

Assessment of impact of Patient Counselling, Nutrition and Exercise in patients with Type 2 Diabetes Mellitus.

D.A. Satpute¹, P. H. Patil¹, V. G. Kuchake^{1*}, P.V.Ingle¹,
S. J. Surana¹, P. N. Dighore²

¹Department of Clinical Pharmacy, R.C.Patel Institute of Pharmaceutical Education and Research, Shirpur, Dhule, Pin Code: 425405, M.S., India.

²Indira Gandhi Memorial Hospital, Shirpur, Dist: Dhule,
Pin Code: 425405, M.S., India.

*Corres author : vitthalkuchake@yahoo.co.in

Abstract:

Aim & Objective: Assessment of impact of patient counseling, Nutrition and Exercise in patients with Type-2 Diabetes Mellitus. The prevalence of type-2 diabetes, especially in India and devolving countries has grown over the past decade. We performed a study to determine whether a patient counseling for Diabetes patients regarding Disease, Medication, Diet/ Nutrition and Exercise can improve Glycemic control & Lipid profile and associated complications. **Research design and methods:** A total of 35 patients with type-2 diabetes, mean age 55 ± 1.4 , 54 ± 2.2 & 55 ± 2.4 years, were randomly assigned in to three groups. All these received basic diabetes education, counseling regarding Disease, Medication, Diet and Exercise for three months at each visit. Glycosylated hemoglobin (HbA1c), Fasting plasma glucose, PPG, total cholesterol, triglyceride, HDL, LDL and BMI were measured at baseline and the end of the study. **Results:** In the 12 months present study, the significant reductions were found in HbA1c in Group-I by 1.0 ± 0.2 %, in Group-II by 1.3 ± 1.71 % and in Group-III by 1.2 ± 0.13 % after 3 month as impact of patient counseling. Also the greater significant reductions were observed in case of FPG, total cholesterol, serum triglyceride and LDL cholesterol in all groups after 3 month. **Conclusions:** Glycemic control of type-2 diabetic patients can be improved through patient counseling regarding disease, medication, personal hygiene, diet and exercise. This study provides an economically feasible model for programs that aim to improve the health status of people with type-2 diabetes.

Key words : Diabetes Mellitus-2, Counseling, Diet / Nutrition, Exercise / Physical activity, Life Style Modification, Patient Education.

Abbreviations : DM: Diabetes Mellitus; FPG: Fasting Plasma Glucose; CVD: Cardiovascular Disease; Group I: On Double combination; Group II: On Triple combination; Group-III: On Insulin GIT: Gastrointestinal Tract; HbA_{1c}: Glycosylated Hemoglobin; HDL: High Density Lipoprotein; LDL: Low Density Lipoprotein; OHAs: Oral Hypoglycaemic Agents; PPG: Post-prandial Plasma Glucose; SEM: Standard Error mean; BMI: Body mass index; M/F: Male/Female; yrs: Years; Kg/m²: Kilogram per meter square; %: Percentage; mg/dl: Milligram per deciliter; ANOVA: Analysis of variance.

Introduction:

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia. The epidemic of DM is ever increasing in developed and developing countries inspite of the enormous facilities available to control its growth. The goal of Pharmaceutical care is to improve patient health outcomes by ensuring effective, safe, and cost-effective drug therapy. Pharmacists are in a prime position to ensure that use of medications by the patients safely and appropriately^{1,2,3}. Patients with diabetes and their families provide 95% of their care themselves; as a consequence, an educational effort to improve self- management is the central components of any effective treatment plan. Patient counseling is an important task for achieving pharmaceutical care by providing medication related information orally or in written form to the patients or their representatives, on topics like direction of use, advice on side effects, precautions, storage, diet and life style modifications^{4,13}. It should include an assessment of whether or not the information was received as intended and that the patient understands how to improve the therapeutic efficacy^{5,6}. Several guidelines specify the points to be covered by the pharmacist while counseling the patients.^{6,7,14}. Numerous clinical trials have established that lifestyle interventions can lower blood pressure or decrease the intake of antihypertensive medications⁸. Nutritional counseling forms an essential component in the management of diabetes^{9,13}. However, unless these diets are highly enriched with fiber, they may impair glucose tolerance, increase triacylglycerol levels, and decrease HDL concentrations¹⁰. A standard recommendation for diabetic patients, as for nondiabetic individuals, is that physical activity includes a proper warm-up and cool-down period. The possible benefits of physical activity for the patient with type 2 diabetes are substantial, and recent studies strengthen the importance of long-term physical activity programs for the treatment and prevention of this common metabolic abnormality and its complications^{11,15}. The patient should be cautioned not to skip meals at any time and to follow regular diet patterns to prevent hypoglycemia. Insulin is a hormone

manufactured by the beta cells of the pancreas. It is the principal hormone required for the proper use of glucose (carbohydrate) by the body¹².

Research Design and Methods :

This 12 month randomized controlled pilot study was carried out in patients with type 2 diabetes mellitus of either sex, above 40 years age, who consented to participate, was included in the study at Indira Gandhi memorial hospital, Shirpur, Dhule (MH) located in the North Maharashtra. The study was approved by human Institutional Ethical Committee of the R.C.Patel College of pharmacy, Shirpur. The patients who were pregnant were excluded from the study on the basis of inclusive and exclusive criteria in concern with physician.

Study Procedure:

1) Research subjects

Subjects with type 2 diabetes had been diagnosed, established through chart review and consultation with treating physicians, were recruited. All study subjects gave written and oral informed consent.

2) Patient enrollment

Those patients, who met the inclusion criteria, were enrolled into the study after their informed consent was obtained. These patients were randomized into three groups, are as follows.

- 1) Patient of DM-2 and on Double combination
- 2) Patient of DM-2 and on Triple combination
- 3) Patient of DM-2 and on Insulin

At baseline patients were interviewed to obtain their medical and medication history and the details were noted in a data collection form. All baseline parameter were also recorded.

3) Patient counseling and Follow up:-

The all patients were counseled regarding disease, medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self monitoring of glucose and self care. The patients were counseled in the presence of concern physician Hospital. At the time of counseling also provided information leaf late covering all essential points and Diabetic identity cards. The patients were asked to come back for follow-up once month, for a period of 3 months. During each follow –up, the pharmacist, educated patients to each group, regarding their disease, medication and life style modification. Feed back question were asked to assess patients understanding of what was taught.

The fasting plasma glucose, postprandial plasma glucose, blood pressure, lipid profile and patients problem were noted down at each follow-up.

Materials:

Patient data relevant to the study was obtained from the following sources;

Patient data collection form (Patient Proforma)

Patient's prescriptions

Patient counseling

Diabetes knowledge, Attitude and Practice Questionnaire (patient feedback form).

Table No: 1 –Baseline characteristics of each group.

