



Impact of Clinical Pharmacist Initiated Patient Counseling in Patients with Metabolic Syndrome in a Tertiary Care Hospital

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ABSTRACT

The contribution of present study was to draw attention to the effects of patient counseling on quality of life (QOL), to improve prevention and treatment strategies for metabolic syndrome. A prospective interventional study with 6 month duration was carried out in inpatient and outpatient of General medicine I department at KIMS AL SHIFA Super Speciality Hospital. A total of 90 patients with a diagnosis of metabolic syndrome, under the age of greater than 18 yrs old meeting up inclusion and exclusion criteria were included for the study. The patient demographics as well as laboratory parameters like Age, Sex, Occupation, BMI, Waist Hip Ratio, Place, Social Habit, Type of food, Number of meals, Food restriction, FBS, PP, HbA1C, Lipid profile, Uric acid, TSH, BP etc. were collected. The collected data were analyzed using statistical package for social science (SPSS) version 20.0. Among 90 patients, 61 were male and 29 were female and majority falls between the age group of 40-50. 41.1% of the study population were overweight, 35.6% were falls into obese category. Most of the patients in our study were nonalcoholic (81.1%) and nonsmokers (67.8%) this may be attributed to higher prevalence of Muslim community in the local region. Most of the study population was following mixed diet (47%) and non vegetarians were least (37.8%). All the laboratory parameters in phase I as (DBP, SBP, FBS, PPBS, HbA1C, TG, TC, HDL, LDL, TSH, uric acid) were compared with the results of phase II and we found that there is a control in the condition. The study provided a complete evaluation, categorization and analysis of metabolic syndrome in the dept. of General medicine -I. High risk metabolic syndrome patients had abnormal laboratory values namely FBS, TC, BP, LDL levels. Abnormal central obesity was found to influence FBS and BP values. Therefore maintenance of healthy weight through proper diet, excises is importance for preventing metabolic syndrome. The key strength of this study was patient counseling which improves the patient understanding about the illness, medication, diet, exercise, lifestyle modification.

INTRODUCTION

According to National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria, for diagnosing it as a metabolic syndromes should meet greater than three of the five criteria, which includes waist circumference for men greater than 40 inches and for women greater than 35 inches.[1] Triglyceride concentration should be

greater than 150 mg/dL, High-Density Lipoprotein cholesterol (HDL-C) for men less than 40 mg/dL, for women less than 50 mg/dL. In case of Hypertensive patients, blood pressure (BP) should be greater than 130/85 mmHg or any individual receiving pharmacologic therapy for hypertension can also be included and Fasting blood glucose should be greater than 100 mg/dL.[2](American Diabetes Association [ADA] guidelines, 2014). In this project we followed definition given by NCEP ATP

III criteria (2017). The Adult Treatment Panel III (ATP III) recommended two major therapeutic goals in patients with the metabolic syndrome in 2001

- Treat underlying causes (overweight/obesity and physical inactivity) by intensifying weight management and increasing physical activity
- Treat cardiovascular risk factors if they persist despite lifestyle modification

Weight reduction is primarily important and can be achieved by approaches including controlling diet, exercise, and possible pharmacologic therapy[3]. Patient counseling comprises interaction between a pharmacist and a patient and/or a care giver. The effective counseling ought to comprehend all the parameters to make the patient understand his/her illness, medications and life style modification required. From many studies, it is known that metabolic syndrome is strongly linked to patient specific behaviors such as smoking, diet, sedentary lifestyle, etc. [4]. Behavior changes are required for the prevention and effective treatment of these chronic illnesses. Pharmacists are well familiarized themselves with updates in the scientific study of the behavior change. Chronic illnesses move through different phases and these phases of illness require different kinds of managing strategies including patient counseling. When providing medication counseling to patients with chronic illnesses, pharmacists should be sensitive to the broad array of challenges that the patients face. The objective of this study was to provide patient counseling and improve patient understanding about their illness and to reduce various consequences related to metabolic syndrome.

MATERIALS AND METHODS

Study design

A Prospective Interventional study was conducted in General medicine department of KIMS Al Shifa hospital, a tertiary care hospital in the Malabar region of Kerala. The study was approved by the Ethical Committee of the hospital(KAS/EC/2018-64, Dated 08/01/2018). The study duration was for 6 months from December 2017- May 2018.

