Phys Med Rehab & Electrodiagnosis 2019; 1(3): 136-44
DOI: https://doi.org/10.22122/pmre.v1i3.44 **Published by** *Vesnu Publications*

Original Article

Efficacy of Pneumatic Collar versus Hard Collar on Cervical Radiculopathy

Received: 27 May 2019
Accepted: 14 July 2019
Published: 05 Sep. 2019

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Keywords
Radiculopathy; Cervical; Cervical collar; Pneumatic collar; Hard collar

Abstract

Background: Cervical radiculopathy is a relatively common neurological disorder. Various treatments have been proposed for cervical radiculopathy, but most of the studies in this regard have not been of high quality. This trial was conducted to evaluate the efficacy of pneumatic collar versus hard collar among individuals with cervical radiculopathy.

Methods: This single-blinded, randomized, clinical trial was conducted on patients aged 18 to 65 years referring to Shohadaye Tajrish Hospital, Iran, with cervical radicular pain. The 60 patients included in the survey were randomly divided into two groups to receive either pneumatic collar or hard collar. The required data were gathered via medical history and cervical MRI. Pain, disability, and cervical range of motion (ROM) were assessed, respectively, using the Visual Analogue Scale (VAS), the Neck Disability Index (NDI), and a goniometer at baseline, and on the second and eighth weeks. Data were entered into SPSS software for analysis.

Results: Mean age of the participants was 49.7 ± 8.2 years, and 58.3% of the participants were men. Intragroup analysis showed that decrease in pain intensity (VAS) and disability was significant on the second and eighth weeks in both groups ($P < 0.001$). Moreover, cervical ROM was significantly increased on the second and eighth weeks in both groups ($P < 0.001$). However, there was no significant difference between the two groups in terms of VAS, NDI, and cervical ROM on the second and eighth weeks ($P > 0.050$).

Conclusion: The present study showed no significant difference in reducing pain, and improving function and cervical ROM in patients with acute cervical radiculopathy in week 2 and 8 follow-ups between pneumatic collar and hard collar treatments. However, both treatments were significantly effective.

How to cite this article: Elyaspour D, Rayegani SM, Elahi-Movahed M, Sedighi S, Hojjati F. **Efficacy of Pneumatic Collar versus Hard Collar on Cervical Radiculopathy.** Phys Med Rehab & Electrodiagnosis 2019; 1(3): 136-44.

Introduction

Cervical radiculopathy is one of the most common causes of neck pain that can cause dysfunction in patients.[1] Cervical radiculopathy is a clinical description of pain and neurological symptoms that is caused by impairment in the cervical nerve mainly due

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to mechanical stress or sometimes inflammation.[2] This mechanical pressure on the nerve root is usually caused by a herniated intervertebral disc or spur due to spinal osteoarthritis (spondylosis), which releases inflammatory mediators, alters vascular mechanisms, and induces intraneural edema.[3] Cervical radiculopathy typically appears as neck pain that spreads to the upper limbs along with symptoms of sensory disorder and dysfunction of muscles in the upper limbs, which often emerges unilaterally, of course all symptoms are not always observed in the patients.[4]

In a study, the incidence of cervical radiculopathy was estimated to be 3.5 per 1,000 individuals with an annual incidence rate of 83 to 210 per 100,000 individuals with a peak age of the fourth and fifth decade of life.[5]

Diagnostic criteria for cervical radiculopathy have not yet been definitively elucidated.[6] Some studies have considered the presence of clinical signs and positive examinations to be sufficient,[7] but others considered the evidence of nerve root compression in a magnetic resonance imaging (MRI) or computed tomography (CT) myelography necessary.[8]

Despite the investigation of cervical radiculopathy in various studies, due to the lack of high-quality studies, unfortunately, the definitive efficacy of different treatments for cervical radiculopathy is still unclear.[8] However, it can be generally claimed that most patients with cervical radiculopathy benefit from conservative therapies including training, exercise, physical modalities [transcutaneous electrical nerve stimulation (TENS), hot pack, ultrasound, etc.], manipulation, cervical traction, cervical collar, and drug treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs) treatment.[9-12] Some studies have considered epidural corticosteroid injections to be among the conservative treatments, which have proven to be more effective than other conservative treatments, especially in more severe cases.[13] Cervical radiculopathy is usually self-limiting and the symptoms may be relieved with non-surgical treatments; however, surgical treatment may be necessary in case of the progression of symptoms and lack of response to conservative treatments, and emergence of neurological deficit or cervical myelopathy.[14]

