ABSTRACT

Traditionally, aloe Vera was used topically to heal wounds and for various skin conditions, and orally as a laxative. Aloe Vera was an ancient and medicinally valued herb mentioned in siddha, ayurveda system of medicine. It contains essential components like Vitamins, mineral and amino acids etc.

Today, in addition to traditional uses, people take aloe orally to treat a variety of conditions, including diabetes, asthma, epilepsy, and osteoarthritis. People use aloe Vera topically for burns, sunburns, and psoriasis. Aloe Vera gel can be found in hundreds of skin products, including lotions and sunblocks. The Food and Drug Administration (FDA) has approved aloe veras a natural food flavoring. NCCAM (National Centre for complementary and alternative medicine) had done many researches on aloe Vera extract for various conditions.

ICMR (Indian council for medical research) doesn’t provide much research details on Aloe Vera extract. Early studies show that topical aloe gel may help in healing burns and abrasions. There is not enough scientific evidence to support aloe vera for any of its other uses.

I took some of the reference studies related with Aloe Vera entrain other indication like Diabetes mellitus, Ulcer etc. This study will be a preliminary study to rule out the influence of Aloe vera extract on Lipid profile and will support to future studies on various indication in a detailed scientific way.

Key words: Aloe vera, Fatty acids, Lipoprotein, Lipids, Triglycerides

INTRODUCTION

ALOE VERA

Aloe is a succulent plant belonging to the Liliaceal family, of which there are more than 360 species. Aloe Vera is a common name for Aloe barbadensis, the
most widely used species of aloe. It is often used anointments, creams, and lotions intended for wound healing or skin protection. The International Aloe Science Council (IASC) describes three components of the plant that are used: leaf juice (whole leaf as the starting point), inner-leaf juice (from the inner gel fillet), and aloe latex (yellow-brown shape between the inner parenchymous tissues).

Aloe vera In Siddha /ayurveda Medicine:

Aloe vera was mentioned as ‘katralai’ in siddha medicine and referred as rejuvenative drug in special medicine. In Ayurveda, Aloe vera was mentioned as “Kumari” and it was used for many indication like Externally for ulcers, wounds and internally for gynecological problems and diabetes mellitus\(^1\)\(^-\)\(^2\). Good scientific evidence exists for beneficial effects of topical aloevera in genital herpes, psoriasis vulgaris, and seborrhic dermatitis.

Monographs from Health Canada, the German Commission E, and the World Health Organization recognize the use of oral aloe vera as laxative; however, limited or conflicting evidence exists for other uses, including diabetes mellitus, dyslipidemia, sore throat, hypertension, osteoarthritis, inflammatory bowel disease, fever, itching, asthma, epilepsy, depression, glaucoma, multiple sclerosis, and vision problems\(^5\)\(^-\)\(^7\).

**CHEMICAL CONSTITUENTS OF ALOE VERA**

Aloe vera has marvelous medicinal properties. Scientists have discovered over 150 nutritional ingredients in Aloe vera. There seems to be no single magic ingredient. They all work together in a synergistic way to create healing and health giving benefits. The ten main areas of chemical constituents of Aloe vera include: amino acids, anthraquinones, enzymes, minerals, vitamins, lignins, monosaccharide, polysaccharides, Salicylic acid, saponins, and sterols. The amino acids in Aloe vera are the building blocks of protein and influence our brain function. Humans require 22 amino acids and the body will make all of them except for eight essential amino acids which our body gets from the food/drinks that we take in\(^3\)\(^-\)\(^4\). Every one of the essential amino acids are available in Aloe vera and they include isoleucine, leucine, lysine, methionine, phenylalanine, threonine,
valine, and tryptophan. Some of the other non-essential amino acids found in Aloe vera include alanine, arginine, asparagine, cysteine, glutamic acid, glycine, histidine, proline, serine, tyrosine, glutamine, and aspartic acid.

MEDICINAL VALUE OF ALOE VERA'S CHEMICAL CONSTITUENT

Located in the sap of the leaves you will find twelve anthra-quinines, a phenol compound that has stimulating effects on the bowels and antibiotic properties. In small amounts the anthra-quinines do not have a purgative effect. They help with absorption from the gastrointestinal tract and have anti-microbial and pain killing effects.

Too many anthraquinones can produce abdominal pain and diarrhea. The most important anthraquinones are aloin and emodin. They are anti-bacterial, anti-viral, and analgesic. The anthra-quinines in Aloe vera breakup residue, pus and lifeless cells, bring blood to the region and flush out material from the wounds and ulcers. Enzymes act as biochemical catalysts that break down the proteins we eat into amino acids.

