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RESEARCH ARTICLE

Treatment effect of head extension by cervical collar on moderate obstructive sleep apnea–A randomized controlled trial

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Summary

As available treatments in obstructive sleep apnea are all associated with side-effects or adherence problems, there is a need for alternative treatment options. In this randomized, open, parallel-group intervention study, the effect of head extension by cervical collar was evaluated in patients with moderate obstructive sleep apnea. One-hundred patients with moderate obstructive sleep apnea (apneas and hypopneas per estimated hours asleep = respiratory events index: 15–30) were randomized to either lifestyle intervention, or cervical collar in combination with lifestyle intervention. Both groups received lifestyle advice. In addition, the treatment group was treated with a cervical collar, which allows adjustment of head extension, during sleep. Assessment with questionnaires and polygraphy were performed at baseline and after 6 ± 2 weeks. A linear regression model was used to assess a total effect on respiratory events index, which was the primary endpoint. In the intention-to-treat analysis, the cervical collar in combination with lifestyle intervention group decreased their respiratory events index ($p = 0.008$) and oxygen desaturation index ($p = 0.008$) more than the lifestyle intervention group, with a mean difference of −4.5 and −4.3, respectively. In the sub-analysis, there was a clear effect on respiratory events index in the supine position (mean difference between the groups −9.1, $p = 0.018$) but not on non-supine apnea–hypopnea index (−2.3, $p = 0.17$). We conclude that head extension by cervical collar during sleep resulted in improved respiratory events index and oxygen desaturation index values in patients with moderate obstructive sleep apnea. Cervical collar can be a second-line treatment option in this group, especially in positional obstructive sleep apnea.

KEYWORDS
cervical collar, collapsibility, head extension, obstructive sleep apnea, upper airway

Clinical trials: The project has been registered as a Clinical Trial: NCT03754270. The project has been approved by the Swedish Medical Products Agency: 5.1-2018-9880.

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1 | INTRODUCTION

Obstructive sleep apnea (OSA) is associated with cardiovascular diseases (Gonzalez-Aquines et al., 2019; Ljunggren et al., 2024; Wang et al., 2013), diabetes (Kamble et al., 2020; Lindberg et al., 2012; Valham et al., 2009), and accidents due to fatigue and daytime sleepiness (Horstmann et al., 2000; Lindberg et al., 2001). Male gender (Franklin & Lindberg, 2015), age (Bixler et al., 1998), smoking (Zhu et al., 2019), obesity (Bloom et al., 1988; Kamble et al., 2020; Palm et al., 2015) and sleeping in the supine position (Farronato et al., 2013) are risk factors that contribute to development of OSA.

The pathophysiology behind OSA involves mechanical obstruction of the upper airways during sleep, which leads to apneas and hypopneas, followed by oxygen desaturations (Ioachimescu & Collop, 2012). The most common treatments for OSA are continuous positive airway pressure (CPAP) and mandibular advancement device (MAD), while pharyngeal surgery is generally considered only in a few selected cases. CPAP is the most effective modality (Richard et al., 2007; Wolkove et al., 2008). CPAP adherence is crucial for treatment, although this continues to be a problem despite different approaches to optimize CPAP adherence such as telemonitoring (Delijaj et al., 2023; Fox et al., 2012). CPAP adherence is negatively affected by several factors, including CPAP side-effects (Ulander et al., 2014), socioeconomic conditions (Palm et al., 2021) and cigarette smoking (Dunietz et al., 2021). Anatomic characteristics and mechanical barriers in the upper respiratory tract may also predict CPAP adherence (Park et al., 2017).

The use of MAD has been shown to be an effective treatment in patients with mild OSA, while less effective than CPAP in moderate and severe OSA (Ramar et al., 2015). The main function of the MAD is to protrude the mandible forward, causing the airway to remain open during sleep (Rose et al., 2002). However, MAD treatment effectiveness is also impeded by limited adherence with long-term treatment; approximately 50% of patients discontinue their treatment after 2 years (Rose et al., 2002).

Hence, as available treatment alternatives in OSA are all associated with possible side-effects (Esclamado et al., 1989) or adherence problems, there is an urgent need for alternative treatment options.

The degree of obstruction especially at the base of the tongue and posterior pharyngeal wall is associated with the severity of OSA (Jordan et al., 2014). Head extension has a marked influence on collapsibility of the upper airway, and decreases the propensity for the upper airway to collapse during sleep (Walsh et al., 2008). Our hypothesis is therefore that a considerable head extension and stabilization of the neck with a cervical collar (CC) could contribute to reducing the obstruction of the upper airways in patients with OSA.

