# Impact of Multifaceted Intervention on Medication Adherence and Quality of Life of Post -Acute Coronary Syndrome Patients

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**Abstract:**

**Problem:** How does implementing comprehensive patient education and medication support strategies impact medication adherence and the quality of life in patients with Acute Coronary Syndrome. **Approach:** A prospective interventional study with a 6-month duration was conducted among 196 post-ACS patients, in a tertiary care hospital in Malappuram, Kerala state, Indiato evaluate the effectiveness or impact of multifaceted intervention on medication adherence and quality of life among post-ACS patients. **Findings:** No statistically significant difference in medication adherence was found between the intervention and non-intervention groups during follow-up 1 ($p = 0.537$, $Z = 0.772$). However, during follow-up 2, there was a significant difference in medication adherence between the intervention and non-intervention groups ($p = 0.002$, $Z = 0.001$). Significant associations were observed between quality of life in both the interventional ($p = 0.01$, $T = 11.658$) and non-interventional ($p = 0.01$, $T = 11.018$) groups, indicating significant improvements in quality of life in both groups. **Conclusion:** The study found that a multifaceted intervention improved medication adherence and quality of life (QOL) in post-acute coronary syndrome (ACS) patients. Patient counseling and the use of a patient information leaflet (PIL) were effective. Sociodemographic factors did not significantly affect medication adherence. The study also highlighted the positive impact of the intervention on QOL. Overall, the findings suggest that a multifaceted intervention enhances patient knowledge, medication adherence, and QOL in post-ACS patients, by which we can prevent the recurrence of ACS.

***Keywords***: Acute coronary syndrome, Quality of life, Medication adherence, Multifaceted intervention, Medication adherence rating scale, Euroqol-5D-5L scale, Percutaneous coronary intervention,Discharge counseling, Adherence evaluation, Cardiovascular disease.

## Introduction:

Cardiovascular disease is one of the leading causes of death worldwide.(1) Acute coronary syndrome (ACS) is most often caused due to plaque rupture or clot formation in the coronary artery. After the initial coronary event, secondary prevention with pharmacologic therapy can reduce the risk of recurrent events and death.(1)

Within a year, at least half of these individuals with chronic diseases stop taking their medications, frequently without telling their doctor. Medication adherence has become a top public health problem as a result of ongoing non-adherence and attrition.(2)

Health is one of the key facets of overall quality of life, there are other facets as well, such as employment, housing, educational opportunities, and neighborhood.Patients undergoing PCI should have better QOL when their physical distress returns to normal, but they still experience emotional distress, such as anxiety, depression, and low self-esteem.(3)

Pharmacists play a significant role in enhancing medication adherence and reducing rates of mortality and re-admission to hospital by performing medication reconciliation and tailoring, and patient education. Acute coronary syndrome (ACS) secondary prevention medication adherence is dismally low, with estimates ranging from 40 to 75 percent. Low adherence is caused by a variety of causes, including as low motivation, forgetfulness, lack of drug knowledge, the complex polypharmacy of ACS regimens, fear of negative side effects, and insufficient practical support. Non-adherence is linked to a higher risk of cardiovascular mortality, hospitalizations for cardiovascular conditions, coronary revascularization surgeries, and higher cost. Hence this study is having significance in current scenario to improve medication adherence and quality of life.(4)

To increase medication adherence and quality of life, the study employs a multifaceted intervention strategy. This method uses a number of techniques, including patient education, prescription reminders, follow-up calls, and individual therapy. Using a multifaceted approach is essential, as adherence is a complex issue, and a single intervention may not be effective.Overall, by addressing the crucial issue of medication adherence via a multifaceted intervention method, the study has the potential to enhance the health outcomes of post-ACS patients.

**Methodology:**

This was a single Centre, prospective interventional study that was conducted for a duration of six months among patients of cardiology department of a tertiary care hospital. The study was conducted in KIMS AL- Shifa super specialty hospital situated at Perinthalmannain Malappuram district of Kerala. The study protocol was approved by the Research Ethics Committee of the hospital (KAS:ADM: IEC: 0440:23). Adult patient18 years or older admitted to cardiology department with primary diagnosis of ACS were included in the study. Both male and female patients were selected. Patient who are unable to identify their own medications, having cognitive impairment and Patient died while admitted in hospital were excluded from the study. The sample was calculated and found to be 98 for each interventional and non-interventional group by using student t-test. In this, 3 patients were dropped out of study from control group.

**Data collection:**

A proper data collection form was designed to identify potential patients according to the study's inclusion and exclusion criteria. Eligible patients were requested to provide consent for the study and

were made aware of the study objectives. Once written consent was obtained, patients were interviewed and their charts was reviewed and data recorded in a standardized data collection form. The sample was divided into two groups interventional and non-interventional group,the interventional group received multifaceted intervention with counselling session.On the other hand, the control group received usual care without theintervention. Each patient, or a family member were surveyed (if the patient was unavailable), after discharge to collect data on medication use, readmission to hospital, and death. Telephone calls to the patients was placed between 28 and 35 days after discharge for the 30-day follow-up and between 8 to 10 weeks after discharge for 60-day follow up. At least 3 attempts were made to contact the patient. The obtained data were recorded on paper forms and wereanalyzed.

