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Research Article

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Hepato-protective evaluation of Praliv-H tablets

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Abstract
Praliv-H tablets, a novel formulation composed of potent hepatoprotective agents, have garnered significant interest in the medical community for their purported efficacy in managing hepatic disorders. Praliv-H tablet is composed of *Boerhavla Diffuse, Picrorhiza kurrow, Solanum miniatum, Eclipta alba, Andrographis paniculata, Embelia ribes, Zingiber officinale, Emblica officinalis, Phyllanthus niruri, Tecomalla undulata, Terminalia arjuna, Tinospora cordifolia, Trubulus terrestris, Acacia Arabica.* In this present work, the SGPT levels were studied in patients administered with Praliv-H tablets

Keywords: Jaundice, SGPT, Bilirubin, Hepato-protective, Praliv-H tablets

Introduction

Jaundice is characterized by the accumulation of bilirubin, a yellow-orange bile pigment, which causes the skin, mucous membranes, and sclera to turn yellow. Bilirubin is an internally produced pigment that can be particularly harmful, especially in newborn infants. Unconjugated bilirubin exhibits a characteristic spectrographic peak at 450 nm. Jaundice is a condition that signals an elevated level of bilirubin in the body, which can be either in the conjugated or unconjugated form. Jaundice becomes clinically evident when the concentration of bilirubin in the blood above 34.2 µmol/L or 2 mg/dL [1-2].

Bilirubin separates from albumin at the hepatocyte membrane within the liver and is then conveyed into the hepatocyte. While the liver's ability to take in bilirubin is not often fully employed and therefore does not significantly affect its clearance, a decrease in the flow of blood through the liver can hinder the removal of bilirubin from the bloodstream and lead to clinical jaundice [3-4].

Hepatitis can result from infection with any of the hepatitis viruses, including A, B, C, D, or E. A significant part of hepatitis virus infections, regardless of the kind, do not exhibit symptoms or only cause mild illnesses that may not be recognized as hepatitis. The Hepatitis A virus often produces a mild illness in childhood, with over 80% of patients showing no symptoms. In adulthood, the likelihood of experiencing clinical signs from an infection is higher. However, only one-third of people with acute hepatitis A infections develop jaundice. Infections caused by hepatitis B and C viruses typically do not show any symptoms, except in cases of intravenous drug users, where 30% of hepatitis B infections are accompanied by jaundice [5].

Prior to the onset of jaundice, the physical examination of patients typically does not reveal any abnormalities. However, in some cases, hepatomegaly (enlarged liver) is observed in 10% of patients, while splenomegaly (enlarged

spleen) and lymphadenopathy (enlarged lymph nodes) are present in 5% of patients. Individuals experiencing a sudden illness should not exhibit indications of long-term liver disease [6].

Fatalities resulting from acute viral hepatitis typically occur as a result of the progression to fulminant hepatitis. Hepatic encephalopathy is typically characterized as the development of symptoms within eight weeks or the start of jaundice within two weeks [7].

Clinicians may fail to recognize liver diseases, resulting in a delay in starting effective treatments. The most common signs and symptoms of liver diseases in children are enlarged liver, yellowing of the skin (jaundice), abnormal blood clotting, and elevated levels of liver enzymes or waste products such as ammonia [8].

The etiology of pediatric hepatic illness exhibits significant variation across different age groups. Conditions such as biliary atresia and idiopathic neonatal hepatitis are typically detected either at birth or shortly after birth. However, acetaminophen toxicity and Wilson disease are commonly seen in older children, particularly teens. In contrast, viral hepatitis can occur at any age. Certain instances of glycogen storage disorders may manifest as persistent liver illness, and a significant number of individuals with the autosomal recessive liver-specific subtype may ultimately develop cirrhosis. Wilson illness is characterized by hepatic damage that is thought to be caused by an excess of copper. This excess copper works as a pro-oxidant, leading to the production of free radicals that can be harmful to the body [9-10]. One potential treatment for Wilson disease is Boerhavia Diffusa, also known as Punarnava.

