

Demographic Risk Factors and Clinical Evaluation of Fecal Occult Blood Testing in Patients with Colon Cancer: A Case-Control Study

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ABSTRACT

Colon cancer remains a major global health challenge with rising mortality rate mostly in sub-Saharan Africa. A growing number of cases are detected at advance stages in Nigeria among younger populations. This study evaluates the socio-demographic and health determinants, and clinical efficacy of Fecal Occult Blood Test (FOBT) across two major tertiary health institutions in Rivers State, Nigeria. The study consisted of 177 participants comprising of 28 confirmed colon cancer cases and 149 healthy controls. The participants' demographics and medical histories were gathered using a structured questionnaire. Fresh fecal samples were collected and analyzed using a rapid immunochemical FOBT. Data obtained were statistically analyzed using SPSS version 2.0. The statistical analysis revealed a significant association between colon cancer and age ($p < 0.001$), with 78.6% of cases among married individuals aged 41-60. A hereditary link to the disease was established ($p < 0.001$) as 25.0% of colon cancer patients reported a first degree relative with the disease. There was significant difference observed between the study group regarding residence, gender and occupation. The clinical evaluation of the FOBT showed a 100.0% diagnostic sensitivity and 100.0% Negative Predictive Value (NPV). This clinical efficacy was backed by a calculated Odds Ratio of 177.25 ($p < 0.001$). The high burden of the disease observed in the 41-60 years age range agrees with the current trend of early onset of colorectal cancer (EOCRC) and FOBT as a highly sensitive, non-invasive screening tool for early clinical diagnosis of colon cancer.

Keywords: Colon cancer, Fecal Occult Blood Test (FOBT), Early-onset Colorectal Cancer, Demographic Risk Factors.

Introduction

Colon cancer is one of the most prevalent forms of cancer worldwide and a major public health challenge with leading cause of cancer-related death of about 9.4% as stated in a statistical report in 2020 (Siegel *et al.*, 2022), with late-stage diagnosis being a major contributor to high morbidity rate. Early detection is key to treatment and survival with chemotherapy being the major form of treatment. The International Agency for Research on Cancer (IARC) has projected a 56% rise in the cases of colon cancer accompanied by a 69% increase in fatalities come 2040 (American Cancer Society, 2023) and (Siegel *et al.*, 2021). Estimations have proposed that come 2030, there will be about 2.2 million colon cancer cases with 1.1 million associated deaths globally. Nigerian is a country with a population of about 160 million people

(United Nations Statistics, 2013). The incidence of colon cancer in Nigeria is a growing health concern as recent data from cancer registries and epidemiological studies has shown a significant and sustained increase in the disease. The prevalence of colon cancer in sub-Saharan African has been estimated to be about 4.38% for men and 3.69% for women while in Nigeria it is estimated to be about 3.4% of every 100 thousand population (Graham *et al.*, 2012), with more Nigerians diagnosed before the ages of 50 and mean age of diagnosis between 41 to 46 years (Anazodo *et al.*, 2024) at a late stage with metastatic stages accounting for the high mortality rate (Mohammed *et al.*, 2024).

The incidence of cancer in Nigeria varies significantly and is influenced by factors such as lifestyle, environmental exposures, healthcare access, and socio-economic conditions.

Unhealthy lifestyle practices such as smoking, poor dieting, and excess alcohol intake predispose persons to colon cancer disease (Chang *et al.*, 2021). Age has also been shown to be a factor with recent clinical trends showing increased early-onset of colon cancer occurring among patients below 50 years old. Addressing the factors capable of triggering the genetics associated with the development of the disease should be encouraged (Chang *et al.*, 2021) as individuals with a medical history of the disease or specific types of polyps are at a higher risk of a reoccurrence in the absence of adequate preventive measures (Chang *et al.*, 2021). The effect of ethnicity must not be ruled out as racial and ethnic backgrounds are important risk factors to be considered (Chang *et al.*, 2021). Colon Cancer statistics have shown male to have a higher incidence and mortality rate compared to females as studies have shown sex to influence biology of tumors associated with colon cancer (Tsokkou *et al.*, 2025). Thus, increased awareness, preventive measures and prompt access to screening and treatment is important so as to reduce the incidence rate within the country.

