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Intraocular pressure changes in bronchial asthma patients on treatment with inhalational steroids at a tertiary hospital in Southern Nigeria

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Background: Elevated intraocular pressure (IOP) has been linked with the use of steroids.

Aim: This study aimed to evaluate the association between the use of inhalational steroids and IOP among patients receiving treatment for bronchial asthma.

Setting: It was a hospital-based cohort study at a tertiary hospital.

Methods: Newly diagnosed asthma patients yet to commence inhalational steroids as cohort 1 gotten from the Respiratory clinic and Family Medicine Department. Cohort 2 was the control group who were age and sex matched with cohort 1 gotten from patients visiting the Ophthalmology Clinic with mild ocular disorders (without any respiratory symptoms). Their baseline IOP and central corneal thickness were used to adjust for corrected IOP. The patients in cohort 1 were placed on inhalational fluticasone 250 mcg twice daily. The IOP was thereafter measured monthly over a period of 5 months for both cohorts.

Results: A total of 210 participants who were enrolled completed the study with 105 participants (mean age ± standard deviation 41.08 ± 11.10) in cohort 1 and another 105 participants (mean age 41.34 ± 10.55 years) in cohort 2. The mean IOP increase was 4.51 ± 2.15 right eye and 4.56 ± 2.03 left eye for cohort 1, while cohort had a mean IOP increase of 4.37 ± 2.40 and 3.83 ± 2.80 for the right and left eyes, respectively. There was no statistically significant difference in IOP increase from the first to third month of study, but a statistically significant association between inhaled steroid and IOP increase was observed in the fourth and fifth months of study ($P < 0.005$). The predictors of elevated IOP among study participants were primary or secondary level education and the presence of allergies.

Conclusion: The study showed a significant increase in IOP after 3 months of use of inhalational steroids.

Contribution: There is a need for physicians to liaise with ophthalmologists to monitor the IOP and associated risk of glaucoma of their asthmatic patients on inhalational steroids.

Keywords: bronchial asthma; inhalational steroids; intraocular pressure increase; glaucoma; central corneal thickness.

Introduction

Asthma is a complex syndrome characterised by airway hyper-responsiveness caused by a multicellular inflammatory reaction that leads to airway obstruction.[1] It is a public health problem, not just for high-income countries but all countries irrespective of their level of development. In 2015, it was estimated that asthma was the most prevalent of the chronic respiratory diseases affecting an estimated 359 million.[2] The prevalence of asthma in adolescent and adults in Nigeria is estimated to be about 10.2% while that for children ranges from 5.1% to 14.3%.[3] In the last decade, the treatment of asthma, chronic obstructive pulmonary disease, allergic and non-allergic rhinitis and sinusitis have dramatically changed. One of the major differences is the increased use of corticosteroids by inhalation and nasal sprays.[4] Treatment with inhalational steroids has been shown to reduce the risk of fatal or near-fatal asthma.[4] There have been associations with the use of steroids and exacerbation of glaucomatous state, and the presence of γ-globulin and plasma cells in the trabecular meshwork of glaucomatous eyes has suggested an immunogenic component.[5,6]

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Elevated intraocular pressure (IOP) is considered a strong risk factor for the development and progression of glaucoma.[7] A study by Shroff et al. showed a relationship between inhaled steroids and IOP.[8] Mitchell et al. showed a positive correlation between risk of glaucoma and use of inhaled steroids in patients with a family history of glaucoma.[9,10] However, some other prospective studies showed no relationship between elevated IOP and inhaled steroids.[11] There are case reports that have shown a rise in IOP after use of inhalational glucocorticoids.[12] Many studies have shown that topical and systemic steroids cause several ocular side effects including glaucoma and cataract.[8,13,14] However, ocular side effects of inhalational steroids are less well understood.[8]

Steroids have been implicated in the pathogenesis of glaucoma, but little is known about the effects of inhaled steroids. The purpose of this study, therefore, is to investigate the association, if any, between inhalational steroids and IOP. This will not only fill the existing knowledge gap but also provide useful data in planning management of asthmatics on inhalational steroids to prevent any untoward effects such as blindness that could result from undetected glaucoma. In addition, this study will help clinicians familiarise themselves with the potential dangers of administering steroids without evaluation of the eyes and the attendant dangers or risk of avoidable irreversible blindness associated with elevated IOP.

