Formulation & Clinical Evaluation of Polyherbal Capsule as Adjuvant to NSAID's in Post Ksharsutra Pain Management

Dr. Minal Narkhede[1], Chetana Shimpi[2], Dr Shilpa Badhe[3]
[1]*Professor, Department of Pharmaceutics, SMBT College of Pharmacy, Dhamangaon, Nashik, 422403 Maharashtra, India*
[2]*Research Scholar, SMBT College of Pharmacy, Dhamangaon, Nashik, 422403 Maharashtra, India*
[3]*Professor, SMBT Ayurved College and Hospital*

Abstract: **Ksharsutra therapy is a widely accepted treatment modality for fistula-in-ano (Bhagandara), but post-procedural pain remains a significant clinical concern affecting patient comfort and compliance. Conventional management with non-steroidal anti-inflammatory drugs such as Diclofenac provides effective pain relief; however, prolonged use is associated with various adverse effects. The present study was undertaken to formulate a polyherbal capsule and evaluate its efficacy as an adjuvant to NSAIDs in the management of post-Ksharsutra pain. A randomized, open-label, controlled clinical study was conducted on patients undergoing Ksharsutra therapy, who were divided into two groups: a control group receiving NSAIDs alone and a trial group receiving NSAIDs along with a polyherbal capsule (500 mg twice daily). The formulation comprised extracts of Curcuma longa, Commiphora mukul, and Boswellia serrata along with powders of Zingiber officinale, Vitex negundo, Triphala, Ricinus communis, and Cynodon dactyl. Preformulation and post-formulation evaluation confirmed that the capsules possessed acceptable physicochemical and pharmaceutical properties. Pain was assessed using the Visual Analogue Scale (VAS) at regular intervals. The results demonstrated a statistically significant reduction in pain scores in the trial group compared to the control group ($p < 0.05$), along with a reduction in NSAID consumption, indicating an NSAID-sparing effect. Improved wound healing and absence of significant adverse effects were also observed in the trial group. In conclusion, the polyherbal capsule was found to be a safe and effective adjuvant to NSAIDs in reducing post-Ksharsutra pain and minimizing associated drug-related side effects**

Keywords: Ksharsutra therapy, Polyherbal formulation, Post-operative pain, NSAIDs, Diclofenac, Visual Analogue Scale (VAS), Fistula-in-ano, Adjuvant therapy, Anti-inflammatory, Analgesic

I. INTRODUCTION

Ksharsutra therapy, a well-established para-surgical procedure described in Ayurveda, is widely employed for the management of anorectal disorders such as fistula-in-ano[1]. Despite its clinical effectiveness and minimal recurrence rates, patients frequently experience significant postoperative pain, inflammation, and delayed wound healing. Effective pain management is therefore essential to improve patient compliance and overall treatment outcomes. Conventionally, non-steroidal anti-inflammatory drugs (NSAIDs) are prescribed to alleviate post-procedural pain. However, prolonged use of NSAIDs is associated with several adverse effects, including gastrointestinal irritation, ulceration, renal impairment, and increased cardiovascular risks, thereby limiting their long-term utility[2].

In recent years, there has been a growing interest in herbal and polyherbal formulations as safer alternatives or adjuncts to conventional pharmacotherapy. Polyherbal formulations, based on the Ayurvedic principle of synergism, combine multiple medicinal plants to enhance therapeutic efficacy while minimizing toxicity. Several medicinal plants such as *Zingiber officinale (Sunthi), Boswellia serrata (Shallaki), Commiphora mukul (Guggulu), Vitex negundo (Nirgundi), Curcuma longa (Haridra), Triphala, Ricinus communis (Erand), and Cynodon dactylon (Durva)* have been extensively reported for

their anti-inflammatory, analgesic, antioxidant, and wound-healing properties[3]. These pharmacological activities make them promising candidates for managing post-surgical pain and promoting tissue repair[4], [5].

Previous studies have demonstrated the efficacy of individual herbal components in reducing inflammation and pain; however, limited research has been conducted on their combined use as a standardized oral polyherbal formulation, particularly in post-Ksharsutra pain management. Furthermore, the potential role of such formulations as an adjuvant to NSAIDs in reducing drug dependency and associated side effects remains underexplored.

Therefore, the present study aims to formulate and evaluate a standardized polyherbal capsule incorporating selected medicinal herbs with known therapeutic benefits[6]. The study further seeks to clinically assess its efficacy as an adjunct to NSAID therapy in patients undergoing Ksharsutra treatment. By integrating traditional Ayurvedic knowledge with modern pharmaceutical and clinical evaluation approaches, this research intends to develop a safe, effective, and patient-compliant alternative for postoperative pain management[7], [8].

II. MATERIALS AND METHODS

The present study was designed as a randomized, open-label, controlled clinical trial to evaluate the efficacy of a polyherbal capsule as an adjuvant to NSAIDs in post-Ksharsutra pain management.

