ISSN: 0976 3325

Original Article

AN INTERVENTIONAL STUDY (CALCIUM SUPPLEMENTATION & HEALTH EDUCATION) ON PREMENSTRUAL SYNDROME - EFFECT ON PREMENSTRUAL AND MENSTRUAL SYMPTOMS

Shailesh Sutariya[1], Nitiben Talsania[2], Chintul Shah[3], Mitesh Patel[3]

[1]Mobile Health Unit Coordinator, Commissionerate of Health, MS & ME, Gandhinagar [2]Professor, [3]Assitant Professor, Department of Community Medicine, B.J. Medical College, Ahmadabad

Correspondent:
Dr. Shailesh Sutariya
Mobile Health Unit Coordinator, Commissionerate of Health, MS & ME, Gandhinagar
Email: drsutariya@gmail.com

ABSTRACT

The study was conducted to study the effect of calcium supplementation on Premenstrual and Menstrual Symptoms. It was a one year follow-up prospective, randomized controlled interventional study. After the initial 2-cycle screening phase, a total of 215 healthy premenopausal women were enrolled in the study group calcium supplementation(500 BD) of the trial and 140 subjects either the relatives or neighbors of the study population were enrolled as control group health, nutrition, hygiene education of the trial. By the second and third treatment months, all symptoms except for fatigue and insomnia showed a significant response to calcium. For the symptom of low backache, the mean screening score was significantly higher than the control group score (0.82±0.74 vs 0.69±0.66,p=0.033) and became significantly lower than the control group score by the end of third treatment cycle. (0.30±0.45 vs 0.49±0.59,p<0.01). Nearly half (55%) of the women in the study group reported ≥50% improvement and one-third (30%) of the women in study group reported ≥75% improvement. Significantly lower symptoms score was detected in the urban sites during the first treatment phase with calcium and during the final treatment phase

Keywords: Premanstrual Syndrom, calcium supplement, intervention, health education

INTRODUCTION

The premenstrual syndrome may be defined as the cyclic recurrence, during the luteal phase of the menstrual cycle of a combination of physical, psychological, and/or behavioral changes of enough severity to deteriorate interpersonal relationships and/or interfere with normal activities [1]. Premenstrual syndrome may affect 30-40% of the female population, and has been implicated in work absenteeism, criminal behavior, marital discord, and billions of dollars worth of business loss. The literature surrounding premenstrual syndrome is voluminous, and undoubtedly the variability in case definition, the paucity of controlled studies, and the uncertainty with regard to pathophysilogic mechanism contribute to the current confusion and poor success in treating Subjects with premenstrual syndrome. [2-5]

MATERIALS & METHODS

Study Design: 1-year follow-up study: A prospective, randomized controlled interventional study. In these there are 3 phases.

(1) Diagnostic or identification phase (PMS)
(2) Intervention by calcium carbonate or Gluconate 500 mg 1BD for 3 cycles, or service for a specific period. (Health, Nutrition, Hygiene education)
(3) Assessment phase for results. Premenstrual symptoms scored on 17 parameters.

Study Area: Urban & Rural Communities

Community based study was planned and carried out in urban field practice area kalapinagar, Babausingh ni Chali, b/h. Parag School & Mali no kuvo attached with UHTC

Mala, community Medicine Dept, B. J. Medical College, Ahmedabad and subcenters of Adalaj PHC, District, Gandhinagar namely Uvarsad, Por, Chandkheda, PTC College & Pre PTC college Adalaj Proper, and Zundal which has been adopted as rural field practice area for UG/PG training of this department.

Study Population

Subjects: Healthy, Premenstrual women between the age of 15 and 45 years were interviewed and inquired about complains regarding premenstrual syndrome between Oct 2004 to Dec 2004, on the basis of following criteria, symptoms occurring during the luteal phase of the menstrual cycle that regressed rapidly after the onset of menstruation, and that were severe enough to disrupt social and work activities with regular menstruation. The primary outcome measure in the study was the symptom complex score, which was calculated as the average of the 17 daily individual symptoms ratings. [6].

Sample Size

Sample size requirements were determined size of 215 (treatment group). Four hundred women were screened. Three hundred fifty five patients were enrolled in the study, 215 met criteria for efficacy analysis. 140 patients not included in study failed to meet criteria. In addition, one more of the following symptoms must have been present during the luteal phase for a woman to qualify- mood swings, depression-sadness, tension-irritability, anxiety-nervousness, anger-aggression-short temper or crying spells.

Inclusion Criteria

(1) General good health as determined by history and routine physical examination (height, weight)
(2) Non-pregnant
(3) Regular menstrual cycle of 23 to 28 days as documented in the daily diaries.
(4) Discontinuance of the use of analgesics for the duration of study,
(5) The requirement that the diagnosis of PMS be prospectively documented for 2 menstrual cycles with the daily self- rating scale (The PMS Diary), a validated self-assessment daily diary.

