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A Prospective Study on Cardiovascular Risk Factors- Control and Management in Patients with IHD at a Tertiary Hospital

Aishwarya Dinakaran[1], Firdous Shazia Sajid[1], Mir Hamed Ali[1], Tahmeena Farooqui[2], Madiha Maryam[1], Shaheem Shaikh[1], Mohathasim Billah A[1]

1. Department of Pharmacy Practice, MRM College of Pharmacy, Telangana
2. Department of Pharmacology and Toxicology, National Institute of Pharmaceutical Education and Research, Hyderabad, Telangana

Address for Correspondence: Dr. Aishwarya Dinakaran
Email: aishumolepharmd91@gmail.com

Abstract

The aim of the study was to assess the management of two major risk factors (HTN and DM) in patients with pre-existing IHD by comparing the therapies of the patients with the standard guidelines as prescribed by AHA/ADA.11110 Categorized them into rational and irrational therapies. The prescriptions of 80 consecutive patients were reviewed with established IHD for GDMT of two major risk factors -HTN and DM, 40% of whom had more than 5 IHD risk factors. For Antihypertensive treatments, the overall rationality was 60% and 40% irrational. The majority of the irrationality for antihypertensives was observed among CAD (33.33%) and BBB (66.66%), with the former lacking the drug of choice (ACE/ARB) and the latter having a contraindicated Drug (Betablockers). Overall, 18% of the therapies used on 59 diabetic patients were rational, while 82 % were irrational. The most common non-compliance with the guidelines reported among antihyperglycemics was the lack of use of metformin as monotherapy 91% of the time. A significant finding of irrational antihyperglycemics was, the use of antihyperglycemics with neutral CV effects rather than those with possible cardio protection. The CHIS score demonstrated that the majority of the population (35%) fell under intermediate control, 33.75 % was in good control, and 31.25 % was in poor control group, The poor control group showed peak MVO2(1294) amongst the three groups, highlighting elevated myocardial oxygen demand as the control declined.

Keywords: GDMT, Rational, Irrational, Risk Factors, MVO2.Cardiovascular Health Index Score (CHIS).

INTRODUCTION:

Ischemic Heart Disease (IHD) is a term that represents a cluster of cardiovascular diseases characterised by an imbalance between myocardial oxygen supply and demand, usually a result of narrowing of coronary arteries that supply blood to the myocardium. The disease remains the world's biggest killer responsible for 16% of the world's total deaths, with India recording deaths of 272 per 100,000 population higher than the global average. – WHO of which more than 80% suffer from multiple risk factors for IHD. One of the reasons for this problem is improper control and management of the modifiable risk factors like DM, HTN, obesity, physical inactivity, smoking and high levels of cholesterol. Our study aims at identifying the gap between guideline recommendations and daily practice in terms of risk factor management and their control.

Rationality: The prescription was compared to the Standard AHA/ADA recommendations for the management of two main risk factors, hypertension and diabetes.

Treatment of DM2 patients with established ASCVD a target-based approach:

1**) MONO-THERAPY**: If A1C is equal to or below 7%, monotherapy is used. • Metformin is the first option. • Monotherapy consists of a combination of lifestyle control and metformin (If not contraindicated).

2)DUAL THERAPY: If the A1C level is 1.5 percent of the target level. (2nd Choice) Lifestyle management plus Metformin plus a 2nd-line agent • Canagliflozin is an example of an additional agent (SGLT-2 inhibitor or GLP1 Agonists) After three months of dual therapy,

if HbA1c is not at target, A third agent of drug-specific side effects and patient variables is required (triple therapy).

3)Combination Therapy: If A1C is equal to or greater than 10% initiate basal insulin with metformin +/- other non-insulin agents.

MATERIAL AND METHODS:

A) Study design:

This is a six-month prospective observational study evaluating risk factor reduction and guideline-directed care in patients with IHD that will run from November 2020 to April 2021. Patients who have been admitted to THUMBAY NEW LIFE HOSPITAL, CHADARGHAT's IPD.

B) Collection of data

Using a suitably designed validated data collection form, the following details will be collected -Patient demographics, Prescription chart, Lab data, Progress chart, medical record, Physician notes.

