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Original Research Article

To assess the effect of intervention package in type 2 diabetes self-care practices, an experimental epidemiological study

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ABSTRACT

Background: Keeping into mind the importance of diabetic self-care practices for control of diabetes burden and preventable complications, the present study was carried out to introduce appropriate health intervention package which upon operationalization leads to improvement in self-care practices and to assess effect of intervention packages with help of predetermined indicators. The objectives were to study of life style adaptations and self-care practices and to study effects of intervention package.
Methods: The present study adapted as an experimental epidemiological study, community based with before and after intervention comparison design. Sample size estimated as 203. Total 250 patients were selected by simple random sampling method and grouped into 8 batches. Intervention package which includes health education, patient counseling, periodic check-up, advise for referral. All batches were followed up with operationalization of intervention package for 12 months. Post intervention data then collected and analyzed with pre intervention data.
Results: Effectiveness of intervention package in glycemic control ($p<0.046$) and decreased calories intake in diabetic patients ($p<0.01$). Major changes in self-care practices have effect on better glycemic control and calorie intake ($p<0.03$). Both lifestyle adaptations and self-care practices improved significantly ($p<0.01$) after intervention.
Conclusions: Health and nutritional education, personal counselling, periodic health check-up, Referral advice are important as an intervention package to bring about blood glucose level control, modify diet and lifestyle and to improve self-care practices amongst the diabetic patients.

Keywords: Self-care, Intervention package, Life style adaptations

INTRODUCTION

The number of people with diabetes in India, currently around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken. During the year 2004, there were an estimated 37.7 million cases of diabetes in country, of these 21.4 million in urban areas and 16.3 million in rural areas. The estimated total mortality due to diabetes was 1.09 lac; 62.5 thousand in urban areas and 46.6 thousand in rural areas. Same year 2.2 million DALYs were lost due to the disease.[1]

In 2013, according to the World Health Organization, at least 347million people worldwide suffer from diabetes, or 2.8% of the population.[2]

Health education and diabetes mellitus

Community-based self-management education differs from traditional education in several ways. First and probably most important is that it is based on patient-perceived problems. Patients' needs determine the program content. Secondly, program content emphasizes

the teaching of skills such as problem solving and decision making. The purpose of the education is to prepare people with diabetes to have the skills and confidence to manage their disease on a daily basis and to manage its impact on life roles and emotions. Thirdly, such education takes place in community settings, which are not only more convenient, but also familiar to the target population. The scheduling of the education is also based on patient rather than professional convenience.[3]

The present study was carried out to introduce appropriate health intervention package which upon operationalization leads to improvement in self carepractices and to assess effect of intervention packages with help of predetermined indicators.

METHODS

Study area and population

Urban slum area of Shivajinagar, Govandi was the study area; it has population 84783 as per record of local health post. (census 2011).

The population of study area consists of people migrated from different parts of India in search of job and are now engaged in small scale industries like Zari work, Bag making, Mat weaving and Carpentry etc. Most of men are self-employed and women are house wives, maid servants or vegetable vendors.

Study design

The present study adapted as an experimental epidemiological study, community based with before and after intervention comparison design. It was conducted during the period of February 2014 to December 2015.

Calculation of sample size and sampling method

- According to NFHS data 2005 -06 the population of more than 40 years is around 25.8%. This when applied to the study area, total Population of more than 40 years totals 21874. Assuming the prevalence of type 2 diabetes around 9.3%in urban slum, total type 2 diabetic expected were 2034.[4,5] Taking 10% of this population, sample size was 203.4.
- Taking into account likely loss to follow up, intervention phase sample size was taken as 250 (20% above calculated sample size). The final sample size of 215 was taken under the study and analysed as 35 study subjects were lost to follow up due to various reasons. Simple random sampling method (using random number table) was used for sample collection.

Intervention package

Intervention package incorporates following measures:

- Health education
- Patient counselling
- Periodic check up
- Advise for referral

Delivery of intervention package

A. Health education sessions

Health education sessions were conducted in an urban health centre in geriatric clinic with the help of power point presentation which incorporate

1. Basic information about diabetes and its symptoms and complications.
2. What type of food should be or should not be taken by diabetic patient.
3. Role of taking regular prescribed medicines and insulin injection.
4. Importance of diet control and regular physical exercise in controlling Blood sugar.
5. Importance of regular follow-up for their physical examination, foot examination, blood pressure and weight check-up.
6. Life style and self-care practices in diabetes mellitus.

Formation of batches

Health education sessions were conducted in batches. Total 250 patients were grouped into 8 batches. Each batch comprised of 30-32 patients. All participants were told to attend health education session on particular day. Health education was given in local language.

