Objective Evidence for the Effectiveness of Single-session Treatment with a Spinal Thermal Massage Device: A Pilot Study

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척추온열마사지기기의 1회 치료의 효과에 대한 객관적 증거: 선행 연구

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Abstract Individuals often report significant relief from pain and stress even after a single session of massage therapy; however, no previous studies have provided objective evidence supporting the effectiveness of a solitary massage therapy session. In the present study, we aimed to investigate the effectiveness of one-time treatment with a spinal thermal massage device reported to exert the same therapeutic effects as massage therapy in terms of pain reduction and stress relief. A man with chronic low back pain (LBP) underwent two rounds of experiments involving spinal massage treatment and bed rest, respectively. Pain was assessed using a visual analog scale, and heart rate variability (HRV) was measured in real-time to examine autonomic nervous system (ANS) activity. Blood samples were obtained at five points during each round of the experiment to examine changes in cortisol, epinephrine, and norepinephrine. Spinal massage significantly reduced pain and enhanced parasympathetic activity when compared with the bed rest condition. In addition, both epinephrine and norepinephrine levels were lower following spinal massage therapy and support the effectiveness of one-time treatment using a spinal thermal massage device.

Key Words : Spinal massage, Massage therapy, Low back pain, Musculoskeletal rehabilitation, Pain

요 약 마사지 치료는 1회 치료만으로 통증을 경감시키고 스트레스를 이완시킵니다. 그러나 아직까지 1회 마사지 치료의 효과에 대한 객관적인 데이터를 확인한 연구가 없었습니다. 그래서 본 연구에서는 마사지 치료와 동일한 효과가 있는 것으로 보고된 척추 마사지 기구로 1회 치료를 실시하여 통증 경감과 스트레스 이완의 효과의 증거를 확인하고자 하였습니다. 10년 전부터 시각적상사척도 4점의 요통이 있었던 45세 남자 환자 1인을 대상으로 척추 마사지 기구를 실시한 1차 실험과 침상안 정을 실시한 2차 실험을 실시하였습니다. 시각적상사척도 측정과 실시간으로 심박 변이도를 측정하여 자율신경계를 확인하 였고 총 5회 혈액검사를 실시하여 스트레스 관련 혈액검사(코르티솔, 에피네프린, 노르에피네프린)를 실시하였습니다. 침상 안정을 취한 2차 실험에 비해 척추 마사지 기구로 1회 치료를 받은 1차 실험에서 유의미한 통증 감소효과를 보였습니다. 또 한 1차 실험에서 자율신경계 활성도 및 부교감 신경계의 활성도가 증가되어 있었으며 혈중 에피네프린과 노르에피네프린이 감소되어 있었습니다. 이것은 기존의 마사지 치료 효과와 동일한 결과이며 1회 척추 마사지 기구를 통해 얻어지는 효과의 증 거라 사료됩니다.

키워드 : 척추 마사지 기구, 마사지 치료, 요통, 통증, 근골격계 재활

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1. Introduction

In Korea, traditional massage is occasionally used for pain management, with many patients reporting substantial relief associated with the compression and relaxation of the muscles, as well as feelings of comfort. Indeed, several studies have documented the effectiveness of massage for alleviating pain and relieving stress [1, 2]. Although the exact mechanism underlying this phenomenon remains unclear, several studies have suggested that massage mitigates pain by promoting physiological balance via the regulation of sympathetic and parasympathetic activity [3].

Home massage devices, such as the CERAGEM V6 spinal thermal massage device, have been developed to reproduce the effects of massage therapy without the need for outpatient appointments. Patients receiving treatment with such devices often report pain relief and increased comfort, and research has demonstrated that the effects of treatment with a spinal thermal massage device are identical to those of traditional massage therapy [4]. Notably, Lee et al. reported that patients who underwent 2 weeks of heat and massage treatment with a spinal thermal massage device exhibited decreased sympathetic activity, increased parasympathetic activity, and reduced plasma cortisol and norepinephrine levels [5]. And also, Kim et al. reported spinal column thermal massage reduces pain more effectively and improves self-reported levels of disability [6]. In this study, heat treatment was not applied to evaluate effect of massage therapy alone. These results suggest spinal thermal massage devices also relieve pain via autonomic regulation, similar to traditional massage therapy.

