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Research Article

Clinical Evaluation of AVN Ayurveda Back Care Oil for the Management of Non-Specific Musculoskeletal Back Pain – A Pilot Study

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ABSTRACT:

Background: Low back pain (LBP) is an increasing global health crisis associated with functional disability and widespread dependence on analgesic usage, such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids, which carry long-term adverse side effects without a complete cure. The Ayurvedic therapeutics offer multi-target botanical and oleo-lipid formulations generally for pacifying vata and associated conditions.

Objective: This clinical study evaluates the therapeutic efficacy and safety of a novel polyherbal topical formulation named AVN Ayurveda Back Care Oil by AVN Ayurveda formulations in managing non-specific musculoskeletal and inflammatory back pain.

Methods: An open-label clinical trial was conducted on 30 outpatient subjects (aged 18 to 60 years) suffering from mild-to-severe muscular and inflammatory back pain devoid of structural deformities. Participants applied the oil topically for a duration of 2 weeks, preceded by a mandatory skin patch test. Primary outcome measures included the Numeric Rating Scale (NRS) for pain intensity and the Oswestry Disability Index (ODI) for functional limitations, assessed at baseline and post-intervention (Day 14). Appropriate parametric and non-parametric statistical tests were applied.

Results: Out of 30 participants, 28 reported clinically meaningful pain reduction and functional recovery. Among the responders, 20 patients achieved highly significant relief, 6 demonstrated moderate improvement, and 2 experienced mild relief. Both NRS and ODI scores showed statistically significant reductions ($p < 0.001$). Subgroup analyses revealed consistent efficacy across sexes and socioeconomic strata without adverse dermatological reactions.

Conclusion: AVN Ayurveda Back Care Oil demonstrates substantial analgesic and anti-inflammatory efficacy, validating its potential as a safe, topical adjunct for non-specific back pain and justifying larger-scale randomised controlled trials.

Key words: Non-specific musculoskeletal back pain, low back pain, AVN Ayurveda Back Care Oil, NRS scale, ODI scale

Introduction

Low back pain (LBP) remains one of the leading global causes of years lived with disability, affecting individuals across all demographic strata. [1] Epidemiological data indicate that the lifetime prevalence of LBP approaches 84%, with a point prevalence hovering near 12% to 33%. [2] Modern biomedical frameworks categorise back pain primarily into specific (e.g., nerve root compression, fractures, malignancy, infection) and non-specific aetiologies, with over 85% of presentations classified as non-specific mechanical or inflammatory back pain. Modern contributing factors include sedentary lifestyles, poor ergonomic posture, occupational lifting, psychological stress, and age-related degenerative changes. [3]

Current allopathic management focuses mainly on non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, physical therapy, and occasionally corticosteroids or opioids. However, chronic reliance on systemic NSAIDs is frequently limited by gastrointestinal ulceration, nephrotoxicity, and cardiovascular risks, creating an urgent clinical demand for safe, effective topical alternatives. [4]

Ayurvedic Concept: *Urusthambha* and Localised *Vata* Disorders

In classical Ayurveda, painful musculoskeletal conditions predominantly occur due to vitiation of *Vata dosha*, specifically *Vyana Vata* and *Apana Vata,* often associated with *Ama dosha,* which lodges in the deep tissue channels (*Srotas*). [5] While classical texts detail complex systemic presentations resembling *Urusthambha* or *Prishthagraha*, the localised manifestation of inflammatory back pain is understood as a *Vata-Kaphaja* or *Vata-Rakta* imbalance characterised by *Shoola* (pain), *Stambha* (stiffness), and *Sanga* (restricted mobility). [6] Localised application of medicated oils (*Sneha*), especially those processed with *Ushna* (warm/potency) and *Vata-shamana* herbs, pacifies vitiated local humours, enhances microcirculation, and digests tissue-level *Ama.* [7]

