Different Conditions of Cold Water Immersion Test for Diagnosing Hand-Arm Vibration Syndrome

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Abstract

The cold water immersion test with finger skin temperature (FST) measurement is used to assess vascular disorders in hand-arm vibration syndrome (HAVS). The test method is currently being standardized within the International Organization for Standardization (ISO) in which a water temperature of 12°C for 5 min of hand immersion and an option of using a waterproof hand covering during immersion are proposed. It is necessary to evaluate the diagnostic significance of the test with FST measurement under different conditions to provide a proper management of HAVS patients. The aim of this article is to review research findings of this test with FST measurement and discuss test conditions influencing the results and diagnostic significance.

Different conditions were employed, and the test results were shown to be influenced by water temperature, immersion time and other conditions such as room temperature, season, ischemia during immersion, and evaluation parameters. These factors need to be considered in the standardization of the cold water immersion test with FST measurement. It has been mentioned that a high water temperature, a short immersion time and other conditions should be chosen to expose a subject to minimal suffering during the test. A water temperature between 10°C and 15°C and a 5 min immersion might be suitable for the cold water immersion test. The reported sensitivity and specificity evaluating rewarming to the initial temperature for the test using a water temperature of 12°C and a 3 min immersion are 58% and 100%, respectively; these are low but similar to those for the water immersion test at 10°C. Therefore, the proposed cold water immersion test at 12°C for 5 min by the ISO (Draft International Standard) is the focus of much interest, and further studies are needed to obtain sufficient data for evaluating the diagnostic significance of the test. At present, the test needs to be used together with a test battery.

Key words: hand-arm vibration syndrome, cold water immersion test, different conditions, finger skin temperature, diagnostic significance

Introduction

At present, almost 1% to 4% of the working population are assumed to be exposed to hand-transmitted vibration since the introduction of hand-held vibrating tools, and it was found that the prevalence of vascular symptoms in workers using vibrating tools can be as high as 70%, depending on the type and duration of exposure (1). For the assessment of the vascular components of the upper extremities in patients with the hand-arm vibration

syndrome (HAVS), the measurement of finger skin temperature (FST) in response to hand immersion into cold water is used with a battery of other tests. The cold water immersion test with FST measurement is under discussion and currently being standardized as a Draft International Standard (DIS) within the International Organization for Standardization (ISO) in which a water temperature of 12°C for 5 min of hand immersion and an option of using a waterproof hand covering during immersion are proposed (2).

It was reported that in the hand, 90% of skin blood flow passes through the thermoregulatory bed and 10% passes through the nutritional capillaries (3). The measurement of skin temperature during the cold water immersion test is an interesting method of evaluating finger circulation. Thermocouples (4) and infrared thermometry (5) are used in the measurements. Since the start of extensive discussions in the 1960s on the

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diagnosis and methods of preventing the hand-arm vibration syndrome, the cold water immersion test with FST measurement using different water temperatures and hand immersion times such as 0°C for 30 sec (6), 4°C for 1 min (7, 8), 4°C for 15 min (9), 5 and 5–7°C for 1 to 20 min (6, 10–13), 10°C for 3 to 10 min (12, 14–25), 12°C for 3 min (5), 14°C for 5 min (26), and 15°C for 1 to 10 min (5, 12, 27–29) for the evaluation of peripheral circulatory disturbance in affected fingers has been investigated by many researchers in Europe, North America, and Japan. It is necessary to evaluate the diagnostic significance of the test with FST measurement under different conditions to provide a proper management of HAVS patients. We previously reviewed research findings of the cold water immersion test with FST measurement and discussed test conditions influencing the results and the diagnostic significance of this test (17, 30). The aim of this review is to update information on the basis of studies already reported in the earlier review and recent reports available in the field and discuss the diagnostic significance of the cold water immersion test under different conditions during immersion.

