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Randomised single blind pilot clinical study of *kharjura* on haemoglobin percentage with special reference to *sushruta's rakta dhatu poshankal.*"

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ABSTRACT:

Introduction: Amongst Saptā Dhatu , Rakta Dhatu is of prime importance as it is mainly responsible for *Jeevan Karma* and *Pranānuvartana*. According to *Dhatu Poshana Kala* theory by *Acharya Susruta*, Rakta Dhatu is formed on the 5th day after formation of *AharaRasa*. Rakta Kshaya can be correlated with symptoms of anaemia due to malnutrition. *Kharjura* (*Phoenix dactylifera*, Linn.) now days well known as dates is of nutraceutical value has been used in treatment of Rakta Dhatu since ages. **Aim:** To assess effect Of *Khajura* with *Dhatriloha* and *Dhatriloha* alone on haemoglobin percentage with special

reference to *Sushruta's Rakta Dhatu Poshankal.*" Present pilot study was performed to set guidelines with special reference to treatment and analysis period for chief clinical trial and taking into consideration *Dhatu Poshana Kala Theory* screening of patients for Hb % was done at intervals of 5 days. **Materials and methods:** *Kharjura Laddu* was prepared, patients fulfilling inclusion criteria of *Rakta Kshaya* were administered with *Kharjura Laddu*(10g)+*Dhatriloha* (250mg) and *Dhatriloha*(250mg) alone in groups A and B respectively for 10 days in *Rasayan Kala*(early in morning). **Results:** *Kharjura Laddu*+*Dhatriloha* group

revealed better results in relieving symptoms and increasing Hb%. Both groups exhibited increase in Hb% at 5 days interval after start of treatment.

Conclusion: *Kharjura* can be used as nutraceutical along with *Dhatri Loha* in management of *Rakta Kshaya*. Insignificant increase in Hb% at interval of 5 days of consumption of drug ascertains *Dhatu Poshan Kala* theory.

Keywords: *Kharjura* , nutraceutical, Hb%, *Dhatuposhana Kala* theory.

INTRODUCTION:

Dosha, Dhatu & Mala are considered as three basic elements of body. The concept of *Sapta Dhatu* of *Ayurveda* refers to the physiology of basic nutritional and structural factors of the body. They are being constantly formed, destroyed and reformed with appropriate material derived from *Poshaka Dravya* (nutrient substances) present in food from the time of conception to death.

Dosha controls all physiological activity while *Dhatu* perform *Dharana Karma* (sustaining action). There are seven *Dhatu* viz. *Rasa, Rakta, Manmsa, Meda, Majja* and *Shukra*. Out of these seven *Dhatu*, *Rakta Dhatu* has prime importance because it is mainly responsible for *Jeevan Karma* and *Prananuvartana*¹. According to modern science, haemoglobin is the protein in

erythrocytes that is responsible for the delivery of oxygen from the lungs to the tissues, and the transport of carbon dioxide from the tissues back to the lungs. This process is similar with *Prananuvartan* function of *Rakta Dhatu*.² All ancient *Samhita* have postulated the view that *Sapta Dhatu* are produced in a kind of progressive metamorphosis, beginning with the *Rasa Dhatu* and ending with *Shukra Dhatu*. The previous *Dhatu* being transformed in to the next higher this theory knows as *Dhatu - Poshankal*. According to *Acharya Susruta*, by this rule *Rakta Dhatu* is formed on the 5th day after formation of *Ahara Rasa*.³

Biosynthesis of *Rakta Dhatu* depends on nutritional supplements from food and if these supplements are not received then person get subjected to *Rakta Kshaya* (deficiency). *Rakta Kshaya* can be correlated with symptoms of anaemia due to malnutrition. It is the most common nutritional deficiency disorder in the world. **World Health Organisation** has defined anaemia as a condition in which the haemoglobin content of blood is less than normal, due to deficiency of one or more essential nutrients, regardless cause of such deficiency. A haemoglobin level of 10 to 11 g/dl has been defined as early anaemia⁴. Anaemia is established if the haemoglobin is below the cut-off points

recommended by W.H.O.⁵ in such condition it is important for people to increase their consumption of iron-rich foods in diet such as dates (which is cheaper), red meat, fish, poultry and legume. *Kharjura* (*Phoenix dactylifera*, Linn.) now days well known as dates has been used in treatment of *Rakta Dhatu* since ages.