Previous attempts to use CC against OSA have shown no effect (Skinner et al., 2004; Bordier et al., 2021) or good effect (Delijaj et al., 2016; Prigent et al., 2017), depending on study design, size of study population and whether head extension was applied or not during treatment with CC. In a previous randomized crossover pilot study (Delijaj et al., 2016), we found a reduction of the respiratory events index in patients with severe sleep apnea who were treated with CC to extend the head and MAD in combination.

1.1 | Aims of the study

The aims were to assess whether the effects measured by respiratory events index are enhanced when extending the head using a CC combined with lifestyle advice, compared with lifestyle advice only in patients with moderate OSA.

2 | MATERIALS AND METHODS

2.1 | Study design and patients

This randomized, open, parallel-group intervention study was conducted at the Ear, Nose and Throat clinic (ENT) at Mälarsjukhuset in Eskilstuna and Nyköping Hospital in Nyköping, Region Sörmland, Sweden. In Sörmland, as in several other Swedish regions, patients with sleep apnea are managed at the ENT clinic including conducting of CPAP trials. All patients referred with moderate OSA to the ENT clinic at one of these hospitals from April 2019 to December 2022 were consecutively invited to participate in the study (Figure 1). The first polygraphy examination was conducted at the patients' homes as part of their initial evaluations in primary care subsequent referral to the ENT clinic. The patients who seemed to fulfil the inclusion criteria were initially identified by a nurse at the ENT clinic through a comprehensive review of referrals. The nurse compiled lists of patients, including their names and phone numbers, and continuously sent this information to the investigator. Following this, the investigator contacted the patients by phone to provide details about the study and ask if they were interested in participating. After receiving positive verbal consent, the investigator reviewed the primary exclusion criteria with the patients over the phone. Those who met one or more of these criteria were excluded from participation at this stage.

Of the 155 contacted patients, 26 patients did not answer the phone after three attempts. Additionally, 18 patients declined to participate in the study and another 11 patients were excluded during the phone call due to one or more exclusion criteria. Aside from the presence of exclusion criteria, the excluded patients did not differ significantly in terms of age, gender, or severity of respiratory events index from the overall group.

One-hundred interested patients who met the inclusion criteria were scheduled for appointments, with the first visit within 3 months from the first polygraphy.

Criteria for inclusion were: moderate OSA (respiratory events index 15–30); body mass index (BMI) < 35 kg m^{-2}; and age 18–75 years. Exclusion criteria were history of whiplash injury or other neck pain, rheumatic diseases, dementia, active alcohol or drug abuse ≤ 2 years back in time, treatment with sleeping pills or other sedatives, being pregnant or breast-feeding or planning pregnancy during the study period, or not being expected to be able to comply with polygraphy or treatment equipment due to medical and/or psychological conditions. Apart from the inclusion and exclusion criteria, no consideration was given to other factors, including driving issues or severity of sleepiness. Patients who did not want to participate and

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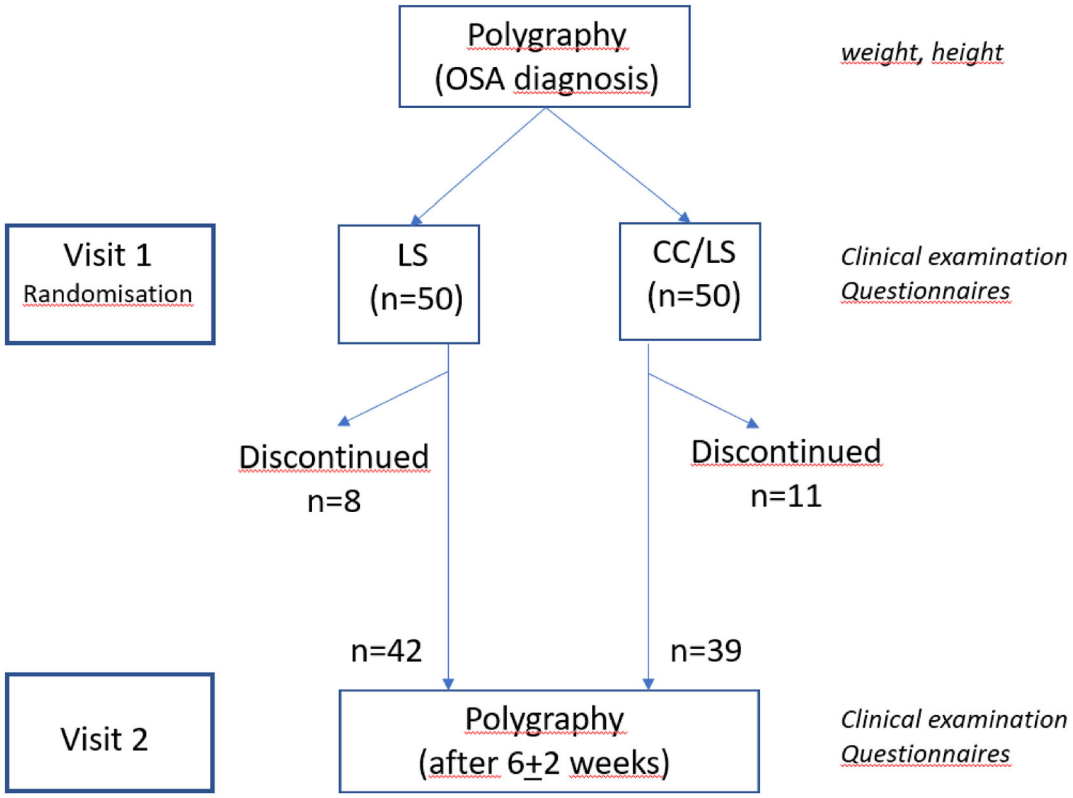

