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Efficacy and safety of microcurrent stimulation of acupoints on the sole of the foot of children with short stature in 25th percentile of height by age: A randomized controlled trial☆

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ABSTRACT

Introduction: This study aimed to evaluate the effect of the microcurrent stimulation of 4 plantar acupoints (including KI-1) on the secretion of insulin-like growth factor (IGF)-1 and IGF binding protein 3 (IGFBP-3) in children with short stature in the bottom 25th percentile of height by age.
Methods: A total of 26 children (7–18 years old) with short stature were randomly divided into the treatment group or the control group at the National Clinical Research Center for Korean Medicine. For 6 weeks, the treatment group wore the microcurrent stimulator while asleep, while the control group did not receive the treatment. The device worked for 5 h during sleep, and the actual stimulation time was 1 h. The 4 acupoints on the foot related to growth, including KI-1 (Yongcheon), were stimulated with a 1 Hz, 32–35 μA microcurrent. The primary endpoints were the changes in IGF-1 and IGFBP-3 from baseline to the 6th week.
Results: In the treatment group, the mean of the change in IGF-1 showed a statistically significant difference. The change between pre- and post-trial in the treatment group was more prominent than in the control group. There were no significant differences in IGF-BP3 in either group.
Conclusion: The microcurrent stimulation of the acupoints may have an effect that promotes growth in short-stature children by increasing IGF-1. Further studies are warranted.

1. Introduction

Microcurrent therapy has been used to treat various diseases such as arthritis, tuberculosis, pneumonia, as well as in wound healing and psychotherapy [1]. Furthermore, it has been applied to diverse pains and nervous, musculoskeletal, and skin diseases [1–3].

Microcurrent treatment in Western and Korean medicine corresponds to a range of physiological currents in the body [1]. Thus, it has been found that microcurrent does not cause muscle contraction and therefore does not cause discomfort [4]. Furthermore, it heals wounds or increases tissue activity with only a small amount of current.

Microcurrents regulate the secretion of cytokines in the body [5]. As a result, microcurrent therapy is involved in the development of fibrosis or scar tissue, the deposition of minerals, the secretion of histamines, and the regulation of inflammation. In addition, microcurrent increases the secretion of β-endorphin. β-endorphin has been found to affect the secretion of growth hormone (GH) by growth-hormone-releasing hormone (GHRH) in preadolescent children. According to a previous study of microcurrent therapy, levels of GH were increased as a result of a combination therapy with microcurrent shoes and exercise in adolescents [6]. These results suggest that microcurrent could possibly promote GH secretion in children and may be a good method for promoting growth in children [7].

GH treatment is generally used to promote growth [8]. However, treatment should continue until the end of growth. It is recommended that treatment should start early, before 5 years

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of age, as the potential for growth greatly declines if the treatment starts after 10 years of age. GH treatment has been known to be relatively safe, but there is a report indicating that the treatment causes sleep apnoea by stimulating lymphoid tissue enlargement [9]. Thus, it is not advised for patients with severe obesity or sleep apnoea. Furthermore, the recovery of psychological satisfaction, which is anticipated from growth hormone treatment, is not remarkable, especially given the high cost [8]. Receiving a shot almost every day is also a heavy mental burden to children [8]. Because of the limitations of GH therapy, there is an increasing demand for an effective, safe, and easy-to-use treatment [10,11].

In Korean medicine, acupoints on the sole of the foot are generally known to stimulate growth. Korean medicine also considers that acupoints on the sole of the foot stimulate serotonin secretion via stimulation of the kidney and adrenal gland. According to a previous study, increased serotonin secretion induced by stimulating acupoints on the sole of the foot influence growth hormone secretion [12].

A prior study reported that there was no safety issue for infants with congenital muscular torticollis using the device 3 times per week for 2 weeks [13]. Rhim and Kim tested the effect of the microcurrent stimulation of points related with growth on the serum GH concentration during exercise in ten 5th grade elementary school students [6]. However, they reported on the combined therapy of exercise and microcurrent, and exercise is a factor that has a great influence on growth by itself. Thus, the results could be considered to be a result of the effect of exercise, and an additional study on microcurrent alone is necessary. The purpose of this study was to identify the neurohormonal effects of microcurrent treatment on the sole of the foot in children with short stature in the bottom 25th percentile of height by age.

