Quality of Electrocardiographic Records in Population Studies: What Can we Achieve?

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Abstract

Measurement precision and validity of the diagnostic interpretation are to a major extent associated with the noise interference in routinely recorded electrocardiograms (ECGs).

In order to provide appropriate quality in the population-based KORA-F4 study, we applied a multi-stage monitoring of the resting ECG recording including a comprehensive training of the technicians to enhance their skills for appropriate electrode application, artefact recognition and prevention, and in addition, computerized measurement of the noise superimposing the ECG.

ECGs of predominantly good quality were obtained from 98.3% (3028/3080) of the study participants.

The quality achieved is a precondition for reliable estimates of population-based ECG characteristics, especially when valid phenotyping for serial ECG analyses and genetic association studies is required.

1. Introduction

Computerized analysis of electrocardiograms (ECGs) seems to be an ideal method in cardiovascular epidemiologic research where consistently operating procedures for ECG measurement and interpretation are required. However, routinely recorded ECGs often contain technical or biological noise which overlaps the ECG signal in the same frequency range. As a consequence, noise superimposing the ECG is an important factor limiting the accuracy of ECG measurements and their diagnostic interpretation as has been shown in several studies, e.g. [1,2], even if computerized methods for signal enhancement and noise rejection are applied. As a consequence, recording of high quality ECGs is of particular interest in epidemiologic research, where unbiased and valid results on a population-based scale are required.

Here we describe the technical quality of the ECG records achieved in the population-based KORA-F4 study, based on a comprehensive training program for technicians performing the ECG recording and the continuous quality monitoring conducted during the data collection period.

2. Methods

2.1. Study population

In the KORA-F4 study - a 7-year follow-up of the KORA-S4 health survey conducted in Southern Germany [3] - 3080 men and women aged 32-81 years were examined between 2006 and 2008, based on a random sample of the general population.

2.2. ECG recording

ECG recording was performed using the PC-based BioSys system (Hörmann Medizintechnik). The 12 lead ECGs of 10 sec duration were recorded according to a standard protocol, after at least five minutes resting in supine position. All examinations were performed using the same equipment for data collection and analysis. To avoid distortions of amplitudes of the QRS complexes, options for low-pass filtering were switched off during the whole study.

2.3. Computerized ECG analysis

Computerized ECG analysis of the 12 lead resting ECG was performed using the Hannover ECG System
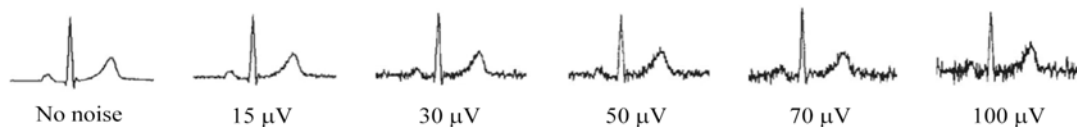
Figure 1. ECG cycles (R amplitude = 1 mV) with increasing noise superposition.

(HES-Version 3.22-12). In a comprehensive international validation study, the HES system turned out to be one of the programs with the best diagnostic performance [4], also providing superior measurement precision. The HES analysis takes into account all ECG cycles within the 10 second record for estimating final measurements based on an average cycle. This procedure minimizes measurement imprecision due to possible noise effects on single ECG cycles. All 12 leads are considered simultaneously. The HES system was certified according to the EU norm DIN-EN 60601-2-51 [5].

The technical quality of each ECG record was quantified by computerized noise level measurement, characterizing each ECG record by the maximum noise level in any of the twelve leads.

2.4. Quality assurance of ECG recording

2.4.1. Technicians' training and supervision

The technicians recording the ECGs play a central role with respect to the quality of the ECG tracings. They have to take care of appropriate handling of the technical equipment (ECG machine, electrodes, PC), skin preparation, relaxed position of the probands to minimize muscle tremor, and to control external magnetic fields (powerline interference).

In the KORA-F4 study, five technicians performed the ECG recording; four of them had already performed ECG recording in previous population studies. Nevertheless, before the beginning of the study, each technician had to perform several ECG examinations under supervision including a comprehensive training to enhance skills for appropriate electrode application, artefact recognition and prevention.

