Evaluation of preparatory informatics on biophysiological parameters and compliance to lifestyle modifications among patients with Acute Coronary Syndrome

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Abstract

BACKGROUND: Acute Coronary Syndrome (ACS) refers to a spectrum of clinical presentation ranging from those for ST segment elevation Myocardial Infarction (STEMI) to presentations found in non- ST- segment elevation Myocardial Infarction (NSTEMI) or in unstable angina. Among this NSTEMI represents the major burden to health care systems and patients face a substantial risk of mortality and cardiovascular events. Educational interventions can be effectively targeted and implemented as primary and secondary prevention strategies to reduce the burden of coronary atherosclerotic heart disease.

OBJECTIVES: Evaluate the effectiveness of preparatory informatics on biophysiological parameters among the patients with ACS.

Determine the effectiveness of preparatory informatics on compliance to lifestyle modifications among the patients with Acute Coronary Syndrome.

DESIGN: A quantitative method, true experimental research design.

SETTING: Cardiac Super specialty Hospital, Chennai, India.

MAIN OUTCOME MEASURES: Change in the BMI, lipid profile, regulate blood pressure and develop good compliance behavior towards lifestyle modifications

SAMPLE SIZE: 200 participants were selected by using power analysis. By simple random sampling technique,100 each in study and comparison group.

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RESULTS: The comparison scores of biophysiological parameters such as BMI, SBP, DBP, TC, LDL and HDL between the study and comparison group was statistically significant at p <.001 except for DBP which was significant at *P*<.01.The comparison scores of compliance to lifestyle modifications between the study and comparison group were statistically significant at *P*<.001.

LIMITATION: The biophysiological assessment were carried out twice only due to hospital protocol.

CONCLUSION: These comprehensive interventions on lifestyle modifications, printed hand outs and telephonic reinforcement are accomplished in increasing the compliance behavior among patients with acute coronary syndrome.

CONFLICT OF INTEREST: None

INTRODUCTION:

Among Cardiovascular diseases, Acute Coronary Syndrome (ACS) refers to a spectrum of clinical presentation ranging from those for ST segment elevation Myocardial Infarction (STEMI) to presentations found in non- ST- segment elevation Myocardial Infarction (NSTEMI) or in unstable angina. Among this NSTEMI represents the major burden to health care systems and patients face a substantial risk of mortality and cardiovascular events. Although evidence suggests that the use of early angiography with a view to revascularization in the management of patients of NSTEMI is associated with the risk of death during hospitalization. (David Coven, 2016) [6]. ACS results in enormous burden of increased mortality and morbidity. The experience of a serious illness, particularly if it is a sudden and life-threatening event is a crisis not only for the individual sufferer but also for the spouse and wider family. These events threaten the patient's stability, security, adaptability, belief and assumptions.

A comprehensive health education for patients with CAD including psychological and educational interventions had significantly improved self-efficacy, self-regulation, self-care, body mass index and quality of life within 6 weeks after hospitalization. (Patrawut, 2012) [7]. In addition to this it is also revealed that personalized interventions for adherence to drugs and lifestyle changes after ACS improved adherence to evidence-based drugs and healthy lifestyles and resulted in an improvement in clinical risk markers. (Xavier, 2016) [8].

For this reason the investigator decided to assess the biophysiological parameters and compliance to lifestyle modifications on the implementation of preparatory informatics to improve the compliance behavior on lifestyle modifications regarding habits, diet, medications and skill in performing exercise and yoga - shavasana. Educational interventions can be effectively targeted and implemented as primary and secondary prevention strategies to reduce the burden of coronary atherosclerotic heart disease in India. Thus, it mandates the investigator to address the demands of the society.

PATIENTS & METHODS

This study was conducted at Cardiac Super Specialty Frontier Lifeline Hospital situated at Mogappair, Chennai, Tamil Nadu, India. This Centre is very familiar for the treatment of cardiac problems. This hospital receives patients from various parts of India and from abroad.

