



Research Article

## A CLINICAL STUDY OF *BALLITARWADI GUTIKA* IN THE MANAGEMENT OF *MANYASTAMBHA* (CERVICAL SPONDYLOSIS)

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### ABSTRACT

*Manyastambha* symptoms and signs are associated to cervical spondylosis. The disease not only negatively impacts a person's health but also greatly impairs quality of life and daily activities. Neck arthritis, also known as cervical spondylosis, can result from disc and ligament problems, as well as bone spurs. This disease primarily affects persons during their productive years of life, with a male-to-female ratio of 3:1 and an incidence of 0.1-1% in the general population. Without regard to sex, religion, or other factors, a total of 45 individuals with the defining signs and symptoms of *Manyastambha* were chosen for this research trial (Cervical spondylosis). In the current study *Ballitarwadi Gutika* in the dose of 500mg thrice in a day with *Anupana* of like warm water for 45 days. Results showed that pain was reduced by 79.33%, stiffness 57.47% and parasthesia 48.44% which were statistically significant. Statistically very significant results were also found in swelling (64.13%), vertigo (52.38%) and neck muscle strength (52.27%). Restricted neck movements like flexion, extension, rotation and lateral flexion were improved by 50.22%, 51.78%, 51.71% and 52.70% respectively. And overall, 57.25% result was observed during the study.

### INTRODUCTION

Ayurveda is a "Science of Life" that offers preventative guidelines for a healthy and long life for people in addition to curative remedies. The combination of the body, sense organs, soul, and *Atma* is referred to as the "Ayus."

The use of vehicles, longer distance travel, prolonged sitting while working late hours, heavy lifting, a lack of exercise, and the eating of unhealthy and unhygienic foods all contribute to *Manyastambha*, a lifestyle disorder. Neck pain is common in those over 50 and may be an expected side effect of ageing. One of the *Vatavyadhis* is *Manyastambha*, which is further defined as one of the eighty different kinds of *Vataja Nanatmaja Vikaras*<sup>[1,2]</sup> and *Urdhwajatrugata Vikaras*. The *Siras* in the neck region is a medical ailment.

Cervical spondylosis symptoms and signs are comparable to *Manyastambha*, despite the fact that *Manyastambha* <sup>[3]</sup> is a neck vein disorder (*Greevagata Siras*).

### Disease Review

*Manyastambha* was mentioned by *Acharaya Charaka* in *Trimarmiya Adhyaya* of *Siddhi Sthana* <sup>[4]</sup>. According to *Acharaya Charaka*, the internal channels (nerves) of the sterno-mastoid area are affected when *Vayu* is exaggerated in this area. It results in *Manyastambha*, sometimes referred to as *Antharayama* (emprosthotonus) or spasticity of the neck (sternomastoid muscle). Additionally, he said that *Bahirayama* (opisthotonus) is the creator of the *Manyastambha*.

*Acharaya Sushruta*, *Vata* gets worse and worse due to daytime sleeping, inappropriate sitting, standing, and looking up. *Manyastambha*, or rigidity or loss of movement of the neck and shoulders, is caused by the *Kapha* envelope. Either *Avarana* or *Dhatu kshaya* vitiates the *Vata*. *Manyastambha* occurs when *Vata* is covered by *Kapha* or *Dosha* accumulation. Even though *Manyastambha* is mentioned in the *Samprapti*

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as a *Vata nanatmaja Vyadhi*, *Kapha Dosha* connections are also discussed. Here is the *Vata* is vitiated and residing in the *Kapha vyaktha vasthaso*, which allows for *Kapha* participation. Gayadasa, a critic of Sushruta, believes that *Manyastambha* is a distinct illness<sup>[5]</sup>. The *Manya Stambha* derives from the following.

"*Manya*" refers to the back of the neck or the area below the head; *Manya* and *Greeva* are synonymous terms. The word "*Stambha*" conveys the idea of halting or delaying neck functions, or the inability to move the neck<sup>[6]</sup>. We can infer from the aforementioned definitions and derivations that *Manya Stambha* is a disorder of the neck that impairs movement which is constrained or altered as a result of the disorder. Because of internal humoral vitiation or exogenic Factors, the pathology is either degenerative or caused by local pathological entities.