Cervical traction is one of the most common therapies for cervical radiculopathy that dates back to the fourth century BC. Cervical traction can be performed manually or mechanically, continuously or intermittent, in the clinic or at home (over-the-door cervical traction). The physiological effects of cervical traction include spacing between the vertebrae and movement of the facet joints, which increases the intervertebral foramen space, thus resulting in decreased pressure on the nerve root, improved blood supply to the nerve root, and spinal cord parenchyma. In addition, by stretching the muscles and ligaments, cervical traction causes the relaxation of the paravertebral muscles and, in general, these mechanisms will improve cervical radiculopathy and its associated symptoms.[15-17]

Although a cervical collar is commonly used to immobilize the head and cervical after trauma or surgery,[15] it is also considered as a cervical radiculopathy treatment. Despite the relatively common use of different types of cervical collars, few studies have been carried out on their effectiveness. However, some studies have reported the efficacy of different types of cervical collars in improving pain and function among patients with acute cervical radiculopathy.[18,19]

The pneumatic collars used in recent years consist of a chamber in which air is pumped by a pump manually or by the device itself, leading to cervical traction with increasing volume. This device has advantages such as comfort, low volume, usability in different locations and situations, suitable force distribution in the occipital and mandible area, neck support, and lack of components such as a painful chin halter, complex hardware, and water bag, and no need to

refer to the clinic for traction. Thus, if it proves to have similar effects, this collar can replace clinical traction devices as well as over-the-door traction devices.[20]

As the studies performed on the impact of traction and cervical collars were scarce and sometimes had poor quality and confounding factors, and very few investigations have been performed on the efficacy of the pneumatic cervical collar, the present study was conducted to investigate the effectiveness of this collar as an appropriate treatment for cervical radiculopathy.

Methods

In this single-blind, randomized, clinical trial, patients with cervical radiculopathy referred to the Physical Medicine and Rehabilitation Clinic of Shohadaye Tajrish Hospital, Iran, in 2018 were studied. The inclusion criteria were neck pain spreading to the upper limbs, visual analog scale (VAS) ≥ 4, suffering from neck pain during the past 3 months, clinical examinations consistent with cervical radiculopathy, and evidence of pressure on the cervical nerve root in the cervical MRI.

The exclusion criteria included age of over 65 years and under 18 years, previous cervical spine surgery, systemic or other neurological diseases (aortic aneurysm, uncontrolled hypertension, carotid or spinal basilar artery stenosis), rheumatologic diseases [rheumatoid arthritis (RA) or connective tissue diseases], infectious diseases of the spine (diskitis and osteomyelitis), symptoms lasting more than 3 months, use of collars or cervical traction for the last 3 months, spinal instability, trauma or spinal fracture during the previous 3 months, myelopathy, severe osteoporosis, and pregnancy.

The patients were informed about the method of treatment, the goals, and the evidence available for this treatment, as well as its possible complications by a physiatrist participating in the project and the informed consent form was completed by them. The patients' personal information such as age, gender, height, weight, body mass index (BMI), education level, physical activity, duration of symptoms and the side of the body on which they are observed, and intensity and level of disk protrusion in the MRI were recorded. In addition, the cervical range of motion (ROM) in the four main directions were measured and recorded using a goniometer. The Neck Disability Index (NDI) and VAS questionnaires were then completed for each patient to evaluate their pain and function (disability), respectively.

