



TO EVALUATE THE CLINICAL EFFICACY OF SHALMALI MOOLA (BOMBAX CEIBA LINN.) AS VRISHYA ON SEMINAL PARAMETER". A CASE STUDY

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ABSTRACT

Traditional healers frequently employ medicinal plants in their daily practises to treat a variety of illnesses. A well-known herb called shalmali is utilised in the conventional system of medicine to cure a variety of illnesses. Flavonoids, phenolics, sesquiterpenoids, shamimicin, bombamalosides, bombamalones, bombasin, bombasin 4-o-glucoside, and bombalin are some of the compounds in shalmali that contribute to its medicinal effect. Attempts have been made in the current study to summarise several elements of scientific investigations on the Shalmali, including ethnopharmacology, phytochemistry, and primarily the pharmacological activity. Studies conducted in vitro and in vivo have shown that the Shalmali has a variety of pharmacological properties, including antioxidant, antibacterial, anticarcinogenic, anti-inflammatory, immune-modulatory, hypotensive, hypolipidemic, antihyperglycemic, and analgesic properties.

Keywords – shalmali, Bombax ceiba Linn., vrishya, etc.

INTRODUCTION

Ayurveda is the richest heritage of the world, whose principles and guidelines are laid by the Vedas, which are considered as the first available literature of the world. An Upaveda of Atharvaveda, i.e. Ayurveda has been subdivided into 8 (Eight) branches of specialty.¹

The main purpose of Ayurveda is to maintain the health of healthy individuals and cure the disease of diseased one. To fulfill both these purpose Bhesaja is mainly divided in two types. To maintain the health of healthy person Swasthasyorjaskara Bhesaja is given which includes Rasayana and Vajikarahna chikitsa and to cure the disease of sick person. Artasya Roganuta Bhesaja is given which include the other diseases and its treatment.²

To achieve the ultimate goal of Ayurveda the knowldege of the dravya (drug) is very much essential, hence Acharya Charaka mentioned Dravya as the second tetrad of treatment , and define Ayurveda as the text which includes Ayusya (beneficial for life) and Anayusya (non-beneficial for life) dravyas with their properties and actions.³

The modern day's life style, socio-economic plights, environmental pollution, mental stress and strain have greatly affected the normal sexual behaviour and fertility as well. In India a very high rate of Infertility has been reported. This trend is slowly affecting all male populations Ayurveda describes the use of Vrishya and Vajikaran therapy for problems related to sexual life. This therapy includes various medications derived either from herbs, metals or animal sources. Semal Mushli (Root of young Shalmali) is one of such medicine.⁴

AIMS AND OBJECTIVES OF STUDY

The present study "To evaluate the clinical efficacy of Shalmali Moola (Bombax ceiba Linn.) As Vrishya on Seminal Parameter" aims at:-

1. To review the upto date classical and recent literature regarding Shalmali.
2. To carry out Pharmacognostical & Phytochemical study of Shalmali Root.
3. To prepare standard quality medicine as per GMP and classical Ayurvedic text.
4. To evaluate the clinical efficacy of Shalmali Root as Vrishya

DRUG REVIEW

Present study is aimed at to assess the effect of Vrishya karma of Shalmali, which is of plant origin. The Dravyas or drugs which possess Madhura (sweet), Snigdha (unctuous), Jivana (promoters of life), Brinhana (nourishing), Guru (heavy) properties and which produce Harsa in mind are generally Vrishya. Shalmali possess the almost all the above mentioned qualities, that is why it has been chosen for the present study.⁵

Shalmali is described in Charak Samhita and widely used in various therapeutic purposes. Shalmali is included in Pureesh Virajaneeya Mahakashaya (Correctives of fecal pigment) in Charak Samhita. Flowers

of Shalmali is mentioned in Annapan Vidhyadhaya under the heading of Saka varga and said to be beneficial in Raktapitta. In addition to that it used as stool binder⁶

