










## Original Article

# Current status of active cooling, deep body temperature measurement, and face mask wearing in heat stroke and heat exhaustion patients in Japan: a nationwide observational study based on the Heatstroke STUDY 2020 and 2021

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**Aim:** The study aimed to determine the current status of face mask use, deep body temperature measurement, and active cooling in patients suffering from heat stroke and heat exhaustion in Japan.

**Methods:** This was a prospective, observational, multicenter study using data from the Heatstroke STUDY 2020–2021, a nationwide periodical registry of heat stroke and heat exhaustion patients. Based on the Bouchama heatstroke criteria, we classified the patients into two groups: severe and mild-to-moderate. We compared the outcomes between the two groups and reclassified them into two subgroups according to the severity of the illness, deep body temperature measurements, and face mask use. Cramer's V was used to determine the effect sizes for a comparison between groups.

**Results:** Almost all patients in this study were categorized as having degree III based on the Japanese Association for Acute Medicine heatstroke criteria (JAAM-HS). However, the severe group was significantly worse than the mild-to-moderate group in outcomes like in-hospital death and modified Rankin Scale scores, when discharged. Heat strokes had significantly higher rates of active cooling and lower mortality rates than heat stroke-like illnesses. Patients using face masks often use

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them during labor, sports, and other exertions, had less severe conditions, and were less likely to be young male individuals.

**Conclusions:** It is suggested that severe cases require a more detailed classification of degree III in the JAAM-HS criteria, and not measuring deep body temperature could have been a factor in the nonperformance of active cooling and worse outcomes.

**Key words:** active cooling, deep body temperature, face mask, heat exhaustion, heat stroke, Heatstroke STUDY

## INTRODUCTION

HEAT STROKE AND heat exhaustion have become a global public health challenge due to global warming and increasingly frequent heat waves. In Japan, approximately 5,000 people are transported to emergency rooms every year due to heat stroke and heat exhaustion.<sup>1</sup>

The Japanese Association for Acute Medicine (JAAM) has been conducting the Heatstroke STUDY (HsS), a nationwide periodical registry of heat stroke and heat exhaustion patients, since 2006. The Heatstroke and Hypothermia Surveillance Committee has been learning about heat stroke through this and other programs. Severe heat stroke is more common in older individuals in their daily lives than in exertional young individuals. Prognostic determinants of heat stroke include impaired consciousness and disseminated intravascular coagulation (DIC),<sup>2–4</sup> while possible prognostic indicators include the Bouchama heatstroke (B-HS) criteria, JAAM heatstroke (JAAM-HS) criteria, Sequential Organ Failure Assessment (SOFA) score, and Early Risk Assessment Tool for Detecting Clinical Outcomes in Patients with Heat-related Illness (J-ERATO) score.<sup>5–7</sup>

Active cooling with cold water immersion for exertional heat stroke and evaporative plus convective cooling for non-exertional heat stroke is important in the initial response to heat stroke and heat exhaustion. However, little evidence from some case series had demonstrated the utility of active cooling except some case series.<sup>8</sup> The study that summarized the HsS during 2010–2019 discovered that active cooling along with the development of severe disturbance of consciousness and DIC is a prognostic determinant of patient outcomes.<sup>9</sup> Although the utility of active cooling was demonstrated, the implementation rate of deep body temperature measurement and active cooling was not always high.<sup>10</sup> Furthermore, there is no report yet on which active cooling method is superior.<sup>11</sup>

This study aimed to provide an overview of the HsS 2020–2021, especially the current status of active cooling, deep body temperature measurement, and face mask use in heat stroke and heat exhaustion patients in Japan.

## METHODS

### Study design

THIS WAS A prospective, observational, multicenter study using data from the HsS 2020–2021. The B-HS criteria were used as prognostic indicators for heat stroke, which was defined as a severe illness characterized by a core temperature  $>40^{\circ}\text{C}$  and central nervous system abnormalities. However, heat stroke as a proper noun might not be consistent with the definition as per the B-HS criteria.<sup>12</sup>

### Patients and classification

The Heatstroke and Hypothermia Surveillance Committee of the JAAM conducted the HsS 2020–2021 in 165 hospitals between July and September in 2020 and 2021 (Table S1). Participating physicians collected patient data from medical records and registered the data in the HsS 2020 and 2021 study repository using a Web-based data collection system. Detailed information on symptom onset (patients' activity and environment of heat illness onset), demographic data (age, sex, height, and weight), clinical data at hospital arrival (bladder or rectal temperature, Glasgow Coma Scale [GCS] score, and laboratory data on liver, hepatic, and coagulation functions), and information on cooling methods and in-hospital deaths were collected. Data on mask-wearing at the time of onset were also collected. The registered cases were defined as hospitalized patients who were treated in the emergency department for heat illnesses. The diagnosis was based on symptoms (pyrexia, dehydration, dizziness, myalgia, headache, nausea, disturbance of consciousness, and convulsions) and a history of exposure to hot environments according to the JAAM HeatStroke Guidelines 2015.<sup>13</sup> An initial review of the heat illness registry database revealed that 11 of the HsS 2020 and 2021 patients tested positive (by antigen or polymerase chain reaction) for coronavirus disease (COVID-19) but were apparently asymptomatic; therefore, they remained in our study cohort as well because of their heat illness status.

