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CLINICAL PHARMACIST INTERVENTIONS IN DRUG THERAPY IN PATIENTS WITH DIABETES MELLITUS AND HYPERTENSION IN A UNIVERSITY TEACHING HOSPITAL

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ABSTRACT: Introduction: Drug related problems occur commonly in patients who often receive polypharmacy with multiple co-morbid conditions. This constitutes a major health problem because of their negative consequences with increased morbidity and mortality. **Aims and Objectives:** The aim of the study was to assess the impact of clinical pharmacist interventions in drug therapy in hospitalized diabetes mellitus patients with hypertension. **Methodology:** A Prospective interventional study was carried out in the medicine wards of a tertiary care teaching hospital over a period of 10 months from September 2013 to June 2014. The drug therapy details of the patients were collected from inpatient case records. Clinical pharmacist reviewed the drug therapy, identified the drug related problems during ward rounds and discussed with the physicians and suitable suggestions was provided which had been documented. **Results:** A total of 147 drug therapy problems were identified from 111 patient case records. The number of drug related problems was predominant in males than females. Drug related problems were commonly seen in patients aged between 61-80 years of age. The most common drug related problems was found to be improper drug selection (22.44%) followed by drug use without indication (19.04%). The most frequent suggestions by the clinical pharmacist were on cessation of drug (25.17%). The acceptance rate of suggestions and the changes in drug therapy was found to be high (52.38%). The level of significance of drug related problems was found to be moderate significance in grade. **Conclusion:** Involvement of clinical pharmacist as a member of healthcare team during the ward rounds in hospitalized patients with diabetes mellitus helps in identification and prevention of drug related problems which will help to rationalise the drug therapy, achieve better therapeutic outcomes and improved quality of patient care.

INTRODUCTION: Diabetes mellitus is a chronic progressive metabolic disturbance characterized by hyperglycemia due to absolute (Type 1 DM) or relative (Type 2 DM) deficiency of insulin hormone or both.

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Uncontrolled diabetes mellitus virtually affect any organ in the human body systems mainly heart, kidney, brain, blood vessels and nerves[1]. Diabetes mellitus may remain silent for years or may manifest as macro and micro vascular complications such as ischemic heart disease, nephropathy, retinopathy, neuropathy and non-healing ulcers (foot ulcer). There is an ample evidence that diabetes in older adults is one of the strongest predictors of functional decline, impaired balance, falls and admissions to the hospitals with

overall increase in their healthcare expenditure. This can also lead to reduced quality of life with increased morbidity and mortality[2].

Hypertension is a common comorbidity in type 2 diabetes mellitus patients with a prevalence of up to two-thirds of the population and it may be present by the time patients are diagnosed to have diabetes mellitus or even before the onset of hyperglycemia. The presence of hypertension increases the risk of cardiovascular diseases in type 2 diabetes mellitus patients and can put the vital organs in the risk of developing micro vascular complications such as diabetic nephropathy, retinopathy and cerebrovascular diseases such as stroke etc [3].

In order to minimize the risk of associated complications many guidelines recommend a target blood pressure (BP) of ≤ 140/90 mmHg in all diabetes mellitus patients with hypertension. Achieving this target still remains a great challenge though different classes of antihypertensive drugs with various combinations are available in the market. Majority of the patients require one or more antihypertensive agents in order to achieve this target optimal blood pressure control.

Diabetes mellitus patients with hypertension often receive multiple medications and this can lead to the occurrence of drug related problems. A drug related problems constitute a major public health problem, because of their negative consequences such as increased morbidity, mortality and healthcare costs[4]. A drug related problem can be defined as any event or circumstances involving the drug treatment, which interferes or potentially interferes with the desired health outcomes [5]. A high prevalence of drug related problems has been observed in diabetes mellitus patients which may lead to suboptimal blood sugar and blood pressure control.

Unresolved drug related problems can contribute to recurrent hospital admissions, prolonged hospitalization and increases the healthcare expenditure. The reason could be either improper drug or the dosage, drug- drug interactions or the patient factors such as drug –disease interaction or adherence problems or any other drug related problems [6, 7].

