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Analgesic characteristics of intrathecal neostigmine versus dexmedetomidine with hyperbaric bupivacaine for labour and delivery: A double blind randomized study

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Abstract

Introduction: The birthing process is one of the most painful events a woman can experience. Minimizing the pain parturients experience is now being considered the right of every parturient globally. The aim of this study was to compare two medications as adjuncts to bupivacaine in labour analgesia.
Materials and methods: One hundred and sixty-six consenting parturients were randomly assigned to receive single shots of intrathecal doses of 2.5 mg of 0.5% hyperbaric bupivacaine with either 2.5µg of dexmedetomidine or 25µg neostigmine as adjuvants. Intrathecal injections were made at the attainment of 5cm cervical dilatation in the labouring woman. The parameters compared included, the haemodynamic parameters, onset/duration of analgesia, pain scores of parturients and the foetal outcome. Data analysed using Stata version 13.0 and $p<0.05$ was considered statistically significant.
Results: The results showed similarity in the socio-demographic variables, obstetric and baseline haemodynamic characteristics between parturients in the two groups. The median onset of analgesia was significantly faster 2(1-2) min and mean duration of analgesia significantly longer (155.55±39.88 min) in the dexmedetomidine group ($p=0.007$) compared to the neostigmine group 2(1-3); 114.11±26.71 min) ($p<0.0001$). The parturients in the dexmedetomidine group had lower pain scores compared to the neostigmine group. ($p<0.001$).
Conclusion: This study showed that dexmedetomidine as an adjuvant to hyperbaric bupivacaine shortened the onset of analgesia/prolonged the duration of analgesia than neostigmine and also offered lower pain scores as an adjuvant to hyperbaric bupivacaine in single shot spinal for labour analgesia. We recommend dexmedetomidine as an adjunct to hyperbaric bupivacaine for single-shot spinal for labour analgesia.

Keywords: Dexmedetomidine, Neostigmine, Hyperbaric Bupivacaine, Single-shot Spinal, Labour

Introduction

Labour is a physiologic process during which the products of conception are expelled from the uterus. Established labour occurs at a cervical dilatation of 3-4 centimetres and heralds the most painful period of labour.[1] Labour analgesia should be considered a right of every parturient.[2] The provision of analgesia during labour is influenced to a large extent by a lot of factors including techniques and drugs.[2] Epidural analgesia is considered the gold-standard but it is

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froth with challenges, hence the quest for some other readily available and equally effective methods.[3] The main objective of this study was to compare the analgesic efficacy of neostigmine against dexmedetomidine as adjuncts to 0.5% hyperbaric bupivacaine for single-shot spinal technique for labour analgesia.

Materials and methods

Study Location: This study was carried out at the Obstetrics complex of the University of Uyo Teaching Hospital, Uyo, Akwa Ibom State, south-south Nigeria. The hospital is the only federally owned tertiary health facility and serves as a referral centre for the various primary and secondary health facilities in the state and beyond.

Sampling Technique and Study Design: One hundred and sixty six consecutive labouring multiparous women were recruited into this prospective, randomized, double blind interventional study.

Study Population with inclusion and exclusion criteria: Included in the study were all laboring multiparous women who consented to be part of the study. Excluded from the study were, all primiparous women, those with gestational age of <37 or >42 weeks, multiple gestations, non-consenting parturients, complicated pregnancies such as, pregnancy induced hypertension, diabetes, and previous Caesarean sections.

Sample size Determination: The sample size for the study was calculated for a hypothesized difference in the labour analgesia duration by 25% between the groups. We considered 80% power, and the sample was calculated with a 95% confidence which gave a sample of 75 patients per group. However, we decided to recruit 83 participants per group using 10% attrition rate which was added to the minimum sample size of 75 (which gave 7.5 and was rounded up to 8) making the total sample size of 83 per group and 166 for the two groups.

Study Procedure: The parturients were randomly allocated into two groups. One group received an intrathecal neostigmine 25µg with 0.5% bupivacaine 2.5mg admixture while the other group had dexmedetomidine 2.5µg and 0.5% bupivacaine admixture. On presenting in the labour ward, the parturient was counseled for labour analgesia. Following the consent for the treatment, an intravenous fluid was commenced using either ringer's lactate or saline as preload. Baseline vital signs such as pulse, blood pressure, peripheral oxygen saturation and foetal heart rates were measured and recorded.

