

Comparative Analysis of Antihypertensive and Anti-diabetic Drug Use in cardio-metabolic patients - A Hospital based observational study.

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ABSTRACT

Background: Hypertension & Diabetes are the utmost cause of morbidity and mortality worldwide. And with the large population of our country i.e. 140 crores, these atrocious disorders are ailing the country's man power, resulting in costing exorbitant rates for hospital admissions and therapeutic treatments.

Objective: Cardiometabolic syndrome includes disorders like Hypertension and Diabetes. This study aims to analyze the utilization patterns of antihypertensive and antidiabetic drugs among Cardio-metabolic patients.

Methodology: A Prospective Observational Study was conducted for a period of 6 months in KLEs Dr Prabhakar Kore Hospital and MRC, Belagavi. 275 patients with hypertension and/or diabetes participated in the study. The Drug Utilization Pattern for the patients was analyzed with the help of JNC 8 guidelines and ADA guidelines

Results: Out of 275 patients, 152 (55.27%) were male and 123 (44.73%) were female. CCB's were mostly prescribed drug class as a Hypertensive therapy for Cardiometabolic patients. Where Nifedipine was prescribed in 26% of patients and prescribed more as an initial therapy instead of ACE inhibitors or ARBs.

Conclusion: Hypertension and Diabetes being life style diseases where the effective medication compliance is required life-long. The drugs prescribed here were rational and followed the guidelines (JNC-8 and ADA guidelines) and showcased Nifedipine as a preferred choice for lowering blood pressure due to its various benefits over the other drugs.

INTRODUCTION

Cardiometabolic Syndrome is a cluster of conditions like Hypertension, Diabetes, Hyperlipidemia and Abdominal Obesity. Under this Cardiometabolic Syndrome, Hypertension & Diabetes are the utmost cause of morbidity and mortality worldwide.^[1] In 2014, 8.5% of the adults aged 18 years and older had diabetes. In 2019, diabetes was the direct cause of 1.5 million deaths and 48% of all deaths due to diabetes occurred before the age of 70 years.^[2] Both Diabetes and Hypertension leads to degraded quality of life and have life threatening complications.³

As day-by-day new drugs are being introduced to the market, for improving clinical care, the continuous research trials and studies are being performed alongside for testing the safety and efficacy of respective pharmaceuticals which has led to unceasing bans on various incompetent drugs as well. Healthcare professional's constant effort for improving the therapy and overall patient's Health Regulated Quality of Life includes the evaluation of prescription and their appropriateness.⁴

History has taught us that successful research in drug utilization requires multidisciplinary collaboration between clinicians, clinical pharmacologists, pharmacists, and epidemiologists.⁵ The study of drug utilization is an evolving field. The use of large computerized databases that allow the linkage of drug utilization data to diagnosis is contributing to expansion of this area.⁶

