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Original Research Article

Clinical profile, drug therapy in patients with complications of hypertension, Type 2 diabetes mellitus and coexistence of both conditions – A prospective observational study

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ABSTRACT

Background: Hypertension (HTN) and Type 2 Diabetes Mellitus (T2DM) are the leading causes of various complications in the elderly population. Clinical profile plays a key role in assessing the health conditions of a patient, based on the severity of the complications appropriate drug therapy will be recommended, thus improving the health and quality of life of a patient.

Objective: This study aimed to assess the clinical profile and drug therapy in patients experiencing complications with HTN and T2DM and the coexistence of both conditions.

Result: A prospective observational study was carried out at the inpatient general medicine department of a tertiary care hospital, for 6 months among 180 patients. The most common complications are seen in males (62.96%). Among the study population, 81(33%) cases were found to be CVA, 53(22%) with CKD, and 43(18%) with HF with significant p-values at 0.0007, 0.0032, and 0.0164 respectively obtained by using Linear Regression analysis. 35.22% of Antiplatelets and 22.27% of Antihyperlipidemics were widely used in CVA. The most common complications among the patients were found to be Cerebrovascular Accidents 81(33%), chronic kidney disease 53(22%), and HeartFailure 43(18%) with a significant p-value at 0.0007, 0.0032, 0.0164respectively obtained by using Linear Regression analysis. 35.22% of Antiplatelets and 22.27% of Antihyperlipidemic's were widely used in Cerebrovascular Accidents.

Conclusion: There was a great association between the risk factors and the development of complications. As a clinical pharmacist, the prime responsibility is to provide information regarding the complications and their risk factors to improve the quality of life of a patient with chronic diseases.

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1. Introduction

Hypertension and Type 2 Diabetes Mellitus exhibit a close association, significantly elevating the risk of atherosclerotic cardiovascular diseases within the population. Hypertension represents a significant health concern with broad societal implications, and addressing its prevention and treatment and mitigating

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target organ damage remains a crucial public health challenge.² Hypertension stands as a major risk factor for Cardiocerebrovascular diseases, including heart failure, stroke, myocardial infarction, and renal complications such as chronic kidney disease, all of which significantly contribute to mortality.³ Patients with type 2 diabetes mellitus face substantial risks of developing both microvascular and macrovascular complications. Macrovascular complications encompass heart failure, coronary artery disease, peripheral vascular

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diseases, myocardial infarction, stroke, and renal failure, while microvascular complications include retinopathy, and nephropathy.⁴ Complications neuropathy, individuals with hypertension, type 2 diabetes mellitus, and the coexistence of both conditions include heart failure, myocardial infarction, coronary artery disease, peripheral vascular diseases, stroke, chronic kidney diseases, retinopathy, neuropathy, and nephropathy. This comprehensive understanding of complications emphasizes the intricate interplay between these two prevalent conditions. It underscores the need for effective management strategies to mitigate their impact on individuals' health and overall well-being.⁵ T2DM is a major health problem among developing countries, according to the World Health Organization 31.7 million people in India had diabetes in the year 2000 and the number is expected to increase to 79.4 million by 2030.6 It was found that older age, changing occupations, BMI, social habits (including alcohol and smoking), truncal obesity, and family history of diabetes were all significant risk factors for T2DM.⁷ Patients with T2DM are at major risk of developing both microvascular and macrovascular complications. Macrovascular complications include Heart Failure, Coronary Artery Disease, Peripheral Vascular Diseases, Myocardial Infarction, Stroke, and Renal Failure, whereas microvascular complications include Retinopathy, Neuropathy, and Nephropathy. 8,9 The primary aim of this current study is to evaluate the clinical characteristics and pharmacotherapeutic interventions in patients experiencing complications associated with Hypertension, Type 2 Diabetes Mellitus, and the coexistence of both conditions within a tertiary care teaching hospital.

2. Objective

- To categorize the patients according to their complications and to assess the clinical profile of the study cohort.
- 2. To identify the prevalent complications in patients with Hypertension, Type 2 Diabetes Mellitus, and the coexistence of both conditions.
- 3. To ascertain the pharmacotherapeutic interventions employed in treating the most frequently encountered complication within the study population.

