World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

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Randomized controlled trial of analgesic effect and movement improvement between Meridian Balancing Acupuncture Method and standard Local Acupuncture in the treatment of Cervical Type Cervical Spondylosis

Massimo Bondi [1], Zhiyuan Bian [2] and Jianqiao Fang [2, 3, *]

[1] *International Education College, Zhejiang Chinese Medical University, Hangzhou 310053, Zhejiang Province, China.*
[2] *Third Clinical Medicine College, Zhejiang Chinese Medical University, Hangzhou 310053, Zhejiang Province, China.*
[3] *Department of Acupuncture, The Third Affiliated Hospital of Zhejiang Chinese Medical University, Hangzhou 310005, Zhejiang Province, China.*

World Journal of Biology Pharmacy and Health Sciences, 2024, 20(03), 509-524

Publication history: Received on 10 November 2024; revised on 22 December 2024; accepted on 24 December 2024

Article DOI: https://doi.org/10.30574/wjbphs.2024.20.3.1062

Abstract

Objective: To compare the therapeutic efficacy of analgesic effects and motility improvement between Meridian Balancing Acupuncture Methods (MBAM) and Local Acupuncture in the treatment of Cervical Type Cervical Spondylosis.

Methods: Sixty patients with Cervical Type Cervical Spondylosis were randomly divided into MBAM group and Local Acupuncture group. In MBAM intervention, up to 10 sensitive/reactive distal points on the limbs were selected and manipulated, while patients rotated their necks. In Local Acupuncture intervention 10 sensitive acupoints were selected and manipulated on the neck, upper back, and shoulders. Both groups underwent 30-minute treatments, three times during one week. Visual Analog Scale (VAS) pain levels and Cervical Spine Range of Motion (ROM) in three directions were assessed before and after each treatment, and at follow-up.

Results:

- VAS Scores were significantly reduced within both groups (P<0.05), however after 2nd and 3rd treatments, MBAM VAS scores were significantly lower (P<0.05). MBAM VAS scores differences were, in general, all significantly higher than Local Acupuncture (P<0.05).
- In general within MBAM group, ROM in all three directions significantly increased (P<0.05). Within Local Acupuncture group, ROM improvements were more limited. After the 3rd treatment, MBAM demonstrated significantly higher Rotation ROM (P<0.05). Overall, ROM differences in all three directions were significantly higher in MBAM than in Local Acupuncture (P<0.05).
- Total effective rate was 100% in both groups. However, significant effective rate was statistically higher in MBAM (93.33%) compared to Local Acupuncture (73.33%) (P<0.05).

Conclusion: Both treatments can effectively relieve pain and improve limited motion in Cervical Type Cervical Spondylosis patients. Although Local Acupuncture showed no immediate improvement in several single treatments. MBAM outperformed Local Acupuncture in immediate and short-term analgesic effects, although both treatments were comparable at follow-up. Overall, MBAM demonstrated superiority in improving cervical motility, with immediate, short term and follow-up better outcomes. After the treatment course, MBAM demonstrated superior curative effect compared Local Acupuncture

* Corresponding author: Jianqiao Fang Email: fangjianqiao7532@163.com

Keywords: Meridian Balancing Acupuncture; Standard Local Acupuncture; Cervical Type Cervical Spondylosis; Analgesic Effect; Neck Range of Motion

1. Introduction

As lifestyles and work practices evolve improperly, the incidence of cervical spondylopathies has rapidly increased and is trending towards affecting younger populations. Cervical Type Cervical Spondylosis is widely considered by the academic community in China and around the world as representative of an early stage of the condition, with potential progression to other types of cervical spondylosis [1, 2]. The condition, characterized by relatively mild symptoms and less severe damage, primarily manifests as frequently recurring discomfort in the neck and shoulder area, often accompanied by non-specific imaging findings. However, it significantly reduces quality of life and imposes considerable psychological and financial burdens on patients. If left untreated, improperly treated, or allowed to progress naturally, it may also develop into more severe forms of cervical spondylopathy [3, 4]. Consequently, an early effective intervention has become a clinical focal issue.

In this context, Acupuncture plays an important role in addressing the limitations of modern medical treatment, which mainly includes conservative approaches such as “Medication” and “Physical Therapy”[5, 6], and surgical approach[7]. With the continuous advancements, the range of acupuncture treatments for Cervical Type Cervical Spondylosis has also expanded. These treatments have evolved from traditional local or distal acupuncture and Tui Na (Chinese massage) to the combination of modern electroacupuncture and various ancient and modern acupuncture methods.

Among these approaches, Meridian Balancing Acupuncture Method (MBAM) is a traditional acupuncture technique, based on the I Ching theory, that applies the principles of imaging correspondences and balance to the human meridian system and body parts. For localized pain and disorders, rather than performing local acupuncture, MBAM, according to its principles, treats the condition at distal reactive points on the limbs and incorporates the concept of holographic acupuncture. For this reason this study focuses on Cervical Type Cervical Spondylosis, primarily evaluating the effects of MBAM on its main symptoms [8, 9], namely neck pain and restricted mobility [10].

In recent years, balancing acupuncture has been reported to be effective in treating various conditions, including movement disorders, pain, and others, but few studies have reported the efficacy of MBAM as a standalone treatment; most studies utilize MBAM in conjunction with Chinese medicine, physical therapy, or other acupuncture therapies. In particular, when treating Cervical Type Cervical Spondylosis, MBAM follows a specific protocol to select distal acupuncture points on the limbs. However, high-quality clinical research providing medical evidence-based results for MBAM's efficacy in this condition remains limited.

This study aims to conduct a standardized, randomized controlled trial for this condition using MBAM. It will utilize internationally recognized outcome measures to compare the clinical efficacy of MBAM versus Local Acupuncture for Cervical Type Cervical Spondylosis, aiming to provide stronger evidence-based medicine results for MBAM's treatment efficacy for this condition, and evaluate its advantages in pain relief and mobility improvement.

