2. DECLARATION BY INVESTIGATOR

The study was conducted as per Good Clinical Practices. To the best of my knowledge, the present study was conducted in compliance with the clinical trial protocol.
Nepal Health Research Council (NHRC) has approved the study protocol and the study was conducted in accordance with the Declaration of Helsinki and ICH-GCP.

Dr. Milan Khadka

Place: Kathmandu

Signature of Principal Investigator

Date: 25th June 2025

Clinical Study Report

1. TITLE PAGE

Study Title:	Role of fixed dose combination of Telmisartan & Amlodipine in management of hypertension in Nepalese population.
Study Population:	Adult hypertensive patients who were initiated on fixed dose combination of Telmisartan + Amlodipine
Sponsor:	Glenmark Pharmaceuticals Ltd.
Study Number:	NIS/2024/20
Study Design:	Retrospective, Cross-sectional study
Investigational Product:	Telma® AM (Telmisartan + Amlodipine)
Indication:	Hypertension
Date of this Report:	10-Jun-25
Type of Report:	Clinical Study report

This study was conducted by the International Council for Harmonization (ICH) guidelines on Good Clinical Practice (GCP) and with the applicable regulatory requirements.

1.1 SIGNATURE PAGE

Study Title:	Role of fixed dose combination of Telmisartan & Amlodipine in management of hypertension in Nepalese population	
Report Prepared by (CRO):	Shaitan Singh Project manager IR Innovate Research Pvt Ltd 3rd Floor, C-120, C Block, Sector 2, Noida, Uttar Pradesh 201301	Signed by: Shaitan Singh 689173E2E170493... 6/12/2025
Report Reviewed By (Sponsor)	Dr Sumit Bhushan DGM- Clinical Studies- Global Medical Affairs- IF Glenmark Pharmaceuticals Ltd. Mumbai- 400099	Sumit Bhushan 13 Jun 2025 11:28:12 IST REASON: Reviewed By 590a80f6-605b-41c5-ba85-34005ec57b23
Report Approved By (Sponsor)	Dr Sanjay Choudhari GM- Global Medical Affairs- IF Glenmark Pharmaceuticals Ltd. Mumbai- 400099	Sanjay Choudhari 13 Jun 2025 16:47:17 UTC REASON: Approved By a347e503-56d7-4be1-bc50-eb4de574f790

2. DECLARATION BY INVESTIGATOR

The study was conducted as per Good Clinical Practices. To the best of my knowledge, the present study was conducted in compliance with the clinical trial protocol.
Nepal Health Research Council (NHRC) has approved the study protocol and the study was conducted in accordance with the Declaration of Helsinki and ICH-GCP.

Place: **Signature of Principal Investigator**

Date:

3. SYNOPSIS

Title of Study: Role of fixed dose combination of Telmisartan & Amlodipine in management of hypertension in Nepalese population

Study Participants: A total of 1061 patients' records were included in the study

Study centers: The study was conducted at 150 centers across Nepal

Principal Investigator: Dr Milan Khadka**,**
National Academy of Medical Science, Bir Hospital, Mahabouddha, Kathmandu, Nepal

Study Period: 6 months
Data collection activity was initiated after receipt of NHRC approval. The data collection was done from Nov 2024 to Mar 2025.

Objective: The objective of this study was to understand the role and usage of FDC of Telmisartan+Amlodipine in Nepalese population for management of hypertension.
This observational study helped to understand the usage of drugs in real world scenario. The Co prescription details helped in understanding or creating a better patient profile or placing molecule in specific patients with different comorbid conditions. This analysis will ultimately benefit the hypertension patients with different characteristics in Nepal.

Endpoints:

Primary endpoint:

- To evaluate pattern of clinical use of FDC of Telmisartan 40/80 + Amlodipine 5 mg in patients with hypertension (patient profiles and current blood pressure status)

Secondary endpoints:

- To determine the baseline demographics (age, gender, comorbidities and concomitant medication) of the patient included in the study.
- To determine the co-prescriptions for the management of hypertension along with FDC of Telmisartan and Amlodipine.
- To determine any co-prescriptions of other drug for the patients existing comorbidities
- To determine the physician feedback through questionnaire on FDC of Telmisartan and Amlodipine

Data Collection: Retrospective data were collected by the investigators from the medical records of respective study sites. Data were collected as per the clinical practice and no mandatory schedule of assessment was adopted. Weblink (eCRF) was shared with investigators to enter the patient data. Data entry was completed by the investigator in electronic CRF and then submit button was clicked. This data was received on CRO's server which was then further analysed and study report was prepared.