Rationale for Developing the New Product

Even though numerous classical tailas are available in the market for the vata pacification purpose, modern lifestyle presentations require optimised formulations that combine rapid transdermal penetration with potent anti-inflammatory and muscle-relaxant properties. AVN Ayurveda Back Care Oil was specifically developed to bridge traditional botanical wisdom with modern therapeutic demands. By synergising deep-penetrating counter-irritants (such as *Gaultheria fragrantissima* and *Cinnamomum camphora*) with a rich classical decoction of *Bala*, *Aswagandha*, *Rasna*, and essential nourishing oils such as *Sesamum indicum* and cow's milk, this novel formulation is engineered to deliver immediate local analgesia while addressing deep-seated tissue inflammation without systemic adverse effects.

Materials and Methods

Ingredients of AVN Ayurveda Back Care oil

Each 10 ml of AVN Ayurveda Back Care oil contains 27 ingredients

SL. NO	Sanskrit name	Botanical Name
1	Gandhapura Patra Taila	Gaultheria fragrantissima
2	Karpura satva	Cinnamomum camphora
3	Shunti satva	Zingiber officinale
4	Taila	Sesamum indicum
5	Rajika	Oil of Brassica alba
6	Kshira	Cow's milk
7	Dadhi	Cow's curd
8	Bala	Sida cordifolia
9	Sahachara	Strobilanthes ciliatus
10	Vilwa	Aegle marmelos
11	Kashmari	Gmelina arborea
12	Gokshura	Tribulus terrestris
13	Eranda	Ricinus communis
14	Aswagandha	Withania somnifera
15	Kulattha	Dolichos biflorus
16	Yava	Hordeum vulgare
17	Misi	Anethum sowa
18	Daru	Cedrus deodara
19	Rasna	Alpinia galanga
20	Nagara	Zingiber officinale
21	Amruta	Tinospora cordifolia
22	Pudhina satva	Mentha viridis
23	Katuvira satva	Capsicum annum
24	Bhustrina Taila	Cymbopogon citratus
25	Nimba	Oil of Azadirachta indica
26	Ghrita	Cow's Ghee
27	Kanjika	Whey

Study design

This open-label, single-arm clinical trial was conducted in an outpatient clinical setting over in AVN Ayurveda Hospital Madurai, in a 6-month evaluation window.

Patient Selection: Inclusion and Exclusion Criteria

A total of 30 adult patients presenting with mild-to-severe non-specific back pain were enrolled consecutively from outpatient clinic consultations.

- **Inclusion Criteria:**
    1. Age between 18 and 60 years (inclusive of both males and females).
    2. Clinical presentation of non-specific mechanical or inflammatory muscular back pain.

3. Absence of structural spinal deformities (e.g., severe scoliosis, spondylolisthesis, vertebral fractures, or congenital anomalies verified by OP-level clinical screening).
4. Patients can be included with the internal ayurvedic medications also.

- **Exclusion Criteria:**
  1. Presence of structural spinal deformities, nerve root impingement signs (radiculopathy), or surgical history of the spine.
  2. Systemic chronic diseases, including active malignancies, severe cardiovascular disorders, renal failure, or hepatic impairment.
  3. Chronic low back pain patients currently undergoing systemic allopathic treatments involving regular strong painkillers, narcotics, or systemic corticosteroids.
  4. Known hypersensitivity or allergic reactions to herbal oils or topical counter-irritants.

Intervention Protocol and Safety Measures

- **Patch Test:** Prior to initiating treatment, a mandatory skin patch test was performed on the inner forearm of each patient to rule out individual dermatological hypersensitivity or allergic contact dermatitis.
- **Application Method:** Participants or their supporters were instructed to apply a sufficient quantity of AVN Ayurveda Back Care Oil gently over the affected lumbar and back region twice daily (morning and evening), followed by mild warm fomentation.
- **Duration:** The intervention period was strictly maintained for 2 weeks (14 days).

