NEW STANDARD CRITERIA FOR COLD PROVOCATION TEST WITH HAND IMMERSION FOR CASES OF HAVS IN JAPAN

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1. INTRODUCTION

In Japan, physicians diagnose hand-arm vibration syndrome (HAVS), a peripheral circulatory disorder, with a cold provocation test (Harada et al., 1999). However, there are no standard protocols for the performance of this test, although several standards have been proposed and used for diagnosis of HAVS. The inconsistencies have led to confusion among practitioners who treat patients with HAVS, and there is demand for a national standard. ISO 14835-1:2005 recommends that the cold provocation test be performed with 12°C water and immersion of the hands for 5 min. However, there is extensive data in Japan where the cold-water provocation test is performed in 10°C water for 10 min. This study aimed to establish a national standard for cold-water provocation tests based on an analysis of Japanese multi-institutional data.

2. METHODS

We collected data from 872 individuals (667 patients, 205 controls) who underwent cold-water provocation testing (10°C for 10 min) at 7 institutions. Data from 340 individuals (280 patients 280, 60 controls) met the selection criteria for analysis (Table 1).

Table 1. Subject selection criteria

Items	Conditions
Age (yrs)	40-69
Sex	Male only
Vibration Exposure and Diagnoses	
Controls	None or < 500 h
Patients	More than 500 h
VWF	+ve within 1 yr of cold provocation test
Complication	No complications of collagen diseases and arteriosclerosis obliterans (ASO)
Testing Conditions	
Season of year	Autumn to winter
Test room T (°C)	20 – 23

2.1. Analysis Index

Three (3) indices were used for the analysis of finger skin temperature:
1) finger skin temperature before immersion,
2) finger skin temperature 5 min after immersion, and
3) finger skin temperature 10 min after immersion.

2.2. Evaluation System

We incorporated the scores from the above 3 indices into an evaluation system that logically combined them. We used the cut-off values for evaluation of the 3 indices. The 5th and 30th percentile cut-off values in the control group were applied (Table 2).

Table 2. The cut-off values for each evaluation systems

Cut-off value	5th percentile	30th percentile
Before immersion (°C)	24.5	30.0
5 min. after immersion (°C)	14.0	15.5
10 min. after immersion (°C)	15.5	18.0

Scored method

If the skin temperature at each time point (the 3 indices) was lower than the value of 5th percentile value, the score was 2 points. If the skin temperature was higher than the 30th percentile value, the score was zero. The score was 1 point in all other cases. The total scores were classified as, "highly abnormal" (total score $\geq$ 4 points), "slightly abnormal" (2 points $\leq$ total score $\leq$ 3 points), and "normal" (total score $\leq$ 1 point).

Logical method

First, we assigned the skin temperature for each index to 3 ranges based on the cut-off values, "normal range" ($\geq$ 30th percentile)", "abnormal range" (5th percentile $\leq$ value $\leq$ 30th percentile)" and "highly abnormal range" ($\leq$ 5th percentile)" for each index. According to the logical combination of these levels, we judged subjects "normal" when all 3 indices were within "normal range". When 1 or

more indices were in the "highly abnormal range", the case was judged "highly abnormal". All other cases were judged "slightly abnormal".

3. RESULTS

The mean ages of the patients and control groups were 59.4 and 51.1 years, respectively. The mean exposure duration to vibration was 22.5 years in the patient group. The most frequently used vibrating tools were chain saws (34%) and chipping hammer (25%) in the patient group. In contrast, bush cutters were used only by members of the control group. When compared to the control group, members of the patient group with vibration white finger (VWF) had significantly lower average values for the 3 indices (Table 3).

Table 3. The comparison of skin temperature at 3 points during cold provocation test between two groups.

Finger skin temperature (℃)	Patient Group (n = 280)	Control group (n = 60)	Statistics
Before immersion	27.4	30.6	P<0.001
5 min. after immersion	15.3	18.0	P<0.001
10 min. after immersion	17.6	21.9	P<0.001

According to the scored method, 28.3% and 71.7% of patients were designated normal and abnormal, respectively. The control group was 72.0% normal and 28.0% abnormal. The logical method designated 29.4% and 70.6% of patients as normal and abnormal.

The sensitivity and specificity of the scored method were 71.7% and 72.0%, while the logical combination evaluation system yielded sensitivity and specificity values of 70.6% and 74.0% (Table 4).

Table 4. Sensitivity and specificity of diagnosis by two evaluation methods.

Evaluation system	Sensitivity (%)	Specificity (%)
Scored method	71.7	72.0
Logical method	70.6	74.0

4. DISCUSSION

We propose two standard criteria after performing an analysis of data from seven Japanese institutions. This study provides new standard criteria for the evaluation of peripheral circulatory disorders, and for the diagnosis of HAVS.

Several Japanese groups have proposed standard criteria for evaluation of cold provocation test with hand immersion for 10 min in 10°C water. However, the choice of which criteria to apply remains at the physician's discretion. Variations in criteria lead to variations in the evaluation of peripheral circulatory function. Many measurement parameters have been used in the evaluation of the cold provocation test, such as rewarming time to room temperature, and rewarming rate at 5 and 10 min after immersion, but skin temperature has not been used (Harada, 2008). We used three skin temperature measurements in this study. We did not apply the common Japanese parameters of rewarming rate. There is some possibility of underestimation in the cases of low skin temperature before immersion.

In this study, we applied two methods for evaluation. There was little difference between the methods' sensitivity and specificity. However, while it was easy to convert the data to scores by weighting according to the scoring method, the logical method was practical and easy to perform. We believe it to be the better choice for defining standard criteria.

When we use these criteria, we should consider several points. Firstly, we could not strictly apply these criteria to patients without VWF. We examined the application of the criteria only in patients with VWF. This problem still remains to be solved in a future study. Second, the provocation test should be performed under the measurement conditions recommended by ISO. In recent years, there has been growing controversy regarding the diagnostic ability of the cold provocation test in distinguishing patients with VWF. These standard criteria are only one evaluation method for diagnosing peripheral circulatory disorder in patients with HAVS. Diagnosis of HAVS should involve a comprehensive evaluation including occupational history, subjective symptoms, physical examinations, and laboratory examinations.

5. CONCLUSION

New national standard criteria are expected to facilitate the diagnostic ability for the cold provocation test used in Japan.

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