Number of Patients: 1061

Study Selection Criteria:
Inclusion Criteria:

- Adults patient with age >18 years
- Patients diagnosed with hypertension and initiated on FDC of Telmisartan + Amlodipine

Exclusion Criteria:

- Adults patient with age <18 years
- Patients contraindicated to Telmisartan and Amlodipine

- Pregnancy
- Lactating mothers
- Patients known to be allergic/intolerant to either content of the study drug
- Patients not willing to switch to FDC of Telmisartan + Amlodipine
- Patients not willing to participate in the study

Patients Flow:

1061 patients' data was collected by 150 sites across Nepal.

Results:

Demographics and Baseline Characteristics

- Mean (SD) age of patients diagnosed with hypertension and initiated on FDC of Telmisartan + Amlodipine was 54.66 (±11.64) years.
- Of the enrolled population, male patients were 63.81%, whereas, female patients were 36.19%.
- In our study, mean duration of hypertension in Nepalese polulation was 5.44 (±6.06) years.
- Mean weight of Nepalese population with hypertension was 70.14 (±12.59) kg.
- Mean Systolic BP was 146.73 (±15.72) mmHg and mean diastolic BP was 92.50 (±10.60) mmHg with a mean pulse rate of 81.35 (±7.70) bpm.
- Family history of hypertension in Nepalese population was observed in 517 (48.73%) subjects.
- Complications observed were Retinopathy in 51 (4.81%) subjects; Neuropathy in 59 (5.56%) subjects and Nephropathy in 28 (2.64%) subjects in this study.

Primary Endpoint

- Of the total patient population, 396 (37.32%) patients were treatment naïve and 665 (62.68%) patients were treatment experienced.
- It was observed that 378 (35.62%) patients shifted from Telmisartan monotherapy to FDC of Telmisartan + Amlodipine.
- Out of 1061 patients, 902 (85.01%) patients were prescribed Telmisartan 40mg + Amlodipine 5 mg strength tablet and 159 (14.98%) patients were prescribed Telmisartan 80mg + Amlodipine 5 mg strength tablet.

Secondary Endpoints

- Most common comorbidity in Nepalese population with hypertension was Dyslipidemia in 199 (18.76%) subjects followed by diabetes mellitus in 143 (13.48%) subjects, obesity in 132 (12.44%) subjects and cardiovascular disease in 117 (11.03%) subjects.
- Monotherapy ARBs (Losartan, Telmisartan) (6.88%) were most commonly used concomitant anti-hypertensive medication in this study followed by CCBs (Amlodipine) (4.71%). These monotherapies were assumed to be taken as second dose during the other time of the day in patients with uncontrolled hypertension.
- Metformin (9.9%) was the most commonly used anti-diabetic followed by DPP4 inhibitors and its combinations (5.84%) whereas Rosuvastatin (9.42%) was the most commonly used dyslipidemic drug in this study.
- In this study, it was observed that mean HbA1c in Nepalese population with hypertension was 6.59 (±1.38) %. Similarly, mean Sr Creatinine was 1.66 (±1.17) mg/dl and mean blood urea nitrogen was 33.54 (±24.52) mg/dl. Mean Sr total cholesterol was 211.65 (±52.97) mg/dl and mean Sr. triglycerides was 217.40 (±78.82) mg/dl.
- As per the physician feedback questionnaire,

- 1035 (97.64%) of subjects on FDC of Telmisartan and Amlodipine showed an increase in efficacy compared to other dual drug FDCs and led to improvement in patient's compliance.
- 1006 (94.82%) subjects on FDC of Telmisartan and Amlodipine also showed better safety profile compared to other dual drug FDCs.
- 1015 (95.66%) subjects on FDC of Telmisartan and Amlodipine showed synergistic effect for the management of hypertension.

STATISTICAL METHODS:
Descriptive statistics was used and data was presented as absolute numbers/percentages.