According to *Ayurveda* all the drugs are *Panchabhautic* and thus no *Dravya* are without medicinal property. Logically and intelligently every *Dravya* in this world can be used as a food and medicine, the same concept is coming forward in medicine which is called as nutraceuticals⁶. Now days dates can be called as a nutraceuticals.⁷ *Kharjura* is the wonderful package of deliciousness and nutrition liked by everyone.

Primary aim of this particular trial is “to assess effect Of *Khajura* with *Dhatriloha* and *Dhatriloha* alone on haemoglobin percentage with special reference to *Sushruta’s Rakta Dhatu Poshankal*.”

Present pilot study was performed to set guidelines with special reference to treatment and analysis period for chief clinical trial .Pilot study was carried out to assess effect of *Kharjura* intake on Hb% in management of anaemia and taking into consideration *Dhatu Poshana Kala Theory* screening of patients for hb

% was done at intervals of 5 days to see whether there is increase in hb% after five days.

AIM AND OBJECTIVES

To compare the efficacy of *Kharjura* as a nutraceutical with *Dhatriloha* to increase Haemoglobin Percentage.

MATERIALS AND METHODS

Materials –

1. *Kharjura Laddu* – Self prepared by investigator.
2. Haemoglobin percentage - Sahli’s Hemoglobinometer.

Material details of both drugs:-

a) *Kharjura* –

Latin Name - *Phoenix dactylifera*, Linn.

Classification

- Kingdom – *Plantae*
- Subkingdom – *Tracheobionta*
- Superdivision – *Spermatophyta*
- Division – *Magnoliophyta*
- Class – *Liliopsida*
- Subclass - *Arecidae*
- Order - *Arecales*
- Family – *Arecaceae*
- Genus – *Phoenix*
- Species – *dactylifer*

Nutritional values – As per USDA

(United States Department of

Agriculture), nutritional values of date fruit- *Kharjura* (*Phoenix dactylifera* Linn.) per 100 gm. are as follows⁸

Method of preparation of *Kharjura*

Laddu :-

Preparation – Self prepared by investigator.

Ingredients: *Kharjura* (marketed by lion company ISO certified and FSSI certified)

Procedure –

- a) Manually removal of seed from *Kharjura*.
 - b) Grinding of *Kharjura* in mixer grinder.
 - c) Obtaining *Kharjura* paste and then lastly prepared *Kharjura* laddu (10 g)
- b) *Dhatriloha*⁹

Market sample of *Dhatri Loha* (tab- 250 mg) manufactured by Baidyanath was used for present study.

Selection of patients:

The study was conducted at SST Ayurved College, Sangamner after obtaining approval from the Institutional Ethics Committee (ks-1/33/Ethics/2017- 2018 dated-14/02/2018).

Inclusion criteria: Female students of 20-24yr age group with haemoglobin

level < 11 gm and >10 gm with prior informed consent were included in study.

Exclusion criteria:

While pregnant and lactating women, *Rakta-Kṣhaya* due to the bleeding disorders, diagnosed with haematological disorders or anaemia due to aplastic anaemia, pernicious anaemia, haemolytic anaemia and other haemoglobinopathies were excluded from study.

Posology

The study was randomized, single blind study. Lottery method was adopted for random allocation of patients and the ones satisfying the inclusion criteria were grouped into two groups, namely, A and B. Patients in group A were administered with *Kharjura Laddu* (10 g) with *Dhatriloha* (250mg tab) while patient in B group were administered only *Dhatriloha* (250mg tab) in *Prabhat Kala* (early in morning) for period of 10 days. Patients were allowed to follow normal routine diet and regimen during treatment period. After completion of study, data were collected and analyzed statistically.

Laboratory investigations

Haemoglobin percentage by Sahli's Hemoglobinometer¹⁰ method was carried out at the time of screening of patients for inclusion and at the interval of 5 days and at 10 days(completion of treatment

period) respectively to assess effect of both the test drugs .

Assessment criteria

The assessment of patients was done before starting treatment, at interval of 5 days and after completion of treatment (10 days). Symptoms of *Rakta Dhatu Kshaya* described by *Acharya Sushruta-Amla-sheeta Pratharna* (craving for sour and cold substances), *Twaka Parushya* (dryness of skin) and *Sira Shaithilya* (loss of tone of veins) were considered as subjective parameters. Gradations of the symptoms were done by giving them score. This Scoring pattern [Table no.3] was used to assess the response of trial drugs objectively and for statistical analysis. Haemoglobin percentage was considered as objective criteria and analysed before treatment, at 5 days and after completion of the treatment (10 days).

