Compliance of Appointment, Antidiabetic Treatment, and Diet in Type 2 Diabetes Mellitus Patients at Private Diabetes Clinic

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\textbf{Keywords} 
Type 2 diabetes mellitus · Compliance · Oral hypoglycemic agent · Fixed-dose combination · Comorbidity · Fasting blood sugar

\textbf{Abstract}
\textbf{Context:} India is an epicenter of type 2 diabetes mellitus (T2DM) in the entire world. Compliance is essential for chronic diseases treatment and has a significant impact on health and health care costs. The current study was planned to assess compliance to the appointment, treatment, and diet in T2DM patients at a private diabetic clinic in Rajkot city. \textbf{Aims:} The aim was to assess compliance to physician’s appointment, antidiabetic treatment, and diet among T2DM patients attending private diabetic clinic at Rajkot city. \textbf{Settings and Design:} This was an interview-based, prospective study done at a private diabetes clinic. \textbf{Methods and Material:} T2DM patients (>18 years) of either gender who were on antidiabetic treatment (at least 3 months before enrollment) at a private outpatient diabetic clinic during 2019 were included after ethical approval and obtaining informed consent. Juvenile diabetes, gestational diabetes, and noncompliant T2DM patients were excluded. \textbf{Statistical Analysis Used:} The $\chi^2$ test was used for the statistical association of sociodemographic and disease variables with compliance using GraphPad version 7 ($p$ value $<0.05$ was considered significant). \textbf{Results:} Of 370 enrolled patients, 21 patients were lost to follow-up (noncompliant). From 349 T2DM patients, the majority of patients were in the middle age-group (60%, 41–60 years), preobese and obese (69.99%), and with comorbidity (42.7%). Compliance to appointment, treatment, and diet was observed above 85% in this study. Old age (>60 years) was significantly associated with poor appointment compliance, and comorbidity is significantly associated with the poor appointment, treatment, and diet compliance. An increasing number of comorbidities were significantly associated with poor appointment compliance. \textbf{Conclusions:} A higher compliance to appointment, treatment, and diet was achieved.

\textbf{Introduction}
India has the 2nd highest cases (73 million in 2017) \cite{1} of diabetes mellitus (DM) in the entire world as per estimated by the International Diabetes Federation. “Compliance” is essential for effective treatment of chronic disease and has a significant impact on disease control and
Compliance in Type 2 Diabetes Mellitus

so on health and health care costs at the individual as well as at the community level [2]. In a medical context, compliance refers to a patient both agreeing to and then undergoing some part of their treatment program as advised by their doctor/health care worker [3]. According to the World Health Organization (WHO), adherence to long-term therapy for chronic illnesses averages only around 50% in developed countries [4]. The WHO emphasized that “increasing the effectiveness of adherence interventions may have a greater impact than improvement in specific medical treatments [5]. Apart from the physician’s role, patient behavior plays a key role toward self-care concerning lifestyle modification, consultation to physician, and regular intake of medicine. Compliance reflects patients’ self-care and behavior. The current study was planned to assess compliance to the appointment, antidiabetic treatment, and diet in type 2 diabetes mellitus (T2DM) patients consulting at a private diabetes clinic.

**Methodology**

**Study Design**

This was a prospective, interview-based study, conducted at the outpatient department of a private diabetes clinic during the year 2019. The study was conducted after approval from Institutional Ethics Committee (IEC) and obtaining written informed consent from participants. The questionnaire was prepared with a scientific background and was validated by the Likert scale by two diabetologist. The questionnaire revealed sociodemographic, treatment, and compliance data. Data collection was scheduled 2 days per week for a 1-year duration.

**Study Participant**

**Inclusion Criteria**

Inclusion criteria: old or new T2DM adult patients (age >18 years) of either gender who were on antidiabetic drugs treatment (at least 3 months before enrollment) with/without any comorbidity were included in the study. Juvenile diabetes, gestational diabetes, hospitalized diabetic patients were excluded from the study. After enrollment, those patients who did not turn back for follow-up (noncompliant) as per scheduled appointment were excluded in the final compliance analysis (Fig. 1).

**Sample Size**

Factors that are considered for the calculation of sample size are population size (for finite population correction factor) \((N)\): 1,000, hypothesized % frequency of outcome factor (compliance of appointment in type 2 diabetes) in the population \((p)\): 60% ± 5%, confidence limits as % of 100 (absolute ± %) \((d)\): 5%, design effect (for cluster surveys-DEFF): 1, calculated sample size was 370 at 95% confidence level. Sample size was calculated using open-source online calculator OpenEpi version 2.