Up to date, there has been very few studies conducted locally and globally to investigate and document drug related problems in diabetes mellitus patients with hypertension. Hence this study intense to assess and qualify the clinical pharmacist interventions in drug therapy in diabetes mellitus patients with hypertension in a tertiary care teaching hospital, Mangalore.

METHODS:

The study was a prospective, interventional study carried out for a period of ten months in hospitalized patients with diabetes mellitus admitted under the general medicine department of Justice K S Hegde Charitable Hospital, Mangalore which is a 1200 bedded hospital with various specialty departments. The study was approved by the Institutional ethics committee. Adult patients with diabetes mellitus above 18 years of age, prescribed with at least one anti-diabetic drug (Insulin or Oral hypoglycemic agents) and one antihypertensive drug were included in the study. Pregnancy induced diabetes mellitus patients and mentally challenged patients were excluded from the study.

The intervening pharmacist was a researcher (clinical pharmacist). All the interventions made by the intervening pharmacist were preceded by the consultation with academic pharmacist (guide) and physician (co-guide). All the hospitalized patients with diabetes mellitus and hypertension were reviewed by the researcher (clinical pharmacist) and those who met the study criteria were enrolled into the study. All the necessary data including patient demographic details, past medical history, allergic status, laboratory investigation reports and drug therapy were collected and documented in the suitable designed data collection form as per need of the study.

The researcher actively participated during the ward rounds on daily basis and routinely reviewed all aspects of patient drug therapy, along with the past medical history, laboratory reports and clinicians notes from the date of admission till the discharge from the hospital and interviewed with the physician as well as patients when necessary. The complaints of the patients were analyzed in regards to drug therapy as a part of the disease

itself and those symptoms attributed to drugs reported as drug related problems. The patient drug treatment including the dose, duration and frequency were reviewed for their appropriateness by using the references like lexi-comps drug information handbook and Micromedex (drugdex) for any drug related problems. The identified drug related problems were then discussed with the co-guide (physician) and with the development of consensus interventions were conveyed to the respective physician along with the best possible approach to rectify drug related problems during the next day ward round visits.

The identified drug related problems were categorized as per the Hepler and Strand Classification and the pharmacist interventions were documented by the researcher in the designed documentation form. The acceptance level of physician for the particular intervention was also recorded as either accepted or not accepted according to the action of the treating physician. Similarly, the outcome of the intervention and the clinical significance of drug related problems were also noted by the researcher.

All the documented data were later evaluated by the members of the team by using the descriptive statistics to assess the impact of clinical pharmacist intervention in patients with diabetes mellitus.

RESULTS: A total of 174 diabetes mellitus patients with hypertension fulfilled the inclusion criteria and were reviewed in the medicine ward over ten month's period. Of the total 174 cases reviewed, 147 drug related problems has been identified from 111 patients. The mean number of drug related problems per patient was 1.30± 1.10. A total of 71.1% of the patients had one drug related problems. Of the total 111 patients, 59 (53.15%) were male and 52 (46.84%) were females. The mean ± standard deviation (SD) of the patient's age was 62.8 ± 12.5 years old with the minimum and maximum ages of 37 and 85 years old respectively. Patients aged range between 61 - 80 years had more drug related problems when compared to others age range in the study.

Among the study population diabetes mellitus with hypertension, 40.5% of the patients were diagnosed to have one co-morbidity and 26.12% of the patients were with two co-morbidities, 13.5% patients had three comorbidities and 17.1% patients had no comorbidities. During the hospital stay, majority of the patients received 6 - 10 medications with average number of medicines per prescription was found to be 9.9 ± 4 (Mean ± SD). The demographic details of the study populations are summarized in the **Table 1**.