2. Material

2.1. General Data

This study included 60 patients diagnosed with Cervical Type Cervical Spondylosis, all of whom were recruited from the outpatient clinics and wards of the Third Affiliated Hospital of Zhejiang Chinese Medical University between March 2022 and June 2023. Patients were randomly assigned to either the MBAM experimental group or the Local Acupuncture control group in a 1:1 ratio utilizing Excel 2010 software to generate random numbers and assign groupings, with 30 patients in each group. During the entire treatment process, no adverse reactions were observed, and no cases were lost to follow-up. A comparison of gender, age, and disease duration between the two groups showed no statistically significant differences ($P > 0.05$), indicating that the two groups were comparable. Detailed demographic data for both groups are summarized in Table 1.

Table 1 General Data Comparison

Groups	Number of Cases	Gender Distribution		Age Range(Years)			Disease Duration (Months)
		Male	Female	Min	Max	MEAN(SD)	
MBAM	30	11	19	22	74	38.50(14.75)	10.00(4.50)
Local Acupuncture	30	12	18	24	73	41.50(23.00)	9.50(7.00)

2.2. Diagnostic Criteria

The diagnostic criteria for Cervical Type Cervical Spondylosis were referenced from the “Merck Manual of Diagnosis and Therapy (18th edition)”[11] and the “Expert Consensus on the Classification, Diagnosis, and Non-Surgical Treatment of Cervical Spondylosis”[1], The diagnosis of cervical spondylosis primarily relies on clinical symptoms, signs, medical history, and imaging examinations, which are assessed based on the following criteria: 1) Abnormal sensations, such as pain in the neck, shoulders, and occipital region, potentially accompanied by corresponding tender points. 2) Imaging findings indicating degenerative changes in the cervical spine. 3) Exclusion of other cervical disorders or diseases causing similar cervical symptoms. If criteria 1) , 2) , and 3) are met, a diagnosis of Cervical Spondylosis of the Cervical Type can be made.

Figure 1 Neck Assessment

Figure 2 Imaging Findings

2.3. Inclusion Criteria

The inclusion criteria for this study were as follows: 1. Meeting the diagnostic criteria for Cervical Type Cervical Spondylosis. 2. Baseline VAS (Visual Analog Scale) score ≥ 3. 3. Age between 18 and 80 years. 4. Presence of neck pain and stiffness episodes within the past week. 5.Clear consciousness, with the ability to perceive and distinguish pain, and the ability to engage in basic communication. 6. Completion of X-ray or other imaging examinations prior to enrollment. 7. Voluntary participation in the study and signing of an informed consent form.

2.4. Exclusion Criteria

The exclusion criteria for this study were as follows: 1. Patients with other types of cervical spondylosis or coexisting cervical disorders. 2. Patients with epilepsy, head trauma, or other related neurological diseases. 3. Patients with severe heart, liver, or kidney damage. 4. Patients with cognitive impairment, depression, mental disorders, or those unable to cooperate with treatment. 5. Patients with poorly controlled hypertension. 6.Patients recently diagnosed with severe depression. 7. Pregnant or breastfeeding patients. 8. Patients deemed unsuitable for participation due to other reasons.

2.5. Culling Criteria, Dropout Criteria and Shedding Standards

Already Enrolled cases should be excluded if any of the following conditions are met: 1. Discovery during the trial that the patient does not meet the inclusion or exclusion criteria. 2. Occurrence of significant adverse reactions during treatment. 3. The subject does not adhere to the treatment protocol after enrollment.

Enrolled cases that do not complete the clinical protocol should be considered as dropouts under the following circumstances: 1. The patient voluntarily withdraws or is lost to follow-up. 2. The patient receives fewer than two acupuncture sessions. 3. The patient experiences severe adverse reactions or adverse events during treatment.

Additionally, the doctor overseeing the diagnosis will monitor any worsening of the patient's condition during the study. If the patient develops discomfort that cannot be relieved through acupuncture, the physician will assess the severity of these symptoms and, if necessary, discontinue the study, categorizing it as a shedding case.

3. Methodology

3.1. Research Type

This study utilizes a single-center, randomized, controlled trial design. A total of 60 patients diagnosed with Cervical Type Cervical Spondylosis were enrolled. Recruitment was conducted through advertisement flyers and posters displayed in the relevant outpatient clinics and wards at the Third Affiliated Hospital of Zhejiang Chinese Medical University. Blinding was applied to all participants involved in the study, including patients, data recorders, and statistical analysts, with the exception of the acupuncture operator. To gather data on participants, including demographic information, clinical observations, and index scores, a Clinical Report Form (CRF) was developed.

3.2. MBAM Group Acupoints Selection

According to the four-step standard protocol of the MBAM, the selection of 10 acupuncture points for needling is based on the following steps procedure: 1.) Identify the affected area, meridian, and corresponding body part. 2.) Select the treating balancing meridians corresponding to the sick meridians in “step 1” according to “Meridian 6 Balancing Correspondences”. 3.) Choose the corresponding limb section to needle, which mirrors the diseased area and is related to the affected tissues in “step 1”. 4.) Search, on the corresponding limb section (step 3) along the balancing meridians (step 2), sensitive and reactive points (at their pressure patient’s pain and movement restrictions are relieved) to select as the acupuncture points.

Figure 3 MBAM intervention

3.3. Local Acupuncture Group Acupoints Selection

Previous studies have shown that acupuncture at tender, sensitive points can yield effective results [12]. Therefore, in this study, based on the location of pain, 10 sensitive tender points were selected from the following acupuncture points for needling: [13, 14], GV14-Dazhui (大椎), BL10-Tianzhu (天柱), EX-B2-Jingjiaji (颈夹脊), EX-HN15-Jing Bailao (颈百劳), GB20-Fengchi (风池), GB21-Jianjing (肩井), SI15-Jianzhongshu (肩中俞), GV16-Fengfu (风府), BL12-Fengmen (风门), BL43-Geshu (膈俞), SI11-Tianzong (天宗), SI10-Naoshu (臑俞), SJ14-Jianliao (肩髎), and LI15-Jianyu (肩髃) .