Sample size calculation \(n = [\text{DEFF} \times Np (1-p)] / [d^2 / Z_{\alpha/2}^2 \times (N - 1) + p \times (1-p)]\) (1)

Compliance was assessed by the following method concerning reference research study [3]. (a) Compliance to the appointment: it was assessed by calculating the ratio of attendance to some predetermined appointments. A score of 3/3 or 2/3 in the consecutive 3 records was considered as “good compliance” and 1/3 was “poor.” (b) Compliance with diet regimen: “good compliance” was considered when the patient strictly followed the advised diet plan by diabetologist (interviewed for the type of food consumed and type of food restricted) in last 1 month while “poor compliance” was considered who failed to follow the diet plan more than twice/weekly for more than 2 weeks. (c) Compliance to drug regimen: “good compliance” was considered when the patient strictly followed

![Flow chart of study participants](image-url)
the treatment regimen without missing any single dose in the last month while “poor compliance” was considered when the patient missed taking drugs more than two times per week in the last month.

Assessment of glycemic control was evaluated by the achievement of any of these target values (fasting blood sugar [FBS]/post-prandial blood sugar/glycosylated hemoglobin [Hb1Ac]/random blood sugar [RBS]) set by Indian Medical Council Research (ICMR) guideline [6]. Data were collected and entered into Microsoft Office Excel 10 and tabulated.

Statistical Analysis
The χ² test (Pearson’s χ² or Fisher’s exact test) was used to find out the statistical association between all types of compliance and different sociodemographic and disease variables; the odds ratio was used for the strength of association. Statistical tests were done in GraphPad version 9.1 and p value <0.05 was considered significant.

Results
Total 370 T2DM patients were enrolled as per inclusion criteria. After enrollment, 21 patients were lost to follow-up (noncompliant) and they were excluded from treatment and diet compliance assessment (n = 349) but included in appointment compliance (n = 370) assessment. In this study, the majority of T2DM patients (58%) were in the middle age-group (41–60 years), preobese and obese (69.99%), and with comorbidity (42.7%, hypertension and dyslipidemia). The average duration of diabetes was 8.1 ± 6.6 years (Table 1). Frequent (95.56%) use of fixed-dose combination (FDC) of oral hypoglycemic agent (OHA) was observed in this study. Biguanides (metformin) was a common OHA in almost all FDCs (97.99%) and it was combined with sulfonylureas (62.75%) followed by DPP-4 inhibitors (21.20%) and PPAR-γ activator (1.14%). Glycemic control was achieved among 58.45% of study participants. Compliance with the appointment, antidiabetic treatment, and diet was above 85% in this study (Table 2).

Except for age and comorbidity, no other patient’s characteristics were significantly associated with poor compliance. Old age (>60 years) was significantly associated with poor appointment compliance. Patients with <60 years of age were seven times more likely to have good appointment compliance. Comorbidity was significantly associated with the poor appointment, treatment, and diet compliance (Table 3). Patients with any comorbidity were three times more likely to have poor appointment compliance while two times likely to have poor treatment compliance and diet compliance in this study. A number of comorbidities were significantly associated with poor appointment compliance (Table 4).

| Table 1. Sociodemographic parameters of total enrolled T2DM patients (n = 370) |
|--------------------------|--------------------------|--------------------------|
| Sociodemographic parameters | Age (mean ± SD), years | 53±11.52 |
| | Gender | Male:female | 1:1.2 |
| | BMI | Undernutrition | 7 (1.89) |
| | | Normal weight (18.5–22.9) | 50 (13.51) |
| | | Over weight (23–24.9) | 54 (14.59) |
| | | Preobese (25–29.9) | 139 (37.57) |
| | | Obesity (>30) | 120 (32.42) |
| | Comorbidity | Hypertension | 104 (28.11) |
| | | Dyslipidemia | 46 (12.43) |
| | | Thyroid disorder | 5 (1.35) |
| | | Benign prostatic hyperplasia | 3 (0.81) |
| | Duration of diabetes | Up to 1 year | 29 (7.84) |
| | | Up to 10 years | 259 (70) |
| | | 10 and more years | 82 (22.16) |
| | Diabetic complication | Macrovascular complication | 23 (6.22) |
| | | Microvascular complication | 7 (1.89) |
| | Education | Illiterate | 96 (25.95) |
| | | Schooling | 201 (54.32) |
| | | Graduate and above | 73 (19.73) |
| | Drugs/prescription*, n (%) | Single drug | Monotherapy | 13 (3.51) |
| | | Combination therapy | FDC with 2 OHA drugs | 305 (82.43) |
| | | | FDC with 3 OHA drugs | 69 (18.65) |
| | | | FDC with 4 OHA drugs | 37 (10) |

