ORIGINAL RESEARCH

Implementation of Head of Bed Elevation Using Adjustable Bed and Its Effects on Sleep: A Pilot Randomized Trial

Sangeun Lee, MD; Joo Hyun Park, MD; Jin Youp Kim, MD; Seok-Won Park, MD; Hong-Bum Shin, MD; Bo Hae Kim, MD

ABSTRACT

Background • Although mild head of bed elevation (HBE) is a proven method to reduce obstructive sleep apnea, there is no study to apply mild HBE in daily life using an adjustable bed.

Objective • We aimed to explore the applicability of mild HBE using an adjustable bed in daily life by investigating adverse events and discomforts induced by mild HBE. This pilot randomized trial additionally investigated the objective effects of mild HBE on sleep using polysomnography (PSG).

Methods • Pilot randomized controlled trial. With a two-tailed alpha of 0.05 and a power of 0.95, the minimum number of participants for each group; control group slept on flat bed and study group slept on bed with mild HBE on follow-up PSG; was calculated to be 12. Considering a 20% follow-up loss, we enrolled a total of 32 participants (16 participants for each group).

Setting • Dongguk University, Ilsan hospital.

Participants • A total of 37 individuals complained of subjective sleep disturbance in the Republic of Korea, 32 of whom met the inclusion criteria between September 2021 to July 2022. 23 participants completed the study and participants were randomly assigned into two groups.

Intervention • A mild HBE of 7.5 degrees using an adjustable bed was implemented. PSG results and questionnaires were evaluated.

Results • There was no difference in the proportion of adverse events between groups after post-intervention which was adjusting mild HBE on study group. Changes in sleep satisfaction from baseline to post-intervention showed no significant difference between groups either. However, changes in respiratory distress index (RDI) (F = 6.088, 95% CI, 17.0% to 26.4%; P = .023) and apnea-hypopnea index (AHI) (F = 5.542, 95% CI, 13.6% to 23.5%; P = .029) were significantly different.

Conclusions • Mild HBE is an implementable method for changing sleep posture without definitely causing discomfort or worsening sleep satisfaction. Since an easily applicable way to implement mild HBE using an adjustable bed in daily life reduces RDI and AHI in both subjects complaining of sleep disturbance and obstructive sleep apnea, it can be an alternative treatment for obstructive sleep apnea. (*Altern Ther Health Med.* 2025;31(3):122-128).

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INTRODUCTION

Interest and effort to improve the quality of life have continued to increase recently. Sleep quality is one of the important factors closely related to the quality of life.[1,2] Sleep quality has a significant impact not only on an individual's physical and mental health but also on social, academic, or occupational performance.[3-5] Among various efforts to improve the quality of sleep, studies have been conducted to minimize sleep disturbance by optimizing sleep postures as solutions beyond their use for managing diseases.[6,7] Easily adjustable beds with an electric remote are commercially available, allowing individuals to customize their positions for comfortable rest and sleep in beds.[8,9] Among various positions that can be implemented using adjustable beds, head of bed elevation (HBE) during sleep has proven its positive effect on multiple diseases such as obstructive sleep apnea (OSA), gastroesophageal reflux disease, or high intraocular pressure in previous studies.[7,10,11]

Increased resistance of the upper airway can result in snoring and OSA, significantly affect restful sleep, and cause deterioration of quality of life.[12] Since head elevation during

sleep can decrease upper airway resistance, several previous studies have proven that mild HBE (7.5 degrees) during sleep can effectively reduce the severity of OSA without compromising the sleep architecture under laboratory settings, which is not commercially available. One study, which was a single-arm study, used a piece of wood under the head of the bed (7.5 degrees) to adjust mild HBE in a total of 52 patients.[7,13] There is an increasing demand for adjustable beds in populations with sleep disturbance.[14] Therefore, HBE during sleep can be a complementary treatment for respiratory distress-induced-sleep discomfort in daily life.[8] HBE can even cause changes in spinal alignment in mild degrees as it is different from a typical sleeping position. Therefore, HBE can cause unexpected adverse effects on sleep, such as lower back pain and difficulty falling asleep.[11] Although the effects of HBE on sleep quality and AHI are widely known, previous studies conducted research in a clinical environment, which was not applicable in everyday life.[7]

Mild HBE is a proven method to reduce obstructive sleep apnea, and it can be easily implemented using adjustable beds in everyday life. Therefore, we aimed to explore the applicability of mild HBE using an adjustable bed in daily life with a comparative, double-arm study, unlike previous studies using clinical settings only in the laboratory. This study investigated adverse events and discomfort induced by mild HBE using a commercially available electrical bed to achieve this goal. Also, this pilot randomized trial additionally investigated the objective effects of mild HBE on sleep using polysomnography (PSG) in an adjustable bed.

