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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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vacuous pulse

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

statistical process and accumulated clinical data on the 180 participants, who were divided into four groups, with each group having the same number of participants; the four groups were male, female, deficiency syndrome, and excess syndrome. We eliminated the nonclassified syndrome group to avoid redundancy of the normal distribution among the deficiency syndrome group, the excess syndrome group. and the nonclassified syndrome group. Correlation of the measured parameters in the body with the parameters of the main pulse wave of the radial artery wave was confirmed using a statistical examination. In particular, we used the method of logistic regression analysis to discuss the use of an empirically determined regression equation to judge the vacuous pulse and the replete pulse [8,9].

2. Materials and methods

2.1. Participants

The participants were recruited using the following three criteria: average people having deficiency syndrome and vacuous pulses; average people having excess syndrome and replete pulses; and average people having nonclassified syndrome, which was defined as neither excess nor deficiency syndrome. The participants chosen for our research had to meet certain selection criteria. Applicants who were not excluded based on the exclusion criteria listed below, or who did not have a communication impediment, such as a reading or writing impediment, and who satisfied the following five criteria were chosen for inclusion in this study:

(1) The candidate must be an adult volunteer aged between 19 years and 75 years who is not rejected based on the exclusion criteria.
(2) The candidate must have a consistent syndrome and diagnostic pulse as verified by five Oriental doctors and must have completed the questionnaire [10].
(3) The candidate must satisfy any of the following three conditions:
   (a) The candidate was found to have deficiency syndrome on the basis of the deficiency syndrome and excess syndrome judgment questionnaire (Appendix 1), and the candidate was diagnosed by five Oriental medicine doctors as having deficiency syndrome and a vacuous pulse.
   (b) The candidate was found to have excess syndrome on the deficiency syndrome and excess syndrome judgment questionnaire, and the candidate was diagnosed by five Oriental medicine doctors as having excess syndrome and a replete pulse.
   (c) The candidate was found to have neither deficiency syndrome nor excess syndrome on the deficiency and excess syndrome judgment questionnaire (nonclassified syndrome), and the candidate was diagnosed by five Oriental medicine doctors as having a nonclassified syndrome and a nonclassified pulse.
(4) The candidate had to be a volunteer who agreed to our clinical studies agreement.
(5) The candidate had to be an individual whose condition could be determined by a clinical trial Oriental medicine doctor.

In this study, we excluded applicants who were not psychologically stable or who had an acute serious illness. We also excluded any person who had a chronic disease of the heart or any other diseases that might interfere with the interpretation of the results and the therapeutic effect. Applicants who had experienced clinical studies related to a pulsimeter within 1 month of our study were excluded, as were those who had diseases such as seizures or perception disorders, who wore cardiac pacemakers or who had implants with metal joints, prosthodontics, etc. All of these could affect the diagnosis made using the pulsimeter and make the clinical study difficult. We also excluded candidates who were currently pregnant or planning a pregnancy; who could not communicate in Korean; who were thought not to be able to abide by the rules for participation in this research; who were currently taking corticosteroids, narcotics, muscle relaxants, anticoagulants, or Oriental medicine for the treatment of other diseases; who were taking medications that were considered to be inappropriate for our research; and who would not agree with our clinical studies agreement.

2.2. Equipment: properties of a clip-type pulsimeter equipped with a magnetic-sensing Hall device

Fig. 1A shows the major parts of the pulsimeter: permanent magnet, Hall sensor, measurement part, light-emitting diode, display, USB port, and switch part. The magnetic material of the contact on the clip-type pulsimeter is easily modified by the vibration of the pulse in the wrist, which is placed within a small cylindrical permanent magnet. There is a flexible silicon housing, which is suitable for skin contact and was needed so as not to press the skin atypically [6,7]. The central part of the housing had a magnetic field of approximately 150 Oe at a distance of 1 mm from the surface of the cylindrical permanent magnet, which had a diameter of 2 mm and a height of 1 mm. In other words, the circular center plate of the permanent magnet was located at the Gwan diagnostic region of the wrist. This position allows for positioning and allows the silicon rubber to stretch evenly over the contact surface of the wrist. Photographs of a pulse-wave signal measured using a clip-type pulsimeter worn on a human wrist and of a clinical trial for acquiring pulse signals using the clip-type pulsimeter are shown in Fig. 1B and C, respectively.