FIGURE 1 Study design.

those who met any criteria for exclusion were treated according to current clinical practice.

2.2 | Visit 1

Each patient received verbal and written information about the objectives, procedures, and possible risks and benefits of the study. All patients were given the opportunity to read the patient information, ask questions and finally decide whether to participate in the study. Patients were informed that they could leave the study at any time without giving any specific reason. The patients were then randomized to either lifestyle intervention (LS) or CC in combination with lifestyle intervention (CC/LS). The randomization was performed without stratification. A set of 100 envelopes was prepared. Of these, 50 contained paper slips stating "lifestyle advice", and the remaining 50 stated "CC + lifestyle advice". The envelopes were sealed and indistinguishable from the outside. Each patient underwent a physical examination, including nose–throat and cardiac status, and measurements of neck circumference and blood pressure. Weight and height had already been measured in conjunction with polygraphy. Patients filled in a questionnaire including questions about nocturnal respiratory disturbances, daytime sleepiness, insomnia, use of tobacco and alcohol, comorbidity, and medication.

2.3 | Intervention

Patients in the LS group ($n = 50$) were encouraged to stop smoking, avoid alcohol, lose weight, be more physically active, and avoid sleeping in the supine position. Patients in the CC/LS group ($n = 50$) received the same instructions and advice, and received a CC with instructions on how to sleep with it. Patients were instructed in how to place the collar around the neck and how to adjust the height. They were instructed to use the CC on its highest setting, which corresponds to an extension level of 24° from the neutral position. Those who felt uncomfortable with the highest setting could lower it one step at a time until they found the appropriate height.

All patients were referred to polygraphy 6 ± 2 weeks after starting treatment.

2.4 | Cervical collar

Vista Cervical Collar (Aspen Medical Products, 6481 Oak Canyon, Irvine, CA 92618, USA) is marketed for conditions such as traumatic cervical injury, cervical disc herniation and other neck problems (Figure 2). The CC has six height settings (0°– 24°) to choose from, and adjustment between them is straightforward and allows adjustment of the elevation level to achieve sufficient effect, i.e. extending the neck.

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FIGURE 2 Cervical collars (CCs) were adjusted to the highest extensions level (24°).

The CC devices were labelled with the name of the study and the investigator's contact information. Each CC contained a unique number so reported problems could be traced to a specific collar. At the end of the study, each participant returned the CC.

2.5 | Visit 2

After an intervention period of 6 ± 2 weeks, a new polygraphy registration was performed. This was followed by Visit 2. Blood pressure and neck circumference were measured, and a physical examination was performed, including nose–throat and cardiac status. Patients filled in a new questionnaire with the same questions as those used at Visit 1. Additional questions about any possible side-effects of the CC were also asked. Patients were asked to report neck pain, discomfort, symptoms suggestive of contact allergic reactions, or any other possible side-effects.

All patients from the CC/LS group were asked if they had used the highest elevation level of CC and if they used the CC for more than 4 hr during follow-up polygraphy. Data from questionnaires were entered into an online survey system SoSciSurvey platform (https://www.soscisurvey.de) from where they were downloaded as spreadsheet files and sent to a statistician for analysis. After Visit 2, the patients were admitted to the normal care flow according to current clinical practice.

2.6 | Polygraphy

Polygraphy was carried out with the Type III device Nox T3 (Nox Medical, USA) registration system. The results were analysed using Noxturnal software. All sleep recordings were performed at the patients' home, and were evaluated and scored manually by the same experienced sleep technician who was blinded to the treatment group.

The CC/LS group wore the collar during the second polygraphy examination. Immediately upon waking in the morning, the subject filled in a diary about estimated sleep time during the night, time of falling asleep, awakenings during the night, and final awakening in the morning. The recordings were transferred to a computer and scored manually for estimated sleep time and respiratory events. Total sleep time was estimated by visual assessments of the overnight tracing in conjunction with the subject's diary.