Conclusion:
The study provided insights into role of FDC of Telmisartan + Amlodipine tablet. Majority of the Nepalese population with hypertension who were initiated on FDC Telmisartan + Amlodipine were treatment experienced.
Mean duration of hypertension in Nepalese polulation was 5.44 (±6.06) years.. Focusing more attention to address the burden of hypertension and associated risk factors in Nepal is needed. Despite widespread prevalence, there was alarmingly low awareness and compliance and the study also showed majority of patients were switched to dual therapy of FDC Telmisartan+Amlodipine due to uncontrolled hypertension.
Dyslipidemia was the most common comorbidity in Nepalese population with hypertension followed by diabetes mellitus, obesity and cardiovascular disease.
Overall, this study contributes valuable data to better understand the real-world clinical use of FDC of Telmisartan + Amlodipine in Nepal and highlights the need for tailored approaches considering diverse patient profiles.

Date of Report: 10-Jun-25

4. LIST OF ABBREVIATIONS

Abbreviation	Explanation
BUN	Blood Urea Nitrogen
CAD	Coronary Artery Disease
CCB	Calcium Channel Blockers
CRF	Case Report Form
CV	Cardiovascular
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDC	Fixed Dose Combination
GCP	Good Clinical Practice
HDL	High density lipoprotein
HTN	Hypertension
ICH	International Council for Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
LDL	Low density lipoprotein
NHRC	National Health Research Council
OPD	Outpatient Department
PIs	Principal Investigators
SD	Standard Deviation

TABLE OF CONTENTS

5. LIST OF TABLES

6. ETHICS AND REGULATORY APPROVAL

Protocol and related documents were granted approval by the Ethical Review Board, NHRC for implementation:

Table 1: Details of the ethics approval

NHRC Approval	
Principal Investigator	Dr Milan Khadka
Address	National Academy of Medical Science, Bir Hospital, Mahabouddha, Kathmandu, Nepal
Date of NHRC approval	23-Oct-2024

7. BACKGROUND

Hypertension (HT) has become a major public health challenge worldwide. According to World Health Organization, elevated Blood pressure (BP) is observed in 40% of world's population aged 25years and above.[1] Hypertension is the leading cause of preventable deaths that accounts for 12.8% of total deaths and 3.7% of total disability adjusted life years (DALYs) worldwide.[1]

A lot of surveys have reported, alarming prevalence of hypertension in Nepal ranging from 22.4 to 38.6%.[1] As per Mehta et al, in Nepal the prevalence of hypertension was more among men (22%) aged 45–69 years (34%), 38% were aware of their hypertensive status and 18% were taking antihypertensive medication. Only half of the hypertensive participants on treatment (52%) had their BP under control.[1] It is noted that approximately, 1 in 4 people in Nepal suffer from hypertension, and less than 5% of hypertensive patients have their condition under control.[2]

Cardiovascular diseases (CVD); remarkably hypertension, is one of the foremost contributors for a higher CVD mortality and sequelae of cerebrovascular events, whereas the evidences are very scarce in Nepal. Some of the risk factors include ageing, high-salt intake, unhealthy diet, alcohol use, physical inactivity, weight gain and exposure to persistent stress.[1]

Hypertensive patients with target organ damage are more likely to require multiple drug therapy in order to achieve targeted BP and reduce their risk towards adverse vascular outcomes.[3]
Angiotensin Receptor Blockers (ARBs) are first line therapy of HT. Telmisartan is a potent, long-lasting, non-peptide angiotensin II antagonist that acts on the Angiotensin 1 (AT 1) receptor subtype. Calcium channel blockers (CCBs) are another class of first line anti-hypertensive drugs. Amlodipine, a third generation dihydropyridine calcium antagonist, is illustrated by a lesser negative inotropic effect and higher vascular selectivity compared to other CCBs. In cases of mild to moderate hypertension, the initiation of drug treatment with a low dose of either CCBs or ARBs is an established therapy.[5] Besides the increased antihypertensive efficacy, the addition of an RAAS blocker has been shown to reduce the incidence of amlodipine-related edema. [3]

8. STUDY RATIONALE

As per the findings of Neupane et al, it was noted that among individuals taking antihypertensive medications in Nepal, 85% of patients were taking monotherapy, mostly amlodipine. Improvements in BP control will likely require intensification of therapy, potentially through greater use of fixed dose combination therapy.[4]

So, there is a current unmet need to understand the role and usage of fixed dose combination of Telmisartan 40/80 + Amlodipine 5mg in Nepalese hypertensive patients and hence, this study was planned to be conducted in Nepalese population.

