Original Article

Prevalence of Dry Eye Disease in Type 2 Diabetic and Non-Diabetics: A Cross-Sectional Hospital-Based Study

Abstract

Aims and Objectives: Dry eye disease (DED) is a common condition that affects the quality of life of may individuals. This study aims to estimate the prevalence of DED and identify potential risk factors in adult patients seeking care at Lagos State University Teaching Hospital., Nigeria. **Materials and Methods:** This was a cross-sectional, hospital-based study that aimed to determine the prevalence of DED in type 2 diabetic and non-diabetic patients. A total of 200 adult participants—100 with type 2 diabetes and 100 non-diabetic patients, were recruited into the study. A symptom screening standard patient evaluation for dryness questionnaire was administered and a fluorescein break-up time test was done to diagnose DED. **Results:** The mean age was 61.4 years (±11.7 SD) and most were females (146, 72.86%). Using the standard patient evaluation for dryness questionnaire, 87.31% of the study participants had symptom(s) of DED. The proportion of DED in diabetics was 63.95% while in the non-diabetics was 68.37%, and this was significantly higher in the non-diabetic group (proportion difference of 16.47%, $P = 0.006$).

The prevalence of DED as measured by the fluorescein break-up time was 55.81% (95% CI: 48.39–63.24). There was no significant difference in prevalence between diabetic and non-diabetic participants. Logistic regression analysis showed that increased duration of diabetes and age were significant predictors of DED in diabetic and non-diabetic groups, respectively. **Conclusion:** The prevalence of DED was high in our study population with increasing duration of diabetes in diabetics and older age in non-diabetics significantly associated with DED.

Keywords: *Africa, diabetics, dry eye disease, non-diabetics*

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Introduction

Dry eye disease (DED) is a multifactorial condition of the tear film and ocular surface that causes symptoms of pain, blurry vision, and unstable tear film with potential injury to the ocular surface.[1] The tear film has three layers, namely, the lipid layer (secreted by the Meibomian glands), the aqueous layer (secreted by the lacrimal glands) and the mucous layer (secreted principally by conjunctival goblet cells).[2] The outer lipid layer keeps the tear film thickness constant and stops the aqueous layer from evaporating. It also functions as a surfactant, enabling the tear film to spread.[2] Immunoglobulin A, lysozyme, and lactoferrin, which have antibacterial properties, wash away debris and unpleasant stimuli, and also provide the cornea with a clean optical surface, are found in the aqueous layer.[2] The mucous layer makes the corneal epithelium's hydrophobic surface hydrophilic, enabling wetting.[2] The normal blink reflex, eyelids, ocular surface, and corneal epithelium are all required for the neuronally regulated blinking mechanism that mechanically spreads the tear film over the ocular surface.[2] The Dry Eye Workshop recognised DED as a disturbance of the lacrimal functional unit, an integrated system comprising the lacrimal glands, ocular surface (cornea, conjunctiva and Meibomian glands), eyelids, the sensory and motor nerves that connect them.[1,3,4] Although the symptoms of DED might vary, they are often the same in both diabetics and non-diabetics.[3] Gritty feeling, pain, blurred vision, photophobia, itching, hyperaemia, burning, and secondary epiphora are possible symptoms.[5] Itching and other symptoms of ocular irritation, according to Bekibele *et al.*,[6] may be a sign of underlying aberrant tear function and ocular surface damage in non-diabetic people. Allergic eye disorders, viral conjunctivitis, bacterial

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conjunctivitis, and ocular surface foreign body are among the conditions that might mimic DED.[2]

DED is a frequent cause of visits to the eye clinic or hospital with a high prevalence ranging between 5% and 50% in population-based surveys.[7,8] and significantly affects the quality of life of those suffering from it.[7,9]

