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EVALUATION OF PREVALENCE, KAP AND PRESCRIBING PATTERN OF DRUGS TO TYPE 2 DIABETIC PATIENTS AND ASSESSMENT OF RISK FACTORS AMONG THE NON-DIABETIC PATIENTS IN A TERTIARY CARE HOSPITAL IN SOUTHERN KERALA

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ABSTRACT: A prospective, observational study was conducted among the 100 diabetic and 100 non-diabetic patients for a period of six months for the evaluation of prevalence, KAP (Knowledge, Attitude and Practice) and prescribing pattern of drugs to type 2 diabetic patients and to assess the risk factors of prevalence of diabetes among the non-diabetic patients. All information relevant to the study was collected from case records and by direct interview method. The data collected was analyzed by using statistical package for the social sciences (SPSS) version 17.0 software. The results showed that, majority of the patients were male, above 61 years age, literates, free from smoking and alcohol habits, had medium physical activity, family history of diabetes and had at least one co existing illness mainly hyper tension. Oral hypoglycaemics and anti-hypertensives were mainly prescribed. After counseling the KAP was improved significantly. Majority of the non-diabetic patients were male, 26 % had less than 35 years age, mainly non-vegetarian. The results showed that age and BMI with the risk had a significant association. From this study it was clear that public health programs involving educational interventions and behavioral changes are necessary for better control and management of this disease.

INTRODUCTION: Globally, about 387 million people are living with diabetes mellitus currently¹. According to the report of International diabetes federation this figure may reach almost 592 million in the year 2035². In developing countries, 35 - 64 years age group is most commonly affected comparing with developed countries where the elders are mostly affected. 80% of the people affected with type 2 diabetes mellitus are living in these developing countries and importantly, almost half of them are in undiagnosed condition¹.

In India, it is reaching to the stage of 'Pandemic'. Recently, the WHO states that about 19 % of the world's diabetic population belongs to India. In 2005, prevalence of diabetes mellitus in urban India was 15.5% which was only 2.4 % in 1970³. Sufficient data are not available about the prevalence of diabetes in rural India.

However, a study indicated that the prevalence was three times higher among urban population (8.2 %) compared with rural population (2.4%)^{3, 4}. This may be due to the differences in life style factors such as physical activity, dietary pattern and mental stress. Not only across the rural-urban divide, may the differences in the prevalence also occur across the Indian states, because of the different stages of demographic transition in different states. Based on this, a higher prevalence of diabetes mellitus could be expected in Kerala.

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In the last 20 - 25 years, the life style and living standards of this state facing a drastic change which will surely reflects in the normal health of the society⁵. Not only the physiological impact, but also the transient or chronic stress interfere with metabolic control and enhance the risk of prevalence⁶. The principles of management of diabetes mellitus mainly focus on prevention of the disease, screening of high risk individuals and proper treatment. Insulin and oral hypoglycaemics agents are the drug of choice for the treatment of diabetes^{2, 7}. Rational use of medicines is very important for the well being of patients. Not only treating the disease, a doctor must keen on reducing the patient's expenditure, adverse drug reaction, drug interactions and extra work load of medical and paramedical staffs⁸.

Adherence with the prescribed drugs has a major impact on health care quality⁹. Medication adherence is defined as the extent to which patients take medications as prescribed by their health care providers¹⁰. Non adherence, lack of knowledge, poor follow up and poverty is the important factors commonly observed in poor control of diabetes⁹.

Thus, the present study was undertaken to evaluate the prevalence, KAP (Knowledge, attitude and Practice) and prescribing pattern of drugs to type 2 diabetic patients and to assess the risk factors of prevalence of diabetes among the non-diabetic patients.