Research methods and design

This was a hospital-based cohort study that compared IOP between asthmatic patients on inhalational steroids and patients who visited the eye clinic for minor ocular disorders such as refractive errors and who were not on any inhalational steroid and did not have any respiratory symptoms.

Patients aged 18 years and older, newly diagnosed with bronchial asthma who had not been commenced on treatment, were recruited from the Respiratory clinic and Family Medicine clinic of University of Port Harcourt Teaching Hospital into the first cohort. The comparative cohort consisted of age and sex-matched patients with mild ocular problems (e.g. mild refractive errors – myopia ≤ –3D, hypermetropia ≤ +2D and astigmatism ≤ 1.50 DC) recruited from the General ophthalmology clinic of the same hospital. Patients with glaucoma, ocular hypertension, family history of glaucoma, previous ocular surgery and patients on treatment with steroids (local or systemic) or treated with other forms of steroids in the previous 3 months were excluded from the study.

A sample size of 105 patients with bronchial asthma in one cohort and 105 patients with minor ocular problems in the comparative cohort was calculated using the following formula (Equation 1):[8]

$$n = \frac{2\,(Z_{\alpha/2} + Z_{\beta})^2(PQ)}{(p_1 - p_2)^2} \qquad \text{[Eqn 1]}$$

Z_{β} = standard normal deviate for power = 0.84 for 80% power

$Z_{\alpha/2}$ = standard normal variate for level of significance = 1.96 for 95% confidence level

p_1 = proportion of subjects with raised IOP among asthmatic patients on inhalational steroids = 5.5% of persons were observed from the study by Shroff et al.[8]

p_2 = proportion of subjects with raised IOP in persons not on inhalational steroids (comparison group) = 0%, none of the subjects in the comparison group not on inhalational steroids had raised IOP as stated by Shroff et al.[8]

$P = p_1 + p_2 \div 2$

$Q = 1 - P$

Using the formula, an estimated sample of 139 per cohort was calculated. However, available data from the University of Port Harcourt Teaching Hospital showed that the number of asthma patients seen in the previous year was less than 10 000. Therefore, the sample size was adjusted using Equation 2:

$$nf = n \div 1 + n/N \qquad \text{[Eqn 2]}$$

where n = minimum sample size calculated; nf = new minimum sample size when the study population is < 10 000; n = 139 persons; N = study population size: 400 persons per annum (at 8 people per week for approximately 50 work weeks in a year).

A stratified sample technique was used to recruit the study participants. Cohort 1 (participants on steroids) was recruited with stratified sampling. Strata were the Internal Medicine respiratory clinic (three to five patients per week) and the Family Medicine clinic (seven to ten patients per week). Within these two strata, simple random sampling was used to select two to three patients from the respiratory clinic and six from General Outpatient Department clinic to recruit eight to nine persons per week. Over a 3-month period, the sample size was completed.

Cohort 2 (control): Age and sex-matched persons selected in cohort 1 were recruited from persons attending the ophthalmology outpatient clinic in University of Port Harcourt Teaching Hospital (UPTH). Recruitment of cohort 2 was done within 1 week of recruitment for cohort 1 participants using simple random technique.

Ethical approval for this study was sought for and obtained from the Ethics and Research Committee of University Port Harcourt Teaching Hospital, Port Harcourt. Informed written consent was obtained from the subjects before commencement of the study. The protocol of the study adhered to the tenets of the Helsinki Declaration on study involving human subjects.

Prior to commencement of the study and obtaining written informed consent, the aim of the study was properly explained to the patients. After recruitment of cohort 1, they were taken to the eye clinic where examinations were carried out. Both Respiratory (Internal Medicine) and Ophthalmology clinics are located almost adjacent to each other. Visual acuity was assessed using Snellen's chart (acuity of < 6/18 was considered abnormal), ocular examination was carried out using the slit lamp biomicroscope and +78D lens. Intraocular pressure was measured using Goldmann applanation tonometer, and the Central corneal thickness (CCT) was measured using the pachymeter (SonoMed model 300 AP + A scan with pachymeter [Sonomed Escalon, Lake Success, New York, United States]) to get the correction factor for the IOP. The one-off CCT reading was used throughout the study to get the corrected IOP anytime IOP was measured. The pupils were dilated with topical tropicamide and phenylephrine combination (appamide plus), and a dilated fundoscopy was performed to assess vertical cup disc ratio.

