Research Article

Nasal Decongestant Effects of *Vitellaria paradoxa* (Shea Butter) Extracts, a Hospital Based Study

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Abstract

Background: Mucosal inflammation underlies many of the specific and interrelated factors that contribute to nasal congestion and shea butter is used by local healers as a treatment for inflammatory conditions including nasal congestion. The aim of this study was to evaluate the effects of extracts of Shea butter on diagnosed patients with Nasal congestion.

Methods: Forty-Two study participants were randomized into two main groups-control (standard of care-Cetirizine, Xylometazoline) and then the shea butter/shea butter extract group which was further subdivided into 4 groups extract 1 (saponifiable); extract 2 (non-saponifiable), extract 3 (Steroid) and shea butter. Following the administration of the various drugs, participants were followed for 24 hours with nasal washout samples taken at baseline and 24 hours later, then analyzed for the presence of inflammatory cells. All test substances were assessed for efficacy in terms of time of onset of action and duration at which almost complete relief from nasal congestion was achieved using median scores and ANOVA within each group.

Results: The participants had moderate to severe nasal congestion. The test group received shea butter and shea butter extracts the control groups received xylometazoline, and Cetirizine treatment. Visual Analogue Scale (VAS) was used to subjectively assess the degree of relief from nasal congestion in these patients with a score of 1 as minimum relief and 10 as maximum relief from nasal congestion per time. The findings suggests that, the shea butter/shea butter extracts test groups experienced nasal decongestion with non-saponifiable extract of shea butter having a short onset of action and eliciting complete relief after 4 hours (median VAS score of 9.7). The non-saponifiable extract was as effective as the standard of care groups–(cetirizine with median VAS score of 7.3 and Xylometazoline with median VAS score of 7.7) for the same time.

Conclusion: From this study, it is clear that shea butter and shea butter extracts may be more effective than conventional standard of care drugs in treating nasal congestion and should be recommended as a healthy non synthetic alternative with almost no adverse effect and may be a latent source of novel therapeutic agent.

Keywords: Shea butter; Nasal congestion; Nasal decongestant; Cetirizine, Xylometazoline; VAS; *Vitellaria paradoxa*

Introduction

Nasal congestion is caused by a wide range of medical and environmental factors, and it is most often described differently by many patients. Nasal congestion may be best described as a perception of reduced airflow or a sense of nasal fullness, and the patient's perception of congestion is the key consideration in clinical medicine. Allergic Rhinitis is one of the most common diseases associated with congestion and it is estimated to affect well over one quarter of the world's population [1].

Shea butter is an edible extract from the seed of the shea tree (*Vitellaria paradoxa*, formerly *Butyrospermum parkii*). Harvested and deshelled seeds undergo a process of grinding, roasting, milling and boiling, which releases the fats and eventually cools into the ivory-coloured shea butter. Shea butter is rich in oleic acid, an omega-9 fatty acid; and is readily absorbed by the skin. It is used in many skincare products for its moisturising and moisture-preserving properties. Shea butter is also used in some African countries as a cooking oil and as medicine.

Globally, people have developed unique indigenous healing traditions adapted and defined by their culture, beliefs and environment, which satisfied the health needs of their communities over centuries [2]. Despite the widespread use of herbal medicines globally and their reported benefits, their quality and quantity control are not assured [3]. The ready availability and unregulated use of several herbal medicines may put the health of their users at risk of toxicity [4,5].

Pharmacological treatment of nasal congestion is based on the use of antihistamines, steroids and anti-cholinergic nasal sprays which contain agents like cetirizine, loratidine, and xylometazoline which may even have a risk for addiction

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in some patients and may not be readily accessible or even expensive. These approaches are not just expensive but come with risk and are not certain to ameliorate Nasal congestion in patients. There is therefore a need to discover and develop more effective nasal decongestant that are efficacious and potent with minimal acceptable side effects.

The extract of *Vitellaria paradoxa* is used in Nigerian traditional medicine for the treatment of skin growth, Hair growth, decongestion of nose, cough and Antibacterial effects etc has not been fully studied to ascertain the exact Nasal decongestant activities and toxicity of it, Hence, this investigation is geared towards linking the healthful effects of shea butter and its extracts in treatment of nasal decongestion as a non-synthetic and readily accessible option and improve the use of the seed among users, and ultimately contribute to knowledge in terms of onset of action, duration of action of treated patients compared to standard of care (cetirizine and xylometazoline) and evaluating if nasal washout confirms improvement in relief observed.

