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Analysis of drug used for the treatment of complications of diabetes in a teaching hospital

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ABSTRACT

Diabetes is a chronic condition with devastating complications, mostly due to accelerated micro vascular and macro vascular disorders. Studies have demonstrated that tight control of blood glucose levels minimizes the complications of diabetes. Drugs play an important role in in the treatment of diabetic complications. A rapidly expanding therapeutic armamentarium is now available to treat diabetic complications. More therapeutic options translate into more complex decision making the prescriber. The present study was therefore undertaken to overview the current trends in the analysis of drugs in the treatment of diabetic complications at Basaveshwara teaching and general hospital (BTGH), Gulbarga. A nine month prospective observational study was carried out in the Department of Medicine at Basaveshwara teaching and general hospital (BTGH), Gulbarga. The data was collected from the case sheets and OPD cards of all diabetic complications patients. Out of 145 patients, 93(64.2%) patients were males and 52(35.8%) patients were females. It is observed that diabetic complications are more common in patients of age group 50-59 years (36.6%). Majority of patients 87 (60.1%) had diabetic nephropathy. Pharmacotherapy revealed that, monotherapy was the preferred approach for the treatment of the patients. Diuretic was the drug of choice in monotherapy while Furosemide and Gabapentin was the preferred drugs used in treatment. The overall usage of diuretic (furosemide) during the study period was in 60.1% of the patients. The use of anticonvulsant was found to be in 55.8% of the patients of which, Gabapentin was prescribed for maximum number of patients in 48.3%. The use drugs like AR-β were found to be less. Other agents like Selective Serotonin reuptake inbhitors and antiarrythmics did not find place for the management of diabetic complications even in a single patient during the study period

Keywords: Diabetes Mellitus, Prescription pattern.

INTRODUCTION

Diabetes mellitus (DM) today is an important single disease in the medical speciality and is a special subject in chronic medicine. [1] As a result of ageing, increasing obesity and decreasing physically active population, the global incidence of prevalence of diabetes mellitus are

exploding, exclusively due to an increase in type 2 diabetes mellitus which represents >90% of all cases of the disease.[2]

Diabetes mellitus is a global problem with devastating human, social and economic impact. Today, around 250 million people worldwide are living with Diabetes and by 2025 these total is expected to increase to over 380 million.[3]

The disease has a severe impact on mortality and morbidity and economic consequences because of its association with long term microvascular complications (eye disease, kidney damage, nerve damage) and macro vascular complications (coronary artery disease, peripheral vascular disease, cerebrovascular disease). Diabetes Mellitus has been recognized as one of the leading causes of death in developing countries.[4,5]

Diabetes has emerged as a major health problem in India. In recent years, India has witnessed a rapidly exploding epidemic of Diabetes. India today, leads the world with its largest number of Diabetic people in a given country.[6]According to the Diabetes atlas published by the International Diabetes Federation (IDF), there were an estimated 40 million persons with diabetes in India in 2007 and this number is predicted to rise to almost 70 million people by 2025 by which time, every fifth diabetic subject in the world would be an Indian.[7]

The risk factor for the high prevalence of diabetes among Asian-Indian are :[8]

- High racial susceptibility to Diabetes.
- High familial aggregation
- Central obesity
- Insulin resistance
- Lifestyle changes due to urbanization.

The number of people with diabetes is increasing due to population growth, ageing, urbanization, and increasing prevalence of obesity and physical inactivity. The highest percentage of increase of disease prevalence are likely to be in non-western and developing nations with major increase in the Middle-East, Sub-Saharan Africa, India, Asia and Latin America. Quantifying the prevalence of diabetes and the number of people effected by diabetes, now and in the future, it is important to allow rational planning and allocation of resources.[9]

Objective

Diabetes complications are a chronic and potentially disabling disease. It is a major and chronic threat to Global Public Health. The biggest impact of the disease is on adults of working age; particularly in developing countries. The prevalence of diabetic complications and its adverse health effects have risen more rapidly in South Asia than in other region of the world.

Both type 1 and type 2 diabetes are chronic condition with devastating complications, mostly due to accelerated microvascular and macro vascular disease. Studies have demonstrated that tight control of blood glucose levels minimizes the complications of diabetes.

Drugs play an important role in the treatment of diabetic complications. A rapidly expanding therapeutic armamentarium is now available to treat diabetic complications. More therapeutic options translate into more complex decision making for the prescriber.

