An audit of two hundred and fifty consecutive breast biopsies in Nigerian women

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Abstract

Objective: This study aims to audit the clinical and pathological features of patients with breast lumps seen at the University of Medical Sciences Teaching Hospital, Akure Complex, Ondo State, Nigeria.

Methods: A retrospective descriptive cross-sectional study was conducted at the surgical outpatient department of the University of Medical Sciences Teaching Hospital, Akure Complex over a three-year duration between May 2018 and April 2021. Histopathological reports of all breast specimens received and processed during the study period were retrieved from a computer database and analyzed using SPSS version 24.

Results: Two hundred and fifty-two patients were seen during this study period of three years between May 2018 and April 2021, two males and 250 females. Two male patients were diagnosed with gynecomastia and were therefore excluded from the study. The age range was 14-75 years and the mean age was 40.12 years with a standard deviation (SD ±10.60 years); The commonest symptoms were, breast lumps in 205 patients, (82%) and breast pain in 50 patients (20%). One hundred and sixty patients (64%) had benign breast diseases out of which 50 (20%) were fibroadenoma, and fibrocystic disease 45 (18%). The main histological type of breast cancer was ductal adenocarcinoma 85 invasive, 17 ductal carcinoma in situ, and 5 infiltrating lobular adenocarcinomas.

Conclusion: Benign breast lesions are more common generally, while invasive ductal carcinoma is the most common malignant lesion. This study affirms that breast diseases in Nigerians are characterized by late presentation, and often dismal mortality.

Keywords: Breast lumps, Breast lesions, Breast biopsy, Histopathology

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Introduction

Globally, breast symptoms are frequently encountered especially among female patients in our clinical settings[1-3]. Some symptoms might just be inconsequential and readily resolve to simple remedies. However, some others become a source

of concern for both the patient and the attending physician especially when they become persistent[1-3]. In most instances, the discovery of any breast lump remains a great concern causing apprehension, uncertainty, fear, anxiety, and depression among enlightened women[4,5]. In such a scenario, these women are compelled to present to hospitals where assessment, necessary investigations, and eventual reassurance are performed[4,6]. The definitive diagnosis of breast lesions relies on histopathological analysis, which is crucial for clinical decision-making[1,4]. Moreover, the most frequently occurring histopathological findings following breast biopsies are benign lesions with fibroadenoma being the most common but at the other end of the spectrum are the greatly feared breast cancers[1,7].

Furthermore, breast cancer in women is a major public health concern worldwide. It is the most common cancer among women both in developed and developing countries and the principal cause of death from cancer among women globally[4,8-10]. Interestingly, various factors that are related to the rising cause of breast cancer are poorly understood such factors are thought to reflect lifestyle changes associated with westernization including late childbearing, having fewer children, consumption of calorie-dense food, physical inactivity, and obesity[8,11]. In Nigeria, breast cancer incidence has increased from 15.3 per 100,000 in 1973 to 33.6 per 100,000 in 1992 and 116 per 100,000 in 2001[4,8-13]. Because of this increasing incidence, several articles have been published about breast diseases in Nigeria[1,4,8-16].

Medical audit is defined as "the systematic critical analysis of the quality of medical care including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient"[17-19]. "The relevance for clinical audit as a tool for quality assessment of laboratory outcomes cannot be overemphasized"[17-19]. "The beneficial role to the practice of laboratory medicine and improved patient care are also indisputable. However, there is a paucity of literature on audit schemes from most laboratories in Nigeria to give credence to this concept"[17-19].

We audit the various tissue diagnoses of patients including both male and female; who presented to the surgical outpatient clinic of the University of Medical Sciences Teaching Hospital complex Akure- Ondo State with complaints of a swelling or lumps in one or both breasts.

Objectives of the study: The paper aims to describe the pattern and characteristics of breast biopsies seen in Akure, Nigeria; in addition to providing useful data for counseling patients, strengthening advocacy for better breast health awareness, and supporting purposeful screening measures.

Materials and methods
A retrospective descriptive cross-sectional study of all patients presenting with breast symptoms was conducted at the surgical outpatient department of the University of Medical Sciences Teaching Hospital complex, Akure over three years between May 2018 and April 2021.

