



(Research Article)

Formulation and Evaluation of Polyherbal Ayurvedic Anti-Inflammatory Lepa

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ABSTRACT

Inflammatory reactions protect damaged tissues during an injury or infection; chronic inflammatory responses produce signs such as pain, swelling, redness, and a variety of systemic diseases. Overuse of synthetic anti-inflammatory drugs has led to side effects that include gastrointestinal irritation, ulcers, kidney damage, and increased skin sensitivity. Therefore, the need for safer and less expensive alternatives such as herbal preparations has developed. This research study aimed at developing and evaluating a polyherbal Ayurvedic lepa containing Amla (*Embllica officinalis*), Turmeric (*Curcuma longa*), Vitex negundo, and Red Ochre (Geru) that would be both safe and effective. Each ingredient was chosen because it is important in traditional medicine and each component has well documented bioactive compounds. Specifically, curcumin in turmeric blocks the production of pro-inflammatory chemical messengers while Amla provides antioxidant activity and tissue repair; Vitex negundo produces analgesia and anti-inflammatory activity; and geru reduces heat in the affected area. After drying, grinding into powder form, sifting through fine mesh screens and mixing together in optimal proportions, the four ground powders were mixed with distilled water and then subjected to mechanical energy to create a smooth paste. The new product was tested for its quality characteristics including physical appearance, taste, odor, texture, pH level, ease of application, ability to remove after application, irritation to intact skin and stability. All results indicated excellent uniformity and mixtures had good physical properties that did not vary significantly over time when stored at room temperature.

Keywords: Ayurvedic lepa; inflammation; polyherbal formulation; *Curcuma longa*; *Embllica officinalis*; *Vitex negundo*; topical herbal preparation; anti-inflammatory.

I. INTRODUCTION

Inflammation represents a critical physiological protective reaction that occurs whenever injured tissues are exposed to foreign substances. This may be due to an infectious agent, toxic substance, or another harmful stimulus. As the primary mechanism by which the body defends itself against potential injury, and begins the process of recovery, inflammation is a pivotal biological event. Five classic signs of inflammation include redness (rubor); swelling (tumor); pain (dolor); increased temperature (calor); and a reduction in functional capacity (functio laesa). Each of these signs has historically been defined and recognized through the discipline of pathology. While inflammation can generally resolve as damaged tissues begin their repair, there exists the possibility of inflammation persisting beyond this time frame. When persistent, inflammation can ultimately become a chronic condition, resulting in various clinical manifestations such as those seen in individuals suffering from rheumatoid arthritis, osteoarthritis, asthma, psoriasis, inflammatory bowel disease, cardiovascular disease, and auto-immune disorders [2]. Historically, the primary treatment modality for reducing inflammation was through the use of nonsteroidal anti-inflammatory medications (NSAIDs) and steroids. Both classes of medications were highly effective in reducing both the severity of pain and inflammation. However, each class also had known and potentially serious adverse effects. For example, prolonged NSAID use has been linked to gastrointestinal mucosal damage/peptic ulceration; renal impairment; and cardiovascular complications [6]. Additionally, steroid therapy results in skin thinning; suppression of immune responses; and significant alterations in systemic metabolism as a result of either topical or systemic administration. Due to the limitations associated with the current therapeutic strategies available for treating inflammatory disorders, researchers have demonstrated growing interest in exploring safer alternative therapies derived from medicinal plants. Plant-based medicines have been used extensively throughout history in the practice of traditional medicine. One of the earliest recorded systems of traditional medicine is Ayurveda, one of the oldest holistic medical practices. Through Ayurveda, patients have access to a vast array of botanicals/mineral products that serve as the basis for all traditional remedies. One form of Ayurvedic external dosing is called "lepa", which is an herbal paste applied

directly onto the area where the problem exists. Lepa therapy serves to provide targeted relief to the local area with minimal systemic absorption leading to fewer side effects. Lepa formulations are developed using a combination of herbs and reflects the Ayurvedic concept of "synergistic phytotherapy." Synergistic phytotherapy refers to the enhanced effectiveness of therapeutics through the interaction of bioactive molecules from two or more individual plants. Curcumin, a compound found within turmeric (*Curcuma longa*), acts to inhibit COX and LOX enzymes involved in the production of prostaglandins and leukotrienes, respectively. Amla (*Emblica officinalis*) contains high levels of vitamins C; tannins; and polyphenolic compounds, which possess strong antioxidant; immunomodulatory; and tissue-healing properties. Flavonoids, alkaloids; glycosides; and volatile oils contained in vitex negundo (nirgundi) contribute to the anti-inflammatory activity. Red ochre (Geru), a mixture of iron oxides (primarily FeO₃), has been used traditionally for its soothing and cooling effect on inflamed tissues [10]. The objective of this research was to create a novel polyherbal Ayurvedic anti-inflammatory lepa utilizing these four plants while adhering to both traditional Ayurvedic preparation techniques and modern pharmaceutical testing methods. The study evaluated several physical characteristics; skin compatibility; and shelf life of the final product to justify scientifically its traditional application.

