Research Article

Economic and Humanistic Outcomes among Patients Receiving Percutaneous Coronary Intervention in a Tertiary Care Hospital of South India

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ABSTRACT

The objective of the study is to evaluate the humanistic outcomes and cost outcomes among patients receiving percutaneous coronary intervention in a tertiary care setup. The quality of life studies data was collected from the patients at Kasturba Hospital, Manipal, India, a tertiary care hospital. The instrument to measure health status was EQ-5D-5L involving English and Kannada version. 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 and observational, evaluation of bare metal stents and drug eluting stents used during percutaneous coronary intervention for the period of nine months. Data pertaining to cost outcomes of the subjects included in the study are derived from case record files of outpatients and inpatients of Cardiology Department. The mean age of patients for bare metal stent group was 57.8 ± 9.3 years and for drug eluting stent group was 60.7 ±10.1 years. Repeated measures ANOVA of utility scores and VAS scores showed significant variation in both groups over a period of nine month follow-up. Mann-Whitney test significance was found to be <0.001 for total cost involved in percutaneous coronary intervention among both the groups. The study was able to provide insight in to the benefit received by the patients with drug eluting stents in terms of humanistic outcomes and the cost to be paid for the same at a tertiary care setup in India

Keywords: Health Related Quality of Life, Cost of Treatment, Percutaneous coronary intervention, Tertiary Care, India.

INTRODUCTION

Ischemic heart disease is the leading cause of mortality in India, and the size of this disease's impact is expected to grow over the next two decades. It is projected that ischemic heart disease will effect in two and one-half million Indian deaths by 2020.[1] Patients in India who have acute coronary syndromes (ACS) have a higher rate of ST-elevation myocardial infarction than the patients in developed countries. Since most of these patients are poor less access to get rational treatments may be the reason for higher mortality. Filling these gaps by improving the access to rational treatment and improving the affordability of the treatment may have a significant effect reduced morbidity and mortality.[2]

Acute Coronary Syndrome is a term used to denote cluster of conditions including ST-elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI) and unstable angina (UA). ACS is an important manifestation of ischemic heart disease and its long term prognosis are worse.[3] The primary goal of the treatment of ACS is the prevention of thrombus, restoration of coronary flow, and reduction in myocardial oxygen demand. To restore the coronary flow revascularization by percutaneous intervention (PCI) or coronary artery bypass grafting is performed.[4]

Health related quality of life (HRQoL) is a measurement of effective way to capture how a patient actually feels and believes the effect of medical treatment on quality of life.[5] HRQoLmeasurement include understanding of broad constructs of patients perception towards their health at any given point of time with regard to physical, mental and social wellbeing.[6] The PCI has shown to improve the HRQoL among patients with myocardial infarction after the intervention.[7]In the procedure of PCI in order to avoid rest enosis the metallic stents are implanted in patients at the site of blockade. The metallic stents are available as bare metallic stents and drug eluting stents (DES). The DES are imbibed with anti-proliferative drugs like paclitaxel and serolemous. DES are designed to release drugs in a continuous fashion to prevent the growth of the cells leading to narrowing of the artery and are claimed to be more effective than bare metal stents in prevention of restenosis. There is need to study the effect of DES versus BMS among PCI patients with ACS with respect to HRQoL and cost of treatment. Such a study will bring out the difference in performance of BMS and DES in terms of cost and improvement in HRQoL assisting to make an intelligent choice as per the needs.

There are a number of studies on the cost of treatment in patients with ACS from the developed countries, however such studies are in less number from developing nations like India.[8-11]In India the health insurance coverage is less than 10 percent and rest of the patients meet the medical expenditure from their personal financial resources. As the treatment usually crosses more than hundred thousand INRs the burden on the family is high and very difficult to make a choice in critical hours. Although there

are government subsidies and philanthropic funds are available it is not sufficient to meet the expenses of all the citizens. Moreover the ACS has become so common due to unhealthy lifestyles and food habits the patients are caught unaware with the condition and are forced to take a decision involving high financial commitment. All the expenditure incurred for the direct cost was met out-of-pocket by the patients.

In this study HRQoL and cost of treatment is measured from the patient perspective to get clarity and help the care giver to explain the pros and cons of the choice of treatment with the support of evidence.