METHODS

Study design, Participants, and Randomization.

A randomized, single-blind, parallel two-arm comparative trial was conducted at a referral hospital from September 2021 until July 2022. This study was designed, conducted, and reported by Consolidated Standards of Reporting Trials (CONSORT) statement [15] and relevant guidelines and regulations carried out by all methods. Before conducting the study, the Ministry of Health and Welfare confirmed that this study evaluates the safety and efficacy of industrial products and this trial was approved by the Institutional Review Board (IRB) (institutional approval number. DUIH 2021-05-048, date of approval 02/07/2021) and registered with the Clinical Research Information Service (CRIS), the official database for randomized clinical trials in South Korea (KCT0007306, registration date 19/05/2022). This study was initially classified as a safety evaluation of industrial products in the domestic Ministry of Food and Drugs. However, as this study targeted human subjects, randomized clinical trial registration was recommended by the IRB during the recruitment. The corresponding author generated a random allocation sequence, enrolled participants, and assigned participants to interventions. Adults aged 19 - 70 years complaining of subjective sleep discomfort were eligible for the trial. Questionnaires of the Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS) were used to measure sleep disturbance in participants.[16, 17] Individuals previously diagnosed or treated with hypertension, diabetes mellitus, sleep disorder, psychological, renal, cardiovascular, lung, musculoskeletal, or hepatic diseases, those who were prescribed medications that might affect the autonomic nervous system, those who underwent surgery of aero-digestive tract or spine, and pregnant or nursing women were excluded from this study.

The number of participants for each group was determined based on the results of a previous study reporting the median improvement of AHI of about 5 when applying HBE at 7.5 degrees.[7] We expected Cohen'd to be 0.9. With a two-tailed alpha of 0.05 and a power of 0.95, the minimum number of participants for each group, control group slept on a flatbed and study group slept on a bed with mild HBE on follow-up PSG, was calculated to be 12. Considering a 20% follow-up loss, we enrolled a total of 32 participants (16 participants for each group).

All participants who met the inclusion criteria voluntarily participated in this study after they were explained the possibility of assigning an HBE group and the possible risks when sleeping in an HBE bed. After obtaining informed consent from participants based on Helsinki Declaration ethical principles, subjects were surveyed to obtain demographic characteristics and information on smoking status, amount of alcohol consumption per week, and main cause of sleep disturbance. Alcohol consumption was classified into heavy alcohol use and no heavy alcohol use according to the standards of the National Institute on Alcohol Abuse and Alcoholism (for men, consuming more than 4 drinks on any day or more than 14 drinks per week; for women, consuming more than 3 drinks on any day or more than 7 drinks per week).[18] Participants who met the inclusion criteria were randomly assigned to intervention or control groups at a 1:1 ratio, stratified by sex in blocks of four, using a table of random numbers. The assigned group was blinded to participants. After assigning participants to the HBE or control group, all participants slept on a flatbed to obtain the results of the baseline survey and PSG (Embla N7000 series, RemLogic Easmed, Natus, Germany). Follow-up PSG was performed within two weeks of baseline PSG. Participants in the control group then slept on flatbeds, and those in the HBE group slept on beds with mild HBE.

We paid participants a financial reward of about ten dollars for each visit to prevent financial attraction from forcing the second visit or completion of the survey. Baseline PSG results were also provided to all participants in accordance with the IRB's recommendations. An additional financial incentive of about eighty dollars was paid to participants who completed evaluations, and the test was ended after the completion.