Variables analysed were respiratory events index, supine respiratory events index, non-supine respiratory events index, supine sleep time, oxygen desaturation index and mean oxygen saturation. Polygraphy variables were scored according to the criteria of the American Academy of Sleep Medicine (https://aasm.org/clinical-resources/scoring-manual).

Obstructive apnea was defined as a decrease in airflow amplitude of more than 90% for more than 10 s. Hypopnea was defined as a reduction in airflow amplitude of 50% or more from baseline for > 10 s in combination with an oxygen desaturation of > 3%. Respiratory events index was defined as the total number of apneas and hypopneas divided by hours of estimated sleep time. In a similar manner, oxygen desaturation index was defined as the total number of desaturations of at least 4% from baseline per hour.

2.7 | Questionnaires

Daytime sleepiness was assessed with the Epworth Sleepiness Scale (ESS), where a higher ESS score indicates a higher degree of daytime sleepiness (Johns, 1991). A cut-off of 10 points is often used to indicate daytime sleepiness.

Subjective sleep problems and daytime symptoms were assessed with an adapted version of the Basic Nordic Sleep Questionnaire (BNSQ; Partinen & Gislason, 1995). Items are scored on a five-point scale (never or almost never; less than once a week; once or twice a week; 3–5 nights/days a week; almost every day or night). A response of 4 or 5 was considered to indicate the respective sleep problem.

Quality of life was assessed using the Medical Outcomes Study Short-Form Health survey (SF-36; Brazier et al., 1992; Ware & Sherbourne, 1992) at baseline and after 6 ± 2 weeks follow-up. The SF-36 is a self-report questionnaire consisting of 36 items grouped into eight domains (functional capacity; role-physical; bodily pain; general health; vitality; social functioning; role-emotional; and mental health), and assesses functional status and well-being referring to the past 4 weeks at the time of the survey. Higher SF-36 scores indicate better quality of life.

2.8 | Ethical considerations

All patients gave their written informed consent, and the study was approved by the Ethical Review Board (Etikprövningsnämnden) in

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Stockholm (2018/619-31) and approved by the Swedish Medical Products Agency: (5.1-2018-98800).

3 | STATISTICAL ANALYSIS

The sample size calculation was based on an assumed effect size of 16 units in respiratory events index with a standard deviation of 25, the values taken from a previous crossover trial (Delijaj et al., 2016). To achieve a power of 80% with a two-sided $\alpha = 0.05$, a sample size of 41 subjects per treatment group would be sufficient. To ensure against potential dropouts, a sample size of $50 + 50$ patients was chosen.

The main study population was the intention-to-treat (ITT) population. Analyses were also carried out per-protocol (PP). The PP population was defined as all patients who completed the second sleep registration. Missing data were handled using last observation carried forward (LOCF) and by using multiple imputation (MI), where missing values were imputed using the method of chained equations (Sterne et al., 2009), as implemented in the R package *mice*.

Imputation was done stratified on trial arm, in agreement with the recommendations of Sullivan et al. (2018). Baseline values of age, gender and BMI were used as predictors, generating 100 imputed data sets. The results were pooled using Rubin's rules.

The primary analysis was defined by primary variable (respiratory events index), ITT study population, LOCF, and no adjustment for baseline data (crude model). We used linear regression as the analysis model, which is equivalent to a *t*-test. From linear regression, we extracted the regression coefficient for CC/LS. The results can be interpreted as the average difference between CC/LS and LS values. In other words, positive regression coefficients correspond to more positive values in the CC/LS arm. Two-sided *p*-values lower than 0.05 were considered statistically significant. All analyses were performed using R. No minimum of any sleep position was required to be included in the analysis.

4 | RESULTS

In total, 81 patients completed the study (LS = 42, CC/LS = 39) and 19 patients discontinued. Most patients were middle-aged males. There were no substantial differences between the LS and the CC/LS groups according to the baseline characteristics (Table 1). For patients who discontinued, there are no data after Visit 1. The mean time interval between performed first and second polygraphy was 137 days for LS group and 131 days for CC/LS group. There were no differences between the groups in perceived sleep quality and self-reported sleep time during the second polygraphy (Table S1). No severe side-effects were reported (Table S2). Of those who completed the study, all patients in the CC/LS group reported that they had used the highest elevation level of CC (24°); however, eight patients (20%) reported wearing the collar less than 4 hr during the follow-up polygraphy. Their sleep recording data were not excluded from the analysis.

TABLE 1 Baseline characteristics of the patients included in the study.