Data analysis

The data obtained in clinical study was subjected to statistical tests and calculated on the basis of percentage of improvement in each parameter in all the treated groups. Statistical tests were performed by using GraphPad Prism 6 Software (Graphpad software Inc, La Jolla, CA 92037 USA) and sigma stat¹¹

Wilcoxon signed rank test was used to evaluate effect of test drugs in subjective parameters ($p < 0.05$) in individual group. Effect on Hb % by both the drugs is assessed by paired t test ($p < 0.05$). Comparison of relief in symptoms and improvement in Hb% by test drugs is done by applying CV (coefficient of variation) test to statistical data. Overall effect of test drugs was compared by unpaired t test ($p < 0.05$).

RESULTS:

In total ten patients were registered (five in each group) for the pilot study. Five patients registered in each group completed treatment. At the end of treatment period data were collected and analysed stastically. (dia1: consort chart)

After completion of treatment period both test drugs produced insignificant relief ($p > 0.05$) in symptoms – *Twaka Parushya* (dryness of skin) and *Amla Sheeta Pratharna* (craving for sour and cold substances). However percentage of relief was observed to be more in group B.(Table no:4 and table no.5)

In both treated groups increase in Hb % was noted at five days as well as ten days interval. Percentage increase in Hb % parameter was observed to be more in group B which was statistically

insignificant ($p>0.05$). (Table no.6 and table no.7)

On comparing effect of drugs by CV(coefficient of variation) test it is observed that relief obtained in *Amla Sheeta Pratharna*(craving for sour and cold substances) was equal in both groups. Group B produced better relief in *Twaka Parushya* (dryness of skin) symptom and improvement in hb%. (table no.8)

When overall effect of test drug was compared by unpaired t test it was statistically insignificant ($p>0.05$)(table no.9).

DISCUSSION:

Above results implies that, at the end of treatment period both the test drugs were effective in producing relief in symptoms of *Rakta Kshaya* described by *Acharya Sushruta- Twaka Parushya* (dryness of skin) and *Amla Sheeta Pratharna* (craving for sour and cold substances). At statistical level improvement was insignificant in both groups ($p>0.05$). However percentage relief was noted maximum in group B where patients were treated with *Dhatri Loha* and *Kharjura Laddu* in comparison to group A in which patients were administered with *Dhatri Loha* alone. CV evaluation also demonstrated group B better in

management of symptoms of *Rakta Kshaya*.

To assess effect of *Kharjuara* on Hb% improvement, Hb% was carried out at 5 days in accordance with *Dhatu Poshana Kala* theory and at the completion of treatment period (10 days). In both the treated groups apparent insignificant ($p>0.05$) increase in Hb% was observed at both five days and ten days interval. Result in Hb% signifies that both test drugs have additive effect on Hb%. As increase in Hb% in both treated groups is noted at five days interval it asserts *Dhatu Poshankala* theory that after consumption of drug process of formation of *Rakta Dhatu* is initiated and is evident within five days. Results of CV evaluation and percentage relief indicates group B better in improvement in hb% parameter where patients have been treated with *Dhatri Loha* along with *Kharjura Laddu*.

Overall results implies group B better in management of *Rakta Kshaya* and improvement in Hb% thus elucidating neutraceutical value of *Kharjura* with *Dhatri Loha* in increasing Hb%. However to form concrete conclusive remark study population should be large enough which will be done in main clinical study.

Probable mode of action of drug:

In context of ayurveda science to increase *Rakta Dhatu*, one has to consume food and nutrients which has properties homologous to *Rakta Dhatu*. *Rakta Dhatu* and *Kharjura* both pursue similar properties (*Guna Samanya*). Both *Rakta Dhatu* and *Kharjura* have properties like *Guru*(heavy)and *Snigdha*(unctuous), *Madhura*(sweet) *Rasa* and it has got *Madhura Vipaka*. *Kharjura* acts as *RaktaPittaprasadak*¹² hence it helps in biosynthesis of *Rakta Dhatu* quantitatively. Nutritional screening shows that the *Kharjura* contains 34mg/100gm of calcium, 6 g/100gm of iron and 30mg/100gm of vitamin C which are essential for formation of haemoglobin.¹³ According to review of the phytochemical constituents of *Kharjura* mentioned by the phytochemists of 20th century, it contains all the necessary materials such as iron, vitamin C, etc. which are required for the formation of erythrocyte¹⁴. *Kharjura* is having erythrogenic properties i.e., it enhances production of red cells; facilitates the absorption of iron in the body there by increases the haemoglobin level.¹⁵

CONCLUSION

Kharjura can be used as nutraceutical along with *Dhatri Loha* in management of *Rakta Kshaya*. Pilot study revealed

insignificant increase in Hb% at interval of 5 days of consumption of drug ascertaining *Dhatu Poshan Kala* theory.