Implementation of Head of Bed elevation (HBE) and Polysomnography

HBE was implemented using a commercially available electric bed (Pharaoh Motion Care, BODYFRIEND Co., Ltd.,

South Korea) which obtained product propagation electronic certification from National Radio Research Agency of South Korea (Product code: 1LDMB04SBLM0, R-R-TGA-Pharaomotionc) (Figure 1A). The frame of the bed has a built-in program that can automatically implement HBE of 7.5 degrees using an electronic motor by pushing the button. The frame size of the bed was 1120 mm wide and 2240 mm long. The mattress on the bed was 200 mm thick. It was made of 93% natural rubber latex because of its springiness in applying mild HBE easily and its capacity to provide adequate support while maintaining comfort to changed positions. The latex mattress used in our study was already commercially and widely used in South Korea, referring to one study that proved that latex mattresses provide a low but equal distribution of body pressure, resulting in good support and comfort to the lumbar region.[19] The bed frame flexion point for HBE was placed 750 mm from the top of the frame where the head was positioned (Figure 1B). When HBE mode was applied to the bed frame, the ranges of actually implemented angles of the frame of the bed were 7.0 - 7.5 degrees on repeated measurements. HBE mode increased the top of the bed frame by an average of 91 mm (± 5 mm). For safety, after the bed was manipulated to HBE mode, patients slept on the bed.

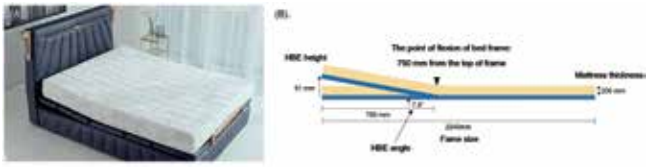
Overnight PSG with an experienced evaluator in attendance at the sleep laboratory (level 1 PSG) was performed for both baseline and intervention evaluations. The optimal environment of the laboratory was set, ranging between 21 - 23 °C in ambient temperature at 40 - 60 % relative humidity.[20] Results of the PSG were recorded and analyzed according to the scoring guideline of the American Academy of Sleep Medicine scoring manual.[21]

Measures

PSQI and ESS questionnaires were obtained before performing both baseline and post-intervention PSGs. Differences in scores of PSQI and ESS between evaluations were used to determine whether there was a significant change in the sleep quality of participants during the period between PSGs.

The primary outcomes of this study were adverse events and sleep satisfaction caused by HBE. Adverse events and satisfaction with sleep were evaluated by an investigator who was blinded to the information about the assigned group of participants. An attendant for PSG observed the event of falling from the bed. Discomfort during and after sleep in bed was evaluated through an open question. The proportion of adverse events for the group sleeping on an HBE bed was compared to that for the group sleeping on a flatbed. Satisfaction with sleep was evaluated using a visual analog scale (VAS) score. It was used as an indirect parameter to measure sleep discomfort. The proportion of worsening sleep satisfaction after sleeping on an HBE bed compared to baseline PSG was compared between HBE and control groups. In addition, the VAS score was a continuous parameter for measuring changes in sleep satisfaction from baseline to post-intervention.

Figure 1. Implementation of head of bed elevation. (A) Commercially available electric bed (Pharaoh Motion Care, BODYFRIEND Co., Ltd.). The frame size of bed was 1120 mm wide and 2240 mm long. (B) Automatically setting HBE of 7.5 degrees has an actual effect on raising the top of bed by an average of 91 mm.



The secondary outcome was used to investigate the objective effect of HBE on sleep by evaluating changes in PSG parameters between baseline PSG and post-intervention PSG. Among various measurements of PSG, total sleep time, sleep latency, sleep efficiency, and arousal index were evaluated as quantitative variables of sleep. Sleep architecture was analyzed using proportions of sleep stages (REM, N1, N2, and N3). The RDI, AHI, snoring time, and saturation of oxygen (mean oxygen saturation and minimal oxygen saturation) were used as respiratory parameters. The proportion of sleep position (supine and decubitus) was also evaluated.

Data analysis

The information about the assigned group of participants was blinded in a dataset for statistical analyses. Demographics and characteristics of participants assigned to each group were compared using an independent *t* test or Mann-Whitney U test according to results of the Shaprio-Wilk test in continuous variables (between-group analyses). Comparisons of scores of PSQI and ESS questionnaires obtained before baseline and intervention PSG in each participant were performed using paired *t* test (within-group analyses). Differences in the proportion of adverse events and worsening in sleep satisfaction after intervention between groups were compared using chi-square or Fisher's exact test (between-group analyses). Baseline results of sleep satisfaction and PSG parameters between groups were also compared using an independent *t* test or Mann-Whitney U-test according to results of data normality (between-group analyses).

