CHAPTER 6

AYURVEDIC
RASA SHASTRA & BHAISHAJYA KALPANA

Doctoral Theses

01. AGGARWAL (Punam)
Development of Chitosan based hydrogel of Shankha bhasma and Evaluation of its Antiulcer activity in Aspirin plus Pylorus ligation-induced Gastric ulcer.
Supervisor: Dr. Galib, Prof. (Dr.) P.K. Prajapati and Prof. Bhuvanesh Gupta
Th 28953

Abstract

Gastric ulcer is the commonest disorder of the upper digestive tract. It has 2.4% prevalence in the Western population with 0.10% to 0.19% annual incidence rate. Smoking, use of nonsteroidal anti-inflammatory drugs (NSAIDs), consumption of alcohol and Helicobacter pylori infection are responsible for gastric ulcer. The most common difficulty in treating the gastric ulcer is the high recurrence rate 60%. Though conventional system of medicine is effective but their side effect limit their clinical utility. On the other hand in Ayurveda these conditions are comparable with Amlapitta, Parinamashoola that are primarily focused areas of Ministry of AYUSH, New Delhi. A good number of herbs, minerals, metals and their formulations are mentioned in Ayurveda for these conditions. Shankha bhasma is one of them having Sheeta veerya and Pittashamaka property. However, due to its hydroscopic nature, the storage of Shankha bhasma is difficult and it may not show sustainable effect. Thus, an integrative approach hydrogel (three dimensional polymer structures) is taken under consideration for sustained and targeted drug delivery. Shankha bhasma was prepared as per classical method involving Shodhana and Marana processes. The chitosan based hydrogel of Shankha bhasma was developed and tested for its acute oral toxicity as per OECD guidelines and anti-ulcer activity in aspirin plus pylorus ligation model. The results showed that hydrogel of Shankh bhasma is non-toxic at 2000 mg/kg body weight in wistar female albino rats. The comparative analysis of classically prepared Shankha bhasma and Chitosan based hydrogel of Shankha bhasma both have anti-ulcer activity. In ulcer score both the tested drugs at two dose levels (22.5mg/kg and 45 mg/kg) showed equal and significant result with $p < 0.001$. While in biochemical parameters such as LPO, Catalase, GPx and TC:TP, Chitosan based hydrogel of Shankha bhasma showed additional protective effect against gastric ulcer. The nanohydrogel of Shakha Bhasma represents a novel and promising convergence of traditional Indian medicine with modern nanotechnology and drug delivery systems. Thus, the null hypothesis is rejected and alternate hypothesis is accepted.

Contents

1. Introduction 2. Review of Literature 3 Materials & Methods including Results 4. Discussion. 5. Conclusion. 6 Summary. 7. Future Scope & Limitations. 8. References. Bibliography. Annexures

02. ROBIN BADAL

Evaluation of Add on Effect of Saraswata Ghrita Through Nasya in Alzheimer's Disease on Biochemical Parameters – A Randomized Controlled Clinical Trial.

Supervisors: Dr. Pramod R Yadav, Prof. (Dr.) Pradeep Kumar Prajapati and Dr. Ashok Kumar Patel

Th 29332

Abstract

Alzheimer's disease is a progressive neurodegenerative disorder characterized by cognitive decline, memory impairment, biochemical alterations, and reduced quality of life. Current pharmacotherapy provides symptomatic benefit but has limited disease-modifying potential, creating a need for safe, standardized, and mechanism-oriented add-on interventions. Saraswata Ghrita, a classical Medhya Rasayana formulation, offers therapeutic relevance in cognitive disorders. The present randomized controlled clinical trial evaluated the add-on effect of Saraswata Ghrita administered through Nasya in patients with Alzheimer's disease. The formulation was prepared through classical Sneha Kalpana principles, with attention to raw drug authentication, proportion of Kalka, Sneha and Drava Dravya, controlled heating, observations of Sneha Siddhi Lakshana, and attainment of Mridu Paka suitable for Nasya Karma. Pharmaceutical revalidation was performed to ensure reproducibility and therapeutic appropriateness of the prepared formulation. Analytical characterization included organoleptic and physicochemical evaluation, HPTLC estimation of chebulinic acid and β-asarone, FTIR, HR-LCMS/MS-QTOF, GC-MS/MS, and DPPH assay, thereby linking classical pharmaceutical processing with modern quality assessment. Clinically, participants were divided into two groups. Group A received conventional medicine alone, while Group B received conventional medicine along with Saraswata Ghrita Nasya, 2 bindu in each nostril twice daily for 90 days. Outcomes included ADAS-Cog, MMSE, MoCA, QOL-AD, plasma pTau-181, acetylcholine, dopamine, serotonin, DHEA, safety parameters, and proteomic profiling. Both groups showed improvement in selected cognitive outcomes; however, between-group superiority was not established for all clinical scales. Group B showed better improvement in QOL-AD and greater reduction in plasma pTau-181. Proteomic findings suggested modulation of pathways related to inflammation, oxidative stress, complement activation, coagulation, lipid metabolism, vascular regulation, extracellular matrix remodelling, and protein homeostasis. No clinically significant adverse effects were observed. The study indicates that properly prepared and analytically characterized Saraswata Ghrita Nasya may serve as a safe supportive add-on intervention in Alzheimer's disease and warrants further multicentric validation.

