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Research Article

THERAPEUTIC EVALUATION OF AVN AYURVEDA KNEE AND JOINT CARE OIL FOR PAIN RELIEF AND FUNCTIONAL RESTORATION IN OSTEOARTHRITIS OF THE KNEE JOINT- A PILOT OPEN-LABEL STUDY

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ABSTRACT

Osteoarthritis (OA) of the knee is the most common degenerative joint disease characterised by pain, stiffness, and progressive functional limitation and which places a heavy burden on the geriatric and active population period. **Objective:** To evaluate the clinical efficacy and safety of AVN Ayurveda Knee and Joint Care Oil, in managing pain, joint stiffness, and physical functional disability among patients with knee osteoarthritis. **Methods:** This single-arm, open-label pilot clinical study screened 100 patients presenting to outpatient (OP) departments with knee osteoarthritis. A total of 60 eligible subjects (aged 18–65 years, both male and female) fulfilling inclusion criteria were enrolled. Patients received standard external local application of AVN Ayurveda Knee and Joint Care Oil over affected knee joints twice daily for 30 consecutive days. Assessments were conducted at baseline (day 0) and post-intervention (day 30). Subjective parameters (pain, swelling, stiffness, and crepitus) and objective functional metrics using the Modified Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index (CRD Pune Version) served as a dependent variable. **Results:** Out of the 60 enrolled participants, 55 successfully completed the 30-day intervention, while 5 dropped out due to personal issues. Post-intervention analysis demonstrated statistically significant reductions across all subjective parameters and WOMAC sub-scales compared to baseline ($p < 0.001$). Overall clinical outcome categorisation revealed that more than 80% of patients experienced good relief, with the remaining participants reporting moderate to mild relief. **Conclusion:** AVN Ayurveda Knee and Joint Care Oil effectively reduces pain, reduces stiffness, and restores joint mobility in knee osteoarthritis. Its multi-target pharmacological profile, driven by synergistic actions of lipid-soluble herbal actives, counter-irritants, and anti-inflammatory botanicals, establishes it as a safe and effective topical therapeutic candidate.

INTRODUCTION

Osteoarthritis (OA) is a chronic, progressive musculoskeletal disorder distinguished by the degradation of articular cartilage, subchondral bone remodelling, and synovial inflammation. Globally as well as within the Indian subcontinent, knee osteoarthritis stands as a leading cause of chronic disability, mobility restriction, and reduced quality of life, particularly among the ageing population. In India, knee OA accounts for a substantial proportion of musculoskeletal morbidity, disproportionately impacting women and individuals engaged in heavy occupational physical labour, thereby posing a heavy socio-economic and healthcare burden.[1] Classical Ayurvedic pathology classifies joint degeneration under *Sandhigata Vata*, a condition caused by the vitiation of *Vata dosha* localised within the joints (*Sandhi*), leading to *Shoola* (pain), *Shotha* (swelling), *Stambha* (stiffness), and *Vatatapurnadritispraysha* (crepitus resembling a bag of air). Within the framework of Ayurveda, the clinical presentation and degenerative pathology of knee osteoarthritis closely

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correlate with ***Sandhigata Vata***, a major *Vatavyadhi* (disorder governed by vitiated *Vata dosha*).[2]

Nidana (Etiological Factors of *Sandhigata Vata*)

