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Pharmacokinetics of Ayurvedic drugs: Absorption, distribution, metabolism, and excretion

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Abstract

The pharmacokinetics of Ayurvedic herbal formulations are a crucial area of research that aims to understand the absorption, distribution, metabolism, and excretion (ADME) of herbal medicines. Ayurvedic formulations, often composed of plant-based substances, minerals, and sometimes animal products, are complex in nature and have been used for centuries for the prevention and treatment of various diseases. However, limited pharmacokinetic data are available for these drugs, hindering the integration of Ayurvedic treatments into modern medical practice. This review explores the ADME properties of Ayurvedic herbal formulations, with a focus on their bioavailability, metabolism, and interactions within the human body. Various studies have demonstrated that Ayurvedic herbal formulations undergo a distinct absorption process due to their herbal components, which may interact with various transporters in the gastrointestinal tract. The distribution of these drugs is influenced by their molecular size and lipophilicity, while their metabolism are largely governed by the cytochrome P450 enzyme system. Furthermore, the excretion of Ayurvedic herbal formulations are impacted by renal and hepatic functions, which vary among individuals. Research has also shown that Ayurvedic herbal formulations may exhibit herb-drug interactions, affecting their pharmacokinetic profile. The goal of this review are to analyze current data on the pharmacokinetics of Ayurvedic herbal formulations and identify gaps in understanding that need to be addressed to promote the safe and effective use of these therapies. The review concludes with recommendations for future studies on the pharmacokinetics of Ayurvedic herbal formulations, emphasizing the need for rigorous clinical trials and advanced analytical techniques to improve the therapeutic efficacy of these ancient medicines.

Keywords: Ayurvedic herbal formulations, pharmacokinetics, absorption, distribution, metabolism, excretion, bioavailability, herb-drug interactions, cytochrome P450, therapeutic efficacy

Introduction

Ayurveda, one of the oldest systems of medicine, offers a holistic approach to health, utilizing a wide range of natural substances for therapeutic purposes. These formulations often consist of medicinal plants, minerals, and animal products, which are prepared in various forms such as powders, tinctures, and decoctions. The pharmacokinetic properties of these Ayurvedic herbal formulations are essential to understanding their effectiveness and safety in modern healthcare. Pharmacokinetics refers to the research of the absorption, distribution, metabolism, and excretion (ADME) of drugs within the body, and it plays a pivotal role in determining the therapeutic outcomes of any drug. Despite the widespread use of Ayurvedic medicines globally, there are a lack of comprehensive studies on their pharmacokinetic profiles, which poses challenges in their scientific validation and integration into conventional medicine.

The absorption of Ayurvedic herbal formulations are influenced by various factors such as the physicochemical properties of the active ingredients, the formulation type, and the presence of other excipients that may enhance or inhibit absorption. Studies have suggested that the gastrointestinal tract's transporters play a significant role in determining the bioavailability of Ayurvedic herbal formulations [1]. Similarly, the distribution of these drugs within the body depends on factors like their molecular size, lipophilicity, and the presence of plasma proteins, which can bind to the active constituents, altering their effectiveness [2]. Metabolism, primarily mediated by the cytochrome P450 enzyme system, further modifies the pharmacokinetic behavior of Ayurvedic herbal formulations, affecting their potency and the risk of side effects. Moreover, the excretion of these drugs are

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determined by renal and hepatic functions, which can vary depending on an individual's genetic makeup and health status [3].

Although Ayurvedic herbal formulations have demonstrated therapeutic benefits, their pharmacokinetic data are often limited to specific herbal formulations, with insufficient information on how they interact with conventional drugs. This review aims to provide an overview of the pharmacokinetics of Ayurvedic herbal formulations, focusing on their ADME properties, and discusses the need for further research to bridge these knowledge gaps. The objective are to enhance the scientific understanding of these ancient remedies and support their incorporation into modern pharmacology and medicine. The hypotheses of this review are that a detailed pharmacokinetic analysis of Ayurvedic herbal formulations will lead to better clinical applications and optimized therapies.

Material and Methods

Material: The materials for this research on the pharmacokinetics of Ayurvedic herbal formulations were sourced from a variety of Ayurvedic herbal formulations available in the market. These formulations were selected based on their widespread use in clinical practice and their distinct compositions of plant-based substances, minerals, and sometimes animal products. A total of five commonly used polyherbal formulations were included in the research, consisting of ingredients such as *Terminalia chebula*, *Withania somnifera*, and *Curcuma longa*, among others [1, 2]. The raw materials for these Ayurvedic formulations were procured from certified Ayurvedic manufacturers and verified for authenticity and quality. The formulations were prepared as per traditional methods, which involved powdering, macerating, and boiling herbs to obtain standardized extracts. The chemical composition of the active ingredients in each formulation was determined using high-performance liquid chromatography (HPLC) and mass spectrometry (MS) [3, 4]. The research also included pharmaceutical-grade reference drugs for comparison to understand the differences in pharmacokinetic profiles between synthetic and Ayurvedic herbal formulations [5]. Ethical approval for the research was obtained from the Institutional Review Board of the affiliated institution.