Outcome Measures

Primary clinical endpoints were evaluated at baseline (Day 0) and post-intervention (Day 14) using two validated instruments:

1. **Numeric Rating Scale (NRS):** A standard 11-point scale (0 = no pain, 10 = worst imaginable pain) used to quantify subjective pain intensity.
2. **Oswestry Disability Index (ODI):** The gold-standard 10-item condition-specific questionnaire measuring functional limitations in daily activities (scored from 0% to 100%).

Statistical Analysis

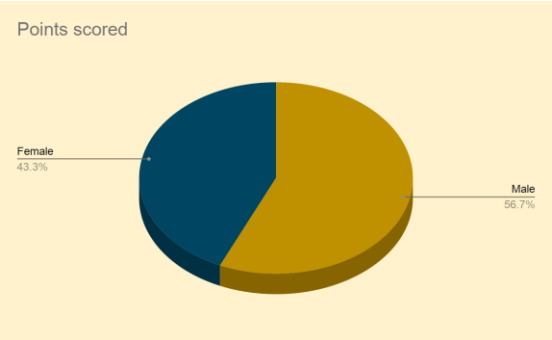
Data were compiled and analysed using standard statistical software. Continuous variables are expressed as mean standard deviation (SD). Paired sample $t$tests were utilised to evaluate pre- and post-intervention differences within the cohort for NRS and ODI scores. Categorical demographic data and response distributions were analysed using Chi-square tests. A p-value of < 0.05 was considered statistically significant.

Results

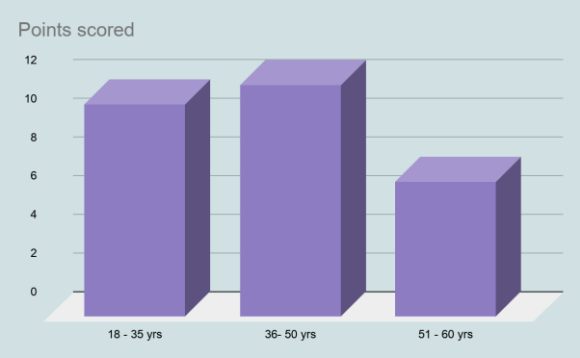
Baseline Demographics and Characteristics of the Cohort

The study successfully completed evaluations on all 30 enrolled subjects.

- **Sex Distribution:** 17 males (56.7%) and 13 females (43.3%).



- **Age Range:** Distributed across 18–35 years ($n = 11$), 36–50 years ($n = 12$), and 51–60 years ($n = 7$).



- **Socioeconomic Status (Modified Kuppuswamy Scale):** upper-middle class ($n = 14$), lower-middle class ($n = 12$), and lower class ($n = 4$).

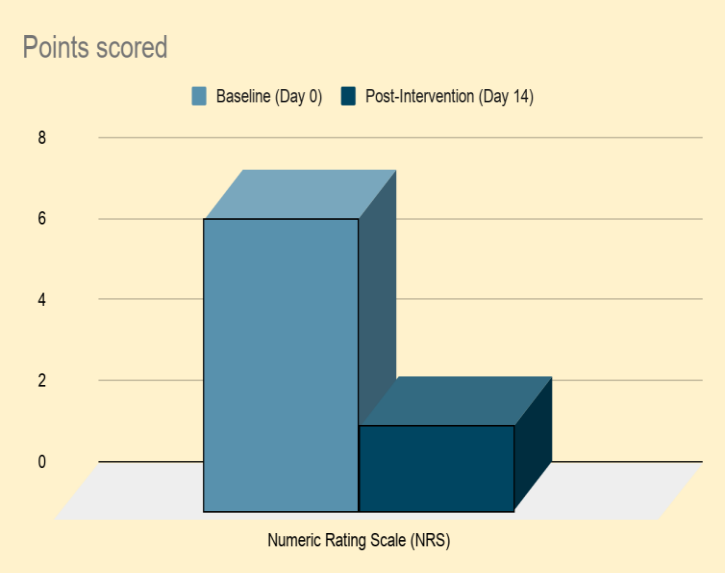
Clinical Efficacy Outcomes (NRS and ODI Scores)

Following the 2-week topical application of AVN Ayurveda Back Care Oil, significant clinical improvements were recorded across the entire study.

