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.

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.
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 Siras causing Ruja and Stambha of the neck [6].

Various types of Swedana such as Nadisweda, Prastarasweda, Sankarasweda 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 decreases the pain, stiffness in neck bones and joints and restricted neck movements. Kukkutanda and Patrapinda sweda also known as snigdha pottali 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), Saindhavalavana 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, *Erond* (Ricinus communis) Leaves 25 gram, *Chincha* (Tarmindus 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 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 M48.38),
- 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 pinda 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.    | Saindhavalavaa        | 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, Shothar |
| 2.    | Erand(Ricinus communis) Leaves | Madhur, Snigdhasukshma, tisksna 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 tikshna | Ushna | Katu | Madak,                      |
| 5.    | Shigru (Moringa oleifera) Leaves | Tikta, katu | Laghu, ruksha, tikshna | Ushna | Katu | Kaphvat shamak, Shothar      |
| 6.    | Arka (Calotropis Procera) Leaves | Katu, Tikta, | Laghu, ruksha, tikshna | Ushna | Katu | Kaphvat shamak, Shothar,vedanahar |
| 7.    | Grated coconut         | Mahur | Snigdha, guru | Sheet | Madhur | Vatpittashamak Shool, dahaprasahman, Vatshlemhar |
| 8.    | Lemon                  | Amla, Katu | Guru, ruksha | Ushna | Amla | Vatshamak Tridoshghan Visghan |
| 9.    | Rasna                  | Katu | Guru | Ushna | katu | Vatashamak Tridoshghan Agnideepak Ruchya, Balya |
| 10.   | Saindhavalaavana       | Madhur | Laghu, Snigdha, Anushnash eet |       |       |                            |
Table 3. Interventions of both groups

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

- **Time duration till following up**: The patient will be followed up during treatment 15\(^{\text{th}}\) days.
- **Follow up period**–0, 7th and 15\(^{\text{th}}\) 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 vrhattiya 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 alleviates 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 ashtthi 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 taken. Ref.No.MGACHRC/IEC/July-2020/55

COMPETING INTERESTS
Authors have declared that no competing interests exist.

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