The Hall device adopted for the clip-type pulsimeter was linear in the intensity of the magnetic field. The model (#A1395) from Allegro Company (Dallas/Texas and USA), which has excellent sensitivity, was chosen as the Hall device unit [6,7]. The output signal of the Hall device was directly proportional to the intensity of the magnetic field, within -0.1 to $+0.1$ V per polarity, on the basis of $V_{CC}/2$ being within the limit of input voltage V_{CC}. V_{CC} is defined as the collector supply line voltage in a common

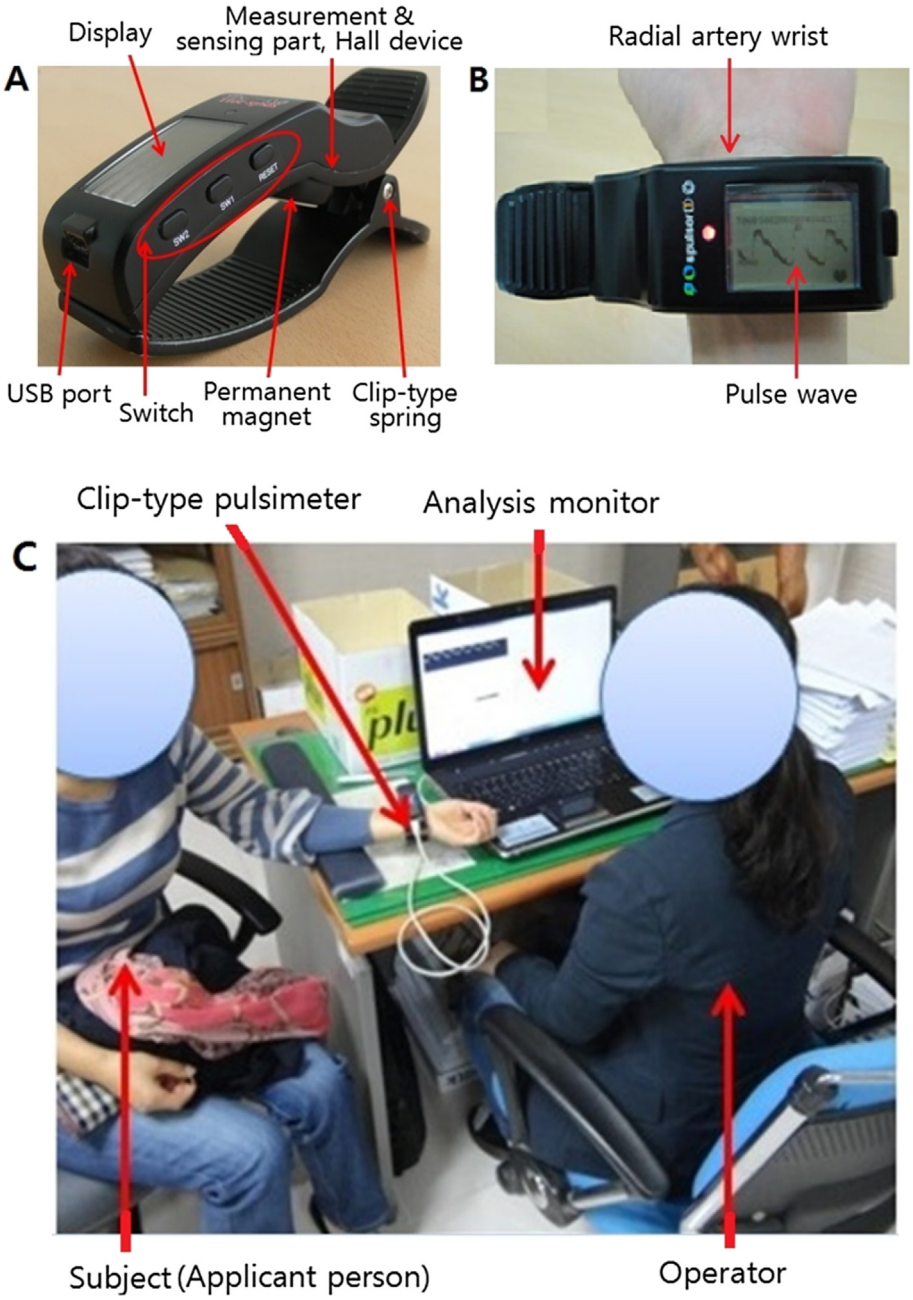

Figure 1 (A) Major functional parts of a typical clip-type pulsimeter: sensing device and display screen for measurements using the Hall device. The three major components are the sensing, the display, and the measurement parts equipped with a Hall device. (B) Photograph of the clip-type pulsimeter. (C) Photograph of an actual clinical trial to acquire pulse signals using the clip-type pulsimeter.

NPN (Negative-Positive-Negative) transistor circuit. Thus, the Hall sensor works because of this supply voltage. The Hall device had a sensitivity of 10 mV/Oe. The power supply unit (3.3 V) could provide magnetic fields up to 155 Oe at the input voltage V_{CC}. Therefore, the distance between the magnet and the sensor was maintained such that the intensity of the magnetic field was below 155 Oe.

