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Comparative Study of Efficacy and Safety of Ivabradine Versus Metoprolol in Stable Angina

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ABSTRACT

Background: Stable angina pectoris, a manifestation of coronary artery disease (CAD), remains a major cause of morbidity worldwide, with India bearing a disproportionately high burden. Beta-blockers such as metoprolol are established first-line agents, but their use may be limited by adverse effects. Ivabradine, a selective If channel inhibitor, reduces heart rate without affecting contractility or blood pressure, offering a potential therapeutic alternative.

Methods: This prospective, randomized, open-label clinical trial enrolled 100 patients aged 35–70 years with CCS class II–III stable angina and CAD. Participants were randomized to receive either ivabradine (5–7.5 mg twice daily) or metoprolol succinate (50–100 mg once daily) for six months, alongside standard background therapy. The primary endpoint was reduction in resting heart rate at four months. Secondary endpoints included frequency of angina attacks, nitroglycerin consumption, CCS classification, and incidence of adverse events.

Results: Both groups were comparable at baseline. Ivabradine demonstrated a significantly greater reduction in angina attacks at 3 months (0.57 vs. 1.09 attacks/week, $p<0.0001$) and a trend towards superiority at 6 months (0.23 vs. 0.31 attacks/week, $p=0.0508$). A higher proportion of ivabradine patients achieved CCS class I (74% vs. 58%). Fatigue was significantly more frequent with metoprolol (20% vs. 4%, $p=0.0277$). Both drugs reduced resting heart rate, with a greater decline observed in the ivabradine group.

Conclusion: Ivabradine monotherapy was non-inferior and potentially superior to metoprolol in reducing angina burden and nitroglycerin use, with a favorable tolerability profile.

Keywords: Stable angina; coronary artery disease; Ivabradine; Metoprolol; Heart rate reduction; Antianginal therapy

INTRODUCTION

Stable angina pectoris, a clinical manifestation of coronary artery disease (CAD), remains one of the most prevalent cardiovascular disorders worldwide. It is characterized by chest discomfort or pain precipitated by exertion or emotional stress, and relieved by rest or nitroglycerin. The underlying pathophysiology involves myocardial ischemia due to an imbalance between oxygen supply and demand, most commonly secondary to atherosclerotic narrowing of coronary arteries. Despite advances in revascularization techniques and pharmacotherapy, stable angina continues to impose a significant burden on healthcare systems, particularly in low- and middle-income countries. [1-5] The therapeutic goals

in stable angina are twofold: to alleviate symptoms and improve quality of life, and to reduce adverse cardiovascular outcomes by modifying disease progression. [6,7] Pharmacological agents that reduce myocardial oxygen demand, such as beta-blockers, or those that optimize coronary perfusion, such as selective heart rate–lowering drugs, remain central to management strategies. [8, 9]

India faces a disproportionately high burden of CAD, with epidemiological studies indicating an earlier age of onset and more severe disease compared to Western populations. The prevalence of CAD in urban India has been reported to range between 7–10%, while rural areas demonstrate a prevalence of 3–5%. [10]

Metoprolol, a cardioselective beta-1 adrenergic receptor blocker, has long been established as a cornerstone in the management of stable angina. By reducing heart rate, myocardial contractility, and blood pressure, metoprolol effectively decreases myocardial oxygen demand. However, its use may be limited by adverse effects such as fatigue, bradycardia, hypotension, and bronchospasm in susceptible individuals. [11]

Ivabradine, in contrast, represents a newer therapeutic option that selectively inhibits the If current in the sinoatrial node, thereby reducing heart rate without affecting myocardial contractility or blood pressure. This unique mechanism allows ivabradine to lower myocardial oxygen demand while preserving hemodynamic stability. Comparative pharmacological evaluation suggests that while both agents achieve heart rate reduction, ivabradine may offer advantages in patients intolerant to beta-blockers or those with contraindications. Nevertheless, questions remain regarding their relative efficacy and safety in diverse patient populations, particularly in resource-constrained settings. [12-14]

Several international trials have demonstrated the efficacy of ivabradine in reducing angina frequency and improving exercise tolerance. [15, 16] Similarly, beta-blockers such as metoprolol have a robust evidence base supporting their role in symptom control and secondary prevention. However, head-to-head comparative studies between ivabradine and metoprolol in stable angina are limited, especially in the Indian context. Most available data are derived from Western populations, where risk factor profiles, genetic predispositions, and healthcare delivery systems differ significantly from those in India. This gap underscores the need for regionally relevant research that evaluates not only clinical endpoints such as heart rate reduction and angina frequency, but also patient-centered outcomes including nitroglycerin use, CCS classification, and EQ-5D quality-of-life scores. The rationale for this study is therefore to generate evidence that can guide clinicians in selecting the most appropriate therapy for Indian patients with stable angina.