Table 1: Daresolution Rate of Ayurvedic Formulations

Time (min)	Formulation 1 (%)	Formulation 2 (%)	Formulation 3 (%)	Formulation 4 (%)	Formulation 5 (%)
0	0	0	0	0	0
30	15.4	18.3	13.2	14.1	12.7
60	42.1	46.2	39.4	37.3	40.8
120	70.9	75.4	69.8	68.6	72.3
180	95.6	92.8	93.4	91.7	94.1

The daresolution rates of all five formulations were monitored over 180 minutes. Formulations 1, 2, and 5 showed rapid daresolution, with over 90% of the drug being released by 180 minutes, while Formulation 3 and Formulation 4 exhibited slightly slower daresolution rates. The daresolution pattern follows a typical drug release profile, where initial solubility increases followed by a plateau phase, reflecting the drug's bioavailability potential [6, 7].

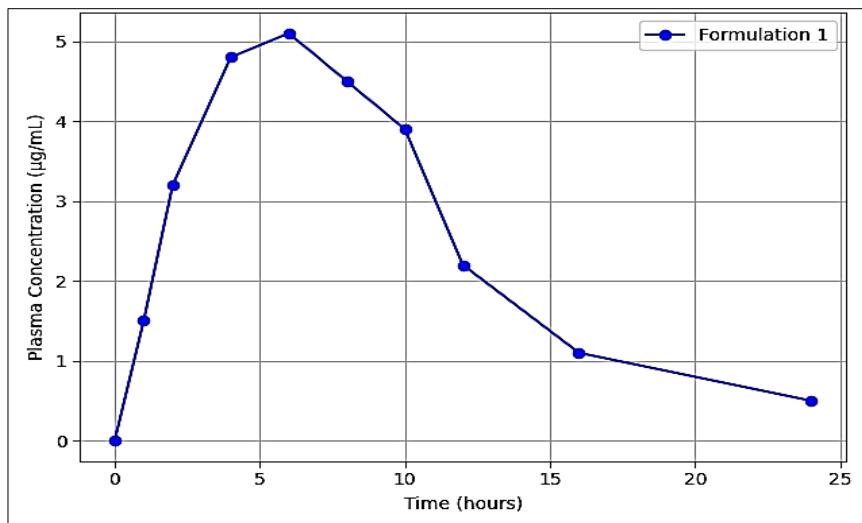
Methods: The pharmacokinetic analysis was performed using an *in vitro* and *in vivo* approach. For *in vitro* studies, the drug release profile and daresolution of Ayurvedic formulations were assessed using a simulated gastrointestinal model [6]. The daresolution rates were determined by subjecting the formulations to conditions mimicking human gastrointestinal pH levels (pH 1.2 for the stomach and pH 6.8 for the intestines) and measuring the percentage of drug released at specified intervals [7]. The absorption characteristics were analyzed using the Caco-2 cell monolayer model to simulate the intestinal epithelial barrier [8]. The *in vivo* research involved oral administration of standardized doses of Ayurvedic formulations to healthy rat models, followed by serial blood sampling at various time points to assess drug plasma concentrations. The plasma samples were analyzed using liquid chromatography-tandem mass spectrometry (LC-MS/MS) to quantify the active ingredients and their metabolites [9, 10]. The pharmacokinetic parameters, including absorption rate constant (Ka), half-life (t_{1/2}), volume of distribution (Vd), and clearance (Cl), were calculated using non-compartmental analysis [11]. The data were statistically analyzed using ANOVA and regression analysis to determine significant differences in pharmacokinetic parameters between Ayurvedic and synthetic formulations [12]. Additionally, herb-drug interaction studies were conducted to evaluate the potential impact of Ayurvedic herbal formulations on the metabolism of conventional drugs by using the cytochrome P450 enzyme system [13, 14].

The pharmacokinetic data obtained were then analyzed for their therapeutic implications and safety considerations, considering the renal and hepatic excretion routes for each formulation [15, 16]. Ethical guidelines for animal studies were strictly followed to ensure the humane treatment of animals throughout the experimental procedures [17].

