Journal of Chemical Health Risks

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JCHR (2026) 16(2), 3913-3925 | ISSN:2251-6727

"A Prescription Study from a Tertiary Care Hospital: Reasonable Use of Fixed-Dose Combinations in Hypertensive Diabetic Patients"

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(Received: 16 February 2026 Revised: 25 March 2026 Accepted: 10 April 2026)

KEYWORDS

Fixed-dose combinations, Hypertension, Diabetes mellitus, Rational prescribing, Antihypertensive therapy, Antidiabetic therapy, Prescription audit.

ABSTRACT:

Background

Hypertension and diabetes mellitus commonly coexist and substantially increase the risk of developing cardiovascular complications like coronary artery disease, stroke, nephropathy and heart failure. Fixed-dose combinations are commonly used for treating these disease conditions as they improve adherence to therapy, reduce pill burden and improve outcomes. Nevertheless, using FDCs irrationally can cause harmful consequences, duplicating drugs and unnecessary polypharmacy.

Aim

To identify the demographic profile and rationality of fixed-dose combination therapy among hypertensive diabetic patients in a tertiary care hospital.

Methods

This prospective cross-sectional observational study involved a total of 290 hypertensive patients with type 2 diabetes mellitus. The patient case records were used to gather the information based on a systematic case proforma. Demographic variables, disease history, prescription behaviors, antihypertensive and antidiabetic medication use, and fixed-dose combinations (FDCs) were noted. The rationality of prescribed FDCs was determined on the recommendation of the world health organization, American Diabetes Association, American College of Cardiology, American Heart Association, and National Institute of Health and Care Excellence. Out of the 290 patients, 55 percent were male and 45 percent were female with the greatest number of the patients falling in the 41 59 years age bracket. FDCs prescribed included antihypertensive FDCs (74.48% of patients) and antidiabetic FDCs (70.34% of patients). Telmisartan + Amlodipine was the most used antihypertensive FDC and Metformin + Teneligliptin was the most used antidiabetic FDC. In general, it was found that 95.71 percent of the prescribed FDCs were rational.

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JCHR (2026) 16(2), 3913-3925 | ISSN:2251-6727

Conclusion

The fixed-dose combinations are widely used in hypertensive-diabetic patients and are largely prescribed as per the guidelines. Regular prescription auditing and clinician awareness of irrational prescribing behaviour should be encouraged to rationalise drug use. In the prescription audit of prescription of fixed dose combination anti-hypertensive &anti diabetic agent in a tertiary care hospital.

1. Introduction

Burden of Hypertension and Diabetes Mellitus

Hypertension and diabetes mellitus are common non-communicable diseases which have important contribution in cardiovascular morbidity and mortality. It is often seen that the two conditions occur together due to several overlapping risk factors such as being overweight and obesity, sedentary lifestyle, unhealthy diet, smoking, alcohol, and advancing age. The presence of both hypertension and diabetes greatly increases the risk of heart disease, stroke, peripheral vascular disease, kidney disease, eye disease, and heart failure. Over 1.28 billion adults are diagnosed with hypertension and over 530 million people with diabetes, says WHO. The high burden is witnessed in Low and Middle-Incomes Countries (LMICs) especially India where rapid urbanization, modification of dietary patterns and physical inactivity resulted in increasing prevalence. India has earned the title of "diabetes capital of the world" primarily due to the high prevalence of type 2 diabetes mellitus amongst the people. Hypertension prevalence in urban and rural population of India, is on the rise (WHO et al., 2021). People who have the two diseases of hypertension and diabetes require aggressive and long-term drug treatment, which helps in the prevention of complications. Research studies reveal that compared to non-diabetic hypertensive patients, diabetic patients with poorly controlled blood pressure (hypertension) are at a greater risk for cardiovascular events. The poor glycemic control in hypertensive patients also aggravates endothelial dysfunction, vascular stiffness, and vascular inflammation with accelerated disease progression (Whelton et al., 2018). The care of such patients is complex and often requires the use of multiple drugs to reach desired blood pressures and sugar levels for the patient. Fixed-dose combinations have emerged as an essential regulated therapeutic strategy.

