

**Research Article**

# Humanistic Outcome Assessment of Type 2 Diabetes Mellitus Patients: A Prospective Study

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## ABSTRACT

**Objectives:** Understanding and measuring the patient's perception on type 2 diabetes mellitus (DM) treatment's and its related health outcomes are important for developing type 2 DM treatment strategic choices which helps clinicians to make appropriate decisions and benefit the patients.

**Methods:** In this context we conducted a study on type 2 DM patients (n=68) using the translated and validated Diabetes Symptoms Check list -revised (DSC-r) (Tamil Version) Scale for measuring the patient's perception on type 2 DM treatment options. Selected type 2 DM patients were categorized based on their oral hypoglycemic regimens such as, Metformin with Glipizide (M+ GP), Metformin with Glibenclamide (M+GB) and Metformin (M). DSC-r 34 items self-administering questionnaire was used to measure the type 2 DM patients HRQoL status on 8 major type 2 DM symptom domains such as cardiology, neurology, ophthalmology, psychology, hypoglycemia, hyperglycemia, fatigue, pain.

**Results:** The DSC-r Mean Dimensional Score (MDS) were identified and it was found to be 1.97896 for M +GP treated group, 2.06448 for M+GB treated group and 1.96597 for M treated group.

**Conclusions:** Humanistic outcome analysis results showed that all the three anti-diabetic regimens produced only partial health status with the quality-adjusted life-year (QALY) average of about 0.60/Year.

**Keywords:** Pharmacoeconomics, Type 2 Diabetes Mellitus, Humanistic Outcome, Health Related Quality of Life, Burden of Disease

## INTRODUCTION

India is labelled as diabetes capital in the world, in accordance with the International Diabetes Federation (IDF) 2017 reports – In India, there are 82 million people with diabetes and it is expected to increase by 151 million by 2045 <sup>[1]</sup>. Type 2 Diabetes Mellitus Pharmacotherapy becomes a complex process due to the increasing availability of new drug therapy regimens and inter individual variability. Additionally, various standard treatment guidelines are followed for selecting the drugs and treating type 2 diabetes but it is always questionable that the treatment outcomes of these guidelines drug regimens are achieving the treatment goals tailored to the individual requirements. Further, often these guidelines shall overburden the patients with direct and indirect medical costs <sup>[2]</sup>. In this context, the utility of the allotted health resources and its related healthcare services need to be evaluated through various pharmacoeconomic health

outcome measures such as, Clinical, Humanistic, and Economical outcomes of the treatment regimens of type 2 DM <sup>[3]</sup>.

Clinical outcomes are the parameters of health that can be measured and it occurs as a result of healthcare treatment or intervention thereby it helps to understand the effectiveness of individual treatment regimens or program. Economic outcome analysis measures the monetary value of health services and resources in to direct cost, indirect cost and intangible costs for selected treatment regimens <sup>[4]</sup>. Humanistic outcome helps to measure the consequences of diseases or on the treatment of patient functional status and Health Related Quality of Life (HRQoL). In general, humanistic outcome has various intermediaries such as, side effects, effectiveness, Willingness to Pay, medication adherence, patient's knowledge and complexity of the treatment regimens <sup>[5]</sup>. Patient Reported Outcomes refers to indicators which quantify the

state of health by analyzing the reported outcomes of the patient. In general, humanistic outcome status is captured using patient questionnaires through surveys. Understanding and measuring the patient's perception on type 2 DM treatments and its related health outcomes are important for setting treatment strategic choices which help clinicians to make appropriate decisions and benefit the patients [6]. In India very less studies are conducted to measure the health outcomes of type 2 DM pharmacotherapeutic treatment regimens and its related services. In this context, a study was conducted using the revised Diabetes Symptom Checklist (DSC-r) scale to determine the humanistic findings of patients with type 2 DM drug treatments in order to understand the perception of patients.