The intervertebral disc changes brought on by ageing are most likely the cause of cervical spondylosis, a common degenerative condition of the cervical spine. Clinical observations include cervical spondylosis, suboccipital pain and headache, neck and shoulder discomfort, and radicular symptoms, among other overlapping and distinct disorders<sup>[7]</sup>.

## Drug Selection

Ayurvedic approach to the *Manyastambha* is to retard the degeneration process and provide strength to the *Dhatus*, pacifying the *Vata dosha* which has special importance in the management of any degenerative phenomenon. In *Manyastambha* there is dominance of *Vata & Kapha Doshas*, and *Ballitarwadi Gutika* selected for this investigation which demonstrates in *Gadh nigras*. These drugs are mentioned in *Ayurvedic* texts as *Vata-Kapha Nashaka*, *Vedanasthapaka* and *Balya* properties. To avoid all the unnecessary clinical obscures and to give a cheaper and secure solution to the disease; following medications, which are conventional preparations, were chosen for the current study:

### 1. *Ballitarwadi Gutika*<sup>[8]</sup>

#### Ingredients of *Ballitarwadi Gutika*

*Shala* (*Shorea robusta*), *Pushkarmool* (*Inula racemose*), *Shunthi* (*Zingiber officinale*), *Kootha* (*Saussurea Lappa*), *Giloy* (*Tinospora cordifolia*), *Devdaru* (*Cedrus deodara*), *Rasna* (*Pluchea Lanceolata*), *Saindhav Lavan* (rock salt) one part each while *Jaggery* (*Guda*) is taken 2 parts.



**Jaggery**



**Saindhav Lavan**



**Shala**



**Pushkarmool**



**Kootha**



**Rasna**



**Shunthi**



**Devdaru**



**Giloy**

## Method of Preparation of *Ballitarwadi Gutika*

Above mentioned contents of *Ballitarwadi Gutika* were taken in the above quantity as per requirement. Each drug will be grinded in a fine powder and mixed with jaggery syrup as mentioned above. After complete mixing of all the drugs 500mg *Gutika* will be prepared. This drug was prepared in the pharmacy of PGIA, DSRRAU, Jodhpur.

### AIMS AND OBJECTIVES

- Clinical Study of "*Ballitarwadi Gutika*" in the management of *Manyastambha* (cervical spondylosis).
- To evaluate the safety, efficacy, sustainability and adverse drug reaction of the trial drug.

### MATERIALS AND METHODS

Following materials and methods have been adopted to conduct the clinical trial.

**Study Type:** Interventional, Randomized controlled, unblinded study.

**Ethical Clearance:** This study was approved by the institutional ethical committee vide letter number-DSRRAU/UCA/IEC/20-21/396

**CTRI Registration:** [CTRI No.-CTRI/2022/10/046905 registered on 31/10/2022].

#### A) Literary Source

The literary references were collected and discussed from Ayurveda classics, commentaries, modern parameters, PubMed, Google Scholar, the AYUSH research portal, and the internet.

#### B) Clinical Study

##### Case Selection

From the OPD and IPD of the Postgraduate Institute of Ayurved, DSRRAU, Jodhpur, 45 patients of "*Manyastambha*" (cervical spondylosis) who had received a clinical diagnosis were chosen for the study. There was no random selection of the case's gender, occupation, or socioeconomic status. Patients were enrolled in the trial after an evaluation of the *Manyastambha* (cervical spondylosis) clinical symptoms. For the objective of maintaining a regular record of each patient's evaluation, a proforma was developed.

##### Clinical Profile

#### Symptoms wise Observation of Patients

S.No.	Symptoms	No of Patients	%
1	Pain	45	100.00%
2	Radiation of pain	39	86.67%
3	Stiffness	44	97.78%
4	Paresthesia	34	75.56%
5	Swelling	43	95.56%

### Inclusion Criteria

- The patients between the age group of 30 to 60 years in either sex presenting with clinical features of *Manyastambha* (cervical spondylosis).
- Prediagnosed patients of *Manyastambha* on the basis of clinical symptoms and valid investigations.
- Patient presented with clinical symptoms with or without radiological changes.
- Willing to participate and able to provide signed informed consent.