The HsS 2020 and 2021 included 1,081 and 659 patients, respectively. According to the B-HS criteria, cases with a deep body temperature of  $\geq 40.0^{\circ}\text{C}$  and severe disturbance of consciousness (GCS score of  $\leq 8$ ) at hospital arrival were classified as heat stroke and those with a deep body temperature of  $\leq 39.9^{\circ}\text{C}$  or nonsevere disturbance of consciousness (GCS score of  $\geq 9$ ) were classified as heat exhaustion.<sup>12</sup>

Cases in which the severity of heat stroke was estimated using surface body temperature and the Japan Coma Scale (JCS) at hospital arrival and emergency transport, instead of deep body temperature and the GCS at hospital arrival, were classified as the partially missing data group. In this group, a surface body temperature of  $\geq 40.0^{\circ}\text{C}$  or JCS score  $\geq 100$  was classified as heat stroke-like illness and a surface body temperature of  $\leq 39.9^{\circ}\text{C}$  or JCS score  $\leq 30$  was classified as heat exhaustion-like illness. At the time of hospital arrival or emergency transport, surface temperature or the JCS score, whichever was higher, was adopted. If the applicable classification differed between deep and surface temperatures or between the GCS and JCS, deep temperature and GCS were prioritized.

We further classified heat stroke and heat stroke-like illness into the severe group and heat exhaustion and heat exhaustion-like illness into the mild-to-moderate group.

Patients whose surface body temperature or JCS data were missing and whose severity was not completely predictable were classified as the complete missing data group.

## Variables

The outcome was determined by in-hospital mortality and the modified Rankin Scale (mRS) when discharged from the hospital.

Cooling methods were categorized as active cooling and rehydration-only. Active cooling included ice packs, evaporative plus convective cooling, the Arctic Sun temperature management system (IMI Co, Koshigaya, Japan), cooling blankets, cold water immersion, cold water gastric lavage, intravascular temperature management, cold water bladder irrigation, renal replacement therapy, and extracorporeal membrane oxygenation.

The place of onset was classified as indoor or outdoor and the onset situation was classified into physical work, sports, office work, and daily life. Physical work and sports fall into the category of exertional heat stroke, whereas office work and daily life fall into the category of non-exertional heat stroke. Detailed types of face masks were not considered for the status of face mask use.

Liver damage was determined by an aspartate transaminase level of  $\geq 30$  U/L or alanine aminotransferase level of

$\geq 42$  U/L (male individuals) or  $\geq 23$  U/L (female individuals). Renal dysfunction was defined as a creatinine level of  $\geq 1.07$  g/dl (male individuals) or  $\geq 0.80$  mg/dl (female individuals). The DIC score was assessed on the basis of systemic inflammatory response syndrome, thrombocytopenia, prolonged prothrombin time–international standard ratio, and elevated D-dimer level to evaluate DIC severity, with scores ranging from 0 (mild) to 6 (severe); a score of  $\geq 4$  was diagnosed as DIC.<sup>14</sup>

The SOFA and J-ERATO scores were used to evaluate severity. A SOFA score includes six items (respiration, circulation, coagulation, nerves, liver, and kidneys) that rate organ function from 0 to 4 for a total score of 0–24.<sup>15</sup> A J-ERATO score comprises six items (respiratory rate, GCS, systolic blood pressure, heart rate, temperature, and age), each of which is valued at 0 or 1, for a total score of 0–6.<sup>6</sup>

## Statistical analyses

We compared the ratios of each variable for the following four patterns. When calculating the ratios, the unknowns for each variable were excluded.

1. 2020 versus 2021.
2. Severe group versus mild-to-moderate group.
3. Heat stroke versus heat stroke-like illness.
4. Face mask wearing versus non-face mask wearing.

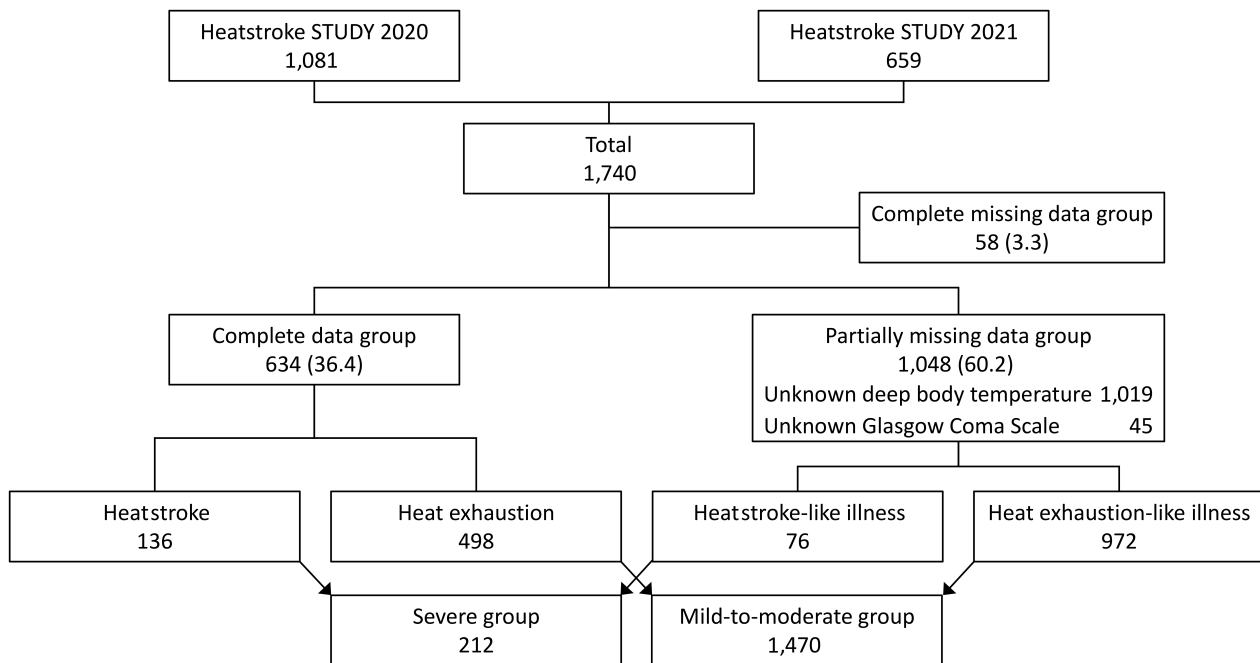
We calculated Cramer's  $V$  to determine the effect sizes for a comparison of groups. A  $P$ -value of  $< 0.05$  indicated statistical significance, and a  $V$ -value of  $\geq 0.2$  indicated practical significance.<sup>16</sup>

