

Original Research Article

A retrospective, non-interventional, electronic medical record based real world data analysis in patients suffering from pruritus in type 2 diabetes mellitus

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ABSTRACT

Background: There is limited data highlighting the association of pruritus with Type 2 Diabetes Mellitus (T2DM). This was the first Electronic Medical Record (EMR) based real-world observational study on the demographics, clinical characteristics, associated risk factors and treatment(s) of pruritus in T2DM in India.

Methods: EMR data of patients was retrospectively analysed with a baseline (V1) visit and two or more follow-up visits between June 2014-December 2019.

Results: Majority of patients were 40-64 years old and mainly females (57%). Body mass index and co-morbidity data indicated a trend of obesity and hypertension. Observed HbA1c values were high (mean value of 9%). Majority of the patients were on hydroxyzine. Miconazole, fluconazole and corticosteroids were prescribed in 40% patients. Correlation between HbA1c levels with clinical pruritus was noted.

Conclusions: Management of glycaemia along with timely dermatological intervention is needed for pruritus relief in T2DM, the use of antihistamines; in particular, hydroxyzine, should be further evaluated.

Keywords: Antihistamines, Blood glucose levels, HbA1c, Hypertension, Pruritus, Type 2 diabetes mellitus

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a chronic condition that prevents the use of insulin in a normal physiological way. T2DM generally occurs in middle-aged or older population, so it is often called adult onset diabetes.¹ Worldwide 463 million adults are living with diabetes and by 2045 this will rise to 700 million.² The proportion

of people with T2DM is increasing in most countries and 79% of adults with diabetes live in low- and middle-income countries. In India, over 77 million people have been diagnosed with diabetes.

About 30% of patients with diabetes mellitus experience skin problems at some stage of their disease and most of these skin disorders may be associated with diabetic

neuropathy³. Association of pruritus with diabetes is well documented and based on the aetiology, pruritus is classified into different categories (Figure 1).³ Pruritus associated with T2DM is often localized to the scalp, ankles, feet, trunk, or genitalia; however, it may also be generalized and have a profound impact on the quality of life, affecting unfavourably sleep and attention. Pruritus can be chronic or acute depending on the pathophysiology and severity.⁴

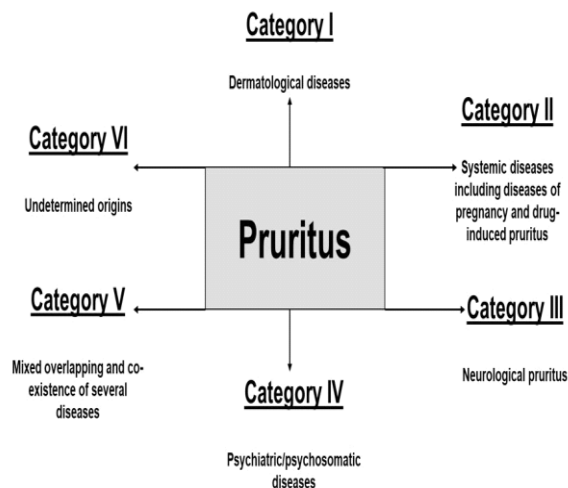


Figure 1: Categories of pruritus.

Optimal management of the underlying systemic disease remains the mainstay of treatment, however; a high rate of therapeutic failure has been observed in a real world setting due to an individualistic approach adopted for the management of pruritus. The British association of dermatologists and the European S2k guideline have laid out a set of evidence-based guidelines on managing generalized pruritus.^{5,6} Treatment options include the use of emollients, topical anti-pruritic agents, and systemic antipruritic agents such as H1-antihistamines, doxepin, and gabapentin.⁷

An insight into the possible treatment regimes, their association with underlying conditions and their outcomes may elicit understanding of the mechanisms that underlie this distressing symptom and identifying right treatments.

