A Comparative HRQOL Study of High Cost and Low Cost Anti-Diabetic Products

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Purpose: This study aims to compare high cost and low cost anti-diabetic products by a HRQOL study.

Methods: This is a cross-sectional, prospective, observational study carried out in a private endocrinology clinic which purchases medicines at a low cost and dispenses them free of cost to the patients. In the private out-patient clinic, medicines are prescribed by the doctor and purchased by patients. The patients purchase them from a pharmacy adjacent to the clinic and these medicines are comparatively of higher cost than the medicines given in a government hospital. The study group includes 117 randomly selected patients using anti-diabetic medicines of high cost and 115 randomly selected patients using low cost medicines. These patients were interviewed using SF-36, and their HRQOL values were recorded. The patients were counseled for three months by trained pharmacy students, with the help of printed brochures that explains the diet, dietary intake measures, dietary restrictions, daily exercise. At the end of three months, their HRQOL was recorded again.

Results: Pre-counseling, the low cost medicine users have a significantly lower mean HRQOL in all the domains and in total HRQOL, when compared to the high cost medicine users. The patient counseling effort has shown a significant improvement in the HRQOL values of all the domains of both high cost and low cost anti-diabetic medicines. However, the mean HRQOL values of the low cost medicine users were still significantly lesser than the high cost medicine users in most of the domains.

Conclusion: In general, users of low cost products of selected medicines showed a lesser HRQOL than the high cost products of the same medicines. Patient counseling resulted in improving the HRQOL values of all the patients in all the groups.

Keywords: Anti-diabetic drugs, HRQOL, Patient counseling, Quality of Life

INTRODUCTION

Prices of medicines influence patient compliance; they have an economic implication for the nation, as prices of medicines effect patient compliance which affects public health. Different nations have different regulatory systems for prices of medicines and differently structured markets. The number of formulations and bulk drugs manufacturing units in India has grown phenomenally in the last decade and the value of production including exports jumped from 10.0% to 15.0% for bulk drugs and 22.0% to 25.0% for formulations in 2009-2010.[1] The prices of the same medicine being formulated by different companies are widely different in the case of many medicines. This complex situation warrants a scientific investigation into the realities of medicines to find out whether there is any correlation between the prices of medicines on one hand and their effectiveness, as measured by the average HRQOL they impart, on the other hand.

Research into the quality of pharmaceutical products that are produced by several pharmaceutical companies has been going on for nearly a decade in the laboratories of AU College of Pharmaceutical Sciences, Andhra University, Visakhapatnam. The central idea was to verify whether the consumer could, with confidence, assume that all the products of a drug in the market are equivalent and interchangeable, because all companies in India are by law, required to release into the market, products that meet Pharmacopoeial requirements only. HRQOL is a good measure of the therapeutic efficacy of the drug. Diabetes causes a rise in blood glucose and this condition is very likely to adversely affect the physical, mental and social domains of the patients.

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As the blood glucose is controlled by a therapy using an effective drug, this adverse effect is likely to be balanced and the HRQOL is expected to return to normal. Diabetes may cause the HRQOL to fall[2] but the treatment of diabetes may cause the HRQOL to rise. Hence the capacity of different brands of the same generic, in whether they are causing proper blood glucose control or not is very likely to be reflected in the HRQOL of the patients using them.

This study was planned to find out whether there is any correlation between the costs of medicines and their effectiveness by carrying out a HRQOL study. This is a cross-sectional prospective observational study. Diabetic medicines are most widely used and their therapeutic effect is determined by clear clinical parameters such as blood glucose levels. There is a wide variation in costs of medicines being prescribed by doctors in endocrinology clinics and in government hospitals in the case of anti-diabetics. Research on HRQOL of diabetes patients was earlier undertaken in the laboratories of AU College of Pharmaceutical Sciences, Andhra University, Visakhapatnam. The hypothesis is that, though several factors affect HRQOL, the medicine being used is also a factor and is a significant factor. When the population being treated in a single clinic or hospital was surveyed for their HRQOL, it may be considered that all other factors are generally similar and the difference if any, in the HRQOL, due to the medicine must come out. In a study carried out by Vedavathi T[3] the hypothesis taken was that if there is a significant difference between the therapeutic efficacy of branded generics and generics, then there should be a significant difference between the HRQOL levels of the patients who are using them over a long period. It was found that there is no significant difference between the HRQOL values of branded generic users and generic users and it was concluded that branded generic drugs and generic drugs result in equally good quality of life.

