

Original Research Article

Influence of dual metabolic modulation with ranolazine and trimetazidine on post-operative outcomes in CABG patients: A retrospective cohort study

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Abstract

Purpose: To investigate post-operative complications of coronary artery bypass grafting (CABG) with ranolazine and trimetazidine compared to conventional guideline-directed therapy among coronary artery disease patients in a tertiary hospital.

Methods: A total of 181 (78.69 %) patients from 230 (underwent CABG surgery) were enrolled to evaluate the outcome. These patients received ranolazine (200 mg twice daily orally) and trimetazidine (35 mg twice daily) along with conventional guideline-directed therapy during perioperative hospitalization. The outcomes and readmission rate with the interventional therapy were compared up to 3 months after surgery.

Results: Mean age was 53.2 ± 7.5 years, gender distribution was predominantly male (96.1 %). Hypertension was the highest comorbidity (85.7 %). Post-operative complications were recorded in 131(72.4 %) of patients. Age, body mass index (BMI), hypertension (HTN), and hyperlipidemia (HLD) showed no significant relationship with incidence of post-operative complications ($p > 0.05$). Furthermore, type 2 diabetes mellitus (T2DM) was significantly associated with post-operative complications ($p < 0.05$). During the 3-month follow-up, a total of 29(16 %) patients were readmitted of which 22(75.9 %) who experienced post-operative complications were again readmitted compared to 7(24.1 %) who did not experience complications.

Conclusion: Adjunct therapy demonstrates no significant clinical effect on either post-operative complications or rate of readmissions in CABG patients. Further multicenter randomized clinical trials are required to evaluate the efficacy and safety of adjunct therapies.

Keywords: Ranolazine, Trimetazidine, Complications, Readmissions, CABG

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INTRODUCTION

Coronary artery disease (CAD) is a leading cause of morbidity and mortality worldwide, with increasing healthcare cost during treatment and

management [1]. Recent advances in therapeutics of percutaneous coronary interventions (PCI) remain insufficient to address adverse clinical outcomes [2]. The coronary artery bypass grafting (CABG) is a developed

surgical procedure intended to reduce post-operative complications among severe obstructive CAD patients [3].

Dual antiplatelet therapy (DAPT) including aspirin and a P2Y₁₂ inhibitor (e.g., clopidogrel) plays a vital role in platelet activation, aggregation and thrombosis. This reduces risk of recurrent myocardial infarction, coronary stent thrombosis in individuals with acute coronary syndrome (ACS), secondary prevention measure on an indefinite treatment basis for patients with stable coronary artery disease (SCAD), ischemic stroke, or peripheral artery disease (PAD) [4]. Increasing evidence suggests that perioperative statin therapy (exerting pleiotropic effect) reduces morbidity following CABG, including incidence of POAF, stroke, and acute kidney injury (AKI) [2].

Certain cardioprotective drugs, such trimetazidine and ranolazine, have exhibited efficacy in lowering myocardial ischemia by selective inhibition of the late sodium current (I_{NaL}), reduces intracellular sodium and calcium concentrations. Therefore, enhancing cardiac function in individuals with chronic stable angina [5]. Ranolazine is considered to maintain cardiac stability and improves diastolic function during CABG surgery. In contrast, trimetazidine (partial fatty acid oxidation inhibitor (pFOX inhibitor)) provides cardioprotective benefits by regulating cardiac energy metabolism, independently of haemodynamic changes (no effect on heart rate or blood pressure) [6]. Although ranolazine and trimetazidine are well-known anti-anginal medications with proven advantages in chronic ischemic heart disease (CIHD), their roles in cardiac surgical settings, particularly during the perioperative period of CABG, remains less clearly established [7,8]. Furthermore, most studies conducted were at the cellular or laboratory level, and as a result, there is limited data available on their impact on surgical clinical outcomes [8].

