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ORIGINAL ARTICLE

Medical adherence and its predictors in Diabetes Mellitus patients attending government hospitals in the Indian Capital, Delhi, 2013: a cross sectional study

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Abstract India has the second highest Diabetes Mellitus burden globally which represents a major public health challenge. Poor adherence to medication and other treatment recommendations in diabetes patients is associated with poor glycemic control which may lead to early onset of complications with high cost of management. We assessed medical adherence and their predictors in type 2 diabetes patients attending Government Hospitals in Delhi. We conducted a cross sectional study among 385 Type 2 DM patients. We assessed medication adherence with the eight item Morisky Medication Adherence Scale. Dietary and exercise adherence were also assessed. Data was analyzed using SPSS Version 17. Prevalence of good medication adherence was 74.5 %, adherence to dietary recommendations was 70 % and adherence to exercise recommendations was 48 % in the study population. On adjusted analysis, lower socio-economic status, oral hypoglycemic agent treatment alone and reporting non-replenishment on exhaustion of drug stocks was associated with higher likelihood of poor medication adherence. Barriers against dietary adherence were differing familial dietary choices, inflation, beliefs that occasional transgression was benign and cultural factors like dining together at same time. Clinical pathology especially knee joint pain was reported as most frequent barrier to exercise adherence. The medication adherence rates found in this study were higher than most other studies conducted in India. Provision of free anti hyperglycemic medication at government hospitals by reducing patient out of pocket expenses facilitates maintenance of a high level of medication adherence. Furthermore, higher dietary and exercise adherence may reflect the improved self efficacy in patients.

Keywords Diabetes · Medical adherence · MMAS-8 · Government Hospital · India

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Introduction

Diabetes Mellitus (DM) in the 21st century has transcended its limited geographical and socio-economic concentration in the affluent and developed world with Type 2 DM constituting around 90 % of all diabetes cases [1]. The public health challenge of diabetes is established by the fact that 80 % of this disease burden is shared by low and middle income countries with India harbouring the second highest diabetes burden in the world, next to China [2]. Comparative prevalence of diabetes in 2001 in low and middle income countries was 8.6 % and 7.9 % in high income countries [2].

The South Asian region is in the grip of a "diabetic epidemic" [3]. This has been linked to an ongoing epidemiological, demographic and nutritional transition in the region [4, 5]. Urbanization, population aging and growing obesity burden is likely to fuel the diabetes epidemic for the next few decades [6].

Poorly controlled DM is associated with both short term and long term (microvascular and macrovascular) complications resulting in high morbidity and mortality [7]. Further, the enormous economic cost of treatment of the disease and its

complications threatens to overwhelm the limited public health infrastructure in developing nations [8].

Landmarks RCTs like the DCCT (Diabetes Control Complications Trial) and the United Kingdom Prospective Diabetes Study (UKPDS) have demonstrated the efficacy of good glycemic control in preventing or delaying the onset of diabetic complications [9]. Medication adherence is a major determinant of glycemic control [10, 11]. However, the World Health Organization (WHO) has observed that medical adherence in chronic diseases is less than 50 % globally with developing nations more at risk [12].

Assessment of medical adherence in Indian diabetic populations is therefore important but especially so for those dependent upon the public healthcare sector. Government hospitals cater predominantly to economically vulnerable populations and are expected to provide quality OPD services as per the National Program for prevention and control of Diabetes in India. They provide free of cost medication, diagnostics and consultation for diabetes treatment which is important since expenditure on diabetes related treatment in Indian patients is significantly increasing which imposes considerable financial hardship on low socioeconomic patients who therefore exhibit greater dependence on the public sector [13, 14]. Moreover, the reduction in out-of-pocket expenses is expected to positively influence patient adherence related behaviour which in turn is known to reduce frequency of hospital admissions and associated morbidity in patients [15]. Also, knowledge of factors associated with medical adherence can help predict patient adherence and design interventions for improving patient outcomes.

The study was conducted with the objectives of assessing medical adherence (medication, dietary and exercise adherence) based on patient self reporting through standardized instruments among diabetic patients undergoing treatment at government hospital OPDs in Delhi, and determine the reasons leading to non-adherence. Further, we ascertained if medical adherence was associated with glycemic control in our study settings.