TABLE 1: DEMOGRAPHIC DETAILS OF THE PATIENTS WITH DIABETES MELLITUS AND HYPERTENSION

Sl no		Charecteristics	Number (%) (n=111)
1	Gender	Male	59 (53.15)
		Female	52 (46.84)
2	Age	<20	Nil
		21-40	4 (3.60)
		41-60	40 (36.03)
		61-80	59 (53.15)
		≥ 81	8 (7.20)
3	Number of drugs received per patient	1-5	7 (6.30)
		6-10	47 (42.34)
		11-15	39 (35.13)
		≥ 16	18 (16.21)
4	Length of hospital stay	1-5	41 (36.93)
		6-10	52 (46.84)
		11-15	7 (6.30)
		≥ 16	11 (9.90)
5	Co morbidities	0	19 (17.11)
		1	45 (40.54)
		2	29 (26.12)
		3	15 (13.51)
		4	3 (2.70)

Improper drug selection was the most common drug related problem, which accounted for 22.44% (n≤33) of the total drug related problems followed by drug use without indication 19.04% (n≤28), sub therapeutic dose 12.92% (n≤19) and adverse drug reaction 11.56% (n≤17). The different types of drug related problems observed in our study are summarized in **Table 2**.

TABLE 2: TYPES OF DRUG RELATED PROBLEMS

Sl No	Drug related problems	Number (%) (n= 147)
1	Drug use without indication	28 (19.04)
2	Improper drug selection	33 (22.44)
3	Sub therapeutic dose	19 (12.92)
4	Drug interaction	10 (6.80)
5	Overdose	11 (7.48)
6	Adverse drug reaction	17 (11.56)
7	Untreated indication	13 (8.84)
8	Failure to receive drugs	3 (2.04)
9	Others*	13 (8.84)

*class duplication (n=4), drug duplication (n=2), transcription error (n=4), prescribing error (n=3)

The most frequent suggestions provided by the clinical pharmacist was cessation of drug 25.17% (n≤37) followed by change in drug dose 19.72% (n≤29). Addition of the drug and substitution of the drug accounted for 28.56% [(n≤23)& (n≤19)] respectively of the total interventions. The various intervention provided by the clinical pharmacist are summarized in the following **Table 3**.

TABLE 3: SUGGESTIONS PROVIDED BY THE INTERVENING PHARMACIST

Sl no	Suggestions provided	Number (%) (n= 147)
1	Cessation of drug	37 (25.17)
2	Addition of drug	23 (15.64)
3	Change in drug dose	29 (19.72)
4	Change in duration of therapy	7 (4.76)
5	Change in frequency of administration	9 (6.12)
6	Substitution of drug	19 (12.92)
7	Change in cost of therapy	2 (1.36)
8	Change in route of administration	6 (4.08)
9	Change in dosage form	2 (1.36)
10	Others*	13 (8.84)

*Need for lab. Investigations (n≤4), need for patient counselling (n≤6), annotation changes (n≤5) and availability of drugs (n≤2)

Of the total drug related problems, the level of significance 'moderate' was found to be high (55.10%) followed by significance level 'minor' (41.49%). The significance level of drug related problems are summarized in the following **Table 4**

TABLE 4: LEVEL OF SIGNIFICANCE OF DRUG RELATED PROBLEMS

Level of significance	Number (%) (n= 147)
Minor	61 (41.49)
Moderate	81 (55.10)
Major	5 (3.40)

Minor: Problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilization or clinical outcome.

Moderate: Which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.

Major: Expected to prevent or address very serious drug related problems, with a minimum estimated effect on reducing hospital stay by no less than 24 hours.

The results of clinical pharmacist recommendations concerning drug related problems are suggestions accepted and therapy changed 52.38% (n≤77), suggestions accepted and therapy not changed 36.73% (n≤54) and neither the suggestion accepted nor therapy changed 10.88% (n≤16). The result of the clinical pharmacist recommended is shown in the following **Table 5**.

TABLE 5: RESULTS OF CLINICAL PHARMACIST RECOMMENDATIONS

Recommendations	Result (%) (n=147)
Suggestions accepted and therapy changed	77 (52.38)
Suggestions accepted but drug therapy not changed	54 (36.73)
Neither suggestion accepted nor therapy changed	16 (10.88)

According to the British national formulary body system wise classification, the therapeutic class of medication most commonly implicated with drug related problems were cardiovascular system

(38.09%) followed by infectious (25.85%) and endocrine system (11.56%) respectively. The system wise distribution of the medicine causing drug related problems is shown graphically in the following **Fig.1.**

