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A Comparative Study of the Validity and Reliability of Two Wireless Telemetry Electrocardiogram Devices in the Emergency Medicine Department

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Background:

This study aimed to compare the clinical validity and reliability of two wireless telemetry electrocardiogram (ECG) devices in the Emergency Medicine Department.

Material/Methods:

Patients who attended the Emergency Medicine Department underwent wireless telemetry ECG testing (N=245) using the Infron Micro Cor and the Nihon Kohden Cardiofax M 1350 K devices. ECG recordings included heart rate, P-wave amplitude, PR segment length, QRS duration, QT and QTc intervals, ST depression and elevation, the number of ECG artifacts, the ECG diagnosis, and duration. Statistical analysis of reliability included the use of Cohen's kappa (κ) values.

Results:

One hundred women (40.8%) and 145 men (59.2%) were included in the study. The duration for the Infron Micro Cor ECG readings (57.5 ± 0.93 seconds) was significantly shorter compared with the Nihon Kohden Cardiofax M ECG readings (65.2 ± 9.72 seconds) ($p=0.0001$). The Infron Micro Cor ECG readings contained significantly more lead artifacts (93 or 37.9%) compared with the Nihon Kohden ECG readings (71 or 28.9%) ($p=0.01$). There was no difference between the two devices in terms of the other ECG parameters. The compatibility of ST-segment elevation detection was found to be almost in complete agreement between the Infron Micro Cor and Nihon Kohden Cardiofax M ECG devices, as determined by the κ -values for ST elevation and ST depression.

Conclusions:


Two wireless telemetry ECG devices were found to be reliable for use in the Emergency Medicine Department. The Infron Micro Cor wireless telemetry ECG device provided more rapid results.

MeSH Keywords:

Electrocardiography • Telemetry • Wireless Technology

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Background

Recent technological developments have resulted in new diagnostic and therapeutic medical devices in many clinical areas. All ECG medical devices are tested for compliance with the International Electrotechnical Commission (IEC) (IEC 6061-2-25) standards and require a clinical testing phase before being approved for use in accordance with the relevant national legislation [1].

Currently, most electrocardiography (ECG) devices that are used in Emergency Medicine Departments are large in size, cumbersome, difficult to use and store the data in the form of paper output. The ECG paper readings may undergo alterations or deterioration when stored for long periods of time, leading to loss of data. The new generation radiotelemetry-based medical devices provide an improved way to store ECG data accessed from the hospital database in digital form. However, there are few real-world studies on the use of portable wireless telemetry ECG devices for use in emergency medicine, and there remains a need to determine the validity and reliability of existing devices for clinical use.

This study aimed to compare the clinical validity and reliability of two wireless telemetry electrocardiogram (ECG) devices in the Emergency Medicine Department. The two devices were the Infron Micro Cor Wireless ECG device (Infron Limited, Medical Devices, Istanbul, Turkey) and the Nihon Kohden Cardiofax M 1350 K (Nihon Kohden Corporation, Tokyo, Japan).

Material and Methods

Study design

Before commencing the study, ethics committee approval was received from Pamukkale University Board of Ethics Committee on Non-Interventional Clinical Research (decision No.17 on 27.09.2016). The study was undertaken in the Emergency Department of Pamukkale University Medical Faculty Hospital between March 1 and April 1, 2017. Two wireless telemetry electrocardiogram (ECG) devices were compared, the Infron Micro Cor Wireless ECG device (Infron Limited, Medical Devices, Istanbul, Turkey) and the Nihon Kohden Cardiofax M 1350 K (Nihon Kohden Corporation, Tokyo, Japan).