METHODS

Data sources

Data was collected from an Indian electronic software owned and administered by HealthPlix Technologies PRV. This software has been in operation since 2016 and fulfils day-to-day operational needs of 12 medical specialties across 150+ cities in 20 states. Clinical information including demographics, diagnoses, underlying risk factors, tests, and test results for patients

receiving ambulatory care at physicians' offices across India was used to conduct analyses.

Ethical compliance with human study

The study was conducted as per the applicable national regulatory laws and guidelines. Patient confidentiality was maintained at all times as the study was performed using anonymized information only.

Ethics approval (Institutional Review Board Approval)

The study protocol was approved in October 2020 by the Suraksha- Ethics Committee, Asian Institute of Medical Sciences, Plot P-72, Milap Nagar, MIDC, Dombivli, 421203.

Study design and sample selection

This retrospective observational study assessed EMR data of Indian patients diagnosed with T2DM and having pruritus between June 2014 and December 2019. Anti-pruritic drugs prescribed to patients were identified by mapping brand name on the prescriptions with the generic name. Patients ≥ 18 years were followed for 2 or more visits. Patients with Type 1 Diabetes Mellitus (T1DM) and/or patients with known chronic skin diseases like psoriasis, etc. which occurs independent of T2DM, were excluded from the study. A total of 3,365,684 patient EMRs were screened, among whom 9,35,022 patients (aged ≥ 18 -years-old) had a diagnosis of T2DM (27.8%) and of these patients with T2DM, 31,287 patients were on antihistamines. Of these, 10,733 patients had complaints including itching, rash, burning and allergic/dry skin etc. Of these, only 466 patients met the inclusion criteria (Table 1). All the patient data was collected through data collection forms. Kindly refer to Figure 2 for detailed study design.

Study endpoints

The primary endpoint was to determine the percentage of patients with complaints of pruritus in T2DM at baseline (V1).

The secondary endpoints were to determine percentage of patients treated with antihistamines, antifungals, moisturizers at baseline (V1) and at end of follow up period. The percentage of patients who switched from using one generation to another generation of antihistamine (s) at the end of study period was assessed. The percentage of patients taking adjuvant therapy other than anti-histamines at baseline (V1) was also determined.

Exploratory endpoints included, demographical assessment of diabetic patients developing complaints of pruritus at baseline (V1), correlation of pruritus with other co-morbid conditions, evaluation of mean change(s) in HbA1c levels from baseline (V1) to end of study,

assessing the mean change in blood pressure from baseline (V1) to end of study and determining the correlation between HbA1c levels and pruritus symptoms.

Assessments

Refer to Figure 2 for baseline (V1) and follow-up clinical assessments.