The specific instructions for ECG recording have been described in detail in a standardized operation procedure taking into account the recommendations according to the 'Tenth Bethesda Conference on Optimal Electrocardiography' [6].

The technicians' basic training was supplemented by a pilot study where 87 probands were examined under routine conditions.

2.4.2. Quality monitoring in the main study

The monitoring of the quality of the ECG records in the main study was based on several steps:

(1) Visual control of the ECG during recording by the technicians
(2) Online computerized noise level measurement
(3) Control by visual inspection of cardiologists
(4) Control of noise level distributions by technician
(5) Control of noise level distributions over time

With respect to step 1 and step 2, improvement of the technical quality could be achieved by repeated ECG recording. The results with respect to steps 3, 4 and 5 were available by statistical analyses on a weekly basis.

In addition, during the study, further individual supervision of the ECG recording of each technician (recertification) was performed controlling especially for the correct positioning of the chest lead electrodes.

3. Results

3.1. Distribution of noise levels

The noise level distribution according to the computerized noise level measurements is shown in figure 2.
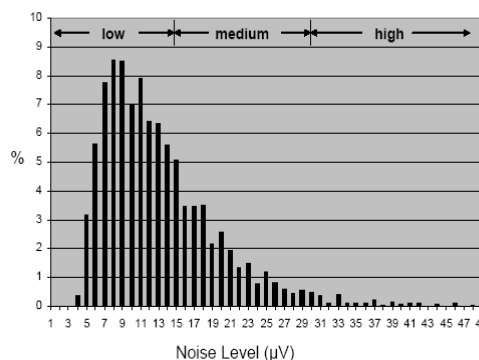

Figure 2. Noise level distribution.

Distribution measures of noise level:
m±s   = 13.2±6.8 µV
Median   = 12.0 µV
80 percentile = 18.0 µV

Prevalence of categorized noise levels:
(1) Low (<15 µV)   72.7%
(2) Medium (16-30 µV) 24.9%
(3) High (>30 µV)   2.4%

3.2.   Noise level over time

Fig. 3 shows the noise level distributions (m, s) over time. When comparing the noise level distributions on a weekly basis, no major differences were observed, with one exception: the increased standard deviation in week 35; this was primarily due to the ECG derived from a handicapped participant, where no better quality could be achieved.
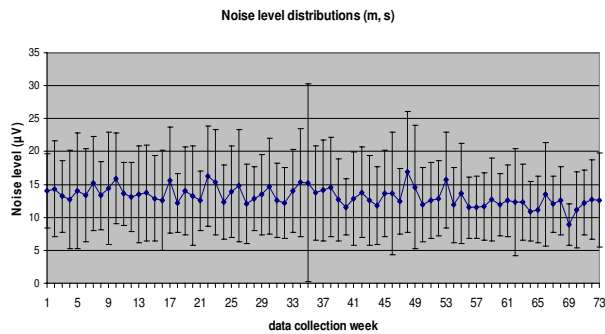

Figure 3. Noise level distributions (m, s) over time.

3.3   Repeated ECG recording

In order to get improved quality of the ECG records in cases with limited quality of the first record, additional ECG records were taken. This option (e.g. in case of temporary muscle tremor) was used in 6.7% (204/3028) of the ECG examinations. On average, it resulted in a reduction of the noise level of 7.4 µV (28.3±14.2 µV vs. 20.9±10.9 µV).

3.4.   Noise level by participants' age

Figure 4 shows the noise level distributions (m, s) by the participants' age. We observed a significant increase of approximately 0.14 µV per year due to increased muscle tremor with increasing age.
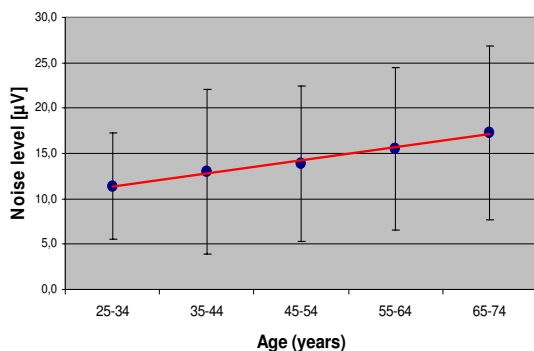

Figure 4. Noise level distributions (m, s) by age group.