Regarding accuracy, analysis of covariance (ANCOVA) was used to evaluate differences in changes of baseline and post-intervention PSG parameters between control and HBE groups in addition to paired *t* test, which was described in the supplementary table (between-group analyses).[22] Continuous variables, satisfaction of sleep, and PSG parameters measured during intervention PSG were dependent variables. The independent variable was the group of participants assigned. The value of each parameter measured in baseline PSG was covaried. Ranked ANCOVA was planned if the result of Levene's Test of Equality of Error Variances had $P < .05$. Adjusted mean with standard deviation was used to present the results of ANCOVA. Values of Levene's test of equality of error variance, F value, and partial eta squared were calculated

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flowchart of this study.

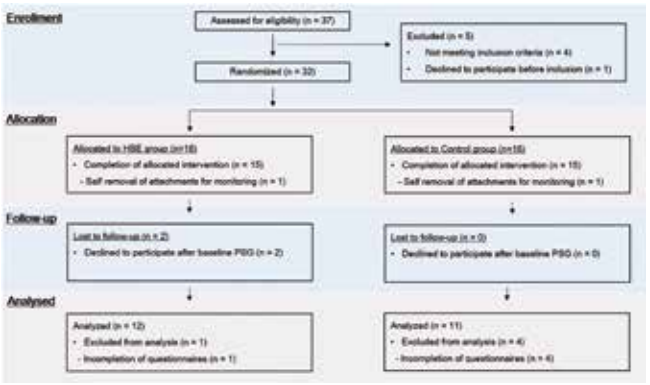


Table 1. Demographic characteristics of participants

	HBE (n = 12)	Control (n = 11)	*P* value
Age	34.8 (5.4)	34.8 (5.5)	.995
Sex (M:F)	10 : 2	9 : 2	.924
BMI	26.0 (4.0)	25.6 (3.6)	.814
Smoker	7	3	.133
Heavy alcohol user	7	5	.537
Questionnaires for inclusion			
PSQI	7.3 (2.8)	7.7 (3.0)	.699
ESS	9.8 (4.1)	9.5 (3.4)	.853
Cause of sleep disturbance			.408
Respiratory events	8	9	
Arousal	4	2	

Note: Results are shown as mean (standard deviation, SD)

Abbreviations: BMI, body mass index; ESS, Epworth Sleepiness Scale; HBE, head of bed elevation; PSQI, Pittsburgh Sleep Quality Index.

Table 2. Baseline results of questionnaires and polysomnography

	HBE (n = 12)	Control (n = 13)	*P* value
Satisfaction of sleep (VAS)	6.2 (2.1)	6.7 (1.2)	.441
Adverse event or discomfort			
Fall-down event	0	0	-
Back pain or discomfort	0	0	-
Difficulty to fall asleep	2	1	.590
Polysomnography			
Quantitative parameters			
Total sleep time (min)	389.9 (71.8)	408.8 (39.3)	.441
Sleep latency	17.1 [11.0 - 21.2]	18.6 [12.6 - 23.7]	.566
Sleep efficiency	87.0 [64.7 - 94.1]	88.3 [75.7-89.6]	.833
Arousal index	17.3 (7.1)	19.4 (8.4)	.533
Sleep architecture			
REM sleep (%)	18.5 (7.3)	20.0 (6.6)	.618
Stage N1 (%)	12.3 [9.0 - 18.7]	9.0 [8.2 - 17.7]	.288
Stage N2 (%)	44.2 [28.5 - 57.7]	47.5 [42.1 - 48.9]	.786
Stage N3 (%)	1.0 [0 - 8.9]	2.2 [0.6 – 11.4]	.347
Respiratory parameters			
RDI	21.4 [2.8 – 32.1]	8.6 [3.5 – 29.7]	.833
AHI	13.6 [2.2 – 27.3]	2.9 [1.7 – 22.9]	.413
Snoring time (%)	17.8 [3.6 – 38.2]	8.8 [1.8 – 23.7]	.449
Mean SpO_2	95.3 [93.2 -96.0]	96.0 [95.1 – 96.4]	.151
Minimal SpO_2	88.0 [78.0 - 91.0]	91.0 [87.0 – 93.0]	.235
Sleeping position			
Supine (%)	78.1 [68.3 – 90.1]	88.5 [70.3 – 100]	.449
Decubitus (%)	21.9 [9.9 – 30.8]	11.5 [0 – 29.7)	.449

Note: Results are shown as median [interquartile range, IQR] or mean (standard deviation, SD).

