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Evaluation of the efficacy of Saplint plus roll-on in the treatment of acute myalgia: A prospective, open-label, single-arm clinical trial

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Abstract

Background: Myalgia, or muscle pain, is a prevalent condition with diverse etiologies ranging from overuse to viral infections. Conventional treatments, while effective, often carry risks of adverse effects with prolonged use. Saplint Plus Roll-On, an Ayurvedic formulation, offers a non-invasive, herbal approach to pain relief.

Objective: To evaluate the efficacy of Saplint Plus Roll-On in the management of acute myalgia over a 7-day period.

Methods: A single-arm, open-label, prospective clinical trial was conducted involving 100 patients diagnosed with acute myalgia. Participants applied Saplint Plus Roll-On three times daily. Efficacy was assessed using the Visual Analog Scale (VAS), Patient Global Assessment, and Modified Oswestry Disability Index (ODI).

Results: The mean VAS score reduced from 7.5 at baseline to 2.0 on Day 7 (73% reduction, $p < 0.01$). The mean ODI score improved from 45.2 to 25.3 ($p < 0.01$). No adverse events were reported.

Conclusion: Saplint Plus Roll-On significantly reduced pain and improved functional ability in patients with acute myalgia, offering an effective alternative to conventional analgesics.

Keywords: Acute Myalgia; Saplint Plus Roll-On; Ayurvedic Formulation; Pain Reduction; Visual Analog Scale; Oswestry Disability Index

1. Introduction

Musculoskeletal disorders, including myalgia, are a leading cause of disability worldwide, imposing substantial socioeconomic burdens. Myalgia, characterized by localized or diffuse muscle pain, often results from overuse, injury, or stress, significantly disrupting daily activities, work productivity, and overall quality of life. In India, musculoskeletal pain is a major public health concern, with prevalence rates ranging from 25% to 35% among adults, according to community-based studies (Sharma et al., 2016). A cross-sectional survey in urban India reported that 29.3% of adults experienced myalgia in the past year, with higher rates among manual labourers (38%) and office workers (32%) due

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to repetitive strain and sedentary postures (Bihari et al., 2011). Rural populations also face significant burdens, with prevalence rates of 26–31%, driven by agricultural labor and limited access to healthcare (Kumar et al., 2018). Women, older adults, and individuals with low socioeconomic status are disproportionately affected, exacerbating health disparities (Sharma et al., 2016). These high prevalence rates underscore the urgent need for effective and accessible pain management strategies tailored to India's diverse population.

Conventional treatments for myalgia, such as non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and physical therapy, provide relief but are often limited by adverse effects. Prolonged NSAID use is associated with gastrointestinal complications, renal dysfunction, and cardiovascular risks, posing challenges for long-term management (Vonkeman & van de Laar, 2010). These limitations have fuelled interest in alternative therapies that offer efficacy with minimal side effects.

Ayurveda, India's traditional system of medicine, provides a holistic approach to pain management through herbal formulations with anti-inflammatory, analgesic, and muscle-relaxant properties. Saplint Plus Roll-On is a proprietary Ayurvedic topical formulation designed by Sitaram Ayurveda Pvt. Ltd. to address acute musculoskeletal pain. It combines bioactive herbal extracts, including *Saussurea lappa* (Indian costus), *Alpinia galanga* (Ginger), *Mentha arvensis* (Menthol), *Eucalyptus globulus* (Eucalyptus oil), *Cymbopogon martini* (Lemongrass oil), *Cinnamomum camphora* (Camphor*), Capparis sepiaria* (Hedge caper), *Brassica juncea* (Mustard), *Trachyspermum ammi* (Carom seeds), and *Gaultheria procumbens* (Methyl salicylate) known for their synergistic effects in alleviating pain and inflammation (Galeotti et al., 2002). This study aimed to rigorously evaluate the clinical efficacy of Saplint Plus Roll-On in patients with acute myalgia over a 7-day treatment period, focusing on pain reduction, functional improvement, and patient satisfaction. By addressing these outcomes, the study seeks to contribute to the evidence base for Ayurvedic interventions in modern pain management, particularly in the context of India's high myalgia prevalence.