Pulsation indicates a maximum vertical displacement of approximately 1.33 mm per single pulse of the radial artery. Therefore, the maximum displacement of the skin in contact with the magnet is also predicted to be approximately 1.0 mm. The closer the Nd—Fe—B permanent magnet and the Hall sensor are located, the bigger the generated magnetic field and the higher the peak of detected pulse wave signal. A wide difference of 100 Oe or more was observed between the maximum and the minimum values of the magnetic field at a distance of 2 cm between the sensor and the magnet, but this difference was a low value of 45 Oe when the separation distance was 3 mm. Thus, the deviation between the magnets could be

decreased by maintaining a distance of 3 mm or more when selecting the distance between the sensor and the magnet.

2.3. Methods

The protocol for this study was approved by the Institutional Review Board of the Oriental Medicine Hospital, the Korea Ministry of Food and Drug Safety, and the Investigational Medical Device Application (approval number: SH IRB/D 120808). After appropriate research volunteers for this study had been identified using our elimination questionnaire, as well as the inclusion and exclusion criteria, we established the process and method of pulse measurement. Then, five Oriental medicine doctors separately performed medical examinations. When the opinions from the five Oriental medicine doctors did not correspond unanimously, the survey result was not accepted.

The process for selecting the participants for inclusion in this study is shown in Fig. 2A. After the participants selected for the deficiency syndrome group, the excess syndrome group, and the nonclassified syndrome group had been given a 5-minute break, as shown in Fig. 2B, the pulse waves were measured using the pulsimeter (3 minutes), which was followed by a 1-minute rest period and then another 3-minute pulse-wave acquisition.

2.4. Selection of the pulse-wave parameters related to efficacy

The definitions of the nine parameters of the pulse wave shown in Fig. 3 are given in Table 1. In addition, the first and the second measurements are the waveforms measured before and after the 1-minute break. The definitions of the nine pulse-wave factors in each area are recorded in Fig. 4. The clinical data were used to calculate the average values of the pulse-wave parameters from the region in which five consecutive pulse waves are located. These average values were saved as clinical data in an Excel file.

We selected sex, age, body mass index (BMI; kg/m^2), diastolic blood pressure (DBP), systolic blood pressure (SBP), and body temperature as secondary variables. Here, BMI is defined as the weight (kg)/[height (m)]^2 of the participant. A logistic regression method with normal statistics was used to find a correlation between the main parameters of the pulse wave, which are the primary efficacy variables, and the 2nd-day variables.