Parameter	Group-I	Group-II	Group-III
Sex (M/F)	6/5	5/7	2/5
Age (yrs)	55 ± 1.4	54 ± 2.2	55 ± 2.4
Diabetes duration (yrs)	4.9 ± 0.44	5.3 ± 0.49	6.3 ± 0.42
BMI (Kg/m ²)	25 ± 0.71	24 ± 1.1	23 ± 0.36
HbA1c (%)	9.2 ± 0.62	10 ± 0.64	9.9 ± 0.84
FPG (mg/dl)	221 ± 11	225 ± 25	228 ± 28
PPG (mg/dl)	280 ± 9.6	311 ± 31	326 ± 37
Total cholesterol (mg/dl)	134 ± 8.6	129 ± 9.8	171 ± 5.3
Serum Triglyceride (mg/dl)	145 ± 16	141 ± 15	167 ± 13
HDL (mg/dl)	40 ± 1.2	37 ± 1.0	39 ± 1.3
LDL (mg/dl)	77 ± 6.8	69 ± 9.9	98 ± 7.7

Results:

A total 35 patients were involved in the study out of which 5 patients didn't complete study. These patients were distributed into different three such as Group-I on double combination, Group-II on triple combination and Group-III on insulin. In the Group-I

total Eleven (n-11) patients were included out of which 6 patients on Metformin + Glimiperide combination and 5 patients on Metformin + Glibenclamide combination. In the Group-II total twelve (n-12) patients were included out of which 8 patients on Metformin+ Glimiperide+ pioglitazone triple combination and 4 patients on Glimiperide+ Glibenclamide + pioglitazone. In the Group-III total seven (n-7) patients were included out of which 4 patients on Mixtard insulin and 3 patients on Actrapids insulin. All patients were counseled after the selection into the study regarding Disease, medication, diet, exercise and personal hygiene and motivate to improve life style modification. All patients baseline parameter were recorded before the counseling as control values and recorded at each follow up. Also values of all parameter were recorded after 3 month and compare the effect of counseling with medication with baseline values. The baseline characteristics of all patients at randomization are summarized in Table No.1.

Effect of counseling on Fasting Plasma Glucose level (FPG)

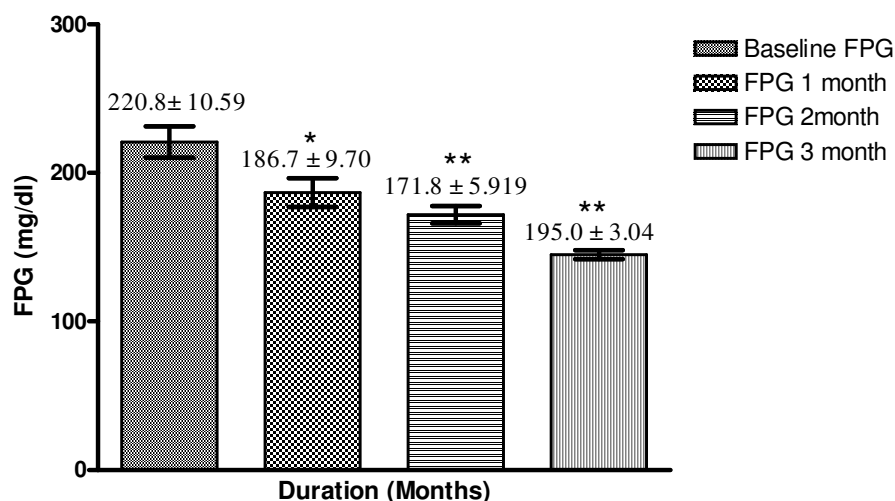
(Given in Table No.2):

The baseline value of FPG of Group-I was 220.8 ± 10.59 and it reduced significantly up to 195.0 ± 3.04 after 3 month. The baseline value of FPG Group-II of was 225 ± 25 and it reduced significantly upto 138 ± 3.7 after 3 month. The baseline value of FPG of Group-III was 228 ± 28 and it reduced significantly upto 140 ± 3.2 as compared baseline. . There were significantly reductions in FPG found in all three groups given in Fig No-1, 2, and 3).

Table No: 2- Baseline and final values of FPG, PPG, HbA1c and BMI.

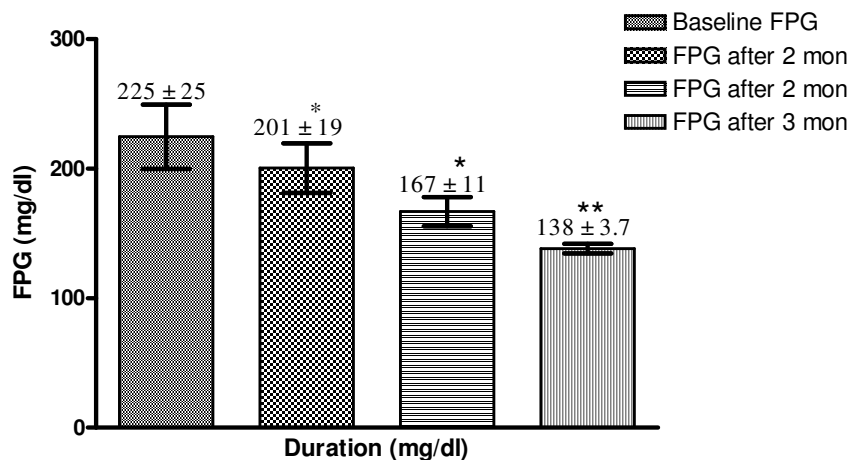
Variables	parameter	FPG	PPG	HbA1c	BMI
Baseline parameter (Before the counseling)	Group-I	220.8 ± 10.59	280 ± 9.6	9.2 ± 0.6	25 ± 0.70
	Group-II	225 ± 25	311 ± 31	10 ± 2.2	24 ± 1.1
	Group-III	228 ± 28	326 ± 37	9.9 ± 0.84	23 ± 0.36
Parameter After 3 month (After the counseling)	Group-I	195.0 ± 3.04	226 ± 3.6	8.2 ± 0.4	24 ± 0.69
	Group-II	138 ± 3.7	230 ± 3.7	8.7 ± 0.49	23 ± 0.96
	Group-III	140 ± 3.2	230 ± 3.1	8.7 ± 0.71	$23 \pm 0.19S$

Fig. No: 1- Effect of counseling on FPG of Group I

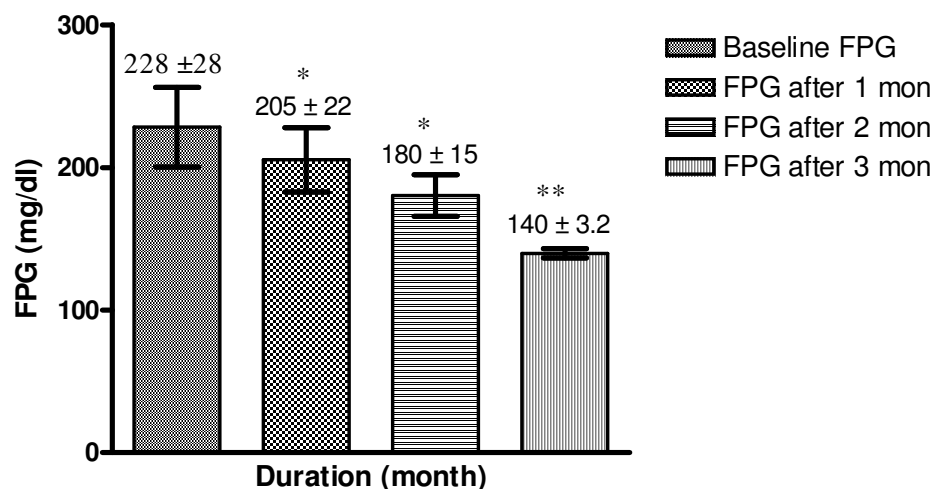


Data represents Mean ± SEM,
 One way ANOVA: $P < 0.0001$ ($F=15.96$, $df=3$, $n=11$)
 Dunnett's Multiple Comparision test, * $p < 0.05$, ** $p < 0.01$
 As compared with baseline