II. LITERATURE REVIEW

A. Herbal Anti-Inflammatory Agents

The anti-inflammatory capability of medicinal plants has been widely researched. According to Sen & Chakraborty [11], there was considerable Nitric Oxide Scavenger Activity as well as significant Free Radical Inhibition from Vitex negundo, which they attributed to Phenolic Compounds & Flavonoids. Water Extracts exhibited greater Anti-Inflammatory Activity than Organic Solvent Extracts and validated this plants traditional usage for treating inflammatory diseases. Dasaroju & Gottumukkala [5] conducted an extensive Review on Pharmacological Properties of *Emblica officinalis* and highlighted how Vitamin C, Tannins & Polyphenols contribute to Antioxidant and Anti-Inflammatory Activities of Amla. They also pointed out that Amla can significantly reduce oxidative stress markers, and help regenerate tissues during inflammation. Similar findings were made by Razavi et al. [20], who confirmed that Curcumin (the primary Bioactive Constituent in *Curcuma longa*) inhibits COX Enzymes & Prostaglandin Biosynthesis; therefore providing Molecular Evidence for both the Potent Anti-Inflammatory and Antioxidative Properties of Curcumin. Sharma et al. [4] studied the Dose Dependent Analgesic & Anti-Inflammatory Effects of Vitex negundo in Experimental Animal Models and found significant decreases in Pain Scores, and Inflammatory Biomarkers. Nguyen et al. [13] published a Review of Multiple Plant Derived Anti-Inflammatory Agents and stated that Herbal Medicines are capable of inhibiting Pro-Inflammatory Cytokines, and have Superior Safety Profiles when compared to Synthetic Nonsteroidal Anti-Inflammatory Drugs (NSAIDS). A Systematic Review by Banik et al. [9] Identified Several Himalayan Medicinal Plants, including Species related to those used in the current Study, with Validated Anti-Arthritic and Anti-Inflammatory Activities.

B. Polyherbal and Topical Herbal Formulations

Wadnerwar et al. [15], studied polyherbal anti-inflammatory formulations and indicated the use of these formulations was beneficial due to a synergistic effect among herbs which allowed for a better efficacy of the product than if used individually. The same authors also stated that when compared to individual herb products, the combination of many different herbs (polyherbalism) is safer. This can be attributed to the practice of polypharmacy within Ayurveda. Tchienou et al. [16] developed an Ayurvedic topical cream (lepa) for swelling and inflammation. The cream had excellent spreadability, a significant reduction in swelling and no signs of skin irritation. Gupta et al. [17] created a stable herbal gel with an acceptable pH value. The patients also showed a higher level of compliance in applying this gel for localized inflammatory conditions. Das et al. [18] developed a polyherbal paste by combining flavonoid- and tannin-rich plants. The results from testing the anti-inflammatory properties of the paste were significantly greater than each of the ingredients tested separately. This indicates that there are benefits to using multiple plants together to achieve a desired outcome (phytochemical synergy). Kulkarni et al. [19] completed a review of Ayurvedic topical products and concluded they have been effective in decreasing swelling and pain without negative side effects. Razavi et al. [20] researched how well patients accepted herbal topical products. They found that patients liked them because they were made from natural materials, easy to apply, and caused fewer side effects—reasons why herbal medicine has seen such a large increase in popularity worldwide. Wadnerwar et al. [15] performed a comparative clinical trial on Ayurvedic lepa formulations for arthritic inflammation. Their results indicated that patients who received treatment had statistically significant improvements in both pain levels and functional status. Razavi et al. [20] reviewed all of the published studies regarding the potential therapeutic uses of Curcumin in inflammatory diseases and concluded it has great potential for treating these types of diseases.

III. AIM, OBJECTIVES AND NEED OF STUDY

Aim

The primary aim of this study was to formulate and evaluate a polyherbal Ayurvedic anti-inflammatory lepa using Amla, Turmeric, Vitex negundo, and Geru as a safe, effective, economical, and skin-compatible topical herbal preparation for managing inflammation, pain, and swelling.

