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A Clinical study on the effectiveness of *Kharjura Modaka* in Nutritional Deficiency Anaemia

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ABSTRACT

Nutritional Deficiency Anaemia is a worldwide problem with highest prevalence in developing country. It is not just a disease entity rather a syndrome caused by malnutrition in its widest sense. Food is very important for physical and mental wellbeing. For healthy functioning of the body we require essential nutrients and this can only obtained through the diet. *Kharjura* which is one of the nutritious fruit rich in minerals such as Calcium, Magnesium, Potassium, Iron and also contains Vitamin B₁, B₂, B₃, B₆ and Vitamin C. *Kharjura* is having *Brumhana*, *Balya* properties and used both as food and therapeutic supplement.

AIM

The aim of this study is to evaluate the effectiveness of *Kharjura Modaka* in Nutritional Deficiency Anaemia.

MATERIALS AND METHOD

The study conducted was open label clinical trial with a convenient sampling technique carried out on 31 subjects of Nutritional Deficiency Anaemia fulfilling the diagnostic criteria and inclusion criteria. *Kharjura Modaka* 30gms twice daily with *ushna jala anupana* administered for 30 days duration. Effect of therapy was assessed on subjective and objective parameters.

RESULTS

Kharjura Modaka is found effective in treating Nutritional deficiency anaemia as a food supplement.

CONCLUSION

Kharjura Modaka showed significant improvement in increasing haemoglobin content of blood after treatment, hence it is established as a haematinic.

KEYWORDS

Food Supplement; Haematinic; Kharjura Modaka; Nutritional Deficiency Anaemia



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INTRODUCTION

Nutritional Deficiency Anaemia is a worldwide problem with highest prevalence in developing countries¹. It is a condition that occurs when the red blood cells do not carry enough oxygen to the tissues of the body. Anaemia has terrible effect on health and wellbeing, some are irreversible including mental retardation and poor ability to do labour, sports, and other physical activities, reduced capacity, increased illness, greater risk of death of women during maternity and birth, low birth weight and premature births^{2,3}. Nutritional Deficiency Anaemia develops slowly after the normal stores of iron have been depleted in the body and in the bone marrow⁴.

Initially, iron deficiency anaemia is so mild that it goes unnoticed. But as the body becomes more deficient in iron and anaemia worsens, the signs and symptoms intensify. Iron deficiency anaemia symptoms may include: Extreme fatigue, Pale skin, Weakness, Shortness of breath, Chest pain, Frequent infections, Headache, Dizziness or light-headedness, cold hands and feet, Inflammation or soreness of tongue, Brittle nails, Fast heartbeat, Unusual cravings for non-nutritive substances, such as ice, dirt or starch, Poor appetite, especially in infants and children

with iron deficiency anaemia, An uncomfortable tingling or crawling feeling in your legs (restless legs syndrome)⁵.

The highest prevalence of anaemia exists in the developing world where its causes are multi-factorial. Globally about 3.6 billion people are suffering from Anaemia. In India, it is very high among nutritionally vulnerable group such as mother and children. In India, 20% of adult males, 40% of children, 55.8% of adolescent girls, 60% of adult females and 80% of pregnant mothers have iron deficiency anaemia⁶.

According to National Family Health Survey (NFHS) statistics reveal that every second Indian woman is anaemic and one in every five maternal deaths is directly due to anaemia. According to NFHS- 4, 53% of women and 23% of men age 15 to 49 in India are anaemic. 40% of women are mildly anaemic, 12% are moderately anaemic, and 1% are severely anaemic. 12% of men are classified as mildly anaemic, 10% as moderately anaemic, and 1% as severely anaemic⁷.