Boerhavia diffusa is a renowned medicinal plant that is utilized in Ayurveda to treat a wide range of human illnesses. The entire plant or its various parts possess numerous medicinal properties and are utilized by indigenous and tribal communities in India for their antibacterial, hepatoprotective, hypoglycemic, antiproliferative, antiestrogenic, anti-inflammatory, anticonvulsant, antistress, and antimetastatic activities. They are also employed in the treatment of stress, dyspepsia, abdominal pain, inflammation, and jaundice. Scientists and researchers have conducted several phytochemical, pharmacological, experimental, and clinical investigations on Boerhavia diffusa. The purpose of these researches is to gain a comprehensive understanding of the traditional Ayurvedic, endemic, and tribal uses of Boerhavia diffusa. The range of values is from 11 to 13.

Picrorhiza kurroa, often known as kutki or kadu. Picrorhiza kurroa (Pk) is a recognized plant with hepatoprotective properties. Picrorhiza kurroa Royle ex Benth. is regarded as a bitter medicinal substance that has been employed since ancient times for the treatment of liver ailments. Picrorhiza kurroa has a concentrated and potent compound of iridoid glycosides, which exhibits hepatoprotective, anticholestatic, antioxidant, anti-inflammatory, and immunological modulating properties. As part of an endeavor to investigate potential applications for beneficial herbal preparations in the future, certain valuable plants are frequently overlooked. One such plant that falls into this category is P. kurroa. Therefore, a comprehensive analysis has been conducted on the existing literature regarding the plant in widely recognized texts. This analysis aims to shed light on the potential utility of this herb in treating various ailments such as liver illnesses, upper respiratory tract issues, and more recently, hyperlipidemia. Hyperlipidemia is a major factor in the occurrence and seriousness of coronary heart diseases. The use of herbal formulations for treating cardiovascular disorders is cost-effective and readily accessible. The hypothesized mechanism proposes that P. kurroa enhances the secretion of the gall bladder, hence aiding in the digestion and metabolism of lipids. Consequently, it effectively regulates fat metabolism in the liver [14-16].

Solanum miniatum, also known as Makoi, is a plant species. The study aims to investigate the liver antifibrotic action of the ethanolic extract obtained from the aerial portions of Solanum villosum Mill subsp. miniatum (Bernh. ex Willd.) (referred to as SVE). Additionally, the study aims to establish a correlation between this activity and the results obtained from high-performance liquid chromatography-quadrupole time of flight (HPLC-qTOF) analysis. The phytochemical profile of Electrospray Ionisation Mass Spectrometry (ESIMS) is described in reference [17].

Eclipta alba, commonly known as Bhringraj, is a plant species.

Eclipta alba (L.), often known as bhringraj or fake daisy, is a plant species belonging to the Asteraceae family. This plant is a type of invasive vegetation that thrives in tropical and subtropical areas across the globe. It has a widespread distribution in India, Brazil, Thailand, and China. Eclipta alba has historically been utilized in traditional medicine, namely in Ayurveda and Siddha practices. Eclipta alba, a herb, includes many bioactive compounds including coumestans (specifically wedelolactone and demethylwedelolactone), triterpenes, flavonoids, steroids, polypeptides,

polyacetylenes, and thiophene-derivatives. Eclipta alba Hassk is known to have hepatoprotective, antibacterial, anti-inflammatory, analgesic, immunomodulatory, antiviral properties, and it also promotes blackening and growth of hair [18-21].

Andrographis paniculata, sometimes known as Kalamegh, is a plant species. Andrographis paniculata, a member of the Acanthaceae family, is a medicinal plant that has been traditionally employed in China, India, and other southeast Asian countries for treating various ailments such as cold, fever, laryngitis, and a range of infectious disorders including malaria, dysentery, and diarrhea. The plant is purported to have immunological, antibacterial, anti-inflammatory, antithrombotic, and hepatoprotective effects. In Malaysia, the plant is employed in traditional medicine to address diabetes and hypertension [22-23].

A considerable decrease was observed in several liver function tests, including serum bilirubin, thymol turbidity, alkaline phosphatase, S.G.O.T., S.G.P.T., and serum globulin proportion of protein. Kalmegh has shown efficacy in treating infective hepatitis [24-25].

