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CLINICAL STUDY TO EVALUATE THE INFLUENCE OF CALCI MALT ON SERUM CALCIUM

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ABSTRACT

Background: Micro nutrients are required to human body in lower quantity but they play a major role in maintenance of health like Macro nutrients. Calcium being such micro nutrient having recommended dietary allowance 1000mg/day among adults is observed to be consumed in comparatively lower quantities leading to its deficiency. As per the nutritional survey, Asian continent population consume less than 400-500mg/day and Indians consume 429 mg/day of calcium in their diet. Lower calcium intake may adversely affect bone health in adults. The effects of calcium deficiency may cause the skeletal weakness or fracture, tooth decay, osteopenia or osteoporosis, insufficient blood clotting. About half of the calcium in the serum is bound to protein, predominantly albumin

Ragi (*Eleusine coracana*) is an important staple food fourth rank among all other millets and rich in protein, calcium, phosphorus, iron and vitamins. Malting of Ragi enhance the Bio availability of nutrients and improve the overall nutritional quality. Calci malt contains Ragi (*Eleusine coracana*), Mudga (*Vignaradiata*), Jeeraka (*Cuminum cyminum*), Shunti (*Zingiber officinale*) and milk which are rich in the calcium. Jeeraka and Shunti have Deepana (appetizers) and Pachana (increase digestion power) properties. Prevention is better than cure, earlier the person starts to eat a healthy and balanced diet, the longer he/she will stay healthy. The supplementation of calcium through diet is most ideal and safe method. Hence an effort is being made to examine the influence of Calci Malt on serum calcium and preventing the calcium deficiency.

Objectives- To clinically evaluate the influence of Calci Malt on serum calcium.

Methods- The present study was planned as a wait listed cross over study on 40 subjects were selected from Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan fulfilling the diagnostic criteria, inclusion and exclusion criteria using the convenience (non-random) sampling technique with pre-test and post-test design. **Assessment Criteria** Objective criteria through laboratory blood investigation. **Results-** This study found that Calci malt had statistically significantly improves serum calcium at the end of intervention compare to study group and control group. **Conclusion-** Influence of Calci Malt shown significant improvement on Serum Calcium values can be considered as a good supplement in Healthy subjects to improve Serum Calcium.

Keywords: Ayurveda, Calci Malt, Serum Calcium, Ragi, Mudga, Jiraka, Shunti, Milk

INTRODUCTION

Calcium is the fifth most abundant element in the human body **[1]**. Calcium which accounts for 1 -2 % of the adult human body weight, is a major component of mineralised tissues, which contains >99% of the total body calcium. The remaining 1 %, found in blood, extracellular fluid (ECF), muscle, and other tissues **[2]**. Calcium is required for normal growth, development and maintenance of the skeleton, where it provides strength and structure. the reminder is present in the blood, extracellular fluid, muscle and other tissue, where it plays a role in mediating vascular contraction and vasodilatation, muscle contraction, nerve transmission and glandular secretion **[3]**.

Properties of Ragi- Rasa - Madhura, Kashaya, Tikta, Virya – Sheeta, Guna-Laghu, Ruksha, Karma-Jalashoshana, Pitta Ashmari, Dosha Karma- Vatavardaka, Pittashamaka.

Ragi (finger Mellit) Nutrient value per 100gms

Protein 7.3gm, Fat 1.3g, Minerals 2.7gm, Crude fibers 3.6gm, Carbohydrate 72.0gm, Energy 328kcal, Calcium 344mg, Iron 3.9mg, Phosphorus 283mg, Zinc 2.3mg, Vitamins Carotene 42 microgram, Thiamine 0.42 mg, Riboflavin 0.19mg, Niacin 1.1mg **[4]**.

Properties of Mudga (green gram)- Rasa-Madhura, Virya-Sheeta, Vipaka-Katu**,** Guna-Ruksha, Laghu, Dosha karma-Kapha Pittahara, Grahi,Karma-Drusta Prasadana, Pustikaraka, Balavardaka.

