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EVALUATION OF A MINDFULNESS BASED COGNITIVE THERAPY IN PATIENTS OF DIABETIC DISTRESS

Pharmaceutical Science

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ABSTRACT

India is also the youngest nations in the world with more than 60% of the population are being under the age of 35. If the diabetes population is 90 million at this stage, how it would be if the majority of the population becomes adult or elder in the near future. Hence there is an urgent need to promote knowledge and quality of life in the Type 2 Diabetes and Diabetic co-morbidities such as Diabetic Distress. The present study would encourage liaison between the physician, patient and the clinical pharmacist to a great extent. The study was initiated after taking the proper ethical approval from the institution. The study was divided in to 3 phases namely, (Phase 1) Collection, (Phase 2) Segregation and (Phase 3) Interpretation. Diabetic distress scale (DDS -17 Scale) was used to determine the diabetic distress levels and to distribute the patients based on the levels of their distress. The patients were distributed based on the psychological complications associated with diabetes mellitus; this distribution was done both in the observational and the interventional groups. In both the groups moderate distress level was the highest also in the diabetic distress types interpersonal distress was the highest. The study was successful in improving the overall QoL of patients and with the proposed objectives was achieved.

KEYWORDS

Clinical Pharmacist; Co-morbidities; Diabetic Distress; Quality of life; Type 2 Diabetes

INTRODUCTION

Diabetes is one of the most common chronic diseases, anticipated to affect more than 400 million people worldwide. Its prevalence is predicted to grow to 642 million by 2040, and it is expected to be the 7th leading cause of death by 2030. Diabetes will affect more than 70 million by 2040 [1]. India with the highest prevalence of diabetes, estimated at 17.6% respectively [2]. Diabetes is a challenging disease that is considered to be hard to live with as it encompasses a lot of restrictive instructions. The emotional distress facing people with diabetes due to such lifestyle restriction is an area of growing clinical interest [3]. The instructions given by the educator or the physician can seem to be complicated for a person from a nonmedical background, which further compounds the emotional distress of the diagnosis and necessary lifestyle changes [4].

Diabetes-related distress (DRD) and diabetes burnout are terms that have been used in the literature to refer to the emotional and behavioral changes caused by diabetes and its demanded lifestyle alterations [5, 6]. Many studies have been conducted in this field using different scales on different populations. These studies have shown that there are many factors related to the presence or absence of DRD, and its severity depends on the characteristics of the population and other psychosocial factors [7]. The dangerous complications (e.g., hypoglycemia) that can result from DRD have made this issue a growing area of interest for researchers. A relatively new scale called Diabetes Distress Scale-17 items (DDS-17) was recently developed as a brief and reliable scale that avoids the limitations and deficits of previous metrics. The brief form of DDS is designed for use in clinical settings not just for research purposes [8].

This study was motivated by the scarcity of studies on DRD in India. To the best of our knowledge, there have been no studies using DDS-17 in this environmental context. Our study aims to assess distress among type 2 diabetes (T2D) patients using DDS-17 and to correlate this DRD to T2D complications, treatment modalities, and glycemic control.

Research Methodology

Here, we present a cross-sectional study on T2D patients of the Endocrine, Psychiatric and General Medicine Department units (Inpatient) of Narayana medical college and hospital, a 1430 bedded tertiary care teaching hospital, chintareddypalem Nellore. Andhra Pradesh. All T2D patients were patients were selected based on the age that are above or equal to 40 years and up to 80 years of age and all recent laboratory results were included. Patients with type 1 diabetes (T1D), untreated hypothyroidism, gestational diabetes, cancer, psychiatric illness, and patients unwilling to participate were excluded.