C) Inclusion criteria:

- All patients with established IHD (defined as 1st or recurrent UA/STEMI or NSTEMI/LVD)

Evaluation of Age and Gender Distribution:
Of the total 80 IHD patients included in our study, 44 (55%) of the participants were males and 36(45%) females, indicating the high prevalence of IHD among males than in

- With none or any of its risk factors (HTN, T2DM, DYSLIPIDEMIA, OBESITY, SMOKING)
- All patients with cardiac history of ACS/LVD or Revascularisations.
- Patients who underwent PTCA/CABG/BOTH

D) Exclusion criteria

- AGE less than or equal to 18 yrs.
- Pregnant or lactating women
- COVID-19 Patients.

E) Method and collection of data

Patient will be interviewed at bedside to determine the chief complaints, history of the present illness, past medical and medication history.

- Patient's prescriptions.
- Medical records of inpatients.
- Interviews with patient and/or care takers.
- Family history for premature CHD

F) Duration of the study

The study conducted for a period of 6 months.

G) Place of study

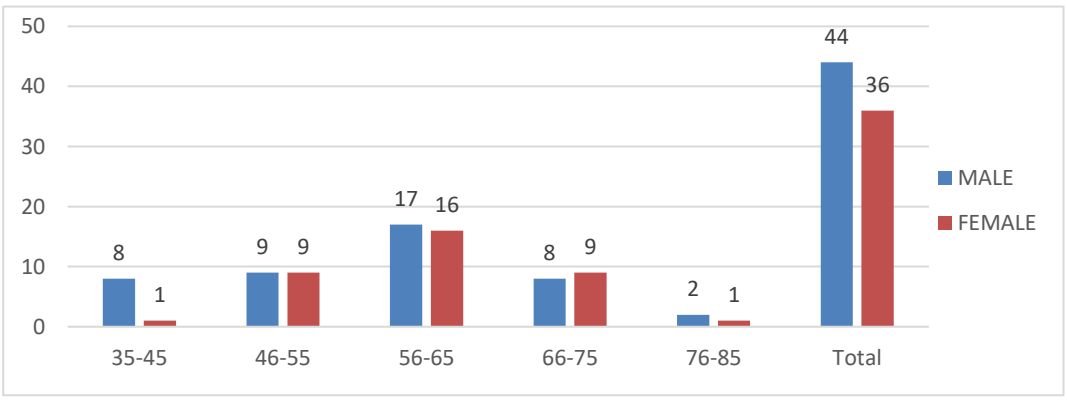
THUMBAY NEW LIFE HOSPITAL. Chaderghat, Hyderabad, Telangana.

H) Statistical Tools: KRUSKAL WALLIS TEST.

RESULTS:

females and a large proportion of the sample, 41.25% falling around 55-65 years, making it the high-risk age group. {results summarized in fig 1}

Fig:1Evaluation of age and gender distribution(n=80)



Prevalence of Risk Factors of IHD:

Of the 80 patient population, Hypertension was found to be the major factor contributing to about 66 (82.5%, P<0.005) of the study population followed by57(71.25%) diabetic, 52 (65%) being overweight/obese,27(33.75%) physically inactive and 10(12.5%) of them were smoker.

Table 2: Prevalence of Risk Factors of IHD (n=80)

RISK FACTOR	NO OF PATIENTS	PERCENTAGES
HTN (hypertension) ***P< 0.005**	66	82.5%
DM (diabetes) ***P< 0.005**	57	71.25%
OW/OBS (overweight/obese) ***P< 0.005**	52	65%
LPA (low physical activity) ***P< 0.005**	27	33.75%
SMOKER ***P< 0.005**	10	12.5%

Note: values in parenthesis are percentages.
∗Statistically significant at level of p < 0.005.

Percentage population with achieved targets for individual risk factors:

It's been observed that 65 (81.25%, p < 0.005) of our population had their BP under control meeting a target of about <130/80mmHg followed by 50% having a target blood sugar of <126mg/ dl, 87.5% Non/Ex-smokers,67.5%, physically active and 33.75 %had a normal weight with their BMI under <25 kg/m2. All of these targets were assessed against ones specified under the 2019 version of AHA/ACC guidelines on CVD prevention

Table 3: Percentage population with achieved targets for individual risk factors(n=80)