Figure 4 Local Acupuncture intervention

3.4. Treatment Procedure, Duration, Frequency and Course of Treatment

Acupuncture Procedure: The patient is placed in a supine position for MBAM intervention and a prone position for Local Acupuncture intervention, with full body relaxation, and the skin is disinfected following routine procedures. Disposable acupuncture needles with specifications of 0.25 mm × 40 mm are used, and the needle is inserted perpendicularly to a depth of 15 mm.

MBAM Group: After inserting the needle into each acupuncture point, manipulation is performed till the patient should feel a localized heaviness or distending sensation ("De Qi"). Then the same small amplitude lifting, thrusting, and rotating technique is applied for 10 repetitions using a neutral reinforcement-reduction method. Simultaneously, for each needle insertion, the patient is instructed to slowly move his neck in all directions, and, provided no discomfort occurs, to check the levels of symptoms[15, 16]. If the patient's pain and movement restrictions are almost completely relieved, no further needles are added, even if the number of ten needles is not reached.

Local Acupuncture Group: After inserting the needle into each acupuncture point, manipulation is performed, and the patient should feel a localized heaviness or distending sensation ("De Qi"). Once this sensation is achieved, a small

amplitude lifting, thrusting, and rotating technique is applied for 10 repetitions using a balancing technique (neutral reinforcement-reduction method).

Treatment Duration: Each treatment session lasts 30 minutes, with needle manipulation performed every 5-10 minutes. During the MBAM group sessions, patients are instructed to move their neck and affected areas gently while the needles are manipulated [17]. Frequency and Treatment Course: Treatment is administered every other day, with a total of 3 treatment sessions [18].

3.5. Primary Outcomes Index

Visual Analogue Scale (VAS): The VAS score ranges from 0 to 10 points, with a 10 cm horizontal line representing varying levels of pain intensity. The leftmost end indicates no pain, while the rightmost end represents the most severe pain, as described in the case report form. The participant marks a point on the line that corresponds to their perceived pain level. The assessor then uses a 10 cm ruler to measure the point marked by the participant, assigning a score from 0 to 10, with 0 at the left end and 10 at the right end, to determine the VAS score rounded to one decimal place [19-21].

3.6. Secondary Outcomes Indexes

Cervical Spine Range of Motion (ROM) in Three Directions: 1) Cervical Spine Anterior-Posterior Direction ROM; 2) Cervical Spine Lateral Flexion ROM; 3) Cervical Spine Rotation ROM.

Cervical spine mobility is measured using an electronic digital protractor to assess the three following angles: Cervical Flexion and Extension Angle (the sum of the flexion anterior angle and extension posterior angle); Lateral Flexion Angle (the sum of combined angles of left and right lateral flexion); Rotation Angle (the sum of combined angles of left and right cervical rotation). This format reflects the assessment of range of motion (ROM) for neck joints, typically used in clinical biomechanics or kinesiology studies. The angles refer to the degree of movement in specific anatomical planes, and remarks and observation may be done on abnormalities, limitations, or asymmetries. Their measurements provide a comprehensive evaluation of cervical spine movement in the sagittal, coronal, and transverse planes . Based on these three angle, we have established the three indicators above, to evaluate the Cervical Spine ROM in three directions for our clinical trial[22-24].

3.7. Duration and Assessment Time Points

The treatment period for this study is 5 days, followed by a 4-week follow-up period. The above parameters will be assessed as the following time points: Baseline Measurement Point (conducted on the day of group assignment, coinciding with the randomization for subjects who meet the inclusion criteria and the first day of treatment); I Treatment Evaluation Points (before and after the conclusion of the first treatment); II Treatment Evaluation Points (before and after the conclusion of the second treatment); III Treatment Evaluation Points (before and after the conclusion of the third treatment), and Follow-Up Evaluation Points (at the end of the 4th week after the third treatment).

