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DEVELOPMENT AND ASSESSMENT OF CORE PHARMACOTHERAPY PLAN FOR COMMON LIFESTYLE DISORDERS

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ABSTRACT

Background: The world today is threatened by a host of new life style related disorders where the advent of pharmaceutical care has led to ever increasing and dynamic roles of pharmacists in patient specific practice.
Method: A prospective study was carried out with a total of 161 cases of life style disorders such as HTN (62), DM (52), COPD (25) and Asthma (22), through an active communication. The CORE formats for the collected cases were developed and are assessed with proper guidelines. **Results:** In study population male patients were more for hypertension (67.74%) and COPD (78%). Whereas, female patients were more for DM (63.46%) and an equal prevalence (50%) of males and females for asthma. A significant association exists in between the factors such as gender, age, educational status, social habits, physical activity and diet with hypertension. The association between the factors such as gender, age, family history, social habits, physical activity and diet with DM was significant. The assessment of developed CORE pharmacotherapy plan showed that majority of the lifestyle disorders were approached by evaluating both subjective and objective evidences, and most of the patients achieved QOL. Most patients were on an existing therapy and the evaluation of efficacy parameters were performed for the patients. **Conclusion:** The study results emphasize the importance of development of CORE pharmacotherapy plan and its assessment, which is a basic element of pharmaceutical care. If CORE was developed systematically, rational drug therapy can be ensured, which may lead to improved QOL for lifestyle disorders.

KEYWORDS: Pharmaceutical care, lifestyle disorders, CORE, clinical pharmacists, QOL.

INTRODUCTION

The changing environments and lifestyles have tremendous impact on the new restless world of human life. WHO (2010) reports that as world's population ages, gets richer, smokes more, eats more and drives more, non- communicable diseases will become bigger killers than the infectious ones. The world today is threatened not only by the traditional diseases but also by a host of new lifestyle related disorders. Lifestyle diseases are permanent and require long periods of excessive care and hence they are termed chronic diseases by medical practitioners, which are putting pressure on the health care system. The four leading chronic diseases in India are cardiovascular diseases, diabetes mellitus, chronic obstructive pulmonary disease and cancer, which are responsible for more than 60% of death globally and are projected to account for 47 million deaths annually in the next 25 years.[1,2]

Hypertension exerts a substantial public health burden on cardiovascular health status and health care systems. In India the prevalence of HTN in urban people were 25% and 10% in rural people. Whereas, the prevalence of diabetes will double globally from 171 million to 366 million with a maximum increase in India. Though several antihypertensive drugs are today available, only a third of treated hypertensive patients achieves the target values. The management of DM2 patients involves comprehensive clinical control including several factors, starting from changes in lifestyle and including correct pharmacological therapy.[3,4]

Chronic respiratory diseases are a potent cause of death globally; the two main types of CRD_s are COPD and Asthma. Although preventable and treatable, COPD remains a leading cause of morbidity, mortality and elevated healthcare costs worldwide. Most of the outcome measures of COPD can be modified by therapeutic strategies and non- pharmacologic strategies. Asthma is a chronic respiratory disorder that affects 1–18% of the world's population. Asthma education and careful pharmacological management are essential interventions for disease control.[5-8]

Pharmacists are well suited to identify and resolve medication related problems and provide medication education to patients and their families to prepare them

to manage medication therapy following discharge from hospitals. Pharmacists, being the expert in a matter of medicines, are in a unique position to think from a different angle than the physicians and nurses due to professional orientation and training. The healthcare services in developed countries are satisfactorily safe due to collaborative healthcare services by physicians, nurses, and pharmacists.