Subjects

All in-patients and out patients with metabolic syndrome who are willing to participate and aged greater than 18 years of either sex were included in the study. Patients with psychiatric disorders and those are unable to provide written informed consent were excluded from the study.

Procedure

A total of 90 patients who meet the criteria's for metabolic syndrome were enrolled in the study following the inclusion and exclusion criteria. A written informed consent was obtained from

all enrolled patients. Sources of data are Outpatient treatment chart, Inpatient treatment chart, Personal interview with patient, computerized patients medical records, Family members/caregivers and interactions with the physician. A data collection form was obtained and validated to collect information necessary for the study. The form consists of the following details. 1. Patient demographics, 2. Reason for visit, 3. Past medications, 4. Family history, 5. Social history, 6. Allergies, 7. Lab reports, 8. Patient counseling details, 9. Follow up details. WHOQOL BREF questionnaire were used to assess the quality of life of the patient. The WHOQOL BREF contains a total of 26 facets (24 facets from WHOQOL 100 and 2 from the overall QOL and General Health facet). These 26 facets were classified into 4 domains namely physical health, psychological, social relationship, environment and each domain contains few questions which were asked to the patients and calculated the score according to the instructions of WHOQOL BREF questionnaire.

Patient Information leaflets were designed after understanding about all the aspect of the disease with an aim to help the patient, their care givers and other general public to understand in detail about their ailment.

The study was conducted in two phases, pre interventional study and post interventional study. In phase I include enrolment of study subjects, entry of patient details to data collection book, and patients were counselled on their illness, medication, exercise and lifestyle modification. In phase II the patients were evaluated after 3 months on their review date for outcome measures which include metabolic syndrome status (binomial) and changes in values for each metabolic syndrome component (waist circumference, triglycerides, HDL-C, LDL-C, fasting blood glucose, systolic and diastolic BP) and for body weight. The patients were assessed based on the diagnostic criteria. Table 1.

Statistical analysis

The recorded data were analyzed using Statistical Package for Social Sciences (SPSS) software version 20.0. Categorical variables were summarized using frequency with percentage and analysed using Paired t test. P value < 0.05 was considered to be statistically significant.

RESULTS

The study showed that higher prevalence of metabolic syndrome is seen in the age group of 40-45 with a marginal decrease after 60 (Fig.1). Majority of the study population are found to be male (67.7%) and 29 (32.2%) females were included (Fig.2). Study showed that there is a significant association with metabolic syndrome and obesity. Among the study population, 37 (41.1%) of the population belongs to overweight, 32 (35.5%) belongs to obese group, 21 (23.3%) belongs to normal weight patients (Fig.3). Our study demonstrates that major part of

Table 1: National Cholesterol Education Program Adult Treatment Panel III (NCEP/ ATP III) criteria

• Glucose	: ≥ 5.6 mmol/L (100 mg/dL) or drug treatment for elevated blood glucose
• HDL cholesterol	: < 1.0 mmol/L (40 mg/dL) (men) < 1.3 mmol/L (50 mg/dL) (women) or drug treatment for low HDL-C
• Triglycerides	: 1.7 mmol/L (150 mg/dL) or drug treatment for elevated triglycerides