Due to high mortality rate associated with the disease, there is a need for a non-invasive, sensitive, and specific diagnostic tool for early detection. Multiple methods have been employed for the screening of colon cancer which includes invasive techniques such as colonoscopy, Computed tomography and even sigmoidoscopy (Rex *et al.*, 2017) with cost, lack of access and technical knowledge being a disadvantage in this part of the world. The use of a cheap, easy and non-invasive tool such as Fecal Occult Blood Test (FOBT) for preliminary diagnosis of the disease will aid in early detection, reduced mortality rate and improved treatment outcomes. FOBT detect microscopic gastrointestinal bleeding in stool, which can be a pointer for early indication of colon cancer thereby allowing for further investigation (Song & Li, 2016). The detection of the blood is based on the ability of the FOBT to identify hemoglobin or any of its degraded products (Khakimov *et al.*, 2015). A study by Zeller *et al.* (2014), highlights the importance of combining FOBT with gut microbiota analysis as this increases the sensitivity by approximately 45% when combined together. This study addresses late-stage colon cancer diagnosis and the effectiveness of FOBT as a preliminary tool for initial diagnosis for the early detection and treatment of the disease.

Materials and Methods

Ethical Approval

Ethical approval was obtained for this study from appropriate authorities and informed consent from all participants. Confidentiality of information was also ascertained.

Study Area, Study Design, and Population Size

This case-control study was carried out from 29th of April, 2025 to 28th of April, 2026 in Port Harcourt, Rivers State, Nigeria. A total of 177 Participants consisting of 28 (15.8%) confirmed colon cancer patients and 146 (84.2%) healthy individuals with no history of colon cancer. Age consideration was below 20 and above 81 years. The sample size was calculated using 95% confidence interval, 5% margin for error, Z score of 1.96 and a prevalence rate of 7.5% (Seleye-Fubara & Gbobo, 2005). The Design Effect (DEFF) was introduced to adjust for complexities of the stratified sampling design used.

The sample size (n) = $\frac{z^2 P(1-P)}{d^2}$

Data Collection

The demographic and healthy-related data of the participants such as age, sex, educational and occupational status and co-morbidities were collected using a structured clinical questionnaire.

Participants Selection Criteria

Colon Cancer Patients: Eligible patients must have histopathologically confirmed colon cancer, the ability to provide informed consent, and the willingness to provide fecal samples. Patients are excluded if they have alternative gastrointestinal malignancies, incomplete clinical records, or a history of recent antibiotic therapy and chemotherapy (Goede & Schulte, 2023).

Healthy Control Participants: Healthy controls are included if they present with a normal clinical screening, are capable of giving informed consent, and are able to provide fecal samples. Exclusion criteria for this group include confounding bleeding conditions, recent antibiotic therapy, a history of gastrointestinal pathology, or general unavailability (Hewitson *et al.*, 2008).

Laboratory Procedures and Fecal Occult Blood Testing (FOBT)

Fresh fecal samples were collected from participants prior to food consumption using a sterile leak-proof collection container and transferred immediately to the laboratory for processing. The analysis was performed by inserting the applicator stick from the buffer into three different locations in the stool and homogenized in the buffer for 20 to 30 seconds after which 3 to 5 drops were placed on the strips and the results read within 10 to 15 minutes. Double red lines on test strips indicates a positive test while a single line denotes a negative test and strips with no line in the control region were considered invalid (Wielandt *et al.*, 2024).

Statistical Analysis

Data was analyzed using SPSS software version 20.0. The Chi-square test was used to compare relationships between variables while a comparison with p-Value > 0.05 was considered statistically significant. Fishers Exact Test was applied to confirm that Chi-square values remain valid while diagnostics specificity and sensitivity of the test tool was calculated.

