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Efficacy and Safety of Flexineck Soft Gel Capsules in the Management of Cervical Spine-Related Disorders: An Open-Label, Randomized, Non-Comparative Clinical Study

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Abstract

Cervical spine-related disorders such as Cervical spondylosis, Radiculopathy, and Fibromyalgia significantly affect quality of life. Traditional Ayurvedic therapies have shown promise in alleviating musculoskeletal disorders, and the encapsulation of medicated oils represents an innovative oral delivery approach. To evaluate the clinical efficacy and safety of Flexineck soft gel capsules—a polyherbal oil-based formulation—in managing pain and related symptoms of cervical spine disorders a clinical study was carried out. An open-label, randomized, non-comparative clinical study was conducted on 50 participants at Sitaram Ayurveda Private Limited. Patients received 2 Flexineck capsules twice daily for 2 weeks. Pain severity was evaluated using the Visual Analogue Scale (VAS). Inclusion and exclusion criteria were applied based on clinical symptoms and imaging evidence. All participants reported symptomatic relief. 25 out of 50 participants experienced 100% reduction in pain, while others reported moderate to significant improvements. No adverse events were noted. Flexineck capsules were effective and well-tolerated in reducing pain and discomfort in cervical spine-related disorders. The findings suggest a promising integrative approach for musculoskeletal care.

Keywords: Flexi neck, Cervical spondylosis, Joint pain, *Greevagraham*, Softgel capsules, Avartita taila

Introduction

Ayurveda, the classical system of healthcare originating in India is a a holistic science that emphasize harmony between the body, mind, and spirit. Its name is derived from the Sanskrit terms *Ayuh* (life) and *Veda* (knowledge), reflecting its foundational goal of promoting long, healthy living through a personalized approach. This traditional medical system is rooted in the concepts of individual constitution (*Prakriti*), the balance of functional energies (*Doshas—Vata*, *Pitta*, and *Kapha*), and the quality of digestive and metabolic function (*Agni*).[1] What distinguishes Ayurveda is its focus on addressing the root causes of illness, rather than just managing symptoms. Ayurvedic formulations are offered in various dosage forms—*tailas* (medicated oils), *ghritas* (medicated ghee), *kashayams* (decoctions), *churnas* (powders), and *vatis* (tablets or pills). Among them, medicated oils have a prominent place in treating neuromuscular and joint conditions, especially those related to *Vata* imbalance.[1]

Neck pain and cervical spine disorders are becoming increasingly common in clinical practice. These conditions are often associated with modern sedentary lifestyles, prolonged screen exposure, and age-related spinal degeneration. The cervical region, which supports head movement and posture, is particularly vulnerable to mechanical stress and degenerative changes. Conditions such as cervical spondylosis, radiculopathy, and fibromyalgia can cause a wide range of symptoms including neck stiffness, restricted movement, radiating pain, and neurological complaints such as tingling or numbness.[2,3]

Conventional medical approaches such as non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, physiotherapy, and surgical interventions offer temporary relief but often fall short of delivering sustained improvement. Moreover, long-term use of such treatments can lead to side effects or complications. These limitations have generated growing interest in integrative and traditional treatment strategies.[4]

In Ayurvedic terminology, cervical disorders are often understood in terms of *Greeva Stambha*, *Vata Vyadhi*, or *Greeva Graha*, with a primary role attributed to the vitiation of *Vata Dosha*. When accompanied by *Kapha* or *Ama* (metabolic toxins), these conditions may become more chronic and complex. Management focuses on pacifying disturbed *Doshas*, removing accumulated toxins, and supporting tissue regeneration through a combination of internal and external therapies such as *Snehana* (oleation), *Swedana* (sudation), *Basti* (medicated enemas), and herbal formulations with nourishing and anti-inflammatory actions.[5]

Among internal remedies, medicated oil formulations used in *Sneha Pana* are traditionally prescribed in *Vata Vyadhis*, including joint and spinal disorders. However, the strong taste and texture of oils often pose considering the convenience of patients. To improve palatability, dosing precision, and bioavailability, advancements in pharmaceutical delivery have been applied to the development of oil-based soft gel capsules.