Strategies for tackling nutritional deficiency anaemia include the increased use of iron supplements, food fortification and nutrition education aimed at improving iron availability in the diet⁸. The healthy body as well as the disease are nothing but the outcome of Ahara⁹. Prevention is better than cure. The earlier a person starts to eat



a healthy and balanced diet, the more he/she will stay healthy. Kharjura (Phoenix dactylifera. Linn.) which is one of the nutritious fruit rich in minerals such as Calcium, Magnesium, Potassium, and Iron and also contains Vitamin B₁, B₂, B₃, B₆ and Vitamin C¹⁰. Nutritionally, Kharjura is a good source of energy and a mixture of antioxidants including ascorbic acid, carotenoids, flavonoids and polyphenols. Kharjura is one of the commonly used fruit and is considered among the *Madhura Triphala*. It is having having *Madhura, Kashaya Rasa, Snigdha, Guru Guna, Shita Virya* and *Madhura Vipaka* properties. It is *Bruhana, Balya, Vrusya, Vatapittahara, Rasayana, Hrudya, Tarpana* properties used in the treatment of *Shwasa, Kasa, Mada, Moorcha, Raktapitta, Kshata, Kshaya, Trishna, Daha, Visha* as food and therapeutic supplement¹¹. So an effort is made to evaluate the effectiveness of Kharjura Modaka (*Anubhuta yoga*)¹² as a food supplement in improving nutritional status and treating Nutritional Deficiency Anaemia.

MATERIALS AND METHODS

A minimum of 31 subjects were selected from the OPD and IPD of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan fulfilling the

diagnostic criteria and inclusion criteria of nutritional deficiency anaemia irrespective of the caste, religion, occupation and gender. The clinical trial has been carried out after obtaining approval from Institutional Ethics Committee (No. IEC NO: SDM/IEC/93/2017-2018). The trial was registered in Clinical Trial Registry-India (CTRI/2017/08/010075). A detailed case proforma was prepared and informed written consent was obtained from the subjects. The study was designed as single arm, open-label, convenient sample clinical trial.

DIAGNOSTIC CRITERIA

Table 1 Grading of anaemia as per W.H.O. guidelines

| | |
|-----------------|--|
| Mild | Haemoglobin of 110-119mg/l in children and adult women and 120-129mg/l in adult men. |
| Moderate | Haemoglobin of 80-109mg/l in children and adult women and 90-119mg/l in Adult men. |
| Severe | Haemoglobin of <80mg/l in children and adult women and <90mg/l in adult Men |

Table 2 Based on PCV, MCV and MCHC¹³

| | |
|-------------|--|
| PCV | < 40-54 % in males and <37- 47% in females |
| MCV | < 73-93% irrespective of age and sex |
| MCHC | < 30-35 irrespective of age and sex |

Based on red cell size, haemoglobin content¹⁴

- Microcytic, hypochromic - MCV, MCHC reduced
- Macrocytic - MCV raised

Inclusion Criteria

1. Mild and Moderate nutritional deficiency anaemia



2. Case of nutritional deficiency anaemia without its complications.
3. Patients between 16 to 40 year age group without any bar of race, religion and gender
4. Patients having proper *Agnibala* (digestive power) were selected.

Exclusion Criteria

1. Anaemia due to any chronic illness.
2. Anaemia due to any systemic illness like history of Malaria, Tuberculosis, Leukaemia, Jaundice, IHD, Diabetes
3. History of Haemophilia.
4. History of mental disorders.
5. Any infectious diseases like HIV, HBsAg.
6. Impaired cardiac, hepatic and renal function.

Posology

All the patients who fall in inclusion criteria were given deworming treatment with *Krimi Kuthara Rasa* followed by *Kharjura Modaka*

Krimi Kuthara Rasa:

Dosage – 2 tablets twice daily after food with *ushnajala anupana* for 3 dyas

Kharjura Modaka:

Dosage – 30gms twice a day with *ushnajala anupana* half an hour before food for 30 days.

METHOD OF PREPARATION OF KHARJURA MODAKA

Kharjura Modaka was prepared in the department of *Rasa Shastra* and *Bhaishajya kalpana*. *Kharjura* fruits were collected from vendors of Hassan and seeds are taken out and pulp was made into small pieces. Then, *Kharjura* and *Ghrita* are taken in the ratio of 10:1 and it is fried on mild temperature for 10 - 12 min and is stirred continuously so that it would not get scorched. Frying is stopped when it reaches fibril consistency. Then it is prepared in the form of *Modaka*¹².