3. Materials and Methods

It was a Prospective observational study conducted in the Inpatient General Medicine department at Sri Venkateswara Ramnarain Ruia Government General Hospital (SVRRGGH) Tirupati, for a period of 6 months (September 2022 – February 2023) with the approval from the institutional ethical committee with proposal no: SPSP/2022-2023/PD01. The cohort study population includes 180 patients who were suffering from the

complications of Hypertension, Type 2 Diabetes Mellitus, and the coexistence of both conditions with or without comorbidities.

3.1. Inclusion criteria

Individuals irrespective of gender, aged 40 years or older, diagnosed with Hypertension, Type 2 Diabetes Mellitus, and the coexistence of both conditions were admitted to the General Medicine inpatient ward, with or without comorbidities.

3.2. Exclusion criteria

Individuals newly diagnosed with Hypertension, Diabetes, or both and patients with secondary Hypertension and Type 1 Diabetes Mellitus were excluded.

3.3. Methodology

Study participants were identified and selected based on inclusion and exclusion criteria. Patient data was gathered using a specifically designed proforma containing the necessary details for the study.

Complications were identified by observation of signs and symptoms followed by subsequently confirmed through laboratory investigations. Each complication underwent assessment employing an appropriate diagnostic methodology. Heart Failure diagnosis involved assessing ejection fraction through an echocardiogram, with classification following the American College of Cardiology criteria. CAD was diagnosed by detecting ventricular abnormalities in echocardiography, and Myocardial Infarction (MI) was confirmed using electrocardiography (ECG). Stroke classification as either ischemic or hemorrhagic was determined through computed tomography (CT) or magnetic resonance imaging (MRI) scans. CKD diagnosis utilizes Renal Function Tests, additional blood tests, urine analysis, and abdominal ultrasonography (USG). Grading of CKD was based on kidney disease: Improving Global Outcomes (KDIGO) criteria. Diabetic Retinopathy was evaluated through eye fundus examination, Diabetic Neuropathy through the assessment of sensation loss, tingling sensations, and diabetic foot symptoms. Diabetic Nephropathy diagnosis involved serum creatinine, BUN, estimated glomerular filtration rate (eGFR), and abdominal USG.

3.4. Statistical analysis

Statistical analysis of the data was performed using Software R Programming version 4.2.1. Sociodemographic characteristics of the study population and complications were assessed through percentage analysis. The association between HTN, T2DM, and the coexistence of both conditions with the complications was determined using

Two-way ANOVA. The subsequent comparisons between the complications were analyzed through linear regression analysis. Significance was established at a p-value < 0.05.

4. Results

4.1. Patient's age-wise distribution

Out of 180 cases, patients are divided into 4 categories according to age. Patients aged between 61-70 have a high probability of being admitted to the hospital.

4.1.1. Gender distribution

In the current study, a large proportion was male, comprising 121 (67%), followed by female 59 (33%).

4.1.2. Patient distribution based on disease condition Out of all patients, 56 (31%) had hypertension, 32 (18%) had type 2 diabetes mellitus and 92 (51%) had the coexistence of both conditions.

4.1.3. Patient Distribution with Complications

Among 180 patients with multiple complications, 43 (20.87%) were diagnosed with heart failure, 6 (2.91%) with coronary artery disease, 8 (3.88%) with myocardial infarction, 81 (39.32%) with cerebrovascular accident, 53 (25.7%) with chronic kidney disease, 5 (2.42%) with diabetic retinopathy, 5 (2.42%) with diabetic neuropathy, and 5 (2.42%) with diabetic nephropathy.

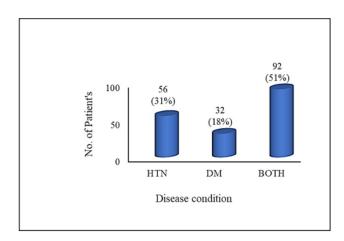


Figure 1: Categorization of study population based on disease condition

4.1.4. Clinical profile of CVA patients

Among patients with CVA, 51 (62.96%) were male, and 30 (37.04%) were female. Among the 81 CVA patients, 72 (89%) had an ischemic stroke, while 9 (11%) had a hemorrhagic stroke.