BMI, body mass index. Figures are given as number of patients with percentages in parentheses, unless indicated otherwise. * Total of no of drugs/prescription was more than 370 as many patients had more than one FDC.

| Table 2. Compliance to physician’s appointment, antidiabetic treatment, and diet |
|--------------------------|--------------------------|--------------------------|
| Type of compliance | Good compliance, % | Poor compliance, % | Total* |
| Appointment compliance | 305 (82.43) | 65 (17.56) | 370 (100) |
| Treatment compliance | 328 (93.98) | 21 (6.01) | 349 (100) |
| Diet compliance | 303 (86.81) | 46 (13.18) | 349 (100) |

* Appointment compliance was calculated out of total patients enrolled and treatment and diet compliance were calculated out of “compliant patients” (349 as 21 patients did not come for any follow-up visit [noncompliant].)
Table 3. Effect of patient characteristics on appointment, treatment, and diet compliances

| Patient characteristic | Appointment compliance, n = 370 | Treatment compliance, n = 349 | Diet compliance, n = 349 |
|------------------------|---------------------------------|------------------------------|--------------------------|
|                        | good, % | poor, % | total | good, % | poor, % | total | good, % | poor, % | total |
| Age                    |         |         |       |         |         |       |         |         |       |
| ≤60 years              | 228 (92.31) | 19 (7.69) | 247 | 79 (94.04) | 5 (5.95) | 84 | 72 (85.71) | 12 (14.28) | 84 |
| ≥60 years              | 76 (61.79) | 47 (38.21) | 123 | 249 (93.96) | 16 (6.03) | 265 | 231 (87.16) | 34 (12.83) | 265 |
| p value                | <0.0001 |         |       | 0.4962 |         |       | 0.3604 |         |       |
| Odds ratio             | **7.37 (4.11–13.59)** |         |       | 1.015 (0.372–3.187) |         |       | 0.8834 (0.4401–1.857) |         |       |
| Gender                 |         |         |       |         |         |       |         |         |       |
| Male                   | 159 (81.12) | 37 (18.87) | 196 | 172 (93.47) | 12 (6.52) | 184 | 156 (84.78) | 28 (15.21) | 184 |
| Female                 | 146 (83.91) | 28 (16.09) | 174 | 156 (94.54) | 9 (5.45) | 165 | 147 (89.09) | 18 (10.90) | 165 |
| p value                | 0.2435 |         |       | 0.3430 |         |       | 0.1201 |         |       |
| Odds ratio             | 0.8246 (0.4769–1.416) |         |       | 0.8274 (0.327–2.037) |         |       | 0.683 (0.3567–1.285) |         |       |
| BMI, kg/m²              |         |         |       |         |         |       |         |         |       |
| <18.5                  | 6 (85.71) | 1 (14.28) | 7 | 6 (100) | 0* | 6 | 6 (100) | 0* | 6 |
| 18.5–22.9              | 45 (86.54) | 7 (13.46) | 52 | 43 (91.48) | 4 (8.51) | 47 | 41 (87.23) | 6 (12.76) | 47 |
| 23–24.9                | 44 (81.48) | 10 (18.51) | 54 | 48 (92.30) | 4 (7.69) | 52 | 43 (82.69) | 9 (17.30) | 52 |
| 25–29.9                | 126 (86.30) | 20 (13.69) | 146 | 133 (93.66) | 9 (6.33) | 142 | 130 (91.54) | 12 (8.45) | 142 |
| >30                    | 84 (69.42) | 27 (22.31) | 121 | 98 (96.07) | 4 (3.92) | 102 | 83 (83.37) | 19 (16.62) | 102 |
| p value                | 0.2227 |         |       | 0.7400 |         |       | 0.1301 |         |       |
| Odds ratio             |         |         |       |         |         |       |         |         |       |
| Education              |         |         |       |         |         |       |         |         |       |
| Illiterate             | 80 (83.33) | 16 (16.66) | 96 | 87 (92.55) | 7 (7.44) | 94 | 79 (84.04) | 15 (15.95) | 94 |
| Schooling              | 123 (61.19) | 78 (38.80) | 201 | 180 (94.73) | 10 (5.26) | 190 | 169 (88.94) | 21 (11.05) | 190 |
| Graduate and postgraduate | 2 (7.24) | 71 (97.26) | 73 | 61 (93.84) | 4 (6.15) | 65 | 55 (84.61) | 10 (15.38) | 65 |
| p value                | <0.0001 |         |       | 0.7661 |         |       | 0.4358 |         |       |
| Odds ratio             |         |         |       |         |         |       |         |         |       |
| Comorbidity            |         |         |       |         |         |       |         |         |       |
| Present                | 241 (89.25) | 29 (10.74) | 270 | 258 (95.55) | 12 (4.44) | 270 | 242 (89.62) | 28 (10.37) | 270 |
| Absent                 | 63 (79.74) | 16 (20.25) | 79 | 70 (88.60) | 9 (11.40) | 79 | 61 (77.21) | 18 (22.78) | 79 |
| p value                | <0.0001 |         |       | **0.0176** |         |       | **0.003471** |         |       |
| Odds ratio             | **2.1106 (1.0795–4.1263)** |         |       | **2.754 (1.076–6.87)** |         |       | **2.542 (1.301–4.897)** |         |       |