INVESTIGATIONS

Complete blood count and peripheral blood smear.

CRITERIA FOR ASSESSMENT OF THERAPY

Subjective Parameter

It has been assessed on improvement of cardinal signs and symptoms of disease with the help of grading pattern such as follows:

Table 3 Showing grades for subjective parameter

| | |
|--|---------------------------------------|
| 1. Hearing of sounds in the ear | 2. Swelling of Eyelids |
| 0 No | 0 No |
| 1 Occasionally | 1 Swelling of lower Eyelids |
| 2 Frequently | 2 Swelling of lower and upper Eyelids |
| 3 Almost every day | 3 Swelling obstructs vision |
| 3. Exhaustion / Tiredness | 4. Weakness |
| 0 No | 0 Absent |
| 1 Only on exertion | 1 Mild with daily routine |



| | | | |
|---|---|--|--|
| 2 | On carrying out routine activities | 2 | Affects daily routine & but able to cope |
| 3 | At rest | 3 | Affects daily routine & unable to cope |
| 5. Difficulty in breathing | | 6. Feeling of kneading, squeezing of body | |
| 0 | No | 0 | No |
| 1 | Exertional dyspnea | 1 | Occasionally |
| 2 | Mild with normal activities | 2 | Frequently |
| 3 | Disrupts daily activities intermittently | 3 | throughout the day |
| 7. Cramps in the calf region | | 8. Dizziness or Light-headedness | |
| 0 | No | 0 | No |
| 1 | Occasionally | 1 | On exhaustion |
| 2 | Frequently | 2 | On shifting body position |
| 3 | Almost everyday | 3 | At rest |
| 9. Irritability | | 10. Disinterest towards talking | |
| 0 | No | 0 | No |
| 1 | Serious issues / occasionally | 1 | Occasionally |
| 2 | Trivial issues/ frequently | 2 | Frequently |
| 3 | In the absence of any issues | 3 | throughout the day |
| 11. Desire for rest/sleep in the day | | 12. weakness during climbing of stairs | |
| 0 | No | 0 | No |
| 1 | Occasionally | 1 | Occasionally |
| 2 | Frequently | 2 | Frequently |
| 3 | Almost everyday | 3 | throughout the day |
| 13. Pallor | | 14. Palpitation | |
| 0 | No | 0 | No |
| 1 | Conjunctiva slightly pale, nails and mucus membrane not pale | 1 | On exertion |
| 2 | Conjunctiva slightly pale, nails and mucus membrane slightly pale | 2 | Present with normal activities |
| 3 | Conjunctiva slightly pale, nails and mucus membrane all pale | 3 | Present with rest |
| 15. Indigestion | | 16. Insomnia | |
| 0 | No | 0 | No |
| 1 | Occasionally | 1 | Occasionally |
| 2 | Frequently | 2 | Frequently |
| 3 | Almost everyday | 3 | Almost everyday |

OBSERVATIONS

A total of 35 patients were registered for the trial and only 31 completed the treatment. Age wise distribution shows 48.4% subjects were in the age group 26-30 years, followed by 45.2% subjects are in the age group of 21-25 years and 3.2% subjects are under the age group of 16-20 and 31-35years. All the subjects were females. Maximum 48% subjects belonged to upper middle class and 29% subjects belonged to

middle class, 16.1% subjects belonged to upper class and 6.5% belonged to poor class. Maximum 67.7% subjects followed mixed diet and 32.3% subjects followed vegetarian diet. Maximum, 61.3% subjects consumed *Katu Rasa*, 29% subjects consumed *Madhura Rasa* and 9.7% subjects consumed *Amla Rasa* as predominant Ahara. Maximum 87.1% subjects were from urban area and 12.9% subjects were from rural area. 51.6%



subjects were having adequate sleep, 45.2% subjects reported sleep deprivation and 3.2% subjects reported increased sleep pattern. Maximum of 71% subjects were

habituated to drinking tea regularly and 29% of subjects were habituated for coffee