MATERIALS AND METHODS

The primary data was captured by case reports of patients of both group of patients receiving BMS and DES, who were admitted to the Department of Cardiology, Kasturba Hospital, Manipal. The ethical approval for the study was obtained from Manipal University Ethics Committee (UESC/12/2011). Patients diagnosed with ACS and who have consented to participate in the study was included in the study after taking consent by signing a form as mentioned in protocol. The criteria to include, only those patients who were treated with PCI for the first time Socio demographic with clinical data were collected along with annual income, occupation, family history and social habits directly from the patients. The data was reconfirmed with the case record for correctness. Clinical information relating to the diagnosis and treatment given were captured from the case sheet in collaboration with interventional cardiologist.

The EQ-5D-5L questionnaire is a validated questionnaire to measure HRQoL from EuroQol. It is already validated for ACS patients and is found to be valid, reliable, and responsive.[12] The purpose of the questionnaire was explained to the patients and their responses were captured on a scale of five for five different dimensions of health mobility, self-care, usual activities, pain/discomfort, and anxiety/depression and overall self-expressed health status was measured with a visual analogue scale (VAS) of 0 to 100. The data were collected from responses first time during discharge (baseline data) and follow-up data were after three, six and nine months of discharge from the hospital.

Each question of EQ-5D-5L consisted of five options such as no problem, slight problems, moderate problems, severe problems and extreme problems assigned a score of one to five sequentially. The total health states from above scale one can define 3125 possibilities. Each health state is recorded as five digit number. For example a code of 55555 indicate extreme problems in all the domains and a code of 54321 indicate extreme problems with mobility, severe problems with self-care, moderate problems with usual activities, slight problems with pain/discomfort domain and no problem with anxiety/depression. For the convenience of evaluation the responses on the questionnaire were bifurcated in to binary scale. If the response was reported as 1 it is considered as 'no problem' and if the response is anything between 2 to 5 it was grouped as 'problem'. The EQ-5D questionnaire also contains a 20 cm visual analogue scale for self-rating of respondent's health at that point of time. This VAS scale is divided in to 100 equal units where in the respondent puts 'x' mark on the scale and writes the number between 0 and 100 in the box provided adjacent to the scale. The VAS score of 0 indicate a worst perceived health of the respondent and a score of 100 indicate best perceived health of the respondent.

The direct expenses of treatment was collected form the bills paid by the patients in the hospital and it was reconfirmed with the billing section. The treatment cost data were grouped as investigation charges, cardiac monitor and respirator charges, consultation charges, procedure charges, drugs charges, nursing and other care charges, bed and food charges as well as miscellaneous charges.

The statistical tests were performed using SPSS (Statistical Package for Social Sciences) with version 16.0 was used (SPSS Inc, Chicago, IL). All the continuous variables were presented in the form of mean with standard deviation or median with inter quartile range whereas categorical and nominal data was presented as proportion. To find the change in the mean VAS score in both groups through all the follow-ups ANOVA was used. 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.

RESULTS

The results are presented in the order of socio-demographic data, clinical data and pharmacoeconomic along with HRQoL evaluations. The socio-demographic data are displayed in table 1. The number of patients participated are 340 in the study. The mean age of the participants was 57.79 ± 9.267 for BMS and 60.65 ±10.103 for DES. The gender distributions of male participants were as follows 79.3% BMS; 80.4% DES and rest of them were females. 72.4% BMS; 80.4% DES were from rural setting with an average monthly income for BMS and DES were Rs. 10212.5±88 for BMS group and Rs. 19859.28±9673.28 for DES respectively. More than 50% of the subjects had a matriculate education. The expenditure for treatment was met through individual family resources with a distribution of 41.4 % BMS; 43.5% DES undergoing PCI.

The clinical data of the patients regarding hypertension was 55.2% BMS and 44.9% DES. The subjects who had diabetes as a comorbidity among participants 34.5% BMS and 43.5% DES. The survey revealed regarding sedentary life style among subjects was 49.5% BMS and 55.2% DES. The other lifestyle data regarding alcohol consumption was 48.3% BMS and 30.2% DES and smoking was 44.8%

BMS; 26.6% DES which are prominent risk factors ACS. The clinical data is given in Table 2.

Table 1: Socio-Demographic Characteristics (n=340) (%)