We also compared the ratios between 2020 and 2021 for the specific method of active cooling, site of measurement of surface and deep body temperatures, and means of transport (categorized as ambulance, walk-in, and transfer from other hospitals).

SPSS Statistics (version 28.0; IBM Corp., Armonk, NY, USA) was used for data analysis.

## RESULTS

**F**ROM 165 FACILITIES, 1,081 cases were enrolled in 2020 and 669 in 2021. Of the total 1,740 cases, 58 were excluded due to complete missing data. There were 136 patients with heat stroke (severe) and 498 with heat exhaustion (mild-to-moderate). Of the 1,048 cases in the partially missing data group for which severity could be predicted, 76 and 972 had heat stroke-like (severe) and heat exhaustion-like illnesses (mild-to-moderate), respectively (Fig. 1).



**Fig. 1.** Distribution of study participants by the severity of heat stroke and heat exhaustion based on the Bouchama heatstroke (B-HS) criteria. Heat stroke and heat exhaustion were diagnosed based on the B-HS criteria. In cases where deep body temperature and the Glasgow Coma Scale were not reported, heat stroke-like illnesses and heat exhaustion-like illnesses were diagnosed by estimating the severity of the illness using surface body temperature and the Japan Coma Scale. Heat stroke and heat stroke-like illness were classified into the severe group, and heat exhaustion and heat exhaustion-like illness were classified into the mild-to-moderate group. Numbers in parentheses for the complete, partially missing, and complete missing data groups indicate the ratio (%) in all the 1,740 patients (2020 + 2021).

## 2020 versus 2021

No items showed differences in statistical or practical significance between 2020 and 2021. The mortality rates were 8.4% and 9.1% in 2020 and 2021, respectively. Based on severity, degree III in JAAM-HS criteria accounted for almost all cases (96.4% and 97.0% in 2020 and 2021, respectively; Table 1).

## Severe versus mild-to-moderate group

The proportion of patients in terms of any of the variables taken into account was significantly higher in the severe group (Table 2).

## Heat stroke versus heat stroke-like illness

Deep body temperature was measured in all heat stroke patients, whereas it was not measured in almost all heat stroke-like illness (74 of 76) patients. A significantly lower in-hospital mortality and higher active cooling rate

were observed for heat stroke, whereas there was no difference in severity between heat stroke and heat stroke-like illnesses according to the JAAM-HS criteria, J-ERATO score, SOFA score, liver injury, renal impairment, and DIC (Table 3).

## Face mask wearing versus non-face mask wearing

Mask-wearing cases had more outdoor onset, more exertional heat stroke, a larger proportion of patients without impaired consciousness, a lower mortality rate, and a larger proportion of patients with mRS scores of 0–2 in terms of outcome (Table 4).

## Others

Evaporative and convection cooling accounted for 50–60% of the active cooling cases. Almost all patients had their surface body temperature measured in the axilla, while 50–60% had their deep body temperature measured in the bladder,

**Table 1.** Differences in factors of heat stroke and heat exhaustion between 2020 and 2021

	2020		2021		V-value	P-value
	<i>n</i> = 1,081		<i>n</i> = 659			
In-hospital mortality						
Death	81	8.4	50	9.1	0.013	0.618
Alive	888	91.6	499	90.9		
Unknown	112		110			
Modified Rankin Scale score (when discharged from hospital)						
3–6	329	34.0	184	33.6	0.005	0.860
0–2	638	66.0	364	66.4		
Unknown	114		111			
Cooling methods						
Active cooling	314	33.5	127	22.3	0.119	<0.001
Rehydration-only	623	66.5	442	77.7		
Unknown	144		90			
Age (years)						
0–64	364	33.7	227	34.8	0.011	0.662
≥65	715	66.3	426	64.6		
Unknown	2		6			
Age (years; details)						
0–14	26	2.4	8	1.2		
15–44	136	12.6	86	13.2		
45–64	202	18.7	133	20.4		
65–74	190	17.6	133	20.4		
≥75	525	48.7	293	44.9		
Sex						
Male	741	69.1	443	67.6	0.015	0.536
Female	332	30.9	212	32.4		
Unknown	8		4			
Place of onset						
Outdoor	523	49.3	336	53.2	0.037	0.128
Indoor	537	50.7	296	46.8		
Unknown	21		27			
Onset situation						
Exertional	352	33.5	240	38.3	0.049	0.046
Nonexertional	698	66.5	386	61.7		
Unknown	31		33			
Onset situation (details)						
Physical work	289	27.5	195	31.2		
Sports	63	6.0	45	7.2		
Daily life	691	65.8	382	61.0		
Office work	7	0.7	4	0.6		
Face mask use						
Wearing	53	18.2	110	27.9	0.113	0.003
Nonwearing	238	81.8	284	72.1		
Unknown	790		265			
Surface body temperature (°C)						
≥40.0	166	17.5	75	13.1	0.058	0.023
≤39.9	783	82.5	798	86.9		
Unknown	132		86			