Prior to the Tear Film and Ocular Surface Society Dry Eye Workshop II (TFOS DEWS II) report in 2017, there were no standardised diagnostic criteria for DED and this may have been partly responsible for the wide prevalence ranges. The TFOS DEWS II helped formed a consensus approach towards DED diagnosis.[7,10] First, a validated questionnaire for DED should be completed following which a positive symptom score should trigger conducting the diagnostic tests.[7] A positive finding from any of these three specified diagnostic tests is indicative of DED—reduced non-invasive break-up time (NIBUT); elevated or a large interocular disparity in osmolarity; or ocular surface staining (of the cornea, conjunctiva, or lid margin) in either eye.[7] This recommendation took into account the diagnostic ability, minimal-invasiveness, objectivity, and clinical applicability[7] of the tests which will be helpful in resource-limited settings. It was also noted that in the absence of NIBUT, a fluorescein break-up time (FBUT) could be used.[7] The standard patient evaluation for dryness (SPEED) questionnaire, which is one of the validated questionnaires by the TFOS DEWS II subcommittee, is easy to administer by trained non-health workers.[11] This will be very relevant in a high-voluminous hospital in a low-resource setting and will be an important tool that can be easily applied in non-ophthalmological clinic settings, for example, diabetic clinic; for early detection of DED, referral, and treatment if required.

Diabetes mellitus (DM) is one of the risk factors for the development of DED.[3,7,10,12-15] The aetiology of DM-associated DED has been attributed to the dysfunction of the lacrimal function unit due to the effects of hyperglycaemia which results in tear hyperosmolarity and tear film instability.[3,15] This tear film dysfunction can lead to cornea epithelial defect causing irreversible changes to the ocular surface and eventual visual impairment.[3] The number of people living with DM in sub-Saharan Africa is projected to reach an alarming figure of 41.4 million by 2035[16] and likewise, its associated diseases including DED which can lead to several ocular complications[14] potentially worsening the vision of those with diabetes.

This study aims to estimate the prevalence of DED and associated risk factors in adult diabetic and non-diabetic patients seeking care at Lagos State University Teaching Hospital (LASUTH).

Most of the studies on DED have been from Asia and Europe[7] with paucity of data from the sub-Saharan African (SSA) region, especially in those with DM. And the few done in SSA have not applied the standardised diagnostic criteria as stated by TFOS DEWS II. Accurate and early diagnosis of DED will not only help efficiently manage scarce resources but will also help the patients reduce their suffering and improve their quality of life.

This study will further provide hospital-based prevalence data of DED in the most populous state (Lagos State) in the region, which might help inform screening, referral and diagnostic guidelines in a hospital setting, to reduce missed opportunities in the prompt management of DED.

Materials and Methods

This was a hospital-based comparative, clinical, cross-sectional study carried out at LASUTH, Nigeria; one of the two tertiary hospitals serving inhabitants of Lagos State and its environs. Lagos is the most populous city in western sub-Saharan Africa with an estimated population of over 15 million in 2022.[17] The study was conducted from March to August 2019.

Diabetic patients and non-diabetic patients attending the endocrinology and ophthalmology clinic, respectively, at LASUTH were included in the study if they met the below criteria:

- Aged 18 years and above
- Not on topical medications 3 weeks before enrolment
- No history of trauma to the eye
- No history of intraocular surgery 6 months before enrolment
- No history of any malignancy or receipt of chemotherapy
- No orbital disease, acute or chronic superficial or intraocular infection or eye-lid pathology
- Random blood sugar level <200 mg/dL on the day of screening (non-diabetic patients)
- No history of contact lens wear

The sample size of 200 was derived using the referenced prevalence of DED in type 2 diabetics 54.3%[18] and adult population 32.5%,[8] a significance at the 5% level, study power of 80% and an assumption of 20% non-response rate. Thus 100 diabetics and 100 non-diabetics participants were recruited.

Participants were consecutively recruited from the endocrinology and ophthalmology clinics. Those willing to be part of the study after explaining the study objectives were screened to ensure that eligibility criteria were met. For each diabetic participant recruited, a non-diabetic participant within the 4-year age bracket and sex-matched was recruited from the ophthalmology clinic. This was to ensure similar proportions by age and sex.

After the identification of the potential participant, each was seen at the eye clinic where details about the study procedure were further given and written informed consent was obtained.

Each participant had an interview where basic demographic information, drug history, medical history, social and occupational history, and other relevant information were collected. Symptoms related to DED were collected via the SPEED questionnaire that was administered in English Language. The SPEED questionnaire assessed the frequency of ocular subjective symptoms (soreness, blurred vision), the severity of symptoms (tolerable, uncomfortable, and intolerable), and previous use of eye drops or ointment. It also monitored diurnal and long-term changes in symptoms over 3 months.[19] The participants answered 13 questions, with higher scores representing greater disability.

