The effect of sleeping with the head of the bed elevated six inches on elderly patients with orthostatic hypotension: an open randomised controlled trial

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Abstract

Background: the evidence for 6-inch tilt sleeping-head-up (SHU), a common therapy for the treatment of orthostatic hypotension (OH) in older people, is unavailable.

Objective: to investigate the effects of 6-inch SHU for 6 weeks in community-living patients with chronic OH.

Design: open labelled randomised controlled trial.

Methods: one hundred patients aged ≥60 with chronic OH were randomised into SHU or control groups. Primary outcome measures were mean arterial pressure (MAP) and symptoms. Repeated measures of orthostatic haemodynamic parameters (systolic blood pressure, diastolic blood pressure, MAP, heart rate, percentage change of Modelflow parameters), weight, frequency of dizziness, 24-h urinary sodium and volume, 24-h ambulatory blood pressure (24-ABPM) and presence of ankle oedema were collected at baseline and at 6 weeks.

Results: symptoms improved, to a similar extent, in both groups. There were no differences in MAP or other haemodynamic parameters, weight, urinary volume or 24-ABPM between SHU and controls. SHU were more likely to have leg oedema.

Conclusions: these findings suggested that SHU at 6 inches has no additional effects on symptoms or haemodynamic parameters at 6 weeks than existing non-pharmacological measures in older patients with OH. Its use in this group should therefore be discouraged.

Keywords: trials, haemodynamics, blood pressure, elderly

Introduction

Sleeping 'head up' (SHU) 12° or greater has been used by clinicians for treatment of orthostatic intolerance since the 1940s [1, 2]. This non-pharmacological therapy has formed part of the management plan for orthostatic hypotension (OH) in patients with severe autonomic failure [1, 3–6], postural orthostatic tachycardia syndrome [1] and latterly in patients with postural-related syncope [7]. In a recent survey of Northern European practice, SHU has become a common treatment for OH in older people, albeit at lower angles of elevation that are more easily tolerated [8]. Among clinicians who use SHU, two-thirds recommended angles less than 10°, the most common of which was 5° elevation.

We recently showed that the physiological response to SHU at a lower angle of 5°, or a tilt load of 9% [9], was associated with orthostatic improvement in a small case series of nine older inpatients with OH [10]. There were significant haemodynamic changes consistent with intravascular volume expansion in patients who underwent SHU at 6 inches for 1 week.

However, the sample size was small, the period of follow-up short and the intervention un-controlled; so both the efficacy and generalisability of this treatment remain uncertain.
The aim of the study was to investigate the physiological effect of SHU at 5° (6 inches) on orthostatic tolerance for 6 weeks in a large group of patients aged 60 and over who had OH from all cause in an open randomised controlled trial.

Methods

One hundred consecutive patients aged 60 and over, who attended a regional syncope unit with symptomatic OH according to consensus criteria (1996) [11], were recruited. Patients were excluded if symptoms’ duration was ≤ 1 month, calculated glomerular filtration rate [12] of <30 ml/min, NYHA class III or greater [13], if they were in a hospital ward, or significant urinary incontinence such that 24-h urine measurement would be unreliable. These patients had received medication optimisation, i.e. reduction or discontinuation of medications, which lower blood pressure, at least a month before enrolment into the study. Patients were advised to remain on the same medications during the 6-week study period.

Protocol

All patients were asked to increase their water intake to at least 2 l a day for the duration of the study. In addition, subjects randomised into the SHU group were given two 6-inch customised blocks to be placed under the head of their beds (EU standard bed length is 75 inches and 6-inch elevation represents 5°). The patients were advised to remain on the same medication for the duration of the trial. Any changes in medications were noted.

