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Verification of a system utilizing heartbeat-induced acoustic pulse waves for estimating the time at which bladder urine increases to a level requiring drainage among individuals with spinal cord injury

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Abstract

Background: Spinal cord injury (SCI) often leads to the loss of urinary sensation, making urination difficult. In a previous experiment involving six healthy participants, we measured heartbeat-induced acoustic pulse waves (HAPWs) at the mid-back, calculated time-series power spectra of heart rate gradients at three ultralow/very low frequencies, distinguished and formulated waveform characteristics (one characteristic for each power spectrum, nearly uniform across participants) at times of increased urine in the bladder and heightened urges to urinate, and developed an algorithm with five of these power spectra to identify when urination is needed by extracting the waveform portion (continuous timepoints) where all of the characteristics were consistent with the formulated characteristics. The objective of this study was to verify the validity of the algorithm fed with data from measured HAPW of participants with SCI and to adapt the algorithm for these individuals.

Methods: In ten participants with SCI, we measured HAPWs continuously and urine volume intermittently, and obtained scores related to urinary sensation. A Boolean output at each data point was obtained by the algorithm fed with the calculated power spectra from each participant's HAPW. Notable times included when the output was positive or when the need to urinate (=(+)) was judged from the urine volume and urinary sensation scores. The outputs at these notable times were examined with the need to urinate and determined to be true/false. The accuracy of the algorithm was evaluated by the number of true/false-positive/negative points via the F-score with a binary classification model. We attempted to adapt the algorithm for participants with SCI.

Results: The outputs at 13 notable times were examined, yielding seven true-positive, one false-positive, and five false-negative times, with an F-score of 0.70. The algorithm was modified by replacing three thresholds that determine the extraction condition

for the slope in the power spectral waveform with new values that included all 12 true-positive points.

Conclusions: Without changing the use of ultralow/very low frequencies or significantly modifying the extraction conditions, the modified algorithm did not miss any true urination times or identify false urination times in ten participants with SCI.

Keywords: Acoustic pulse wave, Autonomic nerve activity, Cardiac sound, Heart rate variability, Spinal cord injury, Substituted sensation, Urethral catheterization, Urinary sensation, Ultralow/very low frequency

Background

Spinal cord injury (SCI) is often caused by mechanical impacts that occur during traffic accidents, falls, and sports accidents. Individuals with SCI leave the hospital once any wounds at site of injury have healed and stabilized. However, in many cases, these individuals continue their social lives with loss of motor and sensory function in parts of the body below the site of injury. Individuals with cervical, thoracic, or lumbar cord injuries may lose the urinary sensation due to damage to the central nervous system, resulting in difficulties with urination [1]. Improper management of the urinary tract system can lead to the development of secondary diseases, such as urinary tract infection, vesicoureteral reflux, and renal dysfunction [2]. Because the degree of functional impairment depends on the spinal level and severity of the injury, urinary management at the individual level is important for preventing the formation of secondary diseases [1]. One way to address the problems associated with urinary disorders is to drain urine in the bladder by inserting a catheter into the urethra (urethral catheterization). Clean intermittent catheterization (CIC) is recommended by the Japanese Continence Society and has been shown to be effective in preventing secondary diseases [2]. However, it is difficult for individuals with SCIs to perform daily urethral catheterization at opportune times if they lack urinary sensation of storage. If they miss their urethral catheterization time, their bladders will completely fill with urine; this bladder fullness then stimulates autonomic dysreflexia, which can lead to severe symptoms [3]. In addition, a disorder of the urinary tract is a significant barrier to social activities [4]. Therefore, detecting when individuals with SCI need to perform urinary drainage can prevent the development of related diseases and reduce barriers to social participation.

Heartbeat-induced acoustic pulse waves (HAPWs) can be measured noninvasively by using a driver's seatback equipped with a sound sensing system that uses stochastic resonance [5–7]. A HAPW, which is generated by a mixture of the apex beat and the heart sound, passes through the trunk, including bones, muscles, body fluids, and skin, and subsequently can be detected on the dorsal surface at the lower thoracic vertebrae. Time-series heart rate gradients can be calculated from HAPW data, which in turn can be used to calculate time-series power spectra in three ultralow/very low frequency bands as a representation of heart rate variability (HRV). The autonomic nervous activity of a driver exhibiting signs of falling asleep or intoxicated driving could be monitored via the extraction of the portions (sequences of timepoints) of these time-series power spectra with a certain characteristic shape [8–12].