(Continued)

**Table 1.** (Continued)

	2020		2021		V-value	P-value
	<i>n</i> = 1,081		<i>n</i> = 659			
Surface body temperature (°C; details)						
≥42.0	14	1.5	3	0.5		
41.0–41.9	52	5.5	18	3.1		
40.0–40.9	100	10.5	54	9.4		
39.0–39.9	143	15.1	70	12.2		
≤38.9	640	67.4	428	74.7		
Deep body temperature (°C)						
≥40.0	140	34.7	57	24.2	0.110	0.005
≤39.9	264	65.3	179	75.8		
Unknown	677		423			
Deep body temperature (°C; details)						
≥42.0	15	3.7	9	3.8		
41.0–41.9	46	11.4	19	8.1		
40.0–40.9	79	19.6	29	12.3		
39.0–39.9	100	24.8	52	22.0		
≤38.9	164	40.6	127	53.8		
Glasgow Coma Scale score						
3–8	250	24.1	138	22.9	0.017	0.797
9–14	395	38.1	227	37.7		
15	393	37.9	237	39.4		
Unknown	43		57			
Liver damage						
Having liver damage	736	69.7	415	66.4	0.034	0.16
None	320	30.3	210	33.6		
Unknown	25		34			
Renal dysfunction						
Having renal dysfunction	802	75.9	470	75.6	0.004	0.859
None	254	24.1	152	24.4		
Unknown	25		37			
DIC						
Having DIC	159	20.3	378	19.2	0.013	0.637
None	623	79.7	90	80.8		
Unknown	299		191			
Severity <sup>†</sup>						
Severe	138	13.1	74	11.8	0.020	0.423
Mild to moderate	915	86.9	555	88.2		
Unknown	28		30			
Severity (details) <sup>†</sup>						
Heat stroke	93	8.8	43	6.8		
Heat exhaustion	308	29.2	190	30.2		
Heat stroke-like illness	45	4.3	31	4.9		
Heat exhaustion-like illness	607	57.6	365	58.0		
JAAM-HS criteria						
Degree III	1,015	96.4	592	97.0	0.018	0.474
Degree I–II	38	3.6	18	3.0		
Unknown	28		49			
J-ERATO score						
≥5	303	33.4	168	31.6	0.019	0.482
0–4	603	66.6	363	68.4		
Unknown	175		128			

**Table 1.** (Continued)

	2020		2021		V-value	P-value
	<i>n</i> = 1,081		<i>n</i> = 659			
SOFA score						
≥11	51	5.5	33	6.0	0.010	0.696
0–10	869	94.5	514	94.0		
Unknown	161		112			

DIC, disseminated intravascular coagulation; JAAM-HS, Japanese Association for Acute Medicine heatstroke criteria; J-ERATO, Early Risk Assessment Tool for Detecting Clinical Outcomes in Patients with Heat-related Illness; SOFA, Sequential Organ Failure Assessment.

<sup>†</sup>See Figure 1.

and 30–40% in the rectum. In terms of transportation, 90% were transported by ambulance and 10% by walk-in, and only a few were transferred from other hospitals (Table 5).

## DISCUSSION

IN JAPAN, IT is common to hospitalize degree III heat stroke patients (based on the JAAM-HS criteria) because of the widespread use of the HeatStroke Guidelines 2015. However, the JAAM-HS definition of this affliction is broad and includes cases ranging from mild disturbance of consciousness to fatal with multiple organ failure; therefore, it would be better to consider the need for subclassification within the JAAM-HS criteria.

Data obtained from the HsS 2020 and 2021 were classified into severe and mild-to-moderate, and the severe group was found to be significantly worse than the mild-to-moderate group in outcomes such as in-hospital mortality and mRS scores when discharged from hospital, organ damage such as disturbance of consciousness and DIC, and other severity indices such as SOFA and J-ERATO scores. Therefore, we believe in the validity of the classification in this study and possibility of subclassification within the JAAM-HS criteria more strictly into severe and mild-to-moderate groups. This is expected to help determine the treatment strategy and therefore necessitates the re-examination of the definition of the JAAM-HS criteria.

Furthermore, in the severe subgroup of the heat stroke group, deep body temperature was measured in all the patients, whereas it was measured in very few patients with heat stroke-like illness. As there were no significant differences in the severity criteria, such as JAAM-HS criteria, J-ERATO score, SOFA score, liver injury, renal impairment, and DIC between the two groups, we believe that the severity of both groups was comparable and that comparing the

two groups can help us to examine the effectiveness of deep body temperature measurement in severe cases of heat stroke and heat exhaustion cases. The heat stroke group showed significantly higher active cooling rates and significantly lower mortality rates. Not measuring deep body temperature, which is an essential monitoring indicator for active cooling, could have led to a lack of active cooling and worsened the in-hospital mortality in the heat stroke-like illness group. However, it should also be noted that the difference in mortality rates between the heat stroke and heat stroke-like groups and the absence or presence of deep body temperature measurement might be due to the fact that some of the heat stroke-like group did not receive aggressive treatment from the beginning because of their background. On the other hand, no significant difference was observed in the mRS scores when discharged from the hospital, a factor that indicates the incidence of permanent disability. We believe that the incidence of permanent disability is influenced not only by active cooling but also by intensive care and rehabilitation after hospitalization, an issue for future study. For the mild-to-moderate group, we did not compare heat exhaustion with heat exhaustion-like illness because, although the majority of mild-to-moderate heat stroke patients go home, this study included only in-patients and was inappropriate for examining trends in the mild-to-moderate group.<sup>2,3</sup> However, very few of the heat exhaustion-like illness patients underwent deep body temperature measurement or active cooling and had better outcomes, including in-hospital mortality and mRS when discharged from the hospital, compared with those with heat exhaustion who did undergo deep body temperature measurement. Deep body temperature measurement might not be essential for mild-to-moderate cases.

