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Original article

A case control study using radial artery pulse signals to evaluate the low pulsatility index in Koreans

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Background: Noninvasive radial artery pulse signal analysis has been widely used to assess vascular diseases, but there is no evidence of a relationship between the radial artery pulse signal and pulsatility index.
Objective: To determine whether radial artery pulse signal changes in patients with a low pulsatility index would provide diagnostic information for evaluating vascular disease.
Methods: In this case control study, 36 Korean subjects were distributed into two groups, a normal pulsatility index group and a low pulsatility index group, based on their Doppler test results. Multivariate logistic regression analysis of these two groups was conducted to identify significant radial artery pulse signals for evaluating the low pulsatility index. A receiver operating characteristic (ROC) curve analysis was used to evaluate the logistic model.
Results: The low pulsatility index group displayed significantly different radial artery pulse signals compared with the normal pulsatility index group (A1; primary amplitude of right Cun, σ1; shape of the primary wave of right Chi, τ2: secondary phase of left Cun, σ2/L: ratio of the shape of the secondary wave to the length of a single-period waveform). A predictive value for the low pulsatility index was obtained using binary logistic regression, which included A1, σ1, τ2 and σ2/L. A ROC curve analysis assessed the accuracy of the test for low pulsatility index evaluation (AUC=0.931).
Conclusion: A1 (primary amplitude), σ1 (shape of the primary wave), τ2 (secondary phase), and σ2/L (ratio of the shape of the secondary wave to the length of a single-period waveform) derived from radial artery pulse signals may be used to assess a low pulsatility index in Koreans.

Keywords: Aortic obstruction, pulsatility index, pulse signal, radial artery, vascular disease

Noninvasive radial artery pulse wave analysis has been widely used for assessing arterial stiffness estimation of the aortic pulse wave from the peripheral pulse wave [1, 2]. Furthermore, the radial artery pulse plays an important role in both allopathic and alternative medicine and can be used to detect cardiac and respiratory pathologies [3, 4].

A relationship exists between blood flow and the radial artery pulse. Noninvasive central systolic blood pressure calculated by radial systolic blood pressure is in accordance with aortic systolic blood pressure measured by the invasive method [5, 6]. Furthermore, both radial artery pulse pressure variations and changes in the aortic blood flow peak velocity, are accurate predictors but may be impractical point-of-care tools [7, 8]. In addition, changes in the pulsatility index are highly correlated with various markers of cardiovascular risk [9, 10]. Middle cerebral artery flow pulsatility and basilar artery velocity are higher in patients with right-sided migraine compared with left-sided migraineurs [11,12]. Pulsatility index and resistance index have velocity characteristics that are independently influenced by various parameters of impedance [13-15].

Certain relationships exist between the pulsatility index and vascular disease. Arterial pressure and pulse pressure, combined with the pulsatility index, add valuable information about the circulatory status in the vasculature [16, 17]. Positive end-diastolic flow velocity is correlated with acidosis at birth [18, 19]. After the intravenous administration of magnesium sulfate to patients with severe pre-eclampsia, there is a decrease in the blood pressure and in the pulsatility

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index of the uterus [20, 21]. Moreover, duplex sonographic determination of the hepatic arterial pulsatility index may contribute to the noninvasive evaluation of portal hypertension [22, 23].

Commonly, blood-pressure-lowering effects are involved in decreasing the pulsatility index [24, 25]. The normal reference has confirmed the diagnostic and prognostic capacity of evaluating the fetal middle cerebral artery pulsatility index in high-risk pregnancies [26, 27]. However, the arterial pulse waveform based on the measured human arterial pulse data is necessary for updating and extending the pulse wave database for many cases and symptoms [28, 29].

Therefore, the aims of the present study were: (1) to assess the usefulness of the method for calculating the estimated vascular disease probability that is gained from radial artery pulse signal analysis to detect the low pulsatility index and (2) to determine whether radial artery pulse signal changes in patients with a low pulsatility index provide diagnostic information for the evaluation of vascular disease.

Materials and methods

Pulse signal analyzer

Pulse diagnosis in Oriental medicine is based on the theory corresponding to three positions ('Cun', 'Guan' and 'Chi') of the left and right wrists [30]. This pulse signal analyzer consisted of independent, three-step motors combined with radial pulse tonometry sensors for the detection of each of the three radial artery pulse signals at three different positions ('Cun, 'Guan', and 'Chi'), as presented in **Figure 1**.

