fill in a questionnaire defining 7 items of importance for evaluation of the actual recording. An 11-point semantic differential scale (0-Not Accepted, 10-Extremely Good) was used. The items used were: Recording quality, Quality of P-waves, Quality of QRS-waves, Quality of T-waves, Accuracy of R-R intervals, Accuracy of arrhythmia detection, and quality of the recording to perform arrhythmia diagnosis.

Statistical analysis was performed using the *SPSS* software (version 16.0), and randomization was achieved with the *Clinstat* software (version 08.05.96).

3. Results

3.1 Baseline data

In table 1, the patients' characteristics give information about the patients' genders and ages, in addition to the actual recording time made by the wireless ECG system. The recording time for the Holter recorder was, according to the normal hospital routines, two days in duration.

A total of 16 patients (8 male, 8 female) aged 11–67 years, mean 38.9 (SD=18.9), were enrolled in the study. An average recording time of the wireless sensor was calculated to more than one and a half days of use. However, the wireless recordings for patients with IDs 03, 04 and 07 were terminated before the scheduled time due to technical reasons, as the recorder aborted the recordings. Patient ID 12 wanted to finish the recordings prior to scheduled time, based on his free will.

Table 1. Patient characteristics and duration of the recording time for use of the wireless sensor.

Patient ID	Group	Gender	Age	Duration of test with wireless sensor
01	A	Male	36	2d22h9m
02	A	Male	22	1d17h54m
03	A	Female	51	0d3h30m
04	A	Male	67	0d10h46m
05	A	Female	48	2d19h57m
06	A	Female	52	1d2h13m
07	A	Female	47	0d0h42m
08	A	Male	58	0d21h15m
11	B	Male	67	3d1h43m
12	B	Male	11	15h34m
13	B	Female	19	13h20m
14	B	Male	22	3d16h3m
15	B	Male	56	2d3h40m
16	B	Female	21	2d2h54m
17	B	Female	26	1d1h58m
18	B	Female	19	1d5h07m
Calculated Mean			38,9	1d13h06m

3.2 Correlation of R-R intervals

Based on comparing concurrent signals with simultaneously recorded QRS complexes by the two recording devices (Holter and wireless) the actual R-R intervals in msec are indicated on the printout from the two systems, as calculated by the system's analyzing software.

Comparisons are made for sequences of 100 consecutive heartbeats (approximately one minute of recordings) for each patient except for patients numbers 04 and 07, as shown in table 2, with a confidence interval of 95%. This confidence interval gives limits of agreement as an average for all the patients within -3.74 msec to + 5.74 msec (-0.5% to + 0.8%).

A scatter plot of the differences against the mean for the sum of all the six patients is given in fig.3. Partial correlation estimated by Pearson's (r) on the actual R-R intervals all showed a strong correlation ($r>0.999$, $p<0.0005$).

Table 2. Estimation of the mean difference and standard deviation (Holter–wireless) for 100 consecutive R-R intervals recorded for each patient. Values of mean R-R interval, mean differences, standard deviation and limits of agreement are given in msec. The limits of agreement are calculated with a confidence interval of 95%.

Patient ID	Mean R-R Interval	Mean Difference	Standard deviation of the differences	Limits of agreement	% of mean R-R interval
01	583.8	0.66	3.83	-7.01 , +8.32	-1.2% , +1.4%
02	650.1	1.06	1.48	-1.91 , +4.03	-0.3% , +0.6%
03	747.0	1.10	1.48	-1.86, +4.06	-0.3% , +0.5%
05	788.6	1.11	1.46	-1.82, +4.03	-0.2% , +0.5%
06	796.5	0.89	0.67	-0.45, +2.22	-0.0% , +0.3%
08	873.7	1.18	3.49	-5.79, +8.15	-0.7% , +0.9%
SUM	740.0	1.00	2.37	-3.74 , +5.74	-0.5% , +0.8%