The self-administered questionnaire collected information on biodata, when diagnosis of asthma was made, drugs presently being used, history of use of other forms of corticosteroid and time of usage, type of inhalational corticosteroids and its dosage, history of allergies and any history of previous visit to an ophthalmologist. Other aspects of the self-administered questionnaire explored risks of glaucoma, past ocular history with the results of the clinical assessment and examination. Similar procedures were carried out for participants in cohort 2. The participants in cohort 1 were then given inhalational fluticasone in a dosage of 250 mcg (1 puff) twice daily. All participants had IOP measurements every month for 5 months. The IOP was measured at least twice, and the mean value was recorded. Patients with elevated IOP (> 21 mmHg) were investigated further for a rise in IOP at the Ophthalmology clinic and appropriate management instituted.

Data analysis

Data were entered into Microsoft Excel and exported into Statistical Package for Social Sciences (SPSS) version 25 for statistical analysis. Means and standard deviation (s.d.) were used to summarise numerical data, while categorical data were presented as frequencies and proportions. Categorical data were compared between the two groups using Chi square statistics. Friedman ANOVA test was used to compare differences in mean IOP across time periods among cases. Statistical significance was set at an alpha level of 0.05.

Ethical considerations

Ethical clearance to conduct this study was obtained from the University of Port Harcourt Teaching Hospital Research Ethics Committee (reference number: UPTH/ADM/90/S.11/VOL.XI/1361). All procedures were in accordance with the standards specified by the Declaration of Helsinki for research involving human subjects. Signed or thumb printed informed consent was obtained from participants before inclusion in the study.

Results

Sociodemographic characteristics of participants

A total of 210 patients participated in this study; the mean age for cohort 1 is 41.08 ± 11.10 years and 41.34 ± 10.55 years for cohort 2. The largest proportion of participants were those in the 30–39 years group (31.4%, *n* = 33) in cohort 1 and 40–49 years (37.1%, *n* = 39) in cohort 2. Most were male participants (53.3%, *n* = 56), but in cohort 2, the majority were female participants (52.4%, *n* = 55). In both cohorts, most of the participants were of the Ijaw ethnic nationality (cohort 1 = 68.6%; cohort 2 = 78.1%). In both cohorts, most participants had tertiary education (90.5% and 78.1%). The details of the participants' socio-demographic characteristics are shown in Table 1.

Visual acuity and intraocular pressure assessment of study participants

More participants in cohort 1 had normal VA compared to those in cohort 2 (56.2% – 59% vs 48.6% – 51.4%). Mean IOP in both eyes of both groups showed a steady increase from baseline to the 5th month, but there was no significant difference between the two groups. Details are shown in Table 2.

Intraocular pressure changes after using inhalational steroids for five-months

Assessment of the baseline and 5-month mean IOP of both cohorts revealed that the difference in the mean IOPs was statistically significant in both eyes (right eye: $P < 0.001$; left eye: $P < 0.001$; see Table 3).

TABLE 1: Socio-demographic characteristics of study participants.

Variable	Cohort 1		Cohort 2		Chi-square	*P*-value
	n	%	*n*	%		
Age group† (years)	-	-	-	-	4.388	0.356
19–29	16	15.2	10	9.5	-	-
30–39	33	31.4	35	33.3	-	-
40–49	30	28.6	39	37.1	-	-
50–59	20	19.0	13	12.4	-	-
60–69	6	5.7	8	7.6	-	-
Gender	-	-	-	-	0.686	0.408
Male	56	53.3	50	47.6	-	-
Female	49	46.7	55	52.4	-	-
Ethnicity	-	-	-	-	7.049	0.133
Hausa	4	3.8	0	0.0	-	-
Igbo	21	20.0	15	14.3	-	-
Ijaw	72	68.6	82	78.1	-	-
Yoruba	8	7.6	8	7.6	-	-
Educational status	-	-	-	-	0.307	0.858
Primary	2	1.9	2	1.9	-	-
Secondary	8	7.6	6	5.7	-	-
Tertiary	95	90.5	97	92.4	-	-
Marital status	-	-	-	-	3.197	0.362
Single	13	12.4	9	8.6	-	-
Married	89	84.8	94	89.5	-	-
Separated or divorced	1	1.0	2	1.9	-	-
Widowed	2	1.9	0	0.0	-	-

†, Cohort 1: mean ± standard deviation (s.d.) 41.08 ± 11.10; Cohort 2: mean ± s.d. 41.34 ± 10.55.