3.5.   Noise level by technician

As shown in table 1, there were only minor differences when comparing the technical quality derived by the different technicians. The maximum mean difference of noise levels between technicians was 3.0 µV (technician A vs. technician C).

Table 1. Noise level distributions (m, s) by technician.

Technician	n	m ± s (µV)	Median (µV)
A	1397	12.0 ± 6.2	11
B	328	13.4 ± 7.0	12
C	697	15.0 ± 6.5	14
D	271	14.5 ± 7.7	12
E	335	13.5 ± 7.8	11
Total	3028	13.2 ± 6.8	12

3.6.   Response rate of the ECG examination

In total, 3080 subjects participated in the KORA-F4 study. As shown in table 2, ECGs could be derived from 98.3% (3028/3080) of the study participants. ECGs are missing from 51 participants who could not come to our study center, mainly due to their poor health status. They could only be examined according to a reduced examination protocol (medical history by interview, blood samples, blood pressure measurement) during home visits. Complete computerized ECG measurements and interpretations were available from 97.6% (3006/3080) of the study participants (in case of electronic pacemaker no measurements were provided by HES).

Table 2. ECG response.

ECG	n	%
F4 participants	3080	100.0
Available ECG records	3028	98.3
Complete computerized ECG	3006	97.6
No ECG record (refusal)	1	0.0
No ECG record – Home visit	51	1.7

4.   Discussion

Up to now, population-based studies within our KORA Project have been conducted for more than 25 years. Since the beginning in 1984 with the first MONICA Augsburg Survey which was part of a WHO project [7],

more than 21,000 ECGs have been derived. During this time period, ECG recording technology has changed, algorithms for computerized ECG analysis have advanced, and priorities of objectives have shifted. However, the challenge of receiving ECG records of high quality for long-term use in the epidemiologic data base has remained. This is a precondition for valid ECG phenotyping, especially for noise sensitive ECG parameters (P wave measurements, ST-T segment measurements, QT interval estimates, etc.) and in addition, it is of prime interest in serial ECG analysis to differentiate random from systematic physiologic changes of the ECG. A general exclusion of ECGs with limited signal quality is not a desirable option, because of possible associations with the subjects' health status.

Beyond the scope of continuous monitoring of the quality of ECG recording with immediate feedback, we defined minimal requirements with respect to the technical quality for our studies, as shown in table 3.

Table 3. Conditions of quality measures.

Quality measure	Condition	Achieved in KORA-F4
Median noise level	$<20\ \mu V$	$12\ \mu V$
80 percentile	$<30 \mu V$	$18\ \mu V$
ECG response rate	$>95\%$	98.3%

All major criteria of quality measures were met in the KORA-F4 study: The ECG data collected was primarily of good quality, electronically stored ECGs were available from 98.3% of the study participants.

Our strategy of a comprehensive training program for the technicians before the beginning of a study, and the additional continuous monitoring of the quality of the ECG records during the data collection period, has proved its value. This does not a priori exclude any deficits with respect to the quality during routine work, however, it helps to identify and to overcome shortcomings at an early stage.

The advantage of ECG recording in a permanent study center - as conducted in KORA-F4 - becomes obvious if compared with other KORA studies where the ECG examinations had to be performed in study centers with sometimes weekly changing locations. Under these conditions, there were temporarily significantly more problems with respect to the technical quality, primarily caused by ambient magnetic fields. Furthermore, our recently conducted 'KORA-Age' study showed that ECG

records obtained during home visits showed a rather poor quality. As a consequence, filtering of powerline interference might be essential in these cases.

5.   Outlook

Every ECG record in our data base includes the date and time of day the ECG was taken, the technician ID and quality measures. These data provide the information necessary for selective inclusion or exclusion of ECG records depending on the noise sensitivity of the ECG measurements of interest.

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