The attending clinician was required to fill out a pre-tested proforma containing the patient's data such as age, sex, educational background, occupation, symptoms, duration of symptoms, history of breast disease, family history of breast disease, age at menarche, menstrual status, parity, history of breastfeeding, height, weight, findings on clinical examination, radiological studies, biopsy technique, diagnosis and treatment at the time of initial consultation. The clinical data of each patient on the proforma was updated at subsequent visits. To minimize inter-observer errors, the first ten patients were seen jointly. Also, the patients gave informed consent, and those patients who absconded from follow-up or without definitive diagnosis are recognized as such.

Furthermore, all the patients were initially seen at the surgical outpatients' clinic where they were interviewed, examined, and scheduled for excisional or incisional biopsies depending on the size of the lumps. All the biopsies were performed as day case procedures under 0.5% xylocaine where the average volume used in infiltration for each patient did not exceed 10ml except in patients with bilateral disease.

Given cosmetic ethical considerations most of the incisions were circum-areolar in nature[1]. In the other cases when feasible the incisions were circumferential when the former was practically impossible due to the site of the lump. No patient had to be converted to general anesthesia. None of the patients were transfused. The incision was

closed with subcuticular stitches using either 3–0 Vicryl or 3–0 Nylon. Patients were discharged the same day with oral analgesics. Prophylactic antibiotics were not prescribed routinely except in a few selected cases when the clinical scenario was unavoidable. Those without drains were seen at the outpatient clinic 9 days later; those with drains were seen 48 hours after the operation to remove the drain and then were seen one week after. The subcuticular nylon stitches were gently withdrawn on the 10th-day post-surgery at the outpatient clinic. The tissue biopsy specimen was fixed in 10% formalin and sent to the histopathology laboratory[1]. "The pathologists did the gross description and cut-up of the specimen and the tissue slides were stained using Haematoxylin and Eosin. The slides were read and interpreted by the pathologists who made the histopathology reports available. The histopathology reports were usually available from the pathology department three weeks after surgery, thus after the 1st post-operative visit to the outpatient clinic most patients were given a 2-week appointment. Decisions about further management were taken at this time"[1].

Statistical data analysis was done using the Statistical Package for Social Sciences (SPSS) software version 22.0 (IBM, USA 2015). Descriptive statistics were employed to calculate categorical variables like percentages. Mean, median, and standard deviation were used to summarize continuous variables. The chi-square test was used to determine the P-values for categorical variables, with a P-value of less than 0.05 considered to constitute a statistically significant difference.

Ethical consideration: The protocol for the study was approved by the Research and Ethical Committee of the University of Medical Sciences Teaching Hospital before the commencement of the study.

Results

Two hundred and fifty-two patients were seen during this study period of three years between May 2018 and April 2021, two males and 250 females. Two male patients were diagnosed with

Table 1: Age distribution of patients with breast lumps

Age (years)	Patients	Percent (%)
11-20	57	22.6
21-30	79	31.3
31-40	46	18.7
41-50	36	14.7
51-60	17	6.7
61-70	7	3.6
71-80	4	1.6
TOTAL	**250**	**100**

Table 2: Clinical presentation of patients with breast lumps

Clinical features	Frequency	Percent (%)
Ulcer	25	10
Axillary lymphadenopathy	75	30
Edema of the upper limb	25	10
Nipple discharge	35	14
Breast pain	85	34
Weight loss	45	18
Family history	50	20
Others	30	12
TOTAL	**250**	**100**

Table 3: Histopathology of breast lumps in Akure

Histological diagnosis	Frequency	Percentage (%)
Breast Cancer	90	36
Fibroadenoma	50	20
Fibrocystic disease	45	18
Ductal carcinoma insitu (DCIS)	20	8
Galactocele	5	2
Phylloides tumor	9	3.6
Lipoma	5	2
Chronic non-specific mastitis	5	2
Abscess	29	11.6
Gynecomastia	2	1.0
Tuberculous mastitis	3	1.0
Ductal ectasia	2	0.8
TOTAL	**250**	**100**

Table 4: Age & histological type of breast lumps

Age	Inva Sive Ductal Ca	Fibro Aden Oma	Fibro Cystic Dx	Dcis	Galac Torrhea	Phyll Odes	Lipo Ma	Others	Total
10-20	10	13	11	0	2	3	3	10	**52**
21-30	28	12	8	4	3	6	2	15	**78**
31-40	20	10	14	3	0	0	0	4	**51**
41-50	10	10	12	5	0	0	0	0	**37**
51-60	10	5	0	3	0	0	0	0	**18**
61-70	10	0	0	0	0	0	0	0	**10**
71-80	2	0	0	2	0	0	0	0	**4**
Total	90	50	45	17	5	9	5	29	**250**

gynecomastia and were therefore excluded from the study leaving only the female patients for the statistical analysis.

