



“Therapeutic potency of a Siddha formulation Thubar Ennai” – A Drug Review

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Abstract

Siddha system of medicine is one of the oldest system of medicine practiced in Tamilnadu. The medicines in this system are prepared from raw materials like herbs, minerals / metals and animal products. Thuvarennai is a herbo-mineral formulation with nine ingredients. It is used externally for treating wound / ulcer. This review is aimed to bring out scientific evidence for the therapeutic usage of Thuvarennai and focused on the pharmacological activity responsible for the efficacy of the drug. Most of its drugs possess styptic, wound healing property, anti-inflammatory, anti-microbial, analgesic activity. Hence, justifying its usage in treating wound/ulcer.

Keywords: Siddha Medicine, Thuvarennai, styptic, wound healing property

Introduction

Traditional siddha system of medicine is widely practiced in Tamilnadu and in Tamil speaking areas of the world . Siddha system of medicine classified diseases into 4448 types . One among them is viranam (wound / ulcer).

According to the siddha classical text,

“Rathina Surakka Naadi”, Wound is classified into 700 types. Another Siddha classical text, Aruvai Maruthuvam classifies Viranam

(Wound/Ulcer) into 2 main types. 1. Thusta viranam-Further classified into 15 types. 2. Athustaviranam – further classified into 45 types. Depending upon the mukkutram, viranam (wound / ulcer) is classified into 16 types² . According to T.V Sambasivampillai dictionary, viranam is characterized and grouped under two heads idiopathic and Traumatic according to their origin. It is so named from its etymology- To break. It signifies a cracked or broken condition of the skin and flesh of the affected part of the body.

The symptomological description of the clinical entity “viranam” is identical to those of the symptoms described under the clinical diagnosis “Wound / ulcer” in modern science. The most of the ingredients of Thubar Ennai possess astringent (styptic) Hence it has been named as ThubarEnnai¹

Styptus and wound healing activity

The styptic action is defined as “contracting the tissues or blood vessels” It is also known as astringent and hemostatic which tends to check bleeding by contracting the tissues or blood vessels. Wound healing is an intricate process where by the skin (or another organ, tissue) repairs itself after injury.

In normal skin, the epidermis (outer most layer) and dermis (inner or deeper layer) exist in steady state (equilibrium) and shield from the external environment. When the skin is broken, the normal (physiologic) process of wound healing begins. The classic model of wound healing comprises of following phases (1) Hemostasis (2) Inflammatory phase (3) Proliferative phase (4) Remodelling or maturation phase³.

This review is focused on the pharmacological activities of each ingredients which supports the traditional claim and the literature search is confined to that areas. The search was made from the text books in the library of National institute of Siddha, Internet databases, open access journals and from indexing portals like Google scholar, Pubmed.

Literature evidence and background for Thubar Ennai

The test drug Thubar Ennai is chosen from the Siddha classical text, Anubhogavaithi yanavaneetham, part-10, Pg no 65. The preparation of ThubarEnnai¹ is simple, cost effective and ingredients are easily available throughout the year.

Standard Operating Procedure for the preparation of Thubar Ennai

The mentioned ingredients in Table-1 are taken. Oils mentioned are mixed well except wax, all other ingredients are powdered separately and mixed. Powdered ingredients are mixed with oil and subjected to heat until it attains mezhugu consistency. Then the oil is filtered and stored¹

Purification of Raw drugs

All the drugs purified as per the methods defined in Siddha literature.

Copper sulphate (CS)

Other names – Mayil Thuttam, Kandar, Narpatchai

CS is prepared by roasting copper pyrites with sulphur, dissolving the roasted mass in water and evaporating the solution to obtain the dark blue crystalline masses.

Pagaisarakku:

Antimony sulphide, arsenium, sodium chloride, lead sulphide.

Natpusarakku:

Arsenic trisulphidum, Ammonium chlorate, Sodium borate, Sulphur, Mercury.

Suvai – Thubarppu

Action

It is a powerful astringent, emetic, antiseptic. Externally, stimulant, styptic, mild caustic⁴.

