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Pharmaceutical and preliminary phytochemical studies on herbal alkaline formulation Tilakshara

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Abstract
Three types of substances namely Jangama (Animal products), Sthavara (Herbal drugs) and Parthiva (Minerals) are considered as basic raw materials in Ayurveda medicines. Using these ingredients innumerable permutations and combinations are possible. Further based on pharmaceutical processing techniques with an aim of making the medicines suitable for internal administration, various dosage forms are possible. Kshara Kalpana is one type of such dosage forms. The dosage forms which can be used to scrape the tissues or erode unwanted growths are termed as kshara. They can be of mrudu (mild potency) Madhyama (Moderately potent) and Teekshna (Potent) varieties based on potency. When used externally they are called as pratisaraneeya kshara and paneeya kshara when used internally. There are three, Five and Eight kshara enumerated based on groups of drugs having similar characteristics. Tila kshara is a herbal alkaline material prepared out of Tila (*Sesamum indicum Linn*.)

In the present work, kshara was prepared from Tila (*Sesamum indicum Linn*.) as per standard methods. It was analysed for the quality standards. The outcome of the study was suggestive that the final product had an alkaline pH and supported the inclusion of Tila under ksharashtaka. Microscopic studies could generate reference standard for Tila kshara.

Keywords: Ksharashtaka, Tila kshara, preliminary standards

Introduction

According to Ayurveda there is not even a single substance in the world that cannot be used as a medicine [1-2]. Based on their origin, three types of substances are used for manufacturing various dosage forms. They are Jangama (Animal products), Sthavara (Herbal drugs) and Parthiva (Minerals) [3-4]. Application of individual material and in combinations leads to various permutations and combinations of these three. By which the raw materials can be converted into a suitable dosage form through selected pharmaceutical processing techniques which aim at preparation of medicines suitable for internal administration. Kshara Kalpana (Alkaline formulations) are one among them which are prepared from selected raw materials. They are usually prepared from ashes of raw drugs of herbal mineral or animal origin the final products of which will be in the form of solutions or crystals [5]. They are named so because of corrosive nature of the final product. Kshara have ability to gradually erode or scrape the tissues of skin and muscles [6-8]. Hence in Ayurveda it is therapeutically adviced to be used in diseases like gulma(growth), shula (colic) and scraping of excessive accumulation of mala [9]. Therapeutically it has gained equal importance in kayachikitsa (General medicine) and shalyachikitsa (Ayurvedic surgery). In kayachikitsa it is useful in treating diseases like ashmari (calculi), gulma (growths), kustha (skin diseases) and mutraghata (dysuria). It can also be used in surgical conditions like arsha (hemorrhoids), bhagandara (fistula) and nadivrana (fissures) [4]. It can be administered by a physicians to treat even the ailments of chronic nature. In Ayurveda much importance has been given to kshara therapy as it can cure the diseases with bad prognosis [10]. Kshara Kalpana are termed as Anushastra (subsidiary surgical instrument) as these formulations can be used in surgical conditions, where patient is not willing to undergo surgery. It suits better for women, children and for those who are afraid of surgery. It controls bleeding and reduces chances of re-occurrence and wound infection is very rare with use of kshara [11]. There are two types of kshara on the basis of form in which it is used. Liquid form of kshara will be like a decoction and called paneeya kshara and the solid or amorphous variety of kshara will be in powder form which is termed as pratisaraneeya kshara or churna kshara [12]. There are many classifications of kshara. However, based on the number of drugs present in a combination, they are termed as dvikshara (two alkaline drugs), trikshara (three alkaline drugs), ksharapanchaka (five alkaline drugs) and ksharashtaka (eight alkaline drugs). This classification probably includes the alkaline materials with similar properties and pharmacological action [13].