Previous studies comparing the effects of massage therapy and treatment with a spinal thermal massage device examined changes in parameters after at least 10 sessions in control and experimental groups that included different participants. Such experimental conditions are highly dependent on external factors, which increase the risk of various biases in research related to the autonomic nervous system (ANS) given that features can vary substantially among individuals. Furthermore, although patients consistently report pain relief and increased comfort following single-session massage therapy performed traditionally or using a specialized device, studies providing objective data related to these effects remain lacking.

Therefore, in this pilot study, we aimed to evaluate changes in ANS activity in a single participant who underwent one treatment session using a spinal thermal massage device. To achieve this aim and present objective evidence regarding the therapeutic effects of one-time spinal thermal massage device treatment, we analyzed changes in stress-related blood parameters (cortisol, epinephrine, norepinephrine) from baseline to mid-treatment and post-treatment, as well as the relationship between ANS activity (based on heart rate variability) and subjective pain.

2. Materials and methods

2.1 Participant

Participant for the study were recruited from patients who had back pain but did not perform surgical treatment. A 45-year-old man with chronic low back pain (LBP) due to L5-S1 disc herniation diagnosed 10 years earlier was enrolled. His visual analog scale (VAS) score for LBP was 4, he reported no acute or radiating pain, and he was not taking any medications for pain. Although he had no history of surgery, he was taking medication to treat diabetes mellitus and hyperlipidemia, which had been diagnosed 1 year earlier. Baseline blood test results revealed no abnormalities, and L-spine x-ray and MRI revealed no acute lesions other than chronic spinal stenosis at L4-L5. The patient provided written informed consent to participate, and the study was approved by the Institutional Review Board at Jesus Hospital.

| Variable | | | | |
|--------------|--------------|--|--|--|
| Age | 45 | | | |
| Sex | Male | | | |
| Site of pain | Low back | | | |
| Onset | 10 years ago | | | |
| VAS | 4 | | | |

Table 1. Characteristic of the participant

2.2 Study design

The participant underwent two rounds of experiments in total 2 weeks, which were conducted in a quiet room at 4 PM on two consecutive Mondays. The 7-day interval was chosen to minimize any confounding effects, and factors potentially influencing the ANS such as cigarette smoking, alcohol use, stress, level of activity, and other medications were controlled to ensure that daily living conditions remained as identical as possible during the 2-week study period. To reproduce identical routine stress situations in the two rounds of experiments, the participant was asked to sit down and type given sentences at an average typing rate of 300 keystrokes per minute for 30 minutes, following which the first blood sample was obtained. Based on a random allocation, treatment with the spinal thermal massage device was performed for 36 minutes in Experiment 1. In Experiment 2, the participant rested for 36 minutes in a supine position on a non-working spinal thermal massage device. The second and third blood samples were obtained 50 and 66 minutes after the start of the experiment, respectively. After both rounds of experiments, the participant was asked to sit up and type given sentences for 30 minutes. The fourth and fifth blood samples were obtained 76 and 96 minutes into the experiment, respectively. HRV was continuously measured throughout the experiment.

HRV data were sampled from the continuously measured HRV data five times (i.e., 5 minutes before each blood sampling). Pain was assessed using the VAS 30 minutes before the experiment, 66 minutes into the experiment, and 96 minutes into the experiment (Fig. 1).

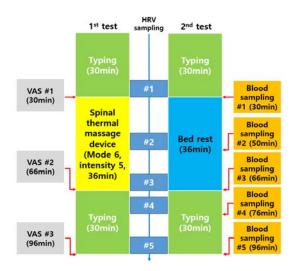


Fig. 1. Flow diagram of the study

2.3 Spinal thermal massage device

The CERAGEM Master V6 spinal thermal massage device (CGM MB-1701, CERAGEM Co. Ltd., Cheonan, Korea) was used during experiment 1 (Fig. 2). The device works by identifying the course and segments of the spine with the user lying in the supine position, and a ceramic roller parallel to the spine applies pressure and heat to the paraspinal muscles while moving in the cervical-to-lumbar direction. However, for the current study, we disabled the heating feature to examine the pure effects of massage. The device features several treatment modes and intensities,



Fig. 2. Picture of the spinal thermal massage device

which were set as follows: mode, 6; intensity, 5; duration, 36 minutes (i.e., programming time of mode 6).