The enzymes turn the food we eat into fuel for every cell in our body, enabling the cells to function and work efficiently. The main enzymes found in Aloe vera include Amylase (breaks down sugars and starches), Bradykinase (stimulates immune system, anti-inflammatory), Catalase (prevents accumulation of water in the body), Cellulase (aids digestion - cellulose), Lipase (aids digestion - fats), Oxidase, Alkaline Phosphatase, Proteolytiase (hydrolyses proteins into their constituent elements), Creatine Phosphokinase (aids metabolism), and Carboxypeptidase. The next thing we need to ask ourselves is what fuels the enzymes? The key is the vitamins and minerals we take in. For instance if we lack in zinc and/or Vitamin B6, our body will not be able to breakdown or use protein. Because of the healing properties of Aloe vera and its synergistic action, the body receives what it needs to work properly.

Aloe vera, an anti-oxidant rich plant, contains vitamins such as A, C, and E plus the minerals, zinc, and selenium. Anti-oxidants help boost the immune system and combat free radicals in the body. It also contains Vitamins B1,
B2, B3, B5, B6, and B12 along with choline, calcium (teeth and bone formation, muscle contractions and heart health), magnesium (strengthens teeth and bones, maintains healthy muscles and nervous system, activates enzymes), zinc (speeds up wound healing, mental quickness assists with healthy teeth, bones, skin, immune system, and digestive aid), manganese (activates enzymes, builds healthy bones, nerves and tissues), chromium selenium which all influence our brain performance. Additional minerals found in Aloe vera include copper (important for red blood cells, skin and hair pigment), iron (involved in oxygen transportation and making of hemoglobin in red blood cells), potassium (helps with fluid balance), phosphorus (helps build bones and teeth, assists with metabolism and body pH), and sodium (regulates body liquids, helps with nerve and muscle performance, and helps deliver nutrients into body cells). Aloe vera also contains the trace minerals of rhodium and iridium used in cancer and tumor research experiments11-12.

Another component of Aloe vera consists of the lignins, a major structural material of cellulose content that allows for penetrative properties. Aloe Vera can soak into the skin up to seven layers deep. Lignin penetrates the toughened areas of the skin being beneficial for skin problems such as eczema and psoriasis. The next elements of Aloe vera we will discuss include monosaccharide’s and polysaccharides. Monosaccharides contain the simple sugars which include glucose. The polysaccharides are the more complex long-chain sugars involving glucose and mannose or the glucomannans. These sugars are ingested whole from the stomach. They do not get broken down like other sugars, and appear in the bloodstream in exactly the same form12.

This process is known as pinocytosis. Once in the blood stream, they exert their healing and immune-regulating effect. Some of these polysaccharides are not absorbed but stick to certain cells lining the gut and form a barrier preventing absorption of unwanted material so helping to prevent a leaking gut syndrome. The sugars are also used in moisturizing preparations. One polysaccharide, acemannan, is known for its ability to restore and boost the immune system by stimulating the production of macrophages and improving the activity of
T-Lymphocytes by up to 50%. Acemannan produces immune agents such as interferon and interleukin which help to destroy viruses, bacteria, and tumor cells. Acemannan improves cellular metabolism by normalizing cellular function and regulating the flow of nutrients and wastes in and out of the cells. It knows how to destroy parasites and fungus. In some AIDS patients, it even protected the immune system from the toxic side effects of AZT. Carrington Laboratories in the United States have separated the acemannan from Aloe vera.

The product is sold as “Carrisyn” and is being used for treatment of AIDS and Feline leukemia. Many sources stated that Aloe vera has mucopoly saccharides, nitrogen containing polysaccharides, found in animals and bacteria. A regulation and testing board for Aloe vera products known as the International Aloe Science Council concludes that some people are misinformed and confused on terminology. Aloe vera contains salicylic acid which is an aspirin-like compound with anti-inflammatory, analgesic, and anti-bacterial properties. Aloevera would include prostaglandins, tannins, magnesium lactate, resins, mannins, proteins such as lectins, monosulfonic acid and gibberlin.

Another constituent of Aloe vera includes saponins. These are soapy substances from the gel that is capable of cleansing and having antiseptic properties. The saponins perform strongly as antimicrobial against bacteria, viruses, fungi, and yeasts. The plant sterols or phytosteroids in Aloe vera include Cholesterol, Campesterol, Lupeol, and B(Beta sign) Sitosterol. The plant steroids have fatty acids in them that have antiseptic, analgesic, and anti-inflammatory properties.

**OBJECTIVES**

To evaluate the safety and efficacy of the Aloe vera extract in primary Dyslipidaemic patients.

To evaluate the safety profile of Aloe Vera extract.

To evaluate Lipid Profile changes and the BMI at the end of the study.