Tila (*Sesamum indicum Linn*.) is a drug known for its kshara properties and is included under ksharashtaka [14-16]. Tila (Sesamum indicum Linn) belongs to family Pedaliaceae which grows as a herb and extensively cultivated throughout the plains of India, as a commercial crop for extraction of sesame oil mainly from the seeds. It is called Tila, Pavitra, Homa dhanya, Papaghna, pitru tarpana in Samskruta language. It is sweet astringent bitter in taste (rasa) and bitter post digestive effect (vipaka). Two varieties of tila namely Sita (white) and Asita (black) can be seen, among

which black variety is said to be superior and wholesome [17]. It is small erect herbs which grows upto 0.9 mtrs. Leaves will be opposite below and alternate above, entire, toothed, lobed or divided. The plant will have axillary, solitary or few, flower with purple and whitish with purple or yellow mark. Fruit capsules will be 2.5cm long, oblong, erect and dehiscent from above downwards. May contain three varieties of seeds namely black, white or red [18]. Root, leaf, seed and oil are usually used for medicinal purpose. Usually, the powder of seeds is used in a dosage of 5-10 gm/day. Sesamum oil is used as substitute and adulterant to olive oil and almond oil [19]. Tila is included under Kshara panchaka [20] and Ksharashtaka [15-16]. and in both groups [14]. Tila promotes longevity, preserves youth and strengthens the body [21]. The oil extracted form seeds of tila is considered best amongst all herbal oils and described it as tvakprasadana (skin tonic) [22], Tila taila is considered as a hair tonic, galactagogue, appetizer general tonic and digestant [23]. Tila is rich with 43.3% oil, 25.3% carbohydrate, and 18.3% proteins [24].

For preparation of kshara the kshara plant has to be dried properly and burnt into ashes. The ash has to be mixed with 4 times or six times water. Then it has to be kept overnight and strained thoroughly 21 times to get a liquid called ksharodaka. It is dehydrated to get a white crystalline powder called kshara. Usually, kshara will be white or shades of white in colour [25-26]. Tilakshara is said to be vranashodhana (cleansing the wound) and Vranropana (healing the wound) [27]. Tila kshara is consumed with curds in mutravarodha (obstruction to urine) [28]. Tila kshara with honey is useful in mutrashmari (calculi) and Tilanalaja kshara is useful in digestion of heavy non-vegetarian meals[29].

Basic requirement of a pharmaceutical compound is that it should be safe and effective. For achieving it, standard qualitative and quantitative values of the final product have to be taken into consideration [30]. So a similar kind of pharmaceutical and analytical work of tila kshara was carried out in present work.

Materials and Methods

Tilakshara was prepared as per standard references and was analysed for the quality control parameters. The details of pharmaceutical and analytical work are explained as under.

1. Pharmaceutical work

The roots, leaves, stem, fruits and flowers of Tila plant (*Sesamum indicum Linn.*) were collected and were authenticated. The standard method of preparation of kshara was followed for preparation of Tila kshara.

For preparation of kshara from the plant the collected useful parts of raw material were completely dried in shade. 10 kg of dry parts of drug was taken and burnt in an open place to convert it into ashes. Next day after complete cooling of burnt material, the ash was collected and weighed. 6 times (v/v) water was used to dissolve the ash in an clean container. The contents were stirred well with help of a stirrer and kept undisturbed overnight. Next day, the contents were filtered for 21 times with help of double folded clean cloth. The liquid obtained after filtration (ksharodaka) was transferred to a broad mouthed iron vessel. It was kept on fire and boiled continuously till all the watery portions gets evaporated. Later stage of heating continous stirring is required to avoid charring of the contents. The obtained tila kshara was dry powder with white colour.

2. Analytical Work

Tila kshara thus obtained was tested for its quality and physicochemical characteristics. For analysis the standard procedures specified for this purpose published by CCRAS were followed [31]. The details of procedures carried out are as follows:

1. **Powder microscopy of Tilakshara:** The powdered drug was sieved through 80 sized mesh. A pinch of the powdered sample was placed on the slide of microscope. A drop of glycerin-water was added to the sample on slide. The slide was mounted on trinocular microscope attached with camera. The characters of the powder were studied under bright field light. Pictures were recorded using the pre calibrated software under specific magnifications.
2. **Estimation of Total Ash:** 2 g of sample was taken in a tared platinum crucible. It was incinerated in a muflle furnace at temperature not exceeding 450˚C till carbon free ash was obtained. Ash value was calculated as percentage of ash with reference to weight of the sample.
3. **Estimation of Acid insoluble Ash:** The ash obtained through previous procedure was taken in a crucible. 25ml of dilute hydrochloric acid was added to the crucible and mixed well. The contents were filtered through whatmann ashless filter paper no 41. Then the contents were washed repeatedly with hot water till the filtrate becomes neutral. After complete filtration, the filter paper containing the insoluble matter was placed in the crucible. It was then dried on a hot plate and ignited to constant weight. The residue was allowed to cool in desiccator for 30 minutes. It was weighed immediately without any delay. The acid insoluble ash was calculated with reference to the air-dried drug.
4. **Estimation of Water-soluble ash:** After testing insolubility in acid, ash is added with 25 ml of water and boiled for five minutes. Filter the contents on an ashless filter paper. Then the contents are repeatedly washed with hot water. It was then heated for 15 min at a temperature not exceeding 450˚C. The weight of the insoluble matter was subtracted from the weight of the ash. The difference in weight represents the water soluble ash with reference to the air-dried sample.
5. **Estimation of pH of tilakshara:** 1 g of sample was taken and added with 10 ml of distilled water. The contents were stirred well and filtered slowly. The filtrate obtained was used as a sample to estimate the pH. Estimation of pH was done with help of pH meter. The Instrument was switched on and 30 minutes time was given for warming. Before estimation of pH the instrument was calibrated. The solution with known pH of 4 was first introduced and the pH adjusted by using the knob to 4 at 30°C. Similar calibrations were done using solutions with known pH of 7 and 9.2. After calibration the test sample of tila kshara solution was introduced and reading was noted. The test was repeated four times and the average value was calculated to establish the pH.

Observation and Results

The results obtained by this study including the details of collection of raw material, The data of Identity Purity and strength of raw material, details of pharmaceutical and analytical works are listed as below from tables 1 to 5 and figure 1.

Table 1: Physico-chemical characters of drug

Parameter	Observed value	Value as per API[32]
Total ash	6.872	Not more than 9%
Acid insoluble ash	0.2	Not more than 1.5%
Water soluble ash	0.18	Not less than 4%

Table 2: Organoleptic characters of Tila ash & Ksharodaka

Parameters	Tila ash	Ksharodaka
Colour	White	Light yellow
Odour	Characteristic	Characteristic
Taste	Salty and bitter	Salty
Appearance	Fine powder	Viscous liquid

Table 3: Pharmaceutical data of Tila kshara

Total weight of the raw material (Tila) collected	13 kg
Total weight of the raw material after drying	10.6 kg
Loss in the weight	2.4 kg
Percentage of loss	18.46%
Total number of days taken for drying	8
Weight of ash obtained after complete burning of the raw material	550 gms
Loss in weight	9450 gms
Ratio of ash in comparison with dried raw material	5.5%
Ratio of ash in comparison with fresh raw material	4.23%
Weight of final product (Tila kshara)	25gms
Percentage of kshara when compared with ash	4.5%
Percentage of kshara when compared with fresh raw material	0.25%
Number of days used for kshara preparation after complete drying of drug	5

Table 4: Physico-chemical parameters of Tilakshara

pH	10.13
Total ash	79.82
Acid insoluble ash	0.2
Water soluble ash	77.01

Table 5: Ash obtained and final quantity of Kshara obtained

Sl	Name of drug	Quantity of raw drug taken	Ash obtained	Kshara obtained
1	Tila	10 kg	550gms	25gms