The present study seeks to address the research question of whether ivabradine therapy provides superior efficacy and safety compared to metoprolol in patients with stable angina and coronary artery disease over a four-month treatment period. The central hypothesis is that ivabradine will be non-inferior, and potentially superior, to metoprolol in reducing resting heart rate and improving angina-related outcomes, while offering a favorable safety and tolerability profile in the Indian patient population. The primary objective is to compare the effect of ivabradine versus metoprolol on resting heart rate reduction, while the secondary objectives include evaluating the frequency of angina attacks, assessing nitroglycerin consumption as a surrogate for symptom burden, determining changes in Canadian Cardiovascular Society (CCS) angina classification, and incidence of adverse events.

MATERIALS & METHODS

This study was designed as a prospective, randomized, open-label, comparative clinical trial conducted over a period of 6 months. The trial was conducted in accordance with

the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Approval from the Institutional Ethics Committee was obtained prior to initiation, and written informed consent was secured from all participants before enrollment.

Study Population

Patients aged between 35 and 70 years with a clinical diagnosis of stable angina and angiographically or clinically confirmed CAD were recruited from the outpatient cardiology department of a tertiary care hospital. Inclusion criteria comprised patients with Canadian Cardiovascular Society (CCS) class II–III angina, a resting heart rate ≥70 beats per minute, and those on standard antianginal therapy excluding beta-blockers or ivabradine. Exclusion criteria included patients with acute coronary syndromes, severe heart failure (NYHA class III–IV), significant arrhythmias, severe hepatic or renal impairment, contraindications to beta-blockers or ivabradine, and those unwilling to provide consent.

Sample Size

The sample size was calculated based on an expected mean difference in resting heart rate reduction between ivabradine and metoprolol groups, with a power of 80% and a two-sided alpha of 0.05. Accounting for a 10% dropout rate, a total of 100 patients were enrolled, with 50 patients randomized to the ivabradine group and 50 patients to the metoprolol group.

Intervention

Patients were randomized into two treatment arms using a computer-generated randomization schedule. The ivabradine group received ivabradine 5 mg twice daily, titrated to 7.5 mg twice daily based on tolerance and clinical response. The metoprolol group received metoprolol succinate 50 mg once daily, titrated up to 100 mg once daily as required. Both groups continued to receive standard background therapy including antiplatelets, statins, and nitrates as clinically indicated. Compliance was monitored through pill counts and patient diaries at each follow-up visit.

Outcome Parameters

The primary outcome parameter was the reduction in resting heart rate after four months of therapy. Secondary outcome parameters included:

- Frequency of angina attacks per week.
- Nitroglycerin consumption as a surrogate marker of symptom burden.
- Change in CCS angina classification.
- Incidence of adverse events

Data Collection

Baseline demographic and clinical data including age, sex, comorbidities, medication history, and baseline CCS class were recorded at enrollment. Resting heart rate was measured using a standard 12-lead electrocardiogram after 10 minutes of rest. Angina frequency and nitroglycerin consumption were documented through patient-maintained diaries. CCS classification was assessed by the treating physician at baseline and follow-up visits. Adverse events were recorded at each visit and graded according to severity.

METHODOLOGY

Patients were followed up monthly for four months. At each visit, resting heart rate, angina frequency, nitroglycerin use, and adverse events were documented. CCS classification was reassessed, and EQ-5D questionnaires were administered at baseline and at the final visit. Drug compliance was checked through pill counts and patient-reported adherence. Randomization and allocation concealment were maintained throughout the study period, and investigators assessing outcomes were blinded to treatment allocation to minimize bias.