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Institutional Ethical committee approval was obtained from the setting and after obtaining the informed consent from the patients the investigator collected data. (Fig: 1 Study Flow Diagram)

Hypotheses:

H1: There is a significant difference in biophysiological parameter BMI among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H2: There is a significant difference in biophysiological parameter systolic blood pressure (SBP) among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H3: There is a significant difference in biophysiological parameter diastolic blood pressure (DBP) among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H4: There is a significant difference in biophysiological parameter total cholesterol (TC) among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H5: There is a significant difference in biophysiological parameter LDL among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H6: There is a significant difference in biophysiological parameter HDL among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

H7: There is a significant difference in compliance to lifestyle modifications among patients with ACS and received preparatory informatics than those who do not at $P<.05$.

Criteria for Sample Collection

Inclusion Criteria

All adult patients in the age group between 30 and 70 years diagnosed with ACS (Unstable Angina, NSTEMI, STEMI), diagnosed for the first time of both the sex, treated ACS with medications, undergone percutaneous coronary intervention, who know to read and understand Tamil and / English, and with or without co-morbidity (diabetes, hypertension and high cholesterol) were included for the study.

Exclusion Criteria

Patients Posted CABG surgery, not willing to participate, critically ill, with musculoskeletal disorders, back pain, associated complications like arrhythmias, peripheral vascular disease, ESRD, who are regularly practicing yoga and or exercise were excluded.

The study was conducted at a selected Hospital in Chennai and Ethical committee permission was obtained by the investigator from the Institutional Ethical committee. The investigator recruited 100 participants each for study and comparison group using probability sampling - simple random sampling using lottery method based on the lot the samples were assigned to study and comparison group. A structured instrument was used to collect the data as discussed below.

Section A: Background Variables

It has two parts

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Part I Demographic Variables:

The tool comprises of demographic variables such as age, sex, marital status, area of residence, educational status, occupation, income per month, type of family, food habits and was obtained by the structured format.

Part II Clinical Variables: It includes diagnosis, extension of Atheroma, ACS localization, Treatment, Co morbid illness, Killip Class obtained from the clinical records.

Section B: Biophysiological Parameters :

It encompasses Body Mass Index, Systolic & Diastolic blood pressure, Total Cholesterol, Low Density Lipoprotein, High Density Lipoprotein those obtained from the clinical records and were categorized and scored based on the AHA guidelines.

Section C: Compliance to Lifestyle Modifications:

The investigator constructed a five-point likert scale with an extensive search of literature and experience to assess the compliance of the patients. It consists of five sub scales such as habits, diet, medications, exercise and shavasana.

This part includes 5 aspects such as habits, diet, medications, exercise and shavasana . The habits include only 2 items i.e. drinking alcohol and cigarette smoking. In the other 3 aspects each aspect has 15 items with positive and negative statements. A five-point Likert scale is formulated (always, sometimes, often, rarely, never) to record the responses. The yoga subscale includes one item of dichotomous type. The reliability of the tool was estimated by test retest method and by using Cronbach's Alpha it was found to be 0.7. The maximum score is 5 and a minimum score is 1 for all the items except for yoga. In yoga, yes carries 2 mark and no carries 1 mark with the total score of 237. The arbitrary grading is done as noncompliance ($\leq$ 79), partial compliance (80- 158) and good compliance (159- 237).

Data Collection Procedure:

The data was collected in three phases

Phase I – On the 4th - 6th day after the patient stabilized and shifted to the cardiac wards the pretest was conducted to collect data on demographic, clinical variables and compliance behavior.

Phase II – Preparatory informatics was administered regarding Lifestyle Modifications for patients with ACS which includes the structured teaching, demonstration (Shavasana Yoga), reinforcement and issuing the hand - outs on lifestyle modifications to the study group. At the time of discharge a hand - outs on "General information, Heart Healthy Diet, Home Exercises and Walking Guidelines and shavasana after ACS, were provided to the study group. Reinforcement was carried out every fortnight by telephonic conversation, till three months after their discharge from the hospital and emphasis was given on compliance to Lifestyle Modifications.

Phase III – Posttest 1 and 2 was conducted on 30th, 90th day. The hand outs were issued for the comparison group participants after posttest 2 on third month (90th day).

The descriptive and inferential statistics were used to analyze the data by using IBM SPSS version 20.

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Results

- The independent 't' value on bio physiological parameter (Table 3) of the post test of BMI, systolic blood pressure, total cholesterol, LDL and HDL were statistically significant at p <.001 between study and the comparison group. The pretest scores of SBP, DBP, LDL, and HDL were not statistically significant. The pretest of BMI, the post test of diastolic blood pressure between study and comparison group were statistically significant at *P*<.01. The pretest of total cholesterol revealed a statistically significant at *P*<.05.