The age range was 14-75 years and the mean age was 40.12 years with a standard deviation (SD ±10.60 years); the median age of 41 and the peak age category was 35–42. Seventy-nine (31.6%) patients were in the 21-30 year age group. The mean age at menarche was 14.5 years (range: 11–20 years) [Table 1]. Ninety-six (38.4%) patients were students, and 71 patients (28.4%) were traders. The educational level was graduate/undergraduate in 100 patients (40.0%), and senior secondary school level in 55 patients (22.0%).

The commonest symptoms were, breast lumps in 205 patients, (82%) and breast pain in 50 patients (20%) [Table 2]. The duration of symptoms range was 1-452 weeks; the mean was 52 weeks and the mode was 15 weeks. The parity mean (range) was 3 (0-7). Twenty patients (8%) had a history of breast disease, and eighty-five patients (34%) had a family history of breast disease. One hundred patients (40%) had children and all of them breastfed their children. Thirty-five patients (14%) were postmenopausal. The body mass index (BMI) mean (range) was 23.9 (17-50) kg/m.

On clinical examination, 241 patients (96.2%) had palpable lumps, while nine patients (3.8%) were normal [Table 2]. All the two hundred and fifty patients had open biopsy, and twenty-eight of these patients had Fine Needle Aspiration Cytology (FNAC) before the open biopsy. The clinical diagnosis of malignancy in 112 (44.8%) patients was confirmed by histology in 107 (42.4%) patients. The remaining five patients had biopsy reports which were inconclusive as a result were deleted from the overall data analysis. One hundred and sixty patients (64%) had benign breast diseases out of which 50 (20%) were fibroadenoma, fibrocystic disease 45 (18%), Chronic non-specific mastitis 5(2%), and breast abscess 29 (11.6%) [Table 3].

Moreover, based on radiological studies (i.e., ultrasonography) reviewed in the patients, the predominant features were irregular borders (65.4%), microlobulated-angulated contours (54.5%), hypo-homogeneous internal echogenicity (61.6%); Breast Imaging Reporting and Data System (BI-RADS) categories which range from category 1(no evidence of cancer) to category 6

(high likelihood of cancer), plus additional category 0 which means more tests are required; Also, mammogram reports include four categories for breast density. One hundred and forty-two patients had breast ultrasonography scan with BI-RADS III and IV category in 107 patients. Mammography commonly showed the presence of a mass (45.8%) and suspicious microcalcifications (50.8%); in our study there were 50 and 57 patients with benign and malignant features respectively on mammography. Magnetic resonance imaging (MRI) essentially revealed mass enhancement (75.4%) with type 2 or 3 dynamic curve (95.5%). Forty-four patients had MRI done in our study which confirmed high-grade tumors that were associated with posterior acoustic enhancement; while low-grade tumors presented with speculated margins more than high grade tumors.

In addition, the age and histological distribution of all the biopsies and the principal diagnoses are as shown in Table 4. More than 80% of discrete masses were found in women less than 40 years old, and for fibroadenoma the mean age was 24.9 + 7.91(SD). Similarly, Table 4 revealed the main histological type of breast cancer which was ductal adenocarcinoma; 85 invasive, 17 ductal carcinoma in situ, and 5 infiltrating lobular adenocarcinomas. Of the two patients with bilateral breast masses, one was reported as Burkitt's lymphoma and the other with Paget's disease of the breast. There were 48 (44.9%) breast cancers in stage I, and 28 (26.2%) in stage II. Four patients were found to have pulmonary metastases representing 3.8% of the series as stage IV.

Of the one hundred and seven patients with histological diagnosis of malignant disease, only 30(18%) had T, N, and M tumors. Ten patients had metastases to the chest and abdomen (M tumors), and twenty had no evidence of metastases (Mx tumors). Moreover, one hundred and three patients (85%) had appropriate therapy while 18 patients (16%) absconded and did not have the therapy indicated. These included four patients with histologically confirmed breast malignancy and four patients with clinical diagnosis of breast cancer.