Data collection forms (DCFs) were compiled during patient interviews using a drug picture chart to help them to identify their treatment correctly. The DCF is composed of three sections: demographic data, past medical history, and drug history. Past history includes history of severe hypoglycemia, which is defined as a decrease of blood sugar less than 55 mg/dl with loss of conscious or/and required help from someone else due to their condition in the last 12 months. Laboratory results were collected from patients' electronic medical records. Patient records were anonymized by replacing patient name and medical record number (MRN) with a serial study code prior to export into a statistical analysis program. Our research proposal was reviewed and approved by the Institutional Review Board (IRB).

We used DDS-17 to assess DRD in study participants. Each of the 17 items of DDS-17 has a six-point scale for response: a mild to moderate problem is 1 or 2, a moderate to serious problem is 3 or 4, and a serious problem is 5 or 6. The total score of DDS-17 was calculated by summing the 17 items' results and dividing by 17. If the total score was >2, then it was considered as clinically significant results (moderate distress), but if it is ≥3, then it is classified as a high distress [3]. DDS-17 assesses four components of DRD, which are emotional, physician-related, regimen-related, and interpersonal distress. Each component scored separately by dividing the sum of its item scores by the number of the items. Patients were considered to have DRD in each component separately if they scored >2 in that component. DDS-17 items were translated to the telugu language by one bilingual person and validated by another 2 bilingual experts, and it was tested on a pilot sample (100) showing good internal consistency for the whole 17 items as shown in Table 1 (Cronbach's alpha = 0.877).

Intervention phase was conducted for 18 months, In this phase diabetic distress patients were identified and distributed into observational and interventional groups, By doing so it was identified that observational group was comprising of 1154 patients and interventional group comprising of 1330 patients, all these patients were suffering with diabetes mellitus with diabetic distress. most of the patients were unknown of their diabetic distress until the patients were empowered with the knowledge and counseled against the disease. For analysis, Student paired t-test and ANOVA to calculate the significance value (p-value) for the purpose of comparison of results in all the groups by using software “Graph pad prism” and A p-value of <0.05 was considered as statistically significant.

RESULTS

A total of 2689 patients were recruited into the study in the initial stages of the study. A total of 2689 patients were divided randomly into 2 groups based on the patient data collection time. All the first month patients were assigned into observational group and second month patients into observational group and so on for 12 months. Here under are the statistics structured after patients' selection procedure. A total of 1300 patients were segregated into observational group and a total of 1389 patients were taken to the intervention group. Intervention phase was conducted for 18 months, In this phase, diabetic distress patients were identified and distributed into observational and interventional groups, By doing so it was identified that observational group was comprising of 1154 patients and interventional group comprising of 1330 patients, all these patients were suffering with diabetes mellitus with diabetic distress. Most of the patients were unknown of their diabetic distress until the patients were empowered with the knowledge and counseled against the disease. In the observational group no pharmacist intervention was intervened but noted all the parameters in the initial stages of the research and noted the parameters only at the end of the research whereas in the interventional group pharmacist intervention was taken place for every 6 months parameters were collected and analysed for the statically significance and at the end of the research both the interventional and observational groups were compared and analysed so the statically significance of the pharmacist intervention

Table 1: Distribution of patients into Observational and Interventional groups – DDS 17 Scale

S.No.	OBSERVATIONAL GROUP (OG) (n=1154)					INTERVENTIONAL GROUP (IG) (n=1330)		
1	Diabetic Distress Level	Level	M	F	Diabetic Distress Level	Level	M	F
		Low	278	99		Low	334	146
		Moderate	421	278		Moderate	497	259
		High	43	35		High	67	27
	Total		742	412	Total		898	432
2	Diabetic Distress Type	Type	M	F	Diabetic Distress Type	Type	M	F
		EB	195	121		EB	275	111
		PRD	131	112		PRD	148	118
		RRD	175	79		RRD	184	89
		ID	241	100		ID	291	114
	Total	742	412			Total	898	432

In both male and female patients, moderate level of diabetic distress was identified as the major percentage of diabetic distress levels and the least were identified as the high diabetic distress levels. In the male patients interpersonal distress identified as the predominant distress type whereas in the female patients physician related distress identified as the major predominant distress type in interventional group.Table-2 compares the observational and interventional groups for the statistical significance in the laboratory parameters at the beginning and at the end of the study. Laboratory parameters were taken at the baseline in both groups.