Humans perceive increased urine in the bladder via a sensory receptor on the bladder wall, which detects a stretch reflex stimulus when a certain amount of urine accumulates

in the bladder; the corresponding signal is then transmitted through the parasympathetic pelvic nerve to the vesicospinal center in the sacral cord [13]. By the time they have passed the acute phase, spinal cord-injured individuals have usually recovered their urinary reflex function [14]; furthermore, if the sacral portion of the spinal cord has not been damaged, stimulation via an increase in urine volume to the level requiring urination will elicit some parasympathetic nervous activity. Accordingly, we reasoned that the time at which the urine increased in the bladder to the level requiring urinary drainage could be detected by an estimation system that monitors autonomic nervous activity for aiding individuals with SCI lacking urinary sensation of storage. Previous studies [5–12] have demonstrated the possibility of monitoring autonomic nervous activity by (1) measuring HAPW, (2) calculating the time-series power spectra of heart rate gradients in the ultralow/very low frequency bands, and (3) extracting the waveform portions with certain characteristic shapes that showed significant changes in these power spectra. Of these, (1) HAPW measurements are known to have good accuracy and had been shown to carry physiological significance [6, 7], indicating that the use of the HAPW sensor was valid; (2) we chose to use time-series power spectra in the ultralow/very low frequency bands, the same bands used to assess autonomic nervous activity in drivers [8–12]; and (3) since the waveform characteristics to be distinguished in the time-series power spectra when the urine in the bladder had increased to a level requiring urination were unknown, we conducted a previous study with healthy participants who had a urinary sensation [15]. In six healthy male participants, HAPWs were measured at the midback, and time-series power spectra in the same frequency bands were calculated using the same method as in these studies. A certain characteristic waveform in each power spectrum appeared similarly in almost all participants, with one waveform portion in five participants and two portions in another, for a total of seven portions, corresponding to an increase in bladder urine and heightened urges to urinate. We formulated these waveform characteristics and developed an algorithm based on five power spectra for identifying when urination is needed by extracting the waveform portions whose characteristics are consistent with the formulated characteristics [15]. This algorithm is named ATUI (algorithm for identifying the timepoint at which the urine has increased in the bladder to the level that requires urinary drainage).

The objective of this experimental study was to verify the validity of the original ATUI—developed using the HAPWs of healthy participants—after it was fed with data from the HAPWs measured from individuals with SCI and make any changes to adapt the ATUI for these individuals.

Results

Participant attributes

The attributes of the ten males who participated in this study are shown in Table 1. The mean age was 45.9 years (range: 34–68 years), and the mean duration since the SCI was 21.2 years (6–53 years). The SCI was located in the cervical cord in three participants, the thoracic cord in four participants, and the bifurcation of the thoracic and lumbar cords in three participants. Six participants self-reported complete paralysis and four self-reported incomplete paralysis. Two participants perceived urine volume increases in the bladder as well as a healthy individual, six relied on other, substituted sensations

Table 1 Participant attributes

ID	Age	Injury cord level	Paralysis	Years after injury	Urinary sensation	Ordinary drainage interval	Drainage cue	Experiment time[§] Total 20:18:36
1	38	C6/7	Complete	19	SubSen*: cold sweat, goose pimples	Indetermination	SubSen episode	1:40:48
2	45	Th4/5	Complete	25	SubSen: palpitation, headache	2 h	SubSen episode	2:19:12
3	35	C5/6	Complete	15	SubSen: cold sweat, chill, palpitation	3 h	SubSen episode	2:21:18
4	68	Th12/L1	Incomplete	53	Normalcy	2 h	Sensation episode	1:16:48
5	48	Th12/L1	Incomplete	6	SubSen: enhancement of pins-and-needles sensation in the lower limb	3 h	SubSen episode	2:12:00
6	64	Th12/L1	Complete	36	Normalcy	2–3 h	Sensation episode	1:51:36
7	38	C5/6	Complete	14	A little sensation, SubSen: heat sensation in the face	3–3.5 h	SubSen episode	1:53:24
8	37	Th7	Incomplete	17	Insensible completely	3 h	On a timed basis	2:21:54
9	45	Th9/10	Incomplete	17	SubSen: sudation, dizziness, nausea	3–4 h	SubSen episode	1:55:30
10	45	Th12	Complete	10	Insensible completely	3–4 h	On a timed basis	2:26:06

[§] Experiment time: hour:minute:second

[*] SubSen: the other substituted sensation

for determining when they had to urinate, and two participants were completely insensitive to the filling of their bladders.

The symptoms of the participants who relied on the substituted sensations included cold sweats, goose pimples, chills, headache, palpitations, sudation, dizziness, nausea, pin-and-needle sensations, and heat sensations. All the participants performed daily CIC by themselves. The cue for self-catheterization was the onset of the urinary sensation or other substituted sensations in eight participants and the set time in two participants. The most common CIC interval was 2–4 h.

One participant performed self-catheterization during the experiment.