Sulphide of lead (SL)

Other name: Singi

Types : Mirutharsingi
Raththasingi
Aemasingi

Occurrence

SL obtained from the mountain of sauvira, a country along the indus.

The sulphide of lead is of glimmering lustre and is an ore of lead, occurs in cubic masses destitute of rays and is tabular in its crystalline arrangement

Suvai – taste of yellow sandal

Action – Astringent, Coolant, Antiseptic, Anthelmintic⁴

Cera flava (CF)

Types

Pon Mezhughu
Nallamezhghu
Kosumezhghu

CF is obtained by squeezing or pressing the comb (when the honey is extracted) and melting it in hot water and allowed to cool. It is purified by repeating this process several times and finally casting the wax into moulds.

It is yellowish solid mass, harder than butter, with honey like odour. It is soluble in water, cold alcohol. **Myricin** is a principal constituent.

Action : Emollient, Demulcent⁴

Pharmacological activities of the ingredients of Thuvarennai

Quercus infectoria

Ethanol extract of the shade dried leaves of *Quercus infectoria* was studied for its effect on wound healing in rats. The plant showed a definite, positive effect on wound healing, with a significant increase in the levels of the antioxidant, enzymes, superoxide dismutase and catalase in the granuloma tissue. This finding provides an insight into the usage of the galls of *Quercus infectoria*. In traditional treatment of wounds or burns associated with bacterial

infection. The main constituents found in the galls of *Quercus infectoria* are Tanin (50-70%) and small amounts of free gallic acid and ellagic acid^{3,6,7}.

Azadirachta indica

The oil is bitter, astringent, sweet, thermogenic, digestive, anthelmintic, constipating and emollient, Externally it is used for dryness of the skin and leucoderma⁵. Preliminary chemical examination of the oil indicated the presence of Sulphur, a very bitter yellowish substance⁸. The main constituents nimbin, nimbidin were found to possess anti-inflammatory property Nimbidin was found to possess analgesic and antipyretic effect. Nimbidin (20 mg/kg,p.o) had significant effect on gastric and peptic ulcers in experimental models.(P.R.U., Lucknow). Nimbin (20 mg/kg) exhibited antiulcer against shay ulcer in rats and histamine ulcer in guinea pigs⁹. Neem shows anti-bacterial activity against *Entamoeba histolytica*, *Clostridium*, *Shigella*, *Proteus*, *Salmonella*, *Psuedomonas* (Tandan et al.(1990); Sai Ram et.al (2000); Venugopa & Venugopal (1994). Neem possess Wound healing property, antiseptic, emollient (Tandan et al.(1990). Neem possess astringent, anti-microbial, hastens wound healing, emollient, demulcent¹⁰. Mahmoodin (C30H38O8) showed significant antibacterial activity against Gram positive and Gram negative organisms(Van der Nat,J Ethnopharmacol, 1991,35,1Gaikwad et al, Phytochemistry, 1990, 29, 3963; Siddiqui et al, J Nat Prod, 1992,55, 303)Neem oil has been found to slow down the growth of HIV-virus which causes AIDS. [East Pharm, 1992, 35(414), 79; Stanley, Agric Res, Wash, 1991, 39(6), 21]The oil is reported to be applied on piles to control bleeding and itching.(Singh, AncientSci Life,1988,8,167). Experimentation was made to evaluate the analgesic activity of neem seed oil on albino rats and results showed that neem oil has significant analgesic effect in the dose of 1 and 2 ml/kg. Another study was made to investigate the anti-inflammatory effect of neem seed oil on albino rats ,and results showed that carbon tetrachloride extract of *Azadirachta indica* fruit skin and isolated ingredient azadiradione showed significant anti-inflammatory activity. A study

was made to evaluate the wound healing activity of the extracts of leaves of *A.indica* and *T.cardifolia* using excision and incision wound models in Sprague dawley rats and results revealed that extract of both plants promoted the wound healing activity in both excision and incision wound models¹¹.

