Personal Sensor-System Modalities Evaluation for Simplified Electrocardiogram Recording in Self-Care

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Abstract

In this paper we propose a new design of a wearable sensor-system produced in three different sizes for recording anywhere and at anytime three pseudoorthogonal ECG leads I, II and V2 according to the Mason-Likar system. It looks like a bib and aims to provide any individual with a sensor-system suitably adapted to his/her morphology. Our research goal is to establish for each citizen the most appropriate sensorsystem size, which produces ECG signals with a diagnostic content that is closest to that of a standard ECG. In order to evaluate the possible automation of this selection process, we performed a series of experiments on eight healthy volunteers and we present the results of 280 ECG comparisons in terms of correlation, RMS values, as well as changes in diagnosis probability and of selected ECG measurements.

1. Introduction

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Self-care is increasingly encouraged with the aim of detecting cardiac events as early as possible. This motivates the development of wearable sensor-systems that will allow a citizen to record an ECG himself and will subsequently support new strategies of preventive medicine. Current research projects are focusing on four groups of monitoring platforms: (i) "Holter-type" systems with standard sensor design and locations, (ii) Body-worn sensor patches, (iii) Body-worn bands and harnesses and (iv) "Smart garments" for long-term application [1]. However, these already established approaches have various limitations for an on demand use of the corresponding sensor-systems by every citizen, especially in self-care situations. In case of occasional monitoring, a potential clinical need is to have at the user's disposal a small, portable system, maybe even integrated into a mobile phone, a watch or a wallet, which

enables a profane user to make a quick and discrete recording of his vital signs and which provides an initial diagnosis leading the user to make a rapid and evidencebased decision upon his health status. This direct feedback or the possibility to send information to a remote monitoring station in case of an emergency was a key target of the European IST EPI-MEDICS project [2]. The project outcome is a prototype of a Personal ECG Monitor (PEM), which includes a reduced-electrodes set that allows 10 seconds recording of three pseudoorthogonal leads I, II and V2 according to the Mason-Likar system. It also embeds algorithms allowing the reconstruction of standard 12-lead ECGs and a risk stratification based on signals analysis. However, as it has been widely reported, the diagnostic accuracy of the ECG and thus the success of the PEM and of similar systems depends on the user ability to apply sensors in the correct anatomical positions. This task requires a specific knowledge and time to find accurate electrodes' locations, and according to several studies remains problematic even for skilful professionals [3-4]. Recently, Sejersten et al. demonstrated that only 9% of all electrodes are placed correctly, while 42% are most likely shifted down [5].

In this paper we propose a new design of a wearable sensor-system, produced in three different sizes: small (S), medium (M) and large (L), which is very easy to setup, anywhere and at any time, and which is compliant with the PEM's ECG recording system proposed by Rubel [2]. Our objective is to provide every citizen with an optimal recording system that is well suited to his peculiarities and that allows to get the same electrodes configuration along the time, and therefore to promote serial ECG analysis, which improves ECG diagnosis accuracy [6].

We also present a methodology for the evaluation of the ECGs obtained with these three representative sizes on subjects of different morphologies, with the objective to detect the most adequate sensor-system, characterised by its ability to yield for an ECG signal of similar diagnostic content than a standard ECG.

2. Material and methods

2.1. Sensor-system modalities design

Following the experience of the EPI-MEDICS project, we chose the same reduced electrodes set consisting in four active electrodes: RA – right arm, LA – left arm, LL-left leg and V2 located in the 4th inter-costal space 1-2 cm left of the sternum, and one so called ground (G) electrode. All peripheral electrodes are aimed to be placed on the subjects' torso according to the Mason-Likar positioning. Therein, we propose a template (Figure 1) of three representative modalities: S, M and L for different subjects' morphologies. The template is made of three semi-rigid strips of different lengths, which keep the same opening angles α and β . The electrodes corresponding to the S or M, or L size are fixed at the end of each strip.

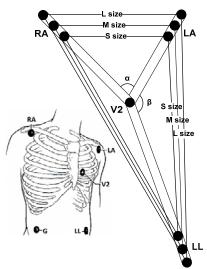


Figure 1. The design of sensor-system modalities.

