



Comparative Assessment of *Kukkutanda Pinda Sweda* and *Patra Pinda Sweda* in the Management of *Manyastambha* (Cervical Spondylosis) - A Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. Author VKV, designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author SP designed the study, managed the analyses of the study managed the literature searches, reviewed and final drafting of the of the manuscript and author MN managed the analyses of the study. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: At the present time, human beings are easily prone to get several degenerative disorders because of their stressful and reckless lifestyle. '*Manyastambha*' is one such lifestyle disorder instigated from excessive use of vehicle, excessive travelling, continuous sitting and working for hours, jobs that require heavy lifting or a lot of bending and twisting, lack of exercise, unhealthy food habits and suppression of natural urges. Thus the avoidance is not possible, and a better curative area is to be identified. Ayurveda suggested many treatments for *Vata vyadhi*. The cervical problems mimic the *Vata* disorders. Thus the *Vata* managements of *Kukkutanda pinda Sweda* and *Patrapinda Sweda* through local apply *manya-pradesh* are better management for the identified clinical condition *Manyastambha* (Cervical Spondylosis) in the present study.

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Aim: studies the effect of *Kukkutanda Pinda Sweda* and *Patra Pinda Sweda* and compare the impact of both procedure in the management of *Manyastambha* (Cervical Spondylosis).

Objectives: To Comparative assessment of *Kukkutanda Pinda Sweda* and *Patra Pinda Sweda* in the Management of *Manyastambha* (Cervical Spondylosis). And to compare the effect of *Kukkutanda pinda Sweda* and *Patra Pinda Sweda* on pain, stiffness in neck bones and joints and X-rays Cervical spine and Goniometer Study.

Methodology: In this study, 60 patients will be divided randomly into two groups (30 in each). In Group (A) –*Kukkutanda pinda Sweda* will be externally administered a day at morning for 15-20 minutes or *samyak swinna lakshan* for 7 days. In Group (B) – *Patra pinda Sweda* will be externally administered a day at morning for 15-20 minutes or *samyak swinna lakshan* for 7 days, and an assessment will be recorded on 0 and 7th and 15th day.

Results: Changes will be observed in objective outcomes.

Conclusion: Based on the result conclusion will be drawn.

Keywords: *Cervical Spondylosis; goniometer; Kukkutanda pinda sweda; manyastambha; Patra pinda sweda.*

1. INTRODUCTION

At the present time, human beings are easily prone to get several degenerative disorders because of their stressful and reckless lifestyle. '*Manyastambha*' is one of such lifestyle disorders. It instigated from excessive use of vehicle, excessive travelling, continuous sitting. At working for hours, jobs that require heavy lifting or a lot of bending, twisting, lack of exercise, unhealthy food habits and suppression of natural urges [1].

The incidence of neck pain in adults is approximately 20-50% per year. It is characterized by neck pain, stiffness, inability in movement, degeneration of the inter-vertebral disc, extrusion of disc materials, surroundings fibrosis, vertebral body edge hypertrophy etc. The majority of individuals over 40 years of age demonstrate significant radiological evidence, and a major percentage develops symptoms. 60 - 70% of women and 85% of men show changes of cervical spondylosis in X-ray investigations [2].

In *Amarakosha*, '*Manya*' is described as '*Greevapashchat Sira*' [3]. *Manyastambha* is one of the *Vataja Nanatmaja Vyadhi* [4]. *Manya* is *Chala*, i.e. movable part of the body. The cervical spine, due to its position, complex structure and excellent mobility, are vulnerable to injuries. Due to etiological factors, the *Vata dosha* gets aggravated and gets lodged at *Manyapradesha*, that affecting the *Manyagata Siras*, which causing *Stambha* (stiffness) and *Ruja* (pain) of the neck that ultimately leads to *Manyastambha* (cervical spondylosis) [5]. The main symptoms of *Manyastambha* are *Ruk* (pain) and *Stambha* (stiffness and restricted movements). According to *Sushruta Samhita*, the *Vata Dosha* and Kapha

Dosha get aggravated and take *Ashraya* at *Manya Pradesha*, affecting the *Manya Siras* causing *Ruja* and *Stambha* of the neck [6].

Various types of *Swedana* such as *Nadiswedana*, *Prastaraswedana*, *Sankaraswedana* are indicated for the *Vatavyadhi* [7]. *Swedana* is considered one of the best treatment modalities for diseases caused due to aggravation of *Vata Dosha*. *Swedana* relieves pain and stiffness mainly [8].