Prior to the administration of the study agents, all the parturients received either 500ml of saline or ringer solution. All procedures were performed on the parturients in sitting position under aseptic conditions by an anaesthetist not involved in the data collection.

Parturients received spinal block using a 25 gauge Quincke needle. The puncture was performed between L4 - L5 intervertebral space, and after a successful dural puncture, 0.5 mL (2.5 mg) 0.5% hyperbaric bupivacaine with 25 µg neostigmine was injected in one of the groups while 0.5 mL (2.5 mg) 0.5% hyperbaric bupivacaine with 2.5 µg dexmedetomidine was injected in the other group. All injections were carried out at the attainment of cervical os dilatation of 5cm.

The numeric rating scale was explained to the parturient, to imagine a line numbered 0-10, where 0 implies no pain at all, 1-3 means mild pain, 4-6 means moderate pain, 7-9 means severe pain and 10 means the worst pain imaginable. All patients were returned in the supine position with a mild head-up position and 15-20o left uterine displacement for the first 15 min; then, they were allowed to have any desired position but prevented from walking around. The cardiotocograph belt was wrapped around the abdomen to monitor the strength, frequency of contractions and the foetal heart rates (FHR). The FHR monitoring was continuous throughout labour, and any deceleration of FHR was recorded.

The primary outcome measure was duration of pain relief; defined as onset of analgesia to end of sensory blockade. The secondary outcome measures were onset of analgesia; defined as time from intrathecal injection to pain scores <6 using numeric rating scale or sensory block height of T10, end of sensory block defined as pain scores >6 or sensory block regression to S1 dermatomal level. Other parameters monitored were haemodynamic

changes from baseline. Parturients blood pressure was checked immediately, then every 2 min in the first 15 min and every 5 min thereafter. Other vital signs such as maternal heart rate, oxygen saturation, foetal heart rate and variability were monitored continuously. The height of sensory block and pain scores were monitored using pin prick test and numeric rating scale (NRS) and respectively at 1 min, 3 min, 5 min, 10 min, 15 min and then every 30 min interval until either at delivery of the foetus or request for additional analgesia. Parturients who needed for additional analgesia were either given boluses of analgesic doses of intravenous ketamine at 0.3 mg/kg or a repeat subarachnoid block. Parturients who experienced nausea and vomiting were given a repeat dose of intravenous metoclopramide 10 mg. A cylinder of oxygen, simple face mask and nasal prong were on stand-by for management of desaturation. Mild decreases in blood pressure were managed using intravenous saline, although ephedrine was available to treat moderate to severe hypotension and, atropine for bradycardia. Persistent wide foetal heart variability was managed by supplemental oxygen, fluid resuscitation or immediate Caesarean delivery.

Data Analysis and Study Variables: Data were entered and analysed using the Statistical Package for Social Sciences [SPSS], IBM SPSS statistics for windows, version 22.0. Categorical data like the occupation, level of education, marital status, religion, and ethnicity were summarized as frequencies and percentages. The quantitative variables like age, parity, gravidity, gestational age, onset of analgesia and duration of analgesia were summarized using means and standard deviations [or median and interquartile range if they were not normally distributed]. To compare the difference in the onset of analgesia, duration of analgesia between the two groups, Student t test [or its non-parametric equivalent, Mann-Whitney U –test] was used to compare the means [or median] of these continuous data. All p-values < 0.05 was considered as statistically significant

Ethical Issues: Following the approval of the University of Uyo Teaching Hospital's Ethics and Research Board with reference number, UUTH/AD/S/96/VOL.XXI/244, informed consent was also obtained from the parturients for participation in the study.

Results

A total of one hundred and sixty-six (166) parturients consented and were recruited for the study. Eighty three (83) were recruited into the dexmedetomidine group and the other eighty three (83) into the neostigmine group. Of the eighty three parturients in the dexmedetomidine group, 3 (3.6%) were excluded. Two (2.4%) were excluded as a result of failed spinal and 1 (1.2%) due to lack of cooperation for the procedure. Hence, eighty (96.4%) parturients were studied to the end. Of the eighty three (83) parturients in the neostigmine group, 4 (4.8%) were excluded from the study. Two (2.4%) were excluded due to failed spinal and another 2 (2.4%) because of precipitate labour. Hence, seventy nine (95.2%) parturients were studied to the end.

