Daily ingestion of alkaline electrolyzed water containing hydrogen influences human health, including gastrointestinal symptoms

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Abstract

In Japan, alkaline electrolyzed water (AEW) apparatus have been approved as a medical device. And for the patients with gastrointestinal symptoms, drinking AEW has been found to be effective in relieving gastrointestinal symptoms. But some users of AEW apparatus do not have abdominal indefinite complaint. Little attention has been given to the benefit for the users which have no abdominal indefinite complaint. The object of this study is to evaluate the effect on health, including gastrointestinal symptoms, when a person without abdominal indefinite complaint, *etc*., drinks AEW on a daily basis. A double-blind, randomized controlled trial has been designed. Four-week period of everyday water drinking, PW drinking group: drink purified tap water as a placebo, AEW drinking group: drink alkaline electrolyzed water which made by electrolysis of purified tap water. Before the experiment and after the 4-week period of water drinking, Blood tests, physical fitness evaluations, and questionnaire evaluations is conducted. In this study, we did not specifically select patients with gastrointestinal symptoms. Sufficiently clear effect could not be confirmed. But the stools were more normal, and, as shown in the previous report, that drinking AEW is considered to contribute to intestinal normalization. In addition, when drinking AEW, a high proportion of the respondents said that they felt they were able to sleep soundly, and the proportion of subjects who answered that they felt good when awakening increased. The effect of reducing oxidative stress, thus allowing for improved sleep, was exhibited by drinking AEW containing hydrogen, which is considered to be an antioxidant substance. This research were approved by the Ethics Committee of the Osaka City University Graduate School of Medicine (No. 837) and were registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN ID: UMIN000031800) on March 22, 2018.

Key words: alkaline electrolyzed water; gastrointestinal symptoms; hydrogen-dissolved water; physical fitness evaluations; questionnaire evaluations; functional beverage

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Introduction

In Japan, water which is obtained on the cathode side by the electrolysis of tap water is called alkaline electrolyzed water (AEW) or reduced hydrogen water.[1] Improvement of gastrointestinal symptoms by ingesting AEW has been confirmed by Japanese researchers. For example, Naito et al.[2] reported the inhibitory effect of AEW ingestion on gastric mucosal disorder caused by aspirin, and Hayakawa et al.[3] reported the inhibitory effect of AEW ingestion on abnormal intestinal fermentation. Tashiro et al.[4] examined the effect of ingesting AEW or purified tap water (PW; as a placebo) at a rate of at 500 mL per day for 4 weeks in patients who had abdominal pain such as heartburn, stomach discomfort, abdominal bloating, diarrhea, constipation, *etc*., and reported that the results of the AEW group were superior to those of the placebo group.[5,6] From these results, apparatus that produce AEW have been approved as medical devices by the Japanese Ministry of Health, Labour and Welfare. AEW is thought to be effective for functional gastrointestinal disorders.[5]

Since AEW is produced by electrolyzing water, hydroxide ions, which are alkaline in nature, are generated. Hydrogen molecules are also generated on the electrode surface and dissolved in water. Therefore, AEW is alkaline water containing hydrogen.[1] In conventional efficacy studies, evaluations with respect to ingesting AEW have typically been conducted focusing on the alkalinity of the water.[2-5] In recent years, however, the assumed effectiveness of the antioxidant effect of dissolved hydrogen on various diseases has been reported.[7-15] Nevertheless, some users of AEW apparatus do not have any definite abdominal symptoms. In many cases, they are drinking AEW on a daily basis to improve their health, and many users also feel health benefits such as improvement in exercise capacity[12]. These may be thought to be due to the action of dissolved hydrogen. There have been no researched studies of these in detail. The object of this study is to evaluate the effect of daily ingestion of AEW on health, including gastrointestinal symptoms, in subjects without any definite abdominal symptoms.