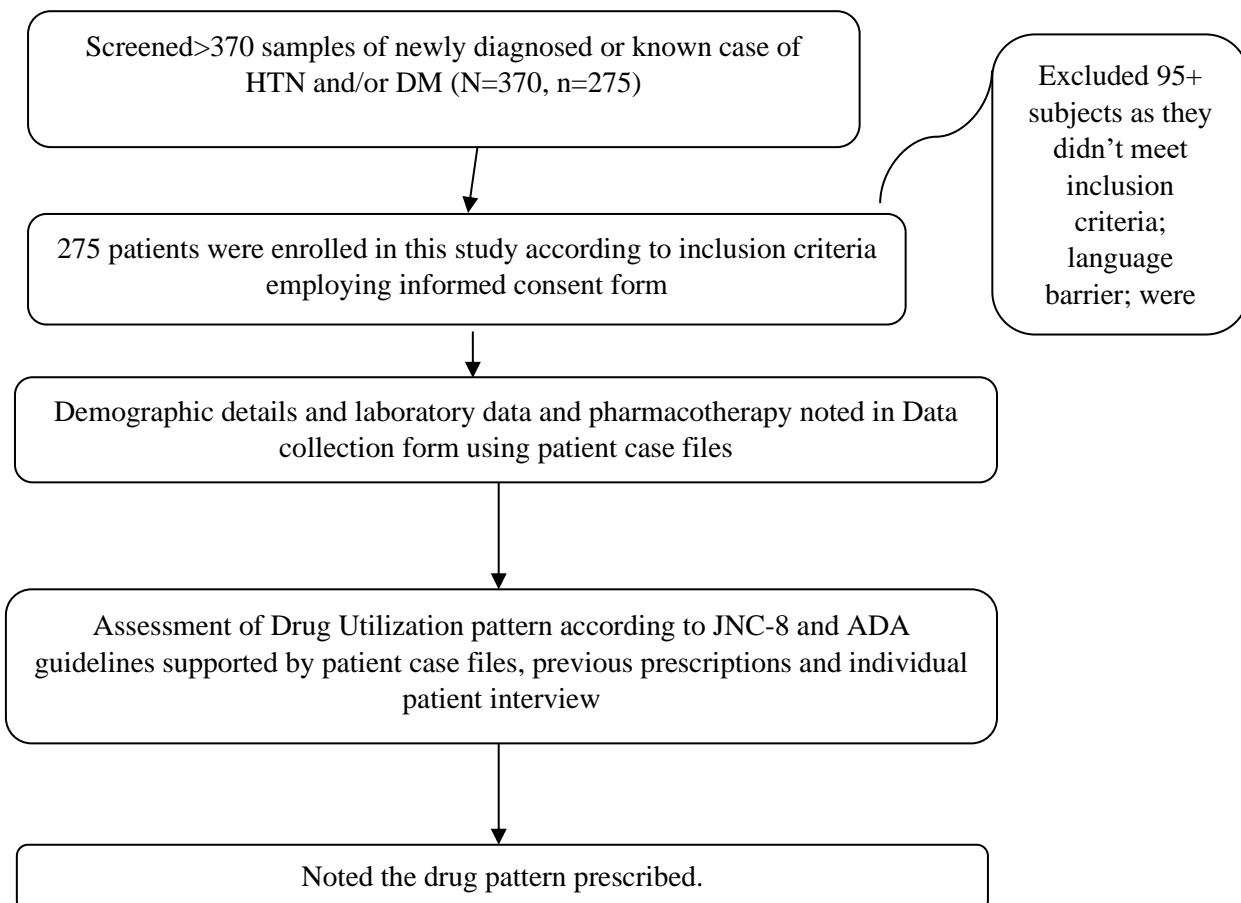
Drug costs are a significant component in healthcare in developing nations such as India. Rational treatment entails recommending the appropriate medication at the appropriate dosage, with appropriate formulation, in an appropriate time-frame, and at an appropriate cost that the patient in question can afford.⁷ Due to the rapidly expanding pharmaceutical industry in India, there are various brands manufactured by several companies available on the national market, each with a wide range of prices for the same composition. Medication compliance is strongly influenced by drug costs. Because of higher costs and longer treatment durations, adherence will be poor and patients will be less compliant with their treatment.⁸

Some studies specifically focuses on Assessment of Drug Utilization Pattern, which may be useful in various ways as: It provides knowledge about current prescribing trends, provides continuing education on new developmental therapeutic guidelines, analysing population ratio exposed to the drugs, measures the effect of educational, informational and regulatory initiatives, as well as price policies to make update later on as necessary, helps in identifying areas where more research on the absolute and relative efficacy and safety of pharmacological therapy is needed. It denotes the excess, underuse or misuse of drugs. It is done to assess the prescribing trends and make use of it in medical, social and economic aspects.⁸ According to International diabetes federation (IDF), 65.1 million of adults in India suffered from diabetes in the year 2013.⁹ It has been predicted that the prevalence of diabetes in the adult population in India will be 6% by the year 2025.¹⁰ It calculates demands based on morbidity statistics to serve as foundation for drug selection, distribution, and use in drug and health policy.⁸ one of the research study was performed for the assessment of Drug Utilization Pattern in Hypertensive and/or Diabetic patients to check if the prescription practices in this hospital are according to JNC 8 guidelines for Hypertension and American Diabetes Association guidelines for Diabetes therapy.¹¹