### Exclusion Criteria

- Cervical fracture and dislocation of cervical vertebrae.
- Cervical compressive myelopathy.
- Space occupying lesions of brain.
- Post spinal surgical case.
- Patients suffering from any acute diseases/any infectious disease/metabolic disease/chronic diseases (like rheumatoid arthritis, SLE, ankylosing spondylitis).
- Uncontrolled diabetes mellitus and hypertension.
- Pregnant or lactating women.
- Patient with evidence of malignancy.

### Criteria for Withdrawal

- During the course of trail if any serious condition or any serious adverse effects occur which require urgent treatment.
- Patient himself/ herself wants to withdraw from the clinical trial.

### Demographical Profile

Age-wise, the fourth decade had the highest proportion of patients, i.e., 20 (44.44%) (30–40 yrs.). The majority of patients, 31, or 68.89% patients, were men. In this study, 42 patients (93.33%) were married. In this study maximum no. of patients were Hindu i.e., 44 (97.78%). The majority of participants in the study, 21 or 46.67%, were from the lower class and 24 patients, or 53.33% of the total, were from urban areas.

6	Vertigo	37	82.22%
7	Neck muscle strength	23	51.11%
8	Flexion	35	77.78%
9	Extension	36	80.00%
10	Rotation	36	80.00%
11	Lateral flexion	42	93.33%

**Radiological Abnormalities**

All the patients in this study were having some sort of pathological cervical spine changes as per radiological investigation. Majority of the patients of this series i.e., 35.23% were diagnosed as having cervical spondylosis with osteophytic changes followed by 28.91% patients, which were found having early cervical spine. As C5 and C6 are the most common levels of degeneration, maximum patients e.g., 66.44% were having lesion in C5-C6, followed by C4-C5 lesion in 48.84% patients.

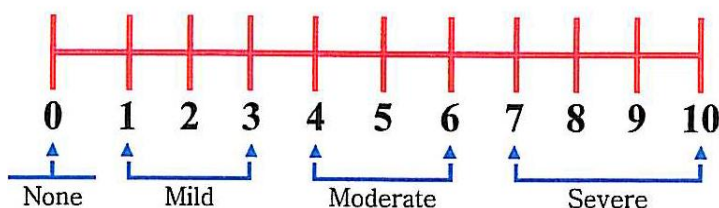
**Assessment Parameters**

**Subjective Parameters**

*Pain (Shoola)*

All the patients registered for present trial will be looked for any changes in their growing feeling of wellbeing, pre and post assessment. "Pain Intensity Instruments" is taken from National Institutes of Health – Warren Grant Magnuson Clinical Centre. July 2003. Archived from the original (PDF) on 2019-03-24.

**Numeric Rating Scale**



The Numeric Rating Scale (NRS-11) is an 11-point scale for patient self-reporting of pain. It is for adults or older.

S.No	Pain level	Rating
1.	No Pain	0
2.	Mild Pain (nagging, annoying, interfering little with activities of daily living)	1-3
3.	Moderate Pain (interferes significantly with activities of daily living)	4-6
4.	Severe Pain (unable to perform activities of daily living)	7-10

**Radiation of Pain**

S.No	Radiation of pain	Grade
1.	No radiation	0
2.	Radiation of pain from neck to shoulders	1
3.	Radiation of pain from neck to arm or anyone upper extremity	2
4.	Radiation of pain from neck to both arms or both upper extremities	3

**Stiffness (Stambha)**

S.No	Stiffness	Grade
1.	No stiffness	0
2.	Mild stiffness (lasting for 1 to 2 hours but, routine works are not disturbed)	1
3.	Moderate stiffness (lasting for more than 2 hours mildly affecting the daily routine)	2
4.	Severe stiffness (lasting for 2-6 hours. Daily routines are hampered)	3

**Paresthesia (Toda)**

S.No.	Paresthesia	Grade
1.	No Paresthesia	0
2.	Paresthesia only at cervical region	1
3.	Paresthesia extended from cervical region to anyone arm or upper extremity	2
4.	Paresthesia extended from cervical region to both arms or upper extremities	3

**Swelling (Shotha)**

S.No	Swelling	Grade
1.	No Swelling	0
2.	Slight Swelling	1
3.	Moderate Swelling	2
4.	Severe Swelling	3

**Vertigo (Bhrama)**

S.No	Vertigo	Grade
1.	Absent	0
2.	Present on neck movements	1
3.	Present Occasionally	2
4.	Present constantly	3