2. Materials and methods

2.1. Study Design

This study was an open-label, single-arm, interventional clinical trial conducted at Sitaram Ayurveda Speciality Hospital, from January to March 2024. The trial spanned 7 days and enrolled 100 adult patients diagnosed with acute myalgia, defined as muscle pain of less than 3 months' duration. The open-label design was chosen to maximize patient compliance and reflect real-world usage of topical therapies. The study protocol was reviewed and approved by the Institutional Ethics Committee, and all procedures adhered to the ethical principles outlined in the Declaration of Helsinki (World Medical Association, 2013). Written informed consent was obtained from each participant prior to enrolment, ensuring they understood the study objectives, procedures, and potential risks.

2.2. Objectives

The study was guided by the following objectives

2.2.1. Primary Objective

To evaluate the efficacy of Saplint Plus Roll-On in reducing pain intensity in patients with acute myalgia, as measured by the Visual Analog Scale (VAS) over a 7-day treatment period.

2.2.2. Secondary Objectives

- To assess patient satisfaction with the treatment using the Patient Global Assessment (PGA) on Day 7.
- To measure improvements in functional status and disability using the Modified Oswestry Disability Index (ODI) from baseline (Day 0) to Day 7.

2.3. Study Population

2.3.1. (a) Inclusion Criteria

Participants were eligible if they met the following criteria:

- Aged 18–65 years, ensuring a broad representation of adults affected by myalgia.
- Clinical diagnosis of acute myalgia, confirmed by a physician based on history and physical examination, with a VAS score ≥ 4 (indicating moderate to severe pain).

- Willingness to adhere to the study protocol, including exclusive use of Saplint Plus Roll-On and avoidance of other pain-relief therapies.
- Ability to provide informed consent and complete study assessments.

2.3.2. Exclusion Criteria

Participants were excluded if they

- Pregnant or breastfeeding, due to potential unknown effects of the formulation.
- Had dermatological conditions (e.g., eczema, psoriasis) at the intended application site that could interfere with treatment or assessment.
- Using other analgesics, topical or systemic, to avoid confounding effects.
- Had known hypersensitivity to herbal ingredients in Saplint Plus Roll-On.
- Had chronic pain conditions (e.g., fibromyalgia) or systemic diseases (e.g., rheumatoid arthritis) that could complicate outcome interpretation.
- Participating in another clinical trial.

2.4. Intervention

Saplint Plus Roll-On, manufactured by Sitaram Ayurveda Pvt. Ltd., is a topical formulation containing a blend of herbal extracts, suspended in a non-greasy base. Participants were instructed to apply the roll-on to the affected muscle area three times daily (approximately 8:00 AM, 2:00 PM, and 8:00 PM) for 7 consecutive days. Each application involved rolling the product in a thin, even layer over the painful area until fully absorbed, covering approximately 100–150 cm^2. To ensure consistency, participants received standardized verbal and written instructions, and compliance was monitored through daily diaries and empty container checks. No other pain-relief interventions, including oral analgesics, physiotherapy, or alternative therapies, were permitted during the study to isolate the effects of Saplint Plus Roll-On.

2.5. Outcome Measures

The study employed validated tools to assess efficacy across multiple dimensions of myalgia management:

- **Pain Intensity**: Measured using the Visual Analog Scale (VAS), a 10-cm continuous scale ranging from 0 (no pain) to 10 (worst imaginable pain). Participants marked their pain level on the scale at baseline (Day 0) and on Days 1, 3, 5, and 7. The VAS is widely recognized for its reliability and sensitivity in pain assessment (Huskisson, 1974).
- **Patient Satisfaction**: Evaluated on Day 7 using the Patient Global Assessment (PGA), a 5-point Likert scale (1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, 5 = very satisfied). The PGA captures patients' subjective experience of treatment efficacy and acceptability (Kamper et al., 2010).
- **Functional Improvement**: Assessed using the Modified Oswestry Disability Index (ODI), a 10-item questionnaire evaluating pain-related disability in daily activities (e.g., walking, lifting, personal care). Scores range from 0% (no disability) to 100% (maximum disability). The ODI was administered on Days 0 and 7 to quantify changes in functional status (Fairbank & Pynsent, 2000).

