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INVESTIGATING HERB-DRUG INTERACTIONS: THE EFFECT OF *TINOSPORA CORDIFOLIA* ON CYTOCHROMES P450 METABOLISM, CLINICAL IMPLICATIONS AND GUIDE TO HEALTHCARE PROFESSIONALS

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ABSTRACT: *Tinospora cordifolia* (TC), family *Menispermaceae*, a widely used herb in Ayurvedic formulations, is known for its therapeutic advantages in the treatment of fever, urinary problems, managing diabetes, metabolic disorders, dysentery, and enhancing immune function. However, its concurrent intake with commonly prescribed drugs raises alarms about potential herb-drug interactions. This review objectives to provide a guide to healthcare professionals (HCP) providing comprehensive knowledge of common pharmacokinetic and pharmacodynamic interactions of TC, focusing on its effects on cytochrome P450 (CYP) enzyme metabolisms, which is critical for the biotransformation of various commonly prescribed drugs. This review also highlighted the mechanism of interaction and clinical implications. By referring to this review, HCP can manage concurrent administration of TC and commonly prescribed medicines, ensuring education to the patient for their safety. Despite the frequent claims that herbal products are natural and safe, it is incorrect to undervalue clinically significant herb-drug interactions or ineffectiveness. Therefore, a careful clinical implication examination has been conducted to assess the effects of TC when used together with commonly prescribed medications. Additionally, this review also incorporates checkpoints concerning the role of HCP and patient education, mitigating the risks associated with interactions.

INTRODUCTION: *Tinospora cordifolia* (Willd.) Hook. f. and Thoms commonly known as Amrita, Guduchi (in Sanskrit), Giloy (in Hindi), and Moonseed plant (in English) is a traditionally popular, glabrous, deciduous climbing shrub belonging to the family *Menispermaceae*, found throughout India, Srilanka, Bangladesh and in some parts of China [1]. Many plants are utilized in medicine for both therapeutic capability and preventive applications. The therapeutic properties of these medicinal plants are mostly due to the presence of active chemical constituents.

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Tinospora cordifolia (TC) is frequently utilized in Ayurvedic medicine and contains a diverse range of bioactive compounds. These include alkaloids such as berberine and palmatine (found in the stem and root), diterpenoid lactones like tinosporides, columbin, steroids like ecdysterone (derived from the stem), glycosides such as tinocordiside, cordioside (also from the stem), and sesquiterpenoids like tinocordifolin (extracted from the stem) [2].

Scientific studies have demonstrated that TC possesses a range of potential therapeutic properties, such as antipyretic, antioxidant, anti-inflammatory, anti-allergic, anti-diabetic, antispasmodic, anti-arthritic, hepatoprotective, antiosteoporotic effects, immunomodulatory, and anti-cancer effects [2, 3, 4, 5]. TC demonstrates antimicrobial properties against a range of bacteria, including those associated with urinary tract

infections, as well as exhibiting effectiveness against multidrug-resistant strains [6]. Additionally, Annisa *et al*. have shown that TC extracts possess potential anticancer effects by promoting apoptosis and suppressing the growth of cancer cells in cell lines [7].

In a recent study Mesileya *et al*. *in-silico* methods to identify potential inhibitors of CYP51 from TC, aiming to find new anti-Chagas disease agents [8]. The investigation conducted by Amrutha *et al*. in the field of network pharmacology seeks to elucidate the multi-target mechanisms of action by identifying bioactive compounds from various sources, along with their interactions with proteins and the associated biological pathways. The docking results indicated that TC metabolites could interact with key Alzheimer's disease targets BACE1 and MAO-B, implying its role in neuroprotection [9].

TC has gained sizable popularity and is frequently included in several Ayurvedic formulations. It is often used alongside commonly prescribed medications, which raises concerns about potential interactions between the herb and these drugs. Herbs have their own pharmacological manners with the prescribed drugs, which may be synergistic or antagonistic to the co-administered drug. Herb-drug interactions are affected by a range of factors that can significantly impact the effectiveness and safety of treatments (refer Figure 1 for factors affecting). The key hypothesized mechanisms for herb-drug interactions involve drug-metabolizing enzymes and drug transporter systems. This review has examined the drug interaction potential of TC so that a healthcare professional can take guidance from this review while prescribing or dispensing medications to patients.