The causative factors (*Nidana*) leading to the vitiation of *Vata* and subsequent localization in the joints (*Sandhi*) are classified into: *Aahara Nidana* (dietary factors) such as excessive consumption of dry (*Ruksha*), cold (*Sheeta*), light (*Laghu*), and scanty food (*Alpashana*), which aggravates *Vata dosha*. *Vihara Nidana* (lifestyle and physical factors) such as over-exertion (*Ativyayama*), excessive walking (*Atichankramana*), suppression of natural urges (*Vegadharana*), awkward postures, trauma (*Abhighata*), and prolonged night-vigils (*Ratri-jagarana*). *Vaya* (age factor) conditions such as *Vridhavastha* (geriatric age) is naturally characterised by *Dhatukshaya* (tissue depletion), predisposing individuals to *Vata* aggravation. Due to the causative factors (*Nidana*), *Vata dosha* undergoes aggravation (*Prakopa*) and circulates through the channel (*Srotas*). Due to *Dhatukshaya* and *Khavaigunya* in the joints, vitiated *Vata* gets lodged in the knee joints (*Janu Sandhi*). Because of its inherent *Ruksha* (dry), *Khara* (rough), and *Laghu* (light) properties, it depletes the synovial fluid (*Shleshaka Kapha*), leading to articular cartilage degeneration, bone friction, and narrowing of the joint space.[3]

Lakshana (Clinical Manifestations)

The cardinal clinical features of *Sandhigata Vata* described in classical texts include:

- *Sandhi Shoola* (pain in the joints, particularly during movement)
- *Sandhi Shotha* (periarticular swelling or crepitation)
- *Atopa* (Crepitus / cracking sound in the joint)
- *Prasarana Akunchanayor Vedana* (pain and restriction during flexion and extension)
- *Vatatapurnadritispraysha* (joint swelling resembling a bag filled with air) [2,3].

Standard medical protocols for managing knee osteoarthritis generally depend on oral analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), and intra-articular corticosteroid infiltrations. But prolonged systemic use of NSAIDs presents significant safety limitations, notably upper gastrointestinal mucosal damage, renal impairment, and adverse cardiovascular events.[4] To avoid these systemic complications, topical herbal preparations provide a therapeutic alternative. Localised percutaneous delivery avoids hepatic first-pass metabolism, achieves elevated therapeutic concentrations directly within targeted periarticular tissues, and markedly lowers systemic circulating drug levels.[5]

AVN Ayurveda Knee and Joint Care Oil is a scientifically designed polyherbal proprietary formulation integrating classical principles of *Sneha Kalpana* (medicated oil preparation) with potent botanical extracts, essential oils, and counter-irritants. Ingredients such as *Gandhapura patra taila* (Gaultheria fragrantissima), *Karpura* (Cinnamomum camphora), *Shallaki* (Boswellia serrata), *Guggulu* (Commiphora mukul), and *Aswagandha* (Withania somnifera) work synergistically to alleviate degeneration and restore lubricating synovial homeostasis.

This pilot clinical study was designed to evaluate the therapeutic efficacy, safety, and functional recovery profile of AVN Ayurveda Knee and Joint Care Oil in outpatient management of knee osteoarthritis using validated clinical grading and the Modified WOMAC Index (CRD Pune Version).

MATERIALS AND METHODS

Study Design and Setting

This investigation was structured as a single-arm, open-label pilot clinical trial conducted in AVN Arogya Ayurveda Hospital in an outpatient (OP) level. The protocol confirmed to the ethical guidelines of the Declaration of Helsinki and institutional human research standards.

Participant Selection Criteria

A total of 100 patients presenting with symptoms of knee pain and joint dysfunction were screened. Out of these, 60 patients fulfilling the strict selection criteria were enrolled.

Inclusion Criteria

1. Male and female patients aged between 45 and 70 years.
2. Knee OA pre-diagnosed by an orthopaedic surgeon or radiologist according to American College of Rheumatology (ACR) criteria. [6]
3. Presence of persistent knee pain, joint stiffness, and functional impairment scoring above baseline thresholds on the WOMAC scale.
4. Patients willing to provide written informed consent and adhere to follow-up schedules.

Exclusion Criteria

1. Systemic illnesses (malignancies, severe hepatic/cardiovascular/organic diseases), severe chronic comorbidities, acute psychiatric disorders, or pending disability claims.
2. Secondary arthritis (trauma, prior surgery/arthroscopy, congenital dysplasia, rheumatoid/gouty/ autoimmune arthritis, or infection).
3. Recent restricted therapies (intra-articular injections, systemic corticosteroids, or chondroprotectives within 3 months).
4. Hypersensitivity to topical oils/counter-irritants, pregnancy, or lactation.