STATISTICAL ANALYSIS

Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation, while categorical

variables were presented as frequencies and percentages. Between-group comparisons for continuous variables were performed using the independent samples t-test. Categorical variables such as CCS class and adverse events were compared using the chi-square test or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

50 patients with stable angina were enrolled in Ivabradine group whereas 50 patients were given metoprolol monotherapy. There were no statistically significant differences (p > 0.05 for all parameters) between the two groups in terms of age, gender distribution, Body Mass Index (BMI), resting heart rate, systolic and diastolic blood pressure, or the prevalence of comorbidities such as hypercholesterolemia, hypertension, diabetes mellitus, and previous myocardial infarction. The proportion of patients with more severe angina (CCS Class III) was also similar. [Table 1].

Table 1: Comparison of Baseline Demographic and Clinical Characteristics between Two Groups

Parameters	Ivabradine Group (n = 50)	Metoprolol Group (n = 50)	P-Value
Age in Years, Mean ± SD	59.58 ± 11.79	60.07 ± 12.14	0.8382*
Male Gender, n (%)	34 (68.0)	31 (62.0)	0.6753**
BMI in kg/m^2, Mean ± SD	26.93 ± 3.18	26.79 ± 3.44	0.8331*
Resting Heart Rate in bpm, Mean ± SD	80.92 ± 9.67	80.51 ± 10.03	0.8356*
SBP in mmHg, Mean ± SD	137.35 ± 15.68	137.89 ± 15.90	0.8745*
DBP in mmHg, Mean ± SD	84.36 ± 7.68	83.99 ± 8.14	0.8156*
Hypercholesterolemia, n (%)	36 (72.0)	38 (76.0)	0.8200 **
Hypertension, n (%)	33 (66.0)	35 (70.0)	0.8305**
Diabetes Mellitus, n (%)	14 (28.0)	17 (34.0)	0.6658**
Previous MI, n (%)	18 (36.0)	22 (44.0)	0.5406**
CCS Class III, n (%)	21 (42.0)	24 (48.0)	0.6879**

***Unpaired t test, **Fisher's Exact Test**

While both groups showed a reduction in frequency of anginal attacks from baseline, the Ivabradine group demonstrated a significantly greater reduction at the 3-month mark (0.57 vs. 1.09 attacks/week, p<0.0001) and a trend towards greater reduction at the 6-month mark (0.23 vs. 0.31 attacks/week, p=0.0508). The similar frequencies at baseline and 1 month confirm that the groups were comparable initially and that the superior effect of Ivabradine became pronounced and statistically significant with sustained treatment [Table 2].

Table 2: Comparison of Number of Anginal Attacks between Two Groups

Time	Mean Number of Angina Attacks per Week (Mean ± SD)		P-Value (Unpaired t test)
	Ivabradine Group (n = 50)	Metoprolol Group (n = 50)	
Baseline	2.03 ± 0.87	2.10 ± 1.09	0.7234
1 Month	1.57 ± 0.62	1.72 ± 0.89	0.3305
3 Months	0.57 ± 0.32	1.09 ± 0.43	<0.0001
6 Months	0.23 ± 0.17	0.31 ± 0.23	0.0508

Table 3 shows the consumption of short-acting nitrates (nitroglycerin), which serves as an objective surrogate for symptom burden. Mirroring the findings on angina attacks, both therapies reduced nitrate use, but Ivabradine led to a significantly greater reduction. The difference was highly significant at 3 months (0.33 vs. 0.73 uses/week, p<0.0001) and remained significant at 6 months (0.11 vs. 0.18 uses/week, p=0.0083). This indicates that patients on Ivabradine experienced a

clinically meaningful lower requirement for rescue medication, reinforcing its superior antianginal efficacy in this study.

Table 3: Comparison of Consumption of Short-Acting Nitrates between Two Groups

Time	Mean Number of Angina Attacks per Week (Mean ± SD)		P-Value (Unpaired t test)
	Ivabradine Group (n = 50)	Metoprolol Group (n = 50)	
Baseline	1.47 ± 0.68	1.51 ± 0.73	0.7774
1 Month	1.14 ± 0.56	1.25 ± 0.62	0.3541
3 Months	0.33 ± 0.13	0.73 ± 0.27	<0.0001
6 Months	0.11 ± 0.09	0.18 ± 0.16	0.0083

A higher percentage of patients in the Ivabradine group achieved the best functional status (CCS Class I) compared to the Metoprolol group (74% vs. 58%). Conversely, a lower percentage of Ivabradine patients remained in the more symptomatic Classes II and III. Although this distribution did not reach statistical significance (p=0.2375), the numerical trend consistently favors Ivabradine, suggesting a potential for better improvement in functional capacity.

