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FRUCTOOLIGOSACCHARIDE (FOS)- A SMART STRATEGY TO MODULATE INFLAMMATORY MARKER AND LIPID PROFILE IN NON INSULIN DEPENDENT DIABETES MELLITUS (NIDDM) SUBJECTS RESIDING IN ASSAM, INDIA- A RANDOMIZED CONTROL TRIAL.

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ABSTRACT

Introduction Diabetes mellitus is an important risk factor for CVD. Currently, Fructooligosaccharide (FOS) has been recognized for its potential to improve glycemic, lipemic control and reduce the expression of inflammatory markers. **Objective:** The study was designed with the broad objective to assess the effect of FOS supplementation to the pre hypertensive type 2 NIDDM subjects in terms of glycemia, lipemia, BMI and hs-CRP levels. **Methodology:** Using the randomized control trial study design, 35 pre hypertensive adults with type 2 NIDDM aged 35-55yrs were purposively selected from Sun Valley Hospital, Guwahati, Assam, and were randomly divided into Control(N=10) and FOS group (N=25). Background information was collected for glycemia, lipemia, hs-CRP and BMI. The FOS group was supplemented with 10ml of liquid FOS daily to be taken along with meals, for 45 days and post data was collected on the parameters similar to the baseline. **Results:** FOS supplementation resulted in a significant reduction ($p<0.001$) in FBS, PP_2BS and HbA1c by 6.3%, 9.8% and 10.6% respectively. A significant reduction ($p<0.001$) was also seen in TG, TC, LDL-C, VLDL by 7.9%, 14.4%, 8%, 9.6% respectively and a significant increase ($P<0.001$) in HDL-C by 25.1%, while hs-CRP and BMI significantly

reduced by 27.2% and 1.3% respectively. **Conclusion:** Daily intake of 10 ml of liquid FOS can be recommended as an attractive therapy to improve glycemia, lipemia, along with hs-CRP in pre hypertensive type 2 NIDDM subjects.

KEYWORDS: FOS, diabetes mellitus, hypertension, hs-CRP.

INTRODUCTION

Cardiovascular diseases (CVDs) are the largest cause of deaths in the world. According to WHO-2014, raised blood pressure is a major cardiovascular risk factor. The global prevalence of diabetes with hypertension is relatively high and rapidly rising in the developing countries like India. (L. Guariguata et al 2014, P. Hossain et al, 2007). The lifestyle practices of the subjects are also deseeding. The current popular mode of treatment and prevention are pharmacological drugs and these drugs are not free from side effects. Therefore, there is a need for a food based strategy and development of an advocacy tool which is easily adaptable and can help in improving the cardiovascular health and reduce the prevalence of diabetes with hypertension. Fructooligosaccharide (FOS) has been recognized for its great potential which is becoming apparent as a considerable food element in increasing the bacterial bionomics which might have a concrete role in reducing the burden of CVDs by regulating hypertension, improving glycemic, lipemic control and reducing the expression of inflammatory markers. (L-G Ooi and M-T Liong, 2010, P. Dehghan, 2014, Z. Asemi et al, 2013).

The study was designed with the broad objective to assess the effect of FOS supplementation to the pre hypertensive type 2 NIDDM subjects in terms of glycemia, lipemia and hs-CRP levels.

MATERIALS AND METHODS

Selection of subjects: Pre hypertensive with type 2 NIDDM aged 35-55yrs were purposively selected from Sun Valley Hospital, Guwahati, Assam and baseline information was collected on their anthropometric profile, lipid profile, FBS, PP_2BS, HbA1c and hs-CRP.

The inclusion criteria for selecting the patients were: pre hypertension (SBP-120-139mmHg; DBP-80-89mmHg), HbA1c between 7-9.5%, BMI between 18.5-<30. Subjects with BMI> 30, HbA1c >9.5%, those suffering from any disease like cancer, HIV, IBD, etc. or would

have taken antibiotics in last two months, who have undergone surgery in last 6 months and those in need of dental treatment were excluded from the study.

Intervention trials with FOS supplementation: Based on their informed consent, 35 subjects fulfilling the inclusion and exclusion criteria were selected purposively and were randomly divided into Control (N=10) and Experimental groups (N=25). The experimental group was supplemented with 10 ml of liquid FOS daily to be taken along with meals for 45 days.

Impact Evaluation of the FOS supplementation: Blood samples were collected and were estimated using standard methods after 45 days of intervention to check the parameters similar to the baseline for both the groups.

Biochemical Assay methods

Fasting blood glucose (FBS) and Post prandial blood glucose (PP2BS) were estimated using enzymatic reference method with hexokinase (Reinauer et al 2002). Glycated Hemoglobin (HbA_{1c}) was quantified assayed using IFFC and FDA approved automated dedicated high performance liquid chromatography (HPLC) method (IFFC 2002). Estimation of hs-CRP was by using automatic chemistry analyzer manufactured by Siemens and Model: Advia 2400.

RESULTS AND DISCUSSION

The present study with liquid FOS supplementation resulted in a significant reduction ($p<0.001$) in FBS, PP_2BS and HbA1c by 6.3%, 9.8% and 10.6% respectively. Another study conducted by supplementing probiotic fermented milk and synbiotic fermented milk revealed a significant reduction of 5.2% and 7.8% for FBS values respectively (S. Parnami and M. Sheth, 2011). Similar finding was revealed by P. Dehghan in the year 2014 on diabetic females who received 10g/d inulin for 8 weeks and exhibited improvement in glycemia by a significant reduction in FBS (8.5%).

