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RESEARCH ARTICLE

Wearable and chest size-adjusted 12-lead electrode array system to record electrocardiogram: A novel design

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ABSTRACT

Background: Cardiovascular diseases are the leading cause of morbidity and mortality worldwide. Majority of human loss caused due to cardiovascular issues can be saved if diagnosed early and treated appropriately. Electrocardiogram (ECG) is the basic screening tool for cardiac ailments. Cumbersome technique, inconvenience to the patients and lack of trained workforce to obtain record, makes ECG a challenge, especially at peripheral rural health centers. Making ECG recording simpler, available, and recordable by even untrained persons can help cardiac patients get timely screened for needful treatment. **Aims and Objectives:** This study aims to design a wearable, 12-lead, electrode array system for ECG recording. **Materials and Methods:** Data of 250 adult men in the age group of 30–70 years were collected. We measured chest circumference and distance of points on chest wall from the midline (anterior chest wall), where chest lead electrodes need to be placed for ECG recording and correlated this value with the height, age, weight, and body mass index (BMI) of the subjects. **Results:** The mean distances (±standard deviation) of the chest lead electrodes from the midline (cm) were 2.8 ± 0.39 (right to the midline), 2.8 ± 0.39, 6.09 ± 0.59, 11.81 ± 1.43, 20.43 ± 2.38, and 25.10 ± 2.10 for V_1, V_2, V_3, V_4, V_5, and V_6, respectively. This distance was significantly correlating with subject's weight and BMI. **Conclusion:** BMI and body weight of the individuals, irrespective of their age, can be considered to design different size wearable electrode array system. A prototype of the chest size-adjusted electrode array system to record ECG is developed.

KEY WORDS: Electrocardiogram; Wearable; Electrodes; Health Monitoring Systems

INTRODUCTION

Cardiovascular diseases and disorders are the leading cause of human loss worldwide, accounting for 17.9 million of total 57 million deaths.[1] There has been unprecedented rise in cardiac diseases and disorders all over the globe among all races, ethnic groups, and cultures in the past few decades.[2] Rapid changing lifestyle such as reduced sleep time, night shift working, and extensive consumption of pre-packaged food along with behavioral changes such as physical inactivity, competitive behavior, smoking, and alcohol consumption has led to increased levels of stress in humans, all of these have been associated with increased risk of cardiac diseases. Among the cardiac diseases and disorders, myocardial infarction (MI) and arrhythmias are the leading causes of sudden deaths.[2] MI, rhythm disorders, and many more fatal and non-fatal cardiac ailments can be diagnosed by electrocardiogram (ECG). ECG is used as the basic screening tool for the assessment of cardiac ailments.

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There is a gradual increase in life expectancy all over the world as a result of improved general awareness, better public health facilities, and health-care technology. Increased life expectancy with declining birth rates is expected shift demographic profile to a large aging population that would impose significant burdens on the socioeconomic structure of the countries.[3] Cardiovascular ailments are common in this age group. Therefore, the development of cost-effective, easy-to-use systems is essential for the sake of health care and well-being of these patients.

However, the cumbersome technique, inconvenience caused to the patients and lack of trained workforce to obtain record, makes ECG a challenge, especially at peripheral rural health centers. Making ECG technique simpler, accessible, and recordable by even untrained persons can be helpful in prompt screening and proper referral of the needful patients from peripheral rural centers to higher centers equipped with intensive cardiac care facilities.

