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Original Article

Ear, Nose and Throat Section

Comparison of Intranasal Saccharin Test and Intranasal Schirmer's Test in Identifying Altered Nasal Mucociliary Clearance Time in Type 2 Diabetic Patients: A Cross-sectional Study

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ABSTRACT

Introduction: Mucociliary Clearance (MCC) is an essential respiratory defence mechanism that is often impaired in patients with Type 2 Diabetes Mellitus (T2DM) due to hyperglycaemia-induced neuropathy and reduced nasal secretions. Identifying reliable methods to evaluate nasal function in patients with Diabetes Mellitus (DM) is crucial for the early detection of dysfunction.

Aim: To compare the intranasal saccharin and Schirmer's tests for assessing nasal MCC in patients with T2DM.

Materials and Methods: This cross-sectional study was conducted in the Department of Ear, Nose, and Throat (ENT) at a tertiary care centre SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, over a period of three months, from March 2025 to May 2025, involving 120 patients with T2DM aged 18-75 years. Patients underwent intranasal saccharin and Schirmer tests under standardised conditions. Data were analysed using descriptive statistics, Chi-square test, and Receiver Operating Characteristic (ROC) curve analysis by IBM Statistical Package for Social Sciences (SPSS) software version 25.0. A p-value <0.05 was considered significant.

Results: The mean age of the participants was 57.70±12.08 years, and 66 (55%) were female. Prolonged Saccharin Transit Time (STT) (≥30 min) was noted in 91(75.8%) of patients, while reduced Schirmer's test values (≤6 mm) were observed in 81 (67.5%) and normal values (>6 mm) in 39 (32.5%) patients. All patients with Schirmer's values ≤6 mm [81 (100%)] had prolonged STT, whereas 29 (74.4%) of those with values >6 mm [39 (32.5%)] showed normal MCC. Schirmer's test showed a sensitivity of 89.01%, specificity of 100%, Positive Predictive Value (PPV) of 100%, Negative Predictive Value (NPV) of 74.36%, and an overall accuracy of 91.67%. The ROC curve yielded an AUC of 0.997.

Conclusion: Schirmer's test demonstrated high sensitivity and specificity as a simple, non invasive screening tool for detecting nasal dysfunction in patients with DM. It may serve as a practical adjunct to the saccharin test in clinical practice, enabling the early recognition of MCC impairment in patients with T2DM.

Keywords: Diabetes mellitus, Diagnostic techniques, Nasal mucosa physiology, Respiratory system

INTRODUCTION

Mucociliary Clearance (MCC) is the main natural defence mechanism of the sinonasal airway, where coordinated ciliary beating and a hydrated mucus layer remove inhaled particles, microbes, and debris from the nasal cavity and sinuses [1]. Any kind of disturbance to this system can result in the development of chronic respiratory diseases, such as Chronic Rhinosinusitis (CRS) [2]. Impaired MCC allows bacteria to remain and reproduce, which can result in recurrent sinonasal infections, impaired quality of life, and long-term complications [3].

According to published literature, Type 2 Diabetes Mellitus (T2DM) is associated with multisystem microvascular and neuropathic changes that can damage the epithelial, neural, and glandular functions of the airway [4]. These conditions can affect the functioning of nerves, blood flow to tissues, and the immune system's ability to maintain normal physiological processes. The changes in the physiological functioning of the body can also result in reduced mucus movement in the nose and impaired MCC [5]. A previous study has reported that Diabetes Mellitus (DM) is associated with altered mucociliary function and gram-negative bacterial sinus infections. Patients with DM and CRS have higher recurrence rates and worse short-term postoperative quality of life [6]. This suggests that early diagnosis and management of MCC in DM patients can significantly improve their outcome and quality of life.

The intranasal saccharine test is one of the most commonly used, simple and inexpensive diagnostic tools for assessing MCC function [7]. It calculates the interval between placing a saccharine particle on the inferior turbinate and the patient's perception of sweetness in their oropharynx. This method indirectly measures the MCC efficiency, where a shorter interval indicates more efficient clearance of mucus from the nasal cavity to the pharynx [8]. Several studies have used saccharin-based measurements under standardised environmental conditions to define normal Mucociliary Clearance Time (MCT) and have reported prolonged MCT in groups with sinonasal disease. They also concluded that the saccharin test is a simple and practical tool for assessing MCC variations [5,9].