Variable		LS group ($n = 50$) Mean ± SD or *n* (%)	CC/LS group ($n = 50$) Mean ± SD or *n* (%)
Sex	Male	32 (64.0)	33 (66.0)
	Female	18 (36.0)	17 (34.0)
Age (years)		55.0 ± 10.5	58.0 ± 10.0
BMI (kg m^{-2})		29.9 ± 3.3	28.5 ± 3.4
Systolic BP		132.9 ± 12.1	137.2 ± 11.2
Diastolic BP		84.1 ± 7.1	83.8 ± 8.3
Neck circumference (cm)		41.1 ± 4.2	40.3 ± 4.2
Respiratory events index		20.1 ± 4.1	20.5 ± 4.4
Respiratory events index in the supine position		33.2 ± 17.7	29.6 ± 16.5
Respiratory events index in the non-supine position		11.0 ± 7.2	13.2 ± 9.2
Supine sleep time (%)		37.6 ± 24.7	41.3 ± 29.0
Oxygen desaturation index		19.2 ± 4.4	19.6 ± 4.6
Mean oxygen saturation (%)		92.7 ± 1.5	92.5 ± 1.7
ESS		8.8 ± 4.8	9.1 ± 5.4
Civil status	Married/ Cohabitant	36 (72.0)	42 (85.7)
	Living alone	14 (28.0)	7 (14.2)
Education	Primary	12 (24.0)	11 (22.4)
	Secondary	24 (48.0)	30 (61.2)
	Higher	14 (28.0)	8 (16.3)
Smoker	Never	27 (54.0)	26 (54.2)
	Former	16 (32.0)	19 (39.6)
	Current	7 (14.0)	3 (6.2)
Overall sleep quality	Very good	3 (6.1)	1 (2.1)
	Rather good	16 (32.7)	14 (29.2)
	Neither	12 (24.5)	14 (29.2)
	Rather poor	14 (28.6)	16 (33.3)
	Very poor	4 (8.2)	3 (6.2)
Comorbidity	Diabetes	5 (10.2)	5 (10.4)
	Hypertension	21 (43.8)	20 (41.7)
	Heart disease	8 (16.3)	2 (4.2)
	Asthma	4 (8.2)	7 (14.6)
	COPD	3 (6.1)	2 (4.2)

Abbreviations: BMI, body mass index; BP, blood pressure; CC/LS, cervical collar in combination with lifestyle intervention; COPD, chronic obstructive pulmonary disease; ESS, Epworth Sleepiness Scale; LS, lifestyle intervention.

The question on how the participants experienced the treatment was answered by 31 patients in the CC/LS group, 45% of whom found it good, 39% neither good nor bad, while 16% found it bad. An

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TABLE 2 Sleep apnea variables before and after treatment period, and *change from baseline to follow-up (Δ) for the respective group.

Variable	Before treatment		After treatment			
	LS group ($n = 50$) Mean ± SD	CC/LS group ($n = 50$) Mean ± SD	LS group ($n = 42$)		CC/LS group ($n = 39$)	
			Mean ± SD	*Mean Δ(SD)	Mean ± SD	*Mean Δ(SD)
Respiratory events index	20.1 ± 4.1	20.5 ± 4.4	18.5 ± 10.2	−1.9 (9.5)	12.4 ± 8.3	−7.7 (7.8)
Respiratory events index in the supine position	33.2 ± 17.7	29.6 ± 16.5	30.0 ± 20.9	−3.2 (19.2)	15.1 ± 14.0	−15.0 (21.5)
Respiratory events index in the non-supine position	11.0 ± 7.2	13.2 ± 9.2	13.3 ± 10.3	1.4 (9.2)	9.9 ± 8.5	−1.4 (9.0)
Supine sleep time (%)	37.6 ± 24.7	41.3 ± 29.0	30.6 ± 24.3	−5.1 (19.6)	37.4 ± 29.5	−9.5 (15.9)
Oxygen desaturation index	19.2 ± 4.4	19.6 ± 4.6	17.9 ± 10.1	−1.5 (9.0)	12.1 ± 8.2	−7.2 (7.8)
Mean oxygen saturation (%)	92.7 ± 1.5	92.5 ± 1.7	92.8 ± 1.4	0.2 (1.0)	92.7 ± 1.7	−0.0 (1.0)

Abbreviations: CC, cervical collar; CC/LS, cervical collar in combination with lifestyle intervention.

open question with possibility to write a comment about treatment was responded by 19 patients. Among the negative comments, it was the poor comfort of the collar that dominated (feeling of pressure over the jaw, feeling of congestion, sharp edges and discomfort). The positive comments were about less snoring, gasping and choking during the night, and experience of being more alert during the day.