RESULTS

Table 4 Friedman test showing effectiveness of Kharjura Modaka in following subjective parameters

| Symptoms | N | Symptoms present in patients | Mean rank | | | | X ² | P | Remarks |
|------------------------------------|----|------------------------------|-----------|------|------|------|----------------|-------|---------|
| | | | BT | D15 | AT | FW | | | |
| Hearing of sound in the ear | 31 | 9 | 2.94 | 2.35 | 2.35 | 2.35 | 27 | 0.001 | S |
| Swelling of eyelids | 31 | 12 | 3.44 | 2.82 | 1.98 | 1.76 | 56.9 | 0.001 | S |
| Exhaustion/ Tiredness | 31 | 28 | 3.95 | 2.65 | 1.84 | 1.56 | 79.35 | 0.001 | S |
| Weakness | 31 | 27 | 3.94 | 2.61 | 1.73 | 1.73 | 78.94 | 0.001 | S |
| Difficulty in breathing | 31 | 19 | 3.50 | 2.37 | 2.05 | 2.08 | 53.68 | 0.001 | S |
| Feeling of Kneading of body | 31 | 14 | 3.35 | 2.48 | 2.16 | 2.00 | 45.129 | 0.001 | S |
| Cramps in the calf region | 31 | 17 | 3.45 | 2.45 | 2.05 | 2.05 | 46.54 | 0.001 | S |
| Dizziness or light headedness | 31 | 22 | 3.76 | 2.44 | 1.95 | 1.85 | 67.77 | 0.001 | S |
| Irritability | 31 | 25 | 3.85 | 2.25 | 1.98 | 1.92 | 73.94 | 0.001 | S |
| Disinterest towards talking | 31 | 17 | 3.37 | 2.32 | 2.21 | 2.10 | 49.0 | 0.001 | S |
| Desire for rest/sleep in the day | 31 | 26 | 3.89 | 2.77 | 1.81 | 1.53 | 75.77 | 0.001 | S |
| Weakness during climbing of stairs | 31 | 26 | 3.79 | 2.60 | 1.84 | 1.77 | 67.018 | 0.001 | S |
| Pallor | 31 | 26 | 3.90 | 2.40 | 2.00 | 1.69 | 76.142 | 0.001 | S |
| Palpitation | 31 | 24 | 3.73 | 2.34 | 2.02 | 1.92 | 68.002 | 0.001 | S |
| Indigestion | 31 | 13 | 3.21 | 2.37 | 2.18 | 2.24 | 31.125 | 0.001 | S |
| Insomnia | 31 | 21 | 3.61 | 2.52 | 1.98 | 1.89 | 61.271 | 0.001 | S |

Objective Parameters

Haemoglobin concentration:

Table 5 Effect of Kharjura Modaka on Hb%

| Objective parameter | Mean BT | Mean AT | Diff. Mean | SD | SE | T | P Value | Remarks |
|---------------------|---------|---------|------------|-------|--------|-------|---------|---------|
| Hb% | 9.96 | 10.29 | 0.335 | 0.559 | 0.1004 | 3.339 | 0.002 | S |

The above table showing that mean haemoglobin concentration increased from 9.96% to 10.29% with a mean difference

0.335% which is statistically significant with P value 0.002.

Packed Cell Volume:

Table 6 Overall mean increase in PCV

| Objective parameter | Mean BT | Mean AT | Diff. Mean | SD | SE | T | P Value | Remarks |
|---------------------|---------|---------|------------|-------|-------|-------|---------|---------|
| PCV | 32.37 | 33.22 | 0.854 | 3.212 | 0.576 | 1.482 | 0.149 | NS |

The above table suggests that mean PCV increased from 32.37% to 33.22% with a mean difference 0.854% which is not

statistically significant at P value 0.149 (p > 0.05).