The gummy extraction of Shalmali, popularly known as Mochras possess multi – Dimensional therapeutic value because of which it has got separate medicinal entity from the pharmacological point of view. Various references are found in this regard in the Brihatraye granthas. Apart from this Shalmali is included in Kashayaskandha in Charak Samhita.⁷

Some important Yog (composition) of Shalmali along with specific indications mentioned in the Charak Samhita are as follows:-

S No.	Parts Used	Name of the Formulation	Indication
1	Both the mochas and bark of Shalmali	Chandanadi toila	Dah and Jwar
2	Flower of Shalmali	Changeri Ghrita	Arsha, Atisar, TridoshaRaktasrava, Pravahika, Gudabhrangsa
3	Mochras	Neelotpaladi Yog (Milk as anupan)	Raktatar
4	Mochras	Urustambha nasak Yog	Urustambha
5	Bark of Shalmali	Udumbaradi Toila	Yoni Chikitsa
6	Mochras	Pushyanug Churna	Yonidosha and Rajadosha Chikitsa

APPLICATION OF DRUGS

- Juice prepared from Shalmali and other Raktapitta nashak leafy vegetables which has been mentioned in Shakavarga in the Sutrasthān 27th chapter of Charak Samhita is useful in Raktapitta.
- Powder of Shalmali flower along with Khair, Priyunga and Kobidar is indicated for Raktapitta and Madhu is used as Anupan
- If juice of Shalmali bark and Gajar (Carrot) is mixed with Dahimalai in proper way and used for the patient suffering from bleeding piles (Raktarsha) gives better result.
- Flower of Shalmali and Mochras along with other ingredients are used in Pichchhabasti, which has the indication in Pravahika, Gudabhramsas, Raktatar and Jwar.

- Kalka made by the bark of Shalmali with equal quantity of Balamool and Batapatra if used in Vrana avapeedan, it produces excellent result.
- Shalmali churna is used in Kritabedhan vidhi (Indicated in Kustha roga, Pandu roga, Pleehavridhi, Shothroga and Gulma roga).⁸
- Shalmali (Flower and fruit) is included in Mahasugandhinamak Agad along with other dravya in Kalpasthan chapter 6th which has got beautiful fragrance. Some prominent Yog (composition) along with its indication as mentioned in Sushruta Samhita is as follows:

Parts Used	Name of the Yoga	Indication
Tender leaf of Shalmali along with Madhu and Mulethi	Seeta Kashay	Atisar
Shalmali	Atisar Kapitthadi Yog	Atisar
Bark of Shalmali	Priyadi Ksheer	Raktatar
Flower of Shalmali	Gayatradyavaleha	Raktapitta

CLASSIFICATION OF SHALMALI

S.No.	Name of the Classic	Mahakashaya/ Varga/ Gana
1.	Charak Samhita	Puresavirajaniya, Sonitasthapana, Vedanasthapana & Kashaya Skandha
2.	Sushruta Samhita	Shakavarga, Priyangvadi Gana (Mochrasa)
3.	Astanga Hridaya	-
4.	Dhanvantari Nighantu	Amradi Varga
5.	Sodhal Nighantu	Amradi Varga
6.	Madanpal Nighantu	Vatadi Varga
7.	Kaideva Nighantu	Ausadhi Varga
8.	Bhavaprakash Nighantu	Vatadi Varga

9.	Raj Nighantu	Shalmalyadi Varga
10.	Shaligram Nighantu	PhalaVarga
11.	Nighantu Adarsha	Shalmalyadi Varga
12.	Priya Nighantu	Harityakadi Varga

TYPES OF SHALMALI:

Acharya Bhavamishra mentioned Shalmali in Vatadivarga as of two types-

1. Shalmali
2. Kuta Shalmali

S.No.	Description	Shalmali	Kuta shalmali
1.	Botanical name	Salmalia malabarica Schott & Engl. or Bombax malabarica Dc. or Bombax ceiba Linn.	Eriodendron anfructuosum D.C. or Ceiba Pentandra Linn.
2.	English Name	Red Silk Cotton tree	White Silk Cotton tree
3.	Leaflets	6/7 in numbers	5 in number
4.	Flowers	Red in colour	white in colour

TAXONOMICAL CLASSIFICATION

Kingdom: Plantae

Division: Magnoliophyta

Class: Magnoliopsida

Order: Malvales

Family: Malvaceae (Bombacaceae)

Genus: Bombax

Species: ceiba

Binomial name: Bombax ceiba Linn.

Bombax malabaricum D.C.

Salmalia malabarica (DC.) Schott & Endl.

FEATURES OF FAMILY BOMBACACEAE

Bark: Bark of Semal looks pale ashy to silver grey, 1.8 -2.5 cm thick, smooth up to middle age, becoming rough with irregular vertical cracks on older trees.

Leaves: Semal tree has the compound leaves which is palmate in appearance. It is exactly appears as the palms appear in man. It is digitate, large, spreading, glabrous which has common petiole, and the size of leaf is 15-30 cm long.

Flowers: The bright red flowers, which appear in January to March, are large and conspicuous on the leafless trees. It presents a strikingly remarkable sight in winter and spring when the usually bare branches are covered with large, fleshy, red flowers.

Capsule: The pods are about 10-18 cm in length, oblong-oval in shape, locucially 5 valved; valves woody, downy outside, lined with silky hairs within.

Seeds: Within the capsule it has many seeds which are obovoid, smooth, 6-9 mm long in size. These seeds are oily and surrounded by a thick mass of long silky hairs or floss, hence easily blown about by wind.

PLANT DESCRIPTION

Bombax ceiba (Hindi name - Semal or Shalmali) grows to an average of 20 meters, with old trees up to 60 meters in wet tropical weather. This tree has a straight trunk and its leaves are deciduous in winter. Red flowers with 5 petals appear in the spring before the new foliage. It produces a capsule which, when ripe, contains white fibres like cotton. Trees from seeds begin flowering when 8 to 10 feet tall, and can reach 30 feet in five years.⁸

Chemical properties and active principles of Shalmali root

Root: Analysis of the dry, skin-free white pulpy portion of the roots from 2 years old plants contains the following-

Starch - 71.2%	Cellulose - 2.0%
Sugar (arabinose & galactose) - 8.2%	Proteins – 1.2%
Moister – 7.5%	Fat – 0.9%
Peptic substances – 6%	Tannins – 0.4%
Minerals – 2.1%	Non tannins – 0.1%

Root bark: The root bark contains Lupeol, 2- sitosterol, 8- formyl-7- hydroxyl-5- isopropyl-2- methoxy-3- methyl-1, 4 naphthaquinone, Iso hemigossypol-1- methyl ether, Iso hemigossypol-1, 2-dimethyl ether, 7- hydroxyl cadalene

FOLKLORE USES

- Roots externally applied for swellings and rheumatic pains.
- Tap root used for gonorrhoea and dysentery; also as an emetic.
- Bark used externally as paste for inflammation and skin eruptions.
- Roots used for diarrhea, dysentery, boils, diabetes, snake bites, leucorrhoea.
- Leaves, ground and mixed with milk, used for urgency and painful urination.

DIFFERENT STUDY ABOUT SHALMALI IN VARIOUS UNIVERSITY OF INDIA

S.No.	Topic	Year	Scholar & University
1	Hypoglycaemic activity of different parts of Shalmali – An experimental study	1991	Durga K ,Rajiv Gandhi University of Health Science, Banglore
2	Bali- Shalmali ka Shukra ke pariprekshya mein prayogika adhyayana	1999	Mehta Mahendra Kumar, Mumbai University, Mumbai
3	Role of Shalmali in Atyartava	2002	Shakuntala M K, BHU
4	A clinical study of vatapatradi lepa in Mukha-Dooshika with Manjisthadi Kashaya (internally) and Shalmali –Kantaka Bashpa- sveda.	2001	Shaila Chrysanthia, A.P. University, Vijayawada.
5	Study of Shalmali and Kutaja for its Rakta Stambhaka Karma in the management of Rakta Pradar	2001	Shoba Rani, A.P. University, Vijayawada.

