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Original Article

Short-term effects of a functional cervical pillow on inpatients with neck discomfort: a randomized controlled trial

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Abstract: Sleeping posture is regarded to be strongly related with quality of sleep, with poor sleeping posture increasing biomechanical stress on the cervical spine. Prevalence of acute and chronic neck pain and discomfort is steadily increasing, and possibly entails poor sleep and consequent delayed recovery. A prospective randomized controlled trial in a Korean medicine hospital was conducted to assess effects of functional cervical pillows (FCPs) in inpatients with neck discomfort. Fifty patients with neck discomfort of visual analogue scale (VAS) ≥4 were recruited consecutively from inpatients admitted between June 15th and August 15th, 2014 and randomly allocated to 2 groups. The experimental group used FCPs and Korean medicine treatment, and the control group, general pillows (GPs) with the same treatment. Outcome measures included difference in neck discomfort VAS, neck disability index (NDI), Pittsburgh sleep quality index (PSQI), satisfaction with current neck state, and EuroQol-5 dimension questionnaire (EQ-5D) between baseline and discharge. Length of stay was similar in both groups (24.3±7.4 and 23.1±7.9 days, respectively). Difference in VAS between admission and discharge showed significant reduction in both groups (P<0.0001 and P=0.0177, respectively), but only FCP displayed significant decrease in NDI (P=0.002). Satisfaction rates and EQ-5D were favorable in both groups, but PSQI was not significant in either. Difference in VAS from admission to discharge between groups was -13.4 (95% CI: -26.2 to -0.6), favoring FCP, while that of NDI, PSQI, satisfaction rate and EQ-5D was non-significant. FCPs may be considered as complementary treatment for neck discomfort and functional recovery. Trial registration: ClinicalTrials.gov NCT02240849. Registered 28 August 2014.

Keywords: Neck discomfort, functional cervical pillow, integrative treatment, complementary treatment, inpatient treatment

Introduction

A considerable percentage of the population is affected by acute or chronic neck pain at any given time. The North American adult population has a point prevalence of 9-14% and lifetime prevalence of 33% of neck pain [1, 2]. The 50-59 year age category has the highest point prevalence, and twice more females are affected than males with respective lifetime prevalence of about 30% and 15% [3-5]. Various epidemiologic studies have estimated lifetime incidence of benign cervical pain syndromes at 35% to 80% [6, 7].

Sleep holds significant importance as a major component of daily life taking up approximately one-third of a person's life, and sufficient high-quality sleep is essential for maintaining regular function. Sleep helps sustain immunity, homeostasis, and health integrity. In addition, sleep regulates judgment, memory, and cognitive abilities needed in daily activities and work [8, 9]. Those deprived of sufficient high-quality sleep tend to have reduced cognitive ability, increased physical discomfort and fatigue, and more mood problems compared to those with normal sleep [10].

Sleeping posture is considered to be strongly related with quality of sleep. More specifically, poor cervical posture during sleep is believed to increase biomechanical stress on cervical spine structures and lead to cervical pain and

stiffness, headache, and arm or scapular pain, in turn resulting in low-quality sleep [11]. Gorden et al. reported 17.6% of study subjects woke with cervical pain at least once a week [12]. Of various sleeping postures, side-sleeping position was reported to be most prevalent at 71.9%, and it also protected against waking cervical pain (odds ratio (OR) 0.6; confidence intervals (CIs) 0.4-0.9) [13]. Timewise, it has been reported that adults spend 59-73% of sleep in side-lying positions [14].

Musculoskeletal discomfort and stress are commonly cited as major causes of lack of sleep [15, 16], and disorders that cause sleep disturbance frequently entail neck pain. Moreover, as certain sleep postures potentially aggravate pain, both acute and chronic neck pain and discomfort patients may benefit from pain management strategies which incorporate such complementary treatment modalities as cervical pillows [17]. Appropriate pillow use has been purported to relieve neck pain [18], and may take on effect by helping optimize sleeping posture and inducing higher quality sleep [19].

Lack of research related to appropriate pillow selection in patients has led health care givers to provide patients with advice based on anecdotal suggestions from colleagues and associations. Suggestions have included use of malleable pillows [20, 21], cervical rolls [21-23], contour pillows [24, 25] and down or urethane pillows [26]. The purpose of this study was to compare the effects of a functional cervical pillow designed to support the cervical alignment and balance in both supine and side-sleeping positions with a general pillow in inpatients with neck discomfort.

Material and methods

Study design

This randomized controlled trial of parallel design investigated the effects of a functional cervical pillow compared with a general pillow on waking neck discomfort, functional recovery, quality of sleep, satisfaction rate and quality of life between admission and discharge. Difference between groups in change in head forward posture through C-spine X-ray measurement at admission and discharge was also included as an objective outcome measure in addition to patient-reported indexes.

Participants

The anticipated number of participants was 60 patients aged 18-69 years hospitalized from June 15th, 2014 to August 15th, 2014 for treatment of musculoskeletal disease at Jaseng Hospital of Korean Medicine in Korea, a Korean Medicine hospital recognized by the Korean Ministry of Health and Welfare to specialize in spinal disorder treatment. Eligible subjects were screened for at least 1 day with waking neck discomfort on a visual analogue scale (VAS) of ≥40 mm on a 10 mm horizontal rule out of the 2nd and 3rd days of admission. Patients who had received neck surgery, or who had been diagnosed with potential causes of severe neck pain such as tumor, fracture, infection, inflammatory spondylitis, cauda equina syndrome, spondylolisthesis, or who had experience of or were currently using functional pillows were excluded.