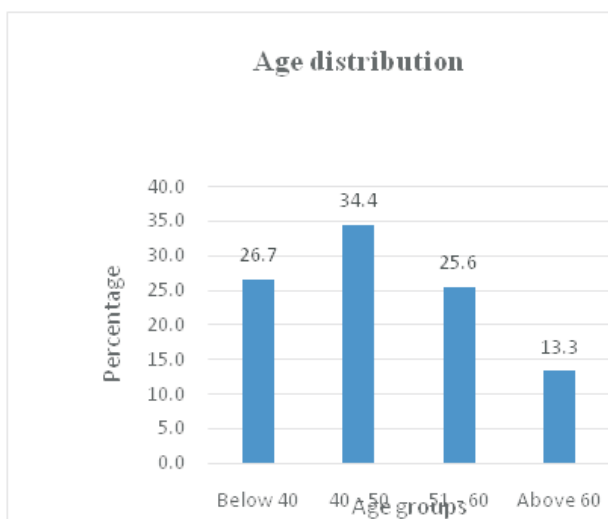


Fig. 1 : Distribution Based on Age

Sex distribution

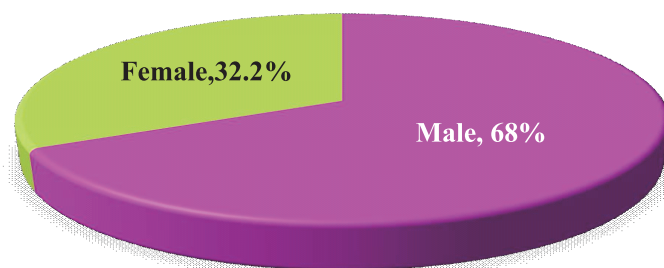


Fig. 2 : Distribution Based on Sex

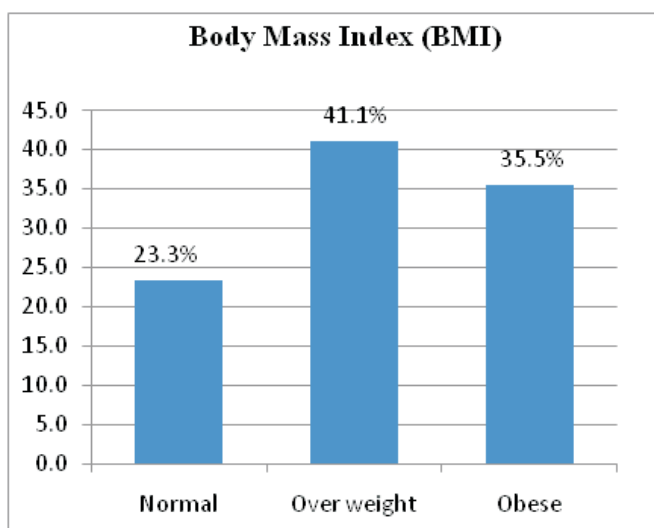


Fig. 3 : Distribution Based on BMI



Fig. 4 : Distribution Based on Social Habits

Table 2: Distribution Based on Type of Food

Category	Percentage
Veg	14,8
Non Veg	37.8
Mixed	47.8

patients were from rural areas of Perinthalmanna 66 (73.3%) and 24(26.6%) are from urban area.

From total of 90 patients 17 (18.9%) were found to be alcoholic and 73 (81.1%) were found to be nonalcoholic. The results show that 61 (67.8%) patients were nonsmokers and 21(32.2%) patients were smokers among the total of 90 (Fig.4). Based on type of food, result indicated that 47.8% patient consuming mixed diet which was the predominant category(Table 2). Our study reveals that majority of the subject were engaged in more meal time behavior i.e. 3-4 meals per day (Table 3). Out of 90 total populations only 25 patients were on food restriction due to their condition and 65 patients were not having any food restrictions.

Table 3: Distribution Based on Number of Meals

No. of meals	Frequency	Percent
2	6	6.7
3	39	43.3
4	39	43.3
5	6	6.7
Total	90	100

Table 4 : Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	fbs 1	135.4751	90	51.66114	5.44556
	fbs 2	124.4729	90	39.98923	4.21524
Pair 2	pp1	171.9101	90	68.83365	7.25570
	pp2	152.9717	90	44.83128	4.72563
Pair 3	HbA1C1	7.1911	90	2.14169	.22575
	HbA1C2	6.5359	90	1.64982	.17391
Pair 4	TC1	219.3467	90	41.43187	4.36730
	TC2	196.8153	90	34.76560	3.66462
Pair 5	HDL1	40.0667	90	11.91725	1.25619
	HDL2	46.2222	90	10.39855	1.09610
Pair 6	LDL1	148.1656	90	37.49918	3.95276
	LDL2	136.8400	90	32.88248	3.46612
Pair 7	Trigly1	174.8667	90	60.08380	6.33339
	Trigly2	159.2033	90	42.03431	4.43081
Pair 8	Uric acid1	6.4109	90	4.57508	.48226
	Uric acid2	5.6582	90	1.62159	.17093
Pair 9	TSH1	2.4338	90	4.59326	.48417
	TSH2	2.2553	90	2.78574	.29364
Pair 10	Systolic1	142.9778	90	16.46923	1.73601
	Systolic2	134.7556	90	11.29115	1.19019
Pair 11	Diastolic1	91.4222	90	13.10200	1.38107
	Diastolic2	86.2778	90	7.76773	.81879

