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A RANDOMIZED TRIAL OF A VERY LOW CARBOHYDRATE KETOGENIC DIET V/S LOW FAT/CALORIE RESTRICTED DIET FOR WEIGHT LOSS AMONG OVERWEIGHT/OBESE ADULTS

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ABSTRACT

BACKGROUND: Ketogenic diet is now in trend. But very less researches were conducted in India to check significant effects on weight loss of Ketogenic Diet among overweight/obese adults compared to calorie restricted Low Fat diet.

OBJECTIVE: To compare the effect of Very Low Carbohydrate Ketogenic (VLCK) diet and energy restricted Low-Fat (LF) diets on weight loss in overweight/obese healthy adults.

Design: An interventional randomized controlled trial of 6 months was initiated.

PARTICIPANTS: 113 overweight/obese adults with a body mass index of 25 kg/m2 or greater; with no abnormalities and more than 20 years of age.

INTERVENTION: Among 113 overweight/obese adults, we conducted a six-month randomized controlled trial of two sets of dietary advice, each providing approximately 12,00-1500 calories per day but differing in protein, fiber, fat and carbohydrate content.

RESULTS: We found that dieters given VLCK advice tended to lose more weight than those given a LF diet.

CONCLUSION: For short period of time VLCK diet is more effective than conventional LF diet for weight loss. But for long term effects further studies are required.

KEYWORDS : Ketogenic diet, Low fat diet, Obesity, Weight Loss

INTRODUCTION

In different studies conducted during last decade in India prevalence of obesity was recorded in range of 2.9%-14.3%, and of overweight in range of 1.5%-24.0%.1,2,3,4. In accordance with this many diet programmes, traditional and modern weight loss programs, and fitness clubs were rapidly popular in past 20 years to lose and maintain weight. Despite of all these, the prevalence of overweight/ obesity has doubled in the past decades and has become a major public health problem. The conventional dietary approach to weight management and weight loss, recommended by the leading research and medical societies, is a high-carbohydrate, low-fat, energy deficit diet (LF).5-8 Very-Low-Carbohydrate, moderate-protein, high fat diets (VLCK-Ketogenic) have become increasingly popular, and many best-selling diet books have promoted this approach in foreign countries other than India.9,10

With increasing obesity, and indications to change their life style are impractical. Therefore, to identify diets able to produce significantly and maintained weight loss is mandatory.[11]

The present work evaluated the efficacy of a Very-Low-Calorie-Ketogenic (VLCK) diet in overweight and obese adults compared to Calorie restricted Low-Fat (LF) diet after six month follow-up.

AIM

To review the six month outcomes between VLCK V/S Ketogenic diets on weight loss.

METHODS

Study type: Interventional Study
Study design: Randomized Controlled Trial
Study period: 1st November, 2019 to 30th April 2019

Data Collection: The participants were selected from advertisement, fitness club, awareness workshops etc. Out of total, 113 participants of whom 65 females and 48 males were selected randomly irrespective of race and religion. All the participants were selected in the month of September-November 2019 by doing a study on prevalence of overweight and obesity among adults of Bhuj city.[12] The selected participants were classified based on their BMI values. All the selected participants were free from any medical complications. The selected participants were informed about the both diet programs and experiment on them.

INCLUSION CRITERIA:

- Health adults with BMI > 25 Kg/m2 and
- Age >20 years

EXCLUSION CRITERIA:

- Normal or underweight with BMI ≤ 25 Kg/m2
- Age ≤ 20 years
- Participants with any abnormalities like cardiac patient, diabetic patient, thyroid patient etc.

INTERVENTION:

A six month (1st November, 2019 to 30th April, 2019) intervention study was implemented to test the significance of objective of the study. Consent forms were taken from all the participants after explaining both the diets. Then on participant's choice, they are assigned to either of both diets. Out of 113 participants, 53 chose VLCK diet and 60 chose LF calorie restricted diet.

Diet groups met in weekly counseling sessions for 4 weeks, followed by two sessions on third month and sixth month. Participants on the VLCK diet were instructed only to reduce carbohydrate intake to less than 20 gram per day for first three months, then every week increased carbohydrate intake up to 5 gram per day. Participants on the conventional LF diet were instructed to reduce caloric intake by 500 calories per day, with less than 30% of calories derived from saturated fat.

STATISTICAL ANALYSIS

Data was compiled in M.S.Excel 2007. The primary end point was weight loss at six months.