Fig. No: 2- Effect of counseling on FPG of Group II



Data represents Mean ± SEM
 One way ANOVA: $P < 0.0001$ ($F=5.1$, $df=3$, $n=12$)
 Dunnett's Multiple Comparision test, * $p < 0.05$, ** $p < 0.01$
 As compared with baseline

Fig. No: 3- Effect of counseling on FPG of Group III

Data represents Mean ± SEM

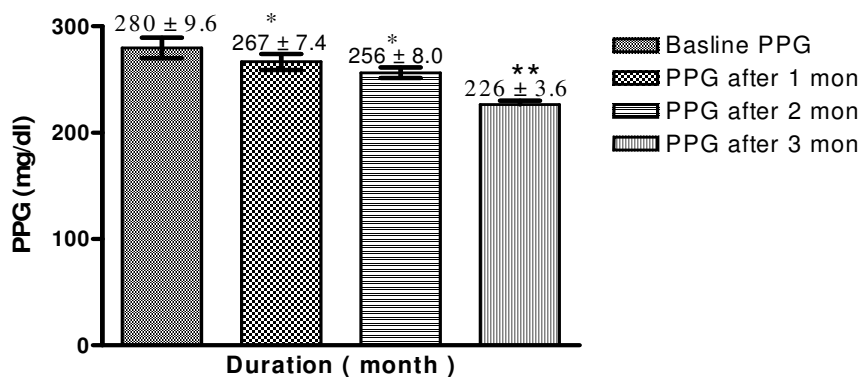
One way ANOVA: $P < 0.0001$ ($F=3.8$, $df=3$, $n=7$)

Dunnett's Multiple Comparision test, * $p < 0.05$, ** $p < 0.01$

As compared with baseline

Effect of counseling on Postprandial Plasma Glucose level (PPG) :

(Given in Table No. 2) The baseline value of PPG of Group-I was 280 ± 9.6 and it reduced up to 226 ± 3.6 after 3 month. The baseline value of PPG of Group-II was 311 ± 31 and it reduced up to 230 ± 3.7 after 3 month. The baseline value of PPG of Group-III was 326 ± 37 and it reduced significantly up to 230 ± 3.1 after 3 month given in Fig No-4, 5 and 6)

Fig. No: 4- Effect of Counseling PPG of group I

Data represents Mean ± SEM, One way ANOVA: $P < 0.0001$ ($F=11$, $df=3$, $n=11$)

Dunnett's Multiple Comparision test, * $p < 0.05$, ** $p < 0.01$

Fig. No: 5- Effect of Counseling PPG of group II

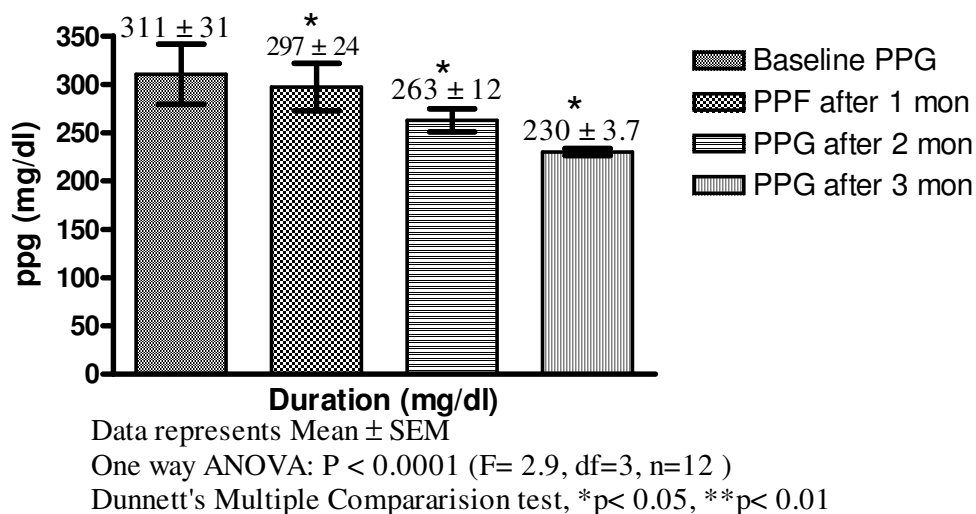
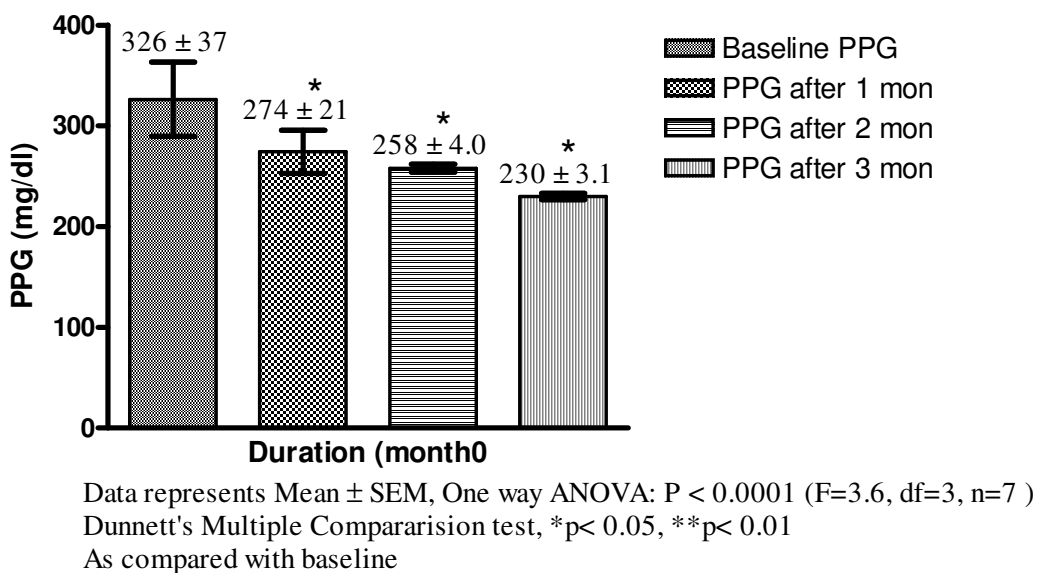


Fig. No: 6-Effect of Counseling PPG of group III



Effect of counseling on Glycosylated Hemoglobin (HbA1C): (Given in Table No. 2)

The significant reductions in the glycosylated hemoglobin level were observed among all the three groups. The HbA1c was found to be reduced more significantly in group II patients who are on oral hypoglycemic triple combination therapy given in Fig No- 7, 8 and 9.