The study was conducted in four major phases;

In phase 1 (Data collection) In this study, data were collected to evaluate the effects of the intervention on the study participants. The collected data were pertinent to the research questions and objectives and were obtained through dependable and valid methods. Commonly employed data collection methods in this prospective interventional study included the use of medical records, surveys, questionnaires, and interviews.

In phase 2 (providing intervention) The intervention group received a multifaceted intervention aimed at enhancing medication adherence and improving the quality of life. The intervention was comprised of three key components: medication counselling, patient information leaflets, and follow-up phone calls. Medication counselling involved a thorough review of the patient's medication regimen along with education on the significance of adhering to the prescribed medication. This session also addressed any queries or concerns the patient had about their medications, providing information on potential side effects and interactions. Patient information leaflets were also provided, containing comprehensive details about the disease, medications, and recommended lifestyle modifications. These leaflets included specific information about the medications the patient was taking and the designated timing for their intake.

In Phase-3 (Evaluation of medication adherence and quality of life after one month of patient discharge).Assessed medication adherence and quality of life in both interventional and non-interventional group after one month of discharge. Medication adherence and quality of life was assessed during the follow up period of the patient and in instance where direct interview of patient is not possible telephonic calls were made to collect medication adherence and quality of life status of patient.Medication adherence was assessed using Medication Adherence Rating Scale and Quality of life was assessed by using EuroQol 5 Dimension 5 Level Scale (EQ-5D-5L).

Phase-4: - (Evaluation of medication adherence and quality of life after two month of patient discharge). Here, medication adherence and quality of life were evaluated in both the interventional and non-interventional (control) groups. Medication adherence was assessed using medication adherence rating

scale (MARS) and Quality of life was assessed using the EuroQol five-dimensional 5-level questionnaire (EQ-5D-5L).

The medication adherence and quality of life data were collected and analyzed from both the interventional and non-interventional groups. Statistical tests were used to compare the differences in medication adherence and quality of life between the two groups at each time point. The purpose of this evaluation was to determine whether the multifaceted intervention was effective in improving medication adherence and quality of life among post-acute coronary syndrome patients, and to compare the outcomes in the interventional and non-interventional groups.

Data analysis was performed using R software or SPSS version 22. Quantitative variable was expressed as mean and standard deviation. Qualitative variable was expressed as frequency and percentage.

**Results:**

Among 196 patients,in the case group of (n=98), the highest number of cases observed with ACS was in the 60-69 age group, with a total of 42 patients (42.86%). In the control group of (n=98), the age group with the highest number of controls with ACS was 50-59, with a total of 37 patients (37.76%). The gender-wise distribution of the patients indicates that in both the interventional and non-interventional groups, the highest number of cases of acute coronary syndrome (ACS) was observed among the male population, with a total of 75 patients (75.76%) and 71 patients (74.1%), respectively.Thelowest number of cases and controls were found in the female population, with 23 patients (23.46%) and 25 patients (25.3%) respectively.Unemployed patients contributed to most of case group with a total of 50 patients,(51.02%) and control group 57 patients (57.9%) respectively.Marital status showed majority of populations were married in both in case and control groups with 97 patients (98.98 %) and 87 patients (91.6 %) respectively. Education wise distribution showed thatmajority of the patients completed only primary education in case and control groups with 36 patients (36.73 %) and 43 patients (45.3 %), while only 28 patients (28.57 %) in the case group and 12 patients (12.6 %) in the control group completed post-secondary education. Number of comorbidities showed that majority of patients had atleast 2 comorbidities in both case and control group having 42 patients (42.86 %) in case group and 44 patients (46.3 %) in the control group.Number of cardiac risk factors also showed that majority of patients diagnosed with ACS had at least 2 cardiac risk factorswith 47 patients (47.96 %) and 48 patients (50.5 %) in the case group and control group respectively.Diagnosis wise distribution showed that in the case group 59.18% were diagnosed with NSTEMI, followed by 30.61 % diagnosed with STEMI and 10.20 % diagnosed with unstable angina. While in the control majority population was also diagnosed with NSTEMI with 48.4 %, followed by 32.6 % with STEMI and 18.9 % diagnosed with unstable angina.Distribution of Insurance coverage among theACS patients showed that majority of the patients enrolled in the study were uninsured in both case and control groups having 62.24 % in case group and 62.1 % in control group respectively. While insured population were less having 37.75 % in case group and 37.9 % in the control group.In the case group, the number of medications at discharge indicated that the majority of patients were discharged with at least 8 medications, accounting for 30.6%. Similarly, in

the control group, the majority of patients were discharged with 8 medications, representing approximately 20%.

Impact ofinterventions on medication adherence in case group compared to control group when statistically analyzed showed that using Pearson chi-square test, there was no significant differences in medication adherence in case and control group in follow up-1.In follow up-2 showed a significant difference in medication adherence in case and control groups (P= 0.002).Impact of interventions on quality of life in case group compared to control group when statistically analyzedusing paired T-test showed that there was a significant difference in quality of life in case group infollow-up-1 and follow up-2 (P= 0.001).