While the saccharin test has been widely used to assess MCC, Lindemann J et al., in 2014, first found an alternate method called the intranasal Schirmer's test to provide a more objective evaluation of nasal function. An adequate nasal surface moisture is important for active mucociliary transport, and the intranasal Schirmer's test, which was adapted from the ocular Schirmer test, was a simple and reproducible tool that measured the intranasal moisture and secretion [10]. In this method, a filter paper strip was placed on the nasal septum, and the distance to which the strip was wetted by the mucus was calculated, which served as an indicator of mucosal humidification and hydration. Few studies have analysed the feasibility of this test and concluded that it is a practical method

for measuring mucosal humidification, with a normal wetting distance of 6-18 mm [10,11]. Though few studies have used these tests individually, only one study utilised both for analysing the nasal function [12].

Recently, T2DM has progressed at a very high rate and is expected to reach 853 million or one in eight adults by 2025 [13]. Despite the higher prevalence of T2DM and its possible association with nasal function, no study has directly compared the efficacy of intranasal saccharin and intranasal Schirmer measurements in analysing nasal function within the same diabetic population. Identifying the practicality of both tests and assessing the sensitivity of the Schirmer's test may help improve screening for nasal dysfunction in patients with DM, followed by early intervention to prevent chronic sinusitis and related complications.

Hence, the present study aimed to evaluate the diagnostic validity of the intranasal Schirmer's test in detecting altered nasal mucociliary clearance among patients with T2DM, using the intranasal saccharin test as the reference standard.

MATERIALS AND METHODS

This cross-sectional study was conducted at the Department of ENT in a tertiary care, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, over three months from March 2025 to May 2025, among 120 participants diagnosed with T2DM. The study was initiated after obtaining ethical clearance from the Institutional Ethics Committee (Ethics clearance number-SRMIEC-ST0325-2704). Written informed consent was obtained from all the patients.

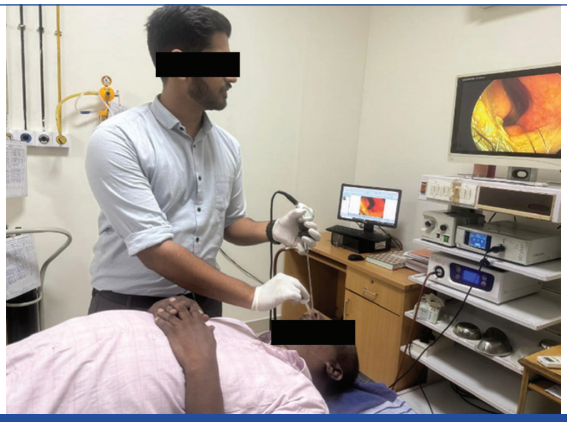
Inclusion criteria: Patients aged 18-75 years with T2DM, confirmed by fasting blood glucose (≥126 mg/dL) or glycated Haemoglobin (HbA1c) (≥6.5%), with or without symptoms of dry nose, such as nasal discomfort, dryness, congestion, crusting, or frequent need to moisturise the nasal passages, were included.

Exclusion criteria: Patients with type 1 DM or secondary diabetes, a history of chronic sinusitis, nasal polyps, severe allergic rhinitis, or structural nasal abnormalities, prior nasal or sinus surgery within 6 months, use of medications affecting nasal secretion (antihistamines, decongestants, corticosteroids) within 4 weeks, pregnancy or lactation, presence of upper respiratory infections, and systemic conditions affecting mucosal hydration (for example, Sjogren's syndrome, rheumatoid arthritis, and cystic fibrosis), smokers, and those unable to complete the tests due to physical or cognitive limitations were excluded from the study.

