Impact of Pharmaceutical Care on Economic, Clinical and Humanistic Outcomes in Type 2 Diabetes Mellitus Patients

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ABSTRACT

Involvement of the pharmacist in collaboration with diabetes care team for effective diabetes management might improve clinical and humanistic outcomes and may reduce health service utilization. Aim: To assess the impact of pharmaceutical care services on economic, clinical and humanistic outcomes in type 2 diabetes mellitus patients (T2DM).Study Design: Prospective descriptive quasi cross over study. Study Setting: Public tertiary care hospital. Study Sample size: 250 Intervention: Pharmaceutical care was provided by clinical pharmacist involved in diabetes care in collaboration with endocrinologist. Clinical pharmacist reinforced endocrinologist advice to people with T2DM utilizing scheduled consultations, clinical goal planning, monitoring, collaborative diabetes care, psychosocial care. Outcome Measured: Changes in direct medical cost of hospitalization and emergency room visit, fasting blood glucose (FBG), blood pressure, knowledge on diabetes and weight. Results: After one year of pharmaceutical care service program, participants mean FBG levels significantly decreased from 154.04 mg/dl to 126.43 mg/dl whereas mean systolic blood pressure levels were significantly decreased from 136.45 mmHg to 125.83 mmHg while mean diastolic blood pressure levels were significantly decreased from 82.57 mmHg to 77.25 mmHg. The mean diabetes knowledge scores were significantly increased from 4.42 to 15.66. There was slight decrease (from 6.2% to 5.4%) in the diabetes related hospitalizations after intervention. Mean cost of hospitalization was decreased from Rs.1763.73 to Rs.1023.54. Mean cost of surgery was increased from Rs.653.52 to Rs. 4459.00 after intervention. Conclusion: Pharmaceutical care services produced better clinical and humanistic outcomes in T2DM patients. Diabetes knowledge of T2DM patients was significantly improved. Hospitalization costs were reduced however surgery cost were increased.

KEY WORDS: Collaborative diabetes care, Outcomes, Patient Active Participation Program, Patient Centered Diabetes Care.

1. INTRODUCTION

Indian population of diabetes continues to increase and diabetes mellitus has considerable negative impact on economic, clinical and humanistic outcomes of people with type 2 diabetes (T2DM). Major problem with diabetes is that if it is poorly controlled it leads to increase in complications associated with diabetes which have major impact on burden of diabetes. However diabetes and its complications can be controlled and prevented by proper and effective management. Good control of T2DM helps in controlling and preventing complications and this requires a multidisciplinary team approach. Diabetes prevalence in India is continuously increasing thus collaborative approach by patient; healthcare professionals and state is required which might enable to tackle challenges of diabetes and its complications. Simple and appropriate strategies of enhanced care provision and increasing disease awareness among people with diabetes need to be adopted (Baruah, 2014).

Though World Health Organization is promoting Good Pharmacy Practice all over the world it is not developed up to the mark in low and middle-income countries when compared with high income countries (Smith, 2009; Ghani, 2010). However in India pharmacist are restricting their role in community pharmacy only to supply medicines but they should extend their role to non-dispensing services such as patient counseling as patient oriented services (Basak, 2009; Sathyanarayana, 2009; Lewis, 1997; Pande, 2013).

For achieving good glycemic control person with diabetes should have proper knowledge of diabetes in order to adopt appropriate therapeutic lifestyle changes and for better adherence with the different medications prescribed. Psychosocial care and other patient specific characters also need to be considered in addition to provision of diabetes knowledge for effective management of diabetes. Several studies have reported that for effective management of diabetes among people with diabetes, diabetes self-management education plays a significant role (Al-Khawaldeh, 2012; Iyer, 2010; Fain, 2015; Balamurugan, 2006; Madhu, 2015).

In developing countries few studies assessed impact of pharmacist intervention on clinical and humanistic outcomes in patients with T2DM and established effectiveness of such strategies (Sriram, 2011; Arun, 2008; Malathy, 2011; Mahesh Gottipati, 2011). In view of the multiple therapies required by people with T2DM, involvement of the pharmacist in collaboration with diabetes care team for effective diabetes management might improve clinical and humanistic outcomes and may reduce health service utilization (Pande, 2013). Thus we postulate that clinical pharmacist in collaboration with endocrinologist has significant role to play in diabetes care of people with T2DM. This study is designed to assess this impact. The aim of the study was to assess the impact of

pharmaceutical care services on economic, clinical and humanistic outcomes in T2DM patients. This pharmaceutical care service pilot project was designed for establishing an improved quality in healthcare delivery services at public tertiary care hospital. A total of 250 patients with T2DM were included in this study for one year duration.
Main objectives of the project comprised:

