Drug Utilization Evaluation in Diabetic and Hypertensive Patients and Adherence to Guidelines at a Teaching Hospital

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Abstract

Background: Drug utilization evaluation is defined by the World Health Organization (WHO) as the marketing, distribution, prescription and use of drugs in the society, laying its emphasis on the resulting medical, social and economic consequences. Hypertension is the most common comorbidity seen in patients suffering from Diabetes mellitus. In order to achieve the b.p goals required for diabetic patients, multiple antihypertensives are required. Therefore, to achieve B.P and blood glucose control, patients are prone to the use of multiple drug regimens which may or may not be rational. Thus, drug utilization review is done for evaluating the prescribing pattern, its adherence according to the standard IDF and JNC-8 guidelines and any other drug-related problem.

Aims and Objectives: Evaluation of prescribing pattern of antidiabetic and antihypertensives and comparing it with the IDF and JNC-8 guidelines respectively, assessment of any ADR.

Methodology: A prospective observational study was carried out in 250 diabetic patients who had been diagnosed with hypertension as well. The study was conducted in Punjab Institute of Medical Science (PIMS) Medical College and Hospital, Jalandhar for a period of 6 months from June 2018 - November 2018. All the diabetic hypertensive patients visiting the medicine department as per the inclusion and exclusion criteria were included in the study. After obtaining approval from the Institutional Ethics Committee survey was further initiated in the pre-designed case record form. The data regarding their demographic details, clinical investigations, treatment regimen, sign and symptoms while diagnosis, co-morbidities, ADR's, physical activity, diabetic complications and patient adherence to medication were collected. The data wereanalyzed using SPSS ver. 24.

Conclusion: The present study highlights the need for careful management of diabetic hypertensive patients, including their lifestyle, adherence to drug therapy, diabetes complications and comorbidities via regular follow up visits. The mono, dual and triple therapy was the cornerstone for the better care of patients. Monotherapy is associated with better compliance and fewer side-effects but on the same hand, combination therapy is appropriate for synergistic actions and to overcome complications. In the present study, there was an optimal adherence to IDF and JNC-8 guidelines by the physicians in the hospital.

Keywords: Prescribing Pattern; IDF; JNC-8; Adherence; Diabetic Complication; ADR

Abbreviations

ADR: Adverse Drug Reaction; HTN: Hypertension; DM: Diabetes Mellitus; JNC: Joint National Committee; IDF: International Diabetes Federation

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Introduction

Drug utilization is defined by the World Health Organization (WHO) as the marketing, distribution, prescription and use of drugs in the society, laying its emphasis on the resulting medical, social and economic consequences. The main objective of drug utilization studies is to contribute to the quality of drug therapy by identifying, documenting and analyzing any hurdles in drug utilization and monitoring the consequences of interventions. Drug utilization studies may be quantitative or qualitative. Quantitative data need to be obtained on the extent and variability in usage and costs of drug therapy, from which medical and social qualitative consequences can be extrapolated [1]. Thus, medication/drug use evaluation studies have become a major tool for evaluating the safety and efficacy of the health system. Drug use evaluation is a method that focuses on the use of drugs and methods to achieve the desired patient outcomes bases on a systematic evaluation of the drug usage [2].

As per IDF diabetes Atlas, 8th edition, 2017, there are 425 million people in this world who are suffering from diabetes. There will be 629 million people with diabetes in the world in 2045. WHO defines hypertension as a condition that causes high or raised blood pressure in which the blood vessels have persistently raised pressure. Blood is carried from the hearts to all parts of the body in the vessels. The prevalence of hypertension is increasing in India as well as in the world. The average prevalence of hypertension in India is 25-30% [3-5]. The prevalence of HTN is said to increase by 25% between 2010 and 2025 as per WHO [6].