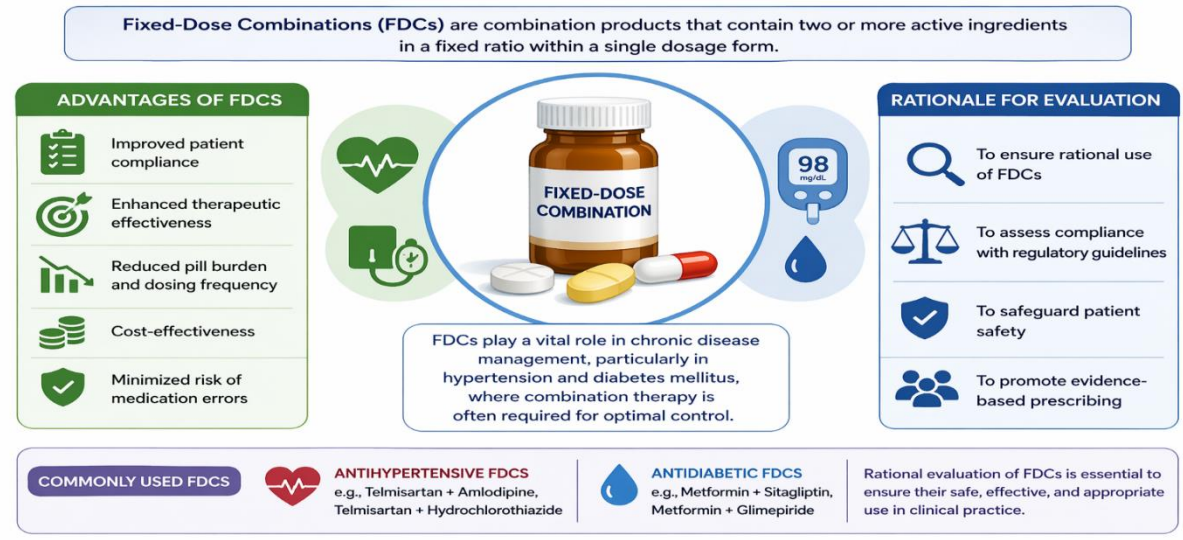

Figure:1 Introduction to Fixed-Dose Combinations in Hypertension and Diabetes Management

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Significance of Fixed-Dose Combinations

A fixed-dose combination (FDC) is a formulation which contains two or more active ingredients in a fixed ratio. The use of these combinations is increasing in chronic diseases such as hypertension and diabetes, where monotherapy often does not reach therapeutic targets. In the management of hypertension, most of the patients require at least two antihypertensive drugs with different mechanism of actions. Two frequently used combinations are angiotensin receptor blockers (ARBs) and calcium channel blockers (CCBs) or diuretics. There are several other combinations which are used like metformin with sulfonylureas, DPP-4 inhibitors, SGLT2 inhibitors, and/or thiazolidinediones for better glycaemic control in diabetes management (ADA et al., 2024).

The application of FDCs is of utmost significance considering the advanced age and additional comorbidities such as dyslipidemia, chronic kidney disease or ischemic heart disease (IHD) in patients with coexisting hypertension and diabetes. Patients in this group are usually on polypharmacy which can lower compliance and increase risk of errors. International guidelines, such as those from the American College of Cardiology/American Heart Association, American Diabetes Association and National Institute for Health and Care Excellence state that a combination therapy should be offered to those patients who do not adequately come under control with a single agent. Taking medications separately is considered difficult or cumbersome and can lead to poor compliance. In such cases, fixed-dose combinations (FDCs) are preferred (NICE et al., 2019; ADA et al., 2024).

Advantages of Fixed-Dose Combinations

Fixed-dose combinations bring several clinical and practical benefits while managing hypertension and diabetes. One of the most important benefits is the reduced pill burden. Patients are likely to forget to take their medications if they have to take them multiple times daily for a long time. The combination of two or more tablets into one tablet reduces the pill burden on a patient and simplifies the regimen. Another important benefit offered by FDCs is improved adherence. According to many studies, those patients who are getting FDCs are more likely to adhere to treatment than patients on the same drugs separately. Improved adherence will ultimately lead to better blood pressure control, better glycaemic outcome and a reduced risk of complications (Gupta et al., 2010).

Because FDCs combine drugs that have complementary mechanisms of action, they may also exert synergistic therapeutic effects. As an illustration, the mixture of telmisartan as well as amlodipine provides better blood pressure reduction than a single drug. This is because telmisartan blocks the renin-angiotensin system while amlodipine relaxes vascular smooth muscle. Likewise, combinations of metformin with sitagliptin or teneligliptin enhance glycaemic control by affecting different underlying pathophysiological mechanisms involved in diabetes. Another key gain is cost efficiency. In many cases, a combined tablet will cost less than the total price for all the individual medicines. This is especially important for developing countries when cost can affect long term adherence. By using FDCs, you may save on transportation costs, pharmacy visits and other indirect costs. Also, FDCs may complicate prescriptions, decrease prescription errors and enhance patient compliance. In seniors and patients with low health literacy, these benefits are especially important.

Patients With Irrational Fixed-Dose Combinations

Not all fixed-dose combinations are rational despite their advantages. Irrational Fixed Dose Combinations (FDCs) are those which contain two or more drugs that do not have complementary mechanism of actions, are not evidence-based, do not cause unnecessary duplication of action, and increase the risk of adverse effects. The irrational use of FDCs is a matter of great concern in a country like India where absence of twenty-seven scientific evidence, a large number of drug combinations are available in the market. Combination of drugs conflicting in pharmacokinetics, wrong dose, overlapping toxicities may appear. There may be treatment guidelines available for some others.