METHODS: After getting necessary approval from institutional ethical committee (R/ADMIN-08/0), a prospective, observational study was conducted for a period of six months from October 2014 to March 2015 in the Department of General Medicine, Cosmopolitan Hospitals Pvt. Ltd., a 550 bedded multispecialty hospital located in Thiruvananthapuram, Kerala, South India with the aim to assess the prevalence, risk factors, knowledge, attitude and practice (KAP) before and after counseling in type 2 diabetic population and prescribing pattern of anti-diabetics. Totally 200 patients, 100 diabetic and 100 non-diabetic patients were enrolled for the study.

The inclusion criteria for the enrollment:

- Both male and female type 2 diabetic and non diabetic patients with age of 18 years or more

- Both in-patients and out-patients with complete medical records
- Patients willing to participate in the study

The exclusion criteria were:

- Patients aged below 18 years
- Patients with incomplete medical records, psychiatric co-morbidities, language and communication problems
- Pregnant and breast feeding women
- Patients not willing to participate in the study

The participants were informed about the study and their consent was received in the prescribed format. Initially, the demographic data was collected from all the participants in the prescribed pro forma. Then all information relevant to the study was collected from case records and by direct interview method. Semi structured interview schedule such as Diabetes risk scoring tool, Cohen perceived stress scale and Medication adherence scale and Knowledge, attitude and practice (KAP) questionnaire were used to collect the required data. Cohen perceived stress scale was used to assess the status of stress in study participants. The score of 0 - 9 indicates low stress, 10 - 19 suggests an average level of stress and the score 20 - 40 indicates the prevalence of high stress.

World Health Organization prescribing indicator was employed to analyze the prescribing pattern of anti-diabetic drugs to the study subjects. The medication adherence scale was used to know the compliance and associated habits of study subjects in medication usage. The score level of 1-3 reflects a medium adherence, 4-10 indicates low adherence and the zero score indicates high adherence.

Before the counseling, the KAP of the participants was assessed. Then the counseling was provided to the diabetic patients in their mother tongue/the language they can understand. The counseling was mainly focused on the information regarding the causes, treatment, importance of diet and life style modifications and complications of improper treatment. It also covered the importance of check-up and contact with the treating physician *etc.* Again, after counseling the KAP of the study subjects was assessed. The KAP questionnaire consists of 25 questions (knowledge part - 14 questions, attitude part - 5 questions and the

practice part - 6 questions). In the KAP assessment, a score of 1 was given to each correct response and zero was given to wrong answer. In case of knowledge part, the total score of 0-7 indicates the poor knowledge and the score from 8-12 suggests a fair knowledge and the score from 13-14 reflects a good knowledge. In case of attitude part, the score of 1-2 indicates poor, 3-4 suggests fair and finally the score 5 reflects a good rank. In case of practice part, the score and the rank are similar with attitude part except the last one in which the score of 5-6 indicates a good rank.

The risk of prevalence of diabetes was assessed in 100 non diabetic patients by using Indian diabetic risk score tool. Particular score was given based on the age, waist circumference, physical activity and family history of diabetes prevalence. Finally, the total score was calculated. If the total score was ≥ 60 , it indicates very high risk, 30-50 score indicates moderate and <30 score indicates low risk of prevalence of diabetes. The data collected was analyzed by using statistical package for the social sciences (SPSS) version 17.0 software. The statistical techniques such as Chi - square tests and Pearson coefficient were employed.

RESULTS: A prospective, observational study was conducted for a period of six months from October 2014 to March 2015 among the type 2 diabetic and non diabetic patients of Department of General Medicine, Cosmopolitan Hospitals Pvt. Ltd., Thiruvananthapuram, Kerala, South India. 100 diabetic and 100 non diabetic patients were covered during the study period. Data were collected from case records and by direct interview method by using a semi structured interview schedule. The collected data was analyzed by using SPSS software.