Health education session was said to be

1) Complete: for those who attended from beginning to end or at least 3-4 times.
2) Partial: for those who attended for less than 3 times.
3) Nil: for those who did not attended at all.

B. Pamphlet mentioning key points on diabetes and diet was given to every patient.

C. Personal counselling

Conducted to address individual specific problems related to self-care practice and life style patterns.

D. Periodic examination

Periodic examination was conducted at beginning of each health education session,witha gap of 3 months so that at least 4 visits were possible for each batch.

A. Advise for referral

Patients with any complications were referred to higher centers for expert's opinion.

F Indicators monitored were:-

1) Number of patients observing practices
2) Changes in lifestyle and self-care scores
3) Blood pressure: systolic diastolic
4) Blood sugar: fasting post prandial
5) BMI
6) Calorie intake
7) Complications

Duration of study

This study was conducted for period of twenty three months. By taking, inclusion and exclusion criteria into consideration, total 250 diagnosed cases of diabetes were identified who were willing to participate in the study by employing simple random sampling method (using random number table).

The information was collected about sociodemographic factors, family history, addiction, duration of disease, complications and associated disorders.

The necessary information on lifestyle and self-care practices was collected by conducting face to face interview using semi constructed pretested questionnaire and written informed consent was taken prior to the interview.

The study subjects were later subjected to general and systemic examination. Height was measured in centimeters from head to toe using a measuring tape in standing position (subject standing with heel touching to the wall). Weight was measured by using potable weighing machine in kilograms in standing position without foot wears.

Blood pressure was measured by using sphygmomanometer as millimeters of mercury in sitting position. Body mass index (BMI) measured by Quetelet's Index, was used as indicator of obesity. A necessary examination such as blood sugar, urine examination was done with appropriate technique in an urban health centre laboratory.

Life style changes and self-care practices were assessed by weighted score method by taking ten points for each and giving one mark to each positive response and zero to each negative response. They were classified as 'some', 'moderate' and 'major' based on scores, <4, 4-7 and >7 respectively.

All participants were registered in clinic in an urban health centre and followed up for 12 months from June 2014 to May 2015 for intervention. 250 patients were grouped in 8 batches. Each batch comprised of 30 to 32 patients. All participants were asked to attend health education session on particular day. The health education was given in local language.

After completion of 12 months of intervention, information was collected about lifestyle modification and self-care practices toward the diabetes.

Composite score method was used to grade different & multiple responses of the patients towards life style and self-care practices adopted by them at the beginning of the study, as well as at the end of 1 year of follow up after intervention.

SPSS (16 version) was used for analysis of the data. The results were analysed using statistical tests (Chi Square test, Paired and unpaired T Tests, One Way Anova).

Inclusion criteria

Inclusion criteri were patients who were above age of 40 years; patients diagnosed case of Type 2 Diabetes mellitus for at least 6 months; patients who were the resident of study area for at least for 1 year; patients those had any one proof of disease like blood sugar report, medical record or prescription from physician or medicines.

Exclusion criteria

Exclusion criteria were bed ridden patients; patient who were out of station during the period of pre intervention data collection; patients unwilling to participate in the study; patients unable to communicate.

RESULTS

Table 1 shows that those patients with 'moderate' to 'major' life style changes after intervention has low mean Fasting and mean post prandial blood sugar level compared to those with only 'Some' changes. This indicates the effectiveness of intervention package on glycemic control in diabetic patients. It was also seen that subjects with 'major' changes in life style adaptations had decrease calories consumption.

It was observed from Table 2 that those patients with 'moderate' to 'major' changes in self-care practices had significantly lower fasting blood sugar and low calories intake compared to those had only 'some' changes in self-care practices post intervention.

On applying paired sample t test on pre intervention to post intervention findings, it was seen that both Life style and self-care are improved significantly after intervention. These are important parameters to control the diabetes (Table 3).

Table 4 shows that there was significant percentages of patients (65%) and (20.5%) respectively adopting moderate to major changes in self-care practices after one year of intervention compared to(27%) and (1.8%) in pre intervention.

Table 1: Mean difference among life style changes (post intervention).