### METHODOLOGY AND MATERIALS

A cross-sectional study was conducted prospectively to measure humanistic outcomes (HRQoL) of type 2 DM patient's treatments regimens such as, Metformin + Glipizide (M+GP), Metformin + Glibenclamide (M+GB) and Metformin(M) from the secondary care government headquarters hospital, Ooty for the period of 6 months. Based on the projected aim and objective a protocol was designed and Institutional Review Board approval was obtained. Tamil lingual patients who were between the age limit of 18 - 80 years and taking the selected oral antidiabetic medications for the last 2 months without any treatment interruption were included for the study. Patients who are taking ayurvedic or any other treatment for diabetes other than the selected treatment regimens from allopathy were excluded. A written informed consent was provided to the patients and the procedure of the

study were detailed to them. Data collection form was made to collect the following information from the selected patients such as, medical history, medication history, dose, frequency, status of medication adherence. Diabetes Symptom Checklist – revised – Health Related Quality of Life Measurement Scale covers eight major domains of diabetes symptoms that includes, neurology- sensory, neurology- pain, cardiology, psychology- cognitive ophthalmology, psychology- fatigue hypoglycemia and hyperglycemia. The scoring system of DSC-r Scale related to the type 2 DM diabetes mellitus symptoms was measured as 1= Not at All, 2= A little, 3= Moderately, 4= Very, 5= Extremely [7][8]. DSC-r scale was translated into Tamil Language version and it was used to measure the Mean Dimensional Score (MDS) of micro and macro vascular complications and quality-adjusted life-year (QALY) of type 2 DM treatment regimens patients.

### RESULTS AND DISCUSSION

Study totally included 120 patients, out of which 68 patients were selected, in that 20 patients were taking Metformin + Glipizide, 21 patients were taking Metformin + Glibenclamide and 27 patients were taking Metformin alone. Out of the 68 patients, 29 males and 39 females were included for the study with the selected anti diabetic regimens such as, M+GP, M+GB and M. There is no major difference in the mean average between the treatment groups and the overall mean age average was found to be  $56 \pm 9$  and that is shown in the (Table-1).

**Table 1: Age and gender classification of selected type 2 diabetes mellitus patients**

Drugs	Gender		Age			Mean±SD
	M	F	<40	40-60	>60	
Metformin (M) + Glipizide (GP)	7	13	2(10%)	12(60%)	6(30%)	56 ± 9
Metformin (M)+ Glibenclamide (GB)	12	9	3(14%)	14(67%)	4(19%)	54 ± 11
Metformin (M)	10	17	0	18(67%)	9(33%)	57 ± 8
<b>Total (n=69)</b>	<b>29</b>	<b>39</b>	<b>5</b>	<b>44</b>	<b>19</b>	<b>56±9</b>

All the 68 patients were self-administered with DSC-r scale, the actual English version of DSC-r scale was translated and validated for Tamil language DSC-r version. Internal consistency and

validity of content of the translated DSC-r scale were estimated through the preliminary pilot studies and the Cronbach's Alpha was = 0.9745, Standard Alpha= 0.9771, Guttman's Lambda 6

(Squared Multiple Correlation) Reliability = 1 and average inter-item correlation R= 0.5715 and these results showed that the translated Tamil Language DSC-r version had acceptable reliability and validity.

The average Mean Dimensional Score (MDS) of the eight domains of type 2 DM symptoms was found to be 1.97896 for M +GP treated group,

2.06448 for M+GB treated group and 1.96597 for M treated group. The average MDS for all the three regimens was found to be 2.00313. These results show (Table- 2) that the selected treatment group patients had little symptoms (MDS 2= A little) of micro and macro vascular complications.

**Table 2: DSC- r mean dimensional score of type 2 diabetes mellitus patients**

Drugs	P, F	P, C	N, P	N, S	C	O	Hypo	Hyper	MDS
Metformin(M) + Glipizide(GP) (n=20)	1.962 ±0.731 5	2.062 ±0.60 09	2 ±0.835 086	1.6 ±0.74 614	1.837± 0.8403	1.79 ±0.738 348	2.0666 7 ±0.841 886	2.5125 ±0.836 955	1.978 96± 0.452 59
Metformin(M) + Glibenclamide (GB) (n=21)	2.2142 9 ±0.685 956	2.011 9 ±0.66 364	2.2857 1 ±0.628 916	1.722 22 ±0.59 239	1.8571 4 ±0.620 34	1.9047 6 ±0.741 941	1.9841 3 ±0.591 384	2.5357 1 ±0.717 17	2.064 48± 0.367 65
Metformin(M) (n=27)	1.787 ±0.678 317	2.064 1 ±0.65 263	2.0556 ±0.875 229	1.679 01 ±0.75 092	2.0185 2 ±0.840 461	1.6444 4 ±0.789 027	2.0246 9 ±0.640 018	2.4537 ±0.730 638	1.965 97± 0.512 688