- The repeated measures ANOVA (Table 4) value on comparison between study and comparison group over a period of time on bio physiological parameter unveiled such as body mass index, systolic blood pressure, diastolic blood pressure, total cholesterol and LDL were significant at *P*< .001. In contrast, the HDL of pretest and posttest between study and comparison group was not statistically significant.

- The distribution of compliance to lifestyle modifications (Table 5) showed that all the participants in the study group 100% improved good compliance behavior whereas in the comparison group 92% of the participants developed only partial compliance.

- In the study group (Table 4) the posttest 1(30th day) 92% and posttest 2 (90th day)100% of participants practiced shavasana. But in the comparison group posttest 1 only 16% and in posttest 2 only 22% participants practiced shavasana.

- The independent 't' value scores of compliance to lifestyle modifications (Fig 2) posttest 1, 2 of overall score, diet, medications and exercise between the study and comparison group were identified as statistically significant at *P*<.001.The comparison scores of posttest 2 of habits between study and comparison group was statistically significant at *P*< .01.The pretest of overall score, pretest of habit, diet, exercise, medications and the posttest 1 of habit were statistically not significant respectively.

- The repeated measures ANOVA (Table 6) value on comparison of compliance to lifestyle modifications between study and comparison group over a period of time discloses that there was a substantial difference between study and comparison group over a period of time on total score of compliance to lifestyle modifications, habits, diet, medications and exercise which were statistically significant at *P*< .001.

Discussion

The first objective was to evaluate the effectiveness of preparatory informatics on bio physiological parameters among the patients with Acute Coronary Syndrome.

The difference in mean between the study and comparison in the pre and posttest are 1.33 and 2.14 respectively and unveiled statistically significant at *P*<.001. The BMI was recorded at 3rd month, however if performed after 6 months BMI evaluation would have given an in-depth observation and would have also be appreciated with good numerical difference. This study was supported with the results of the study conducted by Borowicz et.al (2013) [9] on impact of short term cardiac rehabilitation on changing dietary habits inpatients after acute

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coronary syndrome where controlled, prospective non randomized study was performed on 44 patients. The results showed that in the Cardiac Rehabilitation group, comparing baseline with 3 months post- ACS, daily calorie intake was significantly reduced at *P*<.05 and daily cholesterol intake at *P*<.05. Although both study and control group exhibited increased body mass index, the decrease was significantly greater in the non-rehabilitation group than in the CR group at one year post- ACS at *P*<.001. This study implied that any systematic education could improve the compliance behavior among the participants. In addition to the above findings the repeated measures ANOVA on comparison of body mass index among study and comparison group also depicted a substantial difference over a period at *P*< .001.

Hence **H1** - There is a significant difference in biophysiological parameter BMI among patients with ACS and received preparatory informatics than those who do not at *P*<.05 is **accepted.**

a. Systolic Blood Pressure (SBP)

The mean difference scores of pretest and posttest between study and comparison group were 1.96 and 9.48 respectively and was a statistically significant at *P*<.001. This difference in mean proclaims that the systematic teaching, handouts on compliance to lifestyle modifications lowers the systolic blood pressure and maintained to normal level. The present study finding was supported by the study conducted by "Reibis et. al. (2014) [10] Cardiac Rehabilitation after ACS and outcome revealed that the mean systolic pressure was statistically significant at *P*< .001. The current study finding is also consistent with the study conducted by Neubeck et. al. (2009) [11] " Telehealth interventions for the secondary prevention of coronary heart disease", where the interventions showed a significantly lowered systolic blood pressure on long term follow up of study group than the control group at *P*< .001. The Repeated Measures ANOVA evoked that there was a substantial statistically significant difference between study and comparison group over a period of time at *P*<.001. Hence **H2** - There is a significant difference in biophysiological parameter systolic blood pressure among patients with ACS and received preparatory informatics than those who do not at *P*<.05 is **accepted.**

b. Diastolic Blood Pressure (DBP)

