

Research Article

QUALITY OF LIFE ASSESSMENT AMONG INDIAN DIABETICS ENGAGING AN AYUR-PHARMACO-EPIDEMIOLOGICAL DESIGN

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ABSTRACT: Diabetes related Quality of Life (QoL) and treatment satisfaction data is very scarce from India. The ayur-pharmacoepidemiology study design was assumed to explore the definite situation of perceived QoL among Indian diabetics and to understand the possibilities of interventions provided in Ayurveda hospitals against diabetes by assessing treatment satisfaction among diabetics. Cross-sectional study involving 203 type 2 diabetes patients aged ≥ 25 years were assessed by self-administered Audit of Diabetes Dependent Quality of Life (ADDQoL-19) and Diabetes Treatment Satisfaction Questionnaire (DTSQc). Participants represented both male (68%) and female (32%) with mean age 55.31 (± 10.505 SD) years having age range of 56 years. Family history of diabetes revealed 20.68% paternal and 18.72% maternal diabetes. Mean duration of diabetes was 5.9384 (± 4.0148 SD) years with range of 6 months to 23.5 years. The mean ADDQoL [Average Weighted Impact (AWI)] score of the total participants were (-) 2.7753 where 98.03% participants perceived diabetes to impact negatively on their QoL. Mean DTSQ score was 28.0697. Association between ADDQoL (AWI) score and duration of diabetes showed no significant relationship ($p=0.208$) but strong evidence of diabetes complications was found significantly ($p=0.017$) related to ADDQoL (AWI) score. Negatively impact of Diabetes on QoL among Indians highlight lack of structured education, information programs and integrated diabetes health care model. The study widens the scope for future research opportunities involving ayurpharmacoepidemiological approach for monitoring psychosocial wellbeing and QoL with integrated therapeutic advances involving Ayurveda.

Key words: Ayur-pharmacoepidemiology, Diabetes, Quality of life, Ayurveda.

INTRODUCTION

Ayurpharmacoepidemiology research is required to gauge the effects of Ayurvedic therapeutics on large populations in order to describe and analyze the practices and conditions of use, evaluate the safety and efficacy as a substitute to a clinical trial (including pharmacovigilance observation), evaluate the effectiveness in a predictable condition (comparative effectiveness research), and carry out medico-economic assessments (Debnath *et al.* 2015, Debnath *et al.* 2016a, Debnath *et al.* 2016b). In a populated country like India traditional medicine is practiced widely across diverse geographical and socio cultural niche. The Indian perspective has worsened in case of diabetes. Presently

it is assumed as the diabetes capital having the maximum diabetes population globally and also the highest contributor in terms of diabetes mortality and morbidity (Debnath *et al.* 2015, Tripathy *et al.* 2013). Already 77 million people were affected in the year 2020 (IDF-2020a). Diabetes have emerged as a worldwide pandemic and been rising rapidly from 463 million adults (20-79 years) affected in 2020 to an estimated 700 million individuals by 2045 (IDF 2020b), and among the affected ones approximately 79% living in low and middle income countries. Undiagnosed cases were 232 million with 4.2 million deaths due to diabetes and 374 million people are at increased risk of developing type 2 diabetes (IDF 2020b). The socio-economic and public health impact of

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type 2 diabetes mellitus (T2DM) on both individuals and society is ever growing (Govan *et al.* 2011) with treatment being expensive and complex and necessitating constant education and vigil on the part of the practitioner and patient respectively (Massi-Benedetti 2002, Koopmanschap 2002). In addition, T2DM also plays a huge role in health-related quality of life (HRQoL) as it poses many lifestyle demands and debilitating complications which sometimes are difficult to live with. Many patients find the demands of T2DM exasperating, taxing and overwhelming (Bradley *et al.* 1999). Furthermore, HRQoL worsened with disease progression, treatment progression and the development of complications (UKPDS Group 1999, Redekop *et al.* 2002). Thus the prime goals of diabetes management are to stabilize parameters of metabolic controls and to improve Quality of Life (QoL) (Das *et al.* 2013, Debnath *et al.* 2015).