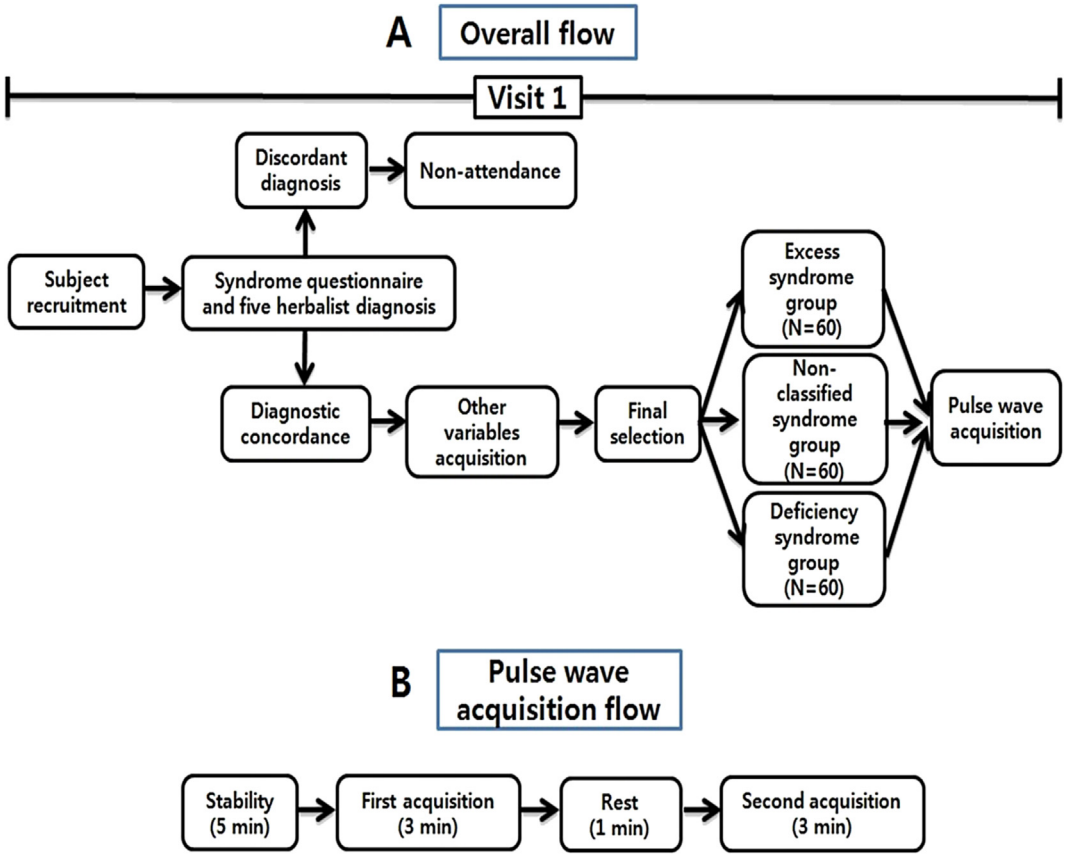

Figure 2 (A) The final selection of the participants with informed consent forms was based on the selection criteria, the diagnoses of five Oriental medicine doctors, and the use of the syndrome questionnaire in order to identify the three pulse waves for deficiency syndrome, excess syndrome, and nonclassified syndrome. (B) The time schedule for the acquisition of pulse waves included a 5-minute stabilization period, followed by the first acquisition (3 minutes), a rest period (1 minute), and then the second acquisition (3 minutes).

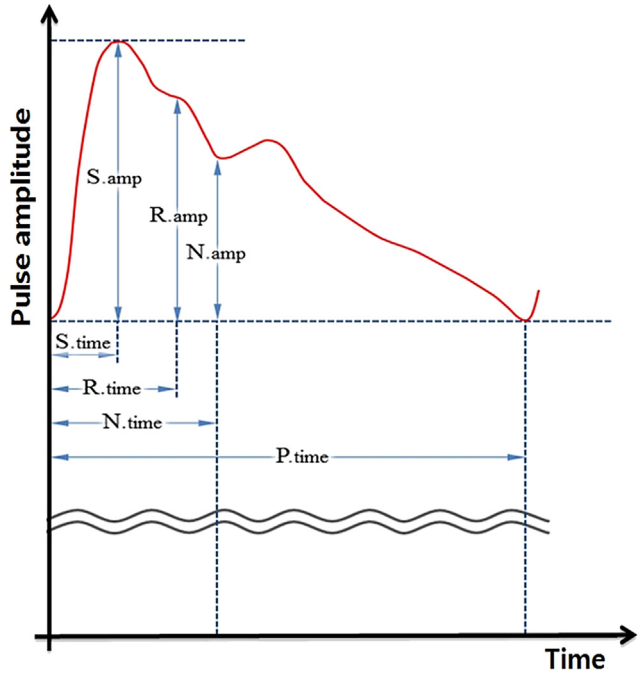

Figure 3 Definition of a typical pulse waveform with major parameters such as S.amp, R.amp, N.amp, S.time, R.time, N.time, and P.time.

2.5. Statistical analysis of clinical data

The diagnosis of the Oriental medicine doctor was adopted as a criterion. A reliability analysis of the diagnosis of the Oriental medicine doctor was implemented only for complete deficiency syndrome and complete excess syndrome. Then, the value of the Cronbach α was obtained. Moreover, the agreement rate between the diagnosis of the Oriental medicine doctor and the truth survey was obtained and was used to adjust the next experimental stage and to complement the questionnaire [8,9]. The number of participants for the clinical trial was not calculated because this research was an exploratory preliminary research to understand the algorithm for using the pulsimeter to measure the vacuous pulse and the replete pulse. For a normal distribution based on 30 people in each group, the parametric statistical method can be used. Thus, such a distribution could be used in our study with 60 participants (30 males and 30 females) in a group. Because measurements using a clip-type pulsimeter may give rise to differences depending on sex, we divided the candidates by sex and then classified them into three groups: deficiency syndrome, excess syndrome, and nonclassified syndrome.

Comparisons of the mean values of the variables age, height, weight, BMI, SBP, DBP, body temperature, and pulse wave were done for the deficiency syndrome, the excess syndrome, and the nonclassified syndrome groups. The analyses used the Student t test in the case of two groups, and the Chi-square test in the case of three groups. The level of significance was set at $p \leq 0.05$ on the one-way analysis of variance in the case of nominal variables. A postanalysis was implemented when the one-way analysis of variance showed significance. We also analyzed the interrelationship between the pulse-wave parameters and each variable. In the postanalysis of the distribution of syndromes, we found that the distributions for the excess syndrome and the nonclassified syndrome groups overlapped, therefore, we removed the nonclassified syndrome group. In addition, we used a binary logistic regression equation to distinguish between the vacuous pulse and the replete pulse based on the significant variables.