- To develop & implement pharmaceutical care in collaboration with endocrinologist model for people with T2DM.
- To evaluate the model in terms of outcome indicators.
- To assess the impact of a pharmaceutical care service in people with T2DM on direct medical cost of hospitalization & emergency room service utilization.
- To assess the impact of pharmaceutical care service in people with T2DM on fasting blood glucose, BP, weight.
- To assess the impact of a pharmaceutical care service in people with T2DM on Knowledge & self - management skills, diet & exercise goals.

2. METHODS

This program was offered to adult patients attending Endocrinology outpatient department of a tertiary care hospital in Hyderabad, for treatment and regular follow up, who were diagnosed with T2DM. Characteristics of site, endocrinologist and clinical pharmacist comprised:

- Endocrinology outpatient department areas for patient with T2DM follow up
- Availability of community pharmacist for dispensing of prescribed medication thus clinical pharmacist was free to provide pharmaceutical care.
- Microsoft excel sheet was utilized for recording and tracking pharmaceutical care interventions.
- Clinical pharmacist was trained for providing patient centered diabetes management program.
- Endocrinologist and clinical pharmacist had good communication skills in Hindi, Telugu and English language.
- Endocrinologist and clinical pharmacist were capable to implement new ideas of care and tackle challenging tasks.
- Nationally recognized guidelines such as ADA (American Diabetes Association, 2017) and AACE guidelines (Feld, 2002), IDF (International Diabetes Federation, 2012), RSSDI (Madhu, 2015) and ASHP guidelines (ASHP, 1997) were utilized.
- Program design was framed for allowing sufficient flexibility yet it was structured in order to accommodate tertiary care hospital setting as it provides services to patient population from different geographical areas surrounding Hyderabad. Pharmaceutical care and recommendation to patients were prepared and provided which was suitable to local and regional healthcare plan.

Intervention: Evidence has been established for improved communication among patients, pharmacists and healthcare professional, encouragement in sharing of relevant clinical data and objective measures occurs (Garrett, 2005). This present study program features were designed to develop enhanced collaboration in care with additional communications among people with T2DM, pharmacist and endocrinologist. This feature provided assistance for estimating participant's progress towards target goals and allowed clinical pharmacist and endocrinologist for making necessary adjustments in provision of further education, diabetes self-management plans and counseling.

Pharmaceutical care was provided to people with T2DM in the form of patient education as per ADA (American Diabetes Association, 2017) and AACE guidelines (Feld, 2002), IDF (International Diabetes Federation, 2012) and patient counseling as per ASHP guidelines (ASHP, 1997). Based on these guidelines, pharmaceutical care and recommendation to patients were adapted and provided to people with T2DM in order to suit local and regional healthcare plan. Pharmaceutical care and intervention plan was adapted as per their language, cultural, socioeconomic status and psychosocial care requirements. Posters were prepared specially for this study; contents of poster were scrutinized and approved by Endocrinologist, tertiary care hospital Hyderabad. These posters were utilized for providing diabetes education to participants. Poster content was in the form of pictograms and titles. Posters were prepared in English and then translated to Telugu and Hindi. Contents of the posters comprised: Acute complications and long term complications, simple precautions and self-care a person with diabetes needs to take to prevent complications, how to recognize hypoglycemia.

A clinical pharmacist reinforced advice and recommendations of the endocrinologist to the participant for effective diabetes management and control which comprised lifestyle modifications, diabetes self-management plan and diabetes education, additional psychosocial care, motivation for active participation. Intervention in the form of patient education was provided in a group of 10 participants at first intervention. However based on individual requirements additional interventions were provided to individual participant at first intervention visit. People with T2DM worked with clinical pharmacist and endocrinologist according to structured series of visits. Education and counseling was provided to individual participant every three months at follow up visit. Focus of each visit was to

provide knowledge, improve skills and performance of the participant. Pharmacist provided assistance to each participant to achieve satisfactory diabetes knowledge score. Details of participant self-reporting were documented and goals for subsequent visits were established at each intervention visit.

