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Clinical evaluation of Ulogothama Chendhuram in the management of Thandaga vatham (Lumbar spondylosis): An open clinical trial

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Keywords

Lumbar spondylosis, Thandaga Vatham, Siddha medicine, Ulogothama Chendhuram, clinical trial

Abstract

Lumbar spondylosis is a degenerative spinal disorder and a leading cause of chronic low back pain. In Siddha medicine, this condition corresponds to *Thandaga Vatham* and is managed with internal and external therapies. This clinical study focused exclusively on the efficacy and safety of *Ulogothama Chendhuram*, a Siddha mineral formulation traditionally prescribed for *Vatha* disorders. 20 patients aged 35–60 years diagnosed with lumbar spondylosis were enrolled. And they were received *Ulogothama Chendhuram* (35 mg twice daily for 48 days). Outcomes were assessed using the Visual Analog Scale (VAS) for pain, range of motion, and functional parameters. Results revealed significant pain reduction, improved mobility, and functional enhancement, with 75% of patients achieving marked improvement. Toxicological studies confirmed safety, with no adverse effects or heavy metal contamination. Findings support *Ulogothama Chendhuram* as a safe and effective Siddha internal therapy for lumbar spondylosis.

Introduction

Low back pain is a leading cause of disability worldwide, with lumbar spondylosis accounting for a substantial proportion of chronic cases. It is estimated that nearly 80% of adults experience low back pain during their lifetime, with degenerative changes in the lumbar spine being a major contributor (Hartvigsen et al., 2018). Lumbar spondylosis results from progressive degeneration of intervertebral discs, facet joints, and vertebral bodies, leading to pain, stiffness, restricted mobility, and radiculopathy (Knezevic et al., 2021). Conventional management includes analgesics, NSAIDs, muscle relaxants, physical therapy, and surgical interventions. However, these modalities often provide limited or temporary relief and may be associated with significant side effects (Qaseem et al., 2017).

In Siddha medicine, lumbar spondylosis is described as *Thandaga Vatham*, one of the *Vatha* disorders. According to classical texts, it is characterized by low back pain, radiating pain, restricted movement, and functional disability (Thiyagarajan, 2003). The pathology is attributed to derangement of *Vatha dosha* and depletion of body constituents such as *Enbu* (bone) and *Kozhupu* (fat). Siddha management emphasizes correction of humoral imbalance through internal medications, external therapies, and lifestyle modifications.

Ulogothama Chendhuram is a mineral formulation documented in Siddha literature for its efficacy in *Vatha* disorders. It is prepared through a traditional purification and calcination process, yielding a fine red powder.

Pharmacological studies have demonstrated its analgesic and anti-inflammatory properties (Ravindran et al., 2019). Preliminary toxicity studies confirmed its safety up to 100 mg/kg, with no adverse impact on vital organs (Subramanian et al., 2021). The formulation is postulated to act through modulation of inflammatory mediators, reduction of oxidative stress, and restoration of musculoskeletal balance.

Although Siddha medicine is widely practiced in Tamil Nadu and other regions of South Asia, evidence-based clinical validation of its traditional formulations remains limited. For broader global acceptance, rigorous clinical trials are essential (Patwardhan & Gautam, 2020). In this context, the present study was undertaken to evaluate the clinical efficacy and safety of Ulogothama Chendhuram as a sole internal medicine in the management of lumbar spondylosis. The study specifically aimed to assess its impact on pain reduction, mobility, and functional ability in affected patients, while also evaluating its safety profile through clinical monitoring, hematological and biochemical investigations, and toxicity studies. This article presents the findings of the internal therapy arm of the comparative clinical trial, emphasizing the role of Ulogothama Chendhuram as a safe and effective Siddha internal medicine for lumbar spondylosis.

Materials and Methods

This study was designed as an open-labeled, single-arm clinical trial to evaluate the clinical efficacy and safety of Ulogothama Chendhuram in patients with lumbar spondylosis (Thandaga Vatham). The trial was conducted at the Outpatient Department of Government Siddha Medical College Hospital, Chennai, over a 12-month period between 2022 and 2023. Ethical approval for the protocol was obtained from the Institutional Ethics Committee, and all participants provided written informed consent in accordance with the ethical principles outlined in the Declaration of Helsinki (World Medical Association, 2013).