Results

The Pearson's Chi-square tests of independence were performed on the Socio-demographic data of participants comprising of 149 (84.2%) healthy control participants and 28 (15.8%) colon cancer patients to evaluate the relationship difference in the demographic characteristics between both categories of the study. Table 1 shows a statistically significant association in Age ($X^2 = 23.45$, $df = 4$, $p < 0.001$) between both categories with the healthy control group distributed across all age groups with a high prevalence observed at 21 – 40 (38.9%) and 41 – 60 (36.9%) while the colon cancer participants were heavily concentrated within the 41 – 60 age group which comprised 78.6% (n=22) of all cases. There was also a statistically significance difference observed in the marital status ($X^2 = 7.84$, $df = 3$, $p < 0.050$) with the colon cancer participants having a higher proportion within the married individuals (78.6%) while the healthy control participants occupy (53.0%). There was no statistically significant difference observed between the colon cancer participants and healthy control participants regarding Gender ($X^2 = 0.19$, $df = 1$, $p < 0.661$), Residence ($X^2 = 2.95$, $df = 3$, $p < 0.229$), and Occupational Status ($X^2 = 7.28$, $df = 4$, $p < 0.122$).

Table 1: Demographic Analysis of Healthy Control Participants and Colon Cancer Patients

Demographic Data	Total N (%)	HCP (%)	CCP (%)	X^2	df	P -Value
Age Group (Years)						
1 – 20	14 (7.9)	14 (9.4)	0 (0.0)	23.454	4	< 0.001
21 – 40	59 (33.3)	58 (38.9)	1 (3.6)			
41 – 60	77 (43.5)	55 (36.9)	22 (78.6)			
61 – 80	20 (11.3)	15 (10.1)	5 (17.9)			
> 80	7 (4.0)	7 (4.7)	0 (0.0)			
Gender						
Male	104 (58.8)	86 (57.7)	18 (64.3)	0.192	1	0.661
Female	73 (41.2)	63 (42.3)	10 (35.7)			
Marital Status						
Married	101 (57.1)	79 (53.0)	22 (78.6)	7.836	3	0.050
Single	29 (16.4)	25 (16.8)	4 (14.3)			
Divorce	31 (17.5)	29 (19.5)	2 (7.1)			
Widowed	16 (9.0)	16 (10.7)	0 (0.0)			
Residence						
Urban	72 (40.7)	58 (38.9)	14 (50.0)	2.946	2	0.229
Rural	49 (27.7)	40 (26.9)	9 (32.1)			
Sub-urban	56 (31.6)	51 (34.2)	5 (17.9)			

Educational status						
Formal	128 (72.3)	103 (69.1)	25 (89.3)	3.830	1	0.050
Non-formal Education	49 (27.7)	46 (30.9)	3 (10.7)			
Occupational Status						
Employed	84 (47.5)	65 (43.6)	19 (67.9)	7.280	4	0.122
Self employed	33 (18.6)	31 (20.8)	2 (7.1)			
Business	50 (28.2)	43 (28.9)	7 (25.0)			
Retired	4 (2.3)	4 (2.7)	0 (0.0)			
Student	6 (3.4)	6 (4.0)	0 (0.0)			

Key: χ^2 : Chi-square, %: Percent, HCP: Healthy Control Participants, CCP: Colon Cancer Participants

An analysis of the participants' health profiles revealed a significant association between a family history of colon cancer and the development of the disease. Figure 1 showed that 4.5% ($n = 8$) of the study population has a known history of colon cancer in their family while 95.5% ($n = 169$) has no knowledge of colon cancer in their family. Among the 28 colon cancer patients 25.0% ($n = 7$) has a first degree relative with colon cancer while 75.0% ($n = 21$) do not have any. 0.67% ($n = 1$) out of the 149 healthy control participants has a known first degree relative with colon cancer and the remaining 99.33% ($n = 148$) do not have any known colon cancer cases in their family. Statistical analysis shows a p -Value below 0.001 which indicates that the presence of colon cancer in the family history is statistically significantly in the development of colon cancer.