Table 2: Laboratory parameters comparison between Observational and Interventional groups

Parameter	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Laboratory		0.0173	Laboratory				<0.0001
	Baseline	End		Base	6 M	12M	18M	
RBS (mg/dl)	224±8	231±5		235±6	198±8	164±2	153±3	
FBS(mg/dl)	146±6	151±4		153±4	146±4	140±2	131±3	
HDL(mg/dl)	35±2	36±2		35±1	38±3	42±2	43±2	
LDL(mg/dl)	105±4	108±4		104±7	98±5	82±2	79±2	
TC(mg/dl)	135±7	142±5		152±4	144±2	131±2	127±3	
HbA1C (%)	6.8±1.9	7.3±2.5		7.1±1.9	7.2±2.5	6.5±1.5	6.3±1.9	
BMI (kg/m²)	31±4	32±3		31±4	31±3	29±2	26±2	

Observational Group Significance - paired t-test; p = 0.0173* (s) Interventional Group Significance - one way ANOVA; p = <0.0001 ****(ss)

Table-3 describes the distribution and comparison between observational and interventional group for the length of hospital stay by the patients. The length of hospital stays was recorded at the baseline and at the end in the observational group, 522 patients were recorded with 3 days hospital stay at the baseline and the same length was noted at the end of the study and observed the patient count was increased to 724. The statistical analysis was performed using paid t test for the recorded data and it was observed the value of p = **0.0290*,** which wasconsidered to be not so significant with respect to the statical analysis, figure number 5 illustrates the paid t test significance for the observational group.

Table 3: Hospital stays length comparison between Observational and Interventional groups

Length (Days)	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Hospital stays		0.0290	Hospital stays				<0.0001
	Baseline	End		Base	6 M	12M	18M	
3	522	724		679	621	543	487	
3-5	651	732		652	634	588	501	
5-7	344	397		459	411	375	309	
7-10	385	421		388	321	305	297	
10-14	219	274		299	225	198	173	
14-21	36	51		98	74	51	43	
>21	41	73		35	30	24	13	

Observational Group Significance - paired t-test; p = 0.0290* (s) Interventional Group Significance - one way ANOVA; p = <0.0001**** (ss)

Table-4 describes the medication adherence comparison between the operational and interventional groups. In this Medication adherence by the patients was observed for all the levels and all the types of diabetic distress.

Table 4: Medication Adherence comparison between Observational and Interventional groups

Diabetic distress	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Medication Adherence		0.0984	Medication Adherence				<0.0001
	Baseline	End		Base	6 M	12M	18M	
	y/n	y/n		y/n	y/n	y/n	y/n	
Low	420/734	399/755		411/919	499/831	564/766	859/471	
Moderate	559/595	599/555		392/938	491/839	609/721	911/419	
High	344/810	310/844		488/842	511/819	657/673	892/438	
EB	412/742	400/754		383/947	421/909	505/825	797/533	
PRD	367/787	320/834		412/918	497/833	691/639	773/557	
RRD	449/705	389/765		319/1011	571/759	716/614	819/511	
ID	399/755	366/788		489/841	572/758	711/619	893/437	

Observational Group Significance - paired t-test; p = 0.0984 (ns) Interventional Group Significance - one way ANOVA; p = <0.0001**** (ss)

A very positive increase in the medication adherence was noticed by the end of the study in the interventional group and the statistical analysis gave a very significant value p = **<0.0001.** Table-5 describes the diabetic distress level comparison between the observational and interventional groups.

