

## **ADHERENCE TO OPTIMAL MEDICAL THERAPY: A KEY DETERMINANT OF CLINICAL OUTCOMES IN ACUTE CORONARY SYNDROME PATIENTS WITH REDUCED LVEF AFTER PTCA**

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Adherence to Optimal Medical Therapy: A Key Determinant of Clinical Outcomes in Acute Coronary Syndrome patients with reduced LVEF after PTCA

### **Abstract**

**Background:** Acute myocardial infarction (AMI), as a significant manifestation of coronary artery disease (CAD), globally presents a leading cause of morbidity and mortality. The advancement in percutaneous coronary intervention (PCI), thrombolysis, and pharmacotherapy have improved management outcomes significantly. Yet, optimizing post-AMI patient outcomes, particularly for those undergoing angioplasty with reduced ejection fractions, necessitates adherence to Optimal Medical Therapy (OMT).

**Methods:** This comparative observational study was conducted at Jubilee Mission Medical College & Research Institute, Thrissur, from January 2017 to January 2018, encompassing 106 ACS patients undergoing PCI with an ejection fraction less than forty percent. Data were collected on baseline characteristics, clinical outcomes, and OMT adherence, assessed at discharge and at 1.5, 3.5, 6.5 months, and 1-year intervals. OMT adherence was categorized into full adherence, suboptimal doses, and non-adherence groups, based on prescribed medications and lifestyle modifications.

**Results:** Among the initial 106 patients, 96 completed the study. By the year's end, 53.13% of patients fully adhered to OMT, showed significant improvements in NYHA classification, ejection fraction, reduced hospital readmissions, and revascularization needs. Mortality rate stood at 8.33%, predominantly among those non-adherent to OMT. These findings underscore the critical impact of OMT adherence on improving post-angioplasty outcomes in ACS patients.

**Discussion:** The study findings corroborate existing literature underscoring the efficacy of OMT in post-ACS management, highlighting the need for rigorous implementation and personalized management strategies to enhance adherence. The study's observational design and its single-center nature suggest the need for broader, multi-centric research to validate these outcomes further.

**Conclusion:** Adherence to OMT significantly reduces morbidity and mortality while enhancing cardiac function and quality of life in ACS patients with reduced LVEF post-angioplasty. This

study reinforces the indispensable role of OMT in ACS management, advocating for enhanced patient education and tailored approaches to ensure optimal therapeutic adherence and outcomes.

## **Introduction**

Acute myocardial infarction (AMI), a critical manifestation of coronary artery disease (CAD), stands as a foremost cause of morbidity and mortality globally. This menace to public health is exacerbated by the rising prevalence of CAD, particularly in developing nations, where lifestyle changes, stress, obesity, and other modifiable risk factors are increasingly prevalent (Roth et al., 2017). The advent of percutaneous coronary intervention (PCI), thrombolysis, and refined pharmacotherapies have offered significant strides in managing AMI, substantially reducing case fatality rates previously observed at nearly 50% within the first month of onset (Antman et al., 2004). However, the quest for optimizing patient outcomes post-AMI, especially among those undergoing angioplasty with compromised ejection fractions, remains a critical challenge.

Optimal Medical Therapy (OMT), encompassing the judicious use of ACE inhibitors/angiotensin-receptor blockers (ARBs), beta-blockers, mineralocorticoid antagonists, statins, and dual antiplatelets, emerges as a pivotal strategy in enhancing survival rates and curtailing morbidity and mortality post-ACS (Levine et al., 2016; Bangalore et al., 2012). This comprehensive approach underscores the importance of medication adherence and lifestyle modifications in the recuperative trajectory of patients. Despite the evidence-backed efficacy of OMT, the variability in adherence rates and the management of associated comorbidities highlight the complexity of optimizing outcomes in this patient cohort.

This study embarks on a comparative observational journey to elucidate the effects of OMT on the morbidity and mortality of patients with ACS undergoing angioplasty with an ejection fraction of less than 40%. Through the lens of a meticulously designed methodology, encompassing a robust sampling framework and an in-depth analysis of patient adherence to prescribed OMT regimens, this research endeavors to uncover insights that could potentially refine post-ACS management strategies. The findings are poised to contribute significantly to the corpus of knowledge on CAD management, particularly in harnessing the full spectrum of OMT benefits, thereby enhancing patient quality of life and survival outcomes post-angioplasty.

