EFFECT OF CAMEL MILK ON GLYCEMIC CONTROL, RISK FACTORS AND DIABETES QUALITY OF LIFE IN TYPE-1 DIABETES: A RANDOMISED PROSPECTIVE CONTROLLED STUDY

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ABSTRACT

The aim of the study was to evaluate the efficacy of camel milk on glycemic control, risk factors and quality of life in patients of type 1 diabetes. Twenty-four randomly selected patients with type 1 diabetes were enrolled in the study. These patients were divided into two groups. Group 1 (n=12) received usual care (diet, exercise and insulin) and group 2 (n=12) received 500 ml camel milk in addition to usual care, for a period of three months. Frequent blood sugar monitoring was done to maintain euglycemia by titrating the doses of insulin. HbA_{1c}, Lipid profile, plasma insulin and C-peptide estimation was done at the beginning and after 3 months. BMI and diabetes quality of life questionnaire were evaluated weekly. In each visit, the patient was queried for any untoward effects after starting camel milk. Baseline data of both the groups were similar in demographic and clinical variables. After 3 months of treatment there was a significant improvement in fasting blood sugar (115.7 ± 7.2 to 100 ± 16.2, $p<0.002$), HbA_{1c} levels (9.54 ± 2.1 to 9.08 ± 1.77, $p<0.002$) and a significant reduction in insulin requirement (mean doses of insulin 41.2 ± 10.3 to 30 ± 12.6 units, $p<0.002$) in patients receiving camel milk. Diabetes quality of life score improved significantly in the form of change in satisfaction score from 28 ± 5.16 to 22.5 ± 3.96 ($p<0.002$), impact score from 34 ± 4.84 to 28.08 ± 5.26 ($p<0.003$) and worry score from 15.5 ± 3.2 to 11.91 ± 1.24 ($p<0.002$). There was 30% reduction in doses of insulin in 92% of patients of group 2. However, there were no statistically significant changes in lipid profile, plasma insulin and C-peptide levels. Camel milk is an effective supplementation in the management of type 1 diabetes as there was significant reduction in doses of insulin along with betterment in BMI and diabetes quality of life. However, there was no change in lipid profile and insulin levels.

KEYWORDS: Type 1 diabetes; Camel milk; Alternative therapy; Diabetes quality of life questionnaire.

INTRODUCTION

Type I diabetes mellitus is an organ specific auto immune disease, characterized by chronic hyperglycemia and disturbances in carbohydrates, fat and protein metabolism associated with insulin deficiency. Cow milk feeding induces primary immunization to insulin in infants at genetic risk for type 1 diabetes (1). The incidence of diabetes mellitus worldwide appear to be increasing (2). Prevention and early treatment is important because diabetes interrupts normal development in children and carries the threat of severe complications in adulthood (3). The primary treatment is insulin replacement. However, at present, physiological insulin replacement is difficult to achieve in clinical practice and metabolic disturbances cannot be normalized. Insulin therapy is still the best treatment, but in our country needle phobia and cost of the treatment forces these patients to adopt alternative treatments. In this connection we have heard many folklore stories that describe the use of camel milk in type-1 diabetes mellitus. There is also an account in memoirs of Emperor Jahangir (1579 - 1627 AD) about usefulness and acceptability of camel milk (4). It is observed that one of the camel milk proteins has many characteristics similar to insulin (5) and it does not form a coagulum in acidic environment (6). This lack of coagulum formation allows the camel milk to pass rapidly through the stomach together with the specific insulin like protein/insulin which remains available for absorption in intestine. Radioimmunoassay of camel milk has revealed high concentration of insulin i.e. 52 units/liter (7). The concentration of insulin in human milk is also high (60.23 ± 41.05 micro u/ml), whereas it is very low in cow milk (16.32 ± 5.98 micro u/ml) (10).

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MATERIAL AND METHODS

Subjects: A total of 24 type 1 diabetic patients were randomly recruited from the outpatient diabetic clinic in PBM Hospital, Bikaner, India. Ethical committee of S.P. Medical College, Bikaner approved the protocol and all subjects gave written consent before participation in the study. The patients were advised to follow a strict diet, exercise and insulin treatment for one month. During this period, frequent monitoring of blood sugar was done to maintain euglycemia. After one-month period, these patients were again randomly divided into two groups. Group 1 patients (n=12) received usual care i.e. diet, exercise and insulin and the Group 2 patients (n=12) received 500 ml of camel milk in addition to usual care for 3 months. Patients with any acute metabolic complications like hypoglycemia, ketoacidosis, cardiovascular event, renal or acute infections were not included in the study.