METHODS

Health related quality of life measures: standardized health related quality of life (HRQOL) measures are critical for a number of purposes, including evaluating the effectiveness of health care interventions for age related diseases. Over the years, the SF-36 has been used in surveys of general and specific populations, for comparing the relative burden of diseases across different sub-groups and in differentiating the health benefits produced by health care treatments. It was also used by the authors in previously reported work.[3] SF-36 is a questionnaire which consists of questions concerning the patients assessment of his/her quality of life in eight domains, viz., PF-Physical Functioning, RP-Role Physical, BP-Bodily Pain, GH-General Health, VT-Vitality, SF-Social Functioning, RE-Role Emotional and MH-Mental Health. In the present research project, HRQOL values are measured to establish the correlation between the selected medicines of the same chemical compounds of high cost and low cost products taking the hypothesis that there is no significant difference between the mean HRQOL of patients using low cost anti diabetic medicines and the mean HRQOL of patients using high cost products of same medicines.

PATIENT POPULATION SELECTION

This study was carried out at King George Hospital, Visakhapatnam, and in the outpatient clinic of an endocrinologist, Dr. A. Mythili, Associate Professor, Department of Endocrinology, Andhra Medical College. The patients attending the outpatient department of King George Hospital (KGH), Visakhapatnam are dispensed with low cost anti-diabetic medicines. The government selects/purchases the medicines after issuing the tenders for submission of quotations and then the quotation with the least prices is selected for purchase, after the pharmaceutical company fulfills the norms of the Government. There are four private outpatient clinics for endocrinology in Visakhapatnam and the outpatient clinic run by Dr. A. Mythili was selected for the study by a randomized procedure. The patients attending the outpatient clinic of Dr. A. Mythili are prescribed high cost medicines, available at the retail medical shops. The prescribed medicines are very high in cost compared to those dispensed in KGH. The high cost glibenclamide tablet is 23.20 times costlier than the low cost glibenclamide tablet and the high cost metformin HCl tablet is 8.93 times costlier than the low cost metformin HCl, This research work was approved by the Institutional Ethics Committee for Human Research of Andhra University as well as by the Superintendent of KGH, Visakhapatnam. The chosen instrument for the study of health related quality of life (HRQOL), was SF-36, whose copy right is owned by Quality Metric. License was obtained from Quality Metric after paying the relevant fee for SF-36, its English version, Telugu version (the local language), and its scoring manual.

SELECTION OF PATIENTS

The investigator waited in the outpatient area of the hospital or clinic and approached the patients whose number in the list of patients corresponded to a randomly identified digit or it's multiple. The investigator waited in the hospital and the clinic, during the outpatient department hours on a number of days and on each day, one digit between 2 and 10 was randomly identified and patients with that number or a multiple of that number were selected into the study. The patients who were on anti-diabetic medicines for more than one year, who were above fourteen years, who were attending the outpatient department in one of the two selected healthcare centers and who were willing to participate in the study were approached by the investigator with a request for

participation in the study. Those patients who accepted to participate were selected into the study. The researcher obtained a written informed consent and then administered the SF-36 questionnaire in English or in the regional language, Telugu, as the situation demanded. The patients were given the opportunity to fill the questionnaire themselves, but where they could not do it, the investigator filled the questionnaire after obtaining answers from them. Each interview lasted for about thirty minutes on an average. For each patient, quality of life (QOL) assessment was done when the patient was enlisted into the study and the second was done three months later. Counseling on the usage of medicines and requirements of diet restrictions and daily exercise was given to the patients in these three months, either by investigator or by trained IV B. Pharm students of Andhra University.

The objective in this study was to find out the HRQOL in a group of patients using a type (either low cost or high cost) of medicines, before and after patient counseling. This plan of work was implemented to obtain information which could help the investigator in establishing whether there is any significant difference between the HRQOL values of patients using low cost medicines and high cost medicines, whether there is any effect for patient counseling and whether the effect of treatment is consistent in both categories.