Table 1 Definitions for the nine major parameters of the pulse wave.

Parameter (1, 2)*	Definition
S.amp	Systolic peak amplitude
R.amp	Reflective peak amplitude
N.amp	Notch peak amplitude
S.time	Systolic peak time
S.amp/S.time	Systolic peak amplitude/systolic peak time
R.time	Reflective peak time
N.time	Notch amplitude time
P.time	Period time
b/a rate	Maximum peak/minimum peak in the second-order derivative

* 1 and 2 denote the first and second measurements of the pulse wave, which occurred before and after the rest time, respectively.

3. Results

3.1. Reliability analysis of the deficiency syndrome and the excess syndrome judgment questionnaire

The reliability results for measuring the scores of 180 participants to identify them as having deficiency syndrome, excess syndrome, or nonclassified syndrome were obtained using a 19-question syndrome judgment questionnaire, with the first question having a weighted value of 2 points and all other questions having values of 1 point for a total of 20 points [10]. The Cronbach α value, which indicates the degree of internal match, was good (0.572). However, we should point out that the total correlations for several items on the survey had low Cronbach α values. When those items were excluded, the value of the Cronbach α increased to more than 0.6 [8,9].

Based on the syndrome judgment questionnaire, the 180 participants were classified as having deficiency, excess, or nonclassified syndrome. After that, a team of Oriental medicine doctors classified the patients in the same manner. The two sets of results for classifying the patients according to the types of syndrome were then compared to obtain the degree of conformity, which was 0.723 ($p < 0.05$). Here, p and the degree of conformity are related to the significance probability and to the degree of accuracy, respectively. A degree of conformity equal to 1 means that the two sets of clinical or diagnostic data are perfectly consistent.