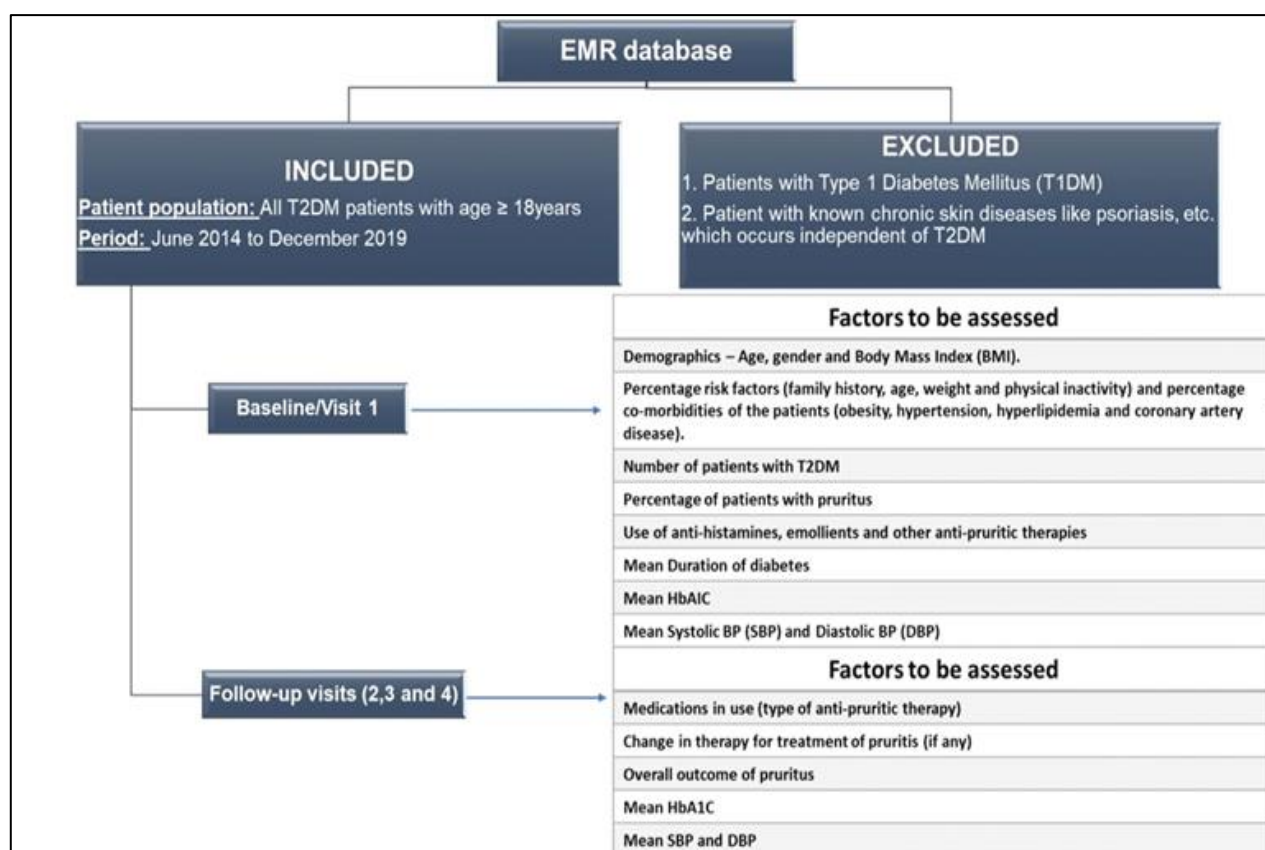


Figure 2: Overall study design with inclusion, exclusion criteria and various parameters at baseline (V1) and follow-up visit to be assessed.

Statistical analysis

Pertinent retrospective data, relevant to the defined study objectives were sourced from the EMR database and collated according to the study parameters using a pre-defined template data collection form. The collated and organized data was investigated to ensure use of an accurate, reliable, consistent and reproducible data set for subsequent statistical analyses.

All variables were summarized using descriptive statistics. Percentages were reported for categorical variables while means and standard deviations were reported for nominal variables. $P < 0.05$ was considered statistically significant.

RESULTS

Primary endpoints

Data analysis at baseline (V1) suggested that majority of patients with T2DM and pruritus were in the age-group of 40-64 years ($n=291$, 62%) and predominantly females

($N=266$, 57%). There was a trend of obesity/overweight, 43% of patients were overweight (BMI 25-29.9) and 30% were obese (BMI ≥ 30). Data collected for comorbidities showed that 63% patients had underlying hypertension ($N=210$), followed by 21% patients with hyperlipidaemia ($N=69$), 6% patients had coronary artery disease, renal disease ($N=19$, each) and 5% patients had hepatic disease ($N=17$).

Secondary endpoints

To determine the percentage of patients treated with both 1st and 2nd generation antihistamines, data was analyzed as shown in Figure 3A. Among all the antihistamines, vast majority of patients consistently across all visits were prescribed hydroxyzine (1st generation antihistamines), followed by cetirizine, levocetirizine and fexofenadine (2nd generation antihistamines). Data on the use of antifungal (topical and oral) and topical moisturizers was analyzed as presented in Figure 3B. Among the antifungals; miconazole (among topical antifungals) and fluconazole (oral) were more commonly used.

Table 1: Patients enrolled based on inclusion criteria.