People with T2DM were permitted to seek information on general questions and assistance support from pharmacist at regular follow up visit to endocrinology outpatient department or through telephone as frequently as desired during 12 months of study period. There is no tracking of people with T2DM in routine follow up and usual care at endocrinology department in tertiary care Hospital. However in this present study pharmacist motivated all participants to attend follow up visits regularly and all participants received one telephone call every month to maintain ongoing communication and track them.

Source of data and system of care: Patients receive medication from public tertiary care hospital at subsidized cost as it is a Government hospital. In routine patient with T2DM need to visit endocrinology department of hospital every fifteen days for follow up and for collecting medication. Endocrinologist assessed people with T2DM at the time of follow up visit and necessary standard treatment and usual care was provided. In addition to usual care clinical pharmacist offered 20 to 30 minutes of pharmaceutical care in the form of patient education and counseling. Enrollment and program duration were established in order to allow clinical pharmacist for monitoring each participant for 12 months.

People with T2DM of either gender who were of age of $\geq$ 18 years and < 85 years were eligible for enrollment. Those who were capable to understand and complete questionnaires were eligible to enroll in this study. People with T2DM who were not willing, not able to understand and complete the questionnaires were excluded. Eligible people with T2DM were included utilizing convenient sampling method and based on their medical follow up visits. The study protocol was approved by the Independent Human Ethics Committee, Hyderabad, India. Interested people with T2DM received patient information leaflet. Pharmacist explained complete procedure of the study. Total 250 people with T2DM gave informed consent and they were enrolled in the study. Confidentiality of the participants was preserved.

Case record form was developed specially for this program. Case record form comprised simple structure which enabled pharmacist to conduct interview and enter the data easily with few open ended questions. On average it took 10-15 minutes to complete case record form. At the time of enrollment visit all the relevant pre-intervention data was collected and documented as per case record form in Microsoft excel sheet. Thus enrollment visit was considered as pre-intervention visit. All the interviews and assessments were carried out by a clinical pharmacist under the supervision of Endocrinologist. Data collected comprise number of hospitalizations related to diabetes, total number of days required to stay in hospital, cost of hospitalization and number of emergency room visits related to diabetes and cost of emergency room visits. To assess the impact of pharmaceutical care on economic outcome, cost of hospitalization and emergency room visit was collected for 12 months prior to and post 12 months from first intervention with clinical pharmacist. Source of data for economic parameters was participant self-report, bills and medical record or charitable hospital pricelist. Some participants were hospitalized in tertiary care hospital and some participants were hospitalized in private hospitals. Public tertiary care hospital i.e. study site provides services at subsidized cost. Thus charitable hospital which provides services at minimal cost was utilized as source of data for participants who were hospitalized or availed emergency room services from public tertiary care hospital. For participants who were hospitalized or availed emergency room services in private hospital, private hospital bills or self-report was utilized.

Source of data for clinical parameters was patient medical record and patient self-report. Data collected comprised patient's demographic, full medical examination report including medical history related to diabetes and past treatment history and past treatment outcome and laboratory investigation report history. To assess the impact of this program on behavior and clinical parameters, participant data was collected at pre-intervention and every three months or more frequently during this program. Pharmacist continuously monitored participant's medical record and laboratory investigation reports. To compensate scarcity of mandatory laboratory evaluation at pre-intervention and post 12 months from first intervention were allowed a 70 day window period. Source of data for diet and exercise outcome was patient self-report. Pharmacist collected and documented this data at pre-intervention and every three months post first intervention with clinical pharmacist either at follow up visit or on telephone.

At pre-intervention visit participant's knowledge on diabetes was assessed utilizing modified DKQ (Kanchana Dussa, 2015) which was originally developed by (Eigenmann, 2011). It has taken approximately 10 minutes to complete the DKQ. Points were given to all the right answer selections for each question. However points were not given for wrong answers. Diabetes knowledge scores were calculated for each participant. Maximum score attainable was 18. After pre-intervention visit, second visit was scheduled after 15 days. Participants were advised, not to use books or any material for improving their diabetes knowledge during these 15 days and a window period of 5 days was allowed. Prior to provision of pharmaceutical care, participant's knowledge on diabetes was reassessed at second visit. Diabetes knowledge scores were calculated for each participant and it was considered as pre-intervention score. After reassessing diabetes knowledge participants received pharmaceutical care for first time at

the time of second visit. Thus second visit was considered as first intervention visit. Follow up visits were scheduled every three months after first intervention visit. At every three months visit prior to provision of pharmaceutical care, pharmacist reassessed participant's diabetes knowledge. A window period of 15 days was allowed for diabetes knowledge assessment at every three months. These DKQ scores were utilized for participant's diabetes knowledge assessment scores. Pharmacist documented data of all the outcomes measured i.e. costs data, clinical data and participant's scores for knowledge on diabetes in Microsoft excel sheet.