**Neck Muscle Strength**

S.No	Strength	Grade
1.	Normal Strength	0
2.	Limb can be held against gravity and strength	1
3.	The limb can be held in the force of gravity but not the examiners resistance	2
4.	Complete Paralysis	3

**Restricted Neck Movements**

**Flexion**

S.No	Flexion	Grade
1.	No restriction i.e., able to touch the interclavicular line	0
2.	Up to 2cm difference between the chin and interclavicular line	1
3.	2-4cm difference between the chin and interclavicular line	2
4.	More than 4cm difference	3

**Extension**

S.No	Extension	Grade
1.	Normal i.e., able to extend the head up to the level when tip of nose and forehead becomes in horizontal plane approximately flexion to extension -130°	0
2.	Movement up to 120°	1
3.	Movement up to 110°- 120°	2
4.	Movement less than 110°	3

**Rotation**

S.no.	Rotation	Grade
1.	Normal i.e., able to make complete rotation of neck	0
2.	Rotation with little difficulty	1
3.	Rotation side to side only	2
4.	Rotation one side only	3

**Lateral Flexion**

S.No.	Lateral flexion	Grade
1.	Normal i.e., ear touches to the shoulder tip	0
2.	Up to 3cm difference between the ear and shoulder tip	1
3.	3-5 cm difference between the ear and shoulder tip	2
4.	More than 5cm difference	3

**Objective Criteria**

Following investigation will be assessed for objective parameter:

- C-Reactive protein (CRP)
- R.A. factor

**Laboratory Investigation**

- Complete blood count (CBC)
- Erythrocyte Sedimentation Rate (ESR)
- Fasting Blood Sugar (FBS)
- Post Parandial blood sugar (PPBS)

**Special Test**

- Spurling test

**Radiological Investigation**

- X- RAY Cervical spine- Anterior posterior view and lateral view.

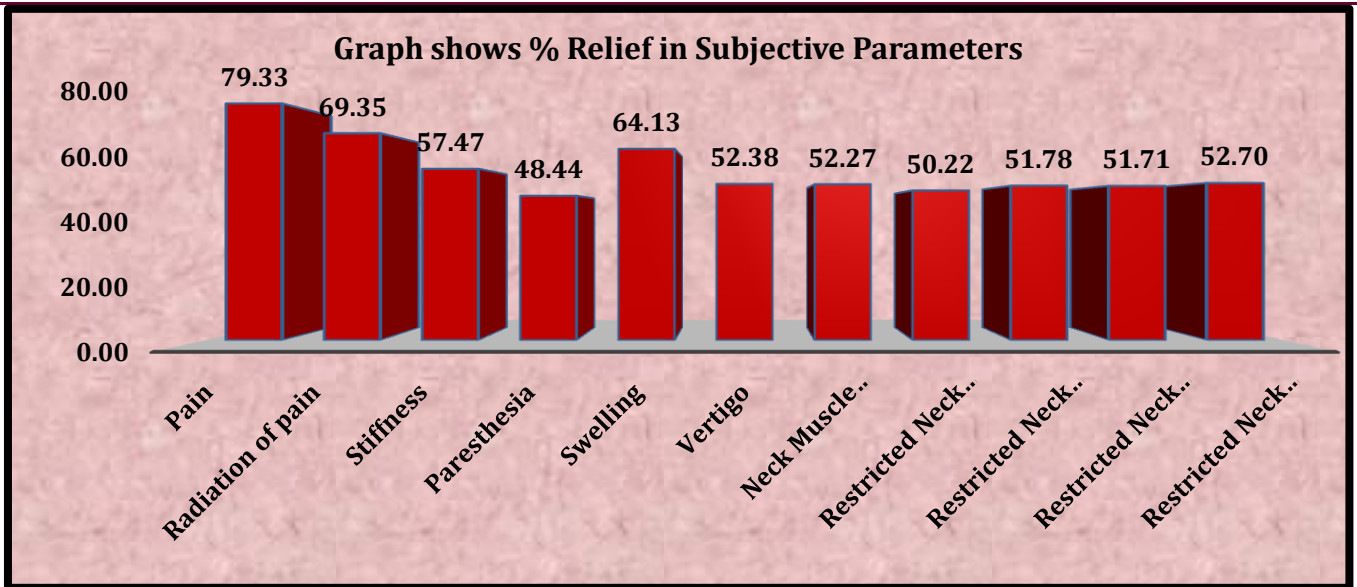
**RESULTS**

**Subjective Parameters**

**Effect of therapeutic trial on Subjective parameters (clinical symptomatology) in 45 patients of Manyastambha (cervical spondylosis) using Wilcoxon signed rank test.**

