

PHARMACOECONOMIC EVALUATION AND AN AUDIT OF QUALITY OF LIFE IN HYPERTENSIVE AND DIABETICS IN A RURAL TERTIARY CARE HOSPITAL

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Abstract

Introduction: Healthcare budget pressure, justification of current expenditures and investments in public health care/individual are flatter a priority in chronic diseases. Hence, this study was carried out with the objective to evaluate the cost of illness in Diabetic Mellitus (DM) and Hypertension (HTN) and their Quality of life (QOL).

Method: It was a prospective and Interventional study conducted in patients over a period of 9 months. The data were subjected to a descriptive statistical method.

Results: Among 110 patients, 60 % was males. 41.8 % were 41-60 years & 52.7 % were former. Only 1.8 % were obese. 37.3 % had a previous diabetes history . 74.5 % of the patient's hospital stay was 6-10 days. The medication history showed 44.5 % was taking insulin therapy. 35.1 % were taking calcium channel blockers. . The direct medical cost mean + SD, was INR 3668.70 + 3326.49 (\$59.36 + 53.8). In which medicine cost was Uppermost. Direct non-medical cost mean + SD, was INR 405.78 + 455.18 (\$6.56 + 7.36), in which food cost was the highest followed by travel expenses. The total direct cost mean + SD, INR was 4074.48 + 3627.506 (\$65.9+ 58.68). The overall Quality of life (SF 6 version) results showed improved (p: ≤ 0.05)

Conclusion: This study showed that Quality of life assessment and simultaneous cost estimation will helps to understand the treatment pattern & drugs cost minimization. Hence, Pharmaco economic research studies are essential in minimizing the cost, enhancing the quality of life.

Keywords: Diabetes mellitus (DM), hypertension (HTN), direct medical cost, direct non-medical cost, Total direct cost, Quality of life (QOL)

INTRODUCTION

Economics is a branch of study of the allocation of limited/scare resources or inputs to satisfy the health gain/income, can be rationally achieved by considering the three major elements: identify the choice among alternatives, assessment of costs consequences and decision-making within limited (or fixed) budgets. [1].

Pharmacoeconomics is a branch of health economics which deals with the measurement of both the costs (i.e. Resource consumed) and consequences (i.e. Clinic, economics, humanistic). [2, 3]. Hence, these studies have been increasingly employed, to assess the efficacy, effectiveness and availability of health care program, procedure and services [4, 5, 6]. The importance of Pharmacoeconomics research is: measuring the total cost of a health program, increasing quality in health, increasing access to care and ensuring sustainability of health care resources, give better health care (quality of life) with minimization of cost, compared to intervention having the equal efficacy of drugs [7]. The methods used in the pharmacoeconomic study are (a) cost benefit (b) cost-effective (c) cost minimization (d) cost-utility analyses [8].

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia associated with abnormalities in carbohydrate, fat and protein metabolism; results in chronic complications like microvascular, macrovascular and neuropathic disorders . The prevalence of diabetes worldwide is projected to reach 382 million, between the age of 40 to 59 by 2035, and 80% are living in low-middle-income countries. DM associated complications caused the negative impact on life; which intern leads to a substantial increase in the cost of health care. So the pharmacoeconomic consideration in each step will help in minimizing the cost therapy and helps in optimizing the Quality of life of patients. [9].

Hypertension is defined as constantly elevated pressure above 140/90 mm/Hg. It is highly prevalent chronic health condition with its devastating consequence of the heart and cardiovascular system. The prevalence of the global burden of hypertension may reach 1.5 billion by 2025. So Hypertension is one of the most leading causes of mortality, disability and its expensive treatment showed the pharmacoeconomic consideration will help in

optimizing the quality of life [5]. The cost analysis results showed Diabetes with hypertension health care cost was more compared to diabetes, Hypertension alone. One of the research studies showed the total world Health care expenditure on DM are expected at least USD 490 billion by 2030 [10].

The Pharmacoeconomic study can establish a basic cost /burden of the disease management by considering the resource used and its humanistic impact [11]. This baseline comparison between follow-up will help in getting of clear economic data/Burden of disease.

Generally Cost-of-illness studies cover, direct and indirect costs. Direct costs refer to medical care in the form of prevention, diagnostics, treatment and rehabilitation, etc. Indirect costs consist of loss of productivity, which had an effect of society due to days off from work, early retirement, and death caused by the disease [12].