Specific Exclusion Criteria: included a history of renal disease, hepatic diseases, digitalis therapy, significant gynecologic abnormality active mental illness, pregnancy or breast-feeding & use of oral contraceptives.

Written informed consent was obtained from all study participants approved by the institutional ethics committee review board chaired by the superintendent of New Civil Hospital, Ahmedabad in August 2004.

Sampling Design

Each subject was required to keep a daily diary of 17 symptoms associated with PMS for the five-month study period, beginning on the first day of menses. After the initial 2-cycle screening phase, a total of 215 healthy premenopausal women who met all inclusion / Exclusion criteria were enrolled in the study group calcium supplementation(500 BD) of the trial and 140 subjects either the relatives or neighbors of the study population were enrolled as control group health, nutrition, hygiene education of the trial.

RESULTS

Analysis of the data indicated that 63 % of the patients in the study group were between 16-35 years of age and rest above 35, while in the control group 56% of the patients were in the age group 16-35 and the rest above it.

Table 1: Demographic data of study population (Mean ± SE)

Particular	Study group	Control group	Total
Age (yrs)	22.7 ±6.7	22.9±6.7	22.8±6.0
Weight (kg)	55.8±15.1	55.9±15.3	55.9±15.1
Height (cm)	150.8±6.8	150.4 ±6.7	150.6±6.0
Cycle length (d)	29.3±2.8	28.8±2.6	29.1±2.7
Bleeding length (d)	5.1±1.3	5.2±1.2	5.2±0.3
Onset of PMS (Days before menses)	7.3±3.0	6.2± 3.0	6.5±3.0

Majority of subjects both in the study and control group were hindus. 39% subjects of the study group were literate, while 68% had less then 10 years of schooling. The marital status of the subjects of the study group indicated that 96% of them were married, while in the control

group 94% were married. House wives accounted for 93% and 90% in the study and the control groups respectively. The socio economic analysis indicated that 67% of the study group and 62% in the control group belonged to lower socioeconomic class.

Following these criteria, the postmenstrual phase was defined as days 5-10; the premenstrual phase was defined as the six days before menses (days 23-28).

Table 2: Mean symptom complex scores for calcium and health education groups by specific treatment cycle and menstrual phase.

Group		Mean screening	First treatment	Second treatment	Third treatment
No. of participants	Study	215	215	210	212
	Control	140	135	138	138
Luteal	Study	0.90 ± 0.52	0.58 ± 0.51	0.48 ± 0.46*	0.43* ±0.40*
	Control	0.92 ± 0.55	0.66 ± 0.49	0.61 ± 0.48	0.60 ± 0.52
Menstrual	Study	0.82 ± 0.54	0.60 ± 0.53	0.53 ± 0.47	0.47 ± 0.44
	Control	0.81 ± 0.52	0.59 ± 0.50	0.59 ± 0.53	0.52 ± 0.52

* P< 0.05, Data are presented as Mean ± SE.

Significant difference were found between groups for the mean screening of the luteal (p=. 659), Menstrual (p= .818), or inter Menstrual phase (P=. 726) of the cycle. The baseline luteal mean symptom complex scores were 0.90 ± 0.52 for the calcium treatment group and 0.92 ± 0.55 for the control group.

Table 3: Calcium treatment on 4 symptoms factor scores

Factor & symptoms	Group	Luteal phase symptom factor score		Menstrual phase symptom factor score	
		Mean screening	Third treatment	Mean screening	Third treatment
Symptom factor 1:Negative Effect Mood Swings, Depression, Tension, Anxiety, Anger, Crying Spells	Study	0.99 ± 0.59	0.46 ± 0.47*	0.77 ± 0.62	0.40 ± 0.52
	Control	1.04 ± 0.66	0.65 ± 0.64	0.80 ± 0.62	0.48 ± 0.62
Symptom factor 2: Water retention, Swelling of extremities, Tenderness of breasts, Abdominal bloating, Headache, Fatigue	Study	0.96 ± 0.58	0.51 ± 0.46*	0.93 ± 0.60	0.59 ± 0.63
	Control	0.97 ± 0.60	0.69 ± 0.58	0.92 ± 0.57	0.63 ± 0.52
Symptom factor 3: Food Cravings, Increased or Decreased appetite, Craving for sweets or salts	Study	0.97 ± 0.76	0.45 ± 0.63+	0.78 ± 0.68	0.40 ± 0.63
	Control	1.02 ± 0.76	0.60 ± 0.75	0.73 ± 0.64	0.42 ± 0.62
Symptom factor 4: Pain Lower abdominal cramping, Generalized aches and pains, Low Backache	Study	0.74 ± 0.63	0.30 ± 0.40*	0.94 ± 0.65	0.52 ± 0.62
	Control	0.69 ± 0.58	0.50 ± 0.52	0.87 ± 0.60	0.58 ± 0.62

* P< 0.001, + P< 0.05, Data are presented as mean ± SE

.