Although prescription data indicate that, the new drugs are being widely prescribed, it is not through systematic study that how the drugs are being used together and while therapeutic agents are beneficial in controlling the disease, there is no single drug available without having any Adverse Drug Reactions (ADRs). Due to complexity of the disease, it poses various challenges for the clinician right from the diagnosis to the choice of treatment that is most appropriate for the patients

Therefore the present study was carried in Basaveshwar teaching and general hospital with the following objectives:

General objective
1 .To analyse the current drug prescribing trends in the management of diabetic complications.
2. To study the prevalence of diabetic complications

Specific Objective
1. To study the demographic profile of the patients suffering from diabetic complications.
2. To analyse the type of therapy used in the management of diabetic complications.

METHODLOGY

Study Site:
The study was conducted in the Department of medicine at Basaveshwar teaching and general hospital (BTGH), Gulbarga.

Study design:
It is a prospective observational study.

Study period:
The study was conducted for a period of nine months from June 2010 to February 2011.

Source of data:
Data was collected from
1. Patient Case sheet and medications chart.
2. Laboratory test reports.

Study criteria:
Inclusion criteria:
1. Diabetic Inpatients and Outpatients of either gender diagnosed with diabetic complications.
2. Diabetic patients both type-I and type-II.
3. Patients who are willing to participate in the study.

Exclusion criteria:

1. Gestational diabetic patients.

Study procedure:

Study was conducted in the Department of medicine at Basaveshwar teaching and general hospital. Patients were enrolled in the study considering the inclusion and exclusion criteria. Informed consent was taken from patient at the time of enrolment into the study. Following data was collected from the case sheets and OPD cards in a specially designed case collection form.

- Demographic profile of the Patients.
- Prevalence of diabetic complications.
- Category of the drugs used in the management of diabetic complications.
- To analyse the type of therapy used in the management of diabetic complications.

Ethical Committee Approval

Intuitional Ethical Committee Clearance was obtained from the Basaveshwar Teaching and General Hospital (BTGH), Gulbarga.

RESULTS

Demographic Details

Table 1: Details of gender distribution of patients during the study period.

Gender distribution	Number of Patients	Percentage (%)
Male	93	64.2
Female	52	35.8
Total (*N)	**145**	**100**

N=Total Number of patients

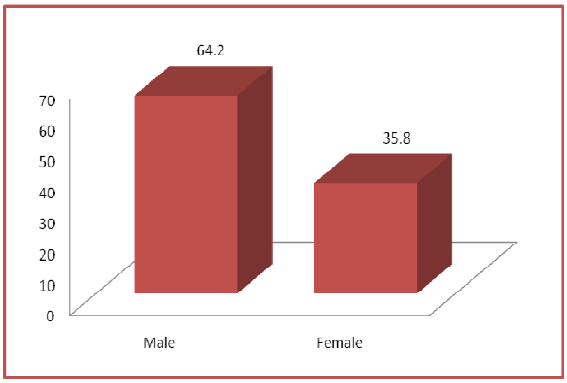

Figure 1 : Details of gender distribution of the study population.

A prospective observational study was carried out with an objective to evaluate the analysis of drugs in the treatment of the diabetic complications in the medicine department of Basaveshwar teaching and general hospital. A total of 145 patients fulfilling the inclusion criteria where enrolled for the present study and the patient data was collected from the IPD and OPD cards and laboratory reports of the patients enrolled for the study. The data collected was analysed for demographic profile of patients and analysis of drug in the treatment of diabetic complications.

Table 2 : Details of Age distribution of patients during the study period

Age distribution (Years)	Number of Patients	Percentage (%)
<30-39	11	7.5
40-49	27	18.6
50-59	53	36.6
60-69	34	23.5
70-79	17	11.7
80-89	3	2.1
Total (*N)	**145**	**100**

N=Total Number of patients

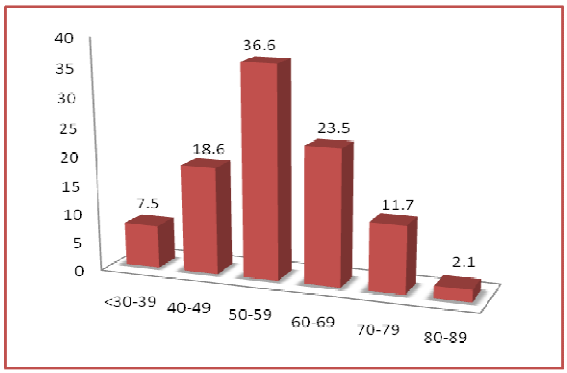

Figure 2: Details of age distribution of the study population.