Soft gel capsules are a modern dosage form that encapsulates oils or semi-solid fills in gelatin-based shells. This form offers several advantages: enhanced absorption of lipophilic herbal compounds, improved stability of ingredients, precise dosing, and greater ease of administration. By masking taste and odour, they also improve compliance, especially in long-term therapies.[6]

This study was undertaken to assess the clinical efficacy and safety of Flexineck soft gel capsules in individuals experiencing cervical spine-related symptoms. By integrating classical Ayurvedic wisdom with contemporary pharmaceutical innovations, this research aims to validate a comprehensive, patient-friendly, and effective approach to managing chronic neck pain and musculoskeletal discomfort.

Materials and Methods

Product Formula

Flexineck, the subject of this study, is a polyherbal soft gel capsule formulation based on a traditional taila preparation used in *Vata Vyadhi* management. The formulation includes 23 carefully selected herbs processed through triple *avarti* (three cycles of Sneha Kalpana) in *Tila Taila* (sesame oil) and *Kshira* milk, are mentioned in the table no 1.

Table no:1 Ingredients of Flexineck softgel capsule

Sl. No.	Sanskrit name	Botanical name	Parts used	Quantity of raw material- Packing size (1 capsule or 700 mg)
1.	Bala	*Sida cordifolia*	Root	180mg
2.	Masha	*Vigna mungo*	Seed	180mg
3.	Prasarini	*Merremia tridentata*	Whole plant	180mg
4.	Erandam	*Ricinus communis*	Root	45mg
5.	Sundi	*Zingiber officinale*	Rhizome	45mg
6.	Lasunam	*Allium sativum*	Bulb	45mg
7.	Rasna	*Alpinia galanga*	Rhizome	45mg
8.	Aswagandha	*Withania somnifera*	Root	45mg
9.	Bala	*Sida cordifolia*	Root	45mg
10.	Gokshura	*Tribulus terrestris*	Fruit	45mg
11.	Guggulu	*Commiphora mukul*	Exudate	45mg
12.	Prasarini	*Merremia tridentata*	Whole plant	45mg
13.	Punarnava	*Boerhaavia diffusa*	Root	45mg
14.	Rasna	*Alpinia galanga*	Rhizome	45mg
15.	Saindhavam	Rock salt	As such	45mg
16.	Sathavari	*Asparagus racemosa*	Root Tuber	45mg
17.	Pippali	*Piper longum*	Fruit	4.6mg
18.	Maricham	*Piper nigrum*	Fruit	4.6mg
19.	Sundi	*Zingiber officinale*	Rhizome	4.6mg
20.	Vidarikhandha	*Pueraria tuberosa*	Tuber	45mg
21.	Varahikhandha	*Tacca aspera*	Tuber	45mg
22.	Kshira	Cow's milk	As such	3ml
23.	Thila taila	Sesame oil	As such	3ml

Method of preparation

The preparation of *Dusparsakadi Kashaya* began with carefully washing, drying, and disintegrating the first set of ingredients (1–7) to prepare the decoction base, ensuring minimal processing loss. The remaining ingredients (8–21) were finely powdered to form the herbal paste (*Kalka*). The disintegrated herbs were then boiled with water in a drug boiler and reduced to one-fourth of the original volume. Once the total solid content reached the desired level, a sample was tested and approved by the quality control team. The filtered decoction was then transferred to a clean boiling pan, where it was combined with the herbal paste, milk, and sesame oil. This mixture was gently heated and continuously stirred, monitoring the consistency of the paste until moisture was fully removed, as indicated by the absence of a crackling sound. To enhance potency, this entire process—adding fresh herbal paste, milk, and decoction to the same oil—was repeated two more times (three *Avarthis* in total). The final product was then filtered and allowed to cool, yielding a potent, traditionally processed Ayurvedic oil.