The socio-demographic variables between the two groups were compared as shown in Table I. There was no statistically significant difference between the mean ages of parturients in the 2 groups (p=0.35), level of education of parturients (Fishers exact p=0.34) and religion of the parturients (Fishers exact p=0.50). There was a significant association between marital status and the study groups of the parturients (Fishers exact p=0.03). The mean Body Mass Index (BMI) of parturients was similar in both groups (Fisher's exact p=0.16).

The obstetric characteristics of the parturients were compared as shown in Table II. The gravidity, parity, number of children alive, complications in index and previous pregnancies of parturients and type of labour onset (spontaneous or induced) in both groups were statistically similar (p=0.80, 0.41, 0.58, 0.37, 0.08 and 0.05 respectively). The cervical dilatation of parturients at presentation, at time of

Table I: Socio-demographic characteristics of parturients

Variable	Study Groups		Total n(%)	Statistical test and values (p-value)
	Dexmedetomidine (n=80)	Neostigmine (n=79)		
Age (in years)	30.87±3.77	30.25±4.52	30.57±4.16	0.35**
Education Level				
Primary	0 (0.00)	3 (3.80)	3 (1.90)	0.34*
Secondary	17 (21.52)	17 (21.52)	34 (21.52)	
Tertiary	62 (78.48)	59 (74.68)	121(76.58)	
Marital status				
Married	80 (100.00)	74 (93.67)	154(96.86)	0.03*
Cohabit	0 (0.00)	3 (3.80)	3 (1.89)	
Single	0 (0.00)	2 (2.53)	2 (1.26)	
Religion				
Christianity	80 (100.00)	78 (98.73)	158(99.37)	0.50*
Islam	0 (0.00)	1 (1.27)	1 (0.63)	
BMI (kg/m²)	29.53±4.85	28.60±5.45		0.26**

*Fischer's Exact test; Number (Percentage); Mean±Standard deviation
**=Student t-test

Table II: Obstetric characteristics of Parturients

bles	Study Groups Dexmedetomidine (n=80)	Neostigmine (n=79)	Total	p values
dity	2 (2-3)	2 (2-3)	2 (2-3)	0.49†
	51 (63.75)	45 (56.96)	96 (60.38)	0.41*
	16 (20.00)	23 (29.11)	39 (24.53)	
	13 (16.25)	11 (13.92)	24 (15.09)	
children Alive				
ıan or equal to 2	71 (88.75)	70 (88.61)	141 (88.68)	0.98*
2	9 (11.25)	9 (11.39)	18 (11.32)	
lications in index pregnancy				
	4 (5.00)	7 (8.86)	11 (6.92)	0.37**
	76 (95.00)	72 (91.14)	148 (93.08)	
lications in previous pregnancy				
	9 (11.25)	17 (21.25)	26 (16.35)	0.08*
	71 (88.75)	62 (78.48)	133 (83.65)	
of labour onset				
aneous	55 (68.75)	65 (82.28)	120 (75.47)	0.05*
ed	25 (31.25)	14 (17.72)	39 (24.53)	
cal dilatation ıtation(median/IQR)	2 (0-4)	2 (2-4)	2 (2-4)	0.12†
cal dilation at block +/-SD) (in cm)	4.67±0.81	4.87±0.98	4.77± 0.90	0.16***
ion of contraction at (in seconds)	38.64±8.11	38.04±7.42	38.34± 7.75	0.63***
al of contraction at ade (in seconds)	167.5±34.91	174.81±32.54	171.13± 33.85	0.17***
ion of ır(n=142) an(IQR) in minutes	135 (85-199)	100 (70-135)	120 (80-185)	0.009f

nn-Whitney U Test, *=(Chi test); **=Fishers Exact Test; ***=Student t -test ; Inter quartile range; SD=Standard deviation

Table III: Mean onset and duration of analgesia between parturients in the two groups

Variable	Study Groups Dexmedetomidine (n=80)	Neostigmine (n=79)	Total n(%)	p values
Duration of analgesia (Mean +/- SD) (in min)	155.55±39.88	114.19±26.71	135.00± 39.72	0.001*†
Onset of Analgesia (median (IQR) (in min)	2(1-2.5)	2 (1-3)	2 (1-3)	0.007∞