Outline of the experiment and analysis

For each participant with SCI, HAPW and R–R intervals of the heartbeat were measured continuously, while the volume of urine in the bladder was measured every 40 min using a bladder ultrasound scanner, and subjective physical conditions, including urinary sensation of storage and other substituted sensations, were assessed during the bladder

urine measurement. Peaks and zero crossings of the HAPW were identified to calculate two time-series heart rates, respectively. The time-series power spectra of the heart rate gradient at three frequencies (0.0017 Hz, 0.0035 Hz, and 0.0052 Hz) were calculated every 18 s for the above two periodic point detections. These spectra were then used to calculate the power spectral rates (PSRs) with respect to the sum of the three powers. Using five PSRs (PSR_Pk35: PSR for the peak detected at 0.0035 Hz; PSR_Pk52: PSR for the peak detected at 0.0052 Hz, PSR_0×17: PSR for the zero crossing detected at 0.0017 Hz, PSR_0×35: PSR for the zero crossing detected at 0.0035 Hz, PSR_0×52: PSR for the zero crossing detected at 0.0052 Hz), the ATUI extracted the portions where all of the waveform characteristics (one characteristic for each PSR) were consistent with the formulated characteristics obtained from the healthy participants at times of increased urine in the bladder and heightened urges to urinate; that is, the integrated Boolean outputs of the ATUI were positive. Notable times included when the ATUI output was positive or when a need to drain urine (=(+)) was judged from the urine volume and urinary sensation scores. The ATUI outputs at the notable times were examined with the need for urinary drainage and determined to be true/false. The accuracy of the ATUI was evaluated according to the number of true/false-positive/negative points via the F-score with a binary classification model.

Case report in detail

Figure 1 shows relevant data for a participant whose PSR waveforms yielded two true-positive outcomes: six time-series PSRs; the Boolean outputs of each PSR and the integrated outputs; the measured urine volume; the physical condition scores; the heart rate; and the power spectrum in the high frequency band 0.15–0.4 Hz (HF) and the LF/HF ratio (LF: power spectrum in the low frequency band 0.04–0.15 Hz). Notably, the PSR_0×17 and PSR_0×35 presented with characteristic waveforms. At two points (34.6 and 121 min) at which the integrated output was positive, PSR_0×17 descended steeply from the higher pre-peak and PSR_0×35 crossly ascended steeply from the lower pre-valley. The true-positive result at 34.6 min, which occurred within 8 min of urinary drainage, was observed because the participant was considered in need for urinary drainage at this point (+). Shortly after the 121-min point, which also had a positive integrated output, the experiment was terminated at the participant's request due to an increased urinary sensation. The urine-to-volume ratio was 100%, as the drained volume measured after the experiment was 270 mℓ (i.e., the maximum). Consequently, the judgment of the need for urinary drainage was judged to be (+), and the examination outcome at this point was a true positive. At the two identified true-positive points, the fatigue and sleepiness scores were also zero, and the LF/HF and LF time-series waveforms had no substantial common features.

From the top, heart rate is shown in the first chart, heart rate variability in HF and LF/HF in the second, Boolean outputs in the third, the three power spectral rates based on peak detection in the fourth and zero crossing detection in the fifth, respectively, measured urine volume in the sixth, and physical condition scores in the seventh.