In India the history of diabetes (*Madhumeha*) persisted since ancient times (Banerjee *et al.* 2015). The spectacle of anti-diabetic treatment through modern medicine couldn't be cured but can only be modified to the changed disease pattern from acute to chronic (WHO 2011). Traditional medicine uses have been given importance currently by many nations, a practical strategy to promote health and to influence the millions affected. The integrative medicine approach recently re-emerged providing hope as an affordable practical solution to the global healthcare crisis with recent developments in the fields of health outcome research and health technology assessment have also fueled the tremendous increase in the use of QoL evaluation as a technique for clinical and public health research. The integrative approach to health care and cure has been the basic matrix of Ayurveda practice through its intuitive, experimental and perceptual methodologies that have averted, alleviated and managed T2DM according to individual patients with a variety of therapeutic measures (Banerjee *et al.* 2015).

Assessment of QoL and diabetes treatment satisfaction is an important step in the direction to evaluating the quality of health care and the economic value associated with new interventions, specifically in the use of traditional medicines such as Ayurvedic herbs and drugs. However, most of the studies on diabetes and HRQoL have been conducted in developed countries (UKPDS Group 1999, Redekop *et al.* 2002) and studies of the HRQoL in diabetic patients in developing countries are rare (Aghamollaei 2003, Ghanbari *et al.* 2005, Savli and Sevinc 2005). Knowing the extensive use of Ayurvedic medicine and the remarkable development of international markets for herbal products, importance of

safeguarding Ayurveda health care to be safe and reliable; the standards for the safety, efficacy, and quality control of Ayurvedic products and therapies are documented and validated. Therefore, the current Ayurpharmacoepidemiological (APE) study is connected with the use of Ayurvedic medicinal products on diabetes patients in order to describe and analyze the practices and conditions of use, and to explore the actual situation of perceived QoL in T2DM and to understand the possibilities of interventions provided in Ayurvedic hospitals against diabetes by assessing QoL and diabetes treatment satisfaction among diabetes patients.

MATERIALS AND METHODS

Hospital based cross-sectional research design was used to conduct this study at Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan, India. Ethical approval was obtained from the Institutional Ethical Committee of SDM College of Ayurveda and Hospital, Hassan (IEC No: SDMCAH/IEC/46/11-12). Objective of the study was to explore the certain situation of perceived QoL among Indian diabetics and to understand the options of interventions provided in Ayurveda hospitals by assessing treatment satisfaction among diabetics.

Since this study did not involve any invasive procedure so concerns regarding strong ethical issues did not arise. Participants were informed about the detailed nature of the study and were assured that participation was voluntary. Convenient sampling technique was used to recruit the participants from the outpatient departments of the hospital who came for regular health checkups and consultation. Considering prevalence of 15% of diabetes among adults in Karnataka with an absolute precision of 5% and 95% confidence level the estimated sample size was 196 participants. Participants were included on the basis of age ≥ 25 years (both male and female) willing to participate by providing written informed consent; who understood and read at least one among the two languages i.e. English and Hindi. Participants were diagnosed and treated for diabetes for at least 6 months. Pregnant women with Gestational Diabetes Mellitus and acute cases with compromised renal, hepatic, pulmonary and cardiac function, which requires the participant to be admitted for more than 2 weeks, were excluded. Participants fulfilling the selection criteria were invited to complete the Audit of Diabetes Dependent Quality of Life (ADDQoL-19) Questionnaire (Bradley *et al.* 1999, Wee *et al.* 2006, Ostini *et al.* 2012) and the Diabetes Treatment Satisfaction Questionnaire (DTSQs) (Bradley 2010). Altogether 203 participants completed the study and were

included for the final analysis.