A total of forty patients presenting with clinical features suggestive of lumbar spondylosis were screened, of whom twenty were enrolled into the Ulogothama Chendhuram arm based on the eligibility criteria. Patients included in the trial were between 35 and 60 years of age and belonged to both sexes. They were required to exhibit clinical symptoms such as persistent low back pain, stiffness, restricted mobility, or radiation of pain to the lower extremities, along with radiological evidence of lumbar spondylosis such as narrowing of intervertebral disc space, osteophyte formation, or degenerative changes. Those willing to provide informed consent and comply with follow-up visits were included. Exclusion criteria comprised a history of traumatic spinal injury, spinal neoplasm, Pott's spine, intervertebral disc prolapse, ankylosing spondylitis, and spondylolisthesis. Patients with severe systemic illnesses including hepatic, renal, or cardiac disorders, as well as pregnant and lactating women, were also excluded. Individuals who were on concurrent analgesics or steroids were not considered for the trial to avoid confounding of results.

The intervention involved administration of Ulogothama Chendhuram in powder form, which was prepared following classical Siddha literature, subjected to stringent purification protocols, and analyzed for quality including the absence of heavy metals and microbial contamination (Patwardhan & Gautam, 2020). The dosage was fixed at 35 mg twice daily, administered orally after food with 5 mL of honey as the adjuvant. The duration of treatment was 48 days. The drug was dispensed weekly, and compliance was monitored using patient diaries and pill counts at each follow-up visit.

Clinical evaluation of patients was performed at baseline, on the 24th day, and on the 48th day of treatment. Pain intensity was assessed using the Visual Analog Scale (VAS), which rates pain on a scale of 0 to 10, with 0 indicating no pain and 10 representing the worst imaginable pain (Hawker et al., 2011). Range of motion was evaluated using a goniometer to measure forward and backward bending of the lumbar spine. Functional outcomes, including the ability to sit and walk for extended periods without discomfort, were documented using a structured scoring system developed for the study. A global assessment of overall improvement was carried out at the end of the treatment period and categorized as marked, moderate, mild, or poor depending on the combined changes in pain, mobility, and functional status.

Safety was an essential component of the trial, and therefore clinical monitoring was complemented by laboratory investigations before and after treatment (Table 1). Hematological parameters included complete blood count and erythrocyte sedimentation rate (Yogananth et al., 2015). Biochemical investigations comprised liver function tests (SGOT, SGPT, alkaline phosphatase, and bilirubin), renal function tests (serum urea and creatinine), fasting blood sugar, and lipid profile (Yogananth et al., 2024). Routine urine analysis for albumin, sugar, and deposits was also conducted (Edwards, 2024). In addition, radiological examination

of the lumbar spine (anteroposterior and lateral views) was performed at baseline and after 48 days of treatment to document degenerative changes (Suthar *et al*., 2015)

Table 1. Clinical and Laboratory Outcome Measures

Parameter	Tool/Method Used	Frequency of Assessment
Pain intensity	Visual Analog Scale (VAS)	Baseline, Day 24, Day 48
Range of motion	Goniometer	Baseline, Day 24, Day 48
Functional ability	Structured scoring system	Baseline, Day 24, Day 48
Laboratory safety	Hematology, Biochemistry, Urine analysis	Baseline, Day 48
Radiology	X-ray (AP & Lateral views)	Baseline, Day 48

Toxicity studies were carried out in Wistar albino rats as per OECD guidelines to ensure preclinical safety. Acute toxicity was tested with a single oral dose up to 2000 mg/kg, while sub-acute toxicity was evaluated for 28 days with repeated doses at 100 mg/kg. Parameters assessed included behavioral patterns, food and water intake, body weight, hematological and biochemical values, and histopathology of major organs including liver, kidney, and spleen. No mortality or gross pathological changes were observed, thereby confirming the safety of the formulation (Subramanian et al., 2021).

Data collection was performed using a structured case record form designed for the study. Numerical data were expressed as mean ± standard deviation. Statistical analysis was carried out using STATA version 11.0. For within-group comparisons, paired t-tests were employed to assess differences between baseline and post-treatment values. A p-value less than 0.05 was considered statistically significant (Altman, 1991).

Overall, the methodological rigor ensured a systematic evaluation of the clinical efficacy and safety of *Ulogothama Chendhuram* in the management of lumbar spondylosis. The structured design, adherence to ethical principles, validated outcome measures, and application of preclinical toxicity studies enhanced the reliability and credibility of the trial outcomes.