Study Design

An open-label, randomized, non-comparative clinical study was conducted to evaluate the safety and efficacy of Flexi Neck, an Ayurvedic proprietary medicine developed by Sitaram Ayurveda. The study was carried out over a period of two weeks at the clinical facility of Sitaram Ayurveda Private Limited (SAPL). A total of 50 patients were enrolled and randomized to receive Flexi Neck as per the prescribed regimen. This pilot investigation is aimed to observe the therapeutic potential of the formulation in improving neck mobility and reducing associated symptoms, providing preliminary insights into its clinical relevance in musculoskeletal care.

Selection criteria

Inclusion Criteria

1. Typically, participants between 18 to 70 years old.
2. Participants in whom for Cervical spondylosis, Fibromyalgia or related conditions, such as Cervical radiculopathy are diagnosed.
3. Patients with arm pain with or without other symptoms for e.g., numbness, paraesthesia (Pin and needle sensation)
4. Neck symptoms including pain, swelling, tenderness, numbness, weakness, muscle spasms, limited range of movements or functional limitations in neck movement.
5. Participants in whom the image findings (X- ray, MRI) suggests Cervical spondylosis, presence of Osteophytes, Disc space narrow owing, calcified or ossified soft tissue etc.

Exclusion Criteria

1. Participants with cervical myelopathy
2. Pregnant or lactating women
3. Participants with a history of Cervical spine surgery.
4. Patients with neoplastic diseases, severe allergic reactions to non-steroidal anti-inflammatory drugs (NSAIDs) etc.
5. Presence of autoimmune diseases or significant undercurrent illnesses that could affect participation

Informed Consent: All participants were provided with written informed consent for their data to be used in the study.

Intervention

Table no:2 shows the details of the intervention of the clinical study

Details of Treatment Particular	Details
No of patients	50 patients
Route of administration	Oral route
Time of administration	After breakfast and After Dinner
Medicine	2 Flexi neck softgel capsules
Duration	14 days
Anupana	Koshnajala
Assessment day	0- Before starting the treatment 1- 1 st - after completion of treatment on 16th day

	2- 2 nd -Assessment after 1month of completion of treatment of 15 days
Pathya-Apathya	Avoid Direct exposure to cold wind and Sunlight

Assessment

Study Objectives

Primary Objectives:

- To evaluate the efficacy of soft gel capsules containing medicated oil in reducing pain, stiffness, and inflammation in patients with Cervical spondylosis.
- To assess the safety and tolerability of this formulation for long-term use.
- Change in pain intensity using the Visual Analogue Scale (VAS) (0–10).
- Pain grading:
  - 0: No pain
  - 1–3: Mild pain
  - 4–6: Moderate pain
  - 7–10: Severe pain

Secondary Objectives:

- To compare the outcomes of soft gel medicated oil capsules with conventional treatments in terms of patient-reported pain relief and quality of life improvements.
- To explore the mechanism of action by analysing biomarkers of inflammation and oxidative stress in participants.