Both ADDQOL-19 and DTSQs were designed as a supervised self-reported questionnaire. That is, the patients should complete the questionnaire themselves, with someone available to provide help if necessary. In the present study patients were offered the choice of having the questions recited to them. It was sensed that this would evade complications regarding reading ability, and certainly get rid of any unjustified burden they may experience in completing such questionnaires. Relevant medical history such as duration of T2DM, complications and concomitant conditions were also obtained from medical files. Once these forms were complete, each questionnaire was coded by assigning each patient with a number, in order to maintain their anonymity and for data capturing purposes. Any blood samples taken formed a routine part of the consultation for these patients *e.g.*

blood glucose values were routinely obtained for all patients at the clinic regardless of whether they were study participants or not. Once all the questionnaires had been completed, the data was checked and corrected by the investigator. After coding, cleaning and editing data was entered into the computer through Statistical Package for Social Sciences (SPSS version 16) software for analysis. Correlation analyses were used to determine the relationship between QoL and the duration of diabetes, as well as between QoL and age of respondents. Due to the fact that many of the variables were not normally distributed, Mann-Whitney U tests was used to compare the relationship between QoL and gender. The ANOVA test was used to test for homogeneity of variance between the various complications and QoL. The non-parametric F-test was used to compare QoL and level of education, work status and religion. Multiple comparisons using

Table 1. Distribution of responses according to different domains of ADDQoL-19.

ADDQOL Domains	Male			Female			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	Sd
1	138	-2.2319	2.30926	65	-1.2769	1.66309	203	-1.9261	2.16623
2	91	-3.0879	2.55016	22	-2.8182	2.48110	113	-3.0354	2.52816
3	138	-2.8913	2.16031	65	-1.9269	1.78848	203	-2.5825	2.09334
4	100	-2.4300	1.98100	51	-1.6520	1.99942	151	-2.1672	2.01468
5	138	-3.3261	2.42301	65	-3.0962	2.25334	203	-3.2525	2.36688
6	136	-3.1176	2.57641	65	-2.8308	2.47215	201	-3.0249	2.54055
7	138	-2.7391	2.37168	65	-1.3385	2.17426	203	-2.2906	2.39621
8	116	-2.8966	2.39339	47	-1.8511	2.06396	163	-2.5951	2.34557
9	66	-2.8939	2.99296	14	-2.6429	3.17701	80	-2.8500	3.00674
10	138	-3.0254	2.34779	65	-2.1077	1.49084	203	-2.7315	2.15101
11	138	-3.5399	2.41049	65	-2.9077	2.22010	203	-3.3374	2.36427
12	138	-3.3714	2.54525	65	-2.5385	2.11451	203	-3.1047	2.44173
13	138	-1.7717	2.16485	65	-1.1385	1.36790	203	-1.5690	1.96445
14	138	-3.5670	2.60991	65	-2.8769	2.15427	203	-3.3461	2.48884
15	138	-3.1250	2.38671	65	-1.6154	1.66482	203	-2.6416	2.28912
16	138	-4.2826	2.68814	65	-3.0923	1.85171	203	-3.9015	2.50942
17	138	-2.5815	2.27874	65	-1.6308	1.64478	203	-2.2771	2.13930
18	138	-3.9819	2.47056	65	-2.8462	2.16673	203	-3.6182	2.43089
19	138	-3.2337	2.63334	65	-2.3231	2.19451	203	-2.9421	2.53186

[1= Leisure activities; 2= Working life; 3= Travel; 4= Holidays; 5= could do physically; 6= Family life; 7= Friendship and social life; 8= Close personal relationship; 9= Sex life; 10= Physical appearance; 11= Self-confidence; 12= Motivation; 13= Society reaction; 14= Feeling about future; 15= Finances; 16= Living conditions; 17= Dependence; 18= Freedom to eat; 19= Freedom to drink].



Fig. 1. Socio-demographic distribution of the participants along with diabetes complication, duration and family history (N=203).