The present study also revealed a significant reduction ($p<0.001$) in TG, TC, LDL-C, VLDL by 7.9%, 14.4%, 8%, 9.6% respectively and a significant increase ($P<0.001$) in HDL-C by 25.1%. A higher reduction by N. Jain and M. Sheth, (2014) was reported on improvement in the lipemic parameters when the young obese subjects were supplemented with 20 g of FOS for a longer duration. Another study by S. Parnami and M. Sheth, 2011 on prebiotic and synbiotic fermented milk supplementation on elderly for a period of six weeks resulted in 3.57% and 6.9% reduction in TC and 0.75% and 4.1% increase in HDL levels respectively. A

significant reduction in TG (4.3%) and LDL levels (8.3%) in synbiotic group was observed. There was a 5.5% reduction in LDL-C in male participants of synbiotic supplemented group respectively.

The present study resulted that hs-CRP significantly reduced ($p<0.001$) by 27.2%. Similarly, P. Dehghan in the year 2014 conducted a study on diabetic females who received 10 g/d inulin for 8 weeks and exhibited a significant decrease in hs-CRP (35.6%) compared to the control group. There is a limited evidence of prebiotic on inflammatory marker. A study by Z. Asemi et al (2013) on consumption of a synbiotic food for 6 weeks among diabetic patients, compared to the control, also resulted in a significant decrease on hs-CRP levels ($P = 0.01$).

The present study revealed that BMI significantly reduced ($p<0.001$) by 1.3%. Significant reduction in BMI was also observed in a study conducted by M. Sheth and A. Asudani in 2014 on obese young adults when 20g FOS/d was supplemented for 90 days. A study by B. Cicek et al (2009) also reported that BMI of the patients significantly decreased ($p<0.001$) on consumption of 20g oligofructose and polydextrose for 6 weeks.

Table I: reveals the impact of liquid FOS supplementation on hs-CRP, glycemia, lipemia and BMI.

Parameters	GROUPS	MEAN±SD	t stat	Paired two tail	% difference
hs-CRP	Control Pre	1.193 ± 0.335	0.14	0.89	0.25↑
	Control Post	1.196 ± 0.287			
	FOS Pre	1.129 ± 0.30	6.81	**4.79*****	**27.25%↓**
	FOS Post	0.796 ± 0.23			
FBS	Control Pre	141.5 ± 17.56	3.61	0.005	4.24↑
	Control Post	147.5 ± 17.55			
	FOS Pre	160.16 ± 20.95	12.67	**4.02*****	**6.29↓**
	FOS Post	147.24 ± 19.43			
PP2BS	Control Pre	170.6 ± 15.19	3.36	0.008	2.63↑
	Control Post	175.1 ± 16.73			
	FOS Pre	184.2 ± 13.70	16.99	**6.90*****	**9.85↓**
	FOS Post	167.04 ± 14.19			
HbA1c	Control Pre	7.48 ± 0.40	1	0.34	0.13↑
	Control Post	7.47 ± 0.40			
	FOS Pre	8.16 ± 0.81	9.14	**2.72*****	**10.64↓**
	FOS Post	7.1 ± 0.76			
TG	Control Pre	197.5 ± 80.68	1.94	0.08	0.89↑
	Control Post	199.6 ± 79.53			
	FOS Pre	160.12 ± 68.40	14.7	**1.63*****	**7.9↓**

	FOS Post	146.68 ± 69.88			
TC	Control Pre	181.7± 38.12	2.43	0.03	5.2↑
	Control Post	184 ± 37.34			
	FOS Pre	166.16 ± 26.50	14.4	**2.47*****	**8.75↓**
	FOS Post	150.52 ± 27.45			
HDL	Control Pre	38 ± 5.92	3.08	0.01	3.15%↓
	Control Post	36.8 ± 5.65			
	FOS Pre	35.84 ± 5.78	15.08	**9.63*****	**25.14%↑**
	FOS Post	46.08 ± 6.43			
LDL	Control Pre	140.4 ± 10.87	2.75	0.02	2.71%↑
	Control Post	141.2 ± 11.94			
	FOS Pre	136.36 ± 14.44	12.4	**6.2*****	**8.03%↓**
	FOS Post	119.32 ± 17.21			
VLDL	Control Pre	29.06 ± 10.89	1.78	0.10	4.26%↑
	Control Post	30.3 ± 10.47			
	FOS Pre	36.92 ± 9.86	5.11	**3.11*****	**9.63%↓**
	FOS Post	33.4 ± 8.33			
BMI	Control Pre	24.93±2.81	2.02	0.07	0.79%↑
	Control Post	25.12±2.83			
	FOS Pre	25.48± 3.37	4.27	**0.00*****	**1.3%↓**
	FOS Post	25.14±3.29			

*Supplied by Tata Chemicals India

CONCLUSION

The pre hypertensive type 2 NIDDM subjects under the present study had poor glycemic control. The lipemic levels were in borderline high with moderate prevalence of hypertension and inflammatory marker in the intermediate level. Supplementation with liquid FOS (10ml) for 45 days is an attractive strategy for the management of type 2 diabetic subjects which resulted in reduction in the blood glucose (FBS, PP2BS and HbA_{1c}), blood lipid (TG, TC, LDL, VLDL), and hs-CRP levels, increase in HDL. Hence incorporation of liquid FOS (Tata Chemicals India) in food products can be recommended in the daily diets for better glycemic and lipemic control.

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