Problems associated with irrational fixed dose combinations. Increased risk of adverse drug reactions, drug-drug interaction, therapeutic duplication, and unnecessary polypharmacy may happen. The physician cannot independently modify the dosage of each component, which may also complicate dose titration. For instance, if a patient becomes hypotensive or hypoglycemic, it becomes difficult to identify the

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culprit. The patient may be exposed to irreversible risks due to irrational triple-drug combinations or inappropriate combined therapy in mild disease in hypertension. Just as in diabetes, a combination of ingredients may increase the risk of hypoglycemic reaction, weight gain, and GI intolerance, without additional benefit (Panda et al., 2016). Rational FDCs are those combinations of two or more drugs fixed in a single dosage form. As a result, regular review of prescribing practices has been emphasized by regulatory bodies and health institutions.

Importance of Rational Prescription Evaluation

Assessment of prescription rationality is essential to make sure that patients receive safe effective and evidence-based treatment. The very first principle of rational prescribing is that the patient's drug therapy should be based on his clinical needs. It should be in the proper dose for him, for a sufficient period and at the cheapest possible cost. The assessment of the rationality of FDCs can be done through the application of certain criteria: pharmacological compatibility, evidence of synergistic action, recommendation in a guideline, inclusion in the list of essential medicines, and absence of therapeutic duplication.

In addition to the latter, prescriptions should be assessed based on the World Health Organization prescribing indicators. These indicators include the number of medicines per encounter, generic names usage, essential medicines usage, and antibiotic as well injection usage. In patients who have hypertension together with diabetes, rational prescription assessment assumes special importance because these people are normally subjected to long-term treatment with multiple drugs. Regular audits of prescriptions can help identify contradictory drug combinations, unnecessary polypharmacy and non-compliance with clinical guidelines.

Need for Rational Prescription Assessment

FDCs may be useful in this patient population to improve adherence and decrease pill burden. But irrational prescribing is still a problem in many developing countries where inappropriate FDCs are still available. Currently, there is limited published evidence on the pattern and rationale of FDC prescriptions among hypertensive diabetic patients at tertiary care. Consequently, this research was done to evaluate the demographic profile, prescribing pattern and rationality of FDCs used by patients with hypertension and diabetes mellitus. The results of the study may help clinicians in selecting commonly used rational combinations, reducing inappropriate prescribing and improving quality of care.

2. Materials and Methods

Study Design

The present study was a prospective, cross-sectional, observational study to assess the prescribing pattern and rationality of fixed-dose combinations in patients of coexisting hypertension and type 2 diabetes mellitus. A prospective study design was found appropriate as it permits systematic collection of prescription-related information during the study period. Due to the specific time frame of cross-sectional study design; this study helped the researchers to observe the prescription trends, use of fixed-dose combinations, and their rationality. Furthermore, the approach also helps without any prolonged follow-up of patients. This study primarily aimed to find out if the prescribed fixed-dose combinations were justified per standards and appropriate for the condition.

Study Setting

The research was conducted at a tertiary care teaching hospital where a large number of patients suffering from chronic diseases like hypertension and diabetes mellitus attend outpatient and inpatient department regularly. The range of prescriptions and case records available at the hospital setting allowed evaluation of real-world prescribing practice. As tertiary care hospitals are often being involved in the management of patients with multiple co-morbidities and long-standing disease, they are the most suitable places for studying combination therapy usage and prescription rationality.

Study Population

The study included patients with diagnosed hypertension and other types with diabetes mellitus and were under treatment with anti-hypertensive drugs. Inclusion was restricted to adult patients who were prescribed at least one antihypertensive and one antidiabetic drug. The study consisted of male and female patients with previous or ongoing comorbidities

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of dyslipidemia, ischemic heart disease, renal disease and obesity. Final analysis included 290 patients from screened records based on inclusion and exclusion criteria for the study of stenosis. The routine clinical population in tertiary care encountered by the doctors was represented by such patients.

Inclusion Criteria

There were included in study all patients more than 25 years age having confirmed diagnosis of hypertension who was also having coexisting diagnosis of type 2 diabetes mellitus. Patients of both sexes were eligible to participate. Individuals who received any one or more antihypertensive drugs and one or more antidiabetic drugs were included by investigators. Patients were also included for additional comorbidities eligible, as long as they met main disease criteria. Patients who consented to participate in the study and whose medical records were complete and accessible were selected for study.

Exclusion Criteria

Patients were excluded if they were pregnant or lactating women with hypertension and diabetes mellitus as their treatment protocols are different from the general adult population. Patients who did not desire to take part in the study were also excluded. Moreover, the patients with incomplete case records, unclear prescriptions, missing information on duration of disease, or those not specifying the details of drug were excluded from analysis. Excluding patients like this allowed for more reliable data to be collected.

Data Collection Procedure

The study's ultimate number of subjects was 290 patients. The number of sample size was determined by the availability of eligible patients attending the hospital and fulfilling the study criteria during the study period. Due to the descriptive nature of the study which evaluated prescription pattern and rationality of fixed-dose combinations, sample size selected was considered adequate to draw meaningful conclusions. The study results became more representative due to the inclusion of a reasonably large number of prescriptions.