1.1 Background and Rationale

The present day world is with more cervical problems as they are habituated with electronic instruments and occupational. Thus the avoidance is not possible, and a better curative area is to be identified. Ayurveda suggested many treatments for *Vata vyadhi*. The cervical problems mimic the *Vata* disorders. Thus the *Vata* managements of *Kukkutanda pinda Sweda* and *Patra pinda sweda* through local apply *manya-pradesha* is better management for the identified clinical condition *Manyastambha* (Cervical Spondylosis) in the present study.

Among such disorders, Ayurvedic classics have described a disease in the name of *manyastambha*. The signs and symptoms of pain, stiffness in neck bones and joints and restricted neck movements have been explained in *Bhavaprakasha Part I Madhyakhandchapter*. Because of present-day lifestyles, food, habits, excessive stress-strain and anxiety, more people are getting these problems and the incidence of the disease *Manyastambha* are drastically increased day by day.

Cervical spondylosis is caused by the chronic degenerative condition of the cervical spine and

the inter-vertebral disc of the cervical spine in the neck. The reported annual incidence of Cervical Spondylosis is most people with spondylotic changes of the cervical spine on radiographic imaging remain asymptomatic, with 25% of individuals under the age of 40, 50% of individuals over the age of 40, and 85% of individuals over the age of 60 showing some evidence of degenerative changes. The most frequently affected levels are C6-C7, followed by C5-C6. Symptomatic cervical spondylosis most commonly presents as neck pain. In the general population, the point prevalence of neck pain ranges from 0.4% to 41.5%, the 1-year incidence ranges from 4.8% to 79.5%, and lifetime prevalence may be as high as 86.8%. Hence the study has been initiated to evaluate the successive management of *manyastambha* using *Kukkutanda pinda* and *Patra pinda sweda*. In this therapy, all selected drugs have properties which effective in treating *Manyastambha* [9,10,11].

1.2 The Rationale of the Study

Without vitiation of *Vata*, *shoola* (pain) cannot be produced. So, *manyastambha* has to be considered within *vaatvyadhi*. In the *chikitsa sutra* of *vatavyadhi*, many *Acharyas* advised *Pottali Sweda*, and *Acharya Bhavprakash* has mentioned *Kukkutanda pinda Sweda* as a *local manya region Snigdha swedan* karma helps to decrease the pain, stiffness in neck bones and joints and restricted neck movements. *Kukkutanda and Patrapinda sweda* also known as *snigdha potali sweda* in Ayurveda. Moreover, *Snigdha swedan* is best to pacify *Vata* and *Kapha awaran*. *Asthi* being the site of *Vata* and *asthi vaha* srotas. The vitiated *Vata* gets subsided when the *manya pradesha* (Nape of neck), *asthi sandhi* is treated with *Snigdha swedan*, as the primary site of *vata*. The *snighdha pottali sweda* acts better with its *Sneha* and *Vata* and *Kapha shamaka* properties. Hence in the present study, *snighdha pottali sweda* is selected. So, this study is undertaken to evaluate the effects of *Kukkutanda pinda and Patra pinda pottali Swedan*

2. AIM AND OBJECTIVES

2.1 Aim

Comparative assessment of *Kukkutanda Pinda Sweda* and *Patra Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).

2.2 Objectives

1. To assess the effect of *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).
2. To assess the effect of *Patra Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).
3. To compare the effect of *Kukkutanda Pinda Sweda* with *Patra Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).

2.3 Case Definition

A subject with symptoms of pain and stiffness in *manya-pradesha* (Cervical Region, nape of neck) with restricted neck movement with positive X-ray degenerative condition and Goniometer cervical parameter test.

Research Question: Whether *Patra pinda Sweda* as equally as effective as *Kukkutanda pinda sweda* in the management of *Manyastambha* (Cervical Spondylosis)?

2.4 Hypothesis

1. *Kukkutanda Pinda Sweda* is more effective than *Patra Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).
2. *Patra Pinda Sweda* is more effective than *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).
3. *Patra Pinda Sweda* is equally effective as *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis)
4. *Kukkutanda Pinda Sweda* is equally effective than *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis)

2.5 Null Hypothesis

1. *Kukkutanda Pinda Sweda* is not more effective than *Patra Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).
2. *Patra Pinda Sweda* is not more effective than *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis).

3. *Patra Pinda Sweda* is not equally effective as *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis)
4. *Kukkutanda Pinda Sweda* is not equally effective than *Kukkutanda Pinda Sweda* in the management of *Manyastambha* (Cervical Spondylosis)

Trial design- A randomized, open comparative clinical trial.