Interventions

Patients randomized to the experimental group (functional cervical pillow group) received functional cervical pillows during admission and instructions on proper pillow use along with Korean medicine usual care provided by Korean medicine doctors (KMDs), and patients randomized to the control group (general pillow group) received general pillows to use during admission and instructions on proper use with Korean medicine usual care from KMDs.

Functional cervical pillow (See Supplementary Data Files 1 and 2)

The size of the functional cervical pillow was 650×350×180 mm, and weight, 1.7 kg±5%. The functional cervical pillow was compartmentalized into the occipital base support structure, 2 cores, cervical support structure, and 2 side-flaps. The functional cervical pillow is designed to support the cervical curve in both supine and side-lying positions and is height-adjustable using pads inserted at the occipital base support. Side-flaps on each side create lateral shoulder space in supine sleeping, and are designed to protect against shoulder compression, to support the cervical curve, and to prevent cervical alignment distortion in side-lying.

The inner lining (functional dyrtex) is tetoron/cotton (cotton 35%, polyester 65%), the outer

lining 100% organic cotton jacquard fabric, and the pillow body 100% polyurethane. The material of the core structure which comprises the lower layer is memory foam, and that of the upper surface (topper) which makes direct contact with the facial area is nogonoflex 2, a softer, supple material. As nogonoflex 2 is too soft and supple to provide adequate support of the axial skeleton, the lower layer is comprised of sturdier memory foam [27].

General pillow

The size of the pillow used in the general pillow group (Daewoong Co., Ltd., Korea) was 400×600×150 mm. The outer lining was made from synthetic leather with a cotton cover, and the pillow body was filled with quilting cotton.

Outcome measures

Outcomes were measured after obtaining consent from participants at baseline (day 3 post-admission), and at follow-up assessments conducted on day 3, week 1, 2, 3, and week 4 post-baseline or at discharge.

Primary outcome measure

Waking neck discomfort: VAS was used to assess waking neck discomfort [28]. VAS has a long history of ubiquitous use across various medical specialties including physical and rehabilitation medicine [29-31]. Waking neck discomfort was measured at baseline (day 3 post-admission) and on day 3, week 1, 2, 3, and week 4 post-baseline or at discharge, and if a participant was discharged at an earlier point, last observation carried forward was used. Participants marked their waking neck discomfort on a 100 mm horizontal line, with 0 mm representing no waking neck discomfort, and 100 mm highest level of discomfort imaginable.

Secondary outcome measures

Satisfaction with current neck condition: Satisfaction with current neck state was rated on a 5-point Likert-scale: very dissatisfied (1); dissatisfied (2); slightly satisfied (3); satisfied (4); and very satisfied (5).

Neck disability index (NDI): The validated Korean version of the neck disability index was used to assess functional recovery and was measured at 2 week intervals post-baseline with baseline measurement on day 3 [32]. Participants were instructed to self-rate their level of neck disability using a printed NDI questionnaire.

Pittsburgh sleep quality index (PSQI): Quality of sleep was assessed using the Pittsburgh sleep quality index from baseline measurement on day 3 post-admission with 2 week interval post-baseline follow-up measurements [33]. Participants filled out Korean PSQI questionnaires, and scores were quantified according to PSQI calculation methods.

EuroQol-5 dimension questionnaire (EQ-5D): EQ-5D was measured to assess change in health-related quality of life (HRQoL) at admission and discharge applying a weighted model developed by Nam et al. for Koreans [34]. EQ-5D is currently widely used across the health care sector. Although EQ-5D has been criticized for being too simple and lacking sufficient sensitivity to discern various health states, many have advocated its use in terms of practicality, reliability and validity, stating that EQ-5D and the health utilities index (HUI) are superior research tools [34].

Weighted values were applied by health status as assessed over 5 dimensions to produce a single EQ-5D index value and allow uncomplicated evaluation of HRQoL and comparison between different regions and countries [34]. Scores range from -1, indicating 'health worse than death' to 1, 'perfect health'. Dimensions are graded in 3 levels (1, no problem; 2, some/moderate problem; and 3, extreme problem) and represent different aspects of current health status and functionality: mobility, self care, usual activities, pain/discomfort, and anxiety/depression [35].

Difference in average of VAS, satisfaction with current neck condition, NDI, PSQI, and EQ-5D of the functional cervical pillow group and general pillow group were observed. In addition, VAS, NDI, and PSQI scores in patients with ≥2 week hospital stay were assessed separately for weekly difference in subgroup analysis.

