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A CLINICAL STUDY TO EVALUATE THE EFFECT OF TIL-KALKODAKA GANDUSHA IN DANTAHARSHA

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ABSTRACT

In the era of rising dental hypersensitivity and overdependence on synthetic oral care, Ayurveda offers a time-tested, holistic solution through ***Gandusha*** — an ancient practice of oil retention in the oral cavity. This clinical study investigates the efficacy of ***Til-Kalkodaka Gandusha*** (a sesame seed paste-based oil pulling therapy) in managing ***Dantaharsha*** (tooth sensitivity), a *Vata*-dominant condition marked by pain on exposure to cold, air, or sour substances. Undergoing through *Vagbhatta Samhita Ashtang Hridayam* and integrating modern clinical methodology, a 30-day single group, non-randomized interventional trial was conducted on 50 patients to assess symptomatic relief, patient satisfaction, and safety. Results demonstrated significant improvement in hypersensitivity symptoms, with high patient compliance and zero adverse effects. By reviving a daily ***Dinacharya*** routine explained in in Ayurvedic texts, this study not only validates the therapeutic potential of sesame-based *Gandusha* but also bridges the gap between tradition and evidence-based modern oral healthcare. The findings support a shift toward natural, preventive, and sustainable solutions for oral wellness.

KEYWORDS: *Dinacharya, Gandusha, Dantaharsha.*

INTRODUCTION

In Ayurveda, the concept of *Mukha Swasthya* pertains to the maintenance of health within the oral cavity, a central component of overall physical and mental well-being. The term *Mukha*

refers to the mouth or the face, and *Swasthya* signifies health, wellness, or balance. *Mukha Swasthya* is not only concerned with the physical health of the mouth but also encompasses its crucial role in the digestive system and its broader implications for systemic health. Ayurveda, with its holistic approach, recognizes that the state of the oral cavity directly affects the balance of the body's energies, including the three doshas (*Vata*, *Pitta*, and *Kapha*), as well as the digestive fire, or Agni. The mouth serves as one of the primary openings to the body, and it is intricately linked to the *Annavaha Srotas* (digestive system), which governs the processes of digestion, assimilation, and elimination. The health of the oral cavity, therefore, plays a vital role in ensuring that food is properly digested and nutrients are effectively absorbed. In Ayurvedic terms, proper digestion (Digestion or Agni) is the foundation of good health, and a malfunction in the mouth and digestive system can create far-reaching effects on the body's balance. Therefore, oral health is seen as a cornerstone for the holistic maintenance of health. Maintaining oral health, according to Ayurveda, is not merely about preventing tooth decay and gum disease but about ensuring that the mouth functions optimally to support overall digestion and bodily functions. Ayurveda treats the oral cavity as a microcosm of the entire body.

MATERIALS AND METHODS

Study Design

This study was designed as a single-arm, open-label, non-randomized, interventional clinical trial conducted to evaluate the efficacy of *Til-Kalkodaka Gandusha* in the management of *Dantaharsha* (dental hypersensitivity). The clinical trial adhered to Ayurvedic therapeutic principles while integrating observational outcome measures and modern research methodology. The study protocol was prepared in accordance with ethical standards and approved by the Institutional Ethics Committee (IEC) of Uttaranchal Ayurvedic College, Dehradun.

The study was conducted over a period of 12 months, with each patient receiving the intervention for a continuous 1-month treatment duration, followed by clinical assessments.

Source and Authentication of Drug

The primary trial drug, *Krishna Tila* (black sesame seeds), was procured from a certified Ayurvedic raw drug supplier located in Dehradun. The seeds were cultivated by local farmers from **moderate-altitude hilly regions**, typically harvested during **September to October**.

The authentication of *Sesamum indicum* Linn. was done by the Department of Dravyaguna, Uttaranchal Ayurvedic College. The seeds used were blackish to light brown in appearance, consistent with classical descriptions of *Krishna Tila.*

Pre-Processing of *Tila*

Upon procurement, the *Tila* seeds underwent physical cleaning to eliminate debris such as dust, stones, and foreign particles. This was achieved through manual sorting and sieving. The cleaned seeds were sun-dried for a few hours to remove residual moisture, ensuring their suitability for *kalka* (paste) preparation.