In India, pharmacists had a little role in the healthcare services. The management of patient's therapy is managed by physicians with the help of nursing faculty thus leading to underutilization of services and knowledge of pharmacists. Physicians, who are unfamiliar with services of pharmacists, may be declined to give authority to less qualify as perceived. Pharmacists need training and support to develop and improve their practical skills to provide comprehensive pharmaceutical care. Provision of pharmaceutical care, complete documentation of pharmacotherapy process, and achieving cost effective use of resources ultimately lead to formation of a comprehensive health care system.[8]

CORE is abbreviated form of condition, outcome, regimen and evaluation parameters to assess the patient condition. Development of CORE pharmacotherapeutic plan will help the HCP_s to follow rational treatment and will help to implement safe, efficacious and cost-effective drug therapy.[9]

Several studies have been carried out regarding the outcome-oriented concept of pharmaceutical care which requires monitoring the regimen's effects, revising the regimen as the patient's condition changes, documenting the results, and assuming responsibility for the pharmacotherapeutic effects. But a study specifically related to development of CORE pharmacotherapy plan, which is an essential component of pharmaceutical care, has not yet published.

In this context a study was planned to develop and assess the CORE pharmacotherapy plan for common life style disorders which will help to emphasize the fact that a positive mutual relationship with all healthcare professionals is beneficial for patient's outcomes, and which will be an opportunity for clinical pharmacist to provide appropriate skills in hospital to practice the pharmacy profession in collaboration with other health care professionals.

MATERIAL AND METHODS

The study was carried out for a period of six months. A prospective observational study was carried out by reviewing prescriptions of 161 patients who are diagnosed with at least one of the life style disorders such as Hypertension, Diabetes Mellitus, COPD and Asthma. The study was started after taking consent from respective authorities.

Inclusion Criteria

- Case sheets of all patients who are diagnosed with at least one of the life style disorders such as Hypertension, Diabetes Mellitus, COPD and Asthma.
- Case sheets of inpatients units of General Medicine and pulmonary with age group above 18.

Exclusion Criteria

- Patients having other life style disorders except Hypertension, Diabetes Mellitus, COPD and Asthma.
- Case sheets of out-patients.
- Special populations like pediatrics, pregnant and lactating women.

A total of 161 cases of lifestyle disorders such as HTN (62), DM (52), COPD (25) and Asthma (22) were collected from inpatient department of general medicine and pulmonary. Data from patient's case files were obtained with regard to age, sex, reason for admission, dose, duration, lab investigation, social habits, physical activity, diet, route of administration etc. The CORE format for the collected 161 cases were developed. The developed CORE for individual patient is analysed and assessed in accordance with the proper guidelines.

RESULTS AND DISCUSSION

A total number of 161 case sheets of lifestyle disorders were reviewed and analysed.

In study population male patients were more for hypertension (67.74%) and COPD (78%). Whereas, female patients were more for diabetes mellitus (63.46%) and an equal prevalence (50%) of males and females for asthma (**Figure: 1**). More number of hypertensives (45.16%), diabetic (53.85%) and asthma patients (45.45%) were in the age group of 58-77years and most COPD patients (48%) were in the age group of 38-57 years (**Figure: 2**). Majority of hypertensive (66.13%), diabetic (57.69%), COPD (72%) and asthma (72.73%) patients were illiterate (**Figure: 3**). Almost 54.84% of hypertensive, 71.15% of diabetic, 68% of COPD and 40.91% of asthma patients were not having a family history of respective disorder. The most commonly prescribed drug for the study population is antibiotic (19.26%). The common drug prescribed for hypertension patients was antihypertensives (29.97%) and among the antihypertensives, CCB_s (24.09%) were more frequently prescribed, followed by $ACEI_s$ (20.43%) (**Figure: 4**).

Table 1 depicts the relationship between the risk factors and hypertension which shows that there is a significant association between gender and the occurrence of hypertension (p value <0.05). Men exhibit higher prevalence of HTN than their female counterparts. Similar findings was reported by previous studies.[5-8] Age also shown significant association with hypertension (p value < 0.05). As the age was advancing so did the prevalence of hypertension among both the sexes.

Similar findings were reported by few other studies.[9-11] With increasing age, the aorta and arteries walls will be stiffened and this contributes to the high prevalence of hypertension in older age groups.[12]

Hypertension was more prevalent in smokers, alcoholic and tobacco users than non-users. This finding is supported by certain studies, but some shown contradictory findings.[9,11]

Table 2 shows that gender is significantly associated with diabetes mellitus (p value <0.05). In the present study, female patients are affected more when compared to males and it could be due to different action of hormones in women during the menopausal period. Age, family history, social habits, diet and physical activity was also significant for diabetes mellitus. Whereas, literacy was insignificant in the present study.