Variable	No of Pt.	Mean		Mean Diff	% Relief	S.D.	S.E.	P-Value	Result
		BT	AT						
Pain ( <i>Shoola</i> )	45	4.622	0.956	3.667	79.33	1.414	0.211	0.00000001	ES
Radiation of pain	45	1.378	0.422	0.956	69.35	0.638	0.095	0.00000007	ES
Stiffness ( <i>Stambha</i> )	45	1.933	0.822	1.111	57.47	0.682	0.102	0.0016171	Sig
Paresthesia ( <i>Toda</i> )	45	1.422	0.733	0.689	48.44	0.596	0.089	0.0054732	Sig
Swelling ( <i>Shotha</i> )	45	2.044	0.733	1.311	64.13	0.557	0.083	0.00000006	ES
Vertigo ( <i>Bhrama</i> )	45	1.867	0.889	0.978	52.38	0.657	0.098	0.00297342	Sig
Neck muscle strength	45	0.978	0.467	0.511	52.27	0.506	0.075	0.00146512	Sig
Flexion	45	1.422	0.708	0.714	50.22	0.535	0.080	0.002831273	Sig
Extension	45	1.489	0.718	0.771	51.78	0.618	0.092	0.00576317	Sig
Rotation	45	1.489	0.719	0.770	51.71	0.548	0.082	0.00197318	Sig
Lateral flexion	45	1.822	0.862	0.960	52.70	0.562	0.084	0.00476188	Sig

Percentage relief observed in pain (79.33%), stiffness (57.47%) and parasthesia (48.44%), swelling (64.13%), vertigo (52.38%), neck muscle strength (52.27%), restricted neck movements like flexion, extension, rotation and lateral flexion were improved by 50.22%, 51.78%, 51.71% and 52.70% respectively. And overall effect observed in subjective parameters during the study was 57.25%.

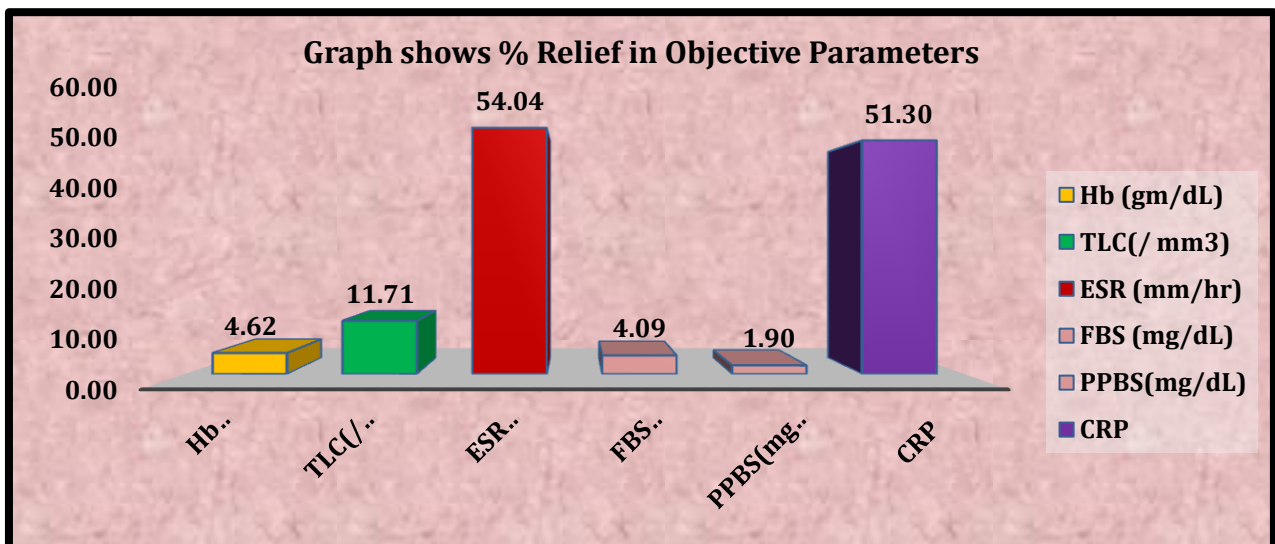


**Objective Parameters**

Effect of therapeutic trial on objective parameters in 45 patients of *Manyastambha* (Cervical spondylosis) using paired 't' test.