During the study period, 9,462 patients were admitted to the emergency service, 956 of these patients had an electrocardiogram (ECG), and 603 patients who had an ECG scan were monitored, two of the patients were pregnant, 12 patients were under 18 years of age, and 72 patients required intubation due to loss of consciousness. Also, 46 patients refused to participate in the study, two patients had their ECGs removed

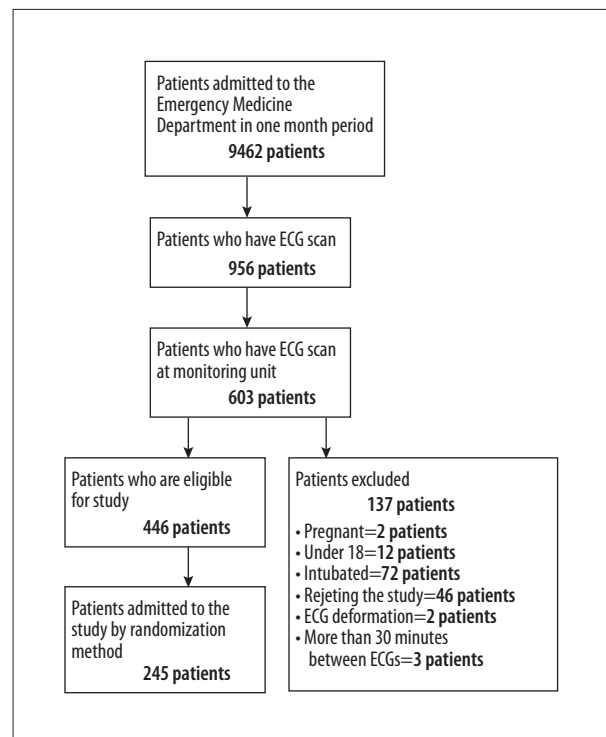


Figure 1. The flowchart of the study.

from the study because they were sub-optimal, and three patients were removed from the study as there was more than a 30-minute interval between the two required ECG procedures (Figure 1). Finally, 245 patients were included in the study who had undergone wireless telemetry ECG testing using the Infron Micro Cor and the Nihon Kohden Cardiofax M 1350 K devices and who were evaluated in a clinical decision unit (CDU), which was a designated section of the Emergency Department where patients were monitored by medical staff for several hours.

Participant inclusion and exclusion criteria

All patients provided written consent to participate in the study who were 18 years of age or older and who were followed up in the CDU of the Emergency Department were included in the study. Patients who were under 18 years of age, who refused to participate in the study, who were pregnant, unconscious or intubated, or who had the two required ECG scans with the two devices performed within more than 30 minutes of each other, and who had ECG output that could not be evaluated were excluded from the study.

Selection of study participants

The study included patients who were 18 years old or more and who were admitted to the adult Emergency Department of Pamukkale University Medical Faculty Hospital, who were evaluated and monitored within the hospital Emergency Department,

and who met the study inclusion criteria. The patient sample size was calculated to be at least 226 (90% effect size and 0.8 kappa level). The patients admitted to the study were selected by a simple random sampling method from among the individuals monitored in the CDU.

Study inclusion and patient randomization

The decision to scan the ECGs was made by a physician in the clinic who was not involved in the study. A simple randomization method was used for the study. An assistant, blinded to the details of the study participants, devised the computerized randomization schedule that showed whether the patient was admitted to the study or not. Each patient who was eligible for the study was assigned a study number.

Wireless telemetry ECG testing with the Nihon Kohden Cardiofax M and Infron Micro Cor ECG devices

A paramedic performed the ECG testing who was trained in electrocardiography and the use of the Nihon Kohden Cardiofax M ECG device, and who was also trained in the use of the computer tablet program for use with the Infron Micro Cor ECG for emergency care by an experienced emergency medicine specialist. All ECGs used in the study were performed and evaluated by the same paramedic. With both devices, the ECG was recorded at an amplitude of 10 mm/mV and a speed of 25 mm/sec. The initial filter data of the devices were set at 35 Hz according to the standard data ranges previously described [2]. An ECG cable with the same type of clip mechanism was used in both ECG devices. Both ECG devices were calibrated at the beginning of the study. ECG electrodes were attached to standard ECG measurement points on the anterior thorax.

ECG measurements

The measurements recorded from the ECG output from both devices included the heart rate (bpm), P-wave amplitude (mV), PR segment length (ms), QRS duration (ms), QT interval (ms), QTc interval duration (ms), horizontal ST-segment depression (recorded separately) (mm), horizontal ST-segment elevation (recorded separately) (mm), the number of lead artifacts, the ECG diagnosis, and the duration of ECG scan. All data were recorded on individual patient forms.