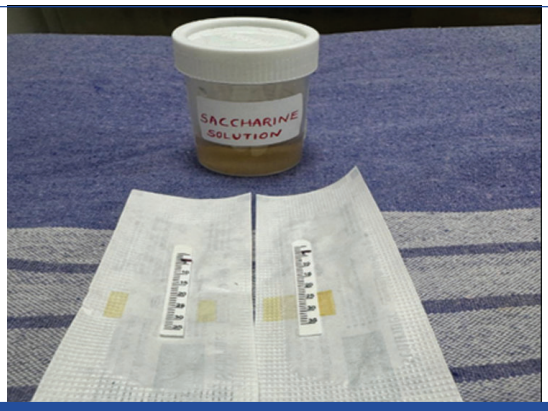
Study Procedure

Participants underwent a comprehensive clinical evaluation, including demographic details (age and gender), clinical characteristics (duration of diabetes and presence of systemic hypertension or other co-morbidities), and biochemical parameters (fasting blood glucose, postprandial blood glucose, and HbA1c), which were recorded. The intranasal saccharin test was conducted by placing a small quantity of saccharin solution on the inferior turbinate, approximately 1-1.5 cm behind the anterior apex of the nose, under direct visualisation with diagnostic nasal endoscopy. The patients were instructed to swallow every 30 seconds until they perceived a sweet taste while avoiding sniffing, forceful inhalation or exhalation, or manipulation of the nasal cavity. Normal MCC is 7-15 minutes, may extend up to 20 minutes, is delayed if >20 minutes, and indicates stasis if >30 minutes. Based on that, MCC time was assessed using the intranasal saccharin test. MCC time exceeding 30 minutes was considered mucociliary stasis [Table/Fig-1] [5].

The intranasal Schirmer's test was performed using a calibrated Schirmer's test strip (5-35 mm in 1 mm intervals), folded at 5 mm to create a 45° angle, and placed bilaterally on the mucosa of the anterior nasal septum. The strips were left in-situ for 10 min and then removed using sterile forceps. The wetted area was measured in millimetres; values between 6 and 18 mm were considered normal, whereas values ≤6 mm indicated reduced nasal secretion [Table/Fig-2] [14]. All tests were performed in a temperature-controlled clinic (22-25°C) under consistent humidity levels (40-50%). The patients were seated and allowed to rest for 10 minutes before testing. Patients were advised to avoid drinking fluids for at least 1 hour before the test. None of the patients was febrile or dehydrated during the general examination. Schirmer's test was conducted before the saccharin test, with a 30-minute interval between procedures to avoid mucosal interference.



[Table/Fig-1]: Intranasal saccharine test being performed under visualisation with diagnostic nasal endoscopy and endoscopic view showing placement of saccharine solution about 1.5 cm behind the anterior apex of the nose.



[Table/Fig-2]: Saccharine solution used for the intranasal saccharine test and Schirmer's papers showing markings made after completion of the intranasal Schirmer's test.

STATISTICAL ANALYSIS

Data analysis was performed using IBM SPSS version 25.0. Data were tabulated as mean, standard deviation, frequency, and percentage, and cross-tabs were created to determine sensitivity and specificity.

RESULTS

The mean patient age was 57.70±12.08 years old. In terms of gender distribution, females were predominant, 66 (55%), while males comprised 54 (45%) of the patients. The duration of diabetes was 0-5 years in 48 (40%), 6-10 years in 44 (36.7%), and > 10 years in 28 (23.3%) patients. Based on HbA1c levels, 81 (67.5%) had values between 6.5 and 6.9, while 39 (32.5%) had values ≥7. Systemic hypertension was present in 63 (52.5%) patients, and 57 (47.5%) had no other co-morbidities [Table/Fig-3].

Regarding the saccharine test, the time was increased (≥30 min) in 91 (75.8%) patients, while 29 (24.2%) had normal (<30 min) results. Regarding Schirmer's test values, 39 (32.5%) patients had >6 mm, whereas 81 (67.5%) had 0-6 mm [Table/Fig-4].

Among participants with Schirmer's test values between 0-6 mm, all 81 (100%) had increased STT (>30 min). Of those with Schirmer's test values >6 mm, 10 (25.6%) showed prolonged clearance times, while the majority, 29 (74.4%), had normal saccharin test results

(<30 min). None of the participants with Schirmer's values of 0-6 mm had normal STT. The association between Schirmer's and saccharin test results was statistically significant (p-value <0.001, Fisher's-exact test) [Table/Fig-5].