Participants and Methods

Participants

Healthy men and women (20–60 years) who use the Osaka City Citizen Health Development Consultation Center were selected as test subjects to determine the health effect of daily AEW ingestion. It was aimed to clarify whether general subjects without gastrointestinal symptoms have another good effect besides gastrointestinal symptoms by drinking AEW

which is good for gastrointestinal symptoms. We explained this purpose to the subjects and asked for research participation. Written informed consent was obtained from all subjects. All procedures used in this research were approved by the Ethics Committee of the Osaka City University Graduate School of Medicine (No. 837) and were registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN ID: UMIN000031800) on March 22, 2018. This study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A double-blind, randomized controlled trial has been designed, and the research design is shown in **Figure 1**.

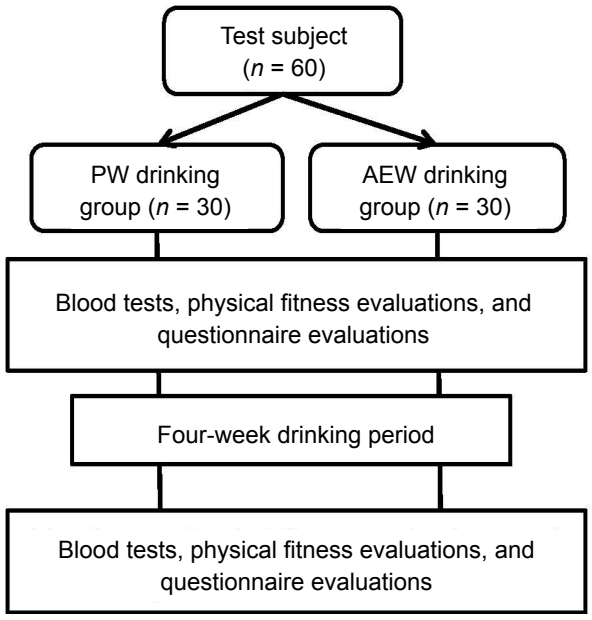

Figure 1: Research design.
Note: PW: Purified tap water; AEW: alkaline electrolyzed water.

Subjects were randomly divided into two groups, with an AEW group (n = 30) and a PW group (n = 30). Blood tests, physical fitness evaluations, and questionnaire evaluations were conducted before the experiment was initiated. Subjects were provided with AEW apparatus[1] that had been modified to produce only AEW or PW. They ingested 500 mL or more of freshly produced AEW or PW per day (they were required to ingest 200 mL immediately after awakening, and 300 mL or more during the rest of the day). After the end of the four-week period, blood tests, physical fitness evaluations, and questionnaire evaluations were conducted again to check whether the ingestion of AEW for four weeks had beneficial effects on the health of the subjects.

Blood sample/urinalysis

General blood test: Red blood cell count, white blood cell count, hemoglobin, hematocrit, and platelet count.

Blood biochemical examination: Total protein, albumin, glutamic oxaloacetic transaminase (GOT), glutamic pyruvic transaminase (GPT), γ-GTP, total cholesterol, high-density lipoprotein (HDL), cholesterol, low-density lipoprotein (LDL) cholesterol, neutral fat, uric acid, creatinine, and blood sugar.

Urinalysis: Urine sugar, urine protein, urine occult blood, and urine pH.

Physical measurements

Right/left grip strength, right/left leg muscle strength, vertical jump, whole body reaction time, standing time on one leg with eyes closed, sit-up, seated forward bend, and resting blood pressure.

Questionnaire variables

Gastrointestinal symptoms (stomachache, heartburn, heavy stomach, lower abdominal pain, bloated stomach), urinary frequency, condition of the stools (fecal properties and bowel movement), and physical condition (sleep quality and upon awakening).

Statistical analysis

In the blood data, the urinalysis and physical measurement values, the statistical significance of the average difference (before and after AEW, PW drinking) was analysed using a paired t-test (Statcel 4 Software [OMS Publishing, Saitama, Japan). The questionnaire data (before and after AEW, PW drinking) was analysed by the Wilcoxon signed-rank test using the same Statcel 4 software. Differences for which P values of < 0.05 and < 0.01 were inferred as significant.