Variables Recorded

Data were collected from the patient case records prospectively using a structured case proforma specially designed for the study. Patients' outpatient prescriptions, inpatient treatment sheets, medical records, and laboratory reports where necessary were used. A careful scrutiny of different prescriptions was made for a better and clearer understanding. It was done to find out the drugs prescribed by the doctor, the presence or absence of any fixed-dose combinations and the suitability of therapy. Information including demographic details, duration of illness, treatment pattern, number of drugs prescribed and use of other medications (antimicrobials, injections) was recorded in a case proforma. After collection of data, the data was entered in the spreadsheet. The fixed dose combination prescriptions were analyzed and verified separately for their rationality against the treatment guidelines.

Data Collected

To have a complete grasp of the prescription practices many variables were recorded during the study. The patient's age and sex made up demographic variables. In this context, clinical variables consisted of the duration of hypertension, duration of diabetes mellitus, etc. The total number of drugs prescribed, use of antihypertensive drugs, use of antidiabetic drugs, presence of fixed dose combinations, use of injectable preparations, and use of antimicrobials. Likewise, the use of generic name, brand name and drugs in the National List of Essential Medicines, was also noted. These metrics were significant since they reflect the rationality of prescription, extent of polypharmacy, and adherence to standard treatment guidelines.

Rationality Assessment Criteria

The reasonableness of fixed-dose combinations was evaluated using standard evidence-based criteria. A fixed-dose combination was deemed rational if the component NDDS have complementary mechanisms of action and additively or synergistically therapeutic effects without duplication of pharmacological action. The specified combinations also had to be supported by recognized national or international clinical guidelines. The evaluation also looked at whether the combination was appropriately indicated, whether the dose of each component was appropriate, and whether the combination was included in STGs or EMLs. It was checked whether unnecessary or irrational combinations were prescribed.

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Use of triple-drug combinations that were inappropriate, use of two drugs along with a mainly ineffective drug in early-stage disease without indication and combinations not recommended in evidence-based treatment were all irrational combinations. Assessment of the rationality was done using the prescribing indicators from the World Health Organization, the Standard of Care from the American Diabetes Association, the High Blood Pressure guidelines from American College of Cardiology/American Heart Association, the NICE guidelines and the National List of Essential Medicines. The study also showed a few common rational combinations such as telmisartan plus amlodipine, telmisartan plus hydrochlorothiazide, metformin plus sitagliptin, metformin plus teneligliptin, metformin plus glimepiride, etc.

Statistical Analysis

After data completion all data were fed into excel and analyzed using descriptive statistics. Data were analysed in terms of frequency, percentage, mean and SD. The distribution of demographic characteristics, duration of disease, prescription patterns, and use of fixed-dose combinations were described by frequencies and percentages. Using a Chi-square test, any association between the demographic variables and the use of fixed-dose combinations was assessed. The fixed-dose combinations' associations with age, sex, the duration of hypertension, and diabetes mellitus were analyzed. A statistically significant p-value is less than 0.05. The data would be presented in tables, percentages and graphs for better understanding and interpretation of results.

3. Results

Demographic Characteristics of Patients

A study was conducted on 290 patients with hypertension and type II Diabetes mellitus. The demographic characteristics reveal that both male and female patients were heavily represented. Within the examined population, there were 159 males and 131 females. This means that nearly 55% of the total population comprised males and 45% females. The result shows that a male patient who visited a tertiary care hospital had a slightly higher prevalence of a dual... The study population consisted of patients of different age groups, indicative of the wide burden of these chronic diseases in adulthood. Most of the patients were middle-aged and elderly, indicating that old age is an important risk factor for co-association of hypertension and diabetes mellitus.

Table 1. Demographic Characteristics of Study Population

Variable	Frequency (n=290)	Percentage
Male	159	55%
Female	131	45%
Age <40 years	54	18.62%
Age 40–59 years	138	47.59%
Age ≥60 years	98	33.79%

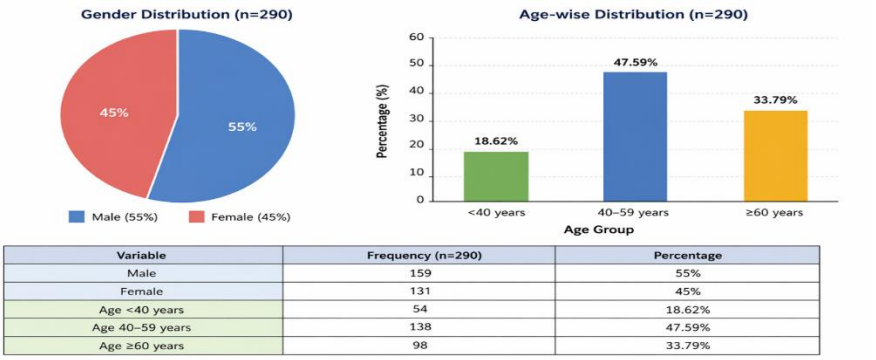

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Figure: 2 Gender Distribution and Age-wise Distribution of Study Participants (n = 290)

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Age and Gender Distribution

Most of the patients fell under the age group of 40–59 years as per age-wise analysis. By taking the 290 patients as a whole, it was seen that 138 patients (47.59%) in this age category. Among the study population, there were a total of 54 cases in the age group of 40 years and below (18.62%). Moreover, those aged 60 years and above (n=98) i.e. 33.79% of the study population. The marked abundance of patients in the 40-59 age bracket indicates that hypertension and diabetes are frequently existing maladies at this age group. This is likely due to an extensive exposure of this group to classical risk factors like obesity. Besides, they are physically inactive, under stress, smoke, have unhealthy diets, and have a family history too. Across all age groups, there was male preponderance found although gender difference was not very significant.