Regarding with the demographic data of 100 diabetic patients, the results showed that 63 patients (63%) were male and 37 patients (37%) were female. According to age, the study population was divided in to four groups. 64 patients (64%) were belongs to 61 years and above age group. 27 patients (27 %) were come under 46-60 years age group. 8 patients (8%) were aged between 31-45 years and only one patient come under 18-30 years age group. Analysis of religious distribution revealed that 63 patients (63 %) were belongs to

Hindu religion followed by 22 participants (22%) were Christian and 15 candidates (15%) were Muslim. The analysis of educational status revealed that all the participants were literate. Among them 30 participants (30 %) had education in the level of under high school level. 25 candidates (25 %) were studied up to high school level. 21 study subjects (21 %) were studied up to higher secondary level and 24 patients (24 %) were graduates.

The results showed that 44 patients (44%) had normal body weight and only 11 patients (11%) were belongs to underweight category. Analysis of duration of prevalence of diabetes revealed that 41 patients (41%) had above 10 years prevalence, 27 candidates (27%) had 5-10 years history of disease followed by 22 study subjects (22%) had 1-4 years and only 10 patients (10%) had less than one year prevalence.

The results showed that 59 of 100 study subjects (59%) do not have smoking and alcohol habits, 25 candidates (25%) are smokers, 12 patients (12%) have smoking and alcohol habits and only 4 patients (4%) have alcohol usage habit. Analysis of physical activity nature of study subjects revealed that the prevalence of diabetes was high in medium physical activity patients. 44 patients (44%) belongs to this category. Low physical activity patients came in the next place. They constitute 37% (37 candidates) and remaining 19 patients (19%) came in the high physical activity class. The results of relationship of hereditary and diabetes prevalence assessment showed that majority of the study population, 63% (63 patients) had a family history of diabetes either in father, mother or in siblings or all. Only 37 patients (37%) did not have the family history of diabetes. Analysis of stress level of study subjects revealed that 46 patients (46%) had high stress, 36 and 18 patients had medium and low level of stress respectively.

The result indicated that the women (41%) scored higher than the men (13%) in chronic stress and minor daily stressors. Results of analysis of co morbidity showed that 92 out of 100 diabetic patients had at least one co existing illness. Among them, 53 patients (53%) had hyper tension. 20 patients (20%) were affected with heart disease and 19 patients (19%) had pulmonary disease.

The results showed that anti diabetic drugs were in top position among the percentage of different group of drugs prescribed. They shared 24 % in total. Anti-hypertensive drugs occupied the second place with 16.5 %, followed by multi vitamins and minerals (13.05%), antiplatelets/anticoagulants/fibrinolytics (11.71%), laxatives/purgatives (11.10%), analgesics/anti-inflammatories (10.88%), anxiolytic/hypnotic-sedative (5.15%), diuretic (5.01%) and antiangina (2.59%) were found the places in this category.

The results also revealed that 61 out of 100 diabetic patients (61%) were under oral hypoglycaemics treatment. 25 patients (25%) were taken insulin treatment and rest 14 patients (14%) were use both oral hypoglycaemics and insulin. Among the oral hypoglycaemics, metformin was most commonly prescribed. Metformin was prescribed to 40 patients (40%), Glimipride was prescribed to 20 patients (20%). Glibenclamide and gliclazide were prescribed to 6 and 5 patients respectively. Tolbutamide and voglibose users individually constituted 2 % of patients.

The prescribing pattern of drugs to the study subjects were analyzed based on WHO prescribing indicators. The results revealed that, in our study, the average number of drugs prescribed per encounter was 5.10 (5.10%) which is above the standard (1.6 - 1.8) derived to serve as ideal. All the drugs (100%) were written with trade (non-generic) names. Percentage of encounters in which the antibiotics prescribed was 25 % in our study. This result is within the standard (20.0% - 26.8%) derived to be ideal. The percentage of encounters in which injections prescribed was 24 %. This result falls within the standard (13.4% - 24.1%) derived to serve as ideal. In our study the percentage of drugs prescribed from essential drug list (EDL) was 57 % which is less than the standard (**Table 1**).