*Student's t-test; ∞Wilcoxon rank sum test; SD=Standard deviation; IQR=Interquartile range;

Table IV: Median Pain scores of parturients in two labour analgesia groups

Time of Assessment (in Minutes)	Frequency (Dex:Neo)	Pain Scores Dex (n=80)	Neo (n=79)	Total (n=159)	p values
0	80:79	10(10-10)	10(10-10)	10(10-10)	0.10*
1	80:79	2(0-6)	3 (0-6)	2 (0-6)	0.40*
3	80:79	0(0-0)	0 (0-2)	0 (0-0)	0.007*
5	80:79	0(0-0)	0 (0-0)	0(0-0)	0.007*
10	80:79	0(0-0)	0 (0-0)	0 (0-0)	0.007*
15	80:79	0(0-0)	0 (0-0)	0 (0-0)	0.007*
30	80:79	0 (0-0)	0 (0-0)	0 (0-0)	0.002*
60	80:79	0 (0-0)	0 (0-2)	0 (0-1)	<0.001*
90	79:77	0 (0-2)	3 (2-5)	2 (0-4)	<0.001*
120	78:73	2.5(0-5)	6 (5-8)	5 (2-7)	<0.001*
150	68:54	5 (3-7)	9 (7-10)	7 (4-10)	<0.001*
180	59:24	7 (5-9)	10 (9-10)	8 (6-10)	<0.001*
210	37:6	10(8-10)	10(10-10)	10(8-10)	0.08*

*=Wilcoxon rank sum test. Pain scores summarized as Median (IQR) where IQR=Interquartile range; Dex=Dexmedetomidine, Neo=Neostigmine

block as well as duration of uterine contractions and interval of uterine contractions at blockade were statistically similar in the 2 groups (p=0.12, 0.16 and 0.68 and 0.17 respectively).

The mean onset and duration of analgesia between the two labour analgesia groups were compared as shown in Table III. The mean onset of analgesia was significantly earlier 2 (range - 1-2) minutes in the dexmedetomidine group compared to the neostigmine group 2 (range - 1-3) minutes (p=0.007). The mean duration of analgesia was significantly longer (155.55±39.88 minutes) in the dexmedetomidine group than neostigmine group (114.11±26.71 minutes) (p<0.0001).

The median pain scores of parturients in both groups were compared as shown in Table IV. The median baseline pain scores of parturients in the two groups were similar. The median pain scores of parturients after blockade in both groups were statistically similar at 1 minute (p=0.40). However, from 3 minutes to 180 minutes, the parturients in the neostigmine group had values that were significantly higher than parturients in the dexmedetomidine group (p= 0.007; 0.007; 0.007; 0.007; 0.002; <0.001; <0.001; <0.001; <0.001; and <0.001 respectively). At 210 minutes, the median pain scores of both groups were again similar (p=0.08).

Table V represents the parturients' mean baseline vital signs/foetal heart rate and regularity. Parturients' mean baseline vital signs; heart rate,

Table V: Haemodynamic parameters of the Parturients and Foetal Heart Rate during labour

Variable	Study Groups Dexmedetomidine (n=80) (Mean±SD)	Neostigmine (n=79) (Mean±SD)	Total n (%)	p value
Maternal heart rate (per minute)	83.41±9.63	84.19±11.08	83.80±10.35	0.64†
Maternal MAP (in mmHg)	86.16±10.65	86.18±8.84	86.17±9.76	0.99†
Maternal SBP (in mmHg)	119.84±16.18	117.83±12.75	118.84±14.56	0.39†
Maternal DBP (in mmHg)	69.77±9.52	70.47±8.30	70.12±8.91	0.62†
Maternal Temp (°C)	36.72±0.34	36.70±0.34	36.71±0.34	0.71†
Maternal Resp rate (cycles/minute)	21.75±2.44	21.29±1.71	21.52±2.11	0.17†
Foetal heart rate (in beats/min)	138.7±6.44	140.58±5.67	139.63±6.12	0.05†

†= Students t-test, SD= Standard Deviation MAP=Mean arterial Pressure, SBP= Systolic Blood pressure, DBP=Diastolic Blood Pressure