During the treatment cycle a significantly lower symptom complex score was observed in the calcium treated group for both the second and third treatment cycles during the luteal phase (p<0.05, p, 0.001). The luteal phase symptom complex score by the third calcium treatment

was 0.43± 0.40 compared with the control symptom complex scores of the 0.60 ± 52. The luteal mean symptom complex score values for the study group were lower for the treatment cycles compared with the symptom complex score values during screening and these mean symptom complex scores progressively decreased for each treatment group. By the third treatment cycle calcium effectively reduced the symptom complex score by 48% compared with the control effect of 30%. This significant calcium effect was not detected in the first treatment cycle.

As noted with mean symptom complex score, a significant calcium effect on all 4-symptom factors was observed during the luteal phase of the menstrual cycle. No significant effect was noted during the menstrual or intermenstrual phase of the cycle for the symptom factors. Three of the four symptom factors (Symptom factor 1, symptom factor 2, symptom factor 4) were observed to have significantly lower symptom factors score by the second treatment month.

There were significantly lower symptom score for all 4 factors (negative affect, symptom factor 1($p<0.001$); water retention symptom factor 2 ($P<0.001$); food graving, symptom factors 3($P<0.05$) and pain, symptom factors 4($P<0.001$); by the third calcium treatment cycle compared with first.

By the third treatment cycle the negative effect symptom factors was reduced by 45% for study compared with 28% for control group, the water retention symptom factors was reduced by the 36% for study compared to 20% for control.

Table 4: Differences between treatment group during luteal phase for individual symptom complex scores

Symptoms	Baseline Mean symptom complex score			Third treatment cycle Mean symptom complex score		
	Study group	Control group	P Value	Study group	Control group	P Value
Mood swings	1.06 ± 0.70	1.11 ± 0.77	P = .484	0.50 ± 0.58	0.70 ± 0.75	P =. 002
Depression-sadness	0.94 ± 0.66	0.95 ± 0.75	P = .809	0.43 ± 0.55	0.58 ± 0.74	P =. 011
Tension-irritability	1.31± 0.68	1.39 ± 0.71	P = .331	0.62 ± 0.58	0.84 ± 0.77	P<. 001
Anxiety-nervousness	0.98 ± 0.77	1.03 ± 0.83	P = .359	0.45 ± 0.58	0.66 ± 0.77	P<. 001
Anger-short temper	1.14 ± 0.68	1.20 ± 0.77	P = .470	0.53 ± 0.57	0.74 ± 0.77	P =. 001
Crying spells	0.51 ± 0.58	0.56 ± 0.65	P = .237	0.23 ± 0.40	0.37 ± 0.57	P =. 002
Swelling of extremities	0.77 ± 0.75	0.74 ± 0.72	P = .701	0.40 ± 0.57	0.56 ± 0.70	P =. 007
Tenderness-breast fullness	1.10 ± 0.85	1.18 ± 0.82	P = .228	0.59 ± 0.67	0.84 ± 0.77	P<. 001
Abdominal bloating	1.12 ± 0.72	1.12 ± 0.75	P = .818	0.55 ± 0.63	0.81 ± 0.77	P<. 001
Abdominal cramping	0.70 ± 0.66	0.73 ± 0.68	P = .741	0.29 ± 0.44	0.50 ± 0.59	P<. 001
Aches and pains	0.70 ± 0.68	0.66 ± 0.63	P = .469	0.31 ± 0.49	0.49 ± 0.60	P<. 001
Low Backache	0.82 ± 0.74	0.69 ± 0.66	P = .033	0.30 ± 0.45	0.49 ± 0.59	P<. 001
Headaches	0.73 ± 0.66	0.76 ± 0.66	P = .445	0.40 ± 0.52	0.52 ± 0.58	P =.033
Fatigue	1.09 ± 0.72	1.05 ± 0.72	P = .573	0.60 ± 0.66	0.71 ± 0.73	P=.0135
Appetite increased/decreased	0.97 ± 0.78	1.03 ± 0.77	P = .483	0.46 ± 0.65	0.61 ± 0.76	P =.025
Craving sweets or salts	0.97 ± .80	1.02 ± 0.79	P = .597	0.43 ± 0.64	0.60 ± 0.78	P =. 010
Insomnia	0.36 ± 0.55	0.38 ± 0.59	P = .469	0.15 ± 0.35	0.19 ± 0.41	P =. 213