Head forward posture

X-rays taken before and after pillow use during admission were analyzed for difference in head

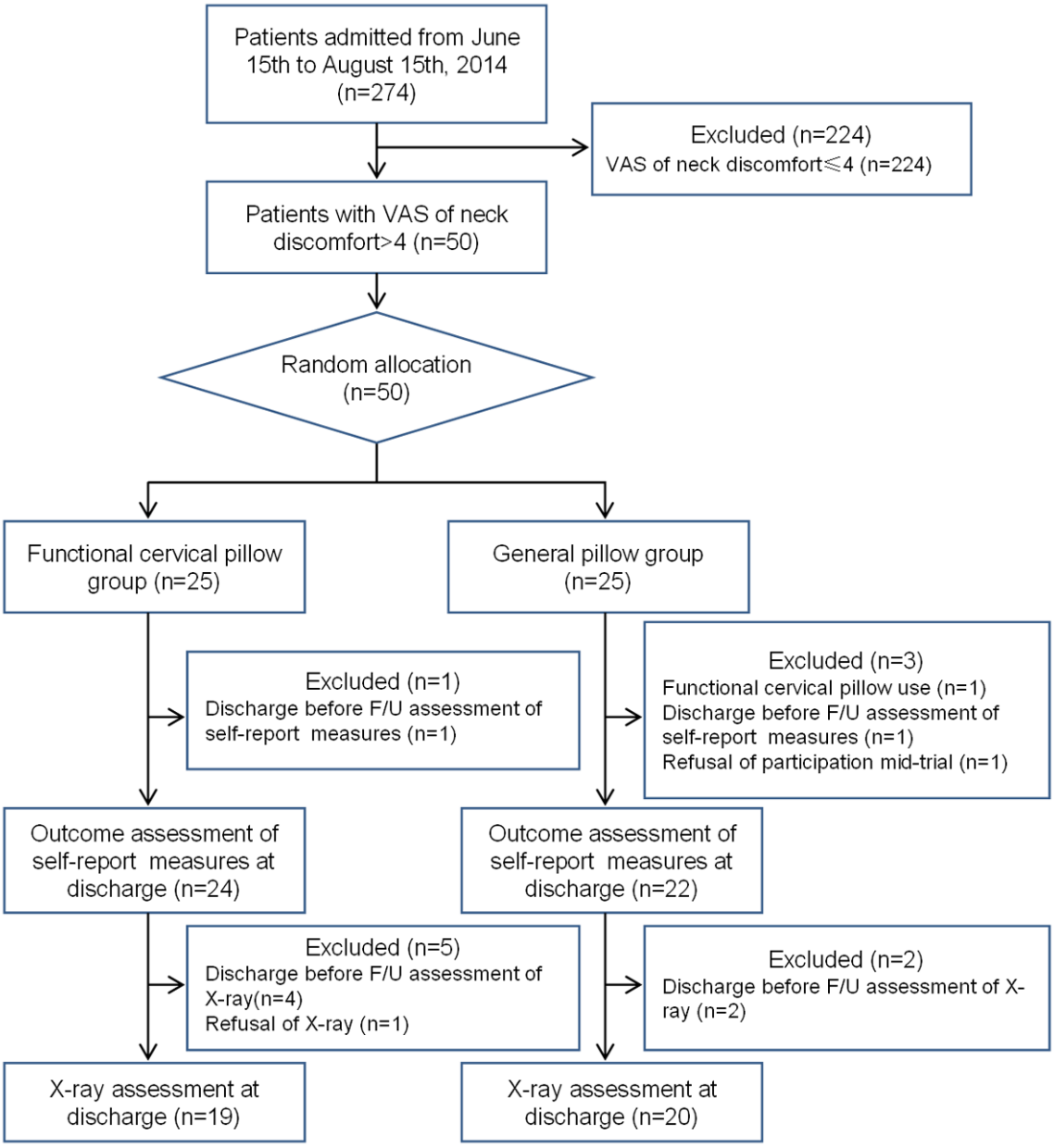

Figure 1. Flow diagram of the study.

forward posture. Participants took X-rays at baseline on day 3 post-admission and at 4 weeks post-baseline or discharge. Radiological examination consisted of anteroposterior, lateral, flexion and extension views of the cervical spine, and 2 independent assessors took measurements of head forward posture on the lateral view of digital X-ray images. Inter-rater agreement was measured after the 2 assessors had made measurements separately, and group difference in averages was compared.

Degree of head forward posture on lateral X-ray was determined following the method reported by Morningstar [36]. Head forward posture was measured as the horizontal distance from the posterior superior border of the C2 vertebra body compared to a perpendicular line drawn superiorly from the posterior inferior border of the C7 vertebra body. This measurement method has been shown to produce small mean absolute difference with high intra- and inter-rater reliability [37]. We therefore employed this

Table 1. Characteristics of participants by allocation group

Variable	Functional cervical pillow group (n=23)	General pillow group (n=21)
	n (%)/Mean ± SD	n (%)/Mean ± SD
Sex		
Male	15 (65.2)	17 (81.0)
Female	8 (34.8)	4 (19.0)
Age	49.2±12	44.7±14.5
BMI	22.7±2.4	21.7±2.9
Length of hospital stay	24.3±7.4	23.1±7.9
Occupation		
No	7 (31.8)	13 (61.9)
Yes	15 (68.2)	8 (38.1)
Smoking		
Ex-smoker	2 (8.7)	1 (4.8)
Current smoker	1 (4.3)	2 (9.5)
Never smoker	20 (87.0)	18 (85.7)
Alcohol consumption		
No	13 (56.5)	15 (71.4)
Yes	10 (43.5)	6 (28.6)
Comorbidity		
No	10 (43.5)	9 (42.9)
Yes	13 (56.5)	12 (57.1)
Chief complaint		
Neck pain	16 (69.6)	13 (61.9)
Low back pain	16 (69.6)	17 (80.9)
Shoulder pain	-	1 (4.8)
Knee pain	-	2 (9.5)

method to assess group difference in posture before and after admission treatment, and used histograms to visually evaluate and compare difference in distribution.