Table 3 : Details of BMI distribution of patients during the study period

BMI	Number of Patients	Percentage (%)
Under weight (< 20)	43	29.6
Normal weight (20-27.5)	67	46.2
Over weight (> 27.5)	35	24.2
Total (*N)	**145**	**100**

N=Total Number of Patients

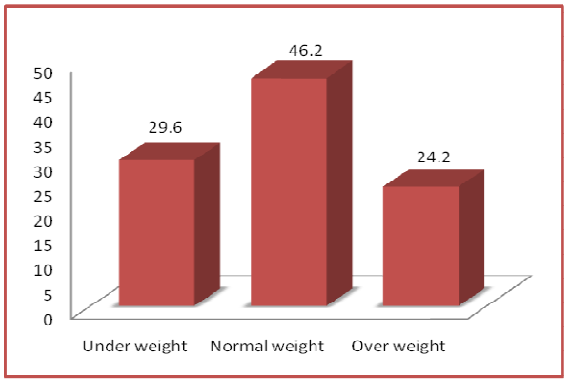

Figure 3 : Details of BMI distribution of the study population.

Table 4 : Details of family history of patients with Diabetes during the study period

Family History	Number of Patients	Percentage (%)
Father	38	26.3
Mother	21	14.4
Both	17	11.7
Brother	19	13.2
Sister	15	10.3
Others	23	15.8
No History	12	8.3
Total (*N)	**145**	**100**

N=Total Number of Patients

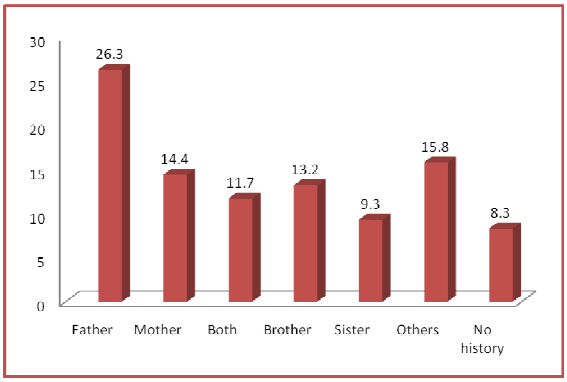

Figure 4: Details of family history of the study population.

Table 5: Details of Education status of patients with diabetes during the study period

Education Status	Number of Patients	Percentage (%)
Grade 0 (Uneducated)	29	20.0
Grade 1 (Upto IXth)	36	24.8
Grade 2 (Upto SSLC/PUC)	47	32.5
Grade 3 (Graduate/Postgraduate)	53	22.7
Total (*N)	**145**	**100**

N=Total Number of Patients

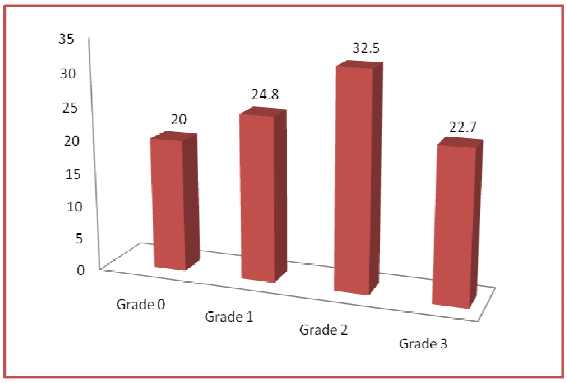

Figure 5: Details of Education status of the study population

Table 6: Fasting Blood glucose levels of patients with diabetes during the study period

Fasting Blood Sugar (mg/dl)	Number of Patients	Percentage (%)
< 80	6	4.1
81-100	17	11.7
101-120	22	15.4
121-140	16	11.0
141-160	19	3.3
161-180	8	5.5
181-200	11	7.6
201-220	7	4.8
221-240	6	4.1
241-260	2	1.3
261-280	4	2.7
281-300	5	3.4
301 above	1	0.6
Not done	21	14.4
Total (*N)	**145**	**100**