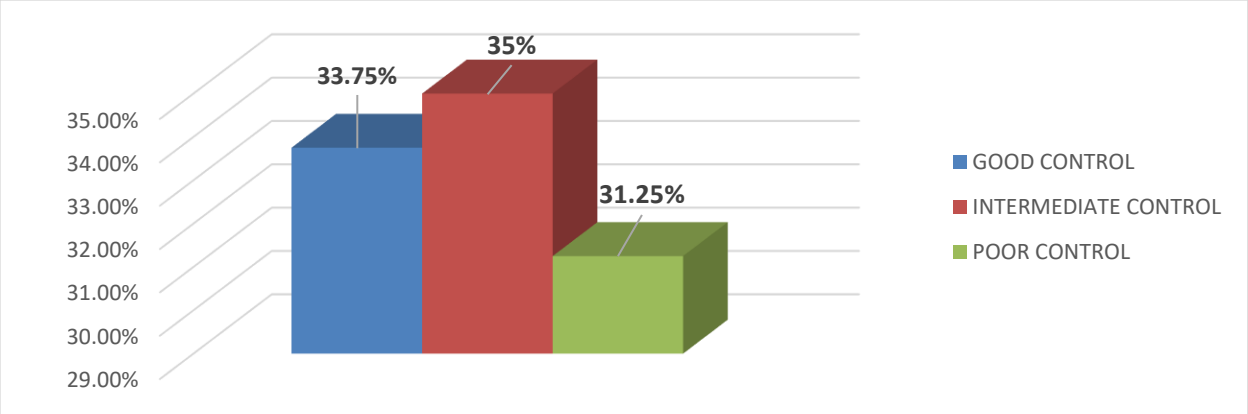
Gender	**Target BP*(<130/80)**	**Target sugar*<130mg/dl**	**Target BMI*<25kg/m2**	**smoking status* (ex/non)**	**phy Activity* (mod/vig)**
Male	34	25	12	34	33
Female	31	15	15	36	21
Total	65	40	27	70	54
%	81.25	50	33.75	87.5	67.5

Note: values in parenthesis are percentages.
∗Statistically significant at level of p < 0.005

CHIS DEMONSTRATING CONTROL OF RISK FACTORS:

As a measure to assess overall adherence towards control of risk factors we used a simplified Cardiovascular Health Index Score (CHIS) and categorized the patients as follows: GOOD n=27 (33.75%), INTERMEDIATE n=30(35%), AND POOR CONTROL n=25 (31.25%). The Kruskal Wallis test applied on MVO2s of each control group showed statistically significant difference with **H=12.8071 at P<0.0023** with highest values noted under poor control groups. Thus, we can conclude that one of the major contributors to a mismatch in the supply and demand equation is poor control of risk factors. Therefore, the higher a person's cardiovascular risk, the greater the benefit in aggressive treatment of modifiable risk factors. Thus, reducing the overall incidence of IHD as increased MVO2 is associated with increased CV risk

Fig 4: CHIS DEMONSTRATING CONTROL OF RISK FACTORS:



PROPORTION OF IHD PATIENTS REVASCULARIZED OR MEDICALLY MANAGED:

Based on their diagnosis, the majority of patients received medical management (n=63,78.75% p<0.005), while others were revascularized either through PTCA (13.75%) or CABG(7.5%).

Table 5: Treatment approaches in IHD patients (n=80):

GENDER	CABG*	PTCA*	MEDICAL Management*
MALE	6	7	31
FEMALE	0	4	32
Total	6	11	63
%	7.5	13.75	78.75

Note: values in parenthesis are percentages.
∗Statistically significant at level of p < 0.005.

MEDICATIONS USED IN THE TREATMENT OF HYPERTENSION:

The most common class of drug is Diuretics 48(60%, P< 0.005) with Betablockers 45(56.25%) as the next highly prescribed drug class, followed by ARA 27(33.75%), ARBs 18(22.5%), CCBs 9 (11.25%) and ACEIs, PDEIs both being 2.5% of the total Antihypertensives Prescribed. The most common Antihypertensive drug was found to be Furosemide in 37 patients followed by Metoprolol Succinate in 31 patients

Table 6: Medications used in the treatment of hypertension (n=80).