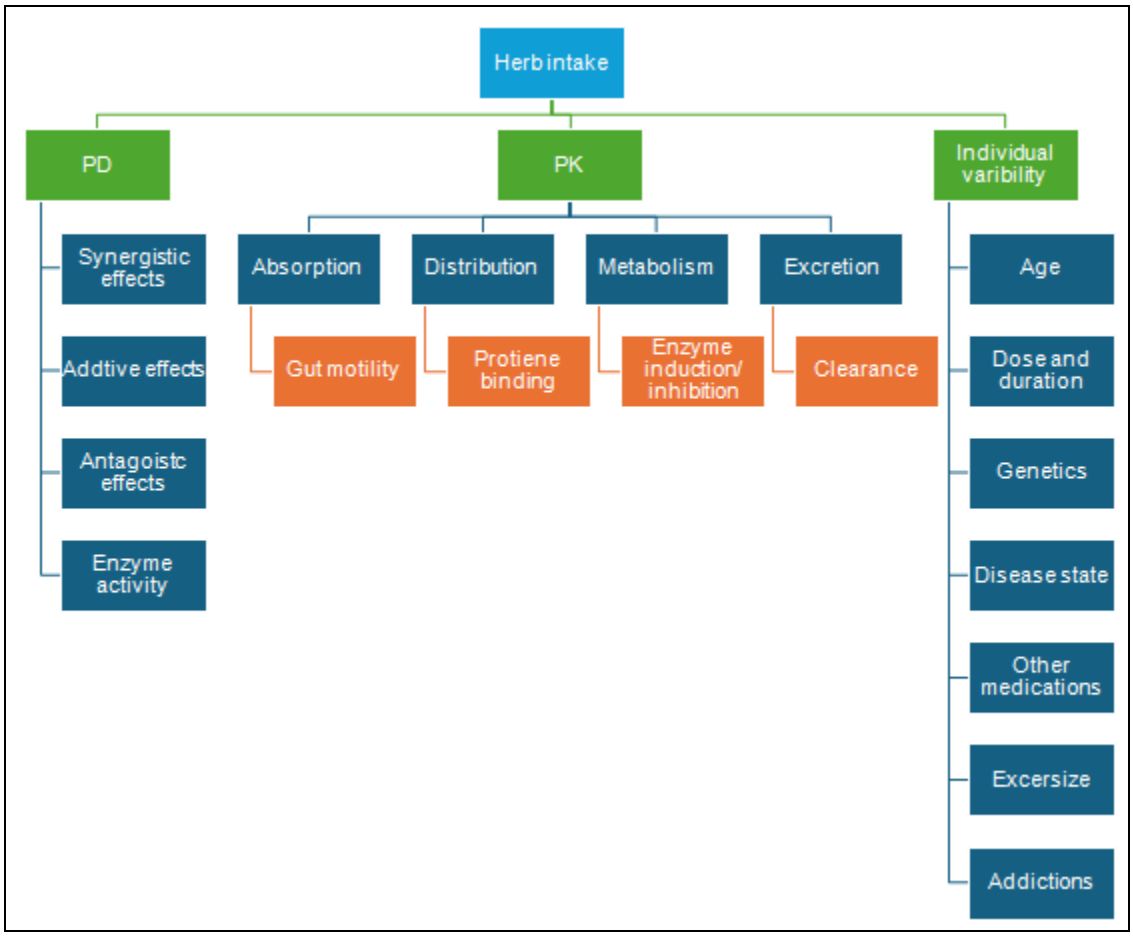

FIG. 1: FACTORS AFFECTING HERB DRUG INTERACTIONS

TC is a Potential Candidate for Herb Drug Interactions: Drug herb interactions of TC are listed in **Table 1.** Bahadur *et al*. (2016) performed valuable research on how TC networks with cytochrome P450 (CYP) enzymes, which are crucial for metabolizing drugs and other

compounds. The finding advocate that TC has little interaction potential with these enzymes, when compared to other plants. This is crucial understanding potential herb-drug interactions. Specifically, the research showed that TC inhibits CYP3A4, CYP2D6, CYP2C9 and CYP1A2 with IC_{50} values of 136.45, 144.37, 127.55, and 141.82 µg/ml, respectively. This is significant understanding how this herb may interact with other medications. This information also confirms that TC may be safe for simultaneous use with other xenobiotics, as its less likely to significantly modify their metabolism [17].