The patients were divided into two groups on the basis of the random number table, with both groups receiving one NSAID drug (celecoxib 100 mg twice daily for 10 days) as baseline treatment for ethical considerations. A pneumatic collar (Runde, China) was used in one group and a hard collar (Paksaman, IRI) in the other group for 2 weeks. The pneumatic collar was used 3 times a day for 20 minutes with the creation of traction by inflation of the collar by the patient to the maximum extent that did not cause discomfort and pain. At other times during the day, the collar was used with less air to the extent to maintain the neck without cervical traction. The hard collar was utilized during hours of the day when the patient was standing or sitting. Then, all patients were re-examined after 2 and 8 weeks and their pain, dysfunction, and cervical ROM were assessed using the NDI and VAS questionnaires and the goniometer.

The collected data were analyzed using the SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). The data was described by mean and variance, as well as percentages. Moreover, paired t-test and independent t-test were employed to compare the variables with a normal distribution.

Furthermore, the repeated-measures analysis of variance (ANOVA) tests such as Mauchly's test of sphericity and the results of the Greenhouse-Geisser epsilon correction test were used to evaluate the effects of the intervention over time. A P-value less than 0.050 was regarded as significant.

Table 1. Baseline characteristics of the patients before the intervention

Variable		Pneumatic [n(%)]	Hard [n(%)]	P
Gender	Male	17 (56.7)	18 (60.0)	0.793
	Female	13 (43.3)	12 (40.0)	
Severity	Bulge	9 (30.0)	10 (33.3)	0.585
	Protrude	16 (53.3)	16 (53.3)	
	Extrude	5 (16.7)	4 (13.3)	
Level	C4-C5	3 (10.0)	2 (6.7)	0.430
	C5-C6	10 (33.3)	11 (36.7)	
	C6-C7	11 (36.7)	10 (33.3)	
	C7-T1	6 (20.0)	7 (23.3)	
Radicular pain	Right	18 (60.0)	12 (40.0)	0.210
	Left	9 (30.0)	15 (50.0)	
	Bilateral	3 (10.0)	3 (10.0)	
		Mean ± SD	**Mean ± SD**	
Age (year)		49.73 ± 8.00	49.77 ± 8.40	0.980
BMI (kg/m^2)		27.63 ± 3.30	27.53 ± 3.30	0.860
VAS		6.03 ± 1.40	5.83 ± 1.50	0.608
NDI		30.60 ± 9.40	29.67 ± 9.20	0.696
Row up		37.97 ± 8.30	38.53 ± 8.60	0.555
Row down		28.50 ± 7.10	29.67 ± 7.00	0.528
Row right		25.00 ± 6.00	26.2 ± 6.50	0.461
Row left		24.87 ± 5.90	26.00 ± 6.30	0.471

SD: Standard deviation; BMI: Body mass index; VAS: Visual Analogue Scale; NDI: Neck Disability Index

Results

The mean age and BMI of the patients were 49.7 years and 27.58, respectively. Moreover, 58.33% and 41.66% of the patients were men and women. The independent t-test results showed no significant difference between the two groups in terms of the demographic characteristics ($P > 0.050$). There was no significant difference between the two groups in terms of the severity and level of neural root involvement, and the side of the body on which radicular pain had spread ($P > 0.050$). Additionally, independent t-test results showed that there was no significant difference in mean VAS and NDI scores, and cervical ROM between the two groups ($P > 0.050$) and the two groups were completely homogeneous before the intervention. The baseline characteristics of the patients before the intervention are presented in table 1.

Evaluation of VAS and NDI in the second and eighth weeks after the initiation of the study in both groups using repeated measures ANOVA tests such as Mauchly's test of sphericity and the results of the Greenhouse-Geisser epsilon correction test showed that the decrease in pain and disability over time was significant in both groups ($P < 0.001$) (Tables 2 and 3). Moreover, the range of the upward, downward, rightward, and leftward motion of the neck in both groups was significantly increased during the study ($P < 0.001$) (Tables 2 and 3).

Based on the independent t test, there was no significant difference in the second week between the efficacy of the pneumatic collar ($P = 0.682$) and hard collar ($P = 0.720$) in reducing pain (VAS) and disability (NDI).