The relationship between various factors and COPD suggests that there is an association between the factors, except diet, such as sex, age, literacy, family history, social habits and physical activity (p value <0.05). Whereas, asthma is associated with literacy, social habits and physical activity (p value <0.05).

CORE pharmacotherapy plan for HTN (Table: 3 and 4)

- C-condition: Majority of the patients (29.03%) were admitted with hypertension without any comorbidity and 22.58% were had DM along with HTN. Majority (51.61%) of their condition was examined with both subjective and objective evidences
- O-Outcome: 62 (100%) were evaluated for symptoms, 44 (70.96%) assessed for comorbidities, 62 (100%) examined for the reduction of disease progression and 09 (17.31%) aimed for the eradication of infection. Therapeutic end points such as normalization of BP, normal glycemic control, normal RFT, normal LFT and normal TFT were assessed. Thus 82.26% of patients achieved patient outcome, i.e., QOL and 77.42% achieved therapeutic end point desired for the condition.
- R-Regimens: 66.13% of hypertensive patient were on existing therapy, 33.87% patients were on initial therapy and 85.48% of total hypertensive's constructed effective behavioral regimens.
- E-Evaluation: 87.10 % of patients were evaluated for efficacy parameter, but only 17.74% were evaluated for toxicity parameters.

CORE pharmacotherapy plan for diabetes mellitus

- C-Condition: From the total of patients diagnosed with DM, 11.54% were having diabetes without any comorbidity and 42.31% of diabetic cases were associated with comorbidity of HTN. Majority (57.70%) of their condition was examined with both subjective and objective evidences.
- O-Outcome: 52 (100%) were evaluated for symptoms, 45 (86.54%) assessed for comorbidities, 50 (96.15%) examined for the reduction of disease progression and 06 (11.54%) aimed for the eradication of infection. Therapeutic end points such as normalization of BP, normal glycemic control, normal RFT and normal LFT were assessed Thus 78.85% of diabetic patients achieved the desired patient outcome and 73.08% achieved desired therapeutic endpoint.
- R-Regimen: 44.23% were receiving initial therapy, 55.77% belonging in existing therapy plan and 82.69% were properly constructed with behavioral regimen.
- E-Evaluation: 87.10% were evaluated for efficacy parameter whereas, only 17.74% cases were evaluated for toxicity parameters.

CORE pharmacotherapy plan for COPD

- C-Condition: Among the comorbidities associated with COPD, it was found that 7 (28%) cases were associated with HTN and others are DM, PTB, polycythemia and alcoholic hepatitis. Among 22 diabetic patients, majority (60.0%) of their condition was examined with subjective evidences.
- O-Outcome: 25 (100%) were evaluated for symptoms, 11 (44.0%) assessed for comorbidities, 24 (96.0%) examined for the reduction of disease progression, 03 (12.0%) aimed for the eradication of infection, 06 (24.0%) were analysed to prevent and treat exacerbations, 21 (84.0%) were observed to improve the exercise tolerance. Therapeutic end points such as normal PFT, normalization of BP, normal glycemic control, normal RFT and normal LFT were assessed. Thus, 56% of patient outcome and 52% of therapeutic end point were achieved.
- R-Regimen: 36 % were on initial therapy and 64% on existing therapy and a percentage of 84 were administered with proper behavioral regimen.
- E-Evaluation: 60% were evaluated for efficacy parameter and 40% for toxicity parameter.

CORE pharmacotherapy plan for asthma

- C-Condition: 40.90% had asthma without any comorbidity. Whereas, comorbidities such as HTN, DM, CKD were seen in associated with asthma. Among 22 diabetic patients, majority (59.09%) of their condition was examined with subjective evidences.
- O-Outcome: 22 (100%) were evaluated for symptoms, 13 (59.09%) assessed for comorbidities, 20 (90.90%) examined for the reduction of disease progression, 00 (0.0%) aimed for the eradication of infection and 10 (45.45%) were analysed to prevent and treat asthma attacks. Therapeutic end points such as normal PFT, normalization of BP, normal glycemic control and normal RFT were assessed. Thus, 81.82% of patient outcome and 50% of therapeutic endpoint were achieved.
- R-Regimen: 40.91% were on initial therapy, 59.09% on existing therapy and 86.36% were provided with proper behavior regimen.