9. DESCRIPTION OF STUDY DRUG

Brand name: Telma® AM
Strength: Telmisartan 40/80 mg and Amlodipine 5 mg

10. STUDY OBJECTIVES

The objective of this study was to understand the role and usage of FDC of Telmisartan+Amlodipine in Nepalese population for management of hypertension.
This observational study helped to understand the usage of drugs in real world scenario. The Co prescription details helped in understanding or creating a better patient profile or placing molecule in specific patients with different comorbid conditions. This analysis will ultimately benefit the patients of Nepal with hypertension with different characteristics.

11. OVERALL STUDY DESIGN AND PLAN DESCRIPTION

This was a multi-centre, retrospective study to understand the role and usage of fixed dose combination of Telmisartan 40/80 + Amlodipine 5mg in Nepalese hypertensive patients.
Predesigned structured proforma in the form of electronic case record form (eCRF) was used for this study to collect information from the medical records of the patients prescribed with Telmisartan + Amlodipine combination by their treating physician. All documents, including the protocol, related to this retrospective study were submitted to Nepal Health Research Council (NHRC), together with the data collection format, and the study was conducted as per the approved protocol. A weblink was provided to all investigators which contained the questionnaire in the form of eCRF for data entry. No patient consent was required as there was no prospective intervention and data was collected of only those patients who were already treated with study drug as per their routine clinical practice.
These data were then analyzed and has been presented in this study report.

12.1 STUDY POPULATION SELECTION CRITERIA

Inclusion Criteria:

- Adults patient with age >18 years
- Patients diagnosed with hypertension and initiated on FDC of Telmisartan + Amlodipine

Exclusion Criteria:

- Adults patient with age <18 years
- Patients contraindicated to Telmisartan and Amlodipine
- Pregnancy
- Lactating mothers
- Patients known to be allergic/intolerant to either content of the study drug
- Patients not willing to switch to FDC of Telmisartan + Amlodipine
- Patients not willing to participate in the study

12.2 STUDY ENDPOINTS

Primary endpoints:

To evaluate pattern of clinical use of FDC of Telmisartan 40/80 + Amlodipine 5 mg in patients with hypertension (patient profiles and current blood pressure status)

Secondary endpoints:

- To determine the baseline demographics (age, gender, comorbidities and concomitant medication) of the patient included in the study.

- To determine the co-prescriptions for the management of hypertension along with FDC of Telmisartan and Amlodipine.
- To determine any co-prescriptions of other drug for the patients existing comorbidities
- To determine the physician feedback through questionnaire on FDC of Telmisartan and Amlodipine

12.3 DATA QUALITY ASSURANCE

This study was conducted in accordance with applicable regulations, GCP, and Standard Operating Procedures. Periodic site connect was done to resolve their queries for data collection. During these contacts, the study manager has checked the progress of the study, reviewed the study data collected, identified any issues, and addressed their resolution. In addition, the study manager has verified that the data were authentic, accurate, and complete and that the study was being conducted in accordance with the currently approved protocol, ICH, GCP and all applicable local regulatory requirements.

12.4 ETHICAL CONSIDERATION AND ANONYMITY, CONFIDENTIALITY AND UNIFORMITY OF DATA

Since this was a retrospective data collection, no personally identifiable information of subjects was captured.

• In the e-CRF-based CDM, the investigator or designee logged into the CDM system using unique log in credentials and entered the data directly at the site.

• Anonymity was preserved while taking notes, while cleaning data and preparing it for storage, or while disseminating results.

• Participant data privacy and security was maintained which was a priority for all researchers.

• Access to master code lists or key codes was limited.

• Electronic data were stored in password-protected computers or files.

12.5 DATA COLLECTION

All information required by protocol was recorded onto the EDC system by designated investigator staff. An Electronic Case Report Form (eCRF) designed on Clinsoft EDC, was utilized for data collection.

The EDC system had an administrative interface accessible by an assigned administrator or study coordinator. Sites and users were created within the EDC system. Users, including Principal Investigators (PIs), were registered with the administrator, receiving unique User IDs linked to their roles and permissions. These User IDs were securely shared with investigators, typically through encrypted means.

Training sessions were conducted to teach investigators how to perform data entry using the EDC system. Each investigator was responsible for completing a specific number of cases on their respective sites.

12.6 STATISTICAL METHODS

Descriptive statistics was used and data was presented as absolute numbers/percentages.

12. STUDY PARTICIPANTS

13.1 DISPOSITION OF PATIENTS/PATIENT FLOW

A summary of patient flow is presented in **Table 2.** Data of 1061 subjects was collected across 150 sites in Nepal.