Pathophysiology of vibration-induced white finger (VWF)

VWF is a typical symptom of HAVS, which is an exaggerated digital vasoconstrictor response to cold or emotional stress causing a sudden interruption in finger blood flow (31). A blanched finger does not bleed when cut, which indicates that the cutaneous blood vessels at this stage have expelled their contents (32). This may be due to hyperactivity of the sympathetic nervous system (33), hypertrophic changes in digital arterial walls (34, 35) or a severe nerve injury with nerve fibrosis and demyelization in the forearm proximal to the wrist (36). Patients with HAVS may have a decreased parasympathetic activity (37–39). Takahashi et al. (40) reported that HAVS patients had a lower cardiac parasympathetic activity than healthy age-matched controls, particularly in winter. They also reported that the response of the autonomic nervous system to cold stimulation was to some extent more clearly observed during the immersion test with water at 10°C and a 10 min immersion than during the test with water at 15°C and a 3 min immersion. The main pathophysiological mechanism underlying VWF has not yet been established; although some hypotheses have been proposed as follows. There may be an imbalance between endothelin-1 (ET1), a very potent vasoconstrictive peptide, and calcitonin-gene-related peptide (CGRP), a powerful vasodilator present in digital cutaneous perivascular nerves (41). During cold exposure in normal subjects, the vasoconstrictive effect of ET1 is counterbalanced by the vasodilative effect of CGRP, but in VWF patients there is a significant loss of CGRP in nerve fibers, and the vasospastic effect of ET1 is then predominant (42). In addition, ET1 is probably also involved in sympathetic nervous system activation (43), aggravating the vasospastic phenomenon (44). It has been pointed out that the cold water immersion test with FST measurement before, during and after cooling reflects the vasodilatation phase (19). A lower FST is expected to reflect a persistent abnormality of finger blood flow in patients with

HAVS. Many workers exposed to vibration complain of a cold sensation in their fingers and hands in their daily life (7). This cold sensation is caused by the persistent decrease in arterial blood flow in the fingers and hands. The cold water immersion test stimulating the sympathetic tonus based on FST measurement could improve the diagnosis of this abnormality.

Cold water immersion test with FST measurement

Searching the literature

To search the literature (Medline), we used some keywords such as the cold provocation test, cold immersion test, cold stress test, finger skin temperature, and hand-arm vibration syndrome. We also used “Proceedings” published in related fields. References in the articles were also examined for relevant information that may be cited in this paper.

Publications from Japan

Thirty-three publications from Japan on the cold water immersion test with FST measurement were included in an earlier review (17). Different water temperatures and immersion times were used, and as a result of discussions among Japanese researchers, a water temperature of 5°C and a 10 min hand immersion at a room temperature from 20°C to 23°C were considered most suitable for diagnosing HAVS. Thereafter, the Japanese Ministry of Labor accepted the test under the above conditions as the basis for the compensation of affected workers in 1975 (45).

In several studies, the results of cold water immersion tests at 5°C and 10°C were compared, showing that the diagnostic significance is relatively greater in the case of using water at 5°C than that using water at 10°C (17). However, the suffering during the cold water immersion test using water at 5°C was severe and the test using water at 10°C was determined to be acceptable on the basis of a positive correlation in FST between tests and a reduced suffering of subjects (17). At present, the immersion of one hand into cold water at 10°C for 10 min is a widely accepted method in Japan.

There were some publications (46–49) from Japan regarding FST measurements that were found available after the review by Harada et al. (17). Yoshimura et al. (46) reported that positive group differences in FST measures between HAVS patients and age-matched controls were found during and after immersion using the test method with water immersion at 10°C for 10 min (method generally accepted in Japan) but not in the case of the test method with water immersion at 15°C for 3 min (method used in France). Ishitake et al. (47) reported that the responses of FST in the test method with water immersion at 5°C and 10°C are strongly correlated to room temperature. Using the test method with water immersion at 10°C for 10 min, Sakakibara et al. (48) found that the FST of the immersed right hand is significantly lower in VWF patients than in controls during the last five minutes of the immersion and in the recovery period. These findings indicate that the sympathetic nervous system response to cold is significantly enhanced in VWF patients. Suizu et al. (49) compared the effects of polyethylene gloves on FST and subjective pain score during cold water immersion tests at 10°C, 12°C and 15°C for 5 min.

They found that the FSTs for the test using polyethylene gloves are higher by about 1°C than those for the test with bare hands at 5 min of immersion. The hand cooling effect during immersion with polyethylene gloves is smaller than that with bare hands at all three water temperatures; the difference at 10°C tends to be larger than those at 12°C and 15°C. The time to recovery of FST and some FST measures with polyethylene gloves also tend to be larger than those with bare hands; the differences are almost similar among the three water temperatures. Furthermore, the pain scores indicate that the subjects' suffering can be reduced using polyethylene gloves during immersion. The difference in subjective pain score between using gloves and bare hands at 10°C tends to be larger than those at 12°C and 15°C. These findings indicate that subjective pain during the cold immersion test with polyethylene gloves can be reduced while the differences in FST between the tests at water temperatures of 10°C and 12°C were small or not apparent at some points during immersion and recovery.