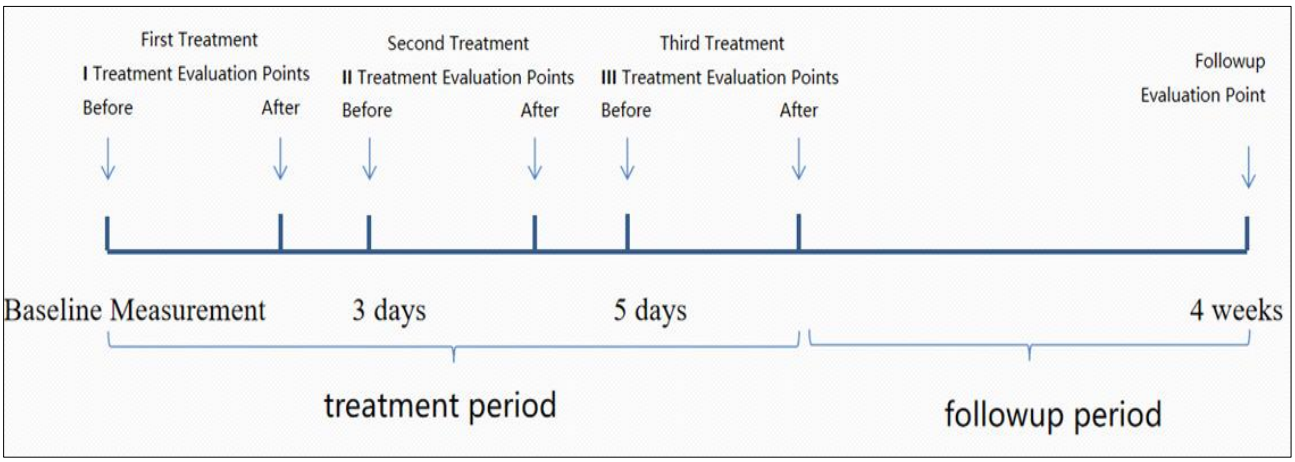

Figure 5 Study Duration and Assessment Time Points

3.8. Clinical Efficacy Assessment

Referring to the "Standards for Diagnosis and Efficacy in Traditional Chinese Medicine" this study evaluates one-week short-term analgesic clinical efficacy, based on the reduction rate of the primary outcome measure VAS score; assessment is conducted after the third treatment. Calculations are performed with the efficacy index defined as[25]:{ Efficacy Index = [(Baseline VAS Score - End-of-Treatment VAS Score) \ Baseline VAS Score X 100%] }. The efficacy ranges are defined as follows: 1) Cured: Efficacy index ≥ 95%; 2) Significantly Effective: Efficacy index ≥ 70% but < 95%; 3) Effective: Efficacy index ≥ 30% but < 70%; 4) Ineffective: Efficacy index < 30%. The Overall Effective Rate is calculated as: {Overall Effectiveness Rate = [(Number of Cured Cases + Number of Significantly Effective Cases + Number of Effective Cases) \ Total Number of Cases X 100%]}. The Significant Improvement Rate is calculated as:{Significant Improvement Rate = [(Number of Cured Cases + Number of Significantly Effective Cases） \ Total Number of Cases X 100%]}.

3.9. Statistical Methods

Data analyses were performed using SPSS software version 22.0. For continuous variables, t-tests were employed; categorical variables were analyzed using chi-square tests; and ordinal data were assessed with rank-sum tests. Data that were normally distributed or approximately normally distributed were presented as mean and standard deviation range. For data that did not follow a normal distribution, median and inter-quartile range were reported, and comparisons were made using non-parametric Wilcoxon rank-sum tests. All statistical tests were two-sided, and a *P*-value of <0.05 was deemed to represent statistically significant differences.

4. Results

4.1. VAS Scores Comparison

There were no statistically significant differences in baseline VAS scores between the two groups ($P > 0.05$).

Intra-group comparison, at each treatment session, post-treatment VAS scores significantly decreased in both groups compared to pre-treatment scores ($P<0.05$). Furthermore, within the same group, compared to baseline, the VAS scores after the 3rd treatment and at the follow-up point were significantly reduced in both groups ($P<0.05$). Between the two groups,the VAS scores after the 2nd and the 3rd treatment in MBAM group were significantly lower compared to the Local Acupuncture group ($P<0.05$).See Table 2 for details.

Inter-group comparison , the difference of pre-treatment and post treatment VAS score in each treatment was consistently higher in the MBAM group compared to the Local Acupuncture group, showing statistically significant results ($P<0.05$). The difference of baseline and post 3rd treatment VAS scores was also higher in the MBAM group compared to the Local Acupuncture group, with statistical significance ($P<0.05$). However, no significant changes were found between the two groups in the difference of baseline with follow-up point VAS scores ($P>0.05$). Refer to Table 3.

Table 2 Comparison of VAS scores for both groups

Groups	N. of cases	1st Treatment		2nd Treatment		3rd Treatment		Follow-up
		Pre	Post	Pre	Post	Pre	Post	
MBAM	30	4.60(1.55)	2.25(1.45)*	3.00(1.92)	1.00(1.15)* $	1.75(1.90)	0.10(0.63) * $ #	0.85(2.05)#
Local Acupuncture	30	4.20(1.40)	2.40(0.92)*	3.00(1.73)	1.45(0.83)*	1.80(1.55)	0.85(1.00)* #	1.05(1.80)#

Note: *Indicates a significant difference compared to pre-treatment within the same group ($P < 0.05$); #Indicates a significant difference compared to baseline within the same group ($P < 0.05$); $Indicates a significant difference compared to the Local Acupuncture group ($P<0.05$).

Table 3 Comparison of VAS Scores differences

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	2.45 (1.15)*	1.70 (1.22)*	1.40 (0.98)*	4.00(1.53)*	3.50(1.62)
Local Acupuncture	30	1.50 (1.25)	1.25 (1.03)	0.80 (0.73)	3.10(1.45)	2.80(2.00)

Note: *Indicates a significant difference compared to the Local Acupuncture group ($P < 0.05$).

4.2. Cervical Spine Anterior-Posterior ROM Comparison

There was no statistically significant difference in the Anterior-Posterior ROM between the two groups at baseline ($P > 0.05$).

Intra-group comparison, at each treatment session, post-treatment Anterior-Posterior ROM significantly increased in both groups compared to pre-treatment ROM ($P < 0.05$). Furthermore, within the same group, compared to baseline, Anterior-Posterior ROM after the third treatment and at the follow-up point were significantly increased in both groups ($P < 0.05$). See Table 4 for details.

Inter-group comparison, the difference of pre-treatment and post-treatment Anterior-Posterior ROM angles in 1st and 2nd treatment was consistently greater in the MBAM group compared to the Local Acupuncture group, showing statistically significant results ($P < 0.05$). However, no significant changes were found between the two groups in difference of Anterior-Posterior ROM angles in the 3rd treatment($P > 0.05$). Finally the difference of baseline with post-3rd treatment and with follow-up point Anterior-Posterior ROM angles showed that the MBAM group had higher values than the local acupuncture group, with statistical significance ($P < 0.05$). Refer to Table 5.

Table 4 Comparison of Anterior-Posterior ROM angles for both groups

Groups	Number of cases	1st Treatment		2nd Treatment		3rd Treatment		Follow - up
		Pre	Post	Pre	Post	Pre	Post	
MBAM	30	74.00 (22.00)	86.00 (16.00)*	82.00 (15.50)	91.00 (11.75)*	89.50 (20.50)	96.50 (12.00)* #	93.00 (14.00)#
Local Acupuncture	30	78.50 (18.50)	86.00 (12.26)*	80.00 (15.50)	88.50 (12.25)*	87.00 (15.50)	93.00 (10.00)* #	92.50 (12.75)#

Note: *Indicates a significant difference compared to pre-treatment within the same group ($P < 0.05$); #Indicates a significant difference compared to baseline within the same group ($P < 0.05$).

Table 5 Comparison of Anterior-Posterior ROM angles differences

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	10.00 (8.25)*	9.00 (7.50)*	7.00 (9.25)	23.00 (14.25)*	18.00 (15.75)*
Local Acupuncture	30	5.00 (5.25)	6.00 (7.00)	5.00 (5.00)	12.00 (14.00)	12.00 (15.25)

Note: *Indicates a significant difference compared to the Local Acupuncture group ($P<0.05$).