The questionnaires filled were given scores by the scoring manual for SF-36. The scores obtained in eight domains and the total QOL values were analyzed graphically and were compared by 't' test.

RESULTS

The demographics of the patients who participated in the HRQOL study are shown in Table 1. The pre and post counseling results of the HRQOL values in the different domains and are shown in Figure 1 and in Tables 2 and 3.

DISCUSSION

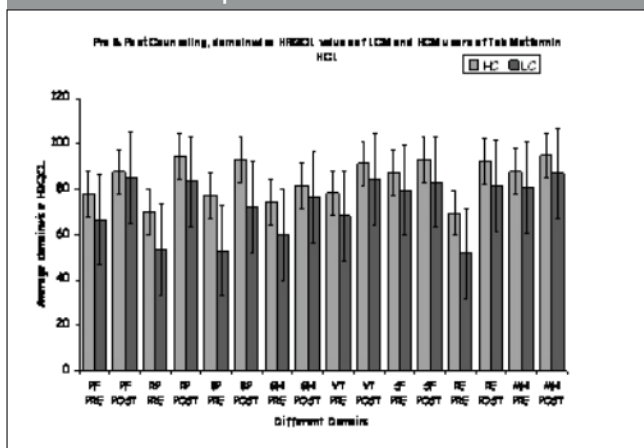Among the patients in KGH, 41 were male patients and 74

Table 1. Demographics of Patients in HRQOL study from KGH and Private Clinic				
Age Distribution	Age(in years) of patients in KGH		Age(in years) of patients in Private Clinic	
	Male	Female	Male	Female
30-39	2	12	6	17
40-49	6	18	18	15
50-59	25	35	19	15
60-69	5	5	14	10
70-79	3	4	3	-
Total Patients	41(35.6%)	74(64.4%)	60(51.3%)	57(48.7%)

Table 2: Pre Counseling Results of Total Patients in HRQOL Study								
	S.No	Component	N	Mean	S.D	P-value	Decision	Power of the test
Total Patients	55	PF HC	117	75.2	24.9	0.002	S	1
(domain scores)		PF LC	115	65	25.7			
	56	RP HC	117	64.3	39.4	0.000	S	1
		RP LC	115	43.3	45.9			
	57	BP HC	117	70	30.6	0.000	S	1
		BP LC	115	52.1	30.1			
	58	GH HC	117	70.4	22.5	0.000	S	1
		GH LC	115	55.7	25.9			
	59	VT HC	117	76.8	21.7	0.000	S	1
		VT LC	115	62.1	26.4			
	60	SF HC	117	85.9	21.9	0.003	S	1
		SF LC	115	76	28			
	61	RE HC	117	68.4	38.9	0.000	S	1
		RE LC	115	47	46.1			
	62	MH HC	117	84.2	18.9	0.000	S	1
		MH LC	115	71.2	26.6			

	S.No	Component	N	Mean	S.D	P-value	Decision	Power of the test
Table 3. Post Counseling Results of Total Patients in HRQOL Study								
Total patients	55	PF HC	117	87.6	15.9	0.021	S	1
(domain scores)		PF LC	115	82.6	16.8			
	56	RP HC	117	88.9	27.4	0.039	S	1
		RP LC	115	80.4	34.7			
	57	BP HC	117	90.8	17.1	0.000	S	1
		BP LC	115	69.7	20.9			
	58	GH HC	117	83	10.7	0.000	S	1
		GH LC	115	70.6	19.2			
	59	VT HC	117	90.5	13	0.000	S	1
		VT LC	115	80.4	18.9			
	60	SF HC	117	92.3	11.6	0.000	S	1
		SF LC	115	83.2	17.8			
	61	RE HC	117	89.5	26.5	0.146	N.S	1
		RE LC	115	83.8	32.6			
	62	MH HC	117	92.9	11.2	0.000	S	1
		MH LC	115	81.7	17.7			

P value: S, significant if P<0.01   **NS**, not significant if P>0.05

Fig. 1: Pre & Post Counseling, domainwise HRQOL values of LCM and HCM users of all patients

were female patients. In both males and females, highest number of patients from the selected group of study was found to be in the age group of 50 to 59 years. Among the patients who attended the clinic 60 were males and 57 were females. Highest number of patients from the selected group of study was in the age group of 50 to 59 years in males and 30 to 39 years in females. Patients who attend private clinics are usually affluent people and one may infer from this observation that diabetes is occurring in affluent females at a younger age.