MATERIALS AND METHODS

The study was approved by the Institute Ethics Committee (No. Dean/2019/EC/1679). Data of 250 adult men in the age group of 30–70 years were collected over the period of 4 months from April 2019 to July 2019. We measured chest circumference and the distance of points on chest wall where various chest lead electrodes need to be placed for ECG recording from the anterior chest midline and correlated this value with the measured height, age, weight, and body mass index (BMI) of the subjects. Electrode array/belt was made using belt material used in army uniforms and the shoulder straps were made by another thinner and narrow belt also used in army combat dress. Appropriate arrangements were made onto the belt to adjust the length of the shoulder straps and at the end of these shoulder straps, karabiner kind of harness was placed which connects with the hooks placed onto chest straps on its posterior aspect. ECG snap lead wires were procured separately. These ECG leads were sewed onto the belt by hand with their electrode buttons placed according to the mean distances (±standard deviation) of the chest lead electrodes, from the anterior chest midline, as calculated for 250 subjects. The distances of chest lead electrodes from midline were 2.8 ± 0.39 cm (right to the midline), 2.8 ± 0.39 cm, 6.09 ± 0.59 cm, 11.81 ± 1.43 cm, 20.43 ± 2.38 cm, and 25.10 ± 2.10 cm for V_1, V_2, V_3, V_4, V_5, and V_6, respectively.

Table 1: Distribution (mean [SD]) of anthropometric and chest circumference, age, and BMI of the subjects recruited (*n*=250)

Parameters	Mean±SD
Age (years)	49.7±12.70
Height (cm)	158.29±6.88
Weight (kg)	61.20±12.34
BMI (kg/m^2)	24.38±4.46
Chest circumference (cm)	92.07±8.02

BMI: Body mass index, SD: Standard deviation

RESULTS

General and anthropometric parameters of the subjects are summarized in Table 1. Chest circumference and distance of all chest leads from anterior chest midline were significantly correlating with the subject's body weight and BMI as summarized in Table 2. Taller subjects had higher chest circumference, but subject's height was not correlating to distance of chest lead from anterior chest midline barring one (V_6). Age of the subject did not correlate to either chest circumference or distance of chest leads from midline.

Based on the above-mentioned results, we designed a wearable electrode array system/belt shown in Figures 1 and 2, capable of recording continuous 12-lead ECG in static as well as ambulatory subjects. Figure 1 (left) shows the schematic design of our electrode array system with chest lead electrodes distance (cm) from midline and photographs of

Table 2: Correlation of BMI, weight, height, and age with chest circumference and chest leads (V_2–V_6)

Variables	Chest circumference	V_2	V_3	V_4	V_5	V_6
BMI						
R value	0.700**	0.279**	0.337**	0.290**	0.205**	0.307**
P value	0.000	0.000	0.000	0.000	0.001	0.000
Weight						
R value	0.781**	0.286**	0.315**	0.233**	0.190**	0.347**
P value	0.000	0.000	0.000	0.000	0.003	0.000
Height						
R value	0.322**	0.091	0.016	−0.063	−0.009	0.142*
P value	0.000	0.153	0.802	0.324	0.883	0.025
Age						
R value	−0.093	−0.054	−0.100	−0.084	−0.016	−0.002
P value	0.144	0.395	0.114	0.186	0.800	0.975

BMI: Body mass index

Figure 1: Frontal view of the schematic design (left) and subject wearing actual device (center) and rear view (right); RA: Right arm, LA: Left arm, RL: Right leg, LL: Left leg

anterior and posterior views (center and right) of a subject wearing the prototype developed by us. Figure 2 shows the real photographs of the prototype device we developed, with its part labeled.

DISCUSSION

The idea to improvise ECG recording technique first struck us while performing exercise stress test. We faced many challenges such as wastage of precious time in repeated placement of electrode, intermittent loss of record due to separation/fall of electrodes from skin surface, introduction of artifacts in the ECG recordings due to improper adhesion and intermittent fall of electrodes, entanglement of long wires of ECG leads, inconvenience caused to the subject in running while handling lot of entangled wires, electrode removal and cleansing gel from skin after the test, undressing for the test, and cost of gel electrodes. To overcome these challenges, we came on with the idea to device a wearable electrode array/belt system. We tried and tested making many designs then zeroed onto the present one. The next challenge was to decide the location of electrodes on this wearable electrode belt. Positioning of limb lead electrodes was done as per Mason and Likar modification widely used in exercise protocols, i.e., infraclavicular region and iliac crest for upper and lower limbs, respectively.[4] For deciding the placement of chest lead electrodes on the belt, we first measured chest circumference and distance of points on chest where various chest leads need to be placed, from anterior chest midline, of 250 men in the age range of 30–70 years. The mean values of the distance of various chest electrodes from anterior chest midline as detailed earlier were used for the placement of chest lead (chest size adjusted). This mean distance was significantly correlating with the weight and BMI of the subjects but not with age and height, thus weight and BMI can be used to categorize individuals into different sizes to develop appropriate size belts.