Results

Conditions of subjects and water quality

Subjects with abdominal symptoms such as heartburn, stomach discomfort, abdominal bloating, diarrhea, and constipation were used in the study previously performed.[4,5] For the current study, subjects aged 20 to 69 years were randomly selected among medical checkup examinees who visited the Osaka City Citizen Health Development Consultation Center, and then divided into two groups. One group ingested PW while the other ingested AEW. Neither the subjects nor the experimenters knew which group the subjects belonged to. **Figure 2** shows that no significant differences were found in dispersion of mean values and distribution values.

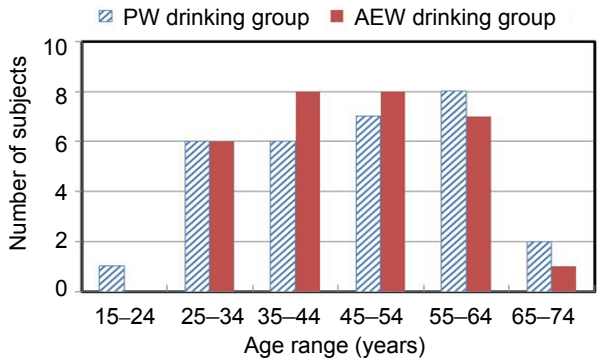

Figure 2: Age distribution of subjects.
Note: PW: Purified tap water; AEW: alkaline electrolyzed water.

Each subject was provided with an AEW apparatus that had been modified to either produce or not produce AEW, and asked to install it at their home. In order to verify the quality of the drinking water, the water produced by the apparatus was taken into aluminum containers and collected when the subjects came in for measurement. **Figure 3** shows the water quality distribution of each drinking water.

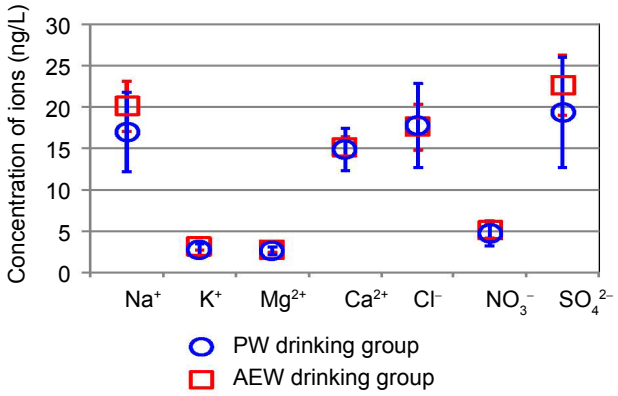

Figure 3: Water quality distribution of two types of drinking water.
Note: PW: Purified tap water; AEW: alkaline electrolyzed water.

Because we selected subjects who live in or around Osaka City, the tap water from either the same or a nearby water source was used for the evaluation. For this reason, the tests have been conducted using water of equivalent quality and which shows little bias in the distribution of ions.

Regarding the water before and after the electrolysis, the pH was 7.6 ± 0.2 for the PW group, and 9.2 ± 0.2 for the AEW group. Dissolved hydrogen concentration was not measurable at the subjects' houses because hydrogen easily escapes water. However, for non-electrolyzed and electrolyzed tap water from the same water source and using the same water apparatus, the hydrogen concentration was confirmed as 0 mg/L in the PW group and 0.2 mg/L for the AEW group for the characteristics of the device.

Comparison of hematological values

The hematological data of subjects in the PW group and the AEW group were compared before and after the four-week period, but no significant differences were observed in both groups. This is consistent with the contents of the previous report.[5] However, the HDL cholesterol level, a newly measured value this time, of the AEW group showed a tendency to increase with $P = 0.097$, as shown in **Figure 4**.

Comparison of data related to physical abilities

For the seated forward bend, vertical jump, right/left grip strength, and sit-up, there was no significant difference before and after the 4-week period for both the PW group and the AEW group.

Regarding the whole body reaction time, no significant differences were observed before and after the 4-week period in the case of the PW group, as seen in **Figure 5B**. However, a significant difference (decrease) ($P < 0.05$) was observed in the AEW group, as seen in **Figure 5A**. As for standing time on one leg with eyes closed, longer times were observed in the AEW group ($P = 0.09$), as seen in **Figure 6A**.