The QRS duration, the QT and QTc intervals were examined on V1 derivation for the output of both devices. The P-wave amplitude was noted by examining the DII derivation on the output of both devices. The ST-elevation and ST-depression measurements were recorded separately for each device, and derivation data were recorded separately. In the QTc calculation, the Bazett formula was employed for patients with a

heart rate of 60–100 bpm and the Federica formula was used for patients with different heart rates [3].

The duration in seconds from the time when the electrodes were attached to the body until the time when the ECG output was obtained was recorded. The application times, which were the duration from attaching the clips to obtaining the output, were recorded and compared. The duration of the ECG scanning times was noted with a stopwatch by another paramedic who was not included in the study. If there was an artifact in at least one QRS junction in the ECG outputs obtained with both devices, that derivation was recognized as a lead artifact. The amplitude of the P-wave, the PR interval, the QRS duration, the QT interval, and cardiac muscle ‘noise’ artifacts that did not interfere with the calculation of the QT interval were not assessed.

Statistical analysis

In calculating the required size of the study population, because the effective size of the study correlations could be weak ($r=0.2$), it was calculated that an 80% effect size could be obtained at a 95% confidence interval (CI) when at least 150 participants were included in the study. The final study population size was 245, which reached a 100% effect size at the 95% CI level, and because of the strong effect size obtained in this study, the lowest correlation value was calculated at 0.704. SPSS version 17.0 was used for data analysis. The same emergency medical specialist assessed the ECG output obtained with both devices. Clinical diagnosis of the ECGs, wave and segment measurements in the ECGs were recorded by emergency medicine specialists. The statistical analysis of reliability of the ECG data, for each separate ECG lead, included the use of Cohen’s kappa (κ) values, where a κ -value of 0 represented no agreement, and a κ -value of between 0.81–1.00 represented almost complete agreement [4]. The Wilcoxon non-parametric signed-rank test was used in the analysis of dependent nonparametric variables. The intraclass correlation coefficient (ICC) reliability index and Cohen’s kappa (κ) statistic were used to evaluate between-group compatibility. A p-value <0.05 was considered to be statistically significant.

Results

Study participants

The study population included 100 women (40.8%) and 145 (59.2%) men, 142 (57.95%) were older than 65 years, and 103 were younger than 65 years. The average age of the study participants was 62.78 ± 18.14 years.

Table 1. Comparison of the patient age, electrocardiogram (ECG) amplitude and time variables between the two ECG devices, the Infron Micro Cor and the Nihon Kohden Cardiofax M.

Variables	Nihon Kohden		Infron MicroCor		p Value or ICC
	Mean ±SD	IQR	Mean ±SD	IQR	
Heart rate (beat perm in.)	92.54±25.25	88 (75–107)	90.46±24.76	88 (74.75–100)	ICC=0.857
ECG time (s)	65.2±9.72	65 (58–72)	57.5±10.93	65 (51–64)	*p=0.0001
Artifacted derivation	0.97±1.92	0 (0–1)	1.69±2.97	0 (0–2)	*p=0.001
P wawe amplitude (mV)	0.77±0.52	1 (0.5–1)	0.84±0.53	1 (0.5–1)	ICC=0.912
PR interval (s)	0.17±0.33	0.16 (0.12–0.19)	0.16±0.32	0.16 (0.12–0.2)	ICC=0.968
QRS interval (s)	0.10±0.26	0.09 (0.08–0.11)	0.10±0.26	0.09 (0.08–0.11)	ICC=0.704
QRS amplitude (mV)	4.62±3.71	3.5 (1–6)	4.52±3.6	4 (1–6)	ICC=0.975
QT inteval (s)	0.36±0.47	0.36 (0.32–0.40)	0.36±0.52	0.36 (0.34–0.40)	ICC=0.892
QTc interval (ms)	438.4±48.67	440 (413–462)	440.43±40.5	440 (413–463)	ICC=0.858

* p values are derivated from Wilcoxon Signed Rank Test. Data reported as mean ±SD and median (IQR). ICC – interclass correlation coefficient.