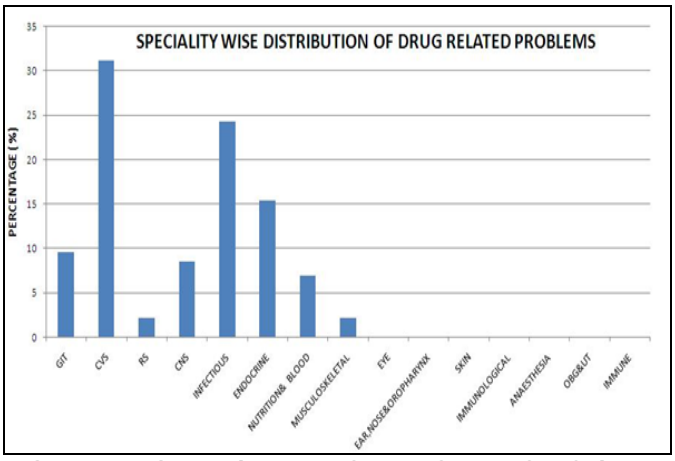

FIG. 1: DRUG RELATED PROBLEMS PER SPECIALITY AVERAGED OVER A PERIOD OF TEN MONTHS

DISCUSSION: The mean age in this study population was higher when compared with the mean age of other published studies which could suggest that older hypertensive diabetic patients were admitted to the ward than were younger patients during the study period. It also confirms drug related problems increases with age and associated comorbidites in aged patients. In this study, there was an average mean of 1.3 drug related problems per patient. To date, drug related problems in diabetes mellitus patients with hypertension is lacking and no comparable study has done both locally and globally. The average number of drug related problems identified in our study is less than the number detected by some other studies which were carried out in patients with diabetes mellitus.

This discrepancy with other studies may be attributed to the differences in study method and setting, different classification systems of drug related problems used and different methods to assess drug related problems. The high occurrence of drug related problem between the age range 61-80 of the study population shows that there was lack of optimal pharmacologic management in clinical practice and regular review of patient medication use especially in this age groups may potentially decrease the drug related problem.

The study revealed that 71% of the patients had at least one drug related problem which was less than the 90.5% and 80.7% reported by ZamanHuri& Fun wee et al[8] and Haugbolle& Sorensen[9] respectively. A study conducted on ambulatory hemodialysis patients showed at least one drug related problem in 97.7% of the total study populations. This variation across the studies may be because of the difference in the study populations and the methodology used.

Improper drug selection was the most common drug related problem observed in our study followed by drug use without indication. This study results were consistent with the study carried out by ZamanHuri& Chai Ling[10] and Ganachari MS et al[11] where drug choice problem or inappropriate drug selection pattern was the most frequently identified drug related problems. The increased incidence of improper drug selection may be attributed to lack of standard treatment protocol in the hospital or the use of drug which are contraindicated to the patient health condition. For example the use of metformin in diabetes mellitus patient with impaired serum creatinine (serum creatinine 1.8 mg/dl) were the manufacturer recommends you to stop prescribing in such situations. Another incidence of improper drug selection involves the choice of drug in diabetes mellitus patients with hypertension.

The guidelines recommends to use ACE inhibitor or ARB blockers as it offers the advantage of renal protective and proteinuria. Irrespective of the guidelines most of the patients were prescribed with calcium channel blocker amlodipine. Later the intervening pharmacist reviewed the case, proper suggestion was made and the drug therapy changed. There are few cases in which drugs that were categorized as high risk in the modified beers criteria were prescribed to elderly patients with diabetes mellitus and diabetic neuropathy placing them at higher risk of developing drug toxicity. The increased incidence of improper drug selection highlight the need of a clinical pharmacist in the healthcare team to pay more attention while prescribing these drugs to older hypertensive diabetic patients. Drug use without indication was the second most common drug related problem observed in our study. This study is contrast with the study carried out by Ramesh A et al[12] found

that the second most common drug related problem was drug use without indication. The study conducted by Ramesh M et al[13] has also shown a high incidence of drug use without indication (18%) as drug related problems. Few instances were drug used without any indication include the use of proton pump inhibitors like pantoprazole, rabeprazole, H_2 blockers like ranitidine and anti-infective agents. Although drugs like omeprazole, pantaprazole are used for the prevention of stress induced or drug induce gastritis or ulcer, these agents were prescribed when there was no such indication. In few other cases drugs like paracetamol and anti-emetics like ondansetron were still continued even after fever and vomiting subsided. However, where appropriate pharmacist intervened in such cases and drug was withdrawn from patient therapy.