Duration of Hypertension and Diabetes

Hypertension duration varied between the patients of the study. A total of 83 patients, which represented 28.62%, had hypertension for less than five years. The highest number of subjects, 112 subjects (38.62%) had a 5-10-year history of hypertension. A further 95 patients (32.75%) were affected by hypertension for more than 10 years.

Out of the 121 patients with diabetes mellitus, 41.72% had diabetes for less than five. A total of 87 patients, or 30% of subjects, were observed for a duration of five to ten years. A total of 82 patients (28.27%) had the disease for more than ten years. According to the study, many patients in the study had longstanding hypertension and diabetes. This explains the need for a lot of drugs and fixed-dose combination in the study population.

Pattern of Antihypertensive Drug Use

The prescription analysis of antihypertensive drugs demonstrated that fixed-dose combinations were prescribed more than monotherapy. Among the antihypertensive prescriptions having a maximum of 290, out of which a total of 216 prescriptions (74.48%) contained fixed-dose combinations. The remaining 74 prescriptions (25.52%) contained monotherapy. Most of the patients suffering from hypertension and diabetes had required more than one antihypertensive agent to achieve optimal blood pressure control. Combination therapy was particularly prevalent in individuals with chronic hypertension, elderly patients, and individuals with comorbidities. The observed levels of fixed-dose combinations and their role in the antihypertensive therapy reflect current guidelines with respect to using combination therapy in all those patients whose blood pressure is not adequately controlled with a single drug.

Pattern of Antidiabetic Drug Use

There was a similar pattern in anti-diabetic prescription. In 204 out of 290 prescriptions (70.34% of antidiabetic therapy). Fixed-dose combinations (FDCs) were prescribed, whereas 86 prescriptions (29.66% monotherapy). The high rates of combination therapy usage indicates that many patients require multiple antidiabetic drugs for optimal glycemic control. This may result from progressive beta-cell dysfunction, long duration of disease, insulin resistance, and the presence of complications, and comorbidities. Combinations that were metformin-based accounted for the majority of combinations, as metformin is the first line agent for type 2 diabetes mellitus and is increasingly combined with other agents to improve blood glucose control.

Frequency of Fixed-Dose Combination Prescriptions

The combination of fixed doses was very widely used. FDCs accounted for 74.48% of prescriptions in case of antihypertensives and were 70.34% in case of antidiabetics. The high use of FDC indicates that combination therapy is an important part of therapy in persons with coexisting hypertension and diabetes mellitus. FDC use was common in patients with a longer duration of disease, elderly, and with multiple comorbidities. The results also indicate that physicians in a tertiary care setting are in favour of fixed-dose combinations as they reduce pill burden and improve adherence and outcomes.

Commonly Prescribed Antihypertensive FDCs

Telmisartan plus amlodipine was the most commonly prescribed among other combination drugs. It accounted for 74.07% of all antihypertensive FDC prescriptions. The second most frequently prescribed medication (15.28%) was telmisartan plus hydrochlorothiazide. Amlodipine plus losartan was 3.24% and amlodipine plus hydrochlorothiazide was 1.85%. Other combinations not so often prescribed made up 5.56%. The majority of telmisartan-based combinations point to

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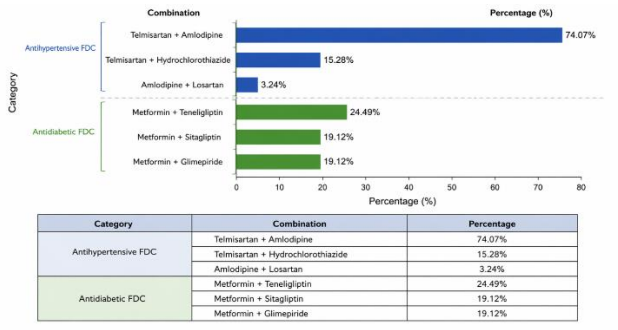
a preference for angiotensin receptor blockers in diabetic hypertensive patients for their renal and cardiovascular protective effects. The addition of amlodipine or hydrochlorothiazide results in complimentary blood pressure-lowering effects and supports rational combination therapy.