N=Total Number of Patients

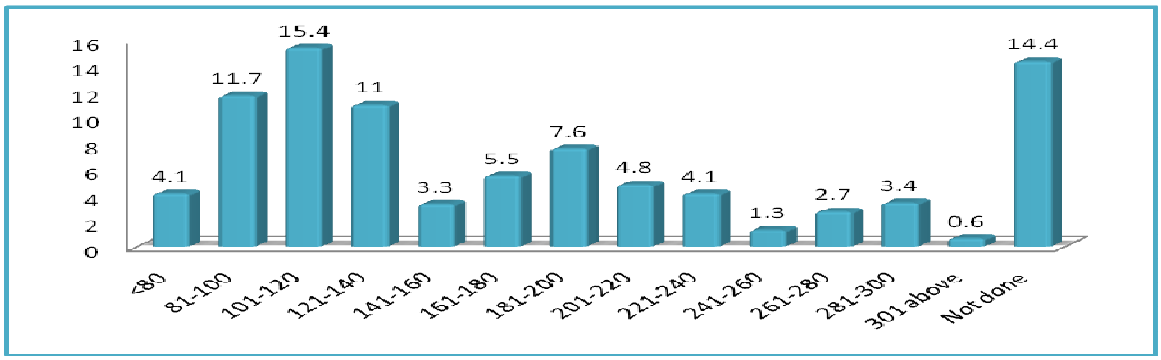

Figure 6 : Fasting Blood glucose levels of the study population.

Table 7:Post-prandial Blood glucose levels of patients with diabetes during the study period.

Post prandial Blood Sugar(mg/dl)	Number of Patients	Percentage (%)
60-100	2	1.5
101-140	15	10.5
141-180	23	15.8
180-220	31	21.3
221-260	17	11.7
261-300	19	13.1
301-340	6	4.2
341-380	5	3.4
380 above	4	2.7
Not done	23	15.8
Total (*N)	**145**	**100**

N=Total Number of Patients

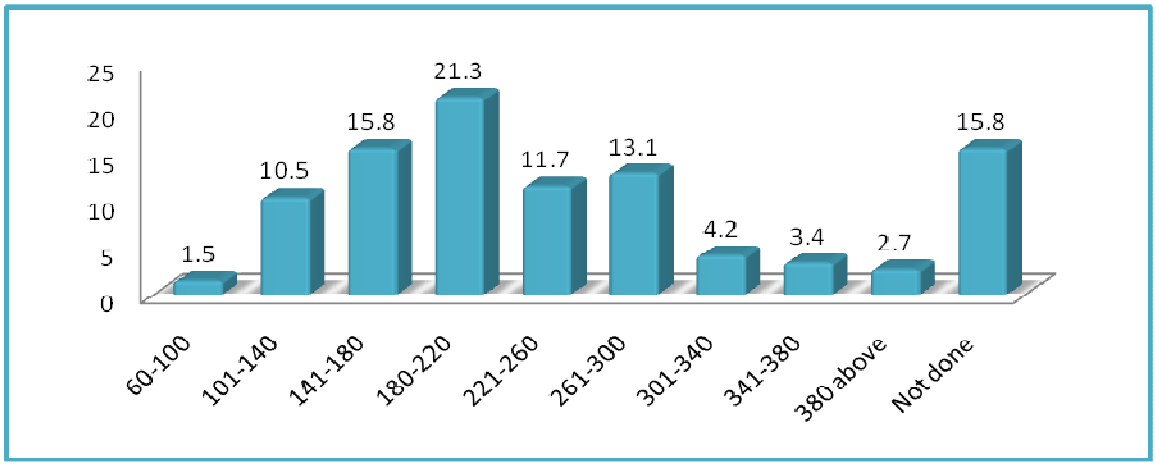

Figure 7: Post prandial Blood glucose levels of the study population.

Table 8: Glycosylated Haemoglobin (HbA1c) levels of patients with diabetes during the study period

Glycosylated Haemoglobin (%)	Number of Patients	Percentage (%)
7-8	12	8.2
8.1-9	23	15.8
9.1-10	21	14.4
10.1-11	12	8.3
11.1-12	9	6.3
12.1-13	5	3.5
Not done	63	43.5
Total (*N)	**145**	**100**

N=Total Number of Patients

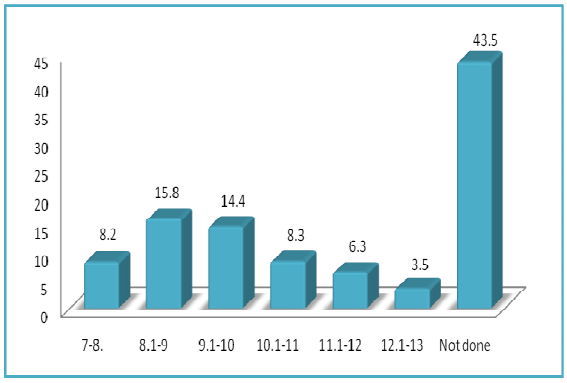

Figure 8: Glycosylated Haemoglobin (HbA1c) levels of the study population.