TABLE 1: DRUG HERB INTERACTIONS OF *TINOSPORA CORDIFOLIA*

Co-administered Medication	Tested species	Extract	Dose of TCE	Type of Interaction	Result	Conclusion	Ref.
Metformin, sitagliptin, and glibenclamide	Streptozotocin (STZ)-induced diabetes in rats	Aqueous extract	400 mg/kg	PK Interaction	TCgenerally does not significantly affect the absorption, metabolism, or excretion of metformin, sitagliptin, and glibenclamide.	This study results suggest no significant PK interactions.	5
				PD Interaction	Substantial improvement was observed in glycemic control and the conditions associated with diabetes mellitus. In addition, no incidences of hypoglycemia were observed.	This study results confirmed improved management of diabetes and its associated conditions.	
Glibenclamide	Rats	Aqua-alcoholic	0, 100 and 400 mg/kg	PK Interaction	At 400 mg/kg dose, an evidenced rise in the bio availability of glibenclamide was observed with a delay of T_{max} and suppression of clearance.	This study results shown the drug interaction of TC with Glibenclamideboosting bioavailability.	10
Gliclazide	Rats	Extract	100 mg/kg	PK Interaction	Bioavailability of gliclazide was notably increased, with a significant influence on C_{max}, AUC_{0-48}, and inhibition of volume of distribution, with no change in $T_{max.}$	Results showed bioavailability of GL had significantly increased	12
Gliclazide	Normal rats and STZ- NIC induced diabetic rats	Alcoholic Extract	100 mg/kg	PD Interaction	Hypoglycemic Activity: The combination of TCE and Gliclazide demonstrated an enhanced hypoglycemic effect compared to Gliclazide alone in diabetic rats. This was characterized by a significant reduction in blood glucose levels, a quicker onset of action, and a prolonged duration of hypoglycemic effect. Pancreatic Function: The combination treatment improved pancreatic function, evidenced by increased insulin secretion and better glucose tolerance. FTIR Analysis: FTIR analysis indicated interactions between the functional groups of TCE and Gliclazide, suggesting a	The study concluded that the combination of TC alcoholic extract and Gliclazide could be clinically beneficial in managing diabetes by enhancing the hypoglycemic effect and improving pancreatic function. This herb-drug interaction highlights the potential for integrating traditional herbal remedies with conventional antidiabetic therapies to optimize treatment outcomes.	11

					synergistic effect that enhances hypoglycemic activity.		
Atenolol, Propranolol	Rats	Methanolic leaves extract	500 mg/kg and *Ocimum sanctum* (50 mg/kg)	PD Interaction	Result showed significant changes inMean arterial blood pressure, Heart rate, electrocardiogram, heart bio-marker enzyme, antioxidant parameters, and histopathology of the heart	Result showed increased cardioprotective in TC extract + beta-blockers activity than they were used alone.	14
Midazolam, omeprazole, dextromethorphan, losartan, and caffeine	Human	Berberine (*T. cordifoli*a contain alkaloids)	300 mg	PK Interaction	There were no statistically significant differences in the pharmacokinetic parameters of the other probe drugs between placebo and the berberine-treated group. Berberine decreased CYP2D6, 2C9, and CYP3A4 activities. For Midazolam (CYP3A4) the C_{max} was increased, prolonged T_{max} and $t_{1/2}$ indicating increased exposure and slower metabolism.	Repeated berberine administration can significantly alter the activity of drug metabolizing enzymes leading to changes in the PK and PD of co-administered medications.	15
				PD Interaction	Inhibition of CYP450 indicated drug-drug interactions and may affect efficacy or toxicity of other drugs with berberine. Study drugs showed changes in the enzyme activity.		
Dextromethorphan (DEX)	Rat plasma	TCE	100 mg/ Kg, 400 mg/ kg	PK Interaction	Increased bioavailability of DEX. Inhibition of DEX metabolism and so reduced conversion to dextrophan. Change in T_{max} and PK parameters more with higher (400 mg) doses.	TC coadministration can alter the PK of DEX increasing the therapeutic effect in Alzheimer's disease.	16
				PD Interaction	Benefits for Alzheimer's disease consider improved spatial memory and reduced hyperactivity in rodents.		
Glibenclamide	Alloxan diabetic rats	aqueous extract of roots	2.5 and 5.0 g/kg	PD Interaction	Diabetic rats were administered the extract at doses of 2.5 and 5.0 g/kg body weight. The treatment significantly reduced serum cholesterol, triglycerides, and LDL levels while increasing HDL levels. The study concluded that TC roots have a beneficial effect on lipid metabolism in diabetic conditions	Hypolipidaemic action of TC roots at 2.5 and 5.0 g/kg body weight was better than glibenclamide.	21

DEX: Dextromethorphan, HDL: high-density lipoprotein, LDL: low-density lipoprotein, PD: Pharmacodynamics, PK: Pharmacokinetics, STZ: Streptozotocin, Nicotinamide: NIC, TC: *Tinospora cordifolia*, TCE: *Tinospora cordifolia* extract.