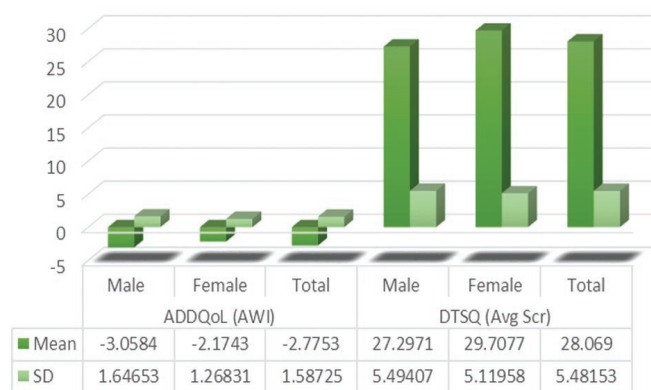


Fig. 2. ADDQoL Average Weighted Impact score and DTSQ average score of the participant.

LSD (Post hoc test) was also done for level of education and religion. Analysis was done with relevant statistical significance ($p < 0.05$) according to study design while keeping in mind the needs/objectives of the study.

Patient-reported outcome measures

ADDQOL-19 was recommended for measuring the impact of diabetes on QoL as well as for a single-item measure of QoL per se. Diabetes-specific QoL was assessed using the ADDQOL-19 questionnaire consisting of two overview items: one quantify generic overall QoL (-3 to +3) and the second quantify the specific impact of diabetes on quality of life (-3 to +1). An additional 19 domains apprehensive with the impact of diabetes on specific aspects of life were also measured. Participants were asked to rate the impact of diabetes on each domain and the importance of the domain for their QoL. These two scores were then multiplied to produce a weighted impact score for each domain (range = -9 [maximum negative impact of diabetes] to +3 [maximum positive impact of diabetes]). As a final point, an average weighted impact score (AWI) was calculated for the entire scale (Bradley 2005, Bradley 2006, Bradley 2011). The DTSQs was recommended for measuring patient satisfaction with precise areas of their diabetes treatment. DTSQ has been recommended by WHO and IDF as useful in assessing outcomes of diabetes care. DTSQs was an authenticated self-administered questionnaire consisting of six items (current treatment, convenience, flexibility, understanding, recommend, continue). Every item was scored on a 7-point Likert scale. The total treatment satisfaction score thus ranged from 0 (very dissatisfied) to 36 (very satisfied). The questionnaire also included two added items measuring perceived perception of hyper or hypoglycemia (Bradley 2010).

RESULTS AND DISCUSSION

Socio-demographic distribution depicted 203 participants representing both male (68%) and female (32%) subjects. Participants mean age was 55.31 (± 10.505 SD) years with age range of 56 years. The level of education of the patients was varied, 98.03% (199) of the patients had finished school and only 1.97% (4) subjects that participated in the study had achieved an education level below grade 10. The majority (87.68%) of the participants were Hindus, with a smaller (11.33%) being made up of Muslims. Work status depicts that (26.11%) of them were retired personnel over the age of 60 years which constituted of mostly males followed by homemakers (20.69%) constituted of females. Physical disability rendered 3 participants unable to work. Enquiries along the respondents’ family history of diabetes revealed 47.8% (97) had no diabetes related family history. While 20.68% (42) had history of patriarchal diabetes and 18.72% (38) had maternal diabetes. The mean duration of diabetes was 5.9384 (± 4.0148 SD) years, ranging between 6 months and 23.5 years. This study population included a variety of patients at various states of disease progression with 22.66% (46) having no complications to 1.48% (3) harboring five diabetes related complications, whereas the majority had one or more complications. The most frequent complications documented in the study having hypertension (33.99%) and dyslipidemia (28.57%), noticeably 17.73% had diabetes foot ulcers (Fig. 1).

ADDQoL: Assessment of individual domains on QoL showed that most negative impact was on domain on living conditions (-3.9015) followed by freedom to eat (-

Table 2. Frequency table demonstrating the perceived Quality of Life of the study participants.