Study Design and Analysis: This was a randomized, open case control, parallel design study. Blood glucose was measured twice in a week before breakfast and before dinner using the glucose oxidase method. Plasma insulin and C-peptide were estimated by fully automated chemiluminescence (CLIA test). Anti-insulin antibodies were estimated by radioimmunoassay. HbA_{1c} was measured by high performance liquid chromatography (HPLC). Plasma total cholesterol, triglycerides, VLDL, HDL, LDL was estimated by fully automated biochemistry analyzer. Urine microalbumin was tested by micral test. Body mass index, waist hip ratio, and 'diabetes quality of life' score were also measured every week (9,10).

Statistical Analysis: As the normality of the variables in the study could not be assured, Wilcoxan matched pair test and Mann-Whitney U test were used instead of t tests. The two groups had equal number of participants

Table 1: Base Line Characteristics of Study Groups

Variables	Group 1, n=12		Group 2, n=12		t	p
	Mean	± SD	Mean	± SD		
Age (Yrs)	20.3	± 5.0	19.5	± 8.15	1.131	0.257
W/H Ratio	0.75	± 0.08	0.81	± 0.05	1.642	0.109
BMI (Kg/m^2)	18.43	± 3.59	20.21	± 2.97	0.346	0.729
HbA_{1c} (%)	9.51	± 2.09	9.54	± 2.10	1.472	0.140
Dose of Insulin (units/day)	40	± 8.6	41.2	± 10.3	0.028	0.976
Mean Blood Sugar (mg/dl)	117.2	±17.7	115.7	± 7.2	0.812	0.416
Cholesterol (mg/dl)	165.8	±19.2	164.6	± 20.7	0	1
HDL (mg/dl)	61.6	± 9.1	62.6	± 13.9	1.944	0.051
LDL (mg/dl)	89.6	±14.7	92	± 11.6	1.097	0.272
VLDL (mg/dl)	14.4	± 4.7	13.5	± 5	0.433	0.664
TG (mg/dl)	72.4	±20.7	66.9	± 25.6	0.636	0.524
Microalbuminuria (mg/dl)	22.54	± 5.62	22.13	± 5.10	0.288	0.772
Plasma Insulin (μIU/ml)	16.37	± 7.57	16.79	± 6.57	0.346	0.729
C Peptide (ng/ml)	1.24	± 0.6	1.26	± 0.61	0.375	0.707
DQOL Score:						
Satisfaction	26.16	± 2.58	28	± 5.16	1.687	0.091
Impact	29.58	± 2.6	34	± 4.84	-1.285	0.198
Worry	13.0	± 0.05	15.5	± 3.20	1.508	0.131

(Values = Mean ± S.D.) (*p=<0.05)

and they were compared with each other using Mann-Whitney U test. The value of $p<0.05$ was considered significant for Mann-Whitney U-test after Satterthwaite correction. The variables were compared at three months to that at the start of the study using Wilcoxan matched pair test with cut off value being decided at $p<0.05$.

RESULTS

Demographic characteristics are summarized in table 1. The group 1 (control group) and group 2 (camel milk group) were similar in age (20.3 ± 5.0 vs. 19.5 ± 8.2 years), sex (10M, 2F in both groups), body mass index (18.43 ± 3.59 vs. 20.21 ± 2.97), fasting blood glucose (117.2 ± 17.7 vs. 115.7 ± 7.2), plasma insulin (16.37 ± 7.57 vs. 16.39 ± 6.57) and C-peptide levels (1.24 ± 0.6 vs. 1.26 ± 0.61). Plasma lipids along with different clinical, demographical and biochemical variables were also comparable.