An additional strip or a chain helping to fix the sensor-system in around the neck (like a bib apron) can be attached. It shall serve for the sensor-system placement and adjustment and shall ensure the stability of the sensors position. Only the first use of this system would require the user to find out the place where the middle electrode corresponding to V2 shall be placed. The user will slide the two upper strips from V2 to RA and from V2 to LA and will adjust the length of the strip in around the neck. This user specific adjustment will be kept for his future recordings.

2.2. Data acquisition

We used data from 8 healthy volunteers (4 women and 4 men) whose characteristics are described in Table 1.

Table 1. Main characteristics of the study population.

Characteristic	Mean/Median	Standard deviation	Range
Age (years)	29.1 / 26	4.9	25-38
Weight (kg)	73.1 / 74.5	11.7	54-92
Height (cm)	174.5 / 179	9.6	160-184
BMI (cm ² /kg)	23.4 / 23.1	2.8	19.8-27.5
Chest or bust girth (cm)	96 / 95.4	8.5	82-112

We successively recorded on each subject six 12-lead rest ECGs using a commercial digital electrocardiograph: a 1st standard ECG (S1), an ECG with the limb electrodes in the Mason-Likar position (ML), 3 ECGs by using our 3 sensor-system templates (S, M, L) for the recording of leads I, II and V2, and an additional standard ECG (S2). Sampling rate was 500 samples per second with an amplitude resolution of $5.0~\mu V$.

The same recording set of six ECGs was recorded again two months later and then three weeks later for three of the female subjects in order to assess the results reproducibility.

2.3. Data analysis method

All ECG records were processed by the Lyon program for waves' typification, delineation and standard ECG analysis [7]. Synthesised 12-lead ECGs were then computed from the 3-lead subset (I, II, V2) of the 12-lead ECGs recorded according to the S, M, L sensor-systems electrode positions, by means of a patient-specific transformation matrix [8], for the subject-by-subject comparative assessment of the 3 recording modalities. Two synthesis methods were considered: artificial neural nets (ANN) and linear regression, by setting-up, for each one, two different strategies for the transformation matrix computation. The first strategy, which yielded in the computation of two patient specific transformation matrixes called M_a (one for the ANN and one for the regression based methods) was derived by using only the standard ECG S1, and designed to reconstruct S1's leads V1 and V3 to V6 from its 3 leads: I, II and V2. The second type of matrixes, called M_b, was computed by taking leads I, II and V2 of the ML-ECG as input of the transformation model and was designed to best reconstruct the 7 standard leads: I, II, V1 and V3 to V6 of S1. All the synthesised 12-lead ECGs were also analysed by the Lyon program.

Three types of ECG comparisons were then performed between the typical beats of the original and synthesised ECGs: (C1) by applying M_a to the S, M and L ECGs, and by comparing the newly reconstructed ECGs to the ML-ECG; (C2) by applying M_b to the S, M and L ECGs and by comparing the 7 reconstructed leads to the

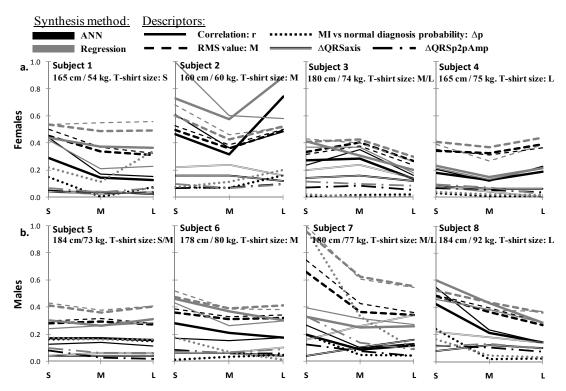


Figure 2. Example of normalised comparison results between a standard and 3 simplified ECGs for 8 healthy volunteers: 4 women (fig. 2a.) and 4 men (fig. 2b.). Total correlation and RMS values for all leads are represented by thick lines, while the median values are represented by thin lines.

homologous leads of S1; and (C3) identical to C2, but by taking S2 instead of S1 for the comparison. Three different descriptors' types were then selected for comparing original and synthesised ECGs: cross-signal measurements (correlation (r) and RMS values (M)), standard ECG measurements differences (QRS axis and QRS peak-to-peak amplitude (K)), and the ECG-based values of the output of an ANN committee measuring the probability of the risk of MI (p) [9].