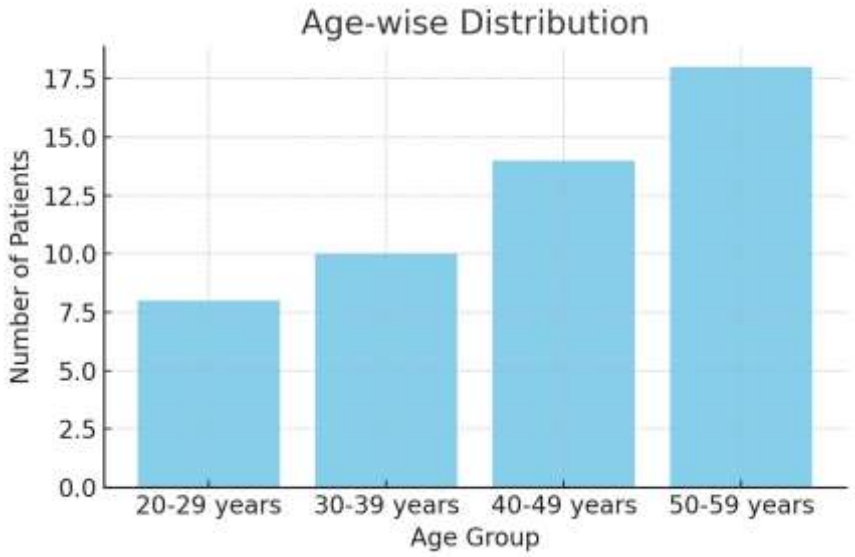
Results

1. Age-wise Distribution

Among the 50 patients enrolled in the study, the age distribution was as in table no:3. The majority of participants belonged to the 50–59 age group, indicating a higher prevalence of Cervical musculoskeletal issues in this bracket.

Table no 3 shows the patients' categorisation-based on the age group.

Age Group	Number of Patients
20–29 years	8
30–39 years	10
40–49 years	14
50–59 years	18

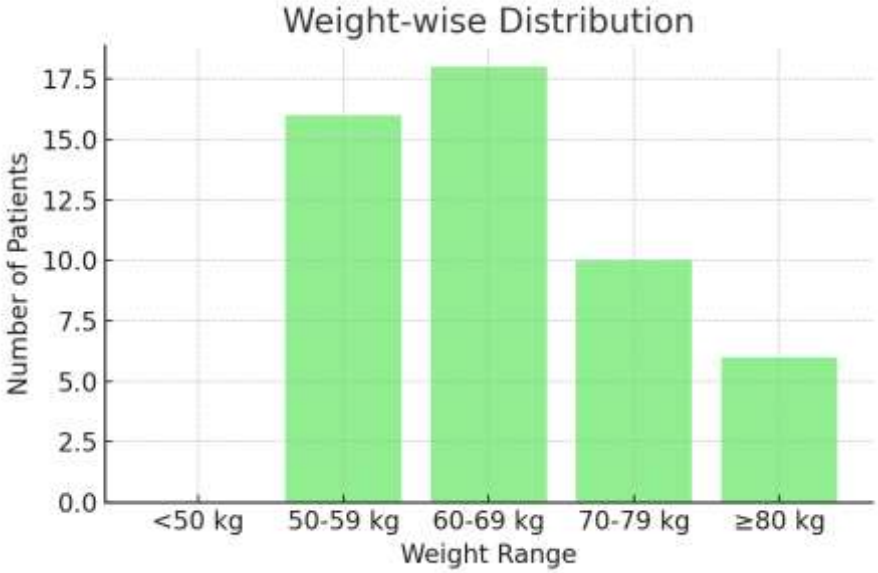


2. Weight-wise Distribution

The weight distribution of patients is detailed below in table no 4. Most patients fell within the 50–69 kg range, which aligns with typical demographic weights for adult patients experiencing cervical discomfort.

Table no 4 shows the weight range of the patients enrolled.

Weight Range	Number of Patients
<50 kg	0
50–59 kg	16
60–69 kg	18
70–79 kg	10
≥80 kg	6



3. Symptom-wise Distribution (Before Treatment)

Patients reported a variety of symptoms, most of them experiencing more than one issue as shown in table no: 5. Shoulder pain and tenderness were the most frequently reported symptoms.

Table no: 5 shows the Symptom-wise Distribution (Before Treatment)

Symptom Type	Number of Patients
Shoulder pain	35
Neck pain / Cervical involvement	22
Swelling	24
Tenderness	30
Pain radiating to arms/hands	20
Elbow joint pain	10
Upper / mid back pain	15