Study Duration – 3 years (Midterm study)

3. METHODOLOGY

Study setting: The study will be conducted in academic hospital MGACH & RC, Salod (H), Wardha.

IEC- MGACHRC/IEC/July-2020/29

Registration Number -CTRI/2020/09/027890.

Composition of the trail drug: *Kukkutanda pinda sweda* [12,13].

Tila tail 50 ml-for *abhyanga*, 4 *Kukkutanda* (eggs), *Saindhalavana* 10 gms, *Ghrita* 30 ml, Cloth for preparing *potali*(45×45 cms), small bowl, tying thread of 30 cms in length to tie a tuft. Spatula for stirring, induction, frying pan, small towel and *abhyanga* table.

3.1 Patra pinda Sweda [14,15,16]

After local *abhyanga*, will take 50 ml *Tila tail* for frying leaves of *Nirgundi* (*Vitex Negundo*) Leaves 25 gram, *Erand* (*Ricinus communis*) Leaves 25 gram, *Chincha* (*Tarminudus Indica*) Leaves 25 gram, *Dhatura* (*Datura metal*) Leaves 5 gram, *Shigru* (*Moringa Oleifera*) Leaves 5 gram, *Arka* (*Calotropis Procera*) Leaves 5 gram, Grated coconut 50g, Lemon 2, , *Saindhav*, *Rasnachurna* each 5 gram, Cloth for preparing *potali* (45×45 cms) tying thread of 30 cms in length to tie a tuft and heating *potali*. Spatula for stirring, induction, frying pan, small towel and *abhyanga* table.

Inclusion criteria:-

- Patients of either gender with signs and symptoms of *Manyastambha* (Cervical Spondylosis)
- Patients in the Age group of 25 to 45 years
- Patients fit for *Swedana* procedure

- Patients ready to give informed consent and abide by instruction

Exclusion criteria:-

- Diseases such as Spinal stenosis “Cervical region” -(ICD-10-CM 48.02),
- Ankylosing hyperostosis(ICD-10-CM M48.14),
- Kissing spine(ICD-10-CM M 48.20),
- Traumatic spondylopathy(ICD-10-CM M48.36),
- Fatigue fracture of cervical vertebra(ICD-10-CM M 48.42 XA),
- Tubercular spine(ICD-10-CM,A18.01)
- Brucella spondylitis(ICD-10-CM M49.1),
- Enterobacterial spondylosis(ICD 10 M 49.2),
- Neuropathic spondylopathy(ICD-10 M 49.4),
- Collapsed vertebra(ICD-10-CM M48.50XA)
- Gouty arthritis(ICD-10-CM M10. 9) ,
- Rheumatoid arthritis(ICD-10-CM M06. 9),
- Congenital torticollis,(ICD-10-CM M43. 6)
- History of any surgical, diagnostic intervention concerning the affected joints
- Patient having Pregnancy will also exclude from the study.
- Patient having fatal complications of serious illness will exclude.

3.2 Criteria for Discontinuing or Modifying Allocated Interventions

The subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity, or any other disease or problem arises; the subject will be offered free treatment till the problem subsides.

Follow up: 0 and 7th-day 15th day.

Primary Outcomes: We will see the effect of *Kukkutanda Pinda Sweda* and *Patra pinda Swedan* on pain, stiffness in neck bones and joints and, restricted neck movements before and after treatment. Data will be expressed as the standard error of the mean at 5% level of significance. It is hypothesized that *Patrapinda Sweda* is more effective than *Kukkutanda pind Sweda* in pain, stiffness in neck bones and joints and, restricted neck movements, with no side effects.

Secondary Outcomes: We will see *Kukkutanda Pinda Sweda* and *Patra pinda swedan* on goniometer parameters reading of all types of neck movement Flexion, Extension, Right Lateral, Left Lateral, Right Rotation, Left Rotation through goniometer device.