Nutritional facts of green gram- Green gram (Mudga) is known for its high nutritional value. 100 grams of it produces 334 Kcal of energy. It is rich in carbohydrates (56.7g/100g) and is very good source for minerals like potassium (843 mg/100g), magnesium (127 mg/100g), calcium (124 mg/100g), phosphorous (326 mg/100g) and Iron (4.4 mg/100g).

Vitamins like carotene, thiamine, niacin, riboflavin, ascorbic acid, and folic acid are also present in green gram **[5, 6]**.

Objectives- To clinically evaluate the influence of Calci Malt on serum calcium.

MATERIALS AND METHODS

The present study was planned as anwait listed cross over study on 40 subjects using the convenience (non-random) sampling technique with pre-test and post-test design. Study was conducted in outpatient department of Sri Dharmasthala Manjunatheshwara College and hospital, Hassan. The plan of the study was approved by Institutional Ethics Committee prior to the starting of the work.

Ethics committee clearance- IEC no: SDM/IEC/49/2019

Materials- Laboratory investigation of Serum Calcium.

Study Design- Non Randomized Clinical Trial

Sample size- 40 (Control 40, Study 40)

Calculated by the formula - (Zα+Zβ)2 (p1q1) +(p2q2)/ d2 [Precision-15,P1-60%, P2- 70%]

Considering dropouts sample size was fixed to 40

Sampling method: Convenient sampling

Source of Participants: Swasthavrittha O.P.D Sri Dharmasthala Manjunatheshwara college of Ayurveda and hospital, Hassan

Duration of the study- One month.

Method of Collection of Data (including sampling procedure if any): A total of 40 healthy subjects fulfilling the diagnostic criteria and inclusion criteria was selected for the study.

Diagnostic Criteria

Subject with no known diseases.

Inclusion Criteria

1. Apparently healthy subjects who are interested and willing to take Calci Malt.
2. Subjects of age group 18-40yrs.

Exclusion Criteria

1. Calcium supplement.

Source and authentication of raw drug- Raw drugs were obtained from Local market and authenticated at Department of Dravyaguna Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital Hassan.

Method of preparation- Calci malt is prepared in teaching pharmacy of Rasa Shastra and Bhaishajya Kalpana department of Sri Dharmasthala Manjunatheshwara Teaching Pharmacy Hassan.

Method of Preparation of Calcimalt- The process of preparation of Calci malt powder and beverage **(Table 1, 2)**.

Observations-

Age- Among 42 Subjects 23 (54.8%) belonged to age group of 18-24, 18(42.9%) belonged to age group 26-31 & 1 patient belonged to age group 32-40(2.4%).

Gender- Among 42 Subjects 21 (50%) Subjects belonged to male & 21 (50%) Subjects belonged to female.

Marital Status- Among 42 Subjects 38(90.5%) are unmarried, 4(9.5%) are married.

Socio-Economic Status- Among 42 Subjects 26(61.9%) belonged to middle class, 15(35.7%) belonged to upper middle class, 1(2.4%) belonged to lower middle class.

Education Status- Among 42 Subjects 26(59.5%) belonged to graduate, 17(40.5%) belonged to post graduate.

Table 1: Preparation of Calci malt powder

Step -1	**Soak Ragi, Mudga in water for 12 hrs**
Step -2	**Sprout Ragi(36 hrs), Mudga(24 hrs)**
Step -3	**Dry the sprouted grains**
Step -4	**Remove the rootlets**
Step -5	**Mill to get the fine powder Sieve**
Step -6	**Calci Malt powdes**

Table 2: Preparation of Calci malt beverage

Step -1	**Boiling one cup of milk**
Step -2	**Make a slurry of 20 gm Calci malt powder with milk**
Step -3	**Slurry add to boiling milk and boil for a minute**
Step -4	**Add sugar and boil for a minute**
Step -5	**Cool and serve a nutri beverage**

RESULTS

Control group –Therefore we conclude that statistically significant in serum calcium from before intervention status to after intervention status **(Table 5)**.