After three months of treatment there was statistically significant increase in body mass index (20.21 ± 2.97 to 21.3 ± 2.95 Kg/m^2, $p<0.05$), and improvement in fasting blood glucose (115.7 ± 7.2 to 100 ± 16.2, $p<0.002$) and in HbA_{1c} (9.54 ± 2.1 to 9.08 ± 1.77%, $p<0.002$), in the camel milk group. These parameters were either unchanged or there was a slight increase in group 1 patients (Table 2). Fasting plasma insulin and C-peptide levels did not reveal a significant change in either group and so were the levels of lipid profile, after three months of treatment. The diabetes quality of life questionnaire score changed significantly in favor of camel milk (i.e. satisfaction score 26.08 ± 4.11 to 22.5 ± 3.96, $p<0.05$, impact score 32.5 ± 2.71 to 28.08 ± 5.26, $p<0.05$ and worry score 14.66 ± 1.15 to 11.9 ± 1.24, $p<0.05$). There was a significant reduction in the mean doses of insulin (41.16 ± 10.32 to 30 ± 12.6u, $p<0.002$) in patients receiving camel milk. (Table-3, Fig

Table 2: Group 1 Versus Group 2 at 3 Months

Variables	Group 1, n=12		Group 2, n=12		Mann-Whitney U test	
	Mean	± SD	Mean	± SD	Z adjusted	p value
Age (Yrs)	20.3	± 4.1	19.5	± 8.2	-1.131	0.257
W/H Ratio	0.75	± 0.08	0.81	± 0.05	-1.379	0.164
BMI (Kg/m^2)	18.41	± 3.51	21.3	± 2.95	-1.328	0.184
HbA_{1c} (%)	9.48	± 1.96	9.08	± 1.77	-1.905	0.056
Dose of Insulin (units/day)	38.5	± 8.5	30	±12.06	-2.139	0.032*
Mean Blood Glucose (mg/dl)	118.2	± 7.2	100	±16.2	-3.935	< 0.05
Cholesterol (mg/dl)	168.1	± 15.6	158.3	±21.6	-0.433	0.664
HDL (mg/dl)	58.7	± 15.61	66.7	±11.3	-0.115	0.907
LDL (mg/dl)	89.7	± 12.3	79.2	±17.8	-0.981	0.326
VLDL (mg/dl)	14.3	± 3.2	12.1	± 5.1	-1.041	0.297
TG (mg/dl)	72.0	± 14.8	60.2	±25.2	-0.520	0.603
Microalbuminuria (mg/dl)	22.9	± 5.43	25.17	± 5.43	-0.230	0.817
Plasma Insulin (mIU/ml)	16.3	± 7.5	16.94	± 6.54	-0.173	0.862
C Peptide (ng/ml)	2.28	± 0.63	2.22	± 0.5	-0.723	0.469
DQOL Score						
Satisfaction	22.75	± 2.37	22.5	± 3.96	-3.034	0.002*
Impact	29.5	± 2.93	28.08	± 5.26	-2.175	0.029*
Worry	12.58	± 1.16	11.91	± 1.24	-4.073	< 0.05

(Values = Mean ± S.D.) (*p=<0.05)

1) The acceptability of camel milk was very good and only one patient complained of mild flatulence for 3-4 days. Mild diarrhea (2-3 semisolid stools) was reported by two patients, which also subsided spontaneously.

DISCUSSION

The present study was performed to observe the role of camel milk in achieving glycemic control in type-1 diabetic patients. We observed a significant improvement in mean BMI (20.21 ± 2.97 to 21.3 ± 2.95, p<0.002) after three months of camel milk treatment. The positive effects in weight gain may be because of good nutritional value of camel milk. There was no change in lipid profile and it may be due to lower fat content of camel milk. (i.e. 2.49-3.1 gm% vs. cow milk 3.79 gm%).

We also observed significant reduction in insulin doses to obtain glycemic control along with significant improvement in HbA_{1c} level at the end of three months. No other studies are available for comparison. Improvement in microalbuminuria may be due to good glycemic control or it may be due to direct effect of camel milk. There was marked improvement in diabetes quality of life score after 3 month of camel milk treatment. It