Microsoft excels sheet continuous tracking and monitoring allowed pharmacist to perform chart review and know patient status from time to time. At conclusion of initial and follow up meeting, summary of intervention provided and data collected were regularly communicated to endocrinologist. Pharmacist has provided regular feedback to endocrinologist and participants regarding patient status. This allowed maintaining communication among participants, pharmacist and endocrinologist continuously.

Monitoring of hospitalization and emergency room visits was carried out every 3 months either through medical record &/or self-report by participant &/or telephone interview. Intervention plan was modified as per individual requirement in order to reduce further hospitalizations and emergency room visits. This program design helped pharmacist and endocrinologist to avoid problems arising from miscommunication and improper implementation of care plan.

Monitoring of clinical evaluation and laboratory investigations, participant self-management goal setting and achievement rate was performed every 3 months or more often if required. Behavioral outcome monitored comprise patient self-management goal setting rate and achievement rate for Diet, Exercise goals. Monitoring of behavioral outcome was performed every 3 months or more often if required. Monitoring of diabetes knowledge scores was performed every 3 months.

Participants were taking active participation in treatment plan, self-management goal setting, monitoring their goal setting, performance rate and achievement rate. Majority of participants met clinical pharmacist at least once every month during 12 months of study period.

Diabetes knowledge assessment: Modified DKQ (Kanchana Dussa, 2015) consist of 18 questions. These questions were framed regarding knowledge of people with diabetes about diabetes and its complications and self-care required to be taken by people with diabetes. Further eleven demographic related questions were also included in Modified DKQ. On the basis of participant capacity to read and / or understand DKQ in language (English, Hindi or Telugu) appropriate for them was utilized.

A clinical pharmacist conducted a face to face interview (orally to illiterate) to assess participant's diabetes knowledge and asked them to provide answers to the questions orally by selecting accurate choices from several options. Clinical pharmacist has provided assistance to participants who were not able to read or write for completing DKQ. However literate people with T2DM completed DKQ themselves in language suitable to them.

Various domains of DKQ allowed assessing and providing aid to the pharmacist at each assessment to identify in which areas individual participant required further education, counseling and diabetes care. Pharmacist addressed these individual participant requirements and motivated them regularly to understand and achieve satisfactory diabetes knowledge. Main objective of achieving satisfactory diabetes knowledge score was to contribute as a tool and to help in regulating goals for all participants.

Design of the study: Design of the study was prospective descriptive quasi cross over study. Healthcare professional involved in collaboration with endocrinologist for providing pharmaceutical care was clinical pharmacist. Participant enrollment was initiated in October 2014 and continued till April 2015. Data collection was continuous till July 2016.

Inclusion criteria for data analysis and outcome data measurement: In order to include in the economic, clinical and humanistic outcome analyses people with T2DM needs to have knowledge scores and laboratory data at initial and 12 month post first intervention with clinical pharmacist. For economic outcome, cost data of 12 months prior to enrollment and 12 month post first intervention with clinical pharmacist was needed. Patients who had all the necessary outcomes parameters at initial visit and at least 3 months of pharmacist care were eligible for data analysis otherwise it was considered as loss to follow up or discontinuation criteria.

Economic outcome measured comprised direct medical costs from patient perspective. It comprised two categories. First category included cost of emergency room visit related to diabetes as outpatient. It was defined as sum of all diabetes-related emergency visit costs comprising laboratory investigations cost, professional visit cost, emergency service cost in Indian Rs. Second category included cost of hospitalization. It was defined as sum of all diabetes-related hospitalization costs comprising laboratory investigations, professional visit cost, cost of medicine, medical supplies, hospital service cost and total stay in hospital in Indian Rs. Pre-intervention hospital and emergency room visits were defined as visits within one year prior to first intervention. Post-intervention hospital and emergency room visits were defined as visits within one year after first intervention. Number of hospitalizations related to diabetes, total number of days required to stay in hospital and cost of hospitalization was calculated. Number of emergency room visits, frequency of emergency room visits and cost of emergency room visit was calculated. In

order to calculate the total direct medical cost for each participant each of the cost component (inpatient services in quantity) was multiplied with a unit cost.