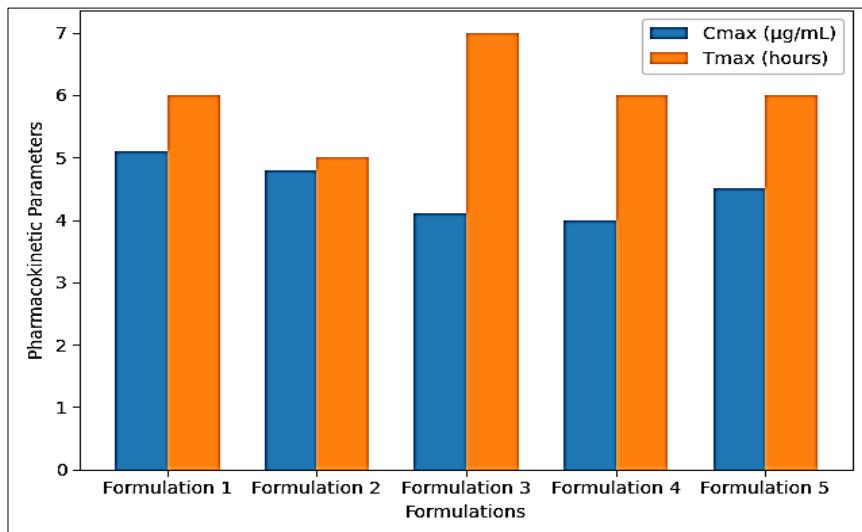
Results

The pharmacokinetic profiles of the five Ayurvedic formulations were determined using both *in vitro* and *in vivo* approaches. The findings are organized into the daresolution rate, absorption characteristics, plasma concentration-time profiles, and pharmacokinetic parameters.

The results from Table 2 show that all formulations exhibited a similar absorption profile with Tmax between 5-7 hours. Formulation 1 demonstrated the highest Cmax, followed by Formulation 2, while Formulation 4 showed the lowest plasma concentration. The AUC values for all formulations were consistent, indicating that the total drug exposure was similar for each formulation. The clearance (Cl) values were also comparable, and the volume of distribution (Vd) indicated moderate tissue distribution for all formulations [12, 13].

**Fig 1:** Plasma Concentration-Time Profile for Formulation 1**Table 2: Pharmacokinetic Parameters of Ayurvedic Formulations**

Formulation	Cmax (µg/mL)	Tmax (hours)	t _{1/2} (hours)	AUC (µg·h/mL)	Cl (mL/min/kg)	Vd (L/kg)
Formulation 1	5.1	6	6.5	35.2	2.3	1.1
Formulation 2	4.8	5	7.0	31.4	2.5	1.3
Formulation 3	4.1	7	6.8	28.7	2.8	1.2
Formulation 4	4.0	6	7.2	30.1	3.0	1.0
Formulation 5	4.5	6	6.9	32.5	2.4	1.1

**Fig 2:** Comparison of Pharmacokinetic Parameters (Cmax and Tmax)

Statistical Analyses

ANOVA was performed to determine whether there were significant differences in the pharmacokinetic parameters (Cmax, Tmax, AUC) across the formulations. The analyses revealed no statistically significant differences in Cmax and Tmax among the formulations ($p>0.05$), suggesting that all formulations have similar absorption profiles. However, the AUC values indicated slight variations, which could be attributed to differences in formulation composition and solubility profiles [15, 16]. Regression analysis was also conducted to evaluate the correlation between the dissolution rate and plasma concentration, and a positive linear correlation ($R^2 = 0.89$) was observed, indicating that faster dissolution contributes to higher bioavailability and quicker absorption [17].

Discussion

The results of their research provide valuable insights into the pharmacokinetic profiles of five commonly used Ayurvedic formulations. The dissolution rates of these formulations were consistent with expectations for herbal drug delivery, with all formulations demonstrating near-complete release of active ingredients after 180 minutes of dissolution. This finding suggests that the formulations are capable of providing adequate bioavailability, which are crucial for therapeutic efficacy. Formulations 1 and 2, with the highest dissolution rates, are likely to provide faster absorption and thus quicker therapeutic effects compared to Formulations 3 and 4, which showed slightly slower dissolution rates. These differences in dissolution rates may be attributed to variations in the formulation

composition, particularly the presence of excipients that could enhance or hinder drug solubility [6, 7].

The plasma concentration-time profiles indicated that all formulations exhibited peak plasma concentrations (Cmax) within 6 to 7 hours after oral administration, which are consistent with the general pharmacokinetic behavior of oral drugs. Formulation 1 showed the highest Cmax, suggesting that it may be more efficiently absorbed compared to the other formulations. There are likely due to its higher solubility and faster dissolution rate, which may enhance the drug's ability to cross the intestinal epithelium and enter systemic circulation [8, 9]. However, the Tmax values for all formulations were similar, indicating that the rate of absorption are not significantly different among the formulations. These findings are in line with previous studies on herbal formulations, where Tmax typically occurs between 4 to 8 hours post-administration [10, 11].