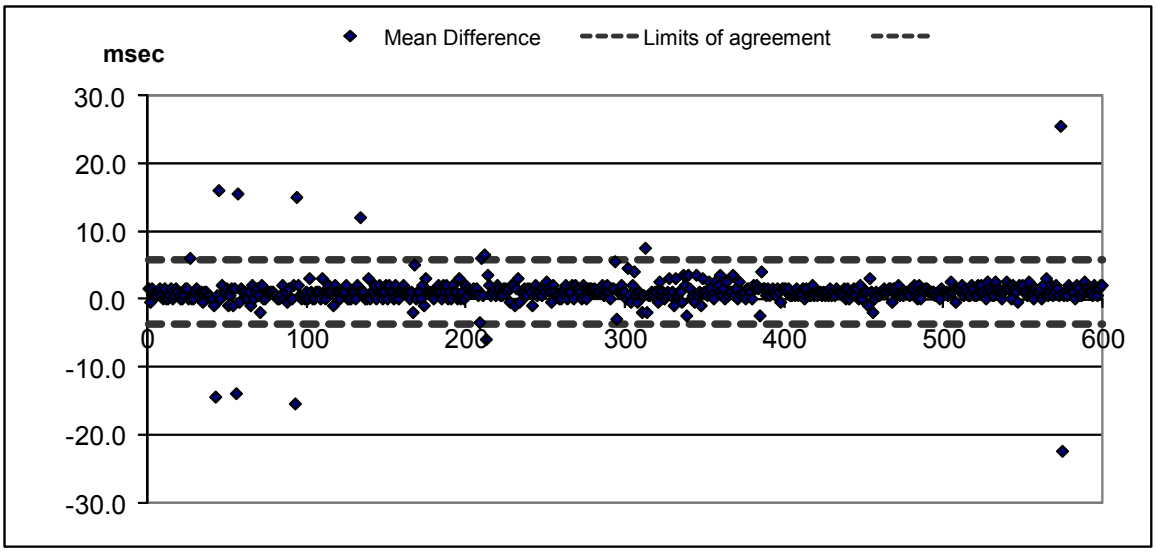

Figure 3. Scatter plot of the difference against mean for the total sum of six patients (600 heartbeats) with a confidence interval of 95% as the limits of agreement.

3.3 Evaluation of validity and reliability

Total selections of 130 ECG sequences were evaluated for arrhythmia detection by the two independent cardiologists, and scores given according to the 7 items defined in the questionnaire. The actual scores were calculated as the mean sum of scores by the two cardiologists.

To test the construct validity of the questionnaire, we used a confirmatory factor analysis [19] (chap. 13). The Kaiser-Meyer-Olkin value was calculated to 0.72, and the Bartlett's test of Sphericity reached significant value ($p<.0005$). Three components with Eigenvalue above 1.0 explaining 87.2 % of the variance were extracted. To interpret these factors, Varimax Rotation with Kaiser Normalization showed a relatively clear loading pattern of three components or Clinical Factors as shown in table 3. Those factors can be defined as *Recording Curve Quality* (consisting of the items Recording quality, Quality of QRS-waves and Quality of T-waves), *Arrhythmia Detection Quality* (consisting of the items Accuracy of R-R intervals and Accuracy of arrhythmia detection) and *Diagnostic Performance* (consisting of the items Quality of P-waves

and quality of the recording to perform arrhythmia diagnosis). This interpretation is according to expectations based on clinical experience, as Component 1 defines the more "technical" quality in the recordings, Component 2 is an indication of the performance for arrhythmia evaluation (especially regarding the quality of the P-waves), while Component 3 evaluates the accuracy of the software for the two systems.

In order to investigate the reliability of the scales used, Cronbach's alpha was calculated for each of the three components defined, ranging from 0.79 to 0.87.