Publications from countries other than Japan

Twenty-three studies were reviewed by Harada in 2002 (30). A review paper (17) summarizing the method with water immersion at 10°C for 10 min, a representative widely accepted test method in Japan, was included. Other papers (4, 5, 10–16, 19–29) were from countries other than Japan. The paper by Hack et al. (12) has three parts describing test methods with water at 5–7°C, 10°C and 15°C. There were seven publications from countries other than Japan that were found available after the review by Harada et al. (17), which employed the cold water immersion test with FST measurement (50–56).

Diagnostic significance

Studies considered in this paper

Twenty-three studies reviewed by Harada in 2002 (30) and another seven recent studies (50–56) are considered in this present review to update information on the diagnostic significance of cold water immersion test under different conditions during immersion (all the thirty studies are summarized in Table 1).

Findings and discussion

Findings related to water temperature and immersion time

Various combinations of cold water temperature and hand immersion time were used by different researchers. Water temperatures varied between 5°C and 15°C, and durations of hand immersion between 1 min and 20 min among these 30 studies. Because of the severe subjects' suffering during the cold water immersion, higher temperatures of cold water and shorter hand immersion times have been used in recent studies. Hand conditions during immersion have varied between wet or dry and ischemic or nonischemic. Ten studies involved the induction of ischemia in the hand(s) during the entire period or the initial 5 min of immersion. Ischemic induction commonly used in the 1980s is not common in recent studies. Among the thirty studies, seventeen (10–17, 19–25, 51) involved water immersion at lower than 12°C, one (5) at 12°C and twelve (4,

12, 26–29, 50, 52–56) at higher than 12°C. The sensitivity and specificity of the cold water immersion test for distinguishing VWF patients from healthy workers were addressed in eleven studies (5, 11, 12, 17, 19, 22, 23, 25, 51, 53, 56), including the review on studies from Japan (17), and one study included workers with tingling or numbness but without VWF as the affected subjects (12). The reported sensitivity and specificity are similar and not satisfactorily high for all studies using different water temperatures and immersion times. A significant positive group difference was reported in six studies (12, 14, 16, 21, 51, 52) of tests mainly with water temperatures of 10°C or lower; with one exception at 15°C (52). A negative group difference was reported in three studies (12, 26, 56) using a water temperature of 14°C in one and 15°C in others. A positive difference between affected and nonaffected fingers was reported in one study (49) and a negative difference in another (13) in which difference was tested between fingers with and without VWF at a water temperature of 5°C and immersion for 20 min. To date, there have not been sufficient data supporting the diagnostic significance of the cold water immersion test at 12°C.

In a study by McGeoch et al. (50) using the cold water immersion test at 15°C for 5 min, the FSTs return to 22°C within 5 min and to 30°C by 10 min were evaluated in workers exposed to hand-arm vibration. When FST at the start of the test was less than 28°C the test was terminated. The test was not accepted when cooling could not be achieved at lower than 17°C. A scoring system was used for the test: score 0, FST returned to 22°C within 5 min and to 30°C by 10 min; score 1, FST failed to return to 22°C within 5 min but returned to 30°C by 10 min; and score 2, FST failed to return to 22°C within 5 min and to 30°C by 10 min. The authors reported that the results were not associated with the vascular staging defined according to the Stockholm Workshop Scales (SWS). The study lacks a control group of subjects without hand-arm vibration. Coughlin et al. (51) reported that the cold water immersion test at 5°C for 1 min has good sensitivity, specificity, positive predictive value and negative predictive value; it strongly supports the clinical diagnosis of digital vasospasm. The sensitivity and specificity they reported are both nearly 100%. Lindsell et al. (52) assessed 21 alternative parameters of interpreting the response of FST to the cold water immersion test at 15°C for 5 min. Differences in response to cooling between fingers reported to blanch and fingers not reported to blanch were tested, and receiver operating characteristics (ROCs) were used to compare the sensitivity and specificity of various measures of VWF symptoms. They found that the area above the response profile, the percentage of initial temperature at the 5-min recovery and the maximum temperature achieved during the 10-min recovery period show the highest sensitivity and specificity to the symptoms of vascular dysfunction, indicating that these are the most suitable measures for monitoring vascular function in workers exposed to hand-transmitted vibration. However, some of these parameters for interpreting the FST response to cold provocation such as time to rise by 3, 4 or 6°C from the lowest finger temperature did not show a high sensitivity or specificity to vascular dysfunction in individual fingers making them unsuitable for detecting