The patients were assessed at two timepoints: Pre (Day 1–2) and post-intervention (Day 42–43). During each 24-h timepoint, the patients wore ambulatory blood pressure monitors (24-ABPM), collected a 24-h urinary sodium and urinary volume, and performed active stands between 0900 and 1100 h. The haemodynamic parameters during the active stand were measured using phasic beat-to-beat digital photo-plethysmography (Finometer™, Amsterdam) during 5-min supine rest and 2-min standing [14]. We ensured that the finger cuff placement was applied in the same manner to minimise difference in finger waveform during active stands pre and post-intervention. Patients were classified as SHU compliant if they self-reported compliance and their beds were raised with blocks at the end of the 6-week study period during a home visit by the researcher, and water compliant if their urinary volume post-intervention was ≥1.5 l/24 h. The patients were asked about symptom improvement post-intervention and the SHU group were questioned about their tolerability of SHU. The study received the local hospital research ethics committee approval and all the participants gave informed consent.

Data analysis

The haemodynamic parameters (systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), Modelflow-derived stroke volume (SV), cardiac output and total peripheral resistance) were exported from 60 s before to 120 s after standing and then averaged at 10-s intervals to reduce beat-to-beat variability in these parameters. We analysed the relative change in Modelflow parameters (rSV, rCO and rTPR) as (post-pre values)/pre-values × 100%. Baseline is defined as an average value between 60 and 30 s before standing, nadir MAP is the lowest value of MAP within 2 min of standing and ΔMAP is baseline-nadir.

In order to establish a clinically meaningful difference, we carried out a pilot study on elderly patients (n = 81) referred to our clinic with and without OH. The mean (standard deviation) difference in nadir MAP between patients with OH and controls was 18.8(22.0) mmHg.

To show a change in MAP of ≥15 mmHg, with alpha of 0.05 and power of 80%, we needed a total sample size of 66 (33 per group). A total sample size of 99 patients (66 cases and 33 controls) was set to allow for a patient drop out of up to 50% in the intervention group (based on our experience in the clinic) [15]. The main outcome variables were MAP and symptoms and other haemodynamic variables as secondary outcome measures.

Design was by minimisation (for factors age, gender and pre-intervention nadir MAP) with weighted randomization. Analysis was on an intention-to-treat basis with last observation carried forward. Patients with at least one time-point assessment were included for analysis.

As initial analysis of MAP in the time domain did not show any particular time latency period (including time of nadir BP) being more affected by SHU it was decided to analyse the entire 180-s period so as to maximise power. As supine and standing periods were considered physiologically distinct, it was decided to analyse them separately.

Analysis was conducted by a repeated measures analysis of variance with MAP as the dependent variable. Subject, condition (pre and post-intervention), intervention group (SHU or control), timepoint during the active stand (−60 to −10 s for supine and 0–120 s for standing period) and the condition × intervention interaction terms were the independent variables. Other haemodynamic parameters (SBP, DBP, HR, rSV, rCO and rTPR) were also studied as the dependent variable in models otherwise identical to above. Symptoms of dizziness and self-reported compliance with SHU were also recorded.

Pre-planned analyses were performed to investigate any modifying effects on SHU by hydration status. Hydration status was categorised by 24-h urinary volume out put ≥ or <1.5 l at post-intervention assessment. The groups were sub-divided according to these criteria and the analyses repeated in a manner identical to those of the full sample.

All results were expressed as mean (standard deviation) and median (IQR) unless stated otherwise. Datadesk statistical software was used (version 8 Ithaca, NY, USA). Paired t-test, Wilcoxon Signed rank test, two-sample t-test, Mann–Whitney U and ANOVA were used to compare continuous results while Chi-squared test was
used to compare categorical results. Statistical significance was set at $P < 0.05$.

**Results**

The basic characteristics of the SHU and controls were similar in sex, age, initial nadir MAP and episodes of dizziness per week (Table 1). Medication usage was similar between groups apart from anti-hypotensives, which was slightly commoner (1/66 vs. 4/33) in the control group. Ninety-two participants completed the 6-week study.

**Haemodynamic variables**

There were no differences in the baseline, nadir and ΔMAP, ΔSBP and ΔDBP between SHU and controls. There was a greater increase in supine and standing HR with SHU compared with controls of 2.7 and 2.1 b.p.m., respectively. Compared with pre-intervention values, there was a greater increase in rSV in controls (19.2(2.7)% vs. 5.4(1.9)%). Controls also had more pronounced increases in rTPR than SHU. See Table 2 for analysis of variance of haemodynamic parameters during active stands. See Figure 1 for graphical plots of MAP, SBP and HR.