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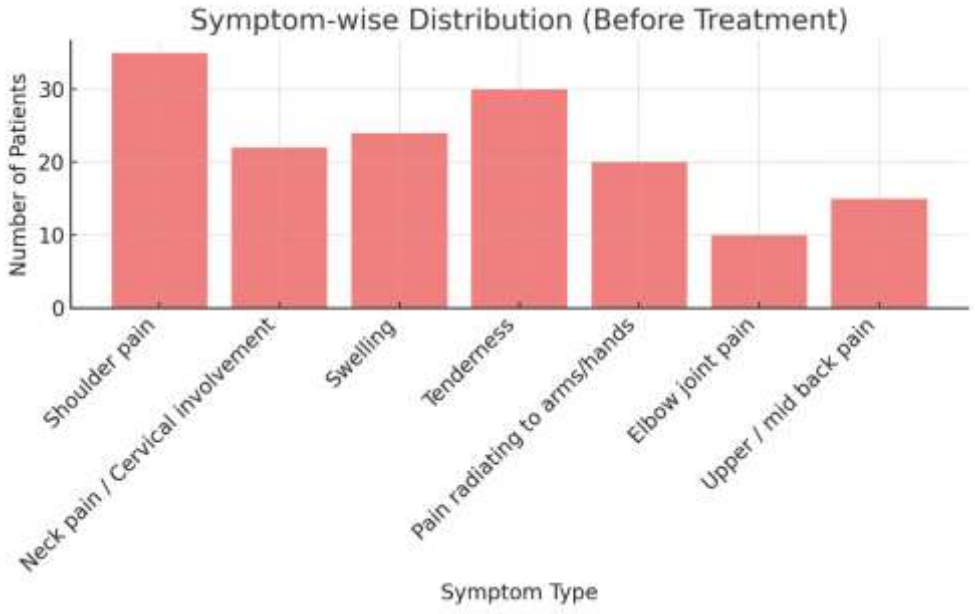


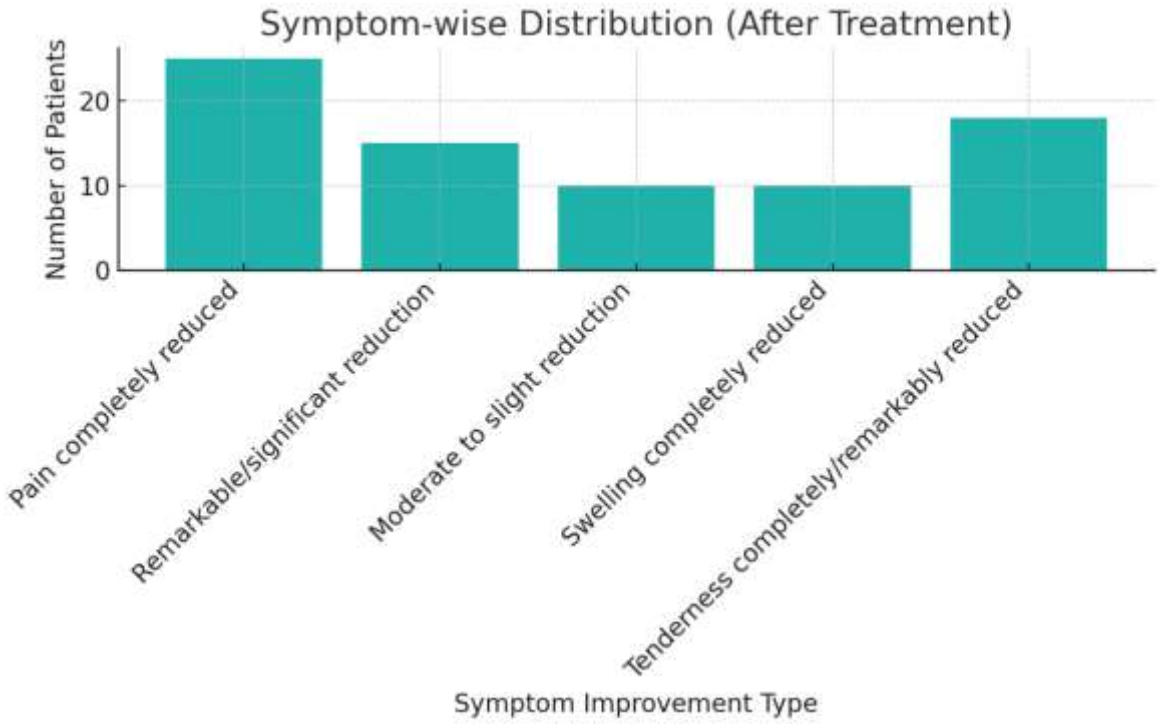
4. Symptom-wise Distribution (After Treatment)

The symptom reduction observed during post-intervention period is summarized in table no 6. The formulation showed promising results in managing pain and associated symptoms, with a majority reporting complete or substantial relief.

