Cardio safe

A Validation Study

Cardio Safe P 12

Transtelephonic 12 lead-EKG device for EKG monitoring,
recording and transmission

Conducted by the
Cardiac Center and Red-Cross Hospital in Frankfurt/Mainz
Prof. D. N. Reifart, Dr. J Weil, S. Gohring
in collaboration with the Airport Medical Center, Munich Airport
Dr. J. Diell

SUMMARY

Background

Testing the reliability of a 12 lead-EKG with transtelephonic transmission, as a monitoring tool for cardiac patients.

Summary of results

For many years in Germany, as well as in the US, Israel, Italy and South-American countries, transtelephonic EKG transmission was performed with 1-3 lead recordings, allowing accurate diagnosis only for arrhythmic disorders.
We tested a new system (CARDIO SAFE P 12, manufacturer: Aerotel, Israel) which allowed patients, for the first time in Europe, to record a 12 lead-EKG with telephonic transmission to an emergency center (CARDIO SAFE "HERZUBERWACHSUNGS-ZENTRALE" at the Medical Service of the Munich Airport).
We compared the recording of a standard 12 lead EKG to that of a Cardio safe P 12 recording transmitted by telephone to a PC at the CARDIO SAFE Center and printed out, in 217 consecutive cardiac patients. Patient's clinical data were also collected.

Quality of parameter	Standard EKG recording	P 12 Telephone EKG recording
Very good	204 (94%)	108 (59%)
Good	14 (6%)	79 (36%)
Satisfying	0	31 (14%)

Clinical Parameter	Standard EKG recording	P 12 Telephone EKG recording
Infarction's signs	40	37
Heart rate	72.2 ± 16	71.2 ± 15 ($p<0.04$)
PQ interval (sec)	0.18 ± 0.09	0.17 ± 0.03
QRS width in V6 (sec)	0.12 ± 0.18	0.17 ± 0.03
QT interval (sec)	0.43 ± 0.78	0.39 ± 0.04
Sokolow index (mV)	2.39 ± 0.78	2.02 ± 0.9
Hypertrophy	27	11

Conclusions

1. The placement and recording of the 12 lead-EKG by laymen with the P 12 and the transmission via telephone is very simple and is well conducted by all patients, allowing excellent transmission of then information.

2. Heart rate, rhythm and conduction correlate well in both types of recordings.
The P 12 recording, via a computer program is able to eliminate disturbances (through the "print –parameter") and can correct the tracing-dimensions, whenever necessary or requested, on-line.

3. The P 12 device seems to be the ideal tool for cardiac patients. It enables mobile self-monitoring, when a Medical Center with competent personnel (trained in cardiology)

is available 24 hours a day for reception, recording and interpretation of on-line EKGs with the appropriate intervention and answers to all patient's questions.

Reliability of a new 12 lead-EKG with telephone transmission for cardiac patients

Introduction

In many countries, the self-monitoring of EKG recordings by the patient, with transmission through the telephone to a medicalized center has proven to be safe and efficient (1,5,7-10). This implies that a medical team provides with the appropriate diagnosis, for example arrhythmia or unstable angina (1,3,5,7-10) and introduces the adequate therapy, which can in the case of an acute myocardial infarction be lifesaving by reducing the time to intervention.

Implications

1) The technique has to be simple and reproducible by laymen.
2) The technique has to be reproducible in movement too (when traveling, for example)
3) The transmission to a competent Center has to be around the clock.
4) The quality of the transmission and the signal are mandatory with the 12 lead- EKG, as the diagnosis and treatment rely upon the signal recorded.

These parameters have to be fulfilled throughout the validation-study, as to date, no study in Europe has determined these facts yet (P 12, Aerotel, Israel).

Material and Methods

We have studied 217 consecutive cardiac patients (86 women, 131 males) in an ambulance, that where worked-up (control or diagnosis) for a cardiac event.
After recording the EKG with a standard 12 lead-EKG (HP 7, Hewlett-Packard), a recording with a P 12 (Aerotel, Israel) 12 lead-EKG, by a layman, was done and transmitted. The P 12 is a 180 grams device, battery-equipped, with the dimensions of a small cellular phone. It records 12 leads (0.05-150 Hz), with an internal acoustic-transmitter (1900 Hz) capable of transmitting through the phone to a PC (Pentium 100 DX with Netware Card) an EKG recording, that will then be printed.
The 6 peripheral leads are recorded with 2 armpit electrodes, and the left area (indifferent electrode) is recorded through 3 contact points at the back of the devise (with 2 different positions to apply, in order to obtain 6 different recorded leads). After transtelephonic transmission to the medical center at the Munich Airport (Cardio Safe), the recording was printed and analyzed, and send to the Frankfort Cardiac Center. Both 12 lead recordings (standard and P 12) were interchanged and re-analyzed at different moments by different physicians. With diverging findings the exchanged EKG were re-analyzed by 2 other cardiologists, in order to correct the bias of observational variability. Comparisons were

then analyzed with correlation tests, and significant differences were considered when appropriate. Sensitivity and specificity ratios were applied for non-numerical parameters.