Table VI: The mean Apgar scores of the neonates in the two groups

Variable	Dexmedetomidine N (80)	Neostigmine N (79)	p-value
APGAR Scores (mins)			
1	8.5±0.4	8.4±0.5	0.96
5	9.68±0.2	9.64±0.3	0.62
10	9.0±0.8	9.97±0.5	0.30

Mean±Standard Deviation. Statistical test used= Students t-test

systolic and diastolic blood pressures, mean arterial pressure (MAP), temperature and respiratory rates were not significantly different between the two groups (p=0.64; 0.99; 0.39; 0.62; 0.71 and 0.17 respectively). Foetal heart rate and regularity was not significantly different in the neostigmine group compared to the dexmedetomidine group (p=0.05).

Discussion

This index study showed that adequate analgesia can be achieved during labour by offering parturients single-shot spinal using low dose 0.5% hyperbaric bupivacaine at 2.5 mg as the principal agent in combination with either low dose dexmedetomidine at 2.5 µg or low dose neostigmine at 25 µg as adjuncts.

The median onset of analgesia in this index study in both the dexmedetomidine and neostigmine group was 2 min, with a statistically significant earlier median onset in the dexmedetomidine group (1-2.5 min) compared to the neostigmine group (1-3 min). The onset of action of 0.5% hyperbaric bupivacaine for subarachnoid block is 3-5 min at a standard dose of 10-15 mg.[4] The quick onset of analgesia observed in our study could be due to the addition of the adjuvants to low dose 0.5% hyperbaric bupivacaine. Dexmedetomidine has been used as an adjuvant to 0.5% hyperbaric bupivacaine in other studies to achieve a faster onset of analgesia.[5] One study by Fyneface-Ogan et al[6] using 2.5 mg of 0.5% hyperbaric bupivacaine and 2.5 µg of dexmedetomidine as an adjuvant demonstrated an earlier onset of analgesia with bupivacaine/dexmedetomidine admixture compared to those of bupivacaine/fentanyl group and bupivacaine alone group respectively. Based on their study, dexmedetomidine demonstrated the property of hastening onset of analgesia compared to the other adjuvants. Although the Fyneface-Ogan et al[7] study used same doses of drug as in this index study. The difference in the onset of action between the study by Fyneface-Ogan et al and this present study cannot be explained. However, the common finding between these two studies using dexmedetomidine as adjuct, were the longer duration of sensory and motor blockade, stable haemodynamic condition and good patient satisfaction. Al-Mustapha et al, studied the effect of dexmedetomidine, although in a higher dose (between 5 and 10µg) with bupivacaine in urology procedures. They found that dexmedetomidine prolongs the duration of spinal anaesthesia.[8] This establishes the fact that dexmedetomidine prolongs the duration of analgesia in a dose-dependent manner.

One study has demonstrated that the addition of intrathecal neostigmine has been shown to be effective in improving analgesia in the acute postoperative period.[9] Nevertheless, the improvement in analgesia after adding intrathecal neostigmine to other spinal medications in peripartum settings was very small. This finding explains the difference in the potency of dexmedetomidine over neostigmine in our study. Intrathecal escalation of the dose of intrathecal neostigmine is well known to produce side effects such as nausea and vomiting reported to be severe, repetitive, prolonged, and resistant to prevention or treatment by antiemetic drugs.[10] Other disturbing effects of neostigmine, even at low doses include increase in risk of agitation, restlessness, faecal incontinence, sweating above the level of the sensory block and intensive salivation.

The differences in onset of action and duration of action between the two study agents could be related to their mechanism of action. An intrathecal neostigmine produces analgesic effects by the inhibition of spinal cholinesterase resulting in an increase of endogenous acetylcholine through muscarinic presynaptic inhibition of glutamatergic afferents. Muscarinic receptor antagonists have been shown to reverse the analgesic effects of intrathecal neostigmine.

However, dexmedetomidine when administered intrathecally acts at the spinal and supraspinal levels. It activates α2-adrenergic receptors in the spinal cord, reducing transmission of nociceptive signals, inhibiting substance P's release, and contributing to their analgesic action, and has a significant opioid-sparing effect.[11] At the supraspinal level, it binds to the presynaptic α2-adrenergic receptors in locus ceruleus, producing sedation and anxiolysis; postsynaptic activation in CNS inhibits sympathetic activity leading to a decrease in heart and blood pressure.