The DBP independent 't' test between the study and comparison group for the diastolic blood pressure enumerated statistically significant difference at *P*< .01. This present finding confounds with the result of the study conducted by "Palmire et. al. (2010) [12] on Technology and information systems enabling transmission of patient's data and ability to provide and exchange professional support remotely to the general practitioners can improve quality and continuity of care. In their study patients were taught about cardiovascular risk, the blood pressure, and the physical activity. The result revealed that there was a significant reduction in blood pressure of both systolic and diastolic as at *P*<.001 respectively. The Repeated Measures ANOVA elicited that there was a substantial statistically significant difference between study and comparison group over a period of time at *P*<.001. Hence **H3** There is a significant difference in biophysiological parameter diastolic blood pressure among patients with ACS and received preparatory informatics than those who do not at *P*<.05 is accepted.

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c. Total Cholesterol (TC)

The mean difference scores of total cholesterols between the study and control group of pretest and posttest were 13.44 and 39.74 and the independent 't' revealed statistically significance at $P<.05$, $P<.001$ respectively. This present finding is also supported by the result of the study on "Telehealth interventions for the secondary prevention of coronary heart disease" conducted by Neubeck et. al. (2009) [11] where the interventions showed a significantly lowered total cholesterol on long term follow up than the control group at $P<.001$. This further substantiates that the teaching on lifestyle modification on diet is effective. Provision of such formal secondary prevention is necessary for the patients to reduce the risk of further complications. In addition, the repeated measures ANOVA displayed that there was a substantial statistically significant difference between study and comparison group over a period at $P<.001$. Hence **H4** - There is a significant difference in biophysiological parameter total cholesterol among patients with ACS and received preparatory informatics than those who do not at $P<.05$ is **accepted.**

d. Low Density Lipoprotein (LDL)

The comparison scores between the study and comparison group strengthens that the change in mean in the pretest of LDL was 87.19 and was not statistically significant. But in the post test the mean difference was 34.03 and the independent 't' test was statistically highly significant at $P<.001$.This concluded that the teaching on compliance to lifestyle modification was effective and thereby the LDL had decreased conservatively. This present finding is consistent with the result of study conducted by Koba (2016) [14] on " Beneficial Effects of Exercise-Based Cardiac Rehabilitation on High-Density Lipoprotein-Mediated Cholesterol Efflux Capacity in Patients with Acute Coronary Syndrome" where the patients attended the cardiac rehabilitation programme had showed statistically significantly decrease in LDL at p <.0001. Further, the Repeated Measures ANOVA evoked that there was a substantial statistically significant difference between study and comparison group over a period at $P<.001$. Hence **H5** - There is a significant difference in biophysiological parameter LDL among patients with ACS and received preparatory informatics than those who do not at $P<.05$ is **accepted.**

e. High Density Lipoprotein (HDL)

The mean scores of HDL within study group comparison of pretest with posttest were and 36.19 ± 8.62, and 40.50 ± 7.61 with a difference in mean was 4.31 and statistically significant at $P< .001$. In the mean scores of within comparison group of pretest with posttest were 36.86 ± 8.02 and 33.98 ± 7.24 with a change in mean of 2.88. This was statistically significant at $P<.001$. The mean difference between the study and comparison group were 0.67 and 6.52 and was not statistically significant. **Hence H6** - There is a significant difference in biophysiological parameter HDL among patients with ACS and received preparatory informatics than those who do not at $P<.05$ is **rejected.**

Though the distribution of HDL showed that half of the participants in the study group had increased HDL to desirable level than the comparison group it was not statistically significant. This could be due to the reverse cholesterol transport system of LDL to HDL, reducing TC might

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take longer duration. However, the lipid profile measured on longer duration, that is on a sixth-month or one-year interval, there could be appreciable increase in the numerical value which may show statistically significant difference.

The second objective was to determine the effectiveness of preparatory informatics on compliance to lifestyle modifications among the patients with Acute Coronary Syndrome.