Characteristics	Categories	n (%)
Duration of diabetes (years)	0-5	48 (40%)
	>5 to 10	44 (36.7%)
	>10	28 (23.3%)
HbA1c (%)	6.5-6.9	81 (67.5%)
	≥7	39 (32.5%)
Co-morbidities	Systemic hypertension	63 (52.5%)
	Nil	57 (47.5%)

[Table/Fig-3]: Clinical characteristics of patients

Characteristics	Categories	n (%)
Saccharine test time	Increased (≥30 min)	91 (75.8%)
	Normal (<30 min)	29 (24.2%)
Schirmer's test value (mm)	>6	39 (32.5%)
	0-6	81 (67.5%)

[Table/Fig-4]: Saccharine test time and Schirmer's test values in patients

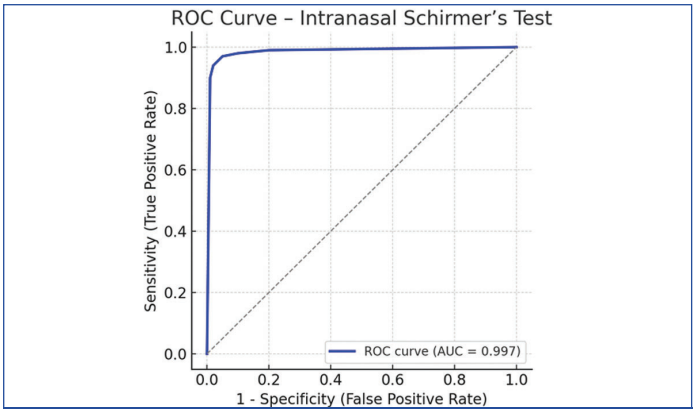
Schirmer's test		Saccharine test time n (%)	
		Increased (>30 min)	Normal (< 30 min)
Schirmer's test value (mm)	0-6	81 (100%)	0
	>6	10 (25.6%)	29 (74.4%)

[Table/Fig-5]: Association between Schirmer's test and saccharine test in patients.
Footnotes: mm: millimetres; min: minutes.

The sensitivity and specificity of Schirmer's test were 89.01% and 100%, respectively. The PPV and NPV were 100% and 74.36%, respectively. The overall accuracy of the test was 91.67% [Table/Fig-6,7].

Diagnostic performance	Schirmer's Test
Sensitivity	89.01%
Specificity	100.00%
PPV	100.00%
NPV	74.36%
Accuracy	91.67%

[Table/Fig-6]: Diagnostic Performance of Schirmer's Test.
PPV: Positive predictive value; NPV: Negative predictive value.



[Table/Fig-7]: Receiver Operating Characteristics curve.
Footnotes: PPV: AUC=0.997 | Cutoff ≤6 mm | Sensitivity=89% | Specificity=100%; Interpretation: The curve closely approaches the upper left corner, indicating excellent diagnostic performance of the test.

Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic accuracy of the intranasal Schirmer's test compared with the saccharin test [Table/Fig-6]. The area under the ROC curve (AUC) was 0.997, indicating an excellent discriminatory ability. Using the Youden Index method, the optimal cut-off for the Schirmer's test was identified as ≤6 mm, which provided a sensitivity of 89% and a specificity of 100%. The maximum Youden Index achieved was 0.97, confirming the robustness of this threshold.

DISCUSSION

In the present study, diabetic individuals exhibited a prolonged STT (≥30 min) in 75.8% of cases, suggesting impaired MCC. Additionally, 67.5% of the patients showed reduced nasal secretion (Schirmer's test values of 0-6 mm), indicating altered nasal physiology. Schirmer's test showed high sensitivity (89.01%) and specificity (100%) for detecting mucociliary dysfunction, reinforcing its utility as a quick screening tool for nasal dryness in patients with diabetes. The primary outcome of the current study highlighted that MCC is significantly impaired in T2DM patients. Gurung N et al., reported that nasal MCC time was significantly prolonged in T2DM patients (16.51±2.44 min) compared to healthy controls (9.96±2.24 min) using the saccharine test [15]. Similarly, Oliveira-Maul JP et al., reported that there was a delay in MCC time among elderly patients with DM and/or hypertension. The percentage of patients with prolonged STT (>12 min) increased with age: from 23 % in those <40 years to 33 % in the 40-59 years age group and 50% among those ≥60 years (p-value <0.001). Similarly, delayed STT was found commonly among DM patients (44 vs. 31 %, p-value=0.04) and 48 % of hypertensive patients (48 vs. 25 %, p-value <0.001) [16].