Results of analysis of medication adherence revealed that majority, 41% (41 patients) had medium adherence. 32 and 27 patients had high and low adherence level respectively. It was also found that there was no significant association between gender and BMI with medication adherence. But there is a significant association between education and adherence was found at 10% level (p - value < 0.1).

KAP of the diabetic study subjects were analyzed before and after counseling. It was identified that only one candidate had a good knowledge, 66 patients had a fair knowledge and importantly 33 candidates had poor knowledge before counseling. But after counseling a significant improvement was found. The results of after counseling analysis revealed that 61 candidates had improved to good knowledge, 37 candidates had fair knowledge and only 2 candidates had poor knowledge. In case of attitude, majority of the study subjects were in poor status (57 candidates), followed by 38 candidates had come under fair status and only 5 candidates were in good category before counseling. But the counseling brought a significant improvement in attitude of participants. After counseling assessment revealed that 13 candidates improved to good status 62 candidates reached a fair status and only 25 candidates were continued in poor status.

In case of practice, the results showed that, before counseling, the practice of majority of study subjects were in poor condition (51 candidates) which was reduced to 30 in numbers after counseling. Similarly, 52 candidates were in fair status after counseling but the same is less in before counseling (only 36) and importantly, the practices of 18 candidates were improved to good after counseling which had less candidates (13 in number) before counseling (**Table 2**).

TABLE 1: ANALYSIS OF PRESCRIBING PATTERN OF ANTI DIABETIC DRUGS BASED ON WHO PRESCRIBING INDICATORS

S. no	Prescribing indicators	Total drugs / encounters	Average/ percent	Standard derived (or) ideal
1	Average number of drugs per encounter	510	5.10	1.6 - 1.8
2	Percentage of drugs prescribed by generic name	Nil	Nil	100%
3	Percentage of drugs encounter with antibiotics	25	25%	20.0 - 26.8%
4	Percentage of drugs encounter with injection	24	24%	3.4% - 24.1%
5	Percentage of drugs prescribed from WHO EDL	57	57%	100%

EDL - Essential drug list

TABLE 2: KAP DIABETIC PATIENTS BEFORE AND AFTER COUNSELING

Aspect		Percentage of patients before counseling (%)	Percentage of patients after counseling (%)
Knowledge	Poor	33	2
	Fair	66	37
	Good	1	61
Attitude	Poor	57	25
	Fair	38	62
	Good	5	13
Practice	Poor	51	30
	Fair	36	52
	Good	13	18

The risk of prevalence of diabetes in non-diabetic patients was assessed in 100 non-diabetic patients. The results of demographic data analysis showed that, among 100 non-diabetic patients 53 patients (53%) were male and the rest, 47 (47%) patients were female. 26 patients (26%) were come under the age group of less than 35 years. 27 patients (27%) were fall under the age group of 35-49 years. 47 patients (47%) were belongs to 50 years and above age group.

Analysis of food habits of study subjects showed that 86 % (86 patients) were non-vegetarian and only 14 % (14 patients) were vegetarian. Results of body weight analysis indicated that 45 patients (45%) had normal weight, 33 patients (33%) were belongs to overweight category. 14 patients (14%) were in obese status and only 8 patients (8%) were belongs to underweight category.

Association between gender, age, food habit and body mass index with risk of prevalence of diabetes in non-diabetic study subjects was analyzed by chi square test. The results showed that there is no significant association between gender, food habit with risk of prevalence at 5% level of significance. But the age and the risk showed a significant association at 1% level of significance. Similarly, the BMI and the risk showed a significant association at 10% level of significance.

DISCUSSION: In the present study, the prevalence, risk factors and prescribing pattern of anti-diabetics based on WHO prescribing indicators was assessed on the patients of Cosmopolitan Hospitals Pvt. Ltd., Thiruvananthapuram, Kerala, South India. The knowledge, attitude and practice (KAP) of study subjects were also evaluated before and after counseling. 100 type 2 diabetic patients were enrolled in this evaluation. The study also assessed the risk of prevalence of diabetes in non

diabetic patients. 100 non diabetic patients were enrolled for this study.