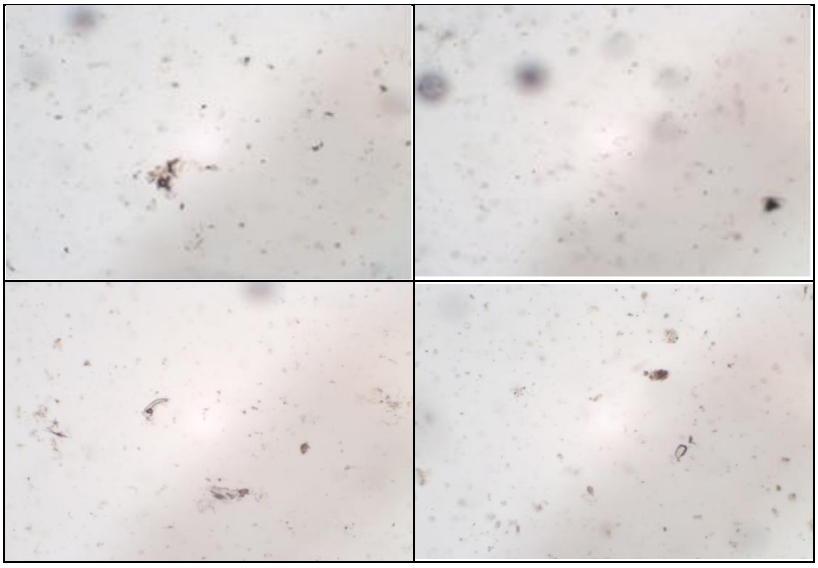

Fig 1: Powder microscopy of Tila kshara

Discussion

An attempt of authentication of raw drug was done before preparing the tila kshara. It is observed that Ash value and acid soluble ash of tila panchanga were within the pharmacopeial limits. The water-soluble extractive however did not match with the values of API (Table 1). Variation in the percentage of water-soluble extractive value can be attributed to place and time of collection. Further, whole plant of tila was used for the analysis in the present study. The physico-chemical characteristics mentioned in pharmacopeia belong to seeds of tila. However, considering 2 observations out of three qualified for identity purity and strength, it can be considered as justification of genuinity of raw material used in the preparation of study drug.

Loss of 2.4 kg of weight (Table 3) after drying indicates that almost 18.46% moisture was present in the collected raw material. Weight of ash obtained after burning the dried tila was only 5.5% (Table 3). It means that the quantity of raw material required is huge in bulk manufacturing, which may reflect in the cost of the final product. Ash of Tila panchanga was in powder form and white after complete burning (Table 2). This may be due to complete burning of drug without leaving behind unburnt traces. The characteristic odour and salty bitter taste of ash, may be because of alkaline nature.

The pH of the tila kshara was 10.13 (Table 4). This high alkaline pH suggests that the final product fulfils the requirement of being called as kshara in Ayurveda. The stability or decomposition of the pharmaceutical compounds largely depends on acidity or alkalinity of a product. The product shows tendency of getting oxidized when the pH is less [33]. By this it can be inferred that tila kshara may have higher stability and shelf life. Earlier studies have recorded a pH of 10 to 11.6 for tila kshara[34-35].

79.82% Total ash in the final product indicates its inorganic nature (Table 4). Organic materials present in the product will get evaporated by heating at a temperature of 450˚c until carbon free material is obtained. Earlier studies have shown a total ash of 85 in tilakshara[34].

The Acid insoluble ash is a test carried out to calculate the insoluble inorganic content of the samples in dilute acid. This test further will give an idea about the solubility of a given substance in stomach which has a therapeutic significance. Adding water, filtration and dehydration procedure involved in preparation of kshara separates insoluble substance like silica and retains soluble substances like potassium and sodium [36]. The present study showed only 0.2% of acid insoluble ash, indicating that there may not be any issue as far as its pharmacological action of the formulation concerned. (Table 4)

Similarly, solubility of the product in water is an important parameter deciding its absorption in human body. Calculating the solubility of the ash in water is a simple test to estimate it. Tilakshara showed 77.01% of water soluble ash. (Table 4). The standard operating procedures advocated for preparation of kshara itself are the way of fractional isolation of water soluble phyto-constituents. So naturally the final product should result in more water-soluble ash.

When the final product of tila kshara was studied under microscope, it showed crystal mass, brown content and uneven shaped crystals (Figure 1). This data and the figures of microscopic studies can be considered as references for future studies.

Conclusion

In this work an attempt was made to prepare tila kshara and to carry out preliminary physicochemical analysis of the same. The data obtained from pharmaceutical and analytical study can be considered as preliminary standards of Tila kshara. The analysis of raw material showed that it is genuine and the values of quality were comparable with API standards. The alkalinity of tila kshara could be established through its pH which further justifies its inclusion under ksharashtaka; a group of eight alkaline herbs. The data and pictures of Microscopic studies of tila kshara can be used for future references.

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Conflict of interest

None

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