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Is self-reported adherence a valid measure of glycaemic control among people living with diabetes in rural India? A cross-sectional analysis

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Abstract

Background—Visual analogue scale (VAS) is one of the simplest to measure medication adherence. It has neither been widely used for Non communicable diseases (NCD) nor validated for in the Indian setting. We examined the validity of self-reported medication adherence measures in relation to HbA1C in a rural population with diabetes mellitus (DM).

Methods—Participants with DM was administered VAS, Diabetes Self-Management Questionnaire (DMSQ) and assessed for missed pills. Descriptive statistics and logistic regression analysis were done.

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Authors' contributions

LR and ME conceptualized the paper. LR interpreted the data and drafted the manuscript. HE performed the statistical analysis, interpreted the data and reviewed the manuscript. KS was involved in data acquisition, and project administration acquired funding and reviewed the manuscript. ME and KS acquired funding, oversaw the project, interpreted the data and reviewed the manuscript. All authors reviewed the manuscript. All authors read and approved the final manuscript.

Ethics statement

Ethics approval was obtained from the Institutional Ethical Review Board at St. John's Medical College and Hospital (reference 38/2013) and the University of California, San Francisco. All the participants were recruited for the study after obtaining informed consent (reference 12–10470).

Conflict of interest statement

None of the authors declare any conflict of interest.

Results—We recruited 1347 participants and 84% of them reported being 100% adherent as per VAS and 83.8% stated that they did not miss any pills. However, 58.2% of participants who reported having 100 % adherence had poor glycaemic control, as did 58.1% of those who did not miss any pills. None of the diabetic self-care measures was significantly associated with glycaemic control.

Conclusion—We found a lack of association between self-reported adherence measures and glycaemic control in participants with DM suggesting that self-reported adherence scales may not be valid in this population.

Keywords

medication adherence; self-reported adherence; diabetes; NCDs; rural India

Introduction

The prevalence of poor glycaemic control is high (76.6%) among diabetes mellitus(DM) patients in India [1]. Non-adherence to oral hypoglycaemic agents (OHAs) and insulin was 74 % in a rural South India study, with the most common reasons reported for missing medications being distance and lack of transport to a health facility, and forgetting to take medications during travel [2,3]. An adequate assessment of medication adherence in diabetes is thus crucial for researchers to accurately estimate the therapeutic efficacy of the medications under trial and for clinicians to optimize the treatment regimen. [4,5]

There are a few measures that have been found to be valid and useful measures of adherence in Low-and Middle-Income countries (LMIC). One of the simplest measures is the visual analogue scale (VAS), which asks participants to self-report the proportion of medication taken in the past month on a scale from 0–100. It has been found to have high levels of concordance with many other measures of anti-retroviral therapy (ART) adherence, including viral suppression in people living with HIV [6]. Since it's a continuous measure, it allows more advanced analytic possibilities than data from categorical response sets or Likert scales [7]. However, the VAS has not been widely used for non-communicable diseases including diabetes. Our objective was to examine the validity of VAS in relation to levels of glycated haemoglobin (HbA1c).

Materials and methods

The cross-sectional analyses in this paper are based on the baseline data from a cluster randomized controlled trial in 49 primary health centres in rural southern India evaluating a collaborative care intervention to improve mental health outcomes in participants with co-morbid physical conditions [8]. Details about the trial including the original sample size calculation, is reported elsewhere [8]. Participants included in the present medication adherence analyses were on oral hypoglycaemic agents DM and at least 30 years old. [8]

The baseline data collection was done between May 2015 and November 2018. Blood glucose levels were measured via HbA1C and classified as good control (<= 8.0) and poor

control (> 8.0) which is based on a Guidance Statement Update From the American College of Physicians [9].

Medication adherence was measured using both the VAS and self-reported missed pills in the last month. Based on the distribution of the responses, we dichotomized VAS and missed pills. In addition, we used nine of the 16 items of the Diabetes Self-Management Questionnaire (DSMQ), covering three subscales - Glucose Management, Dietary Control, and Physical Activity [10]. We tabulated glycaemic control by self-reported adherence measures (VAS & missed pills). In the logistic regression model, glycaemic control was the dependent variable and independent variables were VAS, self-reported missed pills, DSMQ scores and socio-demographic characteristics.

