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Pharmaceutical-Analytical Standardization of *Palasha Kshara* Prepared by Two Different Combinations and Evaluation of Their Diuretic Action in Wister Rats

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ABSTRACT

Background: Rasashastra and Bhaishajya Kalpana, the pharmaceutical and therapeutic branch of Ayurveda consists of various varieties of dosage forms of medicine and *Kshara Kalpana* is one of the medicaments among them. *Kshara* is an alkaline substance prepared from the ashes of plants, animals or minerals. In compendia, *Palash (Butea monosperma Lam)* is referred to as "*Kshara- Shretha*".

Objectives: To standardize the method of preparation of *Palasha Kshara* by preparing it with two combinations i.e. one with *Palasha Panchanga* and the another is with roots, stem, and leaves of *Palasha* Plant and to evaluate their diuretic action in Wister rats.

Methods: The procurement and authentication of parts of *Palasha* plant will be done according to the Dravya Guna Department, MGACH & RC, Wardha. Both combinations of *Palasha Kshara* will be prepared by using the reference of the text *Rasa Tarangini*.

Expected Results: The pharmaceutical- analytical study may reveal that which combination has more efficacies for the diuretic action. The data will be assessed for its pharmaceutical, analytical and experimental results by using Unpaired 't' test and One way ANOVA test.

Conclusion: The method of preparation explained in compendia i.e. using *Palasha Panchanga* has same analytical results and diuretic action as that of the altered one i.e. using the parts of *Palasha* plants which are available all the year along.

Key Words: *Palasha Kshara*, Ayurveda, Alkali Preparation, Two combinations, Diuretic action, Pharmaceuticals, Analytics, Standardization, Experimental Study

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INTRODUCTION

Since the beginning of human civilization, health has been the prime factor for mankind. Humans are blessed with various natural resources in the form of herbs, metals, minerals, and animal products for their consumption. Uses of these resources as medical treatment is globally known in maintaining the health of healthy persons and to treat patients. There are many paths shown by Ayurveda to use these resources in medical treatment since ancient time. The pharmaceutical branch of Ayurveda, "Rasashastra and Bhaishajya Kalpana", has descriptively described the use of these resources by formulating various medicines to treat human diseases.¹ One of

them is *Kshara Kalpana* (alkaline preparation). *Kshara* (alkaline substance as a medicament) is prepared from the ash of plants, animal, and mineral products.¹

Kshara is prepared by the extraction of 'alkalis' from the ash of plants. It is known that *Ksharatherapy* (Therapy by using alkaline medicament) can cure the diseases which are difficult to cure.¹ *Kshara* therapy minimizes complications, reduces the recurrence of the disease and also reduces the chances of infections occurred because of surgery with its alkalinity. According to *Acharya Sushruta Kshara* has the prime place in surgical measures and para- surgical measures.¹ It is used in both ways as externally and internally ac-

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cording to the diseases. In the different text of Rasashastra and Bhaishajya Kalpananumber of *Kshara* are mentioned for preparing metal and mineral formulations.^{2,3} In compendia, *Palasha Kshara* is referred to as “*Kshara Shretha*” i.e. best of all alkalis.^{4,5}

Diuretic efficacy in *Veerataru* (*Dichrostachys cinerea* Linn.) is observed.⁶ Internal administration of *Palasha Kshara* is effective in the treatment of tumour and thus correcting the uterine fibroid. The yield and pH value of *Palsha Kshara* is greater than *Vasa Kshara Kshara Kalpana* is a pharmaceutical area of Rasashastra and BhaishajyaKalpana which has been least explored under scientific research and hence need to be undertaken to evaluate its significance. The study of comparative pharmaceutical and analytical standardization of *Palasha Kshara* prepared from two different combinations: i.e. one *Kshara Kalpana* is prepared from *Palasha Panchanga* and the another *Kshara Kalpana* is prepared from using the plant parts which are available all the year along, which are root, stem, leaves, is not has been done and thus the present study will fulfil this gap. This study is an attempt to solve the difficulty of preparing *Palasha Kshara* in specific seasons. Along with analytical standardization, this study will also contribute to evaluating the effectiveness of both samples with special reference to diuretic action.

MATERIALS AND METHODS

Pharmaceutical preparation:

Palash Kshara will be prepared according to to the reference of *Rasa Tarangini*. *Kshara* preparation will be done in two combinations, each combination will be prepared in 3 batches which are as per given below,

Combination 1: *Palasha Kshara* prepared from *Panchanga* of *Palasha* (PK-1)

Combination 2: *Palasha Kshara* prepared from root, leave and stem of *Palasha* (PK-2)

Flow chart showing the preparation of PK-1⁷

Authentication of the raw material i.e. *Palasha Panchanga* from taxonomist



The foreign matter will be removed and the drug will be shade dried completely



The dried part will be burnt completely to ashes in an iron pan



Ash will be weighed separately and will be taken in the separate stainless steel container



4 times the weight of ash, water will be added, the mixture will be stirred continuously and will be kept undisturbed for 3 hours



The supernatant water will be carefully decanted



It will be heated till water content gets evaporated



Whitish grey coloured powder of *Kshara* will be collected at the bottom,



Kshara will be weighted and stored in a separate glass

Flow chart showing the preparation of PK-2⁸

Authentication of the raw material i.e. Stem, Roots and Leaves of *Palasha* from taxonomist



The foreign matter will be removed and the drug will be shade dried completely



The dried part will be burnt completely to ashes in an iron pan



Ash will be weighed separately and will be taken in the separate stainless steel container