**Discussion:**

Medication adherence significantly impacts therapeutic outcomes, especially in chronic illnesses. Poor adherence reduces treatment benefits and burdens patients and healthcare systems. Cardio protective drug adherence is challenging in managing ACS, as poor adherence may worsen the disease, cause death, and may increase healthcare costs.Pharmacist-led interventions increased patient adherence to medication regimens by over 13% in the first 3 months after ACS hospital discharge, but not quality of life, mortality and readmission.(4)

A total of 196 post-ACS patients were included in this prospective interventional study. Of these 196 patients 98 patients were randomly assigned to case group (interventional group) and control group (non-interventional group). In this, 3 patients were dropped out of study from control group.

The study assessed the impact of multifaceted interventions such as patient counseling, Patient Information leaflet (PIL), Telephone based calls and reminders on the knowledgeand adherence to cardio protective drug therapy. Models that can enhance patient care have qualities that can help patients in other domains in an era where telemedicine has grown more significant.(5)

The majority (42.86%) of patients in the case group were 60-69 years old, whilein the control group majority (37.76%) were 50-59 years old, with a minority under 30.

The study found that most of ACS patients were men when compared to women. Men had a higher prevalence of major ACS etiologies, such as comorbidities and cardiac risk factors, which may contribute to the higher incidence. The results are comparable to Thang Nguyen et al.'s research.(4)

ACS patients in case (51.02% unemployed,17.34% employed) and control patients (56.12% unemployed, 13.27% employed) may have sedentary lifestyles, potentially predisposing them to cardiac illnesses.

Primary education was prevalent while secondary and higher education were least prevalent. Patients with higher education had a lower ACS incidence, while those with lower education had a higher one.Study shows that most of case and control group members were married. In both groups majority of patients were presented with at least 2 comorbidities and cardiac risk factors. According to the

distribution, patients with no comorbidities are less likely to experience cardiac diseases than patients with at least two comorbidities.NSTEMI was the most common diagnosis for patients in the study .(4)

62.2% of patients in the case group had no social health insurance, while 37.8% did. This suggests that one-third of patients use insurance to overcome financial difficulties, potentially improving medication adherence.The study shows 30.6% of patients in the case group were discharged with 7 medications, while 21.1% in the control group were discharged with 6 medications.

The findings matched with research done in Vietnam by Nguyen T et al, the median age (SD) was 61.2 (9.6) years, men made up 72.3% of the population, and 84.3% of the population had social health insurance. Non-ST-segment elevation ACS was the most common discharge diagnosis for patients (75.3%), along with more than two comorbidities (53.6%). (4)

The MARS scale, a 10-item self-reporting instrument, measures medication adherence in three ways: behavior, attitude, unfavorable side effects and attitude towards psychiatric medication. (6)(7). Self-reported adherence measurement is still often used in medication adherence intervention research despite the possibility that it overstates genuine adherence (Szeto & Giles, 1997).(8)

The study found no significant difference in medication adherence between the interventional and non-interventional groups during the initial follow-up. The intervention may need longer time to develop and may have similar adherence patterns to the non-interventional group due to common healthcare practitioner recommendations or individual dedication. Self-reported adherence rates remained high in both groups, consistent with previous pharmacy-led programs showing no improvement in adherence to cardiac medication.(9)The study found a significant association between medication adherence in interventional and non-interventional groups in the second follow-up. The intervention may have improved adherence through encouragement, support, and reminders. Intervention-specific features like teaching materials and customized support may have increased adherence. Another study found that clinical pharmacist intervention among rural residents significantly improved medication adherence and QOL while also raising awareness of the condition and its management.(10) In a PRIMA ACS study, hospital pharmacist' discharge medication counseling intervention did not result in better medication adherence in a patient cohort that had high medication adherence at one year.(1)

The investigation found no significant relationship between medication adherence and age in interventional and non-interventional groups. This may be due to the sample being primarily of one age group and considering Kerala's culture, where patients receive assistance from loved ones.Patients who had very good or exceptional health status were much less likely than those with "good" health status to be non-compliant, while younger patients were more likely to be non-compliant.(11) The study found no significant association between discharge medication quantity and medication adherence in interventional and non-interventional groups. Complexity of medication regimens, frequency of dosing, scheduling, and precise instructions can affect adherence. Low drug adherence is linked to polypharmacy, daily doses, and regimen complexity. Long-term medication use is a strong indicator of high

adherence.(12) In all circumstances, the effects of all additional therapy-related parameters (therapy duration, number of tablets, frequency of intake, ingestion during meals) were unclear.(13)