Table 9:Details of different Diabetic Complications during the study period

Name of complications	Number of Patients	Percentage (%)
Diabetic Nephropathy	87	60.1
Diabetic Neuropathy	46	31.7
Diabetic Retinopathy	12	8.2
Total (*N)	**145**	**100**

N=Total Number of Patients

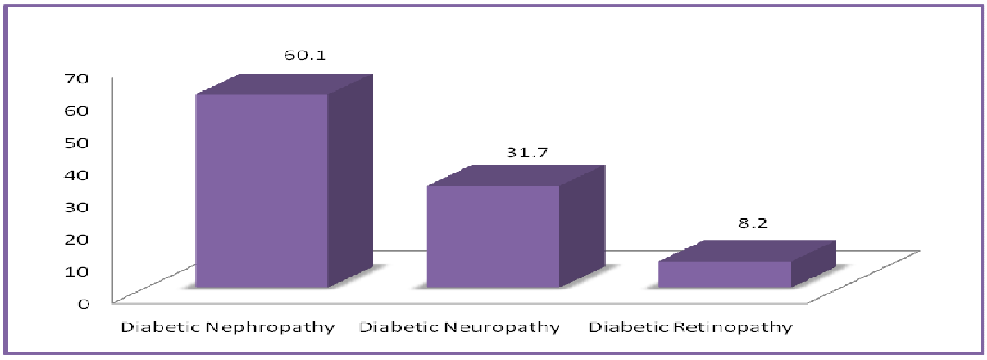

Figure 9:Diabetic complications of the study population.

Table 10: Details of drugs used in Diabetic Nephropathy

Category of drugs	Number of Patients	Percentage (%)
ACE-I	33	22.7
AR-β	25	17.2
Diuretics	87	60.1
Total (*N)	**145**	**100**

N=Total Number of Patients

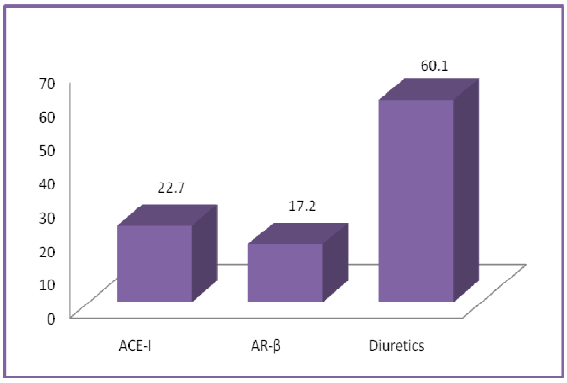

Figure 10: Details of drugs used in diabetic nephropathy

Table 11: Details of different drugs used in diabetic nephropathy.

Category of drugs	Number of Patients	Percentage (%)
ACE-I	**33**	**22.7**
Ramipril	21	63.6
Enalpril	12	36.4
AR-β	**25**	**17.2**
Losartan	16	64.0
Telmisartan	9	36.0
Diuretics	**87**	**60.1**
Furosemide	63	72.5
Torsemide	24	27.5
Total (*N)	**145**	**100**

N=Total Number of Patients

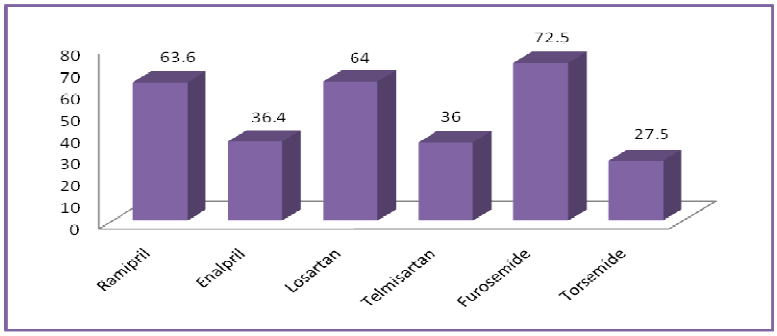

Figure 11: Details of different drugs used in diabetic nephropathy

Table 12:Details of drugs used in diabetic neuropathy

Category of drugs	Number of Patients	Percentage (%)
Anti convulsant	81	55.8
Anti depressant	49	33.7
Opoids	15	10.5
Total (*N)	**145**	**100**