Randomization and sample size

If an attending KMD judged a patient to be eligible for study participation, he/she would inform the screening researcher for screening. Upon study participation, patients were assigned consecutive numbers by the screening researcher from CN001 to CN060. The assigned number was relayed to a KMD researcher in the clinical research department entrusted with the random allocation file created by an independent statistician, who would notify the attending KMD of group allocation to either the functional cervical pillow group or general pillow group. Random block size was set at 2 and block randomization was conducted at a ratio of 1:1 using SAS version 9.1.3 statistical package (SAS Institute, Cary, NC, USA) for random number generation. As we were unable to calculate sample size due to lack of prior studies on the functional cervical pillow used in the current study, this study was originally designed as a pilot with 30 patients allocated to each group, but a total 50 participants were enrolled during the 2 month study period.

Blinding

Though patient and physician blinding was not possible due to marked difference in pillow form, outcome assessment was conducted though assessor blinding.

Statistical methods

Statistical analysis of the results was conducted using SAS version 9.2 statistical package (SAS Institute, Cary, NC, USA). Descriptive statistics were used for general sociodemographics and history of subjects. Primary analysis used intention-to-treat (ITT) analysis on self-report, physiologic and functional measure data (e.g. questionnaires) of all randomized patients, and in participants discharged before 4 weeks, data from time of discharge was used in last observation carried forward. Patients with missing imaging data at admission or discharge were excluded from secondary X-ray analysis as difference in X-ray measurement could not be assessed.

VAS, NDI, PSQI, satisfaction with current neck state, and EQ-5D were checked for normal distribution with Shapiro-Wilks test. If the difference between admission and discharge in each group satisfied the normality assumption, parametric method was used with paired t-test, and if the results did not satisfy normality, nonparametric method was applied with Wilcoxon signed-rank test. Comparison between group averages at different timepoints was conducted with Student's t-test if normally distributed, and Wilcoxon rank sum test if not.

In X-ray data analysis, intraclass correlation coefficient was used to assess level of agreement in head forward posture measurement,

Table 2. Average VAS, NDI, and PSQI score at admission and discharge of functional cervical pillow and general pillow group

	Admission	Discharge	*p* value[a]	Difference (95% CI)
	Mean ± SD	Mean ± SD		
VAS				
Functional cervical pillow group	62.04±12.05	34.83±20.06	0.0001	-13.41
General pillow group	54.24±10.51	40.43±24.02	0.0177	(-26.21, -0.61)
p value[b]	0.0180	0.4735		0.0324
NDI				
Functional cervical pillow group	41.48±14.55	31.09±11.26	0.0024	-5.93
General pillow group	39.51±13.12	35.06±15.14	0.3505	(-15.15, 3.29)
p value[b]	0.9812	0.3905		0.2040
PSQI				
Functional cervical pillow group	10.35±3.49	9.91±3.52	0.4532	0.85
General pillow group	11.95±3.67	10.67±4.13	0.2564	(-1.92, 3.62)
p value[b]	0.1597	0.6623		0.7060

[a]Non-parametric method (Wilcoxon signed-rank test) was used. [b]Non-parametric method (Wilcoxon-rank sum test) was used. VAS; visual analogue scale, NDI; neck disability index, PSQI; Pittsburgh sleep quality index.

and normality was tested as in other outcome measures.

Ethics approval and consent to participate

Participants meeting the inclusion criteria were informed of the study protocol and enrolled after giving written informed consent to participate. The study protocol was approved by the Institutional Review Board (IRB) of Jaseng Hospital of Korean Medicine in Seoul, Korea (IRB approval number: ECJH2014-03).

Results

Fifty patients aged 18 to 69 who were admitted to Jaseng Hospital of Korean Medicine from June 15th, 2014 to August 15th, 2014 were included in the study. Of the 50 enrolled participants, one participant randomized to the general pillow group was excluded due to personal functional pillow use, and one participant refused further participation mid-trial. Outcome measurements at discharge were missing in 2 patients who were abruptly discharged due to personal reasons. A total 46 patients completed assessment of self-report, physiologic and functional measures with 24 in the functional cervical pillow group, and 22 in the general pillow group. X-rays were missing in a further 7 patients out of the total 46 participants. One patient refused X-ray examination, and 6 were referred for X-ray but were discharged before undergoing the follow-up X-ray exam. A total 39 patients were included in secondary X-ray analysis with 19 patients in the functional cervical pillow group, and 20 patients in the general pillow group (**Figure 1**).

Characteristics of the functional cervical pillow group and general pillow group are listed in **Table 1**. Most participants were neck pain and low back pain patients, mainly male, and in their 40s.