Proven on the research results, Sahu *et al.* have conducted on PK interactions of TC particularly concerning its potential to interact with other drugs. Studies have highlighted the potential for TC to

interact with drugs particularly those metabolised by CYP2C9 enzyme. Precisely, research has shown interaction with glibenclamide which is medicine used to treat diabetes. The research specifies that co-administration of TC extract (400 mg/kg) with glibenclamide can lead to changes in the PK, covering improved bioavailability (AUC), changes in maximum concentrations (C_{max}) and change in clearance [10].

Another pharmacodynamic interaction study found that combining TC extract with Gliclazide significantly improves hypoglycemic effects and enhances pancreatic function in diabetic rats. These results suggest potential benefits for integrating herbal treatments with conventional antidiabetic therapies to optimize action outcomes [11]. Potential to inhibit CYP2C9 activity, which is a key enzyme involved in drug metabolism. This inhibition can lead to enhanced levels of drugs that are metabolised by this enzyme, potentially increasing the risk of adverse outcomes. These findings highlight the importance of considering potential herb drug interactions when using TC, particularly in individuals taking medications for chronic conditions like diabetes. The research suggests that healthcare providers should be aware of these potential interactions to ensure patient safety.

CYP2C9 is a fundamental enzyme in the cytochrome P450 system, primarily found in the liver. It is responsible for metabolizing a wide age of clinically important drugs, including warfarin (an anticoagulant), NSAID (non-steroidal anti-inflammatory drugs) like diclofenac, naproxen, Angiotensin II blocker (Losartan), Anti-estrogen (Tamoxifen) and Phenytoin (an anticonvulsant). Metabolism by CYP2C9 may leads to inactivation and elimination of these drugs from the body [18]. Impact of CYP2C9 inhibition may leads to raise in drug levels because of slow down in the metabolism of these drugs, which results in higher concentration of the drug in system. This increased exposure can lead to an enhanced risk of adverse effects and toxicity. In this situation drugs with limited therapeutic index are partially vulnerable, which may result in potentially serious side effects. In case of warfarin with co-administration with high dose of TC can lead to an increased risk of bleeding. There can be exceptions due genetic differences in CYP2C9.

The Mechanism of Interaction: Herb-drug interactions can occur through pharmacokinetic (PK) mechanisms or Pharmacodynamic mechanisms. Here are the explanations.

Pharmacokinetic Interactions: PK interactions mean changes in the absorption, distribution, metabolism, or excretion (ADME) of a drug caused by another drug or herb. For example, if TC affects the liver enzymes that metabolize warfarin, it could alter warfarin's concentration in the blood. A key mechanism involves here is the cytochrome P450. TC and its constituents caneither inhibit or induce CYP enzymes, particularly CYP2C9.

Enzyme Inhibition: TC inhibits CYP enzymes it slows down the metabolism of drugs that are substrates of that enzyme this can lead to increased drug levels in the bloodstream potentially increasing the risk of side effects or toxicity.

Enzyme Induction: conversely if it induces a CYP enzymes it speeds up drug metabolism potentially reducing drug levels and decreasing its effectiveness.

Effect on Drug Transport: Some studies suggest that TC may also interfere with drug transporter proteins [P-glycoprotein, organic anion/ cation transporters (OAT, OCTs)], which play a role in drug ADME, they act as "gatekeeper" controlling the movement of substance across cell membranes, this can further alter drug pharmacokinetics [13, 19, 20].

Pharmacodynamic Interactions: PD interactions imply changes in the effect of a drug due to another drug or herb. For example, the combined effect of TC and antihypertensives on blood pressure might be additive, requiring careful monitoring.