4.3. Cervical Spine Lateral Flexion ROM Comparison

At baseline, there were no statistically significant differences in Lateral Flexion ROM between the two groups ($P > 0.05$).

In the MBAM Intra-group comparison, at each treatment session, post-treatment Lateral Flexion ROM exhibited a statistically significant increase compared to pre-treatment Lateral Flexion ROM ($P < 0.05$). However, in the Local Acupuncture Intra-group comparison, only at 2nd treatment session, post-treatment Lateral Flexion ROM exhibited a statistically significant increase compared to pre-treatment Lateral Flexion ROM ($P < 0.05$), while no statistically

difference was found at 1st and 3rd treatment ($P > 0.05$). Furthermore, within the same group, compared to baseline measurements, Lateral Flexion ROM after the third treatment and at the follow-up point were significantly increased in both groups ($P < 0.05$). For detailed results, please refer to Table 6.

Inter-group Comparison, the difference of pre-treatment and post treatment Lateral Flexion ROM angles, at each treatment, was consistently greater in the MBAM group compared to the Local Acupuncture group, showing statistically significant results ($P < 0.05$). Even the difference of baseline with post 3rd treatment and with the follow-up point Lateral Flexion ROM angles showed that the MBAM group had higher values than the Local Acupuncture group, with statistical significance ($P < 0.05$). Refer to Table 7.

Table 6 Comparison of Lateral Flexion ROM angles for both groups

Groups	Number of cases	1st Treatment		2nd Treatment		3rd Treatment		Follow-up
		Pre	Post	Pre	Post	Pre	Post	
MBAM	30	68.50 (13.25)	78.00 (14.00)*	77.00 (19.25)	84.00 (13.50)*	78.50 (12.50)	87.50 (7.75)* #	86.00 (11.00)#
Local Acupuncture	30	67.00 (17.75)	76.00 (15.50)	70.50 (19.25)	81.50 (16.00)*	80.00 (16.00)	86.00 (14.77) #	85.00 (17.00)#

Note: *Indicates a significant difference compared to pre-treatment within the same group ($P < 0.05$); #Indicates a significant difference compared to baseline within the same group ($P < 0.05$).

Table 7 Comparison of Lateral Flexion ROM angles differences

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	9.50 (7.25)*	8.00 (7.50)*	6.50 (7.25)*	18.00(12.25)*	18.00(13.25)*
Local Acupuncture	30	4.00 (4.25)	5.50 (5.25)	5.00 (6.25)	11.00(10.50)	9.00(12.75)

Note: *Indicates a significant difference compared to the Local Acupuncture group ($P < 0.05$).

4.4. Cervical Spine Rotation ROM Comparison

There were no statistically significant differences in the baseline Rotation ROM angles between the two groups ($P > 0.05$).

In the MBAM Intra-group comparison, at 1st and 2nd treatment session, post-treatment Rotation ROM exhibited a statistically significant increase compared to pre-treatment Rotation ROM ($P < 0.05$), while no statistically significant difference was found at 3rd treatment ($P > 0.05$). In the Local Acupuncture Intra-group comparison, at each treatment session, post-treatment Rotation ROM exhibited no statistically significance compared to pre-treatment ($P > 0.05$). Furthermore, within the same group, compared to baseline measurements, Rotation ROM after the third treatment and at the follow-up point were significantly increased in both groups ($P < 0.05$). Between the two group,the Rotation ROM angles the 3rd treatment in MBAM group were significantly higher compared to the Local Acupuncture group ($P < 0.05$).Please refer to Table 8.

Inter-group Comparison, the difference of pre-treatment and post-treatment Rotation ROM angles, at 1st treatment, was consistently greater in the MBAM group compared to the Local Acupuncture group, showing statistically significant results ($P < 0.05$); while no statistically significant difference was found at 1st and 3rd treatment ($P > 0.05$). Even the difference of baseline with post-3rd treatment and with the follow-up point Lateral Flexion ROM angles showed that the MBAM group had higher values than the local acupuncture group, with statistical significance ($P < 0.05$). Refer to Table 9.

Table 8 Comparison of Rotation ROM angles for both groups

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	9.50 (7.25)*	8.00 (7.50)*	6.50 (7.25)*	18.00(12.25)*	18.00(13.25)*
Local Acupuncture	30	4.00 (4.25)	5.50 (5.25)	5.00 (6.25)	11.00(10.50)	9.00(12.75)

Note: *Indicates a significant difference compared to pre-treatment within the same group ($P < 0.05$); #Indicates a significant difference compared to baseline within the same group ($P < 0.05$;. $Indicates a significant difference compared to the Local Acupuncture group ($P < 0.05$).

Table 9 Comparison of Rotation ROM angles differences

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	15.50 (11.25)*	9.00 (6.25)	7.50 (7.50)	30.50(19.00)*	24.50(23.00)*
Local Acupuncture	30	6.00 (6.25)	7.50 (5.25)	5.00 (5.00)	16.50(15.25)	14.00(20.50)

Note: *Indicates a significant difference compared to the Local Acupuncture group ($P < 0.05$).

4.5. Clinical Curative Efficacy Evaluation

Short-term Therapeutic Effect after one week of three treatment sessions in the MBAM, group 20 cases were cured, 8 showed significant improvement, 2 were effective, and 0 were ineffective. The overall effectiveness rate was 100%, and the significant improvement rate was 93.33%. In the Local Acupuncture, group 9 cases were cured, 17 showed significant improvement, 2 were effective, and 0 were ineffective. The overall effectiveness rate was 100%, and the significant improvement rate was 73.33%.

There was no statistically significant difference between the two groups in terms of overall effectiveness ($P > 0.05$) rate, while significant improvement rate had a significant difference ($P < 0.05$). For details, see Table 10.