Materials and Methods

This was a descriptive interventional (randomised controlled) study that lasted for 12 months (January-December 2022).

All instruments and procedures were approved by the ethics committee of the University of Port Harcourt/University of Port Harcourt Teaching Hospital.

Recruitments

Study participants were recruited from the UPTH ENT out-patient clinics using acceptable methods to include only patients with Nasal congestion. Each participant completed a questionnaire after which they were enrolled and informed consent was obtained. The questionnaires when returned were edited for missing data and stray marks. A Visual Analogue Scale (VAS) was also given to each patient to self-assess their relief from nasal congestion.

A Visual Analogue Scale (VAS) is a psychometric tool commonly used in the Rhinology discipline to subjectively measure the intensity of a patient's symptoms (nasal congestion) [6].

Plant collection

Fresh seeds of *Vitellaria paradoxa* were collected in Birnin Gwari Local Government Area of Kaduna State, Nigeria and authenticated by Dr. Olusayo Shorinwa of the Faculty of Pharmaceutical sciences, University of Port Harcourt with a Herbarium number.

Preparation of shea butter

The collected seeds were washed, boiled in distilled water for at least 1 h and dried by spreading out in the sun for 5.5 hours (10.00-15.30 hours) daily for a period of 4 weeks. After the drying, each seed was cracked to remove the testa and the tegmen which separates easily exposing the kernel. The seeds on the average weighed 15.5 g-17.0 g when collected, and 1 1.0 g-14.5 g after drying, and the average weight of the kernels was usually about 8.0 g-10.5 g. The kernels were then washed with distilled water, dried and were finely ground in an electric grinder with a modest amount of water. The acquired dark paste was worked up till it took on a lighter consistency. When water at 280°C was added to the kneaded mixture, white curds formed and floated to the top of the water. The curds were then transferred into a water-filled container. The separated curds were cooked in an aluminum saucepan until they entirely demulsified after being softly pressed to minimize the amount of water inside of them. After 15 minutes of heating the curds, the mass had completely demulsified without completely evaporating the aqueous layer, at which point the heating was immediately halted. Throughout the boiling process, a small, well cleaned and dried stick was introduced into the pot to make sure the oil layer had completely separated. After letting the combination of oil, water, and sediments in the pot to settle, the generated oil was decanted to form a sharp interphase. This paste was taken up in 20 volumes of distilled water, stirring vigorously for about 30 min and then left at room temperature for 24-48 hours. During this period, globules of a greasy soft waxy solid separated and collected on the surface of the solution. This product was separated and boiled to remove moisture and on being allowed to cool, solidified as shea butter. Thus, from the kernels weighing 1.1 kg, 198 g of shea butter was obtained.

The shea butter was then sent to the laboratory for gas chromatographic separation for the extracts used in this study.

Experimental design group

Forty-Two patients whose nasal congestion was confirmed in clinic by a consultant ENT surgeon participated in this study. Participants were all Nigerians-males and females alike, consisting of staff of the Department of surgery, University of Port Harcourt, members of their families and friends and Patients with ages ranging from 20-50 years.

Any case not responding to symptomatic treatment within 3 hours, or known to have been on antibiotic medication up till at least 3 weeks previously, were excluded from the study. In this way, conditions like sinusitis, for instance, were excluded from the study so as not to delay appropriate treatment, and the study was thus confined primarily to symptomatic relief of inflammatory nasal congestion. All the subjects presented with moderate to severe or complete nasal blockade. All 42 subjects were randomly selected into several treatment groups, notably, the test group which was treated with shea butter and shea butter extracts, the control group treated with 0.1% solution xylometzoline, and 10 mg Cetirizine tablet.