Embelia ribes, also known as Vidang. Embelia ribes Burm F. is a sizable climbing shrub that is found throughout India and is classified under the family Myrsinacae. It is widely recognized as false black pepper or Vidanga. E. ribes is found in semi-evergreen and deciduous forests at a height of 1,500m in the middle and lower Himalayas, as well as in Arunachal Pradesh, Assam, Bengal, Orissa, Andhra Pradesh, and Madhya Pradesh in India. Embelia ribes has demonstrated significant pharmacological potential and is widely utilized as a traditional medication. Herbal remedies incorporate the root, berries, and leaves of Embelia ribes. It has several applications such as antibacterial, antifertility, antiprotozoal, treatment of stomach disorders, lung diseases, constipation, indigestion, fungus infections, mouth ulcers, sore throat, pneumonia, heart disease, and obesity. Additionally, it possesses analgesic, anti-inflammatory, and antioxidant properties [26-28].

Zingiber officinale, commonly known as ginger, is a plant whose rhizome is widely utilized for therapeutic purposes. Ayurvedic texts emphasize the use of ginger in the treatment of both infectious and non-infectious disorders. Recent advancements in the fields of analytical chemistry, cytology, and microbiology have suggested the use of ginger in treating different diseases. This proposal is also supported by Ayurveda literature. The medicinal properties of Z. officinale, such as its antiviral, radioprotective, anti-inflammatory, anticancer, and antioxidant effects, have been highlighted in Ayurveda prescriptions [29-30].

The study assessed the hepatoprotective effects of the crude aqueous extract of Zingiber officinale leaves (ZOL), a plant from the Zingiberacae family, by inducing liver injury in male Wistar albino rats using CCl4. The study focused on analyzing several biochemical markers, including serum glutamic pyruvate transaminase (SGPT), serum glutamic oxaloacetate transaminase (SGOT), and total bilirubin. The ZOL extract dissolved in water provided substantial defense against hepatocellular damage caused by CCl 4 [31-32].

Emblica officinalis, also known as Amla, is extensively utilized in the Indian system of medicine and is considered to enhance the body's immune response to ailments. Emblica officinalis is used in the treatment of cancer, diabetes, liver illnesses, heart disease, ulcers, anemia, and several other ailments. Emblica officinalis has been found to possess a wide range of beneficial properties, including antibacterial, antifungal, antiviral, antidiabetic, hypolipidemic, antiulcerogenic, free radical scavenging, antioxidant, antimutagenic, antiinflammatory, immunomodulatory, antipyretic, analgesic, antitussive, antiatherogenic, adaptogenic, snake venom neutralizing, gastroprotective, antianemia, antihypercholesterolemia, wound healing, antidiarrheal, antiatherosclerotic, nephroprotective, neuroprotective, and hepatoprotective effects [33-35].

Phyllanthus niruri, often known as Bhui amla, is the scientific name for a plant. Phyllanthus niruri is a conventional shrub of to the Phyllanthaceae genus, which has a well-established history in Ayurvedic, Chinese, and Malay ethnomedicine. The extracts of P. niruri have hepatoprotective, antiviral, antibacterial, hypolipidaemic, hypoglycaemic, analgesic, anti-inflammatory, cardioprotective, anti-urolithiatic, and antihyperuricaemic characteristics due to the presence of unique bioactive components [36-38].

Tecomella undulata, often known as Roheda, is a plant species. Tecomella undulata, often referred to as desert teak or Rohiro, is a plant that has been traditionally used for the treatment of liver and spleen illnesses, tumors, conjunctivitis, hepatosplenomegaly, syphilis, gonorrhea, hepatitis, as a blood purifier, and for wound healing. TU has been shown to include compounds such as naphthaquinone derivative, iridoid glucoside, phytosterol, fatty alcohol,

flavonols, flavonoid glucoside, and triterpenoids. The various aerial portions of the plant have been found to possess anti-HIV, antibacterial, antimicrobial, immune-modulating, analgesic, and hepatoprotective properties [39-41].

Terminalia arjuna, also known as Arjun. The herb is traditionally utilized in the treatment of many ailments. T. arjuna possesses potent properties as a hypocholsteremic, hypolipidemic, anticoagulant, antihypertensive, antithrombotic, antiviral, antifungal, and antibacterial medication. Phytoconstituents and pharmacological actions have been examined in different components of plants. A wide range of beneficial phytoconstituents have been extracted from T. arjuna. Triterpenoids mostly contribute to the cardiovascular effects. Tannins and flavonoids exhibit anticancer effects [42-44].