METHODOLOGY

The study is a prospective observational analysis conducted over a 6-month period at KLEs Dr. Prabhakar Kore Hospital, a multispecialty tertiary care hospital in Belgaum, Karnataka. The study focuses on hypertensive and/or diabetic patients over the age of 18. Exclusion criteria include cancer patients, pregnant or lactating women, and those unable to respond, such as severely ill or unconscious patients. Ethical clearance was obtained from the Institute Ethics Committee, and informed consent was provided by participants. The study was conducted in the free wards of the General Medicine Department, ensuring that all data collected remained confidential and used solely for research purposes

Figure no.01: A methodology chart was prepared for the better understanding of the approach and procedure of recruiting the subjects and planning of conduct of the study.



RESULTS

In this study, 370 patients were screened among which, 275 were enrolled and 219 was the final sample size (lost 56 subjects during follow up) considered during the 6 months long prospective observational study. The assessment of Drug utilization Pattern was performed in Hypertensive and/or Diabetic patients.

Table no.01: Comparison of three groups (HTN, DM and both) with demographic profile

Profile	HTN	%	DM	%	Both	%	Total	%	Chi-square	p-value
Gender										
Male	59	58.42	33	63.46	60	49.18	152	55.27	3.6460	0.1620
Female	42	41.58	19	36.54	62	50.82	123	44.73		
Age										
Old	48	47.52	14	26.92	62	50.82	124	45.09	16.6580	0.0020*
Middle	43	42.57	28	53.85	56	45.90	127	46.18		
Young	10	9.90	10	19.23	4	3.28	24	8.73		
Weight										
40-60	43	42.57	10	19.23	32	26.23	85	30.91	15.4340	0.0170*
61-75	39	38.61	21	40.38	51	41.80	111	40.36		
76-80	15	14.85	13	25.00	25	20.49	53	19.27		
>80	4	3.96	8	15.38	14	11.48	26	9.45		
Education										
Illiterate	25	24.75	5	9.62	15	12.30	45	16.36	9.7360	0.2840
Primary	30	29.70	15	28.85	39	31.97	84	30.55		
Secondary	31	30.69	23	44.23	49	40.16	103	37.45		
Graduate	10	9.90	5	9.62	12	9.84	27	9.82		
Post graduate	5	4.95	4	7.69	7	5.74	16	5.82		
Occupation										
Unemployed	74	73.27	33	63.46	98	80.33	205	74.55	5.6030	0.0610
Employed	27	26.73	19	36.54	24	19.67	70	25.45		
Resident										
Urban	54	53.47	34	65.38	80	65.57	168	61.09	3.9060	0.1420
Rural	47	46.53	18	34.62	42	34.43	107	38.91		
Marital status										
Married	79	78.22	49	94.23	103	84.43	231	84.00	10.7790	0.0290*
Unmarried	5	4.95	2	3.85	1	0.82	8	2.91		
Widow/widower	17	16.83	1	1.92	18	14.75	36	13.09		
Total	101	100.0	52	100.0	122	100.0	275	100.0		

Table no. 01 compares three groups (HTN, DM, and both) with demographic profiles among 275 participants. Of the 152 males, 59 (58.42%) had HTN, 33 (63.46%) had DM, and 60 (49.18%) had

both. Among 123 females, 42 (41.58%) had HTN, 19 (36.54%) had DM, and 62 (50%) had both. By age, 124 (45.09%) were elderly, 127 (46.18%) middle-aged, and 24 (8.73%) young adults. In terms of weight, 85 (30.91%) weighed 40-60 kg, 111 (40.36%) weighed 61-75 kg, 53 (19.27%) were 76-80 kg, and 26 (9.45%) weighed >80 kg. Educationally, 16.36% were illiterate, 30.55% completed primary, 37.45% secondary, 9.82% high school, and 5.82% were postgraduates. Occupation-wise, 205 (74.55%) were unemployed. 168 (61.09%) lived in urban areas, and 231 (84.00%) were married. Age, weight, gender, and marital status showed significance, while other variables did not. (Table 03)