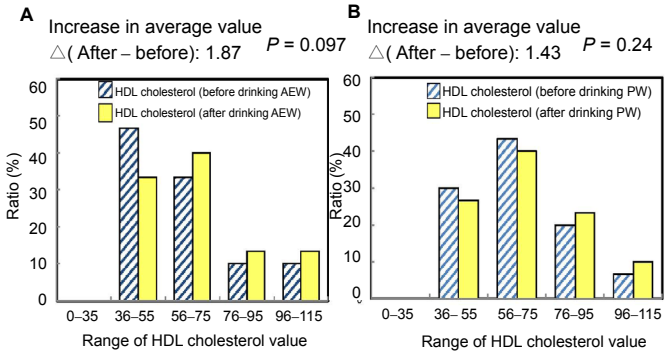

Figure 4: Change in HDL cholesterol before and after drinking.
Note: (A) alkaline electrolyzed water (AEW) drinking group, (B) purified tap water (PW) drinking group. HDL: High-density lipoprotein.

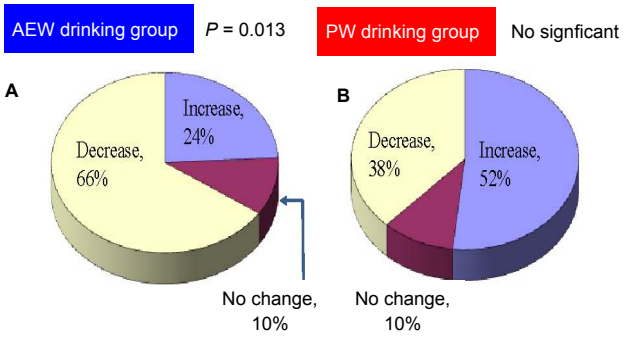

Figure 5: Change in whole body reaction time before and after drinking.
Note: (A) Alkaline electrolyzed water (AEW) drinking group; (B) purified tap water (PW) drinking group.

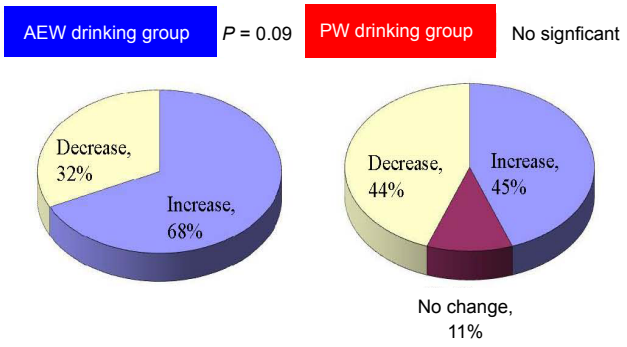

Figure 6: Changes in the standing time on one leg with eyes closed before and after drinking.
Note: (A) alkaline electrolyzed water (AEW) drinking group, (B) purified tap water (PW) drinking group.

Questionnaire to subjects

As for the questionnaire items, we asked the subjects to provide answers in 3 to 5 points about gastrointestinal symptoms (**Table 1**), defecation and urination (**Table 2**), and physical condition (**Table 3**).

Table 1: Gastrointestinal symptoms

Item	1	2	3	4
Stomachache	Not at all	Slightly	Quite a lot	Very much
Heartburn	Not at all	Slightly	Quite a lot	Very much
Heavy stomach	Not at all	Slightly	Quite a lot	Very much
Lower abdominal pain	Not at all	Slightly	Quite a lot	Very much
Bloated stomach	Not at all	Slightly	Quite a lot	Very much

Note: Scoring 1 to 4, where: Not at all = 1, and Very much = 4.

Table 2: Defecation and urination

Item	1	2	3	4	5
Uninary frequency	Very often	Often	Sometimes	Occasionally	Rarely
Fecal properties	Hard	Slightly hard	Normal	Slightly soft	Soft
Bowel movement	Very good	Good	Normal	Bad	Very bad

Table 3: Physical conditionn

Item	1	2	3
Sleep quality	Good	Neither nor	Bad
Waking up	Good	Neither nor	Bad

Note: Scoring 1 to 3, where: Good = 1, and Bad = 3.