Table 5: DDS Level comparison between Observational and Interventional groups

Diabetic distress level	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Diabetic distress		0.0254	Diabetic distress				<0.0001
	Baseline	End		Base	6 M	12M	18M	
Low	377	834		480	480	359	301	
Moderate	699	957		756	704	641	548	
High	78	425		94	91	79	57	

Observational Group Significance - paired t-test; p = 0.0254* (s) Interventional Group Significance - one way ANOVA; p = <0.0001**** (ss)

Table number 6 describes diabetic distress type comparison between observational and interventional groups. Table number 7 describes the comparison between the observational and interventional groups for treatments.

Table 6: DDS Type comparison between Observational and Interventional groups

Diabetic distress Type	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Diabetic distress		0.0010	Diabetic distress				0.0092**
	Baseline	End		Base	6 M	12M	18M	
EB	316	737		386	298	201	172	
PRD	243	691		266	259	198	158	
RRD	254	821		273	261	204	163	
ID	341	911		405	401	281	184	

Observational Group Significance - paired t-test; p = 0.0010 (s) Interventional Group Significance - one way ANOVA; p = 0.0092** (ss)

Table 7: Treatment comparison between Observational and Interventional groups

Treatment Mode	Observational Group (OG)		P-Value	Interventional Group (IG)				P-Value
	Baseline	End	0.1621	Base	6 M	12M	18M	0.1986
Pharmacological	788	1154		1290	1201	1013	989	
Non-Pharmacological	681	978		597	754	912	1039	
Life style management	211	230		273	489	692	894	
Pharmacist counselling	21	27		21	1297	1330	1330	

Observational Group Significance - paired t-test; p = 0.1621 (ns) Interventional Group Significance - one way ANOVA; p = 0.1986 (ns)

At the end of the study the answers were analysed for the statistical significance using one way ANOVA analysis, the value was highly significant with p = <0.0001. Table-8 describes the assessment of diabetes mellitus quality of life in the observational group. The quality of life scale was designed using physical and mental components questionnaire short form with 25 questions in physical components and 14 questions in the mental components. Both the components were analysed at the beginning and at the end of the study, both components were analysed using paired t testwith the value***p* = 0.1761**for physical components significance and ***p* = 0.1161**for mental components significance. Both the componentswere analysed to be statistically not significant in the observational group, figure number 17 and 18 illustrates the physical and mental components statistical significance.

Table 8: Assessment of DM QoL (Quality of Life) in the Observational group

Health Scale (Short Form-36)	Item (No. of Questions)	Observational group Average score		
		Baseline	18 months	P - Value
Physical Components	Physical Functioning (10)	5.41	5.01	0.1761
	Role Physical (4)	1.74	1.70	
	Bodily Pain (2)	1.23	1.15	
	General Health (5)	3.01	2.08	
Mental Components	Vitality (4)	1.29	1.15	0.1161
	Social Functioning (2)	0.99	0.94	
	Role Emotional (3)	1.46	1.45	
	Mental Health (5)	3.44	3.21	

Physical Components Significance –paired t-test;*p* = 0.1761 (ns)Mental Components Significance –paired t-test;*p* = 0.1161 (ns)

Table-9: Assessment of DM QoL in the Interventional group

Health Scale	Item (No. of Questions)	Interventional Group Average score				
		Baseline	6 M	12 M	18 M	P-Value
Physical Components	Physical Functioning (10)	2.91	3.14	6.14	7.92	0.0003***
	Role Physical (4)	1.01	1.08	2.04	3.11	
	Bodily Pain (2)	0.10	0.71	1.12	1.69	
	General Health (5)	2.14	3.47	4.23	4.89	
Mental Components	Vitality (4)	1.07	1.71	2.98	3.52	0.0005***
	Social Functioning (2)	0.53	0.84	1.78	1.88	
	Role Emotional (3)	0.33	1.14	2.12	2.69	
	Mental Health (5)	1.14	2.75	4.32	4.89	

Physical Components Significance – one way ANOVA;*p* = 0.0003*** (ss) Mental Components Significance – one way ANOVA;*p* = 0.0005*** (ss)

DISCUSSION

All the patients Diagnosed and suffering with diabetic distress belonging to the interventional group (1330 patients) were given the essential counselling on the diabetes mellitus', disease, medication, lifestyle adaptations, complete knowledge of the disease. Pharmacist intervention was done by advising the cognitive behavioural therapy, mindfulness techniques and the associated counselling procedures which continued for 18 months with intervening for every 6 months and after the period all the patients belonging to the interventional group were compared with the observational group for the benefits associated with the pharmacist intervention. This is the first kind of comparison study made in the world hence no correlation or deviation can be noticed.