Table 2. Effect of pneumatic collar over time

Variable	Before the study	2 weeks later	2 months later	P
VAS	6.03 ± 1.40	3.03 ± 1.30	2.93 ± 1.10	< 0.001
NDI	30.60 ± 9.40		17.37 ± 3.70	< 0.001
Row up	37.27 ± 8.30	17.67 ± 4.60	52.00 ± 8.10	< 0.001
Row down	280.5 ± 7.10	51.97 ± 5.50	41.87 ± 4.60	< 0.001
Row right	25.00 ± 6.00	42.00 ± 5.30	36.80 ± 5.00	< 0.001
Row left	24.87 ± 5.90	36.90 ± 5.50	36.77 ± 4.90	< 0.001

VAS: Visual Analogue Scale; NDI: Neck Disability Index

Table 3. Effect of hard collar over time

Variable	Before the study	2 weeks later	2 months later	P
VAS	5.83 ± 1.50	3.17 ± 1.10	3.23 ± 1.20	< 0.001
NDI	29.67 ± 9.20	18.07 ± 3.90	18.60 ± 4.10	< 0.001
Row up	38.53 ± 8.10	51.00 ± 4.80	50.47 ± 4.90	< 0.001
Row down	29.67 ± 7.00	41.00 ± 4.70	40.50 ± 5.00	< 0.001
Row right	29.67 ± 6.50	36.20 ± 4.80	36.03 ± 5.20	< 0.001
Row left	26.00 ± 6.30	36.13 ± 4.80	35.93 ± 4.90	< 0.001

VAS: Visual Analogue Scale; NDI: Neck Disability Index

At week 8, although the pneumatic collar group (P = 0.336) showed more improvement compared to the hard collar group (P = 0.232) (0.3 and 1 units, respectively, in VAS and NDI scores), this difference was not statistically significant. A comparison of the rates of pain and disability reduction in the two groups is illustrated in tables 4 and 5.

Table 4. Comparison of pain reduction between the pneumatic collar and hard collar

Variable	Pneumatic collar	Hard collar	P
Before the study	6.03 ± 1.40	5.83 ± 1.50	0.608
2 weeks later	3.03 ± 1.30	3.17 ± 1.10	0.682
2 months later	2.93 ± 1.10	3.23 ± 1.20	0.336

Comparison of the efficacy of the pneumatic and hard collars in increasing the cervical ROM in 4 main directions (upward, downward, rightward, and leftward) based on the independent t-test results in the second week showed no significant differences (P = 0.470, P = 0.450, P = 0.580, and P = 0.520, respectively).

Table 5. Comparison of disability reduction between the pneumatic collar and hard collar

Variable	Pneumatic collar	Hard collar	P
Before the study	30.60 ± 9.40	29.67 ± 9.20	0.699
2 weeks later	17.67 ± 4.60	18.07 ± 3.90	0.720
2 months later	17.37 ± 3.70	18.60 ± 4.10	0.232

In the eighth week, although the increase in the cervical ROM in the pneumatic collar group was slightly higher than in the hard collar group, this difference was not statistically significant (P = 0.230, P = 0.270, P = 0.560, and P = 0.510, respectively) (Figures 1 to 4).

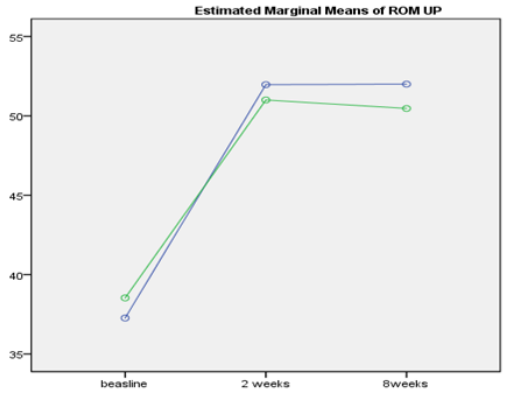

Figure 1. Comparison of the upward cervical range of motion in the two groups

Discussion

Despite the use of different methods for the conservative treatment of patients with cervical radiculopathy, there are few high quality studies on the efficacy of each, and in some cases, the results are inconsistent and unreliable.