Material and methods

We conducted a cross sectional study in three government hospitals of Delhi. The study sites included the Safdarjung Hospital, a 1,531 bed teaching and multispecialty government hospital (South Delhi), a 600 bed tertiary healthcare centre hospital (West Delhi) and the Guru Gobind Singh Government Hospital (GGSGH), a 100 bed secondary care centre (West Delhi). Purposive sampling was used to select the study sites. We conducted the study on Monday and Thursday (October–November'2013) at Safdarjung Hospital, Tuesday at tertiary healthcare centre (September–November'2013) and Monday/Wednesday at GGSGH (September–November'2013).

The sample size for the study was calculated by Statcalc in Epi Info 7 software. Based on two previous hospital studies, the prevalence of poor medication adherence was assumed to be 50 % [16, 17]. Taking 95 % confidence levels, the sample size was calculated to be 384. Further assuming 10 % non-response rate, the final sample size was estimated to be 424. Patients attending the diabetic clinic in outpatient department of the selected hospitals satisfying the inclusion criteria and not meeting the exclusion criteria were requested to participate in the study.

The inclusion criteria were patients diagnosed with Type 2 DM on treatment for at least 1 year duration, those on oral hypoglycemic agent (OHA) treatment and those on combined therapy (OHA+Insulin). Exclusion criteria were patients exclusively on insulin therapy and those on treatment for less than 1 year duration.

DM was diagnosed as patients taking anti-hyperglycemic medication confirmed as per patient's medical record. Medical adherence was considered as per the WHO's definition which is "the extent to which a person's behaviour—taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" [12].

To ensure appropriate data collection, a maximum of 15 patients were interviewed at Safdarjung Hospital and 10 patients at both other sites on any single diabetes clinic day. We selected the participants through systematic random sampling. We tentatively estimated the average number of patients attending the clinic's on each day which divided by 15 and 10 at Safdarjung and both the other sites respectively generated the sampling interval. In this way, we obtained 190, 95 and 100 participants from Safdarjung, tertiary healthcare centre and GGSGH respectively who had agreed to participate (total = 385) for a net response rate of 91 %. The main reason for non response was the delay encountered by study participants in medication collection / securing physician appointment due to already long waiting queues within the hospitals.

We used a pretested, structured interview schedule to collect data from the study participants through some open-ended, close-ended, semi-close ended and few questions on a Likert type scale. The variables included socio demographic factors (age, gender, marital status, education, family income, type of family), clinical history (duration of diabetes, recent blood sugar report, BMI, type of medication) and diabetes self management activities pursued by the patient.

We assessed medication adherence of the patients through the Hindi version of the previously validated (construct validity) eight item Morisky Medication Adherence scale (MMAS-8) [18, 19]. The MMAS-8 is a self administered questionnaires but it was verbally administered to illiterate patients and those with low education standards who had difficulty either in reading or understanding the questionnaire. MMAS-8 is a generic 8-item questionnaire with 7 yes/no questions with the final question on a 5-point Likert-type scale.

Diabetes patients in government hospitals may briefly exhaust their medication stocks due to several reasons including missed clinic appointments, disruption of supplies in hospital / dispensary stores and patient's occasional economic inability to obtain those prescription drugs which are unavailable for free and require out-of-pocket expenses. To establish whether the patients encountered such situations in-between appointments within the past 3 months, the patients were asked whether "you run out of medicine before your next scheduled OPD appointment?" irrespective of its cause. Those who answered in the affirmative were asked a follow up question on whether they replenished the exhausted medicines by purchasing the medicines or skipped a few intervening doses until they could obtain their next refill.

We evaluated dietary and exercise adherence of the patients through questions from the Summary of Diabetes Self Care Activities scale (SDSCA) which possesses inter-item reliability and criterion validity [20]. Adherence to exercise instructions was considered to be adequate if total time allotted to the same in the last 7 days was > 150 min, interspersed over a minimum of 5 days. Adherence to healthcare provider based dietary recommendations was considered adequate if a diabetic diet plan was followed for a minimum of 5 days in the last 7 days.

We evaluated reasons for non-adherence to exercise through an open-ended question (Why don't you adhere to exercise recommendations?). Reasons for non-adherence to dietary recommendations were ascertained through a similar semi close-ended question which consisted of optional responses adapted from the dietary regimen adherence in DM scale (DRADMS) [21].