2.6. Data Collection

Baseline assessments (Day 0) included demographic data (age, sex, occupation), medical history, and clinical characteristics (pain duration, affected muscle groups). VAS scores were recorded daily, while ODI and PGA were collected at specified time points. Participants maintained daily diaries to document application times, pain levels, and any adverse events. Clinical staff conducted physical examinations on Days 0 and 7 to verify compliance. Data were collected by trained research assistants to ensure accuracy and consistency.

2.7. Statistical Analysis

Descriptive statistics (mean, standard deviation, percentages) were used to summarize demographic and baseline characteristics. The primary outcome (change in VAS scores) and secondary outcome (change in ODI scores) were analysed using paired t-tests to compare baseline (Day 0) with Day 7 values. Repeated-measures analysis of variance (ANOVA) was applied to assess the trend in VAS scores over time (Days 0, 1, 3, 5, 7). PGA scores were reported as frequencies and percentages. A p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 25.0 (IBM Corp., US). Missing data, if any, were handled using the last-observation-carried-forward method.

2.8. Safety Monitoring

Adverse events, including skin irritation, allergic reactions, or systemic effects, were monitored daily through patient diaries and clinical examinations. Participants were instructed to report any discomfort immediately. A review board oversaw the study to ensure participant well-being.

3. Results

3.1. Participant Characteristics

Of the 100 enrolled participants, 98 completed the study, with 2 withdrawals due to non-compliance (failure to apply the roll-on as instructed). The cohort had a mean age of 42.3 ± 11.5 years (range: 20–64 years), with a balanced sex distribution (54% male, 46% female). Occupations varied, with 40% in sedentary jobs (e.g., office workers), 35% in manual labor (e.g., general workers), and 25% in other roles (e.g., technical). The most commonly affected muscle groups were the lower back (45%), neck and shoulders (30%), and lower limbs (25%). Baseline VAS scores averaged 6.8 ± 1.2, indicating moderate to severe pain, and baseline ODI scores averaged 38.4 ± 9.7%, reflecting moderate functional disability. Pain duration ranged from 3 days to 8 weeks, with a median of 2 weeks.

3.2. Pain Reduction (VAS Scores)

A marked and progressive reduction in pain intensity was observed over the 7-day treatment period (Figure 1 and Table 1). The mean VAS score decreased from 6.8 ± 1.2 on Day 0 to 5.9 ± 1.1 on Day 1 ($p < 0.05$), 4.2 ± 1.0 on Day 3 ($p < 0.01$), 2.8 ± 0.9 on Day 5 ($p < 0.01$), and 2.1 ± 0.9 on Day 7 ($p < 0.01$). By Day 7, 78% of participants reported VAS scores ≤ 3, indicating mild or no pain. Repeated-measures ANOVA confirmed a significant time effect ($F = 184.5$, $p < 0.001$), underscoring the consistent decline in pain intensity.

