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ABSTRACT: While Ayurveda has traditionally relied on oral, nasal, rectal, and other non-parenteral drug delivery routes, scattered historical texts and 20th-century practices reveal an underexplored tradition of parenteral therapy. This tradition was largely discontinued after the 68th Amendment to the Drugs and Cosmetics Act in 1982 due to concerns over sterility and standardization. However, modern scientific advancements and urgent therapeutic demands have renewed interest in this area. This paper integrates historical, legal, and pharmacological dimensions to propose a roadmap for the safe and scientifically validated revival of Ayurvedic parenteral therapy. We examine recent research, including preclinical studies on polyherbal injectables like Harsha 22, and draw parallels with the successful modernization of Traditional Chinese Medicine (TCM) injections. We also address key challenges such as safety protocols, the erosion of intellectual property rights, and the potential for Ayurvedic formulations to be co-opted under the 'phytopharmaceutical' label, arguing for a new, dedicated regulatory framework to guide this revival.

INTRODUCTION

Ayurveda, the traditional Indian system of medicine, has long been practiced using multiple delivery routes, including oral (Mukha), nasal (Nasa), and rectal (Basti) administration. While oral formulations dominate current practice, classical texts and historical accounts contain references to parenteral-like methods.

These include Suchika Bharan (a term for needle insertion), Sira-vyadha (venesection), and the use of the Uttar Basti Yantra, a hollow metal instrument resembling a modern

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syringe needle. Furthermore, historical records indicate that injectable Ayurvedic formulations were actively manufactured in India until the early 1980s. This historical precedent was abruptly halted by the 68th Amendment to the Drugs and Cosmetics Act of 1982, which effectively excluded Ayurvedic injectables from the legal framework due to a lack of standardized testing and sterility assurance. This regulatory shift stifled innovation despite clear clinical demand. With today's emphasis on integrative healthcare and advanced medical technologies, a critical question re-emerges: can Ayurvedic injections be revived safely and effectively under modern scientific and regulatory protocols? This article argues that a responsible reintroduction is not only feasible but necessary. We will integrate historical evidence with modern pharmacological data to propose a clear roadmap for the revival of this underexplored therapeutic modality.

AIMS OF STUDY

This article aims to investigate the historical precedent for parenteral therapy in Ayurveda, analyze the legal and regulatory factors that led to its decline, and synthesize recent pharmacological and clinical evidence supporting its revival. By drawing a comparison with the successful modernization of Traditional Chinese Medicine (TCM) injectables and other countries, we will propose a comprehensive roadmap for the safe and effective reintroduction of Ayurvedic parenteral therapies within the current healthcare framework.

DISCUSSION

Historical perspective: a legacy of parenteral use:

The practice of injectable Ayurveda is supported by both textual and industrial precedents.

Classical References

Sushruta Samhita describes surgical equipment, which bears a resemblance to

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intravenous injections. The male Uttar Basti Yantra is also described as a hollow metal instrument akin to a modern syringe needle. More explicitly, Suchika Bharan refers to a procedure for introducing medicine directly into the bloodstream. Ravana's treatise on Arka Prakasha also describes distillates that could be adapted for sterile injectable use.

20th-Century Practices and Early Formulations

Before the 1983 ban, many Ayurvedic companies manufactured injectable formulations. Firms such as Siddhi Pharma and Bundelkhand Ayurvedic Unani Pharmacy produced nearly 120 different injectable formulations. Reports from the journal Ayukari in 1962 document these early practices, demonstrating a tangible history of injectable Ayurveda.

LEGISLATIVE SUPPRESSION: THE ROADBLOCKS TO PROGRESS

The history of Ayurvedic injections is marked by significant legal and regulatory challenges that ultimately led to their ban.

Key Regulatory Milestones

The 68th Amendment of the Drugs and Cosmetics Act in 1982 was the most significant legal turning point, as it added Section 3(h), which explicitly excluded parenteral Ayurvedic drugs. This was followed by Rule 158B in 2008, which formally prohibited the manufacture of AYUSH injectables without specific government approval, cementing the ban.

Major Court Cases

Firms that manufactured these products faced legal battles. The case of State of UP vs. S.C. Sen Gupta (Allahabad High Court, 1966) centered on the legal definition of Ayurvedic injections, while Siddhi Pharmacy vs. Union of India (Supreme Court, 2003) addressed licensing disputes and compliance with the Drugs Act.

SCIENTIFIC RATIONALE AND CLINICAL EVIDENCE

The potential for reviving Ayurvedic parenteral therapy is not merely historical; it is supported by a strong scientific rationale and a growing body of clinical evidence.

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Pharmacokinetics and Bioavailability

Parenteral delivery offers a pathway to bypass the first-pass metabolism that often limits the bioavailability of orally administered compounds. This can lead to a more rapid onset of action, crucial in emergency situations. Many active molecules from classical Ayurvedic herbs—such as Withaferin-A (from Ashwagandha), Boswellic acids (Shallaki), and Curcumin (Haridra)—have demonstrated potent pharmacological effects that could be enhanced through direct administration. The nano-sized metallic and mineral-based formulations known as Rasaushadhi also align with modern principles of nanomedicine, offering potential for targeted delivery and improved efficacy, though they require rigorous toxicity and stability testing.

Clinical and Experimental Studies

Historical and recent research provides concrete evidence of efficacy.

1. **Suchikabharan Rasa:** An M.D. thesis from 1981 studied this formulation's effects on sannipatik murcha (a type of unconsciousness), demonstrating its traditional use in critical care.