Table no: 6 Shows the Symptom-wise Distribution (After Treatment)

Symptom Improvement Type	Number of Patients
Pain completely reduced	25
Remarkable/significant reduction	15
Moderate to slight reduction	10

Symptom Improvement Type	Number of Patients
Swelling completely reduced	10
Tenderness completely/remarkably reduced	18



5.Pain Grading Analysis (Before Trial vs After Trial)

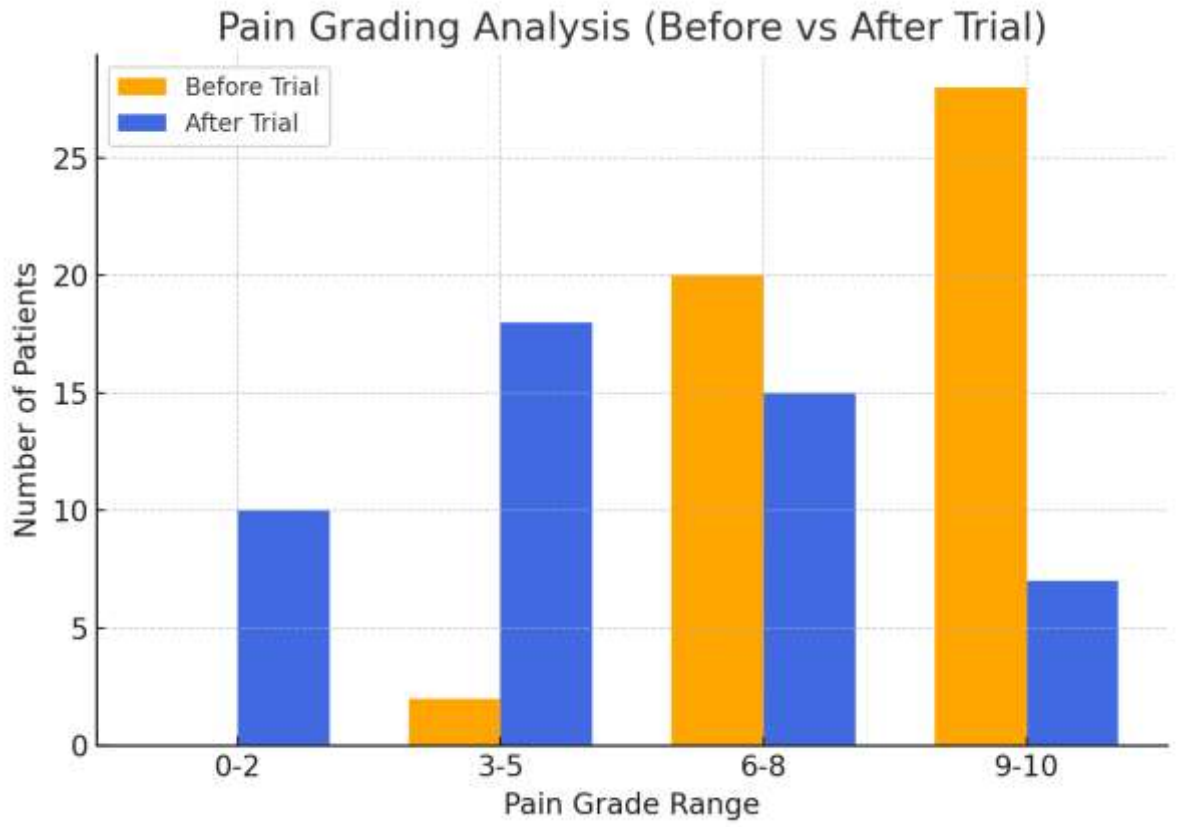
There was a clear shift in pain grading, with a significant number of patients moving from severe pain (9–10) to moderate or mild levels which is shown in the table no 7.