Results

Of the 2486 cohort participants, 1492 (60%) were under treatment for diabetes at baseline, of which 1347 (90.3%) were on oral hypoglycaemic agents and were included in the present analyses. A majority (56%) of participants did not have any formal education and more than two-thirds reported earning less than INR 5,000 (68.7%). (Table 1)

More than half of the participants had poor glycaemic control (56.5%, 785/1388) although the majority (84 %, 1125/1338) reported 100% adherence per the VAS. Similarly 83.8%,1119/1334 stated that they did not miss any pills in the previous month. Despite the high levels of self-reported adherence 58.2% of participants who reported having 100% adherence according to the VAS had poor glycaemic control, as did 58.1% of those who self-reported noting missing any pills in the past month. Self-reported adherence was not significantly associated with glycaemic control in univariate analysis ($p > 0.05$) (Table 2).

The mean score (out of 10) of diabetic self-care subscales for medication, diet and physical activity were 9.0 (SD-1.7), 7.9 (SD-1.8), and 6.9 (SD-2.4) respectively. Logistic regression analyses (Table 3) showed that none of these three measures was significantly associated with glycaemic control. Similarly, VAS-based medication adherence lacked a significant association with glycaemic control.

Discussion

The results show a significant discrepancy between self-reported medication adherence and glycaemic control in this study population, with more than half of the participants reporting 100% adherence, even though only 41.8% of them had good glycaemic control. While it is possible that other factors, such as diet and exercise, contributed to their lack of glycaemic control, it appears more likely that they overestimated their adherence [11]. Consistent with our findings, this phenomenon has also been observed when self-reported adherence measures have been used in other medical regimens, including HIV [12–15]. Similarly, several studies have observed inaccuracies in self-reported HIV risk and treatment adherence behaviours as well as medication adherence in non-communicable diseases such as HTN and patients on anticoagulant therapy. The authors hypothesize that self-reported adherence scales likely lead to overestimates, due to social desirability bias [16–19]. Though subjective measures are inexpensive; easy to administer; identify beliefs and barriers; and

are flexible to accommodate in different settings, it has also been established that they have relatively lower sensitivity and specificity, and are affected by the communication skills of the interviewer as well as patient's desirability bias. [20]

Our work thus demonstrates that self-report of medication adherence in this rural Indian setting has limitations despite using standardized measures and conducting extensive formative work prior to data collection, including cognitive interviews to ensure comprehension and semantic equivalence. Participants were also assured that their responses would not be communicated to their healthcare providers. Our findings suggest that biological and objective measures in these settings are more likely to be valid. While objective measures such as pill counts, electronic monitoring, secondary database analysis and biochemical measures overcome the challenges of subjective measures, they are expensive, sometimes invasive and often time consuming [20]. Doggrell SA and Warot S conclude that the most of studies demonstrate a relationship between HbA1c levels and adherence to anti-diabetes medications, and this relationship appears to be irrespective of the method employed to measure adherence [21]. However, a range of HbA1c readings is required to demonstrate a relationship. In low-income populations, the association is not always evident and these findings are in concordance with ours [21]. Similarly, a self-reported tool in the Mexican population has been found to be valid and reliable but has not been proven to have a positive impact on glucose levels [22].

The major strength of our study was that it was population-based with a large cohort. We used validated tools and trained field staff for data collection and used a biological measure (HbA1C) to glycaemic control. There are also a few limitations of our study. Since HbA1C can be influenced by several other factors such as lifestyle, diet, and stress, we tried to measure some of the lifestyle factors through DSMQ to examine whether they accounted for the poor glycaemic control. However, it appears that these measures too may have been influenced by social desirability biases, so we are unable to rule them out as a contributing factor. This study calls for developing simple, inexpensive objective measures that can be used in resource-limited settings.