Direct costs are subdivided into direct medical costs and nonmedical direct costs. Direct medical costs include hospital inpatients, physician inpatient, physician outpatient, emergency department, outpatient, nursing home care, hospice care, rehabilitation care, specialists and other health professional care, diagnostic tests, prescription drugs and drug sundries, and medical supplies. Nonmedical direct costs include transportation costs to health care providers; relocation expenses; and costs of making changes to one's diet, house, car, or related items. However, some nonmedical direct costs are generally not included in cost-of-illness studies such as research, training, and capital costs [13].

In India growing pressure on the healthcare budget, appropriate justification of current expenditures and future investments in public health care priority, Pharmacoeconomic analyses are the need of the hour [14].

In India Currently, Pharmacoeconomics concepts, usage are in budding & 77% of the health care expenditure spending in the private sector, of which about 86% born out-of-pocket/money. The penetration of insurance schemes in India is very low, estimated at about 10% of the entire population. This signifies the importance of economic considerations. Pharmacoeconomics can be used in drug therapy evaluation, most cost-effective drug selection, preparing the formulary, to take a decision on individual therapy and customize patient's pharmacotherapy, evaluate the value of an existing service and implementing a new service potential vale [11,15] like economic evaluation & QOL outcomes. Hence, the present study was selected, with the objektivte :to know the total cost of illness, cost of medication and its QOL.

Methodology

This is a prospective, observational and Interventional study. This study was conducted for a period of 9 months (May 2014 – January 2015). The Ethical clearance was obtained from the ethical committee of Adichunchanagiri Hospital and Research Centre, B.G. Nagara. (EC No: AIMS/IEC/2014-15 Dt:16/7/2014)

The patients who satisfy the criteria (Inclusion Criteria: Inpatients of DM, HTN alone or with a combination, Exclusion Criteria: Comatose patients) were informed and an interested patient were enrolled after obtaining their consent. The required data were collected in a well-designed data collection form (which includes patient demographic details, treatment charts, and investigation reports of patients of medicine, Direct and indirect cost) and the patient was followed from the day one to the day of discharge. The patient medication chart was audited daily for appropriateness like Dosage omission, brand repetition, serious interactions and if any ADR. If any serious interactions observed were informed of the health care professional for necessary modifications. The patient adherence behaviour [Simplified medication adherence questionnaire (SMAQ)] and Quality of life [SF-6D questionnaire] was obtained at the baseline , first & second follow-ups by interview method. The economic data were obtained from the hospital billing & Pharmacy billing departments and even some of the details from the patient and patient caretakers. The obtained data was subjected for descriptive statistics (Mean SD, paired t-test) by using SPSS 20th version.

RESULTS :

Among 120 patients approached, only 110 patients were enrolled and given their consent. The patients demographic characteristics, socio- clinical characteristics (stratified by the presence diabetic and hypertension), showed that majority were farmers.(Table 1).

Table 1: Demographic details of the patients

Demographic data	Number of patients (n=110)	Percentage
Age in years		
20-40	16	14.5
41-60	46	41.8
61-80	45	40.9
>80	3	2.7
Gender		
Male	66	60
Female	44	40
Occupation		
Housewife	42	38.2
Farmer	58	52.7
Others(Driver)	10	9.1
BMI		
<19 (Underweight)	15	13.6
19-24 (Normal)	73	66.4
24-30 (Over weight)	20	18.2
30-40 (Obese)	2	1.8
Social Habits		
Alcoholic	17	15.5
Smoking	15	13.6
No habits	78	70.9
Monthly income in INR		
<2500	9	8.2
2501-5000	49	44.5
5001-10000	45	40.9
10001-15000	6	5.5
>25000	1	0.9
Previous Medical history		
Without medical history	17	15.5
Diabetics alone	41	37.3
HTN alone	7	6.4
Diabetic and HTN combination	37	33.6
Diabetic, HTN and other comorbid disease	8	7.3

No of hospital stay (day)		
<5	21	19.1
6-10	82	74.5
11-15	5	4.5
>15	2	1.8
Disease		
Diabetic	40	36.4
HTN	3	2.7
Both DM and HTN	67	60.9
Diabetic drugs usage		
None/diet alone	3	2.7
Insulin alone	49	44.5
Tablet alone	24	21.8
Both insulin and tablet	34	30.9
Antihypertensive drug Response		
Calcium channel blocker	34	35.1
ACE inhibitors	12	12.4
Angiotensin antagonists(ARBs)	17	17.7
Beta adrenergic blockers	15	15.5
Diuretics	19	19.6

The direct medical cost minimum (Rs;167), maximum (Rs,24989), Mean \pm SD (3668.70 \pm 3326.498) respectively, in which medicine cost was found more.