The scoring is as follows: 0 is considered as "Normal"; 1–4 "mild dry eye"; 5–7 "moderate dry eye"; and ≥8 "severe dry eye."

Diabetics screening

Diabetic participants were diagnosed at the endocrinology unit before the study using the standard WHO criteria.[20] The result of the HbA1c and fasting plasma glucose of the most recent visit was obtained from the diabetic health card of the patient. The diabetic health card was also reviewed to confirm the date of diagnosis, medications and blood sugar control.

Patients attending the ophthalmology clinic do not routinely have a diabetic blood screening except if there is a suspicion on examination or the patient requires surgery. So verbal report was obtained from the patient, as well as a random plasma glucose of less than 200 mg/dL on the day of the recruitment; which was free to the patient and was used to preclude diabetes. Those with random plasma glucose above 200 mg/dL were excluded from the study and referred to the endocrinology unit for confirmation and management if required.

Ocular examination

The ocular examination included visual acuity using an illuminated Snellen's chart for literate patients and an E chart for non-literate patients at 6 m in the ophthalmology clinic room. Slit lamp examination of both eyes was done first using the broad beam of the slit lamp to assess the condition of the ocular surface and adnexa, observing the tear film meniscus, tear film, conjunctival changes, cornea changes, and eyelids.

Fluorescein break-up time test

The Fluorescein break-up time test was measured by instilling a fluorescein strip moistened with a drop of sterile water, into the inferior conjunctival fornix. The participants were instructed to blink three times and then hold their eyes open. The tear film was examined using the broad beam of cobalt blue light of the slit-lamp bio-microscope for the appearance of dark spots on the cornea representing areas of dryness. A stopwatch was activated when the patient stops blinking and deactivated when the first random dark spot appears. The time interval between the last blink and the appearance of the first dry spot around the central cornea was noted as the FBUT. This was repeated three times at 10 s intervals for each eye, and the average FBUT was recorded. This test was done in a dedicated room with fairly constant humidity and temperature that was achieved through air-conditioning at 20°C with the participants not directly facing the air conditioner.

The participants were classified according to World Health Organization (WHO) International Classification of Diseases (ICD-10) for visual impairment and blindness. The diagnosis used for DED in this study was a FBUT of less than 10 s in either eye. Those diagnosed with DED were treated at the eye clinic of LASUTH using the DEWS II treatment protocol at no additional cost to them.

Data analysis

Each participant had a study report form including the questionnaire, where all the data were entered. This was checked for completeness at the end of the screening and eye examination process. During the eye examination, one of the non-diabetic participants was found to be using contact lenses and therefore was excluded from all the analysis. There were some missing data in some of the variables but these were less than 5% at most, therefore they were treated as missing and no correction was made.

Data were analysed using the Stata 13.0 June 2013, Stata Corp LP College Station, Texas, USA software. Summary statistics for all background characteristics and other variables were presented using tables and graphs. Categorical variables were reported as frequencies and percentages while continuous variables were reported as means ± standard deviation.

Further analysis for DED was done on those with positive symptoms following the administration of the SPEED questionnaire. Univariate analysis to investigate the crude association of the various independent variables (age groups, gender, occupational status, socioeconomic status, and comorbidities) with DED was done using binary logistic regression. Crude odds ratios (OR), 95% confidence intervals (CI) and probability (*P*) values were reported. A multivariate logistic regression analysis was performed using the predictors that were statistically significant at the 5% level in the univariate analysis. All *P* values <0.05 were considered statistically significant.

Results

A total of 199 participants (100 diabetic and 99 non-diabetic) were analysed with similar age and sex parameters as shown in Table 1. The mean age was 61.4 years (±11.7 SD). Most of the study population 89 (44.72%) were within the age bracket of 50–64 years [Table 1]. There were 146 (72.86%) females, 130 (65.66%) were employed, 172 (86.43%) had never smoked a cigarette, 109 (55.05%) spends 1–6 h/day watching TV or using the computer and