- Mean Pain Score (BT): 7.15 ± 1.32
- Mean Pain Score (AT): 2.20 ± 1.85
- Average Pain Reduction: 69.23%

This reduction demonstrates statistically and clinically significant relief following the intervention with Flexineck soft gel capsules.

Table no: 7 shows the Pain grading analysis (Before Trial vs After Trial)

Pain Grade Range	No. of Patients (BT)	No. of Patients (AT)
0–2	0	10
3–5	2	18
6–8	20	15
9–10	28	7



6. Pain Relief Classification

Out of the 50 participants table no 8 shows the Pain relief classification.

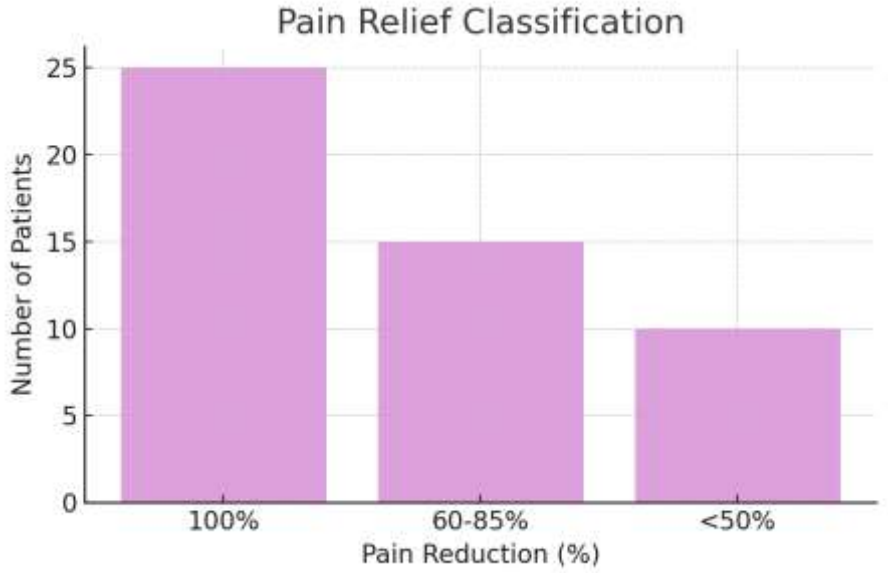
- 25 patients (50%) reported complete pain relief (VAS score of 0)
- 15 patients (30%) showed substantial improvement (VAS reduced by 60–85%)
- 10 patients (20%) reported moderate or mild improvement (VAS reduced by <50%)

Table no: 8 shows the Pain relief classification.

Pain Reduction (%)	Number of Patients
100%	25
60–85%	15
<50%	10

Out of the 50 participants:

- 25 patients (50%) reported complete pain relief (VAS score of 0)
- 15 patients (30%) showed substantial improvement (VAS reduced by 60–85%)
- 10 patients (20%) reported moderate or mild improvement (VAS reduced by <50%)



Discussion

This pilot study highlights the promising therapeutic potential of *Flexineck* soft gel capsules in the management of Cervical spine-related disorders, particularly those marked by pain, stiffness, and radiating discomfort. Over a two-week intervention period involving 20 participants, the formulation demonstrated significant pain relief, with 65% of patients reporting complete resolution and another 25% experiencing substantial improvement. Only two participants showed mild relief, indicating a generally favourable outcome for the majority.