HTN is the most common comorbidity seen in patients with DM. According, to the International Diabetes Federation and JNC-8 guidelines there are different aspects of management, prevention and care for improving the quality of life of those dealing with these conditions. Since DM and HTN are common diseases, therefore, attention is to pay for clinical and pharmacological management. In the present study, the drug usage pattern of drugs used to treat diabetic hypertensive patients was studied. Hence, in order to achieve the blood pressure goals required for diabetic patients, multiple antihypertensives are required [7,8]. Therefore, to achieve blood pressure and blood glucose in control patients are prone to the use of multiple drug regimens which may or may not be rational. Keeping this in view, we conducted a study in a teaching hospital to analyze the prescribing pattern, adverse drug reactions and treatment adherence according to the JNC-8 guidelines for HTN and IDF guidelines for the management of DM [9].

Materials and Methods

A prospective observational study was carried out in 250 diabetic patients who had been diagnosed with hypertension as well. The study was conducted in Punjab Institute of Medical Science (PIMS) Medical College and Hospital, Jalandhar for a period of 6 months from June 2018 - November 2018. All the diabetic hypertensive patients visiting the medicine department as per the inclusion and exclusion criteria were included in the study. Patients suffering from both DM and HTN and patients (in-patients and out-patients) of both genders who were willing to give consent for the study as per biomedical ethics were included in the study. Whereas, patients in I.C.U, critical care units and other non-selected departments were excluded from the study. After obtaining approval from the Institutional Ethics Committee, survey was further initiated in the pre-designed case record form. Patients were clearly explained the objective behind the study and then there respective written informed consent was obtained. Patients were asked a specific set of questions in order to complete the data in the pre designed case record form. The survey was done based on the following set of questions given below:

- Patients socio-demographic characteristics which includes age, gender, weight, social history of alcoholism and smoking, family history of diabetes and HTN, duration of suffering from DM and HTN.

- Laboratory investigations in which information regarding patient's systolic B.P, diastolic B.P, Random blood glucose (RBG), Fasting Blood glucose (FBG) values were noted.

- Complications of Diabetes Mellitus: Diabetic nephropathy, Diabetic Neuropathy, Diabetic Retinopathy, Diabetic foot.

- Symptoms observed in patients during the diagnosis.

- Status of Comorbidities

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- Physical activity performed and Intervals between the blood sugar monitoring test.

- Treatment regimn provided: Mono, Dual and Triple Anti-Hypertensive and Anti Diabetic therapy respectively, adjuvant therapy given.

Apart from this prescriptions were thoroughly analysed to check treatment adherence according to IDF guidelines for diabetes and JNC-8 guidelines for HTN.

Results

Socio demographic characteristics of the patient

Age distribution of patient: Mean age of the patients suffering from both DM and HTN was found to be 58.23 ± 12.04. Maximum patients were found in the age group between 60 - 69 years that is 72 (31.2%). Detailed representation is given in table 1.

Age wise distribution of the patients (years)	Frequency	Percent
20 - 29	3	1.2
30 - 39	11	4.4
40 - 49	47	18.8
50 - 59	63	25.2
60 - 69	78	31.2
70 - 79	34	13.6
80 - 89	14	5.6
Total	250	100.0

Table 1: Age wise distribution of the patients.

Gender distribution of patient: Out of 250 patients, it was observed that 120 (48%) patients were male whereas 130 (52%) patients were female. Figure 1 shows age distribution where age is represented vertically and gender horizontally. The box plot highlights that the age of onset of disease was higher in males and lower in females.
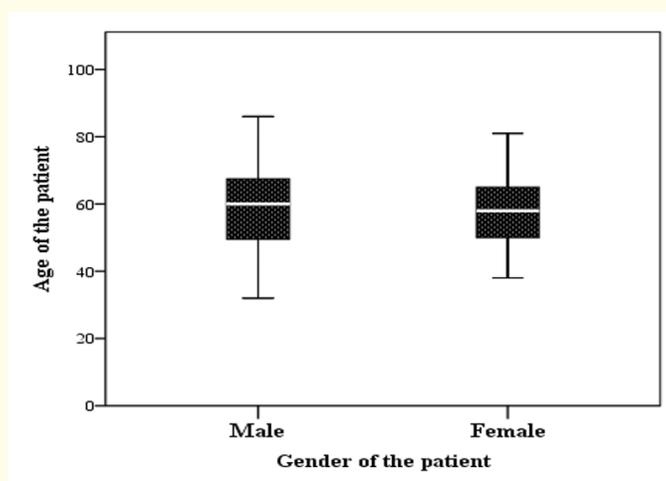
Figure 1: Box plot of mean age of patient versus gender.