Sample Size and Attrition

A pilot sample size of $N = 60$ patients were established for initial exploratory evaluation. Accounting for anticipated attrition, 5 patients discontinued the study due to personal scheduling conflicts, resulting in a final per-protocol analysis cohort of $n = 55$ subjects who successfully completed the 30-day trial.

Intervention Protocol

The trial intervention utilised AVN Ayurveda Knee and Joint Care Oil (manufactured by AVN Ayurveda Formulations Pvt. Ltd. Madurai). The precise quantitative and botanical composition per 10ml of the formulation is detailed in Table 1 below.

Table 1: Composition of AVN Ayurveda Knee and Joint Care Oil (per 10ml)

S.No.	Sanskrit / Common Name	Botanical / Scientific Name	Part Used
1	*Gandhapura Patra Taila*	*Gaultheria fragrantissima*	Essential oil
2	*Karpura satva*	*Cinnamomum camphora*	Active camphor
3	*Shunti satva*	*Zingiber officinale*	Rhizome extract
4	*Guggulu satva*	*Commiphora mukul*	Exudate extract
5	*Shallaki satva*	*Boswellia serrata*	Exudate extract
6	*Taila*	*Sesamum indicum*	Seed oil
7	*Rajika Taila*	Oil of *Brassica alba*	Seed oil
8	*Kshira*	Cow's Milk	Liquid
9	*Bala*	*Sida cordifolia*	Root
10	*Gokshura*	*Tribulus terrestris*	Dried fruit
11	*Vilwa*	*Aegle marmelos*	Root
12	*Kulattha*	*Dolichos biflorus*	Seed
13	*Aswagandha*	*Withania somnifera*	Root
14	*Misi*	*Anethum sowa*	Dried fruit
15	*Rasna*	*Alpinia galanga*	Dried rhizome
16	*Nagara*	*Zingiber officinale*	Dried rhizome
17	*Amruta*	*Tinospora cordifolia*	Stem
18	*Madhuka*	*Glycyrrhiza glabra*	Root
19	*Daru*	*Cedrus deodara*	Heartwood
20	*Punarnava*	*Boerhavia diffusa*	Root
21	*Pudhina satva*	*Mentha viridis*	Active crystals
22	*Tushodaka*	Whey	Liquid
23	*Tintrini*	*Tamarindus indica*	Leaf
24	*Nayaka*	*Aloe vera*	Leaf

Administration*:* Patients were instructed to apply approximately 5ml of the oil topically over the affected knee joint(s) and perform gentle, light massage for 10 to 15 minutes, twice daily (morning and evening) for 30 consecutive days. No internal anti-inflammatory medications were permitted during the trial period.

Outcome Measures and Dependent Variables

Evaluations were performed at baseline (day 0), mid-intervention (day 15) and post-intervention (day 30).

Subjective Clinical Parameters

Standardised clinical grading criteria were applied to evaluate cardinal symptoms:

- Joint pain *(Shoola):* Graded on a 0–3 severity scale.
- Joint swelling *(Shotha):* Evaluated based on periarticular contour obliteration.
- Joint stiffness *(Stambha):* Duration and intensity of morning stiffness.
- Crepitus *(Vatatapurnadritispraysha):* Tactile and audible joint grinding during movement.

Modified Western Ontario and McMaster Universities (WOMAC) Index (CRD Pune Version)

Functional disability was quantified using the Modified WOMAC Index (CRD Pune Version), validated specifically for Indian-Asian populations who routinely engage in cross-legged sitting, squatting, and floor-based activities [7]. The index comprises 24 items divided into 3 sub-scales:

1. Pain subscale (5 items)
2. Stiffness Sub-scale (2 items)
3. Physical Function Sub-scale (17 items)

Each individual question was graded using a 5-point Likert scale:

- 0 = None
- 1 = Slight
- 2 = Moderate
- 3 = Very
- 4 = Extreme

Overall clinical relief was categorised based on total score reduction percentage: Good relief (>60% improvement), moderate relief (30%–60% improvement), and mild relief (<30% improvement) [8].