TABLE 2a: Clinical assessment of visual acuity and intraocular pressure.

Visual acuity	Cohort 1		Cohort 2		Chi-square	*P*-value
	n	%	*n*	%		
Right eye	-	-	-	-	2.318	0.128
Normal	62	59.0	51	48.6	-	-
Abnormal	43	41.0	54	51.4	-	-
Left eye	-	-	-	-	0.479	0.489
Normal	59	56.2	54	51.4	-	-
Abnormal	46	43.8	51	48.6	-	-

*, Significant results (*P*-value ≤ 0.05).

TABLE 2b: Clinical assessment of visual acuity and intraocular pressure.

Intraocular pressure	Cohort 1		Cohort 2		*t*-test	*P*-value
	Mean	s.d.	Mean	s.d.		
Baseline						
Right eye	12.15	1.34	11.74	1.49	2.094	0.037*
Left eye	12.36	1.65	12.29, 1.58	1.58	0.342	0.733
Month 1						
Right eye	12.50, 1.40	1.40	12.20, 1.38	1.38	0.857	0.432
Left eye	13.00, 1.48	1.48	13.33, 1.55	1.55	0.554	0.754
Month 2						
Right eye	13.14	1.53	12.93	1.56	0.982	0.327
Left eye	13.54	1.54	13.45	1.57	0.443	0.658
Month 3						
Right eye	14.04	2.17	13.87	2.26	0.568	0.571
Left eye	14.07	2.63	13.80	2.76	0.716	0.475
Month 4						
Right eye	14.66	3.49	14.49	3.44	0.358	0.721
Left eye	15.16	3.36	14.81	3.55	0.738	0.461
Month 5						
Right eye	16.66	3.49	16.11	3.89	1.064	0.288
Left eye	16.92	3.68	16.12	4.40	1.430	0.154

s.d., standard deviation.
*, Significant results (*P*-value ≤ 0.05).

Association between 4-month intraocular pressure and use of inhalational steroids among cohorts

During the first 3 months, no significant association was found to exist between IOP and the use of inhalational steroids in both left and right eyes (see Table 4).

At the fourth month of the study, a statistically significant association was found to exist between IOP and the use of inhalational steroids in both left and right eyes. In the right eye, those who did not take inhalational steroids were 4 times more at risk of developing abnormal IOP than those who were on inhalational steroids (relative risk [RR]: 3.579, 95% confidence interval [CI]: 0.96–13.40, *P*-value: 0.045) (see Table 4).

During 5 months of the study, a statistically significant association ($P < 0.001$ for the right eye and $P < 0.001$ for the left eye) was found to exist between IOP and the use of

TABLE 3: Intraocular pressure changes at baseline and during 5-month use of inhalational steroids.

Variable	Mean intraocular pressure changes		*t*-test	*P*-value
	Cohort 1	Cohort 2		
Right eye	-	-	16.23	< 0.001*
Baseline	12.15, 1.34	11.74, 1.49	-	-
Month 5	16.66, 3.49	16.11, 3.89	-	-
Difference	4.51, 2.15	4.37, 2.40	-	-
Left eye	-	-	13.92	0.001*
Baseline	12.36, 1.65	12.29, 1.60	-	-
Month 5	16.92, 3.68	16.12, 4.40	-	-
Difference	4.56, 2.03	3.83, 2.80	-	-

*, Significant results (*P*-value ≤ 0.05).

TABLE 4: Comparison of 5-month intraocular pressure among cohorts with or without inhalational steroids.