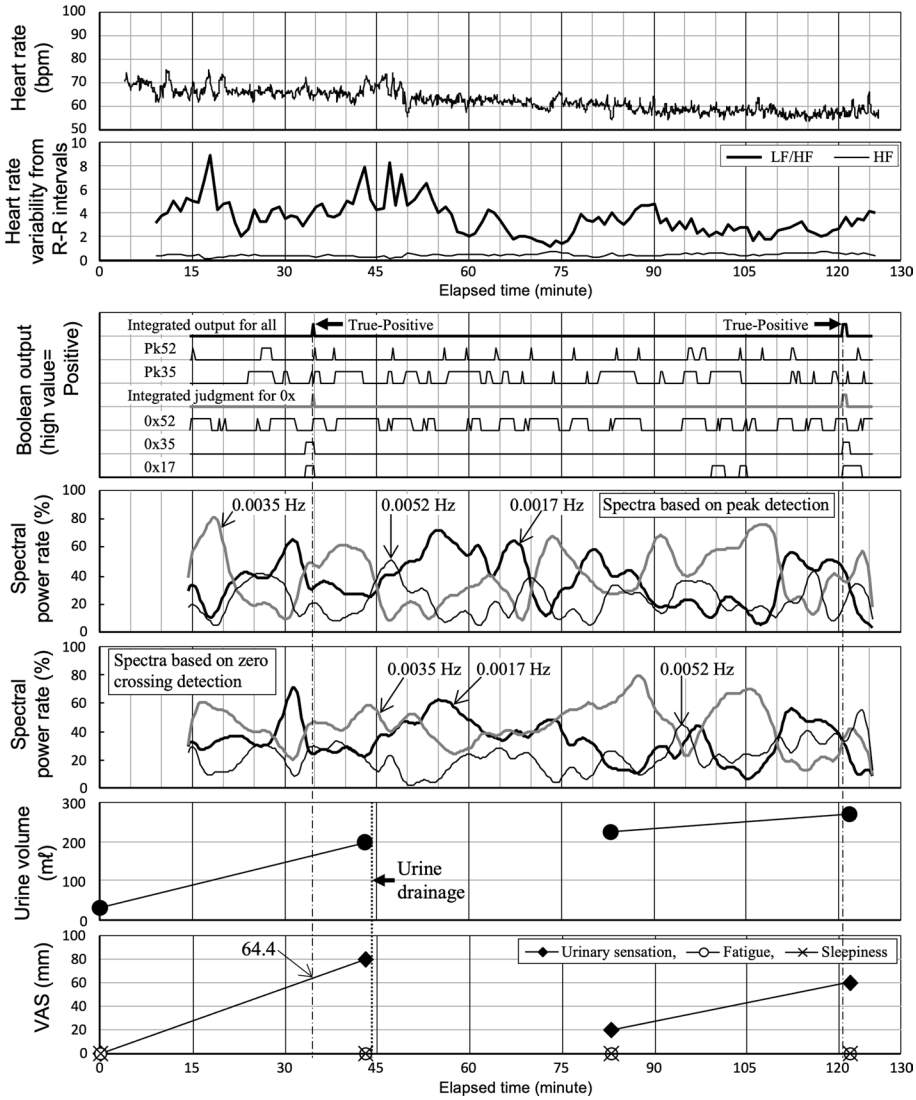

Fig. 1 Power spectral rates, Boolean outputs, urine volume, physical conditions, heart rate, and the heart rate variabilities from R–R intervals for this case

Examination outcomes using the original ATUI

Tables 2 and 3 show the examination outcomes in ten participants with SCI obtained by the original ATUI fed with the data from the measured HAPWs. The ATUI outputs at 13 notable timepoints were examined, resulting in seven true-positive, one false-positive, and five false-negative points. The type I and II error rates were 7.7% and 38.5%, respectively, with an F-score of 0.70.

Adaptation of the ATUI

The ATUI was adapted for the participants with SCI by replacing one threshold in each of the three inequalities for PSR_0×17, PSR_0×52, and PSR_Pk35 (all for waveform slope), with a new value, as shown in bold in Table 4. One false-positive outcome and five false-negative outcomes from the original ATUI were corrected to one true-negative

Table 2 Examination outcomes for the output of the ATUI* fed with data from each PSCI[¶]

ID	Time of drainage[§a] (min)	Timepoint identified by ATUI*									
		Elapsed time (min)	ATUI output		Urine volume[§b] (mℓ [%])	Urinary sensation[§b] (mm)	Need for drain-age	Fatigue score[§b] (mm)	Sleepiness score[§b] (mm)	Examination outcome	
			Healthy subject version	Adaptation to SCI						Healthy subject version	Adaptation to PSCI[¶]
1		80.0	Negative	Positive	149.2 [71]	40.6	(+)	20	0	False-neg. ‡	True-pos
2		83.8	Positive	Positive	123.3 [79]	0.0	(+)	23	80	True-pos	True-pos
3		115.5	Positive	Positive	141.6 [97]	17.3	(+)	37	20	True-pos	True-pos
4		61.6	Positive	Positive	524.7 [95]	21.4	(+)	7	0	True-pos	True-pos
		82.6	Positive	Positive	546.4 [99]	54.6	(+)	18	0	True-pos	True-pos
5		135.3	Negative	Positive	98.7 [82]	100.0	(+)	40	20	False-neg. ‡	True-pos
6	43	34.6	Positive	Positive	201.7 [75]	64.4	(+)	0	0	True-pos	True-pos
		121.0	Positive	Positive	270.0 [100]	60.0	(+)	0	0	True-pos	True-pos
7		42.3	Positive	Negative	122.0 [41]	1.2	(−)	0	19	False-pos. †	True-neg
		112.8	Negative	Positive	276.4 [92]	72.7	(+)	0	0	False-neg. ‡	True-pos
8		141.3	Negative	Positive	417.7 [70]	–	(+)	80	80	False-neg. ‡	True-pos
9		99.1	Positive	Positive	106.2 [82]	0.0	(+)	5	0	True-pos	True-pos
10		136.6	Negative	Positive	123.3 [62]	–	(+)	0	0	False-neg. ‡	True-pos

[*] ATUI: algorithm for identifying the timepoint at which the urine has increased in the bladder to the level that requires urinary drainage

[¶] PSCI: participant with spinal cord injury

[§a] The empty cell indicates that the participant drained urine after this experiment

[§b] The scores are interpolated or extrapolated

[†] Type I error

[‡] Type II error

Table 3 Evaluation of the accuracy of the ATUI* with the binary classification model

Integrated output of the ATUI*	ATUI* (Healthy subject version)		ATUI* (Adaptation to PSCI[¶])	
	Need for drainage		Need for drainage	
	(+)	(−)	(+)	(−)
Positive	7	1	12	0
Negative	5	0	0	1
	Precision, Recall	F-score	Precision, Recall	F-score
	0.88, 0.58	0.70	1.00, 1.00	1.00

[*] ATUI: algorithm for identifying the timepoint at which the urine has increased in the bladder to the level that requires urinary drainage

[¶] PSCI: participant with spinal cord injury

Table 4 Inequalities with the feature value and threshold for extracting characteristic waveforms

