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Comparison of Lab based Device and Cuff-less based Device for Efficient Heart Rate Monitoring in Normal Individuals and Heart Diseased Individuals for Extended Duration

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Abstract

Aim: *This study was performed to validate and compare our designed cuff less device with standard heart rate monitors used in Hospitals.* ***Materials and Methods:*** *The Heart patient data were collected in Government PHC (Primary Healthcare Center), Navalpakkam hospital and the normal individual data were collected in Saveetha School of Engineering (SSE), Saveetha University (CLAB 404/425).* ***Results:*** *The means of the BPM also was found to be very similar with a minor deviation in heart rate of heart patients monitored by our cuff less device. The high insignificance assures that our device has given reading at par with commercial monitors used in the market* ***Conclusion:*** *Within the limits of our study our cuff-less device is as efficient as a vital sign monitor (lab based device) used in hospitals or Laboratories (one way ANOVA, P >0.05, insignificant).*

Key-words: Real Time, Beat Per Minute, Designed Cuff-less Device, Innovative Heart Rate Monitoring Approach, Wearable Technology.

1. Introduction

The need to monitor body parameters and vital signs have always been of great importance in the field of medicine and it's allied sciences. This study was performed to validate and compare our designed cuff less device with standard heart rate monitors used in Hospitals. Our attempt was to find an economical alternative for heart rate monitoring (Tsikriteas et al., 2021). It is important in today's world, to understand the necessity for monitoring heart rate in heart patients. Monitoring heart rate as a (Klingeberg & Schilling, 2012) vital sign parameter every day will be a boon for many. In this current study, a convenient and reliable heart rate monitor for heart patients (Guo et al., 2021) and normal individuals was designed by us using very basic sensors available natively.

If we go through the articles related to our field of research published in the past 5 years we found around 100's of them in many reputed databases. These reports have mainly introduced novel blood pressure estimation systems at home via pulse transit time (Ganti et al., 2020) or smart sensors using subject - specific regression model proof of concept (Ibrahim & Jafari, 2019); (Ganti et al., 2020). Few have devised monitoring device among health care professionals using mixed method study (P=0.51) (Ganti et al., 2020); (Islam et al., 2019). Among all the literature that we went through, we found that novel cuff-less blood pressure monitoring, gives the best related to all studies associated with heart rate monitoring (Watanabe et al., 2017).

Previously our team has a rich experience in working on various research projects across multiple disciplines (Gheena & Ezhilarasan, 2019; Jose et al., 2020; Ke et al., 2019; Krishnaswamy et al., 2020; Malli Sureshbabu et al., 2019; Mehta et al., 2019; Muthukrishnan et al., 2020; M. S. Samuel et al., 2019; S. R. Samuel et al., 2020; Sathish & Karthick, 2020; Sharma et al., 2019; Varghese et al., 2019; Venu, Raju, et al., 2019; Venu, Subramani, et al., 2019; Vignesh et al., 2019; Vijayakumar Jain et al., 2019). Now the growing trend in this area motivated us to pursue this project.

An inspiration to make localized cuff-less heart rate monitoring devices is the lacunae in our existing research with BAN (Body Area Network) being the existing research experience. An efficient and convenient heart monitoring is the ultimate aim of this study (Ganti et al., 2020); (Islam et al., 2019).

2. Materials & Methods

The Heart patient data were collected in Government PHC (Primary Healthcare Center), Navalpakkam hospital and the normal individual data were collected in Saveetha School of Engineering (SSE), Saveetha University (CLAB 404/428). Planet 50- model 200 vital sign monitor (Larsen and Turbo limited) was used in SSE to collect data from normal subjects. The data were collected in the form of Group-1 as Lab based BPM (vital sign monitor) (Heydari et al., 2020) and Group-2 as Cuff less device based BPM (Watanabe et al., 2017) (Mohebbian et al., 2020) (Watanabe et al., 2017). Since we did not work with any human specimens or samples in this study. Based on the base paper which we had taken for the study, we took the sample size to be - 40 (Group 1- 20, Group 2- 20) and the pretest power was calculated using clinical.com ((Kakria et al., 2015). Statistical analysis was done using SPSS (Statistical Package for the Social Sciences) Software for sample size with power- 80% and Alpha- 0.05 (Kakria et al., 2015).