Conclusion

Self-reported adherence scales may not be valid in the study population. Future research should focus on developing simple, inexpensive objective measures that can be used in resource-limited settings to accurately estimate medication adherence.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

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Highlights

- Visual analogue scale (VAS) is a simple tool to measure medication adherence
- VAS has not been widely used or validated in Indian setting
- Self-reported adherence scales may not be reliable in a rural population
- Need for innovative, easy-to-administer measures that can be used in rural settings

Table 1

Sociodemographic Characteristics of the study population (n= 1347)

Variable	Category	Frequency	Percentage
Gender	Male	371	27.5
	Female	976	72.5
Marital status	Married	886	65.8
	Widowed	431	32.0
	Separated or Divorced	17	1.3
	Never married	13	0.9
Age in years	30–44	96	7.1
	45–54	274	20.3
	55–64	491	36.5
	65–74	409	30.4
	>75	77	5.7
Religion	Hindu	1326	98.4
	Others	20	1.5
	Missing	1	0.1
Monthly income (INR) *	<5000 (~ USD 60)	926	68.7
	5001–10000 (~ USD 61–121)	321	23.8
	>10000 (> USD 121)	100	7.4
Education	No formal education	754	56.0
	Primary (1–7 years)	403	29.9
	Secondary or higher	189	14.0
	Missing	1	0.1
Body mass index (BMI)	Underweight (<18.5)	43	3.2
	Normal (18.5–22.9)	433	32.1
	Overweight (23–24.9)	287	21.3
	Obese (>=25)	579	43.0
	Missing	5	0.4

* Approximately <13 USD/month qualifies the family to be poor in rural areas.

Table 2

Number and percent with glycaemic control by adherence (Univariate analysis)

Measurement	Adherence	Glycaemic control		Total	P value*
		Poor (HbAlC >8)	Good (HbA1C <=8)		
Self-report per VAS	< 100% adherence	121 (56.8%)	92 (43.2%)	213	0.701
	100% adherence	655 (58.2%)	470 (41.8%)	1125	
Self-reported missed pill in the previous month	No missed pills	123 (57.2%)	92 (42.8%)	215	0.811
	Missed pills	650 (58.1%)	469 (41.9%)	1119	

*for Pearson Chi-square test (1 degree of freedom)

Table 3

Multivariate logistic regression analysis of glycaemic control on medication adherence and diabetes self-care

Predictor	Unadjusted Odds Ratio	Cluster robust SE	95% Confidence Interval	p-value	Adjusted Odds Ratio (n=1332)	Cluster robust SE	95% Confidence Interval	p-value
Adherence related variables:								
VAS 100% adherence *	0.94	0.14	0.70 – 1.27	0.700	0.80	0.17	0.53 – 1.20	0.281
Diabetes Self Care, Medication subscale	1.04	0.03	0.98 – 1.10	0.161	1.06	0.04	0.98 – 1.15	0.148
Diabetes Self Care, Diet subscale	1.00	0.03	0.94 – 1.07	0.954	0.99	0.03	0.92 – 1.06	0.744
Diabetes Self Care, Activity subscale	1.02	0.03	0.97 – 1.07	0.519	1.01	0.03	0.96 – 1.07	0.702
Sociodemographics:								
Age *				0.140				0.158
45–54	1.16	0.29	0.72 – 1.88		1.19	0.30	0.72 – 1.94	
55–64	1.15	0.27	0.73 – 1.82		1.21	0.30	0.75 – 1.96	
65–74	1.33	0.33	0.81 – 2.16		1.40	0.38	0.83 – 2.38	
>=75	2.17	0.67	1.18 – 3.99		2.31	0.78	1.20 – 4.47	
Female *	1.02	0.12	0.80 – 1.29	0.882	1.10	0.17	0.81 – 1.48	0.544
Married *	0.86	0.09	0.70 – 1.06	0.158	0.91	0.12	0.71 – 1.17	0.475
Working *	0.91	0.09	0.75 – 1.12	0.387	0.99	0.12	0.78 – 1.25	0.916
Education *				0.175				0.072
Primary	1.16	0.10	0.99 – 1.36		1.22	0.11	1.01 – 1.46	
Secondary or higher	1.11	0.17	0.82 – 1.50		1.25	0.21	0.90 – 1.72	

* Reference: VAS- <100% adherence ; Age −30 to 44 years ; Gender-male; Marital status – others ; Occupation- not working; Education- no formal education