Figure 1 and Tables 2 and 3 indicate that, pre-counseling, the low cost medicine users have a lower mean HRQOL in all the domains and in total HRQOL. The mean HRQOL values of the patients using high cost anti-diabetic medicines are significantly different from those using low cost medicines, in all the domains and in total QOL. The variability of the mean HRQOL values is more in the patients using low cost anti-diabetic medicines than in those patients using high cost medicines. It is observed from the probability values that the difference is significant in all the domains of pre-counseling.

The bars in Figure 1 and the post counseling mean HRQOL values shown in Table 3, indicate a rise in height from the pre-counseling stage in all the domains and in total HRQOL. However, the bars of the low cost medicine users are still smaller than the bars of the high cost medicine users. The difference between the means of the two categories is significant in the post counseling HRQOL values in all domains but one and in total HRQOL. There is a reduction in the variability in all the standard deviation values indicating that patient counseling has affected a reduction in variability among patients with respect to their HRQOL. However, the variability in the low cost medicine users is still higher than those of high cost medicine users in all the domains and in total HRQOL. Based on these results, the null hypothesis of no significant difference was rejected and it was concluded that the difference between the two categories of patients, in the mean HRQOL values and their variability was significant.

Patient counseling resulted in improving the HRQOL values of all patients. The power of a test is defined as the probability of the test rejecting the null hypothesis when it is in fact false. The probability of deciding that the null hypothesis is true when it is actually false is the probability of a type II error. The

power of a test is known as "one minus the probability of a type II error " or $(1-\beta)$. The power values of the 't' test carried out to find the significance of the difference between high cost medicine users and low cost medicine users, given in Tables 2 and 3 indicate that in all cases the values are equal to one. This may be attributed to the large differences between the means and the big sizes of the samples. It may be said that the 'α' value used and the sizes of the samples were such that if there is a significant difference, it would certainly be detected in most of the cases.

Comparison with past work

Vijayaratna et al carried out a comparison of quality of life and improvement in blood pressure and blood glucose values of patients using branded generic and generic medicines for hypertensive and diabetes treatment.[1] They concluded that there is no difference between the therapeutic efficacy of the selected products of branded generic medicines and generic medicines. They found that there was good correlation between improvement in biochemical values and improvement in HRQOL (rank correlation coefficient between 0.8 and 1.0).

The present work differs in some experimental conditions from this previously reported work. The present work compares selected products of low cost drugs and high cost drugs. In the previous work the HRQOL values of branded generics were recorded from AU Health Center, Andhra University, Visakhapatnam and in the present work, the HRQOL values are recorded from an endocrinologist's outpatient clinic. It may be said that this difference might have resulted in the HRQOL values of low cost drugs coming out to be significantly lower than those of high cost drugs.

CONCLUSION

1. The mean HRQOL values of the patients using selected high cost anti-diabetic medicines are significantly higher than the corresponding values of users of low cost products of the same medicines.

2. Patient counseling resulted in improving the HRQOL values of all patients. But the difference between the two groups persisted, even after patient counseling.

REFERENCES:

1. Health Care of People- Always in All Ways. IDMA, Mumbai: 49th IDMA Annual Publication; 2011. Page No. 273.

2. Ensaf Saied Abdel G, Baun, Mc Hugh N, Singh A, Wajdula JS, Sato R. Quality of life in Saudis with diabetes. Saudi Journal of Disability and Rehabilitation. 2002, 8(3): 163-68.

3. Vedavathi T, Sidagam N, Ayyagari RK, Vijayaratna.J; Comparison of quality of life and improvement in B.P and blood glucose values of patients using branded generic and generic medicines for hypertensive and diabetes treatment. Indian Journal of Pharmacy practice. Vol.3 (1), 31-42, Jan-Mar 2010.