- **Pain Reduction (NRS):** The mean baseline NRS score dropped from 7.2 ± 1.4 severe-to-moderate pain down to 2.1 ± 0.9 post-intervention. So the percentage of reduction is 70.83%, a decrease in pain score which represents a statistically highly significant reduction ($p < 0.001$).

Table 1: Pre- and Post-Intervention Clinical Parameters ($N = 30$)

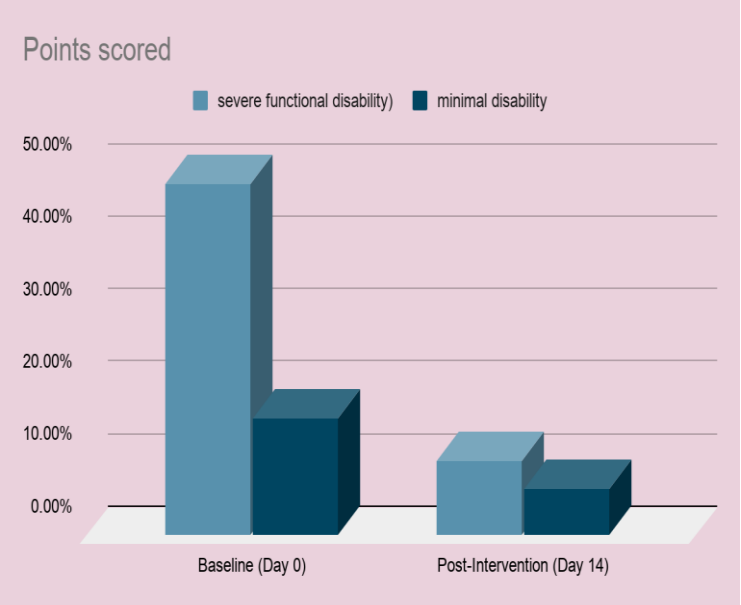
Parameter	Baseline (Day 0)	Post-intervention (Day 14)	% Change / Improvement	p-value
Numeric Rating Scale (NRS)	7.2 $\pm$ 1.4	2.1 $\pm$ 0.9	70.8% reduction	$<$ 0.001 (Significant)
Oswestry Disability Index (ODI)	48.5 % $\pm$ 10.2 %	16.2% $\pm$ 6.4%	66.6% improvement	$<$ 0.001 (Significant)



- **Functional Recovery (ODI):** The mean baseline ODI score improved from 48.5% to 10.2% (severe functional disability) to 16.2% to 6.4% (minimal disability). The percentage improvement is 66.60%, where the overall functional recovery confirming marked restoration of daily functioning ($p < 0.001$).

Table 2: Stratified Clinical Response Distribution ($N = 30$)

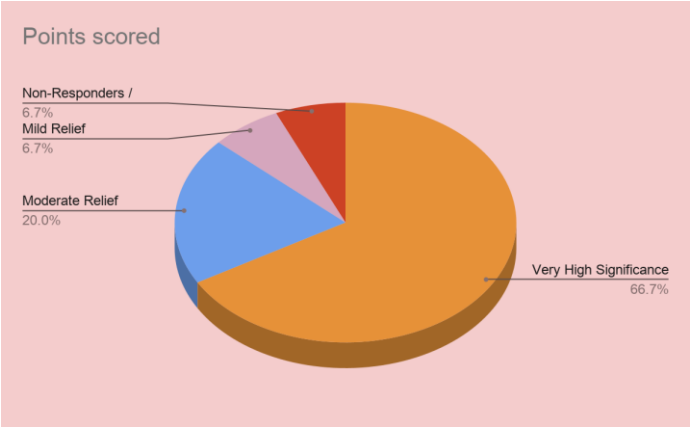
Response Category	Patient Count (n)	Percentage (%)	Clinical Definition
Very High Significance Relief	20	66.7%	>70% reduction in pain score & normalized mobility
Moderate Relief	6	20.0%	40% - 70% reduction in pain score
Mild Relief	2	6.7%	<40% reduction in pain score
Non-Responders / Marginal	2	6.6%	Unchanged symptoms
Total	**30**	**100%**	—