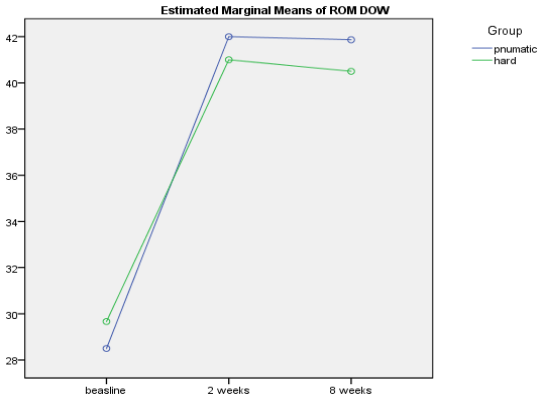

Figure 2. Comparison of the downward cervical range of motion in the two groups

The convenience, availability, and cost of different treatments vary, and thus, researchers always seek new, non-invasive, cost-effective treatments, and compare to the efficacy of the existing treatments.

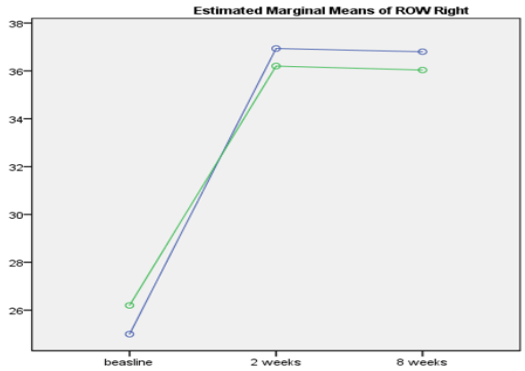

Figure 3. Comparison of the rightward cervical range of motion in the two groups

Traction is a common treatment for cervical radiculopathy; it relaxes the paravertebral muscles by stretching the muscles and ligaments.

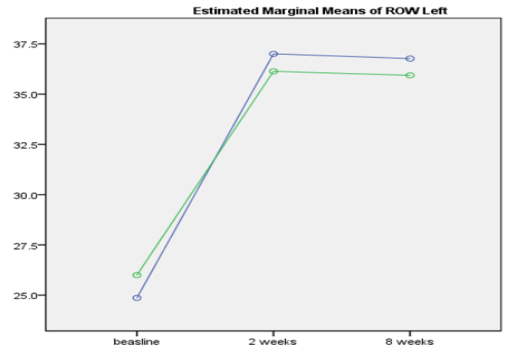

Figure 4. Comparison of the leftward cervical range of motion in the two groups

Furthermore, by increasing the space between the vertebrae and moving the facet joints, this treatment increases the intervertebral space, reduces the pressure on the nerve root, and improves blood supply to the nerve root and the spinal cord parenchyma.[15-17] However, little investigation has been performed on the pneumatic collar, which is a relatively newer method using the traction mechanism. The pneumatic collar has been designed in such a way that an individual can easily perform traction on his/her neck at a low cost anywhere. Moreover, although cervical collars are more commonly used to immobilize the neck after trauma or surgery, there are studies regarding their effectiveness in the treatment of cervical radiculopathy.[18,19]

In the present study, to evaluate the efficacy of the pneumatic collar and hard collar and compare their effects in patients with cervical radiculopathy, 60 patients were randomly divided into 2 groups of 30 individuals and examined for 8 weeks in terms of pain and disability. The pneumatic and hard collars reduced pain and improved function in the patients in the second and eighth weeks of the study, in addition to increasing cervical ROM among them; however, there was no statistically significant difference between the two treatments.

Bagheripour et al. conducted a study to evaluate the effects of pneumatic collars in patients with spinal cord osteoarthritis in which the control group received hot pack, TENS, ultrasound, exercise therapy, and ergonomic training for 10 sessions.[20] In the intervention group, the pneumatic collar intervention (continuously for 20 minutes) was added to the previous treatments. Finally, the pneumatic collar was shown to increase the rate of recovery among the patients with spinal cord osteoarthritis.[20] The present study examined patients with cervical radicular pain and did not use other physiotherapy modalities concurrently. Positive results were also observed in this study in terms of the effects of the pneumatic collar on neck problems.