For Group -1, we used the APB0010 (lab based device) available in the Govt PHC hospital, Navalpakkam and vital sign monitor available in SSE (Saveetha school of engineering) (Tatum et al., 2016). For and Group-2, we used the designed Cuff-less device made up of Arduino pro mini 328 5v/16 mhz with flash memory- 32kb*, DRAM- 2kb*, EEPROM- 1kb, (BME 280 Sensor is used to monitor BPM). All these components were locally available and assembled as per our requirement. Real time monitoring of BPM (Beat per minute) between vital sign monitor and cuff-less device for normal individuals and heart patient was further segregated using BMI < 24 and for BMI >24 BMI (Body Mass Index) (El-Hajj & Kyriacou, 2021; Mohebbian et al., 2020). Lab based data using vital sign monitors for 20 normal individuals and 20 heart patients, were separated based on body mass index (normal and overweight individuals). For Cuff-less Device also the data was collected in the similar fashion as mentioned above (Ibrahim & Jafari, 2019). Each subject was monitored every hour for 7 hours for a week. The average BPM was taken as data for each group. 7 hours was optimized as study time to coincide with working hours of SSE for normal subject data collection.

Statistical Analysis

Hence a total of 4 groups based on heart's condition and device of detection were used for statistical analysis in SPSS 21. The dependent variables were BMI and Heart condition and the standard deviation of vital sign monitor and cuff-less device data were also analysed.

3. Results

From Table 1 we observe the BPM (Beats per minute) generated using Lab Based Device for normal (10) and heart patients (10). The BPM range for normal patients was found to be on an average of 69.5 - 80.1 whereas for heart patients, it was from 66.8-83.2.

Table 1 - Represent the Comparison of the BPM (Beats per minute) using the vital sign monitor (Lab Based Device) for normal (10) and heart patients (10)

NO	BMI	BPM (BEAT PER MINUTE)	Day 1 (BPM)	Day 2 (BPM)	Day 3 (BPM)	Day 4 (BPM)	Day 5 (BPM)	Day 6 (BPM)	Day 7 (BPM)	Average (BPM)	STDEV
	NORMAL INDIVIDUALS										
1	19.5	70	74	76	73	88	78	78	87	79.1	6
2	19.9	74	82	80	81	83	78	73	72	78.4	4.3
3	20	68	64	72	70	69	79	68	71	70.4	4.5
4	20.9	76	87	76	70	84	75	83	60	76.4	9.3
5	21.7	82	85	78	72	74	88	76	73	78	6.1
6	25.5	72	73	74	75	84	87	85	80	79.7	5.7
7	25.9	78	72	75	72	70	83	68	88	75.4	7.3
8	26.5	74	65	68	67	73	78	64	72	69.5	4.9
9	26.5	78	64	70	68	75	78	66	80	71.5	6.1
10	26	76	74	78	85	75	85	80	84	80.1	4.6
	HEART PATIENTS										
1	22.5	84	65	76	75	79	74	70	73	73.1	4.5
2	22.9	72	64	76	63	66	76	73	74	70.2	5.7
3	23	70	68	82	62	68	75	73	66	70.5	6.6
4	23.4	86	64	70	75	84	75	73	83	74.8	7
5	23.6	63	63	68	66	67	62	76	66	66.8	4.6
6	27	82	84	70	80	74	78	74	72	76	4.8
7	27.6	84	78	81	80	84	88	85	87	83.2	3.7
8	27.8	84	87	74	81	77	73	86	84	80.2	5.7
9	28	86	79	71	78	79	80	74	82	77.5	3.7
10	28.5	88	76	77	87	80	84	74	85	80.4	4.9

From Table 2 we observe the BPM (Beats per minute) generated using designed cuffless Device for normal (10) and heart patients (10). The BPM range for normal patients was found to be on an average of 69.5 - 80.1 whereas for heart patients, it was from 66.8-83.2.