Study period EMR records from 2014- 2019				
	Category	Patient count (N)	Patient count (%)	Mean duration between visits (days)
Total Patients	n/a	3,365,684	100	n/a
Total Patients (≥18 years old)	n/a	3,074,143	91	n/a
Total Patients (≥18 years old) diagnosed with T2DM	n/a	935,022	27.8	n/a
Patients on Anti-histamines	n/a	31,287	0.9	n/a
Patients on Anti-histamines with complaints captured in EMR*	n/a	10,733	0.3	n/a
Total T2DM patients with pruritus enrolled in study (patients meeting inclusion criterion minus patients excluded)	Visit 1 (Baseline: V1)	466	0.05	n/a
	Visit 2 (follow-up period ≤1 year from visit 1)	466	0.05	74.5
	Visit 3 (follow-up period ≤1 year from visit 1)	331	0.04	137.5**
	Visit 4 (follow-up period ≤1 year from visit 1)	224	0.02	176.1**

Note: * Some of the complaints mentioned were itching, rash, burning, urticaria, pruritus and allergic skin. ** average duration from visits. EMR= electronic medical records; T2DM= Type 2 Diabetes Mellitus; SD= standard deviation.

Additionally, among emollients/topical moisturizers, the majority of the patients were prescribed liquid paraffin (protective emollient), followed by propylene glycol (fatty emollient). Among steroids, the majority of the patients were prescribed corticosteroids, followed by ketamine-amitriptyline-lidocaine combination and menthol across all visits (Figure 4A).

To determine the percentage of patients who switched from one generation to another generation anti-histamine(s) at the end of the study period, the highlighted data in Fig 4B suggested that 16% of patients switched between one antihistamine generation to another at the last visit, 11% patients at visit 2 and 3% at visit 3 in comparison to baseline (V1) visit. Among the 1st generation antihistamines, the most commonly prescribed agent was hydroxyzine, and 13% of these patients switched to cetirizine, levocetirizine, and fexofenadine (2nd generation antihistamines) from baseline (V1) to the end of study. Among the 2nd generation antihistamines, the most commonly prescribed agents were cetirizine, levocetirizine and fexofenadine, and 11.6% of these patients switched to hydroxyzine and cyproheptadine (1st generation antihistamines) from baseline (V1) to the end of study.

Further, of all the patients on hydroxyzine at baseline (V1) (N=207), 148 patients (71%) at visit 2 switched from hydroxyzine to other agents, followed by 186 patients (90%) at visit 3 and 199 patients (96%) at the last follow-up visit. This switch could either be a shift to another agent (such as antifungals, corticosteroids, emollients etc.) and/or could be discontinuation of the drug. This also included patients who were switching from hydroxyzine to any other antihistamines such as loratadine (N=1), cetirizine (N=8), fexofenadine (N=8) or ebastine (N=2) (Table 2). Lastly, it was observed that 3 patients at visit 1 (30%) were taking adjuvant therapy in the form of probiotics and bacterial products other than antihistamines, followed by 11 patients each at visit 2/visit 3 and 4 patients at visit 4 (Table 2).

Exploratory endpoints

To determine the mean changes in HbA1c levels and changes in blood pressure (in mm of Hg) from baseline (V1) (V1) to the end of study, the collected data suggested no significant changes in HBA1c levels from baseline (V1) to last follow-up visit (Figure 5A).

Table 2: Various treatment patterns at baseline (V1) and follow-up visits.