2.4 Monitoring of stress hormones (serum cortisol, plasma epinephrine, and norepinephrine)

Serum cortisol, plasma epinephrine, and plasma norepinephrine levels were measured to quantify stress levels. Blood was sampled five times (30, 50, 66, 76, and 96 minutes into experiment) at a volume of 10 ml each time (Fig. 3). The participant fasted for at least 2 hours prior to the initial sampling, which was performed at 4 PM on Monday to reduce the effects of circadian variation. To minimize changes in stress hormones (cortisol, epinephrine, norepinephrine) due to pain and physiological tension during blood sampling, an intravenous access with a 3-way stopcock was established 2 hours prior to the experiment. Five rounds of blood sampling were performed at the designated times with care taken to ensure the patient remained as unaware as possible (Fig. 3). All blood analyses were performed by a credible external institution (Korean Red Cross Blood Services).



Fig. 3. The 3-way stopcock and blood sampling procedure

2.5 Monitoring of HRV

HRV was measured to monitor changes in ANS activity using the validated polar HR10 Bluetooth heart rate strap (Polar Electro, Kempele, Finland) and a free smartphone app called Elite HRV (Ashville, North Carolina, USA) (Fig. 4). To prevent potential data errors associated with adjustments to wearing the Polar HR10 Bluetooth heart rate strap, the HRV monitoring device was placed on the chest 2 hours prior to the experiment. HRV was continuously measured for the entire 96-minute study period using the open HRV reading feature of Elite HRV. From the continuously measured HRV data, data from 5 minutes before each blood sampling time (30, 50, 66, 76, 96 minutes into experiment) were extracted and analyzed in chunks of 5 minutes using the Kubios HRV software (version 3.4.0, Biosignal Analysis and Medical Imaging Group, Department of Physics, University of Kuopio, Kuopio, Finland).

We performed time and frequency domain HRV analyses. In the time domain analysis, we calculated the standard deviation of the node-to-node intervals (SDNN) as a measure of physiological resilience to stress. The square root of the mean squared difference of successive R-R intervals (RMSSD) and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50 index) were used to assess parasympathetic activity. In the frequency domain analysis, overall ANS activity was examined based on total power (TP) and low frequency (LF). (In short-term analyses, LF concurrently reflects both sympathetic and parasympathetic activity (SNS, PNS), while it is more indicative of SNS activity in long-term analyses). We further examined high frequency (HF) as a measure of PNS activity. The norm LF (normalized LF), norm HF (normalized HF), and LF/HF ratio were also examined to adjust for limitations associated with the use of short data samples when assessing the overall balance between SNS and PNS activity [7].



Fig. 4. Polar HR10 Bluetooth heart rate strap

3. Results

Pain was significantly lower in Experiment 1 than in Experiment 2 (Table 1). Further, the participant mentioned that he felt more relaxed and comfortable after treatment with the spinal thermal massage device than after bed rest.

Table 2. Changes in visual analog scale (VAS) scores

| Treatment | | | VAS #3 (96 min) |
|-------------------------------|---|---|--------------------|
| spinal thermal massage device | 4 | 1 | 2 |
| Bed rest | 4 | 3 | 4 |

We examined cortisol, epinephrine, and norepinephrine levels at five time points (Table 2). The comparison of these values between Experiment 1 (spinal thermal massage device) and Experiment 2 (bed rest) are shown in Figure 6 and Table 3.

| Table 3. | Results | of blood | sampling |
|----------|---------|----------|----------|
|----------|---------|----------|----------|

| | | Blood sampling | | | | |
|----------------------------|-------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | | 1 st | 2 nd | 3 rd | 4 th | 5 th |
| Cortisol (µg/dl) | spinal thermal massage device | 7.07 | 5.6 | 4.79 | 4.44 | 4.86 |
| | Bed rest | 8.68 | 7.5 | 6.79 | 6.75 | 5.72 |
| Epineph-rine (µg/dl) | spinal thermal massage device | 46.3 | 48.5 | 35 | 27.4 | 45.7 |
| | Bed rest | 29.4 | 25.1 | 28.1 | 34.5 | 33.4 |
| Norepin-ephrine (µg/dl) | spinal thermal massage device | 287 | 258 | 188 | 155 | 239 |
| | Bed rest | 236 | 155 | 157 | 275 | 264 |