Study group –Therefore we conclude that oral administration of calci malt with milk twice daily before food (30 days) elicits a statistically significant in serum calcium from before intervention status o after intervention status **(Table 6)**.

Table 3: Descriptive statistic of Serum calcium

		Control Group		Study Group	
	N	**Mean**	**Std. Deviation**	**Mean**	**Std. Deviation**
Serum Calcium Before intervention	**40**	**8.4650**	**.74474**	**8.5050**	**.72145**
Serum Calcium After intervention	**40**	**8.5050**	**.72145**	**9.0258**	**.60267**

Table 4: Tests of Within-Subjects Effects in Serum calcium

Source	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Sig.**	**Partial Eta Squared**
Control Group						
Sphericity Assumed	**.032**	**1**	**.032**	**8.432**	**0.006**	**.178**
Greenhouse-Geisser	**.032**	**1.000**	**.032**	**8.432**	**0.006**	**.178**
Huynh-Feldt	**.032**	**1.000**	**.032**	**8.432**	**0.006**	**.178**
Lower-bound	**.032**	**1.000**	**.032**	**8.432**	**0.006**	**.178**
Study Group						
Sphericity Assumed	**5.424**	**1**	**5.424**	**50.929**	**<0.0001**	**.566**
Greenhouse-Geisser	**5.424**	**1.000**	**5.424**	**50.929**	**<0.0001**	**.566**
Huynh-Feldt	**5.424**	**1.000**	**5.424**	**50.929**	**<0.0001**	**.566**
Lower-bound	**5.424**	**1.000**	**5.424**	**50.929**	**<0.0001**	**.566**

Table 5: Pairwise Comparisons in Serum calcium

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
Control Group						
1	1	-.040	.014	.006	-.068	-.012
	2	.040	.014	.006	.012	.068
2	2	-.521	.073	.000	-.668	-.373
	1	.521	.073	.000	.373	.668

Table 6: Descriptive statistic of Serum calcium between two Group

Group Statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean
Serum Calcium After Intervention	Group A	40	8.5050	.72145	.11407
	Group B	40	9.0258	.60267	.09529

Table 7: Independent sample test inserum calcium between group (Control group and study group) – After Intervention

Serum calcium	Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances		
F	.901	
Sig.	.345	
t-test for Equality of Means		
T	-3.504	-3.504
Df	78	75.605
Sig. (2-tailed)	0.001	0.001
Remarks	S	S
Mean Difference	-.52075	-.52075
Std. Error Difference	.14864	.14864
95% Confidence Interval of the Difference		
Lower	-.81666	-.81681
Upper	-.22484	-.22469

This study found that calci malt had statistically significantly improves serum calcium (9.0258± 0.60 mg/dl) at the end of intervention compare to study group (8.5050±0.72 mg/dl), t(78)= -3.504, p=0.001.

DISCUSSION

Effect of Calci Malt on serum calcium-

By virtue of its health benefitting properties and environmental sustainability, a traditional but less popular crop like finger millet offers excellent opportunities in enhancing the calcium levels in the body. A foremost priority from geneticists and breeder's viewpoint is capturing and utilizing genetic diversity for Ca content in the elite finger millet gene pools **[7]**. Phenolics in finger millet grain are detrimental to its malt quality as they inhibited malt amylases Finger millet types with higher level of phenolics had superior malt quality than the low-phenol varieties, with respect to diastatic power (DP), and α- and β-amylase activities **[8]**. Finger millet is exceptionally rich in calcium (344 mg%) compared to all other cereals and millets (eightfold higher than pearl millet) **[9]** and Intake of Ragi (rich in phytates) retards the absorption of calcium from the gut. Phytates has inositol hexaphosphate, which chelates calcium in the gutwhich directly influences on the serum calcium **[10]**.