- E-Evaluation: that 73.72% of efficacy parameter and 40.9% of toxicity parameters were evaluated.

TABLES

Table 1: Bivariate Relationship between Risk Factors and Hypertension (N=62)

Variable		HTN		Chi Square Value	P Value (0.05)*
		Yes	No		
Sex	Male	42	20	15.613	0.000
	Female	20	42		
Age	18-37	8	54	39.211	0.000
	38-57	24	38		
	58-77	28	34		
	>77	2	60		
Literacy	Literate	21	41	12.903	0.000
	Illiterate	41	21		
Family history	Known history	28	34	1.161	0.281
	Non history	34	28		
Social habits	Smoking	28	34	27.738	0.000
	Alcohol	21	41		
	Tobacco in any form	3	59		
	Non history	26	36		
Physical activity	Heavy	31	31	24.542	0.000
	Moderate	22	40		
	Sedentary	9	53		
Diet	Veg	14	48	37.290	0.000
	Non-veg	48	14		

Table 2: Bivariate Relationship between Risk Factors and Diabetes Mellitus (N=52)

Variable		DM		Chi Square Value	P Value (0.05)*
		Yes	No		
Sex	Male	19	33	7.538	0.006
	Female	33	19		
Age	18-37	7	45	30.875	0.000
	38-57	15	37		
	58-77	28	24		
	>77	2	50		
Literacy	Literate	22	30	2.462	0.117
	Illiterate	30	22		
Family history	Known history	15	37	18.615	0.000
	Non history	37	15		
Social habits	Smoking	12	40	40.902	0.000
	Alcohol	9	43		
	Tobacco in any form	2	50		
	No social history	38	14		
Physical activity	Heavy	15	37	28.785	0.000
	Moderate	33	19		
	Sedentary	4	48		
Diet	Veg	12	40	30.154	0.000
	Non-veg	40	12		

Table 3: Development of CORE Pharmacotherapy plan for HYPERTENSION (N=62)

CORE	Frequency	Percentage (%)
C- Condition		
Hypertension	18	29.03
HTN with Cellulitis	7	11.29
HTN with OA	2	3.23
HTN with CKD	3	4.84
HTN with COPD	7	11.29
Portal HTN with chronic liver disease	1	1.61
HTN with GE	2	3.23
HTN with Hypothyroidism	2	3.23
HTN with DM	14	22.58
HTN with DM with CKD	1	1.61
HTN with DM with CAD	5	8.06
O- Outcome		
PatientOutcome(QOL)		
Evaluation of symptoms	62	100
Assessment of comorbidities	44	70.96
Reduction of disease progression	62	100
Eradication of infection	09	17.31
Therapeutic Endpoint		
Normalization of BP	62	100
Normal glycaemic control	20	32.26
Normal RFT	3	4.83
Normal LFT	3	4.83
Normal TFT	1	1.61
R-Regimen		
Therapeutic Regimen		
Initial therapy	21	33.87
Existing therapy	41	66.13
Goal Setting and Behaviour Regimen	53	85.48
E-Evaluation		
Efficacy Parameter	54	87.10
Toxicity Parameter	11	17.74

Table 4: Assessment of CORE Pharmacotherapy plan for Hypertension (N=62)