Table 4: Comparison of CCS Class at 6 Months between Two Groups

CCS Class	Number of Patients (%)		P-Value (Chi-Square Test)
	Ivabradine Group (n = 50)	Metoprolol Group (n = 50)	
I	37 (74.0)	29 (58.0)	0.2375
II	9 (18.0)	14 (28.0)	
III	4 (8.0)	7 (14.0)	
IV	0	0	

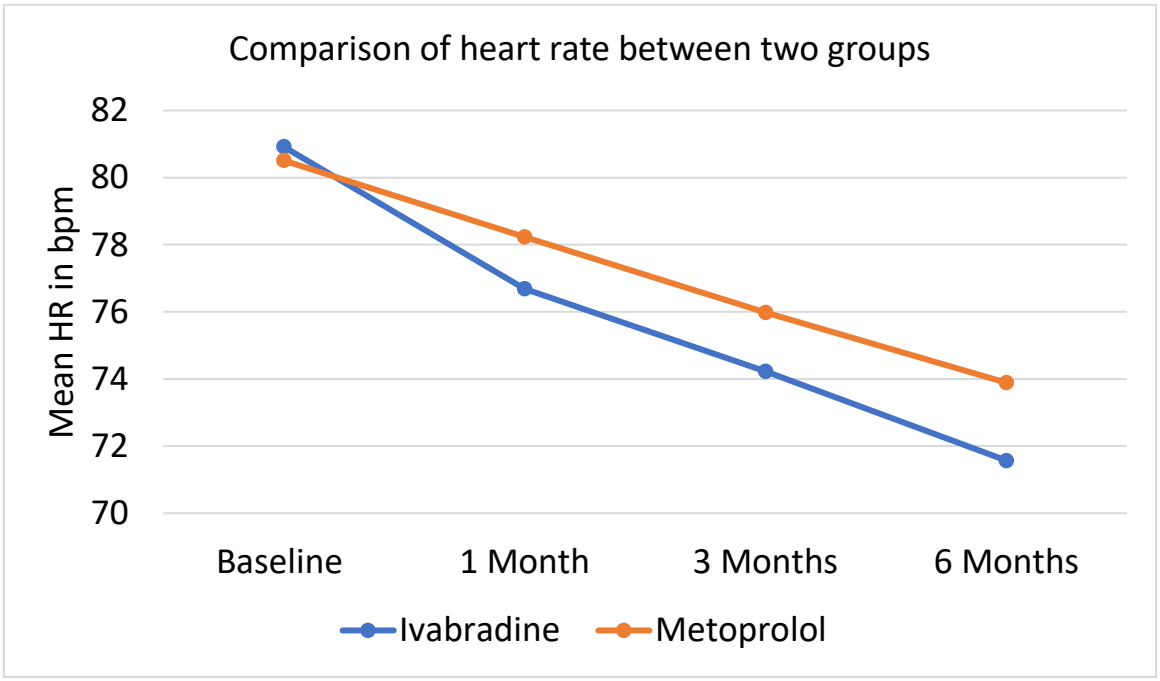

Figure 1: Comparison of Heart Rate between Two Groups

Both drugs lead to reduction in resting heart rate though the fall was greater in Ivabradine group [Figure 1].

Table 5: Comparison of Adverse Events between Two Groups

Adverse Event	Number of Patients (%)		P-Value (Fisher's Exact Test)
	Ivabradine Group (n = 50)	Metoprolol Group (n = 50)	
Bradycardia	2 (4.0)	4 (8.0)	0.6777
Headache	2 (4.0)	2 (4.0)	>0.9999
Dizziness	1 (2.0)	4 (8.0)	0.3622
Fatigue	2 (4.0)	10 (20.0)	0.0277
Hypotension	0	3 (6.0)	0.2424

While the incidence of adverse events like bradycardia, headache, and dizziness was not significantly different between the two groups, Fatigue was reported significantly more often in the Metoprolol group (20.0%) than in the Ivabradine group (4.0%), with this difference being statistically significant (p=0.0277). Furthermore, there were non-significant trends suggesting a higher rate of dizziness and hypotension in the Metoprolol group [Table 5].