Rating *	Total QoL		Frequency	Percent
	From	To		
1	-9.00	-7.50	3	1.48
2	-7.49	-6.50	6	2.95
3	-6.49	-5.50	6	2.95
4	-5.49	-4.50	14	6.90
5	-4.49	-3.50	26	12.81
6	-3.49	-2.50	39	19.21
7	-2.49	-1.50	72	35.47
8	-1.49	-0.50	33	16.26
9	-0.49	+0.50	4	1.97
10	+0.51	+9.00	0	0

3.6182). While least negative impact was shown by the domain related to society reaction on respondent of having diabetes (- 1.5690) followed by domain related to leisure activities (-1.9261) (Table 1). The total QoL values depict the QoL scores that were obtained by totaling the 19 life domains to reach a single score. The values in row 1 show the number of patients who rated their perceived QoL most negatively through to those in row 9 who felt that their T2DM had a least negative impact on their QoL. Row 1 in this table shows that 3 participants (1.48% of the population) felt that their diabetes had the maximum negative impact on their lives, as they scored the questionnaires with the most negative ratings available. The results also show that the majority of the patients (98.03%) perceived T2DM to impact negatively on their QoL. Only one participant (1 in row 9) felt that T2DM had no impact on the QoL (Table 2). Two overview items shows that the mean score for item 1 (present QoL) was 0.6059 while mean score for item 2 (impact of diabetes on QoL) was -1.6108 (Table 3). The mean AWI score of the total participants were -2.7753 which was on the negative side of the QoL impact for diabetes (Fig. 2).

DTSQ: The average score of (4.9064) recommendation of treatment to others was the highest and lowest average score (4.2241) was found for flexibility of treatment (which excluded domain 2 & 3, since these two domains were not included while calculating the total scores of DTSQ). The average score for perceived frequency of hyperglycaemia was 2.1921 whilst that for perceived frequency of hypoglycaemia was 1.0764 (Table 4). Analysis of results indicated that participants had a mean DTSQ satisfaction score of 28.0697 (Fig. 2). Scores ranged from a high of 36 to a low of 8.5.

The distribution of ADDQoL Average Weighted Impact Score was found to be -3.0584 and - 2.1743 among the male and female respondents respectively impacting their QoL. Regarding the DTSQ mean score male respondents recorded 27.2971 lower than 29.7077 their female counterpart on the grounds of treatment satisfaction. Association between QoL scores and duration of T2DM showed no significant relationship ($r = -0.089$; $p = 0.208$) by means of correlation analysis. One-Way ANOVA were performed to elucidate

Table 3. Distribution of overview items score on ADDQoL (N=203).

Overview Item	N	Minimum	Maximum	Mean	Std. Deviation
1	203	-2.00	3.00	0.6059	0.98119
2	203	-3.00	0.00	-1.6108	0.83327

relationship between QoL score with the various diabetes-related complications. The F test provided F value = 1.557 with p value = 0.017 [ADDQoL (AWI)]. Henceforth, strong evidence to conclude that complications of T2DM with ADDQoL (AWI) score differed significantly. Analysis between QoL scores and demographic markers presented that age, religion and education level were not significant and there were no significant difference with age, religion and education level compared by QoL scores among participants. On the other hand, occupation and gender of the participants with QoL score were significantly related and that there was significant difference of QoL score with occupation and gender (Table 5).

Measurement of health not only indicates changes in the occurrence and severity of diseases but also evaluation of well-being (WHOQOL Group 1997). High disease burden of T2DM have instigated to identify new strategies for prevention and control and in assessing the impact of those strategies on survival, disease advancement, complications, co-morbidities, QoL, and cost (Eddy and Schlessinger 2003, Clarke *et al.* 2004). Diabetes related patient well-being and treatment satisfaction are essential outcomes for routine assessment of innovative remedies (Salem *et al.* 1992, Gale 2000, Withaus *et al.* 2001). Studies have demonstrated that diabetes has a strong negative impact on the HRQoL, especially in the presence of complications (Goodridge *et al.* 2005, Lloyd *et al.* 2001, Huang *et al.* 2007). However, most of the studies on diabetes and HRQoL have been conducted in developed countries (Garratt *et al.* 2002) and studies of the QoL in diabetic patients in developing countries like India are uncommon (Gautam *et al.* 2009, Kiadaliri *et al.* 2013, Jain *et al.* 2014).