Table 2: A summary of patient flow

No. of Patients	1061
Recruiting/Active Sites	150

13. STUDY RESULTS

14.1 DATA SETS ANALYZED

All study statistical analysis was conducted on study patients who have completed the study and qualified as per the protocol requirements.

14.2 SUMMARY OF DEMOGRAPHICS AND BASELINE CHARACTERISTICS

The summary of Demographics and Baseline characteristics is presented in **Table 3**.Error! Reference source not found.
Mean (SD) age of patients diagnosed with hypertension and initiated with FDC telmisartan + amlodipine was 54.66 (±11.64) years. Of the enrolled population, male patients were 63.81%, whereas, female patients were 36.19%.
In our study, mean duration of hypertension in Nepalese population was 5.44 (±6.06) years. Mean weight of Nepalese population with hypertension was 70.14 (±12.59) kg.
Mean Systolic BP was 146.73 (±15.72) mmHg and mean diastolic BP was 92.50 (±10.60) mmHg with a mean pulse rate of 81.35 (±7.70) bpm.

Table 3: Summary of Demographics and Baseline characteristics

Parameter (N= 1061)	**Mean (±SD)**
Age (years)	54.66 (±11.64)
Gender n (%)	
Male	677 (63.81%)
Female	384 (36.19%)
Height (cm)	163.51 (±7.85)
Weight (Kg)	70.14 (±12.59)
Systolic BP (mmHg)	146.73 (±15.72)
Diastolic BP (mmHg)	92.50 (±10.60)
Pule Rate (bpm)	81.35 (±7.70)
Duration of hypertension (in years)	5.44 (±6.06)
Note:[1] Percentages were calculated using respective column header count as denomi nator.	

14.3 SUMMARY OF MEDICAL HISTORY

Summary of Medical history is presented in table 4 below.

History of dizziness was observed in 419 (39.49%) subjects whereas history of headache was observed in 469 (44.20%) subjects. History of chest pain was observed in 109 (10.27%) subjects.

94 (8.86%) subjects recorded hospitalizations due to different causes as listed in table below.

Table 4: Medical History

Parameter	Category	Statistics (N=1061)
History of dizziness	n (%)	419 (39.49%)
History of Headache	n (%)	469 (44.20%)
History of chest pain	n (%)	109 (10.27%)
Number of episodes in the past year	Mean (±SD)	2.11 (±1.12)
History of limitation of physical activity	n (%)	187 (17.62%)
Number of hospitalizations due to any causes in past year	n (%)	94 (8.86%)
Reason for hospital admissions	Accident	3 (0.28%)
	Chest Pain and Angina	18 (1.69%)
	COPD and Pneumonia	14 (1.31%)
	Anxiety and dizziness	6 (0.57%)
	Cardiovascular disease cause (IHD, MI, HTN)	12 (1.13%)
	Renal cause (CKD, Dialysis, UTI)	9 (0.84%)
	Others	28 (2.63%)
Note:[1] Percentages were calculated using respective column header count as denominator.		

Summary of Personal History is presented in Table 5 below. Smoking history or history of tobacco use was seen in 347 (32.70%) subjects since 16.31 (±12.59) years. History of alcohol use was seen in 257 (24.22%) subjects since 13.47(±10.57) years.

Table 5: Personal History

Parameter	Category	Statistics (N=1061)
Smoking status or history of tobacco use	n (%)	347 (32.70%)
Since(years)	Mean (±SD)	16.31 (±12.59)
Alcohol status or history of alcohol use	n (%)	257 (24.22%)
Since(years)	Mean (±SD)	13.47 (±10.57)
Note:[1] Percentages were calculated using respective column header count as denomi nator.		

Summary of Family History is presented in Table 6 below. Family history of hypertension in Nepalese population was observed in 517 (48.73%) subjects.

Table 6: Family History

Parameter (N=1061)	**n (%)**
Family history of Hypertension	517 (48.73%)
Note:[1] Percentages were calculated using respective column header count as denominator.	

Summary of complications due to hypertension is presented in Table 7 below. Myocardial infarction was observed in 46 (4.34%) subjects; Stroke was observed in 27 (2.54%) subjects whereas Peripheral arterial disease was observed in 45 (4.24%) subjects in the study.