Table 1 Studies using cold water immersion tests with finger skin temperature (FST) measurement for diagnosis of hand-arm vibration syndrome (HAVS) (an earlier review (30) included twenty-three studies, which are presented in this Table starting from the top)

Reference number	Year	Cold water immersion test			Test room		FST parameter	Diagnostic significance		Remarks
		Immersion	Water temperature (°C)	Time (min)	Temperature (°C)	Adaptation period (min)		Sensitivity %	Specificity %	
13	1970	One hand	5	20	25–28	60	Cold-induced vasodilation			Finger difference (–)
11	1987	One finger	5 ^b	5	22–24	30	Percentage recovery at 20 min after immersion	60	92	
10	1991	Both hands	5 ^c	1	25±1	45	Rewarming time and rewarming pattern after immersion			
12	1986	Both hands	5–7	15	20–22	15	FST at 3, 5 and 7 min after immersion			Group difference (+)
12	1986	Both hands	10 ^d	10	20–22	15	Rewarming at 3 min after immersion	73	74	
25	1983	One hand	10 ^d	10			Rewarming at 3 min after immersion	72	82	
22	1985	One hand	10 ^d	10	30 ^e		FST recovery to 30°C after immersion	65/80	43/80	
23	1987	One hand	10 ^d	10	20–23 ^e		FST recovery to 30°C and rewarming time after immersion	73/76	52/43	
24	1992	One hand	10 ^d	10			FST recovery to 30°C and rewarming rate after immersion			
21	1986	One hand	10	10	24–25		FST at 0, 5 and 10 min after immersion			Group difference (+)
20	1988	One hand	10	10	23–25		FST after immersion			
18/19	1990/91	One hand	10	10	20–23	20	Rewarming rate and rewarming temperature _{max} after immersion	67/69	70/68	
17 ^a	1999	One hand	10	10	20–23	30	FST at 5 and 10 min after immersion	22–44	85–98	
16	1981	One hand	10 ^b	5	22–24 ^e	15	Rewarming time to room temperature after immersion			Group difference (+)
15	1994	Both hands	10 ^b	5	21	30	Rewarming time to room temperature after immersion			
14	1986	One hand	10 ^b	3 ^e			Rewarming time to 21°C after immersion			Group difference (+)
5	1998	Both hands	12	3	22	20	Rewarming to initial temperature after immersion	58	100	
26	1990	Both hands	14	5	30/14	60/20	FST at 0, 10, 15 and 20 min after immersion			Group difference (–)
12	1986	Both hands	15 ^d	10	20–22	15	Rewarming at 3 min after ischemia during immersion			Group difference (–)
29	2000	One hand	15 ^e	5	22±2	15	Rewarming time after immersion			

Table 1 (continued)

Reference number	Year	Cold water immersion test		Test room		FST parameter	Diagnostic significance		Remarks
		Immersion	Water temperature (°C)	Time (min)	Temperature (°C)	Adaptation period (min)	Sensitivity %	Specificity %	
28	1992	Both hands	15	3	21±1	10			
4	1995	Both hands	15	3	21±1	15			
27	1987	Both hands	15	1	22–24	20			
50	2000	One hand	15	5					
51	2001	Both hands	5 ^c	1	25	45			
52	2000	One hand	15 ^c	5	23.4±1.3		~100	~100	Results were not associated with vascular staging Group difference (+) Finger difference (+), Group difference (+), except for time to rise by 3, 4, 6°C, %initial-temperature at 10 min of recovery
53	2003	Both hands	15 ^c	5		Stabilizing period of 2 min	66	59	
54	2003	Both hands	15 ^c	5		Stabilizing period of 2 min			
55	2003	Both hands	15 ^c	5	20–22				
56	2004	Both hands	15 ^c	5		Stabilizing period of 2 min	71	77	Vascular staging of 52490 compensation claimants for HAVS: with no vibration-induced white finger (VWF) attack =21%, and with VWF attack(s) =79% A group of 19909 miners for vascular assessment: positive test result in 53.7%, and negative test result in 46.3%