Table 1: Sociodemographic status of the study population

Variable	Diabetic Freq (%)	Non-diabetic Freq (%)	Total Freq (%)
Age group			
35–49 years	14 (14.00)	14 (14.14)	28 (14.07)
50–64 years	45 (45.00)	44 (44.44)	89 (44.72)
65–79 years	37 (37.00)	37 (37.37)	74 (37.19)
80–94 years	4 (4.00)	4 (4.04)	8 (4.02)
Total	100 (100.0)	99 (100.0)	199 (100.0)
Sex			
Male	27 (27.00)	27 (27.27)	54 (27.14)
Female	73 (73.00)	73 (72.73)	146 (72.86)
Total	100 (100.0)	99 (100.0)	199 (100.0)
Occupational status			
Employed	60 (60.61)	70 (70.71)	130 (65.66)
Unemployed	13 (13.13)	9 (9.09)	22 (11.11)
Retired	26 (26.26)	20 (20.20)	46 (23.23)
Total	99 (100.0)	99 (100.0)	198 (100.0)
Cigarette Smoking status			
Never smoked	87 (87.00)	85 (85.86)	172 (86.43)
Current smoker	3 (3.00)	2 (2.02)	5 (2.51)
Past Smoker	10 (10.00)	12 (12.12)	22 (11.06)
Total	**100 (100.0)**	**99 (100.0)**	**199 (100.0)**
Computer/TV screen time per day			
Less than an hour	29 (29.29)	28 (28.28)	57 (28.79)
One to six hours	53 (53.54)	56 (56.57)	109 (55.05)
More than six hours	13 (13.13)	9 (9.09)	22 (11.11)
Do not watch TV or use computer screen	4 (4.04)	6 (6.06)	10 (5.05)
Total	**99 (100.0)**	**99 (100.0)**	**198 (100.0)**
Comorbidity			
None	23 (23.00)	57 (57.58)	80 (40.20)
Hypertensive	73 (73.00)	42 (42.42)	115 (57.79)
Others	4 (4.00)	0 (0.00)	4 (2.01)
Total	100 (100.0)	99 (100.0)	199 (100.0)
HbA1c			
<6.5%	35 (35.00)	–	–
≥6.5%	65 (65.00)	–	–
Total	100 (100.0)	–	–
Duration of diabetes			
<5 years	29 (29.29)	–	–
5–10 years	30 (30.30)	–	–
>10 years	40 (40.40)	–	–
Total	99 (100.00)	–	–

115 (57.79%) of the participants have hypertension as associated comorbidity. For the diabetic group, (65%) had glycosylated haemoglobin (HbA1c) values of ≥6.5% and 40.40% have been diagnosed diabetic for >10 years.

The result of the SPEED questionnaire showed that out of 197 participants, 172 (87.31%) reported one or more symptoms of DED, whereas 25 (12.69%) reported no symptoms. The symptoms were classified into mild, moderate and severe dry eye as shown in Table 2. The proportion of severe DED symptoms was significantly higher in the non-diabetic group (30.61%) compared to the diabetic group (14.14%) with a proportion difference of 16.47% and a *P* value of 0.006.

Out of those with positive symptoms of DED (172 of 197) using the SPEED questionnaire, the results of FBUT, which is the standard diagnosis for DED in this study, indicated that the prevalence of DED in our study population was 55.81% (96 of 172). Although the prevalence was higher by 5.16% in the non-diabetic group, this was not statistically significant (*P*-value of 0.497) as shown in Table 2.

Table 3 and 4 shows the logistic regression analysis of DED in the diabetic group and non-diabetic group, respectively. For the diabetic group, the odds of having DED in the univariate analysis significantly increased with only the duration of diabetes as shown in Table 3. The odd was