Table 10 Evaluation of Short Term Curative Effect after a course of three treatments

Groups	Number of cases	1st Pre-Post Difference	2nd Pre-Post Difference	3rd Pre-Post Difference	Baseline vs. Post 3rd Difference	Baseline vs. Follow-up Difference
MBAM	30	15.50 (11.25)*	9.00 (6.25)	7.50 (7.50)	30.50(19.00)*	24.50(23.00)*
Local Acupuncture	30	6.00 (6.25)	7.50 (5.25)	5.00 (5.00)	16.50(15.25)	14.00(20.50)

Note: *Indicates a significant difference compared to the Local Acupuncture group ($P < 0.05$).

5. Discussion

5.1. Modern Medical Significance for Criteria Selection

The central pathological alteration in Cervical Type Cervical Spondylosis is the degeneration of the intervertebral disc, characterized by annular fissures, nucleus pulposus dehydration and overall disc dissecation, and protrusion or bone spurs formation. Osteophyte formation contributes to reduced cervical stability, leading to cervical canal stenosis and symptoms of nerve compression. Ligamentum flavum thickening occurs as cervical ligaments hypertrophy due to prolonged stress, exacerbating the nerve compression symptoms. The development of these pathological changes mainly involves the combination of three etiological causes and factors: 1. “Degenerative Changes” due to advancing age; 2. “Mechanical Injury” from long-term poor posture, excessive neck activity, or trauma; 3. “Inflammatory Responses” triggered by the above degenerative changes and mechanical injuries[26, 27].

The above pathological changes result in a range of clinical manifestations, from impairing the quality of life to affecting the patient's basic activities. Pain is the most common clinical manifestation of Cervical Type Cervical Spondylosis, with patients frequently experiencing persistent neck pain that may radiate to the shoulder or upper limbs. Impaired movement also an important symptom, patients may also experience neck stiffness, accompanied by limited movement in various directions, particularly in the morning or after prolonged periods in a fixed posture.

Based on these considerations, this study recruited patients with Cervical Type Cervical Spondylosis based on pain and movement impairment as the primary clinical manifestations and X-ray examinations to confirm the cervical spine degenerative changes[15, 26]. Considering the impact of the condition, pain was the primary symptom of concern; therefore, pain relief was established as the main outcome of interest in this research on acupuncture for Cervical Type Cervical Spondylosis. The VAS score was used as the main outcome index and as the clinical curative efficacy criterion. Restricted neck movement frequently accompanies pain and significantly affects the patient's life; therefore, Cervical Spine ROM in three directions was introduced as secondary efficacy criterion.

However, pain assessment remains incomplete; most studies assess only the post-treatment efficacy at the end of the treatment course, without evaluating the immediate effect of acupuncture at each treatment session[28]. A notable feature of acupuncture, especially for musculoskeletal and pain-related disorders, is its potential for immediate symptom relief, yet this immediate effect is often not assessed in existing studies. Similarly, there is a lack of immediate post-treatment assessments for alleviating neck stiffness symptoms following single treatment sessions. Thus, in designing this clinical study to address this gap, an immediate effect assessment at each treatment session was included.

It is easy to understand that the recurrence of these two symptoms in the neck, shoulder, and head regions can dramatically affect even the simplest human activities. Thus, Cervical Type Cervical Spondylosis significantly impacts the quality of life, primarily due to continuous neck pain and stiffness, which interfere with daily activities and work. Limited neck mobility may affect basic activities like dressing and driving, thus impacting self-care abilities. For this reason, in this experiment, we introduced a follow-up assessment point four week after the end of the treatment course, to evaluate sustainability of the treatment effect over time.

5.2. MBAM Intervention Effect on Pain Level

Our VAS score results suggest that in each treatment session, both MBAM and Local Acupuncture protocols effectively provided significant immediate analgesic effect ($P < 0.05$); moreover, in the 2nd and 3rd treatments, the pain relief was significantly more pronounced in MBAM group ($P < 0.05$). After a one-week course of three treatments, both protocols also demonstrated short-term significant analgesic effect ($P < 0.05$); additionally, at four-weeks follow-up, there was significant pain relief for both groups ($P < 0.05$).

Although both treatment were effective, according to the VAS scores differences, MBAM treatment for Cervical Type Cervical Spondylosis was significantly superior to Local Acupuncture in terms of immediate pain relief during each treatment session, as well as in short term pain relief over the one-week treatment course ($P < 0.05$).

By comparing the above results on pain level with other studies utilizing balancing acupuncture for Cervical Type Cervical Spondylosis, it is notable He Yuhan's study[29] randomly assigned 60 subjects with Cervical Type Cervical Spondylosis to either a conventional acupuncture group or a balanced acupuncture group. The conventional acupuncture group received treatment at bilateral BL10-Tianzhu points, GB21-Jianjing, and the pain location EX-B2-Jianjing points, while the balanced acupuncture group selected points between the 4th and 5th metacarpal joints on the back of the hand, with acupuncture performed on the opposite side and no needle retention after manipulation. Both groups were treated every other day for a 2-week period. Results showed that balanced acupuncture had a significantly superior immediate effect in improving pain and mobility restrictions compared to Local Acupuncture($P < 0.05$). However, no significant differences were observed between the groups at the end of 2-weeks treatment course. These findings are consistent with the immediate analgesic effect observed in our MBAM group but differ in terms of short-term pain relief.

Another evaluation of the effectiveness of balancing acupuncture in combination with Local Acupuncture was conducted by Li Wenjian[30], who divided 120 Cervical Type Cervical Spondylosis subjects into three groups: a balanced acupuncture group, a conventional acupuncture group, and a combination of both. It was found that using balanced acupuncture alone was comparable to conventional acupuncture in terms of pain relief, but the combination group demonstrated superior pain relief compared to either method alone, also showing significant immediate and long-term analgesic effects($P < 0.05$). Here, the difference in our study lies in both immediate and short-term analgesic effects.