Given an anticipated dropout rate of 25 percent, we set the Enrollment target at 113 subjects. By six months, 73 subjects remained in the study (30 in the very-low-carbohydrate-ketogenic group and 43 in the low-fat group). The significance level was set at 0.05 for all statistical tests. Descriptive statistics (mean, standard deviation(SD), etc.) were reported for all dependent measures such as body weight, energy, BMI, Waist Circumference and macronutrient intake, etc. The primary outcome was a comparison of body weight during weight loss 6 months for the two treatment conditions t tests, paired for within the group and unpaired for between the groups were used to detect differences in the change in body weight over time.

RESULTS

In present study, 113 participants have participated. Out of that 53(46.9%) choose VLCK diet, and 60(53.1%) choose LF calorie restricted diet to follow for intervention study. Male to female ratio of participants in VLCK diet was 21:32, whereas in LF diet was 27:33 at

baseline. By the end of third month 6 out of 53 participants dropped out from VLCK Diet group and 4 out of 60 participants dropped out from LF diet group. By the end of six months 40 and 47 participants had completed weight loss intervention on VLCK and LF diets respectively.

Table 1: Baseline Characteristice Of Study Participants

CHARACTERISTICS	VLCK DIET	LF DIET	T-STAT	P-VALUE
N	53(46.9%)	60(53.1%)		
Age (year)	39.86±10.30	41.45 ± 9.98	0.82	0.40
Height(cm)	163.12 ± 9.04	163.62 ± 8.62	0.30	0.76
Weight(kg)	82.20 ± 11.78	86.34 ± 13.49	1.74	0.08
Waist circumference (CM)	100.55 ± 8.36	99.82 ± 8.86	0.45	0.64
Body Mass Index(kg/m^2)	30.82 ± 3.05	32.13 ± 3.38	2.14	0.03*
Waist to Height Ratio (cm/cm)	0.62 ± 0.06	0.61 ± 0.05	0.58	0.55

*p-value<0.05, Significant

Among 53(46.9%) participants in the VLCK diet group, 21 were male and 32 were female with mean age 39.86 years[SD,10.30], mean weight was 82.20 kg [SD,11.78], mean waist circumference was 100.55 cm[SD,8.36] with mean BMI 30.82 kg/m^2 [SD,3.05].

Among 60(53.1%) participants in the LF diet group, 27 were male and 33 were female with mean age 41.45 years[SD,9.98], mean weight was 86.34 kg [SD,13.49], mean waist circumference was 99.82 cm[SD,8.86] with mean BMI 32.13 kg/m^2 [SD,3.38].

Body Mass Index of the participants of both the groups was found statistically significant.(p<0.05)

Table 2: Nutrient Composition Of The Different Diets

Variable	VLCK Diet		LF Diet	
	No of participants	Mean (SD)	No. of participants	Mean(SD)
Total Energy Intake, kcal*#				
Baseline	53	2274.4(333.8)	60	2368.75(316.9)
3 month	47	1079.9(251.3)	56	1455.0(156.2)
6 month	40	1320.4(272.0)	47	1142.8(268.8)
Total Carbohydrates, g*#				
Baseline	53	200.7(26.3)	60	197.7(29.3)
3 month	47	45.9(4.8)	54	155.5(31.5)
6 month	40	52.3(7.6)	45	151.7(31.4)
Dietary Fiber, g*				
Baseline	53	23.1(4.3)	60	21.8(4.6)
3 month	47	21.5(2.4)	54	21.9(2.0)
6 month	40	19.3(3.3)	45	20.2(3.3)
Net Carbohydrates, g*#				
Baseline	53	200.7(26.3)	60	197.7(29.3)
3 month	47	13.5(3.1)	54	133.6(31.7)
6 month	40	33.0(6.8)	45	131.4(3.9)
Fat, g *#				
Baseline	53	70.1(18.3)	60	70.8(19.0)
3 month	47	84.0(19.5)	54	38.7(9.2)
6 month	40	95.4(19.7)	45	38.1(9.0)
Protein, g *#				
Baseline	53	40.50(14.02)	60	45.32(14.25)
3 month	47	67.49(15.70)	54	69.7(16.5)
6 month	40	82.5(17.0)	45	68.6(16.1)