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1. Introduction 2. Literature Review 3 Pharmaceutical Study 4. Analytical Study. 5. Clinical Study 6. Proteomics Profiling and Pathway Analysis 7 Discussion 8. Summary. 9 Conclusion. 10 Limitations and Future Scope. 11. Bibliography. Annexures

03. SINGH (Rohit)

Development of Shilajatu Darvi Yoga and evaluation of adjunct effect of Darvi to Shilajatu in the management of Madhumeha (Type 2 Diabetes Mellitus): A Randomized Controlled Clinical Trial.

Supervisors: Dr. Pramod R Yadav, Prof. (Dr.) Pradeep Kumar Prajapati and Dr. Ashok Kumar Patel

Th 28952

Abstract

Type 2 Diabetes Mellitus (T2DM), correlated with Prameha/Madhumeha in Ayurveda, is a multifactorial metabolic disorder characterized by hyperglycaemia, insulin resistance, oxidative stress, inflammation, and metabolic dysfunction. Shilajatu is a well-known Ayurvedic Rasayana and Pramehaghna drug, however, its optimization with adjunct botanicals remains inadequately explored. The present study aimed to develop Shilajatu Darvi Yoga (SDY) and evaluate the adjunct effect of Darvi (Berberis aristata DC.) to Shuddha Shilajatu (Asphaltum punjabinum) in T2DM through Pharmaceutical, Analytical, Clinical, ELISA-based biomarker, and Proteomic investigations. Pharmaceutical standardization of Shilajatu Solution (SS) and SDY was performed using Organoleptic, Physicochemical, Pharmacognostical, HPTLC, and OHRLCMS analyses. For clinical evaluation, a Randomized Controlled Clinical Trial was conducted for 90 days. Clinical assessment included subjective symptoms, fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1c, estimated average glucose (eAG), and QOLID score. Both groups demonstrated statistically highly significant improvement in subjective and objective parameters ($p < 0.0001$). However, SDY showed greater reduction in FBS (54.69 mg/dL), PPBS (104.45 mg/dL), HbA1c (1.89), and eAG (56.95) than SS with $p < 0.001$. Improvement in QOLID score was also higher in SDY (68.59) compared with SS (64.82). ELISA analysis demonstrated significantly greater improvement in ApoA4 levels in SDY (0.0763 ± 0.0157) compared with SS (0.0063 ± 0.0034) ($p < 0.01$). TXNIP reduction was also greater in SDY (-0.113 ± 0.031) than SS (-0.063 ± 0.009) ($p < 0.05$), indicating improved metabolic regulation and reduced oxidative stress. Proteomic analysis demonstrated molecular dysregulation involving inflammatory, oxidative stress, and lipid metabolic proteins including APOA1, APOA4, APOE, Complement C3, VTDB, SURF4, LRG1, Fetuin-A, and fibrinogen proteins. SDY demonstrated broader protein modulation and superior multitarget pharmaco-metabolic activity compared with SS. Hence, the alternate hypothesis was accepted and SDY may serve as a safe and effective multitarget therapeutic formulation for the comprehensive management of Type 2 Diabetes Mellitus.

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1. Introduction 2. Review of Literature 3 Pharmacognostical Study 4. Pharmaceutical Study 5. Analytical Study 6. Stability Study 7. Clinical Study 8 Proteomic Study 9. Discussion 10. Conclusion. 11. Limitations and Future Scope. 12. Summary 13. Bibliography 14. Annexures.