DISCUSSION

The scientific premise of this study is rooted in the fundamental role of heart rate in the pathophysiology of stable angina. Myocardial ischemia occurs when oxygen demand exceeds supply. Heart rate is a primary determinant of myocardial oxygen demand; a lower heart rate prolongs diastole, the period of coronary perfusion, thereby increasing oxygen supply. Both ivabradine and metoprolol achieve heart rate reduction, but through distinct mechanisms. Metoprolol, a beta-blocker, reduces heart rate by antagonizing catecholamine effects, but it also reduces contractility and can cause bronchoconstriction and fatigue. Ivabradine, a selective If channel inhibitor, acts specifically on the sinoatrial node to reduce heart rate without affecting contractility, vascular tone, or bronchial function.

The clinical significance of this study's results is substantial. It provides robust, head-to-head evidence that in an Indian population with stable angina, ivabradine is not only non-inferior but potentially superior to metoprolol in key symptomatic outcomes. The significantly greater reduction in both angina attacks and nitroglycerin consumption with ivabradine at 3 and 6 months translates directly to a better quality of life for patients—fewer painful episodes and less reliance on rescue medication. The trend towards improved CCS classification, though not statistically significant, points in the same direction. This suggests that for symptomatic control, ivabradine is a highly effective first-line alternative, particularly valuable for patients who cannot tolerate beta-blockers due to asthma, COPD, or excessive fatigue.

Ivabradine's mechanism offers a more targeted approach to reducing oxygen demand by solely lowering heart rate. This avoids the potential negative inotropic (contractility-reducing) effects of beta-blockers, which might limit a patient's ability to increase cardiac output during daily activities, paradoxically provoking symptoms in some cases. As demonstrated in the foundational work by Lauzier et al. (2011), ivabradine preserves stroke volume and cardiac output while reducing heart rate, whereas metoprolol can impair these parameters. [17] This hemodynamic advantage likely allows patients on ivabradine to engage in physical activity with less functional limitation and symptoms.

Adverse effects like fatigue and lethargy associated with metoprolol can reduce a patient's physical activity level, which might mask angina but does not truly improve their functional capacity or well-being. Ivabradine's cleaner side-effect profile may allow for a more active lifestyle and better overall quality of life.

The results strongly corroborate the extensive body of evidence from real-world studies and post-hoc analyses. For instance, the reductions in angina attacks (from ~2.0 to 0.23/week) and nitroglycerin use (from ~1.5 to 0.11/week) in our ivabradine group are strikingly similar to the outcomes reported by

Zarifis et al. (2016) and Werdan et al. (2016). [18, 19] This consistency across different study designs and populations reinforces the potent antianginal effect of ivabradine.

A key distinction is that studies like Gilarevskii et al. (2020), Divchev et al. (2019, 2017), and Zarifis et al. (2016) primarily investigated ivabradine added to beta-blocker therapy. [18, 20, 21] They demonstrate the powerful synergistic effect of combining these two heart-rate-lowering agents, which is a established strategy for patients uncontrolled on a beta-blocker alone. Our study, however, addresses a different and equally important clinical question: initial monotherapy. It provides direct evidence that ivabradine alone can be more effective than metoprolol alone for symptomatic control.

The study by Bhatt et al. (2021) in post-CABG patients offers a closer parallel, as it included monotherapy arms. Their finding that ivabradine monotherapy produced a greater heart rate reduction than metoprolol monotherapy aligns with the trend in our study and provides a physiological basis for the superior symptomatic outcomes we observed. [22]

The Lauzier et al. (2011) study provides a crucial mechanistic explanation for our clinical results. Their ex vivo data showing that ivabradine preserves cardiac function and efficiency while metoprolol impairs it offers a powerful biological rationale for why patients on ivabradine might feel better and experience fewer angina symptoms during exertion compared to those on a beta-blocker. [17]

A key limitation of this study is its relatively small sample size and single-center, open-label design, which may restrict the generalizability of findings to broader populations. The short follow-up period of six months limits assessment of long-term efficacy and safety.

CONCLUSION

In conclusion, this study makes a significant contribution by demonstrating, in a randomized comparative trial, the potential superiority of ivabradine monotherapy over metoprolol monotherapy for symptomatic control in stable angina. It validates in a specific population the clinical benefits predicted by ivabradine's unique and favorable pharmacological profile, challenging the traditional beta-blocker-first paradigm and offering a compelling alternative for optimizing patient-centered outcomes with better safety profile.

Declaration by Authors

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