PSR[§]	Feature of power spectral rate	Inequality
Zero crossing detection 0.0017 Hz	Low current value	Current value < [35]
	Steep decline at the current point	$\delta <$ **[−2.2] → [−1.5]**
	High pre-peak value	Pre-peak value > [40]
	Large decrease from the pre-peak	$\Delta <$ [−23]
Zero crossing detection 0.0035 Hz	High current value	Current value > [33]
	Steep incline from the pre-valley to the current point	$\delta_{max} >$ [3.4]
	Low pre-valley value	Pre-valley value < [19]
	Large increase from the pre-valley	$\Delta >$ [26]
Zero crossing detection 0.0052 Hz	Moderate decline at the current point	$\delta <$ **[−0.8] → [−0.3]**
Peak detection 0.0035 Hz	Moderately current value	Current value < [70]
	Gradual slope at the current point	[−0.6] < $\delta <$ **[0.9] → [1.1]**
Peak detection 0.0052 Hz	Gradual decline at the current point	[−0.5] < $\delta <$ [0]

[§] PSR: power spectral rate

δ difference from the previous value to the current value

δ_{max} maximum δ value in the period from the pre-valley point to the current point

Δ difference from the value of the immediately preceding extreme point to the current value

All numerical values are shown as a percentage

The numerical value in square brackets [] is the threshold (%)

The phrase of the threshold in bold and including "→" was replaced for the adaptation of the algorithm

The Boolean value is positive when all inequalities for each PSR are met

outcome and five true-positive outcomes, respectively. Regarding the adapted ATUI, the examination outcomes at 13 notable times were all scored as true (12 true-positive outcomes and one true-negative outcome, Table 2) and there were no type I or type II errors, resulting in an F-score of 1.00 (Table 3).

LF/HF and HF time-series waveforms

At the 12 true-positive points identified with the adapted ATUI, the LF/HF and LF time-series waveforms demonstrated no common, significant features among the ten participants.

Discussion

Significance of the results

The ATUI modified in this study accurately derived the times when the urine increased in the bladder to a level requiring urinary drainage in ten participants with SCI. The fact that changing only three thresholds allowed the ATUI to be adapted for the participants with SCI suggests that the HRVs in three ultralow/very low frequency bands (0.0017 Hz, 0.0034 Hz, and 0.0052 Hz) and the distinguished waveform characteristics in the PSRs, the features of this estimation system, are important indicators of autonomic nervous activity associated with increased urine in the bladder.

This is the only study that has sought to detect an increase in bladder urine on the basis of HRV via autonomic nervous activity. A previous study compared the efficacy of several state-of-the-art wearable devices for monitoring urine volume in the bladder [16]; however, these devices are all limited by low accuracy. In addition, since these devices measure urine in the bladder percutaneously, the sensor must be in close contact with the skin at all times, creating a risk of skin disease. In this study, the estimation system uses a sensor located just inside the surface of the wheelchair backrest and is able to measure the HAPW even through clothing. Consequently, there is essentially no risk of skin disease. The system is also highly practical, because it can compensate for missing data even if the back is off the surface of the backrest for several seconds.

Many of the participants timed their urinary drainage based on the basis of the perception of other, substitute sensations, such as palpitations, chills, sudation, dizziness, nausea, headache, cold sweats, goose pimples, pins-and-needles sensations, and facial heat sensations. These phenomena include autonomic hyperreflexia, which is often caused by bladder enlargement and bowel distension [17]; autonomic hyperreflexia also leads to elevated blood pressure and is a particularly strong risk factor for intracerebral hemorrhage [18]. Therefore, relying on these compensatory urinary urges to obtain urinary drainage timing is risky; our estimation system could be a practical solution to this potentially dangerous alternative method.

Improving the accuracy of the ATUI

The remaining issues regarding the accuracy of the ATUI can be addressed by implementing an AI-based mechanism. The mechanism of such a system would involve the dynamic determination of the thresholds to distinguish the waveform characteristics in the time-series PSRs at the time of the need for urinary drainage, potentially improving the accuracy of the ATUI. A previous study [19] reported that several CIC practitioners should increase the frequency of urinary drainage to prevent urinary tract infection. This approach indicates not only the need for aseptic urinary continence, but also the need to empty the bladder as often as possible. This means that slightly more frequent urinary drainage is acceptable but that even more frequent drainage is better. To improve the accuracy of the algorithm, false positives (type I errors) can be allowed, whereas false negatives (type II errors) should be minimized.

Perception of increased urine volume and autonomic nervous activity

SCI impairs the urinary system, including urinary sensation. However, people with SCI who have progressed past the acute phase have usually recovered their urinary reflex

function. The onset of the urinary reflex conveys an excitatory signal to the autonomic nerves involved in the urinary system. In general, autonomic nervous activity can be monitored through HRV; therefore, our attempt to detect increased urine in the bladder on the basis of HRV in people with SCI is reasonable.