Fig.No:7- Effect of Counseling on HbA1c of Group I

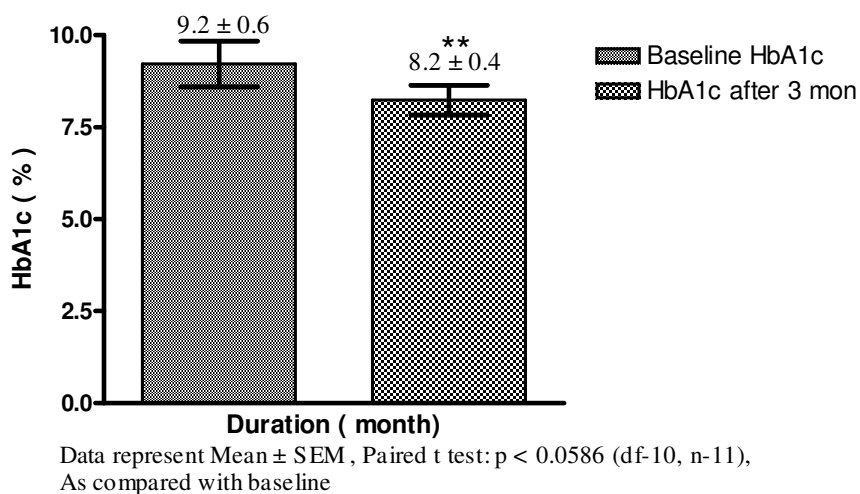


Fig.No:8-Effect of Counseling on HbA1c of Group II

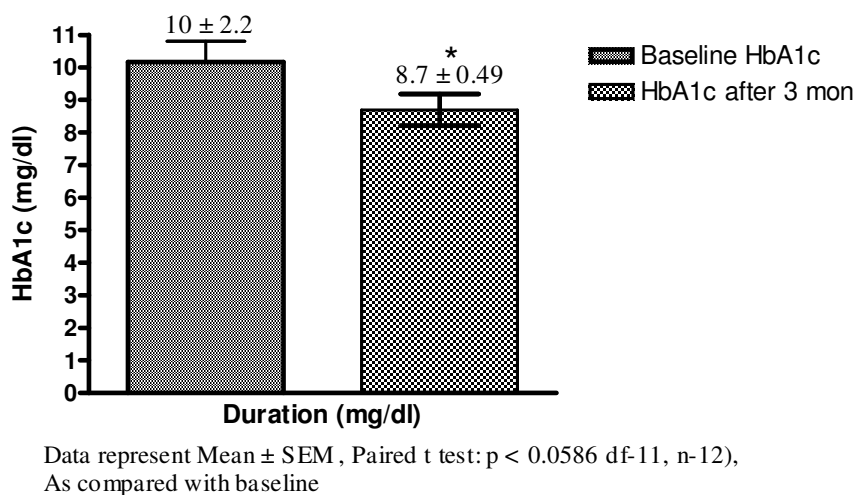
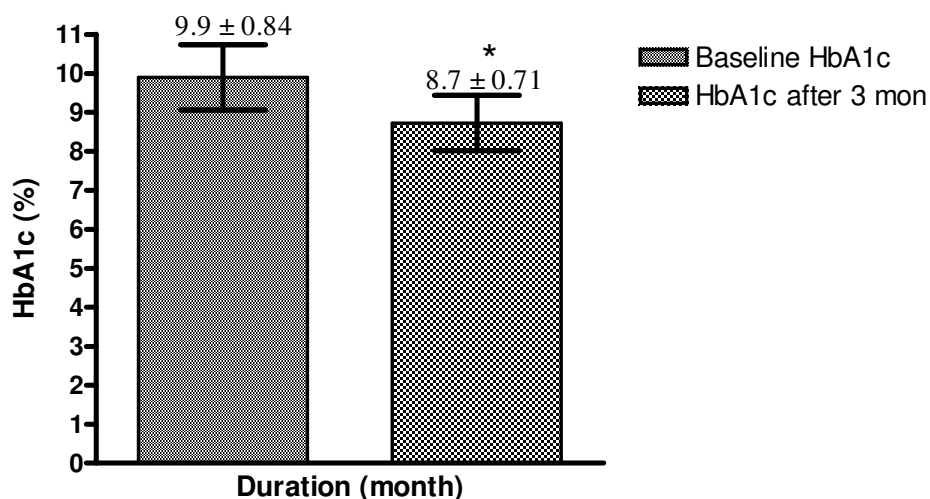
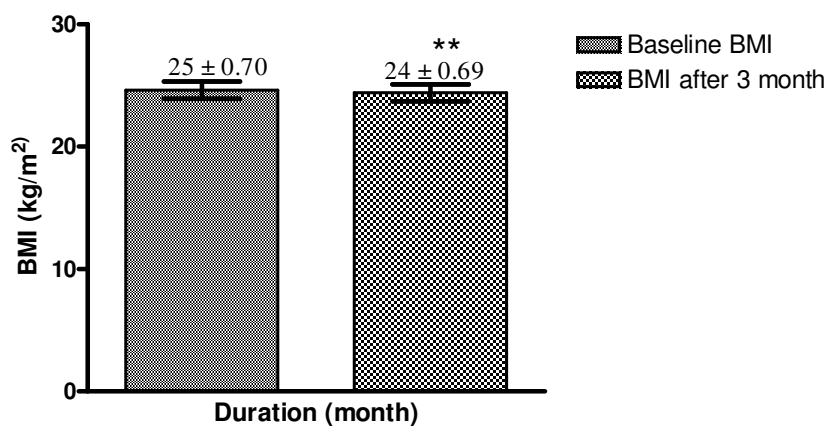


Fig.No:9Effect of Counseling on HbA1c of Group III

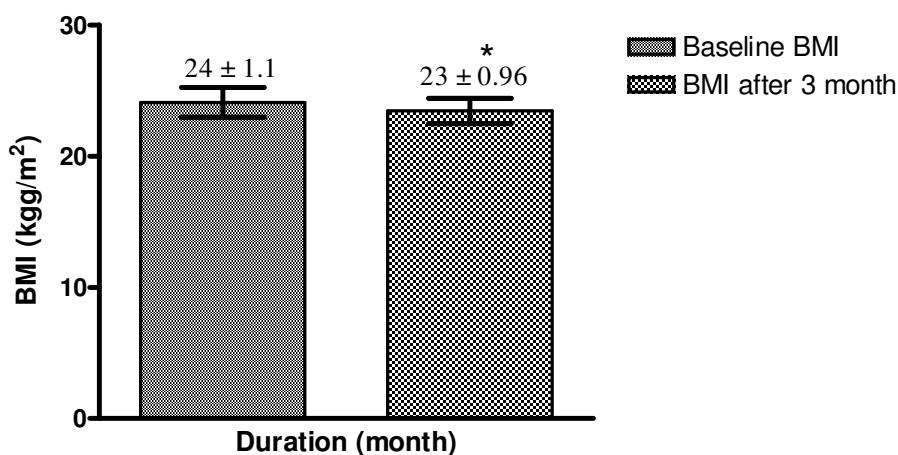
Data represent Mean \pm SEM, Paired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

Effect of counseling on BMI: (Given in Table No. 2)

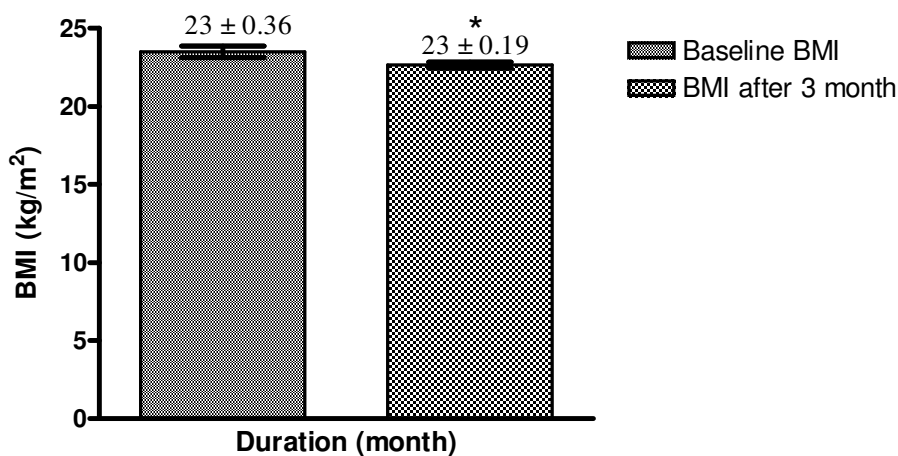
The baseline values of BMI of G-I, Group-II and Group-III were 25 ± 0.70 , 24 ± 1.1 and 23 ± 0.36 respectively. There was no large difference in BMI of final values and small decrease in values. There was significantly reduction of BMI of Group-I value given in Fig No- 10, 11 and 12.