Comparison of the electrocardiogram (ECG) readings from the Infron Micro Cor and Nihon Kohden Cardiofax M devices

From the Infron Micro Cor ECG readings, the mean heart rate was 90.46±24.76 bpm; from the Nihon Kohden Cardiofax M ECG readings, the mean heart rate was 92.54±25.25 bpm. Using the intraclass correlation coefficient (ICC), a high degree of compatibility was found between the devices to detect heart rate (ICC=0.857).

ECG duration and lead artifacts in the ECGs

The Infron Micro Cor ECG duration of the ECG scan was 57.5±0.93 seconds, and 65.2±9.72 for the Nihon Kohden Cardiofax M ECG readings, which was significantly different (p=0.0001). The mean duration of the ECG scan in the Infron Micro Cor ECG readings was about 12% shorter than that of the Nihon Kohden Cardiofax M ECG readings. The Infron Micro Cor ECG readings had at least one lead artifact in 93 ECGs (37.9%), and the mean number of lead artifacts were 1.69±2.97. The Nihon Kohden Cardiofax M ECG readings had at least one lead artifact in 71 ECGs (28.9%), and the mean number of lead artifacts was 0.97±1.92. A significant difference was found between lead artifact counts (p=0.01) as there were more artifacts in the ECGs from the Infron Micro Cor ECG device.

The P-wave amplitude and PR-interval measurements in the ECGs

ECGs with P-wave amplitudes and PR-interval sinus rhythm were taken into account in ECGs with sinus rhythm (167 patients) because a P-wave was not found in patients with an

ECG diagnosis not in sinus rhythm. The mean P-wave amplitudes were 0.84±0.53 mV in the Infron Micro Cor ECG readings, and 0.77±0.52 mV in the Nihon Kohden Cardiofax M ECG readings. The mean PR interval was established as 0.16±0.32 mV in the Infron Micro Cor ECG readings and 0.17 ± 0.33 mV in the Nihon Kohden Cardiofax M ECG readings. Regarding the measurements of P-wave amplitudes and PR intervals, very good compatibility was found between the two devices (Infron Micro Cor, ICC=0.912) (Nihon Kohden Cardiofax M, ICC=0.968).

QRS and QT interval in the ECGs

The QRS interval averages were measured as 0.10±0.26 ms in the Infron Micro Cor ECG readings and the Nihon Kohden Cardiofax M ECG readings. High compatibility was achieved between the two groups (ICC=0.704). The mean QRS amplitudes were 4.52±3.6 mV in the Infron Micro Cor ECG readings and 4.62±3.71 mV in the Nihon Kohden Cardiofax M ECG readings, and high compatibility was established between the two groups (ICC=0.975). The mean QT interval was 0.36±0.52 sec in the Infron Micro Cor ECG readings and 0.36±0.47 sec in the Nihon Kohden Cardiofax M ECG readings. The results showed that high compatibility was found between the two groups in terms of QT interval measurement (ICC=0.892). The mean QTc interval was 440.43±40.5 ms in the Infron Micro Cor ECG readings and 438.4±48.67 ms in the Nihon Kohden Cardiofax M ECG readings, and high compatibility was found between the two devices (ICC=0.858) (Table 1).

ST-segment elevation and ST-segment depression in the ECGs

ST-segment elevation in ECGs, measured in millivolts, was recorded separately for each lead. The compatibility of ST-segment

Table 2. Cohen's Kappa Coefficients between the derivations.

Derivations	ST segment elevations	ST segment depressions
	κ Value	κ Value
DI	0.836	0.89
DII	1	0.94
DIII	0.963	1
aVR	0.911	1
aVL	0.954	0.82
aVF	0.931	0.92
V1	1	0.71
V2	0.871	1
V3	0.852	0.82
V4	1	0.78
V5	1	0.79
V6	0.726	0.85

κ Values are derived from Cohen's Kappa Test.

elevation was found at high levels in the ECGs scanned with the Infron Micro Cor and Nihon Kohden Cardiofax M ECG devices. The κ -values for ST elevation were $\kappa_{DI}=0.836$, $\kappa_{DII}=1$,

$\kappa_{DIII}=0.963$, $\kappa_{aVR}=0.911$, $\kappa_{aVL}=0.954$, $\kappa_{aVF}=0.931$, $\kappa_{V1}=1$, $\kappa_{V2}=0.871$, $\kappa_{V3}=0.852$, $\kappa_{V4}=1$, $\kappa_{V5}=1$, and $\kappa_{V6}=0.726$ (Table 2).