	Bare Metal Stent (n = 153)	Drug Eluting Stent (n = 187)
Age*	57.79 ± 9.267	60.65 ±10.103
Male	79.3	80.4
Type of Place		
Rural	72.4	70.1
Urban	27.6	29.6
Education		
Uneducated	17.2	9.8
Less than 10th	65.5	56.5
10^{th} to 12^{th}	10.3	16.8
Graduate	3.4	11.4
Professional Degree	3.4	5.4
Occupation		
Home Maker	20.7	19.0
Professional	3.4	11.4
Skilled Labour	20.7	23.4
Business	10.3	11.4
Retired	13.8	14.7
Agriculture	27.6	13.6
Fishing	3.4	3.8
Govt. Services	Nil	2.7
Monthly Income*		
INR	10212.5±88	19859.28±9673.28
Payment Mode		
Self	41.4	43.5
Arogya Suraksha	13.8	12.0
Sampoorna Suraksha	24.1	12.5
Yashasvivni	6.9	8.7
ESI	3.4	8.2
Others	10.4	15.1
Comorbid conditions		
Diabetes	34.5	43.5
Hypertension	55.2	44.9
Asthma	3.4	2.2
Risk factors		
Smoking	44.8	26.6
Alcohol	48.3	30.2
Sedentary Lifestyle	49.5	55.2
Tobacco Use	24.1	19.0
Family History		
Diabetes	31.0	42.1
Hypertension	55.2	52.7
BMI*	22.77±3.78	24.32±3.92

* Mean ± SD

Table 2: Clinical Characteristics (n = 340) (Mean ± SD)

	Bare Metal Stent (n = 153)	Drug Eluting Stent (n = 187)
No. of Hospital Stay days	6.00±1.167	6.13 ±1.684
Primary Diagnosis*		
STEMI	72.2	58.5
NSTEMI	27.8	41.5
Type of Block*		
SVD	62.1	49.5
DVD	27.6	38.0
TVD	10.3	12.5
SBP	134.86±14.549	131.91±12.564
DBP	82.57±7.96	79.87±7.314
Total Cholesterol	190.24±76.69	191.76±55.34
HDL	36.0±11.82	38.70±15.69
LDL	128.76±72.33	126.35±49.64
Triglyceride	126.29±78.17	124.67±66.39
FBS	131±35.46	160.94±117.04
PPBS	265.06±105.14	185.67±49.42
HbA1c	5.7±1.2	8.6±3.92

* Percentage value; STEMI – ST elevated myocardial infarction, NSTEMI – Non ST elevated myocardial infarction, SVD – Single vessel disease, DVD – Double vessel disease, TVD – Triple valve disease, SBP – Systolic blood pressure, DBP – Diastolic blood pressure, HDL – High density lipids, LDL – Low density lipids, FBS – Fasting blood sugar, PPBS – Post prandial blood sugar

Table 3: EQ 5D Utility Values and VAS Scores

Utility Value (Mean ± SD)			
	Total	**BMS**	**DES**
At Discharge (Baseline)	0.4768 ± 0.1648	0.5054 ± 0.1848	0.4715 ± 0.1615
1^{st} Visit (3 Months)	0.6442 ± 0.1880	0.7211 ± 0.1937	0.6321 ± 0.1848
2^{nd} Visit (6 Months)	0.3348 ± 0.4309	0.4410 ± 0.4143	0.3181 ± 0.4322
3^{rd} Visit (9 Months)	0.4415 ± 0.3696	0.4037 ± 0.4035	0.4477 ± 0.3646
Visual Analogue Score (Mean ± SD)			
At Discharge (Baseline)	60.72 ± 13.844	62.07 ± 13.786	60.15 ± 13.878
1^{st} Visit (3 Months)	78.20 ± 10.756	80.00 ± 9.714	77.92 ± 10.909
2^{nd} Visit (6 Months)	79.62 ± 8.193	82.48 ± 7.199	79.17 ± 8.267
3^{rd} Visit (9 Months)	79.57 ± 8.392	78.68 ± 9.109	79.71 ± 8.287

Total number of days of hospital stay for both the groups was found to be six days and the primary diagnosis revealed the patients with STEMI for BMS 72.2% and DES 58.5% and NSTEMI BMS 27.8% and DES 41.5%. The subjects with single vessel disease were BMS 62.1% and DES 49.5% respectively.

Table 3 shows the utility values and visual analogue scale scores calculated as per the manual of EuroQol.

The ANOVA one way and Mann Whitney statistical analysis was performed on the data. Table 4 shows the results of one-way repeated measures analysis (ANOVA). The one-way ANOVA was conducted to compare the VAS scores at discharge, 3 month follow-up, 6 month follow-up and 9 month follow-up. The means and standard deviations are shown in table 3. There was a significant effect for time, Wilk's Lambda = 0.13, F(3, 25) = 53.87, P = 0.001 for BMS group and wilk's Lambda = 0.24, F(3, 167) = 168.61, P = 0.001 for DES group. The pair wise comparisons between visits are show in Table 4.