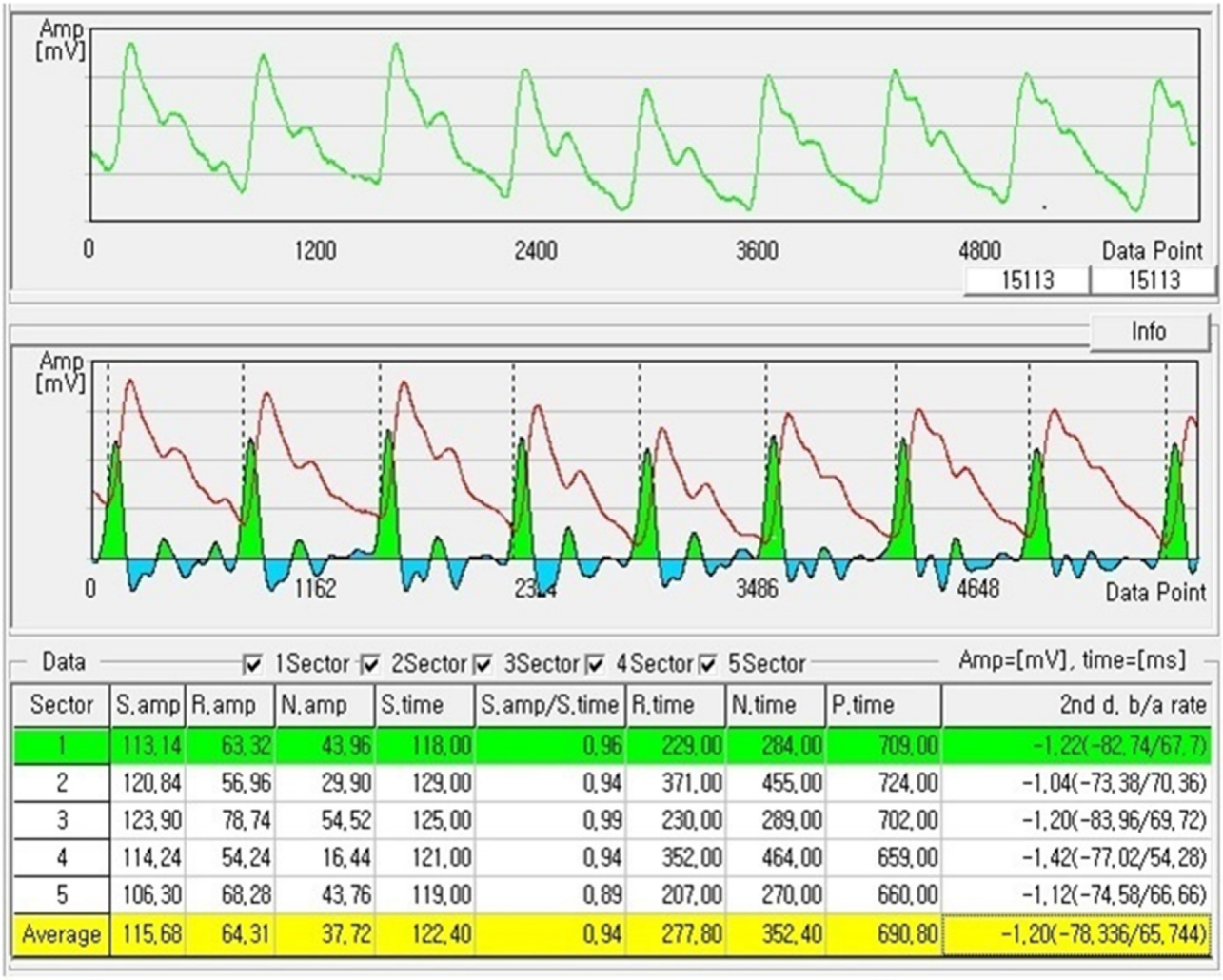

Figure 4 Analysis program for the pulse wave obtained using a clip-type pulsimeter, showing the original pulse wave, the pulse wave after a filtering process, the selection of five sectors, and the final average data: S.amp, R.amp, N.amp, S.time, S.amp/S.time, R.time, N.time, P.time, and *b*/*a* rate.

Table 2 The *p* values for four parameters [age, BMI, BMI (male), BMI (female)] of the clinical participants ($n = 180$).

Clinical participants and parameters	Age (y)	Clinical participants (*n*)			*p*
		Deficiency syndrome	Nonclassified syndrome	Excess syndrome	
Clinical participants	Below 30	23	28	18	0.200
	40	20	10	48	
	50	48	14	18	
	Above 60	6	48	16	
BMI (total)	Below 25	46	40	31	0.015
	Above 25	14	20	29	
BMI (male)	Below 25	22	20	15	0.134
	Above 25	9	9	15	
BMI (female)	Below 25	24	20	16	0.068
	Above 25	5	11	14	

BMI = body mass index.

3.2. Analysis of participants

Overall, the number of research participants was 180, consisting of 90 males and 90 females. Sixty participants were assigned to each of the three groups: the deficiency syndrome group, the nonclassified syndrome group, and the excess syndrome group. All were between 19 years and 75 years of age, and the average age was 45 years. Their height varied from 142 cm to 190 cm, with the average height being 168 cm, and their weight varied from 39 kg to 110 kg, with the average weight being 65.2 kg.

The p value for the statistical significance evaluation of the participants' BMI was 0.015 (Table 2). Thus, BMI was considered to be a suitable anthropometry variable to distinguish between the vacuous pulse and the replete pulse. The significance probabilities (p values) for distinctions based on age and sex were all more than 0.05, therefore, age and sex were not considered to be appropriate variables for distinguishing between the vacuous pulse and the replete pulse. The average SBP for the participants who participated in the clinical test was 130.6 mmHg (range, 90–186 mmHg), the average DBP was 82.5 mmHg (range, 55–128 mmHg), and the average body temperature was 36.7°C (range, 36.0–37.5°C).

3.3. Comparison and correlation of the averages of the main pulse's wave parameters

Table 3 shows the average values and standard deviations for the test variables for the three groups used in this study. For the variables of primary significance for the pulse, only the S.amp/S.time ratio showed a statistically significant difference among the groups, with $p \leq 0.05$. As for the secondary effectiveness variables, only BMI and SBP showed statistically significant differences among the groups, with $p \leq 0.05$.

The measured values for the pulse-wave variables, in principle, are indications of the distribution of values for each of the syndrome groups: the deficiency syndrome, the excess syndrome, and the nonclassified syndrome groups. As the data for these three groups significantly overlapped, we removed the data for the nonclassified syndrome group and redid the analysis, and the overlapping between the deficiency syndrome and the excess syndrome groups was decreased sufficiently when the nonclassified syndrome group was removed. After the nonclassified syndrome group had been removed, the comparison between the two remaining groups indicated statistically significant differences between the groups with respect to BMI, age, sex, and SBP, but not DBP, as indicated in Table 4.

Table 4 Logistic regression coefficient (B), standard error (SE), rating scale (Wals), and significance probability (p) values for seven major parameters.

Parameters	B	SE	Wals	Degree of freedom	p	Exp (B)
Sex	0.14	0.416	0.001	1	0.974	1.014
Age	−0.001	0.013	0.002	1	0.961	0.999
BMI	0.127	0.073	3.030	1	0.082	1.136
SBP	0.038	0.017	5.418	1	0.020	1.039
DBP	0.000	0.025	0.000	1	0.985	1.000
S.amp/S.time	0.120	0.039	9.237	1	0.002	0.127
Constant	−9.662	2.500	14.932	1	0.000	0.000

BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure.