Mudga (*Vignaradiata*) is explained under Shimbi Dhanya and it has Madhura

and Kashaya Rasa, Laghu, RukshaGuna and KatuVipaka **[11]**. Mudga has nutritive value (in 100gm) protein(24.0gm), fat (1.3gm), minerals (3.5gm), crude fibres (4.1gm), carbohydrate (56.7gm), energy (334Kcal) calcium (124mg), iron (4.4mg) and phosphorus (326mg) **[12]**. For those individuals who cannot consume animal proteins or those who are vegetarian, the mung bean is of a comparatively has a good source of protein for them. Furthermore, mung bean protein is easily digestible, as compared to protein in other legumes **[13]**. Mudga is known to possess a unique property in initiating physiological effects in the human body. It belongs to the category of substances possessing a distinctive property known as "Vichitrapratyarabdha". In Sanskrit this term means "a unity of paradoxes" **[14]**. A drug or a substance is known to act at various levels based on its attributes. After intake of the Calcimalt, Calcium metabolism is regulated in large part by the parathyroid hormone PTH–vitamin D endocrine system, which is characterized by a series of homeostatic feedback loops. The rapid release of mineral from the bone is essential to maintain adequate levels of ionized calcium in serum. During vitamin D deficiency states, bone metabolism is significantly affected as a result of reduced active calcium absorption. This leads to increased PTH secretion as the calcium sensing receptor in the parathyroid gland senses changes in circulating ionic calcium. Increased PTH levels induce enzyme activity (1α-hydroxylase) in the kidney, which converts vitamin D to its active hormonal form, calcitriol. In turn, calcitriol stimulates enhanced calcium absorption from the gut. Not surprisingly, the interplay between the dynamics of calcium and vitamin D often complicates the interpretation of data relative to calcium requirements, deficiency states, and excess intake **[15]**.

Jeeraka (*Cuminum cyminum)* is good Deepana and Panchana Dravya having Tikshna Ushna Guna, Katu Rasa and Agni Vardhaka and Shleshmanilahara and also Krimihara action **[16]** Jeeraka has nutritive value (in 100gm) protein (18.7gm), fat (15.0gm), minerals (5.8gm), crude fibres (12.0gm), carbohydrate (36.6gm), energy (356Kcal), calcium (1080mg), iron (11.7mg) and phosphorus (511mg) **[17]**. The anti-osteoporotic activity of Cuminum cyminum was evaluated in rats. Adult Sprague-Dawley rats were bilaterally ovariectomized. Later Serum was evaluated for calcium, phosphorus, alkaline phosphatase and tartarate resistant acid phosphatase. And there was significantly increased calcium content and mechanical strength of bones in comparison to OVX

control. It showed greater bone and ash densities and improved microarchitecture of bones in Scanning Electron Microscope analysis **[18]**.

Shunti (*Zingiber officinale*) is Snigdha, Rochaka, Vrishya, Hrudya, Deepana, LaghuGuna, UshnaVeerya, Vatakaphahara, MadhuraVipaka **[19]**. Shunti has nutritive value(in 100gm) protein (2.3gm), fat (0.9gm), minerals (1.2gm), crude fibres (2.4gm), carbohydrate (12.3gm), energy (67Kcal) calcium (20mg), iron (3.5mg) and phosphorus (60mg) **[20]**. Previous studies that were conducted on rats and patient simultaneously had shown that increase in serum calcium was observed in animal as well as patients treated groups. The treatment of Zingiber officinale rosc showed extremely significant and increase of serum calcium level compared to standard drug of Dexamethasone in both tested groups, further study need to extend the mechanism of calcium increases in the treatment groups **[21]**.

CONCLUSION

Influence of Calci Malt shown significant improvement on Serum Calcium values can be considered as a good supplement in Healthy subjects to improve Serum Calcium. In the present study there were no adverse drug reaction by administering 20grams of Calci Malt with 100ml of Milk twice a day before food for a period of 1 month.

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Conflicts of interest: There are no conflicts of interest.

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