Table no. 02: Comparison of three groups (HTN, DM and both) with family history, diet, Social Habits, Length of hospital stay & No. of co-morbidities

Profile	HTN	%	DM	%	Both	%	Total	%	Chi-square	p-value
1. Family history										
Yes	35	34.65	22	42.31	47	38.52	104	37.82	0.9020	0.6370
No	66	65.35	30	57.69	75	61.48	171	62.18		
2. Diet										
Vegetarian	28	27.72	16	30.77	42	34.43	86	31.27	5.8870	0.2080
Non vegetarian	28	27.72	10	19.23	18	14.75	56	20.36		
Mixed	45	44.55	26	50.00	62	50.82	133	48.36		
3. Social Habits										
a. Smoking										
Yes	42	41.58	24	46.15	44	36.07	110	40.00	1.7130	0.4250
No	59	58.42	28	53.85	78	63.93	165	60.00		
b. Alcoholic										
Yes	37	36.63	23	44.23	47	38.52	107	38.91	0.8470	0.6550
No	64	63.37	29	55.77	75	61.48	168	61.09		
4. Hospital stay										
0-5 days	8	7.92	3	5.77	7	5.74	18	6.55	12.3790	0.0500*
6-15 days	67	66.3	38	73.08	62	50.82	167	60.73		
16-30 days	23	22.7	9	17.31	46	37.70	78	28.36		
>30 days	3	2.97	2	3.85	7	5.74	12	4.36		
5. No of co-morbidities										
No	12	11.88	8	15.38	13	10.66	33	12.00	3.4770	0.7470
One	66	65.35	32	61.54	72	59.02	170	61.82		
Two	19	18.81	8	15.38	28	22.95	55	20.00		
Three	4	3.96	4	7.69	9	7.38	17	6.18		

The comparison of three groups (HTN, DM, and both) with family history and diet among 275 participants shows that 104 (37.82%) had a family history of either condition, while 171 (62.18%) did not. Regarding diet, 86 (31.27%) were vegetarian, 56 (20.36%) non-vegetarian, and 133

(48.36%) had a mixed diet. Neither family history nor diet showed significance. In comparing habits, 110 (40.00%) were smokers and 107 (38.91%) were alcoholics, with no significance found. The comparison of hospital stays showed 167 (60.73%) had stays of 6-15 days, with a significant relationship ($p=0.05$). Regarding comorbidities, 170 (61.82%) had at least one, but this did not show significance. (**Table no. 02**)

Table no. 03: Comparison of three groups (HTN, DM and both) with SBP and DBP

BP	HTN		DM		Both		Total		Chi-square	p-value
	n	%	n	%	n	%	n	%		
SBP										
Normal	25	24.75	18	34.62	21	17.21	64	23.27	19.3320	0.0130*
Elevated	9	8.91	9	17.31	26	21.31	44	16.00		
HTN stage 1	16	15.84	12,	23.08	17	13.93	45	16.36		
Stage 2	45	44.55	13	25.00	49	40.16	107	38.91		
Hypertensive crisis	6	5.94	0	0.00	9	7.38	15	5.45		
DBP										
Normal	33	32.67	19	36.54	25	20.49	77	28.00	21.1300	0.0070*
Elevated	22	21.78	24	46.15	47	38.52	93	33.82		
HTN stage 1	30	29.70	6	11.54	37	30.33	73	26.55		
Stage 2	14	13.86	3	5.77	12	9.84	29	10.55		
Hypertensive crisis	2	1.98	0	0.00	1	0.82	3	1.09		

Table no. 04: Comparison of three groups (HTN, DM and both) with levels of HbA1c, FBS and RBS

	HTN		DM		Both		Total		Chi-square	p-value
	n	%	n	%	n	%	n	%	%	
HbA1c										
5.7 to 6.9	0	0.00	12	23.08	23	18.85	35	20.11	5.8350	0.6660
7 to 8	0	0.00	12	23.08	36	29.51	48	27.58		
8.1 to 11	0	0.00	23	44.23	42	34.43	65	37.35		
11.1 to 13	0	0.00	4	7.69	16	13.11	20	11.49		
>13	0	0.00	1	1.92	5	4.10	6	3.44		
FBS										
50-115	0	0.00	7	13.46	20	16.39	27	15.51	15.8920	0.0140*
116-180	0	0.00	37	71.15	64	52.46	101	58.04		
181-215	0	0.00	2	3.85	28	22.95	30	17.24		
>215	0	0.00	6	11.54	10	8.20	16	9.19		
RBS										
<140	0	0.00	13	25.00	23	18.85	36	20.68		