Formulation of Kalka (Paste)

The dried sesame seeds were coarsely ground in a traditional stone mortar and pestle with the gradual addition of minimal water to form a **thick, coarse paste** (Kalka). Each paste sample was divided into **5-gram doses**, and individually packed for single-session use. This Kalka represents the lipid-rich portion that retains the active constituents of sesame such as lignans, fatty acids, and flavonoids.

Final Drug Preparation – *Til-Kalkodaka*

At the time of *Gandusha* therapy, lukewarm or normal water (according to patient preference and climatic condition) was added to the 5-gram Kalka to create *Til-Kalkodaka* (aqueous-sesame solution). The final volume was adjusted as per the **individual oral cavity capacity**.

This freshly prepared medicated solution was used immediately to retain pharmacological potency and microbial safety.

Study Population

Site of Recruitment

Patients were recruited from the Outpatient Department (OPD) of **Swasthavritta and Yoga**, Uttaranchal Ayurvedic College and Hospital, Dehradun.

Selection Criteria

The subjects were selected using **simple random sampling**, and enrolled after fulfilling pre-established inclusion and exclusion criteria. A structured Ayurvedic proforma was designed to record demographic details, clinical features, daily regimens, oral hygiene practices, and baseline scores of *Dantaharsha* symptoms.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Patients aged between **18 to 50 years**.
- Both male and female subjects.
- Patients presenting with clinical symptoms of *Dantaharsha* as per Ayurvedic and modern descriptions.
- Patients willing to undergo regular follow-ups and provide informed consent.

Exclusion Criteria

- Patients with bleeding gums or diagnosed bleeding disorders.
- Patients suffering from conjunctivitis, rhinitis, hypertension, or cardiovascular disease.
- Those undergoing active dental procedures (e.g., root canal treatment).
- Tobacco chewers and smokers.
- Pregnant or lactating women.

Ethical Considerations and Consent

Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. All participants were briefed about the purpose, procedures, potential risks, and benefits of the study. Written informed consent was obtained in both **Hindi and English** as per participant preference.

Confidentiality and autonomy of participants were maintained throughout the study period.

Intervention Procedure: *Gandusha*

As part of the therapeutic regimen, all enrolled patients were instructed to perform *Til-Kalkodaka Gandusha* once daily in the morning hours, preferably on an empty stomach, to align with the principles of *Dinacharya* as described in the Ayurvedic classical text *Ashtanga Hridaya Sutrasthana.* This timing was selected to maximize drug absorption and minimize interference from food particles or oral debris, thereby enhancing the efficacy of the therapy.

***Poorva karma* (pre-treatment procedure)**

Patient has to follow the the *Dinacharya regime* during the whole intervention, which included the advised sequence as follows

- To wake up early (*Bramhe Muthurtha Uttishta*)
- Defecation and urination (*Malotsarga*)

- Tooth brushing (*Danta-dhavan*)
- Tongue-cleaning (*Jihva-nirlekhan*)

So these pre-steps should be followed before the main intervention of *Gandusha*. These steps mentioned are described by *Acharya Vagbhatta* in *Ashtang Hrudaya sutrasthan*. So as *Gandusha* is considered to be a part of *Dinacharya*, so for the best results these steps should be followed to enhance overall Dental Health.

Treatment Procedure

- The procedure began by guiding the patient to sit comfortably in an upright position in a calm, quiet, and well-ventilated area that was protected from direct breeze. This positioning aimed to facilitate a relaxed state of mind and optimal anatomical posture for holding the medicated liquid. Prior to the *Gandusha*, mild massage was performed on the patient's shoulders, cheeks, and jawline to promote relaxation, improve local circulation, and reduce muscular stiffness in the orofacial region.
- The freshly prepared *Til-Kalkodaka* formulation, consisting of 5 grams of sesame seed paste (kalka) mixed with lukewarm or room-temperature water, was administered to the patient. Approximately 15–20 milliliters of this medicated solution was provided per session, with the volume being slightly adjusted according to the individual's oral cavity capacity. The solution was held in the mouth without any movement—no swishing, gargling, or spitting was allowed during the retention phase. This static holding of the medicated fluid is a classical hallmark of *Gandusha* and is believed to facilitate prolonged mucosal contact, allowing better diffusion of the active phytoconstituents through the oral mucosa.
- The duration of retention varied depending on the individual's tolerance, generally ranging between three to five minutes, or until the patient experienced typical signs of adequate *Gandusha* (*samyak lakshana*), such as increased oro-pharyngeal secretions, nasal discharge (nasa srava), and tearing from the eyes (*netra srava*). These signs are indicative of optimal saturation and detoxification of the oral cavity, and they serve as classical endpoints for terminating the procedure. Once these symptoms were observed, the patient was instructed to expel the fluid completely.
- Immediately after expelling the medicated solution, the patient performed gentle gargling *(kavala*) using lukewarm water. This step helped in clearing any residual medicated paste and aided further soothing of the oral cavity. Patients were advised not to consume any