Positive effects on respiratory events index, supine respiratory events index and oxygen desaturation index were seen in the CC/LS group after 6 ± 2 weeks of treatment compared with the LS group (Table 2).

Among patients that completed the study, 25 patients had respiratory events index < 10 (LS group = 8 and CC/LS group = 17) and eight patients had respiratory events index < 5 (LS group = 1 and CC/LS group = 7) after 6 ± 2 weeks at the end of treatment.

Individual changes in respiratory events index and supine respiratory events index by treatment group are presented in Figure 3.

The spaghetti plot (Figure 3) shows a potentially highly influential point among the CS/LS sample in which supine respiratory events index was seemingly reduced by > 100 events per hr. It was noted that the patient only had a short sleep period in the supine position during the second polygraphy registration. When rerunning the analysis without this patient, the results did not change radically (Table S3).

When analysing the effect on supine and non-supine respiratory events index separately, it was seen that the positive effect was driven by an improvement of respiratory events index in the supine position, while no significant effect was seen for non-supine respiratory events index (Table 3). The results were similar whether calculations were made on ITT or PP. Oxygen desaturation index was also improved by CC, while no effect was seen on mean oxygen saturation (Table 3). The calculations were repeated with MI instead of LOCF, and gave similar results (Table S4).

Table 3 shows the total effect in CC/LS group compared with LS group using linear regression models.

Changes in daytime sleepiness, quality of life, subjective sleep problems, BMI, alcohol consumption, smoking and physical activity did not differ substantially between LS and CC/LS groups after 6 ± 2 weeks of treatment (Table S5).

5 | DISCUSSION

In this randomized controlled trial on patients with moderate OSA, a reduction in respiratory events index in CC/LS patients compared with LS only was observed. In the sub-analysis, there was a clear effect on respiratory events index in the supine position but not in the non-supine position.

It has been long recognized that head extension is a commonly used manoeuvre in resuscitation and in anaesthesia to maintain airway patency by reducing upper airway obstruction (Atanelov et al., 2023; Safar et al., 1959). Walsh et al. (2008) assessed the pharyngeal critical closing pressure (Pcrit) and upper airway collapse during head flexion, extension and rotation in patients undergoing propofol anaesthesia. They showed that head flexion increases, and head extension decreases the propensity for the upper airway to collapse compared with the neutral position. Vista CC allows its height to be adjusted, which improves the conditions for extending the head during sleep. Head extension by CC helps to sustain airway patency, which in turn contributes to reducing obstruction of the upper airways. Sleeping in the supine position is a strong risk factor for the occurrence of apneas/hypopneas (Farronato et al., 2013). We found that head extension using CC had the most positive effect by reducing apneas and hypopneas during sleeping in the supine position.

A positive effect of extending the head by using a CC was also found in the previous randomized crossover pilot study (Delijaj et al., 2016) when patients with severe sleep apnea were treated with CC and MAD in combination therapy. In the current study, we used the same model of CC (Vista CC) that was also used in this pilot study. Skinner et al. (2004) and Bordier et al. (2021) have, in contrast, found no improvement of respiratory events index using rigid and soft CC for stabilization of the neck during sleep. Skinner et al. (2004) studied 10 patients with mild to moderate OSA for 1 month using a rigid collar to maintain the neutral (natural) head position with the head in slight extension equivalent to 5°. They observed an effective respiratory events index reduction in two patients. In contrast, we had a significantly larger patient population, and the collar we used in our study allowed for a much greater degree of head extension. We chose the