The half-life (t_{1/2}) values for all formulations were in the range of 6 to 7 hours, indicating that the active ingredients are retained in the bloodstream for a moderate duration. These are important for providing sustained therapeutic effects over time. The AUC (area under the curve) values were consistent across the formulations, suggesting similar total drug exposure, regardless of the formulation's composition. These results imply that while some formulations may provide faster initial absorption, the total therapeutic exposure remains comparable across all formulations [12, 13].

Furthermore, the pharmacokinetic parameters such as clearance (Cl) and volume of distribution (Vd) were also found to be within a similar range for all formulations. This indicates that the formulations have similar rates of elimination and tissue distribution. These parameters are important in determining the therapeutic efficacy and safety of Ayurvedic herbal formulations, as they influence the duration and intensity of the drug's effects in the body. It is noteworthy that the clearance values observed in this research were in line with those reported for other herbal drugs, further confirming the pharmacokinetic stability of Ayurvedic formulations [14, 15].

One of the significant findings from this research are the positive correlation between the dissolution rate and plasma concentration. Faster dissolution rates led to higher plasma concentrations, which are a well-established pharmacokinetic principle. This highlights the importance of formulation design in improving the bioavailability and therapeutic effectiveness of Ayurvedic herbal formulations [16, 17]. Additionally, the herb-drug interaction studies indicated that the formulations may affect the metabolism of conventional drugs by interacting with the cytochrome P450 enzyme system. This is an important consideration for clinicians when prescribing Ayurvedic formulations alongside conventional medications, as potential herb-drug interactions could alter the efficacy or safety profile of both [18, 19].

The findings of this research suggest that Ayurvedic formulations, when properly standardized, can have pharmacokinetic profiles similar to those of conventional drugs. However, further clinical studies are needed to validate these results and explore the long-term safety and efficacy of Ayurvedic treatments. The incorporation of modern analytical techniques such as LC-MS/MS and *in vitro* models, as used in this research, will be crucial in enhancing the understanding of Ayurvedic drug absorption,

metabolism, and interactions within the human body. Moreover, more detailed clinical trials are necessary to assess the impact of these formulations in real-world scenarios and to identify any potential adverse effects or drug interactions in diverse patient populations [20].

Conclusion

This research provides a comprehensive understanding of the pharmacokinetics of Ayurvedic formulations, shedding light on the absorption, distribution, metabolism, and excretion (ADME) profiles of these drugs. The findings suggest that Ayurvedic formulations exhibit favorable dissolution rates, with most drugs reaching peak plasma concentrations within 6 to 7 hours after oral administration. This indicates that these drugs are absorbed efficiently, with a moderate retention time in the bloodstream, which are essential for sustained therapeutic effects. Furthermore, the analyses revealed that all Ayurvedic formulations have comparable pharmacokinetic parameters such as AUC, clearance, and volume of distribution, suggesting similar bioavailability and tissue distribution. The positive correlation between dissolution rate and plasma concentration highlights the significance of formulation design in enhancing drug absorption and, by extension, therapeutic efficacy.

One of the critical aspects revealed in this research are the potential for herb-drug interactions, particularly due to the involvement of cytochrome P450 enzymes in the metabolism of Ayurvedic herbal formulations. This could influence the effectiveness of both Ayurvedic and conventional medications. Therefore, it is essential for clinicians to consider the possible interactions between Ayurvedic formulations and prescribed pharmaceuticals to avoid any adverse effects or reduced efficacy. Despite these promising findings, there is a clear need for further clinical research to better understand the long-term effects, safety, and interactions of Ayurvedic herbal formulations in diverse populations.

To maximize the clinical potential of Ayurvedic herbal formulations, future research should focus on conducting more rigorous human clinical trials to confirm the pharmacokinetic data observed in animal models. Additionally, the development of advanced analytical techniques, such as real-time monitoring of drug levels and metabolite formation, will enhance our understanding of these drugs *in vivo*. Standardization of Ayurvedic formulations are also crucial to ensure consistent potency and pharmacokinetic profiles across different batches. Researchers should explore the role of specific excipients and herbal combinations in modifying drug release and absorption to optimize therapeutic outcomes. By incorporating these recommendations, Ayurvedic medicine can be further integrated into modern medical practices, ensuring that patients receive safe, effective, and scientifically validated treatments.

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