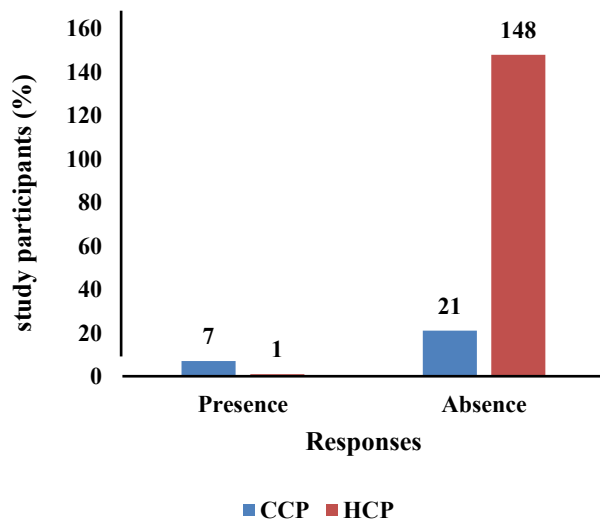


Figure 1: Prevalence of Family History of colon cancer among the participants in the study area

Key: CCP: Colon Cancer Participants and HCP: Healthy Control Participants

Figure 2 illustrates the distribution of co-morbidities among the study participants, with diabetes exhibiting the highest prevalence at 38.1% ($n = 8$) followed by hypertension with 28.6% ($n = 6$) cases. The data reveals that a vast majority of the study participants 88.1% ($n = 156$) reported no underlying medical conditions while 11.9% ($n = 21$) of the participants has co-morbidities. Also, 14.3% ($n = 3$) are Hypotensive, 4.7% ($n = 1$) have abnormal heart rhythm known as arrhythmia while 14.3% ($n = 3$) of the study population are faced with cardiovascular disease (CVD). The calculated p -Value using the Chi-square goodness of fit test is approximately ($p = 0.119$) and the Pearson's Chi-square statistic (χ^2) is 7.33 denoting that the distribution of underlying illnesses is not statistically significant.

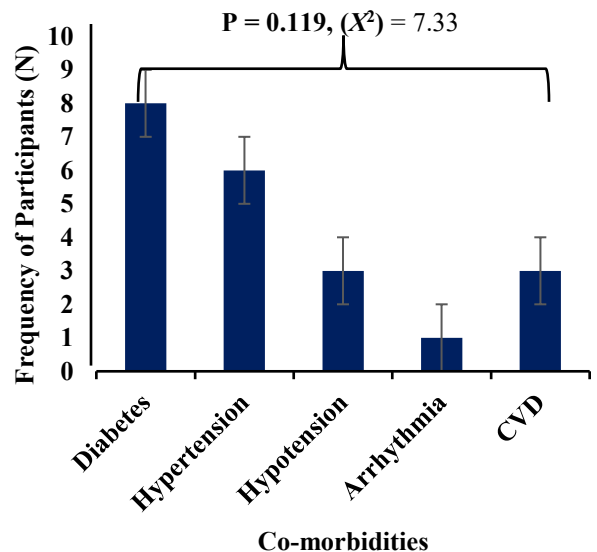


Figure 2: Frequency Distribution of Underlying Medical Co-morbidities within the Study Population

As shown in Figure 3, a positive fecal occult blood test was significantly associated with the occurrence of colon cancer ($P = 0.001$) as seen in Figure 3. The diagnostic performance of the FOBT within the study population ($N = 177$) showed that all 28-colon cancer patient tested positive to the test attaining an absolute sensitivity of 100% (95%CI, 87.7%-100.0%) with no false negative results recorded within this group. Contrarily, the healthy control population ($n = 149$), 113 of the population were negative for the test resulting in a diagnostic specificity of 75.84% (95%CI, 68.2%-82.4%) while a total of 36 false-positive were recorded. The overall diagnostic accuracy of the FOBT was 79.66% (95%CI, 73.0%-85.3%). The risk analysis yielded a very high calculated Odds Ratio (OR) of 177.25 denoting that an individual with a positive FOBT has an elevated odd of having the disease. The Phi Coefficient (Φ) of 0.696 showed a strong strength of association between screening positivity and clinical diagnosis. The Negative predictive Value (NPV) of 100% (95%CI, 96.8%-100.0%) was obtained indicating there was a zero false-positive rate within the participants while the Positive Predictive Value (PPV) of 43.75% (95% CI, 31.4%-56.7%) obtained reflects the expected inflated rate of false-positive counts among the healthy control group. A Chi-square test of independence performed (85.73) revealed a highly statistically significant association between the two categories. These analyses reveal the efficacy of FOBT as a strong preliminary diagnostic tool for the clinical diagnosis of colon cancer.