Fig.No:10- Effect of counseling on BMI of Group I

Data represent Mean \pm SEM, Paired t test: $p < 0.0586$ (df-10, n-11),
As compared with baseline

Fig.No:11-Effect of counseling on BMI of Group II

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-11, n-12),
As compared with baseline

Fig.No:12 Effect of counseling on BMI of Group II

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

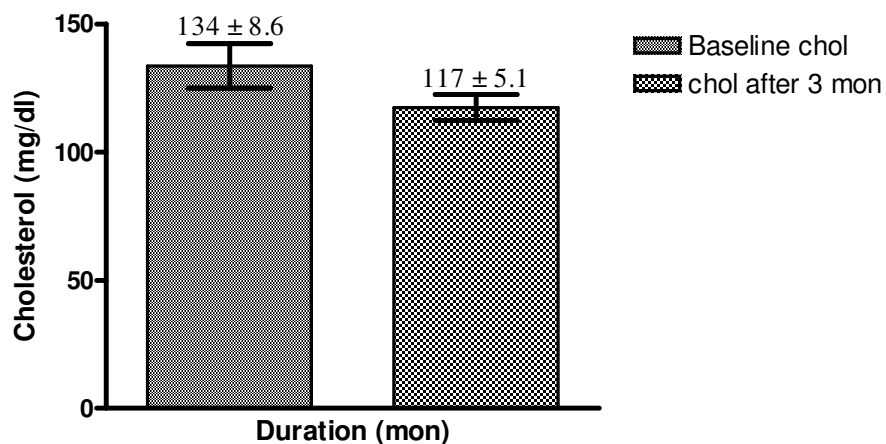
Effect of counseling on Cholesterol : (Given in Table No. 3)

The baseline value of cholesterol of G-I, Group-II and Group-III were 134 ± 8.6 , 129 ± 9.8 and 171 ± 5.3 and it reduced 117 ± 5.1 , 114 ± 4.4 and 152 ± 3.7 after 3 month.. The values of cholesterol were not significantly reduced in Group-I but significantly reduced in Group-III. Given in Fig No-13, 14 and 15.

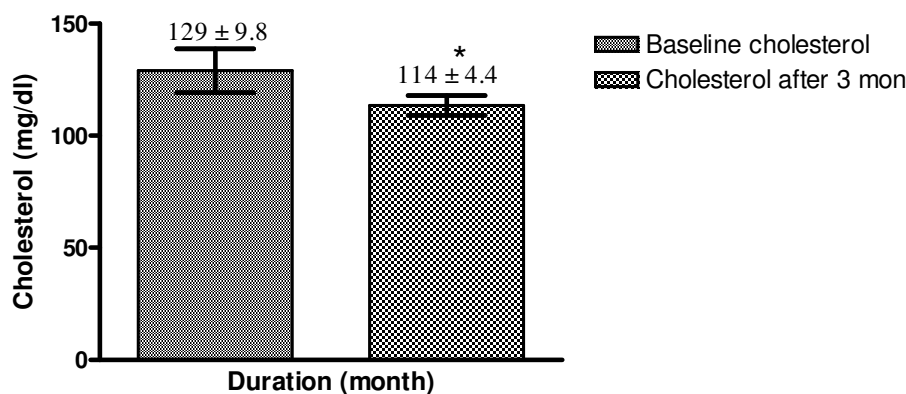
Table No: 3- Baseline and final values of Cholesterol, Triglyceride, HDL and LDL.

Variables	parameter	Cholesterol	Triglyceride	HDL	LDL
Baseline parameter (Before the counseling)	Group-I	134 ± 8.6	145 ± 16	40 ± 1.2	77 ± 6.8
	Group-II	129 ± 9.8	141 ± 15	37 ± 1.0	69 ± 9.9
	Group-III	171 ± 5.3	167 ± 13	167 ± 13	98 ± 7.7
Parameter After 3 month (After the counseling)	Group-I	117 ± 5.1	124 ± 16	48 ± 2.4	49 ± 4.9
	Group-II	114 ± 4.4	117 ± 9.8	43 ± 5.3	50 ± 4.3
	Group-III	152 ± 3.7	148 ± 7.6	148 ± 7.6	72 ± 5.1

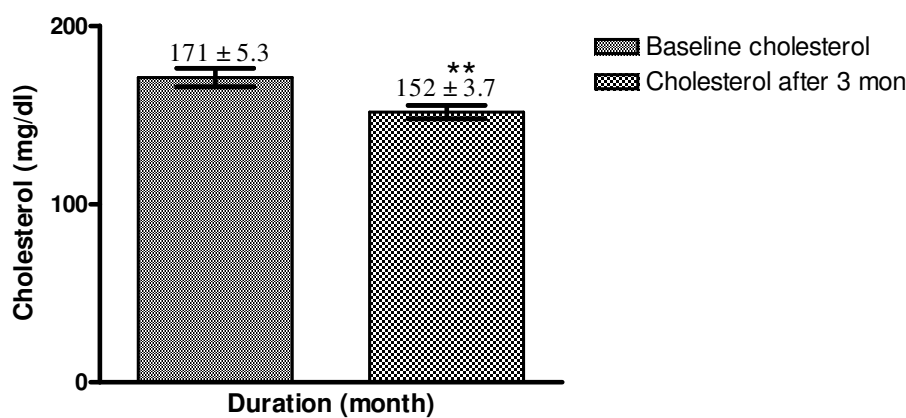
Fig. No: 13- Effect of counseling on cholesterol of Group-I



Data represent Mean ± SEM, Pired t test: $p < 0.0586$ (df-10, n-11),
As compared with baseline

Fig. No: 14-Effect of counseling on cholesterol of Group-II

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-11, n-12),
As compared with baseline

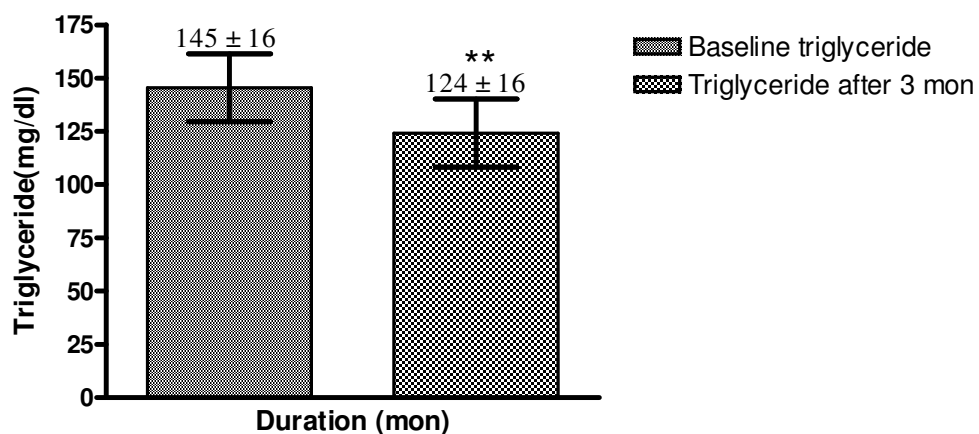
Fig. No: 15Effect of counseling on cholesterol of Group-III