As compliance with SHU was only 77%, a *post hoc* analysis restricted to those who complied (i.e. an as per protocol analysis) was also carried out. There was no significant difference in standing SBP, DBP or MAP before or after the intervention between groups.

A planned sub-group analysis of patients was carried out according to hydration status. In patients whose urinary output were >1.5 l/day, standing SBP and MAP were higher in controls than SHU by 13.7(1.4) mmHg, $F(1,1199) = 30.8, P < 0.0001$ and 6.0(0.9) mmHg, $F(1,1199) = 32.5, P < 0.0001$, respectively, while supine and standing HR were lower in controls than SHU (7.1(0.6) b.p.m., $F(1,597) = 17.8, P < 0.0001$ and 8.6(0.5) b.p.m., $F(1,1199) = 7.8, P = 0.0053$). Repeating the analysis for haemodynamic variables and symptoms with the five subjects on anti-hypotensive medications excluded did not change any results.

**Non-haemodynamic variables**

Both SHU and controls reported overall improvement and had fewer episodes of dizziness per week after interventions (median (IQR) SHU 7(1,7) episodes per week before vs. 0.26(0, 2) episodes per week after, $\chi^2 = 2.88, P = 0.0039$; Controls 7(1, 7) episodes per week before vs. 2(0, 7) episodes per week after, $\chi^2 = 3.22, P = 0.0013$). While both groups had a symptomatic improvement, there was no significant difference in the improvements between SHU and control however, $F(1,199) = 1.23, P = 0.27$. There was no difference in weight change between SHU and controls following intervention ($F(1,199) = 1.1, P = 0.29$). The SHU group had more leg oedema than controls (41 vs. 19%, $P = 0.038$).

There were no significant changes in urinary volume and sodium between SHU and controls following the intervention between groups.

### Table 1. The basic characteristics of the participants

| Variables | SHU, n = 66 | Control, n = 34 | $\chi^2$ | P
|-----------|-------------|----------------|--------|--
| Female (%) | 37 (56%) | 19 (56%) | 0.01 | 0.98
| Age (years) Median (IQR) | 76 (71, 80) | 76 (72, 83) | 0.14 | 0.89
| Pre intervention Nadir MAP, mmHg | 66.1 (14.5) | 69.0 (18.4) | 0.86 | 0.39
| Symptom of dizziness per week median (IQR) | 7 (1,7) | 7 (2,7) | 0.60 | 0.55
| Medications | | | | |
| Hypertension | 14 | 23 | | 0.66
| Heart medicationsa | 18 | 45 | | 0.19
| Cardiac medicationsb | 8 | 11 | | 0.43
| Antidepressants, psychotropics and benzodiazepine | | | | |
| Parkinson medication | 3 | 3 | | 0.41
| Fludrocortisone/ midodrine | 4 | 1 | | 0.044
| Othersc | 18 | 38 | | 0.67

a Diuretics, alpha-blocker, beta-blocker, calcium channel blocker, ACE-inhibitor, Angiotension receptor blocker.
b Aspirin, warfarin, statin, nitrates.
c Bone protection medications, inhalers, proton pump inhibitor, analgesia, elnarin.

**Table 2. Comparison of interval change in haemodynamic variables between intervention and control groups in the supine and standing phases during active stands**