Of the 1,740 patients in this study, 11 (0.6%) were COVID-19 positive. As the study was carried out on patients

**Table 2.** Differences in factors of heat stroke and heat exhaustion between the severe and mild-to-moderate groups

	Severe group			Mild-to-moderate group			V-value	P-value
	Heat stroke	Heat stroke-like illness	Total	Heat exhaustion	Heat exhaustion-like illness	Total		
	n = 136	n = 76	n = 212	n = 498	n = 972	n = 1,470		
In-hospital mortality								
Death	32	27.6	27	42.2	59	32.8	31	6.9
Alive	84	72.4	37	57.8	121	67.2	419	93.1
Unknown	20		12		32		48	
Modified Rankin Scale score (when discharged from hospital)								
3-6	74	61.2	42	64.6	116	62.4	164	36.6
0-2	47	38.8	23	35.4	70	37.6	284	63.4
Unknown	15		11		26		50	
Cooling methods								
Active cooling	102	79.1	25	37.9	127	65.1	226	48.2
Rehydration only	27	20.9	41	62.1	68	34.9	243	51.8
Unknown	7		10		17		29	
Age (years)								
0-64	54	39.7	15	20.0	69	32.7	118	23.7
≥65	82	60.3	60	80.0	142	67.3	379	76.3
Unknown	0		1		1		1	
Age (years; details)								
0-14	0	0	1	1.3	1	0.5	4	0.8
15-44	12	8.8	4	5.3	16	7.6	33	6.6
45-64	42	30.9	10	13.3	52	24.6	81	16.3
65-74	24	17.6	20	26.7	44	20.9	113	22.7
≥75	58	42.6	40	53.3	98	46.4	266	53.5
Sex								
Male	94	69.1	48	64.0	142	67.3	331	66.7
Female	42	30.9	27	36.0	69	32.7	165	33.3
Unknown	0		1		1		2	
Place of onset								
Outdoor	71	52.2	32	42.1	103	48.6	256	51.5
Indoor	65	47.8	44	57.9	109	51.4	241	48.5
Unknown	0		0		0		1	



**Table 2.** (Continued)

	Heat stroke			Heat stroke-like illness			Severe group			Mild-to-moderate group			V-value	P-value
	n = 136	n = 76	n = 212	n = 498	n = 972	n = 1,470	Total	Heat exhaustion	Heat exhaustion-like illness	Total	Heat exhaustion-like illness			
Onset situation														
Exertional	38	13	51	24.6	147	390	537	37.1	0.086	537	37.1	<0.001		
Nonexertional	95	61	156	75.4	349	561	431	62.9		431	62.9			
Unknown	3	2	5		2	21	106			106				
Onset situation (details)														
Physical work	37	27.8	13	17.6	128	25.8	303	31.9	25.8	128	25.8			
Sports	1	0.8	0	0.0	19	0.2	87	9.1	0.2	19	0.2			
Daily life	95	71.4	61	82.4	348	70.2	551	57.9	70.2	348	70.2			
Office work	0	0	0	0.0	1	3.8	10	1.1	3.8	1	3.8			
Face mask use														
Wearing	9	14.8	1	3.3	49	21.1	102	28.7	21.1	151	25.7	0.118	0.002	
Nonwearing	52	85.2	29	96.7	183	78.9	254	71.3	78.9	437	74.3			
Unknown	75	46	121		266	616	882			882				
Surface body temperature (°C)														
≥40.0	65	63.7	47	68.1	89	22.7	39	4.1	22.7	151	25.7	<0.001		
≤39.9	37	36.3	22	31.8	303	77.3	909	95.9	77.3	437	74.3			
Unknown	34	7	41		106	24	882			882				
Surface body temperature (°C; details)														
≥42.0	5	4.9	6	8.7	5	1.3	0	0.0	1.3	5	0.4	<0.001		
41.0–41.9	28	27.5	16	23.2	19	4.8	7	0.7	4.8	26	1.9			
40.0–40.9	32	31.4	25	36.2	65	16.6	32	3.4	16.6	97	7.2			
39.0–39.9	21	20.6	10	14.5	81	20.7	98	10.3	20.7	179	13.4			
≤38.9	16	15.7	12	17.4	222	56.6	811	85.5	56.6	1,033	77.1			
Deep body temperature (°C)														
≥40.0	136	100	0	0.0	61	12.3	0	0.0	12.3	151	25.7	<0.001		
≤39.9	0	0	2	100.0	436	87.6	3	100.0	87.6	437	74.3			
Unknown	0	74	74		1	969	882			882				
Deep body temperature (°C; details)														
≥42.0	24	17.6	0	0.0	0	0	0	0	0	0	0.0			
41.0–41.9	49	36.0	0	0.0	16	3.2	0	0	3.2	16	3.2			
40.0–40.9	63	46.3	0	0.0	45	9.1	0	0	9.1	45	9.0			
39.0–39.9	0	0.0	1	50.0	150	30.2	1	33.3	30.2	151	30.2			
≤38.9	0	0.0	1	50.0	286	57.5	2	66.7	57.5	289	57.6			