Knowledge of autonomic nervous activity is based mainly on the use of LF/HF and HF. With respect to HRV in the very low frequency band, previous studies have reported that the signs of recovery of HRV in this band differ from those in LF/HF and HF when the subject performs a mental stress task [20] and evaluated the predictive potential of HRV in this band for the development of infectious complications in the immediate post-stroke period [21]. Few studies have clarified the relationship between autonomic nervous activity and HRV in the ultralow/very low frequency band that we used in this study.

Urine storage and urination are partially controlled by the autonomic nervous system. However, the exact mechanisms leading to bladder dysfunction in patients with neurodegenerative diseases involving autonomic components are poorly understood [22]. Future research should investigate the relationship between the autonomic nervous system activity associated with the detection of increased urine in the bladder and HRV in the ultralow/very low frequency band.

Limitations

Although this experimental study had a total experimental time of more than 20 h, only 12 sets of training data of increased urine in the bladder were collected from ten participants with SCI, which is insufficient for achieving high reliability, and overfitting cannot be completely ruled out.

At the time of the experiment, the measurement equipment could only measure the intravesical urine volume intermittently. This reduced the temporal accuracy of the algorithm output examination. That technology has advanced to the point that continuous, noninvasive measurement of intravesical urine volume is possible, the experimental procedure could be modified to continuously measure HAPW and intravesical urine volume to obtain data from many individuals with SCI in the future to improve the reliability of the required urinary drainage timing.

We attempted to determine the point at which urine in the bladder increases to a level that requires urinary drainage on the basis of phenomenological data, i.e., HRV in the ultralow/very low frequency bands. Further knowledge on these data, which serve as the basis for the proposed estimation system, is needed.

Conclusions

The outputs of the original ATUI, fed with the data from the measured HAPWs of ten participants with SCI, were examined at 13 notable times, resulting in seven true positives, one false positive, and five false negatives, with an F-score of 0.70. After replacing three thresholds that determine the extraction condition for the slope in the PSR waveforms from the original ATUI, without changing the use of the three ultralow/very low frequencies or significantly modifying the extraction conditions for the waveform

characteristics, the adapted ATUI did not miss any urination times or identify false urination times in ten participants with SCI, thus achieving an F-score of 1.00. In addition, we were able to comprehend the issues that should be addressed to improve the accuracy and versatility of the system for estimating the time at which the urine in the bladder increases to a level requiring urinary drainage. Our results represent an advancement of this system toward practical implementation.

Methods

Participants

Males with SCI who engaged in social activities after leaving the hospital were recruited for this experimental study in cooperation with the Kyoto and Shiga branches of the Spinal Injuries Japan. Individuals without kidney, bladder, or voiding dysfunction and those who could perform daily self-catheterization were included. Candidates who offered to participate were confirmed to have no other health problems, such as the possibility of developing bedsores while performing an assigned tasks for approximately 2 and a half hours. Ten individuals were ultimately included in this study and provided written informed consent for participation. This study was conducted in accordance with the Declaration of Helsinki, and was approved by the ethics committee of Shiga University of Medical Science (approved number: 23–91).

Experiment

Experimental task

Each participant typed on a notebook PC while seated in his own wheelchair in a sound-shielded room at a controlled temperature (24–26 °C).

Continuous measurement

HAPW data were collected with a seatback containing a sound sensing system, and the signals were recorded with a warning device for drowsy driving (Sleep Buster, Delta Tooling Co., Ltd., Hiroshima, Japan). The R–R interval of the heartbeat was measured with a heart rate meter (RS800CXN, Polar Electro Oy, Finland) consisting of an electrocardiographic sensor built into a chest belt and a wristwatch-like recording device with a wireless connection. All the data were recorded throughout the experiment.

Intermittent measurement

The volume of urine in the bladder of each participant sitting in his wheelchair was measured every 40 min with a bladder ultrasound scanner (BladderScan® BVI 6100, Verathon, Inc., USA). This scanner is intrinsically applied to a subject in the supine position, and the measurement accuracy is reduced when the participant is in the sitting position due to the difference in bladder shape between the two positions. However, the intraindividual changes in bladder shape were small according to repeated ultrasound echo imaging. The repeatability and availability of the measured values were confirmed for each participant by recording the data for several subjects in the seated position.

Subjective physical conditions, including urinary sensation of storage, the other substituted sensations, fatigue, and sleepiness, were assessed on a visual analog scale (0–100 mm) during the period when urine volume was measured. In addition, blood