Direct non-medical cost minimum zero maximum (Rs3200), Mean \pm SD was, 405.78 \pm 455.18 respectively in which total food cost was found more followed by travel expenses.

The Mean + SD of total direct cost was Rs 4074.48 \pm 3627.50. (Table 2)

Table 2: Distribution of Total cost of Diabetic and Hypertensive patients.

costs	Minimum	Maximum	Sum	Mean	SD
Total drug cost	72	15959	232140	2110.36	2090.778
Laboratory cost	0	6800	126150	1146.82	1062.728
Hosp charge, bed charge, nursing, micelles charge, etc	0	5150	46033	418.48	818.339
Direct medical cost	167	24989	403557	3668.70	3326.498
Total travel cost	0	1400	19386	176.24	213.441
Total food cost	0	2000	25550	232.27	296.035
Other expenses	0	0	0	.00	.000
Direct non medical cost	.00	3200.00	44636.00	405.7818	455.18530
Total direct cost	167	28189	448193	4074.48	3627.506

The paired t - test had applied to know the level of significant at 95% CI for medication adherence and quality of life. The base line to first follow up Medication adherence scores, showed that, the Mean \pm SD was 0.573 \pm 0.280 & the p value is \leq 0.05 (significant). (Table3)

Table 3: Medication adherence questionnaires between Base line to 1st follow up:

SMAQ	Mean	SD	Std. Error Mean	T	P
M1base - M1first	.048	.215	.027	1.761	.083
M2base - M2first	.048	.215	.027	1.761	.083
M3base - M3first	.143	.353	.044	3.215	.002
M4base - M4first	.032	.177	.022	1.426	.159
M5base - M5first	.159	.368	.046	3.420	.001
M6base - M6first	.143	.353	.044	3.215	.002
Base –First	0.573	0.280	0.035	2.466	0.05

M: Medication Adherence, SMAQ: Simplified medication adherence questionnaire

The QOL base line to first follow up , P Values of various domains shown for : physical functioning (0.006) the role participation (0.003), the social functioning (0.402), the bodily pain (0.0005), the mental health (0.0005) and the vitality (0.000) respectively. The overall score showed that p value is \leq 0.05 (significant) (Table4)

Table 4: Comparative QOL distribution between base line and 1st follow up:

SF-6D Questionnaire	Mean	SD	Std. Error Mean	T	P
1.Physical functioning	0.423	0.476	0.18	6.837	0.0006
2.Role participation	-0.357	0.501	0.063	-4.887	0.003
3.Social functioning	.079	.747	.094	.843	0.402
4.Bodily pain	0.412	0.703	0.397	4.331	0.0005
5.Mental health	-0.222	0.473	0.059	-3.734	0.0005
6.Vitality	0.889	0.571	0.072	12.354	0.000

The P value of QOL first to second follow up for various domains are ; physical functioning (0.00) respectively, the role participation (0.045) ,social functioning (0.002) ,bodily pain (0.172) mental health (0.121) vitality (0.000) respectively. The over score p value was \leq 0.05 (significant) (Table5)

Table 5: Comparative QOL distribution between 1ST follow up and 2nd follow up:

SF-6D Questionnaire	Mean	SD	Std. Error Mean	T	P
1.Physical functioning	0.576	0.471	0.059	10.049	0.000
2.Role participation	-0.063	0.246	0.031	-2.050	0.045
3.Social functioning	0.238	0.588	0.074	3.215	0.002
4.Bodily pain	0.047	0.199	0.025	1.656	0.172
5.Mental health	-0.04	0.196	0.0245	-1.593	0.121
6.Vitality	0.619	0.580	0.073	8.472	0.000

The P value of QOL baseline to second follow up for various domains are ; physical functioning (0.00) the role participation (0.003), social functioning(0.004) bodily pain (0.001) mental health (0.000) vitality (0.000) respectively. The over score p value was ≤ 0.05 (significant) (Table6)

Table 6: Comparative QOL distribution between base line and 2nd follow up

SF-6D Questionnaire	Mean	SD	Std. Error Mean	T	P
1.Physical functioning	1.001	0.528	0.066	15.966	0.000
2.Role participation	-0.405	0.517	0.065	-5.074	0.003
3.Social functioning	0.317	0.839	0.106	3.003	0.004
4.Bodily pain	0.46	0.806	0.101	4.176	0.001
5.Mental health	-0.262	0.540	0.068	-3.854	0.000
6.Vitality	1.508	0.535	0.067	22.372	0.000

Discussion

The majority of the age group observed was 41-80 years. This may be because of less self-care, less health consciousness, more stress for earning/burdens and improper nutrient. According to current worldwide ratios of the incidence disease (DM & HTN) was more in these 41-80 years. A similar type of study conducted by Mehdi Java bash et al [18] showed 45-70years of age was common.