C- Condition		Frequency	Subjective Evidence	Objective Evidence	Subjective + Objective Evidences
Hypertension		18	05	06	07
HTN with Cellulitis		7	02	02	03
HTN with OA		2	02	00	00
HTN with CKD		3	00	00	03
HTN with COPD		7	02	02	03
Portal HTN with chronic liver disease		1	00	00	01
HTN with GE		2	01	01	00
HTN with Hypothyroidism		2	00	00	02
HTN with DM		14	02	04	08
HTN with DM with CKD		1	00	00	01
HTN with DM with CAD		5	01	00	04
Total (%)		62 (100%)	15 (24.19%)	15 (24.19%)	32 (51.61%)
O- Outcome		Yes	No	Yes(%)	No (%)
Patient outcome(QOL)		51	11	82.26	17.74
Therapeutic Endpoint		48	14	77.42	22.58
R-Regimen		Yes	No	Yes (%)	No (%)
Therapeutic Regimen	Initial Therapy	21	41	33.87	66.13
	Existing Therapy	41	21	66.13	33.87
Goal Setting and Behaviour Regimen		53	09	85.48	14.52

E-Evaluation	Yes	No	Yes (%)	No (%)
Efficacy Parameter	54	08	87.10	12.90
Toxicity Parameter	11	51	17.74	82.26

FIGURES

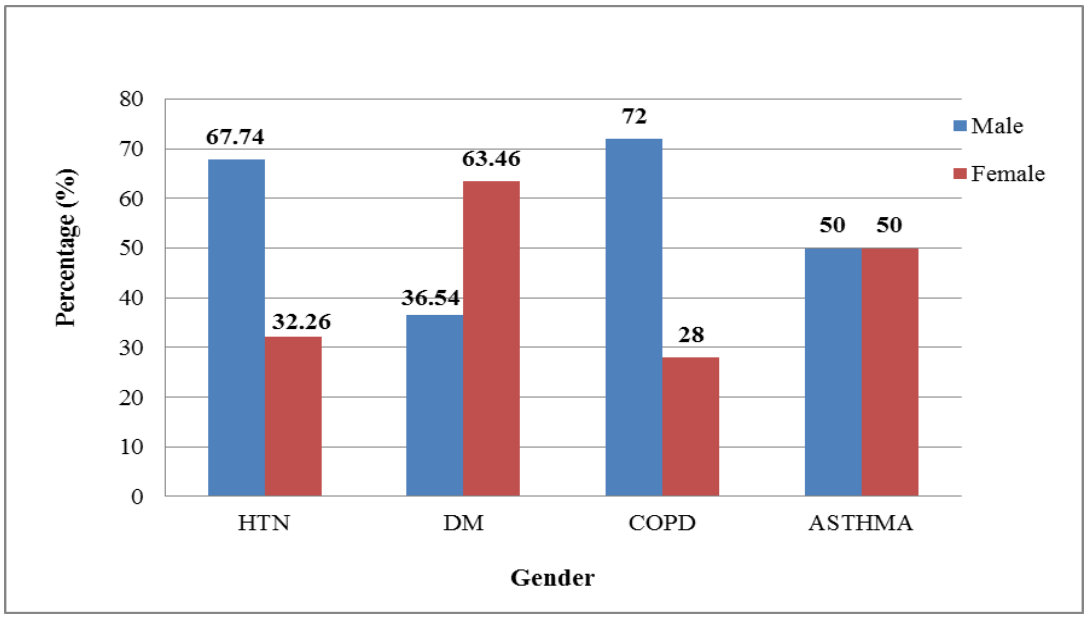

Figure 1: Gender Distribution(N=161).