3.4. Logistic regression equation algorithm for judging the vacuous pulse and the replete pulse

Normally, if the p value is the probability of the actual survey, the logistic equation of the regression model that can be explained using the six pulse-wave variables can be found [8,9]. In the general regression equation, the coefficient B_0 is a constant, and the other regression coefficients, B_1, B_2, B_3, B_4, and B_5, are the slopes of the graphs of the five correction variables (X_1 = sex, X_2 = age, X_3 = BMI, X_4 = SBP, and X_5 = DBP). The final coefficient, B_6, is the slope of the graph of the pulse-wave variable S.amp/S.time as a function of time.

Table 3 Comparison of the average values and p values of the parameters for the three syndromes (n = 180) with standard deviations.

Parameters	Deficiency syndrome (n = 60)	Nonclassified syndrome (n = 60)	Excess syndrome (n = 60)	p
S.amp	158.10 ± 79.68	164.02 ± 82.83	192.04 ± 117.37	0.106
R.amp	118.51 ± 63.64	121.25 ± 67.66	143.47 ± 90.08	0.127
N.amp	88.60 ± 49.69	91.91 ± 56.90	109.31 ± 73.83	0.130
S.time	170.68 ± 29.50	168.44 ± 34.84	171.83 ± 29.04	0.825
S.amp/S.time	12.06 ± 5.53	14.49 ± 5.50	14.86 ± 5.93	0.013
R.time	302.82 ± 32.93	299.93 ± 55.33	309.29 ± 32.26	0.437
N.time	354.22 ± 37.75	351.49 ± 63.32	362.79 ± 33.77	0.373
P.time	722.54 ± 137.03	714.44 ± 1 68.59	765.65 ± 123.35	0.105
b/a rate	−1.05 ± 0.16	−1.10 ± 0.21	−1.04 ± 0.16	0.165
Age (y)	44.03 ± 15.19	44.03 ± 15.84	46.37 ± 16.17	0.633
BMI	23.46 ± 2.24	23.90 ± 4.24	25.29 ± 4.39	0.021
SBP	126.10 ± 16.20	128.38 ± 19.11	137.16 ± 19.08	0.002
DBP	80.07 ± 10.94	82.45 ± 12.43	84.86 ± 12.83	0.093

BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure.

The logistic regression analysis of the binary clinical data from the deficiency syndrome group and the excess syndrome group yielded a distinct regression equation that allowed the vacuous pulse and the replete pulse to be assessed using the variables sex, age, BMI, SBP, DBP, and S.amp/S.time ratio. The *p* and *B* values from the regression coefficients are presented in Table 4, along with the value of the S.amp/S.time ratio, which is the ratio of the systolic peak's amplitude to the systolic peak's time. Based on the above data and analyses, we were able to express a logistic regression equation for the probability (*p*) as follows:

$$\log\left(\frac{p}{1-p}\right) = -9.662 + 0.14 \times \text{Sex} - 0.001 \times \text{Age} + 0.127 \times \text{BMI} + 0.038 \times \text{SBP} + 0.120 \times \left(\frac{\text{S.amp}}{\text{S.time}}\right) \quad (1)$$

$$p = \frac{1}{1 + e^{\left(9.662 - 0.14 \times \text{Sex} + 0.001 \times \text{Age} - 0.127 \times \text{BMI} - 0.038 \times \text{SBP} - 0.120 \times \frac{\text{S.amp}}{\text{S.time}}\right)}} \quad (2)$$

4. Discussion

A clinical research test was performed to evaluate the effectiveness of a clip-type pulsimeter using a magnetic-sensing Hall device to detect the minute movement of the radial artery. A statistical analysis of the clinical data from 180 participants was performed. First, the 180 participants were classified as having deficiency syndrome, excess syndrome, or nonclassified syndrome; then, the averages of the anthropometric variables—age, height, weight, BMI, SBP, DBP, and body temperature—were compared. Next, the pulse-wave variables were measured and analyzed for each of the three groups. A significant difference in the S.amp/S.time ratio between the deficiency syndrome group and the excess syndrome group was found in the *post hoc* comparison. This was also true for BMI and SBP. With these data, five Oriental medicine doctors using an empirical binary logistic regression analysis were able to distinguish between the vacuous and the replete pulses for the participants in the deficiency syndrome, excess syndrome, and nonclassified syndrome groups. Equation 2, which was a major result of these results, is a logistic regression equation and algorithm that will allow the vacuous pulse to be distinguished from the replete pulse.