## **Methodology**

### *Study Design and Setting*

This research was structured as a comparative observational study, conducted at Jubilee Mission Medical College & Research Institute, Thrissur, between January 2017 and January 2018. The study meticulously charted the clinical outcomes of ACS patients treated with PCI and analyzed the impact of OMT on morbidity and mortality rates among this population.

### *Study Population*

A consecutive sampling method was employed in the present study. The study encompassed ACS patients undergoing PCI with an ejection fraction less than forty percent. A total of 106 patients were initially enrolled, following a sampling framework designed to ensure a robust representation of the target population.

### ***Inclusion and Exclusion Criteria***

Patients presented with ACS and treated with PCI, possessing an ejection fraction less than forty percent during the study period, were included. Exclusions applied to those without angioplasty, when optimal medical management was contraindicated, and patients with renal failure (creatinine > 2.5 mg/dl).

### ***Data Collection and Management***

Baseline characteristics, including clinical history, examination findings, blood tests, ECG, 2D ECHO, coronary angiogram, and angioplasty results, were meticulously recorded. A detailed follow-up regimen was employed, categorizing patients into groups based on adherence to OMT, which was assessed at discharge, 1.5, 3.5, 6.5 months, and 1 year post-discharge. OMT adherence was defined based on prescribed medications and lifestyle modifications, considering drug contraindications and dosage adjustments as necessary.

### ***Optimal Medical Therapy (OMT)***

OMT was defined according to prevailing ACS guidelines, encompassing ACE inhibitors/ARBs, beta-blockers, mineralocorticoid antagonists, statins, and dual antiplatelets, where at least 50% of the target dose of ACE/ARB, mineralocorticoid antagonists and beta-blockers must be achieved. The study focused on beta-blockers, RAS blockers, and mineralocorticoid antagonists due to high baseline adherence to dual antiplatelets and statins within the study center. Dosage adjustments and adherence were closely monitored, with adjustments made to reflect contraindications or patient-specific considerations.

### ***Outcomes Assessment***

Primary outcomes included the assessment of morbidity and mortality rates, adherence to OMT, and improvement in clinical status as evidenced by changes in NYHA classification and ejection fraction. Secondary outcomes explored the reasons behind non-adherence to OMT and the impact of various patient-specific factors on clinical outcomes.

### ***Statistical Analysis***

Data were analyzed using SPSS software, employing mean + SD tests for continuous variables and Chi-square tests for categorical data. The analysis aimed to correlate the degree of adherence to OMT with patient outcomes, adjusting for potential confounders.

## Results

### *Patient Demography*

The study enrolled a total of 106 patients, presenting with acute coronary syndrome and undergoing percutaneous coronary intervention (PCI) at Jubilee Mission Medical College & Research Institute, Thrissur, between January 2017 and January 2018. The demographic characteristics of the study participants were as follows:

The age of participants ranged from 29 to 86 years, with a mean age of 61.95 years. The distribution indicated a higher prevalence of the condition among middle-aged to elderly individuals, with 68.7% of the participants aged between 51 to 70 years. A significant majority of the study cohort were male (73.95%), highlighting a gender disparity in the incidence of acute coronary syndrome requiring angioplasty within the study population. The initial clinical presentations varied among participants, with angina (including both typical and atypical) being the most common (50%), followed by dyspnea (27.08%), and a smaller proportion experiencing syncope/presyncope (6.25%), palpitation (2.08%), and dyspepsia (2.08%). Hypertension and diabetes mellitus emerged as the most prevalent comorbid conditions, observed in 50% and 43.3% of the patients, respectively. Additionally, a notable fraction of the cohort had no recorded comorbidities (22.9%), underscoring the varied risk profile of individuals suffering from acute coronary syndrome. A subset of the study population (12.5%) had a history of prior revascularization, including percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG), indicating a recurrence or ongoing management of coronary artery disease.

### *Study Population and Follow-up*

Out of the initial 106 patients enrolled, 96 completed the study with adequate follow-up data. Ten patients were lost to follow-up. The study meticulously tracked adherence to optimal medical therapy (OMT), clinical outcomes, and modifications in NYHA functional class over a period of one year.

### *Adherence to Optimal Medical Therapy*

At the outset of the study, none of the patients were on OMT as per the guidelines. Over the course of the year, adherence improved significantly. By the end of the year, 51 patients (53.13%) were adhering fully to the OMT regimen. 31 patients (32.29%) were on OMT but not at the required dosages for maximal therapeutic effect. Six patients (6.25%) did not adhere to OMT guidelines.