Dependent variable	Life style changes	N	Mean	Std. deviation	Std. error	F	Significance
Fasting blood sugar	Some	20	151.65	41.97	9.38	3.127	0.046
	Moderate	116	131.66	38.94	3.61		
	Major	79	128.80	32.07	3.60		
	Total	215	132.47	37.23	2.53		
PP blood sugar	Some	20	199.55	69.16	15.46	4.607	0.011
	Moderate	116	199.76	70.59	6.55		
	Major	79	174.89	24.16	2.71		
	Total	215	190.60	58.81	4.01		
Calories intake	Some	20	1600.20	688.47	153.94	3.994	0.02
	Moderate	116	1399.91	387.51	35.97		
	Major	79	1306.06	392.97	44.21		
	Total	215	1384.06	431.06	29.39		

Table 2: Mean difference among self-care changes (post intervention).

Dependent variable	Self-care	N	Mean	Std. deviation	Std. error	F	Significance
Fasting blood sugar	Some	31	153.10	41.86	7.51	6.06	0.03
	Moderate	140	127.96	31.34	2.64		
	Major	44	132.27	46.12	6.95		
	Total	215	132.47	37.23	2.53		
Calories	Some	31	1625.77	598.78	107.54	6.019	0.03
	Moderate	140	1337.47	405.52	34.27		
	Major	44	1361.98	305.49	46.05		
	Total	215	1384.06	431.06	29.39		

Table 3: Paired sample correlations (pre-post intervention).

Variables (pre and post intervention)	Paired differences			Correlation	t value	Significance
	Mean difference	Std. deviation	Std. error			
Lifestyle	1.77	2.38	0.16	0.6	10.9	0.001
Self-Care	2.49	1.65	0.11	0.62	22.09	0.001
BMI	0.56	0.99	0.07	0.98	8.31	0.001
Systolic BP	11.43	13.82	0.94	0.71	12.13	0.001
Diastolic BP	7.14	13.38	0.91	0.21	7.82	0.002
Fasting blood sugar	39.09	36.77	2.5	0.71	15.58	0.001
PP blood sugar	64.1	78.33	5.34	0.39	11.99	0.001
Calories intake	505.11	573.3	39.09	0.4	12.92	0.001

Table 4: Self-care adaptations pre and post intervention.

Dependent variable	Self-care changes		Pre intervention	Post intervention	Total
Self-care	Some	N	153	31	184
		%	71.2	14.4	85.6
	Moderate	N	58	140	198
		%	27	65.1	92.1
	Major	N	4	44	48
		%	1.8	20.5	22.3
	Total	N	215	215	430
		%	100	100	200
Tests	**Value**		**Df**	**P value**	
Pearson Chi-Square					
	24.25		4	0.001	

Table 5: Comparison of means with health education (post intervention).

Dependent variable	Health education	N	Mean	Std. deviation	Std. error mean	t value	Significance
Fasting blood sugar	Complete	184	128.99	35.35	2.60	3.42	0.001
	Partial	31	153.10	41.86	7.52		
Calorie intake	Complete	184	1343.33	383.34	28.26	3.46	0.001
	Partial	31	1625.77	598.79	107.55		
Life style score	Complete	184	6.30	2.07	0.15	1.94	0.05
	Partial	31	5.52	2.23	0.40		
Self-care score	Complete	184	6.16	1.64	0.12	11.42	0.001
	Partial	31	2.77	0.42	0.07		

Table 6: Comparison of means of pre and post intervention indicators amongst those who have availed benefit of all 4 interventions i.e. (health education, periodic examination, personal counselling, and referral advice) (N= 32).

Indicators	Pre intervention	Post intervention	Significance
Self-care score	3.66	6.22	0.01
Life style score	4.81	6.47	0.01
Systolic blood pressure	135.94	125.62	0.01
Diastolic blood pressure	92	87.62	0.05
Fasting blood sugar	172.78	130.37	0.01
Post prandial blood sugar	266.19	189.31	0.01
BMI	25.58	24.97	0.05
Diet Intake	1864	1418	0.05

Table 7: Comparison of means of pre and post intervention indicators amongst those who have availed benefit of 3 interventions i.e. health education, personal counselling and referral advice (N=59).

Indicators	Pre Intervention	Post intervention	Significance
Self-care score	3.69	6.22	0.01
Life style score	4.83	6.54	0.05
Systolic blood pressure	139.32	129.89	0.01
Diastolic blood pressure	94.27	88.24	0.01
Fasting blood sugar	173.81	129.57	0.01
Post prandial blood sugar	257.61	177.55	0.05
BMI	25.23	24.72	0.04
Diet Intake	1834	1371	0.05

Table 8: Comparison of means of pre and post intervention indicators amongst those who have availed benefit of 2 interventions i.e. health education and personal counselling (N= 85).