Table 2 - Represent the Comparison of the BPM (Beats per minute) using designed Cuff-less device for normal (10) and heart patients (10)

NO.	BMI	BPM (BEAT PER MINUTE)	Day 1 (BPM)	Day 2 (BPM)	Day 3 (BPM)	Day 4 (BPM)	Day 5 (BPM)	Day 6 (BPM)	Day 7 (BPM)	Average (BPM)	STDDEV
	NORMAL INDIVIDUALS										
1	19.5	70	74	76	73	88	78	78	87	79.1	6
2	19.9	74	82	80	81	83	78	73	72	78.4	4.3
3	20	68	64	72	70	69	79	68	71	70.4	4.5
4	20.9	76	87	76	70	84	75	83	60	76.4	9.3
5	21.7	82	85	78	72	74	88	76	73	78	6.1
6	25.5	72	73	74	75	84	87	85	80	79.7	5.7
7	25.9	78	72	75	72	70	83	68	88	75.4	7.3
8	26.5	74	65	68	67	73	78	64	72	69.5	4.9
9	26.5	78	64	70	68	75	78	66	80	71.5	6.1
10	26	76	74	78	85	75	85	80	84	80.1	4.6
	HEART PATIENTS										
1	22.5	84	65	76	75	79	74	70	73	73.1	4.5
2	22.9	72	64	76	63	66	76	73	74	70.2	5.7
3	23	70	68	82	62	68	75	73	66	70.5	6.6
4	23.4	86	64	70	75	84	75	73	83	74.8	7
5	23.6	63	63	68	66	67	62	76	66	66.8	4.6
6	27	82	84	70	80	74	78	74	72	76	4.8
7	27.6	84	78	81	80	84	88	85	87	83.2	3.7
8	27.8	84	87	74	81	77	73	86	84	80.2	5.7
9	28	86	79	71	78	79	80	74	82	77.5	3.7
10	28.5	88	76	77	87	80	84	74	85	80.4	4.9

Table 3a depicts the statistical data between the BPM recorded from lab based vital sign monitor and cuffless device. There was a statistically insignificant difference between each group (0.99), as shown in Table 3b. The means of the BPM also was found to be very similar (75.65) among the 4 groups, with a minor deviation in the heart rate of patients monitored by our cuff less device (5.2). This is depicted in Table 3a. The other 3 groups had a standard deviation of nearly 4.

Table 3a - Depicts the descriptive statistical data between the BPM recorded from lab based vital sign monitor and cuffless device. The means of the BPM also was found to be very similar with a minor deviation in heart rate of heart patients monitored by our cuff less device

BPM					95% Confidence Interval for Mean			
	N	**Mean**	**Std. Deviation**	**Std. Error**	**Lower Bound**	**Upper Bound**	**Minimum**	**Maximum**
lab based normal	10	75.80	4.13	1.306	72.8440	78.7560	69.50	81.60
cuff less based normal	10	75.85	4.00	1.265	72.9883	78.7117	69.50	80.10
lab based heart patient	10	75.69	4.82	1.527	72.2356	79.1444	68.50	83.40
cuff less based heart patient	10	75.27	5.20	1.647	71.5442	78.9958	66.80	83.20
Total	40	75.65	4.39	0.695	74.2465	77.0585	66.80	83.40

Table 3b - Depicts the ANOVA results between the BPM recorded from lab based vital sign monitor and cuffless device. There was a statistically insignificant difference between each group

BPM	**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	2.085	3	0.695	0.033	0.992
Within Groups	751.715	36	20.881		
Total	753.800	39			

