BIOMEDICAL ENGINEERING RECENT DEVELOPMENTS

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HEART RATE VARIABILITY SIGNAL PARAMETERS QUANTIFY SKIN COOLING EFFECT OF ENERGY PATCHES DURING REST AND EXERCISE IN YOUNG HEALTHY INDIVIDUALS

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ABSTRACT

Heart rate variability (HRV) signal analysis provides a non-invasive and sensitive marker of autonomic nervous system (ANS) activity. Spectral parameters of HRV signal are used to quantify the balance between sympathetic and parasympathetic (sympathovagal) influences under various physiologic conditions. ECG signals were acquired, filtered and further processed to derive the HRV signal. The low frequency (LF), high frequency (HF), and their ratio LF/HF were calculated to assess the parasympathetic dominance or the skin cooling effect of a set of non-transdermal Energy Patches on young healthy individuals during Rest and immediately after mild Exercise. HRV data acquired from 20 young healthy volunteers (10 males and 10 females, 19-25 years of age), in a double-blind placebo-controlled study, were used to evaluate the skin cooling effect of these wearable devices on the ANS during rest and immediately after mild exercise while wearing active (A) and placebo (P) patches. Data from condition (A) and condition (P) were compared using statistical analysis (one-sample inference). The LF/HF decreased significantly both during rest and immediately after mild exercise in condition (A) compared to condition (P) with □or $p < 0.01$ with a statistical power of at least 85%. This study shows that the normalized LF/HF derived from spectral analysis of HRV signals could be used to quantify the parasympathetic dominance or the localized skin cooling effect of non-transdermal energy patches during rest and immediately after mild exercise in young healthy individuals.

Keywords*:* *Heart rate variability signal analysis, Localized skin cooling effects, Non-transdermal energy patches, Autonomic nervous activity, Wearable devices*

INTRODUCTION

The autonomic nervous system (ANS) is structurally and functionally subdivided into two antagonistic divisions: sympathetic and parasympathetic. The sympathetic division responds to fight-or-flight situations, increasing heart rate (HR) and blood pressure (BP), among others, under stressful conditions. The parasympathetic division is responsible for relaxation and energy conservation (i.e., decreasing HR and BP). The heart as well as other organs, receives opposing influences from these two arms of the ANS. This dual innervation underpins a fine and continuous regulatory system and simply means an increase in the activity of one division results in a smooth and reciprocal decrease in the activity of the other. The dynamic interplay between the two divisions increases or decreases the HR depending on the predominance of one over the other.

Heart Rate Variability (HRV) signal refers to beat-to-beat variation of heart rate and represents the cyclical changes in HR. As HR is modulated by both parasympathetic and sympathetic inputs, HRV can be utilized as an indirect and non-invasive marker of autonomic regulation and control under different physiological conditions [1]. High HRV reflects an ANS that is adaptable and dynamically responsive to change whereas reduced HRV is indicative of an abnormal or restricted ability of the ANS in maintaining homeostasis [2, 3]. Pharmacological studies and spectral analysis of the HRV signal have revealed two clear peaks in its power spectrum: a high frequency (HF) and a low frequency (LF) component. The HF peak which is typically centered around 0.25 Hz (0.15 – 0.4 Hz) arises standard deviation of ± 49% of the mean. With these values a statistical power of at least 85% at a significance level α or $p < 0.01$ was achieved. This level of significance reflects a *very significant* effect. As a value of α or p = 0.05 is considered *statistically significant*, the results in these subjects reflect a *statistically significant effect* with a power of 90%.

TABLE 1. Typical normalized power spectral parameters derived from 5-minute HRV signals acquired from ECGs of a healthy male volunteer under 6 different conditions [16]

Condition	LF n.u.	HF n.u.	LF/HF n.u.
Rest with *no* Patches	97.70	2.28	*42.75*
Rest with *Placebo* Patches	97.62	2.31	*42.23*
Rest with *Energy* Patches	96.95	3.01	*32.29*
Exercise with *no* Patches	97.42	2.56	*38.03*
Exercise with *Placebo* Patches	97.97	2.03	*48.36*
Exercise with *Energy* Patches	94.72	5.23	*18.10*

TABLE 2. Typical normalized power spectral parameters derived from 5-minute HRV signals acquired from ECGs of a healthy female volunteer under 6 different conditions [16].

Condition	LF n.u.	HF n.u.	*LF/HF n.u.*
Rest with *no* Patches	99.15	0.83	*119.25*
Rest with *Placebo* Patches	97.33	2.58	*37.61*
Rest with *Energy* Patches	94.20	5.37	*17.54*
Exercise with *no* Patches	90.58	9.41	*9.62*
Exercise with *Placebo* Patches	96.40	3.54	*27.23*
Exercise with *Energy* Patches	95.32	4.62	*20.63*

DISCUSSION AND CONCLUSION

From the spectral parameters of typical datasets and the statistical analysis results for 20 subjects, the following observations could be made:

1. There was a noticeable difference between spectral parameters when the subjects wore the *Placebo* patches compared with when the subjects wore *no* patches. Such differences in spectral parameters are indicative of the *Placebo Effect*. This is an indication of how the subjects responded to the feeling of wearing a patch.
2. There was a *decrease* in the normalized *LF* when the subjects wore the *Energy* patches compared with the condition when the subjects wore the *Placebo* patches during both *Rest* and immediately after 5 minutes of mild *Exercise*.
3. There was an *increase* in the normalized *HF* when the subjects wore the *Energy* patches compared with the condition when the subjects wore the *Placebo* patches during both *Rest* and immediately after 5 minutes of mild *Exercise*.
4. There was a *statistically significant decrease* in the normalized *LF/HF* when the subjects wore the *Energy* patches compared with the condition when the subjects wore the *Placebo* patches during both *Rest* and immediately after 5 minutes of mild *Exercise*.
5. On average, *female* subjects were more responsive to *Energy* patches compared to male subjects during *Rest*. While, on average male subjects were more responsive to *Energy* patches compared to females after mild *Exercise*. These differences were not statistically significant.
6. On average, there was a higher *reduction* in *normalized LF/HF* after 5 minutes of mild *Exercise* compared to the *reduction* in *normalized LF/HF* during *Rest*.

Based on these observations it could be concluded that both during *Rest* and immediately after 5 minutes of mild *Exercise*, the *Energy* patches elicited an enhanced *parasympathetic response* (due to a localized skin cooling effect) which could be *quantified* by a reduction in *normalized LF/HF*. A further reduction of *normalized LF/HF* immediately after 5 minutes of mild *Exercise* (as a consequence of more body heat production) compared to *Rest* may be indicative of the higher activation level of the *Energy* patches in response to enhanced physical activity resulting in an increased localized skin cooling effect during *Exercise*. The statistical results revealed that the *Energy* patches showed a *very significant* effect ($p < 0.01$) compared to *Placebo* patches in reducing the *normalized LF/HF* during *Rest* and even further after 5 minutes of mild *Exercise* with a statistical power of at least 85% in this sub-population.

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