Driving part

The driving part consisted of a step motor, a DC motor, and a motor driver. The step motor for the pulse measuring system and the DC motor independently operated in an up-and-down motion for the radial pulse tonometry sensor. While this system operated, the driving part moved slowly downward and stopped when the sensor contacted the subject's skin. Subsequently, the pulse tonometry sensor moved downward until the radial artery pulse signals were the strongest and most precise. Because the observed pulse signals were deemed appropriate, the pulse signal was measured for ten seconds.

Measuring part

The measuring part consisted of a pulse sensor and an analog circuit. This measuring part had three piezoresistive pressure sensors (C33 series, EPCOS, Germany) that could detect the pulse signal from 'Cun', 'Guan', and 'Chi' at the radial artery. These sensors amplified and filtered the pulse signals using the analog circuit and output as the mV by pressing force.

Controller

The controller consisted of a DAQ board and a pulse signal program. The DAQ board functioned as an interface between the DC motor, the motor drive and the program. The program controlled and operated the step motor and the DC motor; in addition, the program analyzed the radial artery pulse signals.

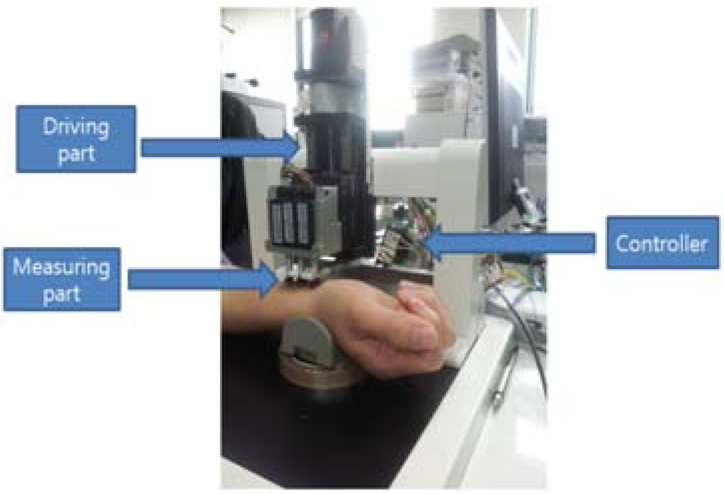

Figure 1. Radial artery pulse signal analyzer

Study design

A case-control study has a widely used design that is often employed in epidemiology. This investigation is an observational study in which two existing groups differing in outcome are identified and compared based on a supposed causal attribute. Additionally, case-control studies are often used to identify factors that may contribute to a medical condition by comparing subjects who have that disease (the "cases") with patients who do not have the condition/disease but are otherwise similar (the "controls").

The present study was designed as a case-control study, which is a type of epidemiological study, and the cases were defined as patients with a low pulsatility index. By contrast, the controls were defined as participants whose pulsatility index exceeded 5.4. All of the parameters relevant to the radial artery pulse signals were analyzed to identify factors related to a low pulsatility index. Using the differences in the radial artery pulse signals between the normal pulsatility index group and the low pulsatility index group, the probability of aortic obstruction was calculated using binary logistic regression.

Participants

The present study included patients who were admitted to the Oriental Hospital of Daejeon University, Korea. In July 2012, we identified patients for inclusion in the study who were aged 20 years or older and had a general medical record at the time of randomization. Of the 123 participants who were randomized for this study, we selected patients with a low pulsatility index and normal subjects (controls) lacking any characteristics of a low pulsatility index. A pulsatility index less than 3.9 indicated significant obstruction, whereas a pulsatility index greater than 5.4 were observed only in limbs without a significant pressure gradient across the aortoiliac segment [31]. We used this criterion for the selection of the low pulsatility index group and the normal pulsatility index group. Based on the above criteria, we selected 36 subjects consisting of 12 patients and 24 controls. We selected the case and control groups based only on the pulsatility index, with the control group representing the general population. Therefore, the control group satisfied the requirement for a normal pulsatility index, but its sample size was not the same as that of the patients. All of the subjects provided informed consent for participation in the study. This study was approved by the institutional review board at the Oriental Hospital of Daejeon University.

Outcome measure

The pulsatility index test was performed by trained medical staff using established methods with a bidirectional portable echo-Doppler of 8 MHz (Bidop ES-100V3; Hadeco, Kawasaki, Japan) and a calibrated mercury sphygmomanometer. To avoid interobserver variations; the same examiner measured all of the pulsatility indexes. Briefly, after the participants had rested in the supine position for 5 min, the pulsatility index was measured in the radial arteries of both arms. Variations existed in the position of the radial artery in the subjects' wrists. To solve this problem, we used six sensors to detect the pulse signal from different positions, and we selected the best-detected data among the six sensors, which were arrayed vertically as shown in **Figure 2**.