Table 7: Summary of complications due to hypertension

Parameter	**Category**	**Statistics (N=1061)**
Myocardial infarction	n (%)	46 (4.34%)
Duration (years)	Mean (±SD)	2.28 (±2.26)
Stroke	n (%)	27 (2.54%)
Duration (years)	Mean (±SD)	2.26 (±1.87)
Peripheral arterial disease	n (%)	45 (4.24%)
Duration (years)	Mean (±SD)	2.80 (±2.73)
Note:[1] Percentages were calculated using respective column header count as denominator.		

Summary of any other complications is presented in Table 8 below. Retinopathy was observed in 51 (4.81%) subjects; Neuropathy was observed in 59 (5.56%) subjects whereas Nephropathy was observed in 28 (2.64%) subjects in the study.

Table 8: Summary of any other complications

Parameter	**Category**	**Statistics (N=1061)**
Retinopathy	n (%)	51 (4.81%)
Duration (years)	Mean (±SD)	3.08 (±2.79)
Neuropathy	n (%)	59 (5.56%)
Duration (years)	Mean (±SD)	2.69 (±2.60)
Nephropathy	n (%)	28 (2.64%)
Duration (years)	Mean (±SD)	3.50 (±2.63)

Parameter	Category	Statistics (N=1061)
Note:[1] Percentages were calculated using respective column header count as denominator.		

14.4 Primary Endpoint- Pattern of clinical use of FDC of Telmisartan 40/80 + Amlodipine 5 mg in patients with hypertension

Pattern of clinical use of FDC of Telmisartan 40/80 + Amlodipine 5 mg in patients with hypertension is presented in **Table 9**.

Of the total patient population, 396 (37.32%) patients were treatment naïve and 665 (62.68%) patients were treatment experienced.

It was observed that 378 (35.62%) patients shifted from Telmisartan monotherapy to FDC of Telmisartan + Amlodipine.

Out of 1061 patients, 902 (85.01%) patients were prescribed Telmisartan 40mg + Amlodipine 5 mg strength tablet and 159 (14.98%) patients were prescribed Telmisartan 80mg + Amlodipine 5 mg strength tablet.

Table 9: Pattern of clinical use of FDC of Telmisartan 40/80 + Amlodipine 5 mg in patients with hypertension

Parameter (N= 1061)	Category	Results
Is the patient treatment naïve or treatment experienced for the management of hypertension? n (%)	Treatment experienced	665 (62.68%)
	Treatment naïve	396 (37.32%)
Is the patient being shifted from Telmisartan monotherapy to FDC of Telmisartan + Amlodipine? n (%)	Yes	378 (35.62%)
	No	287 (27.04%)
Duration since patient is on Telmisartan monotherapy (months)	Mean (±SD)	7.2 (±5.3)
Dose of Telmisartan monotherapy at the time of switching to Telmisartan + Amlodipine FDC	20 mg	54 (14.28%)
	40 mg	240 (63.49%)
	80 mg	84 (22.22%)
Dose & strength of Telmisartan + Amlodipine FDC	40 + 5 mg	902 (85.01%)
	80 + 5 mg	159 (14.98%)
Number of times the drugs have been switched before FDC of Telmisartan +Amlodipine	Mean (±SD)	2 (±1.30)
Drugs prescribed before	Amlodipine	146 (13.76%)

Parameter (N= 1061)	Category	Results
FDC of Telmisartan +Amlodipine	Amlodipine and combination (Losartan, Atenolol, HTZ, Metoprolol)	52 (4.9%)
	Telmisartan	258 (24.31%)
	Telmisartan and combination (HTZ)	3 (0.28%)
	Cilnidipine	4 (0.37%)
	ACE Inhibitors (Enalapril, Ramipril)	5 (0.47%)
	Hydrochlorothiazide	2 (0.19%)
	Losartan	116 (10.93%)
	Losartan and combination (HTZ)	6 (0.56%)
	Beta blockers (Metoprolol, Nebivolol, Atenolol	12 (0.38%)
Note:[1] Percentages were calculated using respective column header count as denomi nator.		

14.4 Secondary Endpoints- Comorbidites

The summary of comorbidities is presented in **Table 10.**

Most common comorbidity in Nepalese population with hypertension was Dyslipidemia in 199 (18.76%) subjects followed by diabetes mellitus in 143 (13.48%) subjects, obesity in 132 (12.44%) subjects and cardiovascular disease in 117 (11.03%) subjects.