Therapy			Molecule		Visit 1 (Baseline)		Visit 2		Visit 3		Visit 4	
					Patient Count							
			N	%	N	%	N	%	N	%		
	Total no of Patients		466		466		331		224			
Anti-histamines	1st generation antihistamines	Hydroxyzine	207	41	74	44	25	39	10	32		
		Cyproheptadine	6	1	3	2	0	0	0	0		
	2nd generation antihistamines	Cetirizine	103	20	16	10	13	20	5	16		
		Levocetirizine	66	13	33	20	12	19	6	19		
		Fexofenadine	73	14	17	10	7	11	4	13		
		Loratadine	29	6	12	7	4	6	3	10		
		Desloratadine	12	2	6	4	1	2	2	6		
		Bepotastine	7	1	3	2	1	2	0	0		
		Ebastine	7	1	4	2	1	2	1	3		
		Total	510*	100	168	100	64	100	31	100		
Anti-fungals	Topical antifungals	Miconazole	28	39	14	37	4	24	3	23		
		Clotrimazole	6	8	8	21	2	12	2	15		
		Ketoconazole	4	6	3	8	2	12	1	8		
		Terbinafine	0	0	2	5	2	12	0	0		
	Oral antifungals	Fluconazole	26	37	8	21	6	35	6	46		
		Terbinafine	4	6	1	3	0	0	1	8		
		Itraconazole	3	4	2	5	0	0	0	0		
		Ketoconazole	0	0	0	0	1	6	0	0		
		Total	71	100	38	100	17	100	13	100		
Emollients	Fatty emollients	Propylene glycol	4	10	7	28	4	24	0	0		
	Protective emollients	Liquid paraffin	35	90	18	72	13	76	10	100		
		Total	39	100	25	100	17	100	10	100		
Others	Non histamine based anti-itch therapies	Corticosteroids	36	88	41	80	23	74	13	68		
		Ketamine-amitriptyline-lidocaine	0	0	10	20	8	26	6	32		
		Menthol	5	12	0	0	0	0	0	0		
		Total	41	100	51	100	31	100	19	100		
	Adjuvant therapies other than antihistamines	Probiotics and bacterial products	3	100	11	100	11	100	4	100		
		Total	3	100	11	100	11	100	4	100		

Note: *-One patient could be on multiple antihistamines and/or other co-medications.

Table 3: Patient demographics and vitals at baseline (V1) visit.

			Visit 1 (Baseline)			
Parameter		Category	Patient count (N)	Patient count (%)	Mean value	SD
Demographics	Age (Years)	18-39 years	41	9	33.14	4.86
		40-64 years	291	62	53.17	6.57
		> 64 years	134	29	72.45	5.94
	Gender	Male	200	43	n/a	n/a
		Female	266	57	n/a	n/a
	BMI (Kg/m²)	BMI <25	37	27	22.9	2.08
		BMI 25-29.9	60	43	27.2	1.28
		BMI >30	42	30	33.6	4.74

Continued.

		Visit 1 (Baseline)			
Parameter	Category	Patient count (N)	Patient count (%)	Mean value	SD
Co-morbidity	Hypertension	n/a	210	63	n/a
	Hyperlipidemia	n/a	69	21	n/a
	Coronary artery disease	n/a	19	6	n/a
	Renal disease	n/a	19	6	n/a
	Liver disease	n/a	17	5	n/a
T2DM patients	Mean HbA1C	n/a	97*	8.55	1.91
	HbA1C>6.5%	n/a	82	9	1.8

Note: BMI= basal metabolic index; HbA1c= glycated haemoglobin; SD = standard deviation; T2DM = Type 2 Diabetes Mellitus.