PHARMAOGNOSTICAL STUDY

Aim and Objectives

To study macroscopic and microscopic character of root as well as root powder of young Shalmali.

Collection of Sample

Root of young Shalmali plant was collected from the field around Dehradun.

Macroscopic Study

Sample of Shalmali Root was put under macroscopic and microscopic examinations. Specific macroscopic characters are enumerated

S. No	Appearance	Description
1.	Size	Procured root is about 30- 40cm. long, on an average about 1-2cm thickness of fresh roots will become all most 0.5-1cm thick when dried.
2.	Shape	Nearly uniformly cylindrical, though in most cases they are irregularly bent, curved or slightly twisted, slightly woody and rigid.
3.	Colour	Fresh roots covered with glistering salmon orange bark and white inside.
4.	Texture	Surface generally smooth in young roots but becomes slightly rough in matured ones due to formation of warty lenticels. Roots thick, hard with woody central core.
5.	Odour	Sweet and distinct
6.	Taste	Sweet and on eating mouth become slimy.
7.	Fracture	Dried root breaks with dull sound and thick root pieces are not easily breakable.

MICROSCOPIC STUDY

Powder microscopy of root of Shalmali.

- Starch grains and oil globules are present in the slide.
- Fixed oil and fat contents are more in the slide, which are having brown or black soluble contents.
- More starch (Insoluble polysaccharide - Simple or compound) contents are present which are of eccentric or concentric characteristic and gelatized observation found.
- Lignin (A complex phenyl propanoid polymer) was seen in the slide after stained by phenoglycerol.

PHYTOCHEMICAL STUDY

Photochemistry is the branch of natural product chemistry in which qualitative and quantitative analysis of herbal drugs take place. Photochemistry is in the strict sense of the word, the study of Phytochemical. These are chemicals derived from plants.⁹

The systematic investigations of plant materials for its phytochemical behaviour involves four different stages-

- The procurement of drug material.
- Examination, Purification and Characterization of the constituents for pharmaceutical interest.
- Investigation of Bio-synthetic pathways of a particular compound.
- Quantitative evaluations of the Phytochemicals.

In the plants, two types of phyto -chemicals are present,

- 1) Inorganic matters
- 2) Organic matters.

Inorganic Matters are those which are free from carbon i.e. all electrolytes comes under inorganic matter.

Organic Matters are secondary metabolite products in the plants. Role of these components for medicinal purposes are important. Examinations of both Organic and Inorganic matters are done both qualitatively and quantitatively.¹⁰

All the organic active compound commonly present in medicinal plant are as follows:-

- Carbohydrates
- Alkaloids
- Proteins
- Glycosides
- Saponin
- Tannins

CLINICAL STUDY

This is the main part of the study which was carried out in the patients who have seminal abnormality as per seminal parameters

Material and Method

Selection of patients

Patients selected from OPD of Uttaranchal Ayurvedic Hospital Dehradun of age group 20-60 years, irrespective of caste, religion and race etc. It was an open trial method with single group only.

Diagnosis of patients: Patients were diagnosed on the basis of their history and disturbed seminal parameters.

Inclusion criteria

- 1) Patients willing for the trial. Only male patients suffering from seminal abnormality found after seminal analysis were taken for the study.
- 2) Patients of age group 20– 60 years.

Exclusion criteria

- Patients not willing for trial.
- Patients not fulfilling the criteria for inclusion.
- Patients having H/O present illness in following diseases were excluded – Absent testis, Cryptorchidism, Varicocele, Kline-felter syndrome, Hypogonadism, Testicular atrophy, Sexually transmitted diseases, Liver cirrhosis, Renal failure, Infection, injury.
- Patients below 20 years and above 60 years.