The study found no significant association between patient educational status and medication adherence. Health literacy levels vary among groups, including understanding medical information and adhering to directions. Higher education levels are significantly correlated with medication adherence.According to research from Jordan (2015), a patient's level of education affects how well they take their medications.(14) The results suggest no connection between comorbidities and medication adherence in interventional and non-interventional groups. Successful comorbidity management treatments may have contributed to adherence. Effective treatment, adequate medication administration, and healthcare support are crucial for enhancing adherence.Strong and efficient patient education is necessary for hypertensive patients with CVA in order to obtain good adherence.(15)The study's both group indicate no evidence of a significant association between patient gender and medication adherence . Demographics and medical conditions of the study population may have had an impact on the lack of significant association between gender and medication adherence. The effect of gender on medication adherence might be significant if the sample contained a very well distributed mix of people who were both male and female and shared similar features.Between men and women with ACS, there are no variations in adherence to beta-blockers, ACEIs/ARBs, or antiplatelet drugs,research by Sophie H. Bots et al.(16)The study found no association between diagnosis and medication adherence in both groups. Participants were treated using similar or successful regimens, and similar levels of adherence could be achieved with similar prescription regimens, monitoring, and support.Duration of disease was the only disease-related factor.(13) In both the interventional and non-interventional groups, the study did not find a correlation between marital status and medication adherence.Medication adherence can be influenced by social support from family, friends, or caregivers. Access to support systems beyond marital status could minimize the impact. The patient's mental health, such as depression or being single, appears to be linked to a higher chance of non-adherence.(17) In the interventional group, the study discovered a statistically significant association between patient job status and medication adherence, but no such relationship was detected in the non-interventional group.The interventional group's multifaceted interventions may have addressed medication adherence difficulties, while the non-interventional group did not receive special support or treatments. Costs prevent many Canadians from taking their prescription prescriptions as prescribed, especially those with poor incomes, illnesses, or no insurance.(18)Individuals newly treated for hypertension are at increased risk for both death and hospitalization due to CVD due to poor medication adherence and low family revenue, but those at increased risk are more likely to have low income.(19) The study found no correlation between cardiac risk factors and medication compliance in interventional and control groups. Participants managed risk factors using similar treatment approaches, possibly due to similar medication regimens, monitoring, and support.According to this study, there is no connection between patients' access to social health insurance and medication adherence in both groups. Even while social health insurance can help pay for medical treatments, there are other factors besides just access to medication that affect how well people take their medications. Lower levels of education, immigration status, and unsatisfactory care transitions

have all been identified as common obstacles to clopidogrel adherence.(17) Costs/affordability and lack of availability at the pharmacy were the most often mentioned factors for medication non-compliance.(11) It is uncertain whether patients with chronic or cardiovascular illnesses' adherence is affected by their health insurance status (whether they are insured or not).(13)

The EQ-5D tools, with three variants: EQ-5D-5L, EQ-5D-3L, and EQ-5D-Y, are used to evaluate health in various situations. With over 25 years of experience, they are valid, reliable, and responsive in various diseases and populations. This study assessed quality-of-life improvements attributed to the intervention using the EQ-5D-5L version.The study found no significant correlation between patient quality of life at the first follow-up in interventional or control groups. The intervention timetable required a month for significant changes, but it may take longer for benefits to become apparent. The subjective measure of quality of life may differ from person to person, making it difficult to find a consistent link with initial follow-up. After being discharged from the hospital, patients with ACS showed increased adherence to cardio protective medicine, but not to quality of life, mortality, or readmission to the hospital.(4)The study found a significant association between second follow-up and patient quality of life in interventional and non-interventional groups. Patients can rate their experiences and improve self-awareness during the second follow-up interview, resulting in more accurate and comprehensive reporting of quality-of-life outcomes.Patients may have encountered numerous outside influences and life events over time, which could have an impact on their quality of life. The second follow-up interview captures these modifications and offers a more thorough evaluation of the results in terms of quality of life. A study found that all patients showed a favorable trend towards QOL improvement, with female patients showing a higher rate of improvement than male patients.(20)

The study had a relatively small sample size, with only 196 post-ACS patients included. This may limit the generalizability of the findings to a larger population. The study had a relatively short follow-up period of six months. Longer-term follow-up would be beneficial to assess the sustainability of the intervention's effects on medication adherence and patient outcomes.The assessment of medication adherence and quality of life relied on self-reporting questionnaires, such as the MARS scale and EQ-5D-5L. Self-reported measures may be subject to recall bias and may not always accurately reflect the actual behavior or experiences of the patients.The study was conducted in a single cardiology department of a multispecialty hospital in Perinthalmanna. The findings may not be applicable to different healthcare settings or regions, where patient characteristics, access to healthcare, and cultural factors may differ. The study was conducted in a specific geographic region and cultural context. The findings may not be generalizable to other populations with different sociodemographic characteristics, healthcare systems, or cultural norms.

The strengths of the study were, the study used tools like MARS and EQ-5D-5L for assessing medication adherence and quality of life respectively.Patient information leafletswere provided along with patient counseling.Interventions provided helped to improve medication adherence and quality of life.The study adds to existing knowledge and emphasizes the importance of multifaceted approaches to improve medication adherence in post-ACS patients.