Table 2: Prevalence of dry eye in diabetics and non-diabetics

Variable	Diabetic Freq (%; 95% CI)	Non-diabetic Freq; (%; 95% CI)	Total Freq (%; 95% CI)	Proportion difference (95% CI)	*P* value
SPEED questionnaire					
Normal	18 (18.18; 10.58–25.78)	7 (7.14; 2.04–12.24)	25 (12.69; 8.04–17.34)		
Mild	41 (41.41; 31.71–51.12)	46 (46.94; 37.06–56.82)	87 (44.16; 37.23–51.10)	−11.04 (−20.19 to −1.89)	0.020*
Moderate	26 (26.26; 17.59–34.93)	15 (15.31; 8.12–22.43)	41 (20.81; 15.14–26.48)	5.52 (−8.32 to 19.37)	0.435
Severe	14 (14.14; 7.28–21.01)	30 (30.61; 21.49–39.74)	44 (22.34; 16.52–28.15)	−10.10 (−22.18 to 0.27)	0.058
Total	99 (100.0)	98 (100.0)	197 (100.0)	16.47 (5.05–27.89)	0.006*
FBUT test					
No dry eye	38 (46.91; 36.05–57.78)	38 (41.76; 31.63–51.89)	76 (44.19; 36.76–51.61)	−5.16 (−20.01 to 9.70)	0.497
Dry eye	43 (53.09; 42.22–63.95)	53 (58.24; 48.11–68.37)	96 (55.81; 48.39–63.24)	5.16 (−9.70 to 20.01)	0.497
Total	81 (100.0)	91 (100.0)	172 (100.0)		

*Statistically significant at the 5% level; proportion difference = non-diabetic − diabetic

Table 3: Logistic regression analysis of dry eye disease (using FBUT) in diabetics

Variable/category	Univariate			Multivariate		
	OR	95% CI	*P*-value	AOR†	95% CI	*P*-value
Sex						
Male	1.00					
Female	0.54	0.19–1.53	0.246			
Age group						
35–61 years	1.00					
≥62 years	1.76	0.73–4.25	0.206			
Occupational status						
Employed	1.00					
Unemployed	1.23	0.34–4.44	0.750			
Retired	1.06	0.38–2.92	0.916			
Cigarette smoking status						
Never smoked	1.00					
Current/past smoker	1.89	0.52–6.85	0.333			
Computer/TV screen time per day						
None or less than an hour	1.00					
1–6 h	1.11	0.42–2.91	0.836			
>6 h	0.87	0.22–3.35	0.836			
Comorbid status						
No comorbidity	1.00					
Hypertension	0.60	0.21–1.74	0.349			
Others	0.58	0.03–10.86	0.718			
Visual acuity						
Normal/mild visual impairment	1.00					
Moderate visual impairment	0.87	0.27–2.80	0.811			
Severe visual impairment + blindness	1.21	0.34–4.29	0.764			
Glycosylated haemoglobin						
<6.5%	1.00					
≥6.5%	1.13	0.46–2.79	0.795			
Duration of diabetes						
<5 years	1.00					
5–10 years	5.55	1.59–19.38	0.007*			
>10 years	3.47	1.14–10.57	0.029*			

*Statistically significant at the 5% level.
†Adjusted odds ratio (AOR) for only parameters significant at the 5% level in the univariate analysis

highest in those that have had diabetes for 5–10 years (OR: 5.55; 95% CI: 1.59–19.38; $P = 0.007$). No multivariate analysis was done as the duration of diabetes was the only predictor of DED.

In the non-diabetic group, older age group and retired occupational category showed significantly increased odds of DED in the univariate analysis as shown in Table 4. These variables were accounted for in the multivariate

Table 4: Logistic regression analysis of dry eye disease (using FBUT) in non-diabetics

Variable/category	Univariate			Multivariate		
	OR	95% CI	*P*-value	AOR†	95% CI	*P*-value
Sex						
Male	1.00					
Female	1.34	0.52–3.47	0.543			
Age group						
35–61 years	1.00			1.00		
≥62 years	3.57	1.50–8.55	0.004*	2.78	1.10–6.99	0.030*
Occupational status						
Employed	1.00			1.00		
Unemployed	2.58	0.47–14.26	0.278	2.28	0.39–13.22	0.359
Retired	4.12	1.24–13.68	0.021*	2.70	0.76–9.63	0.125
Cigarette smoking status						
Never smoked	1.00					
Current/past smoker	0.84	0.26–2.72	0.767			
Computer/TV screen time per day						
None or less than an hour	1.00					
1–6 h	0.67	0.27–1.65	0.385			
>6 h	1.50	0.25–8.98	0.657			
Comorbid status						
No comorbidity	1.00					
Hypertension	0.99	0.43–2.28	0.985			
Others	–	–	–			
Visual acuity						
Normal/mild visual impairment	1.00					
Moderate visual impairment	3.10	0.80–12.06	0.102			
Severe visual impairment + blindness	0.85	0.16–4.48	0.844			

*Statistically significant at the 5% level.
†Adjusted odds ratio (AOR) for only parameters significant at the 5% level in the univariate analysis

analysis, and although it still showed increased odds of having DED albeit reduced as compared with the univariate analysis, this association was only statistically significant for the older age group category (AOR = 2.78; 95% CI: 1.10–6.99; $P = 0.03$).