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

Effect of counseling on Triglyceride: (Given in Table No. 3)

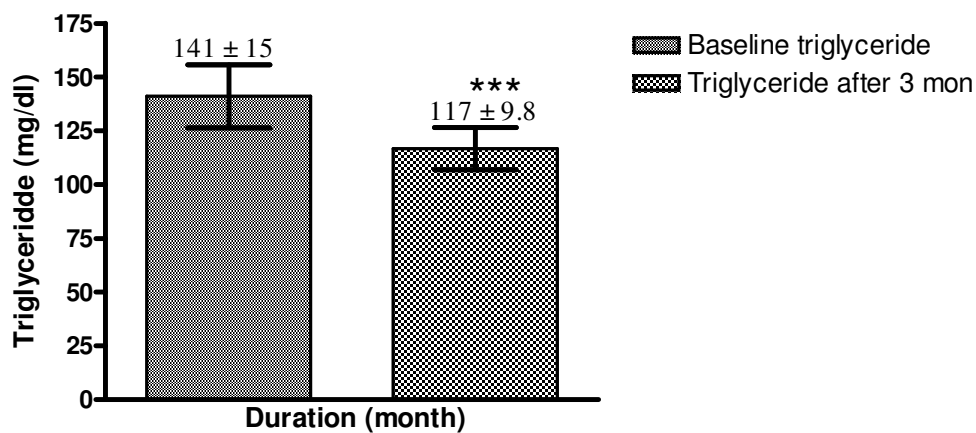
The baseline value of triglyceride of Group-I was 145 ± 16 and it reduced significantly up to 124 ± 16 after 3 month. The baseline values of Group-II and Group-III were 141 ± 15 and 167 ± 13 and it reduced significantly up to 117 ± 9.8 and 148 ± 7.6 after 3 month respectively. The values of triglyceride were significantly reduced in Group-II and Group-III. Given in fig No -16, 17 and 18.

Fig. No: 16 - Effect of counseling on Triglyceride of Group-I

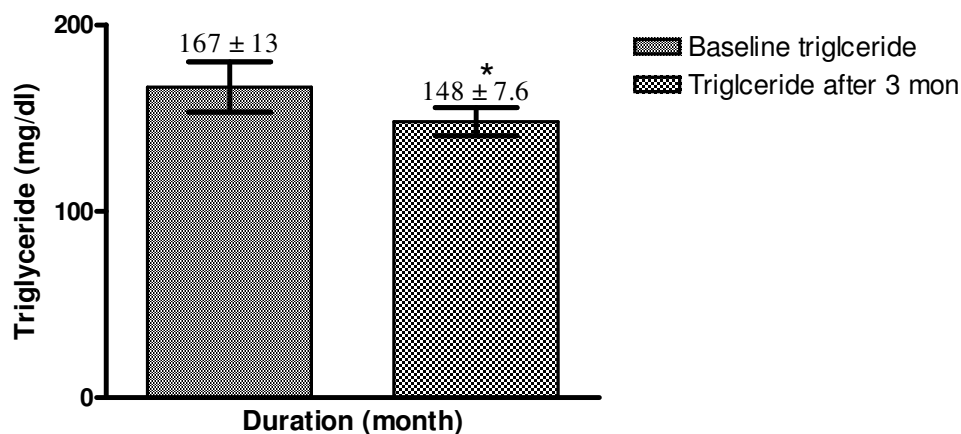


Data represent Mean \pm SEM, Paired t test: $p < 0.0586$ (df-10, n-11),
As compared with baseline

Fig. No: 17- Effect of counseling on Triglyceride of Group-II



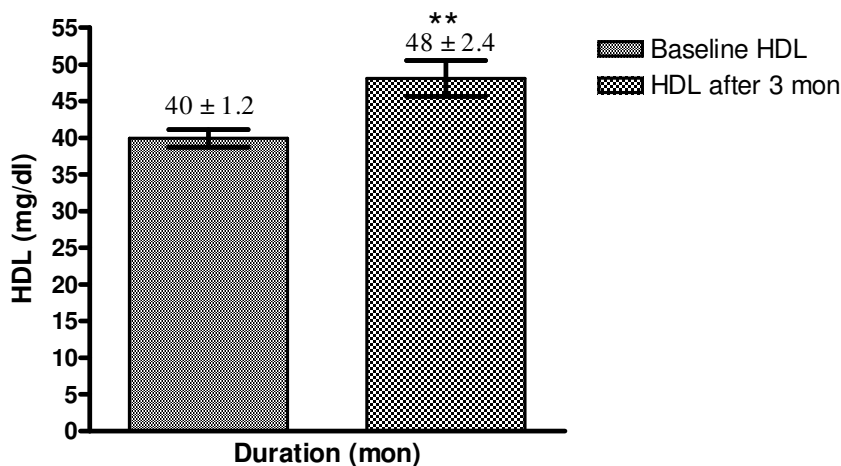
Data represent Mean \pm SEM, Paired t test: $p < 0.0586$ (df-11, n-12),
As compared with baseline

Fig. No: 18-Effect of counseling on Triglyceride of Group-III

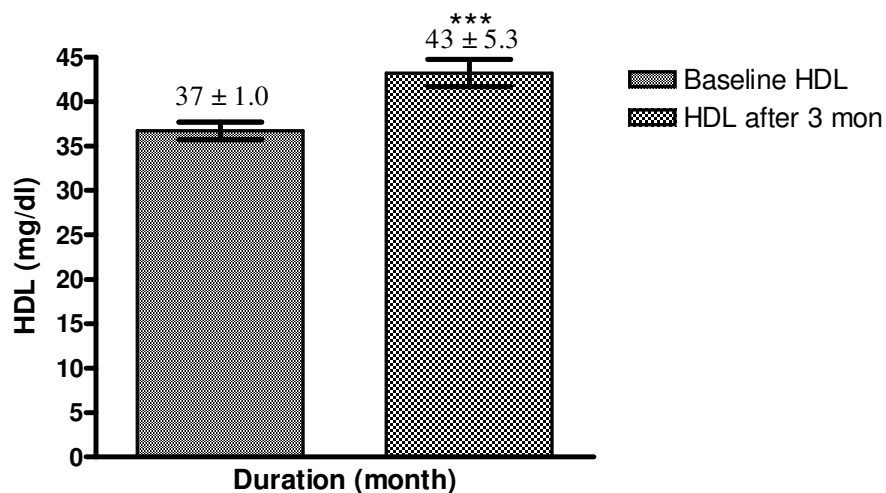
Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

Effect of counseling on High Density Lipoprotein (HDL): (Given in Table No.3)

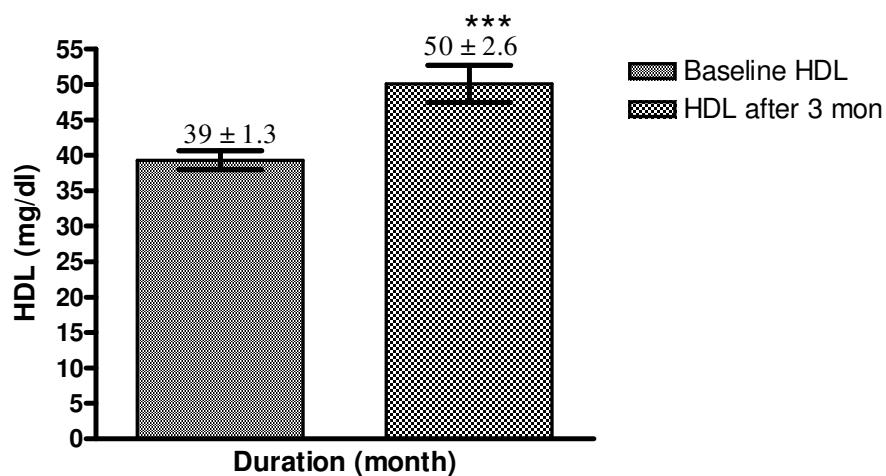
The baseline values of HDL of Group-I, Group-II and Group-III were 40 ± 1.2 , 37 ± 1.0 , 39 ± 1.3 and increased up to 48 ± 2.4 , 43 ± 5.3 and 50 ± 2.6 after 3 month respectively. The values of HDL were increased in Group-II and Group-III given in Fig No-19, 20 and 21.