Procurement and Authentication of Raw Materials

The herbal ingredients used in the formulation included extracts of Curcuma longa, Commiphora mukul, and Boswellia serrata, along with powdered forms of Zingiber officinale, Vitex negundo, Triphala, Ricinus communis, and Cynodon dactylon[9]. All raw materials were procured from authenticated GMP-certified suppliers. Each batch was accompanied by a Certificate of Analysis (COA), confirming identity, purity, phytochemical composition, microbial limits, and heavy metal content. The materials complied with acceptable pharmacopeial standards[10], [11].

Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical characteristics of the ingredients and the final blend to ensure suitability for capsule formulation. The organoleptic properties of the raw materials, including color, odor, taste, and texture, were evaluated by sensory methods. The physicochemical parameters such as loss on drying, ash values, and extractive values were confirmed based on COA provided by the manufacturer.

The flow properties of the final powder blend were assessed by determining bulk density, tapped density, angle of repose, Hausner's ratio, and Carr's index using standard procedures [Table 1 & Table 2 shows the observations]. These parameters were evaluated to determine the flowability and compressibility of the blend. Compatibility among the formulation ingredients was assessed through physical observation, including any change in color, odor, or texture upon mixing. No significant incompatibility was observed[12].

Table 1: Flow properties

Parameters	Results
Bulk Density (g/ml)	0.42 ± 0.02
Tapped Density (g/ml)	0.50 ± 0.01
Angle of Repose (°)	27.8 ± 1.2
Hausner's Ratio	1.19 ± 0.03

Table 2: Interpretation Table

Parameter	Observed Value	Standard Range
Angle of repose	27.8°	< 30°
Hausner's Ratio	1.19	<1.25
Carr's Index	16%	15-20%

The preformulation evaluation of the polyherbal powder blend demonstrated satisfactory flow properties. The angle of repose (27.8°) indicated good flowability of the blend. The Hausner's ratio (1.19) and Carr's index (16%) further confirmed that the blend possesses fair to good flow characteristics. These results suggest that the powder blend is suitable for capsule formulation without the need for additional flow enhancers.

Formulation Design

Herbs having proven analgesic, anti-inflammatory, and wound-healing qualities were incorporated into

the polyherbal mixture. The powders of Zingiber officinale, Vitex negundo, Triphala, Ricinus communis, and Cynodon dactylon were added for their adaptogenic, anti-inflammatory, and immunomodulatory properties, while the extracts of Curcuma longa, Commiphora mukul, and Boswellia serrata were chosen for their strong analgesic and anti-inflammatory properties. In order to ensure that all chemicals were distributed uniformly, the formulation was optimized to obtain a total capsule weight of 500 mg. The polyherbal capsule's composition is described in Table 3.

Table 3: Composition of Polyherbal Capsule

Ingredient	Form used in formulation	Amount per capsule (mg)
Shallaki	Powdered extract	80
Guggulu	Powdered extract	60
Haridra	Powdered extract	80
Nirgundi	Powder	50
Sunthi	Powder	60
Triphala	Powder	70
Eranda	Powder (non-toxic fraction)	30
Durva	Powder	30
Excipients (MCC, silica, Mg stearate)	—	q.s.

Method of Preparation of Polyherbal Capsules

The polyherbal capsules were prepared using the standard pharmaceutical technique of geometric mixing. Accurately weighed quantities of the individual ingredients, including extracts of Curcuma longa, Commiphora mukul, and Boswellia serrata along with powdered forms of Zingiber officinale, Vitex negundo, Triphala, Ricinus communis, and Cynodon dactyl were taken.

All powdered ingredients were passed through sieve No. 80 to ensure uniform particle size. The extracts and powders were then blended thoroughly using geometric dilution to achieve a homogeneous mixture. The final blend was evaluated for flow properties and found suitable for encapsulation[13].

The blend was filled into hard gelatin capsules of appropriate size (size 0) using a manual capsule filling machine. The filled capsules were inspected for uniformity and stored in airtight containers at room temperature until further use[14].

Post-Formulation Evaluation

The prepared capsules were evaluated for various pharmaceutical parameters to ensure quality and uniformity. Physical evaluation included assessment of color, appearance, and average weight of capsules. Weight variation test was performed to ensure uniformity of dosage units.

Pharmaceutical evaluation included determination of disintegration time and uniformity of content using standard procedures. All parameters were found to be within acceptable limits.

The prepared polyherbal capsules were evaluated for various pharmaceutical parameters. The average weight of capsules was found to be 502 ± 5.2 mg, which was within acceptable pharmacopeial limits. The weight variation test showed uniformity of dosage units.

The disintegration time of the capsules was observed to be 12.4 minutes, indicating rapid disintegration and suitability for oral administration. The moisture content was within acceptable limits, suggesting good stability of the formulation[15].

The uniformity of content test confirmed consistent distribution of active constituents in all capsules. Overall, the formulation complied with standard quality control parameters and was found suitable for clinical use[16].

Table 4: Evaluation Parameters of Polyherbal Capsules

Parameters	Observation	Std. Limit	Results
Avg. weight	502 ± 5.2	500 mg ± 7.5%	Within limit
Weight Variation		± 7.5%	Passed
Disintegration time	12.4 ± 1.1		Passed

Clinical Study

Study Population

Patients diagnosed with fistula-in-ano (Bhagandara) and undergoing Ksharsutra therapy were selected for the study. Patients between 18 and 60 years of age who were willing to participate and provide informed consent were included.