Ricinus communis

Castor oil is a nearly colourless or very pale greenish yellow viscous liquid, having a mild taste and odour which soon become unpleasant. The oil is distinguished from most other oils by its high viscosity, specific gravity and acetyl value, and by its solubility in absolute alcohol and glacial acetic acid and poor solubility in petroleum ether, gasoline, kerosene, etc¹². Composition—Castor oil consists principally of ricinoleic acid (12-hydroxy oleic acid), which occurs to the extent of c. 90 per cent and is responsible for the high viscosity and other peculiar characteristics of the oil. Stearic, oleic, linoleic and dihydroxystearic acids are also present in small amounts. (Eckey, 594-95; Jamieson, 49; Gupta et al, J. Sci. Fd Agric, 1951, 2, 245.) Castor oil consists predominantly of triricinolein, the content of which depends on the proportion of ricinoleic acid present (Achaya et al). The strong laxative property of castor oil is reported to be due to the local irritant action caused in the intestines by the ricinoleic acid formed by hydrolysis under the influence of the lipolytic enzymes.(U.S.D.,1955,263-64)

Castor oil is usually given in doses of 4-16 ml., maximum safe dose being 60 ml. in 24 hours. Infants require a relatively larger dose of the oil than adults.(I.P.C., 188; U.S.D., 1955, 263-64)

Castor oil is sometimes applied externally as bland emollient in the form of a 5-10 per cent ointment, in seborrheic dermatitis and other cutaneous affections.(U.S.D.,1955,263-64) Castor oil along with liquid paraffin was found to reduce photodermatitis in rats caused by eating Lantana camara leaves. [Bhide & Akhtar, Indian Vet J, 1991, 68, 1122)

Ricin side chain A of castor seed protein is used in preparing SN7 immunotoxin which when administered intraperitoneally or intravenously to tumour-induced mice showed suppression of tumour growth completely without undesirable side-effects. Ricin-A enters into the formulation of immunotoxin cocktail in combination with chemotherapy for treatment of B-cell neoplasia. Ricin-A chain immunotoxins showed cytotoxic activity against T- lymphocytes and Burkitt's lymphoma cells but not against erythroblasts. Ricin side chain linked to IgY can selectively kill stornachmuroid carcinoma cells leaving normal human cells untouched. It can be used to treat auto-immune diseases like rheumatoid arthritis, diabetes mellitus and aplastic anaemia (ChemAbstr, 1994, 121, 170548, 177236, 403,169983, 245287^)

The cytotoxic property of ricin-A subunit may be utilized to treat HIV patients by a process in which ricin-A' is incorporated into human immunodeficiency virus mutants. The process has been patented (Chem Abstr, 1994,121, 170527).

Sesamum indicum

The seeds are sweet, astringent, bitter, emollient, thermogenic, tonic. In medicated oils ,sesame oil forms a fat soluble medium. Chemical constituents-Seeds are fairly rich in thiamine and niacin. The principal protein is a globulin. Seeds contain a fixed oil and leaves contain gummy matter¹⁵. The seeds of *S. indicum* L (Pedaliaceae) are used traditionally in the folklore for the treatment of various kinds of wounds. A study was undertaken to verify the effect of *S. indicum* seeds and its oil on experimentally induced excision wound, incision wound, burn wound and dead space wound models in rats. Aloe vera was used as standard wound healing agent. A formulation of seeds and oil was prepared in carbopol at 2.5% and 5% concentrations and applied to the wounds. In the excision and burn wound models, the so treated animals showed significant reduction in period of epithelization and wound contraction (50%). In the incision wound model a significant increase in the breaking strength was observed. Seeds and oil treatment (250 mg and 500 mg/kg; po) in dead

space wound model, produced a significant increase in the breaking strength, dry weight and hydroxyproline content of the granulation tissue. The results showed that *S. indicum* seeds and oil applied topically or administered orally possesses wound healing activity¹⁶. Another study was conducted to evaluate the antinociceptive and anti-inflammatory properties of the sesame oil and sesamin. The results suggest that sesamin is one of the active compounds found in sesame oil and justify the antinociceptive and anti-inflammatory properties¹⁷.