Measured in millivolts, ST-segment depression in ECGs was recorded separately for each lead. The compatibility of ST-segment depression was found at high levels in the ECGs scanned with the Infron Micro Cor and Nihon Kohden Cardiofax M ECG devices. The κ -values for ST depression were $\kappa_{DI}=0.89$, $\kappa_{DII}=0.94$, $\kappa_{DIII}=1$, $\kappa_{aVR}=1$, $\kappa_{aVL}=0.82$, $\kappa_{aVF}=0.92$, $\kappa_{V1}=0.71$, $\kappa_{V2}=1$, $\kappa_{V3}=0.82$, $\kappa_{V4}=0.78$, $\kappa_{V5}=0.79$, and $\kappa_{V6}=0.85$ (Table 2).

ECG diagnoses

There were 37 different diagnoses in the 245 patients found using both devices. The Infron Micro Cor ECG readings identified of 81 patients with normal sinus rhythm (NSR), 36 patients with atrial fibrillation (AF) or flutter, 18 patients with acute coronary syndrome (ACS), 29 patients who had AF with aberrant conduction, nine patients with left ventricular hypertrophy, 27 patients with sinus tachycardia, and 45 patients with other diagnoses. The Nihon Kohden Cardiofax M ECG readings identified 79 patients with normal sinus rhythm (NSR), 36 patients with AF or flutter, 18 patients with ACS, 31 patients with AF with aberrant conduction, nine patients with left ventricular hypertrophy, 28 patients with sinus tachycardia, and 44 patients with other diagnoses (Table 3). Also, 78 of the 79 NSR patients with the Nihon Kohden Cardiofax M ECG readings had the same diagnoses as the Infron Micro Cor ECG readings.

Table 3. ECG diagnosis of the patients.

Diagnosis	Nihon Kohden							Total
	NSR	Atrial fibrillation/ flutter	Acute coronary syndrome	Atrial fibrillation with aberrant conduction	Left ventricular hypertrophy	Sinus tachycardia	Other	
NSR	77	1	0	2	0	1	0	81
Atrial fibrillation/flutter	1	35	0	0	0	0	0	36
Acute coronary syndrome	0	0	18	0	0	0	0	18
Atrial fibrillation with aberrant conduction	0	0	0	29	0	0	0	29
Left ventricular hypertrophy	0	0	0	0	9	0	0	9
Sinus tachycardia	0	0	0	0	0	27	0	27
Other	1	0	0	0	0	0	44	45
Non diagnostic (cause of artifact)	0	0	0	0	0	0	0	0
Total	79	36	18	31	9	28	44	245

Rhythm changes were found in the ECG scans in three patients from the Infron Micro Cor ECG readings and in one patient in the Nihon Kohden Cardiofax M ECG readings (Table 3). In both groups, the ECGs were identical in terms of ACS, left ventricular hypertrophy, and AF and atrial flutter (Table 3).

Practical considerations

The Infron Micro Cor ECG device weighs 70 gms and measures 85×87×23mm in size, and can fit into the palm of an adult person. In contrast, the Nihon Kohden Cardiofax M device weighs approximately 3.9 kg and measures 236×120×322 mm [5,6].

Discussion

Review of the published literature has shown that there have been few real-world clinical studies on the validity and reliability of portable wireless telemetry and telephonic electrocardiogram (ECG) devices. Mansuroğlu et al. reported the findings of a feasibility and reliability study of the use of transtelephonic electrocardiography systems that included the use of smartphones in the diagnosis of acute myocardial infarction and showed that the device had a low level of compatibility with a standard ECG device [7]. Also, Alejandro et al. compared a wireless ECG prototype, named TIPS, with an ECG simulator and found compatibility with an intraclass correlation coefficient (ICC) of 0.97 [8].

In the present study, 245 patients were consecutively investigated with the Nihon Kohden Cardiofax M ECG device and the Infron Micro Cor ECG device, and data were analyzed including ECG output, output time, ECG diagnosis, ECG waveforms and segments.