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Test for normality was conducted to check the normality distribution of age and gender of the patient. It was found that as per Kolmogorov Smirnov (KS) and Shapiro-Wilk (SW) was p = 0.078[a], p = 0.243[b] respectively for males and p = 0.200[a], p = 0.038[b] respectively for females.

Weight distribution of the patients: Weight range of study group was observed to be 42 to 89 kgs. A maximum number of patients that is 94 (37.6%) were observed in the weight category of 70 - 79 kgs. Test for normality was conducted to check the normality distribution of the weight of the patient, it was found that the value of Kolmogorov-Smirnov (KS) (p = 0.000) and Shapiro-Wilk (SW) (p = 0.000) respectively. Weight was found to be not normally distributed because the p-value was found below the cut-off point. But the value of Skewness, Kurtosis and standard error was found to be 0.154, 0.307 and 0.066 respectively. the median of the weight observed in the study was 70.5.

Social habits of the patients: During the study, it was observed that majority of the patients that is 50.8% were non-alcoholic and non-smokers. Whereas 33.6% of patients were alcoholic, 11.6% of patients were smokers and 4.0% of patients were both smokers as well as an alcoholic.

Family history of the patient: During the study, 41.2% of patients were observed to have a positive family history of DM and 27.2% of patients had a positive family history of HTN. 16.8% of patients had a positive family history of both DM and HTN.

Duration of diabetes mellitus: The study revealed that a maximum number of patients who suffered from DM was newly diagnosed that is 60.4% patients. Whereas, the minimum number of 3.2% of patients were observed to have DM since past 5 years, 18.4% patients were suffering from DM from past 5 - 10 years and 18.0% were suffering from DM for more than 10 years.

Duration of hypertension: The study revealed that a maximum number of patients who suffered from HTN were newly diagnosed that is 76.8% patients. Whereas, the minimum number of 11.6% of patients were observed to have HTN since past 5 years, 9.2% patients were suffering from HTN from past 5 - 10 years and 2.4% of patients suffered from HTN from >10 years.

Symptom: The most frequently observed sign and symptom was tingling in extremities and weakness in 29 (11.6%) patients; painful heels, tiredness, fatigue and painful micturition in 25 (10.0%) patients; aggressiveness, numbness, muscle pain, weakness in 19 (7.6%) patients; fatigue, weight loss and thirst in 16 (6.4%) patients; polyuria, fatigue and weight gain in 13 (5.2%) patients.

Diabetic complication: It was observed that there were 89.2% of patients who did not have any have a diabetic complication. Whereas, the most frequently observed was diabetic nephropathy 8% of patients followed by diabetic foot observed in 1.2% patients. A detailed representation is given in table 2.

Diabetic Complication	Frequency	Percent
None of these	223	89.2
Diabetic nephropathy	20	8.0
Diabetic foot	3	1.2
Diabetic retinopathy	2	.8
Diabetic neuropathy	2	.8
Total	250	100.0

Table 2: Diabetic complication.

Status of comorbidities: Maximum 23.6% were observed suffering from vitamin D deficiency followed by 21.2% patients with GIT disorders.