2. Methods

2.1. Participants

This study was conducted at the National Clinical Research Center for Korean Medicine in the Korean Medicine Hospital of Pusan National University. The participants were recruited from September 13th, 2014 to December 26th, 2014. The children with short stature in the bottom 25th percentile of height by age were suitable, according to the inclusion criteria.

2.2. Ethics

This study protocol was approved by the Korean Food and Drug Administration (KFDA) (protocol registration number: 641). We conducted this study based on the Declaration of Helsinki. This study was approved by the Institutional Review Board (IRB) of Pusan National University Korean Medicine Hospital (PNUKH), Yangsan, South Korea (approval No.: 2014003).

2.3. Inclusion and exclusion criteria

We included participants who fulfilled all of the following criteria: (1) healthy children and adolescents between 7 and 18 years old whose stature was in the bottom 25% of the percentile by sex and age in the '2007 Korean Children and Adolescents Growth Standard [14]' but did not have endocrine diseases, metabolic diseases, or nutritional deficiency causing short stature; (2) voluntary participation, signed written consent, and signed the written consent by the parents.

Two authors (Kim K.B. and Jung A.) evaluated the eligibility of the participants in accordance with the inclusion criteria. The two authors checked vital signs, blood, and performed a physical examination of participants on the first visit. Subsequently, the authors excluded unsuitable participants on the basis of test results. We excluded participants who had any of the following: (1) underlying diseases that can cause hormonal imbalance, such as pituitary adenoma; (2) inability to wear the medical device for the clinical trial because he/she had sensitive skin or because of other reasons; (3) required aggressive treatments because he/she had severe physical or mental diseases; (4) had received a medical or Korean medical treatment related to the symptoms, as mentioned above; and (5) other cases that the investigator deemed inappropriate.

2.4. Study procedure

This study was a prospective randomized controlled trial. Prior to starting this clinical trial, the investigator obtained each subject's baseline characteristics and medical history in an interview and recorded them on the case report form. The baseline characteristics included demographic information (name, age, height, weight, gender, and contact information), vital signs (blood pressure and pulse rate), past history, history of present illness, physical examination, basic blood test, assessment of height percentile by age, and bone age.

A basic blood test was conducted not as the primary endpoint for growth but to check the health of the subjects. The complete blood count measured the following components via a basic blood test: differential (CBC and DC), blood glucose, Na^+, K^+, Cl^-, ferritin, liver function test (AST and ALT), and C-reactive protein (CRP). We also identified hormones levels, including that of GH. We chose hormones that directly affected growth as the primary endpoints.

Studies involving children should investigate all potential risks including factors that are generally not considered in adult studies; these factors include the effect of growth [8]. The investigator then performed a thorough medical history to screen subjects for the inclusion criteria. During the trial, a compliance assessment was performed. Before starting the trial, we offered a questionnaire assessing compliance. To increase compliance, investigators made a weekly phone call to the subjects or their guardians and checked on progress. When the subjects visited after 6 weeks, the investigator assessed the compliance, which was checked via pamphlet.

Based on previous studies using microcurrent, we anticipated that there would be few adverse events. However, we anticipated allergic reactions such as contact dermatitis, hives, and pruritus on the electrode-contacting area and pain or paraesthesia on the area where the device was worn.

Via phone call, the investigator checked for adverse events at the 2nd and the 4th weeks during the 6 weeks of the study period. We frequently reminded the subjects to voluntarily report adverse events. We also checked for adverse events when the subjects visited at the 6th week.

2.5. Intervention

This study used a plantar-reflective microcurrent stimulator (Dr. Park's Growth Pad, SJay Medience Co., Ltd., South Korea) for 6 weeks. The shape of the device is the same as that illustrated in Fig. 1. It was used during sleep and consistently stimulated specific areas of the foot with a microcurrent that flows with a specified waveform at a specified time. This device was developed for the easy, consistent, and efficient administration of a 1 Hz, 32–35 μA microcurrent that humans cannot feel. The actual stimulation time was 1 h during a 5 h period. The microcurrent was emitted 3 times for 20 min at a time. The 4 acupoints related with growth were as follows: (1) KI-1 (Yongcheon), (2) the area connecting the sole and the largest toe, (3) the area connecting the sole and the little toe (at