Table 10: Summary of comorbidities

Parameter	Category	Statistics (N=1061)
Cardiovascular disease	n (%)	117 (11.03%)
Since (years)	Mean (±SD)	4.74 (±8.39)
Chronic kidney disease	n (%)	38 (3.58%)
Since (years)	Mean (±SD)	4.68 (±9.56)
Dyslipidemia	n (%)	199 (18.76%)
Since (years)	Mean (±SD)	5.78 (±7.67)
Obesity	n (%)	132 (12.44%)
Since (years)	Mean (±SD)	9.31 (±8.32)
Obstructive sleep apnea	n (%)	16 (1.51%)
Since (years)	Mean (±SD)	5.00 (±5.18)
Anxiety/Depression	n (%)	47 (4.43%)
Since (years)	Mean (±SD)	3.06 (±3.21)
Diabetes mellitus	n (%)	143 (13.48%)
Since (years)	Mean (±SD)	6.58 (±7.10)
Osteoporosis	n (%)	16 (1.51%)
Since (years)	Mean (±SD)	3.38 (±2.53)

Parameter	Category	Statistics (N=1061)
Others	n (%)	10 (0.94%)
	Benign prostatic hyperplasia	1 (0.09%)
	COPD	2 (0.19%)
	Gall stone	1 (0.09%)
	Hypothyroidism	1 (0.09%)
	Ischemic stroke	1 (0.09%)
	Hypothyroidism	2 (0.19%)
	Weakness	2 (0.19%)
Note:[1] Percentages were calculated using respective column header count as denomi nator.		

14.5 Mean values of lab parameters of patients on FDC Telmisartan + Amlodipine

The summary of mean values of lab parameters of patients on FDC Telmisartan + Amlodipine is presented in **Table 11.**

In this study, it was observed that mean HbA1c in Nepalese population with hypertension was 6.59 (±1.38) %. Similarly, mean Sr Creatinine was 1.66 (±1.17) mg/dl and mean blood urea nitrogen was 33.54 (±24.52) mg/dl. Mean Sr total cholesterol was 211.65 (±52.97) mg/dl and mean Sr. triglycerides was 217.40 (±78.82) mg/dl.

Table 11: Mean values of lab parameters of patients on FDC Telmisartan + Amlodipine

Parameter	Mean (±SD)
HbA1c %	6.59 (±1.38)
Serum creatinine (mg/dl)	1.66 (±1.17)
Blood Urea Nitrogen (BUN) (mg/dl)	33.54 (±24.52)
Sr. total cholesterol (mg/dl)	211.65 (±52.97)
LDL cholesterol (mg/dl)	125.63 (±37.54)
HDL cholesterol (mg/dl)	48.49 (±15.01)
Sr. triglycerides (mg/dl)	217.40 (±78.82)

14.6 Concomitant Medications

Summary of concomitant medications prescribed with FDC Telmisartan + Amlodipine tablet is presented in **Table 12.**

Monotherapy ARBs (Losartan, Telmisartan) (6.88%) were most commonly used concomitant anti-hypertensive medication in this study followed by CCBs (Amlodipine) (4.71%). These monotherapies were assumed to be taken as second dose during the other time of the day in patients with uncontrolled hypertension.
Metformin (9.9%) was the most commonly used anti-diabetic followed by DPP4

inhibitors and its combinations (5.84%) whereas Rosuvastatin (9.42%) was the most commonly used dyslipidemic drug in this study.

Table 12: Summary of concomitant medications prescribed with FDC Telmisartan + Amlodipine tablet (N= 1061)