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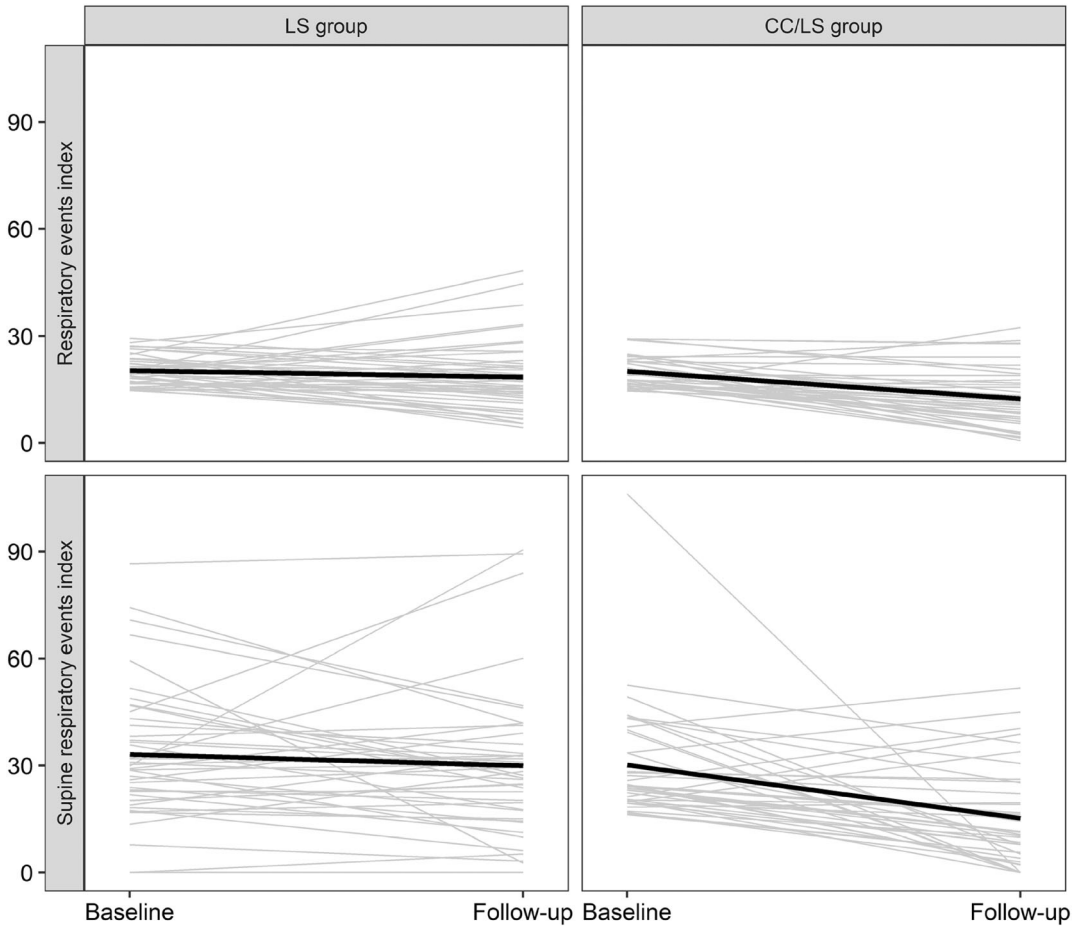

FIGURE 3 Respiratory events index and supine respiratory events index as a spaghetti plot, showing the baseline and follow-up values of patients with a follow-up sleep registration (per-protocol [PP] population). The group means are shown using thicker lines.

highest level (24°), which presumably affected pharyngeal patency during sleep. A soft CC used in the pilot study by Bordier et al. (2021) could not demonstrate any effect on upper airways patency. Only 20 patients were included in their pilot study, and there is no evidence that the soft collar caused head extension. The CC was, however, well tolerated, which is in accordance with our findings in the present study. The Skinner et al. (2004) and Bordier et al. (2021) studies suggest that it is uncertain whether a stabilization of the neck without considerable head extension effect is sufficient to optimize the conditions in sustaining airway patency during sleep. Although head extension at the 24° using CC had a positive effect on respiratory events index and oxygen desaturation index, it is still not entirely certain if it is the optimal level for all patients. Therefore, individual adjustment of head extension and testing is required to be able to find an individual optimal level. The effectiveness of the Vista CC is found in its level of extension, and that has to be the most important difference compared with other CCs that have been used in previous studies. However, the collar needs to be optimized especially in terms of design and comfort in order to reduce the side-effects, and adherence needs to be tested in a more rigorously controlled study.

In our study, despite a positive effect on respiratory events index and oxygen desaturation index in the CC group, we could not find any effect on daytime sleepiness, quality of life or subjective sleep problems. A possible explanation is that only a minority of the patients in the study had daytime sleepiness when defined as an ESS score > 10. In addition, the treatment period was short, and it is possible that a longer period is needed to obtain a symptom reduction. However, reduction of respiratory events index and oxygen desaturation index is most important for avoiding long-term health consequences.

5.1 | Strengths and limitations

The strength of this study is the randomized controlled design and patient cohort of considerable size. We acknowledge that there are limitations to our study. First, all recordings were performed with polygraphy, which means that sleeping time could only be estimated by the manual evaluation of sleep by the experienced sleep-technician and standardized questionnaires. Another disadvantage of using unattended polygraphy is that we cannot make sure that treatment was used during the second polygraphy and had to rely on self-reports from the participants. However, identical scoring rules were used in both treatment groups. Furthermore, if some of the patients had used the collar less than reported, the present results are an

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TABLE 3 Total effect when extending the head using the CC combined with lifestyle advice in CC/LS group as compared with lifestyle advice only, in LS group.