The participants in this study representing a diverse population group, were mostly middle aged (55.31 ± 10.505 SD years) and well-educated due to the selection criteria for self-administered questionnaire. Even the majority of the population practiced Hinduism, however it allowed for comparisons between these groups in order to ascertain perception difference for QoL issues. This is important because in a culturally diverse country such as India, in the development of programs to educate patients the use of culturally sensitive and appropriate data would be of importance. Work status of participants depicts that majority (26.11%) of them were retired personnel constituted of mostly males followed by homemakers (20.69%), which constituted females. This may be due to the social construct in Indian families where men work and female stay at home. Enquiries along the respondents' family history of diabetes revealed 47.8% (97) had no

diabetes related family history. While 20.68% (42) had history of patriarchal diabetes and 18.72% (38) had maternal diabetes. The mean duration of diabetes was 5.9384 (± 4.0148) years, ranging between 6 months and 23.5 years. It is well-known fact that diabetes related complication is associated with increased duration of diabetes (Aalto *et al.* 1997, Glasgow *et al.* 1997, Klein *et al.* 1998).

This study population included a variety of patients at various states of disease progression. Several studies have reported that the incidence of complications will vary according to the duration of disease (Peyrot and Rubin 1997, UKPDS Group 1998a). Few studies from India which had looked at the micro-vascular complications of diabetes in a population hold to be similar with our results (John *et al.* 1991, Reema *et al.* 1996, Dutta *et al.* 2005). Prevalence of macro-vascular complications was also found to be higher in subjects with T2DM (Mohan *et al.* 2000, Mohan *et al.* 2001, Viswanathan *et al.* 2006). Coronary artery disease (CAD) was the major causes of mortality documented (Bhansali *et al.* 2003, Mohan and Pradeepa 2009). Therefore it was possible to say that micro and macro vascular complications are associated with a worse T2DM outcome (UKPDS Group 1998b). Results showed that 98.03% participants perceived T2DM to impact negatively [based on ADDQoL-AWI score (-2.7753)] on their QoL.

A review on patients' perceptions on diabetes and diabetes management revealed universally negative impact on diabetes-related QoL (Bradley and Speight 2002, Koopmanschap and CODE-2 Advisory Board 2003, Wändell 2005). Diabetes treatment satisfaction was on the higher side with mean DTSQ score of 28.0697. All of the study participants were treated with Ayurvedic poly-

herbal and herbo-mineral preparations (Banerjee *et al.* 2015, GOI 1978). Markedly many patients were administered conventional oral hypoglycemic drugs and/or insulin with Ayurvedic medicine as adjunct therapy (Biswas *et al.* 2010, Debnath *et al.* 2015). Patients perceive their current treatment as the best without comparing with somewhat better options by expressing positive satisfaction, which results in less variation in patient satisfaction surveys conducted everywhere (Bradley *et al.* 2007). Most often people with diabetes are compared to the general population sometimes to persons without any chronic disease, and sometimes to persons who have the same additional diagnoses other than diabetes (Franz 2008).

Numerous researchers found that augmented duration of diabetes was linked with reduced QoL (Aalto *et al.* 1997, Glasgow *et al.* 1997, Klein *et al.* 1998). Alternatively, some have established no significant association between QoL and disease duration (Wredling *et al.* 1995, Peyrot and Rubin 1997) which is comparable to our results ($p=0.208$). Consistent findings for the presence of complications, particularly the occurrence of two or more complications (Peyrot and Rubin 1997, Anderson *et al.* 1997) and greater severity of complications (Jacobson *et al.* 1994) are connected with worsened quality of life well supported by analyses performed to elucidate relationships between QoL and the various diabetes-related complications yielded significant ($p=0.17$) results in our study. In addition there were no significant relationships between QoL scores with age ($p=0.191$) or religion ($p=0.757$). Similarly, age was found to influence HRQoL as increase in age resulted in a decrease in QoL (Prause *et al.* 2005). On the contrary to age and religion, QoL was significantly related to

Table 4. Distribution of responses and scores according to different domains of DTSQ.