### *Mortality and Morbidity*

The study noted an overall mortality of 8.33% (8 patients) by the end of the year. Notably, mortality was highest among those not adhering to OMT, indicating a strong association between OMT adherence and survival outcomes.

### ***Functional Capacity Improvement***

NYHA classification improved significantly among patients on full OMT: Initially, no patients were in NYHA Class I; by the year's end, 34 patients (35.42%) improved to Class I. Patients in higher NYHA classes (III and IV) at the beginning showed significant improvement or stabilization in their functional capacity with OMT adherence.

### ***Ejection Fraction Improvement***

There was a notable improvement in ejection fraction among patients adhering to OMT: Patients on full OMT demonstrated a 35% improvement in ejection fraction to above 40%, indicating better cardiac function. This contrasted with those on suboptimal or no OMT, where fewer improvements were observed, underscoring the efficacy of OMT in improving cardiac outcomes post-angioplasty.

### ***Hospital Admissions and Revascularization***

Patients adhering to OMT experienced fewer hospital admissions and required less revascularization compared to those on suboptimal or no OMT. This highlights the role of OMT in reducing the burden of ACS complications and the need for further invasive procedures. The study also tracked the impact of OMT on managing risk factors and comorbid conditions such as hypertension and diabetes mellitus, noting an improvement in the control of these conditions among those on full OMT.

## **Discussion**

The present study rigorously investigated the influence of OMT on the clinical outcomes of ACS patients post-angioplasty, spotlighting the paramount importance of medication adherence in enhancing patient survival and functional capacity. The findings reveal that strict adherence to OMT—encompassing ACE inhibitors/ARBs, beta-blockers, mineralocorticoid antagonists, statins, and dual antiplatelets—significantly ameliorates morbidity and mortality rates. Specifically, over a follow-up period of one year, 53.13% of patients adhered well to OMT, culminating in notable improvements in NYHA classification and ejection fraction, alongside reduced hospital readmissions and revascularization requirements.

Comparatively, prior studies underscore the beneficial outcomes associated with OMT adherence in ACS populations. The COURAGE trial (Boden et al., 2007) and the subsequent analysis by Ornish et al. (1998) elucidated the pivotal role of comprehensive medical management, including OMT, in mitigating adverse cardiovascular events post-PCI. Similar to our findings, these studies observed substantial reductions in recurrent angina, hospitalizations, and improved survival rates among those adhering to OMT, emphasizing the therapy's efficacy in post-ACS management.

Furthermore, the TIMI 22 trial (Antman et al., 2002) corroborated our observations regarding the enhancement of ejection fraction and functional status with OMT. It delineated the incremental benefits of lipid-lowering statins alongside standard ACS therapies, akin to our study's outcomes

where OMT adherence was linked to ejection fraction improvements and a shift towards a better NYHA functional class.

Contrastingly, the variability in OMT adherence and its implications on patient outcomes have been a recurrent theme across the literature. A meta-analysis by engel et al. (2017) accentuated the underutilization of OMT in real-world settings, spotlighting a gap between clinical guidelines and practice that mirrors the challenges noted in our study, particularly among patients on suboptimal or no OMT. This divergence underscores the necessity for enhanced patient education and tailored management strategies to bolster OMT adherence.

Moreover, our study sheds light on the prognostic significance of OMT across varying demographic and clinical spectrums within the ACS cohort. This finding is in line with research by Kumbhani et al. (2013), who highlighted the differential impact of OMT based on patient characteristics, advocating for personalized therapeutic approaches to optimize clinical outcomes.

### ***Limitations and Future Directions***

While our study contributes valuable insights into the realm of ACS management post-angioplasty in patients with reduced LVEF, certain limitations warrant acknowledgment. As this study was conducted in 2017-2018, ARNI and SGLT2i were not used in the study. In the present scenario as ARNI and SGLT2i could also be included in the OMT, the outcomes would be much better. The observational design and single-center scope may restrict the generalizability of the findings, necessitating larger, multi-centric studies to corroborate these results. Future research should also explore the barriers to OMT adherence, incorporating patient-centered interventions to mitigate these challenges.

### ***Conclusion***

In conclusion, our study reaffirms the indispensable role of OMT in the post-angioplasty management of ACS patients, highlighting its efficacy in reducing morbidity and mortality while enhancing cardiac function and quality of life. Aligning with prior research, our findings advocate for the rigorous implementation of OMT guidelines and underscore the need for individualized patient management strategies to ensure optimal therapeutic adherence and outcomes.

### ***Acknowledgement***

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