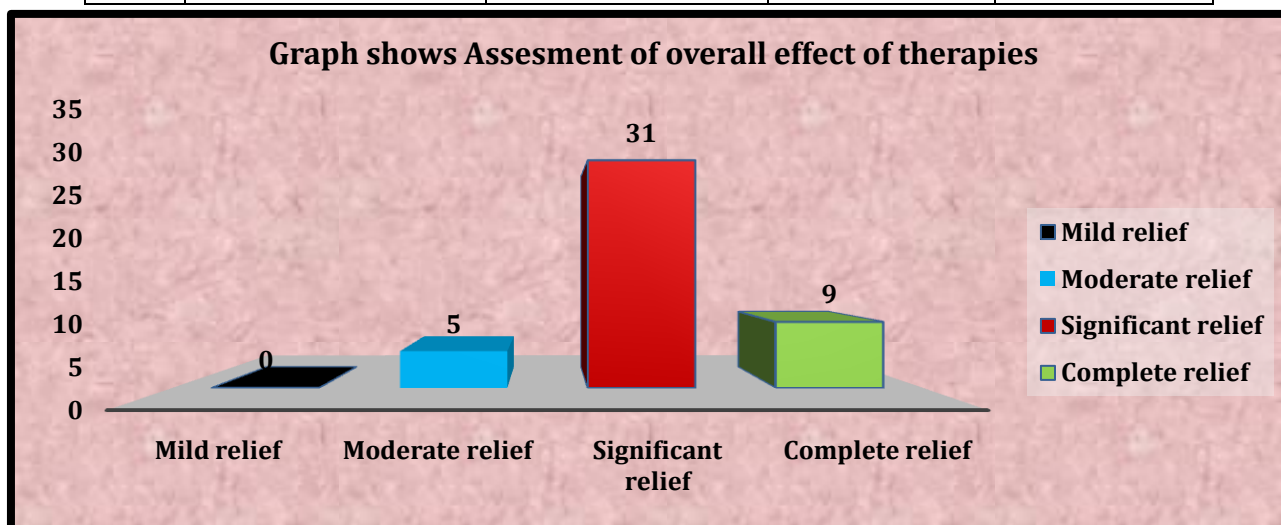
Objective Parameters	Mean	N	SD	SE	t-Value	P-Value	% Relief	Result
Hb	BT	11.88	45	1.14	-3.501	<0.05	4.62	Sig
	AT	12.43	45	1.22				
TLC	BT	8605.18	45	1316.80	4.003	<0.05	11.71	Sig
	AT	7597.91	45	1614.93				
Fasting BSL	BT	84.80	45	6.17	-13.294	<0.05	4.09	Sig
	AT	88.27	45	5.73				
PP BSL	BT	129.89	45	4.95	-8.168	<0.05	1.90	Sig
	AT	132.36	45	4.61				
ESR	BT	61.27	45	32.99	9.432	<0.001	54.04	ES
	AT	28.16	45	13.72				
CRP	BT	7.71	45	1.53	12.320	<0.001	51.30	ES
	AT	3.76	45	1.73				

Percentage relief observed in Hb (gm/dL)- 4.62%, TLC (/mm<sup>3</sup>)- 11.71%, ESR (mm/hr)- 54.04%, FBS (mg/dL)- 4.09%, PPBS (mg/dL)- 1.90%, CRP - 51.30%, overall effect observed in objective parameters during the study was 21.28%.



**Assessment of Overall Effect of the Therapies**

S. No.	Symptoms	Grading	No. of patients	Percentage
1	Less than 25%	Mild relief	0	0.00%
2	25% to 50%	Moderate relief	5	11.11%
3	50% to 75%	Significant relief	31	68.88%
4	75% to 100%	Complete relief	9	20%



**DISCUSSION**

**Subjective Parameters**

**Pain**

Effect of *Ballitarwadi Gutika* on the pain before and after the treatment in 45 patients of *Manyastambha*. The assessment of pain was done using the Visual Analogue Scale (VAS) method. The mean of VAS score for pain, before treatment was 4.622. It was lowered down to 0.956 with 79.33% relief which is statically extremely significant (P <0.001).