^a represents publications by Japanese authors, ^b ischemia during immersion, ^c thin water proof covering, ^d ischemia for initial 5 min during immersion, ^e use of hot blanket.

blanching amongst the subjects. Lindsell et al. suggested that the FST response to cold provocation should be interpreted with respect to the state of initial blood flow. Mason et al. (53) investigated the diagnostic significance of the cold water immersion test at 15°C for 5 min in miners exposed to hand-arm vibration. The time to rise by 4°C from the lowest finger temperature was used as the output metric from the cold water immersion test. Using normative data for the time to rise by 4°C, the time <300 sec was considered normal and ≥300 sec abnormal. The authors found that the rewarming time was significantly lower in subjects classified into SWS vascular stage 0 than those classified into stages 1–3 combined, but the results did not discriminate between the stages of abnormality. Using the suggested cut-off value, the sensitivity and specificity were calculated as 43 and 78%, respectively. ROC suggested that the rewarming time of highest accuracy gave a sensitivity of 66% and a specificity of 59%. In 10 miners who reported unilateral hand blanching, there was no significant difference in rewarming time between blanched and nonblanched hands. In an attempt to establish a single medical assessment process for determining general damage in workers exposed to hand-arm vibration, Lawson et al. (54) investigated 52490 claimants and reported that 21% of these claimants were at 0V, 13% at 1V, 38% at 2V and 28% at 3V according to a modified SWS. The time to rise by 4°C from the lowest finger temperature was used as a parameter for the cold water immersion test. This was found to be <300 sec. When one finger had a time to rise by 4°C ≥300 sec, then the findings of the entire test were considered abnormal. A scoring system was used for the test: score 0, when the time to rise by 4°C was ≤300 sec; score 1, when the time to rise by 4°C was >300 sec and ≤600 sec; and score 2, when the time to rise by 4°C was >600 sec. They also used vibrotactile thresholds (VTT), thermal aesthesiometry (TA), and time for questioning by a doctor for medical history and clinical examinations (doctor's time). The average testing times were 31 min for TA, 18 min for VTT, 21 min for cold water immersion test, and 38 min for the doctor's time, making an overall assessment time of 1 hour and 48 min for an individual claimant. Four claimants were examined per session of 4 hours. The protocol of time schedules is not clear enough from their report. It is notable that their study lacks subjects without hand-arm vibration as a control group. In a similar study, Proud et al. (55) reported results of the cold water immersion test of 19909 miners at 15°C for 5 min. They used similar parameters and scoring conditions for the test to those of Lawson et al. (54). It is mentioned in their report that after a stabilizing period of 2 min, the hands were placed inside plastic gloves and then immersed. However, the duration of the accommodation of subjects in the test room is not clear. A positive result of the cold water immersion test was recorded in 10692 miners (53.7%) and 9217 (46.3%) had bilateral negative results. They suggested that the cold water immersion test at 15°C, with the measurement of digital rewarming times, has no value in assessing vibration-induced damage to the hands as clinical severity correlated only very slightly with test results. In the assessment of vascular HAVS, Poole et al. (56) investigated and compared the diagnostic significance of the cold water immersion test at 15°C for 5 min involving the rewarming of

the finger skin. The time to rise by 4°C from the lowest finger temperature was used as the output metric of the cold water immersion test. The time <276 (right middle finger) or 261 (average of all fingers of the right hand) sec was considered as normal. The authors found no difference in the time for FST to rise by 4°C between HAVS patients and controls. The sensitivity and specificity of the time for FST to rise by 4°C were 71 and 77%, and by ROC 68% and 71%, respectively. They concluded that the above-described form of finger rewarming during the cold water immersion test is a useful diagnostic test for vascular HAVS, although it may have some moderate influence on ruling out vascular problems.