The molecular subtypes of breast cancer observed in this study are as follows: 1. Luminal A: Hormone receptor-positive, human epidermal growth factor

receptor (HER)-2 negative- 45(18%); 2. Luminal B: Hormone receptor-positive, HER-2 positive- 30(12%); 3. Basal-like: Hormone receptor and HER-2 negative- 38(15.2%); 4. HER-enriched: HER-2 positive, hormone receptor-negative- 29(11.6%).

Discussion

A breast lump is a major health concern among Nigerian women and constitutes a reason for seeking surgical consultation. The discovery of a breast lump is often associated with heightened anxiety due to the possible risk of breast cancer in the general population[20,21]. Tissue biopsy is a critical step in confirming the diagnosis of breast cancer and plays an important role in breast lump management[17,18].

Besides, most breast lumps are likely to be benign and roughly one out of ten biopsies turns out to be malignant, but that is only generally speaking[1,22-24]. Equally, breast pain is usually associated with benign breast disease[21-26]. In this study 25 patients out of 50 patients who had pain as a presenting complaint had carcinoma of the breast (P≤005)[15,16,20-22]. The mean duration of symptoms for patients with malignant breast disease was (28.5 weeks SD 47.6) less than mean duration of symptoms in patients with benign disease (47.5 weeks, SD 90.5). The parity mean for patients with malignancy was significantly higher than those with benign disease (4. SD 2 versus 1. SD 1, P value ≤0.05); and these findings were comparable to those in other literature[15,16,20-22,26].

Interestingly, developing a successful breast screening program in a resource-limited setting as our, requires substantial logistical and cultural considerations[22-24]. Although mammography is the gold standard for breast cancer screening in high-income countries (HICs), personnel constraints, financial limitations, and infrastructural challenges hinder its routine use in Nigeria[25,26]. As a result, breast ultrasonography remains the main radiological modality for the diagnosis of breast cancer in young Nigerian women, but mammography and MRI can help in both diagnosis and evaluation of the extent of disease[25,26]. The choice of radiological modality underscores the need for a cost-effective screening model tailored to the available human and infrastructural capabilities

and designed to meet individual patient needs[25,26]. From the radiological viewpoints, our study confirmed that, the predominant features were irregular borders (65.4%), microlobulated-angulated contours (54.5%), hypo-homogeneous internal echogenicity (61.6%) on ultrasonography, similar report was corroborated by Durhan G *et al*[27]. Also, the most predominant category on breast ultrasonography scan were BI-RADS III and IV category in 107 patients which support previous report of late presentation of women with breast cancer in Nigeria in general, especially the advanced stage of the disease[28,29]. There is no significant difference in the mammographic findings compared with that found by Durhan G *et al* which commonly showed the presence of a mass (45.8%) and suspicious microcalcifications (50.8%). The MRI features highlighted in our study include mass enhancement (75.4%) with type 2 or 3 dynamic curve (95.5%) equally agreed with other literature[27] Other similar findings on MRI in our report as compared with Durhan G *et al* confirmed that high-grade tumors were associated with posterior acoustic enhancement; while low-grade tumors presented with spiculated margins more than high grade tumors[27].

Ibikunle *et al* suggested that "open surgical excision biopsy remains the diagnostic 'gold standard' to which other methods must be compared"[30,31]. An estimated 28 (11%) cases of FNAC were done before the excision/incisional biopsies 250(100%) performed in this study. However, "compared to FNAC, excision biopsy is expensive and associated with a greater degree of patient morbidity"[30,31]. "The reported benefits of FNAC in breast lesions over other modalities include 1. Cheap, 2. Less painful due to smaller needle size, 3. Fast, hence could be performed in the clinic" etc.,[30,31]. "The disadvantages include 1. Lower diagnostic yield than core needle biopsy, 2. Four percent to 13% of samples found to be inadequate or non-diagnostic, 3. More difficult to distinguish invasive versus in-situ carcinoma, 4. May require more experienced cytopathologist for diagnosis"[30,31].

Several authors submitted that there are lots of breast lesions in both males and females within the West African sub-region[26,32,33]. The findings in the present study are consistent with other existing reports[26,34,35] which confirmed that there are more

benign breast lumps than malignant ones. A similar report was corroborated by Olu-Eddo *et al*[26,36]; they reported that 72.4% of all breast lumps in Benin City, Nigeria were benign. The figures reported by Olu-Eddo *et al* in Benin, and Nuhu *et al*[26] in Maiduguri were both higher than our figure of 60% in Akure. We also found out that the most frequently occurring histological type of breast lump is cancer (carcinoma) of the breast in our present study; and basically because our study is hospital-based.