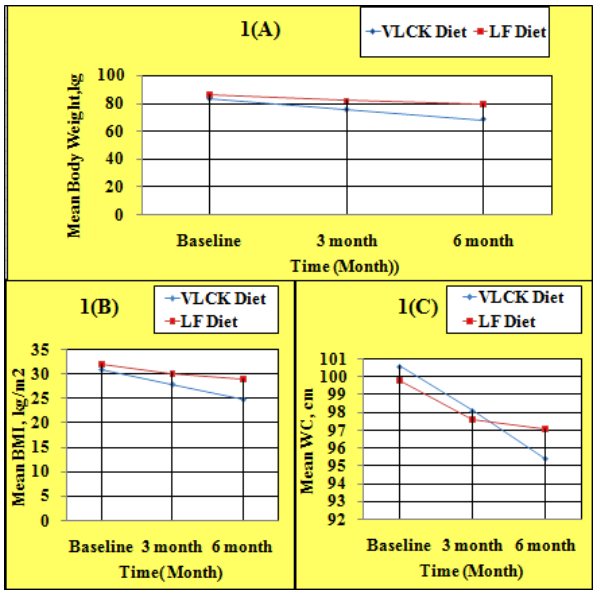
*indicates p<0.05 by paired t test for within group; #indicates p< 0.05 by student's unpaired test for between groups

Assessment of dietary intake

Above table shows the nutrient composition of both the diets VLCK diet and calorie restricted LF diet over different time periods.

As compared with the subjects on the low-fat diet, subjects on the VLCK diet reported a significantly greater decrease in caloric intake (P<0.05), a significantly greater reduction in the percentage of calories from carbohydrates (P<0.01), and a significantly greater increase in the percentage of calories from protein (P<0.01) and fat (P<0.01).

Figure 1: Mean change: (A) Bodyweight, (B) BMI and (C) waist circumference during six months with VLCK and LF diets in the study participants



Above figure shows the change in the body weight (Kg), Body Mass Index (Kg/m^2), and Waist circumference (cm) over the periods of 6 month by two different diets VLCK diet and LF calorie restricted diet.

It was observed that participants on VLCK diet reduce more body weight , BMI and waist circumference with respect to participants on calorie restricted LF diet. (Figure 1(A),(B) and (C)).

DISCUSSION

A total of 103 participants completed 3 months of the study (47 on the VLCK diet and 56 on the LF diet), 87 participants completed 6 months (40 on the VLCK diet and 47 on the LF diet).

The percentage of participants who had dropped out of the study at 3 and 6 months was higher in the group following the LF diet (4(6.67%), 9(15%), respectively) than in the group following the VLCK diet (6(11.32%), 7(13.2%), respectively), but these differences were not statistically significant.

Overall, 87(77%) of participants completed the six-month study and 103(91.15%) of those who completed the three-month assessment completed the full study.

WEIGHT

During the weight loss period (months 1–6) both groups lost significant amounts of body weight. The VLCK diet group decreased body weight by 20.4 ± 6.2 kg (19%) and the LF group 19.1 ± 5.4 kg (18%); the difference between groups was not statistically significant.

Similarly, Body Mass Index and waist circumference, decreased significantly for both groups but differences between groups were not significant.

At the beginning of weight loss the VLCK diet group had a body weight of 89.2 ± 14.4 kg that decreased to 89.3 ± 16.1 kg at 6 months (*P* = 0.84) and the LF diet group had a body weight of 86.3 ± 12.0 kg at 3 months that decreased to 86.0 ± 14.0 kg at 6 months (*P* = 0.96). (Table 2, Figure 1A).

In the statistical analysis in which base-line values were carried forward in the case of missing values, the group on the VLCK diet had lost significantly more weight than the group on the LF Calorie restricted diet at 3 months (P<0.05) and 6 months. (P<0.05) (Table 2 and Fig. 1A).

WAIST CIRCUMFERENCE AND BMI

Waist circumference and BMI were not statistically different between or within groups at any time period (Figure 1(B), and 1(C)).

Comparison of energy and macronutrient intake data during weight loss intervention trial showed that the VLCK diet group consumed significantly more grams of protein, fat, and percentage of total energy intake from protein and fat compared to the LF diet group. The low fat group consumed significantly more total energy, grams of carbohydrate and fiber and a greater percentage of total energy intake from carbohydrate compared to the VLCK diet group. After adjusting for baseline, total energy intake and protein intake were no longer significantly different between groups during weight loss (Table 2).

CONCLUSION

Current study focused a significant gap in the current literature by comparing body weight in participants on either a very low carbohydrate ketogenic diet or low fat calorie restricted diet during a 6 month weight loss period. The primary finding of this study was that a very low carbohydrate ketogenic diet and low fat diet are comparable for body weight reduction over 6 months; however, there was significant variation in weight change within each group.

VLCK dist observed a better diet to reduce body weight as well as reduces inches by fat reduction than the conventional calorie restricted low fat (LF) diet.

RECOMMENTATION

However ketogenic diet provides better results than low fat diet, further long term research is require at least of one year follow up to make the conclusions.

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