First, as seen in **Figures 7** to **11**, as for gastrointestinal symptoms, sufficiently clear effect could not be confirmed in this study. Next, as seen in **Figure 12**, the urinary frequency significantly increased in both groups, likely due to an increase in urine volume resulting from water ingestion. Regarding bowel movement, the stools slightly changed from slightly soft to normal or slightly hard, or from soft to normal ($P < 0.05$) in the AEW group, as can be seen in **Figure 13A**. There was no difference between subjects of the two groups who had answered that they were in "good" or "bad" physical condition.

Regarding sleep quality, there was a significant increase ($P < 0.01$) in the number of AEW group subjects who responded that they were able to sleep well, as shown in **Figure 14A**, and there was a significant increase ($P < 0.05$) in the number of subjects from the same group who said that they felt good upon awakening, as seen in **Figure 15A**.

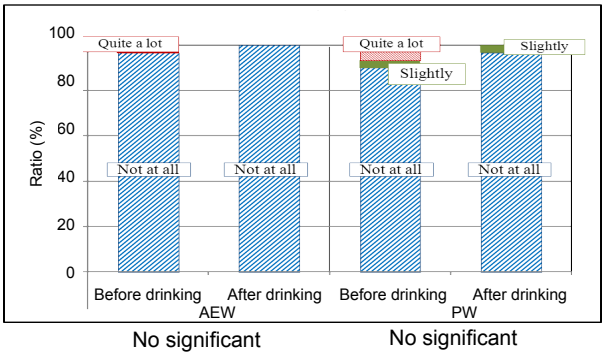

Figure 7: Change in stomach ache before and after drinking.
Note: Left side: alkaline electrolyzed water (AEW), and right side: purified tap water (PW).

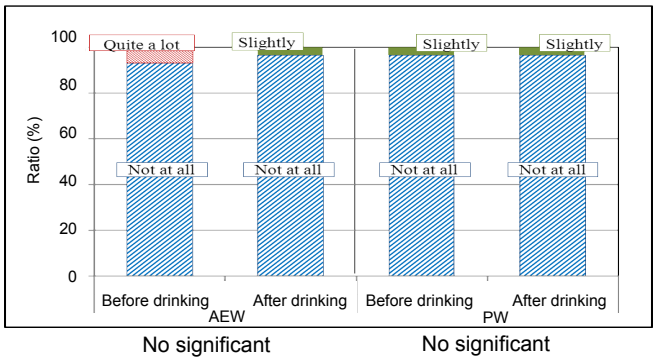

Figure 8: Change in heartburn before and after drinking.
Note: Left side: alkaline electrolyzed water (AEW), and right side: purified tap water (PW).

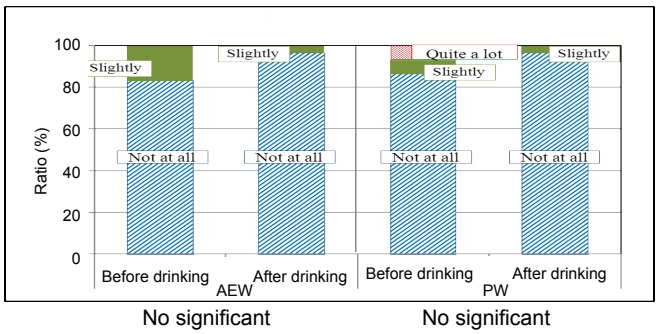

Figure 9: Change in heavy stomach before and after drinking.
Note: Left side: alkaline electrolyzed water (AEW), and right side: purified tap water (PW).