Small trials and preliminary studies, suggest that these medications might provide additional perioperative benefits, including enhanced hemodynamic stability, reduced incidence of POAF, and decrease markers of myocardial injury such as troponin I and Creatine Kinase-MB CKMB [6-9]. Combination of these adjunctive therapies (ranolazine and trimetazidine) in the perioperative setting of CABG is efficacious for the prevention of post-operative complications [10]. Therefore, this study investigated the impact of this combination therapy on post-operative complications (including, PAF, bleeding, infections, and Acute kidney injury (AKI) and

readmission rates among patients who underwent CABG surgery at Burjeel Hospital, Abu Dhabi, United Arab Emirates (UAE).

METHODS

Study design

This was a retrospective cohort study to evaluate the impact of combination therapies with guideline-directed medical therapy (GDMT) in patients admitted for CABG surgery. The study was approved by the Institutional Review Board (IRB) of Burjeel Hospital (approval number: BH/REC/091/25) and complied with the Declaration of Helsinki [11].

Sample size

All the patients admitted during June 2022 till December 2024 were included for screening using universal sampling technique. This sampling method was adopted to increase statistical power and reduce selection/sample size bias. The sample size calculation based on 95 % confidence level ($Z = 1.96$), 5 % margin of error, and 50 % response with a finite population of 230 patients underwent CABG. The minimum sample size required was 145, and enrolled study population was 181 fulfilling the requirement.

Inclusion criteria

Patients aged 18 years or older, undergoing elective or urgent CABG, received both ranolazine and trimetazidine in addition to standard care at pre-operative level.

Exclusion criteria

Patients with reported hypersensitivity or assumed contradiction with either ranolazine / trimetazidine or both, underwent other cardiac surgeries simultaneously (e.g., valve surgery), incomplete or missing medical records, significant comorbidities during the time of surgery (e.g severe heart failure, active infection), and no signed informed consent form.

Study setting

The study was conducted at Burjeel Hospital in Abu Dhabi, a tertiary care center that performs sophisticated cardiac surgery treatments. The research examined medical records of patients who underwent CABG and were given a combination of ranolazine (200 mg twice daily, per oral) and trimetazidine (35 mg twice daily, per oral) in addition to conventional guideline-

directed medical care. All clinical and perioperative data were obtained through the electronic medical record system of the hospital.

Duration of the study

The trial lasted roughly a year. It took 3-4 months for topic-specific planning and research. Data extraction took around a month to include all ICD-10 diagnosis codes. Data collection was estimated to be around 1-2 months, for a period from June 2022 to December 2024.

Study instrument and data collection tool

A structured self-developed data collection form was used to collect demographic characteristics, previous medical history, medications history, current medication, pre-operative care, and other clinical variable including complications, adverse drug reactions or events, readmission record within 3 months, and hemodynamic changes from record files.

Treatment protocol

All patients who received ranolazine or trimetazidine in addition to standard CABG pre-operative care were included in the study. Combination adjunct therapies were initiated immediately at least 2 days before CABG surgery and continued to 3-5 days after surgery (depending on length of stay in the hospital). In emergency CABG procedure, these drugs were immediately administered prior to surgery. Combination adjunctive therapies were not given as discharge medications in any case. The hospital protocol was guided to prescribe (ranolazine and trimetazidine) during hospitalization only.

Data analysis

Data analysis was conducted using Statistical Package for Social Sciences, version 27.0 (SPSS Inc., Chicago, Illinois, USA). The Shapiro-Wilk test was for normality testing. Normally distributed data were presented in mean $\pm$ standard deviation (SD), whereas non-normally distributed variables were presented as median with interquartile range (IQR). Categorical variables were summarized using frequencies and percentages. Although this was a single-cohort study with no comparison group, subgroup analyses were conducted to assess the influence of age, body mass index (BMI), number of grafts and underlying comorbidities on treatment outcomes. Comparative analyses between groups, such as patients who developed post-operation complications and

those who did not, were performed using the student's t-test or Mann-Whitney U test for continuous variables, depending on the data distribution. Categorical variables were compared using Chi-squared test or Fisher's exact test, as applicable. $P < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics

Between June 2022 and December 2024, 230 patients underwent CABG at Burjeel Hospital in Abu Dhabi, United Arab Emirates (UAE), 49 patients did not satisfy the inclusion eligibility requirements, therefore only 181 patients were enrolled in the research study. Mean age was 53.2 ± 7.5 years, majority of the patients were males 174(96.1 %), South Asians (86.7 %), with pre-existing cardiac disease 28(15.5 %; Table 1).