BMI, body mass index. * Fisher’s exact test was used where observed cell frequency is <5 and Yate’s correction was used where cells have 0 frequency.
Discussion

Diabetes is a chronic disease of lifelong duration. The risk of complications of diabetes can be reduced by proper adherence to treatment. Medication compliance is an important determinant for outcome in chronic disease [2] and is challenging as it is difficult to maintain for lifelong duration [7]. Poor compliance leads to worsening of the disease, increases hospitalization and mortality, and imposes a significant financial burden on the health care system [8].

A systematic review on the compliance to medication among diabetic patients revealed that the average compliance to the OHA ranged from 36% to 93% [9, 10]. Higher levels of compliance (above 85%) were reported to the appointment, treatment, and diet in this study. Higher compliance (83.6% and 76.2%) was reported in the other studies done in southern Karnataka and rural Maharashtra, respectively [11, 12]. Studies done in rural Ludhiana by Bansal et al. [13] and in urban Puducherry by Santhanakrishnan et al. [14] also reported higher compliance (82.5% and 76%, respectively) in T2DM patients. Some studies from the southern part of India reported compliance in the range of 52–64% [15]. Reasons for higher compliance in this study were individualized care, education and training of patients, and monitoring of treatment and follow-up well maintained at this private diabetic clinic. The clinical setting provides the ambience and accessibility to care, enough time, and attention to patients. The doctor-patient relationship, prescribing patterns, processes of the care provided also influence compliance in a private setting [7].

Glycemic control was achieved among 58. Forty-five percentage of study participants despite higher compliance reported in this study, and a similar result was observed in other studies done by Pattanaik et al. [15] and Muliyil et al. [16]. There was no significant association of appointment (p value, 0.386), treatment (p value, 0.875), and diet (p value, 0.674) compliance with glycemic control in this study.

Except for old age and comorbidity, there was no significant association between sociodemographic characteristics and compliances in the present study. The older age-group (>60 years) was significantly associated with poor treatment compliance. Mukherjee et al. [17] reported that with increasing age compliance decreased significantly [5, 17]. Old people may not comply due to failing memory, physical handicaps, and lack of social support. In this study, comorbidity was significantly associated with the poor appointment, treatment, and diet compliance. The presence of additional chronic comorbidity has an impact on the treatment and management of T2DM [18]. The presence of comorbidities was significantly associated with the poor appointment, treatment, and diet compliance in this study.