The mean baseline pain score on the Visual Analogue Scale (VAS) was 7.15 ± 1.32, reflecting moderate to severe pain levels. Post-treatment, the average score dropped to 2.15 ± 1.90, accounting for a 70% mean reduction. The consistency of these outcomes across most participants is further supported by the low standard deviation, suggesting a reliable therapeutic effect of the intervention.

Flexineck combines traditional Ayurvedic wisdom with modern pharmaceutical technology. The encapsulated lipid-based delivery system ensures enhanced bioavailability of lipophilic herbal actives, while improving patient compliance over conventional external applications. The absence of adverse reactions throughout the study also affirms the formulation's safety and tolerability.[7]

From an Ayurvedic perspective, cervical musculoskeletal pain is primarily linked to *Vata* vitiation affecting *Asthi* (bone) and *Majja Dhatu* (nervous tissue). The ingredients in *Flexineck*—including *Bala, Guggulu, Rasna, Eranda,* and *Nirgundi*—are well-documented in classical texts for their anti-inflammatory, analgesic, adaptogenic, and tissue-regenerating properties. These herbs work synergistically to address both the symptoms and root imbalances contributing to cervical dysfunction.[8]

The observed clinical benefits suggest that *Flexineck* may serve as a viable alternative or adjunct to conventional therapies such as NSAIDs and muscle relaxants, especially for patients seeking holistic options with fewer side effects. And this study supports the efficacy and safety of *Flexineck* soft gel capsules for the short-term management of cervical spine disorders. Its integrative approach, blending classical Ayurvedic principles with contemporary formulation science, holds promise for broader applications in musculoskeletal care.

Conclusion

This preliminary clinical study suggests that *Flexineck* soft gel capsules may offer an effective and well-tolerated solution for managing pain and discomfort associated with cervical spine disorders. Most participants experienced noticeable relief within just two weeks, without any reported side effects. The formulation's success can likely be credited to its thoughtfully chosen Ayurvedic ingredients known for their pain-relieving and *Vata*-balancing properties and the use of a modern soft gel format, which may help the body absorb the herbs more efficiently. *Flexineck* stands as a strong example for how traditional medicine can be innovatively adapted to meet contemporary therapeutic needs.

Reference:

1. *Ashtanga Hridayam*, Sutrasthana, Chapter 1. In: Paradkar HS, editor. Varanasi: Krishnadas Academy; 2000.
2. Wang Y, Li J, Wang H, et al. Sedentary behavior and risk of neck pain: a systematic review and meta-analysis. *BMC Public Health*. 2025;25(1):123.
3. Borenstein D. Cervical spondylosis and neck pain. *Bull World Health Organ*. 2000;78(8):1040-1046.
4. Yasir M, Goyal A, Sonthalia S. Corticosteroid Adverse Effects. [Updated 2023 Jul 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK531462/
5. Bharti, Katyal S, Kumar A, Makhija R, Devalla RB. Clinical observation on Greeva Stambha (cervical spondylosis) Chikitsa. Ayu. 2010 Apr;31(2):218-22. doi: 10.4103/0974-8520.72402. PMID: 22131713; PMCID: PMC3215367.
6. Gullapalli, Rampurna. Soft Gelatin Capsules (Softgels). Journal of pharmaceutical sciences. 2010.99. 4107-48.
   Furst DE, et al. Herbal medicine in musculoskeletal diseases. *Rheum Dis Clin North Am*. 2011;37(1):11-23.
7. Ezike TC, Okpala US, Onoja UL, Nwike CP, Ezeako EC, Okpara OJ, Okoroafor CC, Eze SC, Kalu OL, Odoh EC, Nwadike UG, Ogbodo JO, Umeh BU, Ossai EC, Nwanguma BC. Advances in drug delivery systems, challenges and future directions. Heliyon. 2023 Jun 24;9(6):e17488.
8. Deepak Srivathsav D, G Nidhi, Yadu Gopan, Vibhu Powar, Lakshmiprasad L Jadhav, Ayurveda management of Adharanga Vata (Cervical Myelomalacia) – A Case Report. J Ayu Int Med Sci. 2022;7(4):161-167.