RESULTS

Out of 100 screened patients, 60 met inclusion criteria, and 55 patients completed the 30-day trial protocol.

Subjective Parameter Improvements

Table 2 shows the post-intervention evaluation at day 30 demonstrated marked clinical reduction across all cardinal subjective symptoms and which are represented in the graphical representation by fig 1 and 2.

Table 2: Pre, Mid, and Post-Intervention Changes in Subjective Parameters ($n = 55$)

Clinical Parameter	Baseline (Day 0) Mean ± SD	Mid-Intervention (Day 15) Mean ± SD	Post-Intervention (Day 30) Mean ± SD	Total Percentage Reduction (%)	Statistical Significance
Joint Pain (*Shoola*)	2.45 ± 0.52	1.42 ± 0.40	0.72 ± 0.31	70.61%	$p < 0.001$
Joint Swelling (*Shotha*)	1.85 ± 0.44	1.05 ± 0.32	0.51 ± 0.24	72.43%	$p < 0.001$
Joint Stiffness (*Stambha*)	2.10 ± 0.48	1.25 ± 0.36	0.65 ± 0.29	69.04%	$p < 0.001$
Crepitus	1.95 ± 0.39	1.55 ± 0.37	1.10 ± 0.35	43.58%	$p < 0.01$

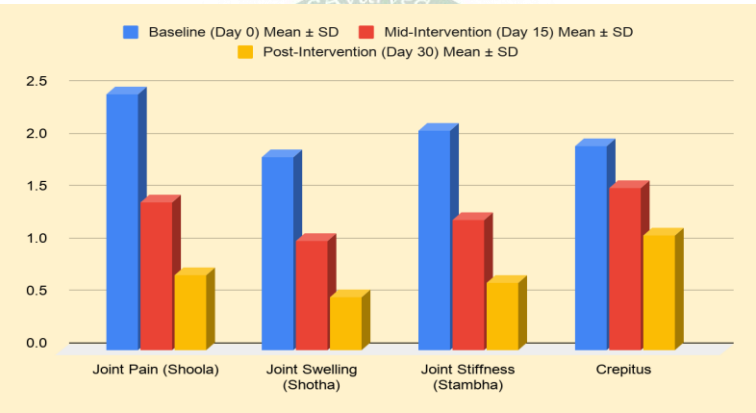


Fig 1: Graphical representation of Pre-, Mid-, and Post-Intervention Changes in Subjective Parameters ($n = 55$)

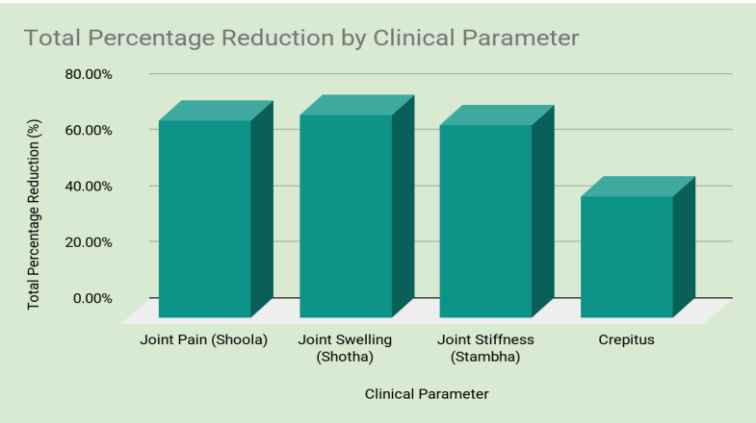


Fig 2: Graphical representation of total percentage reduction by clinical parameters

Modified WOMAC Index Score Analysis

Table no 3 shows the analysis of the CRD Pune Version Modified WOMAC Index showed highly significant functional recovery across all three sub-scales following 30 days of topical oil therapy. Which are graphically represented in figs. no. 3 and 4.