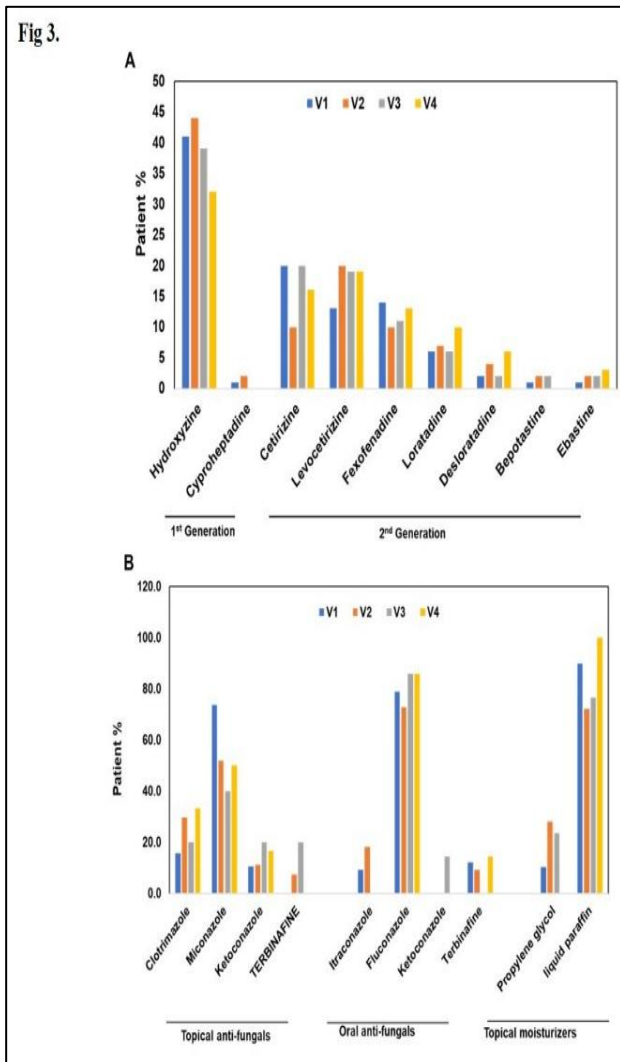


Figure 3: (A) Anti-histaminic usage. (B) Displays antifungal usage at all study visits.

A significant decrease in systolic blood pressure (SBP) and diastolic blood pressure (DBP) values were observed in patients with pruritus between baseline (V1)/visit 4 (for SBP) and baseline (V1)/visit 3 (for DBP) (Figure 5B). To understand the different causes/aetiology of pruritus in patients with T2DM, data collected from patients with HbA1c values reported at baseline (V1)

visit suggested that majority of patients (85%, 82 of 97) had HbA1c values >6.5% with a mean value of 9%, indicating deranged glucose levels in these patients (Table 3).

Finally, a significant correlation between HbA1c levels and overall pruritus symptoms (in T2DM patients on anti-pruritic therapy with recordable HbA1c levels) was observed, suggesting that the overall levels of HbA1c in patients with T2DM are associated with pruritus (Figure 6).

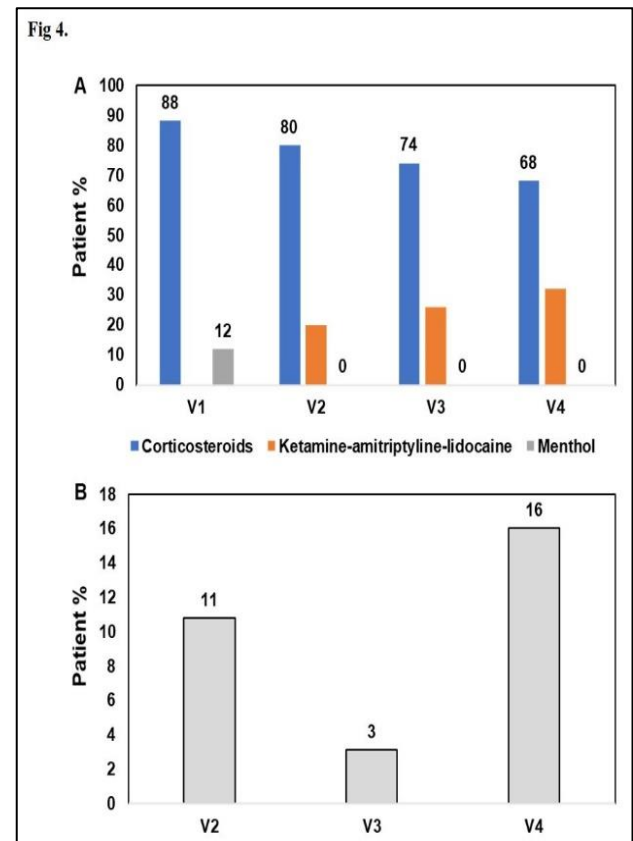


Figure 4: (A) Use of corticosteroids, ketamine-amitriptyline-lidocaine and menthol across all visits. (B) the percentage of patients switching between one antihistamine generation to another in comparison to first visit.