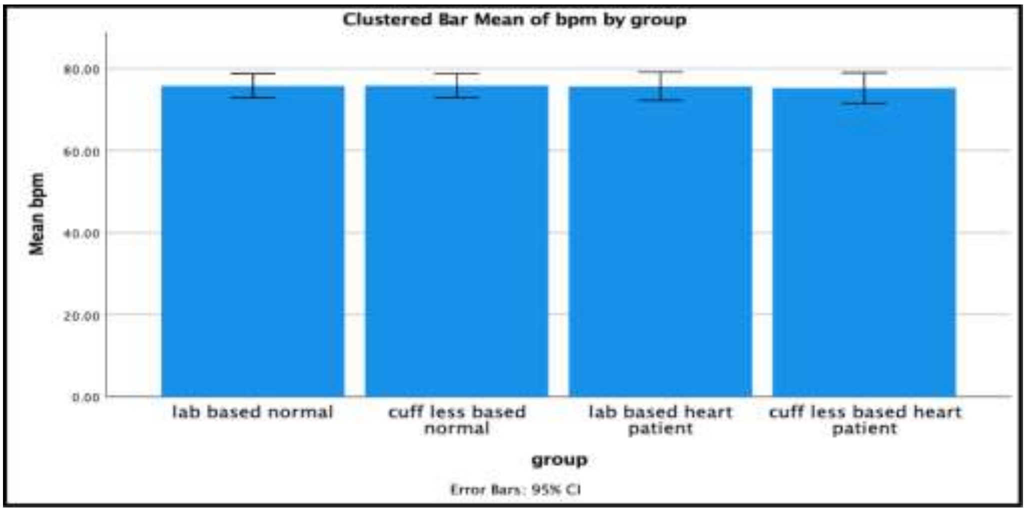
Table 4 represents ANOVA - Post hoc bonferroni pairwise comparison of BPM (Beat Per Minute) using Vital Signs Monitor (Lab Based Device) and Designed Cuff Less Device in Normal individuals and Heart Patients. They were 4 groups Group(a)- Lab based Normal individual, Group(b)- Cuff-less Based Normal individual, Group(c)- Lab based heart Patient and Group(d)- Cuff-less Based heart patient. The data was tabulated for 7 hours a day for a week. Average BPM of the week was taken for SPSS analysis. P value was 1 for all the 4 groups. Hence they were found to be statistically insignificant ($p > 0.05$ One way ANOVA with post hoc Bonferroni Pairwise comparison). Lab based BPM from patients and normal subjects had a mean difference of 0.11, whereas a similar pattern was also seen in cuffless monitored BPM with a mean difference of 0.58.

Table 4 - Represent ANOVA - Post hoc bonferroni pairwise comparison of BPM (Beat Per Minute) using Vital Signs Monitor (Lab Based Device) and Designed Cuff Less Device in Normal individuals and Heart Patients ($p > 0.05$ One way ANOVA + post hoc Bonferroni Pairwise comparison)

BPM Bonferroni					**95% Confidence Interval**	
(I) group	**(J) group**	**Mean Difference (I-J)**	**Std. Error**	**Sig.**	**Lower Bound**	**Upper Bound**
lab based normal	cuff less based normal	-0.05000	2.04357	1.00	-5.7556	5.6556
	lab based heart patient	0.11000	2.04357	1.00	-5.5956	5.8156
	cuff less based heart patient	0.53000	2.04357	1.00	-5.1756	6.2356
cuff less based normal	lab based normal	0.05000	2.04357	1.00	-5.6556	5.7556
	lab based heart patient	0.16000	2.04357	1.00	-5.5456	5.8656
	cuff less based heart patient	0.58000	2.04357	1.00	-5.1256	6.2856
lab based heart patient	lab based normal	-0.11000	2.04357	1.00	-5.8156	5.5956
	cuff less based normal	-0.16000	2.04357	1.00	-5.8656	5.5456
	cuff less based heart patient	0.42000	2.04357	1.00	-5.2856	6.1256
cuff less based heart patient	lab based normal	-0.53000	2.04357	1.00	-6.2356	5.1756
	cuff less based normal	-0.58000	2.04357	1.00	-6.2856	5.1256
	lab based heart patient	-0.42000	2.04357	1.00	-6.1256	5.2856

Figure 1 represents BPM (Beat per minute) using a vital sign monitor (lab based device) and designed cuff-less device in normal individuals and heart patients. It is depicted in the form of a bar chart. The mean (+- 1 SD) showed no significant difference between the four groups. The $p > 0.05$ calculated by independent T Test. The standard deviation in the heart rate of patients monitored by our cuff less device (5.2) was found to be little higher than the other 3 groups.