In this way *Ballitarwadi Gutika* was proved better in pain relieving might be due to better pain relieving effect.

**Parasthesia Over the Cervical Region**

The mean score of the Paraesthesia, before treatment was 1.422. It was lowered down to 0.733 with 48.44% relief which is statistically significant (P <0.05).

Parasthesia indicates loss of function of *Vyan Vayu*.

**Stiffness**

The mean score of stiffness, before treatment was 1.933. It was lowered down to 0.822 with 57.47% which is statistically significant (P <0.05).

**Swelling**

The mean score of swelling, before treatment was 2.044. It was lowered down to 0.733 with 64.13% which is statistically extremely significant (P <0.05).

**Vertigo**

The mean score of vertigo, before treatment was 1.867. It was lowered down to 0.889 with 52.38% relief which is statistically significant (P <0.05).

**Radiation of Pain**

The mean score of radiation of pain, before treatment was 1.378. It was lowered down to 0.422 with 69.35% relief which is statistically extremely significant (P <0.001).

**Neck Muscle Strength**

The mean score of neck muscle strength, before treatment was 0.978. It was lowered down 0.467 with 52.27% relief which is statistically significant (P <0.05).

**Flexion**

The mean score of flexion, before treatment was 1.422. It was lowered down 0.708 with 50.22% which is statistically significant (P <0.05).

**Extension**

The mean score of extension, before treatment was 1.489. It was lowered down 0.718 with 51.78% which is statistically significant (P <0.05).

**Neck Rotation**

The mean score of neck rotation, before treatment was 1.489. It was lowered down 0.719 with 51.71% which is statistically significant (P <0.05).



**Lateral Flexion**

The mean score of lateral flexion, before treatment was 1.822. It was lowered down 0.862 with 52.70% which is statistically significant ( $P<0.05$ ).

**Objective Parameters****Haemoglobin**

In present study, mean score before treatment was 11.88 which increased to 12.43 after treatment, with  $SD\pm 1.22$  giving a relief of 4.62% which is statistically significant ( $P<0.05$ ).

**TLC**

In present study, mean score before treatment was 8605.18 which reduced to 7597.91 after treatment, with  $SD\pm 1614.93$  giving a relief of 11.71% which is statistically significant ( $P<0.05$ ).

**Fasting BSL**

In present study, mean score before treatment was 84.80 which increased to 88.27 after treatment, with  $SD\pm 5.73$  giving a raise of 4.09% which is statistically significant ( $P<0.05$ ).

**Post Parandial BSL**

In present study, mean score before treatment was 129.89 which increased to 132.36 after treatment, with  $SD\pm 4.61$  giving a raise of 1.90% which is statistically significant ( $P<0.05$ ).

**ESR**

In present study, mean score before treatment was 61.27 which reduced to 28.16 after treatment, with  $SD\pm 13.72$  giving a relief of 54.04% which is statistically extremely significant ( $P<0.001$ ).

**CRP**

In present study, mean score before treatment was 7.71 which reduced to 3.76 after treatment, with  $SD\pm 1.73$  giving a relief of 51.30% which is statistically extremely significant ( $P<0.001$ ).

**CONCLUSION**

- One of the *Vatavyadhis* that is frequently used in modern practise is *Manyastambha*. Shift work, excessive riding of two-wheelers, irregular eating patterns, and improper postures are a few factors

that contribute to the vitiation of *Vata*. It is abundantly obvious that the *Vatavyadhi* are growing when all the aforementioned criteria are taken into account. Combining *Vyana Vayu* and *Slesaka Kapha* yields *Manyastambha*.

- From the current study, it can be concluded that *Ballitarwadi Gutika* can be beneficial for neurological symptoms of cervical spondylosis, such as tingling, numbness, weakening of the muscles, and slowed reflexes.
- Ayurvedic medication can be used to maintain the myelopathy that results from acute and severe herniations, which can only be treated surgically. Early problems can be avoided with regular exercise and posture correction during work, travel, and sleep.

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