Compliance to Lifestyle Modifications

a. Habits

The mean score of compliance to lifestyle modifications within study and comparison group regarding the sub scale habits of pretest with posttest 1 and posttest 2 were statistically significant at $P<.001$. The scores between study and comparison group was not statistically significant in posttest 1 but was significant in posttest 2 at $P<.001$. Further the repeated measures ANOVA result incarnate that over a period was significant at $P<.001$.

b. Diet

The mean difference of study and comparison group on the aspect of diet on compliance to lifestyle modifications depicted that the 30th, 90th day observation data the diet aspect were statistically significant at $P<.001$ but was not significant in the pretest. This finding further fortified with the repeated measures ANOVA result that was statistically significant at $P<.001$. This present finding affirmed with the study result conducted by "Froger et. al. (2009) [17] on assessment of the effectiveness of cardiovascular rehabilitation programme on adherence to dietary recommendations. 14 item food questionnaire was used to collect data from 32 patients at acute phase of coronary syndrome and 104 patients who had completed cardio rehabilitation programme. The results suggested that sustained improvement in dietary habits in patients with coronary heart disease who received nutritional education during cardiovascular rehabilitation programme.

c. Medications

In the aspect of medications, the independent 't' test between study and comparison group of pretest was not statistically significant but the posttest 1, posttest 2 and repeated measures ANOVA were statistically significant at $P<.001$ respectively. This finding is substantiated by the study on "Trends in adherence to secondary prevention medications in post-Acute Coronary Syndrome patients" conducted by Yaman et. al. (2015) [18]. The data obtained on three consecutive periods. The obtained repeated measures ANOVA showed statistically significant difference on adherence to cardio-protective medications during study period at $P<.001$. Thus, the study finding emphasis that systematic patient education is needed and effective for secondary prevention measures.

d. Exercise

In the aspect of exercise of compliance to lifestyle modifications within, between the study and comparison group were statistically significant at $p<.001$ respectively. Additionally, the repeated measures ANOVA between the study and comparison group on exercise of pretest, posttest 1, 2 were statistically significant at $P<.001$. The results of this study are consistent with the study conducted by Houle et. al. (2011) on impact of a socio-cognitive intervention

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association with a pedometer-based program on physical activity, cardiovascular risk factors and self-efficacy expectation for one year following an acute coronary syndrome. On the 3rd month of the follow up both the groups demonstrated increased in their physical activity and were found statistically significant at *P*<.05, but this increase was higher in the experimental group at *P*<.001. Thus, it enforced that cardiac rehabilitation program using socio - cognitive intervention was effective. Similarly, the present study finding is also consistent with the finding of another study conducted by Abbas et. al. (2015) [20] on "Relationship between awareness of disease and adherence to therapeutic regimen among cardiac rehabilitation patients". 340 patients with heart disease were selected and the data were collected using three questionnaires on demographic, awareness of disease and treatment adherence on medication, diet and physical activity. On analysis it was identified that the diet and exercise were statistically significant at *P*<.05 and *P*<.001 respectively. This finding further fortified the findings of the present study.

Overall, the findings of scores of within study and comparison group explicated that though the groups were statistically significant in all the aspects such as habits, diet, medication, and exercise. It disclosed that even the comparison group also adopt some change in lifestyle modifications but when the mean scores and difference in mean of study group between the pretest, posttest 1, 2 were wide. Further the independent 't' test between study and comparison group and the repeated measures ANOVA substantiated statistically significant difference at *P*<.001 in all the aspects of compliance to lifestyle modification.

The finding of the present study was substantiated with the result of the study conducted by Seon et. al. (2015) [21] on "Risk Factor–tailored Small Group Education for Patients with First-time Acute Coronary Syndrome" where patients were recruited from a national university hospital for a period of one year in Korea. The group education was given for the study group (n=34). The control group ($n = 40$) received usual care and counseling upon request. The result showed a statistically significant difference at *P*<.001 on compliance to medication, diet, habit of smoking and exercise, respectively.

This further confirmed that any tailored education and continuous counseling was effective and beneficial for a long-term compliance to lifestyle modifications among patients with acute coronary syndrome. In addition, the handouts given to the participants, was available round the clock for the participants as posted positive reinforcement and was also used to clarify their doubts. **Hence H7 -** There is a significant difference in compliance to lifestyle modifications among patients with ACS and received preparatory informatics than those who do not at p< .05 is adequately supported and **accepted**.

Conclusion

Lifestyle modifications improve the compliance behavior among patients with Acute Coronary Syndrome and it is an effective Secondary prevention intervention. This comprehensive systematic tailored form of education or patient-led education for patients admitted with cardiac ailments is mandatory to reduce the risk, improve prognosis, and for secondary prevention.

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