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Systolic blood pressure of the patient: A maximum number of patients were found to be in the category of 140 - 159 mm Hg that is 63.2% patients, followed by 20.4% of patients who fall in the category of 120 - 139 mm Hg. Only 0.8% of patients were observed in <120 mm Hg category. The minimum systolic blood pressure seen was 110 mm Hg whereas maximum systolic blood pressure seen was 210 mm Hg. The data is represented in table 3.

Category of systolic blood pressure	Frequency	Percent
<120 mm Hg (normal)	2	.8
120 - 139 mmHg (prehypertension)	51	20.4
140 - 159 mm Hg (grade 1)	158	63.2
>= 160 mmHg (grade 2)	39	15.6
Total	250	100.0

Table 3: *Category of Systolic blood pressure of the patients.*

Diastolic blood pressure of the patient: A maximum number of patients were found to be in the category of 90 - 99 mm Hg that is 58% of patients followed by 80 - 89 mmHg that is 22.8% patients. Minimum numbers of patients were found to be in the category of <80 mm Hg that is 5.6% patients. Detailed representation is given in table 4.

Category of diastolic B.P	Frequency	Percent
<80 mm Hg (normal)	14	5.6
80 - 89 mm Hg (prehypertension)	57	22.8
90 - 99 mm Hg (grade 1)	145	58.0
>=100 mm Hg (grade 2)	34	13.6
Total	250	100.0

Table 4: *Category of Diastolic blood pressure of the patient.*

Fasting blood sugar of the patient: Minimum fasting blood glucose value observed was 101 mg/dl and the maximum value of fasting blood glucose observed was 359 mg/dl. Detailed representation is given in table 5.

Fasting blood sugar (mg/dl)	Frequency	Percent
100 - 200 mg/dl	179	71.6
201 - 300 mg/dl	67	26.8
301 - 400 mg/dl	4	1.6
Total	250	100.0

Table 5: *Fasting blood sugar of the patient.*

Random blood sugar of the patient: Minimum random blood glucose value observed was 159 mg/dl and the maximum value of random blood glucose observed was 550 mg/dl. Detailed representation is given in table 6.

Management of diabetes

Intervals between blood sugar monitoring tests: 40.0% of patients were observed to get their blood sugar monitored once daily and a minimum number of 4.0% patients were observed to get their blood sugar monitored thrice weekly.

Random blood sugar (mg/dl)	Frequency	Percent
150 - 250 mg/dl	113	45.2
251 - 350 mg/dl	90	36.0
351 - 450 mg/dl	38	15.2
451 - 550 mg/dl	9	3.6
Total	250	100.0

Table 6: Random blood sugar of the patient.

Physical activity: It was observed that 81.2% of patients performed physical activity. While 18.8% of patients did not perform any sort of physical activity.

Treatment regimen

55.2% patients were on antihypertensive mono therapy. The most frequently prescribed drug was angiotensin antagonist i.e. Telmisartan prescribed to 63 (25.2%) patients. Detailed representation is given in figure 2.
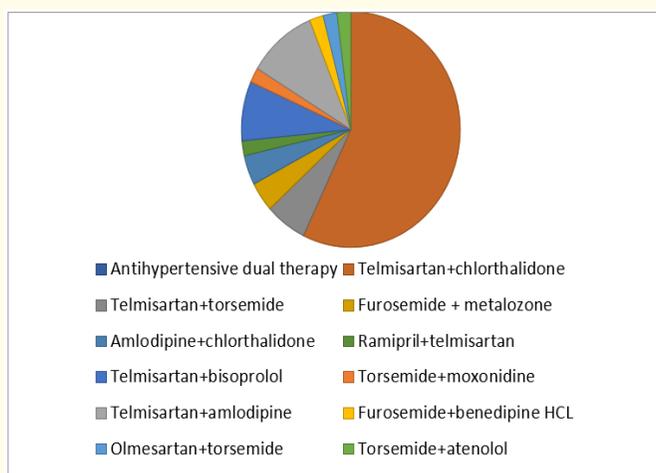
Figure 2: Antihypertensive mono therapy.