Fig. No: 19- Effect of counseling on HDL of Group I

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-10, n-11),
As compared to baseline

Fig. No: 20Effect of counseling on HDL of Group II

Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-11, n-12),
As compared to baseline

Fig. No:21- Effect of counseling on HDL of Group III

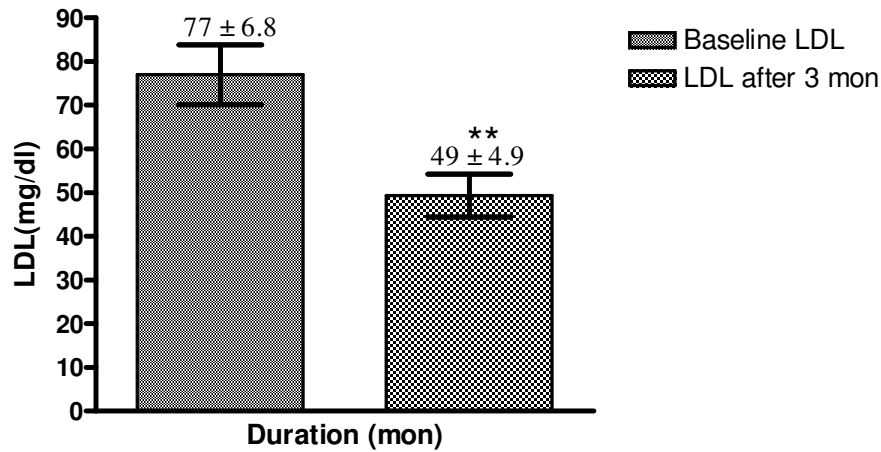
Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

Effect of counseling on Low Density Lipoprotein (LDL): (Given in Table No. 3)

The baseline value of LDL of Group-I was 77 ± 6.8 and reduced up to 49 ± 4.9 after 3 month. Also the baseline value of LDL of Group-II and Group-III were 69 ± 9.9 and

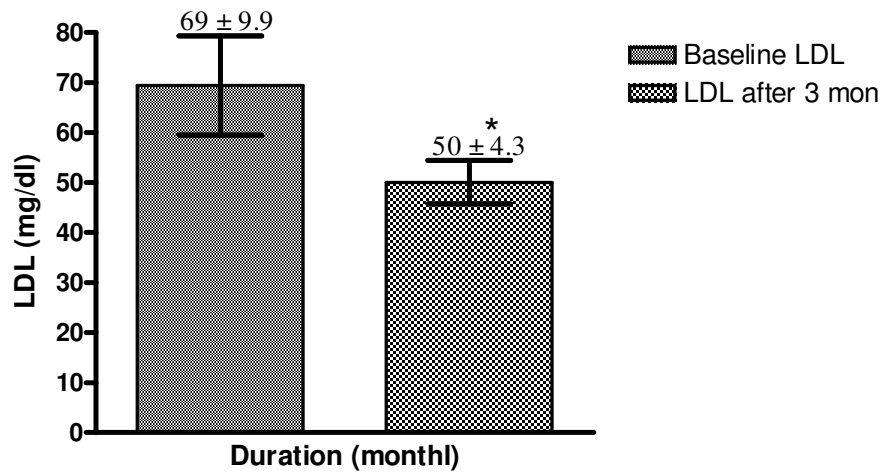
98 ± 7.7 and reduced up to c after 3 month respectively. The value of LDL was significantly reduced in Group-I and Group-III given in Fig No-22, 23 and 24.

Fig.No:22 - Effect of counseling on LDL of Group-I

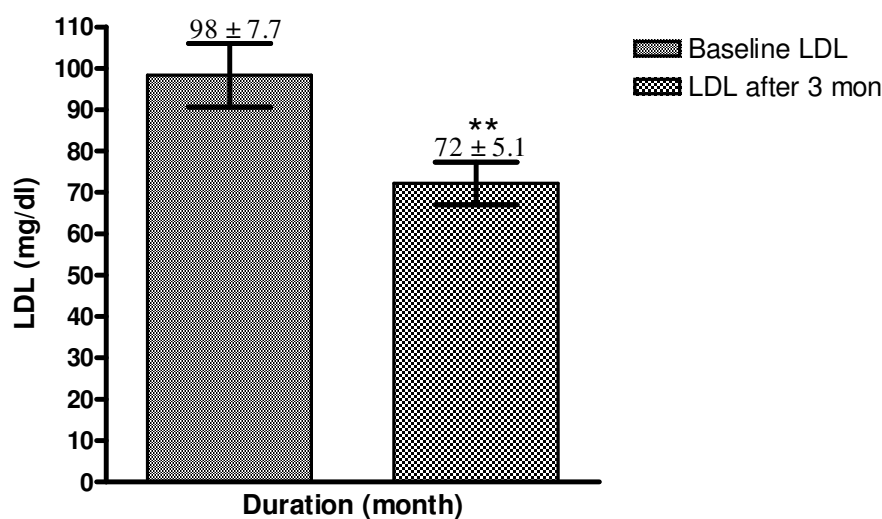


Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-10, n-11), As compared with baseline

Fig.No:23- Effect of counseling on LDL of Group-II



Data represent Mean ± SEM, Paired t test: $p < 0.0586$ (df-11, n-12), As compared with baseline

Fig.No:24.Effect of counseling on LDL of Group-III

Data represent Mean \pm SEM, Pired t test: $p < 0.0586$ (df-6, n-7),
As compared with baseline

Discussion:

The management of Diabetes Mellitus not only requires the prescription of the appropriate nutritional and pharmacological regimen by the physician but also intensive education and counseling of the patient. Diabetes is a chronic disease with altered carbohydrate, lipid and protein metabolism. The chronic complications of diabetes are known to affect the quality of life of diabetic patients. Various factors like understanding of the patients about their disease, socioeconomic factors, dietary regulation, self-monitoring of blood glucose are known to play a vital role in diabetes management.^{1, 16, 17, 18, 19}.The present study was carried out for 10 months. Of the 10 months patients was selected in first 4 months. Selected patients were categorized into three groups. Total 35 patients were selected for counseling regarding disease, medication, personal hygiene, diet and exercise at hospital. The values of all parameter were recorded before and after the counseling. A total 35 patients were included into the study out of which 30 patients were completed the study successfully and dropout rate was five patients. The selected 30 patients were distributed in to three groups such as Group-I on double combination (n-11), Group-II on triple combination (n-12) and Group-III on insulin (n-7). All these distributed patients in each group already on the same combination and same insulin from 1-2 years but there is no significant reduction in FPG, PPG, BMI, HbA1c and lipids profile by before result chart because of resistance to the medication and patient Non-compliance. Also there is no awareness about Diabetes disease, foot care, eye care, teeth care, self monitoring of glucose, diet and exercise. Also patient feedback form