<table>
<thead>
<tr>
<th>Variable</th>
<th>SHU mean (SE)</th>
<th>Controls mean (SE)</th>
<th>$F$-ratio ($df$)</th>
<th>P</th>
<th>SHU mean (SE)</th>
<th>Controls mean (SE)</th>
<th>$F$-ratio ($df$)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP (mmHg)</td>
<td>1.45 (0.91)</td>
<td>0.45 (1.27)</td>
<td>1.48 (1,1199)</td>
<td>0.22</td>
<td>1.98 (0.87)</td>
<td>2.36 (1.23)</td>
<td>0.066 (1,2399)</td>
<td>0.80</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>2.42 (0.55)</td>
<td>1.75 (0.77)</td>
<td>0.51 (1,1199)</td>
<td>0.47</td>
<td>2.61 (0.47)</td>
<td>1.73 (0.66)</td>
<td>1.18 (1,2399)</td>
<td>0.28</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>0.94 (0.62)</td>
<td>0.94 (0.56)</td>
<td>0.00 (1,1199)</td>
<td>0.99</td>
<td>2.07 (0.58)</td>
<td>2.48 (0.81)</td>
<td>0.17 (1,2399)</td>
<td>0.62</td>
</tr>
<tr>
<td>HR (b.p.m.)</td>
<td>1.23 (0.36)</td>
<td>-1.48 (0.50)</td>
<td>19.41 (1,1199)</td>
<td>&lt;0.0001</td>
<td>1.02 (0.36)</td>
<td>-1.08 (0.43)</td>
<td>11.58 (1,2399)</td>
<td>0.0007</td>
</tr>
<tr>
<td>rSV (%)</td>
<td>-0.77 (1.95)</td>
<td>5.56 (2.72)</td>
<td>3.59 (1,1199)</td>
<td>0.059</td>
<td>11.72 (2.14)</td>
<td>16.07 (2.99)</td>
<td>1.40 (1,2399)</td>
<td>0.24</td>
</tr>
<tr>
<td>rCO (%)</td>
<td>6.48 (2.26)</td>
<td>0.52 (3.14)</td>
<td>2.37 (1,1199)</td>
<td>0.12</td>
<td>20.26 (2.50)</td>
<td>25.20 (3.50)</td>
<td>1.17 (1,2399)</td>
<td>0.28</td>
</tr>
<tr>
<td>rTPR (%)</td>
<td>17.93 (2.10)</td>
<td>25.29 (2.93)</td>
<td>4.15 (1,1199)</td>
<td>&lt;0.0001</td>
<td>17.93 (2.10)</td>
<td>25.29 (2.93)</td>
<td>4.15 (1,1199)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

rSV, rCO and rTPR were calculated as (post-pre)/pre × 100%.
interventions although urinary sodium in controls fell by 25 (8) mmol/24 h, \( P = 0.010 \). Forty-five (49\%) participants reported compliance with drinking 2 l of water a day. Of the patients with complete urinary collections (\( n = 96 \)), 47\% of controls and 60\% of SHU had urinary output of 1.5 l/24 h at 6 weeks. There was moderate agreement between self-reported water intake compliance and urinary output >1.5 l at 6 weeks, \( K = 0.485, 95\% CI(0.294, 0.675) \). There was no overall change in the day, night and overall 24-ABPM in SHU and controls. Eight patients (five SHU, three controls) dropped out of the study following first assessment due to ill health; none of the reasons was related to the intervention.

**Discussion**

This is the first randomised controlled trial to test the effectiveness of head-up sleeping at 6 inches as a treatment for chronic OH from all cause in subjects aged 60 years and over. The result of the study showed that SHU at 6 inches had no clinical benefit on blood pressure or symptoms in the treatment of OH compared with controls.

Both groups reported (similar) symptomatic improvement, which may have been due to better use of physical counter manoeuvres (all clinic patients are advised about these at their first visit) or due to a placebo response. Neither group changed weight significantly though the SHU group had more ankle oedema suggesting a relatively greater shift in fluid from the intravascular to the extravascular compartments in subjects with this intervention. The increase in SV during the standing phase and reduction in HR during both phases observed in the control group tends to support greater intravascular volume in this group. Patients from both limbs of the RCT were asked to drink extra water as part of the intervention though neither group succeeded in raising their urine.
output or gaining weight. The failure of a group of older individuals to significantly increase their water intake during a monitored clinical trial suggests that water drinking as a primary treatment is unlikely to be a widely tolerated or effective treatment for most older patients with OH despite promising evidence of its effectiveness in younger subjects [15–18]. It is noteworthy that compliance with water was less than with SHU. There was only moderate agreement between stated compliance with water intake and urine output, suggesting that the latter should be used in future research studies though direct questioning may be sufficient for clinical practice.