164 (65.6%) patients did not receive any dual therapy, followed by 28 (11.2%) patients who received telmisartan/chlorthalidone regime. A total of 6 (34.4%) patients were on dual therapy. Detailed representation is given in figure 3.

A total of 24 (9.6%) patients were on triple therapy. Clonidine/telmisartan/metoprolol was the most frequently prescribed triple therapy in 15 (6.0%) patients. A detailed representation is given in figure 4.

138 (55.2%) patients were on anti diabetic monotherapy. 45 (18.0%) patients received DPP-4 inhibitor i.e. Teneligliptin followed by 36 (14.4%) patients who received Metformin (biguanide). Maximum patients i.e. 108 (43.2%) patients received a combination of glimepiride and metformin as dual therapy. A total of 144 (57.6%) patients were on dual therapy. A total of 38 (15.2%) patients were on triple therapy. Maximum patients i.e. 212 (84.8%) patients did not receive any antidiabetic triple therapy followed by 15 (6.0%) patients who received a combination of glimepiride, metformin and voglibose.

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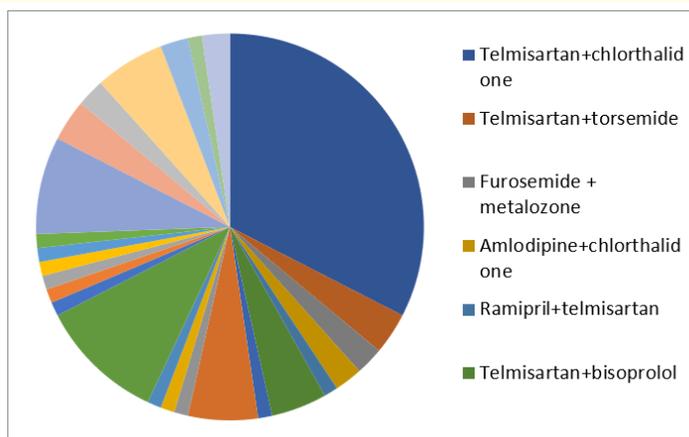
Figure 3: Antihypertensive dual therapy.
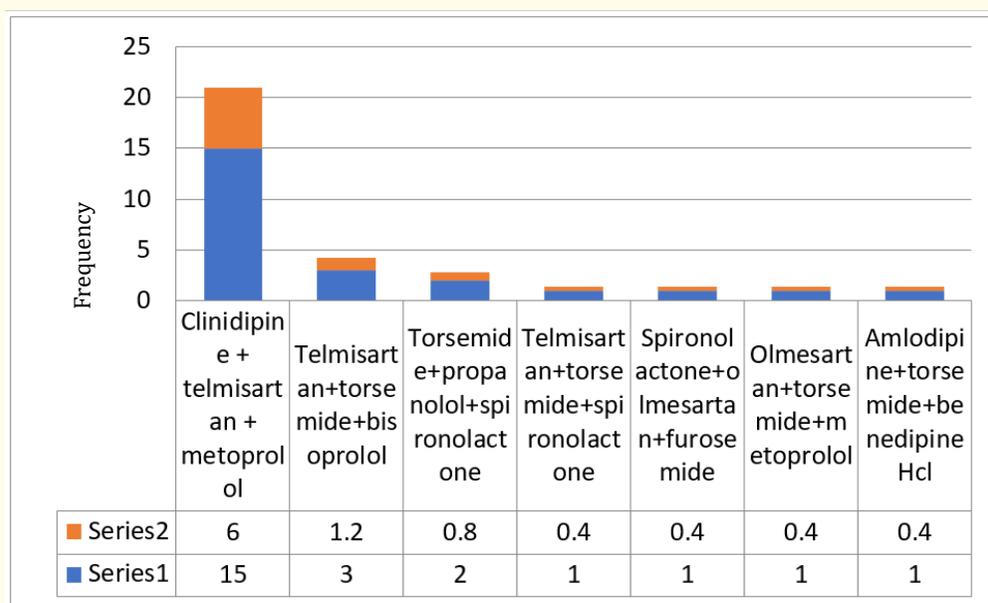
Figure 4: Antihypertensive triple therapy.