N=Total Number of Patients

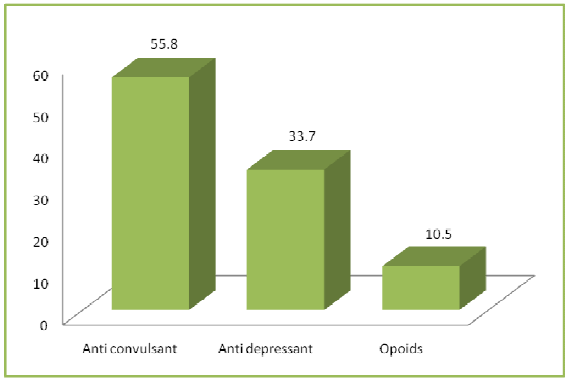

Figure 12: Details of drugs used in diabetic neuropathy

Table 13:Details of different drugs used in diabetic neuropathy

Category of drugs	Number of Patients	Percentage (%)
Anti convulsant	**81**	**55.8**
Gabapentin	39	48.3
Lamotrigine	17	20.9
Carbamazepine	25	30.8
Anti depressant	**49**	**33.7**
Amitriptyline	27	55.2
Impiramine	22	44.8
Opoids	**15**	**10.5**
Tramadol	15	100
Total (*N)	**145**	**100**

N=Total Number of Patients

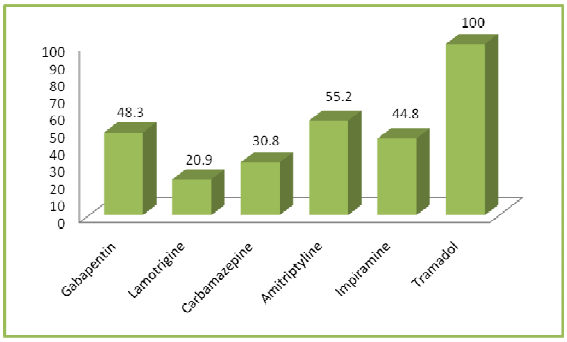

Figure 13 : Details of different drugs used in diabetic neuropathy.

Demographic profile details:-

Gender

Table 1 shows the gender distribution of the patients enrolled in the study. The results showed that out of 145 patients, 93(64.2%) patients were males and 52(35.8%) patients were females.

Age

Table 2 shows the distribution of the patients enrolled in the study in different age groups. The results revealed that, more number of patients were in the age group of 50-59 years (36.6%) followed by the patients in the age group of 60-69 years (23.5%) and 18.6% of the patients in the age group of 40-49 years.

BMI

Table 3 shows the BMI distribution of the patients enrolled in the study. The results revealed that, more number of patients were in the normal weight of 67 (46.2%) followed by the patients are underweight 43(29.6%) and 24.2% of the patients are overweight.

Family History

Family history of diabetes of the patients recruited in the present study is shown Table 4. It was observed in the present study that,26.3% of the patients had a family history of father being diabetic followed by 14.4% of mother being diabetic and 15.8% of the patients having a family history of other family members being diabetic. Only 11.7% of the patients had a family history of both father and mother being diabetic. 8.3% of the patients had no family history of diabetes.
A total of 91.7% of the patients having the family history of diabetes reinforces the fact that there is a strong genetic predisposition in diabetes mellitus.

Educational status:

Table 5 shows the educational status of the patients enrolled in the study. The results showed that, more number of patients (32.5%) belonged to grade 2 followed by 24.8% in grade 1, 22.7% in grade 3 and 20% in grade 0.

Blood Glucose Levels:

Results of the Fasting Blood Glucose (FBS) estimation and 2 hour-Post Prandial Blood Glucose (2 hr-PPBS) estimation of the patients during the present study are shown in Table 6 and Table 8. The results recorded in table 6 and table 7 are the values observed during the treatment periods of the patients and hence, reveals control of their plasma glucose levels.

FBS levels of the patients Table 6 revealed that, 31.2% of the patients had FBS in the range 80-120 mg/dl indicating good control over FBS with their present treatment. 14.3% of the patients had an FBS in the range of 121-160 mg/dl followed by 13.1% in the range of 161-200 mg/dl, indicating that their FBS were not being adequately controlled with their present treatment. It was also observed that 22% of the patients had an FBS in the range of 200-300 mg/dl and 1% had FBS above 301 mg/dl indicating that their present treatment was inadequate and needs to be changed. Table 6 also reveals that, in 14.4% of the patients, FBS was not tested.