The mean duration of analgesia observed in our index study in the dexmedetomidine group was 155.55±39.88 minutes while that in the neostigmine

group was 114.19±26.71 minutes. The study by Fyneface-Ogan et al[7] using 2.5 mg of 5% hyperbaric bupivacaine as the principal agent and 2.5 µg of dexmedetomidine as an adjuvant resulted in duration of analgesia of 268.9 min and 107.9 minutes for the bupivacaine alone group. Although our index study using similar doses of 0.5% hyperbaric bupivacaine and dexmedetomidine resulted in duration of analgesia of 155.55±39.88 minutes, the reason for the differences in the results cannot readily be explained. The mean duration of analgesia in the study by Yogarasimha et al[12] using 50 µg of neostigmine with 12.5 mg of 0.5% hyperbaric bupivacaine resulted in 300±25 min. The longer duration of analgesia observed in their study could be due to the higher doses of drugs used compared to our index study where low doses of drugs (0.5% hyperbaric bupivacaine 2.5mg and neostigmine 25 µg) were used.

There was a reduction in the median pain scores in parturients in both study groups compared to baseline. This reduction was noted from the 3rd minute after institution of block, with significantly lower median pain scores in the dexmedetomidine group compared to the neostigmine group. The lowered median pain scores lasted significantly longer in the dexmedetomidine group (150 min) compared to the neostigmine group (about 120 min). The pain scores correlated well with the onset and duration of sensory blockade in this index study. Fyneface-Ogan and colleagues also reported lower pain scores in the dexmedetomidine group compared to the fentanyl group and bupivacaine-alone group in their study.[7] The presence of lower pain scores in the dexmedetomidine group compared to the neostigmine group can be explained by the potential of dexmedetomidine to potentiate the analgesic effect of local anaesthetic agents irrespective of the route of administration.[13]

Choosing a medication needs consideration for the highest efficacy yet having the lowest side effects. In our study the haemodynamic profile of the parturients in the two groups was comparable. Whilst neostigmine can elevate the blood pressure and heart rate due to its excitatory actions on preganglionic sympathetic neurons, dexmedetomidine is well known to cause a decrease in blood pressure and heart rate. The lack of recordable wide variations in the haemodynamic parameters in our study could have been due to the low doses used.

Dexmedetomidine has the propensity to cause respiratory depression in the newborn. However, this effect appears to be in a dose-dependent manner. Both neuraxial neostigmine/bupivacaine and dexmedetomidine/bupivacaine admixtures used in our study had no adverse effect on Apgar scores, and no effect on the incidence of abnormal foetal heart rate patterns as evidenced by the comparable outcomes. This finding in our study confirms an earlier observation by other workers.[14,15]

We performed the current study in a prospective manner, eliminating selection bias by randomization, and ensured double blinding by masking the syringe for the administration of the intrathecal drug and using an equally competent anaesthesiology not involved in the data collection to administer the injectate. However, the index study is not free of limitations. One of the limitations is the involvement of a single centre for this study. A multi-centre study would have given a broader perspective of the study. Secondly, only healthy parturients were recruited and the study findings may not be reproducible with some or other diseases. Finally, only two drugs were used for the study. A better comparison would have been achieved if a third medication had been used. Therefore, a multicentre double blind prospective study using other adjuvants could be added to investigate the best-suited intrathecal adjuvant for labour analgesia.

Conclusion

In conclusion, efficient labour analgesia can be practiced in Nigeria within the available manpower and resources. This has been demonstrated in this index study where neostigmine, a readily available drug, was combined with hyperbaric bupivacaine in low doses to provide some analgesia to parturients. Dexmedetomidine, an alpha 2 adrenergic agent provided a longer duration of analgesia when used as an adjuvant in low dose to bupivacaine, but dexmedetomidine is not readily available.

Conflict of interest: None to declare

Authors' contribution: Udeme N conceived, designed the study and wrote the manuscript, while Ekanem A performed the data analysis. Eyo C, Etta

O and Edubio M supervised the research and read through the first and final draft of the manuscript. Abasiatai A provided some research materials and also supervised the research. Fyneface-Ogan supervised the research and also contributed to the final manuscript writing.

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