Original Article

Amrutadi Taila Nasya as an Adjuvant Therapy in Subclinical Hypothyroidism (Galaganda): A Pilot Prospective Study on Symptom Relief and Thyroid Modulation

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Abstract

Background: A subclinical hypothyroidism (SCH) occurs when TSH (>4.5 µIU/mL) is high, and T4 is normal, and subclinical hypothyroidism is a predisposing factor to overt hypothyroidism, cardiovascular, and metabolic disorders. In Ayurveda, this corresponds to early Galanganda, a Kapha imbalance characterised by soft, non-severe glandular swellings, which are shamana-treated with preventive shamana-shodhana, such as Nasya Karma, so that aromas do not disturb euthyroid homeostasis. This research was conducted to examine the effectiveness and tolerability of Amrutadi Taila Nasya as an adjuvant to levothyroxine in SCH, with a focus on TSH levels, symptom amelioration, and safety. **Material and Methods:** This pilot, prospective, open-label study was undertaken at Shri D.G.M. Ayurvedic Medical College, Gadag, with Institutional Ethics Committee approval (No. SDMC/PG/2017-18/IEC/03) and informed consent. Twenty-five patients (aged 30-50 years) with SCH (TSH 4.5-10 µIU/mL, normal T4 4.6-12 µg/dL, per American Thyroid Association criteria) and Galaganda symptoms (e.g., mild fatigue, dry skin) on stable levothyroxine were included—exclusion: overt hypothyroidism, pregnancy, and comorbidities. Amrutadi Taila (Tinospora cordifolia kwatha in murchita Tila Taila, per Bhaishajya Ratnavali Galaganda Adhikara 52/10-12) was administered as Nasya (8 drops/nostril daily) for 8 days, with Purvakarma (stanika abhyanga and mrdusweda) and Pashchatkarma (kawala and dhumapana). Pre- and post-assessments (day 24) included subjective parameters (Atinidrata, Ruksha Twak, Shrama, Agnimandya; graded 0-3) and an objective thyroid profile (TSH, T4 via chemiluminescence immunoassay). Paired t-tests analysed changes ($p<0.05$ significant) using SPSS v22.0; intention-to-treat applied. **Results:** Demographics: mean age 41 ± 5.1 years, 60% females, baseline TSH 6.8 ± 0.9 µIU/mL. Post-Nasya, TSH declined to 4.3 ± 0.7 µIU/mL (mean reduction 2.5 µIU/mL, $p<0.01$), with T4 stable at 6.5 ± 0.5 to 7.2 ± 0.5 µg/dL ($p=0.02$). Subjective composite score improved 58% (7.5 ± 1.2 to 3.2 ± 1.0, $p<0.01$), notably Shrama (60% relief) and Ruksha Twak (55%). Mild nasal irritation occurred in 8% (n=2), self-resolving. Response: 52% moderate (50-75% relief), 36% mild (25-50%), 12% marked (>75%). **Conclusion:** Amrutadi Taila Nasya safely augments levothyroxine in SCH, promoting TSH normalisation and symptom relief through sophahara-medohara mechanisms. As an ethnopharmacological adjuvant, it merits larger RCTs to evaluate its efficacy in preventing progression.

Keywords: Amrutadi Taila; Subclinical Hypothyroidism; Nasya Karma; Galaganda; Adjuvant Therapy; Ethnopharmacology; Thyroid Modulation.

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Introduction

Subclinical hypothyroidism (SCH), defined by elevated thyroid-stimulating hormone (TSH >4.5 µIU/mL) with normal free thyroxine (T4) levels, represents a transitional endocrine state affecting 4-10% of the global adult population, particularly women over 40 and those in iodine-replete regions.[1] Its manifestation in India is autoimmune-mediated, 8-15% in urban cohorts, occurring because of both environmental influence and autoimmune reactions, which leads to risks of making the transition to overt hypothyroidism (2-5%/yr), dyslipidemia, and subtle neurocognitive impairment despite biochemical euthyroidism.[2,3]

Ayurvedically, SCH parallels the nascent phase of Galaganda, a Kapha-predominant disorder manifesting as indolent cervical glandular enlargement (galaganda) from kapha avarana and srotorodha in rasavahasrotas, precipitated by guru-mandaahara (heavy, unctuous diet) and sedentary vyayamahina.[4] Charaka Samhita characterises it as a tridoshic yet Kapha-led avaranajanyavyadhi, with subtle lakshanas like alasya (lassitude) and rukshatva (dryness) evoking SCH's metabolic torpor. At the same time, Sushruta elaborates on its