**MATERIALS AND METHODS**

**Inclusion Criteria**

Informed consent Form Clearance

Both Sex Group
Age Group between 18-65 years
Lipid profile Shows
Triglycerides - >150mg/dl
HDL - < 30mg/dl
Cholesterol - > 250mg/dl

**Exclusion criteria:**

- History of Diabetes Mellitus/Ischemic Heart Disease/Chronic Congestive Failure/Any type of cardiac disease.
- Pregnant women/Lactating women.
- Terminally ill patients/HIV patients
- History of hypo/hyperthyroidism.
- History of cancer in the past five years
- History of Chronic liver and renal disease and any systemic Disease.
- Have received any other lipid lower drugs within 30 days

A single Randomized group study involving patients with primary Dyslipidaemia of either sex who satisfy the inclusion criteria were selected from the OPD of Arya vaidya pharmacy selaiyur, East Tambaram. After obtaining the consent form, blood sample will draw for the evaluation of lipid profile. Aloe Vera extract will be administered orally 15 ml twice a day for 30 days period. Every 15 days will have a follow up visit. At the end of 30th day Blood sample will be collected. Physical examination, Socio-economic status, Diet Pattern will be observed. No other lipid lowering or lipid affecting agents are allowed during the study. Diet restriction or Advise was not implemented. Diet Pattern wills be observed. At the end of the study pre and post drug visit blood sample will be analyzed. Adverse Events was instructed to report.

**Study Population**

Men and women with primary dyslipidemia.

Sample Size: 10 patients

**Specific criteria for early withdrawal and discontinuation**

The criteria for discontinuation from the study are pre-specified:

a. Failure to meet randomization criteria;

b. Protocol non-compliance

c. Adverse events

d. Investigator judgment

e. Patient withdraws consent

f. Pregnancy

**Primary endpoints**

a. Percentage of changes in total cholesterol and LDL from base line to one month.
b. Incidence of adverse events safety parameters.

**Secondary endpoints**

a. Specific changes in triglycerides.
b. Body weight influence in comparison with diet.

**Investigational product**

Aloe vera extract was prepared from aloe vera plant. Aloe Vera juice was mixed with 15% salicylic acid as a preservative. It will be packed in a 500ml plastic bottle. Advise to keep at room temperature 24-30 degree Celsius.

**Laboratory Investigation**

Blood sample will be collected from the subject for the lipid profile analysis on an empty stomach. Sample will be collected on day 0 pre-drug administration and Day 30 post drug administration.

**Dropout**: 15% of total population will be allowed.

**Sampling**: Sampling was done in simple random sampling method.

**DATA ANALYSIS**

The primary objective of the study is to assess changes and differences in cholesterol levels, triglycerides, in terms of whether these recommended therapeutic objectives were achieved or not. Some of the secondary variables of the study are to take anthropometric measures, which will allow researchers to assess changes in patients’ weight and body composition (weight, height, BMI).

All data were evaluated statistically with spss. Hypothesis testing methods included one-way analysis of variance (ANOVA) followed by the least significant difference (LSD) test. $P < 0.05$ was considered as significant. All results are expressed as the levels of plasma cholesterol, triglycerides and lipoproteins. The levels of serum cholesterol, triglycerides, (LDL) Low density Lipoprotein were significantly decreased, whereas levels of HDL–cholesterol (High density Lipoprotein) were significantly increased. Considerable change (decrease) in body weight is occurred in patients.
RESULTS AND DISCUSSION

Lipids constitute a broad group of naturally occurring molecules that include fats, waxes, sterols, fat-soluble vitamins (such as vitamins A, D, E, and K), monoglycerides, triglycerides, phospholipids, and others. The main biological functions of lipids include energy storage, as structural components of cell membranes, and as important signaling molecules. Lipids may be broadly defined as hydrophobic or amphiphilic small molecules; the amphiphilic nature of some lipids allows them to form structures such as vesicles, liposomes, or membranes in an aqueous environment. Biological lipids originate entirely or in part from two distinct types of biochemical subunits or "building-blocks": ketoacyl and isoprene groups. Using this approach, lipids may be divided into eight categories: fatty acids, glycerolipids, glycerophospholipids, sphingolipids, saccharolipids, and polypeptides (derived from condensation of ketoacyl subunits); and sterol lipids and phenol lipids (derived from condensation of isoprene subunits). Although the term lipid is sometimes used as a synonym for fats, fats are a subgroup of lipids called triglycerides.

Lipids also encompass molecules such as fatty acids and their derivatives (including tri-, di-, monoglycerides, and phospholipids), as well as other sterol-containing metabolites such as cholesterol. Although humans and other mammals use various biosynthetic pathways to both break down and synthesize lipids, some essential lipids cannot be made this way and must be obtained from the diet.