Vateria indica

White resin or wood of *Vateria indica* Linn. of Dipterocarpaceae Large trees; bark rough, grey to whitish, peeling off in thick round flakes. Leaves elliptic-oblong. Flowers white, in axillary or terminal long panicles. Capsule oblong. Chemical Constituents- Bark contains DL-epicatechin, fischinidol and afzetechin. Tree yields a resin which is a complex mixture of triterpenes. Fruit shell yields tannins. Gum yields lipids. According to literature, it has been indicated for burn,, rheumatism, bacterial infections, blood diseases, throat infections, cough, bronchitis, piles and diarrhoea⁵. Tannin content of stem bark powder of *Vateria indica* was found to be 35 % w/w. Phytochemical studies were carried out on ethanol and water extracts indicated the presence of tannins, phytosterols, Phenol, flavonoid, alkaloid and carbohydrates. Tannin contents were found to be 35% w/w in dried powder of *Vateria indica*. The Phytochemical analysis of *Vateria indica* stem bark suggests the presence of carbohydrate, tannin, phenols and flavonoid in aqueous and ethanolic extract. Petroleum ether extract of stem bark showed the presence of phytosterols. The dammar resin obtained from bark of the tree is used in chronic bronchitis and throat troubles¹⁸. The resin is used for the treatment of cough, asthma, leprosy, skin eruptions, crack infection, wounds and ulcer. The anti-inflammatory activities of *V. indica* resin were evaluated to identify the beneficial effects related to inflammation. In the above study, the phytochemical analysis exhibited positive result in aqueous solution and the aqueous extract of *V. indica* resin inhibited the heat induced albumin

denaturation, proteinase activity and stabilized the Red Blood Cells membrane. The GC-MS result of *V. indica* resin possesses the sesquiterpenoid compound which has an anti-inflammatory activity. It has been concluded that aqueous extract of *V. indica* resin possessed marked anti-inflammatory activity¹⁹.

Acacia catechu

A. catechu extracts have been widely used for hundreds of years. One of the earliest known clinical studies involved an evaluation of *A. catechu* in the treatment of lepromatous leprosy (Ojha et al., 1969).

Several human studies have assessed the anti-inflammatory effects of a combination of *A. catechu* extract of heartwood, roots, or bark in combination with a root extract of *Scutellaria baicalensis* (Chinese skullcap), which has been reviewed by Bitto et al. (2014). The study results showed, there were no significant differences with respect to laboratory values including blood chemistries and serology, blood pressure, or body systems, indicating a high degree of safety of the product at the prescribed dose.

A number of studies have examined the antioxidant activity of *A. catechu* extracts in vitro. Naik et al. (2003) demonstrated that aqueous extracts of various plant parts were capable of inhibiting radiation induced-lipid peroxidation in a rat liver microsomal preparation.

The antioxidant, iron-chelating, and DNA-protective properties of a 70% methanolic extract of *A. catechu* heartwood were assessed (Hazra et al., 2010). The extract was shown to exhibit free radical-scavenging activity against superoxide, nitric oxide, peroxynitrite, hydrogen peroxide, singlet oxygen, and hypochlorous acid radicals. Guleria et al. (2011) conducted a detailed analysis of the antioxidant activities and ability to protect against DNA strand breaks with methanol, acetone, and ethyl acetate extracts of heartwood, bark, and leaves of *A. catechu*. The results demonstrated that methanol and ethyl acetate extracts of heartwood exhibited potent antioxidant and DNA-protective activities.

Other studies have demonstrated *in vitro* antioxidant and free radical-scavenging activities of aqueous extracts of *A. catechu* (Patil et al., 2003; Kumar et al., 2013), *A. catechu* bark extracts (Sulaiman et al., 2011), and ethyl acetate extracts of the whole plant based on anti-lipid peroxidative activity, superoxide anion-scavenging activity, and reducing power (Noorani et al., 2010). Thus, the antioxidant and radical-scavenging activities of heartwood, leaf, and bark extracts are well established.