**Table: 1 Demographic Details**

**Table: 2Impact of intervention on medication adherence in case group compared to medication adherence in control group.**

**Table: 3 Impact of intervention on quality of life in case group compared to control group.**

## Conclusion

The study found that multifaceted intervention, including patient counseling and the use of a patient information leaflet (PIL), improve medication adherence and quality of life (QOL) in post-acute coronary syndrome (ACS) patients. The intervention had a positive impact on medication adherence and QOL, as compared to a non-intervention group.The study results did not identify any significant associations between patient sociodemographic characteristics (age, gender, education, marital status) and medication adherence. The findings of the study indicate that there is a significant correlation between the patient's employment status and medication adherence in the interventional group, while no such relationship exists in the non-interventional group Factors like co-pays, the number of medications, and cardiac risk factors did not strongly influence medication adherence either.Patients, particularly those who have undergone percutaneous coronary intervention (PCI), should receive counseling, a patient information leaflet, and other suitable interventions to support their adherence to medications and lifestyle modifications.

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**Figures:**

**Figure: 1 Flow chart of the study**

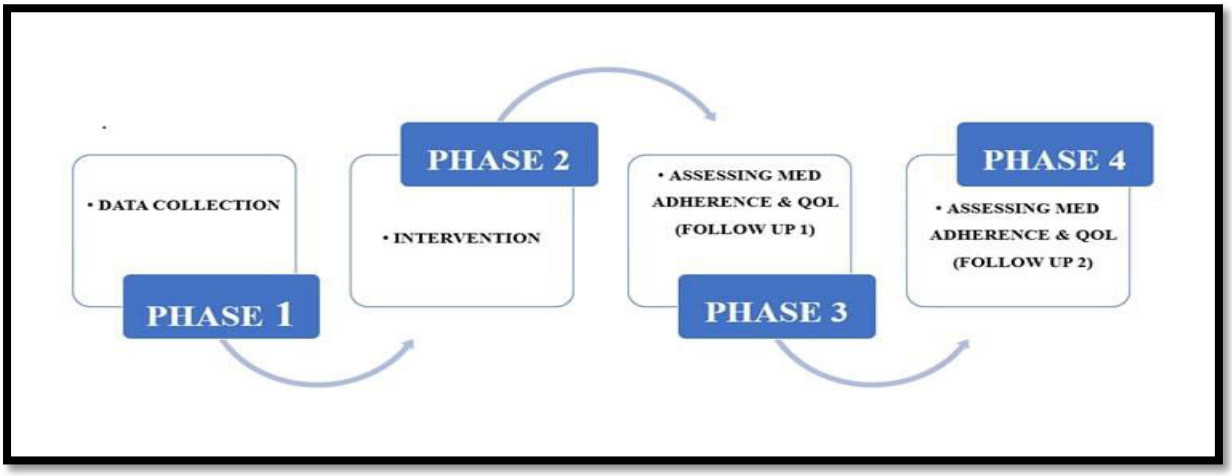


**Figure: 2 Age-wise distribution**

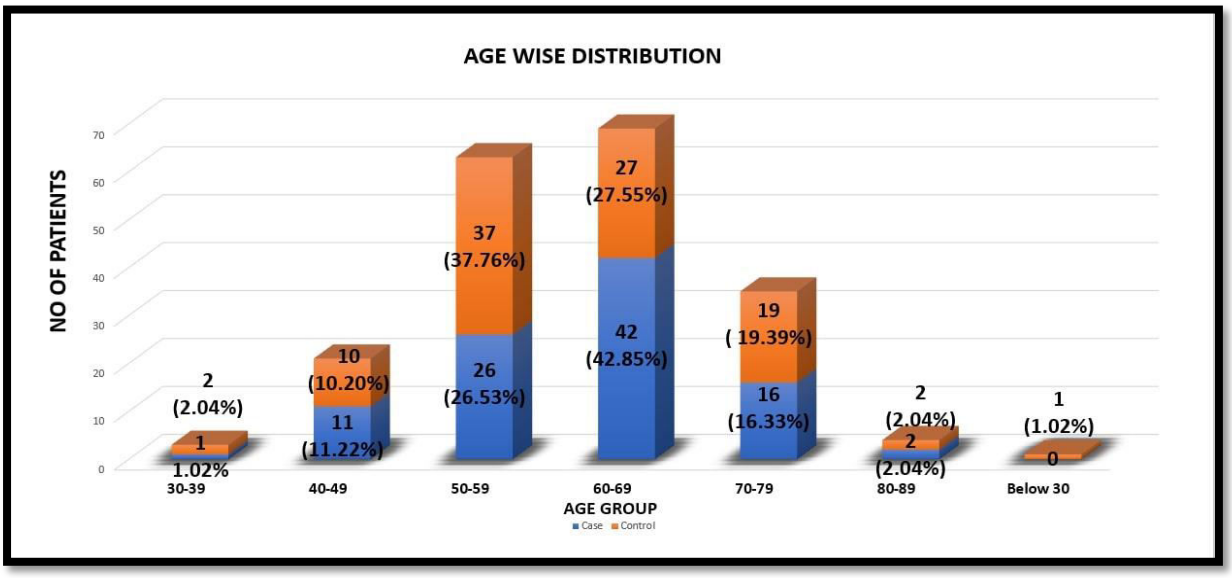

**Figure:3 Gender wise distribution**

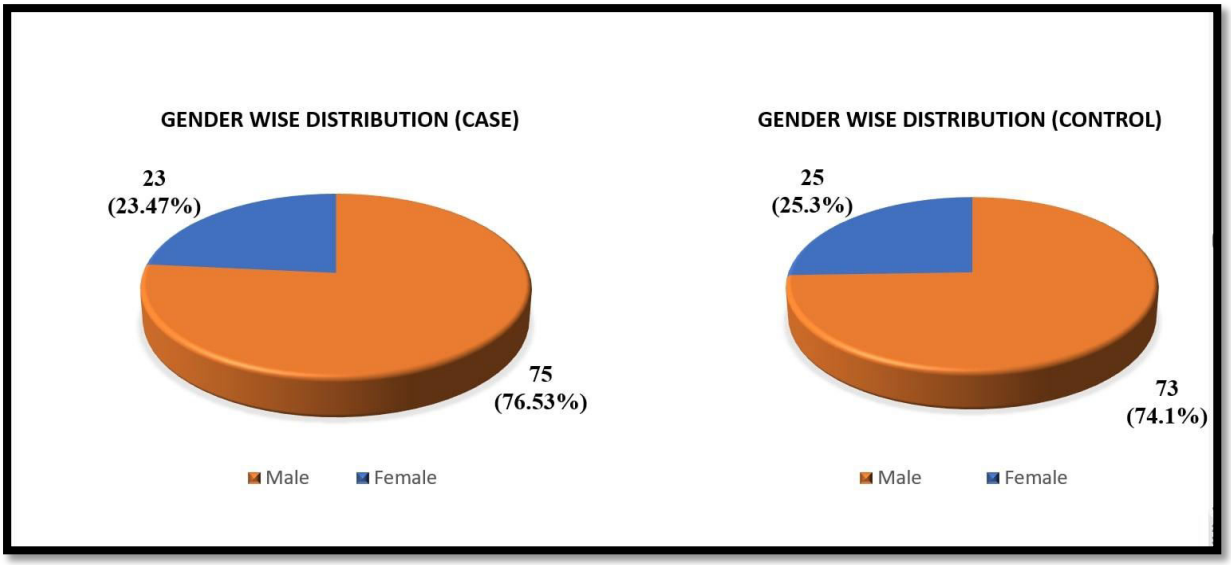


**Figure: 4 Diagnosis-wise distribution**

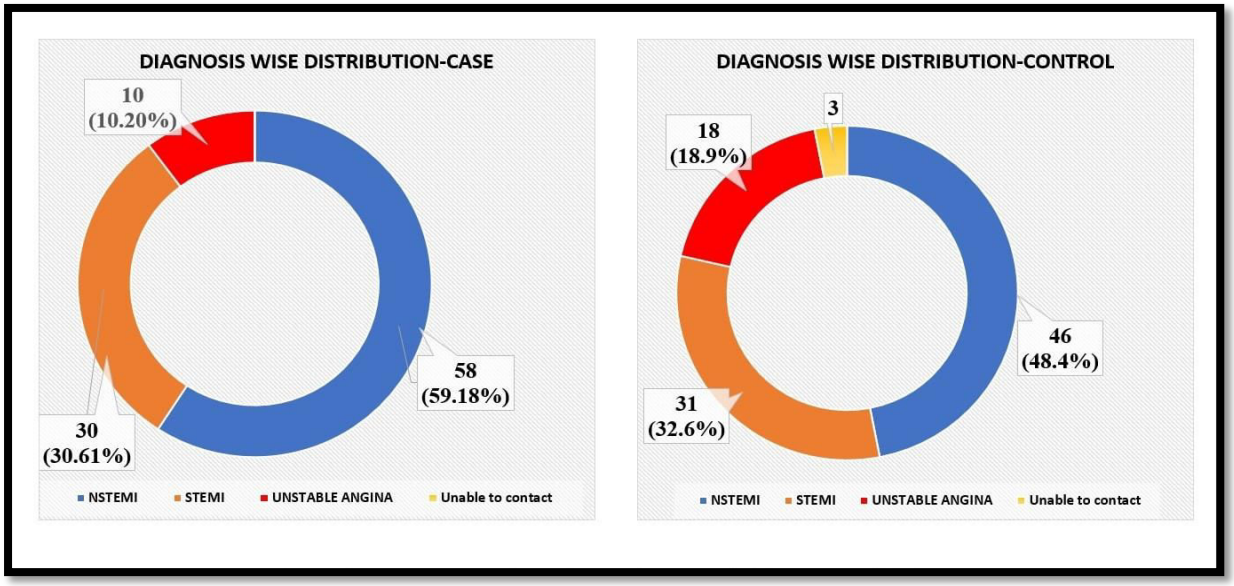

**Figure: 5Impact of intervention on medication adherence in case group compared to control group**

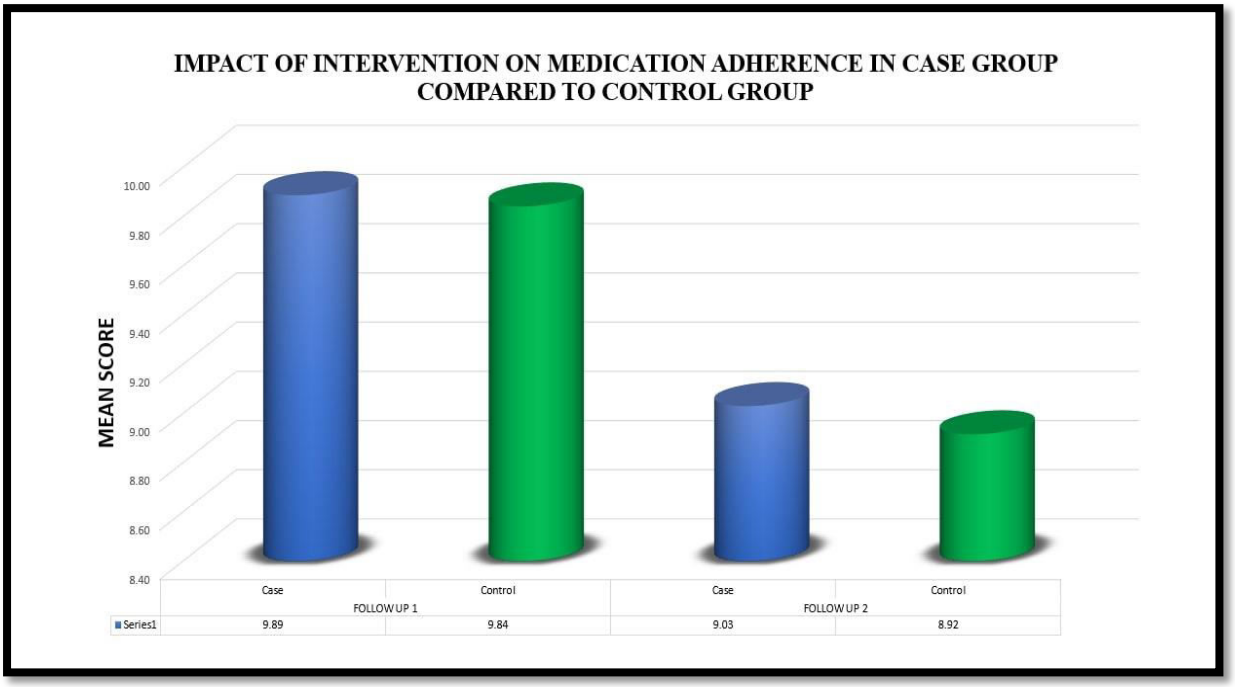


**Figure: 6Impact of intervention on quality of life in case group compared to control group**

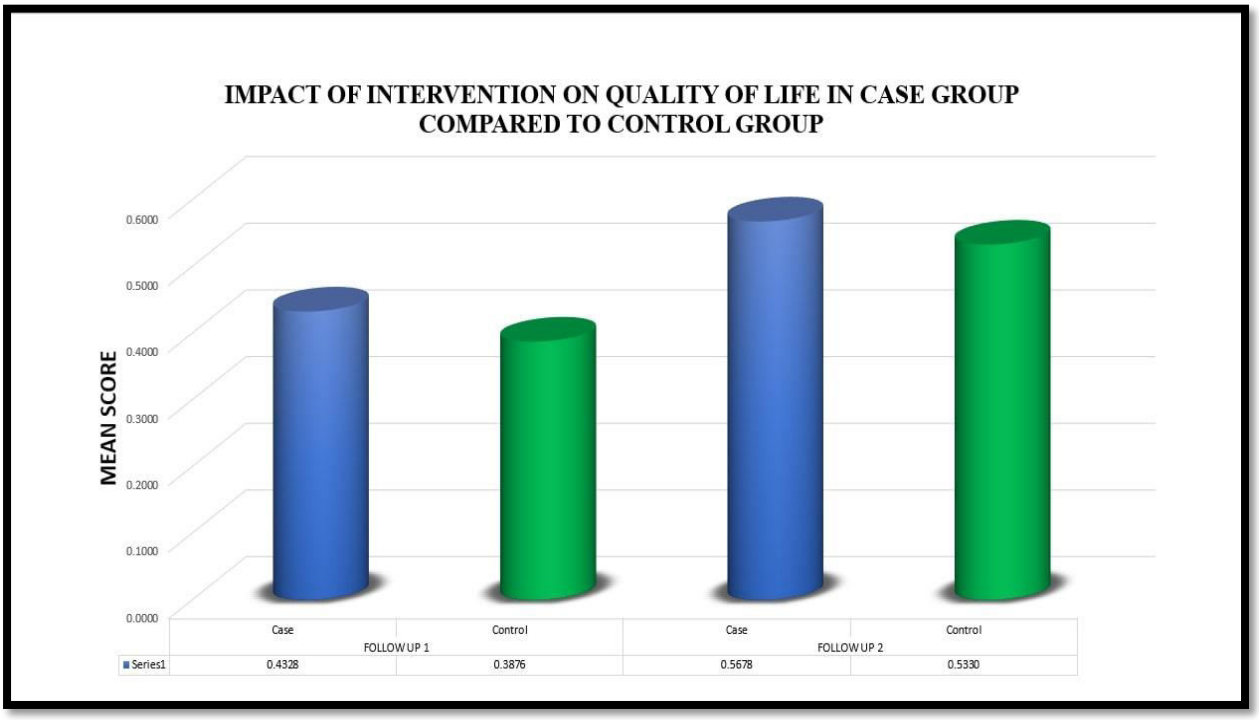

**Table: 1 Demographic Details**

| Demographic details | | | |
|---|---|---|---|
| Employment Status | Employed | 17.34 % | 13.7 % |
| | Self Employed | 31.63 % | 28.4 % |
| | Unemployed | 51.02 % | 57.9 % |
| | | | |
| Marital Status | Married | 98.98 % | 91.6 % |
| | Single | 1.02 % | 2.1 % |
| | Widow/Widower | 0 % | 6.3 % |
| | | | |
| Education | Grade 10 Or Less | 36.73 % | 45.3 % |
| | Higher Secondary | 28.57 % | 33.7 % |
| | Post Secondary | 28.57 % | 12.6 % |
| | No Response | 6.12 % | 8.4 % |
| | | | |
| Insurance | Insured | 37.75 % | 37.9 % |
| | Uninsured | 62.24 % | 62.1 % |
| | | | |
| No of Comorbidities | No Comorbidities | 3.06 % | 1.1 % |
| | At least 1 Comorbidity | 8.16 % | 15.8 % |