(Continued)

**Table 2.** (Continued)

	Heat stroke n = 136		Heat stroke-like illness n = 76		Total n = 212		Severe group n = 498		Heat exhaustion n = 972		Heat exhaustion-like illness n = 972		Mild-to-moderate group Total n = 1,470		V-value	P-value
Glasgow Coma Scale score																
3-8	135	100	62	86.1	197	96.2	117	23.6	69	7.4	186	13.0	0.645	<0.001		
9-14	0	0	8	11.1	8	3.9	277	55.8	337	36.2	614	43.0				
15	0	0	2	2.8	2	1.0	102	20.6	525	56.4	627	43.9				
Unknown	1		4		5		2		41		43					
Liver damage																
Having liver damage	117	87.3	62	83.8	190	86.1	339	68.8	619	64.3	958	65.8	0.144	<0.001		
None	17	12.7	12	16.2	16	13.9	154	31.2	343	35.7	497	34.2				
Unknown	2		2		4		5		10		15					
Renal dysfunction																
Having renal dysfunction	126	94.7	64	87.7	190	92.2	391	79.1	679	70.8	1,070	73.6	0.143	<0.001		
None	7	5.3	9	12.3	16	7.8	103	20.9	280	29.2	383	26.4				
Unknown	3		3		6		4		13		17					
DIC																
Having DIC	38	32.5	25	41.7	63	35.6	105	27	78	11.6	183	17.2	0.161	<0.001		
None	79	67.5	35	58.3	114	64.4	284	73	596	88.4	880	82.8				
Unknown	19		16		35		109		298		407					
JAAM heatstroke criteria																
Degree III	136	100	76	100.0	212	100.0	486	98.6	884	94.7	1,370	96.1	0.073	0.003		
Degree I-II	0	0	0	0.0	0	0.0	7	1.4	49	5.3	56	3.9				
Unknown	0		0		0		5		39		44					
J-ERATO score																
≥5	75	65.2	41	64.1	116	64.8	225	49.7	130	16.4	355	28.5	0.256	<0.001		
0-4	40	34.8	23	35.9	63	35.2	228	50.3	664	83.6	892	71.5				
Unknown	21		12		33		45		178		223					
SOFA score																
≥11	30	26.5	15	25.9	45	26.3	27	5.9	12	1.4	39	3.0	0.322	<0.001		
0-10	83	73.5	43	74.1	126	73.7	429	94.1	825	98.6	1,254	97.0				
Unknown	23		18		41		42		135		177					

DIC, disseminated intravascular coagulation; JAAM-HS, Japanese Association for Acute Medicine heatstroke criteria; J-ERATO, Early Risk Assessment Tool for Detecting Clinical Outcomes in Patients with Heat-related Illness; SOFA, Sequential Organ Failure Assessment.

**Table 3.** Differences in factors of heat stroke and heat exhaustion between heat stroke and heat stroke-like illness

	Heat stroke		Heat stroke-like illness		V-value	P-value
	<i>n</i> = 136		<i>n</i> = 76			
In-hospital mortality						
Death	32	27.6	27	42.2	0.149	0.046
Alive	84	72.4	37	57.8		
Unknown	20		12			
Modified Rankin Scale score (when discharged from hospital)						
3–6	74	61.2	42	64.6	0.034	0.643
0–2	47	38.8	23	35.4		
Unknown	15		11			
Cooling methods						
Active cooling	102	79.1	25	37.9	0.409	<0.001
Rehydration only	27	20.9	41	62.1		
Unknown	7		10			
Age (years)						
0–64	54	39.7	15	20.0	0.201	0.003
≥65	82	60.3	60	80.0		
Unknown	0		1			
Age (years; details)						
0–14	0	0.0	1	1.3		
15–44	12	8.8	4	5.3		
45–64	42	30.9	10	13.3		
65–74	24	17.6	20	26.7		
≥75	58	42.6	40	53.3		
Sex						
Male	94	69.1	48	64.0	0.052	0.448
Female	42	30.9	27	36.0		
Unknown	0		1			
Place of onset						
Outdoor	71	52.2	32	42.1	0.097	0.158
Indoor	65	47.8	44	57.9		
Unknown	0		0			
Onset situation						
Exertional	38		13		0.122	0.078
Nonexertional	95		61			
Unknown	3		2			
Onset situation (details)						
Physical work	37	27.8	13	17.6		
Sports	1	0.8	0	0.0		
Daily life	95	71.4	61	82.4		
Office work	0	0.0	0	0.0		
Face mask use						
Wearing	9	14.8	1	3.3	0.172	0.102
Nonwearing	52	85.2	29	96.7		
Unknown	75		46			
Surface body temperature						
≥40.0	65	63.7	47	68.1	0.045	0.554
≤39.9	37	36.3	22	31.8		
Unknown	34		7			

(Continued)

Table 3. (Continued)