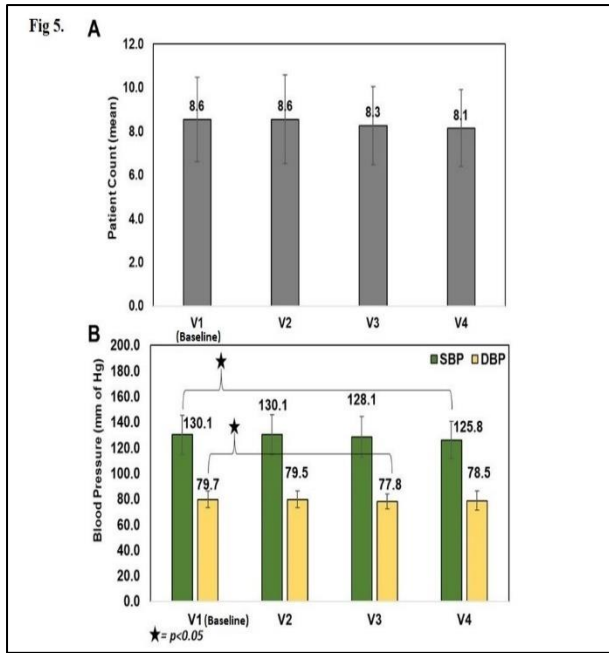


Figure 5: (A) Mean changes in HbA1c levels. (B) Changes in blood pressure (in mm of Hg) from baseline (V1) to the end of study.

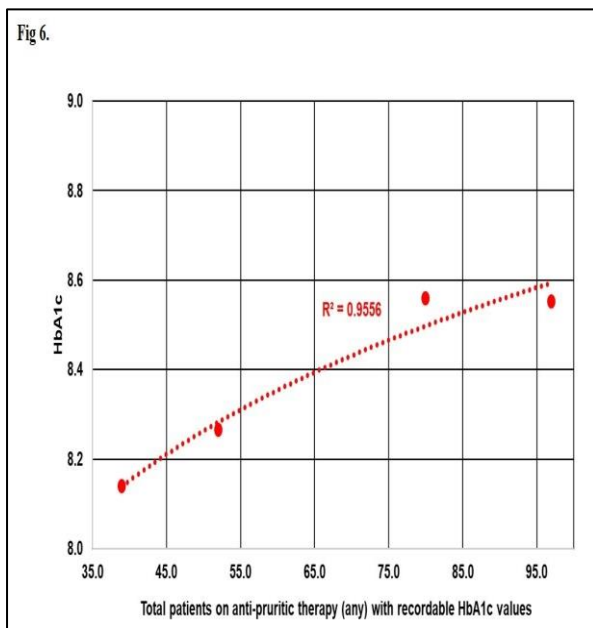


Figure 6. Correlation between overall levels of HbA1C levels in type 2 diabetic patients with pruritus.

DISCUSSION

Pruritus is a common dermatological manifestation of T2DM.⁸ It is often associated with psychological distress arising from intense scratching and sleep disturbances in patients. Pruritus was shown to be second most common cutaneous manifestation affecting 49% of diabetic patients.⁸ Higher postprandial glucose levels increase the probability of generalized pruritus.^{8,10} However, evidence

also suggests that skin disorders, including pruritus, are usually neglected and frequently underdiagnosed among people with diabetes.^{10,11} As in this study, despite a high number of patients (n=10,733) using anti-histamines and exhibiting complaints that could be attributed as pruritus, the low number of patients with pruritus as specific diagnosis with T2DM (n=466) suggested that majority of patients were either underdiagnosed or did not get a proper diagnosis. The majority of patients in the study were in the age-group of 40-64 years, an observation also noted in other research studies.^{9,12} Similar to a previous study, the proportion of female patients was more than male in our study.¹²