Objectives

- Select herbal ingredients with anti-inflammatory, antioxidant, analgesic, and soothing properties based on traditional use and documented pharmacological studies.
- Prepare a smooth, homogeneous polyherbal lepa using powdered herbal drugs and distilled water as the vehicle.
- Optimize ingredient ratios for desirable consistency, homogeneity, and spreadability.
- Evaluate the formulation for organoleptic and physicochemical parameters including pH, spreadability, washability, homogeneity, and consistency.
- Assess skin compatibility through irritancy testing and stability under ambient storage conditions.
- Evaluate anti-inflammatory potential based on known pharmacological properties of the selected herbs.
- Develop a herbal alternative to synthetic anti-inflammatory formulations associated with chronic adverse effects.

Need of the Study

As conventional anti-inflammatories (e.g., corticosteroids) have serious long-term side-effects (gastrointestinal ulcerations; kidney damage; thinning skin; heart problems), there is an increasing interest in using alternative remedies which contain many natural compounds that act to reduce inflammation; decrease oxidative stress; and produce pain relief. These alternatives are usually less expensive than conventional treatments, they are often more acceptable to patients and because these products are applied locally to the area of concern, they may be safer when used for extended periods. Furthermore, when each of the individual compounds is combined together in a mixture or synergy, it has been shown in some instances that this produces a greater benefit than would be expected from the sum of their individual benefits [1-2] [3] [5] [14][16]. Therefore, the purpose of this research was to develop and test a stable, safe, and affordable topical herbal remedy for inflammatory disease.

IV. PLAN OF WORK

The research was conducted systematically across sequential stages: (1) procurement and authentication of raw materials; (2) cleaning, drying, and size reduction; (3) sieving and powder blending; (4) preparation of lepa by trituration with distilled water; (5) physicochemical and organoleptic evaluation; (6) stability testing; and (7) data interpretation and conclusion. This structured workflow ensured reproducibility and quality of the final formulation [23].

V. DRUG AND EXCIPIENT PROFILE

1. Amla (*Emblica officinalis* Gaertn.)

Biological Source: Dried fruits of *Emblica officinalis* (Family: Phyllanthaceae).

Chemical Constituents: Ascorbic acid (vitamin C), tannins, gallic acid, ellagic acid, flavonoids, polyphenols.

Pharmacological Actions: Antioxidant, anti-inflammatory, immunomodulatory, wound healing, anti-aging [5].

Amla neutralizes free radicals, reduces oxidative stress, and inhibits inflammatory mediators responsible for tissue damage. Its potent antioxidant capacity promotes faster healing of inflamed tissues and forms the basis for its role as an antioxidant and tissue-repair agent in the present formulation [5], [24]. (Figure 1.)



Figure 1. Amla.

2. Turmeric (*Curcuma longa* L.)

Biological Source: Dried rhizomes of *Curcuma longa* (Family: Zingiberaceae).

Chemical Constituents: Curcumin, demethoxycurcumin, bisdemethoxycurcumin, volatile oils, turmerone.

Pharmacological Actions: Anti-inflammatory, antioxidant, antimicrobial, wound healing [20].

Curcumin inhibits COX and LOX enzymes, reducing prostaglandin and inflammatory cytokine synthesis. It also exhibits antioxidant activity protecting tissues from oxidative damage. Turmeric serves as the primary anti-inflammatory ingredient in the lepa, reducing swelling, pain, and redness at the application site [20], [22], [24]. (Figure 2.)



Figure 2. Turmeric.

3. *Vitex negundo* L. (Nirgundi)

Biological Source: Leaves of *Vitex negundo* (Family: Verbenaceae).

Chemical Constituents: Flavonoids, alkaloids, glycosides, essential oils, terpenoids.

Pharmacological Actions: Anti-inflammatory, analgesic, antimicrobial, anti-edematous [9].

Vitex negundo inhibits peripheral inflammatory mediators and modulates pain perception. Constituent flavonoids and essential oils contribute to its analgesic and anti-inflammatory effects. In the formulation, it provides anti-edematous and analgesic activity, reducing pain and swelling associated with inflammation [9], [11], [12].



Figure 3. *Vitex negundo* L.

4. Geru (Red Ochre)

Nature: Naturally occurring mineral composed primarily of ferric oxide (Fe_2O_3), silica, and alumina.

Pharmacological Actions: Cooling effect, soothing action, mild anti-inflammatory property [10].

Geru provides a cooling and calming effect at the application site, reducing irritation, burning sensation, and patient discomfort. As a traditional Ayurvedic mineral ingredient, it enhances overall patient compliance and complements the anti-inflammatory activity of the herbal components [10].



Figure 4. Geru.

Table 1. Drug and Excipient Profile of Polyherbal Lepa.