The conditions of cold provocation should be chosen so as to achieve maximal vasoconstriction with minimal suffering of subjects (56). A water temperature lower than 10°C for the cold water immersion test can cause a cold-induced vasodilation (57), the hunting phenomenon (58) and pain (59, 60). On the other hand, a higher water temperature will be insufficient to cause vasoconstriction in patients with HAVS. The evaluation parameters used by different researchers varied among studies, and fell into two main types: rewarming indices during immersion and rewarming indices after immersion. The differences in parameters used for evaluating abnormality might influence diagnostic significance. It has been argued that there is currently insufficient evidence that supports the diagnostic significance of the test at water temperatures of approximately 15°C (30). In some recent studies (50, 53–56) with analyses of a large claims database, the diagnostic significance of the cold water immersion test at 15°C has been questioned. From the reports of these studies, it may be argued that there may be some difficulties in most of these studies regarding the protocol of time schedules for examining the subjects in a session with different examinations that may have influenced their study results. Furthermore, the time to rise by 4°C was used in these studies as a parameter of interpreting the FST response to cold provocation, which was considered an unsuitable parameter (52). These studies have been met with some criticism regarding the conduct of the testing (61), interpretation of results (62, 63) and other concerns (64). At present, there is no perfect test for evaluating the vascular components of HAVS. Therefore, it is suggested that the cold water immersion test needs to be used with a battery of other tests (2).

It seems that water temperatures between 10°C and 15°C are potentially useful for avoiding cold-induced vasodilation, pain, and the hunting phenomenon while achieving the maximal cold-induced vasoconstriction. It also seems that regardless of water temperature, a minimum FST is achieved after about 5 min of immersion (19, 59, 65). The durations of cold immersion greater than 5 min have not been shown to improve the diagnostic sensitivity and specificity of this test (66). In a study (5) using the cold water immersion test at 12°C for 3 min, the sensitivity and specificity of the test were reported to be 58% and 100%, respectively, which are not markedly different from those at 10°C. Therefore, the cold water immersion test at 12°C for 5 min as proposed by ISO/DIS (2) is of great interest and suitable for its repeatability (46). Further studies are needed to obtain sufficient data for evaluating the diagnostic significance of the test.

Findings related to other factors

It has been shown that test results may be influenced by season, room temperature, food intake, waterproof hand covering and possibly other conditions (17, 46, 67–71). FST is significantly influenced by the subject's age, that is, older subjects tend to achieve lower FSTs during immersion (72), and lower FSTs during recovery (17, 73, 74). The time of day has a direct influence on FST (75). The room temperatures used by different researchers ranged from 20°C to 30°C, and some researchers used hot blankets, such as an electric heating or a hot water perfusion blanket. The use of body-warming procedures or a warm environment may result in a decrease in central sympathetic activity during the cold water immersion test; however, the enhancement of the diagnostic significance of the test with these procedures does not seem evident. When the possibility of an increased sympathetic activity in patients with HAVS is considered (76, 77), body-warming procedures or a warm environment during the cold water immersion test might decrease the diagnostic significance of the test. A room temperature of 21±1°C is recommended by ISO/DIS (2). Subjective hand pain is often experienced during the cold water immersion test, particularly when the water temperature is low (59, 60, 70, 71), which can result in physiological changes in the peripheral vasculature through a stress response (58). A higher water temperature and a shorter immersion time may reduce the invasive characteristics of the test; however, the diagnostic significance might also be reduced, which is not

desired. Further studies are needed to obtain sufficient data for determining the point for a compromise in evaluating the satisfactory diagnostic significance of the test.

Summary

A higher water temperature, a shorter immersion time and other conditions of the cold water immersion test should be chosen so as to achieve vasoconstriction in patients exposing to minimal suffering during the test. Test results are influenced by water temperature, immersion time and other conditions such as room temperature, season, ischemia during immersion and evaluation parameters. These factors need to be considered for the standardization of the cold water immersion test with FST measurement. A water temperature between 10°C and 15°C and a 5 min immersion might be suitable for the cold water immersion test. The reported sensitivity and specificity of the test at a water temperature of 12°C and 3 min immersion are low (58% and 100%, respectively), but similar to those of the test at a water temperature of 10°C as found in this and other previous reviews. The test needs to be used together with a test battery under all mentioned conditions. From this point, the cold water immersion test at 12°C for 5 min proposed by ISO/DIS is the focus of much interest; however, information is not sufficient at present. Therefore, further studies are needed to obtain sufficient data for evaluating the diagnostic significance of the test.

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