The demographic data of diabetic patients enrolled for the study showed that 63% patients were male and 37% females, indicating that males predominated over females. However, contributing the higher proportion of male cases in this study may be in contrast to the fact that females tends to use public health facilities more than males. More than half of the patients that is 64% were in the age group of 61 years and above, more than one fourth, that is 27 % were in the age group 46-60 years, 8 % were in the age group of 31-45 years of age and 1% were in the age of 18-30 years of age, indicated the high prevalence of diabetes in elder patients. Majority of the diabetic patients belong to Hindu religion (63%) followed by Christian 22% and 15% Muslim.

Previous literatures indicated that education of patients is important in the management of disease. In our study, majority of the study subjects (30%) were qualified below high school level. 25% patients were found with high school level qualification. 21 study subjects (21%) were studied up to higher secondary level and 24 patients (24%) were graduates. Obesity and overweight are major risk factors for type 2 diabetes mellitus. The present study also revealed that the incidence was more in patients with normal bodyweight (44%) and less in underweight patients (11%).

From the present study it was identified that most of the patients had the duration of diabetic prevalence above 10 years. 41% patients were belongs to this category. Next, the duration of 5-10 years constitute 27% patients followed by 22% patients came under 1-4 years duration and only 10 patients (10%) had less than one year prevalence. It was found that majority of the patients under study (59%) were free from the habits like smoking and

alcohol usage. 25% patients were smokers, 12% patients had both smoking and alcohol usage habits and only 4 patients (4%) had alcohol usage habit. The present study revealed that the incidence of diabetes was high in medium physical activity patients (44%) followed by low physical activity (37%) and high physical activity (19%). Lack of physical activity seems to contribute to overweight and obesity that assists for the incidence of diabetes. From the present study it was identified that 63% of patients under study had a family history of diabetes either in father, mother or in siblings or all. Only 37% patients did not have a family history of diabetes.

The present study revealed that in 100 diabetic study subjects, highly stressed (46%) patients were more when compared to medium (36%) and low (18%) stressed patients. The result indicated that the women (41%) scored higher than the men (13%) in chronic stress and minor daily stressors, although there was no difference in the number of life events. This may be due to the women rated their life events as more negative and less controllable than the men.

The results clearly indicated that 92 out of 100 diabetic patients had at least one co-existing illness. Among them, 53 patients (53%) had hypertension. 20 patients (20%) were affected with heart disease and 19 patients (19%) had pulmonary disease. The present study indicated that hypertension is more prominent co-morbidity in diabetic patients.

Of course, the anti-diabetic drugs were in top position with 24% in total among the percentage of different groups of drugs prescribed. Anti-hypertensive drugs occupied the second place with 16.5%, followed by multi-vitamins and minerals (13.05%), antiplatelets/anticoagulants/fibrinolytics (11.71%), laxatives/purgatives (11.10%), analgesics/anti-inflammatory (10.88%), anxiolytics/hypnotic-sedative (5.15%), diuretic (5.01%) and anti-angina (2.59%) were found in this category. It was also identified that 61% of patients were under oral hypoglycaemic treatment. 25% patients were under insulin treatment and rest 14% patients were using both oral hypoglycaemics and insulin. Among the oral hypoglycaemics, metformin was most commonly prescribed. Metformin was prescribed to 40% patients; glimepiride was prescribed

to 20% patients. Glibenclamide and gliclazide were prescribed to 6% and 5% patients respectively. Tolbutamide and voglibose users individually constituted 2% of patients. In the present study, the average number of drugs prescribed per encounter was 5.10 (5.10%) which is above the standard (1.6-1.8) derived to serve as ideal. It suggested a tendency for polypharmacy, many of the prescriptions recorded up to 7 to 9 drugs per prescription, thereby the risk of drug-related problems may increase and the quality of life may be reduced.