Table 3. In a Principal Component Analysis, three components explaining 87.2% of the variance were extracted in a Varimax Rotation method with Kaiser Normalization. If the threshold is set to .5, the 7 items had a clear loading in the Components 1-3.

Item	Component		
	1	2	3
Recording Quality	.798	.486	
Quality QRS-waves	.913		
Quality T-waves	.820		
Accuracy of R-R intervals			.894
Accuracy in Arrhythmia Detection		.307	.886
Quality P-waves		.929	
Evaluation of Arrhythmias	.364	.870	

3.4 Visual evaluation of ECG recordings

In all the 130 ECG sequences, the cardiologists gave their comments with evaluation of the actual rhythms shown. There were no divergences in the arrhythmia findings diagnosed from the two systems. Fourteen of the patients had actual arrhythmia events (several different types of arrhythmias), while two patients had normal sinus rhythm. Nearly all the patients' recordings showed satisfactory P-wave quality, but for two patients, the quality obtained with the wireless recorder was evaluated as Poor, with small and indistinct P-waves.

In table 4, calculations of the mean score and standard deviation for the three Clinical Factors are shown for the two different types of equipment used, together with one-way between-groups analysis and independent samples t-test. The factors Arrhythmia Detection Quality and Diagnostic Performance showed significantly higher scores for the Holter system compared to the wireless system. The Recording Curve Quality had a higher score for the wireless system; however, this difference was not at a significant level.

Table 4. Calculation of Mean and Standard Deviation (SD) for the three clinical factors used in evaluations of the recorded curves obtained from the two systems Holter and wireless, together with variance analysis and independent samples t-test where equal variances are not assumed. Significant differences are marked with *($p<.005$) and **($p<.0005$).

Clinical Factors	Total score			Holter			Wireless			F	t	
	N	Mean	SD	N	Mean	SD	N	Mean	SD			
Recording Curve Quality	130	8.22	1.35	48	7.91	1.59	82	8.39	1.16	3.98	-1.84	
Arrhythmia Detection Quality	130	9.02	1.30	48	9.44	0.97	82	8.78	1.41	8.15	3.14	*
Diagnostic Performance	130	6.97	2.02	48	7.99	1.62	82	6.38	2.00	22.66	4.76	**

The lower scores for the wireless recordings were mainly caused by the quality in the P-waves, which were evaluated to have low signal amplitude in the recordings. However, even though the P-waves recorded with the wireless solution were of lower quality compared to the Holter, the signals were considered sufficient to be used in arrhythmia diagnostics, and none of the recordings were rejected from arrhythmia evaluations.

The QRS complexes were shown to be of good quality in the wireless recordings. There was also a tendency to improved quality regarding artefacts and noise disturbances in the wireless recordings. Especially this was the situation for patients in Group B, during their physical activities, such as outdoor soccer training, cross-country running, and aerobics and fitness centre exercise. An example of the wireless ECG recordings obtained during physical activity is shown in fig. 4, when the patient was participating in outdoor football game training.