Table 2. Commonly Prescribed Antihypertensive and Antidiabetic Fixed-Dose Combinations

Category	Combination	Percentage
Antihypertensive FDC	Telmisartan + Amlodipine	74.07%
Antihypertensive FDC	Telmisartan + Hydrochlorothiazide	15.28%
Antihypertensive FDC	Amlodipine + Losartan	3.24%
Antidiabetic FDC	Metformin + Teneligliptin	24.49%
Antidiabetic FDC	Metformin + Sitagliptin	19.12%
Antidiabetic FDC	Metformin + Glimepiride	19.12%



Category	Combination	Percentage
Antihypertensive FDC	Telmisartan + Amlodipine	74.07%
	Telmisartan + Hydrochlorothiazide	15.28%
	Amlodipine + Losartan	3.24%
Antidiabetic FDC	Metformin + Teneligliptin	24.49%
	Metformin + Sitagliptin	19.12%
	Metformin + Glimepiride	19.12%

Figure:3 Commonly Prescribed Antihypertensive and Antidiabetic Fixed-Dose Combinations

Widely Used Antidiabetic FDCs

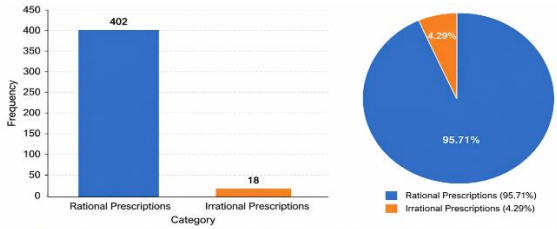
Among antidiabetic fixed dose combinations, metformin plus teneligliptin was the most prescribed combination, contributing 24.49% of antidiabetic FDCs. Metformin plus sitagliptin and metformin plus glimepiride were performed in 19.12% of prescriptions each. 11.76% of the prescriptions were metformin plus vildagliptin, while metformin plus gliclazide (10.78%). The rest 14.73% included other less common combinations. Metformin has a predominant presence in diabetes treatment, especially as a combination with other drugs. Combining DPP-4 inhibitors with metformin such as teneligliptin and sitagliptin was quite popular as it improves the glycemic control without causing significant risk of hypoglycemia.

Assessment of FDCs Rationality

A total of 420 prescriptions for fixed-dose combinations were assessed for rationality. Of these, 402 prescriptions (95.71%) were rational. Only 18 prescriptions (4.29 %) were found potentially irrational. Most likely the majority of physicians prescribed fixed-dose combinations based on the evidence, rational prescriptions. The above phrases are the commonly prescribed combinations like telmisartan plus amlodipine, metformin plus sitagliptin, etc which were considered rational combinations because they have complementary mechanisms of action. They offer established clinical benefits and support from treatment guidelines.

Table 3. Rationality Assessment of Fixed-Dose Combinations

Category	Frequency	Percentage
Rational Prescriptions	402	95.71%
Irrational Prescriptions	18	4.29%
Total FDCs Evaluated	420	100%



Category	Frequency	Percentage
Rational Prescriptions	402	95.71%
Irrational Prescriptions	18	4.29%
Total FDCs Evaluated	**420**	**100%**

Figure:4 Rational and Irrational Prescription Patterns among Evaluated Fixed-Dose Combinations (FDCs)

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Different Factors Behind Irrational Prescriptions

The irrational prescriptions reported in this study were primarily associated with inappropriate multiple drug use without any clear condition. duplication of drug mechanisms and use of combinations not supported by standard treatment. On some occasions prescriptions included drugs not on the essential medicine list. The need for prescription review and clinician education to minimize irrational prescribing is shown by these findings.

Association with the Use of FDC

Statistical analysis showed that there existed a significant association between the duration of hypertension and fixed-dose combinations used. Those patients with hypertension of more than five years' duration were more likely to receive combination therapy in comparison with those with less. Patients older than 50 years had a greater incidence of being prescribed fixed-dose combinations as they generally had long disease duration and comorbidities requiring aggressive management.

4. Discussion

Major Key Findings

The current research showed that patients with coexisting hypertension and type 2 diabetes mellitus frequently use fixed-dose combinations. Out of the total study population, most patients belonged to the middle-aged and elderly groups and most require multiple drugs for adequate disease control. 74.48% percent of antihypertensive prescriptions were fixed dose combinations. 70.34% antidiabetic prescriptions had fixed dose combinations. Among the antihypertensives, the most frequently prescribed combination was telmisartan plus amlodipine whereas metformin plus teneligliptin was the most common antidiabetics' FDC. It is worth noting that a staggering 95.71% of fixed-dose combinations were deemed rational, suggesting good adherence to standards. But a small share of prescriptions required further attention because they remained potentially irrational. I'm sorry, but the text you have provided does not make sense. It appears to be a code or icon that is copying the citation for a dot file. Can you please provide me with anything specific to paraphrase?

Historical Studies Comparison

The current study's results as comparable to those of several studies done in other areas and India. Studies of this nature have disclosed that patients having coexisting hypertension and diabetes often require combination therapy due to unsuccessful one-drug therapy in achieving blood pressure and glycemic goals. According to a report by Gupta et al. (2010), fixed-dose combinations were believed to improve medication adherence. Chronic diseases require long-term treatment so a fixed-dose combination is often prescribed. In addition, Patel et al. (2014) reported in their study that antihypertensive FDCs are used very widely in Indian clinical practice. This is because it makes it easy to treat the patients while also reducing the pill burden.