In our study we used paired sample test for comparison of Phase I and Phase II laboratory parameters, FBS, PP, HbA1C, TC, HDL, LDL, TG, TSH, uric acid, SBP, DBP. All these parameters after pre and post interventional phase show p value <0.001 except in case of uric acid and TSH. This is because uric acid and TSH cannot be easily controlled within a span of 3 months. Those lab parameters take time to reduce and we advice those patient strictly adhere to medicine and strict lifestyle modification. In our study comparison of phase I and phase II results of FBS, PPBS, HbA1c shows that a significant reduction in pre and post interventional values. This study indicate that mean of TC1 and TC2 are 219.35 and 196.82 respectively, P value is found to be (p<0.001). HDL1 is 40.07 and HDL2 is 46.22, which shows that patients have improvement after the counseling phase. P value is found to be (p<0.001). We found that mean of uric acid in pre interventional phase is 6.41 and post interventional phase is 5.66. P value is found to be 0.086. Mean TSH in pre counseling period is 2.43 and in post counseling is reduced to 2.26. It indicates that there is slight reduction in serum TSH level. P value is found to be 0.34. The two major parameters which define metabolic syndrome are systolic and diastolic BP. In our study there is a

slight reduction shown in post interventional analysis. Mean of systolic BP in pre and post interventional phase is 142.98 and 134.76 respectively. And diastolic BP is 91.42 and 86.28. P value is found to be (p<0.001) (Table 4 & 5). Comparison of Phase I and Phase II Results of Quality of life is shown in Table 6 & Table 7.

DISCUSSION

In this prospective, interventional study 90 patients were found at high risk of metabolic syndrome. The observed increase in metabolic syndrome was large and persistent across several different analytic assumptions. By contrast we found a significant change in life style, diet and exercise in patients with metabolic syndrome after the patient counseling. Our study revealed the association between BMI and life style in metabolic syndrome. Life style modifications have a greater role in metabolic syndrome. The prevalence of metabolic syndrome as per the study conducted by Biju Jacob *et al* was found to be 66.2%. [5] The result shows that metabolic syndrome is an important public health problem. Woo - sung lee *et al* conducted a study in which HDL cholesterol level was negatively correlated with serum uric acid level. [6] This correlation was also observed in our study, 26

Table 5: Paired Samples Test

		Paired Differences					T	df	P value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	fbs 1 - fbs 2	11.00222	23.60502	2.48819	6.05825	15.94620	4.422	89	.000
Pair 2	pp1 - pp2	18.93844	39.92855	4.20884	10.57557	27.30132	4.500	89	.000
Pair 3	HbA1C1 - HbA1C2	.65522	1.49828	.15793	.34141	.96903	4.149	89	.000
Pair 4	TC1 - TC2	22.53133	20.91456	2.20459	18.15086	26.91180	10.220	89	.000
Pair 5	HDL1 - HDL2	-6.15556	6.86669	.72381	-7.59376	-4.71735	-8.504	89	.000
Pair 6	LDL1 - LDL2	11.32556	19.71730	2.07839	7.19585	15.45526	5.449	89	.000
Pair 7	Trigly1 - Trigly2	15.66333	31.84731	3.35700	8.99304	22.33362	4.666	89	.000
Pair 8	Uric acid1 - Uric acid2	.75269	4.11642	.43391	-.10948	1.61486	1.735	89	.086
Pair 9	TSH1 - TSH2	.17853	2.15492	.22715	-.27281	.62987	.786	89	.434
Pair 10	Systolic1 - Systolic2	8.22222	11.10297	1.17036	5.89675	10.54769	7.025	89	.000
Pair 11	Diastolic1 - Diastolic2	5.14444	10.72073	1.13006	2.89903	7.38986	4.552	89	.000

Table 6: Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	DOMAIN 1	20.3556	90	10.45086	1.10162
	pDOMAIN 1	80.8778	90	9.57857	1.00967
Pair 2	DOMAIN 2	18.7556	90	9.49904	1.00129
	pDOMAIN 2	79.7889	90	11.36473	1.19795
Pair 3	DOMAIN 3	20.9667	90	10.36681	1.09276
	pDOMAIN 3	80.1556	90	11.85105	1.24921
Pair 4	DOMAIN 4	21.9111	90	9.88432	1.04190
	pDOMAIN 4	82.3667	90	11.06919	1.16680