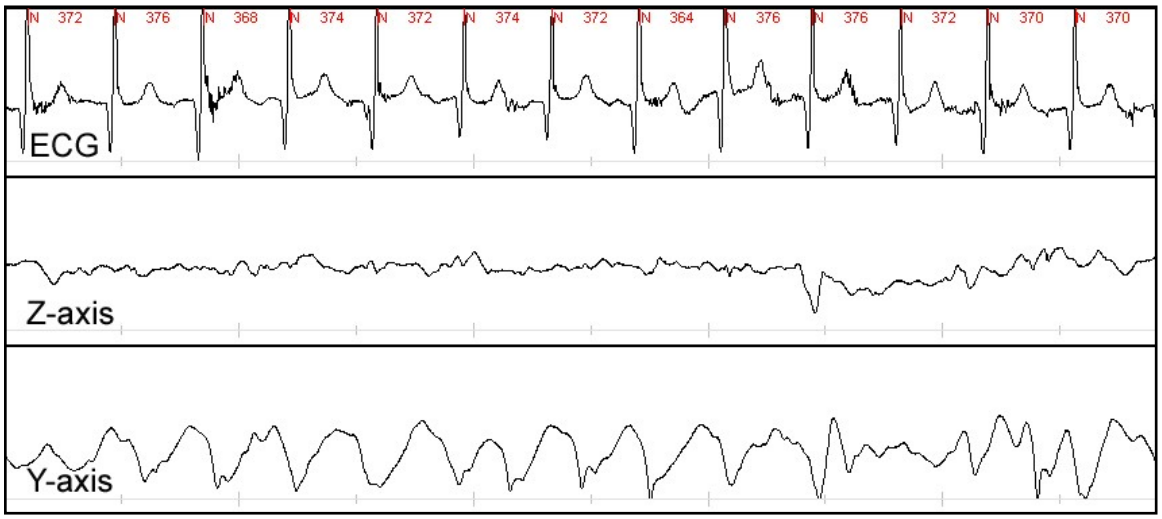

Figure 4. Recordings obtained with the wireless ECG sensor system during outdoor football game training, where the upper curve shows the ECG signal, while the two lower curves show a signal from an accelerometer in z-axis (sideways) and Y-axis (upwards) directions indicating the level of physical activity. The actual Heart Rate is approx.160 b/min. The recording is from patient ID 12.

4. Discussion

4.1 General considerations

In this study, a total of 16 patients were included for the wireless ECG recordings, while only 8 patients were simultaneously wearing both the wireless system and a conventional Holter recorder. When evaluating the actual printouts, 48 printouts were collected from concurrent time series of the Holter recorder and the wireless ECG sensor system.

Even though the wireless ECG recordings of three of the patients terminated prior to the scheduled time, the obtained average number of recordings from each patient is six, which is comparable to what was used in the study by Christiansen et al. [13], who used a similar method.

When evaluating the questionnaire use by the two cardiologists, the principal component analysis with Varimax rotation method showed satisfactory internal validation, and the Cronbach's alpha showed acceptable scale reliability with values >0.7. Even if the sample size is limited to 130, the relatively clear loading in the three components gives a satisfactory basis for calculation of significant differences between the two systems compared.

4.2 Comparison of R-R intervals

The comparison of recorded R-R intervals for the two systems (Holter–wireless) shown in table 2 was considered very acceptable, with a standard deviation at the utmost of only -7 msec to +8 msec. As the sampling frequency used in the Holter recorder was 256 Hz, the sampling interval was approx. to 4 msec. This means that the deviation was within ±2 samples, which can be considered as nearly identical for any practical purpose. Clinical evaluation of the calculated difference showed that this was of no practical consequence, and the two systems can be judged to be of similar accuracy in calculations of R-R intervals, as long as artefact disturbances do not corrupt the R-wave detections.

Pandian et al. evaluated 10 consecutive beats for the R-R interval comparison [4]. However, due to arrhythmia events, the accuracy in R wave onset detection can vary for the actual system used, caused by changes in the QRS pattern due to the extra systole with a different ventricular contraction sequence. We have thus analyzed longer time-series with a variation on the R-R intervals, including premature beats with a prolonged R-R interval for the consecutive beat. As can be seen from the premature beat in fig. 2 (beat number 7), the actual shape of the R-wave has changed. The normal pattern in the first six beats shows a sR pattern, while beat number seven shows a distinct Sr pattern. The Holter recorder seems to be triggering on the distinct negative S-peak, while the wireless system has triggered on the positive r-peak. The divergences out of the limits of agreement as can be seen in fig.3, are due to such different triggering criteria.