140 -200	0	0.00	18	34.62	62	50.82	80	45.97	7.7790	0.1000
>200	0	0.00	21	40.38	36	29.51	57	32.75		

A comparison of three groups (HTN, DM, and both) with SBP and DBP showed that 64 (23.27%) had normal SBP, 44 (16%) had elevated SBP, 45 (16.37%) had Stage 1 hypertension, 107 (38.91%) had Stage 2, and 15 (5.45%) were in hypertensive crisis. For DBP, 77 (28%) had normal levels, 93 (33.82%) had elevated DBP, 73 (26.55%) were in Stage 1 hypertension, 29 (10.55%) in Stage 2, and 3 (1.09%) had hypertensive crisis. SBP and DBP comparison showed significance. Regarding FBS, 25% of diabetic and 18.85% of hypertensive-diabetic patients had levels >215. Among RBS levels, 45.97% had values between 140-200. For HbA1c, 37.35% had levels between 8.1-11, and 3.44% had values >13. Among FBS levels, 58.04% were in the 116-180 range, while 17.24% had levels between 181-215. Both FBS and HbA1c comparisons showed significance.

(Table no. 03 & 04)

Table no. 05: DRUG UTILIZATION PATTERN OF ANTI-HYPERTENSIVE DRUGS IN HYPERTENSION/ HYPERTENSION AND DIABETES PATIENTS (MONOTHERAPY, TWO DRUG COMBINATION & THREE DRUG COMBINATION)

A	Treatment (Monotherapy)	HTN		BOTH		TOTAL	
		n	%	n	%	n	%
	CCBs (Amlodipine)	22	21.78	17	13.93	39	14.18
	CCB (Nifedipine)	25	24.75	33	27.05	58	21.09
	ACEI (Captopril)	0	0.00	1	0.82	1	0.36
	BETA BLOCKERS (Metoprolol)	5	4.95	8	6.56	13	4.73
	BETA BLOCKERS (Carvedilol)	0	0.00	2	1.64	2	0.73
	ARBs (Telmisartan)	18	17.82	27	22.13	45	16.36
	ARBs (Losartan)	1	0.99	4	3.28	5	1.82
B	Treatment (Two drug combination)	HTN		BOTH		TOTAL	
		n	%	n	%	n	%
	CCB + ARB	4	3.96	2	1.64	6	2.18
	CCB + Beta Blockers	5	4.95	6	4.92	11	4.00
	CCB + diuretic	0	0.00	1	0.82	1	0.36
	ARB + diuretic	12	11.88	14	11.48	26	9.45
	ARB + Beta Blockers	0	0.00	2	1.64	2	0.73
	Beta Blockers + diuretic	3	2.97	0	0.00	3	1.09
C	Treatment (Three drug combination)	HTN		BOTH		TOTAL	
		n	%	n	%	n	%

	CCB + diuretic + ARB	1	0.99%	5	4.09%	6	3.46%
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The data shows that CCB (Nifedipine) was the most prescribed drug, used in 58 (21.09%) cases, while Captopril (ACEI) was the least prescribed at 1 (0.36%). ARB (Telmisartan) was prescribed in 45 (16.36%) cases, CCB (Amlodipine) in 39 (14.18%), Beta Blocker (Metoprolol) in 13 (4.73%), ARB (Losartan) in 5 (1.82%), and Beta Blocker (Carvedilol) in 2 (0.73%) cases. Among two-drug combinations, ARB + Diuretic was the most common, prescribed in 26 (9.45%) cases, while CCB + Diuretic was least used at 1 (0.36%). CCB + Beta Blockers was used in 11 (4%) cases, CCB + ARB in 6 (2.18%), Beta Blockers + Diuretics in 3 (1.09%), and ARB + Beta Blockers in 2 (0.73%). For three-drug combinations, CCB + Diuretic + ARB was given in 1 (0.99%) Hypertensive and 5 (4.09%) Hypertensive-Diabetic patients, totaling 6 (3.46%) cases.