CLASS	DRUGS	NO OF PATIENTS	TOTAL	PERCENTAGE
Diuretics ***P< 0.005**	Furosemide Hydrochlorothiazide Metolazone Torsemide Indapamide	37 04 03 03 01	48	**60%**
Beta-Blockers ***P< 0.005**	Carvedilol Metoprolol Succinate Nebivolol Atenolol	12 31 01 01	45	**56.25%**
Aldosterone Antagonist ***P< 0.005**	Spironolactone Eplerenone	24 03	27	**33.75%**
ARBS ***P< 0.005**	Telmisartan Valsartan Metosartan Olmesartan losartan	12 03 01 01 01	18	**22.5%**
CCBS ***P< 0.005**	Amlodipine Cilnidipine Verapamil	03 05 01	09	**11.25%**
ACEIs ***P< 0.005**	Perindopril & Ramipril	02	02	**2.5%**
PDE Inhibitors ***P< 0.005**	Sildenafil	02	02	**2.5%**

Note: values in parenthesis are percentages.
∗Statistically significant at level of $p < 0.005$.

PRESCRIBING PATTERN OF ANTIDIABETICS:

The Antidiabetics employed were OHAs8(14.3%), Insulin 42(72.88%), OHAs along with Insulin in 2 (3.5%), thus indicating Insulin as the most used antidiabetic agent.

Table 7: Prescribing pattern of Antidiabetics:

Antidiabetics	TYPE OF THERAPY	No. of Diabetic patients (n=53)	TOTAL	PERCENTAGE
OHAs	**Monotherapy** Metformin Glimepiride **Dual therapy** Metformin+Glimepiride Metformin+Dapagliflozin **Triple therapy**	 **02** **02** **02** 01	**8**	**13.55%**

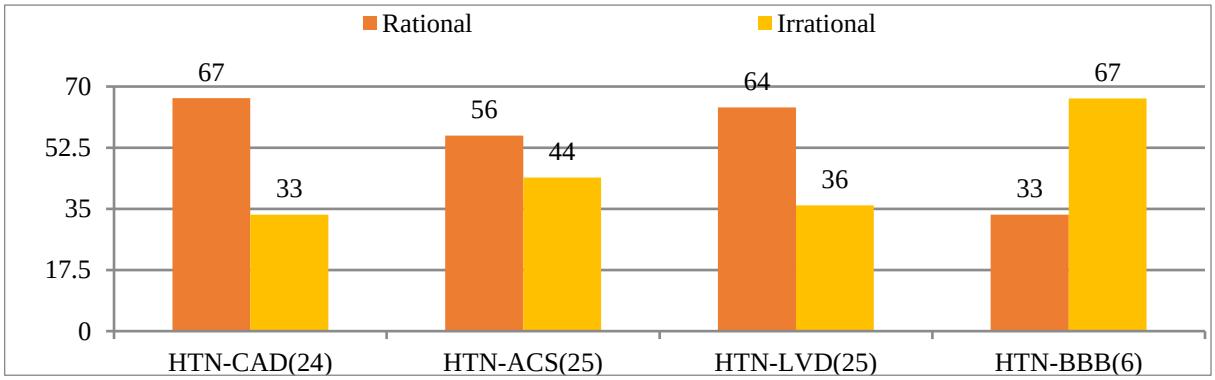
***P< 0.005**	Metformin+Glimepiride+voglibose	01		
INSULIN ***P< 0.005**	HAI HAI Glargine	**38** **04**	**42**	**72.88%**
OHAs+INSULIN ***P< 0.005**	Glargine+Metformin	**02**	**2**	**3.3%**
COMBINATION THERAPY(>10% A1c) ***P< 0.005**	HAI+Glargine+Dual OHAs (Glimepiride+Vildagliptins)	**01**	**1**	**1.75%**

Note: values in parenthesis are percentages.
⁎Statistically significant at level of p < 0.005.

Rationale for Hypertension:

Out of 24 CAD cases 16(66%, P< 0.005) of the therapies were found to be rational and 8 (33.33%) irrationals. Among 25 ACS cases 14(56 %, P< 0.005) detected rational and 11 (44%) irrational. LVD/HF constituted about 25 IHD cases having 16(64%, P< 0.005) rational therapies and 9(36%) Irrational. Total of 6 BBB cases were observed of which 2 were rational and 4irrational. unlike other rationality checks performed the no of irrational (66.66%, P< 0.005) cases of BBB were more when compared to Rational (33.33%). Thus, in our study, out of 80 patients, 60% were Rational and 40% were Irrational for Anti-Hypertensive therapies