Upon establishment of moderate to severe nasal congestion, about 2-4 g each of shea butter, various shea butter extracts were applied to the interior of the nose of each subject by means of the swab stick smeared with extracts. The outside of the nose was wiped clean of any excess shea butter or shea butter extracts, using tissue paper. In the control group, with the head held well back, 2-3 drops of xylometazoline were dropped into each nostril and the head held in that position until the taste of the nasal drops was felt in the mouth, another group received 2.5 mg of cetirizine. As soon as decongestion was experienced, onset of action was charted by patient using VAS. The study on each subject was followed up for 24 hours. 2 ml of nasal washout was collected from each participant in the study at

recruitment and 24 hours post administration of 1st dose (end of study) in a Plain bottle for smear cytology.

Co-primary endpoints

No relief after 3 hours of application; or worsening congestions; Reversal of Nasal congestion.

Secondary endpoints

Improved Quality of life; Nasal Smear cytology showing regression in inflammatory cells; Programme acceptability.

Sample collection and analysis

Statistical analysis would be calculated using the computer software Microsoft Office Excel 2017 for the graph and Statistical Packages for Social Science (SPSS) version 25 for inferential statistics

Discrete data were analysed and presented as frequencies and % frequencies, while continuous variables were mainly presented as mean with: arithmetic means, median scores and standard deviations. The data was not normally distributed hence difference in median scores were measured using Kruskal_ Wallis ANOVA.

Results

The level of control was determined using the following cut-off values (median scores) for nasal decongestion relief per time: mildly controlled (VAS<2), moderately controlled (VAS 2 and <5), and highly controlled (VAS ≥ 5). A score of 1-10 for relief perceived was requested verbally from 20 randomly chosen non-responders who matched the inclusion criteria in order to best mimic the impact of the scale and eliminate any potential responder bias from the written questionnaires.

Mildly controlled corresponds to onset of action of relief from nasal congestion as represented on VAS per time using median scores were Xylometazoline 1.8 then Saponifiable and steroid 1.3, followed by Non saponifiable 1.2, shea butter 1 and least response was seen with cetirizine 0.5 within one minute (Table 1).

Highly controlled corresponds occurred first at 20 minutes with non-saponifiable. Maximal response was seen with in 4 hours with non-saponifiable (Figure 1).

After 1 hour only non-saponifiable and saponifiable had achieved a median VAS score of 7 and above. Maximal VAS score after 4 hours was 7.3-7.7 shared between Standard of care and Steroid extract of shea butter.

Discussion

A questionnaire was issued to 60 persons who satisfied the inclusion criteria, and 42 returned a completed questionnaire (response rate 70%). Eighteen patients were removed due to incomplete questionnaire completion and/or lack of informed permission. The eligible patient's data were used for analysis after completing the VAS symptom severity ratings questionnaire. Seventy Six percent of the 42 participants studied were females, while 23.8% were males. The average age of the people surveyed was 29.41 years, with a range of 20 to 50 years. About 30 of the 42 participants lived in urban setting while the remaining 12 lived in semi-urban to rural setting. Only 6 of the 42 participants were exposed to artisanal refining (Table 2).

Table 1: Sociodemographic characteristics of study participants.

Variable	Treatment Group						Chi square	P-value
	Cetrizine n (%)	Nonsaponi n (%)	Otrivine n (%)	Saponi n (%)	Shea n (%)	Steroid n (%)		
Gender								
Male	2 (25.0)	0 (0.0)	3 (50)	2 (28.6)	2 (25.0)	1 (16.7)	4.675f	0.5
Female	6 (75.0)	7 (100.0)	3 (50)	5 (71.4)	6 (75.0)	5 (83.3)		
Age								
45-49	2 (25.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)		
40-44	0 (0.0)	1 (14.3)	0 (0.0)	2 (28.6)	3 (37.5)	0 (0.0)		
35-39	1 (12.5)	2 (28.6)	2 (33.3)	0 (0.0)	2 (25.0)	1 (16.7)		
30-34	1 (12.5)	1 (14.3)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)	29.417f	0.223
25-29	1 (12.5)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)		
18-24	3 (37.5)	0 (0.0)	2 (33.3)	2 (28.6)	3 (37.5)	2 (33.3)		
≥ 50	0 (0.0)	3 (4.29)	0 (0.0)	2 (28.6)	0 (0.0)	1 (16.7)		
Refining								
Yes	2 (25.0)	1 (14.3)	0 (0.0)	2 (28.6)	0 (0.0)	1 (16.7)	4.131f	0.586
No	6 (75.0)	6 (85.7)	6 (100.0)	5 (71.4)	8 (100.0)	5 (83.3)		
Residence								
Urban	3 (37.5)	5 (71.4)	4 (66.7)	7 (100.0)	6 (75.00	5 (83.3)		
Semi Urban	4 (50.0)	1 (14.3)	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	10.425f	0.273
Rural	1 (12.5)	1 (14.3)	1 (16.7)	0 (0.0)	0 (0.0)	1 (16.7)		