Clinical outcome measured comprised fasting blood glucose (FBG) based on IDF (International Diabetes Federation, 2012), RSSDI (Madhu, 2015), ADA guidelines (American Diabetes Association, 2017) and systolic blood pressure and diastolic blood pressure based on JNC-8 guidelines (James, 2014). Behavioral outcome measured comprised patient self-management goal setting rate and achievement rate for diet (diabetes specific diet always) and exercise (at least 30 minutes walking everyday) and weight. BMI measured were as per RSSDI (Madhu, 2015). Behavioral outcome measured were as per standards set by endocrinologist. Pre-intervention FBG, systolic blood pressure, diastolic blood pressure, diet goal, exercise goal were defined as data obtained prior to provision of first intervention. Post-intervention FBG, systolic blood pressure, diastolic blood pressure, diet goal, exercise goal were defined as data obtained after provision of first intervention at every three months up-to one year.

Humanistic outcome measured comprise diabetes knowledge of the participant. Diabetes knowledge score assessment was set as per standards set by endocrinologist. Out of maximum attainable score of 18, if participant achieved a score of (≥ 9) then it was stated as satisfactory knowledge and a score of (<9) was stated as poor knowledge. Pre-intervention diabetes knowledge score was defined as data obtained prior to provision of first intervention. Post-intervention diabetes knowledge score was defined as data obtained after first intervention at every three months within one year. Pre-intervention and post intervention data of all the outcomes measured were utilized for data analysis.

Sample size: Sample of 250 patients with T2DM was included in this study to minimize error rate.

Data analysis: Data was tabulated and analyzed using descriptive statistical methods. Two tailed student's *t* test for paired data was utilized for statistical analysis for comparison of initial and final clinical and humanistic outcomes. The level of significance was established at $P < 0.05$ to assess the impact of program. Participants were evaluated based on an intention to treat (ITT) population. The ITT population consisted of participants who have pre-intervention reading and received at least three months of intervention.

To illustrate the impact of this program on behavior and clinical parameters mean changes, change in percentage of target goals achieved from pre-intervention visit to post-intervention for FBG, systolic blood pressure, diastolic blood pressure, weight and BMI were calculated. To illustrate the impact of this program on lifestyle parameters change in percentage of participants who achieve target goals set for Diet, Exercise from pre-intervention visit to post-intervention were calculated. To illustrate the impact of this program on humanistic outcome, mean changes in diabetes knowledge scores, change in people with T2DM who achieved satisfactory scores from pre-intervention visit to post-intervention were calculated. To illustrate the impact of this program on economic outcome mean cost of hospitalization for pre-intervention and post-intervention was calculated and simple comparison of mean annual cost of hospitalization and emergency room visit was carried out.

3. RESULTS

Table.1. Demographics of Participants of Final Analysis Set [a] (n=241)

Characteristic	**Number (%) or (mean ± SD)**
Age (years)	53.90± 9.549
Height (meters)	1.55±0.08
Males	80 (33.2)
Female	161 (66.8)
Level of education	
Primary	26 (10.8)
Higher secondary	73 (30.3)
Inter/diploma	9 (3.7)
Graduation	4 (1.7)
Post-graduation/other	4 (1.7)
Illiterate/no response	125 (51.9)
Employment status	
Employed	79 (32.8)
Unemployed	162 (67.2)
Time since diagnosis(years)	8.60 ± 6.74
People with T2DM receiving oral medication only	162 (67.22)
People with T2DM receiving injection insulin + oral medication	69 (28.63)
People with T2DM receiving injection insulin only	10 (4.15)

[a] Inclusion criteria: Participants who completed the study.

Table.2. Impact on Clinical Measures with Program Intervention[a] (n=241)

Clinical outcome parameter	Mean (SD) Initial measure	Mean (SD) Final measure	Mean change (SD)	P[b]	t
Weight (Kg)	68.95 (±11.48)	68.67 (±11.82)	0.28 (±3.77)	1.156	0.249
BMI(Kg/m^2)	28.59 (±4.65)	28.49 (±4.88)	0.10 (±1.62)	0.318	1.001
FBG (mg/dl)	154.04(±55.13)	126.43 (± 49.65)	27.61 (±64.47)	0.000	6.648
Systolic BP(mmHg)	136.45 (±19.16)	125.83 (±12.78)	10.62 (±19.69)	0.000	8.378
Diastolic BP(mmHg)	82.57 (±11.01)	77.25 (±7.20)	5.32 (±10.88)	0.000	7.591

DBP-diastolic blood pressure; FBG –fasting blood glucose; SBP-systolic blood pressure.