Self-report measures

In VAS of waking neck discomfort, functional cervical pillow and general pillow groups both showed significant improvement at discharge (P=0.0001, and P=0.0177, respectively). Comparison of group difference between admission and discharge showed that VAS of functional cervical pillow group decreased -13.41 (95% CI: -26.21~-0.61), which was larger than the general pillow group (P=0.0324). Neck function was measured with NDI, and while the functional cervical pillow group neck function improved at discharge (P=0.0024), that of the general pillow group did not show significant improvement (P=0.3505). In quality of sleep, both groups did not show significant difference at discharge, and difference between groups was also non-significant (**Table 2**). Satisfaction with current neck state improved in both groups at discharge (P=0.0003, and P=0.0027, respective-

Table 3. Average satisfaction rate, and EuroQol-5 dimension (EQ-5D) score at admission and discharge of functional cervical pillow and general pillow group

	Admission	Discharge	*p* value[a]	Difference (95% CI)
	Mean ± SD	Mean ± SD		
Satisfaction with current neck state[b]				
Functional cervical pillow group	3.87±0.46	2.87±0.76	0.0003	-0.24
General pillow group	3.95±0.50	3.19±0.75	0.0027	(-0.77, 0.29)
p value[c]	0.5738	0.1137		0.3804
EQ-5D				
Functional cervical pillow group	0.67±0.19	0.80±0.07	0.0012	0.05
General pillow group	0.69±0.10	0.77±0.13	0.0074	(-0.05, 0.14)
p value[c]	0.8775	0.8129		0.6378

[a]Non-parametric method (Wilcoxon signed-rank test) was used. [b]Satisfaction with current neck state was assessed with 5-point Likert-scale; very dissatisfied (1); dissatisfied (2); slightly satisfied (3); satisfied (4); and very satisfied (5). [c]Non-parametric method (Wilcoxon-rank sum test) was used.

Table 4. Average head forward posture at admission and discharge in functional cervical pillow and general pillow group

	N	Admission	Discharge	*p* value[a]	Difference (95% CI)
		Mean ± SD	Mean ± SD		
Functional cervical pillow group	19	10.69±8.52	10.85±9.04	0.7475	0.96
General pillow group	20	10.99±7.43	12.12±8.12	0.1913	(-3.30, 5.23)
p value[b]		0.6870	0.8567		0.2354

[a]Non-parametric method (Wilcoxon signed-rank test) was used. bNon-parametric method (Wilcoxon-rank sum test) was used.

ly), but difference between groups was not significant. EQ-5D was used to assess quality of life, and though both groups showed improvement at discharge (P=0.0012, and P=0.0074, respectively), between-group difference was not significant (**Table 3**).

Comparison of head forward posture on C-spine X-ray

X-ray assessment of head forward posture showed a high agreement rate of 0.978. Head forward posture at admission and discharge did not show significant difference (**Table 4**). However, comparison of distribution difference in histograms in each group before and after admission showed that the functional cervical pillow group exhibited small change while the general pillow group showed a tendency to increase (**Figure 2A-D**).

Adverse events

Though adverse events were not specifically investigated for clinical trial purposes, the researchers and attending physicians were informed regularly of adverse events related to treatment or hospital stay through internal audit, and none were reported during the trial period.

Discussion

This randomized controlled study investigated the effect of use of functional cervical pillows and general pillows as a means of complementary treatment in inpatients. The primary outcome was VAS of neck discomfort, and the functional cervical pillow group displayed significantly greater improvement than the general pillow group. Also, while the general pillow group did not show statistically significant improvement at discharge in NDI which assessed neck function, the functional cervical pillow group did. Statistically significant difference and clinically meaningful change may differ, and minimal clinically important difference (MCID) is widely used to determine meaningful patient response. Change in NDI in the functional cervical pillow group was over 10 points, which surpasses the reported MCID of NDI [38, 39].