Adjuvant therapy: 22.4% of patients received Vitamin D3 and calcium orotate combination, 15.2% of patients who received pantoprazole and domperidone dual therapy, 9.6% of patients received antioxidant pregator.

Treatment adherence to international diabetes federation guidelines: It was observed that 207 (82.8%) patients received treatment according to the guidelines laid down by IDF. Whereas, 43 (17.2%) patients did not receive appropriate therapy according to the guidelines.

Treatment adherence to JNC-8 guidelines: It was observed that 227 (90.8%) patients received treatment according to the guidelines laid down by JNC-8. Whereas, 23 (9.2%) patients did not receive appropriate therapy according to the guidelines.

Adverse drug reactions reported: Among 250 patients it was observed that 1.6% [4] patients experienced adverse drug reaction. Out of which, 1.2% [3] patient experienced anxiety due to omeprazole and 0.4% [1] patient experienced abdominal pain, nausea and constipation due to tenelighliptin. Detailed representation is given in table 7.

Content	Class of drug	ADR	Frequency	Percent
Omeprazole	Proton pump inhibitor	Anxiety	3	1.2
Teneligliptine	DPP-4 inhibitor	Abdominal pain, nausea and constipation	1	0.4

Table 7: Adverse drug reaction.

Discussion

Our study showed that maximum diabetic hypertensive patients ranged between 60 - 69 years and mean (SD) of the age of the patients was observed to be 58.23 ± 12.04. While Sharma A., *et al*. [10] concluded that maximum patients were found to be in the age group of 51 - 60 years and mean (SD) of the age of the patients was observed to be 53.5 ± 10.02. Our results showed that diabetes is more prevalent in females (52%) than in males (48%). While, Alti Aparna., *et al*. [11] also reported that females were more prevalent to suffer from diabetes than males. In our study, the median (IQ) of the weight observed was 70.5 (17.5) whereas, Neil., *et al*. [12] concluded median weight to be 80.5 which was higher in comparison to our study. Familial association with type 2 DM is seen in 41.2% of patients and Sharma A., *et al*. [10] reported a family history of DM type 2 in 49.3% patients. In the present study the mean duration of being diagnosed with diabetes was 2.69 ± 4.46 year compared to 6.6 ± 5.8 year in a similar study performed by Mandana Moradi., *et al* [2]. This may reflect evidence that we may not be as successful as other countries in early detection of diabetic patients despite the fact that patients with a prolonged history of diabetes are at an increased risk of developing micro and macro vascular complications of diabetes. This calls for the need for frequent visits and careful monitoring of the signs and symptoms. The median (IQ) duration of HTN observed in our study is 2 [2] whereas Dhanraj., *et al*. [13] reported a median duration of HTN to be 4 (1 - 10) years. The most common symptom reported at the time of diagnosis is tingling in extremities and weakness in 29 (11.6%) patients whereas Bela Patel., *et al*. [14] reported weakness/fatigue in 71.2% patients. Diabetic nephropathy (8.0%) is the most commonly seen complication in this study whereas Dorchoom., *et al*. [15] reported diabetic retinopathy in 46.63% of the patients and diabetic nephropathy in 29.17% of the patients studied. 88% of patients claimed to monitor their blood sugar daily and 81.2% performed some sort of physical activity. Whereas, Mandana., *et al*. [2] reported that only 40.0% of people claimed to monitor their blood glucose on a daily basis and 9.6% of people were engaged in physical activity. Lack of knowledge regarding the impact of physical activity for the achievement of the desired results in diabetes management is a major contributor, which justifies investing in better education of both physicians and patients, about this therapeutic model. In our study, 56.0% are observed to be on antihypertensive therapy, 34.4% on antihypertensive dual therapy, 9.6% on antihypertensive triple therapy. Whereas, Jay Shah., *et al*. [16] reported that 76.0% of patients were on single drug therapy, 22.0% on dual therapy and only 2.0% were on antihypertensive triple therapy. Angiotensin antagonist is the most prescribed drug in our study which is similar to the study reported by Jay Shah., *et al* [16]. In our present study telmisartan/chlorthalidone (11.2%) dual therapy was most frequently prescribed whereas, in a study reported by Vikas Pandey., *et al*. [17] amlodipine/atenolol (14.05%) patients were prescribed the most. In our study, 52.0% of patients are on antidiabetic monotherapy, 57.6% of patients on antidiabetic dual therapy and 15.2% on triple therapy. Whereas, in a study reported by Amit Sharma., *et al*. [10] 52% of patients were on antidiabetic monotherapy, 28% on antidiabetic dual therapy and 20% on antihyperglycemic triple therapy. It is observed that teneligliptin (18.0%) is the most frequently prescribed drug as antidiabetic monotherapy. Whereas, in other previous studies reported insulin (48.0%) was the most prescribed drug. Combination of metformin/glimepiride (43.2%) was maximum prescribed in our study and in a study reported by Mandana Moradi., *et al*. [2] combination of metformin/glibenclamide (28.5%) was the maximum prescribed drug therapy. In our study, 30.4% of patients did not completely stick to medication adherence. Whereas in a previous study by Manikandan R., *et al*. [18] 18.0% of patients were nonadherent towards their therapy. HTN and diabetes are major chronic diseases in the world. Early detection and screening programs can hamper the onset of disease complications. The lifestyle inter-