Class of Drugs	**Medication Name**	**n (%)**
Anti-hypertensive	CCBs (Amlodipine)	50 (4.71%)
	Beta blockers (Atenolol, Bisoprolol, Carvedilol, Metoprolol, Propranolol	25 (2.35%)
	ARBs (Losartan, Telmisartan)	73 (6.88%)
	Diuretics (Furosemide, Furosemide+Spironolactone, HTZ, Torsemide)	12 (1.13%)
	Others (Prazosin, Ramipril, Eplerenone)	8 (0.75%)
Dyslipidemia	Atorvastatin	47 (4.42%)
	Fenofibrate	10 (0.94%)
	Rosuvastatin	100 (9.42%)
Anti-diabetic	Alpha glucosidase inhibitors (Acarbose, Voglibose)	3 (0.28%)
	SGLT2 inhibitors (Empagliflozin, Dapagliflozin)	8 (0.75%)
	SU and its combinations (Glimepiride, Glimepiride+Metformin, Gliclazide)	10 (0.94%)
	Insulin	3 (0.28%)
	DPP4 inhibitors and its combinations (Linagliptin, Linagliptin+Repaglinide, Sitagliptin, Sitagliptin+Metformin, Teneligliptin)	62 (5.84%)
	Metformin	106 (9.99%)
Others	Acetylsalicylic Acid	27 (2.54%)
	Amitriptyline	3 (0.28%)
	Calcium supplements	1 (0.09%)
	Cilostazole	1 (0.09%)
	Clopidogrel	6 (0.56%)
	Aspirin	13 (1.22%)
	Escitalopram	3 (0.28%)
	Levothyroxine Sodium	7 (0.65%)
	Mirtazapine	5 (0.47%)
	Nitroglycerin	2 (0.19%)
	Omeprazole	1 (0.09%)
	Pantoprazole	3 (0.28%)
	Tiotropium	1 (0.09%)
	Clonazepam	1 (0.09%)

Class of Drugs	Medication Name	n (%)
	Febuxostat	2 (0.19%)
	Finasteride	1 (0.09%)
	Pregabalin	5 (0.47%)
	Salmeterol +Fluticasone	1 (0.09%)
	Sertraline	1 (0.09%)
	Tamsulosin	2 (0.19%)

Note:[1] Percentages were calculated using respective column header count as denominator.

14.7 Physician feedback through questionnaire on FDC of Telmisartan and Amlodipine.

Summary of physician feedback through questionnaire on FDC of Telmisartan and Amlodipine is presented in **Table 8**.

- As per the physician feedback questionnaire,
  - 1035 (97.64%) of subjects on FDC of Telmisartan and Amlodipine showed an increase in efficacy compared to other dual drug FDCs and led to improvement in patient's compliance.
  - 1006 (94.82%) subjects on FDC of Telmisartan and Amlodipine also showed better safety profile compared to other dual drug FDCs.
  - 1015 (95.66%) subjects on FDC of Telmisartan and Amlodipine showed synergistic effect for the management of hypertension.
  - Physicians do not agree with the fact that with FDC Telmisartan and Amlodipine, it is difficult to identify which medicine has caused adverse effects.

Table 13: Physician feedback through questionnaire on FDC of Telmisartan and Amlodipine

Parameter	Category	Statistics (N=1061)
Do you agree that FDC of Telmisartan and Amlodipine may result in increased efficacy compared to other dual drug FDCs?	Yes	1036 (97.64%)
	No	17 (1.60%)
	Do not know	8 (0.75%)
Do you agree that FDC of Telmisartan and Amlodipine lead to improvement in patient's compliance?	Yes	1036 (97.64%)
	No	19 (1.79%)
	Do not know	6 (0.57%)
Do you agree that FDC of Telmisartan and Amlodipine better safety profile compared to other dual drug FDCs?	Yes	1006 (94.82%)
	No	21 (1.98%)
	Do not know	34 (3.20%)
Do you agree that FDC of Telmisartan	Yes	1015 (95.66%)

Parameter	Category	Statistics (N=1061)
and Amlodipine lead to synergistic effect for the management of hypertension?	No	29 (2.73%)
	Do not know	17 (1.60%)
Have you found that in FDC with Telmisartan and Amlodipine, it is difficult to identify which medicine has caused adverse effects.	Yes	260 (24.51%)
	No	701 (66.07%)
	Do not know	100 (9.43%)
Note:[1] Percentages were calculated using respective column header count as denomi nator.		

15. CONCLUSION

The study provided insights into role of FDC of Telmisartan + Amlodipine tablet. Majority of the Nepalese population with hypertension who were initiated on FDC Telmisartan + Amlodipine were treatment experienced.

Mean duration of hypertension in Nepalese polulation was 5.44 (±6.06) years. Hypertension was associated with male gender, smoking and alchohol use. Hence, focusing more attention to address the burden of hypertension and associated risk factors in Nepal is needed. The study also showed majority of patients were switched to dual therapy of FDC Telmisartan+Amlodipine due to uncontrolled hypertension.

Dyslipidemia was the most common comorbidity in Nepalese population with hypertension followed by diabetes mellitus, obesity and cardiovascular disease.

Overall, this study contributes valuable data to better understand the real-world clinical use of FDC of Telmisartan + Amlodipine in Nepal and highlights the need for tailored approaches considering diverse patient profiles.

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