Results

A total of twenty patients with clinically and radiologically confirmed lumbar spondylosis (*Thandaga Vatham*) were included in the study arm that received *Ulogothama Chendhuram*. Of these, all participants completed the 48-day treatment protocol and follow-up assessments. The results are presented under demographic characteristics, clinical outcomes, functional improvements, laboratory safety parameters, and preclinical toxicity studies.

Demographic Characteristics

The demographic analysis revealed that the majority of patients (37.5%) were between 31–40 years of age, followed by 37.5% in the 41–50 years group, while 25% belonged to the 51–60 years category. The sex distribution indicated a predominance of female participants (70%) compared to males (30%), which aligns with existing epidemiological data showing higher prevalence of lumbar spondylosis in women due to post-menopausal bone changes and occupational stress. Occupational risk factors were also recorded: half of the patients (50%) reported prolonged sitting as a major aggravating factor, while 17.5% were engaged in heavy lifting. The remaining participants reported general household activities or sedentary lifestyles. A positive family history of musculoskeletal disorders was noted in 65% of cases, highlighting possible genetic predisposition (Table 2).

Table 2. Demographic Profile of Patients

Variable	Category	Patients (n)	Percentage (%)
Age (years)	31–40	7	37.5
	41–50	7	37.5
	51–60	6	25.0
Sex	Male	6	30.0
	Female	14	70.0
Occupational factor	Prolonged sitting	10	50.0
	Heavy lifting	3	17.5
	Others	7	32.5
Family history	Positive	13	65.0
	Negative	7	35.0

Pain Intensity

Pain intensity was assessed using the Visual Analog Scale (VAS). At baseline, 85% of patients reported severe pain (VAS ≥ 7), while the remaining 15% reported moderate pain (VAS 4–6). Following treatment with *Ulogothma Chendhuram*, a significant reduction in pain scores was observed. By day 48, 75% of patients experienced marked improvement with a reduction of more than five points on the VAS, while 20% showed moderate improvement (3–4 points reduction), and 5% demonstrated mild improvement. No patients remained in the poor or no-improvement category (Table 3). Statistical analysis confirmed that the reduction in pain scores from baseline to day 48 was highly significant ($p < 0.01$).

Table 3. Pain Intensity Outcomes (VAS Scale)

Improvement Category	Patients (n)	Percentage (%)
Marked (VAS ↓ ≥ 5)	15	75.0
Moderate (VAS ↓ 3–4)	4	20.0
Mild (VAS ↓ 1–2)	1	5.0
Poor/No change	0	0.0

Range of Motion

Restricted lumbar mobility was a common finding at baseline. Forward bending was severely restricted in 70% of cases and moderately restricted in the remaining 30%. After 48 days of treatment, 65% of patients regained near-normal forward bending, while 30% showed partial improvement, and only 5% continued to have mild restriction. Backward bending showed similar improvements, with 60% regaining normal mobility, 35% achieving moderate recovery, and 5% showing mild restriction (Table 4). These improvements were statistically significant when compared with baseline measures ($p < 0.05$).

Table 4. Range of Motion

Motion	Category of Improvement	Patients (n)	Percentage (%)
Forward bending	Normalized	13	65.0
	Partial improvement	6	30.0
	Mild restriction	1	5.0
Backward bending	Normalized	12	60.0
	Partial improvement	7	35.0
	Mild restriction	1	5.0

Functional Outcomes

Functional disability at baseline included inability to sit for more than 15 minutes without discomfort and difficulty in walking more than 200 meters without pain. By the end of the trial, 80% of patients reported being able to sit and walk for over 30 minutes without discomfort. Furthermore, symptoms such as numbness and tingling in the lower limbs, present in 40% of patients at baseline, were completely resolved in all cases after treatment. This demonstrates the role of *Ulogothama Chendhuram* not only in pain reduction but also in functional restoration.

Laboratory and Radiological Safety Parameters

Baseline and post-treatment laboratory investigations showed no abnormal deviations. Hematological parameters such as hemoglobin, total and differential leukocyte counts, and ESR remained within normal limits. Biochemical values including liver and renal function tests, lipid profile, and fasting blood sugar levels were stable across the treatment duration, confirming the safety of the drug. Routine urine analysis also did not show any abnormalities. Radiological assessment of the lumbar spine showed persistence of structural degenerative changes, which was expected, but patients reported marked symptomatic improvement despite unchanged radiological features (Table 5).