Perioperative characteristics

Majority of the CABGs performed were elective 171(94.5 %) cases. Median number of grafts per patient was 5 (IQR of 4 – 6; Table 2).

Primary and secondary outcomes

During the perioperative period, post-operative complications were observed in 131(72.4 %) patients of which acute post-haemorrhagic anaemia was most prevalent 76 (42 %; Table 3).

Comparison of baseline characteristics with post-operative complications

Age, BMI, HTN, HLD, and cardiac disease were not significantly associated with postoperative complications ($p > 0.05$). Type 2 diabetes mellitus was significantly associated with post-operative complications ($p < 0.05$; Table 4).

Surgical and postoperative complications

Intraoperative factors were done to compare those who developed post-operative complications with those that did not experience postoperative complications. Number of grafts and incidence of readmission were not significantly associated with postoperative complications ($p > 0.05$).

DISCUSSION

Majority of the study population were men, while women comprised a relatively small percentage of the sample group.

Table 1: Baseline characteristics

Characteristic	Sub-item	Total (N = 181)
Age (mean ± SD) years		53.2±7.5 years
BMI (median / IQR)		26.2(23.9-28.3)
Gender	Male (N, %)	174(96.1)
	Female (N, %)	7(3.9)
Ethnicity	African (N, %)	4(2.2)
	American (N, %)	2(1.1)
	Caribbean / Hispanic (N, %)	1(0.6)
	Middle Eastern/Arabic (N, %)	17(9.4)
	South Asian (N, %)	157(86.7)
Comorbidities	Hypertension (HTN; N, %)	155(85.7)
	Hyperlipidemia (HLD; N, %)	146(80.7)
	Pre-Diabetes (Pre-DM; N, %)	2(1.1)
	Type 2 Diabetes Mellitus (DM; N, %)	129(71.3)
	Cardiac Disease (N, %)	28(15.5)
	G6PD Deficiency (N, %)	2(1.1)
	Chronic Kidney Disease (CKD; N, %)	8(4.4)
	Hypothyroidism / Thyroidectomy (N, %)	5(2.8)
	HBV +ve / Hepatitis C (N, %)	2(1.1)
	Benign Prostatic Hyperplasia (BPH)	1(0.6)
	Bronchial Asthma (N, %)	1(0.6)
	Chronic Anemia (N, %)	1(0.6)
	Obstructive Sleep Apnea (OSA)	1(0.6)
	Crohn's Disease (N, %)	1(0.6)
	Schizophrenia (N, %)	1(0.6)
	Systemic Lupus Erythematosus (SLE)	1(0.6)
No Previous Medical History (PMH)		3(1.7)

Body mass index (BMI), Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency, hepatitis B virus (HBV)

Table 2: Perioperative information

Variable	Procedure	Value
CABG performed	Elective CABG (N, %)	171(94.5)
	Urgent CABG (N, %)	10(5.5)
Number of grafts (median, IQR)		5(4–6)
ICU stay (days, median, IQR)		4(4–5)
Total hospital stay (days, median, IQR)		6(6–8)

Interquartile range (IQR), coronary artery bypass grafting (CABG)

Table 3: Frequencies of primary and secondary outcomes

Outcome Category	Frequency (%)
Postoperative Complications	131(72.4)
POAF*	53(29.3)
Infection	55(30.4)
Acute post- hemorrhagic anemia	76(42.0)
AKI*	27(14.9)
No complications reported	50(27.6)
Re-admission (within 3 months)	29(16.0)
Yes	29(16.0)
No	152(84.0)

Post-operative atrial fibrillation (POAF), acute kidney injury (AKI)

Table 4: Comparison of baseline characteristics

Characteristic	Postoperative complications (N = 131)	No postoperative complications (N = 50)	P-value
Age (mean ± SD; years)	53.75±7.70	51.68±6.98	0.099 ^a
BMI (median / IQR)	26(23.9-28.3)	26.7(24.0-28.8)	0.459 ^b
Hypertension (HTN; N, %)	116(74.8)	39(25.2)	0.070 ^c
Hyperlipidemia (HLD; N, %)	108(74.0)	38(26)	0.326 ^c
Diabetes Mellitus (DM; N, %)	100(77.5)	29(22.5)	0.015 ^c
Cardiac Disease (N, %)	23(82.1)	5(17.9)	0.255 ^c