The Optimal glycemic control in this study was accepted as per 2012 American Diabetic Association (ADA) guidelines which recommends HbA1c < 7 %, preprandial capillary plasma glucose 70–130 and peak postprandial capillary plasma glucose < 180 [22]. When HbA1c testing or recent reports were unavailable, the latest plasma glucose report was used for estimating glycemic control.

The socioeconomic status of the study participants was determined using the Kuppuswamy socioeconomic scale, revised for income criteria [23].

Ethical clearance for the study was obtained from the Institutional ethical committee, National Centre for Disease Control, Delhi and from Institutional ethical committee, Safdarjung Hospital & Vardhaman Mahavir Medical College, Delhi. Written and informed consent was taken from all study participants and they were allowed to opt out of the study anytime and free to skip any questions as they desired.

Statistical analysis

The Statistical Package for Social Sciences for Windows (IBM SPSS Version 17) was used to analyze the data. Through descriptive statistics, we described socio-demographic, clinical and adherence related attributes of the patients. In Bivariate analysis, Chi square test of association was done between patient characteristics and medical non adherence. Variables found to be significantly association with poor medication adherence at $p<0.05$ were further evaluated through binary logistic regression analysis. The Hosmer Lemeshow goodness of fit test was used to assess fitness of data with the model.

Results

The mean age of our study participants was 53.15 +/− 10.2 years (95 % CI 52.12–54.18). We enrolled 159 males and 226 females. Of the 385 participants, 33 % (127) were illiterate, 18 % (70) were literate with highest educational attainment within primary school and 48.3 % (188) were educated beyond primary and higher (Table 1).

Bases on response to the MMAS-8, we found good medication adherence among 74.5 % (287) of our study participants. However, 42 % (161) of the study participants reported exhausting their anti hyperglycemic drug stock prior to their scheduled OPD appointment, and within this subset 55 (33 %) admitted occasional skipping of doses until they could obtain their next refill (Table 2).

Causes attributed to poor medication adherence were forgetfulness (21.8 %), perceived side effects (11 %) and intermittent cessation of therapy on absence of symptoms (6 %).

Fifty-two percent (200) patients were non adherent to exercise recommendations in the previous 7 days. Nevertheless, 76.4 % (294) of the patients reported adequate continuous physical activity (CPA) on accounting for their time expended in CPAs as part of work or household chores apart from exercise related CPAs during the same period.

Causes attributed by non adherent patients to exercise recommendations were knee joint pain (49 %), no time to exercise (20 %), perception that household or work related physical activity was adequate (12 %), don't like exercising (12 %), pain in the lower extremities (10 %), fatigue (10 %) and dyspnea on exertion (13 %).

Seventy-one percent (272) participants reported adherence to their dietary recommendations in the previous 7 days. However, only 12.7 % (49) of study participants pursued an individualized and specific eating plan differing from rest of the family.

Multiple causes were also attributed by patients reporting dietary non adherence. The divergent food habits of family members (82 %), belief in inevitability of infrequent dietary transgressions (42 %), high prices of green vegetables due to inflation (36 %), inability to overcome the temptation of food items understood by patients to be undesirable in maintaining good glycemic control (25 %) and erroneous belief that dietary adherence was useless in control of DM (11 %). Improper

Table 1 Distribution according to the patient characteristics in the study population, Delhi, 2013