On searching literature, we could find only a handful of studies related to the development of wearable ECG devices. Most of the groups working on wearable health devices have proposed only theoretical design of ECG acquisition and wired or wireless transmission of analog signal for digital conversion and visualization. Prototype devices based on similar design for acquiring and wireless transmission of ECG signal have been developed for only single-lead ECG recording.[5] The diagnostic accuracy of single-lead electrocardiograph on smartphone-based ECG recording to evaluate heart rate and rhythm in dogs also showed promising results.[6] Single-lead ECG records of wearable garment-based device, which could store ECG data, compared to standard 3-lead Holter recordings gave promising yet statistically insignificant signal quality and accuracy.[7] Increasing sampling frequency and better placement of electrodes could improve signal quality and accuracy with such devices and the same has been done in our design. Dry electrode-based wearable "smart shirt" for continuous 12-lead ECG monitoring and having single-chip wireless transmission system is also being developed.[8] Work of only two groups seems to have some similarities in conceptual designs[9] and ideas to ours.[10] Yet, our design is different and ergonomically more suitable than these. The design, size, shape, and type of electrodes play a crucial role in acquisition biopotentials like ECG. Some groups are working to design and develop better electrodes that can be the part of wearable clothing.[11] If available, these electrodes would be of great help to us for materializing our concept. We are working to develop low cost, wireless, portable, and easy-to-use 12-lead ECG recording systems. Teletransmission and teleconsultation of 28,557 ECG records

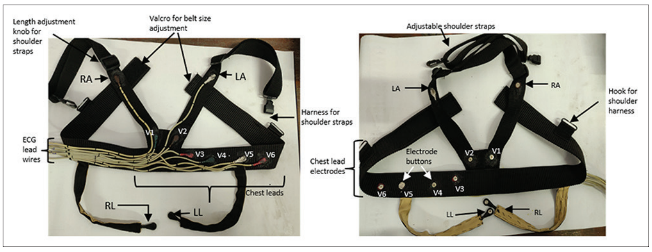

Figure 2: Outer (left) and inner (right) views of the electrocardiogram electrode array system with parts labeled

by basic medical rescue teams of emergency medical services in Poland reported it to be highly useful in making decisions on transporting patients to appropriate health-care centers.[12] Thus, such device could be of great help in timely screening and referral of needy patients to higher centers for appropriate treatment.

No study has reported the development of a chest size-adjusted electrode array system to record ECG. Our design is unique as it is chest size adjusted, the limb lead placement is different, allows length adjustment for chest circumference as well as for limb strips for different heights. Thus, the design seems to be more ergonomic and patient friendly. We shall further modify our design with lightweight, stretchable, comfortable to wear fabric with inclusion of dry electrodes to do away with the need of cost ineffective sticky gel electrodes. In Indian health system, especially in rural health centers, we do not have trained workforce to record and interpret techniques like ECG. Our design has the potential to be developed into device that can make a relatively complex cardiac investigation as a simple, home-based recording such as blood pressure and sugar monitoring. This can help the patient sought timely medical care which may prevent morbidity and mortality related to delayed diagnosis. We further intend to make it more patient friendly, easy to use, artificial intelligence based and mobile phone compatible, capable of diagnosing rate, and rhythm disorders to share the same over mobile data network for specialist opinion. With more extensive data from both the genders, we wish to develop different size electrode array systems for both middle age groups.

CONCLUSION

A chest size-adjusted, wearable 12-lead ECG electrode belt is developed which can be improvised into a wireless, home-based, and easy-to-use ECG recording device with different size options.

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