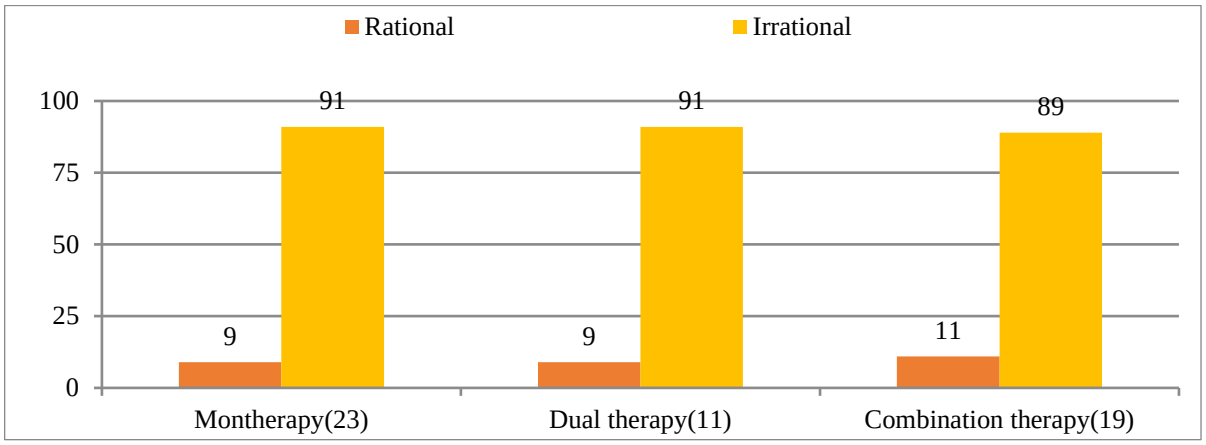
Fig 8: Rationale for Hypertension



Rationale for Diabetes Mellitus:

Out of 23 patients with their FBS>130mg/ dl i.e., not at target HbA1c >7% (130mg/dl), only 2(9%) of the antidiabetic prescriptions were found to be rational and 21(91%, P<0.005) irrational. A total of 11 patients had an FBS >175mg/dl ie HbA1c >1.5%(175mg/dl) of the target of which only 1(9%) received rational therapy while the rest10(91%, P< 0.005) were found to be irrational. Among 19 patients with FBS of >220mg/dl i.e., HbA1C>10% (220mg/dl FBS) of the target, only 2(11%) were found to receive rational combination therapy and the remaining 10 (89%, P< 0.005) were irrational. Thus In our study, out of **59 Diabetic patients**, 18% were rational and 82% were Irrational for Antihyperglycemic therapie

Fig 9: Rationale for Diabetes Mellitus



KRUSKAL WALLIS TEST ANALYSIS:

For Comparison of MVO2s of good, intermediate, and poor control groups (based on CHIS grouping).

Null hypothesis**:**

There is no significant difference between the MVO2s of good, intermediate and poor control groups.

Since the data compares more than 2 variables and is non-parametric, the Kruskal Wallis test is used to analyse the hypothesis. *Nonparametric* means that the test doesn't assume your data comes from a particular normal distribution.

Kruskal Wallis test is sometimes called the *one-way ANOVA on ranks*, as the ranks of the data values are used in the test rather than the actual data points. Like most statistical tests, you calculate a test statistic (**$H_{calculated}$/ H statistic**) and compare it to a distribution cut-off point (**$H_{critical}$**). **If the critical H value is less than the H Calculated/ H statistic , we reject the null hypothesis** and If the $H_{critical}$ value is **not less** than the H statistic, there is enough evidence to accept null hypothesis.

The test is run at 5% level of significance.

CHIS SCORE	NO OF PATIENTS	PERCENTAGE (%)
GOOD CONTROL	27	33.75%
INTERMEDIATE CONTROL	28	35%
POOR CONTROL	25	31.25%

The statistic for the **KRUSKAL WALLIS (H) TEST**:

Here, $R_i^2 = R_1^2 + R_2^2 + R_3^2$

n1 = 27 R1= 793

n2 = 28 R2 = 1153

n3 = 25 R3= 1294

$$H = \left[\frac{12}{N(N+1)}\sum_{j=1}^{k}\frac{Ri^2}{ni}\right] - 3(N+1)$$

$$= \frac{12}{80(80+1)}\left(\frac{793^2}{27} + \frac{1153^2}{28} + \frac{1294^2}{25}\right) - 3(80+1)$$

$$= \frac{12}{6480}(137747.0366) - 3(81$$

$= 0.001851(137747.0366) - 24$

$H = 255.0871 - 243$

$\boldsymbol{Hcalculated = 12.0871}$

The critical value obtained at a 5% significance level is ***Hcritical* = 5.7308**
12.0871 >5.7308

$H_{calculated}$ > $H_{critical}$ at P value (0.002373) less than significance level (0.05), we conclude that Highlighting the importance of appropriate control of risk factors. Therefore indicating, there exists a difference between the MVO2s the difference between medians is statistically significant.

