4. Methodology

This was an open labeled, randomized control trial (CTRI-2014/03/006557) conducted at Kasturba Hospital, Manipal, Karnataka, India. Patients admitted in the cardiology wards with unstable angina and myocardial infarction and underwent angioplasty procedure, were randomized into control group (CG) where, standard care along with counseling about drug therapy is provided and intervention group (IG) where, pharmaceutical care (PC) was provided with tailor made counseling about diseases, drugs, diet and lifestyle modifications. It also involved medication reconciliation; adherence aids and follows up with the subjects up to 12 months. The primary outcome was the evaluation of pharmaceutical care services in the patients of angioplasty by Economical, Clinical, and Humanistic Outcomes model. Study protocol was approved by Manipal University Ethics Committee (UESC/11/2011 dated 27/01/2011). Informed consent was obtained from patient / patient party for enrollment in the study.

4.1 Patient Enrollment

Patient Enrollment began in January 2011 and ended in July 2012. Patients admitted in cardiology wards with unstable angina and Myocardial Infarction (MI), who were at least of 18 years of age and less than 80 years and underwent angioplasty procedure with confirmation diagnosis by ECG, Troponin T test and coronary angiography. Patients with psychiatry conditions, pregnant women, who are discharged into long term care facility other than their home, inability to communicate in Kannada, Hindi or English, previously underwent angioplasty for MI, previous enrollment in any other study and those who are not willing to participate in the study were excluded.

In the hospital, Research pharmacist (RP) identified the potential subjects within 24 hours of admission through, participation in the medical ward rounds along with the cardiologist and medical records review. Then, RP approached each patient to confirm
eligibility, provide study information and seek written informed consent. The consent process, study procedure and materials were approved by the Manipal University ethics committee. Following informed consent, RP conducted an interview with patients about their demographics, their awareness about the disease, medical history, medication history, lifestyle and the risk factors. These data were entered in formulated data collection form (Annexure 1). Flow chart of the methodology is represented in figure 2a.

4.2 Randomization

Consented patients were randomized into control group to receive standard care and intervention group, to receive pharmaceutical care by RP. The randomization sequence was computer generated in block randomization manner (Age-below 60 years and above 60 years, Sex- Male and female) by the statistic department of the University and concealed in the opaque sealed covers. On the day of discharge, once the discharge summary was prepared by medical team, RP opened the sealed covers and designated the patient into the respective group.

4.3 Intervention

RP performed medication reconciliation upon enrollment, at discharge and during in hospital transfers. When unintended discrepancies were identified, RP contacted the medical team to resolve the same.

Intervention patients received tailored counseling by the RP at enrollment and at discharge. During the initial counseling session, assessment of patient’s awareness about disease, medication history, medical history, and level of social support was performed. During the discharge counseling session, the RP provided tailored counseling based on the initial assessment of individual needs and discharge regimen of drugs. This counseling process was involved the caregivers also. The RP emphasized differences between the pre admission medication regimen and the discharge medication regimen,
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reviewed strategies to enhance medication adherence and techniques to prevent side effects. Information about disease is explained by the visual aid (specifically prepared for the coronary artery disease), why they should take medications, diet and lifestyle modifications as per individual need was performed at discharge counseling. Patients received a personalized medication schedule covers, serves as medication reminders, which had the information -when, and how they should take medications in - both Kannada and English language. Quality of Life assessment was done with EQ 5D 5L and MacNew Questionnaires by interview method. Patients were given the instruction by the cardiologist, to undergo certain biochemical investigations like – Lipid profile, Fasting Blood Sugar on follow up visits. Intervention group patients received the further counseling during the follow up period to assess the need of participants and resolve the issues if any and performed the pill count to measure the adherence.

Since the counseling was performed in the wards, to avoid contamination and to confirm the understanding, patients were asked to teach – back the information.

4.4 Control group

Control group patients were received the standard care plus personalized medication schedule covers by RP only at the discharge time as per the ethical committee decision. Standard care involves routine counseling by the nurse and the cardiologist at hospital discharge.

4.5 Outcome Assessment

Outcomes were based upon patient responses during the follow up period i.e. 3 months, 6 months, 9 months and at 12 months. Patients were asked to meet the RP during their follow up visit to the cardiologist which is also reminded to them by text message/ phone call. The follow up interview with RP, included a detailed medication review, assessment
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of healthcare utilizations, and quality of life evaluation. Biochemical parameters were checked and discussed the same with patients. Discrepancy like - change in frequency, dose, omission, additional medications were noted and resolved during the interview.

4.6 Power and sample size calculation

Considering effect size of 0.3, between two groups along with power of 80%, level of significance of 5% and repeated measure at 4 levels i.e., 3 months, 6 months, 9 months and at 12 months, we arrived at sample size of 68 per group. Assuming the dropout rate of 20%, sample size increased to 82 per group.

4.7 Statistical Analysis

Data was analyzed on the basis of per protocol method. Both the groups were examined for proportions of categorical variables, and means and standard deviations for continuous variables. Repeated measures analysis was performed for the analysis of change in the quality of life and pill count score. Paired t test was used to identify the differences between Baseline and at 12 months for biochemical parameters and body mass index. Statistical analyses were performed using the SPSS statistical version 16.0 (SPSS inc., Chicago IL).

4.8 Quality of Life Instruments

4.8.1 EQ-5D-5L

A generic measure of perceived health status developed by the EuroQol Group, was used to assess general health status of the participants in the current study.

This questionnaire was simple, standardized, validated and available in regional language (Kannada). Visual Analogue scale was explained and asked them to mark on the scale and write the same value in the response sheet. Same procedure was repeated at follow ups.
4.8.2 MacNew Questionnaire

A disease specific quality of life questionnaire designed for cardiovascular disease. This instrument was translated into Kannada, by forward and backward translations and performed validation process and used for the purpose.
Methodology

Myocardial Infarction, Unstable Angina patients who underwent angioplasty procedure

Informed Consent

Baseline Data collection (Demographics, Clinical Profile, costs, Laboratory profile, Quality of Life data)

Block Randomization (Age, Gender)

Control group (n=105) Standard Care

Follow up at 3 months

Follow up at 6 months

Follow up at 9 months

Dead (n=2), Unable to trace (n=7)

Follow up at 12 months (n=96)

Intervention group (n=108) Pharmaceutical Care

Follow up at 3 months

Follow up at 6 months

Follow up at 9 months

Dead (n=1), unable to trace (n=5)

Follow up at 12 months (n=102)

225 patients were identified, 3 refused to give consent, 9 were unable to communicate either in Kannada, English or Hindi.

Figure 11: Flow Chart of methodology