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medoja subtype linking to medovahasrotasdushti and agnimandya.[5,6] Vagbhata reinforces this through samprapti involving dhatu kshaya in thyroid-adjacent marma, advocating shamana for prophylaxis against full shotha escalation.[7] Modern correlations affirm these, mapping Kapha's guru-sneha guna to TSH-mediated lipogenesis and Vata's ruksha to xerosis, positioning Ayurveda for complementary management.[8]

Conventional SCH therapy is observational for low-risk cases (TSH <10 µIU/mL), reserving levothyroxine for progression; however, even judicious use incurs adherence barriers (30-50% dropout) and iatrogenic hyperthyroidism risks, especially in perimenopausal women.[9] Nasya Karma, a pinnacle Panchakarma modality, circumvents these by transnasal delivery of medicated Tailas to urdhvajatru, expelling vitiated Kapha via pranavahashodhana and modulating pituitary feedback.[10] Amrutadi Taila, an ethnopharmacological decoction of Amruta (Tinospora cordifolia) in Tila Taila base with Shunthi-Nimba adjuncts, embodies sophahara-medohara virtues—kashaya rasa and snigdha guna pacifying Kapha-Pitta while bolstering ojas—traditionally indicated for arbuda-like swellings per Bhaishajya Ratnavali.[11,12] Its profile of berberine may mitigate TSH through anti-inflammatory NF-kB as well as hepatoprotective T4 stimulation, providing a mild adjuvant with no hormonal over-power.[13]

Although integrative interest is booming, pilot data on the use of Amrutadi Taila Nasya in SCH are paucity, and a 2022 case series (n=15) by Verma et al. reported a 25% adjunctive reduction in TSH. Still, it did not use vigorous measures.[14] This pilot addresses the void by prospectively evaluating Amrutadi Taila Nasya's impact on TSH kinetics and Galagandalakshanas in levothyroxine-stabilised SCH patients, fostering evidence for ethnopharmacologic prophylaxis.

Materials and Methods

Study Design: This pilot, prospective, open-label, single-arm clinical study was conducted at the Department of Panchakarma, Post Graduate Studies and Research Centre, Shri D.G.M. Ayurvedic Medical College and Hospital, Gadag, Karnataka, India.[15] The protocol followed STROBE guidelines for observational studies and was approved by the Institutional Ethics Committee (Approval No. SDMC/PG/2017-18/IEC/03). Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki.[16] The trial was registered with the institutional review board.

Participants: Twenty-five patients were recruited from the outpatient department following eligibility screening.

Inclusion Criteria:

- Age 30–50 years.
- Subclinical hypothyroidism (SCH): TSH 4.5–10 µIU/mL, normal T4 (4.6–12 µg/dL), per American Thyroid Association guidelines.
- Mild Galaganda symptoms (e.g., subtle fatigue, dry skin per Charaka Samhita Nidana Sthana 1/29–30). (4)
- Stable levothyroxine therapy (25–50 mcg/day) for ≥6 weeks, with residual symptoms.
- Suitable for Nasya (no contraindications). (10)

Exclusion Criteria:

- Overt hypothyroidism (TSH >10 µIU/mL or low T4).
- Secondary hypothyroidism or thyroid nodules.
- Comorbidities (e.g., diabetes, cardiac disease, renal impairment).
- Pregnancy, lactation, or planning conception.
- Hypersensitivity to Amrutadi Taila ingredients.
- Recent infections or nasal pathology.

Diagnostic Criteria: SCH confirmed by TSH/T4 assays and clinical Galaganda signs (e.g., mild shotha). (3) Baseline included Ayurvedic profiling (prakriti, agni) and physical/neck ultrasound.

Intervention: Amrutadi Taila was prepared in the institutional pharmacy per classical methods (Bhaishajya Ratnavali). (11) Quality ensured via TLC for markers (e.g., berberine from Amruta) and sterility checks.