Among the sex, Male was more, when compared with female patients (40%).Male patients were more because of exposure of various stressful moment, working areas and their lifestyle. The similar type of study conducted by Bhavik shah et al [19] showed slightly more than our study of males & less in female i.e. (72.3 % male and 27.3 % female).

Because rural study, farmers was more 52.7%, than housewife 38.2 %. This may be because of an agriculture profession, and their education, showed low literacy, lack of awareness. Even their economic status was poor, 45.5 % patients had monthly income between 2501-5000 (40.46-80.9 USD). This may be because of lack of job opportunity in the rural area. Even this similar type of study was conducted by Filipe Prazeretal et al [20] showed 44.6% had not enough money to fulfill their daily needs.

Interestingly Majority of the patients BMI results showed normal, a very few patient had overweight, this may because of their hereditary lack of conscious about the diet maintenance. The underweight were least because of poor diet.

The alcoholic patient 15.5 % was more compared to smoker patients 13.6 % because of lower monthly income and daily consuming of cheaper alcohol than cigarette price. The Even similar study was conducted by Siddhartha Kashruthy et al [9] showed double than our study result [alcoholic (31.7%) and smoker (28.1%)].

The medical history of diabetic patient 37.3 % were found more in our study compared to hypertensive patient 33.6 %. The only diabetic patients were more because of the improper balance diet maintenance and lack of physical health and awareness. Even the similar study conducted by Maxwell O et al [21] showed, diabetic patient percentage was almost double 64.5% , Majority 74.5% stayed in the hospital for 6-10 days because of poor control of blood sugar level, health status, nutritional status and even their socioeconomic status due to free food facility.

Among 110 patients 36.4 % patients had only diabetics, and 67 had both diabetic and hypertension. The only insulin therapy was given in 44.5 % , oral therapy was given in 21.8 % and both oral and insulin therapy was given in 30.9 % patients , among hypertension CCB (35.1%), ACE Inhibitor(12.4%), ARB(17.7%), B-blocker (15.5%)and diuretic was given in 19.6% diabetic and hypertensive patients. The insulin therapy usage was most widely used restore the physiological to normal at the admitting time and CCB usage was more because of low cost and its effectiveness in cardiac disease. Even the similar study was conducted by Bhavik shah [22]and Hanken Demirci et al.[23] showed more no of patients were using insulin therapy and ACE inhibitor.

The drug interaction observed in 22 patients, generally which will increase the cost of illness treatment. Five drug interactions were major (Ciprofloxacin + ondansetron, levofloxacin +H.Actrapid, levofloxacin+ondansetron) and 10 were moderate (Ramipril+Furosemide, Enalapril + Aspirin, Atenolol+Amlodipine, Metformin+levofloxacin) and 7 were minor (spironolactone-telmisartan, metformin – milk, paracetamol-tramadol).

Cost-of-illness in Diabetic and hypertensive was done on the sum of direct medical and direct nonmedical cost.

Direct medical cost is the sum of medicine cost, lab test charges, and hospital charges. Since it was carried out in a rural service-oriented hospital. Patients in ICU/CCU were charged for physician consultation, nursing, medicines, oxygen and bed while patients in general wards were charged only for oxygen and medicines. Among the 110 patients enrolled 93.6 % were admitted in general wards. 9.1% of the patients had direct medical cost Rs. <1000 (\$16.8), in which the patients who stayed inwards were charged nominally for lab investigations. 68.2 % of patients had direct medical cost in between Rs. 1000-5000(\$16.8-80.09). Indirect medical cost, medicine cost was more, because the patients were treated with insulin therapy and with antibiotics. In some patients, the direct medical cost was high because of other complication diseases. The lab charges for patients in ICU/CCU were more than other patients since ICU/CCU patients undergo hematological, urinary, blood sugar level analysis. The similar study was conducted by Mehdi Javanbakht et al [18] showed the average direct cost was 406.6 USD per capita.

Direct non-medical cost is the sum of travel expenses and food expenses of the patient and patient caretaker. In total 76.4% of the patients had direct non-medical cost Rs. <500 (\$8.09), 17.3 % had direct non-medical cost in between Rs. 501-1000 (\$8.1-16.1), 3.6 % had direct non-medical cost in between 1001-2000 (\$16.12-32.3) and only 2.7 % patients had a direct non-medical cost Rs. >2001(\$32.35), the direct non-medical cost is less when compared with other cost-of-illness studies, since this study was carried out in a rural, service-oriented hospital. when compared to other studies, the travel expenses were less in our study because the transport used by patients was auto-rickshaw, bus and car, in which most of the patients used auto rickshaws. In general wards, the food provided was free for the patients. Patients near to the hospital locality had food from their home. Hence, No other particular charges were found here. The similar study was conducted by Mehdi Javanbakht et al [18] showed the average nonmedical was\$ 18.5 per capita.