shows that there were less awareness in patients about personal hygiene and Life style modification. In the present study according to sex distribution curves, the ratio of Male: Female were 6:5 in G-I, 5:7 in G-II and 2:5 in G-III respectively. The female quantity was more than male. The Mean age of G-I, G-II and G-III were 55 ± 1.4 , 54 ± 2.2 and 55 ± 2.4 respectively and mean duration of Diabetes Mellitus of Group-I, II and III were 4.9 ± 0.44 , 5.3 ± 0.49 and 6.3 ± 0.42 respectively. The baseline values of BMI of Group-I, II and III were 25 ± 0.71 , 24 ± 1.1 and 23 ± 0.36 and it reduced up to 24 ± 0.69 , 23 ± 0.96 and 23 ± 0.19 after 3 month. There is not significant reduction in BMI of patients due to no large weight reduction within three month. There were significantly reductions in FPG found in all groups due to there is positive impact of regular diet control and exercise on fasting plasma glucose. The cholesterol values were not significantly reduced in Group-I but significantly reduced in Group-III. The baseline values of LDL of Group-I, II and III were 77 ± 6.8 , 69 ± 9.9 and 98 ± 7.7 reduced up to 49 ± 4.9 , 69 ± 9.9 and 98 ± 7.7 after 3 month as compared to baseline. The value of LDL was significantly reduced in Group-I and Group-III than in Group-II. In the present study baseline values of HbA1c of Group-I, II and III were 9.2 ± 0.6 , 10 ± 2.2 and 9.9 ± 0.84 respectively and it reduced significantly up to 8.2 ± 0.4 , 8.7 ± 0.49 and 8.7 ± 0.71 after 3 month as compared with baseline values. The significant reductions in the glycosylated hemoglobin level were observed among all the three groups. The HbA1c were found to be reduced more significantly in Group-II and Group-III subjects who are on oral hypoglycemic triple combination therapy and on insulin with counseling. There were significant reductions in HbA1c in Group-I by 1.0 ± 0.2 %, in Group-II by 1.3 ± 1.71 % and in Group-III by 1.2 ± 0.13 % after 3 month as impact of patient counseling.

Conclusion:

Diabetes is a chronic illness that requires a combination of pharmacological and non-pharmacological measures for better glycemic control. Patient adherence to medication and lifestyle modifications plays an important role in diabetes management. The majorities of individuals with type 2 diabetes were overweight, did not engage in recommended levels of physical activity, and did not follow dietary guidelines for fats, fruits and vegetable consumption. Additional measures are needed to encourage regular physical activity and improve dietary habits in this population. This study provides evidence that a community-based patient counseling regarding Disease, medication and Life style modification for type 2 diabetic patients, can be effectively implemented in developing nations and that important health indicators significantly improve. In particular, BMI and Glycemic levels decreased. The decreased glycosylated hemoglobin should translate into a reduced risk of further

complications. The knowledge of the subjects visiting the first time was found to be inadequate. This probably is due to inadequate information, non-availability of educational material and improper guidance. The reasons of the poor knowledge need to be further studied in detail in these populations. Similar results were also observed in different educational modules. It means it is concluded that continuous education programmes and counseling should be conducted for Diabetic patients to emphasize and re-emphasize the importance of risk factor, prevention, adherence to medication and behavioral changes to prevent recurrences of disease, there progression, and ultimately minimize hospitalization. Overall outcome would be cost effectiveness in health care system and better life of the sufferer.

References:

- 1) Palaian S., Chhetri A.K., Prabhu M., Rajan S., Shankar P. V., Role of Pharmacist in Counseling Diabetes Patients, *IJP.*, 2005, ,4,1.
- 2) Gerber R.A., Liu G., Mccombs J.S., Impact of pharmacist consultations provided to patients with diabetes on healthcare costs in a health maintenance organization, *Am J Manag Care.*, 1998, 4(7), 991-1000
- 3) American Diabetes Association, Standards of medical care for patients with diabetes mellitus, *Dia. care.*, 2004, 27, S15- S35
- 4) USP medication counseling behaviour guideline. USP di update volumes I and II Rockville, the USP Convention Inc., 1997, 664-75, 1739-48.
- 5) Beardsley R. S., Review of literature: oral patient counseling by pharmacists. Proceedings of the National Symposium on oral counseling by pharmacists about prescription medicines, 1997, 19-21; Lansdowne, Virginia.
- 6) Dooley M., Lyall H., Galbriath et al. SHPA standards of practice for clinical pharmacy. In: SHPA practice standards and definitions 1996, p. 2-11
- 7) Omnibus Budget Reconciliation., Act of 1990, Pub. L .no. 101-508, and 4401, 104 stat 1388, 1990.
- 8) Mellen P.B., Palla S.L., Goff D.C., Bonds D.E ., *Prevalence* of Nutrition and Exercise Counseling for Patients with Hypertension, *JGI MED.*, 2004, 19,917-924.
- 9) Singh K., nutritional counseling in management of diabetes mellitus, *int. j. diab. dev. countries.*, 1997, 17, 109-110.

- 10) Heilbronn L.K., Noakes M., Clifton P. M., Effect of Energy Restriction, Weight Loss, and Diet Composition on Plasma Lipids and Glucose in Patients with Type 2 Diabetes, *Dia. Care.*, 1999, 22:889–895.
- 11) Franz M.J., Bantle J. P., Beebe C. A., Brunzell J.D., Chiasson J. L., Garg A., Holzmeister L.A., Hoogwerf B., Davis D.E., Mooradian A.D., Purnell J.Q., and Wheeler M., Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications, *Dia. Care.*, 2002, 25,148-198
- 12) Powar A. C., Kasper L. K., Fauci A. S., Longo D. L., Harrison's principles of Internal Medicine, 16th Edition, Mc Graw-Hill Medical Publishing Division, 2002, 2152-2179.
- 13) American Diabetes Association, Physical Activity/Exercise and Diabetes, *Dia. Care.*, 2004, 27:S58-S62.
- 14) Adepu R., Rasheed A., Nagav, B.G., Effect of patient counseling on quality of life in type-2 diabetes mellitus patients in two selected South Indian community pharmacies: A study, *ijps*, 2007, 69 (4), 519-524S.
- 15) Albright A.L., Apovian C.M., Clark N.G., Franz M. J., Hoogwerf B. J., Lichtenstein A. J., Nutrition Recommendations and Interventions for Diabetes; A position statement of the American Diabetes Association, *dia. care*, 2007, 30 (1), S48-S64.
- 16) Goldhaber-Fiebert J.D., Goldhaber-Fiebert S., Randomized Controlled Community-Based Nutrition and Exercise Intervention Improves Glycemia and Cardiovascular Risk Factors in Type 2 Diabetic Patients in Rural Costa Rica, *Dia. Care*, 2003, 26:24–29
- 17) Kim H.S., Jeong H.S., A nurse short message service by cellular phone in type-2 diabetic patients for six months, *J Clini.Nur.*, 2007, 16, 1082–1087.
- 18) Hardcastle S., Taylor A., Bailey M., Castle R., A randomized controlled trial on the effectiveness of a primary health care based counseling intervention on physical activity, diet and CHD risk factors; *Patient Edu. and Counseling.*, 2008, 70, 31–39.
- 19) Kiel P.J., Mccord A.D., Pharmacist impact on Clinical Outcomes in a Diabetes Disease Management Program via Collaborative Practice, *Ann Pharmacother.*, 2005, 39, 1828-32.