A traditional Chinese-medicine practitioner palpates six locations (three points on each wrist, called "cun", "guan", and "chi") and describes the pulses in terms of various characteristics [32]. Therefore, the radial artery pulse signals were measured at the 'cun', 'guan', and 'chi' positions relative to the radial arteries in both hands of each subject.

To extract a feature point, the radial artery pulse signals were measured for 20 seconds for collection by the pulse signal analyzer that we developed. The Gaussian model used in this study may be expressed with seven parameters including A1, A2, $\tau1$, $\tau2$, $\sigma1$, $\sigma2$, and L. A1 and A2 are the amplitudes of two signals, $\tau1$ and $\tau2$ are the phases of the two signals, $\sigma1$ and $\sigma2$ are the width of two bell-shaped signals, and L is the number of points between two consecutive starting points [33]. It is well established that relative values between two signals provide information that is more reliable. Therefore, an additional 7 parameters, including A2/A1, $\tau2/\tau1$, $\sigma2/\sigma1$, $\tau1/L$, $\tau2/L$, $\sigma1/L$, and $\sigma2/L$, were calculated.

Statistical analysis

Characteristics of the normal pulsatility index group and the low pulsatility index group were compared using Fisher's exact test for categorical variables and Student's *t* test and a Mann–Whitney *U* test for continuous variables. Clinical and demographic characteristics were compared to examine the homogeneity and heterogeneity in each group. For the reliability test of the RPT sensor, a Shapiro–Wilk test was used, and if the data were normally distributed, we considered the data obtained by the RPT sensor to be reliable. We analyzed the effectiveness of the radial artery pulse signal diagnosis for evaluating a low pulsatility index by fitting subject-level multivariable logistic regression models to predict the risk of having an aortic obstruction. To verify the logistic regression model, a receiver-operating characteristics (ROC) curve was generated, and the area under the ROC curve (AUC) was obtained. IBM SPSS software (version 20, IBM Corporation, NY) was used for the analysis.

Results

Reliability of the radial artery pulse signal analyzer

For the reliability check for the wrist pulse analyzer, we tested 10 subjects' primary peak waves from the radial artery in both hands. We measured the pulse signals in 3 cycles and compared the average peak wave values using a one-way ANOVA. There was no significant difference in the wrist pulse signals in the measured cycles in either wrist (**Table 1**).

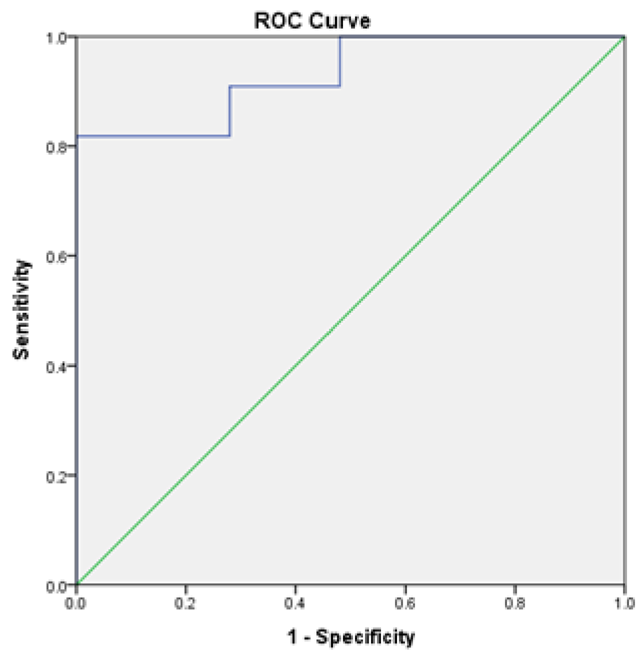

Figure 2. ROC curve for low pulsatility index

Table 1. Primary peaks of radial artery pulse signal

(Mean□SD)