Table 4: Pair wise comparison for BMS group

Visit (I)	Visit (J)	Mean Difference (I-J)	Std. Error	Significance	95% Confidence Interval for Difference [a]	
					Lower Bound	Upper Bound
1	2	-17.857*	1.773	0.000	-22.906	-12.809
	3	-20.500*	3.057	0.000	-29.202	-11.798
	4	-16.893*	3.343	0.000	-26.409	-7.377
2	1	17.857*	1.773	0.000	12.809	22.906
	3	-2.643	1.975	1.000	-8.265	2.979
	4	0.964	2.059	1.000	-4.897	6.826
3	1	20.500*	3.057	0.000	11.798	29.202
	2	2.643	1.975	1.000	-2.979	8.265
	4	3.607*	1.230	0.041	.104	7.110
4	1	16.893*	3.343	0.000	7.377	26.409
	2	-0.964	2.059	1.000	-6.826	4.897
	3	-3.607*	1.230	0.041	-7.110	-0.104

Table 5: Pair wise comparison for DES group

Visit (I)	Visit (J)	Mean Difference (I-J)	Std. Error	Significance	95% Confidence Interval for Difference [a]	
					Lower Bound	Upper Bound
1	2	-17.559*	0.776	0.000	-19.631	-15.487
	3	-19.235*	1.179	0.000	-22.382	-16.089
	4	-19.641*	1.224	0.000	-22.910	-16.373
2	1	17.559*	0.776	0.000	15.487	19.631
	3	-1.676	0.824	0.261	-3.877	0.524
	4	-2.082	0.878	0.113	-4.428	0.263
3	1	19.235*	1.179	0.000	16.089	22.382
	2	1.676	0.824	0.261	-0.524	3.877
	4	-0.406	0.606	1.000	-2.025	1.213
4	1	19.641*	1.224	0.000	16.373	22.910
	2	2.082	0.878	0.113	-0.263	4.428
	3	0.406	0.606	1.000	-1.213	2.025

Mann-Whitney test significance is <0.001 for total cost. The cost data was the expenditure spent by the patient while he was treated in the hospital and also during the length of stay till the discharge are given in table 6 in INRs.

The Mann Whitney test showed significant difference (P<0.001) in total treatment cost of BMS and DES.

DISCUSSION

In India the awareness of consequences of serious illness is missing among the public. The people neglect

their health and adopt sedentary life style along with negative health habits like smoking and alcoholism.

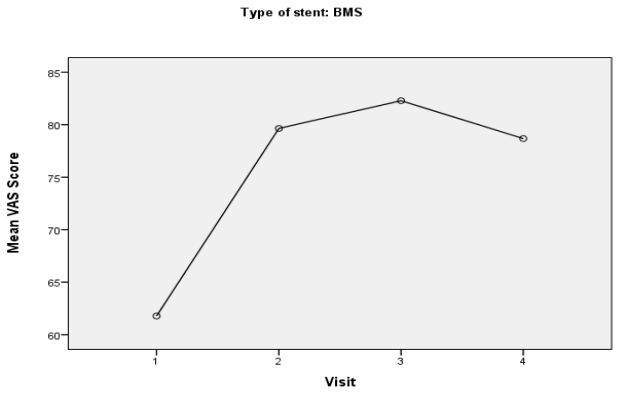

Figure 1: Mean visual analogue score for bare metal stent group

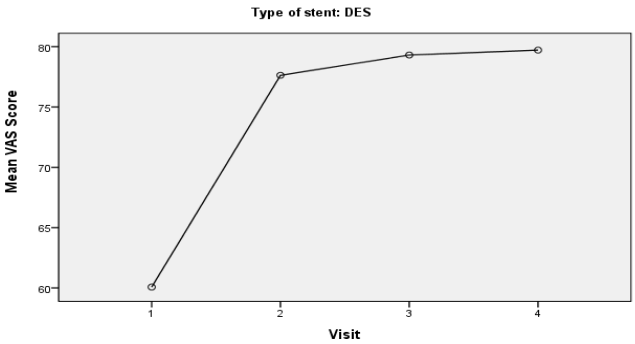

Figure 2: Mean visual analogue score for drug eluting stent group

Table 6: Treatment Cost data for BMS and DES

Cost (INR)	BMS Median (IQR)	DES Median (IQR)
Investigation Charges	1900 (1070 - 3047)	1705 (1035-4767)
Cardiac monitor and respirator charges	500 (500- 1150)	500 (500-1000)
Consultation charges	6350(6112- 7696)	6500 (6000-8500)
Medicine Charges	44970(44970-60582)	110568 (75088-118801)
Nursing and other care charges	50(50-125)	275 (75-800)
Bed and other charges	180 (60-225)	550 (120-600)
Miscellaneous charges	7019 (6379-7448)	1782(781-2484)
Total Charges	68373.93(49890.42-74706.86)	121883.10(97087.57-134468.18)