Variables	Total (*N*=385)	Poor medication adherence (*N*=98)	*P* value	Dietary non adherence n (%)	*P* value
Age (years)					
< 60	247 (64 %)	67 (27.1 %)		69 (27.9 %)	
≥ 60	138 (36 %)	31 (22.4 %)	0.314	44 (31.8 %)	0.415
Gender					
Male	159 (41.3 %)	43 (27 %)		48 (30.1 %)	
Female	226 (58.7 %)	55 (24.3 %)	0.548	65 (28.7 %)	0.762
Spouse					
Alive	301 (78 %)	73 (24.2 %)		92 (30.5 %)	
Absent	84 (22 %)	25 (29.7 %)	0.305	21 (25 %)	0.32
Education					
Up-to class V	197 (51.7 %)	52 (26.4 %)		63 (31.9 %)	
≥ class VI	188 (48.3 %)	46 (24.4 %)	0.6	50 (26.5 %)	0.25
SES					
Middle/Up.	191 (49.6 %)	38 (19.9 %)		49 (25.6 %)	
Lower	194 (50.4 %)	60 (30.9 %)	0.01	64 (32.9 %)	0.11
DM Duration					
<= 5 years	170 (44 %)	50 (29.4 %)		48 (28.2 %)	
> 5 years	215 (56 %)	48 (22.3 %)	0.11	65 (30.2 %)	0.67
BMI					
<= 24.9	237 (61.5 %)	58 (24.4 %)		59 (24.8 %)	
> 24.9	148 (38.5 %)	40 (27 %)	0.29	54 (36.4 %)	0.01
Glycemic control					
Poor	209 (54.3 %)	73 (34.9 %)		86 (41.1 %)	
Good	176 (45.6 %)	25 (14.2 %)	< 0.001	27 (15.3 %)	< 0.001

carbohydrate spacing was attributed to lack of awareness of correct spacing requirements (33 %), waiting for spouse or children to return home before dining together (44 %) and occupation related delays before meals (31 %).

Poor glycemic control was associated with poor medication ($p<0.001$) and poor dietary adherence ($p<0.001$) but not poor exercise adherence.

Our logistic regression model was statistically significant with Chi2(3) = 24.21 ($p<0.001$). This model correctly classified 74.5 % of the cases. The Hosmer Lemeshow goodness of fit test-statistic had p value of 0.885 from which we concluded that the model estimates the data acceptably. Based on this adjusted analysis, we found patients from lower socio-economic status, on OHA alone and those reporting intermittent skipping anti diabetic medications on exhausting their medication stocks have significantly higher likelihood of poor medication adherence (Table 3).

Discussion

Good medical adherence is indispensable for maintaining good glycemic control which prevents or delays the onset of diabetic complications. This study evaluated medical adherence at three government hospitals of Delhi. We found three fourths of our study participants exhibiting good medication adherence, most (70 %) exhibited good dietary adherence but a majority (52 %) were non adherent to their exercise recommendations. Despite the high medication adherence majority (54 %) of patients had poor glycemic control. It has been observed that suboptimal treatment regimen may undermine glycemic control in spite of good medication adherence [24].

The medication adherence rates reported in our study are higher than most other studies conducted in India. In a teaching hospital of Delhi, Sultana et al. through the MMAS-4 scale reported good medication adherence rate of only 47.7 % [16]. A study in the diabetic clinic of a teaching hospital in Calcutta by Mukherjee et al. reported good medication compliance among 57.7 % patients [17]. Sasi Sekhar et al. in Chennai reported good medication adherence among 61 % patients [25]. A community based study in the state of Kerala by Sankar et al. through the MMAS-8 scale reported poor medication adherence among 75 % of the patients [26]. Since in these studies financial constraints was a factor significantly associated with non adherence to medication, the provision of free of cost medication in government hospitals of Delhi may account for the high medication adherence levels found in our

Table 2 Distribution according to the medical adherence in the study population, Delhi, 2013

Variables	Total (*N*=385)
Morisky Medication Adherence Scale (MMAS-8)	
Mean±SD	6.88±1.2
Poor medication adherence	98 (25.5 %)
Good medication Adherence	287 (74.5 %)
Run out of anti- diabetic medicines (last 3 months)	
No	224 (58 %)
Yes	161 (42 %)
If run out medicine?	(*n*=161)
Always buy medicines	106 (66 %)
Sometimes skip doses until next refill	55 (34 %)
Specific exercise session averaging 30 min /day	
Mean±SD	3.6±2.3
< 5 days (non adherent)	200 (52 %)
≥ 5 days (adherent)	185 (48 %)
Consumption of a healthful eating plan	
Mean±SD	4.8±1.4
< 5 days (non adherent)	113 (29.4 %)
≥ 5 days (adherent)	272 (70.6 %)
Even spacing of carbohydrates	
Mean±SD	4.54±1.63
< 5 days	130 (33.7 %)
≥ 5 days	255 (66.3 %)
Consumption of green vegetables / fruit	
Mean±SD	3.43±1.51
< 3 days	112 (29 %)
≥ 3 days	273 (71 %)

study. Nevertheless, we also found poor medication adherence to be significantly associated with low socioeconomic status. Unlike another study in a Kolkata hospital, we did not find a statistically significant association of medication adherence with age or sex [17].