Indicators	Pre intervention	Post intervention	Significance
Self-care score	3.69	6.3	0.01
Life style score	5.15	6.47	0.05
Systolic blood pressure	138.39	129.05	0.01
Diastolic blood pressure	94.3	87.83	0.01
Fasting blood sugar	166.02	126.49	0.03
Post prandial blood sugar	242.63	176.56	0.01
BMI	25.09	24.53	0.05
Diet intake	1918	1407	0.01

Table 5 shows that Mean fasting blood sugar and calorie intake are significantly lower in patients who has received complete health education as compared with those received health education partially. The importance of this finding is essentiality of diabetic health education to improve life style and self-care practices. Health education is also important strategy for maintaining glycemic control and dietary modifications in diabetic patients.

4 interventions i.e. (health education, periodic examination, personal counselling, and referral advice) shows the effectiveness of delivery of best whole intervention package available to improve self-care practices and life style adaptations (Table 6). Three interventions i.e. (health education, personal counselling, and referral advice) shows the effectiveness of delivery of best 3 interventions combination package (Table 7).

2 interventions i.e. (health education and personal counselling) shows the effectiveness of delivery of best 2 interventions combination package (Table 8).

Table 9: Comparison of means of pre and post intervention indicators amongst those who have availed benefit of only 1 intervention i.e. complete health education.

Indicators	Pre intervention	Post intervention	Significance
Self-care score	3.44	6.16	0.01
Life style score	4.75	6.3	0.01
Systolic blood pressure	141.98	129.99	0.01
Diastolic blood pressure	94.05	87.08	0.05
Fasting blood sugar	171.26	128.99	0.01
PP blood sugar	253.85	188.66	0.05
BMI	25.68	25.09	0.05
Diet intake	1879	1343	0.01

Table 10: Life style changes pre and post intervention (N=215).

Life style	Pre intervention		Post intervention		Chi sq	P value
	Yes	No	Yes	No		
Cut down sweets	187	28	200	15	4.36	0.04
Cut down oil	155	60	175	40	5.21	0.03
Space the meal	15	200	75	140	50.58	0.001
increase vegetable consumption	50	165	80	135	9.92	0.01
Cut down non veg consumption	144	71	167	48	6.14	0.03
Doing exercise	48	167	101	114	28.85	0.001
Cut down addiction	28	57	70	15	107.5	0.001
Cut down outing	28	187	88	127	42.49	0.001
Cut down attending ceremony	98	117	158	57	34.75	0.001
Cut down eating outside	105	110	164	51	34.56	0.001

Table 11: Self-care practices pre and post intervention (N=215).

Self Care	Pre intervention		Post intervention		Chi sq.	P value
	Yes	No	Yes	No		
Taking medicine	199	16	210	5	6.05	0.02
Visiting doctor	196	19	209	6	8.6	0.004
Adjust dose by self	36	179	18	197	6.86	0.02
Check urine sugar at home	6	209	31	184	18.48	0.001
Taking insulin by self	5	17	12	10	4.69	0.03
Identify hypoglycemic spell	200	15	211	4	6.66	0.01
Care of feet	28	187	48	167	6.39	0.01
Carry biscuit/ sugar	12	203	33	182	10.94	0.01
Carry diabetic card	91	124	112	103	4.11	0.03
Regular blood sugar monitoring	160	55	177	38	3.97	0.03

Complete health education asthe single best intervention available to improve self-care practices and life style adaptations (Table 9).

Table 10 shows that number of patients adopting healthy life style has significantly increase from pre intervention to post intervention.

Table 11 shows that number of patients adopting self-care practices has significantly increased from pre intervention to post intervention. Table 12 shows that there are significant percentages of patients (54%) and (36.7%) respectively adopting moderate to major changes in Life style patterns after one year of intervention.

Table 12: Life style changes pre and post intervention.

Dependent variable	Life style changes		Pre intervention	Post intervention	Total
Life Style	Some	N	116	20	136
		%	54	9.3	63.3
	Moderate	N	38	116	154
		%	17.7	54	71.7
	Major	N	61	79	140
		%	28.3	36.7	65
	Total	N	215	215	430
		%	100	100	200
Tests	**Value**	**df**		**P value**	
Pearson Chi-square	20.14	4		0.001	

DISCUSSION

In this study, post intervention phase it was observed that those patients with moderate to major lifestyle pattern changes had low mean blood sugar level compared to those patients who adopted only some changes, this means blood sugar level can be kept under control with lifestyle changes. Also the calories intake was less in those adopted moderate to major changes in lifestyle patterns than those with only some changes (Table 1).