Further, the trend towards obesity/overweight and underlying hypertension among these patients correlates with T2DM trends. Similar findings were observed in a study of 106 diabetic patients with skin diseases, where hypertension was identified as the most common systemic manifestation.⁹

Consistent with other reports, our findings showed that HbA1c values were higher in patients. The prevalence of dermatological diseases has been reported to be higher in patients with higher HbA1c levels.¹³ But another study suggested that generalized pruritus in T2DM patients was associated with higher PC blood glucose, rather than HbA1c levels. Improving glycaemic control is generally supposed to reduce symptoms experienced by patients with T2DM, but the relationship between glycated haemoglobin (HbA1c), diabetes-related symptoms, and self-rated health are unclarified.¹⁰

In line with the British association of dermatologists and the European S2k guidelines, most of the patients were on antihistamine therapy at baseline (V1) visit, majority were prescribed hydroxyzine during the study period.⁶ Being a selective histamine H1 receptor inverse agonist, hydroxyzine easily crosses the blood-brain barrier and exerts its effects systemically.¹⁴ Hydroxyzine can be administered orally, is rapidly absorbed/ distributed, and due to its sedative effect would also provide relief from pruritus associated sleeplessness.¹⁵ It was observed from the study data that 1st generation antihistamines were more popularly used than 2nd generation antihistamines.

In a study conducted by Mahajan et al 54.69% were affected by cutaneous bacterial and fungal infections, suggesting that fungal infections are common in patients with T2DM.¹² As deranged glucose levels in diabetes are commonly associated with a higher incidence of fungal infections, a general therapeutic approach to treatment is not clearly defined. Further, T2DM exerts an immunosuppressive effect on the patient predisposing them to fungal infections, including Candidiasis. The data from previous reports suggests that topical antifungals are the medication of choice in such patients. Oral management with fluconazole is the second line treatment, if topical treatment is ineffective.¹⁶ Our study shows that most of the patients were given antifungals

along with corticosteroids. Corticosteroid use only provides symptomatic relief without treating the underlying cause of pruritus. Some studies suggest that corticosteroids worsen hyperglycaemia by alterations in glucose metabolism and lead to further functional deterioration.¹⁷ Additionally, topical steroids are linked to increased insulin resistance (by increasing blood glucose levels).¹⁸ Therefore, the use of steroids requires careful consideration, as the management of blood glucose levels is an absolute necessity in diabetic patients.^{19,20}

Evidence is suggestive that the topical use of emollients/topical moisturizers may help in derma-cosmetic management and skin hydration. As the dermis undergoes biophysical alterations in diabetes, and pruritus is more likely in diabetic patients with dry skin.²¹ It has been stated that emollients can be useful in diabetes management by reducing skin complications that are associated with elevated blood sugar.²¹

Despite non-significant changes in HbA1c levels, a significant correlation between the overall HbA1c levels with clinical pruritus was observed in our study. Although, this data suggests that regulation of glucose levels could be a key indicator in the effective management of pruritus, there is evidence to suggest that pruritus in diabetic patients might be a symptom of diabetic polyneuropathy and therefore, further studies should be undertaken to study the complex pathophysiological patterns of pruritus in T2DM patients.¹⁰

CONCLUSION

Effective management of blood glucose levels and timely dermatological intervention could improve pruritus management, reducing morbidity and complications related to it. Overall, our study provides the first insight into the demographics and various treatment patterns of pruritus in T2DM patients across India. The study had a small sample and shorter follow up duration. Also, the study does not include clinical/ laboratory skin manifestations to understand the skin changes in diabetes. These can offer insights as to appropriate management and recognition of T2DM associated conditions. Further, studies on use of antihistamines, in particular hydroxyzine would be useful to recommend treatment guidelines for pruritus in T2DM.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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