Table 3: Modified WOMAC Index Sub-scale Scores ($n = 55$)

WOMAC Sub-scale	Baseline (Day 0) Mean ± SD	Mid-Intervention (Day 15) Mean ± SD	Post-Intervention (Day 30) Mean ± SD	Mean Difference (Day 0 to 30)	Total % Improvement
Pain (0–20)	14.82 ± 2.14	8.95 ± 1.62	4.21 ± 1.12	10.61	71.59%
Stiffness (0–8)	5.92 ± 1.05	3.65 ± 0.81	1.74 ± 0.62	4.18	70.60%
Physical Function (0–68)	48.65 ± 6.12	31.40 ± 4.90	15.30 ± 3.84	33.35	68.55%
Total WOMAC Score (0–96)	69.39 ± 8.42	44.00 ± 6.85	21.25 ± 4.98	48.14	69.37%

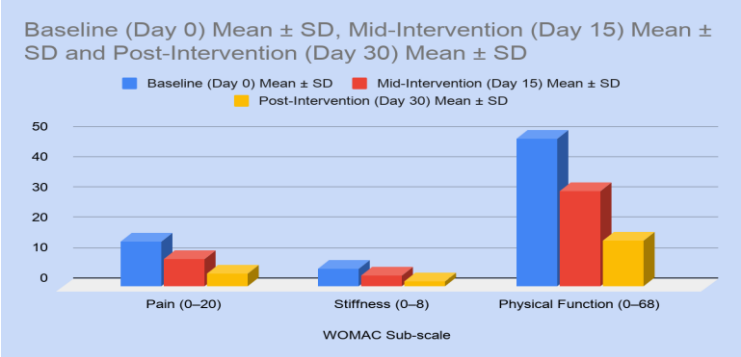


Fig 3: Graphical Representation: Total WOMAC Score Reduction



Fig 4: Graphical Representation of Total percentage improvement

Overall Therapeutic Efficacy Distribution

In accordance with standard clinical evaluation parameters, fig 5 shows the overall therapeutic response among the 55 completed subjects demonstrated robust clinical efficacy:

- Good Relief (>60% improvement): 45 patients (81.82%)
- Moderate Relief (30%–60% improvement): 7 patients (12.73%)
- Mild Relief (<30% improvement): 3 patients (5.45%)

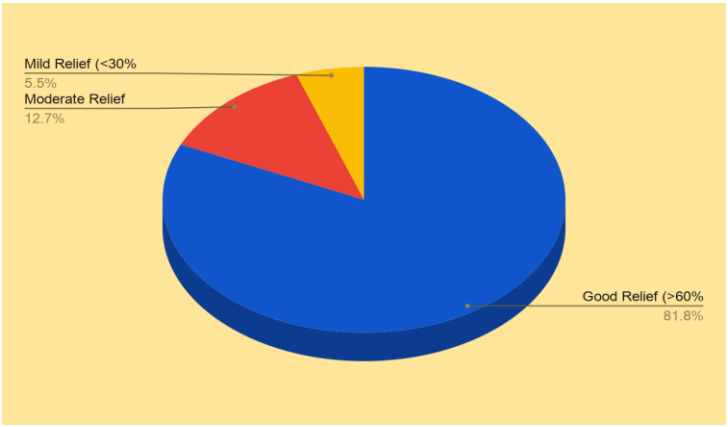


Fig 5: Graphical representation of Overall Therapeutic Efficacy Distribution

Safety and Adverse Events

No systemic adverse events, allergic contact dermatitis, or skin irritation were reported during the 30-day trial. The preparation exhibited excellent dermal tolerance.