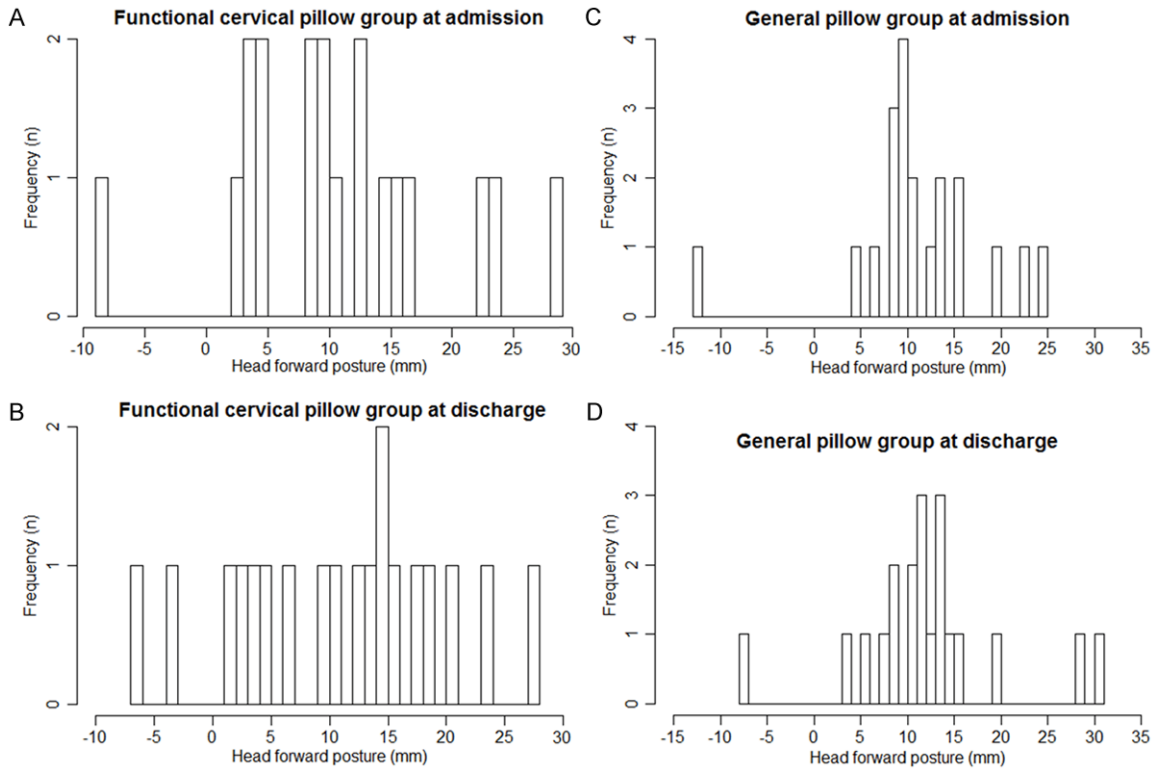

Figure 2. A-D. Histogram of head forward posture distribution at admission and discharge in functional cervical pillow and general pillow group.

There is a multitude of studies on how and why pillow use can affect neck pain or discomfort and sleep. One of the most important factors in appropriate pillow selection is adequate support of cervical lordosis, and a major role of pillows is to support and maintain the cervical spine in a neutral position during sleep [1, 23, 24, 40-42]. End-range positioning of spine segments is minimized in the neutral position, and thus keeping the spine in neutral prevents against hypolordosis of the cervical spine and cervical waking symptoms [40]. In side-lying position, the cervical and thoracic spine should be so aligned that there is no excessive loading on facet joints nor muscle stiffness [43, 44]. In addition, pillows with suitable support can increase contact area between neck and pillow to more evenly distribute pressure exerted on muscles [9]. Similarly, Hyland concluded in a review of the aforementioned studies that pillows which provide the sleeper with a choice of sides are more likely to be of help to a broader range of clients, and that cervical pillows that provide good support may be an important complementary treatment method in management of neck pain and discomfort [45].

Persson and Moritz tested 6 types of neck support pillows for effect on neck pain and quality of sleep in a comparative study. Over the course of 3 weeks, 55 participants tried all 6 pillows in random order for 3 consecutive nights per pillow, and the authors recommended that pillows with firm cervical lordosis support should be used for neck pain and improvement of quality of sleep [46]. Other previous studies on pillows included evaluation of pillow performance in pillows of new shape and design [46-48], comparison of contour and non-contour shape pillows [5, 49], and contour and participants' originally used pillows [50]. A 2006 systematic review on the effect of contour pillow and cervical pillow use for neck pain commented on the methodological limitations of these studies and concluded that there was insufficient evidence to support contour pillow use in chronic neck pain [51].

In a case study by Jackson involving lateral cervical spine radiographs with regular and roll-shaped pillows, roll-shaped pillows reduced neck pain and discomfort during sleep and restored cervical lordosis by supporting the

head and neck [52]. However, this study is limited in that not enough information is given on how data regarding symptom relief was collected. Gordon et al. reported on the comparative effect of various pillows with participants' original pillow on common waking symptoms, including cervical pain intensity, stiffness, headache and scapular pain or arm pain [18], and the findings that pillows custom adjusted to or supportive of the neck were protective of waking pain were consistent with recent research on the influence of pillows in symptomatic cervical patients [19, 49]. Also, Lavin et al. reported that water-based pillows were associated with decreased waking pain, improved sleep quality, and longer duration of sleep after testing three pillows types on 47 neck pain patients in a 5 week study [5].

The main strength of this study is that it investigated whether functional cervical pillows could influence neck discomfort improvement in patients admitted for musculoskeletal disorders using rigorous methodology. For multidimensional and comprehensive evaluation, self-report and functional measures on cervical discomfort and quality of sleep were supplemented with physiologic measures of head forward posture to further objectively assess effect on cervical alignment. Self-reported and functional measures included not only discomfort but also neck function (disability), quality of sleep, quality of life, and general satisfaction scores. Korean versions of questionnaires verified for validity and reliability including NDI, PSQI, and EQ-5D were used. Two assessors measured predefined distances on X-ray after discussion and concurrence for standardized measurement on sample X-ray images of patients not participating in the study. X-ray measurements were tested for interobserver agreement after independent assessment for reliability. Also, considering that a substantial proportion of the population prefers side-sleeping, there is a distinct paucity of research on functional pillows specifically designed for use in side-lying positions. A marked strength of the functional pillow tested in this study is that it has side flaps with shoulder room to prevent compression and maintain support of the spine in side-lying.