DTSQ Domains	Male			Female			Total		
	N	Mean	SD	N	Mean	SD	N	Mean	Sd
1	138	4.7174	1.15252	65	5.2308	1.02727	203	4.8818	1.13705
2	138	2.3623	1.66081	65	1.8308	1.94108	203	2.1921	1.76813
3	138	1.2283	1.68085	65	.7538	1.40346	203	1.0764	1.60917
4	138	4.3406	1.26431	65	4.8615	1.04398	203	4.5074	1.22017
5	138	4.0543	1.44192	65	4.5846	1.28565	203	4.2241	1.41255
6	138	4.6920	1.49002	65	4.9692	1.14522	203	4.7808	1.39215
7	138	4.8043	1.20133	65	5.1231	.94386	203	4.9064	1.13282
8	138	4.7246	1.02536	65	4.9846	.97616	203	4.8079	1.01476

[1= Current treatment, 2= Perceived frequency of hyperglycaemia, 3= Perceived frequency of hypoglycaemia, 4= Convenience, 5= Flexibility, 6= Understanding, 7= Recommendation to others, 8= Willingness to continue].

Table 5. Relation between ADDQoL (AWI) score and demographic markers.

Demographic marker	Statistical Test		p-value	Outcome
Age	Linear Regression Analysis		0.191	NS
Gender	Mann-Whitney U Test		0.000	S
Religion	ANOVA (non-parametric F-test)		0.757	NS
Education	ANOVA (non-parametric F-test)		0.444	NS
	Post hoc test (LSD)	High school completed - Secondary school completed	0.036	S
				S
Occupation	ANOVA (non-parametric F-test)		0.014	
	Post hoc test (LSD)	Government employee - Homemaker	0.030	S
		Government employee - Unemployed (unable to work)	0.015	S
		Non-government employee - Unemployed (unable to work)	0.023	S
		Self-employed - Homemaker	0.005	S
		Self-employed - Unemployed (unable to work)	0.007	S
		Homemaker - Retired	0.034	S
		Unemployed (unable to work) - Retired	0.018	S

NS = Non-significant; S = Significant; LSD = least significant difference.

gender and work status of patients.

Researchers have described that QoL is better among diabetic men than among diabetic women, consistent with reported gender differences in HRQoL in the general population (Kandrack *et al.* 1991, Glasgow *et al.* 1997). Also men were more satisfied with their diabetes treatment regimen than women did (Wredling *et al.* 1995, Peyrot and Rubin 1997, Ward *et al.* 1997). Others have also found that females were more likely to report a more negative impact on their daily life than were males (Wredling *et al.* 1995, Ward *et al.* 1997). These findings, suggest that diabetic men have an advantage over diabetic women in HRQoL, reinforce the need to control for gender in future investigations of quality of life in diabetes. The lack of a relationship between education level and QoL was also evident regardless of whether patients had not completed school or whether they had a post graduate degree. Demographic variables are associated with QoL measures and several factors independently predict a poorer QoL score (Koopmanschap and CODE-2 Advisory Board 2003, Prause *et al.* 2005). There seems to be a universal association between QoL measures and demographic variables and perhaps a larger multi-centric study would find relationships in this population group.

CONCLUSION

Regardless of increased prevalence of diabetes and its related morbidity and mortality, Indians notably lack awareness about the proper management and treatment of diabetes. Quality of life assessment is a major tool for APE study. Traditional Ayurvedic medicine showed higher scores on treatment satisfaction among participants. This widens the scope for monitoring of psychosocial wellbeing and QoL in people with diabetes. This novel study identified patients who are depressed or anxious; evaluating Ayurvedic treatments, its psychological costs and benefits; satisfaction with treatment and other aspects of care. Comprehensive approach like these studies can specifically address the present situation where the larger population will be represented. The results of the present study serve to highlight the need for APE studies and programs that take care of the differences between population groups. The APE studies designed appropriately identify that Ayurvedic intervention are culturally acceptable and appropriate in case of Indian diabetics. It suggests that widespread integrated approach and rational intervention programs for future diabetic health care is important.

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