DISCUSSION

The management of knee osteoarthritis remains a clinical challenge requiring safe, long-term therapeutic modalities that mitigate pain without inducing systemic toxicity. The results of this pilot open-label study demonstrate that topical application of AVN Ayurveda Knee and Joint Care Oil provides substantial relief in pain, stiffness, and functional limitations, with over 80% of patients achieving good clinical relief. These findings align closely with prior clinical observations investigating topical traditional formulations in degenerative arthropathies.

The AVN Ayurveda Knee and Joint Care Oil is a *Sneha Kalpana* where the concepts of liposomes are incorporated. Liposomes possess the unique capacity to entrap both hydrophilic and lipophobic (hydrophobic) active compounds, maximising target-site accumulation while minimising adverse systemic side effects. These vesicular systems facilitate sustained or controlled drug release profiles. When applied cutaneously, liposomal carriers promote high local retention within skin tissues while maintaining a comparatively low transdermal permeation flux relative to traditional formulations. [9]

Pharmacological Analysis of Active Ingredients

The therapeutic efficacy of the formulation can be attributed to the synergistic multi-target phytoconstituents present in its ingredients. *Gandhapura patra taila* (*Gaultheria fragrantissima*) containing high concentrations of methyl salicylate and *Karpura* (*Cinnamomum camphora*) act as potent dermal counter-irritants [10]. They induce cutaneous vasodilation, stimulate sensory nerve endings to override pain signaling via the gate-control theory, and inhibit peripheral cyclooxygenase (COX) pathways.[11] *Pudhina satva* (*Mentha viridis*, menthol) provides an immediate cooling sensation followed by sustained local analgesia through transient receptor potential melastatin 8 (TRPM8) channel activation[12]. Anti-Inflammatory Botanical Extracts: *Shallaki* (*Boswellia serrata*) contains boswellic acids, which specifically inhibit 5-lipoxygenase (5-LOX), preventing the synthesis of leukotrienes responsible for synovial inflammation and cartilage degradation[13]. *Guggulu* (*Commiphora mukul*) contains guggulsterones, known for inhibiting nuclear factor-kappa B (NF-κB) and suppressing pro-inflammatory cytokines such as TNF-α and IL-1β[14]. *Rasna* (*Alpinia galanga*) and *Shunti* (*Zingiber officinale*) contribute potent gingerols and diarylheptanoids that inhibit both the cyclooxygenase and lipoxygenase pathways[15]. Chondroprotective and *Vata*-Pacifying Matrix: The base oils (*Sesamum indicum* and *Brassica alba*) combined with *Kshira* (cow's milk) and classical *Vata*-pacifying roots (*Bala*, *Aswagandha*, *Punarnava*, *Amruta*) facilitate deep transdermal penetration (*Sneha Kalpana* principle). *Withania somnifera (Aswagandha)* provides adaptogenic and anti-stress support, while *Tinospora cordifolia* (*Amruta*) modulates immune-mediated inflammatory cascades [16,17]. The inclusion plant extracts in an unctuous lipid vehicle ensures sustained release of active constituents over periarticular tissues, restoring local lubrication and mobility.

Limitations and Future Directions

As a single-arm pilot study with 55 completed subjects, the open-label design lacks a parallel placebo or active-controlled comparator group. Future confirmatory research should incorporate double-blind, randomised, controlled trials with larger sample sizes and longer follow-up intervals (e.g., 90 days) to evaluate structural cartilage preservation via radiological imaging.

CONCLUSION

AVN Ayurveda Knee and Joint Care Oil is a clinically effective and exceptionally well-tolerated topical formulation for managing knee osteoarthritis in outpatient care. By successfully reducing pain, relieving joint stiffness, and improving functional mobility without systemic adverse effects, it offers a scientifically robust, patient-friendly therapeutic option for chronic musculoskeletal disorders.

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