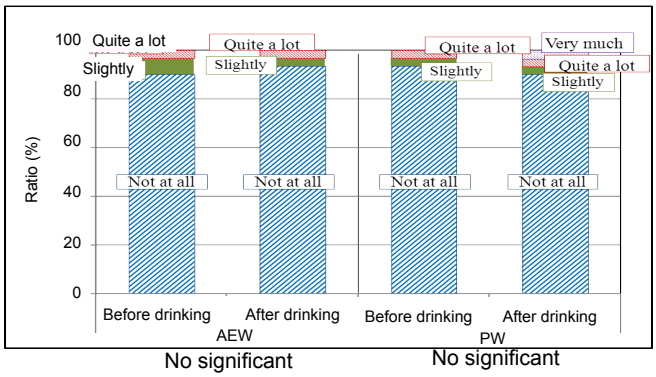

Figure 10: Change in lower abdominal pain before and after drinking.
Note: Left side: alkaline electrolyzed water (AEW), and right side: purified tap water (PW).

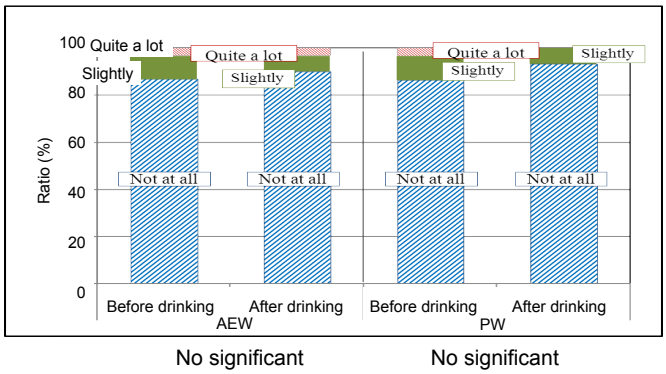

Figure 11: Change in bloated stomach before and after drinking.
Note: Left side: alkaline electrolyzed water (AEW), and right side: purified tap water (PW).

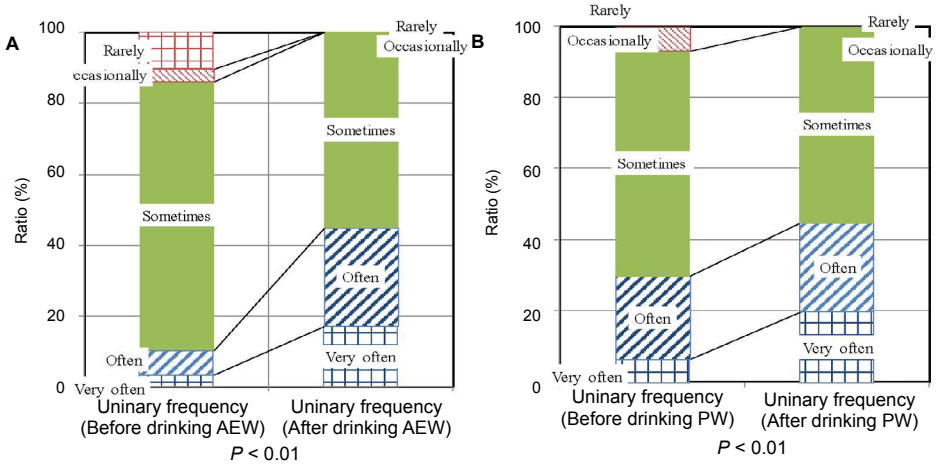

Figure 12: Change in urinary frequency before and after drinking.
Note: (A) Alkaline electrolyzed water (AEW) drinking group, and (B) purified tap water (PW) drinking group.