MDS – Mean Dimensional Score; Hyper – Hyperglycaemic; Hypo-Hypoglycemic; P, F – Psychology, Fatigue; P, C – Psychology, Cognitive; N, P – Neurology, Pain; N, S – Neurology, Sensory; C – Cardiology; O – Ophthalmology

Further, average QALY of individual treatment regimens of patients were calculated based on the formula QALY= ELY × Utility Value. (ELY) Estimated Life Years is assumed to be equal = 1. Mean Dimensional Scores (MDS) of various type 2 DM treatment regimens were converted into utility index values based on the rating scale that ranges from 0 to 1, 0=dead, 0.5= partial health and 1= full health. The individual patient's utility value

was multiplied with the expected life years to find out the Quality of Life Year (QALY). The average QALY of M+GP, M+GB and M treated groups was found to be 0.60/Year, 0.58/Year and 0.60/Year respectively. The average QALY of these three regimens was equal to 0.60/Year and it shows that patients of these regimens achieved only the partial health status. The results are shown in the (Table- 3).

**Table 3: QALY of different type 2 diabetes mellitus treatment regimens**

Drugs	Number of Patients	Expected Life Years (ELY)	Average Utility Value	QALY= ELY * Utility
Metformin (M) + Glipizide (GP)	20	1	0.60	0.60
Metformin (M)+ Glibenclamide (GB)	21	1	0.58	0.58
Metformin (M)	27	1	0.60	0.60

ELY –Expected Life Years; QALY-Quality Adjusted Life Years

As per WHO CHOICE recommendations type 2 DM treatment medication price was calculated from the mean average price of the twenty available brands of each treatment groups. MPV was found in rupees and converted into US dollars. It was found to be \$ 0.024 (₹1.67) in the

M + GP treated group, \$ 0.033 (₹2.27) in the M + GB treated group, \$ 0.018 (₹1.24) in the M treated group. In our study we found that M+ GB treatment cost was found to be high based on the direct cost measurement. This was shown in the (Table- 4).

**Table 4: Mean price value for type 2 diabetes mellitus treatment regimens**

Drugs	Number of Brands	Mean Price Value/ Tablet (in rupees)	MPV / Tablet (in dollars)
Metformin (M)+ Glipizide (GP)	20	1.67	0.024
Metformin (M)+ Glibenclamide (GB)	20	2.27	0.033
Metformin (M)	20	1.24	0.018

**MPV- Mean Price Value**

As per the findings from the World Bank, the average lifespan of Indians was found to be 68.56 years [9] and the mean average age of the study population was 56±9 years. If we subtract the study population age average from the average lifespan years, the expected life years is found to be 12.56 per patient. The average QALY= 0.60/year gained by the different type 2 DM treatment regimen groups and if we calculate the same for the projected ELY of 12.56, then the QALY gained by the individuals is 7.536. The QALY of individuals might be affected by other confounding factors like age, disease progression, comorbid conditions, lifestyle changes and medication compliance. Further studies should be conducted to understand and improve the QALY and also to reduce the Burden of Disease (BOD) of type 2 diabetic patients.

**CONCLUSION**

Study concludes that selected type 2 anti-diabetic regimens did not offer full health status to its respective patients based on the patient perceptions scores of MDS/Year (Average=2.00313) and QALY/Year (Average=0.60) Hence, none of the selected treatment regimens reached the expected outcomes as full health=1, to the rating scale of 0-1. M+GP denoted QALY= 0.60/year, M+GB displays QALY=0.58/year while M (Metformin) alone gives QALY=0.60/year.

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**COMPLIANCE WITH ETHICAL STANDARDS**

**Informed consent**

A written informed consent in Tamil language, explaining the procedure of the study was obtained from the study participants.

**Consent for publication**

The authors grant the publisher the sole and exclusive license of the full copyright in the contribution. The publisher shall have the exclusive right throughout the world to publish and sell the contribution.

**Ethics approvals**

IRB approval was obtained on 13<sup>th</sup> October 2018 to perform the study.

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Nil

**CONFLICT OF INTEREST**

The authors declare that they have no conflict of interest.

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