THUS, REJECTING NULL HYPOTHESIS

DISCUSSION:

According to WHO global health estimates, IHD remains the world's biggest killer responsible for about 16% of the world's total deaths. Despite an emphasis on identifying risk factors and their significance for disease prevention, managing and controlling them remains a challenge. Of the various categories of drugs used Antihyperlipidemic were prescribed the most in 68(85%) patients, followed by Antihypertensives in 66(82.5%) and Antidiabetics in 54 (67.5%). Antiplatelets (97.8%), Anticoagulants (61.25%), and Antianginals (88.75%) were prescribed to avoid further disease development and management of ischemia symptoms, with the proportions of Mono, Dual, and Triple therapy as follows,

Monotherapies: Antiplatelets 19 (24.35%), Anticoagulants 47 (95%), Antianginals 32 (45%), **Dual therapies**: Antiplatelets 59 (75.64%), Anticoagulants 41 (2%), Antianginals 18 (25.35%), and **Triple therapies**: Anticoagulants 1 (2%), Antianginal 19 (25.35%). (26.76%).

Rationale for Anti-Hypertensives:

Rationality is derived from the AHA/ACC guidelines on TREATMENT OF HTN IN THE PREVENTION AND MANAGEMENT OF IHD. Management and the specified goal vary with diagnosis.

1. **Rationality for Anti-Hypertensives in CAD:**

Out of 24 CAD cases 16(66%) of the therapies were found to be rational and 8 (33.33%) irrationals.

of each (good, poor & intermediate) control group.

Reason for irrationality: Class I ACC/AHA recommendation (level of evidence A). Many major Trials have addressed the importance of the use of ACEIs in CAD patients such as HOPE, SAVE, EUROPA which showed a 20% relative risk reduction in major CV events. They led to a decrease in rates of revascularisations and all-cause mortality

2. **Rationality for Anti-Hypertensives in ACS:**

Among 25 ACS cases, 14(56 %) of the prescriptions were found to be rational and 11 (44%) irrationals.

Reason for irrationality:

Nitrates were administered for a longer duration of time than recommended. Tolerance can occur even during the first 24 hours and can be minimized by decreasing IV dosing and switching to non-IV routes with intermittent dosing as soon as the patient gets stable from ischemic standpoint.

3. **Rationality for Anti-Hypertensive in LVD/HF:**

LVD/HF constituted about 25 IHD cases having 16(64%) rational therapies and 9(36%) Irrational. Reason for irrationality:

Despite having an LVEF of <40%, no Aldosterone antagonists were administered. Aldosterone antagonists have secondary protective effects in patients with severe HF and individuals with LVD (LVEF <40%) after MI. This is evident from the RALES and EPHESUS studies that showed a reduction in mortality up to 30% and 15% respectively and as early as within 30 days of initiation, emphasizing the clinical need to start therapy before discharge.

4. **The rationality of Anti-Hypertensive in BBB;**

A total of 6 BBB cases were observed and unlike other rationality checks performed, the no of irrational cases 4(66.66%) were more when compared to Rational,2 (33.33%).
Reason for irrationality:
Despite the fact that they are contraindicated, beta blockers were administered to individuals with BBB. All BBs because of their negative inotropic and negative chronotropic effect, have the potential to cause hypotension and conduction disturbances, particularly when used in conjugation with NDHP CCBS and so must be avoided.

Thus, in our study of 80 patients, 60% were rational and 40% were Irrational for Anti-Hypertensive therapies
Rationale for Antidiabetics in ASCVD:

Rationality is based on the use of Target-Specific choice of therapy to reduce future CVD risk.

1. **Rationality for Monotherapy (Metformin)**:
Out of 23 patients with their FBS>130mg/dl,2(9%) of the prescriptions were found to be rational and 21(91%) irrational.
Reason for Irrationality:
Monotherapy with METFORMIN was not initiated during the disease course; rather, few received monotherapies with SU's and Insulin.
In all diabetic patients having ASCVD with preserved renal function, if HbA1c is not at target >7% (130mg/dl), monotherapy with metformin is the treatment of choice with potential cv safety, in view of side effects like weight gain and hypoglycaemia associated with SU and Insulin.