In the present study, the average number of drugs prescribed per encounter was 5.10 (5.10%) which is above the standard (1.6-1.8) derived to serve as ideal. It suggested a tendency for polypharmacy, many of the prescriptions recorded up to 7 to 9 drugs per prescription, thereby the risk of drug-related problems may increase and the quality of life may be reduced. Physicians may prescribe unnecessary medications like multi-vitamins, minerals and enzymes unless absolutely required by the patient. All the drugs (100%) are written with trade (non-generic) names, while none of the drugs was mentioned with their generic name. This indicates that the prescribers' hospital needs to improve in the prescribing pattern by using more of generic names. Percentage of encounters in which antibiotics were prescribed was 25% in our study, which is within the standard (20.0% - 26.8%) derived to be ideal.

It showed that the prescribers are judiciously using antibiotics. The percentage of encounters in which injections were prescribed was 24%. This result falls within the standard (13.4% - 24.1%) derived to serve as ideal. Injections are always expensive compared to other dosage forms, moreover, unhygienic use of injections can increase the risk. In our study, the percentage of drugs prescribed from the essential drug list (EDL) was 57% which is less than the standard. It reflects the decreased awareness among the prescribers about EDL. Over all percentage distribution of medication adherence in diabetic patients showed that majority of them (32%) had high adherence, 41% shows medium adherence and 27% had low adherence. It was also found that there was no significant association between gender and BMI with medication adherence.

But there is a significant association between education and adherence was found. KAP of the diabetic study subjects were analyzed before and after counseling. The results showed that the KAP of the study subjects were improved significantly after counseling. From this it was clear that the effective clinical pharmacist intervention improve the KAP of the patients.

The risk of prevalence of diabetes in non-diabetic patients was assessed in 100 non-diabetic patients. The demographic data of study subjects showed that 53 % were male and the rest 47 % patients were female. 26 % were come under the age group of less than 35 years. 27 % were fall under the age group of 35-49 years. 47 % were belongs to 50 years and above age group. Analyses of food habits of study subjects showed that 86 % were non-vegetarian and only 14 % were vegetarian. Results of body weight analysis indicated that 45 % had normal weight, 33 % were belongs to overweight category. 14 % were in obese status and 8 % were belongs to underweight category.

The results of association between gender, age, food habit and body mass index with risk of prevalence of diabetes in non-diabetic study subjects showed that there is no significant association between genders, food habit with risk of prevalence. But the age and also the BMI with risk of prevalence showed a significant association. Thus, the Indian Diabetic Risk Score helps to detect people at risk of prevalence and assist the individuals in taking appropriate intervention in the form of dietary changes and increasing the physical activity and ultimately helps to prevent or at least delay the onset of diabetes.

CONCLUSION: A prospective, observational study was carried out on type 2 diabetic patients for a period of six months in a tertiary care, corporate hospital. After collecting the data, statistical tests were applied and the results were obtained. The study reveals that the prevalence of diabetes mainly attributed to reduced physical activity and family history. Sex and age also relevant factors, it was found that male subjects are more susceptible. High stress level was identified among female patients as compared to males. Most of the patients have comorbid conditions; therefore, they require more than one medication for their proper treatment.

It was observed that there is a high tendency and frequency to prescribe more than two drugs but less prescribed from essential medicine list. Cardiovascular related drugs and vitamins combined with oral anti-diabetic drugs are mostly prescribed. A moderate adherence was reported from this sample. This study proves that the KAP of the patients were improved by clinical pharmacist intervention and patient counseling. Public health programs involving educational interventions and behavioral changes are necessary for better control and management of this disease. The present study demonstrates that Indian diabetic risk score helps in the identification of undiagnosed diabetic and also risk population. Screening and early diagnosis of diabetes followed by early interventions would aid in prevention or effective management of diabetes and its associated complications.

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CONFLICT OF INTEREST: Nil

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