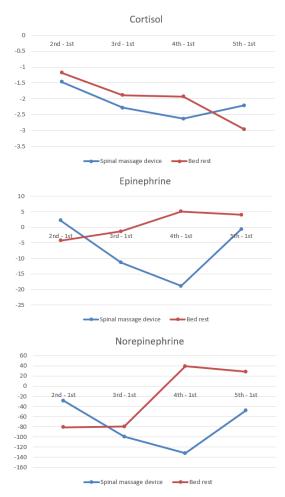


Fig. 5. Differences in blood sampling results

| Table 4. Rate of change in blood test parameters for |
|--|
| the 2 nd -5 th blood tests with reference to |
| the 1 st blood test |

| | | Rate of change (%) ¹⁾ | | | |
|--------------------------------|-------------------------------------|--|-----------|----------------------|--------|
| | | 2 nd -1 st 3 rd -1 st 4 th -1 st 5 th -1 ^s | | | |
| Cortisol (µg/dl) | spinal thermal massage device | -20.79 | -32.25 | -37.2 | -31.26 |
| | Bed rest | -13.59 | -21.77 | -22.24 | -34.1 |
| Epineph-rine (µg/dl) | spinal thermal massage device | 4.75 | -24.4 | -40.82 ²⁾ | -1.29 |
| | Bed rest | -14.63 | -4. 42 | 17.34 | 13.6 |
| Norepin-ephrin e (µg/dl) | spinal thermal massage device | -10.01 | -34.54 | -45.95 ²⁾ | -16.56 |
| | Bed rest | -34.15 | -33.56 | 16.52 | 11.92 |

1) Rate of change = {(X - baseline)/baseline}*100

 Maximum reduction in epinephrine and norepinephrine at the 4th blood test in Experiment 1.

In both rounds of the experiment, cortisol levels progressively decreased across the 2nd-5th blood tests when compared with those observed in the 1st blood test. Epinephrine and norepinephrine results differed between the two rounds of the experiment. In Experiment 1, epinephrine levels were 4.75% higher in the 2^{nd} blood test (20 minutes into the experiment) than in the 1st blood test but declined by 24.4% in the 3rd blood test (treatment completion), by 40.82% in the 4th blood test (10 minutes after treatment completion), and by 1.29% in the 5th blood test (30 minutes after treatment completion). In Experiment 2, epinephrine levels dropped by 14.62% in the 2^{nd} blood test and 4.42% in the 3^{rd} blood test when compared with baseline levels. However, epinephrine concentration increased by 17.34% and 13.6% relative to baseline in the 4th and 5th blood tests, respectively. In Experiment 1, norepinephrine levels changed by -10.01% in the 2^{nd} blood test, -34.59% in the 3^{rd} blood test, -45.94% in the 4^{th} blood test, and -16.55% in the 5th blood test, consistently decreasing when compared with the baseline value. However, in Experiment 2, the norepinephrine concentration was lower than baseline in the 2^{nd} (-34.15%) and 3^{rd} blood tests (-33.55%) yet higher in the 4^{th} (+16.52%) and 5th blood tests (+11.91%). In Experiment 1, both epinephrine and norepinephrine levels consistently decreased throughout the study period. Levels continuously dropped treatment with the spinal thermal massage device, with the maximum reduction observed 10 minutes after the completion of treatment (4th blood sampling). In Experiment 2, however, both values were at their lowest in the 2nd blood test, with a smaller reduction observed in the 3rd blood test. Interestingly, concentrations were actually elevated above baseline levels following bed rest (Table 3).

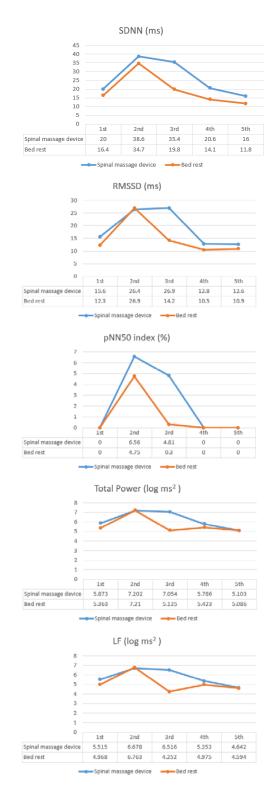




Fig. 6. HRV time and frequency domain analysis

SDNN, TP, and LF increased until the 2^{nd} blood test in both rounds of the experiment. However, whereas values remained elevated in the 3^{rd} blood test in Experiment 1, they dropped below baseline in Experiment 2. In the 4^{th} and 5^{th} blood tests, these values dropped to the baseline level in both rounds of experiments.

The RMSSD, pNN50 index, and HF were elevated in the 2^{nd} blood test in both rounds of the experiment. However, whereas they remained elevated in the 3^{rd} blood test in Experiment 1, they dropped to baseline levels in Experiment 2. In the 4^{th} and 5^{th} blood tests, these values dropped to the baseline level in both rounds of experiments.