FATTY ACID

Fatty acids, or fatty acid residues when they form part of a lipid, are a diverse group of molecules synthesized by chain-elongation of anacetyl-CoA primer with malonyl-CoA or methylmalonyl-CoA groups in a process called fatty acid synthesis. They are made of a hydrocarbon chain that terminates with a carboxylic acid group; this arrangement confers themolecule with a polar, hydrophilic end, and a nonpolar, hydrophobic end that is insoluble in water. The fatty acid structure is one of the most fundamental categories of biological lipids, and is commonly used as a building-block of more structurally complex lipids.
The carbon chain, typically between four and 24 carbons long, may be saturated or unsaturated, and may be attached to functional groups containing oxygen, halogens, nitrogen, and sulfur. Where a double bond exists, there is the possibility of either a cis or a Trans geometric isomerism, which significantly affects the molecule configuration. Cis-double bonds cause the fatty acid chain to bend, an effect that is more pronounced the more double bonds there are in a chain.

This in turn plays an important role in the structure and function of cell membranes. Most naturally occurring fatty acids are of the cis configuration, although the trans form does exist in some natural and partially hydrogenated fats and oils. Examples of biologically important fatty acids are the eicosanoids, derived primarily from arachidonic acid and eicosapentaenoic acid, that include prostaglandins, leukotrienes, and thromboxanes. Docosahexenoic acid is also important in biological systems, particularly with respect to sight. Other major lipid classes in the fatty acid category are the fatty esters and fatty amides.

Fatty esters include important biochemical intermediates such as wax esters, fatty acid thioester coenzyme A derivatives, fatty acid thioester ACP derivatives and fatty acid carnitines. The fatty amides include N-acyl ethanolamines, such as the cannabinoid neurotransmitter anandamide.

TRIGLYCERIDES

A triglyceride consists of three molecules of fatty acid combined with a molecule of the alcohol glycerol. Triglycerides serve as the backbone of many types of lipids (fats). Triglycerides come from the food we eat as well as from being produced by the body. Triglyceride levels are influenced by recent fat and alcohol intake, and should be measured after fasting for at least 12 hours. A period of abstinence from alcohol is advised before testing for triglycerides. Elevated triglyceride levels are considered to be a risk factor for atherosclerosis (hardening of the arteries) because many of the triglyceride-containing lipoproteins that transport fat in the bloodstream also transport cholesterol, a known contributor to atherosclerosis. High triglyceride levels (greater than 500mg/dl) can cause
inflammation of the pancreas (pancreatitis).

Therefore, these high levels should be treated aggressively with low fat diets and medications, if needed. The word "triglyceride" reflects the fact that a triglyceride consists of three ("tri-") molecules of fatty acid combined with a molecule of the alcohol glycerol ("glyceride") that serves as the backbone in many types of lipids (fats).

LIPOPROTEIN

A complex of lipid and protein, the way lipids travel in the blood. Cholesterol, a building block of the outer layer of cells (cell membranes), is transported through the blood in the form of water-soluble carrier molecules known as lipoproteins. The lipoprotein particle is composed of an outer shell of phospholipids, which renders the particle soluble in water; a core of fats called lipid, including cholesterol and a surface apoprotein molecule that allows tissues to recognize and take up the particle. These lipoproteins are characterized by their density: high-density lipoprotein (HDL), low density lipoprotein (LDL), very low density lipoprotein (VLDL).

The first stages of cholesterol build up in the blood vessels (Atherosclerosis) occur when LDL particles circulating in the blood penetrate through the inner lining of blood vessels and become trapped in the artery wall. Eventual build up of LDL, fat-filled cells, cells of inflammation, and blood clotting can block the normal blood flow in the coronary arteries. This is a catastrophic event that stops the flow of nutrients and oxygen to the heart muscle, leading to heart attack (myocardial infarction).

CONCLUSION

Most of the fat found in food is in the form of triglycerides, cholesterol, and phospholipids. Some dietary fat is necessary to facilitate absorption of fat-soluble vitamins (A, D, E, and K) and carotenoids. Humans and other mammals have a dietary requirement for certain essential fatty acids, such as linoleic acid (an omega-6 fatty acid) and alpha-linolenic acid (an omega-3 fatty acid) because they cannot be synthesized from simple precursors in the diet. Both of these fatty acids are 18-carbon polyunsaturated fatty acids differing in the number and position of the double bonds.
Most vegetable oils are rich in linoleum acid (safflower, sunflower, and corn oils). Alpha-linolenic acid is found in the green leaves of plants, and in selected seeds, nuts, and legumes (in particular flax, rapeseed, walnut, and soy). Fish oils are particularly rich in the longer-chain omega-3 fatty acids Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA). A large number of studies have shown positive health benefits associated with consumption of omega-3 fatty acids on infant development, cancer, cardiovascular diseases, and various mental illnesses, such as depression, attention-deficit hyperactivity disorder, and dementia.

In contrast, it is now well-established that consumption of trans fats, such as those present in partially hydrogenated vegetable oils, are a risk factor for cardiovascular disease. Alovera has proven a considerable change in weight, this is a promising result for future detail study.

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