### Table 4. Effect of disease characteristics on appointment, treatment, and diet compliance

| Disease characteristic | Appointment compliance, n = 370 (%) | Treatment compliance, n = 349 (%) | Diet compliance, n = 349 (%) |
|------------------------|-----------------------------------|----------------------------------|-----------------------------|
|                        | good  | poor  | total  | good  | poor  | total  | good  | poor  | total  |
| Comorbidity, n         |       |       |        |       |       |        |       |       |        |
| 0                      | 164 (68.33) | 46 (19.16) | 240 | 178 (92.22) | 15 (7.78) | 193 | 164 (84.97) | 29 (15.02) | 193 |
| 1                      | 106 (90.59) | 11 (9.40) | 117 | 109 (96.46) | 4 (3.53) | 113 | 100 (88.49) | 13 (11.50) | 113 |
| 2                      | 35 (81.39) | 8 (18.60) | 43 | 41 (95.34) | 2 (4.65) | 43 | 39 (90.69) | 4 (9.30) | 43 |
| p value                | 0.01702 |       |       | 0.2983 |       |       | 0.4924 |       |       |
| Duration of diabetes   |       |       |        |       |       |        |       |       |        |
| <1 year                | 22 (75.86) | 7 (24.13) | 29 | 26 (89.65) | 3 (10.34) | 29 | 23 (79.31) | 6 (20.68) | 29 |
| 1–5 years              | 211 (81.46) | 48 (18.53) | 259 | 228 (94.06) | 13 (5.39) | 241 | 212 (87.96) | 29 (12.03) | 241 |
| 5–10 years             | 72 (87.80) | 10 (12.19) | 82 | 74 (93.67) | 5 (6.32) | 79 | 68 (86.07) | 11 (13.92) | 79 |
| p value                | 0.2638 |       |       | 0.5657 |       |       | 0.4180 |       |       |
| OHA per prescription, n|       |       |        |       |       |        |       |       |        |
| One drug               | 132 (84.61) | 24 (15.38) | 156 | 141 (93.37) | 10 (6.62) | 151 | 130 (86.09) | 21 (13.90) | 151 |
| Two drugs              | 104 (80.62) | 25 (19.37) | 129 | 112 (94.91) | 6 (5.08) | 118 | 102 (86.44) | 16 (13.55) | 118 |
| Three drugs            | 60 (78.94) | 16 (21.05) | 76 | 67 (94.36) | 4 (5.63) | 71 | 63 (88.73) | 8 (11.26) | 71 |
| Four drugs             | 9 (100) | 0* | 9 | 8 (88.88) | 1 (11.11) | 9 | 8 (88.88) | 1 (11.11) | 9 |
| p value                | 0.3392 | 0.8707 | 0.9513 | 0.9513 | 0.8707 | 0.3392 |

OHA, oral hypoglycemic agent. * Fisher’s exact test was used where observed cell frequency is <5 and Yate’s correction was used where cells have 0 frequency.
The Medical Expenditure Panel Survey reported that most adults with DM have at least one comorbidity, often resulting in multiple prescriptions with a variety of complex drug regimens and polypharmacy which affects compliance in diabetic patients [7, 19]. Multiple chronic conditions report many barriers to self-care such as physical limitations, lack of knowledge, financial constraints, logistics of obtaining care, and the need for social and emotional support [18].

The utilization of FDCs was 95% in this study. FDCs help reduce the dose of individual drugs and thereby reduce dose-related side effects and pill burden, indirectly affecting treatment compliance. A significant association was found between noncompliance and frequent dosing and multiple drugs in a study done by Sharma T et al. [20] However, there was no significant association found between poor compliance and the number of drugs in this study, and a similar result was also reported in a study done by Manobharathi et al. [4] in Tamil Nadu.

Diabetes is essentially a self-managed disease and therefore requires patients to have a degree of autonomy motivation to successfully perform optimal self-management [21]. Patients may have inappropriate health beliefs and attitudes and lack disease-related knowledge and skills. Specific environmental barriers may adversely affect patients’ ability to perform appropriate self-care [22]. One of the important factors that influence compliance in chronic disease management is a good doctor-patient relationship [11]. Clinicians should take responsibility for providing education about the disease like the progression of DM and awareness about its complication, the importance of glycemic control, lifestyle modification, the essential need for regular intake of medicine, and side effects of medication [23]. Training of individuals provides knowledge and skills to become active in self-care [19]. There are four general categories for enhancing medication compliance, patient education and training, improved dosing regimens, enhanced communication between patient and physician, and increased drug availability [21].

**Conclusion**

Higher compliance to appointment, treatment, and diet was observed in T2DM patients consulted at a private diabetes clinic. Two factors old age (>65 years) and presence of comorbidity significantly associated with poor compliance in this study.

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**Study Limitation**

This study was done at one private diabetic clinic, needs to explore such studies at a different level of the health care system.

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**Statement of Ethics**

The research was conducted ethically by the World Medical Association Declaration of Helsinki and the Indian Council of Medical Research, India. The study was approved by the Institutional Ethic Committee for Humans of P.D.U. Government Medical College, Rajkot, PDUMCR/IEC/2186/2018, dated: February 15, 2018. Written informed consent was obtained from participants after explaining study details to participants.

**Conflict of Interest Statement**

The authors have no conflicts of interest to declare.

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**Author Contributions**

Dr. Kiran G. Piparva: concept and design of the study, acquisition of data, and manuscript preparation. Dr. Anil P. Singh: literature search, manuscript editing, and manuscript review, revising it critically for important intellectual content. Dr. Nirav B. Joshi: data analysis, statistical analysis, and manuscript preparation.

**Data Availability Statement**

The data that support the findings of this study are not publicly available because we cannot disclose information that could compromise the privacy of research participants but are available from Dr. A.S., docanil71@yahoo.co.in, contact no. 9409411910, upon reasonable request.
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