Tinospora cordifolia, often known as Amrita and Guduchi, is a member of the Menispermaceae family. It is regarded as a crucial medicinal plant in the Indian system of medicine (ISM) and has been utilized for treating many ailments such as fever, urinary issues, dysentery, skin illnesses including leprosy, diabetes, and several other maladies. Tinospora cordifolia contains a variety of chemical compounds, such as alkaloids, terpenoids, lignans, steroids, and others. These compounds contribute to the plant's phytochemistry and pharmacological activity. Tinospora cordifolia has significant pharmacological value due to its antioxidant, antimicrobial, antibacterial, antifungal, anti-diabetic, antistress, hypolipidaemic, hepatic disorder, anticancer, anti-HIV, antiosteoporotic, antitoxic, wound healing, anticomplementary, immunomodulating, and neuroprotective effects [45-47].

ribulus terrestris, a member of the Zygophyllaceae family, is widely recognized as Gokshur or Gokharu or puncture vine. It has a longstanding history of use in traditional Indian and Chinese medicine for the treatment of diverse ailments. The many components of it consist of a diverse range of chemical compounds that have pharmacological significance, including flavonoids, flavonol glycosides, steroidal saponins, and alkaloids. It possesses diuretic, aphrodisiac, antiurolithic, immunomodulatory, antidiabetic, absorption enhancing, hypolipidemic, cardiotonic, central nervous system, hepatoprotective, anti-inflammatory, analgesic, antispasmodic, anticancer, antibacterial, anthelmintic, larvicidal, and anticariogenic properties [48-50].

Acacia arabica is a widely favored tree for decorative purposes along roads and pathways. Babool, also known as Acacia nilotica, is widely utilized in the Indian System of Medicine to prevent and treat numerous health conditions. This traditional practice has been followed for centuries in India. Acacia arabica has demonstrated efficacy in treating various diseases, including diabetes, skin ailments, and notably, cancer. The fresh plant parts of Acacia arabica are regarded as having astringent, demulcent, aphrodisiac, anthelmintic, antibacterial, and antidiarrheal properties, and are thought to have good nutritional value in the Indian traditional medicine system [51-53].

Product Name - Praliv-H Tablet			**Composition**		
Sr. No.	**Ingredient**	**Latin name**	**Part of plant**	**Quantity**	**Proof of Concept**
1	Punarva	Boerhavia Diffuse	Panchang	20 mg	API I/IV
2	Kutki	Picrorhiza kurroa	Root	20 mg	BPN
3	Makoi	Solanum miniatum	Panchang	20 mg	BPN
4	Bhrangraj	Eclipta alba	Panchang	20 mg	BPN
5	Kalmegha	Andrographis paniculata	Panchang	20 mg	BPN
6	Vaividang	Embelia ribes	Seed	20 mg	API I/I
7	Sonth	Zingiber officinale	Kand	20 mg	API I/I
8	Amla	Emblica officinalis	Fruit	20 mg	API I/I
9	Bhui amla	Phyllanthus niruri	Panchang	20 mg	API I/I
10	Rohitak	Tecomalla undulata	Twak	20 mg	BPN
11	Arjun	Terminalia arjuna	Twak	10 mg	BPN
12	Giloy	Tinospora cordifolia	Kand	10 mg	API I/I
13	Gokhru	Trubulus terrestris	Fruit	10 mg	API I/I
14	Babool Gond	Acacia Arabica	Niryas	10 mg	API I/I

Jaundice is one of the maximum extensive unfold disorder situations happening all through the world. It is likewise a life-threatening condition, normally withinside the underdeveloped countries. Jaundice is resulting from increased serum bilirubin attention withinside the body.

The unconjugated bilirubin is basically insoluble in water, but may be reversibly conjugated to albumin. It is transported to the liver, escaping the filtration in kidneys. Generally 90–95% of the bilirubin circulating withinside the blood is unconjugated. In the case of hypoalbuminemia (a form of hypoproteinemia), bilirubin displacement from the albumin molecules may also reason diffusion of bilirubin throughout the Blood Brain Barrier.