4.3 Comparing the Holter–wireless recorder, visual evaluation

A comparison of the factor Recording Curve Quality showed that the wireless recorder had a slightly higher score compared to the Holter system. Even though this difference is not at a significant level, the clinical evaluation showed that the ECG-recording quality of the wireless recorder was at a very satisfactory level and with almost negligible disturbances from artefacts, as long as the sensor was properly attached to the patient's skin. The signals and the quality obtained with the Holter recorder was evaluated to be typical for those types of ECG recordings, and it would not have changed the results if another Holter recorder had been used as the "normal diagnostic standard" to which the wireless ECG sensor was compared.

The factor Arrhythmia Diagnostic Quality showed in the same analysis a significantly higher score for the Holter system compared to the wireless system. This was mainly based on the arrhythmia annotations made by the two systems' arrhythmia detection software and will reflect the software performance, which was found to be more precise for the Holter system.

The factor Diagnostic Performance showed in the same analysis a significantly higher score for the Holter system compared to the wireless system. Included in this evaluation was both the clinical judgment of the ability to perform a reliable arrhythmia diagnostic evaluation based on the actual ECG recording, and the quality of the P-waves detected. As time delay between the occurrences of the P-wave compared to the R-wave is of major importance for arrhythmia evaluations, it is important to obtain P-waves of good quality. The main reason for the relatively low scores for the wireless recorder was a lower quality of the P-waves detected, caused by lower

P-wave signal amplitude in the recordings. However, all recorded ECG curves had an acceptable level of the P-wave signals, and none of the recordings were rejected because the P-waves were missing or of unacceptable quality.

In the first four patients, the wireless sensor was placed in position V2-V3, and it was during the off-line analysis after the patients had used the system that the quality of the P-waves was not as expected. For the rest of the patients, the sensor was placed higher up at the left side of the patient's chest, where more significant P-waves were recorded. This finding is according to what can be expected based on the simulations made by Puurtinen et al. [20], who estimated the best electrode locations for a small bipolar ECG device.

When the actual ECG recordings from the two systems are compared, the traditional Holter recorder uses three different leads. This can be an advantage, especially if one electrode is influenced by artefact disturbances, whereas the other two leads may show acceptable quality. However, the wireless ECG recorder showed acceptable quality in general, even though it only uses one lead, and the evaluation of the QRS complexes and T-waves showed especially good quality.

As the wireless technology will avoid the "cable spaghetti," it has improved functionality for the patients, and has been shown to give valuable advantages compared to existing wired solutions used in the traditional Holter recorders [6]. The wireless technology showed some improvements compared to the existing Holter recorder when the patient performed physical activity. This may be of particular interest for use during athletic sport activities, as this wireless system has the capacity to produce qualitatively acceptable ECG recordings without obstacles and artefacts even under such conditions.

Despite the uncertainties and possible bias, it is reasonable to conclude that the differences between the two recording systems regarding their ability to perform arrhythmia diagnostics are minor, even though the wireless recorder showed lower signal amplitude for P-waves on some patients. The evaluations of the ECG signals obtained with the wireless ECG recorder showed adequate quality for arrhythmia diagnostic purposes. There were no significant differences between the two systems regarding the quality of the recorded curves. However, a tendency to qualitatively better recordings from the wireless system was noticed, especially during the patient's performance of physical exercise.

4.4 Strengths and weaknesses of the study

This study was limited to sixteen patients, where four of the patients used the wireless ECG sensor only for a relative short time period. The study has been conducted at one hospital and we used only one Holter recorder as the "normal standard". However, the study design made it possible to compare two ECG recording systems simultaneously, and synchronized in time for the patient's actual heart beats. In the triangulation of methods, it was possible to evaluate the findings based on different criteria. Due to the fact that the printout of the actual ECG recordings was made using both systems' software programs, it was not possible to make double-blind evaluations. The evaluations were only blind regarding the pairing relationship; however, the experts were not able to identify coinciding recordings.