	Heat stroke		Heat stroke-like illness		V-value	P-value
	<i>n</i> = 136		<i>n</i> = 76			
Surface body temperature (°C; details)						
≥42.0	5	4.9	6	8.7		
41.0–41.9	28	27.5	16	23.2		
40.0–40.9	32	31.4	25	36.2		
39.0–39.9	21	20.6	10	14.5		
≤38.9	16	15.7	12	17.4		
Deep body temperature (°C)						
≥40.0	136	100.0	0	0.0	1.000	<0.001
≤39.9	0	0.0	2	100.0		
Unknown	0		74			
Deep body temperature (details)						
≥42.0	24	17.6	0	0.0		
41.0–41.9	49	36.0	0	0.0		
40.0–40.9	63	46.3	0	0.0		
39.0–39.9	0	0.0	1	50.0		
≤38.9	0	0.0	1	50.0		
Glasgow Coma Scale score						
3–8	135	100.0	62	86.1	0.309	<0.001
9–14	0	0.0	8	11.1		
15	0	0.0	2	2.8		
Unknown	1		4			
Liver damage						
Having liver damage	117	87.3	62	83.8	0.049	0.482
None	17	12.7	12	16.2		
Unknown	2		2			
Renal dysfunction						
Having renal dysfunction	126	94.7	64	87.7	0.126	0.070
None	7	5.3	9	12.3		
Unknown	3		3			
DIC						
Having DIC	38	32.5	25	41.7	0.091	0.227
None	79	67.5	35	58.3		
Unknown	19		16			
JAAM heatstroke criteria						
Degree III	136	100.0	76	100.0	-	-
Degree I–II	0	0.0	0	0.0		
Unknown	0		0			
J-ERATO score						
≥5	75	65.2	41	64.1	0.012	0.877
0–4	40	34.8	23	35.9		
Unknown	21		12			
SOFA score						
≥11	30	26.5	15	25.9	0.007	0.923
0–10	83	73.5	43	74.1		
Unknown	23		18			

DIC, disseminated intravascular coagulation; JAAM-HS, Japanese Association for Acute Medicine heatstroke criteria; J-ERATO, Early Risk Assessment Tool for Detecting Clinical Outcomes in Patients with Heat-related Illness, SOFA, Sequential Organ Failure Assessment.

**Table 4.** Differences in factors of heat stroke and heat exhaustion between individuals wearing a face mask or not

	Face mask wearing		Non-face mask wearing		V	P
	n = 163		n = 522			
Year						
2020	53	32.5	238	45.6	0.113	0.003
2021	110	67.5	284	54.4		
In-hospital mortality						
Death	3	2.2	58	12.6	0.145	<0.001
Alive	134	97.8	402	87.4		
Unknown	26		62			
Modified Rankin Scale score (when discharged from hospital)						
3–6	13	9.3	213	54.6	0.315	<0.001
0–2	127	90.7	256	45.4		
Unknown	23		53			
Cooling methods						
Active cooling	24	18.8	131	27.8	0.085	0.038
Rehydration only	104	81.3	340	72.2		
Unknown	35		51			
Age (years)						
0–64	86	53.1	148	28.4	0.222	<0.001
≥65	76	46.9	374	71.6		
Unknown	1		0			
Age (years; details)						
0–14	1	0.6	17	3.3	0.087	0.024
15–44	36	22.2	53	10.2		
45–64	49	30.2	78	14.9		
65–74	30	18.5	99	19.0		
≥75	46	28.4	275	52.7		
Unknown						
Sex						
Male	119	73.9	335	64.3	0.087	0.024
Female	42	26.1	186	35.7		
Unknown	2		1			
Place of onset						
Outdoor	116	71.2	196	37.6	0.287	<0.001
Indoor	47	28.8	325	62.4		
Unknown	0		1			
Onset situation						
Exertional	93	57.1	148	28.5	0.255	<0.001
Nonexertional	70	42.9	371	71.5		
Unknown	0		1			
Onset situation (details)						
Physical work	81	49.7	102	19.7	0.132	0.001
Sports	12	7.4	46	8.9		
Daily life	69	42.3	370	71.3		
Office work	1	0.6	1	0.2		
Surface body temperature (°C)						
≥40.0	13	8.6	97	20.3	0.132	0.001
≤39.9	139	91.4	381	79.7		
Unknown	11		44			

(Continued)

Table 4. (Continued)

	Face mask wearing		Non-face mask wearing		V	P
	n = 163		n = 522			
Surface body temperature (°C; details)						
≥42.0	0	0.0	7	1.5		
41.0–41.9	4	2.6	23	4.8		
40.0–40.9	9	5.9	67	14.0		
39.0–39.9	13	8.6	83	17.4		
≤38.9	126	82.9	298	62.3		
Deep body temperature (°C)					0.130	0.026
≥40.0	10	17.2	76	32.1		
≤39.9	48	82.8	161	67.9		
Unknown	105		285			
Deep body temperature (°C; details)						
≥42.0	1	1.7	6	2.5		
41.0–41.9	5	8.6	20	8.4		
40.0–40.9	4	6.9	50	21.1		
39.0–39.9	14	24.1	59	24.9		
≤38.9	34	58.6	102	43.0		
Glasgow Coma Scale score					0.295	<0.001
3–8	18	11.2	157	30.5		
9–14	49	30.4	221	42.9		
15	94	58.4	137	26.6		
Unknown	2		7			
Liver damage					0.100	0.010
Having liver damage	94	59.5	361	70.5		
None	64	40.5	151	29.5		
Unknown	5		10			
Renal dysfunction					0.050	0.152
Having renal dysfunction	115	72.8	400	78.3		
None	43	27.2	111	21.7		
Unknown	5		11			
DIC					0.168	<0.001
Having DIC	9	8.1	105	25.1		
None	102	91.9	313	74.9		
Unknown	52		104			
Severity <sup>†</sup>					0.118	0.002
Severe	10	6.2	81	15.6		
Mild to moderate	151	93.8	437	84.4		
Unknown	2		4			
Severity (details) <sup>†</sup>						
Heat stroke	9	5.6	52	10.0		
Heat exhaustion	49	30.4	183	35.3		
Heat stroke-like illness	1	0.6	29	5.6		
Heat exhaustion-like illness	102	63.4	254	49.0		
Unknown	2		4			
JAAM heatstroke criteria					0.101	0.009
Degree III	139	92.7	500	97.3		
Degree I–II	11	7.3	14	2.7		
Unknown	13		8			