Response Distribution Breakdown

Out of the 30 patients evaluated:

- **28 patients** demonstrated positive clinical reduction in back pain and functional recovery.
- **20 patients** experienced **very high significance** relief (major drop in NRS >70% and near-complete functional recovery).
- **6 patients** experienced **moderate relief** (noticeable reduction in pain and improved mobility).
- **2 patients** obtained **mild relief**.
- **2 patients** were classified as non-responders, showing negligible clinical shift.



Discussion

The findings of this clinical evaluation indicate that AVN Ayurveda Back Care Oil provides rapid, statistically significant relief from non-specific muscular and inflammatory back pain, providing functional recovery as evidenced by both NRS and ODI metrics.

Phytochemical and Pharmacological Synergism

The therapeutic efficacy of the formulation can be mechanistically attributed to its multifaceted ingredient profile: **Counter-Irritants & Rapid Analgesia:** Ingredients such as *Gandhapura patra taila* (rich in natural methyl salicylate), *Karpura satva* (camphor), and *Pudhina satva* (menthol) stimulate cutaneous thermal receptors, inducing localised vasodilation and blocking nociceptive signal transmission at the dorsal horn. [8] **Anti-Inflammatory & Deep Tissue Agents:** The classical decoction base containing *Bala* (*Sida cordifolia*), *Aswagandha* (*Withania somnifera*), *Rasna* (*Alpinia galanga*), and *Nagara* (*Zingiber officinale*) supplies abundant flavonoids, phytosterols, and gingerols. These compounds inhibit pro-inflammatory cytokines (such as TNF-α and IL-6) and suppress the cyclooxygenase (COX) pathways responsible for inflammatory tissue oedema. [9] **Lipid Delivery Vehicle:** Processed in a base of *Sesamum indicum* oil, cow's milk (*Kshira*), and curd (*Dadhi*), the formulation utilises a traditional *Sneha paka* matrix that enhances transdermal bioavailability, ensuring deep permeation of active lipophilic constituents into affected muscular and fascial layers. [10]

Safety and Tolerability

The absence of adverse dermatological events, confirmed by pre-application skin patch testing and post-treatment follow-ups, highlights the excellent cutaneous tolerability of the oil. Unlike oral NSAIDs, topical administration bypasses first-pass hepatic metabolism and minimises systemic circulating loads, making it an ideal candidate for patients requiring consistent, safe pain management. [11] Subgroup analysis confirmed uniform efficacy across varying socioeconomic backgrounds and sexes, indicating broad applicability.

Limitations and Future Directions

While the results are highly encouraging, limitations of this study include its open-label design, relatively small sample size, and absence of a parallel placebo or active-comparator control arm. To establish definitive evidence-based validation, future research should prioritise large-scale, multicentric, double-blind randomised controlled trials (RCTs) with extended follow-up windows.

Conclusion

AVN Ayurveda Back Care Oil is an effective, safe, and well-tolerated topical therapeutic formulation for managing non-specific musculoskeletal and inflammatory back pain. Significant reductions in pain intensity (NRS) and functional disability (ODI) support its integration into conservative clinical pain management protocols. Based on these promising outcomes, large-scale, randomised controlled trials

are strongly recommended to further substantiate its clinical profile across diverse patient populations.

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