In Experiment 1, the LF/HF ratio in the 2nd (2.87) and 3rd blood tests (2.32) were similar to those in the 1st blood test. However, in Experiment 2, the ratio was markedly lower in the 3rd blood test (0.88) than in the 1st blood test (3.58). In both experiments, the ratio was substantially higher in the 4th blood test than in the 1st blood test (Experiment 1 : 2.88 \rightarrow 5.31, Experiment 2 : 3.58 \rightarrow 4.23), again decreasing to the baseline level in the 5th blood test. Similar patterns were observed for norm_HF and norm_LF values. Notably, the norm_HF to norm_LF ratio was 53.08:46.89 in the 3rd blood sampling in Experiment 2, which is markedly lower than that in the 1st blood test (Fig. 6).

4. Discussion

In Experiment 1, epinephrine and norepinephrine levels were the lowest in the 4th blood test, and the values remained lower than the baseline until the 5th blood test. However, in Experiment 2, these levels decreased during treatment but rose above baseline after the end of treatment. These results suggest that treatment with a spinal thermal massage device diminishes SNS activity, while simple bed rest may actually activate the SNS.

As cortisol levels were consistently lower than the baseline throughout both experiments, this may indicate that both massage device treatment and bed rest were effective in lowering cortisol. However, cortisol may also have been elevated due to circadian variation, and typing before and after treatment may not have been sufficiently stress-provoking to elevate cortisol levels, as reported by Bon. J et al. [8] (Fig. 5).

The SDNN and TP, which reflect ANS regulation, were elevated in the 2nd blood test in both experiments, as were indicators of parasympathetic activity (i.e., pNN50 index and HF) [9]. However, while results for the SDNN, TP, pNN50 index, HF, and LF in the 3rd blood test were similar to those in the 2^{nd} blood test in Experiment 1, they were lower in the 3rd blood test than the 2nd blood test in Experiment 2. Further, the LF/HF ratio, norm_HF, and norm_LF values did not markedly change in Experiment 1, although the LF/HF ratio and norm_LF were markedly reduced in Experiment 2 (Fig. 6). These results indicate that overall ANS activity increased in Experiment 1 yet decreased in Experiment 2, with more evident decreases in SNS activity in Experiment 2. The finding of elevated sympathetic activity in Experiment 1 is slightly different from those reported in previous studies, which indicated increases in parasympathetic activity only [10]. The increased sympathetic activity observed in this study may be attributable to the generation of an exercise pressor reflex (EPR) by the spinal thermal massage device, which may have in turn repeatedly stimulated the central ANS via Ad and C fibers [11]. These results align with the conclusions of Moyer et al., who argued that the central ANS activates the PNS and SNS, resulting in an overall increase in ANS activity to restore autonomic balance [12]. Restoration of physiological balance may explain further reductions in epinephrine and norepinephrine levels under stress (typing) even after the conclusion of treatment $(4^{th} and 5^{th} blood tests)$. On the other hand, bed rest in Experiment 2 seems to have reduced sympathetic activity, thereby lowering the alternative parasympathetic activity and overall ANS activity,

resulting in poorer restoration of physiological balance. This may explain why epinephrine and norepinephrine levels were elevated beyond the baseline in the 4^{th} and 5^{th} blood tests (Fig. 5). During the two stress-inducing periods of the current study (typing), HRV analyses indicated that sympathetic and parasympathetic activity patterns were similar between the two experiments (Fig. 6). These results suggest treatment with the spinal thermal massage device influenced activity in the central ANS, thereby leading to decreased adrenal medulla activity, modified sympathetic ganglion activity, and decreased release of epinephrine and norepinephrine into the blood. These processes may explain the analgesia and stress relief observed following spinal massage.

Our study had some limitations, as only a single participant was included. In addition, we did not utilize assessments to determine self-reported stress, and use of a routine-level stressor may have been insufficient for evaluating changes in cortisol levels.

5. Conclusion

When compared with bed rest, single-session treatment with a spinal thermal massage device improved pain scores in our patient; increased HRV parameters related to overall autonomic, sympathetic, and parasympathetic activity; and decreased epinephrine and norepinephrine levels. These results may be attributable to activation of the SNS via repetitive stimulation of paraspinal muscles during treatment with the spinal thermal massage device and consequent compensatory activation of the PNS to restore balance, in turn leading to overall increases in ANS activity. These findings are consistent with previously reported results regarding the effects of massage therapy and provide objective data supporting the pain relief and comfort experienced following a single session of treatment with a spinal thermal massage device [13, 14].

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