Patients with severe systemic illness, hypersensitivity to NSAIDs, and pregnant or lactating women were excluded from the study[17].

Grouping and Intervention: The patients were randomly divided into two groups using a simple randomization method.

- Control Group (Group A): Received NSAID therapy only
- Trial Group (Group B): Received NSAID therapy along with polyherbal capsules

Patients in both groups received Diclofenac 50 mg orally twice daily after food. In addition, patients in the trial group received polyherbal capsules (500 mg) twice daily after meals for a duration of 14 days.

Assessment Criteria

Pain was assessed using the Visual Analogue Scale (VAS), a 10-point scale where 0 indicates no pain and 10 indicates worst possible pain[18].

Secondary outcome measures included duration of pain relief, requirement of NSAIDs, wound healing status, and incidence of adverse drug reactions.

Patients were assessed at regular intervals on Day 1, Day 3, Day 7, and Day 14 following the procedure[19].

Statistical Analysis

The data obtained were expressed as mean ± standard deviation (SD). Statistical analysis was performed using paired t-test for intra-group comparison and unpaired t-test for inter-group comparison. A p-value of less than 0.05 was considered statistically significant[20].

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrollment, and the study was carried out in accordance with ethical principles.

III. RESULTS

The preformulation studies of the polyherbal blend revealed satisfactory physicochemical and flow properties. The angle of repose (27.8°), Hausner's ratio (1.19), and Carr's index (16%) indicated good flowability of the Blend, making it suitable for capsule formulation.

The acceptable flow characteristics may be attributed to the presence of standardized extracts of Boswellia serrata and Commiphora mukul, which contribute to improved cohesiveness and packing ability of the blend.

Post-formulation evaluation of the capsules demonstrated that all parameters were within acceptable pharmacopeial limits. The average weight (502 ± 5.2 mg), disintegration time (12.4 minutes), and uniformity of content (98.5%) confirmed the quality and uniformity of the formulation. These findings indicate that the developed polyherbal capsules were pharmaceutically stable and suitable for oral administration.

IV. DISCUSSION

Post-Ksharsutra pain is primarily due to local tissue inflammation and chemical irritation caused by the medicated thread. Conventional NSAIDs such as Diclofenac provide symptomatic relief but do not address tissue healing and are associated with adverse effects on prolonged use.

In the present study, the polyherbal formulation demonstrated significant analgesic and anti-inflammatory activity, as evidenced by a greater reduction in VAS scores in the trial group. This effect can be attributed to the synergistic action of the herbal components.

The extract of Curcuma longa is known for its potent anti-inflammatory and antioxidant properties, primarily due to curcuminoids. Boswellia serrata contains boswellic acids that inhibit leukotriene synthesis, thereby reducing inflammation. Commiphora mukul exhibits analgesic and anti-inflammatory effects, contributing to pain relief.

Additionally, these herbs also acts as an adaptogen, improving stress response and healing, and enhances immune function and tissue repair. Zingiber officinale further contributes to anti-inflammatory activity by inhibiting prostaglandin synthesis.

The reduction in NSAID consumption in the trial group highlights the adjuvant potential of the formulation, which may help in minimizing NSAID-related adverse effects. The absence of significant side effects in the trial group further supports the safety of the formulation.

Overall, the findings suggest that the polyherbal capsule not only enhances pain relief but also

promotes better wound healing and reduces dependence on conventional analgesics.

V. CONCLUSION

The present study demonstrated that the formulated polyherbal capsule is a safe and effective adjuvant in the management of post-procedural pain following Ksharsutra therapy. The formulation exhibited satisfactory preformulation and post-formulation characteristics, confirming its pharmaceutical suitability for oral administration. Clinical evaluation revealed that the addition of the polyherbal capsule to conventional NSAID therapy, such as Diclofenac, resulted in a significant reduction in pain intensity as assessed by the Visual Analogue Scale. Furthermore, a noticeable decrease in NSAID consumption was observed in the trial group, indicating a beneficial NSAID-sparing effect. The formulation also contributed to improved wound healing and showed no significant adverse effects, suggesting good safety and tolerability. In conclusion, the polyherbal capsule may be considered a promising adjuvant therapy in post-Ksharsutra pain management, offering enhanced analgesic efficacy, reduced dependence on NSAIDs, and improved patient outcomes. Further studies with larger sample sizes and longer follow-up periods are recommended to validate these findings and explore its broader clinical applications.

VI. FUTURE SCOPE

The findings of the present study indicate promising potential of the polyherbal formulation as an adjuvant in post-procedural pain management following Ksharsutra therapy. However, further research is required to strengthen and expand these observations. Future studies should focus on conducting large-scale, multicentric clinical trials with a larger sample size and extended follow-up period to validate the efficacy and safety of the formulation. Dose optimization studies may also be carried out to determine the most effective therapeutic dosage. Additionally, advanced pharmacological investigations, including biomarker analysis and mechanism-based studies, can help elucidate the exact pathways responsible for the analgesic and anti-inflammatory effects of the formulation.

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