[a] Inclusion criteria: Every participant must have a baseline value and follow up value at end of the study.

[b]All ending measures *P* values calculated versus baseline (*t* tests for paired samples)

Table.3. Impact on Clinical Measures Target Goal Achieved with Program Intervention[a] (n= 241)

	Baseline	End of study
	No. of participants (%)	No. of participants (%)
FBGless than 110 mg /dl of target goal achieved	55 (22.8)	122 (50.6)
SBP target goal achieved	176(73.0)	229(95.0)
DBP target goal achieved	204 (84.6)	232 (96.3)

DBP-diastolic blood pressure; FBG –fasting blood glucose; SBP-systolic blood pressure.

[a] Inclusion criteria: Every participant must have a baseline value and follow up value at end of the study.

Table.4. Impact on Percentage of Participants Who Achieved Target Goals for Diet and Exercise Regimen with Program Intervention[a] (n= 241)

	Baseline	End of study
	No. of participants (%)	No. of participants (%)
Diet goal achieved	12 (5.0)	201 (83.4)
Exercise goal achieved	58 (24.1)	207 (85.9)

[a] Inclusion criteria: Every participant must have a baseline value and follow up value at end of the study .

Table.5. Impact on Diabetes Knowledge Scores with Program Intervention [a](n=241)

Diabetes knowledge parameter	Mean (SD) Initial measure	Mean (SD) Final measure	Mean change (SD)	P[b]	T
Diabetes knowledge score [c]	4.42 (±2.67)	15.66 (±1.40)	-11.24 (2.83)	**0.000**	**61.66**

[a]Inclusion criteria: Every participant must have a baseline value and follow up value at the end of the study.

[b]All ending measures *P* values calculated versus baseline (*t* tests for paired samples)

c based on a 18point scale where 0 = is lowest knowledge level and 18= is highest level

Table.6. Impact on Change in Percentage of Participants with Satisfactory Diabetes Knowledge Scorenoticed with Program Intervention[a] (n=241)

	Baseline	End of study	% change from baseline
	No. of participants (%)	No. of participants (%)	
Diabetes knowledge score[b],n (%)	10(4.15)	240 (99.58)	95.43

[a]Inclusion criteria : Every participant must have a baseline value and follow up value at end of the study .

[b]based on a 18point scale where ≥9 = is satisfactory knowledge level and < 9 = is poor knowledge level.

Table.7. Summary of changes noticed in healthcare services utilization at baseline and end of the study[a] (n=241)

Economic outcome parameter	Baseline No.(%)	12 Months No.(%)	% change from baseline[b,c]
Emergency department visits	9 (3.7)	17 (7.1)	-3.4
Hospitalization	15 (6.2)	13 (5.4)	0.8
Surgery	9 (3.7)	16 (6.6)	-2.9

[a]Inclusion criteria: Every participant must have a baseline value and follow up value at end of the study.

Table.8. Summarizes the Changes Noticed in Healthcare Services Expenditure Incurred by Participant in 12 Months Prior and Post Program Enrollment[a] (n=241) (unit cost in actual Rs)

	Mean (SD)	Mean (SD)
Healthcare category	12 months prior enrollment	12 months post enrollment
Total hospitalization costs	1763.73 (SD ± 14111.15)	1023.54(SD ± 7821.85)
Emergency Room visits costs	29.62 (± 219.64)	35.97 (± 130.85)
Total surgery costs	653.52 (SD±3819.87)	Rs. 4459.00 (SD± 37129.03)

[a]Inclusion criteria: Every participant must have a baseline value and follow up value at end of the study.

Total 250 participants were enrolled in this study over a period of 7 months (October 2014 to April 2015). 241 (96.4%) participants met the inclusion criteria for analysis that received pharmacist care for 3 or more months and had necessary laboratory, diabetes knowledge scores and economic data. Total 9 (3.6%) participants lost to follow up. The major reasons are death and voluntarily decided to discontinue the study without informing any reasons. The average age of the participants who completed the program was 53.90 ± 9.54 years among them 66.8% were female. Participant's education status: 10.8%, 30.3 %, 3.7%, 1.7 %, 1.7 %, and 51.9% of primary, higher/ secondary, intermediate/ diploma, graduation, post-graduation and illiterate respectively. Out of total 241 participants 32.8 % and 67.2% were employed and unemployed respectively. The average time period of participants diagnosed with T2DM was 8.60 ± 6.74 years. The data are presented in the Table.1.