Seven final descriptors were thus computed for the whole leads: $\sum_{\{leads\}} (1-r)$, $\sum_{\{leads\}} M$, 1-Median(r),

Median(M), $\Delta QRSaxis$, $\Delta Median(K)$, and Δp , and $\{leads\}$

their values were normalised between 0 and 1, in order to facilitate the results comparison. Paired t-tests were also performed among 3 types of ECG comparisons C1 to C3.

3. Results

Figure 2 illustrates the results of the C3 type comparisons for 8 subjects. The values of our seven defined descriptors are represented for each modality: S, M and L. The best results are obtained when the differential descriptors' values between the synthesised ECG and the reference ECG (S2 in C3 case) are close to zero. Results observation shows that there is no clear

tendency of a greater inter-signals difference when the larger modality (further from the heart) is used. There is no linear values progression according to the modalities shift per sizes. We also notice that descriptors' values are specific to each subject and form a subject specific descriptors' profile. Globally, we see that the ANN method seems to reconstruct ECGs better than the regression method, as it has been already reported in the literature [8]. By looking only to ANN values for some subjects we could define the most suitable modality. This could be L for the 1st subject, M for the 2nd and for example L for the 8th subject, though subject profiles show a great variability and the final decision needs to be based on a confirmed decision-making strategy.

Table 2 displays results of differences expressed by the p value of paired t-tests between the comparisons' types: C3 versus C1 and C2. Results show a high data heterogeneity for most of the subjects. Summarizing the whole we can indicate that C2 and C1 are quite similar, while C3 is rather different.

The results heterogeneity is also confirmed by the repeatability experiment. Indeed, paired t-tests of the descriptors values at about 2 and 3 months interval show significant differences (p<0.05) of the results within each ECG comparisons' type Ci, i=1,2,3, for at least one and at most two subjects, but not specifically to one subject or to one comparisons' type.

Table 2. Paired t-tests results

Subject	Gender	C3 vs C1	C3 vs C2	C1 vs C2
1	Female	0.7116	0.6467	0.8730
2	Female	0.115×10^{-4}	0.0003	0.0151
3	Female	0.0256	0.0054	0.2311
4	Female	0.444×10^{-5}	0.0031	0.5329
5	Male	0.0002	0.6016	0.0001
6	Male	0.0042	0.0022	0.0830
7	Male	0.3669	0.0328	0.8776
8	Male	0.829×10^{-7}	0.5458	0.272×10^{-6}

4. Discussion and conclusion

A total of 280 ECG comparisons were performed on the basis of 20 comparisons per subject (6 « involving 2 synthesis methods for the 3 S, M, L modalities » for each of the 3 types C1, C2 and C3, plus the S1 vs. S2 and S1 vs. ML ECG comparisons) and for a total of 14 "subjects" (8 subjects during the 1st experiment, and 3 subjects recorded twice for the repeatability study). The small number of subjects limited our study, although it already clearly shows the complexity and the variety of the results. The most important outcome of our study is that, as Figure 2 demonstrates, the sensor-system size does not correspond to the person clothes size. Also, with respect to our results, we can see that one size for everyone can introduce important signal distortions and that a subject specific sensor-system personal to each citizen shall be used to provide high diagnostic quality signals. We firmly believe that the personal adjustment can be and should be performed automatically on the basis of the ECG signal information and not of the chest/clothes size of the individuals. We highlight the importance of using different signals' recordings, synthesis methods. transformation strategies and descriptors typologies for the personal modality selection. As a matter of fact, this approach produces a lot of data and thus makes more complex their processing. Though here, we suggest to appeal to the Central Limit Theorem, which supports the plan of having more data in order to approach the truth. Then, the more methods on the more signals are used and the more descriptors are evaluated, the more precise selection can be performed. The integration of various services which perform the needed computations could be one of the possible solutions for mastering the complexity. This integration could be based on a dynamic and services oriented architecture, which adapts to the context of each specific user. This approach still requires research in the domain of context-adaptive business processes.

In conclusion, we have proposed a three sizes sensorsystem that can be used in self-care and that was evaluated on 8 healthy volunteers. The results obtained so far confirm that there is a need to carefully select the "best" sensor-system modality for each subject in order to ensure the diagnostic quality of his vital signs recording. The results show that the evaluation process shall be automated by involving a large typology of ECG signal descriptors.

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