Only two independent cardiology experts comprised the "golden standard" evaluated with the Holter recorder normally used at the hospital. Therefore a similar evaluation should be performed as a randomized control study involving more hospitals and cardiologists. Furthermore, several different Holter recorders should be considered, as there might be limited accuracy in the automatic ECG interpretations as described by Shah and Rubin [11]. It would be preferable if ECG recordings from the two different systems could be exported to a standardized format in which a third party arrhythmia detection software could be able to compare actual findings from the two recording systems, as this would be an independent evaluation to be manually confirmed by the cardiologists.

As the wireless ECG recorder is a novel system, it is not possible to compare the findings to related studies other than those mentioned. No comparative clinical studies with patients using wearable wireless ECG sensor solutions have previously been published. This may be caused by the fact that details of automatic ECG analysis software are usually not disclosed because of competition in the field; and almost no data for comparison between different analysis techniques are available, as Enseleit and Duru found in their review of long-term ECG recording solutions [21].

5. Conclusion

By comparing ECG recordings obtained from the novel wireless ECG recorder with concurrent time series of recordings from a conventional Holter recorder as a "golden standard", two independent cardiology specialists have evaluated its quality and ability to perform arrhythmia diagnostics. Total selections of 130 ECG sequences from 16 patients were evaluated. Even though the number of patients and ECG recordings was limited, a triangulation in methods was used to obtain an adequate evaluation quality.

The clinical evaluation showed that the ECG recording quality of the wireless recorder was at a very satisfactory level with negligible disturbances from artefacts as long as the sensor was properly attached to the patient's skin.

There was a significant difference in the evaluations of Arrhythmia Detection Quality and Diagnostic Performance in favour of the Holter recorder compared to the wireless ECG recorder. This was mainly due to lower amplitude of the P-wave signals and lower accuracy in the arrhythmia detection software. This better P-wave quality performance for the Holter recorder may be due to the position of the wireless ECG sensor on the patient's chest. Nearly all patient recordings showed a satisfactory P-wave quality, and no recordings were rejected as a result of unsatisfactory quality. Even though the Holter recorder had a higher score, the wireless ECG system showed a satisfactory signal quality for arrhythmia diagnostic purposes. Preliminary testing of alternative sensor positions on the patient's chest confirmed that it might be possible to obtain improved quality of the P-waves recorded, which will be evaluated in future studies.

In future studies, it would be beneficial if the ECG recordings from the two systems could be imported by third party arrhythmia detection software, in order to obtain independent analysis suited for double-blinded evaluation by the cardiologists.

Today, there is a need for improvements in ECG recording equipment used during athletic sport activities, and the new wireless ECG-recorder can obviously be used with acceptable quality even under such conditions. This makes improvements in correlating arrhythmias to physical activities possible.

Acknowledgement

The study is supported by funding from the Research Council of Norway, project number 169279/I50. The authors acknowledge the help of Einar Gunnarson in the preparation of the research protocol, the valuable help of Åse Løsnesløkken and Ellen Ytrehus in managing the patients and the good assistance from Eirik Aanonsen and Jarle Kaste of WPR Medical AS.

Conflict of interest

Ass. Prof. Rune Fensli holds equity interest in and is a consultant for WPR Medical AS. Otherwise there are no conflicts of interest other than those mentioned in the project funding.