There are various studies on the association between pillow use and cervical structure and alignment, and most involve cervical lordosis angle and head forward posture. Average anterior head translation was estimated at 15±10 mm by Harrison et al. in asymptomatic individuals in 1996 [53], while in 1997, Harrison et al. asserted that the mean of the normal group was 10 mm [54]. The authors of this study compared distribution of head forward posture before and after admission in each group using histograms. However, subjects of the studies by Harrison et al. differed from our study in that the former excluded cases of cervical intervertebral disc herniation and degeneration where evidence suggests that stresses on the vertebral body and disc is increased [55], whereas only patients who had received neck surgery, or had been diagnosed with potentially severe causes of neck pain such as tumors, fractures, infection, inflammatory spondylitis, cauda equina syndrome, and spondylolisthesis were excluded in our study. Also, all patients included in the present study were hospitalized, and both groups included pain patients with degenerative change and/or cervical disc herniation symptoms, which may have influenced the current results suggestive of anterior head translation (>10 mm). Meanwhile, comparison of head forward posture in a 2005 study by McAviney et al. showed that degree of head forward in groups with and without cervical complaints was not significantly different at 21.1 mm, and 21.3 mm, respectively [56].

There is still a lack of consensus on what constitutes 'normal' posture in cervical lordosis and head-neck alignment, and valid method of measure. The results of this study may hold wider clinical relevance as they illustrate tendencies and differences seen in inpatients with neck discomfort including cervical disc herniation symptoms. Further diagnostic studies are warranted in tandem with clinical studies on effect of functional cervical pillows to verify measurement and calculation methods of higher external validity.

The biggest limitation of this study is that as multiple Korean medicine co-interventions were used, the results do not reflect the sole effect of pillow use. Still, treatment modality did not differ greatly between patients with neck discomfort through standardized use of herbal medicine and acupuncture, and the integrative Korean medicine intervention led to improvement in both groups. There is also limitation in

interpretation of results as the subject group is heterogeneous, and participants were recruited from patients admitted to a spine-specialty hospital for musculoskeletal complaints including both patients with chief complaint of neck pain and those with other main complaints such as low back pain. Another issue to be considered is whether the participants used the functional cervical pillow in accordance with instructions. As the researchers could not consistently monitor pillow use, it is unclear whether the pillows were used as originally intended, and proper usage is likely to be a major factor for clinical significance [47].

It should also be taken into account that this study did not consider for transition to functional cervical pillow or general pillow use during admission from participants' own pillows used at home. Yin et al. established washout periods in a crossover study where the participants returned to their own pillow after testing each trial pillow to allow the participant to return to usual 'normal' sleeping state [57]. Though there was no washout period to eliminate carryover effects at baseline measurement, all patients were supplied with standard pillows upon admission and prior to trial participation (day 3 post-admission).

There were no significant between-group differences in assessment of quality of sleep with PSQI, but as participants were submitted to an unfamiliar hospital environment during admission, circumstances may have influenced sleep quality over pillow type. Satisfaction with current neck state showed significant difference at discharge compared with admission in both groups, and considering that subjects received mostly similar integrative Korean medicine treatment, it can be inferred that the interventions were effective. The functional cervical pillow group displayed larger change in satisfaction rate, suggesting that the functional cervical pillow acted as a complementary treatment more effectively relieving discomfort and improving functional recovery. Given that pillows are a generally safe and widely accessible tool, implications of effective pillow use for cervical symptom management and sleep are large.

Some studies have recommended select pillows for patients with cervical disc disorders [58] and after whiplash injury [59]. These pillows were advocated on the basis of reduction of neck pressure and support of proper alignment. Pillow use for neck pain treatment has also been reported in traditional Chinese medicine in the form of medicinal pillows using herbs [60]. In light of prior research and these study results, it can be deduced that functional cervical pillows may provide significant effect in patients with neck discomfort as complementary treatment.

Functional cervical pillows were effective in aiding recovery of neck discomfort and function in inpatients treated with Korean medicine treatment, implying that they may be considered a feasible complementary treatment means. While this study compared the recovery rate of 2 groups utilizing functional cervical pillows and general pillows, diversity in pillow shape, size and material is extensive. Further studies on various pillow types are warranted for patients to benefit from more informed and customized pillow selection.

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Disclosure of conflict of interest

JS Shin, JH Lee, and HK Yoo are joint registered creators of Design Patent Registration for Functional cervical pillow (patent application no. 30-2014-0056790) submitted to the Korean Intellectual Property Office (KIPO).