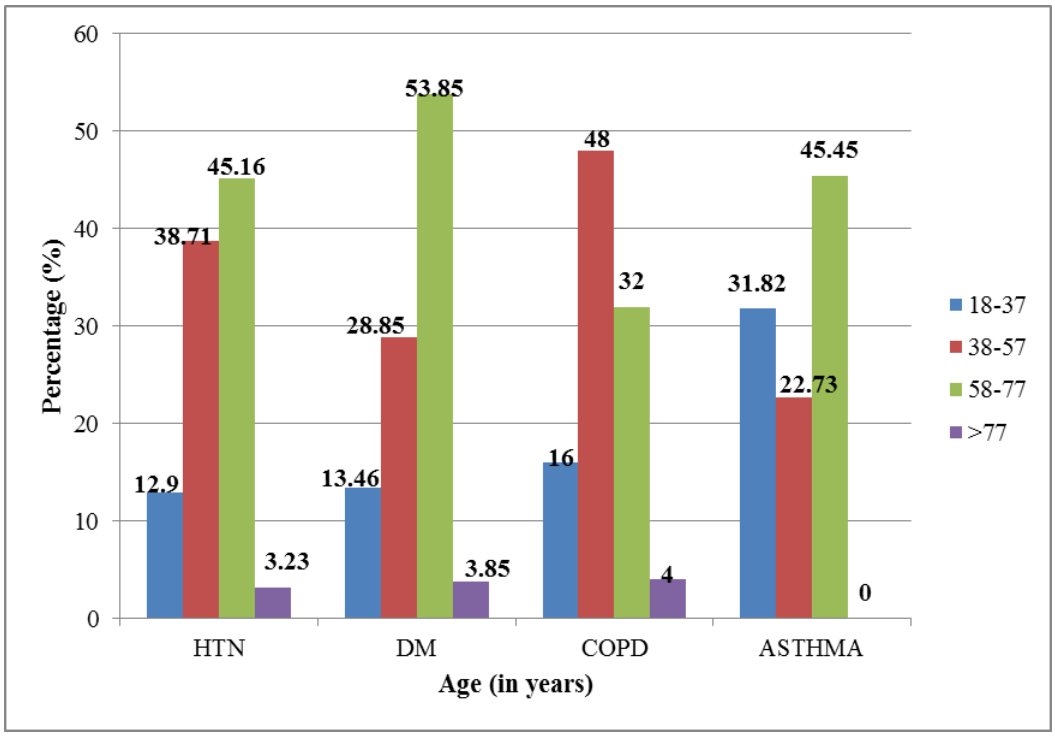

Figure 2: Age Distribution(N=161).

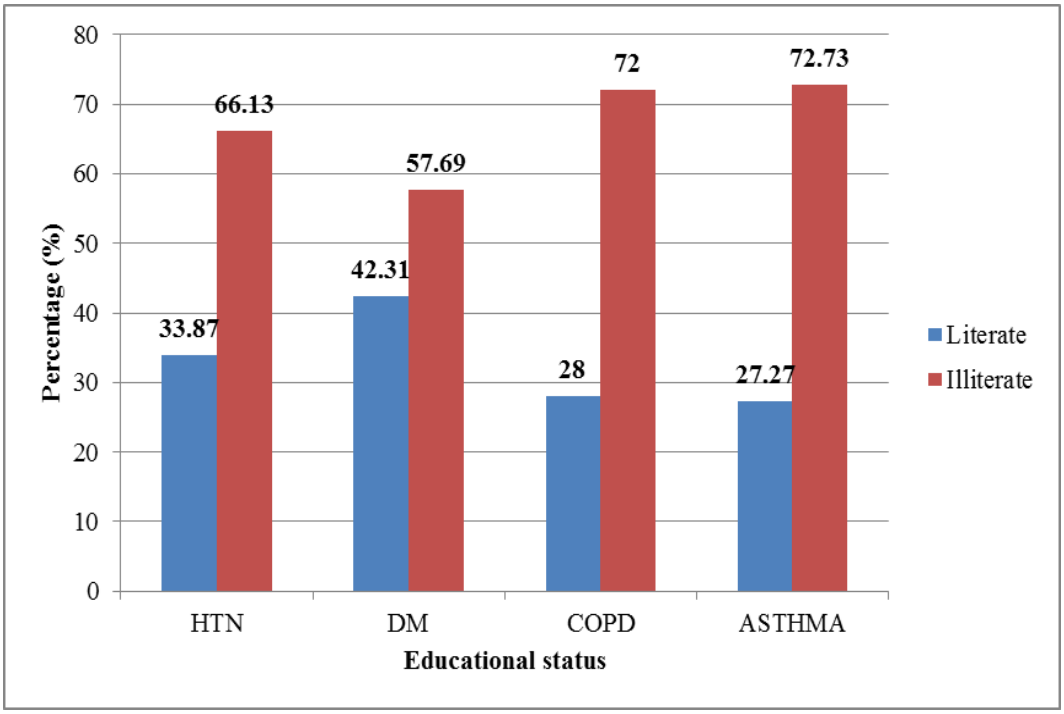

Figure 3: Educational Status (N=161).