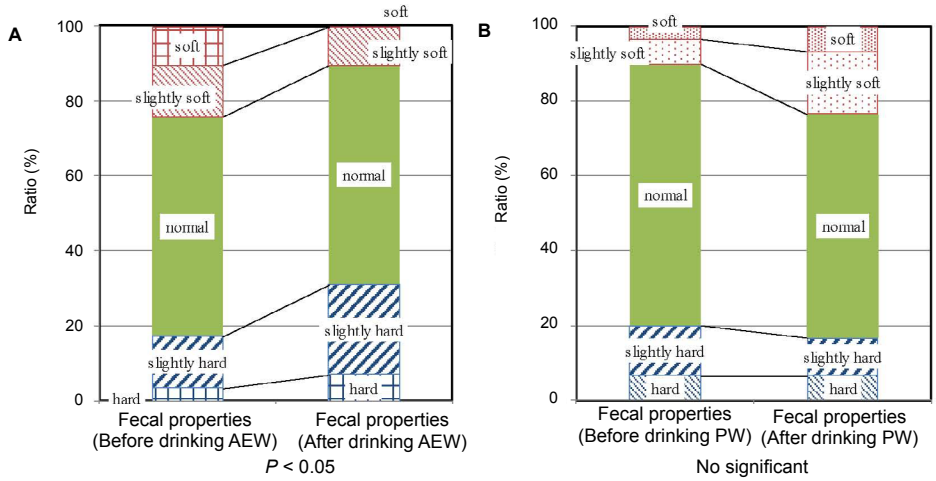

Figure 13: Changes in the condition of stools before and after drinking.
Note: (A) Alkaline electrolyzed water (AEW) drinking group, and (B) purified tap water (PW) drinking group.

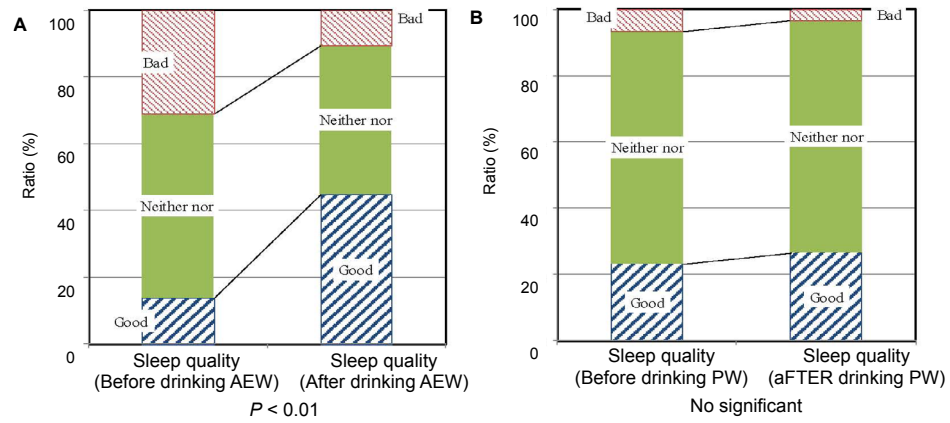

Figure 14: Change in sleep quality before and after drinking.
Note: (A) Alkaline electrolyzed water (AEW) drinking group, and (B) purified tap water (PW) drinking group.

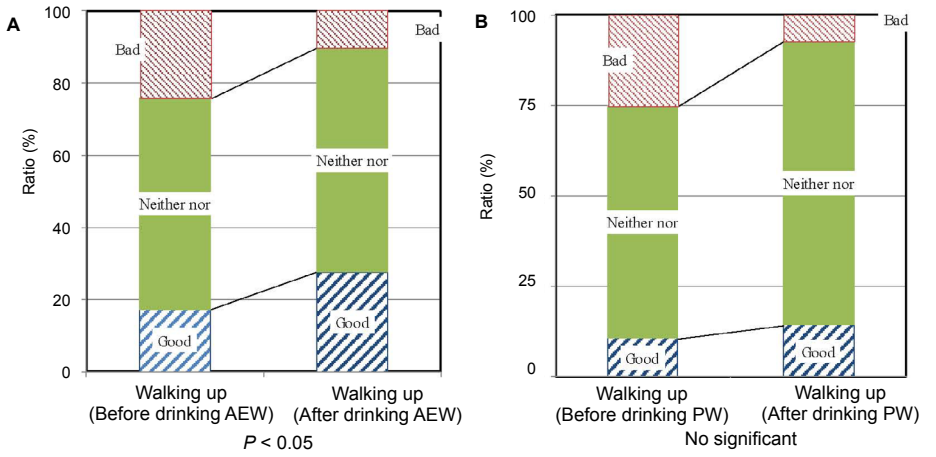

Figure 15: Changes in the state of getting up before and after drinking.
Note: (A) Alkaline electrolyzed water (AEW) drinking group, and (B) purified tap water (PW) drinking group.