- These interactions occur when TC and a drug affect the body in a similar or opposing way.
- Additive or synergistic effects: for example, both TC and antidiabetic drugs lower blood sugar when taken together they can have an additive or synergistic effect potentially leading to excessive blood sugar lowering hypoglycemia.

The study by Prince *et al*. (1998) confirmed the hypolipidaemic effects of TC roots in alloxan-

induced diabetic rats. The administration of the aqueous extract significantly reduced serum cholesterol, triglycerides, and LDL levels while increasing HDL levels, indicating a beneficial impact on lipid metabolism in diabetic conditions [21]. This finding suggests that TC could be a valuable natural remedy for managing dyslipidemia in diabetes. Also, the wide-ranging review by Stage *et al*. (2015) on drug-drug interactions with metformin highlighted the complexity of metformin's interactions as both a victim and perpetrator. The review underlined the importance of considering pharmacodynamic endpoints and pharmacogenetic variations in drug–drug interaction (DDI) studies, pointing to significant gaps in current knowledge and the need for personalized medicine approaches to optimize metformin therapy [22].

Furthermore, Patel *et al*. (2011) discovered the hypoglycemic action of the alkaloidal fraction of TC, showing that it meaningfully declined fasting serum glucose and improved insulin secretion in both *in-vitro* and *in-vivo* studies [23]. Together, these studies contribute valuable insights into the management of diabetes and its associated complications as an example of additive or synergistic effects of TC.

Opposing Effects: TC as immune stimulating effects can oppose the effects of immunosuppressant drugs reducing their effectiveness. In a study conducted by Manjrekar *et al*. the water and ethanol extracts of stems of TC inhibit immunosuppression produced by cyclophosphamide [24]. Therefore, concurrent use could potentially decrease the effectiveness of immunosuppressant medications in condition like organ transplantation, autoimmune diseases and should not administered concurrently.

Role of Healthcare Professionals: The role of HCP and patient education are paramount in mitigating the risks associated with interactions. Here is breakdown of responsibilities:

Obtain Detail Patient History: HCPs should inquire about medical history and medications including herbal products, dietary supplements and over the counter medications, additional to prescription medications. Dose, frequency need to be captured specifically.

Interaction Risk Assessment: Herbal medicines may contain multiple active ingredients. HCPs should explore to understand the herb-drug interactions utilizing possible sources including patient records, patient information sheets.

Education to Patient: The patient must be educated about potential adverse reactions or interactions and should receive guidance on the proper use of herbal medications. If the patient is using herbal products alongside pharmaceutical drugs, it is essential to monitor and follow up with them closely. HCP should be vigilant for any signs of interactions in terms of diminished efficacy of prescribed drug or less severe adverse effects.

Position of Patient Education: The fundamental approach to identifying herb-drug interactions is to encourage a trusting relationship with patients, as many do not reveal their use of herbal products to HCP. This confidence will encourage open discussions about their supplement consumption. Patients must recognize the importance of this educational process in safeguarding their health. Patient should be warned against placing trust misleading claims of advertisements. It is crucial for patients to understand that herbal products are not always safe; they may interact with prescribed medications and can have adverse effects. Patient should be educated for under and over dosage effects of herbal and prescribed medicine, also regarding the step they need to follow if they miss any dose.

Patient should encouraged report all the adverse effects to their HCP irrespective of their intensity (minor or major). Additionally, patient should be advised to carefully read the labels of herbal products before purchasing, ensuring they check the details including ingredients, claims and certifications. A collaborative approach between HCP and informed patients is crucial to mitigate the risks linked to interactions between herbal remedies and medications.

CONCLUSION: The concurrent use of *Tinospora cordifolia* with commonly prescribed medications presents a substantial concern for healthcare professionals due to its possibility to interact with cytochrome P450 (CYP) enzymes. These interactions can change the metabolism of many

commonly prescribed drugs, leading to modifications in their efficacy and safety profiles. This review highlights the consequence of knowing the pharmacokinetic and pharmacodynamic interactions of TC, particularly its effects on CYP3A4, CYP2D6, CYP2C19, CYP2C9, and CYP1A2. By identifying the potential for herb-drug interactions, healthcare providers can better monitor and manage patients using TC alongside standard therapies. Tailored medicine approaches, involving pharmacogenetic testing, may suggest constructive insights into predicting and mitigating these interactions, eventually optimizing drug therapy and minimizing adverse effects. Persisted research and awareness are key to ensure safe and efficient use of TC in clinical practice.

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