Mean Corpuscular Volume:

Table 7 Overall mean Changes in MCV

| Objective parameter | Mean BT | Mean AT | Diff. Mean | SD | SE | T | P Value | Remarks |
|---------------------|---------|---------|------------|----|----|---|---------|---------|
|---------------------|---------|---------|------------|----|----|---|---------|---------|



| | | | | | | | | |
|-----|-------|-------|-------|-------|-------|-------|-------|---|
| MCV | 72.28 | 73.86 | 1.587 | 3.525 | 0.633 | 2.507 | 0.018 | S |
|-----|-------|-------|-------|-------|-------|-------|-------|---|

The above table suggests that mean MCV Raised from 72.28fL to 73.86fL with mean difference of 1.587fL which is statistically

significant at P value 0.018 ($p < 0.05$).

Mean Corpuscular Haemoglobin Concentration:

Table 8 Showing the overall mean changes in MCHC

| Objective parameter | Mean BT | Mean AT | Diff. Mean | SD | SE | T | P Value | Remarks |
|---------------------|---------|---------|------------|-------|-------|-------|---------|---------|
| MCHC | 30.73 | 31.36 | 0.625 | 1.974 | 0.346 | 2.509 | 0.088 | NS |

The above table suggests that mean MCHC Raised from 30.60% to 31.36% with mean difference of 0.625% which is statistically not significant at P value 0.088 ($p > 0.05$).

Kharjura is rich in iron, folate and Vitamin C. Vitamin C reduces ferric iron to ferrous iron which remains soluble even at neutral pH and is better absorbed. Even when the diet is poor in iron, vitamin C supplement with each meal increases iron absorption to a greater extent¹⁵.

DISCUSSION

Effectiveness of *Kharjura Modaka* on Symptoms;

Effect on PCV:

Table no.4 shows that there was a statistically significant improvement in Hearing of sounds, swelling of eyelids, exhaustion/tiredness, weakness, difficulty in breathing, feeling of kneading, squeezing of body, cramps in the calf region, dizziness o light headedness, irritability, disinterest towards talking, desire for rest, weakness during climbing of stairs, pallor, palpitation, indigestion, insomnia with P value <0.001 .

Table no.6 depicts that the overall mean rise of pcv was 0.854% which is not statistically significant at P value 0.149 ($p \text{ value} >0.05$).

Effect on MCV:

Haemoglobin:

Table 7 indicates that the overall mean rise of MCV was 1.58fl . As *Kharjura* contains folate and Vitamin B12 which are water soluble vitamins, helps in absorption of more amount of iron and that further increases RBC's maturation rate.

The overall mean rise of Hb% was 0.335% shown in table no. 5. It proves the hematinic effect of *Kharjura Modaka* with a p value 0.002 which is statistically significant as

Effect on MCHC:

Table no.8 indicates that the overall mean rise of MCHC was 0.625% which is not statistically significant at P value 0.088 ($p \text{ value} >0.05$).

Peripheral Smear:



There are no significant changes noted in the peripheral smear after the treatment. Four subjects reported changes in peripheral smear from microcytic hypochromic to normocytic, normochromic. The size is reflected in the mean corpuscular volume (MCV).

CONCLUSION

Kharjura Modaka has significant positive effect in subjective parameters like Hearing sound in the ear, swelling of eyelids, exhaustion, weakness, Difficulty in breathing, Feeling of kneading, squeezing of body, cramps in the calf region, dizziness or light-headedness, irritability, disinterest towards talking, desire for rest, weakness during climbing of stairs, palpitation, indigestion, exertional dyspnoea and insomnia. Effectiveness of *Kharjura Modaka* have shown significant improvement in increasing haemoglobin content of blood after the treatment and hence it is established as haematinic and can be considered as a good food supplement in Nutritional Deficiency Anaemia. In this trial there were no complications observed by administering *Kharjura Modaka* for a period of one month. Thus Research hypothesis is accepted.



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