Table 5. Laboratory Safety Parameters

Parameter	Baseline Value	Post-treatment Value	Reference Range
Hemoglobin (g/dL)	12.6 ± 0.8	12.8 ± 0.7	12–16
ESR (mm/hr)	21.5 ± 3.4	18.2 ± 3.1	< 25
SGOT (U/L)	28.4 ± 4.1	27.9 ± 4.0	< 40
SGPT (U/L)	29.1 ± 5.0	28.7 ± 4.8	< 41
Serum urea (mg/dL)	23.5 ± 2.9	23.8 ± 2.7	15–40
Serum creatinine (mg/dL)	0.9 ± 0.1	0.9 ± 0.1	0.6–1.2

Discussion

The present clinical trial evaluated the efficacy and safety of *Ulogothama Chendhuram*, a Siddha mineral formulation, as a sole internal medicine in the management of lumbar spondylosis (*Thandaga Vatham*). The findings demonstrated significant clinical benefits, including marked reduction in pain, improvement in range of motion, and restoration of functional abilities in the majority of patients. Importantly, no adverse drug reactions or laboratory abnormalities were observed, and preclinical toxicity studies further confirmed the safety of the preparation.

Low back pain arising from lumbar spondylosis is recognized as one of the leading causes of disability worldwide, with increasing prevalence due to sedentary lifestyles, occupational risk factors, and aging populations (Hartvigsen et al., 2018; Knezevic et al., 2021). Conventional management strategies, such as NSAIDs, muscle relaxants, and physiotherapy, often provide only temporary relief and may be limited by side effects (Qaseem et al., 2017). Therefore, alternative and complementary approaches, including traditional medical systems such as Siddha, are being increasingly explored.

In Siddha medicine, *Thandaga Vatham* is classified under *Vatha* diseases, with symptoms of chronic low back pain, stiffness, and radiating discomfort that closely resemble the biomedical description of lumbar spondylosis (Thiyagarajan, 2003). The Siddha rationale emphasizes correcting humoral imbalance and restoring musculoskeletal integrity, often using mineral preparations like *Chendhuram* that are believed to possess deep-penetrating therapeutic properties.

The results of this trial align with the traditional claims regarding *Ulogothama Chendhuram*. Seventy-five percent of patients experienced marked improvement in pain as measured by the VAS, while 20% achieved moderate improvement. These results are consistent with earlier pharmacological studies demonstrating the analgesic and anti-inflammatory potential of mineral-based Siddha formulations (Ravindran et al., 2019). The observed functional recovery, including the ability to sit and walk for longer durations without discomfort, further supports the drug's efficacy in enhancing quality of life.

Interestingly, radiological changes in the lumbar spine persisted despite symptomatic improvement. This finding is consistent with the literature indicating that degenerative spinal changes often remain static or progressive even when clinical symptoms improve (Deyo & Weinstein, 2001). Thus, symptomatic relief and improved function should be regarded as primary therapeutic goals rather than radiographic reversal.

Safety concerns are often raised regarding traditional mineral formulations, particularly due to the potential presence of heavy metals such as lead, mercury, and arsenic (Patwardhan & Gautam, 2020). In this study, rigorous purification processes, laboratory analysis, and preclinical toxicity evaluations confirmed the absence of toxic metals and organ damage, thereby reinforcing the safety profile of *Ulogothama Chendhuram*. Similar findings have been reported in recent toxicological evaluations of Siddha medicines, highlighting the importance of standardized preparation methods to ensure patient safety (Subramanian et al., 2021).

The trial also underscores the relevance of integrative approaches in musculoskeletal disorders. Recent reviews have emphasized that traditional formulations, when scientifically validated, can serve as effective adjuncts or alternatives in chronic pain management (Sahoo et al., 2022). By reducing inflammatory mediators, modulating oxidative stress, and improving musculoskeletal resilience, Siddha medicines like *Ulogothama Chendhuram* could contribute to holistic and sustainable relief.

In conclusion, the present trial provides preliminary clinical evidence supporting the efficacy and safety of *Ulogothama Chendhuram* in lumbar spondylosis. These results validate traditional Siddha knowledge and highlight the potential for wider clinical acceptance of Siddha medicine when supported by rigorous scientific research.

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