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ventions, monitoring blood glucose levels and practicing regular medication are needed for the patients to prevent any further disease complication. Excess weight, particularly abdominal obesity, causes or exacerbates cardiovascular and metabolic risk factors, including hypertension, dyslipidemia and T2DM. These risk factors synergistically increase the likelihood of morbidity and mortality of CVD which leads to rising healthcare costs. Increasing physical activity, in combination with a diet that emphasizes assumption of fresh fruits and vegetables, whole grains and low-fat dairy products, can help patients reduce their weight and obesity co-morbidity. Less do we known about the long-term effect of weight loss on the development of T2DM and CVD outcomes in the form of death, myocardial infarction and stroke [19]. The risk factors like high TG, low HDL, high BP and high fasting glucose were found higher particularly in younger population which may lead to diagnosis & complications of diabetes, hypertension and lipid abnormality. Due to changing physiology in young and middle age population these individuals are moving towards metabolic syndrome easily and needs frequent monitoring, preventive checkups and lifestyle changes to prevent complications [20]. Even though diabetes and hypertension are considered as important risk factors for cardiovascular and chronic kidney diseases, the awareness about the prevention, treatment and control of these diseases remains alarmingly low in the developing countries like India. The healthcare system in India should focus on better hypertension screening and control, especially in diabetic patients, to minimise the burden of the dual epidemic [21].

Conclusion

Diabetes and Hypertension are considered to be the lifestyle diseases. Apart from appropriate prescribing, there is a need for lifestyle modifications to obtain desired outcomes. The mono, dual and triple therapy was the cornerstone for the better care of patients. Monotherapy is associated with better compliance and fewer side-effects but on the same hand, combination therapy is appropriate for synergistic actions and to overcome complications. Vitamin D deficiency was most likely observed in the patients. Patients should be educated about the importance of being aware of their medical history, drug allergies. Future management of HTN and diabetes should involve not only the more efficient use of existing agents but hopefully future agents that will provide enhanced clinical efficiency. In the present study, there was an optimal adherence to IDF and JNC-8 guidelines by the physicians in the hospital.

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