Discussion

In our study, we found that the prevalence of DED was high in both diabetic and non-diabetic groups. The increasing duration of diabetes (≥5 years) was the only significant predictor of DED in the diabetic group. While in the non-diabetic group, older age and retired occupational status showed some increased association in the univariate analysis, after adjusting for both variables in the multivariate analysis, only older age group remained significant. The high prevalence observed in our study is consistent with what was observed in other studies as stated in the meta-analysis of the prevalence of DED in Africa and the DEWS II report of 5%–50%.[7,21] The choice of using ophthalmic outpatients even though we excluded those with previous eye surgeries, might have influenced the higher prevalence in the non-diabetic group. Albeit, the value is still consistent with the prevalence of DED in hospital-based–studies of 38.7% (95% CI, 21.9%–57.0%).[21] The association between diabetes and DED has been documented in several studies[3,7,18,22,23] and the increased risk with duration of diabetes.[7,24] Considering the recognition of the gradual increase in the burden of DED in sub-Saharan Africa, there is still a huge lag in its early detection and treatment.[24,25] Part of the initial challenge has been the accurate diagnosis of DED which the DEWS II report[7,10] has greatly helped in providing clarity and standardisation. It is now possible for a practitioner to make a diagnosis of DED using a positive symptom score and any of the recommended validated tests considered for measuring the disrupted homeostasis of the ocular surface.[7]

In this study, we used the SPEED questionnaire for the initial screening for DED and employed the FBUT as the diagnostic test. The SPEED questionnaire has been validated for measuring DED symptoms[10,11,19,26] and is very applicable to our settings.[11,26] The advantages of the SPEED questionnaire are that it takes less time to complete as compared with the other recommended questionnaires, asks about the most common DED symptoms[11] and is easy to administer by trained non-health personnel. The questionnaire can also be used as a measure of disease severity—an important criterion in the DEWS II report recommendation.[7,11,19]

The non-invasive break-up time is the preferred choice according to the DEWS II report[10]; however, it correlates with the FBUT measurement provided that external factors that affect tear film stability such as humidity and temperature are kept constant.[10,27] FBUT was the available option in the hospital and we think using the same room (with air-conditioning unit always set at 20°C) and the same observer for the measurements might have alleviated the drawbacks of the test as stated in the DEWS II report. Although air-conditioning systems have been shown to regulate temperature and also control humidity levels, it would be important to formally measure the room temperature and humidity during the conduct of FBUT, which might further support its use in routine practice. As the FBUT is the most widely used test in clinical practice,[10] it is important to note these limitations as fully explained in the DEWS II report[10] and ensure to alleviate them by adjusting for these factors to improve the accuracy of the measurement.

The high prevalence of DED in this study underscores the fact that the burden of DED is high in our environment, thus instituting a routine screening for all patients with possible symptoms of DED presenting to the eye and diabetic clinic will go a long way in reducing this burden. The SPEED questionnaire can be easily employed in our setting without significantly adding to the cost of eye care. And in a very busy environment like LASUTH, the short duration of time to complete the questionnaire will be very attractive and likely increase its feasibility.

We fully acknowledge that using a convenient method of sampling might have resulted in some selection bias in our study despite the same method used in both groups. Thus, this might affect the generalisation of our study findings but albeit it provides valuable information on the use of DEW II diagnostic criteria in our setting. And it would be important going forward that studies on DED employ the recommended diagnostic criteria according to the DEWS II report, this will help to objectively compare findings and provide evidence-based practical guidance for routine clinical activity, as we did in this study.

Conclusion

The prevalence of DED was high in our study population with older age and increasing duration of diabetes significantly associated with DED. Our study showed that the SPEED questionnaire is a good symptom screening tool and we believe this can be easily utilised in the outpatient clinics without significantly adding to the burden of work and cost of eye care (although this will need to be further assessed).

Ethics approval

Approval to conduct this study was obtained from the Lagos State University Teaching Hospital (LASUTH) Medical and Health Research Ethics Committee. All participant provided written informed consent prior to study participation.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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