Subjects	Left hand				Right hand			
	1st	2nd	3rd	*P*	1st	2nd	3rd	*P*
1	108.3±0.7	108.8±1.0	107.5±2.0	0.109	9.5±0.4	9.8±1.0	10.3±0.9	0.091
2	5.9±1.8	5.5±1.7	7.4±2.0	0.067	43.3±13.2	52.0±0.7	46.3±2.8	0.055
3	2.0±2.1	3.6±1.8	2.9±1.9	0.207	3.8±1.9	4.7±2.0	2.7±1.6	0.056
4	21.0±5.3	21.2±1.9	24.0±0.2	0.085	16.9±0.6	17.1±0.4	17.5±0.6	0.065
5	29.4±4.6	28.8±2.5	31.6±5.9	0.364	24.9±3.8	24.5±0.8	26.0±3.4	0.532
6	22.0±10.3	20.1±3.6	25.8±0.7	0.140	25.3±6.1	26.2±3.1	28.6±4.5	0.310
7	11.7±9.8	13.4±3.1	18.8±4.8	0.055	28.5±1.4	29.3±0.5	29.1±0.5	0.127
8	5.7±4.0	5.2±2.2	7.2±1.4	0.255	8.0±1.3	7.9±1.3	7.0±1.6	0.282
9	48.6±1.8	49.9±1.7	49.0±0.7	0.129	24.8±4.5	25.6±1.7	27.5±1.3	0.124
10	9.0±1.6	9.9±1.6	10.8±1.4	0.055	13.9±3.4	14.7±1.2	15.9±2.3	0.131

Table 2. Characteristics of participants

(N(%), Mean±SD)

Variables		Normal PI group (n=25)	Low PI group (n=11)	*P*
Sex	Male	19 (52.8%)	8 (22.2%)	0.571
	Female	6 (16.7%)	3 (8.3%)	
Smoking	Nonsmoking	17 (47.2%)	6 (16.7%)	0.342
	Smoking	8 (22.2%)	5 (13.9%)	
Age (years)		30.3±6.9	26.3±5.6	0.124
Height (cm)		173.6±7.7	171.8±4.6	0.470
Weight (kg)		68.3±11.7	62.5±8.4	0.151
Body Mass Index (kg/m^2)		22.5±2.8	21.1±2.1	0.144
Systolic blood pressure (mmHg)		128.6±16.3	123.7±10.2	0.288
Diastolic blood pressure (mmHg)		73.1±10.1	67.6±8.0	0.124
Heart rate (beat/min)		72.4±10.9	83.5±12.0	0.010
Right PI		17.0±13.6	1.7±0.6	<0.001
Left PI		14.6±18.9	2.1±0.5	<0.001

Characteristics of the participants

The characteristics of the participants are listed in **Table 2**. Of the 36 participants, the normal pulsatility index group included 25 subjects (52.8% men and 16.7% women), and the low pulsatility index group included 11 subjects (22.2% men and 8.3% women) who underwent radial artery pulse signal analysis. Gender, height, weight, body mass index, smoking status, systolic blood pressure, and diastolic blood pressure showed no statistically significant differences between the normal pulsatility index group and the low pulsatility index group. The heart rate was higher in the low pulsatility index group but was similar to the normal range.

Multivariate analysis of the relevant factors of an abnormal lipid profile

Table 3 shows the relevant variables that were included in the logistic regression model for evaluating the low pulsatility index. Using the pulsatility index results of the subjects, we categorized the patients into either the normal pulsatility index group or the low pulsatility index group. Next, we defined the dependent variable as the different pulsatility index group, and the independent variables were gender, age, systolic blood pressure, diastolic blood pressure, height, weight, BMI, heart rate, and all of the radial artery pulse signals in both hands. The variables included in the logistic regression model were tested by the significance of score statistics and excluded variables in the logistic regression model tested the probability of Wald statistics estimates. Four significant variables in the final logistic regression model remained after all of the variables were tested, and these four variables were found in "Cun" and "Chi" positions in both wrists. A1, $\tau 2$, $\sigma 1$, and $\sigma 2/L$ were the significant relevant factors for low pulsatility index evaluation. Therefore, we used a regression equation employing these variables for the low pulsatility index evaluation, and this equation calculated the probability of the subject having aortic obstruction using radial artery pulse signals, as follows:

$$P = \frac{1}{1 + e^{-(-0.120 \times \text{Right Cun A1} - 1.181 \times \text{Right Chi } \sigma 1 + 0.068 \times \text{Left Cun } \tau 2 + 1.884 \times \text{Left Chi } \sigma 2/L - 1.561)}}$$

Table 3. Multivariate analysis of wrist pulse signals

Variables	Regression coefficient β	Odds Ratio (e^{β})	95% CI	*P*
Right Cun A1	–0.120	0.887	0.784–1.004	0.057
Right Chi $\sigma 1$	–1.181	0.307	0.108–0.877	0.027
Left Cun $\tau 2$	0.068	1.071	0.985–1.164	0.110
Left Chi $\sigma 2/L$	1.884	1.734	1.262–2.059	0.014
Constant	–1.561			0.760

ROC analysis

Using the above-described logistic model, ROC analysis was conducted as depicted in figure 5. The area under the ROC curve for that model was 0.931 (95% CI: 0.833-1.000, $p<0.001$). We used Youden's index to identify the optimal cutoff point for the low pulsatility index evaluation, which is described in **Table 4**. The optimal cutoff point implies the greatest Youden's index, which was 0.617 based on the low pulsatility index evaluation. For the optimal cutoff value, the sensitivity was 81.8%, the specificity was 100.0%, and the maximal Youden's index was 0.818.