One of the earliest CVOTs (Cardiovascular Outcome Trials) in T2DM patients, **UKPDS 34** demonstrated statistically significant reductions in the risk of MI and CV death. After UKPDS, all the CVOTs were on top of metformin as a baseline, therefore the researchers consider the CV benefits of these trials inseparable from the metformin. Also, in case of unachieved targets with monotherapy, any alterations done in the therapy of antidiabetics must be made in addition to metformin.

2. **Rationality for Dual Therapy (Metformin+GLP1-RAs /SGLT2Is):**

A total of 11 patients had their FBS >175mg/dl of which only 1(9%) received rational therapy while the rest 10(91%) were found to be irrational.
Reason for irrationality:
Lack of dual therapy with GLP1-RA/SGLT2Is in addition to Metformin. Rather than using this second-line medication, a SU was combined with metformin.
ADA recommends the addition of either (GLP1-RA/SGLT2Is) of the two agents in addition to metformin in those not meeting the target alone with metformin or >1.5%(175mg/dl) of the target. Many major trials such as LEADER, SUSTAIN-6, and REWIND have demonstrated a significant reduction in CV mortality, and all-cause mortality, MI, and HF. With as high as 38% reduction seen in
EMPAREG Trial
.

3. **Rationality for Combination therapy (Basal Insulin+Metformin**):

Among 19 patients with FBS of >220mg/dl, only 2(11%) were found to receive rational combination therapy and the remaining 10(89%) were irrational.
Reason for Irrationality**:**
Insulin was administered without metformin in the majority of patients, and as of the choice of insulin, HAI was used instead of basal insulin.
ADA recommends initiation of a combinational therapy in patients if HbA1C>10% (220mg/dl FBS) of the target with basal insulin along with metformin+/- other non-insulin agents. In Trials like DEVOTE,40% of patients were not on metformin at baseline. The primary adverse effect observed was hypoglycaemia and weight gain (counteracted by metformin). the incidence of severe hypoglycaemia may increase the risk of death for up to a year after its occurrence, as mentioned in many CVOTs.
In patients with HF, use of insulin has been associated with a worse prognosis, including increased death rate, CV mortality and HF

hospitalizations. However, utilising basal insulin, such as insulin glargine, in conjunction with metformin early in the disease can prevent the elevated occurrences of HF, as reported in the ORIGIN TRIAL.

Thus, in our study, out of 59 Diabetic patients, 18% were rational and 82% were Irrational for Antihyperglycemic therapies.

LIMITATIONS: The study limits to a period of about 6 months with a sample size of80.
One of our study's key findings was, despite the guidelines recommend CVD risk analysis, which involves lipids evaluation as part of a diagnostic workup, data on lipid profile was not accessible. • No matter how strong the preventative guidelines are, effective risk factor control is impossible if there is no record of the risk variables in question.

CONCLUSION: Despite the well-established relevance of risk factors in IHD care, our research found a major difference between GDMT and Clinical practice. In this study of 80 IHD patients treated for risk factors, 40% were irrational for antihypertensive drugs and 80% for antihyperglycemic drugs. Most common non-compliance with the guidelines discovered among antihypertensives was the prescription of contraindicated Beta-blockers in patients with BBB and the lack of medication of choice ACEI/ARB in CAD, while the most common non-compliance with the guidelines observed among antihyperglycemics was the lack of metformin as monotherapy and metformin+ GLP1-RA/SGLT2-Is as dual therapy in those not meeting targets. A notable finding in the considerable number of irrational Antihyperglycemic prescriptions was, the usage of antihyperglycemics with neutral cv effects rather than ones that offer potential cardio protection.
Also, 60% of antihypertensives and 18% of antihyperglycemics advised to them were rational, with the major irrationality being observed in the therapy selection rather than failure to fulfil targets.
When CHIS was applied to the targets met, it revealed that a large majority of them were under intermediate control, indicating that to reduce uncontrolled risk variables and achieve populations with good control. The poor control group showed peak MVO2s amongst the three groups, highlighting elevated myocardial oxygen demand as the control declined.

The most important component in managing these chronic illnesses is guideline directed therapy selection, which has a direct impact on overall health. As a result, implementation of which can greatly reduce morbidity and mortality.

CONFLICT OF INTEREST:
There is no conflict of interest.

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