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Table no.1: Nutritional evaluation of dates

| Principle | Nutrient value | Percentage of RDA (Recommended Dietary Allowances) |
|---------------|----------------|---|
| Energy | 277 Kcal | 14% |
| Carbohydrate | 74.97 g | 58 % |
| Proteins | 1.81 g | 3 % |
| Total fat | 0.15 g | < 1 % |
| Cholesterol | 0 mg | 0 % |
| Dietary fiber | 6.7 gm | 18 % |
| Elecrolytes | | |
| Sodium | 1 mg | 0 % |
| Potassium | 696 mg | 16 % |
| Minerals | | |

| | | |
|------------------|----------------|-------------|
| Calcium | 64 mg | 6.5 % |
| Copper | 0.362 mg | 40 % |
| Iron | 0.90 mg | 11 % |
| Magnesium | 54 mg | 13 % |
| Vitamins | | |
| Folate | 15 µg | 4 % |
| Niacin | 1.610 mg | 10 % |
| Pantothenic acid | 0.805 mg | 16 % |
| Pyridoxine | 0.249 mg | 19 % |
| Riboflavin | 0.060 mg | 4.5 % |

Table no.2: Ingredients of *Dhatriloha* with proportion

| Sr no | Name of ingredient | Latin name | Part used | Proportion |
|----------|---------------------|---------------------------------|-----------|------------|
| <u>1</u> | <i>Amalaki</i> | <i>Embelia ribes</i> Linn | Fruit | Equal |
| <u>2</u> | <i>Haridra</i> | <i>Curcuma longa</i> Linn | Rhizome | Equal |
| <u>3</u> | <i>Pippali</i> | <i>Piper longum</i> Linn. | Fruit | Equal |
| <u>4</u> | <i>Shunthi</i> | <i>Zinziber officinale</i> Linn | Fruit | Equal |
| <u>5</u> | <i>Maricha</i> | <i>Piper nigrum</i> Linn | Fruit | Equal |
| <u>6</u> | <i>Lauha Bhasma</i> | incinerated iron | - | Equal |

Table no.3: Details of the score adopted for the *Rakta Dhatu Kshaya Lakshana*

| Sr no | Symptoms | 0 | 1 | 2 | 3 |
|-------|---|---------------------|--|---|--|
| 1 | <i>Amla-sheeta Pratharna</i> (craving for sour and cold substances) | Absent | Occasional desire to take either <i>Amla</i> or <i>Sheeta Dravya</i> | Occasional desire to take both <i>Amla</i> and <i>Sheeta Dravya</i> | Always desires for the <i>Amla</i> and <i>Sheeta Dravya</i> that subside on the intake |
| 2 | <i>Twaka Parushya</i> (dryness of skin) | No dryness at all – | Dryness in the cold season only | Dryness in other seasons also but only on the exposed parts | Dryness throughout the year but present in the whole body |
| 3 | <i>Sira Shaithilya</i> (loss of tone of veins) | Absent | Present occasionally and subside itself after some time | Present occasionally and doesn't subside itself | Present always and subsides on medication |

Table no.4: Effect of test drugs on *Amla Sheeta Pratharna*(craving for sour and cold substances)

| Group | Mean score | | D | % | SD | SE | W | T+ | T- | P | Sig |
|--------|------------|-----|-----|----|-------|-----|----|----|------|--------|-----|
| | BT | AT | | | | | | | | | |
| A(n=5) | 1.6 | 0.4 | 1.2 | 75 | 0.447 | 0.2 | 15 | 15 | 0.00 | 0.0625 | IS |
| B(n=5) | 1.4 | 0.2 | 1.2 | 80 | 0.447 | 0.2 | 15 | 15 | 0.00 | 0.0625 | IS |

A: *Dhatri Loha* treated group, B: *Dhatri loha+Kharjura* treated group, SD: standard deviation, SE: standard error, IS:insignificant