| | At least 2 Comorbidities | 42.86 % | 46.3 % |
| | At least 3 Comorbidities | 32.65 % | 28.4 % |
| | At least 4 Comorbidities | 13.27 % | 7.4 % |
| | At least 5 Comorbidities | 0 % | 1.1 % |

| | | | |
|---|---|---|---|
| No of Cardiac Risk Factors | No Cardiac risk factors | 0 % | 3.06 % |
| | At least 1 Cardiac risk factor | 12.24 % | 15.8 % |
| | At least 2 Cardiac risk factors | 47.96 % | 50.5 % |
| | At least 3 Cardiac risk factors | 29.59 % | 28.4 % |
| | At least 4 Cardiac risk factors | 6.12 % | 5.3 % |
| | At least 5 Cardiac risk factors | 0 % | 1 % |
| | | | |
| No of Medications on Discharge | 4 | 1.1 % | 1.1 % |
| | 5 | 6.12 % | 8.4 % |
| | 6 | 10.20 % | 12.6 % |
| | 7 | 16.33 % | 21.1 % |
| | 8 | 30.6 % | 20 % |
| | 9 | 8.4 % | 10.5 % |
| | 10 | 14.28 % | 8.4 % |
| | 11 | 7.14 % | 4.2 % |
| | 12 | 5.10 % | 7.4 % |
| | 13 | 1.02 % | 6.3 % |

| Chi-Square Tests | | | | | | |
|---|---|---|---|---|---|---|
| Follow up | | Value | df | Asymptotic Significance (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
| 1.00 | Pearson Chi-Square | .772[c] | 1 | 0.380 | | |
| | Continuity Correction[b] | 0.323 | 1 | 0.570 | | |
| | Likelihood Ratio | 0.782 | 1 | 0.377 | | |
| | Fisher's Exact Test | | | | 0.537 | 0.286 |
| | N of Valid Cases | 193 | | | | |
| 2.00 | Pearson Chi-Square | 10.389[d] | 1 | 0.001 | | |
| | Continuity Correction[b] | 9.232 | 1 | 0.002 | | |
| | Likelihood Ratio | 10.807 | 1 | 0.001 | | |