Ingredient	Category	Role in Formulation
Amla (<i>E. officinalis</i>)	Drug	Antioxidant and healing agent
Turmeric (<i>C. longa</i>)	Drug	Primary anti-inflammatory agent
<i>Vitex negundo</i>	Drug	Analgesic and anti-inflammatory

Ingredient	Category	Role in Formulation
Geru (Red Ochre)	Excipient	Cooling and soothing agent
Distilled Water	Excipient	Vehicle for paste formation

VI. MATERIALS AND METHODS

1. Procurement and Authentication of Materials

Amla powder, Turmeric powder, and Vitex negundo leaf powder were procured from a certified herbal supplier and authenticated based on morphological characteristics, color, odor, and official monograph descriptions. Geru was obtained from a pharmaceutical raw material supplier. Foreign matter was removed manually and only pure; adequately dried materials were used [21].

Table 2. Formulation Ingredients.

Sr. No.	Ingredient	Biological Source	Quantity	Role
1	Amla powder	E. officinalis fruit	20 g	Antioxidant
2	Turmeric powder	C. longa rhizome	10 g	Anti-inflammatory
3	Vitex negundo powder	V. negundo leaves	15 g	Analgesic/Anti-inflammatory
4	Geru	Natural mineral	5 g	Cooling agent
5	Distilled water	—	q.s.	Vehicle

2. Processing of Crude Drugs

Shade-drying plant material at room temp helped in preserving heat labile phytoconstituent of the plant material. Mechanical grinding was carried out for size reduction. Size reduced powder samples were then sieved with sieve number 60 to ensure that the size distribution is uniform throughout. This helps to achieve a consistent particle size for all ingredients which results in an improved consistency of the final paste product [23]

3. Preparation of Polyherbal Lepa

The following quantities of powdered Amla (20 g), Turmeric (10 g), Vitex Negundo (15 g) and Geru (5 g) were accurately measured on an electronic balance and placed in a clean mortar. All ingredients were then combined by grinding for approximately 2 minutes in order to produce a uniform powder. Gradually increasing amounts of distilled water were then added while continuously grinding all powders together in order to create a consistent, semisolid paste that could be easily applied as a Lepa. Once the desired pasty consistency had been achieved, the prepared Lepa was immediately packaged into new, dry, closed containers and labeled accordingly; the Lepas were stored at room temperature without exposure to direct sunlight or moisture [24].

4. Evaluation Parameters

The prepared formulation was examined to determine whether it met: (i) organoleptic characteristics (texture, color, odor, appearance and uniformity); (ii) the pH value of the product using a calibrated pH meter when 1 g of product is dissolved in deionized water; (iii) how well it could be spread (spreadability) by determining the distance that the product spreads across two flat surfaces of glass under a given load; (iv) its physical consistency through visual observation; (v) washing ability, based upon its ease of removal from the skin with water; (vi) irritation to the skin by testing the product on an area of skin and checking for redness, itching, swelling or burning; and (vii) stability tests conducted at room temperatures over 15 days, noting any changes in color, odor, pH, consistency and uniformity [17] [24].

VII. RESULTS AND DISCUSSION

Table 3. Evaluation Results of Polyherbal Anti-inflammatory Lepa.

Sr. No.	Parameter	Observation	Inference
1	Color	Brownish-yellow	Due to turmeric; consistent with ingredients
2	Odor	Characteristic herbal	Acceptable; no off-odor
3	Texture	Smooth, homogeneous	Proper trituration achieved
4	pH	6.5	Within skin-compatible range (5.5–7.0)
5	Spreadability	Good	Uniform application over skin possible

Sr. No.	Parameter	Observation	Inference
6	Consistency	Semi-solid	Adequate retention at application site
7	Washability	Easy (water-removable)	Good patient convenience
8	Skin Irritation	None observed	Safe and non-irritant
9	Stability (15 days)	Stable; no change	Suitable shelf life under ambient conditions

1. Organoleptic Characteristics:

The brownish yellow color of this product is due to its inherent coloration from the components of turmeric (Curcumin), and the other medicinal plant parts that were added together [20]. Odor was typical and therapeutically acceptable. The smooth feel and complete uniformity of the mixture was a result of the mechanical mixing and uniform screening of all of the various powder components [17]. Such characteristics are an indication of successful formulation development; they will also contribute to patient compliance with the medication.

2. pH evaluation:

At 6.5 pH, this preparation has a pH within the normal limits of healthy skin (range 5.5 – 7.0) [24], thus, indicating it should have skin compatibility. Maintaining the correct pH is essential for protecting against irritation of the skin, maintaining the acid barrier layer of the skin, and maximizing efficacy of the drug. As previously indicated by Gupta et al. [17] and Shimpi & Pawara [24], the natural acidity of the Amla extracts (tannins, ascorbic acid) plus using distilled water as the medium could be responsible for the suitable pH found in this product.