In the study, it was observed that after nutritional education both fasting and post prandial blood sugar level reduced significantly (pre FBS 114.89±7.7, post FBS 111.49±8.5) (p=0.007) and (pre PPBS 162.74±15.16, post PPBS 153.89±10.87) (p=0.001).[6]

In this study it was observed that those patients with moderate to major changes in self-care practices post intervention had significantly lower fasting blood sugar and low calories intake compared to those who adopted only some changes (Table 2).

There had been various studies done in western countries which revealed that eight face-to-face counselling visits with a healthcare professional over a 3-month period, led to a significant improvement in physical activity levels, as measured by mean energy consumed from physical activity, compared with control (no intervention).[7] In addition, patients who received the intervention had significantly better clinical outcomes, with reduced levels of weight gain, and decreased waist circumference, blood pressure, glucose levels, and HbA1c levels, versus no intervention recipients.[7] A similar kind of studywas carried out by Shabbidar et al at the Department of Food and Nutrition, Iran, to assess the effectiveness of dietary education in reducing plasma glucose levels in patients with type 2 diabetes.[8] The intervention group lost 1.5±2.2 kg as against a weight gain in the control group of 0.5±2.3 kg (p=0.01). Fasting plasma glucose decreased 21±55 mg/dl in the intervention group and increased 19 ± 78 mg/dl in the control group (p=0.028). Glycosylated haemoglobin decreased 1.9±2.1% in the intervention group and 0.2±2.2% in the control group.

But there had been very few attempts in India regarding the effect of health education on diabetes. The study done by Uma Iyer, et al in Vadodara Gujrat shows that through IPC (interpersonal counselling) and NHE (Nutritional health education) to the diabetic patients for 4 months led to a significant reduction in the fasting blood glucose (FBG; 14.2%) and HbA1c levels indicating a physiologic fall with good metabolic control.[9] NHE also resulted in a significant reduction in total cholesterol, low density lipoprotein cholesterol, and non-high density lipoprotein cholesterol, thereby reducing the risk of cardiovascular disease.

Satpute et al in their study assessed the impact of patient counselling, Nutrition and Exercise in patients with Type-2 Diabetes Mellitus.[10] A total of 35 patients with type-2 diabetes were involved. Glycosylated haemoglobin (HbA1c), fasting plasma glucose, PPBS, total cholesterol, triglyceride, HDL, LDL and BMI were measured at baseline and the end of the study. It was shown that glycemic control of type-2 diabetic patients can be improved through patient counselling regarding disease, medication, diet and exercise. So this shows that there is role of health education in diet modification, change in life style and improvement in glycemic status of diabetic patients.

Life style and self-care practices both significantly improved after intervention. These are important parameters to control diabetes (Table 3). The mean fasting blood sugar and calories intake were significantly low in patients who had received complete health education as compared to those who received health education partially. Also it was seen that life style score and self-care scores were significantly high in those patients who received complete health education. This indicates that after health education, life style patterns and safe care practices improved in patients (Table 5).

The interventional study of diabetes education programme done by Ampiro Castillo in Chicago reveals that there was significant improvement in knowledge about the diabetes and hence the diabetes awareness among the patients.[11] This shows that if there is increase

in diabetes awareness through appropriate community based health education, glycemic control can be achieved effectively.

Both lifestyle and self-care improved after interventions which are important parameters to control diabetes (Table 4, 12). Before intervention only 28.3% of patients had adopted major lifestyle modification and after one year intervention 36.7% of patients adopted major lifestyle modifications (Table 12). Before intervention only 1.8% of patients had adopted major modification in self-care practices and after one year of intervention 20.5% patients done major modification in self-care practices (Table 5). Number of patients adopting healthy lifestyle and adopting self-care significantly increased from pre intervention to post intervention (Table 10 and 11).

Table 6 shows the status of various process indicators like self-care and lifestyle scoring, blood pressure, blood sugar, BMI and diet intake. There was significant reduction in mean systolic and diastolic blood pressure, fasting and post prandial blood sugar, BMI, diet intake, post intervention amongst those who had availed benefit of all 4 interventions i.e. (Health education, periodic examination, personal counselling, and referral advice). Self-care and life style scores improved after intervention. This indicates the effectiveness of delivery of intervention package for improving self-care practices and life style measures.

Similarly Table 7 shows, 3 out of 4 interventions i.e. (Health education, personal counselling, and referral advice). Table 8 shows, 2 out of 4 interventions i.e (Health education and personal counselling). Table 9, indicate the effectiveness of delivery of single best intervention i.e. (Complete Health education) available to improve self-care practices and life style measures.

CONCLUSION

From above all observations we found that health and nutritional education, personal counselling, periodic health check-up are important as an intervention package to bring about glycemic control, modify diet and lifestyle and to improve self-care practices amongst the diabetic patients.

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