Discussion

In Japan, AEW apparatus have been approved as medical devices, and ingesting AEW has been found to be effective in relieving gastrointestinal symptoms. A clinical evaluation of this effect was conducted with patients with gastrointestinal symptoms (heartburn, stomach discomfort, and abdominal symptoms such as abdominal bloating, diarrhea, and constipation).[5]

Antioxidant action by hydrogen and gastric acid neutralization by alkaline pH have been considered.[6] In addition, recent studies have shown that the intestinal bacterial flora distribution changes. It seems that these are involved in the normalization of the gastrointestinal activity.[11] However, for this study, patients with gastrointestinal symptoms were not specifically selected. As for these as well as the previous results, in general, there was no difference in the hematological values between the PW group and the AEW group.[5] However, the newly measured HDL cholesterol value showed a tendency to increase with $P = 0.097$. The increase in HDL cholesterol by ingesting water containing hydrogen is reported by Gadek and colleagues.[16] The effect of hydrogen can be considered to have had an effect in the AEW group this time as well.

As for gastrointestinal symptoms—which showed a significant difference during the previous study (significant improvement of abdominal symptoms and improvement of abnormal bowel movement)[4,5]—sufficiently clear effect could not be confirmed by this study because the subjects did not show gastrointestinal symptoms, and very few of them responded that they had abnormal abdominal symptoms and bowel movement before participating in this study. Therefore, we believe this is the reason the answers of the subjects were the same before and after their participation in the study.

However, with respect to bowel movement, the stools slightly changed from soft to normal or slightly hard, or from loose to normal in the AEW group. This reflects that the stools are more normal, and, as shown in the previous report, that ingesting AEW is considered to contribute to intestinal normalization.[4-6] Regarding items other than the gastrointestinal tract, a high proportion of the respondents said that they felt they were able to sleep well, and the proportion of subjects who answered that they felt good when awakening increased. Various studies on the relationship between the ingestion of antioxidant substances and the condition of sleep have been undertaken,[17] and the effect of reducing oxidative stress, thus allowing for improved sleep quality, is exhibited by ingesting AEW containing hydrogen, which is considered an antioxidant substance.

Regarding sports performance, various reports on the effects of sleep on sports performance have concluded that willingly sleeping longer can lead to faster running, shortened reaction time, and improved motivation during practice and games.[18] Improved sleep quality by ingesting AEW is, therefore, believed to help reduce fatigue, ensure appropriate endurance recovery, and improve overall sports performance.

The findings of this study indicate that ingesting AEW on a daily basis improves health and exercise capacity, even in healthy people who do not have gastrointestinal symptoms.

Author contributions
Conception of the work, literature search, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing, and manuscript review: YT, HN. Design of the work, definition of intellectual content, and literature search: YS. Clinical studies, experimental studies, and data acquisition: KI.

Conflicts of interest
The corresponding author (YT) is a salaried employee of the Panasonic Corporation. One of the authors (SY) was a salaried employee of the Panasonic Corporation. This study does not alter our adherence to *Medical Gas Research* policies on sharing data and materials. Another authors (KI and HN) report no conflict of interest related to this manuscript.

Financial support
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Institutional review board statement
All procedures used in this research were approved by the Ethics Committee of the Osaka City University Graduate School of Medicine (No. 837) and were registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN ID: UMIN000031800) on March 22, 2018.

Declaration of participant consent
The authors certify that they have obtained participant consent forms. In the form, participant have given their consent for their images andother clinical information to be reported in the journal. The patients understand that their names and initials not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Reporting statement
This study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Biostatistics statement
The statistical methods of this study were reviewed by the biostatistician of the Osaka City University, Osaka, Japan.

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Data sharing statement
Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices). Study protocol and informed consent form will be available immediately following publication, without end date. Results will be disseminated through presentations at scientific meetings and/or by publication in a peer-reviewed journal. Anonymized trial data will be available indefinitely at www.figshare.com.

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Peer review
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