References

[1] Roth A, Korb H, Gadot R, Kalter E. Telecardiology for patients with acute or chronic cardiac complaints: The `SHL' experience in Israel and Germany. Int J Med Inf. 2006;75(9):643-5.
[2] Magrabi F, Lovell NH, Celler BG. A web-based approach for electrocardiogram monitoring in the home. Int J Med Inf. 1999;54(2):145-53.
[3] Anliker U, Ward JA, Lukowicz P, Troster G, Dolveck F, Baer M, et al. AMON: a wearable multiparameter medical monitoring and alert system. Information Technology in Biomedicine, IEEE Transactions on. 2004;8(4):415-27.
[4] Pandian PS, Mohanavelu K, Safeer KP, Kotresh TM, Shakunthala DT, Gopal P, et al. Smart Vest: Wearable multi-parameter remote physiological monitoring system. Med Eng Phys. 2008;30(4):466-77.
[5] Fensli R, Gunnarson E, Gundersen T. A wearable ECG-recording System for Continuous Arrhythmia Monitoring in a Wireless Tele-Home-Care Situation. In: Proc. 18th IEEE Symposium on Computer-Based Medical Systems; 2005 June 23-24; Dublin, Ireland; 2005. p. 407-12.
[6] Fensli R, Pedersen PE, Gundersen T, Hejlesen O. Sensor Acceptance Model - Measuring Patient Acceptance of Wearable Sensors. Methods Inf Med. 2008;47(1):89-95.
[7] Joshi AK, Kowey PR, Prystowsky EN, Benditt DG, Cannom DS, Pratt CM, et al. First experience with a Mobile Cardiac Outpatient Telemetry (MCOT) system for the diagnosis and management of cardiac arrhythmia. The American Journal of Cardiology. 2005;95(7):878-81.
[8] Gula LJ, Krahn AD, Massel D, Skanes A, Yee R, Klein GJ. External loop recorders: determinants of diagnostic yield in patients with syncope. Am Heart J. 2004;147(4):644-8.
[9] Hoefman E, van Weert H, Reitsma JB, Koster RW, Bindels PJE. Diagnostic yield of patient-activated loop recorders for detecting heart rhythm abnormalities in general practice: a randomised clinical trial. Fam Pract. 2005;22(5):478-84.
[10] Ariet M, Zhou SH, Deluca DC, Greenfield Jr JC. Computerized Serial Comparison of Electrocardiograms - Program Performance in Acute Myocardial Infarction. Computers in Cardiology. 2005;32:211-4.
[11] Shah AP, Rubin SA. Errors in the computerized electrocardiogram interpretation of cardiac rhythm. J Electrocardiol. 2007;40:385-90.
[12] Deery A, Chambers D, Moriarty D, Connolly E, Lyons G. Clinical Trials of a Wireless LAN Based Patient Monitoring System. Computer-Based Medical Systems, CBMS 2006 19th IEEE International Symposium on; 2006; Salt Lake City, USA; 2006. p. 479-84.
[13] Christiansen JL, Guccione P, Garson Jr A. Difference in QT interval measurement on ambulatory ECG compared with standard ECG. Pacing Clin Electrophysiol. 1996;19(9):1296-303.
[14] Friedman CP, Wyatt JC. Evaluation Methods in Biomedical Informatics. 2nd ed. New York: Springer-Verlag 2006.
[15] Huntleigh Healthcare. Medilog AR4 Digital Holter Recorder. [cited 2007 30 March]; Available from: http://www.medilogdarwin.com/Medilog_AR4.html
[16] Wireless Patient Recording Medical AS. Wireless ECG sensor. [cited 2009 15 March]; Available from: http://www.wprmedical.com
[17] O'Donoghue J, Herbert J, Fensli R, Dineen S. Sensor Validation within a Pervasive Medical Environment. IEEE Sensors 2006, The 5th IEEE Conference on Sensors; 2006 October 22-25; EXCO, Daegu, Korea; 2006. p. 972-5.
[18] Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-10.
[19] Tabachnick BG, Fidell LS. Using multivariate statistics. 4th ed. New York: HarperCollins 2001.

[20] Puurtinen M, Viik J, Hyttinen J. Best Electrode Locations for a Small Bipolar ECG Device: Signal Strength Analysis of Clinical Data. Ann Biomed Eng. 2008;SpringerLink Date 2008 Nov 20, :331-6.
[21] Enseleit F, Duru F. Long-term continuous external electrocardiographic recording: a review. Europace. 2006 April 1, 2006;8(4):255-66.