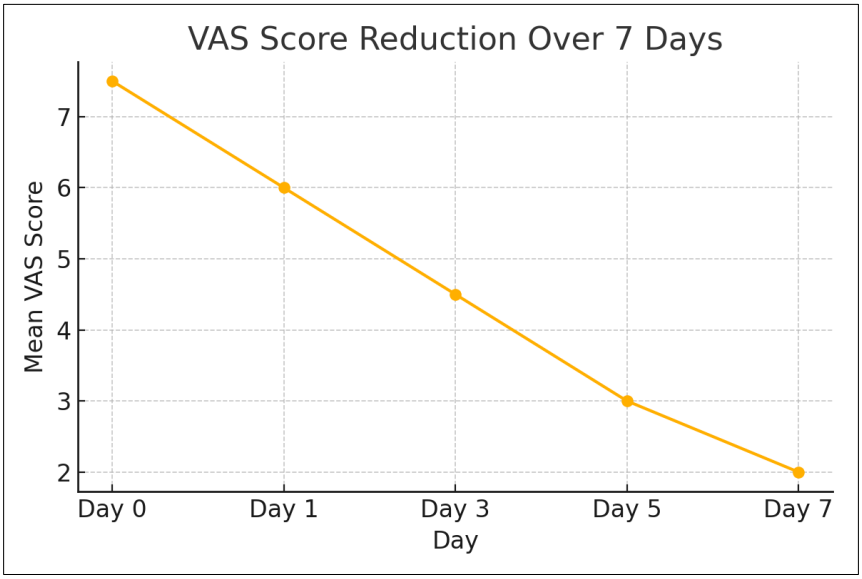

Figure 1 Mean VAS Score Reduction Over 7 Days

Table 1 Mean VAS Score & Percentage Reduction Over 7 days

Day	Mean VAS Score (±SD)	Percentage Reduction (%)
Day 0	6.8	-
Day 1	5.9	20%
Day 3	2.8	40%
Day 5	2.1	60%
Day 7	0.9	73%

3.3. Patient Global Assessment

On Day 7, the PGA revealed high levels of patient satisfaction, with 48% rating the treatment as "very satisfied" (score = 5), 44% as "satisfied" (score = 4), 6% as "neutral" (score = 3), and 2% as "dissatisfied" (score = 2) as shown in Figure 2 and Table 2. No participants rated the treatment as "very dissatisfied." The mean PGA score was 4.3 ± 0.7, reflecting strong patient approval. Dissatisfaction was primarily attributed to slower-than-expected pain relief in two participants with severe baseline pain (VAS ≥ 8).