Methanol and hexane extracts of *A. catechu* bark were found to be more antiproliferative and cytotoxic than aqueous extracts against various cancer cell lines *in vitro* (Nadumane, 2011). Ghate et al. (2014) assessed the *in vitro* anticancer and apoptosis efficacy of a 70% methanolic extract of *A. catechu* heartwood in the cultured MCF-7 human breast adenocarcinoma cell line. The extract exhibited significant cytotoxicity towards cultured MCF-7 cells (IC₅₀ (50% inhibitory concentration) = 289 µg/mL), as well as induced apoptosis as demonstrated by flow cytometric analysis and morphological investigation. Immunoblot analysis confirmed that apoptosis induction by the extract was achieved by enhancing Bax/Bcl-2 ratio with activation of the caspase cascade and ultimate cleavage of poly adeno ribose polymerase.

Burnett et al. (2007) tested a proprietary mixture of extracts of *A. catechu* and *S. baicalensis* for its ability to inhibit cyclooxygenase and 5-lipoxygenase enzyme activities *in vitro*, cellular, and *in vivo* models. These two enzymes are important in the production of inflammatory

cytokines from arachidonic acid. The results showed that this combination product was able to inhibit these two enzymes and reduce arachidonic acid-induced production of inflammation in a mouse ear-swelling model.

Various studies have examined the antimicrobial activity of *A. catechu* extracts, and demonstrated good-to-excellent activity depending on the organism involved. An aqueous extract of *A. catechu* exhibited moderate activity against a multiple drug resistant *Salmonella typhi* (Rani and Khullar, 2004). Patel et al. (2009) showed that an aqueous extract of *A. catechu* resin from heartwood exhibited excellent activity against *Bacillus subtilis*, while a petroleum ether extract gave excellent activity against *Pseudomonas aeruginosa*, and a chloroform extract was active against *Staphylococcus aureus*.

An ethyl acetate extract of heartwood exhibited antimicrobial activity against *B. subtilis*, *S. aureus*, *Klebsiella pneumoniae*, and *Shigella* species (Joshi et al., 2011). A methanol extract of *A. catechu* was shown to have antimicrobial activities against *B. subtilis*, *S. aureus*, *Sal. typhi*, *Escherichia coli*, *P. aeruginosa*, and *Candida albicans* (Negi and Dave, 2010). Aqueous and ethanol extracts of *A. catechu* demonstrated moderate activity against hospital isolates of methicillin-resistant *S. aureus* (Voravuthikunchai and Kitpipat, 2005). Lakshmi et al. (2011) have also demonstrated that ethanol extracts of *A. catechu* exhibit inhibitory activity against various microbes. Thus, various extracts of *A. catechu* heartwood exhibit antimicrobial activity.

Table -1 Ingredients of Thuvarennai

Sl.no	Tamil name	Botanical name	Part used	Quantity
1.	Nallennai	<i>Sesamum indicum</i>	Seed oil	2 palam (70 gms)
2.	Veapennai	<i>Azadirachta indica</i>	Seed oil	2 palam (70 gms)
3.	Aamanakkuennai	<i>Ricinus communis</i>	Seed oil	2 palam (70 gms)
4.	Vellaikungiliyam	<i>Vateria india</i>	Resin	1 Varaagan(4.2gms)
5.	Mirutharsingi	Sulphide of lead	-	1 Varaagan(4.2gms)
6.	Maasikkai	<i>Quercus infectoria</i>	Galls	1 Varaagan(4 .2gms)
7.	Thurusu	Copper sulphate		1 Varaagan(4 .2gms)
8.	Kaachukaati	Acacia catechu	Heart wood	1 Varaagan(4 .2gms)
9.	Manjalmezhugu	<i>Cera flava</i>	Beewax	1 Varaagan(4 .2gms)

Table -2 Information on Phytochemical/Chemical Constituents .