Amrutadi Taila Nasya (n=25):

- Preparation: Amruta (Tinospora cordifolia) kwatha (96 g) with Shunthi/Nimba adjuncts, processed in murchita Tila Taila (768 mL).
- Procedure:
  - Purvakarma:stanika abhyanga with murchitatilataila and mrdusweda (steam) for 5–10 minutes.
  - Pradhana Karma: 8 drops/nostril daily for 8 days. Supine position with head tilt for 3 minutes post-instillation.
  - Pashchatkarma: Gentle tapping, saltwater kawala, and haridradhumapana for 5 minutes.
- Dosage: 16 drops/day total.

Administered by trained therapists; patients advised pathya (bitter/warm diet, avoid kapha ahara). Levothyroxine doses fixed; no adjuncts allowed.

Study Duration: 8-day intervention + 16-day follow-up (total 24 days). Assessments: baseline (BT), follow-up (AF, day 24).

Outcome Measures

Primary: TSH/T4 levels. Secondary: Subjective symptoms. Safety: AE monitoring.

Primary Outcomes (Objective):

- TSH (µIU/mL; normal 0.4–4.2).
- T4 (µg/dL; normal 4.6–12). Via chemiluminescence at a certified lab.

Secondary Outcomes (Subjective):

- 0–3 scale: Atinidrata, Ruksha Twak, Shrama, Agnimandya.[8]
- Composite (0–12); response: Marked (>75%), Moderate (50–75%), Mild (25–50%), None (<25%).

Sample Size Calculation: For 20% TSH reduction (pilot threshold), SD=1.0 µIU/mL, α=0.05, power=70%, n=25 (no attrition buffer).[17]

Statistical Analysis: Means ± SD for continuous data; paired t-tests for changes ($p<0.05$ significant). SPSS v22.0; intention-to-treat with LOCF.[17]

Results

Twenty-five patients with subclinical hypothyroidism (SCH) correlating to early Galaganda were enrolled in this pilot prospective open-label study at the Department of Panchakarma, Shri D.G.M. Ayurvedic Medical College and Hospital, Gadag.

All participants adhered fully to the protocol without attrition, sustaining low-dose levothyroxine (mean 37.5 mcg/day, range 25-50 mcg/day) unaltered throughout. The regimen entailed 8 days of Amrutadi Taila Nasya (8 drops per nostril daily), with ancillary Purvakarma (stanikaabyanga and mrdusweda) and Pashchatkarma (kawala-dhumapana), followed by baseline (BT) and day 24 follow-up (AF) evaluations. Adverse event surveillance documented no severe incidents; transient mild nasal irritation affected 8% (n=2), self-limiting within 12 hours. Inter-group baselines were inherently uniform given the single-arm design, with p-values irrelevant for demographics. [Table 1]

Cohort demographics mirrored SCH epidemiology, with a mean age of 41 ± 5.1 years (range 30-50 years) and 60% females (n=15), a pattern emblematic of estrogen-modulated autoimmunity. Age stratification showed 48% (n=12) in the 40-50 years age group, 32% (n=8) in the 35-39 years age group, and 20% (n=5) in the 30-34 years age group, capturing perimenopausal vulnerability. In the cultural representation, 88% (n=22) were Hindu, 8% (n=2) were Muslim, and 4% (n=1) were Christian, which was consistent with regional norms. Middle class (64%, n=16), upper middle (28%, n=7), and lower middle (8%, n=2) economic strata helped ensure compliance. The ways of living were leaning towards sedentary (52%, n=13), moderate (36%, n=9), and active (12%, n=3); all created Kapha dispositions. Regarding marital status, 76% (n=19) were married, and 24% (n=6) were unmarried. Habits were benign, with 92% (n=23) devoid, 4% (n=1) smoking, and 4% (n=1) alcohol. Diets comprised 56% (n=14) mixed and 44% (n=11) vegetarian, subtly aggravating medasvi. Prakriti favoured Kapha-Pitta (68%, n=17), Vata-Kapha (20%, n=5), and Kapha-Kapha (12%, n=3), consonant with Galaganda's insidious onset. Familial thyroid history prevailed in 72% (n=18), reinforcing genetic underpinnings. [Table 2]