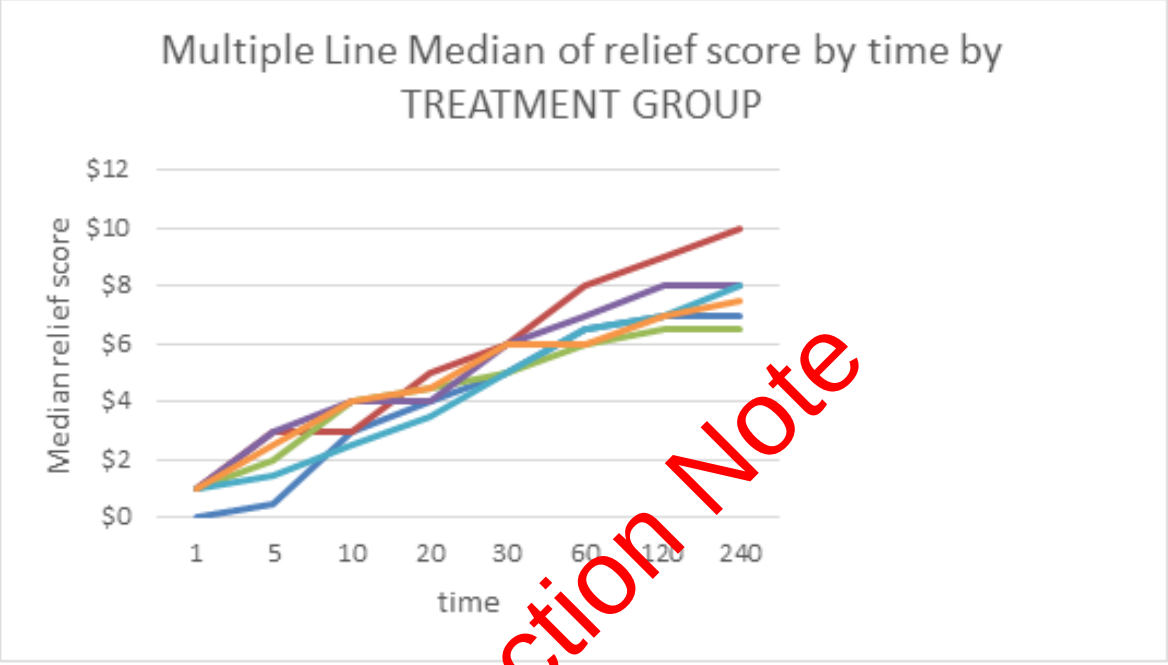

Figure 1. Multiple line median of relief score by time by treatment group. Multiple line median of relief score by time by treatment group. **Note:** (▬) Cetrizine, (▬) Non Saponifiable Group, (▬) Otrivine, (▬) Saponifiable

Table 2: Difference in relief scores between study groups by time.

Variable	Treatment Group							
	Standard of Care Group			Shea butter/ Shea butter extract				
Relief Scores at different time points	Cetrizine Cetrizine (10 mg) n=8 median Cetrizine (10 mg) n=8 median	Xylometazoline (2-3 drops) a n=6 median	Xylometazoline (2-3 drops) a n=6 median	Saponifiable (2-4 g) n=7 median	Shea Butter (2-4 g) n=8 median	Steroid (2-4 g) n=6 median	Kruskal_ Wallis ANOVA	P-value
1 min	0.5	1.8	1.2	1.3	1	1.3	2.849	0.723
5 min	0.8	2.2	2.8	3.2	1.8	2.6	6.031	0.303
10 min	2.7	4	3.5	4.2	2.5	4	5.381	0.371
20 min	4	4.6	5	4.5	3.8	4.7	2.151	0.828
30 min	5.2	5.9	6	6.3	5	6	5.047	0.41
60 min	6.5	6.9	7.5	7	6.7	6	2.315	0.804
120 min	7	7.7	8.8	8.4	7	6.7	6.393	0.27
240 min	7.3	7.7	9.7	8.4	8.3	7.5	8.773	0.118