The association of evidence with rational prescriptions in the present study is comparable to Panda et al (2016) who found that the most commonly used antihypertensive-antidiabetic combination being justified both by evidence and pharmacological issues. The report authors underlined that a small proportion of irrational combinations persist in the Indian market which could cause adverse effects and wasteful healthcare expenditure.

Trends in Antihypertensive FDC Prescribing

The current study found that the prescription rate of fixed-dose combinations was higher than monotherapy. Among various FDCs, the most commonly prescribed antihypertensive FDCs were telmisartan plus amlodipine followed by telmisartan plus hydrochlorothiazide. In accordance with current hypertension guidelines, the goal of this trend is to combine drugs with different mechanisms for better control of blood pressure.

Telmisartan and other angiotensin receptor blockers are preferred in diabetic hypertensives as it provides renal protection apart from blood pressure lowering effect. Amlodipine's vasodilatory effects are further enhanced by adding hydrochlorothiazide to treat hypertension. According to Whelton et al. (2018), similar prescribing patterns were observed, and ARB based combinations were effective in reducing cardiovascular risk in patients having hypertension and diabetes. The present study observed a deliberate preference for telmisartan-based combinations due to its better safety profile,

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once-daily dosing schedule and decreased risk of adverse metabolic effects compared to some other anti-hypertensive agents.

Antidiabetic FDC Prescription Trends

Metformin plus teneligliptin and metformin plus sitagliptin were most frequently prescribed fixed-dose combinations among antidiabetic drugs. The growing use of DPP-4 inhibitors. With metformin in patients with type 2 diabetes mellitus is reflected by this pattern. Metformin has been the first-line antidiabetic treatment because it improves insulin sensitivity, lowers hepatic glucose production, and provides modest weight reduction. When metformin alone is insufficient, other drugs are frequently employed to achieve glycemic control. DPP-4 inhibitors such as teneligliptin and sitagliptin have become increasingly preferred as they improve glycemic control without causing significant hypoglycemia or weight gain.

According to findings of this study, our findings are similar to those American Diabetes Association (ADA et al., 2024) recommends metformin-based combination therapy in patients who are unable to achieve target glycemia with monotherapy. Similar trends have been noted by Sharma et al. (2018), who reported that metformin plus DPP-4 inhibitors was the most used antidiabetic FDC in tertiary care settings.

Rationality of Prescriptions

Assessment of rationality showed that 95.71% fixed-dose combinations prescribed in the study were rational. Most combinations had complementary mechanisms of action, were endorsed by standard treatment guidelines, and were appropriate for the clinical conditions of the patient. Combining telmisartan with amlodipine makes sense because it integrates an angiotensin II receptor blocker and a calcium channel blocker, which achieves a better blood pressure lowering effect because of non-overlapping pharmacology. The combination of metformin and sitagliptin was deemed logical as they work through distinct mechanisms, resulting in additive glycaemic advantages. The finding of high rational prescribing in our study could be due to the Tertiary Care setting where the prescribers are more likely to be aware of updated guidelines and evidence-based therapeutics. Patel et al. (2014) and Panda et al. (2016) also reported similar findings revealing a high level of rationality of FDC prescribing in tertiary care setting.

Clinical Implications of Irrational Prescribing

Despite the low percentage of irrational prescriptions, the clinical significance of these prescriptions remains important. Patient might be unnecessarily exposed to adverse effects, experience an increased risk of drug interactions and therapeutic duplication. The treatment may become more expensive without being of any real clinical benefit. Sometimes patients are placed on multiple drugs despite having a mild disease that could be easily controlled with monotherapy. The inappropriate use of combination therapy may increase the risk of hypotension, hypoglycemia, electrolyte disturbance, and non-adherence to medications. Irrational triple-drug combinations may also complicate titration and make it hard to pinpoint the element responsible for adverse reactions. According to Panda et al. 2016, irrational FDCs may pose a hazard to patient safety and result in avoidable expenditure on healthcare.

Polypharmacy and Elderly Patients

According to the study, older patients and patients with longer disease duration were more likely to receive fixed-dose combinations. Older adults often have numerous coexisting conditions like dyslipidemia, ischemic heart disease and chronic kidney disease. Thus, these patients often require several drugs. Even though the fixed-dose combinations help in reducing pill burden, elderly patients are still at high risk for polypharmacy. Using multiple medicines could lead to higher odds of negative side effects and improper use of medicine. It may be more difficult to treat the elderly because of changes in drug metabolism. Research shows that elderly patients with hypertension and diabetes are high-risk for inappropriate prescribing. Maher et al. (2014) have found that the use of more medications increases the risk of hospitalisation, falls and poor quality of life. Because of this, clinicians should be particularly cautious in prescribing several drugs to seniors.