Investigations

- Hb%
- TLC, DLC, ESR
- FBS
- LFT – SGOT, SGPT, S. Bilirubin
- Lipid profile
- B. Urea, S. Creatinine

Routine investigations were done just to exclude other systemic or organic pathologies

Parameters of Semen examination

- Appearance
- Liquefaction time
- Volume
- Viscosity
- pH
- Sperm count
- Sperm motility
- Sperm morphology

Method of Study

Consent: - Written & informed consent of the patients was taken before their registration for the study.

Patient Information Sheet: - An information sheet was prepared for the patients registered in the study giving all the details of the study protocol, benefits of the trial & any expected adverse effects. This was given to all the patients registered for the trial.

Case Record Form: - A clinical research proforma was prepared to note down all the details of the patients and also about seminal analysis.

Drug

Young Shalmali roots [root of *Bombax ceiba* Linn.] Were collected from young plants of about one to two years of age from field area of Dehradun. Sample was identified by the experts of Deptt. of Dravya Guna Vigyan, Uttaranchal Ayurvedic College. After then it was processed for the uses in clinical trial.

- Administration of Drug
- The trial drug Young Shalmali roots was given by oral route.
- Dose
- 5 gm twice a day with water.
- Duration of trial
- 30 days

Criteria of Assessment

Subjective assessment- To make the assessment of concise sexual functions, scoring system was adopted to assess the subjective manifestation.

Subjective Assessment criteria

	Grade	Score
Sexual Desire	No desire at all	0
	Lack of desire	1
	Desire only on demand of Partner	2
	Normal desire	3
	Excess desire	4
Erection	No erection by any methods	0
	Erection with artificial methods	1
	Erection but unable to hold the	2
	Erection whenever desired	3
	Grade	Score

Penetration	Unable to penetrate	0
	Initial difficulty but able to penetrate	1
	Penetration with occasional failure	2
	Penetration whenever desired	3
Rigidity	Unable to maintain erection and unable to continue sexual act	0
	Some loss in erection but able to continue sexual act	1
	Normal rigidity to continue sexual act	2
Ejaculation	Mere thought/slight/No ejaculation at all	0
	Ejaculation during Foreplay	1
	Ejaculation before penetration	2
	With penetration <30 sec & 1-5 pelvic thrusts	3
	With penetration <60 sec & 5-10 pelvic thrusts	4
	With penetration >60 sec at least 10 pelvic thrusts	5
Orgasm	No enjoyment at all	0
	Lack of enjoyment in most of occasions	1
	Enjoyment in 25% of sexual encounters	2
	Enjoyment in 50% of sexual act	3
	Enjoyment in 75% of sexual act	4
	Enjoyment in every sex act	5

OBJECTIVE ASSESSMENT

Seminal analysis was done before treatment and after treatment, change noted in these parameters though in numbers, but some of the parameters were also given score. The viscosity was evaluated by introducing a glass rod into the sample and observing the length of the thread, formed on withdrawal of the rod. Following scoring was adopted for viscosity during study.

Thread Formation

No thread formation

Thread Formation < 1 cms

Thread Formation < 2 cms

Thread Formation > 2 cms

STATISTICAL ANALYSIS

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). Paired 't' test was carried out at $p < 0.05$, $p > 0.05$, $p < 0.01$, $p < 0.001$. The obtained results were interpreted as.