3. Spreadability:

This product had a desirable amount of spreadability enabling even coverage when applied to the intended area. In addition to achieving a very fine particle size utilizing a #60 screen sieve, and having enough moisture to adequately mix the product while in a semi-solid state, these two factors greatly aided in producing an excellent spreadability. Adequate spreadability is important in topical formulations since it affects how easily patients can apply products and subsequently how long products remain in contact with the skin's surface [17],[24].

4. Consistency/Washability:

The consistency of the semi-solid paste provided sufficient hold at the application site such that it did not leak off and allowed sufficient contact time for the active ingredient(s) to be released into the skin. Easy removability with water enhanced both patient convenience/hygiene. The solubility of some of the constituents from the herbal extracts (e.g. water soluble ascorbic acid from Amla and other water soluble phenolics) along with being made up of an aqueous medium assisted in easy cleaning [5],[24].

5. Skin Irritation:

During the skin irritation testing there were no signs of redness, itching, swelling, or burning sensations observed. Thus, the product is safe for topical use. It is likely that the lack of irritation experienced was due to: (1) natural ingredients used; (2) suitable pH; and (3) cooling/soothing action of Geru [10]. Additionally, the anti-inflammatory and antioxidant effects associated with Turmeric, Amla, and Vitex negundo extracts can also provide protective effects on the skin's health [20],[5],[4].

6. Stability Testing:

The product remained physically unchanged over 15 days with little to no visible changes in color, odor, pH, consistency, or homogeneity. Stability testing results demonstrated that: (1) proper drying of crude drug material; (2) uniform distribution of particles; (3) airtight container storage; and (4) antioxidant properties of the herbal extracts (especially the high levels of ascorbic acid present in Amla) helped maintain stability [5],[24]. Further extended stability studies for a longer duration and under ICH recommended accelerated conditions would be needed in future research.

7. Anti-Inflammatory Activity:

Properties related to physical/physiological activity and safety suggest therapeutic activity for this product. The anti-inflammatory mechanism of this product is multi-factorial including: (1) Curcumin mediated inhibition of COX-2 and LOX enzymes [20],[22]; (2) Antioxidant protection against oxidative damage via polyphenolic and vitamin C compounds from Amla [5],[24]; (3) Modulation of peripheral pain/inflammation mediators via flavonoids from Vitex Negundo [9],[11],[12]; (4) Topical soothing/cooling via Geru [10]. The cumulative pharmacological profile of this product parallels prior studies involving polyherbal combinations [15],[18] and provides further justification for Ayurvedic rationale for multi-ingredient topical treatments [3],[8].

VIII. CONCLUSION AND FUTURE SCOPE

The purpose of this current investigation was to formulate and evaluate an anti-inflammatory lepa that combines four polyherbs (Turmeric, Amla, Vitex negundo, and Geru). The lepa was made using inexpensive and reproducible processes that are consistent with the principles of Ayurvedic medicine. In addition to being made according to Ayurvedic traditions, this lepa has been tested based on modern pharmaceutical evaluation

techniques. The test data show that this lepa meets all required criteria regarding its appearance, texture, and functionality. It also demonstrates no irritation of the skin upon contact, and it maintains its physical integrity during 15 day storage at room temperature. Based on the combination of these factors, there exists a scientific rationale for the formulation's therapeutic benefit from the combined anti-inflammatory activity of each of the selected herbs. Therefore, while the data clearly demonstrate that the lepa is safe and physically stable, they do not provide evidence of efficacy. However, the results suggest that this herbal lepa is a cost-effective alternative to chemical anti-inflammatory agents for treating localized inflammation, pain and swelling. As a result of our study, several additional investigations will be necessary: (1) in vivo pharmacology testing of animals (using well-established animal models of paw edema due to carrageenan or granulomas due to cotton pellets), so that we can measure the anti-inflammatory effect; (2) in vitro testing (for example, through COX-2 inhibition and DPPH radical scavenger assays) to further understand how the herbs function together; (3) ICH Q1A compliant stability testing to estimate shelf life; (4) inclusion of natural preservatives to prolong the microbial stability; (5) creation of new dosage forms (such as nanoemulgelel or liposome-based cream), which could increase absorption into the skin; (6) HPLC/HPTLC analysis to quantify and standardize the content of bioactive phytochemicals within the lepa; and (7) human subject clinical trials to assess both the safety and effectiveness of this formulation for use in patients who have inflammatory joint or skin diseases.

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