Abbreviations: AHI, apnea-hypopnea index; HBE, head of bed elevation; RDI, respiratory distress index; REM, rapid eye movement.

and presented. Differences between baseline and intervention PSG parameters in each group were additionally compared and presented to recognize changes between PSG trials easily using paired *t* test or Wilcoxon signed-rank test referring to results of data normality (within-group analyses). We performed subgroup analysis for the HBE effect on PSG results in participants who met the diagnostic criteria of OSA (RDI ≥ 5) using ANCOVA (between-group analyses), as mentioned above. All statistical analyses were performed using IBM SPSS Statistics for Windows version 22.0 (IBM, Armonk, NY, USA). The null hypothesis of no difference was rejected if the $P < .05$.

RESULTS

Participants

Among 37 individuals who were voluntarily involved in our study, a total of 32 participants who met the inclusion criteria were finally included in this study. They were randomly assigned to control or HBE groups. One participant in each group dropped out from the study due to self-removal of attachments for monitoring during baseline PSG. Two participants assigned to the HBE group declined to participate after completing baseline PSG due to the COVID-19 pandemic in South Korea. One participant in the HBE group and four participants in the control group did not complete questionnaires or surveys due to personal issues. Therefore, a total of 23 participants, 12 participants (10 males and 2 females) in the HBE group and 11 participants (9 males and 2 females) in the control group were finally included for analyses (Figure 2).

Demographics, characteristics, and baseline PSG results

The mean age of each group was 34.8 (SD, 5.4) years in the HBE group and 34.8 (5.5) years in the control group. There was no significant difference in mean age, gender distribution, body mass index, the proportion of smokers, or the proportion of heavy alcohol users between the two groups (Table 1). There were no significant differences in scores of PSQI or ESS questionnaires for measuring subjective sleep disturbance between groups. The main cause of sleep disturbance was respiratory events during sleep in both groups (8 participants in the HBE group and 9 participants in the control group). There was no significant difference in the proportion of sleep disturbance caused between the two groups either ($P = .408$) (Table 1). Satisfaction after sleeping in a flatbed (baseline PSG) was 6.2 points in the HBE group and 6.1 in the control group, showing no statistically significant difference between the two groups ($P = .441$) (Table 2). Three participants (two participants in the HBE group and one participant in the control group) complained of difficulty falling asleep in the survey conducted after completing baseline PSG ($P = .590$). All measurements of quantitative parameters, sleep architecture, respiratory parameters, and sleep postures showed no significant differences between the two groups (Table 2).

Results after intervention

Differences in scores of questionnaires of PSQI and ESS between baseline and intervention PSG were not found in the within-group analysis. Therefore, there was no significant change in the sleep quality of participants during the period

between PSGs (Supplementary Table 1). During the intervention PSG, fall-downs from the bed did not occur in either group. The score of sleep satisfaction worsened in three participants of the HBE group and four participants of the control group compared to that of baseline PSG (Table 3). Among the three participants of the HBE group who complained of worsened adverse events during sleep, one participant complained of both difficulty falling asleep and discomfort of postural change during sleep, one participant reported discomfort during sleep, and the other participant complained of difficulty falling asleep. However, there were no significant differences in the proportions of adverse events or worsening sleep satisfaction after intervention between the two groups (Table 3). Changes in sleep satisfaction from baseline to intervention showed no significant difference between the two groups. Changes in quantitative parameters of sleep, sleep architecture, and sleep postures from baseline to intervention were not significantly different between the two groups either in within-group (Paired t or Wilcoxon signed-rank test) or between-group (ANCOVA) analyses. Among respiratory parameters, the RDI difference between baseline and intervention PSG showed a borderline significance in within-group analysis determined by Wilcoxon signed-rank test (P = .050) (Supplementary Table 2). Differences in RDI change was significant between groups (F = 6.088, P = .023, η^2= 0.233) in ANCOVA. Although the AHI difference between baseline and intervention PSGs was not observed in the HBE group (Supplementary Table 2), AHI (F = 5.542, P = .029, η^2 = 0.217) was significantly decreased in the HBE group compared to that in the control group (Table 4) determined by ANCOVA. Other respiratory parameters showed no significant difference in between-group analysis. Subgroup ANCOVA analyses for patients who were not previously diagnosed with OSA (RDI > 5 with symptoms) showed that arousal index (F = 5.835, P = .033, η^2 = 0.327), RDI (F = 6.714, P = .024, η^2 = 0.359), and AHI (F = 5.931, P = .031, η^2 = 0.331) were significantly improved in the HBE group (Table 5).