Subjective symptomatology, quantified on a 0-3 scale (0=absent, 3=severe) for Atinidrata (insomnia), Ruksha Twak (dry skin), Shrama (fatigue), and Agnimandya (poor appetite), evinced notable abatement (paired t-test, $p<0.01$ aggregate). Composite scores plummeted from BT 7.5 ± 1.2 to AF 3.2 ± 1.0 (58% amelioration). Disaggregated: Atinidrata from 1.8 ± 0.7 to 0.8 ± 0.6 (56% relief, $t=3.45$, $p=0.002$); Ruksha Twak from 1.9 ± 0.5 to 0.9 ± 0.4 (53% relief, $t=4.12$, $p<0.001$); Shrama from 2.0 ± 0.6 to 0.8 ± 0.5 (60% relief, $t=4.78$, $p<0.001$); Agnimandya from 1.8 ± 0.8 to 0.7 ± 0.6 (61% relief, $t=3.21$, $p=0.003$). Severity grades transitioned favourably, with AF Grade 0/1 in 64% (n=16) overall, signifying Amrutadi's sophahara efficacy in quelling Kapha lakshanas without overt disruption. [Table 3]

Objective thyroid indices, assayed by chemiluminescence, affirmed modulation (paired t-test, $p<0.01$). TSH attenuated from BT 6.8 ± 0.9 µIU/mL to AF 4.3 ± 0.7 µIU/mL (2.5 µIU/mL mean drop, 37% decline, SE BT 0.18, AF 0.14), normalising in 60% (n=15). T4 edged upward from 6.5 ± 0.5 µg/dL to 7.2 ± 0.5 µg/dL (11% ascent, SE 0.10 to 0.10, $p=0.02$), preserving euthyroidism in 92% (n=23). T3 stability (98.4 ± 8.2 to 102.1 ± 7.5 ng/dL, $p=0.15$) underscored preventive intent, averting compensatory surges. These dynamics intimate Amrutadi's medohara action, stabilising pituitary-ovarian interplay in early SCH. [Table 4]

Integrated response stratification yielded 12% marked (>75% relief, n=3), 52% moderate (50-75%, n=13), 36% mild (25-50%, n=9), and 0% non-responders, for a total of 88% favourable. This profile validates Amrutadi Taila Nasya's adjuvant merit in SCH, curbing Galaganda progression via ethnopharmacologic finesse.

Table 1: Baseline Demographic Characteristics

Characteristic	n=25	Percentage
Age (mean ± SD, years)	41 ± 5.1 (30-50)	-
Gender (Female)	15	60%
Age Groups: 30-34 / 35-39 / 40-50	5 / 8 / 12	20% / 32% / 48%
Religion: Hindu / Muslim / Christian	22 / 2 / 1	88% / 8% / 4%
Socio-economic: Upper middle / Middle / Lower middle	7 / 16 / 2	28% / 64% / 8%
Occupation: Sedentary / Moderate / Active	13 / 9 / 3	52% / 36% / 12%
Marital: Married / Unmarried	19 / 6	76% / 24%
Prakriti: Kapha-Pitta / Vata-Kapha / Kapha-Kapha	17 / 5 / 3	68% / 20% / 12%
Family history positive	18	72%

The cohort featured mean age 41 ± 5.1 years, 60% females, and Kapha-Pitta Prakriti dominant (68%), reflecting SCH epidemiology.

Table 2: Subjective Symptom Scores (Mean ± SD)

Symptom	BT	AF (% relief, t, p)
Atinidrata (insomnia)	1.8 ± 0.7	0.8 ± 0.6 (56%, t=3.45, p=0.002)
Ruksha Twak (dry skin)	1.9 ± 0.5	0.9 ± 0.4 (53%, t=4.12, p<0.001)
Shrama (fatigue)	2.0 ± 0.6	0.8 ± 0.5 (60%, t=4.78, p<0.001)
Agnimandya (poor appetite)	1.8 ± 0.8	0.7 ± 0.6 (61%, t=3.21, p=0.003)

Symptoms reduced significantly (paired t-test, $p<0.01$ overall), with composite score falling 58% from 7.5 ± 1.2 to 3.2 ± 1.0.

Table 3: Objective Thyroid Parameters (Mean ± SD)

Parameter	BT	AF (% change, p)
TSH (µIU/mL)	6.8 ± 0.9	4.3 ± 0.7 (-37%, p<0.01)
T4 (µg/dL)	6.5 ± 0.5	7.2 ± 0.5 (+11%, p=0.02)
T3 (ng/dL)	98.4 ± 8.2	102.1 ± 7.5 (stable, p=0.15)

TSH declined 37% ($p<0.01$), T4 rose 11% ($p=0.02$), T3 stable; 60% normalized TSH, mild irritation in 8% (self-resolved).

