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RESEARCH ARTICLE

Analysis of Vacuous Pulse and Replete Pulse Using a Clip-type Pulsimeter Equipped with a Hall Sensor

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Abstract
A logistic regression equation for the vacuous pulse and the replete pulse was determined based on data obtained using a clip-type pulsimeter equipped with a Hall device that sensed the change in the magnetic field due to the minute movement of a radial artery. To evaluate the efficacy of the two different pulses from the deficiency and the excess syndrome groups, we performed a clinical trial, and we used a statistical regression analysis to process the clinical data from the 180 participants who were enrolled in this study. The ratio of the systolic peak's amplitude to its time in the pulse's waveform was found to be a major efficacy parameter for differentiating between the vacuous pulse and the replete pulse using an empirical equation that was deduced from the data using a statistical logistic regression method. This logistic regression equation can be applied to develop a novel algorithm for pulse measurements based on Oriental medical diagnoses.

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1. Introduction

The increased demand on healthcare for the treatment of chronic diseases is driven by an aging population and is a main concern globally. The number of people aged 65 years and older will double as a proportion of the global population from 7% in 2000 to 16% in 2050, and this aging society has a right to peace of mind and happiness. The coming neosenior-generation market is the focus of attention for social groups and industry. In general, these social groups and industry have a big responsibility in the field of healthcare as they supply labor for the aging society and help reduce the social burden. These trends are expected to be an exponential driving force for developing countermeasures to prepare for this elderly society. Moreover, the markets will be economically impacted by the growing global complement of alternative medicines and by increasing demands for novel treatments based on Oriental medicine. In a bid to reduce the social burden due to healthcare, health status should be monitored, and cardiac, cerebrovascular, and peripheral vessel diseases should be managed. Measurements of continuous vascular pressure and analyses of radial artery waves need to be used to overcome high blood pressure and other cardiovascular disorders. In particular, the radial artery offers baseline data for healthcare [1].

Bio-space Inc. (Centennial/Colorado and USA) and DK-city Inc. (Tan Tzu Dist./Taichung city and Taiwan) have developed and released new pulse-measuring devices to check impedance at the wrist's radial artery. These were put on the market in September 2007. However, these products are hobbled by several problems. For example, they have an extremely high signal/noise (S/N) ratio from the hand pulse, which is caused by exterior conditions, such as humidity and dryness, that may significantly modulate the signal. These new devices were developed to overcome the weaknesses of previous generations of wrist-type blood-pressure gauges, including the gauge developed by Korea-Meditech Inc. (Sungdong-gu/Seoul and Republic of Korea). Users of the Korea-Meditech gauge complained that over long periods of usage, there was some pain, which was mainly attributed to their being manually operated. The U-healthcare system developed by ETRI (Electronics and Telecommunications Research Institute) (Yuseong-gu/Daejeon and Republic of Korea) and KERI (Korea Electrotechnology Research Institute) (Yuseong-gu/Daejeon and Republic of Korea) has a capability to transmit and analyze in real time multiple biometric signals, such as heartbeat, body temperature, and breathing rate. This product uses a portable terminal, which can be attached to the wrist or the chest. However, it has a drawback in that it cannot measure the pulse and blood pressure [2,3]. A pulse wave monitor developed by Omron Colin Company (Seocho-gu/Seoul and Republic of Korea), which uses a multichannel sensor, was introduced into the market, but it has a limitation in that it must be used only in a static state and is inappropriate for use while in motion. The wearable-type sleep sensor, 2006 Japanese Toshiba TEC (Minato-ku/Tokyo and Japan), is designed to monitor the body's condition while the user is moving at home or while traveling. It reports any alarm by synching with a mobile phone. However, its fidelity, based on evaluations by clinicians, was only 25%. Kwan-Chang Kim attached a sensor with seven lines on WristOx, a wearable plethysmograph from US Medtek Inc. (Woodland Hills/California and USA). This device, which is attached to the finger, measures digital pulse using the oxygen concentration in the hemoglobin in erythrocytes, but it does not provide information on the pulse or blood pressure. Therefore, an Oriental diagnosis instrument for the pulse and the tongue is acutely needed in order to improve the reliability of Oriental treatment internationally. Because the results from existing pulsimeters depend on the location of the measurement, measurements using the same device may be different. If clinical demands are to be satisfied and the credibility of Oriental medical devices is to be enhanced, the low reproducibility owing to inconsistent measurement procedures needs to be rectified [4].

According to Oriental diagnosis, the vacuous pulse and the replete pulse are very important pulse phases. These phases are widely used in Oriental diagnosis and treatment. In addition, these pulse phases are very important main parameters for Oriental medicine and can lead to the development of a determinable pulsimeter, which is urgently needed. Oriental pulse wave classification is based on spot, time, and intensity. There are 28 types of pulse phases, but the existing pulsimeters only cover seven types of pulse phases. In particular, among the seven phases of pulse, the vacuous (weak) and the replete (strong) pulses can be diagnosed as distinct pulses, but a formula that can be used to estimate them has not yet been determined. Research on the vacuous pulse and the replete pulse tends to be insufficient because of the difficulty in establishing a normal value—variations related to age, sex, etc., exist. Conceptually, the vacuous pulse and the replete pulse can be determined using the heights of the peaks obtained using a pulsimeter. Raw data from the pulsimeter can be filtered by quadratic differential processing [2,4]. In the case of traditional Chinese medicine, research on the vacuous pulse, the replete pulse, the magnus pulse, and the microsphygmia pulse is scarce. However, research on the floating pulse and the sinking pulse does exist. The amplitude of the floating or the sinking pulse is influenced by three things: the vascular diameter (radius), the vascular strength, and the strength of the soft tissue around the vessel [3,5].

In this study, we evaluated the efficacy of a clip-type pulsimeter that uses a magnetic-field-sensing Hall device at the Oriental Medicine Hospital of Sangji University (Wonju, Korea). The results could improve the ongoing process for certifying devices that can be used as pulse-wave analysis devices in the degree-3 category of medical devices. A clip-type pulsimeter that uses a magnetic-field-sensing Hall device, model "spuls-2011" developed by the Cooperation of Sangji Univeristy and SM Information & Communication Co. Ltd. (Kumcheon-gu/Seoul and Republic of Korea was used to obtain the pulse wave [6,7] by applying it to a wide area, in which case blood pressure measurements using a simple pressure sensor would be difficult. This pulsimeter, which observes the change in the waveform, may be an alternative solution. In the clinical trials for this study, 180 participants were classified as being normal (no syndrome) or as having deficiency syndrome, excess syndrome, or nonclassified syndrome for each sex (male and female). We performed the