This has led to the epidemics of chronic diseases like diabetes and hypertension along with obesity. As the above chronic conditions are symptomless and are slow in morbidity the people ignore early symptoms and continue to practice unhealthy lifestyle. People seldom recognise the above conditions are gateway to cardiovascular diseases, stroke and kidney diseases. The cardiovascular diseases like angina and myocardial infarctions are one of the leading diseases causing heavy casualty among rich and poor, educated and uneducated, men and women. The cardiovascular diseases can lead to death due to heart failure. The ACS is one of the conditions reported in large number to the department of cardiology. The ACS being a medical emergency needs an immediate treatment. ACS also causes unbearable referred pain for the patient increasing the morbidity and suffering affecting the quality of life of the patient. The ACS can be treated either by bypass surgery or by angioplasty, which depends upon the clinical condition of the patient as diagnosed by cardiologist. The angioplasty is preferred over bypass surgery due to the less recovery time reduced surgical procedure. In bypass surgery is also known as open heart surgery involves the heavy surgical intervention compared to PCI. Further length of stay for open heart surgery is higher due to recovery time being more. The PCI is a procedure which takes couple of hours and recovery is quick. One of the important issue in PCI is restenosis is drawback of the vessels after few days of angioplasty. In order to overcome and ensure the restenosis doesn't happen antiplatelet drugs like aspirin and clopidogrel are to be taken for rest of the life period. In order to be more certain the metal stents are introduced in to the coronary artery where the block was present. The stents are made by metallic alloys which doesn't allow the restenosis of coronary artery.

The stents were improved further by embedding the antiproliferative drugs like placlitaxil and serolemous which prevent the growth of cells inside the vessel at the site of blockade. The DES are more expensive than the BMS by fifty percent. The patients in India are usually under covered by health insurance and the government support and philanthropic help are inadequate making the patient to take a decision involving high expenses. The average BMS cost in our study was 40000 INR whereas DES cost was 100000 INR.

The ACS has heavy burden of morbidity highlighted by angina pain. The patients are too much psychologically stressed due to suffering and expenses of treatment which leads to depression causing poor quality of life. The drug treatment and wait and watch techniques by the patient are only time buying as there is no way to get relief from ACS other than bypass surgery or angioplasty.

The Xavier Et al., has created a registry of ACS patients in 2008 to study the treatment and outcomes in India[2]. This study compared the distribution of patient population for STEMI and NSEMI amongwestern countries and India. Further the study reported 70 percent STEMI prevalence a strikingly different trend

compared to west. The reason for high rates of STEMI in India is attributed to poor access to facilities due to socioeconomic causes. In our study we have also observed high rate of STEMI than NSTEMI. As STEMI is a condition where complete blockade of a vessel leading to heart failure, needs an aggressive treatment with thrombolytic like streptokinase whereas NSTEMI there is a partial blockade. Our patient pool is a combination of Urban and Rural, the patients from rural are farmers and fishermen by occupation without having regular occupation and income. Their economy mainly dependent on monsoon and income earned out of agricultural produce. The results strongly reinforce the role of economic background being one of the predictor for high rate of STEMI among Indian rural patients.

Although the partial finance is given as a government subsidy the expenses of nearly 40 percentage in BMS group and 43 percentage of patients in DES group pay by self-resources rest of the patients except ESI receive a partial subsidy. The economic burden is definitely on patient and family leading to distress influencing the quality of life negatively. We are the first to report quality of life data for ACS patients on PCI intervention patients. In our previous communication we have reported the quality of life results before and after the PCI. In this study we are reporting the quality of life data among patients for combined group and BMS and DES (Table 3). The quality of life data had a significant improvement from discharge to the first visit and in subsequent second and third visit the marginal improvement is seen in both groups. However the quality of life for DES group was achieved in the first visit only. The probable reason for attaining the higher quality of life in short period among DES patient may be due to psychological confidence perceived by the patients that they have chosen a better performing stent apart from the clinical benefits the DES offers due to anti-proliferative drugs.

CONCLUSION

The clinical outcomes are not available except for the baseline data when patient was admitted to hospital for PCI. Hence we are excluding the impact of BMS and DES on clinical outcomes. There is a need to include more patients and multi-centric to get more clarity on pharmacoeconomic burden and quality of life for BMS and DES. The outcomes clearly indicates there is a substantial economic burden for the patients of DES group and also the quality of life attainment is quick in comparison to BMS group.

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