(Table no.05)

Table no. 06: DRUG UTILIZATION PATTERN OF ANTI DIABETIC DRUGS IN DIABETES / HYPERTENSION AND DIABETES PATIENTS ((MONOTHERAPY, TWO DRUG COMBINATION & THREE DRUG COMBINATION)

A	Treatment (Monotherapy)	DM		BOTH		TOTAL	
		n	%	n	%	n	%
	Biguanides (metformin)	5	9.62	12	9.84	17	6.18
	Sglt2 inhibitors (dapagliflozin)	1	1.92	3	2.46	4	1.45
	Alpha glucosidase inhibitors (voglibose)	1	1.92	0	0.00	1	0.36
	HUMAN INSULIN (Human actrapid)	22	42.31	46	37.70	68	24.73
	HUMAN INSULIN (Human mixtard)	4	7.69	9	7.38	13	4.73
B	Treatment (Two drug combination)	DM		BOTH		TOTAL	
		n	%	n	%	n	%
	Metformin+ glimepiride	12	23.08	34	27.87	46	16.73
	Human mixtard+ human insulin	0	0.00	3	2.46	3	1.09
C	Treatment (Three drug combination)	DM		BOTH		TOTAL	
		n	%	n	%	n	%
	Metformin + glimepiride + pioglitazone	1	1.92	1	0.82	2	0.73
	Metformin + glimepiride + insulin	9	17.31	14	11.48	23	8.36

The data indicates that Human Insulin (Human Actrapid) was the most prescribed medication, used in 68 (24.73%) cases, while Alpha Glucosidase Inhibitors (Voglibose) were the least prescribed at 1 (0.36%). Among oral hypoglycemic agents (OHAs), Biguanides (Metformin) was the most common, prescribed in 17 (6.18%) cases. Insulin Analogs (Human Mixtard) were used in 13 (4.73%) cases, and SGLT2 inhibitors (Dapagliflozin) in 4 (1.45%) cases. The two-drug combination of Metformin + Glimepiride was prescribed in 46 (16.73%) cases, with 12 (23.08%) for diabetic patients and 34 (27.87%) for those with both hypertension and diabetes. Human Mixtard + Human Insulin was prescribed in 3 (1.09%) hypertensive-diabetic cases. For three-drug combinations, Metformin + Glimepiride + Insulin was the most used in 23 (8.36%) cases, while Metformin + Glimepiride + Pioglitazone was prescribed in 2 (0.73%) cases, the least. (**Table no. 06**)

DISCUSSION

This study was conducted in free wards of General Medicine Department in KLEs Dr. Prabhakar Kore's Hospital and MRC situated in Belgaum, Karnataka where 275 subjects were selected who had either Hypertension or Diabetes or both for reviewing their Drug Utilization Pattern according to 8th JNC guidelines and ADA guidelines.

In a study by **Whelton et al.**, family history of hypertension was recognized as a risk factor, but, like your findings, it did not significantly affect clinical outcomes in well-managed individuals. Smoking and alcohol are established risk factors for hypertension and diabetes.¹² However, **Go et al.**, found that smoking and alcohol, though prevalent, did not correlate significantly with worse outcomes across groups, possibly due to medication adherence or other health behaviors.¹³

The significant relationship between hospital stays (6–15 days) in present study is consistent with **Banerjee et al.**, where longer stays were linked to managing complex comorbidities. However,

like your findings, the presence of comorbidities, despite being common, did not always significantly affect clinical outcomes.¹⁴

This study showcased the maximized use of CCBs over ACE/ARBs as single drug therapy implying more acceptance from the prescribers for opting the drug class with comparative lower side effects and organ damage. In contrast to other studies done in similar conditions such as in one study conducted by **Sukhrala F et al.**, for evaluating the drug utilization pattern in hypertensive patients comprising of 223 patients (121 male), (102 female). Among those, 46.18% patients were taking single drug regimen while remaining patients were taking multidrug therapy. Most commonly ARBs were prescribed to the patients. (ACE inhibitors and ARBs) were utilized in 71% of the patients.¹⁵ Few other studies done previously also showed similar results with ARBs as most prescribed treatment where as in the current study setting the higher usage of CCBs by physicians implies lower compliance with evidence-based recommendations as the high risk of adverse medication responses and instances of renal & hepatic failure is in question.