The 120 participants, from among the total 180 individuals, who had been targeted using our survey as having deficiency syndrome and excess syndrome, were separated into the vacuous pulse group and the replete pulse group. The reason the reliability result of the deficiency syndrome and the excess syndrome survey was applied to this research is that the research needed to understand a replete pulse that had a vacuous pulse and deficiency excess syndrome. Exploratory research was needed to develop the tools necessary to distinguish between deficiency syndrome and excess syndrome because our country currently has no verified reliable survey for distinguishing deficiency syndrome from excess syndrome. Because of this, we used a relatively short and simple Japanese deficiency syndrome and excess syndrome judgment questionnaire [10], which had been translated into Korean. Because the Japanese thesis had no criteria for distinguishing between the three syndromes, we used the following criteria: a total score 0—8 for deficiency syndrome, 9—12 for nonclassified syndrome, and 13—20 for excess syndrome. The Cronbach α value is 0.572, which is a satisfactory level. However, the item—total correlation had a negative value among the scores of these survey items, so the Cronbach α can increase.

In the future, in addition to surveys, systematic research is needed. In this study, a clip-type pulsimeter with a magnetic-sensing Hall device for its pulse sensor was used to acquire data that could be used to identify significant independent variables, such as the S.amp/S.time ratio, that could be used to distinguish between a vacuous pulse and a replete pulse. This was done by analyzing the pulse-wave form that had been obtained using only the force from the spring of the clip and maintaining a constant pressure. To develop an algorithm for distinguishing between a vacuous pulse and a replete pulse using the clip-type pulsimeter, we analyzed data from 120 of the 180 participants. Our results hold forth the possibility that a clip-type pulsimeter equipped with a magnetic-sensing Hall device can be used to distinguish between deficiency syndrome and excess syndrome. In addition, the results of this study may suggest a foundation for an algorithm to identify pulses for deficiency syndrome and excess syndrome.

The efficacy of using a clip-type pulsimeter equipped with a Hall device for magnetic-field sensing of the minute movement of the radial artery was evaluated through a clinical trial. The possible existence of a logistic regression equation for the vacuous pulse and the replete pulse was investigated. Based on the results of a statistical analysis of the clinical pulse data obtained during this study, we developed a logistic regression equation that included the variables age, sex, BMI, and SBP, as well as the pulse-wave variable the S.amp/S.time ratio. This equation could be used to distinguish between the vacuous pulse and the replete pulse. This research demonstrated that the use of a clip-type pulsimeter equipped with a magnetic-sensing Hall device that detects minute movement of the radial artery, along with the developed algorithm, by Oriental medicine doctors in making a diagnosis may be feasible.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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Appendix 1. Deficiency syndrome and excess syndrome judgment questionnaire (translated from Japanese to Korean for use in this study and then to English for this report).

Name: , Phone No: , Age: Sex: , Total score: , Judgment: Read the following questions; please check the correct answer. If you are unsure, proceed to the next question. There are a total of 19 questions [10].	
1. My body type? (1) It is weak. ( ) (2) It is Strong. ( ) 2. My body type? (1) There is fat. ( ) (2) There is muscle. ( ) 3. The color of my face? (1) It is light red. ( ) (2) It is pale or white. ( ) 4. State of my skin? (1) Have fine luster. ( ) (2) Lusterless. ( ) 5. My abdominal muscles? (1) They are soft. ( ) (2) They are hard. ( ) 6. State of my voice ? (1) It is weak. ( ) (2) It is strong. ( ) 7. I overeat? (1) Sometimes. ( ) (2) Never. ( ) 8. I skip meals? (1) I do feel like eating.( ) (2) I want to eat, but I am drained.( ) 9. I have an appetite? (1) Rarely. ( ) (2) Usually. ( ) 10. On average, my bowel movement? (1) Once a day and more than once a day. ( ) (2) Less than once a day, or once in 2–3 days. ( )	11. My excrement? (1) It is loose or diarrhea. ( ) (2) It is hard or constipated. ( ) 12. Excrement is difficult, eat for diarrhea? (1) There is no feeling. ( ) (2) It is refreshing. ( ) 13. My feeling? (1) I am lethargic and easily tired. ( ) (2) I am energetic and stay up all night. ( ) 14. My sweat? (1) I sweat with difficultly. ( ) (2) I sweat easily. ( ) 15. Sweat at my bedtime? (1) I sweat with difficultly. ( ) (2) I sweat easily. ( ) 16. My shoulders? (1) They tense easily. ( ) (2) They rarely tense. ( ) 17. I drink? (1) I prefer a hot drink. ( ) (2) I prefer a cold drink. ( ) 18. I fall asleep? (1) It is easy. ( ) (2) It is difficult. ( ) 19. I? (1) Hands and feet are cold. ( ) (2) The face is warm. ( )

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