Fig. 1 - BPM (Beat per minute) using vital sign monitor (lab based device) and designed cuff-less device in normal individuals and heart patients. Bar chart comparing the mean (+- 1 SD) showed no significant difference between the Four groups. $p > 0.05$ (Independent Samples T Test). X Axis: Lab based normal BPM, Cuffless based normal BPM, Lab based heart patient BPM, Cuffless based heart patient BPM. Y Axis: Mean BPM +/- 1 SD



4. Discussion

The high insignificance in our data set assures that our device has given reading at par with commercial monitors used in the market. One way ANOVA was found to be insignificant (0.0992) for our sample Size-40. Previously in 2015, Kakira and her team reported an advanced wireless and wearable sensor for real time heart monitoring system of cardiac patients at considerable cost (Kakria et al., 2015)**.** Similarly in 2019, Ibrahim reported that he predicted the future of cardiovascular disease based on heart rate. They presented a new cuffless BP Method using an array of wrist-worn bioimpedance sensors (correlation coefficient - 0.77) (Ibrahim & Jafari, 2019). In 2019, Islam and his team reported the Blood pressure (BP) using wearable cuff less devices enable the capture of multiple BP measures during every activities. It was a wrist born device with a deviation of 5.4. (Islam et al., 2019); (Ganti et al., 2020). A team of scientists in 2020 reported a wearable watch based cuff less blood pressure monitor (BP) with a correlation coefficient (PCC) of 0.69 (Ganti et al., 2020). Wrist based heart rate monitoring using photoplethysmogram (PPG) showed degraded signals due to high activity in the sport individuals in the form of noise (Gillinov et al., 2017); (Koshy et al., 2018). Even data collected in post operative patients showed efficiency only at rest (Harju et al., 2018). That when in 2019, Ahmed and team reported 'beat to beat' monitoring by wrist based device was most effective in the general population (Al-Kaisey et al., 2020); (Heydari et al., 2020).

Due to the wearable and convenient nature of cuffless devices, literature states monitoring through these devices to be very effective, thus we were unable to cite any negative articles on the same (Hu et al., 2016); (El-Hajj & Kyriacou, 2020)). Finally, we would like to infer that efficient working of a cuff-less monitoring system is possible in normal subjects in their daily routine when BPM is used as a parameter. Fig.1 justifies this inference of our study. But an exclusive comparative study like ours to validate the prototype with lab devices based on heart conditions and BPM for such a sample size is first of its kind. BMI didn't show any difference in BPM for the two groups. Hence this parameter was neglected while tabulating. The performance validation of BME280 as a sensor for monitoring heart rate in real time among both healthy and heart patients is the innovative approach we opted in the current study. Thus, showing potential for further upgradation of the prototype to enhance its efficacy towards BPM monitoring.

Our institution is passionate about high quality evidence based research and has excelled in various fields ((Ezhilarasan et al., 2019; Mathew et al., 2020; Pc et al., 2018; Ramadurai et al., 2019; Ramesh et al., 2018; Sridharan et al., 2019; Vijayashree Priyadharsini, 2019). We hope this study adds to this rich legacy.

The Limitation of a study was time constraints and the influence of one's health condition towards the final data set. Although all the data sets seemed to be similar, but, our device has a larger standard deviation for heart patients when compared to other groups.

Monitoring heart rate as a vital parameter everyday using our upgraded wearable device is our ultimate aim. Regime based study on the same device is also under scrutiny in our laboratory. It would be a good example for a ‘make in India initiative’, to have a native vital sign cuff less device for BPM Monitoring.

5. Conclusion

Within the limits of our study our cuff-less device is as efficient as a vital sign monitor (lab based device) used in hospitals or Laboratories (one way ANOVA, $P > 0.05$, insignificant). Our device showed good potential for improvement as the standard deviation was found to be more when compared to other 3 groups under study.

Declarations

Conflict of interests

No conflict of interest in this manuscript.

Authors Contributions

Author SS was involved in data collection, data analysis and manuscript writing, Author ND was involved in conceptualization, data validation and critical review of manuscript.

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