It is important to note that in both of the above studies, there is a fundamental difference between their balancing acupuncture protocols and the MBAM protocol used in this study. In their balancing acupuncture groups, the acupoints prescriptions consisted of a limited number of needles localized in the same area for all patients, with no differentiation between subjects in the group. Furthermore, needle retention time was either very short or entirely absent. On the other hand, the MBAM intervention in our study possesses high complexity in several aspects. Specifically, it incorporates three different principles of balancing acupuncture (meridians, body tissues, and limb holography), which enable a differentiated acupoints prescription for each subject in the experimental group, based on the location of cervical spondylosis symptoms and syndrome manifestations. This approach increases the likelihood of identifying sensitive points on the limbs, which can also vary based on the different manifestations and meridian responses of each patient. Furthermore, in our study, the MBAM intervention retained needles for 30 minutes. This relatively longer retention time may help sustain the acupuncture effect, leading to better therapeutic outcomes and explaining the discrepancies with findings from other studies.

5.3. MBAM Intervention Effects on restricted Cervical Spine Motility

The scores for the ROM angles in all three directions suggest that the MBAM treatment protocol effectively provides immediate, short-term, and follow-up significant improvement for restricted cervical spine movement in Cervical Type Cervical Spondylosis patients($P < 0.05$). This effect was registered in each individual treatment session, for the entire course of treatment, and even at 4-weeks follow-up, for all three ROM directions, with the only exception being no immediate improvement in 3rd treatment's Rotation ROM, possibly because the Rotation ROM had already reached the average healthy level. On the other hand, the Local Acupuncture treatment protocol effectively provided immediate significant improvement primarily in the Anterior-Posterior ROM($P < 0.05$). These data suggest that MBAM can result in immediate improvement in cervical spine motility in directions where Local Acupuncture has no immediate effect.

This result can be explained by the difference in the needling methods used by the two protocols. While in Local Acupuncture intervention, the patient receives needles on the neck and is required to remain in a fixed position throughout the entire treatment session, in MBAM intervention, the needles are inserted distally on the limbs, and the neck area is free to move.Comparing the two acupoints selection methods for treating Cervical-Type Cervical Spondylosis, another potential advantage of MBAM's distal acupoints selection is that it allows for immediate assessment of the patient's neck pain and mobility limitations during both the needle insertion and retention phases. It is clear that distal acupuncture can be combined with dynamic needling techniques, where the patient is encouraged to move the affected area, in our case, the neck, which can significantly enhance immediate motility improvement. Such maneuvers are generally not feasible with local needling due to the risk of retained needles in the pain area, which may lead to complications. Additionally, some patients may experience discomfort from maintaining a fixed neck position during local needling, especially in the prone position with the face in the treatment bed cavity; for these individuals, distal acupoints prescription can significantly reduce discomfort during treatment.

Dynamic needling is not only widely used in treating Cervical Type Cervical Spondylosis but also in managing pain in other body areas. Si Ye[31] summarized existing clinical research and found that distal acupuncture with dynamic needling for neck and lower back pain is more effective in alleviating pain compared to traditional acupuncture, electroacupuncture, Western medical treatments, and other methods. Additionally, this study evaluated cervical ROM before and after acupuncture. Future studies could further assess changes in cervical mobility during needle retention using MBAM.

In any case, for the one-week treatment course and at the 4-week follow-up, Local Acupuncture treatment aligned with the MBAM group results; both effectively provided short-term and follow-up significant improvements for restricted cervical spine movement in Cervical Type Cervical Spondylosis patients in all three ROM directions($P < 0.05$). Comparing our data with He Yuhan's[29] balancing acupuncture protocol described earlier, we can suggest that MBAM protocol has stronger immediate efficacy, but at the short term, the protocols may have similar effects.

Although the Local Acupuncture intervention has general significance in improving neck motility, according to Cervical Spine ROM angle differences, MBAM appears significantly superior in the majority of individual treatments, in the treatment course, and at the 4-week follow-up for all three ROM directions ($P < 0.05$) .

We must note that other studies using balancing acupuncture therapy to treat Cervical-Type Cervical Spondylosis have seldom evaluated cervical mobility. Some have reported the effects of balancing acupuncture therapy on cervical motion in other types of cervical spondylosis. For example, Zhang Pu et al[32] described how Professor Zhang Weihua used cubit tibia acupuncture therapy combined with decompression loosening techniques to treat a case of Radicular Cervical Spondylosis, resulting in improved neck stiffness post-treatment. Similarly, Wang Shuai et al.[33] divided 150 patients

with vertebral Artery Type Cervical Spondylosis into a group treated with warm needling acupuncture combined with balanced lancet therapy and a warm needling acupuncture group. After three weeks, the combined therapy group showed significant improvements in cervical flexion-extension and rotational movement, statistically surpassing the warm needling acupuncture group alone.

These studies, along with the current research, suggest that balancing acupuncture therapy may have certain advantages in improving impaired cervical activity in patients with cervical spondylosis. We can observe that impaired cervical movement is a relevant symptom in Cervical Type Cervical Spondylosis, and in evaluating how balancing acupuncture can improve restricted Cervical Spine ROM, the current experiment makes an innovative contribution given the scarcity of studies on this topic

5.4. MBAM Curative Effects

This study evaluated the clinical effectiveness of MBAM based on the reduction rate of the primary outcome indicator, the VAS score. The results showed that MBAM and Local Acupuncture had favorable short-term curative effects, with 100% overall effectiveness rate in both groups. In particular, MBAM demonstrated statistical superiority, with 93.33% of the subjects showing significant improvement and 20 cases fully recovered, compared to 73.33% of the subjects showing significant improvement and only 5 cases fully recovered in the Local Acupuncture group ($P < 0.05$). These results indicate that both MBAM and Local Acupuncture can effectively treat Cervical Type Cervical Spondylosis, although MBAM has a better curative effect.

In other studies, balancing acupuncture has also demonstrated significant efficacy for Cervical Type Cervical Spondylosis. For example, Dong Jiayi[34] treated 36 patients with Cervical Type Cervical Spondylosis using balancing acupuncture, targeting 2 to 4 points on the hands. The final results showed that 24 cases were clinically cured, 12 cases were effective, yielding an overall effectiveness rate of 100%. These findings are consistent with our research and existing studies on distal acupuncture.