The overall results revealed that, out of 145 patients recruited for the present study, in 45.5% of the patients treated with drugs for the diabetic complications, FBS was found to be beyond the upper limit of the normal range of 120 mg/dl and hence, their FBS was not adequately controlled with their ongoing treatment.

Table 7 shows the 2 hour Post-Prandial plasma glucose levels during the treatment of the patients. The results revealed that, in only 10.5% of the patients, the 2 hr PPBS was adequately controlled with the 2 hr PPBS values falling in the range of 101-140 mg/dl and 1.5% of the patients had a 2 hr PPBS in the range of 60-100mg/dl. Over all, it can be said that 2hr PPBS was adequate with the ongoing treatment in 12% of the patients. The results revealed that, 21.3% of the patients had a 2 hr PPBS in the 180-220 mg/dl, followed by 15.8% and 13.1% in the range of 141-180mg/dl and 261-300mg/dl respectively. In 15.8% of the patients, the 2 hr PPBS estimation was not performed.

The overall results revealed that, out of 145 patients recruited for the present study, 74.2% of the patients treated with drugs for diabetic complications, the 2 hr PPBS was found to be beyond the upper limit of the normal range of 140 mg/dl and hence, their 2 hr PPBS was not adequately controlled with their ongoing treatment.

The HbA1c value of patients in whom the test was performed is shown in Table 8. The results revealed that, though HbA1c is one of the important parameters to be monitored during the treatment of diabetic complications, out of 145 patients enrolled for the study, tests for HbA1c was performed in only 56.5% of the patients.

The values of the HbA1c detected were above the normal value expected in twelve patients who had a near normal HbA1c value of 7.1. This indicates that, in majority of patients no adequate control of blood glucose was achieved during the past three months of their treatment.

Treatment

For the purpose of analysing the drugs in the treatment of diabetic complications the pharmacotherapy was classified as monotherapy, dual therapy, and triple therapy where single drugs, two drugs and three drugs respectively were used for the treatment. When more than 3 drugs were used for the treatment of the patients, they were classified under the group of more than 3 drugs. In present study only single drugs were used for the treatment of the diabetic complications

There are number of drugs which are used in the treatment of diabetic complications as discussed below:

The results revealed that, out of 145 patients the percentage of patients who were diagnosed with diabetic nephropathy are 60.1%, diabetic neuropathy 31.7% followed by diabetic retinopathy 8.2%. Among these pateints the percentage of diabetic nephropathy was higher than diabetic neuropathy and diabetic retinopathy. So diabetic nephropathy was common in gulbarga region.

Diabetic nephropathy:-
The treatment have analysed that Diuretics, ACE-I, AR-β class of the drugs were used in the treatment of the diabetic nephropathy. In diabetic nephropathy 87 (60.1%) patients were treated with diuretics followed by 33 (22.7%) patients treated with angiotensin converting enzyme inhibitors (ACE-I) and 25 (17.2%) patients treated with angiotensin receptor blockers (AR-β). The above classes of drug categories were further analysed as follows

In case of diuretics furosemide 72.5% was maximally used compared to toresmide 27.5%. Among ACE-I Ramipril 63.6% was maximally used when compared to Enalpril 36.4% followed by AR-β in this category Losartan 64.0% was maximally used compared to Telmisartan 36.0%.

Diabetic neuropathy:-
The treatment of diabetic neuropathy analysed as follows:
In diabetic neuropathy 81(55.8%) patients were treated with anticonvulsants followed by 49 (33.7%) patients treated with antidepressants and followed by 15(10.5%) patients treated with opoids.

The above classes of drug categories were further analysed as follows:

Among anticonvulsants gabapentin 48.3% was maximally used when compared to lamotrigine 20.9%, carbamazepine 30.8%. In anti-depressants, amitriptyline 55.2% was maximally used compared to Impiramine 44.8%. In Opoids tramadol was maximally used.

Diabetic retinopathy:-
The present study reveals that only 12 patients were found to be diabetic retinopathy and all were sent for photocoagulation therapy.

CONCLUSION

As there is a strong epidemic rise in diabetic complications in our country, the present prospective study was carried out to assess the analysis of drugs used for the treatment of complications of diabetes in medical IPD and OPD of Basaveshwar teaching and general hospital Gulbarga.