**Table 4.** (Continued)

	Face mask wearing		Non-face mask wearing		V	P
	n = 163		n = 522			
J-ERATO score						
≥5	28	20.9	188	58.5	0.179	<0.001
0–4	106	79.1	265	41.5		
Unknown	29		69			
SOFA score						
≥11	4	2.7	32	6.9	0.075	0.065
0–10	142	97.3	435	93.1		
Unknown	17		55			

DIC, disseminated intravascular coagulation; JAAM-HS, Japanese Association for Acute Medicine heatstroke criteria; J-ERATO, Early Risk Assessment Tool for Detecting Clinical Outcomes in Patients with Heat-related Illness; SOFA, Sequential Organ Failure Assessment.

<sup>†</sup>See Figure 1.

diagnosed with and treated for heat stroke by the responding physicians, it can be concluded that these 11 cases were enrolled in this registry after the responding physicians determined that COVID-19 was asymptomatic. Therefore, these 11 cases were not excluded from this study. Additionally, considering that the patients themselves represented less than 1% of the total number of patients, we concluded that their inclusion would not affect the purpose or findings of this study. However, the impact of COVID-19 on heat stroke is an issue that should be examined as more cases accumulate.

Finally, this study shows that heat illnesses in face mask-wearing patients were more exertional, less severe, and less likely in younger male individuals, differing from most cases of heat illness in Japan, which tend to be nonexertional and occur indoors in older individuals. This might be because patients who engage in manual labor and perform outdoor activities while wearing a mask are usually younger and healthier than older adults who spend most of their time indoors. Previous studies have reported that face mask use is not associated with increased deep body temperature and that it does not worsen the outcome but instead leads to milder cases with better outcomes.<sup>17</sup> Therefore, we believe that to prevent heatstroke, other measures such as air conditioning and hydration must be taken besides just removing the mask.

### Features of this study

A major feature of our study included the fact that only 3.3% of total cases were excluded as the complete

missing data group because we substituted surface body temperature and the JCS for cases with unknown deep body temperature and GCS and established the partially missing data group.

### Limitations

The classification of the patient cohort used in this study would be too complex to adapt to clinical practice. As deep body temperature measurement is not necessarily considered essential in mild-to-moderate cases, an algorithm is required to examine the necessity of deep body temperature measurement against surface body temperature and other physical findings, which could be the basis of the criteria for determining the severity of severe heat stroke. However, as the definitions of heat stroke and heat exhaustion and their inference in this study are based on the widely used B-HS criteria, this limitation does not diminish the significance of this study.

### CONCLUSIONS

**I**N SEVERE CASES of heat stroke and heat exhaustion, it was suggested that a more detailed classification of degree III in the JAAM-HS criteria is needed, and not measuring deep body temperature could have been an attributable factor for the failure of active cooling and worse outcomes. Heat illnesses in face mask-wearing patients were more exertional, less severe, and less likely to be in younger male individuals, differing from most cases of heat illnesses in Japan.

**Table 5.** Differences in details of active cooling, surface body temperature measurement site, deep body temperature measurement site, and transportation between 2020 and 2021

	2020		2021	
Active cooling				
Cold water gastric lavage	39	12.4	10	7.9
Cold water bladder irrigation	10	3.2	0	0.0
Intravascular temperature management	44	14.0	24	18.9
Extracorporeal membranous oxygenation	0	0.0	0	0.0
Renal replacement therapy	1	0.3	0	0.0
Evaporative plus convective cooling	178	56.7	75	59.1
Arctic Sun temperature management system	8	2.5	1	0.8
Cooling blankets	36	11.5	7	5.5
Cold water immersion	8	2.5	0	0.0
Ice packs	25	8.0	13	10.2
Unknown	38	12.1	13	10.2
Surface body temperature measurement site				
Axilla	860	99.9	509	99.8
Forehead	1	0.1	1	0.2
Unknown	88		63	
Deep body temperature measurement site				
Rectum	125	30.9	86	36.4
Bladder	245	60.6	129	54.7
Esophagus	2	0.5	3	1.3
Tympanic membrane	18	4.5	4	1.7
Intravascular	0	0.0	1	0.4
Unknown	14		13	
Transport				
Ambulance	906	87.1	520	85.7
Walk-in	99	9.6	55	9.1
Transfer from hospital	35	3.4	32	5.3
Unknown	41		52	

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## DISCLOSURE

APPROVAL OF THE research protocol: The study protocol was approved by the Teikyo University Ethical

Review Board for Medical and Health Research Involving Human Subjects (protocol code 17-021-5 and date of approval May 21, 2020). The study was performed in accordance with the ethical standards set in the 1964 Declaration of Helsinki and its later amendments.

**Informed consent:** Informed consent was obtained from all subjects who participated in the study at each site in the form approved by Teikyo University Ethical Review Board for Medical and Health Research.

**Registry and registration number of the study/trial:** N/A.

**Animal studies:** N/A.

**Conflict of Interest:** Y. Okada has received research grants from the Zoll Foundation and the Fukuda Foundation for medical technology. The other authors have no conflicts of interest to declare.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

**Table S1** Facilities that participated in both the 2020 and 2021 surveys.