Clinical outcomes: Statistically significant improvements in clinical outcome parameters were noticed for the enrolled participants utilizing initial and final fasting BG and systolic and diastolic blood pressure measures. Participants mean fasting BG levels decreased significantly from 154.04 mg/dl to 126.43 mg/dl. Participants mean systolic blood pressure decreased significantly from 136.45 mm Hg to 125.83 mm Hg. Participants mean diastolic blood pressure decreased significantly from 82.57 mm Hg to 77.25 mm Hg. Participants mean weight decreased from 68.95 Kg to 68.67 Kg. Participants mean BMI decreased from 28.59 to 28.49. No statistically significant changes were noticed for anthropometric parameters. At initiation of this program i.e. pre-intervention, participant who achieved target goals for FBG, systolic blood pressure, diastolic blood pressure and normal BMI were 22.8%, 73.0%, 84.6 % and 9.54% respectively. People with T2DM who achieved target goals for FBG, systolic blood pressure, diastolic blood pressure and normal BMI at end of the study were increased to 50.6%, 95.0%, 96.3% and 11.61% respectively. Data of changes in clinical measures and percentage of people who achieved target goals set for clinical outcome parameter is presented in table.2 and table.3 respectively.

Patient self-management goal for diabetes and lifestyle modification outcomes: Nature of intervention comprised encouraging participants for their active participation and self –management in managing diabetes; it has shown considerable positive impact on self -management of participants and their attention towards diet, and exercise. At initiation of this program participant who had specific self-management goals for diet and exercise were 5.0 % and 24.1 % respectively .People with T2DM who identified and achieved target goals for diet and exercise at end of the study were increased to 83.4 % and 85.9 % respectively. The data of changes in percentage of people who achieved target goals set for diet and exercise is presented in table.4.

Humanistic outcomes: Mean diabetes knowledge scores increased significantly from 4.42 to 15.66. Participant's had shown significant improvements in diabetes knowledge scores. Percentage of people with T2DM who achieved satisfactory diabetes knowledge scores was increased from 4.15% to 99.58%. The data of changes noticed in diabetes knowledge assessment scores and percentage of participants who achieved satisfactory diabetes knowledge score at baseline and end of the study is presented in table.5 and table.6 respectively.

Economic outcomes: Mean cost of hospitalization was decreased from Rs.1763.73 to Rs.1023.54. People with T2DM hospitalized were slightly decreased from 6.2 % at baseline to 5.4 % at end of study. Mean cost of surgery was increased from Rs.653.52 to Rs.4459.00. People with diabetes hospitalized for surgery were slightly increased from 3.7 % at initial to 6.6 % at end of study. Reason for this was participant's achievement of target goals for glycemic control. Therefore Endocrinologist could advise participants as fit for surgery. Surgeries carried out post program enrollment in this study period to prevent further progression of diabetic cardiovascular complications were 2.07%. Surgeries carried out prior to and post program enrollment in this study to prevent further progression of diabetic eye complications were 2.9 % and 4.56% respectively. Surgery carried out prior to program enrollment in this study for finger amputation due to foot ulcer and for removal of gall bladder stones was 0.41% each.

People with T2DM who required emergency room visits were slightly increased from 3.7 % at baseline to 7.1% at end of study. However there was no significant change in mean cost of emergency room visit prior and post program enrollment. Hospital provide emergency department services at free of cost thus cost for emergency room were calculated based on charges of nearby local tertiary care hospital which were nominal. The data of changes noticed in healthcare services utilization and healthcare services expenditure incurred by participant in 12 months prior and post program enrollment is presented in table.7 and table.8 respectively.

DISCUSSION

The purpose of this article is to provide a description of pharmaceutical care model in collaboration with endocrinologist within tertiary care hospital setting which can be implemented in various healthcare organizations. Our idea was to provide a simple model which can be adopted by any healthcare organization for improving quality of care for patients with T2DM and reducing healthcare costs. The value of this project was provision of additional pharmaceutical care and services to patient population, majority of them were illiterate, from low socioeconomic status, and uninsured who were receiving free treatment from Public tertiary care hospital. This was model which was implemented in real world situation rather than controlled pattern of study.