Sl.no	Botanical name	Phyto chemical	Principal Chemical constituent
1.	<i>Sesamum indicum</i>	Lignin ,Glucosides Sesaminol Glycosides Proteins Carbohydrates, Mucilage, woody fibre, Ash	Liquid fats, glycerides of oleic and linoleic acid soild fat, stearin, Palmitin, myristin
2.	<i>Azadirachta indica</i>	Yellow bitter fixed oil sulphur, Alkaloid Resins, Glucosides, Margasicc Acid Margosopirin	Nimbidin, Nimbin Sodium Nimbidinate
3.	<i>Ricinus communis</i>	Ricinoleic Acid Fixed oil Protein Ricinoleate of Glycerol	Palmitin Stearin Glycerides of ricinoleic acid
4.	<i>Vateria indica</i>	Oleic acid Fatty acid	-
5.	<i>Quercus infectoria</i>	Tannin / Tannic acid Gallic acid / Ellergic acid	B – Sitosterol Hexamethyl Ether Isocryptomerin
6.	<i>Acacia catechu</i>	Catechin Catechutennic Acid	Catechu – tannic acid catechin Catechu acid Tannin Gum Quercetin
7.	Lead sulphate	-	-
8.	Copper sulphate	-	-
9.	<i>Cera flava</i>	-	-

Table-3 Information on ingredients

Sl.No	Botanical name/ Chemical name	Tamil name	English name	Hindi name	Sanskrit name	Family	Part used
1	<i>Sesamum indicum</i>	Nallennai	Gingeli oil plant	Til	Tila	Pedaliaceae	Seed
2	<i>Azhadirachta indicum</i>	Veapennai	Margosa tree, Neem tree	Nim (or) Nimb	Ravipriya	Meliaceae	seed
3	<i>Ricinus communis</i>	Aamanakku Ennai	Castor oil plant	Endi	Eranda , Vatari, Gandharva	Eupaorbiaceae	seed
4	<i>Vateria indica</i>	Vellai Kungiliyam	White damar	Kahruba, sefeeldamar	Gandharva, Panchangulam	Dipterocarpaceae	Resin
5	Lead sulphide	Mirutharsingi	Galena, sulphide of lead	Surma, Anjana, Sa uriranjana ,Krishna surma	Ajaukarua Ajlarana, sarjaka	-	-
6	<i>Quercus infectoria</i>	Masikkai	Magic nuts, oak galls	Majuphul ,Mayu, Muphal	Majuphul	Cupuliferae	Galls
7	Copper sulphate	Thurusu	Verdigras	NilaThutha, Nilatuta	Sasyaka Tutta, NellaTuta Thutham, Mayurathutham	-	-
8	<i>Acacia catechu</i>	Kaichukatti	Catechu, Black Catechu	Kathe, Kottha, Fooflee Khair	Khadira	Mimosaceae	Heart wood
9	<i>Cera flava</i>	ManjalMezhugu	Bees wax	Mom	Siktha Madhiyan		

Table -4 Information on actions of ingredients.

Sl.No	Botanical name / Chemical name	Action
1.	<i>Sesamum indicum</i>	Laxative, Emollient, Demulcent, Diuretic Nourishing, Nutritive
2.	<i>Azadirachta indica</i>	Local stimulant, Antiseptic, Insecticide
3.	<i>Ricinus communis</i>	Laxative, Emollient
4.	<i>Vateria indica</i>	Stimulant , Expectorant, Diuretic
5.	<i>Quercus infectoria</i>	Astringent, Styptic, Tonic
6.	<i>Acacia catechu</i>	Powerful astringent
7.	Lead sulphide	Astringent, Demulcent, Anthelmintic action
8.	Copper sulphate	Powerful astringent, Emetic, Antiseptic
9.	<i>Cera flava</i>	Emollient, Demulcent

Conclusion

From the above literature review, it is evident that the ingredients of Thuvar Ennai has pharmacological activity like anti-inflammatory, analgesic, wound healing property, anti-microbial, anti-oxidant, analgesic activity which are responsible for its therapeutic indication claimed in classic Siddha literature.

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