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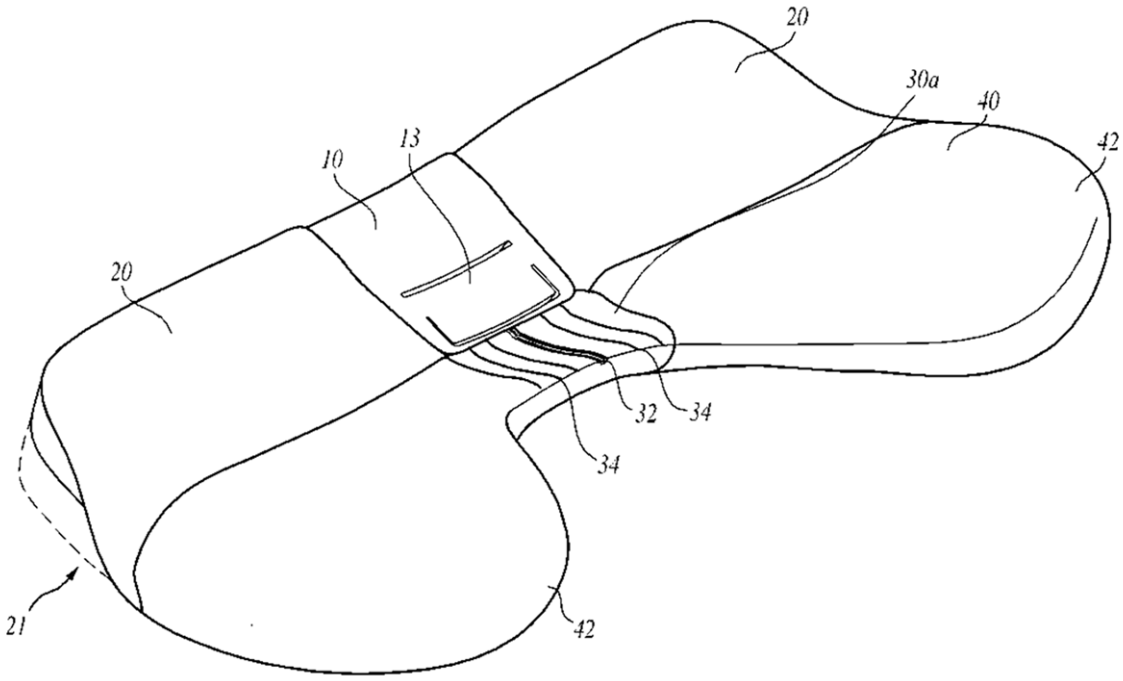
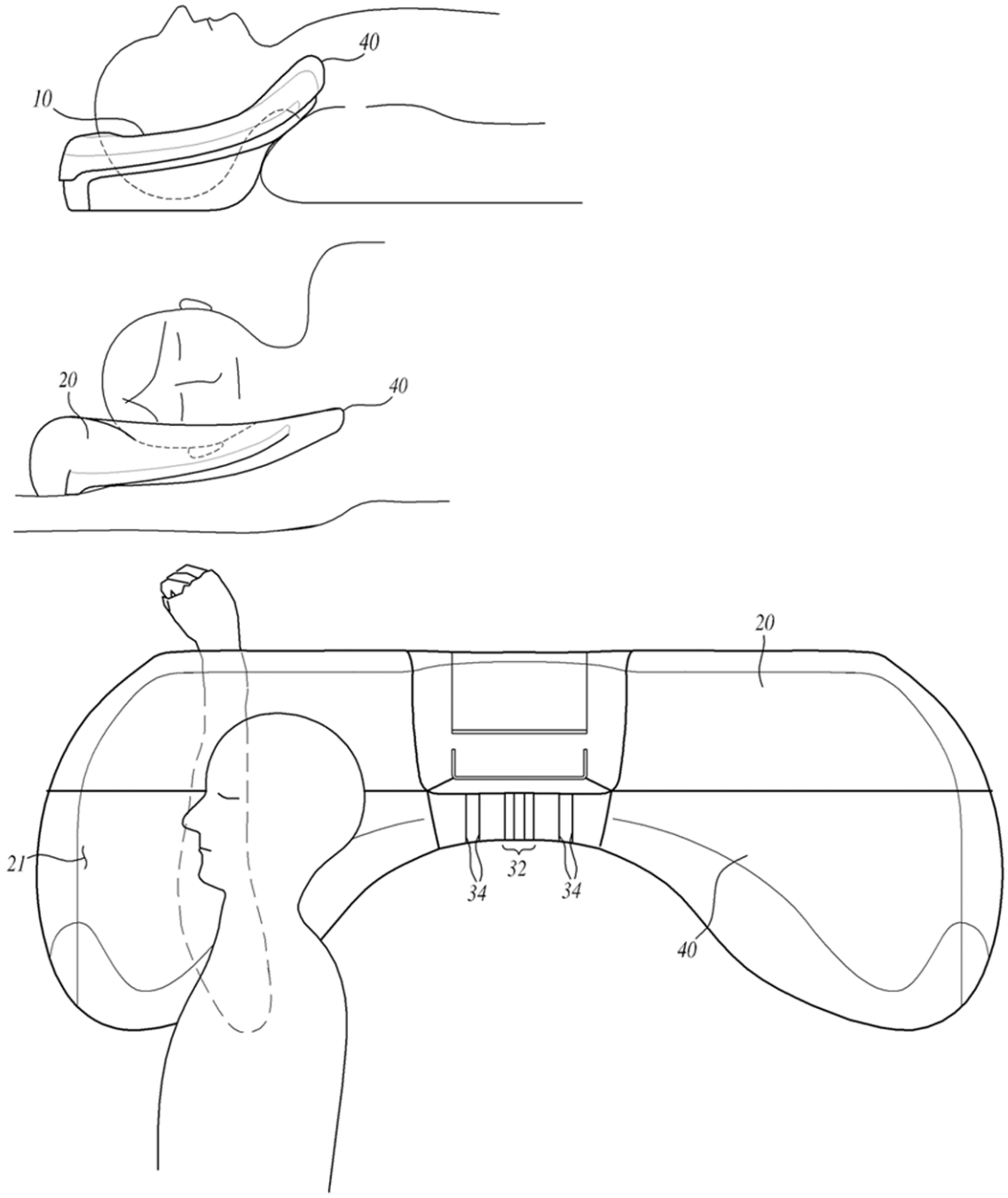


Supplementary Data File 1. Diagram of perspective view of functional cervical pillow currently under patent application.



Supplementary Data File 2. Diagram of suggested methods of functional cervical pillow use.