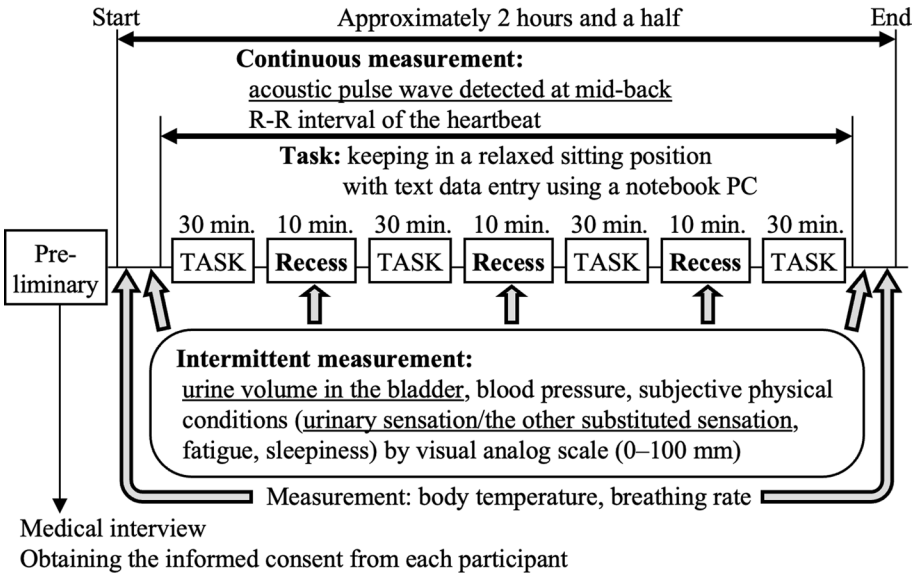

Fig. 2 Experimental protocol in a sound-shielded room at a controlled temperature (24–26 °C)

pressure was measured with a sphygmomanometer (UA-772 A&D ELECTRONICS Co., Ltd., Saitama, Japan) to assess the participants' health status.

Experimental protocol

The experimental protocol is shown in Fig. 2. At the beginning of the experiment, each participant's health status was assessed via medical interview. In the experimental room, an investigator affixed the measuring seatback to the participant's wheelchair; measured the participant's body temperature, respiratory rate and urine volume in the bladder; and asked the participant to report on his physical condition. After the preparations for the experiment were completed, the HAPW and R–R data were recorded, and the participant began the first task. The participant performed four tasks with three 10-min rest periods in between, during which the urine volume and physical conditions of the participant were assessed between tasks. After the fourth task was completed, the investigator measured the participant's body temperature, respiratory rate and urine volume, and the participant self-reported his physical conditions. The drainage volume was measured with a graduated cylinder when performing urethral catheterization after or during the experiment.

Data analysis

HAPW data calculation

The digitally recorded HAPW data were processed with the Savitzky–Golay smoothing and differentiation filter to identify peaks and zero crossings stably in the waveform. The identified peaks and crossing points were used to determine two time-series heart rates, calculated from the inverse of the time between the peaks and between the crossing points, respectively. The unequally spaced time-series heart rates were averaged in each 6-s period for the two periodic point detections. The gradient of the heart rate over

a 180-s period was calculated using the least squares method to approximate a linear function. The same calculation was carried out for the next 180-s period, which overlapped the previous period by 162 s. This process was repeated every 18 s to create the time-series gradient of heart rate for the two detections [6]. The 32 data points of the heart rate gradient were Fourier transformed, resulting in three power spectra at 0.0017 (=1/576) Hz, 0.0035 (=2/576) Hz, and 0.0052 (=3/576) Hz. These spectra were then used to derive three power spectral rates against the sum of the three powers. The same calculation was carried out for the next 32 data points, offset by one data point. This process was repeated for each subsequent data point to create the three time-series power spectral rates for the two detections. To check over the variation of the waveforms for approximately 3 min, the time-series power spectral rates were smoothed using a Butterworth lowpass filter with a cutoff frequency of 0.0033 Hz. The six processed PSRs are represented as PSR_Pk17 (PSR for the peak detected at 0.0017 Hz), PSR_Pk35, PSR_Pk52, PSR_0×17, PSR_0×35, and PSR_0×52.

Identification of the timepoint at which the urine volume increased

The ATUI is a special procedure that uses five time-series PSRs (PSR_Pk35, PSR_Pk52, PSR_0×17, PSR_0×35, and PSR_0×52) to identify the times at which urination is needed. Identifying these times consists of performing a Boolean analysis to extract the portions (the Boolean value=positive) that match the characteristic waveform obtained from the healthy subjects in each of the PSRs and integrating of the Boolean result values in the five PSRs into a single value at each timepoint with a logical formula.

First, the set of inequalities with the pair of a feature value in the PSR waveform and a threshold is used to determine a Boolean value at each timepoint for each PSR; the Boolean variable is positive if all of these inequalities were met and is negative otherwise. These feature values include the magnitude of the current point, the sign and magnitude of the slope for the current point, the magnitude of an immediately preceding extreme point (peak or valley), and the difference between the value of the extreme point and the current value. Several features are selected according to the PSR.

Second, the five Boolean values in the PSR (Bool(PSR)) at the same point are integrated into a single value with the logical AND operator according to the following formula: Bool(PSR_0×17)=positive AND Bool(PSR_0×35)=positive AND Bool(PSR_0×52)=positive AND Bool(PSR_Pk35)=negative AND Bool(PSR_Pk52)=negative [15].

The timepoints at which the integrated Boolean output is positive are estimated to indicate when urinary drainage should be performed.