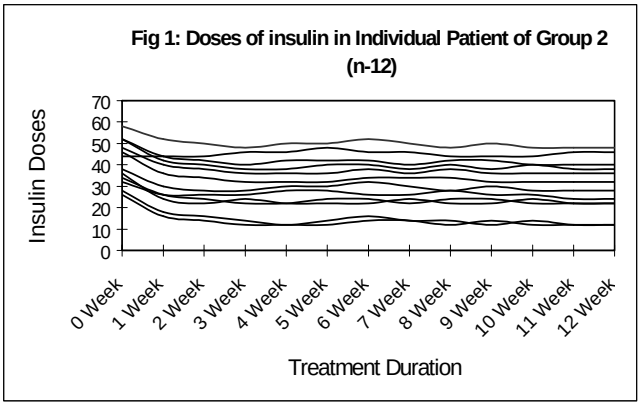

Table 3: Group 2 Before and After Treatment

Variables	0 Month		3 Months		Wilcoxon matched pairs test	
	Mean	± SD	Mean	± SD	Z	p value
Age (Yrs.)	19.5	± 8.15	19.5	± 8.15		
W/H Ratio	0.81	± 0.05	0.81	± 0.05	1.01	0.312
BMI (Kg/m^2)	20.81	± 2.97	21.3	± 2.95	3.06	0.002*
HbA_{1c} (%)	9.54	± 2.1	9.08	± 1.77	3.06	0.002*
Dose of Insulin (units/day)	41.2	±10.3	30	± 12.06	3.06	0.002*
Mean Blood Glucose (mg/dl)	115.7	± 7.2	100	± 16.2	3.06	0.002*
Cholesterol (mg/dl)	164.6	±20.6	158.3	± 21.6	1.29	0.195
HDL (mg/dl)	62.6	±13.9	66.7	± 11.3	0.86	0.388
LDL (mg/dl)	92	±11.6	79.2	± 17.8	2.04	0.040*
VLDL (mg/dl)	13.5	± 5	12.1	± 5.1	1.42	0.155
TG (mg/dl)	66.9	±25.6	60.2	± 25.2	1.02	0.306
Microalbuminuria (mg/dl)	22.13	± 5.1	25.17	± 5.43	0	1
Plasma Insulin (mIU/ml)	16.79	± 6.57	16.94	± 6.54	1.17	0.239
C Peptide (ng/ml)	2.26	± 0.61	2.22	± 0.5	1.45	0.146
DQOL Score						
Satisfaction	28	± 5.16	22.5	± 3.96	3.06	0.002*
Impact	34	± 4.84	28.08	± 5.26	2.93	0.003*
Worry	15.5	± 3.2	11.91	± 1.24	3.05	0.002*

(Values = Mean ± S.D.) (*p=<0.05)

may be because of good glycemic control or anabolic effect of camel milk. El Agamy (1992) (11) found good amount of lysozyme, lactoferrin, lactoperoxidase, immunoglobulin G and secretory immunoglobulin A in camel milk.

Requirement of mean doses of insulin/day before treatment in patients of group-2 was 41.2 ± 10.32. It came down very fast initially and then gradually to a mean level of 30±12.06, ($p<0.05$). Only one patient out of 12 patients required the same doses of insulin and the other 11 patients had lower requirement to maintain euglycemic blood level. Camel milk was found to contain about 52 units/liter insulin (Raghvendra Singh, Senior Scientist, NRCC, Bikaner, Personal Communication) and it may be the reason for lesser requirement of insulin in camel milk group. Oral insulin has been known since many years but the important drawback is its coagulum formation in acidic media in stomach thereby neutralizing its potency. The lack of coagulum formation of camel milk may act as an effective vehicle to take the insulin present in it in an unchanged form to the intestine and from there it can be absorbed, even if some amount is destroyed in the passage. Beg (1986) (12) has found that the amino acid sequence of some of the camel milk protein is rich in half cystine, which has superficial similarity with insulin family of peptides.

The data of this study shows a significant hypoglycemic effect of camel milk when given as an adjunctive therapy. The action is presumed to be due to presence of insulin/insulin like protein in it. Its therapeutic efficacy may be due to lack of coagulum formation of camel milk in acidic media. There is no doubt that the discovery and development of oral insulin for therapeutic use is a Himalayan task. It has been observed that oral administration of insulin initiated at clinical onset of type 1 diabetes did not prevent the deterioration of beta cell function (13). P. Pozzilli et al in IMDIAB VII study indicates that addition of 5mg of oral insulin does not modify the course of the disease in the first year after diagnosis and probably does not statistically effect the humoral immune response against insulin (14). It is important to note that a certain level of scientific testing on camel milk has been already attempted and documented, particularly, insulin levels in camel milk and this scientific wisdom can be a remarkable achievement for diabetic patients.

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