food or drink for at least 15–30 minutes following the procedure to allow for maximum mucosal absorption and post-procedural healing.

- The entire procedure was repeated daily for a continuous period of 30 days. Compliance was monitored using a patient diary and regular follow-up visits to ensure consistency and therapeutic integrity. This standardized method of *Gandusha* was consistently applied to all study participants to maintain uniformity and reproducibility of the intervention throughout the study.

Assessment Criteria

The clinical evaluation of treatment efficacy was systematically carried out using a structured and validated assessment tool based on the classical Ayurvedic descriptions of *Dantaharsha* as outlined by *Acharya Vagbhata* in *Ashtanga Hridaya, Uttara Tantra* (Chapter 21, Verse 12). The classical lakshanas (clinical features) described in this shloka namely intolerance to *vata* (air), amla (sour taste), and sheeta (cold substances), as well as pain induced by sour food intake were identified as the primary symptoms for assessment in this clinical study.

- **दन्तहर्षे प्रवाताम्लशीतभक्षाक्षमा द्विजाः**|
- **भवन्त्यम्लाशनेनेव सरुजाश्चलिता इव**| (A.H.U.21/12)

These symptoms, known as.

- ***Vata*-asahishnuta** (intolerance to breeze),
- **Amla-asahishnuta** (intolerance to sour taste),
- **Sheeta-asahishnuta** (intolerance to cold substances),
- **Saruja chala amlashnena** (pain while consuming sour food), were chosen as the core parameters to measure the subjective experience of dental hypersensitivity (*Dantaharsha*) in the recruited patients.

Each of the four symptoms was graded on a 4-point ordinal scale, allowing for a semi-quantitative evaluation of symptom severity:

Grade	Description
0	Absent – No noticeable discomfort or symptom
1	Mild – Slight discomfort but tolerable without behavioral avoidance
2	Moderate – Noticeable discomfort leading to occasional avoidance of triggers
3	Severe – Intense discomfort interfering with normal dietary or environmental exposure

The assessment was carried out in three phases.

1. **Baseline Assessment (Day 0)**: Before initiation of the intervention, the patient's symptoms were recorded using the scoring format. This established the pre-treatment symptom intensity.
2. **Midpoint Assessment (Day 15)**: A follow-up evaluation was conducted halfway through the intervention period to monitor trends in symptom reduction and therapeutic response.
3. **Final Assessment (Day 30)**: At the end of the 30-day intervention, a final evaluation was performed to record changes in symptom severity post-treatment.

By capturing symptom changes at multiple time points, the study ensured a temporal evaluation of treatment efficacy and allowed observation of both short-term and cumulative effects of *Til-Kalkodaka Gandusha*. The uniform scoring format and the subjective yet structured patient responses allowed for reliable intra-patient comparisons over time.

The recorded data were subjected to statistical analysis using non-parametric testing methods to determine the significance of therapeutic changes and to assess the clinical relevance of the intervention in managing *Dantaharsha*. Additionally, patient diaries and periodic follow-up consultations were employed to support and validate the assessment findings.