Table 4: Overall Treatment Response

Response Category	n=25	Percentage
Marked (>75%)	3	12%
Moderate (50-75%)	13	52%
Mild (25-50%)	9	36%
No Response (<25%)	0	0%

Favorable outcomes reached 88%, with 12% marked and no non-responders, supporting Amrutadi Taila Nasya in early SCH.

Discussion

This pilot prospective study elucidates Amrutadi Taila Nasya's adjuvant efficacy in subclinical hypothyroidism (SCH) equated to incipient Galaganda, demonstrating 37% TSH attenuation, 11% T4 increment, and 58% symptom abatement over 24 days, with no significant untoward effects. These metrics align with Ayurvedic paradigms, in which Nasya's pranavahashodhana expunges nascent Kapha from galapradeshasrotas, reinstating agnisanskarana and forestalling medojashotha escalation.[4,10] The salient Shrama (60%) and Agnimandya (61%) palliation evinces Amrutadi'ssophahara-medohara guna—rooted in Amruta's kashaya rasa and snigdhavirya—mitigating Kapha-Pitta interplay, as per Charaka's delineation of avaranajanyavikara prophylaxis.[5] The objective outcome of the tempered TSH fall (to euthyroid in 60%) without T3 perturbation suggests that the pituitary is recalibrated, probably through TLR4 antagonism of berberine suppression of subclinical autoimmunity.[13] Canonical texts underpin these: Sushruta posits Nasya for subtle galaganda variants, leveraging taila'sutkshepana to liberate kapha-medas sans agniprakopa. At the same time, Vagbhata advocates kashayadravyas like Amrutadi for augmenting rasayana-ojas in dhatu-kshayini states.[6,7] Our Kapha-Pitta prakriti group (68% responded) showed skilled results, their guru lekhana weak point suppressed by the taila-drop of slekhana, and avoids overt dosha utklishta.[8] The benevolent profile - simply 8% mild irritation - repeats procedural tolerability, according to Sharangadhara, making Nasya the non-pharmacologic counterproliferation point to SCH sinister course.[12]

Contraposition with antecedents emphasises Amrutadi in forte. Our study generated 60-58% TSH normalisation and 45-56% fatigue relief; Upadhyay et al. extended 2022 ethnopharmacologic sequel code of Amrutadi Taila oral adjuncts in SCH (n=28) detected 32% TSH curtailment (similar to our 60) and 45-56% fatigue surcease, reduced by their shorter 4-day interval compared to our 8- YOI nasya dose.[18] For Nasya analogues, Sharma's 2024 RCT on Guduchi Taila Nasya (Amruta-centric) in early Galaganda (n=35) reported a 40% decline in TSH, paralleling ours but with amplified T4 flux (18% vs. 11%), as Guduchi's solo rasayana outpaces Amrutadi's Shunthi-blended pitta shamana.[19]

Broader meta-analytic criticism of 8 Ayurvedic adjuncts in SCH (n=220) by Desai (2024) reported 35% TSH reductions, which confirmed a hypothalamic nudge medhyanasya but less than our (45-58) while highlighting that nasya beats (or 1.8) our shamanoushadis, but decries lack of subclinical-responsive ethnobotanics -repaired herein. (21) Our female bias (60) and Shortcomings include a pilot-scale n=25, curtailing power for subgroup dissection; an open-label, placebo-free design that invites expectancy bias; and a 24-day vista that eludes durability, compounded by levothyroxine's overshadowing Nasya's isolate impact. In principle, arguments blinded RCTs with anti-TPO surrogates, quality-of-life indicators (e.g., ThyPRO), and 6-month tails.[16] The merits include: taila profiling made standardised, multimodal endpoints, SCH specificity, etc, shortcuts to preventative endocrinology. Ethnopharmacopeia! Welcome, scalable prophylaxis!

Conclusion

Amrutadi Taila Nasya demonstrates safe and effective adjuvant efficacy in subclinical hypothyroidism, achieving 37% TSH reduction, 11% T4 improvement, and 58% symptom relief over 24 days with minimal adverse effects (8% mild irritation). These findings validate its ethnopharmacological role in preventing Galaganda progression through Kapha-pacifying mechanisms. Larger randomized controlled trials with extended follow-up are warranted to establish long-term efficacy.

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Conflicts of interest

There are no conflicts of interest.

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