Standard deviation (SD), body mass index (BMI), interquartile range (IQR), ^astudent's t-test, ^bMann Whitney U-test, ^cChi-square test

Table 5: Comparison of surgical and postoperative complications

Variable	Postoperative complications (N = 131)	No postoperative complications (N = 50)	P-value
Number of Grafts (Median/IQR)	5(4-6)	5(5-6)	0.263 ^a
Readmission (N, %)	22(75.9)	7(24.1)	0.647 ^b

Interquartile range (IQR), ^aMann Whitney U-test, ^bChi-square test

Numerous studies demonstrate that ischaemic heart disease (IHDs) is generally less common in females than males except those over 65 years [12,13]. This aligns with this study average age of 53.2 years (± 7.5), which falls within the age distribution in real population. Also, majority of the patients had significant comorbidities (< 70 % had T2DM, HTN, and HLD) which is in tandem with established risk factors for CAD and postoperative complications [14]. Analysis of the primary endpoint revealed that incidence of postoperative complications in this cohort was 72.4 %, which was frequently linked to POAF, infection, AKI and acute post-hemorrhagic anaemia. Incidence of POAF in this study appears to be higher than that reported in general CABG population, it is still comparable with other studies of similar comorbidity, and pharmacological profiles. In a previous study, incidence of a POAF rate post-CABG was higher compared to this current study probably due to higher prevalence of diabetes and other risk factors [15]. Post-operative atrial fibrillation (POAF) not only increases the health burden of individuals, it is also a predictor of prolonged hospital stay, increased morbidity, and long-term adverse outcomes [16].

Studies has consistently demonstrated that individuals with POAF have a higher risk of stroke and heart failure, emphasizing the therapeutic importance of interventions intended for prevention and management [17]. Although HTN and HLD were very prevalent, neither disease was independently associated with a significant rise in postoperative complications. However, it is established that HTN is a risk for postoperative (CABG) complications [18]. The findings showed that HTN was not significantly associated with postoperative complications. In a previous study, cardiac disease was more common in patients who developed postoperative complications indicating that pre-existing cardiac disorders may increase patients' susceptibility to poor postoperative outcomes and increased complications [18].

Presence of DM is associated with development of postoperative complications as established in various studies and clinical trials [16-19]. It is evident that diabetes impairs wound healing,

increases risk of systemic infection, and alters endothelial function [19]. Recent study has reported that diabetic patients developed higher rates of POAF, infections, AKI, and in-hospital mortality [20]. The study findings are consistent with reports from other studies regarding the influence of pre-existing comorbidities on postoperative complications.

The median number of grafts was five in the group that experienced in-hospital postoperative complications. All study patients had identical overall surgical complexity in term of number of grafts used during CABG procedure. These findings suggested that complexity of surgery in terms of the number of grafts, might not be the primary determinant of development of post-operative complications [21,22]. Similarly, other factors such as patient's comorbidities, intraoperative procedure, preoperative risk profile, and postoperative care are associated with development of poor surgical outcomes to post CABG. This study also suggested that identifying and addressing these significant factors are important for improving patient clinical outcomes and reducing complications after surgical procedure. Another important aspect of the clinical outcomes is the readmission rate, and this study reported significantly lower readmission rates than those reported in other studies conducted among certain Western populations [23-25]. Although, under-reporting of readmission and/or complication in the retrospective study design could be a possible reason. Also, this deviations from the literature could be reflection of the differences in patient demographics, healthcare access, and/or post-operative care pathways. The findings reported no significant difference in re-admission rate among those who experienced postoperative complications compared to those who did not. Possible reason is that postoperative complications were primarily addressed during hospitalization prior to discharge, thus reducing the need or risk for future readmissions. Alternatively, readmission rates might be driven by institutional discharge protocols including strong follow-up strategies, and/or limited observational windows [23]. Complications or adverse effects were high due to delayed follow-up period. It is therefore important to develop