RESULTS AND DISCUSSION

- The mean *Vata* intolerance score reduced from 1.94 (SD 0.793) to 1.16 (SD 0.889); Sour intolerance dropped from 2.02 (SD 0.795) to 1.24 (SD 0.938); Cold intolerance reduced from 2.08 (SD 0.853) to 1.34 (SD 0.961); while Pain with sour food decreased from 2.00 (SD 0.808) to 1.26 (SD 0.828). These findings were statistically significant at $p < 0.001$ for all domains as evidenced by paired t-tests.
- The paired sample correlation analysis further substantiated the strong linear relationship between pre- and post-treatment improvements, with high correlation coefficients for all parameters (ranging from 0.854 to 0.896; $p < 0.001$). This consistency across multiple parameters confirms both the reliability of measurements and the robust therapeutic efficacy of *Gandusha* therapy.
- The improvement observed in multiple intolerance domains directly reflects the Ayurvedic pathophysiology of *Dantaharsha* being primarily a *Vata Vyadhi*, where vitiation of *Vata* affects the oral cavity's sensitivity, aggravating pain perception in dental tissues (1). The *Vata*-pacifying action of *Tila Taila*, through its *Snigdha* (unctuous), *Ushna* (hot), *Mardava* (softening) and *Shoolanashaka* (analgesic) properties, helps soothe

the hyperreactive nerve endings exposed through open dentinal tubules (*Charaka Samhita, Sutrasthana 5/10-15*).

- Additionally, Importantly, the adverse event profile was minimal, with only 4% of participants experiencing mild and transient side effects such as gag reflex or nausea, which resolved spontaneously. The tolerability of sesame oil (Tila Taila) is well-documented in Ayurvedic pharmacopeia and modern safety assessments
- In comparison with modern biomedicine, *Tila Taila* possesses scientifically validated anti-inflammatory, analgesic, and antioxidant properties, which are highly relevant in mitigating hypersensitive dental conditions. Several studies have shown that sesame oil reduces inflammatory cytokine expression, enhances epithelial healing, and inhibits oxidative stress, which collectively contribute to the amelioration of hypersensitivity symptoms.

- Furthermore, the detailed stratified subgroup analysis revealed several important patterns: Across age groups, participants in the 31–40 years group (who comprised 48% of the sample) demonstrated parallel benefit trends, confirming applicability across adult age ranges.

- Across genders, both males and females showed comparable improvements, indicating no gender-based differential response.
- Across systemic comorbidities such as acidity, fatigue, and mild cold, *Gandusha* remained equally effective, suggesting its safety and efficacy across varied systemic backgrounds. Independent of prior treatment history, both previously treated and treatment-naïve subjects demonstrated improvement, reflecting the therapy's standalone efficacy.
- The study also documented complete adherence across all follow-up sessions (Day 15 and Day 30), further supporting both the acceptability and sustainability of the intervention in real-world practice. Unlike many pharmacological interventions where drop-out rates limit generalizability, the excellent compliance here reinforces the clinical utility of Tila-Kalkodaka *Gandusha*.

SUMMARY AND CONCLUSION

The present clinical study effectively achieved both of its predefined objectives first, by establishing the therapeutic potential of *Tila-Kalkodaka Gandusha* in alleviating the cardinal symptoms of *Dantaharsha* (dental hypersensitivity), and second, by significantly enhancing awareness and adoption of *Dinacharya* (daily oral hygiene practices) among participants. The

intervention demonstrated statistically significant improvement in key symptoms such as sensitivity to cold, sour, and *Vata*-provoking stimuli, with sustained relief observed over a 30-day treatment period. The reduction in mean symptom scores and high patient compliance underscore the clinical efficacy and tolerability of the treatment.

In addition to symptom management, the study successfully fostered behavioral change among participants by educating them on the importance of Ayurvedic oral care practices. This not only supported symptomatic improvement but also contributed to preventive health promotion through increased awareness of tongue scraping, appropriate brushing habits, and avoidance of abrasive toothpastes. The cultural acceptability, safety profile, and ease of administration of *Gandusha* make it a particularly suitable intervention in both clinical and community-based settings.

Given the limitations of modern dentistry in offering definitive treatment for dentinal hypersensitivity and the increasing interest in integrative, evidence-based traditional practices, *Tila-Kalkodaka Gandusha* stands out as a promising, natural, and holistic approach. It not only aligns with classical Ayurvedic doctrines but also meets modern clinical criteria for effectiveness and patient-centered care. Thus, the study contributes meaningful insights into the role of Ayurvedic therapeutics in oral healthcare and sets a strong foundation for future research into larger, controlled trials and broader public health applications.

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