In general, few studies have evaluated the curative effects of balancing acupuncture for treating Cervical Type Cervical Spondylosis. However, studies on distal acupuncture for this condition show results consistent with ours. Some studies indicate that both local acupuncture on the neck and distal acupuncture on the limbs can effectively improve symptoms of neck pain and restricted movement in patients with Cervical Type Cervical Spondylosis, as well as enhance their quality of life[35]. In particular, a study suggests that a treatment course of 7 days, with each acupuncture session lasting 25 minutes, showed an overall effectiveness of 83% for the distal acupoints group, compared to 76% for the cervical group in pain improvement, suggesting that distal acupoints therapy may be superior to local acupoints therapy[36].

Further studies have evaluated the effects of balancing acupuncture combined with other acupuncture methods on Cervical Type Cervical Spondylosis, achieving sometimes even better results. For instance, Huang Junyu[37] divided 60 patients into a group receiving a combination of beryllium needle and balance acupuncture and a group receiving standard acupuncture. Both therapies significantly improved pain symptoms, but the combination therapy showed superior immediate and overall efficacy compared to standard acupuncture. Another study by Xia Yi[15] compared the effects of balance acupuncture combined with massage versus microwave therapy with cervical traction for treating Cervical Type Cervical Spondylosis. The balance acupuncture with massage group had a overall effectiveness rate of 85%, which was superior to the 72.5% effectiveness rate of the microwave and cervical traction group.

6. Conclusion

Currently, while acupuncture is widely used in clinical practice for patients with Cervical Type Cervical Spondylosis and demonstrates favorable efficacy, there is no standardized acupoints selection protocol in clinical applications and in clinical researches. In general, there is no definitive evidence indicating the superiority of any single acupuncture technique for this condition. In the treatment of Cervical Type Cervical Spondylosis, a meridian-based approach is also employed, wherein specific acupoints along the body's meridians are stimulated to achieve therapeutic goals. However, there is relatively limited research on the evaluation of distal acupoints selection. Therefore, the clinical trial design of this study incorporates MBAM as primary treatment for the experimental group, focusing on distal acupoints application to evaluate and compare its efficacy.

Our research findings support the efficacy of both MBAM and local acupuncture in alleviating pain, improving restricted cervical motion, and curing the disease for Cervical Type Cervical Spondylosis patients. Nevertheless, MBAM demonstrates superior pain relief and mobility improvements, consistent with existing studies on distal and balancing acupuncture methods. Especially regarding the curative effect, after one week of a three-session course of treatment,

both treatments showed absolute overall clinical efficacy; however, MBAM showed a higher curative effect and more healed cases.

This can be explained by the fact that MBAM treatment is based on ancient TCM principles of correspondence and balance for meridians and physiology. It employs the distal acupuncture technique, which incorporates and standardizes the principles of holographic acupuncture and utilizes a dynamic needling approach in clinic. Both MBAM and Local Acupuncture align their treatment with TCM classical principles; however, the MBAM method extends beyond merely addressing local symptoms of pain and stiffness in the neck and upper back, aiming also to harmonize the meridian network and address internal imbalances. This systemic approach underscores its ability to offer a more comprehensive therapeutic effect and acupoints prescriptions tailored for each different patient.

Following the results of our research, MBAM presents distinct advantages over simple Local Acupuncture in the treatment of Cervical Type Cervical Spondylosis. In terms of improving VAS scores, MBAM outperformed Local Acupuncture in single treatment immediate analgesic effects and in one-week short-term analgesic effects, although both treatments were comparable during the follow-up period. Regarding the improvement of Cervical Spine ROM in anterior-posterior flexion, lateral flexion, and rotation, Local Acupuncture can also effectively relieve pain and, in the majority of cases, improve limited motion in Cervical Type Cervical Spondylosis. However, MBAM also demonstrated superiority compared to Local Acupuncture in the majority of single-treatment immediate efficacy, in one-week short-term efficacy, and after four weeks of follow-up efficacy.

Furthermore, Local Acupuncture shows no immediate improvement in several single treatments. On the other hand, MBAM shows immediate improvement in almost every treatment, which can be related to its treatment's dynamic nature. This is a key advantage of MBAM over Local Acupuncture, allowing for real-time assessment and adjustment of treatment based on immediate feedback from the patient. Unlike local acupuncture, which limits assessment to pre- and post-treatment evaluations, MBAM enables repeated symptom evaluation at needle insertion and during the session. This adaptability facilitates refinements in needle placement and technique, ensuring a personalized treatment prescription, which justifies the superior curative outcomes achieved in our experimental group.

Additionally, MBAM's dynamic needling encourages patient movement during treatment, enhancing both the therapeutic effect and patient comfort. By allowing for active motion, MBAM enhances the release of tension in the neck, upper back, shoulders, and head, while significantly reducing discomfort during the session.

The dynamic nature of MBAM also makes it compatible with adjunctive treatments such as Tuina or chiropractic techniques, which can amplify therapeutic outcomes during the same session. This contrasts with local acupuncture, where this approach is not feasible, as needles restrict movement and increase discomfort in sensitive areas. The combined use of local and balancing acupuncture has been reported to yield remarkable outcomes, suggesting that these different modalities address distinct aspects of Cervical Type Cervical Spondylosis pathology. This opens avenues for further exploration into the integration and optimization of MBAM techniques.

Compliance with ethical standards

Disclosure of conflict of interest

The first authors Massimo Bondi, the second coauthor Zhiyuan Bian, and the corresponding author Jianqiao Fang declare no conflicts of interest in this work.

Statement of ethical approval

This study has been reviewed and approved by the Medical Ethics Review Committee of the Affiliated Third Hospital of Zhejiang Chinese Medical University, project number: ZSLL-KY-2022-022-01.The study was sponsored by National Administration of Traditional Chinese Medicine. The research strictly adheres to the Declaration of Helsinki, and all participants signed informed consent forms prior to enrollment.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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