The study reveals that, among different approaches of treatment, diuretic was found to be the most preferred choice of treatment, and in this furosemide was the most preferred drug.

Analysis of the overall usage of drugs revealed that, Diuretics (Furosemide) was prescribed in highest number of patients followed by Anticonvulsant. Among the various Anticonvulsants, Gabapentin was found to be the drug of choice.

The use drugs like AR-β, Antidepressant was found to be less. Newer agents like anti arrhythmic did not find place for the management of diabetic complications, even in a single patient during the study period. Results of the laboratory investigation reveals that, adequate control of FBS and 2-hrs PPBS was not achieved in a large number of patients with their on going treatment. And also test for HbA1c was performed in only 56.5% of the patients which again revealed inadequate glycaemic control. These facts reflect the need for the urgent and intense management of the diabetic complications for adequate metabolic control.

In chronic diseases like diabetic complications, day to day management and adjustment of treatment, constant follow up for the successful management and extra treatment added or withdrawn in the face of complication is a must. In diabetic complications, the patient is as much responsible for its adequate control as the treatment given to him. Hence, educating the patient on the importance of diet and exercise in the management of diabetic complications are of vital importance. The importance of educating diabetic complications patient is appreciated by pioneering clinicians all over the world. Continuing education for the clinicians to keep themselves abreast of the latest development in the field of diabetic complications treatment would also contribute in the effective management of diabetic complications. In India, the role of the pharmacist in direct interactions with patient is often limited. But in certain advanced countries, a pharmacist has a ample scope in playing the role of a diabetic educator. This aspect needs exploration in our countries. Though the study was carried for a period of 9 months, the actual prescribing patterns cannot be revealed as, in order to get that it has to be carried for further period of time.

Diabetes mellitus (DM) today is an important single disease in the medical speciality and is a special subject in chronic medicine. As a result of ageing ,increasing obesity and decreasing physically active population, the global incidence of prevalence of diabetes mellitus are exploding, exclusively due to an increase in type 2 diabetes mellitus which represents >90% of all cases of the disease.

Diabetes mellitus is a global problem with devastating human, social and economic impact. Today, around 250 million people worldwide are living with Diabetes and by 2025 these total is expected to increase to over 380 million.

The prospective study was carried out for the duration of nine months from June 2010-feb 2011 in the medicine department of Basaveshwar teaching and general hospital Gulbarga.

The source of data of the present study was the IPD, OPD and laboratory reports of the diabetic complications patients. During the study period, a total number of 145 patients fulfilling the inclusion criteria were recruited for the study. The data collected during the study period was analyzed for the demographic profile of the patients and analysis of drugs for the treatment of diabetic complications.

Analysis of the demographic profile of the patients recruited for the study revealed that, out of 145 patients prescribed with drugs, 93(64.2%) patients were males and 52(35.8%) patients were females. It was observed that maximmum numbers of patients (36.6%) were in the age group of 50-59 years and maximum numbers of patients (46.2%) were in the normal weight.

Review of the patient's family history of diabetic complications revealed that, 90.7% of the patients had a history of one or the other family members having diabetic complications reinforcing the fact that diabetes has a strong genetic predisposition.

Analysis of educational status of the patients revealed that, more number of patients 32.5% belonged to grade 2 followed by 24.8% in grade 1, 22.7% in grade 3 and 20% in grade 0.

Analysis of the laboratory reports of FBS and 2-hr PPBS of the patients revealed that, adequate control of the FBS was achieved in 31.2% and of 2-hr PPBS was achieved in only 12% of the patients with their ongoing treatment. It was also observed that, in 14.4% of the patients, FBS was not tested and in 15.8% of the patients, 2-hr PPBS estimation was not performed.

Test for HbA1c was performed in only 56.5% of the patients .The values of HbA1c detected were above the normal range except in twelve patients who had a near normal HbA1c of 7.1 indicating glycemic controls.

Treatment of the diabetic complications with drugs were classified as monotherapy, dual therapy, triple therapy and more than 3 drugs based on the number of drugs prescribed for the patients. It was observed that, monotherapy was the preferred approach for the treatment of the patients.

Detailed analysis of the drugs used in different treatment regimens revealed that, Diuretic was the drug of choice (60.1%) monotherapy followed by anticonvulsant in55.8% of the patient's. The use of AR-β was observed to be less.

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