Subtherapeutic dose accounted for 12.92% of the total drug related problems identified in the study population. These were assumed when patients' blood pressure, sugar levels or lipid levels were not on target levels despite being on pharmacological treatment when discharged from the hospital. In two cases where the antibiotic dosage were reduced despite a normal border line creatinine (S.Cr: 1.4 mg/dl) suspecting that a dosage adjustment is required. In one another case of dilated cardiomyopathy where carvidelol 3.125mg was prescribed as half the tablet once daily, the dose prescribed was lower than the recommended dose in drug literature.

A total of 7.48% cases of overdose was reported in our study. These includes few cases in which full dose of drug was prescribed in patients with impaired renal function and in other instances were drug linezolid prescribed in thrice daily regimen were also documented. In another case where metformin sustained release preparations has been prescribed as thrice daily. Antimicrobial agents were the most implicated drug for dosing problems.

The percentage of dosing problems reported in our study was found to lesser than that reported by Van Roozendaal and Krass[14] and this may be due to the lack of assessment of patients hepatic and renal functions in the their study. Caution should be taken in consideration when prescribing drugs in patients with impaired renal function and low glomerular filtration rate as dosage reductions helps to prevent unwanted side effects and decrease unnecessary drug expenditure ad drug toxicity. So the involvement of a clinical pharmacist who is well expertise in drug, dose and its dosing schedule in a healthcare team will helps in deciding the dosing of drugs in special populations.

A total of 11.56 adverse drug reactions has been reported in our study. Most of the adverse reactions reported in our study is hypoglycemia in patients receiving insulin's and oral hypoglycemic agents. Antihypertensive agents were also commonly associated with adverse drug reactions. These include hydrochlorthiazide induced hyponatremia, frusemide causing hypokalemia and beta blocker induced giddiness. Also there were cases of antiplatelets aspirin induced gastritis and aminoglycoside drugs like amikacin induced renal failure. In most of the cases the suspected drug dose was reduced and few cases the identified drug was withdrawn from the treatment chart. Therefore all potential adverse drug reactions should be taken into consideration especially in special populations who might suffer significant deleterious effects.

Few untreated indications were identified in the study population during the study period. These includes anemia, dyslipidemia, hyperuricemia and constipation. This has bought to the notice of the concerned physician by the intervening pharmacist and the drug therapy was added. Studies carried out by Ramesh M et al[13] also identified few incidence of untreated indication as the drug related problems in their study

Quite few drug interactions were also reported during the study period. In this study, the drugs that were most implicated in drug interactions were aspirin, clopidogrel, warfarin, atorvastatin and some drugs acting on the central nervous system. By contrast, studies carried out by Koh Y et al[15] also identified drug interactions with most common implicated class of drugs as cardiovascular agents. The identified drug interactions in our study is mostly on the evidence based established literature. In clinical practice it is well known that when patient receive poly pharmacy for multiple comorbid condition, there is a chance for the

occurrence of drug interactions. But still drugs can be used together with close monitoring and in case any toxicity identified then immediate measures should be taken for the corrective actions.

Failure to receive drugs was accounted for 2.04% of the total drug related drugs. This includes a case where patient was prescribed with fondaparinix for ST elevated myocardial infarction, but it was noticed that the patient didn't procure the medicine because of the financial economic constraints. In another case where the nurse didn't administer the night dose of insulin as the patient was not willing to take food at night.