Diabetic distress levels were compared between the observational and interventional groups, In both the groups moderate distress level was the highest (421, 497 patients respectively)also in the diabetic distress types interpersonal distress was the highest (241, 291 patients respectively). Laboratory parameters were compared between both the group patients and statistical analysis was applied, paired t-test was applied to the observational group and one way ANOVA was applied to the interventional group to identify the P-values, which were p = <0.0001 (IG) and p = 0.0173 (OG). Based on these values it is very clear that interventional group patients were significantly improved their laboratory parameters than observational group. Graphical representations were also done for the same. Hospital stays were compared with p value <0.0001 for IG group and 0.0290 for OG. It demonstrates that patients from IG were staying less than that of OG, graphical representation was done for the same. Medication adherence was observed to be successfully increased in the OG patients with p value <0.0001 than IG with p value 0.0984.

DDS levels were compared between the groups, and it was noted that IG p value <0.0001, OG p value 0.0254 demonstrates the significant improvement in the IG patients with number of patients suffering from distress were gradually decreased over the course of intervention

period, whereas in the OG the patient count was increased exponentially by the end of the study. This trend was not observed with the DDS type comparison, very slight significance was noted in the IG with p value 0.0092, and no significance in OG with p value 0.0010. in the treatment options, no significant variations were noted with in the groups as both the group patients were necessarily needed to follow the pharmacological medicines as they are in the serious chronic stages of their disease. In the OG p value was 0.1621, and in the IG p value was 0.1986, both the values were statistically non-significant.

Diabetes KAP was done for both the groups with 24 questions questionnaire involving diabetes basic knowledge, disease progression, diagnosing parameters, medications, consequences, lifestyle adaptations and critical care questions and which was observed for statistical significance, in the OG counselling was done in the beginning of the study and at the end KAP was recorded which came to be p value 0.8418. in the IG at the baseline and for every 6 months patients were counselled, checked for their mindfulness therapies progression and at the end KAP was recorded with p value <0.0001, which was highly significant, the patients were highly understood their disease and its complications.

To assess the Quality of Life (QoL), Short form – 36 was used to statistically distinguish QoL in both the groups. This scale is a standard scale for addressing the QoL of any diseased patient it comprises of 2 components, one is Physical components with 21 questions pertaining to physical functioning, role physical, bodily pain, general health, and vitality and second is Mental components with 14 questions pertaining to vitality, social functioning, role health and mental health. All the patients were given the questionnaire and recorded the response for analysing statistically. The p value for OG was 0.1761 (Physical Component) and 0.1161 (Mental Component), both were analysed with paired t – test and found out to be statistically insignificant. The p value for IG was 0.0003 (Physical Component) and 0.0005 (Mental Component), both were analysed with paired t – test and found out to be statistically highly significant, which represents the study was successful in improving the overall QoL of patients and with the proposed objectives were achieved.

CONCLUSION

Our study shows that DRD is a medically relevant issue that clinicians need to address to successfully manage T2D. The associations found in this study mirrored those found in previous studies and further endorsed the need for clinical attention to DRD, especially in societies with a high prevalence of T2D. This study demonstrates a low prevalence of DRD compared to the majority of other studies. We observed significant correlations between DRD total score and/or DRD components scores. DRD has an effect on glycemic control as shown in this study and previous studies. So, it is a considerably important issue that has to be taken in caring the people with diabetes.

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