Inclusion criteria

1. Willing to provide written informed consent.
2. Male or female, age ≥ 18 years.
3. Patients must have the following laboratory parameters at screening:

a) Alanine aminotransferase (ALT) ≤10 × upper limit of normal (ULN)

b) Aspartate aminotransferase (AST) ≤10 × ULN

c) Hemoglobin ≥12 g/dL for male, ≥11 g/dL for female patients

d) Platelets ≥ 50,000/mm^3.

e) International normalized ratio (INR) ≤1.5 × ULN unless patient has known haemophilia or is stable on an anticoagulant regimen affecting INR.

f) Albumin ≥3g/dL. g) Direct bilirubin ≤1.5 × ULN h) HbA1c ≤10.0%

i) Creatinine clearance (CLcr) ≥60 mL/min, as calculated by the Cockcroft-Gault equation (1-2).

72 subjects has been identified for the study. Started the tablet Praliv-H for 30 day. SGPT was estimated

Estimation of SGPT

The enzyme alanine aminotransferase is widely reported in a variety of tissue sources. The major source of ALT is of hepatic origin and has led to the application of ALT determinations in the study of hepatic diseases. Elevated serum levels are found in hepatitis, cirrhosis, and obstructive jaundice. Levels of ALT are only slightly elevated in patients following a myocardial infarction. UV methods for ALT determination were first developed by Wroblewski and LaDue in 1956. The method was based on the oxidation of NADH by lactate dehydrogenase (LDH). In 1980, the International Federation of Clinical Chemistry recommended a reference procedure for the measurements of ALT based on the Wroblewski and LaDue procedure. The ALT reagent conforms to the formulation recommended by the IFCC.

The enzymatic reaction sequence employed in the assay of ALT is as follows:

L-Alanine + α-Ketoglutarate $\xrightarrow{ALT}$ Pyruvate + L-Glutamate

Pyruvate + NADH + H^+ $\xrightarrow{LDH}$ Lactate + NAD+ + H_20

The pyruvate formed in the first reaction is reduced to lactate in the presence of lactate dehydrogenase and NADH. The activity of ALT is determined by measuring the rate of oxidation of NADH at 340 nm. Endogenous sample pyruvate is converted to lactate by LDH during the lag phase prior to measurement.

Result and Discussion

Total 72 patients have been enrolled in this study, SGPT results showing the

Table 1: SGPT Levels after Treatment

S. No.	Age Group (Years)	SGPT mg/dL (30 Days)
1	21-30	37.5
2	31-40	41.55
3	41-50	42.43
4	51-60	53.14
5	Above 61	44.5

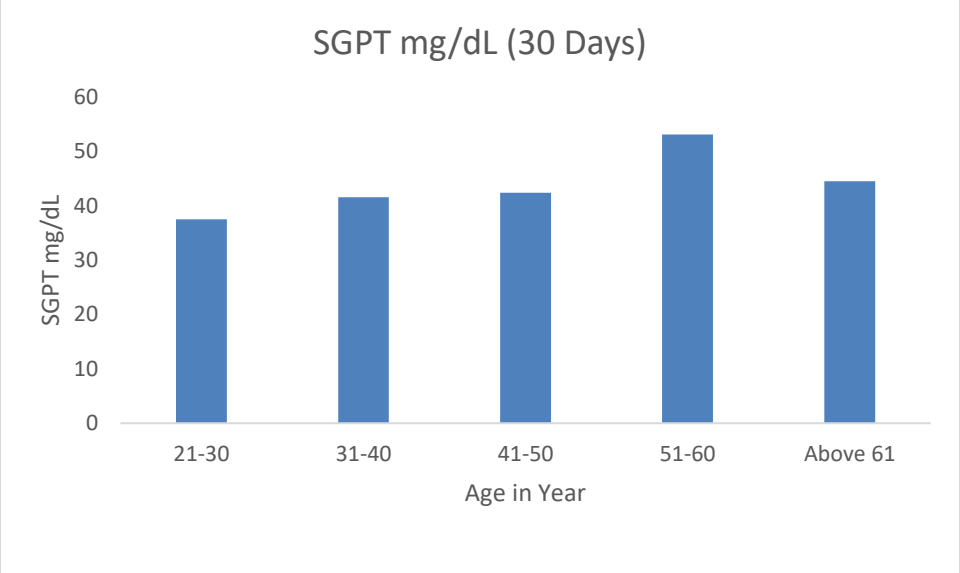

Figure 1: SGPT Levels after Treatment

Tablet Praliv-H showing good result in Jaundice patients. The data suggested that the decrease the value of SGPT after 30 days.

This data suggested that we can consider as alternative formulation for the management of Jaundice as hepatoprotective.

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