The other types of drug related problems includes drug and class duplication were majority due to availability of different formulation with different brand names from different manufacturers leading to error in prescribing. Few cases of transcription error has also been identified in our study. This includes missing out of few drugs from the patient chart when rewriting or transferring the drugs from one to another chart. For example a stroke patient was receiving and antihypertensive drug during their hospital stay, but pharmacist during his routine review of the treatment chart it was found that the antihypertensive has been missed while transcribing the drug to new treatment chart. This incidence has been bought to the notice of the concerned doctor and the remedial action has been taken immediately. This may be because of the increased workload, fatigue and stress on the physician as reported in other studies. So such kind of errors can be minimized by making it mandatory of prescribing generic names and also by reviewing and rechecking of medication order regularly prior to the administration by a clinical pharmacist in a healthcare team.

Cessation of the drug was the most frequently provided by the clinical pharmacist during the study. This includes improper drug selection and drug use without indication. This findings were similar to the study carried out by Ramesh M et al[13] were cessation of drug was the most common suggestions provided by the clinical pharmacist but differs from the observation made in another Indian study by Parthasarathi et al[16] where in change in drug dose was reported as the most frequently provided suggestions by the clinical pharmacist. Improper drug selection includes prescribing a broad spectrum of antibiotics in the treatment of mild urinary tract infections which can be managed by narrow spectrum antibiotic and also prescribing an antibiotic in the treatment of malaria. Examples warranted the cessation of drug includes use of unnecessary vitamin supplements, proton pump inhibitors and antimicrobial agents. Substitution of the drug and addition the drug was accounted for 28.56% of the total interventions provided by the clinical pharmacist.

Addition of the drug was advised in the case of untreated indications. Substitution of the drug was suggested in ACE inhibitors or ARBs in case of diabetic patients with hypertensive where a channel blocker amlodipine was prescribed. Other suggestions made in our study include change in drug dose, change in duration of therapy, change in frequency of administration, change in route of administration etc.

Cardiovascular agents and anti-infective agents were the most common therapeutic class of medications implicated with drug related problems. This result is consistent with the studies carried out by Sathvik et al, Krska J et al, Zaher Al Salmi and Al-hajje et al [17, 18, 19, 20] where cardiovascular agents were the highest rate associated with drug related problems but differ from the studies carried out by Struck P et al[21] in which antibiotics are the most frequently involved in drug related problems. The reason for the difference in the therapeutic classes involved may be because of the differences in the underlying diseases. This findings in our study is not surprising given that patients with diabetes mellitus are usually prone for infection and have cardiovascular comorbidities like hypertension, ischemic heart disease, myocardial infarction etc. This complex medical conditions and use of multiple drug therapy for long term makes this group of patient with diabetes mellitus at high risk of drug related problems.

Considering the clinical level of significance of the total 147 drug related problems identified from 111 patient in our study, 55% were categorized as 'moderate' in grade, followed by 41.49% as 'minor' and 3.4% were graded as 'major' level of

significance. This findings correlate with a study that reported 49% of drug related problems as moderate level of significance requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.

The acceptance rate of intervening pharmacist suggestions was found to be high (89%) but the drug therapy was changed only in 52.38%.This results is consistent with the other studies carried out in various settings across the world with reported acceptance ranging from 85% to 98%. There were (36.73%) interventions where pharmacist suggestions were accepted, but therapy was not changed. This may be because (a) in few cases where the recommendation if valuable according to the evidence based medicine, was not taken into account because of the already precarious situation of the patient (patient was very ill, so decided not to change drug therapy because benefits outweighed the possible risk) and (b) the recommendation was not valuable enough according to the treating physician.

In the remaining (10.88%) cases, the suggestions were neither accepted nor therapy changed, may be because of the prescribing decisions governed by experience of physicians.

CONCLUSION: The present study highlights the impact of clinical pharmacists in a multidisciplinary health care team. The clinical pharmacist participation in ward rounds can be helpful in identifying and preventing drug related problems by prompt interventions; and their expertise in pharmacotherapy can assist in managing drug therapy based on patient specific factors. Improvements in patient's safety, level of care, quality of the prescription and therapeutic management in addition to the control of risk factors and reduction in overall healthcare cost justify the need of a joint effort between clinical pharmacist and physician in providing a safer system which will help in achieving better therapeutic outcomes in diabetes mellitus patients with hypertension and cardiovascular diseases.

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