care plan with longer follow-up period which will assist in accurate reporting of post-discharge morbidity/complications. A general 30-days readmission rate post-CABG surgery showed 12 – 20 % depending on population demographics, hospital setting, and pre-existing comorbidities [24,25]. A multicenter clinical study reported the factors influencing the 30-days readmission rate include systemic infection, heart failure, arrhythmias, and recurrent angina [25]. Similar findings are reported in this study, highlighting the importance of optimal discharge plan, extended follow-up duration, and individualize care plans for patients with pre-existing risk factors to improve post-CABG recovery. Other studies have found that diabetes, renal failure, and prior cardiac surgery are strong predictors of readmission [24,25].

Ranolazine and trimetazidine have demonstrated clinical efficacy to minimize ischemia-reperfusion damage and improve clinical outcomes in CAD patients undergoing revascularization [3,5-6]. Several studies have examined both ranolazine and trimetazidine efficacy individually for cardiac procedures. The findings revealed that administering ranolazine preoperatively decreased the incidence of POAF and other ischemic consequences, indicating that it may be a useful adjuvant therapy in CABG patients [7,8]. Similarly, trimetazidine decreased markers of postoperative myocardial damage while improving left ventricular function post-CABG (cardioprotective benefits). More study on the efficacy of these medications are required, particularly as some randomized controlled studies revealed no effect in lowering long-term mortality [6-7,9-10]. Combination of ranolazine and trimetazidine investigated in this study, has not been thoroughly found in the literature. A synergistic combination of these medications may have clinical advantages such as electrophysiologic alteration (ranolazine), and metabolic effects (trimetazidine). This clinical approach may potentially improve myocardial protection and reduce post-operative adverse effects. This study showed no significant difference in postoperative complication rates with/without adjunct therapy. This may be attributed to a number of factors, including retrospective design, small sample size, and potential confounders such as surgical approach and postoperative care.

This study reported high prevalence of comorbidities, including T2DM and HTN, complicating the interpretation and conclusion of the outcomes. *Diabetes mellitus* alone is a significant independent predictor of poor surgical outcomes and is associated with a

proinflammatory state, which may limit preventive effects of the medications used in preoperative care [24,26]. Furthermore, the large male population in this study is considered to mask the clinical outcome, similar to other studies [12]. There were no adverse reactions to ranolazine or trimetazidine during the perioperative hospitalization period. This is consistent with favorable safety profiles observed in other cardiovascular research [27,28]. Even in individuals with several comorbidities and complex surgical profiles, the combination treatment was well tolerated.

Limitations of the study

This study has some limitations. It is a retrospective design that lacked a control group. Thus, the findings may not definitely be attributed solely to ranolazine and trimetazidine. Follow-up was limited only for patients who visited the same hospital. Any complication that may have happened in a different facility and addressed were not accounted for. Furthermore, the follow-up period was short (3 months), and 78 % of the participants were limited to certain nationalities including Indian, Bangladesh and Pakistan. Although the study framework tried to include the number of grafts used to address the severity of coronary disease, medication adherence, perioperative glycemic control, and intraoperative factors may have influenced the outcomes. Very limited number of females underwent CABG during the period of data collection which may have limited gender-based comparison.

CONCLUSION

The study showed that concurrent administration of ranolazine and trimetazidine alongside standard guideline-directed medical treatment in patients who underwent coronary artery bypass graft did not significantly decrease incidence of postoperative complications relative to past control studies. Further, clinical trials are required to thoroughly assess the clinical parameters and long-term readmission follow-up.

DECLARATIONS

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Use of artificial intelligence / large language models

The authors confirm that AI-based tools were used solely for language editing and manuscript

polishing purposes (e.g., grammar, phrasing, and clarity). No AI tools were used to generate content, interpret data, or influence study design, results, or conclusions. All intellectual contributions, study analyses, and interpretations reported in the manuscript are the original work of the authors.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

No conflict of interest is associated with this work.

Contribution of authors

We declare that this work was done by the author(s) named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

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