Nasal congestion is characterized by inflammatory oedema of the upper respiratory mucosa (nose and larynx) as well as airway obstruction. Vasoconstrictors, such as xylometazoline, as well as loratadine (a histamine H1 antagonist), are the most commonly used drugs to treat the symptoms of this conditioz [7,8]. Some drugs bring relief, but they can have some drawbacks. They irritate the nostrils and cause ischaemia of the nasal mucous membrane, resulting in subsequent hyperaemia and further inflammatory oedema, as well as rebound or reactionary congestion. In this study however, there was no obvious adverse events leading to use of shea butter or its extracts except that it acted well as a mucolytic as patients observed nasal decongestion. Although one patient had complained of the harshness of the non-saponifiable option they still had a median VAS response of 1.2 within the one minute (Table 3).

Table 3: Effects of shea butter, non-saponifiable extract, saponifiable extract, Steroid extract, Cetirizine and xylometazoline in nasal congestion.

Variable	Treatment group					
	Standard of care group		Shea butter/Shea butter extract			
	Cetirizine	Xylometazoline	Non-Saponifiable	Saponifiable	Shea butter	Steroid
Number of Subjects	8	6	7	7	8	6
Duration of Experiment(h)	24	24	24	24	24	24
Dose	10mg	2-3dropsa	2-4g	2-4g	2-4g	2-4g
Onset of action (min)	5	1	0.5-1.5	0.5-1.5	1.5-5.0	01-May
Duration of action (h)	05-Jun	02-Apr	>4	>4	05-Aug	>4
Period from first dose till moderate to high congestion occurred (mins)	30	30	20	30	30	30
Period from first dose till congestion ceased	-	48-72	Dec-24	Dec-24	Dec-24	-
Number of Application of drugs during this period	1	2	1	1	1	1
Nasal Discharge after usage	No	No	Yes (Mucolytic)	Yes	Yes	Yes
Side Effects/Allergic reaction	Dizziness	Nasal Irritation	Harsh	Harsh	None	None

Utilizing a straightforward and trustworthy self-assessment instrument that can be utilized by all healthcare professionals and individuals is crucial [9,10]. As a result, VAS has been included in several mHealth tools. New technologies may promote patient involvement in therapy selection [11]. As a result, these new technologies could boost degree of control, encourage treatment compliance, and streamline communication between doctors and patients [12]. The results within one minute of one-time application of xylometazoline and Cetirizine (Standard of care) showed a mild relief with median VAS scores of 1.8 and 0.5 respectively. Although the onset of action was rapid for xylometazoline group, the action was not well sustained. It took at least 30 mins for all test groups to achieve well controlled relief from nasal congestion except for non-saponifiable extract of shea butter with VAS score of 5.0 within 20 mins of one-time application and lasted more than 240 mins with complete relief from nasal congestion (see Table 3). Shea butter also had longer control with duration of action peaking at 30 mins and lasting more than 4 hours. Its onset of action, however, was slightly less rapid within one minute with median score of 1.0. Studies by Tella 1979 and Adam et al 2018 also demonstrated these findings.

Verma, et al. showed that shea butter extracts can substantially and dose-dependently lower the amounts of Lipopolysaccharide (LPS) induced nitric oxide, Tumor Necrosis Factor (TNF), Interleukin-1 (IL-1), and Interleukin-12 (IL-12) in the culture supernatants and that shea butter can also reduce the expression of Cyclooxygenase-2 (COX-2) and Inducible Nitric Oxide Synthase (iNOS), two pro-inflammatory enzymes. Shea butter extracts inhibitory impact on LPS-induced iNOS, COX-2, TNF-, IL-1, and IL-12 mRNA expressions was the cause of these anti-inflammatory actions. Additionally, LPS-induced IKB phosphorylation and NF-B nuclear translocation were successfully prevented by Shea butter extracts. These findings support shea butter extract – non-saponifiable component-as a latent source of new therapeutic molecules and explain the molecular underpinnings of its bioactivity against diverse inflammatory diseases. In this current study, it is believed that shea butter and its extract may have shared a similar path in the extent of relief experienced by the study participants. The single application of non-saponifiable extract of shea butter appeared to produce complete relief after 4 hours (with median VAS score of 9.7) and this was better than the standard of care groups-cetirizine (with median VAS score of 7.3), Xylometazoline (with median VAS score of 7.7) for the same time [13].