In a study by Sammito and Böckelmann on the use of mobile devices to identify and monitor heart rate, Holter ECG devices were identified as the gold standard devices to measure heart rate [9]. In the present study, the mean heart rates of patients determined by the Infron Micro Cor ECG readings were lower than those shown by the Nihon Kohden Cardiofax M ECG readings. The reasons for his finding might be that the patient may have rested between sequential ECG investigations and the influence of stressor factors might have declined from the first ECG measurement to the second ECG measurement. Also, the Infron Micro Cor ECG device provided ECG recording for 10 minutes, which is similar to that of Holter monitor ECGs.

It is often important to obtain ECG readings as quickly as possible, particularly in the Emergency Medicine Department. To obtain ECG output in a shorter time, devices have been developed to attach chest leads more rapidly and efficiently, and some of these methods and devices have been patented [10–12].

The ECG output time of the Infron Micro Cor ECG readings was shorter than that of the Nihon Kohden Cardiofax M ECG readings, indicating that the Infron Micro Cor ECG device might be of use in emergency medicine.

As this study has shown, artifacts can arise in ECG testing, which can be caused by tremor of the extremities (motion artifact), excess chest hair (electrode contact artifact), and problems with the device, such as breaks in or damage to the leads. Also, telephones and ventilators used in Emergency Departments can lead to artifacts in ECG readings [13,14]. In this study, when the output with at least one artifact in the ECGs scanned with both devices were compared, the ECGs in the Infron Micro Cor ECG readings were found to have significantly more artifacts ($p=0.01$). Although there were some lead artifacts, ECGs could still be evaluated. Previous studies have attempted to develop filters for wireless ECG devices to eliminate artifacts [15]. The Infron Micro Cor ECG device might potentially remove the problem of artifact through the development of a better filtering algorithm.

The compatibility of QTc intervals was found to be excellent in the ECG data obtained from both devices in this study. The Infron Micro Cor ECG device does not have an automatic QT calculation algorithm, while the Nihon Kohden Cardiofax M does. In the study by Janssen et al. [16], the correlation between the manually measured QTc and the automatically measured QTc values, with the algorithm, was 0.60. The QTc ICC value was 0.858 in this study, which was considerably higher than that reported by Janssen et al. [16].

In the present study, excellent compatibility was found between the Infron MicroCor ECG device and the Nihon Kohden Cardiofax M ECG device in terms of specifying P-wave amplitude, PR interval, QRS amplitude, and QT interval, and the compatibility between devices for detecting QRS intervals was found to be very high. The Infron Micro Cor ECG device does not have an algorithm to measure ECG waves and intervals. From this data, it can be seen that the P-wave amplitude, PR interval, QRS amplitude, QTc measurement, QT and QRS intervals could be manually determined, but an algorithm calculating this data in the Infron Micro Cor ECG device would be of value.

The diagnoses were identified well in the ECG data from both devices, indicating that the Infron Micro Cor ECG device was diagnostically equivalent to the Nihon Kohden Cardiofax M ECG device. Also, the Infron Micro Cor ECG device was safe to use clinically. The Infron Micro Cor ECG device can be carried in the pocket and is volumetrically about one-eighth of the size of the Nihon Kohden Cardiofax M ECG device, making it easy to use in emergency medicine services. The Infron Micro Cor ECG device is battery-operated by two AA alkaline batteries, while the Nihon Kohden Cardiofax M ECG device is AC powered.

However, the Infron Micro Cor ECG is dependent on a computer or computer tablet and does not have its own screen, which can be considered as a disadvantage. Yet installing the display and WiFi connection module on the device by changing the device hardware has been envisaged in future to offer a considerable advantage.

There were limitations to the present study. The study did not compare both ECG devices with an ECG calibrator device. The study did not include an investigation into the satisfaction of the patients and the staff who performed the ECGs and did not compare these factors between the two devices. Also, the costs of obtaining and servicing both devices were not compared.

Conclusions

In a study that included 245 cardiology patients attending an Emergency Medicine Department, two wireless telemetry electrocardiogram (ECG) devices were used and the findings

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Conflict of interest

None.