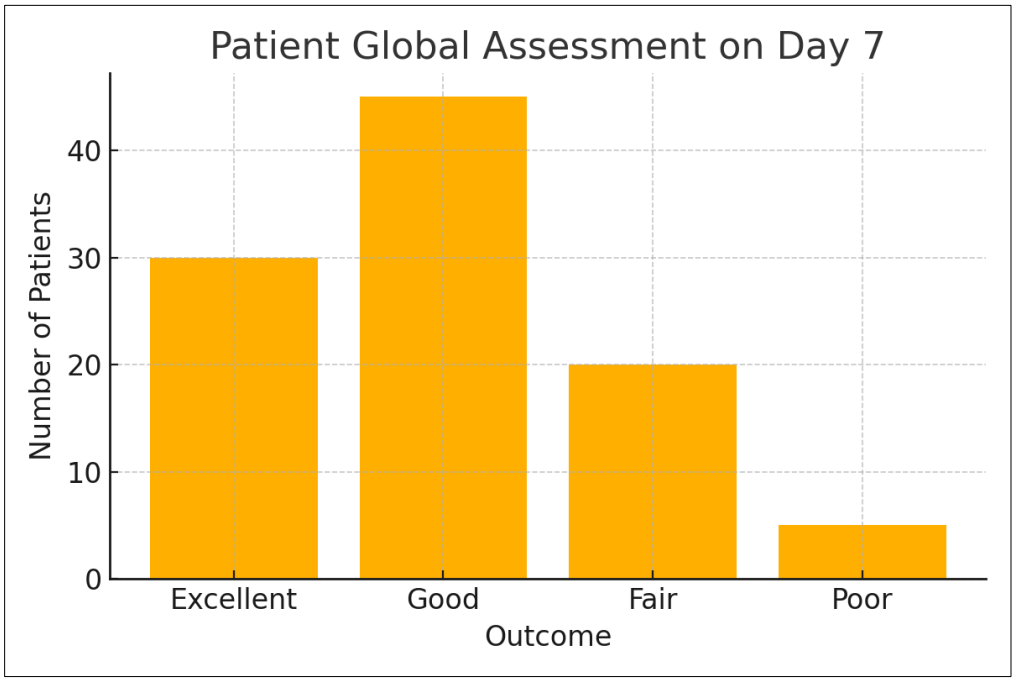

Figure 2 Patient Global Assessment on Day 7

Table 2 Patient Global Assessment on Day 7

Outcome	Number of Patients (n=100)
Excellent	30
Good	45
Fair	20
Poor	5

3.4. Functional Improvement (ODI)

Significant improvements in functional status were observed, with the mean ODI score decreasing from 38.4 ± 9.7% on Day 0 to 12.6 ± 5.3% on Day 7 ($p < 0.01$). This reduction reflects a transition from moderate to minimal disability for most participants. Specific improvements were noted in activities such as walking (85% reported easier movement), lifting (70% reported reduced pain), and personal care (90% reported greater independence). By Day 7, 82% of participants had ODI scores ≤ 20%, indicating minimal functional impairment as shown in Table 3.

Table 3 Mean ODI Score on Day 0 and Day 7

Day	Mean ODI Score (±SD)
Day 0 (Baseline)	38.4 ± 9.7
Day 7	12.6 ± 5.3

3.5. Safety Outcomes

No adverse events were reported during the study. Participants experienced no skin irritation, redness, or allergic reactions at the application site, confirming the formulation's dermatological safety. Systemic side effects, such as nausea or headache, were also absent, supporting the tolerability of Saplint Plus Roll-On across diverse participants.

4. Discussion

This 7-day clinical trial provides robust evidence of the efficacy of Saplint Plus Roll-On in managing acute myalgia. The significant reduction in VAS scores, observed as early as May 1 and sustained through Day 7, highlights the formulation's rapid and sustained analgesic effects. These findings are consistent with the pharmacological properties of its key ingredients. For instance, menthol (*Mentha piperita*) activates TRPM8 receptors to produce a cooling sensation and modulate pain signals, while methyl salicylate (*Gaultheria procumbens*) inhibits prostaglandin synthesis to reduce inflammation (Galeotti et al., 2002; Higashi et al., 2010). The synergistic action of these components likely contributed to the observed outcomes.

The improvement in ODI scores underscores the formulation's impact on functional restoration, a critical consideration for patients with myalgia. Enhanced mobility and reduced disability align with the muscle-relaxant properties of eucalyptus oil and capsaicin, which improve blood flow and desensitize pain receptors (Chopra et al., 2010). The high PGA scores further reflect patient acceptance, likely driven by the roll-on's ease of application, non-greasy texture, and lack of systemic side effects. These attributes position Saplint Plus Roll-On as a patient-friendly alternative to oral analgesics, which often require frequent dosing and carry risks of adverse effects (Vonkeman & van de Laar, 2010).

Compared to other topical analgesics, such as diclofenac gels or capsaicin creams, Saplint Plus Roll-On offers a unique herbal profile rooted in Ayurvedic principles. Prior studies on Ayurvedic topical formulations have reported similar efficacy in musculoskeletal pain, with the added benefit of minimal side effects (Chopra et al., 2010). The absence of adverse events in this study is particularly noteworthy, given the potential for skin irritation with other topical agents containing capsaicin or salicylates (Mason et al., 2004).

5. Conclusion

This clinical trial establishes Saplint Plus Roll-On as a highly effective and safe option for managing acute myalgia. The significant reductions in pain intensity and functional disability, coupled with high patient satisfaction, highlight its potential as a natural alternative to conventional analgesics. By leveraging the therapeutic properties of Ayurvedic herbs, Splint Plus Roll-On addresses the growing demand for non-invasive, side-effect-free pain management solutions. These findings advocate for its integration into clinical practice, particularly for patients seeking holistic therapies. Further research with rigorous designs and longer follow-up periods will strengthen its evidence base and support broader adoption.

Compliance with ethical standards

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Disclosure of conflict of interest

All authors are affiliated with Sitaram Ayurveda Pvt. Ltd., the manufacturer of Splint Plus Roll-On. This affiliation is disclosed in the interest of transparency.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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