- Insignificant $P > 0.05$
- Significant $P < 0.05$
- Moderately significant $P < 0.01$
- Highly significant $P < 0.001$

OBSERVATIONS

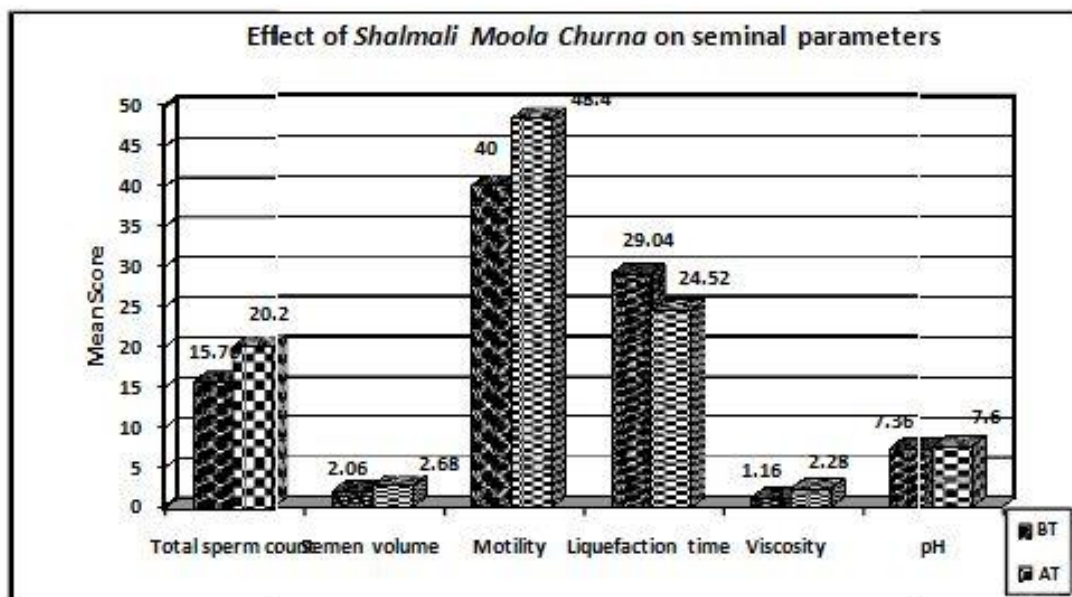
The data collected from the clinical trial was compiled and subjected to statistical analysis and presented under following sections.

1. The first section incorporates the general observations i.e. Demographic profile including age, sex, religion etc.
2. Second part incorporates the effect of therapy evaluated by improvement in subjective as well as objective criteria.

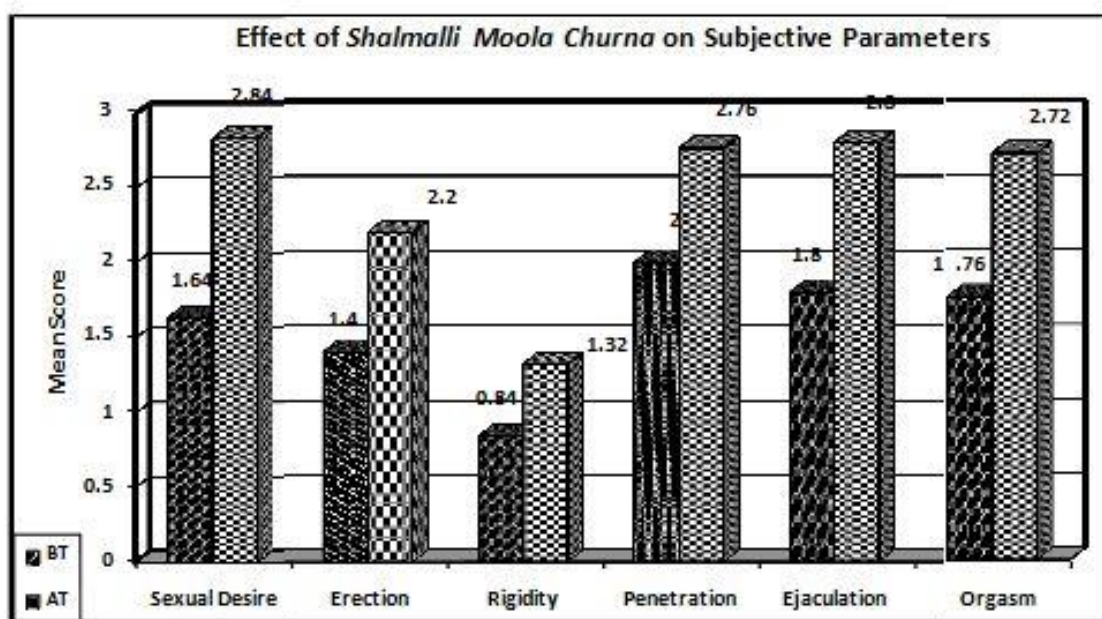
In the present study, total 30 patients were registered which completed the trial.