Table 1: Overall complications in the study population

Complication	No of cases (n =206)	Percentage (%)
Heart Failure	43	20.87
Coronary	6	2.91
Artery Disease		
Myocardial	8	3.88
Infarction		
CVA	81	39.32
Diabetic	5	2.42
Retinopathy		
Diabetic	5	2.42
Neuropathy		
Diabetic	5	2.42
Nephropathy		
Chronic Kidney	53	25.7
Disease		

^{*} A single patient may have more than one complication.

Table 2: Significance of the relationship between disease condition and complications

Condition	Complications	ʻp ' value
HTN, T2DM, and the	CVA, CKD, MI, CAD, HF, Diabetic Retinopathy, Diabetic	0.002*
coexistence of both conditions	Neuropathy, Diabetic Nephropathy	

Table 3: Linear regression analysis

Complications	Level of significance
HF	0.0164*
CAD	0.7946
MI	0.8763
CVA	0.0007***
CKD	0.0032**

^{*} A p-value less than 0.05 is considered as significant.

4.1.5. Clinical profile of CKD patients

In the overall cohort of CKD patients, 75.57% were male, and 24.53% were female. In CKD patients, staging was conducted based on eGFR values, revealing that 39.62% of patients were classified as stage V CKD, followed by stage IV at 35.84%, stage III at 15.09%, and stage II at 9.43%.

4.1.6. Clinical profile of heart failure patients

In the collective cohort of patients with heart failure, 29 (67.44%) were male, while 14 (32.56%) were female. Among Heart Failure patients, 28% were with mild HF, 46% were with moderate HF, and 26% were with severe HF.

4.2. Drug therapy for the most common complications

Antiplatelets were the primary therapeutic choice for treating ischemic stroke, accounting for 35.22%, followed by 22.27% utilizing Antihyperlipidemics, 13.47%

employing Calcium channel blockers, and others. In the case of hemorrhagic stroke patients, major utilization was observed with 35% for Diuretics and 25% for Calcium Channel Blockers, with the remainder employing alternative treatments. For CKD, the predominant use of 28.45% for Diuretics, 20.30% for Alkalinizing agents, 12.19% for Hematinics, and others were noted. Heart Failure management primarily involved 31.94% Diuretics, 25% Antiplatelets, and 16.66% ACE inhibitors, with supplementary treatments also being administered as indicated.

5. Discussion

Among 180 study participants males were significantly more affected, constituting 67% of the total, these findings are consistent with the study of Tegegne AS et al., ¹⁰ where males accounted for 51.6% of the total population. The prevalence of complications such as CVA, CKD, and HF displayed a similar pattern, with males being more predominant than females, contributing 67.44%, 62.96%, and 75.47%, respectively. Consistent findings were echoed in studies such as Vishal Gupta et al., ¹¹ this trend may be attributed to factors such as increased stress, familial burdens, and social habits, which could make males more susceptible to these health complications.

The prevalence of ischemic stroke among CVA patients was identified at 89%, surpassing the occurrence of hemorrhagic stroke. This observation is consistent with the findings presented by Harthi H A.AL et al., ¹², where more than 80% of cases demonstrated a higher incidence of ischemic strokes compared to hemorrhagic strokes. This trend may be attributed to a higher prevalence of risk factors associated with ischemic strokes within our study population in comparison to those linked to hemorrhagic strokes.

The clinical profile of CVA in all patients was evaluated through brain CT and MRI scans. This diagnostic approach is consistent with the methodology endorsed by Kannan V et al., ¹³ highlighting the reliability of CT and MRI imaging studies for CVA diagnosis. This preference may be attributed to the comprehensive data and accuracy of these imaging techniques in the diagnosis of cerebrovascular accidents. Staging of CKD was determined based on estimated eGFR values in our study. These findings are similar to the results reported by Sriramulu B et al., ¹⁴ and Rinku Joshi et al., ¹⁵ where a significant proportion of patients also fell under stage V, this may be due to CKD did not have any symptoms until later stages of the disease. As a concern of this, reliable estimates of GFR were important for identifying CKD as early as possible.

6. Conclusion

The current study concluded that the complications were more prevalent among patients suffering from HTN and T2DM than a single disease condition. The study suggests that there is a need for early detection, routine check-ups, and diagnosis of complications in the case of HTN, T2DM, and the coexistence of both conditions in patients to improve and prolong life expectancy.

7. Source of Funding

None

8. Conflict of Interest

None.

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