4 Methodology

The quality of life studies data was collected from the patients at Kasturba Hospital, Manipal, a tertiary care hospital. The patients were treated either with BMS or DES. The instrument to measure health status was EQ-5D-5L involving English and Kannada version. The permission to use the above instrument was obtained by requesting the Euro QoL group and informing them that the instrument is used for research in an academic institution. The ethics committee reviewed the protocol and approved the same for administering the study. (Manipal University Ethics Committee approval was taken for the study. Ref: UESC/12/2011 (See Appendix I) and Informed consent was obtained from the patient/patient party for enrolment in the study (See Appendix II).

The pharmacoeconomic data was computed from data record sheets and data pertaining to socio-demographic information along with cost of treatment and clinical outcomes. The model of the study was prospective, observational, cost effectiveness analysis of BMS and DES used in the treatment of ACS with PCI.

Data pertaining to cost and clinical outcomes of the subjects included in the study are derived from case record files of outpatients and inpatients of Cardiology Department of Kasturba Hospital, Manipal.

Health related quality of life data was collected directly from subjects using self-administered EQ-5D questionnaire.

Sample Plan:

Sample size is calculated using the equation

\[ N = \frac{2[Z_{\text{crit}} \sqrt{2P(1 - P)} + Z_{\text{pwr}} \sqrt{p_1(1 - p_1) + p_2(1 - p_2)}]^2}{D^2} \]

N= Total sample size (Sum of the sizes of both the groups)

\( Z_{\text{crit}} \) = Standard normal deviate corresponding to selected Significance criteria

\( Z_{\text{pwr}} \) = Standard normal deviate corresponding to selected statistical power

D = Minimum expected difference between the two means

\( p_1 \) and \( p_2 \) = estimates of the two proportions to be compared

\[ P = \frac{p_1 + p_2}{2} \]
Considering effect size of 0.3, between two groups along with power of 80, level of significance at 5% and repeated measure at 5 levels i.e., at discharge, 3 months, 6 months, 9 months and at 12 months, a total sample size of 136 was arrived at. Assuming the dropout rate of 20%, extra sample size was calculated which was 32 subjects per group, making it to a total of 164. The complete plan for the patient recruitment is given in Figure 4.1

Inclusion Criteria:

- In patients and out patients with ACS receiving treatment either with BMS or with DES.
- Patients with ACS within the age group 18-75 years.

Exclusion Criteria:

- Pregnant women with ACS.
- Patients having known sensitivity for any of the medication used during the PCI procedure.
- Patients previously treated for revascularization with stents.

Statistical methods used:

The statistical tests were performed using SPSS (Statistical Package for Social Sciences) with version 15.0 (SPSS Inc, Bangalore). All the continuous variables of normal distribution were presented in the form of mean with standard deviation. Data with skewed presented as median with interquartile range. Categorical and nominal data was presented as proportion. Repeated measures ANOVA was used for calculating the differences in mean VAS scores among group for evaluating humanistic outcomes for comparison for BMS and DES groups. To compare the cost difference among both the groups Mann-Whitney test was used and for all the tests ‘P’ value of less than 0.05 was taken significant.

Study site: The study was conducted in Department of Cardiology, Kasturba Hospital, Manipal, a multidisciplinary tertiary care teaching hospital.

Ethical Approval:

- Manipal University Ethics Committee approval was taken for the study. Ref: UESC/12/2011 (Appendix I)
- Informed consent was obtained from the patient/patient party for enrolment in the study (Appendix II).
**Patient Recruitment and Data collection**

Subjects fulfilling inclusion and exclusion criteria were recruited between 2011 and 2013, who were identified as suitable candidates and their consent was obtained. The follow-up was done till December, 2014. Convenience sampling method was used for selection of patients into study. For collection of cost and clinical outcomes data, a data record sheet was prepared and used (Appendix III). The prepared data record sheet was pilot tested to check for completeness of the information gathered. The data record sheet also collected the data pertaining to socio-demographic information in addition to cost and clinical data.

The direct cost data from bills paid by the patients were recorded into data sheet and were further reconfirmed with the accounts department of the hospital. The various costs incurred by the patients were grouped into eight groups as investigation charges, cardiac monitor and respirator charges, consultation charges, procedure charges, medicine charges, nursing and other care charges, bed and food charges as well as miscellaneous charges. The investigation charges included the sum of biochemical investigation charges, clinical lab investigation charges, blood bank investigation, ECG Investigation, pathology investigation, microbiology investigation, radiology investigation ultra sound and CT scan charges. The cardiac monitor and respirator charges included charges for cardiac monitor, oxygen and respirator. The consultation was the total of consultation charges, professional charges and sub-consultation charges. The procedure charges include the total of procedure charges and cardiac procedure charges. Medicine charges minus medicine refund were considered as total medicine charges. Nursing and other care charges included patient care charges, nursing charges, physiotherapy and dressing charges. Bed and food charges is the sum of bed charge, hospital food, special diet and water bed charges. All the other charges are grouped together as miscellaneous charges.

The clinical data collected included risk factors, comorbid conditions, BMI, primary diagnosis, blood pressure, lipid profile, blood sugar levels, HbA1c, along with major clinical outcomes such as restenosis, stent thrombosis, repeat MI and death.

Humanistic outcomes were measured with EQ-5D-5L questionnaire which recorded the self-reported outcomes in five domains of health such as mobility, self-care, usual activity, pain and anxiety along with VAS score. EQ-5D-5L is a simple, standardised, validated questionnaire (Schweikert et al., 2006, Goldsmith et al., 2009, Kramer et al., 2012) available in English as well as Kannada language (Appendix IV). The self-reported baseline humanistic data were collected during discharge, and follow-up during 3 months, 6 months,
9 month and 12 month visits. Third party interviewing was done to avoid the interviewer bias.

![Flow chart for patient recruitment and follow up](image)

**Figure 4.1: Flow chart for patient recruitment and follow up**