Results

Qualitative and quantitative parameters are presented in Table 1.

Parameter	Standard EKG recording (SEKG)	P 12 Telephone EKG recording (TTEKG)
Patient	217	217
Very good quality	202/217	108/217
Good quality	14	78
Satisfying	1	31
Insufficient	0	0
Infarction's signs	40	37
ST segment change	15	15
T wave negative	82	80
Heart rate	72.2 ± 16	71.2 ± 15 ($p<0.04$)
PQ interval (sec)	0.18 ± 0.09	0.17 ± 0.03
QRS width in V6 (sec)	0.12 ± 0.18	0.17 ± 0.03
QT interval (sec)	0.43 ± 0.78	0.39 ± 0.04
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The quality of printing was 89% with conventional EKG as opposed to 86% in the TTEKG, although the overall recording was very satisfying in most patients.
The patients in whom the recording was less than good, was mainly due to the fact that in thin patients, the contact with the devise for the V5 and V6 leads was less than optimal.
While the heart rate and form of the QRS-complex were similar, the maximum height (peak) was 15% lower with the TTEKG as compared to the SEKG (correlation $r = 0.88$, $p< 0.001$). The sensitivity for a left heart hypertrophy, based on the Sokolow-index, was 50% lower with the TTEKG. The sensitivity and specificity of ST-segment changes was 100%, and so was the T wave in all patients with a sure diagnosis of myocardial infarction.

Discussion

Telemetry served for many years as a monitoring tool for risk patients, particularly after myocardial infarction, coronary arteries bypass-grafts and life-threatening arrhythmias. The immediate EKG recording in symptomatic patients implies a close collaboration between the physician (cardiologist) and the patient, allowing also the patient to be constantly reassured without repetitive and costly visits to the cardiologist. The newest technology allows for the first time in Europe, a 12 lead recording which is of utmost importance in our experience, as 1 lead, 3 lead or even 9 lead recordings can only diagnose arrhythmia's with no recognition of lateral wall infarction (11).

The TTEKG has always been a useful tool for paroxystic supra-ventricular tachycardia, which can usually be detected in 70% of patients, with a sensitivity of 91% when the patient is symptomatic. In a short randomized published study, the authors were able to demonstrate the superiority of cardiac event recorders (67% versus 35%), as opposed to 48 hours Holter monitoring in patients with palpitations (12). Other authors published the high sensitivity of ST segment changes (95%) when using the TTEKG (7). Up to now, in Germany, the mean time between cardiac symptoms and therapeutical intervention was 3.5 hours, which should definitely be reduced with the use of TTEKG, offering a higher chance of recovery with no sequels after myocardial infarctions, with rapid thrombolysis or coronary angioplasty. A first evaluation in the UK lead to the following results: 2563 patients called for a TTEKG consultation out of which 1% was urgent, 18% necessitated a physicians intervention, 12% had no significant condition and 69% had no cardiac-related event (13).

With the P 12 technology, recordings should be performed by laymen, who can then transmit the information to a telephonic Center, which will print out the recording, and fax it to the physician or cardiologist in charge. The recordings seem particularly reliable for ST-segment and T wave changes, allowing precise diagnosis of acute ischemic event. We are aware of the 15% difference in amplitude recording between the TTEKG and the SEKG, but it seems to be irrelevant in acute emergent medicine, as it only reveals hypertrophic changes, that do not impact at the time of the diagnosis and intervention. These changes in recording will also be taken into account for those patients who have a continuous monitoring, and can also be altered by modifying certain recording parameters in the devise itself.

Our impression is that patient are satisfied and reassured, knowing that wherever they are, 24 hours a day, they can self-monitor their EKG and have online advise and diagnosis for any occurring condition. Remains only to be seen whether the personal collaboration between patients and physicians will allow better quality of care, with a significant decrease in cost of care.