$P < 0.001$, OR = 177.25, $\Phi = 0.696$, PPV = 43.75% and NPV = 100%

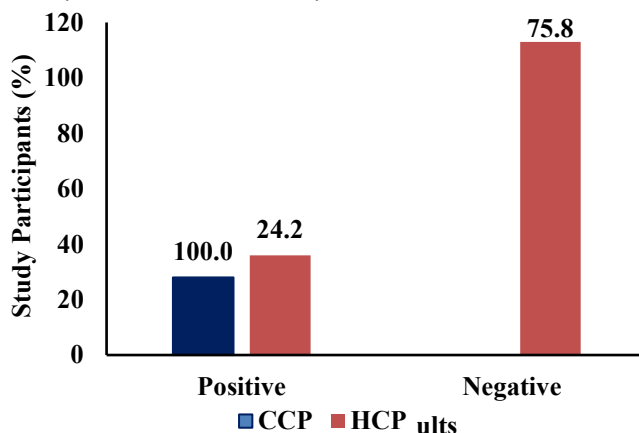


Figure 3: Diagnostic Efficacy of Fecal Occult Blood Testing (FOBT) [CCP: Colon Cancer Patients, HCP: Healthy Control Participants, PPV: Positive Predictive Value, NPV: Negative Predictive Value].

Discussion

The Socio-Demographic Distribution revealed that Age is a vital consideration for the development of colon cancer by an individual. This study showed a significant ($p < 0.001$) association between colon cancer and the age distribution as more cases occurred at the middle age and few older age range cases. This study aligns with the works of Siegel *et al*, (2023) which established age as a predominant risk factor in the occurrence of the disease. This study also identifies the male gender to be more prone to the development of the disease which might be related to body biology as also reported by González-Flores *et al*, (2025).

The health related profiles of participants: family history of colon cancer shows that, the family history of colon cancer is vital as it helps relates the genetic link between the disease and occurrence of the disease within other members of the family. This study shows a prevalence of association between family history and the occurrence of colon cancer with 25.0% of colon cancer patients reporting a first-degree relative with the disease. This result denotes that family history is a risk on the occurrence of the disease which agrees with findings by Liu *et al*, (2022) and Sartor & Al-Ahmadi, (2023). Colon cancer patients are presented comorbidities such as cardiovascular diseases, Hypertension, and diabetes (Qasem *et al.*, 2024). The study shows a low (11.9%) prevalence of comorbidities indicating a healthy category used in the study. The analysis of the participants resulted in a non-statistically significance indicating these diseases are not co-founding factors for colon cancer.

Colon cancer screening tests is aimed for increased detection, reduce cancer mortality by aiding early detection of the disease and guiding patient selection for follow-up (Li & Yuan, 2019). The Clinical Efficacy of Fecal Occult Blood Test (FOBT) test demonstrated a high sensitivity of 100.0% and a Negative Predictive Value of 100.0% indicating the effectiveness of the test as a preliminary screening tool for colon cancer. The results from the study showed a strong association between diagnosis and positive results ($p = 0.001$) which was also supported by the calculated Odds Ratio of 177.25. This study is limited by the small sample size used in the study most especially the colon cancer patient's category compared to the healthy control participants.

Conclusion

This study has revealed the epidemiological trend of colon cancer in Port Harcourt, Rivers State and has identified a high burden of colon cancer in individuals aged 41 – 60 supporting the information on Early Onset of colorectal cancer. Age, marital status, and a first-degree family history of the disease emerged as a critical demographic risk determinant of the disease. Fecal Occult Blood Testing in this study shows the presence of gastrointestinal bleeding as a signature in colon cancer patients thereby making the test an exceptionally sensitive non-invasive screening tool.

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