These findings align with those of Unsal MA and Bulgurcu S, who evaluated nasal MCC dysfunction using the saccharin test and found that the MCC time significantly prolonged with the severity of diabetic polyneuropathy (p-value=0.007, r-value=0.42). Thus, supporting the idea that autonomic dysfunction in diabetes affects MCC impairment [17].

The present study found that most patients with DM had Schirmer's test values between 0 and 6 mm, indicating nasal dryness. Hazmi A et al., also observed that diabetic patients, especially those with poor glycaemic control, had significantly reduced Schirmer's test values compared to well-controlled diabetes (p-value <0.05) [18]. Lindemann J et al., established that values <6 mm indicate reduced nasal secretion [10].

The findings of the current study support the evidence that T2DM impairs nasal physiology and increases susceptibility to CRS and recurrent respiratory infections. Sachdeva A et al., showed that nasal pH and mucus composition are altered in diabetics, affecting MCC function [4]. Yue WL found that poor glycaemic control worsens mucosal dysfunction, reduces nasal secretion, and prolongs MCC times in patients with diabetes [5]. Clinically, the intranasal Schirmer's test is a valuable, rapid screening tool for detecting nasal dryness in patients with diabetes, with high sensitivity (89.01%) and specificity (100%). As nasal dryness can lead to epistaxis, crusting, and infection, early identification and management may improve sinonasal health in patients with diabetes [19].

One key controversy in MCC assessment is whether the saccharin test alone is sufficient to assess nasal dysfunction in diabetics. While the present findings support its utility, the addition of the Schirmer's test provides a more comprehensive evaluation, as a dry nasal mucosa can contribute to impaired MCC. Pandya VK and Tiwari RS suggested that STT should be interpreted in conjunction with other mucosal function tests for a holistic understanding [20]. Additionally, there is debate on whether reduced nasal secretion is a direct result of diabetes or an independent process. While some studies support the role of Schirmer's test in nasal dryness assessment, others argue that systemic hydration and autonomic function may play more significant roles [10,21].

Future research should focus on longitudinal studies evaluating the progression of nasal dysfunction in patients with diabetes and its association with glycaemic control. Additionally, studies comparing

Schirmer's test values in diabetic and non diabetic patients would help establish normative values for diabetic populations. The role of neuropathy and microvascular disease in MCC dysfunction warrants further investigation, particularly through studies correlating MCC parameters with nerve conduction studies and diabetic complications [17]. Additionally, the potential role of nasal humidification therapy and mucosal protective agents in improving MCC in patients with diabetes remains unexplored. Randomised controlled trials evaluating interventions such as nasal saline irrigation, mucosal lubricants, and nasal corticosteroids in patients with diabetes could provide valuable insights into managing MCC dysfunction.

One major strength of the present study is its comparative evaluation of two diagnostic methods, the saccharine test and Schirmer's test, in a single cohort of T2DM patients, providing insights into both MCC function and nasal secretion status. The present study included 120 participants, making it one of the largest investigations of nasal dysfunction in diabetes, and the use of standardised methods for both tests added to the robustness of the findings.

Limitation(s)

The authors did not prioritise stratifying patients into symptomatic and asymptomatic groups, which is a limitation of the current study. Another important limitation of this study is the absence of a healthy control group. Without comparison to non diabetic participants, it remains uncertain whether the observed prolongation of saccharin transit time and reduced Schirmer's test values are diabetes-specific changes or lie within the spectrum of normal variation. Furthermore, as this was a single centre study conducted in a tertiary care hospital, the findings may not be fully generalisable to wider community-based diabetic populations. Larger multicentre studies incorporating both diabetic and healthy cohorts are needed to validate these findings and establish normative reference ranges for Schirmer's test in patients with diabetes.

CONCLUSION(S)

In conclusion, most patients had lower Schirmer's test values and longer STT, supporting the strong link between T2DM and impaired nasal MCC. With its high sensitivity and specificity, the Schirmer test can be utilised as a simple screening tool for detecting nasal dysfunction in patients with diabetes. Schirmer's test may serve as a supportive non invasive adjunct to the saccharin test in diabetic patients, especially in cases where saccharin testing is not feasible. Additional research is needed to better understand the long-term effects of MCC dysfunction in patients with diabetes and to develop individualised treatments to improve nasal health.

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