DISCUSSION

Postural management with an adjustable bed in patients with specific diseases has been commonly used as a supportive treatment for managing disease in hospitals. The use of an adjustable bed is also increasing in the general population to improve sleep quality and to take a comfortable rest.[7,14] Changing posture during sleep

Table 3. Adverse events and sleep satisfaction after intervention

	HBE (n = 12)	Control (n = 11)	*P* value
Fall-down event	0	0	-
Back pain or discomfort	2 (discomfort)	0	.478
Difficulty to fall asleep	2	3	.538
Worsened sleep satisfaction	3	4	.667

Abbreviation: HBE, head of bed elevation.

Table 4. Sleep satisfaction and results of polysomnography of post-intervention analyzed by analysis of covariance (between-group analyses)

	HBE (n = 12)		Control (n = 11)		L	F	*P* value	η^2
	Adj. Mean (SD)	95% CI	Adj. Mean (SD)	95% CI				
Satisfaction of sleep	6.6 (0.5)	5.6 – 7.6	6.1 (0.5)	5.1 – 7.2	0.209	0.471	.500	0.023
Polysomnography								
Quantitative parameters								
Total sleep time (min)	416.5 (16.8)	381.4 – 451.6	410.3 (17.6)	373.6 – 447.0	0.988	0.064	.803	0.003
Sleep latency	9.9 (2.9)	3.9 – 15.9	12.1 (3.0)	5.8 – 18.4	0.793	0.268	.610	0.013
Sleep efficiency	86.7 (3.6)	79-2 – 94.3	85.3 (3.8)	77.5 – 93.2	0.862	0.073	.790	0.004
Arousal index	17.0 (1.7)	13.5 – 20.5	19.2 (1.8)	15.6 – 22.9	0.527	0.842	.370	0.040
Sleep architecture								
REM sleep (%)	21.0 (1.9)	17.1 – 24.9	19.7 (1.9)	15.6 – 23.7	0.267	0.256	.618	0.013
Stage N1 (%)	14.7 (2.0)	10.6 – 18.8	16.5 (2.1)	12.2 – 20.8	0.972	0.379	.545	0.019
Stage N2 (%)	48.1 (3.5)	40.8 – 55.3	45.7 (3.6)	38.2 – 53.3	0.381	0.208	.653	0.010
Stage N3 (%)	4.9 (1.3)	2.3 – 7.6	5.3 (1.3)	2.5 – 8.1	0.878	0.040	.843	0.002
Respiratory parameters								
RDI	14.0 (2.2)	9.5 – 18.5	21.7 (2.3)	17.0 – 26.4	0.808	6.088	.023[a]	0.233
AHI	10.8 (2.3)	6.1 – 15.5	18.5 (2.4)	13.6 – 23.5	0.961	5.542	.029[a]	0.217
Snoring time (%)	1.92 (3.1)	12.7 – 25.7	24.4 (3.2)	17.6 – 31.1	0.368	1.326	.263	0.062
Mean SpO_2	95.6 (0.2)	95.2 – 96.0	95.1 (0.2)	94.7 – 95.6	0.523	2.486	.131	0.111
Minimal SpO_2	85.7 (1.1)	83.4 – 88.0	85.7 (1.2)	83.3 – 88.1	0.183	0.001	.973	<0.001
Sleeping position								
Supine (%)	75.9 (5.1)	65.3 – 86.6	77.6 (5.3)	66.5 – 88.8	0.389	0.052	.821	0.003
Decubitus (%)	24.1 (5.0)	13.6 – 34.6	22.9 (5.3)	11.9 – 33.8	0.326	0.028	.870	0.001

[a]$P < .05$.

Note: Results are shown as adjusted mean (adjusted standard deviation, SD) with 95 percentile confidence interval (CI).

Abbreviations: Adj., Adjusted; AHI, apnea-hypopnea index; HBE, head of bed elevation; L, Levene's Test of Equality of Error Variances; η^2: Partial Eta squared; RDI, respiratory distress index; REM, rapid eye movement.