Some studies have documented shea butter as having anti-inflammatory properties. This was evident in this current study seen from the nasal wash out where 11 Out of 18 study participants had reductions in the inflammatory cells of their Nasal wash out after treatment (Table 4). Furthermore, a significant portion of non-saponifiable fraction and triglycerides are the shea butter constituents that have an impact on its physicochemical qualities and does not dissolve in acetone. The non-saponifiable fraction might alternatively be described as a blend of several polyisoprenes that makes up a highly unsaturated molecule. Depending publication from various authors, the average amount of non-saponifiable content ranges from 1.2% to 17.6% [14-18].

At every time point in this current study, the mean relief scores obtained from the data set between standard of care groups and Shea Butter and shea butter extracts groups were not statistically significant (Table 5) [19-23]. Further, during the period of the study using shea butter and shea butter extracts, findings suggest that shea butter and its extracts, as a mucolytic and nasal decongestant, outperformed standard of care in management of nasal congestion in terms of potency and duration of effect [24-28].

Table 4: Mean differences in relief scores between two consecutive time points.

Variable	Treatment group							
Differences in relief scores between time points	Cetrizine n=8 mean	Nonsaponifiable n=7 mean	Otrivine n=6 Mean	Saponifiable n=7 Mean	Shea Butter n=8 Mean	Steroid n=6 Mean	ANOVA	Pvalue
1-5 min	0.1	1.3	0.5	1.8	1	1.3	9.73	0.083
5-10 min	1.5	0.6	1.6	0.7	0.4	1.4	6.405	0.269
10-20 min	0.7	1.3	1	0.4	1.3	0.8	1.632	0.897
20-30 min	1.4	1	0	0.8	0.7	1.3	5.349	0.375
30-60 min	1.6	1.4	0.8	1	1.6	0.4	5.421	0.367
60-120 min	0.2	1.3	0	0.8	0.7	0.3	10.03	0.074
120-240 min	0.3	1	0.4	0	0.8	0.4	10.75	0.057

Table 5: Reduction in Inflammatory cells from nasal wash out within groups after treatment.

Variables	Frequency before treatment	Frequency after treatment
Shea butter	4	3
Saponifiable	3	2
Non saponifiable	2	2
steroid	2	1
Cetirizine	7	2
Total	18	11

Conclusion

These findings demonstrate that the non-saponifiable and saponifiable extracts of shea butter when used as nasal decongestants, appear to outperforms traditional nasal drops like xylometazoline in terms of response time and maximum response obtained following one-time application. Shea butter and its extracts do not show any negative side effects that are associated with conventional treatments for nasal congestion. They to take effect quite quickly and to have a consistent, long-lasting impact.

Further studies will be necessary to determine possible long term use toxicity of shea butter and its extracts as nasal decongestant.

Contribution to Knowledge

Non-Saponifiable extract of shea butter may be the potent ingredient with maximal efficacy in terms of completely relieving nasal congestion within 20-240 mins

Authors' Contributions

The authors verify that they have met all the criteria for authorship and are qualified to be listed as authors of this work by their substantive contribution to the conception and design of the project or analysis of the data, their drafting or critical revision of the content of this manuscript, and their approval of the final version to be published. OB, IM, SA designed the study, revised it critically, and approved the final version to be published. SA, OE analysed the data, drafted the manuscript and approved its final version. OB, IM, SA, OE, and MS have all contributed to data interpretation, revised the manuscript. All authors read and approved the final manuscript.

Limitation of study: Each patient reported the level of relief they felt which was largely subjective.

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Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

The study has been approved by the University of Port Teaching Hospital, Choba, Nigeria

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