Inhalational steroid use	Intraocular pressure				Chi-square	*P*-value	Relative risk	95% CI
	Normal		Abnormal					
	n	%	*n*	%				
Month 1, Month 2 and Month 3								
Right eye	-	-	-	-	-	-	-	-
Cohort 1-on steroid	105	100.0	0	0.0	-	-	-	-
Cohort 2-No steroid	105	100.0	0	0.0	-	-	-	-
Left eye	-	-	-	-	-	-	-	-
Cohort 1-on steroid	105	100.0	0	0.0	-	-	-	-
Cohort 2-No steroid	105	100.0	0	0.0	-	-	-	-
Month 4								
Right eye	-	-	-	-	4.018	0.045*	3.579	0.96–1.40
Cohort 1-on steroids	102	97.1	3	2.9	-	-	-	-
Cohort 2-No steroids	95	90.5	10	9.5	-	-	-	-
Left eye	-	-	-	-	8.317	0.004*	1.082	1.03–1.14
Cohort 1-on steroids	97	92.4	8	7.6	-	-	-	-
Cohort 2-No steroids	105	100.0	0	0.0	-	-	-	-
Month 5								
Right eye	-	-	-	-	18.497	< 0.001*	1.193	1.10–1.30
Cohort 1-on steroids	88	83.8	17	16.2	-	-	-	-
Cohort 2-No steroids	105	100.0	0	0.0	-	-	-	-
Left eye	-	-	-	-	20.890	< 0.001*	1.221	1.12–1.34
Cohort 1-on steroids	86	81.9	19	18.1	-	-	-	-
Cohort 2-No steroids	105	100.0	0	0.0	-	-	-	-

CI, confidence interval.
*, Significant results (*P*-value ≤ 0.05).

inhalational steroids in both left and right eyes. However, the risk of developing abnormal IOP could not be quantified considering that in both eyes, no participant in the second cohort (cohort not taking inhalational steroids) was found to have abnormal IOP. This is further buttressed by the streamlined confidence interval of both associations (see Table 4).

Predictors of elevated intraocular pressure among study participants

Assessment of independent variables associated with elevated IOP among study participants showed that primary or secondary education as well as the presence of allergies were contributory factors to the development of elevated IOP. When analysed within the logistic regression model, being aged less than 41 years (adjusted odds ratio [AOR]: 2.900, CI: 1.087–7.739), having primary or secondary education (AOR: 7.412, CI: 1.623–33.854) and the presence of allergies (AOR: 7.912, CI: 2.722–23.001) were significant predictors of the occurrence of elevated IOP in study participants. These are shown in Table 5.

Discussion

This study estimated the risk of development of elevated IOP among people on treatment for asthma using inhalational steroids and the relationship between duration of use and incidence of elevated IOP.

The incidence of elevated IOP in the right and left eyes was almost zero at the start of the study and close to one-fifth of the sample population by the fifth month of the study. The study's findings for right and left eyes showed a two-fold risk of developing raised IOP among those on inhalational steroids compared to those not on steroids. This finding of increased IOP has been reported in other studies.[2,15] In one of such studies, an increase of 40% in the incidence of ocular hypertension and glaucoma was observed in patients who were using steroid inhalers to treat asthma.[2,16] In another study, it was reported that the odds of elevated IOP and glaucoma among study participants aged at least 49 years were 2.5 times higher among those using inhalational corticosteroids than non-steroid users.[15] A systemic literature review showed that out of twelve studies reviewed for inhalational steroids and IOP, only three showed an increase in IOP, which is in keeping with this study, while eight were not in agreement as IOP was not affected.[17]

This effect of elevated pressure has been identified among users of oral, systemic and topical steroids in other studies.[8,18] The implication of this finding is that the use of inhalational steroids for treating asthma (which have been preferred over systemic steroid medications)[5] still has a propensity for adverse effects. This risk increases with increased daily use of the inhalational steroid, and for this reason, the smallest daily dose sufficient to control the disease is given.[19] Considering the gravity of the inadvertent increase in IOP, which may result in glaucoma when inhalational steroids are used over a prolonged period, even at low doses, there may be the need to revise the management protocol for asthma and other diseases requiring the chronic use of steroids.[8,20]

Assessment of the baseline and 5th month means IOP of both study cohorts revealed that the difference in mean IOP was statistically significant in both eyes. This result is, however, different from another study, which reported insignificant differences in the pre-therapeutic and post-therapeutic administration of inhaled steroids.[21] This disagreement may be related to the small sample size (n = 30) of the other study, which did not provide sufficient room for the statistical assessment of differences in the pre- and post-therapy phases. Another study that reported a different result from this study had a shorter duration (baseline to 6 weeks) of use of the inhalational steroid.[22] While the mean IOP increased in both cohorts from month to month, the significant difference in the change in IOP between the two cohorts may indicate a relationship between the use of inhalational steroids and raised IOP.