All 17 individual symptoms were analyzed to determine differences between treatment groups during the luteal phase of the menstrual cycle with the exception of low backache, no significant differences were found in treatment groups in individual symptoms score during the mean screening. Within the first treatment for the individual symptoms of generalized aches and pains to prove significantly from control. By the second and third treatment months, all symptoms except for fatigue and insomnia showed a significant response to calcium (as shown in table IV) for the symptom of low backache the mean screening score was significantly higher than the control group score (0.82±0.74 vs 0.69±0.66,p=0.033) and became significantly lower than the control group score by the end of third treatment cycle. (0.30±0.45 vs 0.49±0.59,p<0.01).

The percent change from baseline was characterized into 4 groups: a) negative improvement. b) <50% improvement. c) ≥50% improvement d) ≥75% improvement. Nearly

half (55%) of the women in the study group reported ≥50% improvement and one-third (30%) of the women in study group reported ≥75% improvement.

Table 5: Percentage improvement in all 17 symptoms of women in study group

Symptoms	women in study group	
	No.	%
Negative improvement	17	8
More than 50% improvement in all the 17 symptoms	118	55
More than 75% improvement in all the 17 symptoms	60	29
Total	215	100

When we analyzed the differences urban versus rural sites (Kalapinagar Vs Adalaj), significantly lower symptoms score was detected in the urban sites during the first treatment phase with calcium and during the final treatment phase (data not shown). This may be due to more awareness, follow-up and motivation treated by own medical social workers in their urban health training center and its field practice area viz. Kalapinagar, Babu sing ni chali, b/h parag school, and mali no kuvo survey.

COMMENTS AND DISCUSSION:

PMS afflicts millions of premenopausal women and has been described as one of the most common disorders in women. Despite its overwhelming prevalence, clinical investigations exploring its patho-physiologic features have been disappointing. Few therapeutic modalities have proved consistently effective.

This study has found that calcium supplementation effectively alleviates the luteal phase symptoms of PMS. Calcium treatment resulted in an approximately 50% reduction in total mean symptom scores with a significant benefit on symptoms such as depression, Mood swings, Headache, and irritability and breast engorgement. The findings in this community based randomized control trial both in urban & rural area of Ahmedabad and Gandhinagar districts respectively are consistent with an earlier trial reporting a significant benefit. With the use of calcium therapy in women with PMS, calcium was not found effective during the menstrual or inter- menstrual phase of the cycle.

Calcium therapy is inexpensive does not result in bone loss is effective in mood and depression as well as own all 4 symptoms complex and did not result in significant non-compliance due to adverse effects. Calcium supplementation may act by replanting an underlying physiologic deficit suppressing parathyroid hormone secretion, and ultimately reducing neuromuscular irritability and vascular reactivity.

Should PMS prove to be an indicator of low calcium status that encourages premonopausal women to increase their calcium intake, the public health benefit in areas such as osteoporosis; risk reduction could be significant.

Further investigation into adequate close and duration of therapy may provide further benefits for women with PMS. In the study by Kendall & schnurr[7]. A positive effect of B6 (150-mg/ daily) for 2 months treatment period was seen on premenstrual autonomic reactions, such as dizziness & nausea, and on behavior change.

BIBLIOGRAPHY

1. Robert F.Casper, Margaret T. Hearn, The effect of hysterectomy and bilateral oophorectomy in women with severe premenstrual syndrome; American journal of Obstet Gynecol,volume 162;1990: page105-109.
2. Susan Thys-Jacobs, MD, Paul Starkey, MD, "Calcium carbonate and the premenstrual syndrome: Effects on premenstrual and menstrual symptoms " Am. J. Ob/Gy Vol 179 No 2,1998, Page 444- 453.
3. Monika Malhotra, "premenstrual syndrome" Obs. & Gynae. Vol VIII No 3: March 2003 Page: 125-128
4. Robert L. Reid, S.S.C. Yen, "premenstrual syndrome" Am. J. Obstet. Gynecol Vol 139 No 1 Page 85-97.
5. Pradeep Agarwal, S. G. Malik, V.Padubidri "Psychiatric morbidity in patients suffering from menstrual disturbances" Indian F. psychiat (1989) 31(2) Page: 173-176.
6. P.Casson,D.A. Van Vugt, and R.L. Reid, "Lasting response to ovariectomy in severe intractable premenstrual syndrome."; American journal of Obstet Gynecol,volume 162;1990: page99-105.
7. Kendall K, Schnurr P. "The effect of vitamin B6 supplementation on premenstrual symptoms." Obstet Gynecol 1987;70:145-9.