Table 1. Property of the drug

Sr.no.	Drug	Ras	Guna	Virya	Vipak	Karma
1.	Kukkutanda (eggs)	Madhur	Laghu, Snigdha	Ushna	Madhur	Vrushya Avidahi Shukravardhak
2.	Go Ghrita	Madhur	Sheeta	Sheeta	Madhur	Dhee, Smriti, Agni Shukral, Vatpittahar
3.	Saindhalavaa	Madhur	Laghu, Snigdha,	Anushnasheet		Tridoshghan, Agnideepak Ruchya, Balya
4.	Tila oil	Madhur	Guru, Snigdha	Ushna	Madhur	Vathar, vedana sthapak

Table 2. List of drugs for the study

Sl.no.	Drug	Ras	Guna	Virya	Vipak	Karma
1.	Nirgundi (Vitex negundo) Leaves	Katu Tikta	Laghu, ruksh	Sheet	Katu	Kaphvat shamak. vednasthapan, Shothhar
2.	Erand(Ricinus communis) Leaves	Madhurr,	Snigdha sukshma tikshna Sar	Ushna	Madhur	Vathar, Kaphvat shamak, dahashamak
3.	Chincha (Tarmindus Indica) Leaves	Madhur, Amla	Laghu, Ruksha	Ushna	Amla	Vatshamak
4.	Dhatura (Datura metel) Leaves	Tikta, katu	Laghu, ruksha vyavyi. vikasi	Ushna	Katu	Madak,
5.	Shigru (Moringa oleifera) Leaves	Tikta, katu	Laghu, ruksha, tikshna	Ushna	Katu	Kaphvat shamak, Shothhar
6.	Arka (Calotropis Procera) Leaves	Katu, Tikta,	Laghu, ruksha, tikshna	Ushna	Katu	Kaphvat shamak, Shothhar, vedanahar
7.	Grated coconut	Mahur	Snigdha, guru	Sheet	Madhur	Vatpittashamak Shool, dahaprashman
8.	Lemon	Amla , Katu	Guru ,ruksha	Ushna	Amla	Vatshlemhar
9.	Rasna	Katu	Guru	Ushna	katu	Vatashamak Vishghan
10.	Saindhava lavana	Madhur	Laghu, Snig dha,	Anushnash eet		Tridoshghan Agnideepak Ruchya, Balya

Table 3. Interventions of both groups

Group	Sample size	Intervention	Abhyanga With Tila Taila	Procedure Time	Duration	Follow-up
A.	30	Kukkutanda pinda Sweda	5minutes	15-20 minutes Or Samyak Swinna Lakshan 10 AM	7 Days	0 th Day, (Base Line) 7 th Day 15 th Day
B.	30	Patra pinda Sweda	5minutes	15-20 minutes Or Samyak Swinna Lakshan 10 AM	7 Days	0 th Day, (Base Line) 7 th Day 15 th Day

- **Statistical analysis:** The study data will generate and collect will be put to statistical analysis to reach the final results and conclusions.
- The demographic data will present in tables and graphs. The data obtained in the studies will subject to tests of significance. Results will express as mean value ± standard deviation (SD) and Median and range (minimum-maximum).
- GraphPad InStat (www.graphpad.com) software will be used for statistical analysis of data.
- For Subjective Parameters:

- a) For within the group comparison (Intra-group comparison): Wilcoxon Matched-Pairs Signed-Ranks Test
- b) For between the group comparison (Inter-group comparison): Mann-Whitney test

P value < 0.05 will be considered significant.

- For Objective Parameters:

Kolmogrov – Smirnov test will be applied to test the normality of data.

For within the group comparison (Intra-group comparison):

- a) Student's Paired t-test will be used when the data pass the normality test.
- b) Wilcoxon Matched-Pairs Signed-Ranks Test will be used when the data fail the normality test.

For between the groups' comparison (Inter-Group Comparison):

- a) An unpaired t-test will be used when the data passed the normality test.
- b) Mann-Whitney will be used when the data failed the normality test.

P value < 0.05 will be considered significant.

- For Discrete Data:

Chi-Square Test for Independence will be applied to compare overall outcome in Group A and Group B.

P value < 0.05 will be considered significant.

Time duration till following up: The patient will be followed up during treatment 15th days.

Follow up period–0, 7th and 15th day

Time schedule of enrolment, interventions: *Kukkutanda pinda Sweda* and *Patra pinda Sweda* will be given 0, 7th, and 15 days at morning 10 AM from 0 to 15th days

Recruitment: 60 (30 in each group) patient will be recruited by randomized, open comparative clinical trial and PI will allocate and enroll the patient.

Methods: Data collection, management, and analysis

Data collection methods: Assessment criteria

3.3 Objective Criteria

X-ray cervical spine, Neck Pain and Disability Index, Cervical goniometer reading. All parameters will be assessed before and after treatment. All patients will stay at the hospital.

Data management: The data entry coding will be done by the Principle investigator.

Statistical methods: Kolmogrov – Smirnov test will be applied to test the normality of data.