Need for Prescription Audits

The findings from the present study show that prescription audits must be done regularly in institutions. Through prescription audits, we will be able to find irrational combinations, unnecessary poly-

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pharmacy, over-use of branded drugs and/or deviance from standard treatment guidelines and more. The routine practice of undertaking audits makes prescribers aware of evidence-based treatment practices and rational prescription of medicines. It is recommended that hospitals set up drug and therapeutics committees to monitor prescribing patterns and promote essential and generic drugs.

5. Limitations

Single-Centre Design

The current study was conducted in only one tertiary care teaching hospital which is a major limitation of the study. Due to potentially varying prescribing practices between different hospitals, regions and health care settings, the results may reflect only the prescriptions of the selected institution. Physicians in tertiary care hospitals are usually more likely to adhere to evidence-based guidelines and prescribe rational fixed-dose combinations than practitioners in primary care or smaller healthcare facilities. Thus, the results obtained in the present study may not represent all healthcare settings prescribing practices.

Limited Generalizability

A total of 290 patients with coexisting hypertension and type 2 diabetes mellitus. While the sample size is adequate for descriptive analysis, it may not be sufficient to generalise to the larger population. Variations in factors like demographic profile, socioeconomic status and access to healthcare may cause difference in the prescribing patterns. Moreover, the study was done at the tertiary care hospital where all 3 parameters like severity of disease, comorbidities, and complex treatment are more not the community. The frequency of use of fixed-dose combinations observed in the present study could be higher than in primary health care centres or rural hospitals.

Lack of Dose Adequacy Assessment

The objective of the study was to determine the type and rationale behind the use of fixed-dose combinations among hypertensive diabetic patients. Nonetheless, the specific doses of each drug in each combination were not appropriately studied. The study did not determine whether doses were optimal for the specific patient based on age, severity of disease, renal function, liver function and associated co-morbidities. If the dose of one or more components is too high or too low, even a pharmacologically appropriate fixed-dose combination is rendered irrational. Thus, adequacy of dose is an important consideration in rational prescribing. Consequently, it is possible that the ability of the study to assess the appropriateness of all prescriptions fully is limited.

Absence of Follow-Up Data

The lack of long-term follow-up data is another limitation of the study. Given the cross-sectional design of the study, the evaluations of prescriptions were only recorded at a single point, and no other assessment was made regarding patient outcome after treatment. The study did not assess whether the fixed-dose combinations at the prescribed doses achieved adequate blood pressure control, glycemic control, reduction of complications, and quality of life. Just like that, hospitalization, long-term safety, medication adherence, adverse drug reaction was also not assessed.

Follow-up studies are crucial for establishing whether rational prescriptions improve outcomes within routine clinical practice. Through longitudinal studies, we will gather more information about the effectiveness, safety, and long-term benefits of fixed-dose combinations in patients with hypertension and diabetes mellitus.

6. Conclusion

Summary of Key Findings

According to the present study, patients with coexisting hypertension and type 2 diabetes mellitus are commonly treated with fixed-dose combinations. The predominant patients were middle-aged and elderly showing a high prevalence of longstanding disease. The study found that 74.48% of antihypertensive prescriptions and 70.34% of antidiabetic prescriptions were fixed-dose combinations. The most prescribed antihypertensives combination was telmisartan plus amlodipine and metformin plus teneligliptin was the most prescribed antidiabetic fixed-dose combination. Out of 420 fixed-dose combination prescriptions analysed, 95.71% were found to be rational. These findings indicate that most doctors in tertiary care settings follow guidelines for prescription drugs and use combinations that are evidence-based, pharmacologically compatible, and therapeutically effective. Although a minor fraction of

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prescriptions was detected as capable of being irrational due to unnecessary multiple drugs being used, inappropriate use of triple-drug and other combination, and lack of indication.

Clinical Relevance

The clinical significance of this study is that growing number of fixed-dose combinations are being used for the management of chronic diseases. Such as hypertension and diabetes mellitus. Fixed-dose combinations reduce the number of pills that patients need to take, improve patient adherence to medications, simplify treatment regimens, and may also lead to better blood pressure and glycemic control. The researcher equally recommends judicious use of medications in the elderly and those with multiple ailments. Patients often get polypharmacy and this irrational combination increases risk of ADRs, medication error, and poor compliance. The present study showed a high proportion of rational prescriptions which is quite encouraging. It indicated that the prescriptions in tertiary care hospitals are evidence-based. Simultaneously, it highlights the need of constant surveillance to identify and diminish unsuitable orders.

Recommendations for Future Practice

Future studies should incorporate a wider population and multiple healthcare settings to enhance their generalizability. Conducting multi-center studies on primary, secondary, and tertiary hospitals would help in developing an overall understanding of prescribing patterns. Further research needs to assess also adequacy of dose, effectiveness of treatment, adverse drug reactions, adherence to medication, etc. of the fixed dose combinations. Longitudinal follow up studies may help us understand whether rational prescribing results in better BP control, glycemic outcomes and cardiovascular complications. To keep an eye on the usage of fixed-dose combinations and to spot irrational prescribing practices, healthcare institutions should be encouraged to carry out regular prescription audits. Involving clinicians and regulators in monitoring, education, and evolving therapeutic and pricing guidelines will enhance effectiveness.

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