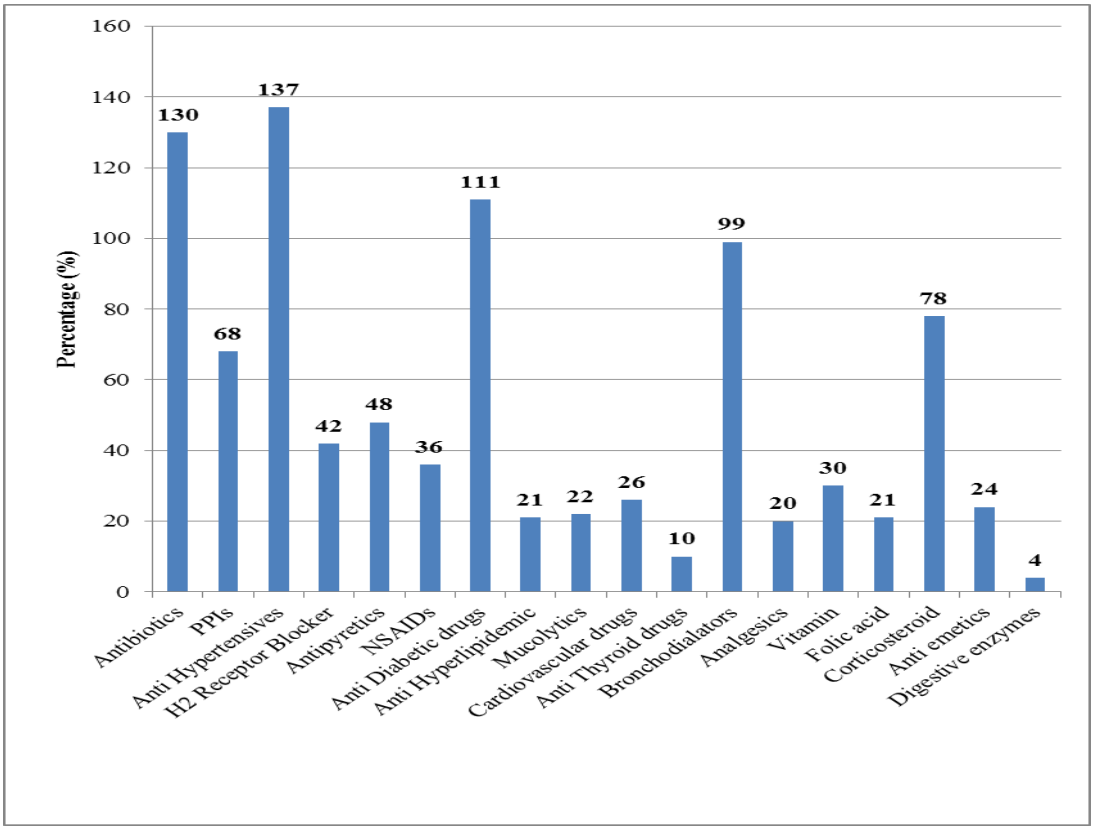

Figure 4: Drugs Prescribed for HTN, COPD, DM and Asthma (N= 675).

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CONFLICTS OF INTEREST

None declared.

KEYPOINTS

- It underscores the need for speedy implementation of pharmaceutical care in disease state management which help to minimize associated complications and improve the actualization of patient's treatment outcomes and goals.
- As the study was based on a concept of evidence based pharmaceutical care, seems promising to promote evidence based clinical practice and appropriate use of technologies.
- Quality lifestyle interventions need to be delivered can be detected and proper treatment can be prioritized.
- The study of pharmaceutical care encourages all health system pharmacists to adapt, disseminate and promote the concept to improve the pharmacy profession.
- Further studies including an economic assessment need to be conducted for the present study to demonstrate the effectiveness of pharmaceutical care and the results of such studies may provide support for actions to implement pharmaceutical care plan programs that would have a positive effect on health care and prevent complications in patients with chronic diseases.

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