Qayyum et al. explored the effect of mechanical traction and manual therapy on pain relief in patients with radicular pain caused by C5-C6 spondylosis.[21] In their study, 50 patients in two groups of 25 received shortwave diathermy and ultrasound as baseline treatments. Mechanical traction in one group and manual therapy in the other group were executed for 12 sessions (3 sessions a week), and it was found that mechanical traction was more effective than manual therapy in the treatment of patients with radicular pain caused by C5-C6 spondylosis.[21] Fritz et al. compared the effectiveness of exercise alone, exercise with mechanical traction, and exercise with over-the-door traction among

86 patients in 3 groups for 4 weeks.[22] They found that adding traction to exercise alone reduced pain and disability, but there was no significant difference between the effectiveness of mechanical traction and over-the-door traction.[22] Bagheripour et al. carried out a study on 20 patients with cervical osteoarthritis in two groups of 10 patients who received routine physiotherapy (hot pack, TENS, ultrasound, and exercise) as the baseline treatment, and over-the-door traction was added to the baseline treatment in the intervention group.[23] The findings indicated that over-the-door traction, albeit effective in reducing pain and disability in patients with spinal osteoarthritis, was not significantly better than the usual physiotherapy.[23] Romeo et al. published a systematic review and meta-analysis on the effects of the addition of traction to physiotherapy.[24] In this meta-analysis, 5 randomized control trials (RCTs) were found to be of good quality, with overall results suggesting the effect of cervical traction plus physiotherapy on pain relief and, to a lesser extent, improved performance in patients with cervical radiculopathy.[24] McKivigan and Gilmour conducted a systematic review on the effects of intermittent mechanical traction in patients with cervical radiculopathy.[25] In this study, of the total of RCTs, 4, 4, and 1 had very low level of evidence, low level of evidence, and moderate level of evidence, respectively.[25] They concluded with a low to medium level of evidence that intermittent traction declined pain and disability in patients with cervical radiculopathy.

Overall, all the above-mentioned studies were indicative of the positive effect of cervical traction on the treatment of patients with cervical spine complications; it should be noted that the pneumatic collar method was not utilized in any of these studies and physiotherapy was the control and baseline treatment in most cases.

To evaluate the efficacy of cervical collars in treating cervical radicular pain, Kuijper et al. studied approximately 200 patients with cervical radiculopathy in 3 groups for 6 weeks.[19] One group used a semi-hard collar and rested for 6 weeks, and the other group received a home physiotherapy and exercise program for 6 weeks. It was found that pain and disability significantly decreased in both groups compared to the control group participants, who only continued their daily activities.[19] In a study on 100 patients with cervical radicular pain, Kasapoglu Aksoy et al. showed that soft and semi-rigid cervical collars were more effective compared to exercise training alone in improving neck pain and function in patients with radiculopathy.[18] In this study, the patients were divided into 3 groups and received NSAID and a 6-week home exercise program as the baseline treatment, and the hard cervical collar was used in one group and the soft cervical collar in the other group for 4 weeks.[18]

The results of the current study also confirmed the same positive effects of the cervical collar on pain relief and function of patients with cervical radiculopathy, although the baseline treatment and control group used differed from those of the above-mentioned studies. Based on the results of the present study, the positive effects of pneumatic and hard collars in reducing pain and enhancing the function of patients with cervical radiculopathy, and the ease of use, availability, and suitable cost of the cervical collars, they can be utilized to treat patients with cervical radiculopathy.

Conclusion

The current study showed that both pneumatic and hard collars reduced pain and disability and improved cervical ROM in patients with cervical radiculopathy in the second and eighth weeks after the beginning of the study; there was no statistically significant difference between the two treatments in terms of their effectiveness.

Limitations: The present study was a single-blind study, but the therapist could not be blinded, although explanations for

filling out the questionnaire were provided by another therapist. Due to ethical considerations, a drug therapy (NSAID) had to be used as a baseline treatment in both groups, which could be somewhat confounding. Additionally, a longer follow-up duration and the use of an independent control group could also reinforce the conclusions of the study, which were not possible given the circumstances.

Acknowledgments

We would like to express our gratitude to all patients for cooperating with us during the course of this research.

Conflict of Interest

Authors have no conflict of interest.

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