RESULTS

Effect of Shalmali Moola Churna on seminal parameters



Effect of Shalmali Moola Churna on subjective parameters



CONCLUSION

Botanically the drug Shalmali is *Bombax ceiba* Linn. And it belongs to family Malvaceae (old family - Bombacaceae). Another variety of it is known as Kuta. Shalmali, botanical source of which is *Eriodendron anfructuosum* D.C. or *Ceiba pentandra*. Shalmali is one of the Dravya having the Vrishya property according to various Ayurvedic classics. In Vedic period Shalmali was mentioned for religious purpose rather than medicinal uses.

Shalmali was mentioned in all the brihatrayi granthas regarding various therapeutic indication of all most all of its parts used for medication along with other dravya. But no references were found in Samhita kaal regarding its Vrishya effect. Harit Samhita and Bhaishajya Ratnavali have mentioned the root of Shalmali as Vajikaran. Later on all most all the nighantukar has acknowledged the root of Shalmali as Vrishya dravya. Mochras is also described as Vrishya in Kaidev and Bhavaprakash Nighantu. Shalmali is having Laghu, Snigdha and Picchilla guna , Madhura Rasa, Madhura Vipaka and Seeta Virya while Mochras is having Kashaya Rasa and Katu Vipak.

Powder microscopy of the root of Shalmali shows the presence oil globules and starch granules. Apart from this fixed oil, fat content and lignin are also present in it. In laboratory experiment inorganic matters like Iron, Magnesium, Phosphorous, Potassium and Sulphur were present in root of Shalmali. Heavy metal like Lead, Mercury and Arsenic were absent. Organic matters like Carbohydrate, Alkaloid, Glycoside, Flavonoids and Tanin were present in the sample. Whereas Protein is found to be in trace amounts. Extraction value of the root of young Shalmali in Aqueous solution was 24.92%, Chloroform solution was 2.67%, Petroleum ether was 2.18%, and Ethanol solution was 6.01%.

Total 30 patients were taken to complete the study. It was an open trial comprising a single group. Young Shalmali Moola Churna was given in dose of 5 gm. b.i.d. with water for 30 days. Shalmali Moola has a definite Vrishya effect which is evident from the statistical evaluation of symptoms. Thus on the basis of clinical trial, it can be concluded that Churna of Young Shalmali Root is an effective drug as Vrishya. Very encouraging results were obtained in relation to subjective parameters and it was found that quality of sexual life also improved among the patients.

The probable mode of action of Shalmali root can be directly attributed to its guna profile. Due to Madhura Rasa, Laghu, Snigdha, Picchila Guna, madhur vipaak and shita virya it directly nourishes the body and gradually increases Dhatu and updhatu. As almost all qualities of Shukra dhatu are similar to those present in shalmali root, its intake increases the quantity and quality of shukra. This follows the principle of Samanyam Vriddhikaranam.

However, this is only a preliminary study conducted as a part of educational research program in a small number of patients, in fixed duration of time. Further multi-centric, clinical and experimental studies are required with larger sample to establish the Vrishya effect of Shalmali Moola. No adverse effects were observed during the study.

Conflicts of Interest –Nil

Source of Support- Nil

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