R–R interval calculation

The time-series heart rate was calculated from the inverse of the R–R intervals. The unequal interval heart rates were converted to equal interval time-series data with the spline function approximation. Two power spectra in the low-frequency band (0.04–0.15 Hz, LF) and the high-frequency band (0.15–0.4 Hz, HF) were calculated with the Fourier transform, and the LF/HF ratio was obtained. The LF/HF ratio and HF are indices of sympathetic and parasympathetic activity, respectively [23].

Need for urinary drainage

The urine volume in the bladder and the scores of subjective physical condition scores were obtained intermittently. The values corresponding to the timepoints of the ATUI output were calculated with linear interpolation/extrapolation. Interpolation was used when the data were available before and after the determined timepoint, and extrapolation was used in all other cases.

The ratio of urine volume to bladder capacity was defined as the ratio of the interpolated/extrapolated urine volume divided by the maximum urine volume measured for each participant. The need for urinary drainage was judged as (+) if the urine volume ratio exceeded 50% and the scores related to the urinary sensation of storage exceeded 50 mm; otherwise, the need for urinary drainage was judged as (−) [15]. The bladder capacity of an adult is 250–500 mℓ; and a person urinates via bladder contraction when the volume of urine is typically 300–400 mℓ [14]. The earliest urinary sensation is perceived at a urine volume of approximately 150 mℓ; at 400 mℓ, the urinary sensation is difficult to tolerate [13]. Therefore, we assumed the bladder capacity to be 500 mℓ, and we set the two thresholds of the urine volume ratio and the urinary sensation score to 50%, i.e., 250 mℓ of urine in the bladder.

Notable timepoints and validity examination of the ATUI outputs

A notable timepoint was defined when the ATUI output was positive. Other notable timepoints included when the need for urinary drainage was judged to be (+) and when the integrated ATUI output was negative but at least one of the three PSRs for detecting zero crossings had a positive Boolean output.

The ATUI output at each notable timepoint was examined with the need for urinary drainage and determined to be true/false. The examination outcome was a false positive when the ATUI output was positive and there was no need for drainage (−), in other words, a Type I error, and a false negative when the ATUI output was negative and there was a need for drainage (+), in other words, a Type II error, as shown in Table 5.

Evaluation of ATUI accuracy with the binary classification model

The examination outcomes (true positive, false positive, false negative, or true negative) were counted to evaluate the accuracy of the ATUI with a binary classification model. The F-score, precision, and recall were also calculated as metrics.

Table 5 Examination method of the results from the ATUI*

Integrated output of the ATUI*	**Need for urinary drainage**	
	(+) **Urine volume ratio > 50% or score related to urinary sensation > 50 mm**	**(−)** **Except for the matters listed at left**
Positive	True positive	False positive (Type I error)
Negative	False negative (Type II error)	True negative

* ATUI: algorithm for identifying the timepoint at which the urine has increased in the bladder to the level that requires urinary drainage

Adaptation of the ATUI for participants with SCI

As some type I/II errors were present in the examination outcomes of the points identified with the original ATUI, the ATUI was adapted to the HAPW data of the participants with SCI by changing some thresholds in the inequalities without changing any waveform features. The thresholds were modified to reduce the occurrence of errors as much as possible, with a particular focus on minimizing the occurrence of Type II errors. The calculations for identifying the points at which the ATUI output was positive in all participants were repeated each time the threshold was changed. The adapted ATUI and the results at the points identified with the final thresholds are reported in this study.

Abbreviations

SCI	Spinal cord injury
CIC	Clean intermittent catheterization
HAPW	Heartbeat-induced acoustic pulse wave
HRV	Heart rate variability
ATUI	Algorithm for identifying the timepoint at which the urine has increased in the bladder to the level that requires urinary drainage
PSR	Power spectral rate

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Author contributions
KT conceived first idea of this study. HS, HT, TK and KT designed the experimentation. HS recruited and collected the participants. In addition, HS arranged and carried out all experiments, and collected data at all. YO and EF structured the HAPW measuring system and calculated the fluctuations of the heart rate gradients in ultralow/very-low frequency bands. HT developed the ATUI and analyzed. HT made the figures/tables and helped to draft the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the Declaration of Helsinki, and was approved by the ethics committee in Shiga University of Medical Science (approved number: 23-91). The aim and procedure of the experiment were explained to the participants in detail both in writing and orally. We told the participants that the participation in the experiment was voluntary, and they could cancel the experiment at any time. In conducting the experiment, a physician and a nurse were on site, if any change in physical condition was observed to the participant, the experiment was stopped immediately and a system was in place to deal with the change. All participants provided written informed consent.

Consent for publication
Not applicable.

Competing interests
Hitomi Suzuki, Hiroji Tsujimura, Teruyo Kitahara and Kazushi Taoda declare that they have no competing interests. Yumi OGURA and Etsunori FUJITA are employees of Delta Tooling Co., LTD. The seatback with a built-in air-pack sensor in this experiment was loaned to us free of charge by the company.

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