2. **Kshara Injections:** Clinical studies on hemorrhoids using 5–10% Kshara solutions showed high success rates (86–88%) with minimal complications. Similarly, studies have shown Apamarga Kshara injections to be a safe and effective sclerosing agent, comparable to allopathic polidocanol. Ksharodaka injections have also been successfully used for wart removal.

3. **Injection Harsha 22:** A 2023 animal study evaluated this polyherbal local anesthetic. The results showed an anesthetic effect lasting up to 90 minutes, which was comparable to lignocaine, with no hematological toxicity.

Lessons from a global parallel:

1. TCM: China’s experience with Traditional Chinese Medicine (TCM) injections demonstrates how traditional systems can modernize parenteral therapy. The first herbal injection (Chai Hu) was developed for fever in the 20th century, and today numerous TCM injections are used in mainstream clinical practice, such as Xiaoaiping for

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chemotherapy-induced thrombocytopenia. Their success has been possible due to strict regulatory oversight, adherence to Good Manufacturing Practices (GMP), and rigorous clinical validation, which allowed TCM injectables to gain acceptance in biomedical sciences.

2. **Korean pharmacopuncture:** Similarly, herbal injectables, known as pharmacopuncture, are widely practiced in Korea. Pharmacopuncture involves injecting diluted herbal extracts into acupuncture points or meridian lines to treat pain, inflammatory diseases, and other conditions. In Korea, specialized dispensaries called pharmacopuncture-EHDs prepare sterile herbal injections under the supervision of Korean Medicine doctors, ensuring both safety and efficacy.

3. **Kampo medicine**: In Japan, Kampo Medicine has also developed injectable formulations of specific herbal extracts. Kampo injections integrate classical Japanese herbal knowledge with modern pharmaceutical techniques and are used in clinical settings for managing pain and chronic disorders.

Taken together, the experiences of China, Korea, and Japan highlight a clear lesson for Ayurveda: with scientific standardization, sterility assurance, and clinical research, traditional systems of medicine can successfully establish injectable therapies in modern healthcare. This global parallel provides a strong foundation for the revival of Ayurvedic injectables.

Their success is a result of strong regulatory enforcement, adherence to Good Manufacturing Practices (GMP), and rigorous clinical validation, which allowed them to gain acceptance in the biomedical community. In stark contrast, Ayurveda lost this momentum after the 1983 ban.

CHALLENGES AND THE PATH FORWARD

The path to reviving Ayurvedic injections is not without significant challenges, particularly concerning safety and intellectual property.

1. **Safety and Quality Control Issues:** Herbal variability, contamination, and the historical presence of heavy metals have long been concerns. Any revival must mandate strict quality control measures, including sterility testing (e.g., for endotoxin-free solutions), aseptic processing, and stability trials, to meet modern safety standards.

2. **Protecting Ayurvedic Intellectual Property:** The regulatory framework for

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phytopharmaceuticals presents a complex challenge to the identity and intellectual property of Ayurveda. The reclassification of classical plant-based drugs as 'phytopharmaceuticals' allows allopathic doctors to use and research herbal medicines that are rooted in traditional Ayurvedic knowledge. This creates a valid concern among AYUSH practitioners that their traditional knowledge base may be sidelined, and the intellectual property associated with it could be diminished. This stands in contrast to the legal support provided to TCM practitioners in China, where traditional knowledge is protected within the modern scientific framework.

PROPOSED ROADMAP FOR REVIVAL

Based on the historical context, scientific evidence, and global parallels, we propose the following multi-faceted roadmap for the responsible re-introduction of Ayurvedic parenteral therapies.

1. **Controlled Clinical Re-introduction:** Begin with pilot projects focused on well-documented conditions (e.g., pain management, local anesthesia) with strong pre-existing evidence.

2. **Establish a New Regulatory Framework:** Develop and implement AYUSH-specific GMP standards for parenteral formulations. This must include mandatory protocols for sterility testing, aseptic processing, and stability trials.

3. **Prioritize Research:** Launch and fund multicentric randomized controlled trials (RCTs) on key injectable formulations for conditions like chronic arthritis (Shallaki) or immune modulation (Guduchi).

4. **Educational Reform**: Introduce comprehensive modules on parenteral pharmacology, aseptic techniques, and emergency care into BAMS and MD curricula.

5. **Protect Intellectual Rights:** Provide legal support and regulatory clarity to prevent the co-option of classical Ayurvedic knowledge under the phytopharmaceutical framework.

6. **Historical Data Collection:** Systematically collect and filter clinical data from the users and manufacturers of Ayurvedic injections before the 1982 ban to inform modern research and development.

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CONCLUSION

The discontinuation of Ayurvedic injectables in 1983 was a consequence of the safety limitations of that era, not a definitive refutation of their therapeutic potential. With modern sterile manufacturing techniques, advancements in nanotechnology, and rigorous regulatory oversight, Ayurveda can responsibly revive its injectable therapies. Historical precedents, compelling clinical observations, and recent experimental data all support this direction. Reviving Ayurvedic injections is not merely a nostalgic endeavor; it is a scientific necessity that can bridge tradition, innovation, and clinical need. By adopting a framework that prioritizes safety, mandates Good Manufacturing Practices (GMP), and protects the intellectual property inherent in Ayurvedic knowledge, this traditional system of medicine can reclaim and modernize a powerful delivery route for the benefit of global healthcare.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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