Moreover, the mean age of 24.9 + 7.91(SD) years reported for patients with fibroadenoma in this study is consistent with the figures reported in other studies[26,36,37]. Interestingly, fibroadenoma is mostly found in younger aged women especially below the age of 20 years, with a peak incidence at age 15-21 years[26,35]. There have been several reports of other types of large-sized fibroadenoma described as a giant fibroadenoma, beyond 5cm diameter in size especially in young girls[26,37,38]. The mean size of giant fibroadenoma could reach up to 10-13cm in juveniles/teenagers as reported in some African countries[26,35]. Contrary to the findings in this present study, other authors reported from Kano[37,38], Ilesha, also in Nigeria[37,39], Westminster, UK[39-41], and Italy[39,41], that mammary dysplasia is the most common benign lesion, and the mean ages were 33, 31.6, and 39 years, respectively. This disease entity is said to result from an imbalance of ovarian hormones, probably estrogen excess and progesterone deficiency, and gradually resolves following menopause. It is thought to be an aberration of normal development and involution[39-41]. Various racial and ethnic groups appear to have some variability in the prevalence of fibroadenomas. Some literature demonstrate variations in the incidence of fibroadenomas among individuals of different racial backgrounds[39-41]. Interestingly, this observation presents evidence in support of genetic and environmental factors, further research is required to elucidate these disparities fully[39-42].

Fibrocystic disease was diagnosed in 45 patients, with a mean age of 42 years; the youngest patient was 25 years old. Also, breast cysts are generally benign lesions resulting from growth abnormality involving the milk glands. They are found commonly in premenopausal women, especially in their 30s and 40s. Surprisingly, they are not found usually post menopause[39]. From the present study,

other benign lesions found include mastitis, adenoma, phyllodes tumor, and galactocoele, which occurred in very few patients. A similar report has been corroborated by other studies[39,43]. Phyllodes tumors, also known as cystosarcoma phyllodes, are rare, mostly benign tumors that occur in the female breast. They are usually felt as a firm, painless lump in the breast, but some may hurt. They tend to grow large fairly quickly, and they often stretch the skin. These fibroepithelial tumors that account for about 1% of all breast neoplasms[39,44]. There were 9 patients with phyllodes tumors with a mean age of 23.5 years; in contrast to other reports that this occurs in patients in their 50s[39,45]. The finding in this study is in keeping with other reports about phyllodes tumors. Even though phyllodes are known for their recurrence following excision; we did not record any cases of recurrence in our present study[39,46].

One hundred and seven patients accounting for 42% of the total breast biopsy cases were confirmed to be breast cancers, with an average age of 42.5 years, and the majority was invasive ductal carcinoma [Table 4]. Similar findings were recorded in Ghana, where the majority of the patients were aged 40-49 years, and in Ibadan, where the median age was 48.8 years[39,47]. Twenty patients in this study with an age range of 21-74 years had ductal carcinoma in situ. A similar report from a Ghanaian study showed that the age range was 24-75 years. Clegg-Lamptey submitted that cancer of the breast affects a relatively young population in Ghana[37,45]. The same finding has been reported recently in Nigeria, which is contrary to the earlier heard viewpoint that breast cancer is a disease of older women[39,48]. Equally, the finding confirmed that breast cancer among adolescents and young adult females is associated with significant aggressiveness, as well as psychosocial and economic issues[49].

In this report, we made significant emphasis on the World Health Organization (WHO) 2013 classification of breast diseases in our study to include 19 subtypes of breast carcinoma. These are categorized into invasive breast carcinomas, precursor lesions, intraductal proliferative lesions, and papillary lesions etc.,[50]. Moreover, male breast cancer is rare, and the incidence varies. Interestingly, we did not report any case of male breast cancer in our present study; which is consistent with the finding of Nzegwu *et al*[46] who

found no male breast cancer in a study of 1050 breast biopsies. On the contrary, Irabor et al found only one in a study of 147 breast biopsies[1,39,48]. Analysis in a Ghanaian study put the incidence of male breast cancer at 1.3%, while in Jos (Nigeria) it was reported to be as high as 8.6%[47,50]. This study, however, affirms that breast diseases in developing countries are characterized by late presentation, an occurrence at relatively young ages, and probably dismal mortality as also reported by Anyanwu[3,12]. Moreover, late presentation of patients diagnosed with breast cancer is due to poor healthcare seeking behavior, resulting in delayed diagnosis and treatment[28]. Surprisingly, healthcare systems delays, poverty, lacks of comprehensive state welfare schemes, and social support have constituted altogether hindrances to standard patient-centered care[28].