Table 5. Analysis of covariance (ANCOVA) for polysomnography in participants with obstructive sleep apnea (between-group analyses)

	HBE (n = 8)		Control (n = 7)		L	F	*P* value	η^2
	Adj. Mean (SD)	95% CI	Adj. Mean (SD)	95% CI				
Quantitative parameters								
Total sleep time (min)	413.2 (24.9)	359.1 – 467.4	388.3 (26.6)	990.3 - 446.3	0.757	0.455	.513	0.037
Sleep latency	7.7 (3.2)	0.6 – 14.8	14.7 (3.5)	7.1 – 22.3	0.898	2.075	.175	0.147
Sleep efficiency	86.1 (5.3)	74.6 – 97.6	80.3 (5.6)	68.0 – 92.6	0774	0.558	.469	0.044
Arousal index	17.7 (1.9)	13.7 – 21.8	24.4 (2.0)	20.0 – 28.7	0.301	5.835	.033[a]	0.327
Sleep architecture								
REM sleep (%)	21.5 (1.8)	17.4 – 25.5	16.6 (2.0)	12.3 – 20.9	0.904	3.253	.096	0.213
Stage N1 (%)	13.3 (2.3)	8.2 – 18.3	19.7 (2.5)	14.3 – 25.1	0.202	3.570	.083	0.229
Stage N2 (%)	45.5 (4.6)	35.5 – 55.6	40.0 (5.0)	29.1 – 50.8	0.443	0.590	.457	0.047
Stage N3 (%)	6.4 (1.6)	2.9 – 10.0	7.2 (1.7)	3.4 – 11.0	0.774	0.107	.750	0.009
Respiratory parameters								
RDI	20.2 (3.1)	13.5 – 26.9	31.9 (3.3)	24.7 – 39.1	0.680	6.714	.024[a]	0.359
AHI	15.9 (3.3)	8.8 – 23.1	27.6 (3.5)	20.0 – 35.2	0.831	5.931	.031[a]	0.331
Snoring time (%)	23.6 (3.7)	15.6 – 31.5	34.5 (3.9)	26.0 – 43.0	0.179	4.142	.065	0.257
Mean SpO_2	95.1 (0.3)	94.5 – 95.7	94.5 (0.3)	93.9 – 95.1	0.932	2.407	.147	0.167
Minimal SpO_2	82.4 (1.7)	78.8 – 86.1	82.5 (1.8)	78.6 – 86.4	0.192	0.001	.980	<0.001
Sleeping position								
Supine (%)	69.5 (6.3)	55.8 – 83.3	78.6 (6.8)	63.8 – 93.3	0.067	0.926	.355	0.072
Decubitus (%)	30.4 (6.3)	16.7 – 44.2	21.4 (6.8)	6.7 – 36.2	0.067	0.927	.355	0.072

Note: Results are shown as adjusted mean (adjusted standard deviation, SD) with 95 percentile confidence interval (CI).

Abbreviations: Adj., Adjusted; AHI, apnea-hypopnea index; HBE, head of bed elevation; L, Levene's Test of Equality of Error Variances; η^2: Partial Eta squared; RDI, respiratory distress index; REM, rapid eye movement.

can have a positive effect on various diseases. The effect of mild HBE on patients with obstructive sleep apnea by improving the AHI has been proven.[7] Considering results of the previous study,[7] HBE with 7.5 degrees significantly improved RDI and AHI (direct parameters on PSG by estimating the resistance of the upper airway) without affecting adverse events, the satisfaction of sleep, quantitative sleep parameters, sleep architecture, or sleep position in individuals with subjective sleep disturbance.

Although mild HBE is known to be generally well tolerable,[7] investigating the safety or inconvenience caused by postural changes during sleep is necessary to apply HBE to daily life.[23] In this study, there was no fall-down event or subjective slipping sensation in the HBE bed during sleep. Although fall-down events are rare in previous studies,[11] sliding down from the bed (20 of 63, 31.7%) was the most commonly reported adverse event when applying HBE using 20 cm wedges in a previous study.[24] This difference might be caused by different HBE degrees used in a previous study,[24] the actual height difference of HBE caused by compression of the latex mattress by the participant's weight, or high resistance between the mattress and the participant.[25] Among the 12 participants assigned to the HBE group, three (25%) complained of discomfort, with actual worsened sleep satisfaction after sleeping in the HBE bed. The reported discomforts caused by HBE in the present study were mild, and it was due to a change in sleep posture in two participants and difficulty falling asleep in two participants (one participant complained of both difficulty falling asleep and discomfort due to the changed sleep posture). However, since statistical differences in discomforts and satisfaction between groups were not observed, the reasons for the discomfort and worsened sleep satisfaction caused by HBE remain unclear. It indicates that mild discomfort due to postural changes can actually be caused by using an HBE bed, especially when using it for a long-term period.