Total direct cost of the patient is the sum of direct medical cost and direct non-medical cost. Only 3.1 % of the patients had direct cost Rs. >10001(\$161.8) and 4.5 % patient had direct cost Rs. <1000 (\$16.1) Since it was a tertiary care hospital running a charity organization, the lion part of the treatment cost had been paid by hospital organization itself. This kind of financial assistance helped in the minimization of the overall treatment cost of the patients enrolled in this study. A maximum number of patients (42.7%) had a total direct cost between Rs. 1001-3000 (\$16.12-48.54), 25.5% and 23.6 % had total direct cost in between Rs. 3001-5000 (\$48.55-80.9) and Rs. 5001-10000 (\$80.92-161.8) respectively. The similar study conducted by Mehdi Javanbakht et al [18] showed, drug cost was 23%, lab 9%, hospital charge were 9.5 % and indirect cost of 2.2 % of \$842.6 per capita.

This study showed the total cost of diabetics and hypertensive patients from the day of admission to the day of discharge, showed a minimum cost of Rs. 167(\$2.7) and a maximum cost of 28,189(\$456.1). The mean cost was Rs. 4074.48 + 3627.506 (\$65.93 + 58.6). The least cost with travel & its Mean was 176.24 + 213.441 (\$2.84 +

3.45). A similar study conducted by Mehdi Jayanabkht et al [18] showed the average annual direct cost per patient was \$842.6 per capital.

Among of 110 patients 63 patients came for complete follow-up. The remaining patients were not coming due to of financial problem, away from a home place and referring to other practitioner's follow-ups. The Simplified medication adherence questionnaire (SMAQ) was asked to know the patients were taking medicine or not. Pair t-test had applied to know the level of significant at 95% CI, between baseline to first follow-up, the results showed that p-value is ≤ 0.05 (significant) this clearly showed that monitoring/stressing to the patient about their health by the Pharmacist in the follow-ups will help them to take the medicine regularly. Even the similar study was conducted by Hernando Knobel et al 34 showed significant P-value i.e. ($P < 0.001$).

Among of 110 patients 63 patients have come for complete follow-up. The remaining patients were not coming due to of financial problem, away from a home place and referring to another practitioners follow-ups. After admitting the patient in the ward, the questionnaires (SF-6D) was administered at the baseline, during treatment. The patient was administered the same questionnaires at the follow-ups. The paired t-test had applied to know the level of significant at 95% CI, between the base line to 1st follow-up, 1st follow up to 2nd follow up and base to 2nd follow up. The Physical functioning, Role functioning, Bodily pain, Mental health, and Vitality were significant and social functioning was not significant in the baseline to first follow-up comparison. Similarly in the first line to the second line the Physical functioning, social functioning, and Vitality were significant. The Role participation, Bodily pain, and mental health were not significant because of poor health control and lack of basic health knowledge and less counseling aids. The counseling aids like patients drugs and disease leaflets were used in the first follow-up helps them to increase in these scores. Similarly in overall comparison that is the base to second the Physical functioning, Role participation, Social functioning, Bodily pain, mental health, and vitality were showed significant P value less than 0.05. The result showed that a significant enhancement in the quality of life of patients because of pharmacist medicated patient counseling and proper treatment. Even the same study was conducted by Siddhartha kaskurthy et al [9] showed similar results i.e. ($p < 0.05$).

Conclusion

The present study could serve as a framework upon which further studies on the cost of illness and quality of life of the patient can be conducted to investigate the scope for pharmacoeconomic studies and quality of life of diabetic and hypertensive rural patients.

This study concluded that medical cost was major among all the cost and hospital cost were less except the patients they had stayed in ICU\ICCU. Direct medical costs were more when compared with direct nonmedical cost. Even this study also showed, Pharmacist role in multi-disciplinary healthcare team & patient counseling, showed a significant enhancement in quality of life and clinical outcomes in patients.

Limitation

The sample size & study was done for shorter periods, Even this study can be done for longer.

The study was conducted in a research/service oriented hospital; the hospital charges like a bed, nursing, physician checking were free of cost except ICU/ICCU and special wards Hence this cost was not observed in our study.

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Reference

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