The most prescribed drug in diabetic patients in Monotherapy was Human Actrapid (24.73%) in DM followed by Biguanides. In Two Drug combination Biguanides + Sulfonylureas (16.73%) was prescribed the most in three drug combination Biguanides + Insulin + Metformin (4.36%) was most preferred in this study.¹⁷

Similarly in another study carried out by **Huziri, Leena et.al**, carried out a study in the general medicine outpatient department of Sardar Patel Medical College out of 300 patients screened 58.33% was male and 41.66% was female patients and majority of patients came under the age group of 51-60yrs. Biguanides (97%) were commonly prescribed among all the antidiabetic drugs as single drug therapy. Sulfonylureas was second most prescribed drug than DDP 4 inhibitors (24%). 66% patients were on multiple drug treatment and in combination therapy Biguanides + Sulfonylureas was commonly prescribed.

In this study regarding DM patients, the most prescribed treatment is Insulin because our study

setting was in-patient where Insulin treatment was preferred and given according to blood glucose level.¹⁶

This study was conducted to monitor the rational use of Antihypertensive and Antidiabetic drugs, which is of paramount importance as Hypertension and Diabetes are one of the most common diseases in India and must continue the medications for their entire life. And being life style disease they have several comorbidities and with life-long treatment comes the long-term effects of medications which should be kept in check. Hence the rational use of these medication plays a key role in maintain the combined health of the society.

In comparison to other studies, the higher prescription rate of CCBs in this study contrasts with findings where ARBs were commonly prescribed for hypertension. For example, a study by **Gupta et al.** noted ARBs like Telmisartan as the most prescribed antihypertensive agents due to their renal-protective effects, particularly in hypertensive patients with comorbidities like diabetes.¹⁷ Similarly, **Pathak et al.** reported ARBs as the first-line treatment in 31.5% of cases, emphasizing the adherence to evidence-based guidelines in hypertension management. However, in the current study, the higher use of CCBs, especially Nifedipine (21.09%), suggests potential non-compliance with these recommendations, particularly given the concerns of adverse effects like renal and hepatic impairment associated with CCBs. Additionally, the use of two-drug combinations, such as ARB + Diuretic (9.45%), is in line with the combination therapy approach advocated in prior studies, underscoring its effectiveness in blood pressure control.¹⁸

In comparison to other studies, the pattern of insulin and OHA use aligns with the findings of a study by **Neupane et al.**, where Metformin was the most prescribed OHA (57%), while Human Insulin (26%) was frequently used for insulin therapy.¹⁹ A similar trend is seen in research by **Tharkar et al.**, highlighting that Metformin remains the preferred choice for diabetes management, prescribed in 69.3% of cases. The lower use of newer agents such as SGLT2 inhibitors, observed in only 1.45% of cases in this study, corresponds to findings where newer OHAs were less frequently prescribed, possibly due to cost and accessibility factors. These

comparisons emphasize that while Metformin and insulin therapies dominate, the adoption of newer agents like SGLT2 inhibitors remains limited, requiring further exploration of cost-effectiveness and clinical outcomes in diverse populations.²⁰

CONCLUSION

The study provides a comparative analysis of antihypertensive and antidiabetic drug use in cardiometabolic patients, highlighting the most commonly prescribed medications and drug combinations. Human Insulin and Nifedipine were the most frequently used for diabetes and hypertension, respectively. The combination of ARB + Diuretics was common for hypertension, while Metformin + Glimepiride was widely used for diabetes. The findings emphasize the need for tailored treatment strategies, considering comorbid conditions to optimize therapeutic outcomes in cardiometabolic patients

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