Table no.5: Effect of test drugs on *Twaka Parushya* (dryness of skin)

| Group | Mean score | | D | % | SD | SE | W | T+ | T- | P | Sig |
|--------|------------|-----|-----|----|-------|-----|----|----|----|--------|-----|
| | BT | AT | | | | | | | | | |
| A(n=5) | 1.4 | 0.6 | 0.8 | 60 | 0.447 | 0.2 | 10 | 10 | 0 | 0.125 | IS |
| B(n=5) | 1.6 | 0.4 | 1.2 | 80 | 0.447 | 0.2 | 15 | 15 | 0 | 0.0625 | IS |

A: *Dhatri Loha* treated group, B: *Dhatri Loha+Kharjura* treated group, SD: standard deviation, SE: standard error, IS:insignificant

Table no.6: Effect of test drugs on Hb% at 5 days

| Group | B.T. | | A.T. | | Change | | % change | ‘t’ |
|--------|--------------|-------|--------------|-------|-------------|-------|----------|--------|
| | Mean±SEM | SD | Mean±SEM | SD | Mean±SEM | SD | | |
| A(n=5) | 10.900±0.483 | 1.079 | 11.140±0.417 | 0.932 | 0.240±0.214 | 0.477 | 2.39 ↑ | -1.124 |
| B(n=5) | 10.340±0.273 | 0.611 | 10.760±0.328 | 0.733 | 0.420±0.159 | 0.356 | 4.05↑ | -2.635 |

** =p<0.001, * = p<0.05, ↓ = Decrease, ↑ = Increase. SEM: standard error of mean Hb%: haemoglobin percentage, A: *Dhatri Loha* treated group, B: *Dhatri loha+Kharjura* treated group,

Table no.7: Effect of test drugs on Hb% 10 at days

| Group | B.T. | | A.T. | | Change | | % change | ‘t’ |
|--------|--------------|-------|--------------|-------|--------------|-------|----------|--------|
| | Mean±SEM | SD | Mean±SEM | SD | Mean±SEM | SD | | |
| A(n=5) | 10.90±0.483 | 1.079 | 11.300±0.467 | 1.044 | -0.400±0.164 | 0.367 | 3.76 ↑ | -2.434 |
| B(n=5) | 10.340±0.273 | 0.611 | 10.980±0.350 | 0.782 | -0.640±0.250 | 0.559 | 6.23↑ | -2.558 |

** =p<0.001, * = p<0.05, ↓ = Decrease, ↑ = Increase. SEM: standard error of mean Hb%: haemoglobin percentage, A: *Dhatri Loha* treated group, B: *Dhatri Loha+Kharjura* treated group.

Table no.8: Comparison of effect of test drugs on subjective parameters and Hb% by CV test:

| Sr no | Parameter | Group A(n=5) | | | Group B(n=5) | | | Better group |
|-------|---|--------------|-------|-------|--------------|-------|-------|--------------|
| | | Mean | SD | CV | Mean | SD | CV | |
| 1. | <i>Amla Sheeta Pratharna</i> (craving for sour and cold substances) | 1.2 | 0.447 | 0.372 | 1.2 | 0.447 | 0.372 | Equal |
| 2. | <i>Twaka Parushya</i> (dryness of skin) | 0.8 | 0.447 | 0.558 | 1.2 | 0.447 | 0.372 | Group B |
| 3. | Hb% at 5 days interval | 0.24 | 0.447 | 1.862 | 0.42 | 0.356 | 0.847 | Group B |
| 4. | Hb% at ten days interval | 0.4 | 0.559 | 1.397 | 0.64 | 0.559 | 0.873 | Group B |

SD: standard deviation, CV: coefficient of variation, Hb%:percentage of haemoglobin, A: *Dhatri Loha* treated group, B: *Dhatri Loha+Kharjura* treated group.

Table no.9: Comparison of effect on Hb% by unpaired t test

| Group | Mean±SEM | SD | DIFFERNCE | T | P | S |
|--------|-------------|-------|-----------|--------|-------|----|
| A(n=5) | 0.240±0.214 | 0.477 | -0.400 | -1.216 | 0.259 | IS |
| B(n=5) | 0.640±0.250 | 0.559 | | | | |

SEM: standard error of mean, SD: standard deviation, IS: insignificant, A: *Dhatri Loha* treated group, B: *Dhatri Loha+Kharjura* treated group

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