4 times the weight of ash, water will be added, the mixture will be stirred continuously and will be kept undisturbed for 3 hours



The supernatant water will be carefully decanted



It will be heated till water content gets evaporated



Whitish grey coloured powder of *Kshara* will be collected at the bottom



Kshara will be weighted and stored in a separate glass

1. Standardization parameters for raw material *Palasha*

1.1) Description (Organoleptic characters)

1. *Sparsha*
2. *Rupa*
3. *Rasa*

4. *Gandha*

1.2) Physicochemical parameters

1. Foreign matter
2. Loss on drying at 105°C
3. Total ash
4. pH
5. Particle size
6. Water-soluble extract
7. Acid-insoluble ash
8. Alcohol-soluble extractive
9. HPTLC
10. Microbial contamination
11. AAS

2) Standardization parameters for *Palsha Kshara*:

2.1) Description (Organoleptic characters)

1. *Sparsha*
2. *Rupa*
3. *Rasa*
4. *Gandha*

2.2) Physico chemical parameters

1. Foreign matter
2. Loss on drying at 105°C
3. Total ash
4. pH
5. Particle size
6. Water-soluble extract
7. Acid-insoluble ash
8. Alcohol-soluble extractive
9. Microbial contamination
10. ICP-AES

Housing and Husbandry

The animals should be acquainted with the researcher. The animals will be kept in controlled temperature and humid-

ity. They will be provided with food and drinking water of standard quality. The diuretic study will be done by using a metabolic cage. The animals will be continuously observed for their health and hygiene.

Allocating animals to experimental groups

The animals will be acclimatized for 14 days for the research study. The acclimatized animals will be kept in cages according to the groups formed as per the required study. The animals will be marked with numbers according to the groups with an ink marker. Marking will be done before the experiment.

Sample size: 24 (6x4 group) 3 male and 3 female Wister rats will be used as an animal model. All animal experiments will be conducted following the guidelines of CPCSE after the approval of the institutional animal ethical committee.

Case definition: 24 (6x4 group) 3 male and 3 female Wister rats will be used as an animal model. All the rats will be healthy and will be kept in the standard environment for 15 days.

Inclusion criteria: Wister rats weighing 180-200 g of either sex.

Exclusion criteria: Wister rats suffering from any illness or injury, Wister rats of less than 180 gm weight, and pregnant female Wister rats.

Grouping and Drug administration

Animal dose for PK-1 and PK-2 will be calculated based on FDA guideline for the calculation of dosage in experimental studies (table 1).

Table 1: Animal dose for PK-1 and PK-2 will be calculated based on FDA guideline

Group	Group code	Drug	No. of Animal	Dose	Route	Study duration*
Group I	NC	Normal Saline	06	-	Oral	15 days
Group II	SC	Furosemide	06	2 mg/kg	Oral	15 days
Group III	PK -1	PK -1	06	26 mg/kg	Oral	15 days
Group IV	PK -2	PK -2	06	26 mg/kg	Oral	15 days

*14 days as acclimatization period and 1 day for diuretic study.

Assessment criteria for animal study

This will be an experimental study with animal experiments and will involve laboratory tests of CBC, KFT, LFT, before and after the intervention. The study will be conducted from a certified institute of national repute. The study protocol has been submitted to the Institutional Ethical Committee for approval and approval has been received from Animal Ethical Committee.

EXPECTED RESULTS

The primary outcome will be the effect of the drug dose and its efficacy on diuretic action. And Secondary outcome will be to observe psychosomatic changes, whether there any abnormal or behaviour pattern changes and to analyse haematological changes. Unpaired t-test, One-way ANOVA will be applied to compare diuretic action in the experimental

study. Descriptive statistics will be applied for pharmaceutical study. The study protocol has been submitted to an institutional ethical committee for approval and animal Ethical committee approval also received.

DISCUSSION

To treat ailments with the medicament in the dosage form of *Kshara* (Alkali) prepared from various plants is known since ancient time. *Kshara Sutra* treatment in the management of Fistula in ano is gaining popularity day by day due to its high success rate. *Kshara- Sutra* treatment is an external application of the medicament.¹⁰ *Acharya* Sushruta has elaborately narrated the preparation and application of both the forms of *Kshara* i.e. as internal as well as an external application in the name of *Paneeya Kshara* and *Pratisaraniya Kshara* respectively.¹¹ He Stated names of twenty-three plants for the preparation of *Kshara*.¹¹ Few research studies have been documented about the application of *Kshara* as a medication.

It is well known that modern medicines are costlier and associated with side effects, whereas herbal medicines are gaining more interest across the globe due to its lower cost, more efficacy, negligible and easily treatable side effects and all-time availability of the dosage form. As *Palasha* is referred to as "*Kshara-Shrestha*" in compendia, it will be important documentation about the efficacy of *Palasha Kshara* with respect to its diuretic action prepared with two different combinations.^{14,15} This study will also reveal that whether both the combinations of *Kshara* has a same or different outcome in an analytical, pharmaceutical and experimental study which may further useful in saving of time irrespective of depending on the specific season for its preparation. The factors on which volume of urine depends are glomerular filtration rate and tubular re-absorption, and this study will guide the efficacy of *Palasha Kshara* in this regard.^{16,17} In this study, whether the *Palasha Kshara* causes significant alteration of urinary Na^+ and K^+ levels will also be observed.

CONCLUSION

The present study will reveal that which combination of *Palasha Kshara* has more significant diuretic activity. The observed activity may be due to the individual or combined action of bioactive constituents present in it. Further phytochemical and pharmacodynamic studies will be required to find the active constituent responsible for diuretic activity.

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