When the objective effect of HBE on sleep was evaluated using PSG, the HBE did not affect changes in quantitative parameters (total sleep time, sleep latency, sleep efficiency, and arousal index) compared to baseline PSG results. Interestingly, although two participants in the HBE group and four participants in the control group complained of difficulty falling asleep in the survey, sleep latency was not different between the two groups. Therefore, the difficulty falling asleep complained by these participants might be due to a changed sleep environment or mild HBE rather than actual physiological changes caused by HBE. A previous study implemented the same degree of HBE in patients with OSA and reported significant improvement in sleep efficiency after applying HBE.[7] In contrast to the result of the previous study, HBE did not improve sleep efficiency in the present study. This inconsistent result might be due to differences in the severity of OSA of participants between the present study and previous studies. The HBE can affect sleep architecture or sleep posture.[8] Effects of HBE on these parameters were inconsistent with those of a previous study.[7] This inconsistency of the HBE effect on sleep architecture might be due to different degrees of HBE. Therefore, the effect of HBE on sleep architecture should be determined through further study by applying long-term HBE to a large population. With the electrical bed system, we used, which was applicable to everyday life, the long-term effect of HBE in a large population seems possible to evaluate.

Preventing excessive collapse of the upper airway by minimizing the gravity effect on upper airway structures, especially on the soft palate and tongue base, is thought to be the main cause of increasing demands for HBE, mainly from populations experiencing snoring or OSA.[7, 8] A study that used the same degree for head elevation showed a significant median reduction value of AHI of about five in patients with OSA.[7] Without postural change that can decrease upper airway resistance, such as decubitus position, HBE reduced respiratory parameters of RDI and AHI with median values of 5.2 and 3.0 in the present study, respectively. HBE decreased RDI and AHI more in participants with previously unrecognized OSA than in participants subjectively complaining sleep disturbance based on results of partial eta square of RDI and AHI calculated in subgroup analysis. The arousal index in patients with OSA was also significantly decreased in the HBE group compared to that in the control group. The reduction of airway resistance decreased arousal during sleep.[26] This finding might be mainly related to the reduction of respiratory effort-related arousal which is included in RDI.[8] However, the percentage of snoring during sleep, mean saturation of oxygen, and minimum saturation of oxygen were not significantly improved by HBE.

This study has several limitations. Thus, results of the present study should be interpreted with caution. First, the number of participants who dropped out from the control group was higher than expected, which might be a cause of bias[27] therefore the total number of participants became smaller. The study period overlapped with the pandemic period of COVID-19 in South Korea. Some participants withdrew their intention to participate due to the pandemic issue of infectious disease. Some participants were reluctant to fill out questionnaires in an enclosed space of a medical institution after they completed baseline PSG. Although causes of drop-out between two groups were similar, the high drop-out rate itself needs caution when interpreting results of this study. Additionally, the participants were younger than expected which lacks representativeness. Second, this study was conducted on those who subjectively complained of sleep disturbance. It was not focused on patients with OSA. We provided subgroup results of analyzing participants with OSA. It was found that HBE reduced RDI and AHI in both participants with subjective sleep disturbance and participants with OSA. However, the heterogeneity of participants should be considered when interpreting results of this study. Third, although we blinded information about the group they were included, there was a possibility that the participant was aware of whether HBE was applied or not during sleep. This point could cause bias to survey results. Finally, the study for determining the long-term effect of HBE on sleep in necessary in the future.

In conclusion, mild HBE using adjustable bed does not cause obvious adverse events during sleep and worsening sleep satisfaction. Therefore, it might be safely applied in daily life. In addition, since HBE, even if it is implemented by adjustable bed, also reduces RDI and AHI in participants complaining subjective sleep disturbance and OSA, using adjustable bed for mild HBE seems to have similar effects on OSA patients compared to the previous study done in clinical settings. Thus, this study shows the possibilities of using adjustable electrical bed for mild HBE to be an effective alternative treatment in daily life. The results of this study may provide the evidence of mild HBE effects on sleep for further randomized clinical trial in large population.

CONFLICT OF INTERESTS

Dr. B.H.K's work has been funded by BODYFRIEND Co., Ltd., Seoul, Republic of Korea which had supported electrical bed with a grant for this basic research. Dr. B.H.K did not have any other conflict of interests including salary, stock ownership, or other equity interest. In addition, other co-investigators including Dr. S.E.L, Dr. J.H.P, Dr. J.Y.K, Dr. S.W.P, and Dr. H.B.S declare no competing and conflict interests.

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REGISTRY INFORMATION

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