Results of this present study have shown significant decrease in fasting blood glucose levels of people with T2DM from pre-intervention to post-intervention. Our study results are similar to previous studies conducted in India

(Sriram, 2011; Arun, 2008). This present study has shown a significant improvement in diabetes knowledge of people with T2DM. This present study results are in consistent with two previous studies from India (Malathy, 2011; Mahesh Gottipati, 2011) and few previous studies from other countries (Garrett, 2005; Krass, 2005; Garret, 2008). Results of this present study have shown significant decrease in systolic and diastolic blood pressure of people with T2DM from pre-intervention to post-intervention. As per the centers for disease control and prevention, with every 10 mm Hg decrease in systolic blood pressure, any of the diabetes related complications risk get reduced by 12% (Centers for disease control and prevention. 2011). This present study had shown a 10.6 mm Hg reduction in systolic blood pressure which indicates reduction in complications and improvement in overall health. This present study results are similar to results of several previous studies conducted in India (Sriram, 2011; Arun, 2008) and other countries (Iyer, 2010; Rothman, 2005). Statistically significant changes were not noticed for anthropometric parameters i.e. weight and BMI in this present study. However previous study results had shown reduction in weight and BMI with provision of pharmaceutical care (Arun, 2008).

In this present study improvement was noticed in percentage of people with T2DM achieving target goals for behavioral outcomes i.e. diet goals. These present study results are consistent with the previous study results (Redmond, 2006). In this present study improvement was noticed in achieving target goals set for exercise. These results were similar to previous study results (Al Hayek, 2013).

In this present study reduction in cost of hospitalization for diabetes related reasons was noticed. People with T2DM who required emergency room visits were slightly increased from pre-intervention to post-intervention. In this present study decrease in direct medical cost of hospitalization was noticed which was similar to previous two studies (Borges, 2011; Garrett, 2005). Number of surgeries performed for diabetes related reasons were increased from baseline to end of the study. The cost of surgeries was increased from pre-intervention to post-intervention.

This study assessed the impact of pharmaceutical care on clinical, humanistic and economic outcomes in people with T2DM. This present study results have revealed that significant positive impact on clinical, humanistic and economic outcomes can be achieved by providing pharmaceutical care to people with T2DM. This present study results for clinical, humanistic and economic outcomes are in consistent with the results of the previous study (Garrett, 2005). Results of this present study support the increasing evidence demonstrating that positive impact on clinical and humanistic outcomes were attributable to the appropriate provision pharmaceutical care in the form of diabetes education, counseling and psychosocial care.

4. CONCLUSION

Patient centered pharmaceutical care services–produced better clinical and humanistic outcomes in people with T2DM. Additional psychosocial support and patient education aimed for effective diabetes management has improved subject's diabetes knowledge and percentage of people with T2DM who achieved target goals for glycemic control and blood pressure. Hospitalization costs were reduced however surgery cost were increased. Active participation, self-management practice and improvement in target goal achievements by people with T2DM were noticed. Results of this study indicate that it is feasible to expand role of pharmacist in non-dispensing area for providing diabetes education and care to people with type 2 diabetes to improve clinical, humanistic and economic outcomes of people with type 2 diabetes.

Recommendations: This project was planned to educate, counsel and motivate patients with T2DM to actively participate, achieve self-management goals and lower direct medical costs. Adding pharmacist to the diabetes care team in collaboration with endocrinologist can play a vital role and link for achieving continuity of diabetes education and care to people suffering from T2DM. Thus clinical pharmacist can enhance communication between patient and endocrinologist and have positive impact on economic, clinical and humanistic outcomes. Ongoing education and monitoring of the progress of people with type 2 diabetes for self- care and self-management and achieving target goals appeared to be vital element of continuousness of diabetes care practice. In future studies of diabetes education and care, people with type 2 diabetes should be monitored for longer duration in order to evaluate the impact of such program on complications due to diabetes and its cost.

Limitations of the study: Limited data interpretation and generalizability as in this present study control group was lacking. Economic data reporting system was established for patients with T2DM in this study. We developed a case report form especially for this study for recording data from medical record and also for completing details provided by patient self-report. Thus we were able to collect data and enter into excel according to this format and analyze the data from pre-intervention and post-intervention.

This present study was carried out at a large tertiary care hospital in Hyderabad. Various hospital settings, patient populations and method used for providing pharmaceutical care could impact results and variation in results could be possible. However pharmacist had opportunity for providing care to these participants, most of them were illiterate and required translation in Hindi, Telugu language as per their convenience to simple terminologies.

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