Within the group comparison (Intra-group comparison): a) Student's Paired t test will be used when the data pass normality test. b) Wilcoxon matched-pairs Signed-Ranks Test will be used when the data fail the normality test.

For between the groups' comparison (Inter-Group Comparison): c) Unpaired t-test will be used when the data passed the normality test. d) Mann-Whitney will be used when the data failed the normality test. P-value < 0.05 will be considered significant for objective criteria.

Dissemination policy: The data will be disseminated by paper publication. Authorship eligibility guidelines and any intended use of professional writers

Informed consent materials: With all the information, model consent form and other related documentation will be given to participants.

4. DISCUSSION

While explaining the *swedan* procedure, Acharya Charak has told that those procedures that remove the stiffness, heaviness, coldness, and bring sweat are called *swedan* procedures. *Sweda* is internal human body *mala*. *Mala* of *meda dhatu*. *Patra Pinda Swedana* and *Kukkutanda pinda Swedana* uses since Vedic ancient period according to the ancient literature of Ayurveda *laghutriya* and *vrihatriya Samhita* and *tika Rachana* of both ancient sources its help in management of cervical spondylosis successfully [17].

Kukkutanda pinda and *atrapinda sweda* helps in *manyastambha* as *vata kaphahara* and *rujahara*. It pacifies *Vata dosha*, and egg helps to strengthen muscles of the neck and relieves pain. The ingredient of *Patrapinda potali* like *Nirgundi*, *Erand*, *Chincha*, *Dhatura*, *Shigru*, *Arka*, *Rasna* has *Vata slesmahar* properties removes stiffness and alleviate the pain [18,19].

Saindhav Lavan has *vat pitta Kapha shamak* properties and *kaphavilayan-chedana* properties. *Go-Ghrita* is *vatashamak* properties and activity

of *Go-ghrita* as *yogavahi* and *sanskaranuvartan* which helps increase qualities of drugs.

Swedana karma like *Snigdha-swedana* and *ushna-swedana* removes stiffness and pain of muscles and produces sweat from skin, muscles became soft. *Swedana karma* pacifies the *Vata dosha* and *Kapha dosha*. It works on *kaphavilayan* from the all small and large joints of the human body. *Kukkutanda pinda* and *Patra pinda Swedan* has action on vasodilatation, deep tissue stimulation, increases the max amount the blood flow from the area of the applied region, improve oxygen & nutritive materials of drugs absorption and removes toxins from the affected area. *Swedana Karma* acts like a muscle relaxant and reduces the inflammation and pain, and stiffness from the cervical region *manya pradesha*.

The ayurvedic procedure of *swedana* to the cervical disease spondylosis, *manyastambha* is to slack up the degeneration of disc and cervical bones joints and improve the quality of *mansa*, *meda* and *ashthi dhatus* and pacifying the *Vata dosha* and *Kapha dosha*. The *tikshnata* and *ushnata* rates of *Kukkutanda pinda swedana* procedure with *Saindhava-lavana* applied in the method of *Swedana-karma* causes *kaphavilayana* from the affected site and *snehana* and *snigdha guna* of *ghruta* and *ushna guna* of *swedana* will pacify the *Vata dosha*. According to modern *Kukkutanada Madhya pita*, *bhaga* egg yolk strengthens the cartilage of bone and ligament, and muscles. *Patrapinda* and *Kukkutanda sweda* have no complication and easy to practice [20]. *Patrapinda* ingredient readily available in village and herbal garden very cast effective treatment procedure, along with therapies mentioned above, this two procedure of *swedana karma* may be beneficial in corrections of routine daily work, sleeping, travelling, kitchens work official work computers work through preventing the cervical spondylosis. Related studies by Jain et al. [21], Lozano et. al. [22] and Khatib et. al. [23] were reviewed.

Strengths: If *Kukkutanda pinda Sweda* and *Patra pinda Sweda* works, then it directly improve pain, stiffness in neck bones and joints and restricted neck movements. If the proposed study results in a positive outcome, then it will give the best parallel modality for the management of *manyastambha* with protecting and repair degenerative condition and movement of neck and functions.

5. LIMITATIONS

The sample size is so tiny for better results sample size can be added.

6. CONCLUSION

Conclusion will be drawn by suitably analyzing data. It may be concluded that both procedures are effective in the management of *manyastambha*.

CONSENT

The written permission will be taken from the patient before starting the study. During the study, the confidentiality of each patient will be maintained.

ETHICAL APPROVAL

Ethics approval from a research ethics committee has been taken.
Ref.No.MGACHRC/IEC/July-2020/55

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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