			Respiratory events index	Respiratory events index in the supine position	Respiratory events index in the non-supine position	Oxygen desaturation index	Supine sleep time (%)	Mean oxygen saturation
A1	ITT LOCF $N = 100$	Difference[a]	−4.5	−9.1	−2.3	−4.3	−3.2	−0.2
		95% CI	(−7.7, −1.2)	(−16.5, −1.6)	(−5.5, 1.0)	(−7.4, −1.2)	(−9.7, 3.3)	(−0.5, 0.2)
		p-value	0.008	0.018	0.17	0.008	0.34	0.35
A2	PP $N = 81$	Difference[a]	−5.9	−11.9	−2.8	−5.6	−4.4	−0.2
		95% CI	(−9.7, −2.0)	(−20.9, −2.9)	(−6.8, 1.2)	(−9.4, −1.9)	(−12.4, 3.5)	(−0.6, 0.2)
		p-value	0.003	0.011	0.17	0.004	0.27	0.36
B	ITT LOCF $N = 100$	Difference[a]	−4.4	−11.1	−1.6	−4.3	−2.5	−0.2
		95% CI	(−7.7, −1.2)	(−17.6, −4.6)	(−4.7, 1,5)	(−7.4, −1.1)	(−8.7, 3.8)	(−0.5, 0.1)
		p-value	0.008	<0.001	0.32	0.008	0.43	0.21
	PP $N = 81$	Difference[a]	−5.9	−13.8	−3.1	−5.7	−2.1	−0.2
		95% CI	(−9.8, −2.0)	(−21.3, −6.3)	(−6.8, 0.7)	(−9.4, −1.9)	(−9.9, 5.7)	(−0.6, 0.2)
		p-value	0.003	< 0.001	0.11	0.004	0.59	0.37

Note: A1 and A2 = non-adjusted analysis (A1 = primary analysis), B = adjusted for the baseline value of the respective variable. Results is presented as differences between the groups. LOCF is not applicable on PP because no data is missing.
Abbreviations: CI, confidence interval; ITT, intention-to-treat; LOCF, last observation carried forward; PP, per-protocol.
[a]Mean difference between the effects in CC/LS group compared to the LS group.

underestimation of the treatment effect. Another limitation is Vista CC. The collar is designed and intended as a relieving collar associated with cervical disc rupture, traumatic neck injury, postoperative stabilization and other neck stabilization, it is not designed for long-term treatment for patients with OSA, and some patients have experienced discomfort when wearing it. This fact may have caused some drop-outs, although the majority of patients tolerated the equipment very well.

The drop-out rate of 19% is also a possible cause of bias, especially if there are systematic differences between the patients that dropped out and the remaining. However, the number of drop-outs were of similar magnitude in both groups, and the results were similar when performing the analyses PP as ITT, indicating that the bias caused by drop-outs was limited.

Another limitation is the open trial of our study, where both the participants and the investigator knew which intervention was being administered. This entails an increased risk of enrolment bias and bias related to the use of imputation methods for missing data. However, lifestyle treatment was equally well received by the patients, and we have not observed any clear signs of dissatisfaction after randomization.

We primarily employed the LOCF method to handle missing data. However, we also recognize that this method has limitations. In addition to LOCF, we applied MI as an alternative method. We agree that MI does not necessarily remove the potential bias due to drop-out, but as it takes baseline information into account, we believe that the underlying assumption of MI is more realistic than the assumptions of either a complete case analysis or LOCF, thus at least reducing the bias.

5.2 | Clinical implications

The results of the study provide evidence of the potential efficacy of head extension by CC in moderate sleep apnea.

This, combined with the fact that CC is non-invasive, cheap and simple to use equipment, it may be a valuable tool for second-line treatment of OSA, especially in positional OSA.

6 | CONCLUSION

In conclusion, treatment with head extension using CC had a positive effect on respiratory events index and oxygen desaturation index in patients with moderate OSA. The improvement was most pronounced on respiratory events index in the supine position. There is need for long-term follow-up of this treatment regarding treatment effect and tolerability.

AUTHOR CONTRIBUTIONS

Florim Delijaj: Conceptualization; investigation; writing – original draft; methodology; writing – review and editing; validation; visualization; software; formal analysis; project administration; resources; data curation. **Lars Lindhagen:** Formal analysis; writing – original draft; data curation. **Linus Johnsson:** Conceptualization; writing – original draft; methodology; validation; writing – review and editing; supervision; resources; software; formal analysis. **Per Kristiansson:** Conceptualization; writing – original draft; validation; methodology; writing – review and editing; project administration; supervision. **Eva Lindberg:** Conceptualization; investigation; writing – original draft;

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methodology; validation; visualization; writing – review and editing; software; formal analysis; project administration; data curation; supervision; resources.

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CONFLICT OF INTEREST STATEMENT

All authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to ethical or privacy restrictions.

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