Prophylactic bilateral mastectomy is a primary breast cancer prevention modality which is established based on breast cancer genetic predispositions; besides, prophylactic mastectomy is practiced frequently in the western world[51-55]. We did not record any case of prophylactic mastectomy in our study, probably due to paucity of such practice in our center and Nigeria in general. Moreover, an estimated 5–10% of breast cancers are linked to gene mutations inherited from a parent. The most common cause of hereditary breast cancer is an inherited mutation in the BRCA1 or BRCA2 gene[51-55]. For instance, a woman with a BRCA1 or BRCA2 gene mutation has about 70% chance of getting breast cancer by age 80[51-55]. Other oncogenes implicated include PTEN, PIK3CA, AKT1, and PIK3R1 mutations have been reported to be mutually exclusive, etc.[51-55].

On the basis of the various molecular subtypes of breast cancer obtained in this study, we identified the following: 1. Luminal A: Hormone receptor-positive, human epidermal growth factor receptor (HER)-2 negative- 45(18%); 2. Luminal B: Hormone receptor-positive, HER-2 positive-30(12%); 3. Basal-like: Hormone receptor and HER-2 negative- 38(15.2%); 4. HER-enriched: HER-2 positive, hormone receptor-negative-29(11.6%). Interestingly, hormone receptor-positive tumors which consist of luminal A and B subtypes tend to be less aggressive, with improved survival rates[56]. HER-2 enriched tumors are more

aggressive, with a poor prognosis without targeted therapy. The most common targeted anti-HER therapy is trastuzumab[57], which significantly impacted on the outcome in a few cases even in our study. Basal-like tumors are negative for the molecular markers and tend to have a worse prognosis with poor survival rates as corroborated in our study[58].

Limitations
1. Our study participants were patients attending the breast clinic at a tertiary hospital in the State capital-Akure, and environ; hence might not be representative of the Nigerian women population though the demographic analysis reflects the country's ethnic mix.
2. The clinical survey is a single-center and hospital-based study as opposed to population-based study; therefore the homogeneous style of the design could be a constraint.
3. The nature, design of the study, and small sample size are equally limitations; hence a larger sample size, multi-centered study, and randomized controlled trials would impact significantly the eventual outcome of this study.

Conclusion
Breast lumps occur across all age groups, with benign diseases being the most common lesions in the study population. Breast cancer among adolescents and young adult females is associated with significant aggressiveness, as well as psychosocial and economic issues. Histopathological analysis remains essential for accurate diagnosis and treatment planning. This study, equally, affirms that breast diseases in developing countries are characterized by late presentation, occurrence at relatively young ages, and probably dismal mortality. It also provides baseline descriptive data of breast disease patterns in Akure, Southwestern Nigeria.

Recommendations
1. There should be an aggressive public health campaign in communities to educate women of childbearing age group and to focus on the importance of carrying out breast cancer screening.
2. The community–based public health campaign that could provide adequate required support to

breast cancer patients by both government and non-governmental organizations.

3. There is a need for political will on the part of our government to support the provision of infrastructures and diagnostic facilities for breast cancer screening services in our health facilities to enable health workers to detect breast cancer at its early stage.

4. An adequately subsidized or completely free breast cancer screening service would make a significant impact; such as allowing the services to be accessible to indigent patients in general.

5. A larger sample size, multi-centered study, and randomized controlled trials would impact significantly on the eventual outcome of this study.

Declarations

Authors' contributions: The study was conceived by ONA, and ABJ; also they were both involved in the design and coordination as well as helped to draft the manuscript; also read and approved the final manuscript. OAA, OES, AA, and AA participated in its design, manuscript draft, also read and accepted the final manuscripts.

Ethics considerations: Institutional Ethical Approval was obtained. Confidentiality was ensured by not writing the names of patients on proforma by the Helsinki declaration. A copy of the written Approval is available for review by the Editor-in-Chief of this journal.

Competing interests: No conflict of interest declared.

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