Discussion

The most important finding in the present study was the association between the radial artery pulse signal and the low pulsatility index in the Korean subjects. The results of our study revealed that four major variables associated with a low pulsatility index in Koreans, including right Cun A1, right Chi $\sigma1$, left Cun $\tau2$ and left Chi $\sigma2/L$, were the most important predictors among the radial artery pulse signals. In clinical practice, these variables might be crucial surrogate indicators for a low pulsatility index and may be typically observed patients with in aortic obstruction. Likewise, A1, $\sigma1$, $\tau2$, and $\sigma2/L$ derived from the radial artery pulse signals were reasonable indicators of a low pulsatility index.

This pulsatility index might be considered in the evaluation of various diseases. The middle cerebral artery pulsatility index decreases as the gestational age increases, namely, from 1.97 at 20 weeks to 1.15 at 37 weeks [34]. Furthermore, normalization of the pulsatility index may improve the predictive values for small-for-gestational age infants and cesarean delivery in pregnancy-induced hypertension [35]. Certain radial artery detection methods might not be appropriate for the diagnosis. Radial artery applanation tonometry is not suitable to determine the cardiac output in critically ill and hemodynamically unstable patients [36]. However, applanation tonometry and pulse wave analysis are minimally invasive methods that are suitable to assess endothelium-dependent vasodilation [37].

Our AUC result (0.931) for radial artery pulse signals of a low pulsatility index might be greater than the AUC associated with aortic obstruction. Based on the results, radial artery pulse signals enable the physician to diagnose aortic obstruction using a pulse signal analyzer. Generally, the area under the receiving operator characteristic curve criterion is specifically designed for the classification of binary outcome data [38]. Additionally, the area under the receiver operating characteristic (ROC) curve is a measure of diagnostic test accuracy, and a model may define information regarding the test accuracy [39]. Therefore, the method in the present study might be appropriate for radial artery pulse signal-based evaluation of a low pulsatility index.

It is difficult to draw a conclusion as to the predictive value of radial artery pulse signals for the low pulsatility index. Although the AUC was 0.931, it appears to be insufficient for aortic obstruction evaluation using radial artery pulse signals. Therefore, our future research will investigate the utility of an elevated AUC of the radial artery pulse signal for diagnosing aortic obstruction.

This study applied several dependent variables for the low pulsatility index; however, there are other variables used to characterize aortic obstruction, such as the resistance index, systolic velocity and diastolic velocity. Therefore, several variables should be considered for aortic obstruction. Generally, binary logistic regressions apply 0.5 as the cutoff point, but in our model, a cutoff point of 0.5 was not appropriate because of the low sensitivity. Based on Youden's index, a cutoff point of 0.617 was the optimal value for low pulsatility index evaluation using radial artery pulse signals. Therefore, we recommend a cutoff point of 0.617 for low pulsatility index evaluation using radial artery pulse signals.

Table 4. Optimal cutoffs value and AUC

Best Cutoff value	Sensitivity (%)	Specificity (%)	Youden's Index
0.617	81.8	100.0	0.818
AUC	Standard error	95% CI	*P*
0.931	0.050	0.833–1.000	<0.001

Based on our research, assessing vascular disease risk might require consideration of the probability of a low pulsatility index associated with the radial artery pulse signal. This initial study was not designed to supply a definitive answer regarding the relationship between vascular disease and the radial artery pulse signal. A definitive answer will only be obtained from more thorough and detailed studies of this potentially valuable and complex relationship.

Conclusion

The radial artery pulse signal is associated with a low pulsatility index in some Korean subjects; the right Cun A1, right Chi σ1, left Cun τ2, and left Chi σ2/L of the radial artery pulse signals is correlated with a low pulsatility index. ROC analysis indicated that the optimal cutoff value for a low pulsatility index evaluation using the radial artery pulse signal is 0.617 in association with aortic obstruction. Several characteristics of the radial artery pulse signals might be used to assess the low pulsatility index in Korean individuals.

Acknowledgments

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