SHU has been in clinical practice since the 1940s. While the evidence mainly favours younger patients, often with autonomic dysfunction, with tilt angles in excess of 10° [1, 3–5, 7] its use at lesser degrees of elevation in older patients with chronic OH (and usually intact autonomic function) has subsequently become common in Northern Europe [8]. While it could be argued that a 5-degree tilt (as used in this study) is insufficient to induce haemodynamic improvement, we recently reported a case series [10] in which SHU at 5° (6 inches) of tilt was associated with improvement at 1 week in a group of older inpatients with OH. It is noteworthy that even at 6 inches elevation, the SHU patients in the RCT were more likely to develop leg oedema than controls suggesting physiological changes to the intervention. In our experience, greater degrees of elevation are unlikely to be tolerated by older people and the dose of elevation used in this trial was based on the median used by Northern European syncope practitioners attending a conference in the UK [8]. The finding of similar symptomatic improvements in both groups suggests that a placebo response may play a part in this intervention and we would suggest that any future studies should use a control group.

There were a number of limitations to this trial. We did not measure haemoglobin, haematocrit and plasma creatinine to detect an intravascular haemodilution effect of SHU or investigate humoral mechanisms of action by measuring plasma aldosterone, renin and ADH levels. However, the main purpose of the trial was to investigate any clinical effectiveness of SHU; so mechanisms of action were considered less relevant. The study was not blinded though the use of an intervention in both groups (i.e. increased water drinking) would have tended to reduce any differential placebo effects. Also patient blinding would not have been possible.

The study has several strengths also. It is the first study looking at the effectiveness of SHU in older patients. Sample size was determined by power calculation and using pilot studies from a similar clinical population and almost all patients completed the study. By using a stratified randomisation process, the control group was very similar to the intervention group at baseline and compliance with interventions was observed directly and objectively. The use of existing accepted treatments (water and medication modification) was optimised prior to study entry. By analysing measurements over the entire 60 s before and 120 s after standing, we were able to explore any effects more fully than if we had concentrated on specific time points.

In conclusion, in patients with OH, SHU at 6 inches for 6 weeks was not associated with improvement in blood pressure or symptoms in older patients with OH attending a blackout clinic. SHU at 6 inches is therefore not recommended for older patients with OH.

Key points

- Sleeping head up at 6 inches for 6 weeks (SHU6) was well tolerated by older patients and was associated with ankle oedema.
- Treatment of OH with SHU at 6 inches has no additional effects on symptoms and blood pressure.
- SHU6 is therefore not recommended as an outpatient treatment for OH in older patients.

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Conflicts of interest

None declared.

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Comparing the importance of different aspects of quality of life to older adults across diverse cultures

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Abstract

Background: there is limited research examining the relative importance of aspects of quality of life (QOL) to older adults across cultures.

Objective: to examine the relative importance of 31 internationally agreed areas of QOL to older adults in 22 countries in relation to health status, age and level of economic development.

Design: a survey quota sampling design was used to collect cross-cultural data. This study reports a secondary analysis of WHOQOL-OLD pilot study, which was collected simultaneously in 22 centres.

Settings: a variety of community, primary, secondary and tertiary health care settings located in Australia, France, Switzerland, England, Scotland, USA, Israel, Spain, Japan, China (mainland and Hong Kong), Turkey, Lithuania, Czech Republic, Hungary, Canada, Norway, Sweden, Denmark, Germany, Brazil and Uruguay.

Participants: the total sample contained 7,401 people over 60 years with a mean age of 73.1 years; 57.8% were women and 70.1% considered themselves ‘healthy’.

Results: there were significant differences in the importance given to various aspects of QOL for people living in medium and high-development countries. Culture explained 15.9% of the variance in the importance ratings of QOL. However, the interaction showed that cultural differences were reduced once health status, gender and age were taken into account. The