| | Fisher's Exact Test | | | | 0.002 | 0.001 |
| | N of Valid Cases | 193 | | | | |
| Total | Pearson Chi-Square | 9.956[a] | 1 | 0.002 | | |
| | Continuity Correction[b] | 8.998 | 1 | 0.003 | | |
| | Likelihood Ratio | 10.294 | 1 | 0.001 | | |
| | Fisher's Exact Test | | | | 0.002 | 0.001 |
| | N of Valid Cases | 386 | | | | |

**Table: 2Impact of intervention on medication adherence in case group compared to medication adherence in control group.**

**P value :- 0.02 < 0.05 (Significant)**

**Table: 3 Impact of intervention on quality of life in case group compared to control group.**

**Case**

| Paired Samples Test | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Paired Differences | | | | | t | df | P value |
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | | Lower | Upper | | | |
| Pair 1 | QOL SCORING (CODED) - QOL SCORING followup 2 | -0.13502 | 0.11466 | 0.01158 | -0.15801 | -0.11203 | -11.658 | 97 | 3.73029E-20 |

**T-value:- -11.658 (Case)**

**-11.018 (Control)**

**Control**

| Paired Samples Test | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Paired Differences | | | | | t | df | P value |
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | | Lower | Upper | | | |
| Pair 1 | QOL SCORING (CODED) - QOL SCORING follow-up 2 | -0.14540 | 0.12863 | 0.01320 | -0.17160 | -0.11920 | -11.018 | 94 | 1.28951E-18 |

**P value :- 0.01 < 0.05 (Significant)**