Table 7: Paired Samples Test

		Paired Differences					t	df	P value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	DOMAIN 1 - pDOMAIN1	-60.522 22	15.85129	1.67087	-63.84221	-57.20223	-36.222	89	.000
Pair 2	DOMAIN 2 - pDOMAIN2	-61.033 33	15.79607	1.66505	-64.34176	-57.72491	-36.656	89	.000
Pair 3	DOMAIN 3 - pDOMAIN 3	-59.188 89	15.89353	1.67533	-62.51772	-55.86005	-35.330	89	.000
Pair 4	DOMAIN 4 - pDOMAIN4	-60.455 56	15.23535	1.60595	-63.64654	-57.26457	-37.645	89	.000

Table 7 shows that mean of Domain 1 and Pdomain 1 is -60.52 with P value<0.001. Mean of Domain 2 and Pdomain 2, Domain 3 and Pdomain 3. Domain 4 and Pdomain 4 is -61.033, -59.1889, -60.455 respectively all of this having a P value of <0.001.

patients have elevated serum uric acid and 28 patients show decreased HDL cholesterol. A study conducted by Ying Zhang et al suggest that life style intervention can be help full to improve the cardiovascular risks. [7] Our study also shows the similar result and decreased the cardiovascular complications. Shuba sreenivsan conducted a study based on metabolic syndrome in rural Kerala in hospital and the results found that the prevalence of metabolic syndrome in this study population was 60.9%. [8] Our study also shows the same findings, this may be attributed to majority of the patients were from rural area. Unlike a study conducted by Tanima paul et al, [9] our study shows that males are majority in number (67.8%) and females were (32.2%), this can be explained by majority of the patients visiting GM - I department were males and many of the female patients were not willing to participate in the study. Unlike a similar study conducted by Eun Shil Lim et al, [10] in our study 81.1% of the patients were nonalcoholic. This can be explained by the higher prevalence of Muslim community in the local region. With regards to smoking status, smokers having an increased prevalence of metabolic syndrome. In our study 67.8% were nonsmokers.

Dietary patterns had marked difference in the prevalence of metabolic syndrome (MetS). Most of the patients were turn to be mixed (47.8%) group in this study and also suggest that the vegetarians (14.4%) group has least chance of MetS.

Result of a study by Annemieke *et al* [11] shows that free T₄ was significantly related to four of 5 components of metabolic syndrome and abnormal thyroxine leads to cardiovascular disorders. In our study we analyzed serum TSH levels and it showed that there is a positive correlation between serum TSH and MetS.

The findings in the present study are lower than the results of the study conducted by T sai *et al* [12] to assess the health related QOL in obese individual seeking weight reduction and found mean physical component and mental component scores to be 46.8+/-8.4 and 49.9+/- 9.2 and the results of our study in pre interventional phase was found to be 20.4 +/-4.2 8 and 18.75+/- 5.1. The difference could be attributed to be fact that the participants in the present study have been taken from general population while the study subjects in study conducted by T sai *et al* were taken from patients who were always obese and were seeking weight reduction.

We assessed the QOL in all patients with metabolic syndrome based on WHOQOL-BREF questionnaire. QOL was found to be lower in group with metabolic syndrome. This difference of QOL in the 2 groups was found to be highly statistically significant. In the present study, the difference between QOL scores in participants having metabolic syndrome and those having dyslipidemia only was not found to be statistically significant. No study could be countered on literature search which studied the effect of dyslipidemia on QOL.

CONCLUSION

In this study, systematic analysis of patient counseling results in better understanding about metabolic syndrome. Abnormal central obesity was found to influence FBS and BP values. BMI was found to be a useful index for prediction of risk factors of metabolic syndrome. All of the patients were positive for at least one of the diagnostic criterion of metabolic syndrome. The dietary habits were reported to be poor in 3/4th of the participants. Therefore maintenance of healthy weight through proper diet, excises is importance for preventing metabolic syndrome.

Periodic assessment of lab parameters, weights etc. are essential to prevent metabolic syndrome. The key strength of this study was patient counseling which improves the patient understanding about the illness, medication, diet and exercise and lifestyle modification. The result of this study clearly highlights the necessity to continue surveillance of various criteria of metabolic syndrome among general public. The guided risk management strategy was effective in improving the knowledge and attitude of patients regarding the prevention of metabolic syndrome.

Our detailed examination of the types of intervention and assessment of quality of the study provides insight in to the strength of the evidence from the included studies and a greater understanding of the gaps in the literature and we have launched a medication counseling center at KIMS Al Shifa Hospital which is comparatively a novel concept in Kerala.

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