Different reports of cases of glaucoma have been reported and attributed to the use of inhalation corticosteroids, but evidence continues to provide conflicting results with regard to the increased risk of developing elevated IOP and glaucoma.[23] The clinical indications for use of inhalational steroids for bronchial asthma cases has increased over time, with the production of more potent drugs, more concentrated formulations possessing more efficient delivery and therapeutic effect of the medications.[19] It is therefore

TABLE 5: Predictors of elevated intraocular pressure among study participants in the left eye.

Variables	Crude odds ratio	95% CI	*P*-value	Adjusted odds ratio	95% CI	*P*-value
Age (< 41 years vs ≥ 41 years)	0.088	-0.003 to 0.179	0.058	2.900	1.087 to 7.739	0.034*
Sex (male vs female)	0.038	-0.054 to 1.29	0.417	-	-	-
Marital status (single vs married)	0.045	-0.102 to 0.192	0.548	-	-	-
Educational status (primary and secondary vs tertiary education)	0.206	0.032 to 0.380	0.021*	7.412	1.623 to 33.854	0.010*
Wearing spectacles (Yes vs No)	-0.095	-0.235 to 0.044	0.178	-	-	-
Pachymetry reading (normal vs abnormal)	-0.036	-0.162 to 0.090	0.574	-	-	-
Visual acuity (normal vs abnormal)	-0.045	-0.213 to 0.123	0.602	-	-	-
Ophthalmology visit (Yes vs No)	0.053	-0.097 to 0.203	0.486	-	-	-
Presence of allergies (Yes vs No)	0.230	0.121 to 0.339	< 0.001*	7.912	2.722 to 23.001	< 0.001*

CI, confidence interval.

*, Significant results (*P*-value ≤ 0.05).

imperative that the use of inhalational corticosteroids for treatment of asthma and other conditions be better monitored and regulated including mainstreaming regular IOP assessments for these patients. What is your recommendation based on this statement?

Regarding the predictors of the risk of elevated IOP among the study population, it was found that being aged below 41 years, having received primary or secondary education or less than tertiary education and the intake of inhalational steroids were predictive of developing elevated IOP. These findings agree with the results of other studies. Different factors have been reported in various studies to be predictors of developing elevated IOP and glaucoma. These include younger age (< 41 years of age), previous history of glaucoma, long-term use of corticosteroids, history of cataract surgery, eye trauma history and alcohol consumption, among others.[12,24] The implication of this finding is its applicability as an early warning system for individuals at risk of developing glaucoma. It is important to observe that prompt identification of these people can take place at the primary care level where these predictive factors can be used as a screening tool for people at that level of care. When identified, these people can then be referred to higher levels of care where more objective risk factors can be used to make the appropriate diagnosis and promptly commence treatment.[12,24]

Conclusion

In this study, inhalational steroids use by asthmatics was identified as a risk factor for increase in IOP from the fourth month of use. The proportion of participants with elevated IOP was also found to increase further 5 months after use of inhalational steroids. Younger patients, lower levels of education and use of inhalational steroids were identified as predictors of elevated IOP among study participants. Therefore, there is a need for asthmatics who are likely to be on prolonged use of inhalational steroids to have IOP measurements at regular intervals, so that IOP elevation can be readily identified and timely management instituted to prevent the development of glaucoma.

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRediT authorship contribution

Diamond Tonye-Obene: Conceptualisation, Data collection and processing, Writing – initial draft. Kate Akokwu: Conceptualisation, Data collection and processing, Writing – initial draft. Godswill I. Nathaniel: Literature search, Data curation, Editing. Omosivie Maduka: Literature search, Data curation, Editing. Elizabeth A. Awoyesuku: Review, Writing – final draft. Chinyere N. Pedro-Egbe: Review, Writing – final draft. All authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication and take responsibility for the integrity of its findings.

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Data availability

The data that support the findings of this study are available from the corresponding author, Godswill I. Nathaniel, upon reasonable request.

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