Clinic based studies in some Middle Eastern nations have reported variable levels of self reported medication adherence. While Khan Ataur et al. in Saudi Arabia and Jamous et Al. in Palestine found low adherence rates (32.1 and 31.2 % respectively), Khattab et al. in Jordan reported high adherence rates (91 %) among their study participants [27–29]. In Bangkok, Howteerakul et al. also reported high adherence in most (92 %) study participants [30]. Cramer et al. evaluated global medication adherence rates through a systematic review and found it ranging between 32 and 93 % [31].

Lifestyle adherence in our study participants was also higher compared to the few other Indian studies [17, 26]. Enhanced dietary adherence could reflect the higher self-efficacy among patients assured of their daily medication. However, the lack of individualized dietary planning by most patients indicates the limitations of dietary interventions in diabetes management among middle and low income Indian households.

In our study, non adherence to exercise was found usually unrelated to sociodemographic factors and most patients attributed it to clinical pathology especially knee joint pain. Similarly, Dutton while assessing barriers against adherence to physical activity in low income African American patients observed them mostly relating to their medical conditions as opposed to their environmental factors [32].

In conclusion, most Type 2 DM patients in government hospitals of Delhi entitled to free medication exhibited good medication and dietary adherence. Familial, cultural, occupation and economic factors are the most common barriers against good dietary adherence. Healthcare providers should target improvement in patient knowledge on spacing of carbohydrates while being conscious of a potential barrier in the patient's social environment relating to their desire for communal dining at home.

Our findings also suggest that patients reporting exhaustion of drug stocks without timely replenishment is not uncommon and such patients are likely to show poor medication adherence. Therefore, it is important that medical practitioners in

Table 3 Distribution of factors association with poor medication adherence in study population, Delhi, 2013 (Binary Logistic Regression Analysis)

Variables	Total (*N*=385)	Poor medication adherence (*n*=98)	Adjusted OR 95 % CI	*P* value
SES				
Upper	191 (49.6 %)	38 (19.9 %)	1	
Lower / middle	194 (50.4 %)	60 (30.9 %)	1.65 (1–2.7)	0.041
Treatment				
OHA + insulin	47 (12.2 %)	6 (12.7 %)	1	0.027
OHA	338 (87.8 %)	92 (27.2 %)	2.8 (1.1–7.0)	
Skip doses on exhausting drug stocks				
No	330 (85.7 %)	72 (21.8 %)	1	< 0.001
Yes	55 (14.3 %)	26 (47.2 %)	3.0 (1.6–5.5)	

Abbreviations: *OR* Odds Ratio, *95 % CI* 95 % Confidence Interval

government healthcare centers anticipate a decline in medication adherence among diabetic patients belonging to low economic households when their acquisition of free medication is disrupted due to any reason. Future longitudinal studies could evaluate whether the expansion of anti diabetic medication like newer generation oral hypoglycemic agents under universal health coverage further improves overall medication adherence and glycemic control in diabetic patients.

Limitations

It could be argued that the higher adherence rates are the outcome of over-reporting due to self desirability bias of the patients. However, we also compared our results with medication adherence studies based on patient self reporting. Self reporting through validated instruments has been suggested to be comparable to other medication adherence assessment methods [33]. Moreover, evaluation of medication adherence through other indirect methods like pill counts and prescription refills may not be feasible in the Indian healthcare system where dispensing of anti diabetic drugs on an outdated prescription may not be a major barrier in several private pharmacies.

This study did not evaluate regimen complexity which is known to impede medication adherence [34]. We excluded those patients exclusively on insulin therapy and the results cannot be extrapolated to them. We also could not evaluate for multiple patient comorbidities which were potential confounders.

Since this study was undertaken exclusively in government hospitals, its findings may not reflect medical adherence levels in the diverse Indian private sector which caters to large sections of diabetic populations [14]. Finally, this study in absence of qualitative research methods may lack certain insights into patient attitudes towards medical adherence.

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