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Monoclonal Stool Antigen Test of *Helicobacter pylori* in Sub-Saharan Dyspeptic Patients

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Abstract

Helicobacter pylori (*H. pylori*) infection is a public health concern in sub-Saharan Africa (SSA). This study aimed to assess the monoclonal stool antigen test (SAT) in dyspeptic patients and the associated behavioral factors. It was cross-sectional from clinical records between January 2022 to February 2025. The eligible population was at least 18 years old with gastrointestinal disorder (GID) symptoms and a SAT result. Patients included were anonymized using a consecutive numeric identifier number increasing to the calculated size. The collected data were analyzed with STATA 16. A p-value < 0.05 was considered statistically significant. Prevalence of *H. pylori* infection was 55.69%. The sex ratio was 0.81. Mean age was 41.62 years and the oldest was 86 years. Comparing results according to the age group and results of monoclonal SAT, the p-value was 0.03. Residence was urban for 69.11%. Alcohol consumption was: beer (62.65%), wine (15.66%), liquor (4.82%) and multiple types (16.87%). All were symptomatic with various medical histories, chronic diseases and other associated symptoms. The GID symptoms were bloating (75.2%); EPS (56.91%); esophageal disorders (55.28%); constipation (41.06%); belching disorders (31.3%); nausea or vomiting disorders (17.89%); postprandial distress syndrome (12.6%); diarrhea (5.28%) and halitosis (2.44%). Endoscopy was performed in 49.19%. Tests for serum IgG antibodies against *H. pylori* had been done in 50% and 32.52% (1/3 patient) were positive. Compared with the presence of *H. pylori* in histology (88.24%), SAT had sensitivity at 76.47% and serum IgG antibodies sensitivity at 32.52% (p = 0.18 and 0.17). Histology was performed by 34 patients (13.82%): all had gastritis including 32 chronic; 26 with atrophy and one dysplasia. Prevalence remains high in symptomatic pa-

tients. This research was not in accordance with the "African enigma." Findings highlight the need for a population-based *H. pylori* test-and-treat strategy.

Keywords

Helicobacter pylori, Monoclonal Stool Antigen Test, Sub-Saharan Africa

1. Introduction

Helicobacter pylori (*H. pylori)* infection is a public health concern. It's a gram-negative bacterium first cultured in 1982. Barry Marshall and Robin Warren were awarded the Nobel Prize for discovery in 2005. *H. pylori* is identified as a type I carcinogen. The global prevalence of *H. pylori* is more than 50% [1]. In sub-Saharan Africa (SSA), the prevalence remains high [2], pooled at 70.1% [3] and over 80% in Burkina Faso [4]-[8]. The "African enigma" describes a mystery of high prevalence of *H. pylori* in Africa without a corresponding severe pathology [2].

Updates in the management of *H. pylori* infection are covered by the Maastricht VI international consensus report [1]. Other 94% agreed that test-and-treat is an appropriate strategy for uninvestigated dyspepsia, and monoclonal SAT (stool antigen test), if properly validated, is an appropriate test before and after *H. pylori* treatment, with confidence grade A1 (= high quality. Further research is very unlikely to change their confidence in the estimate of effect, with strong recommendation for or against using an intervention) [1].

The topic was to evaluate the strategy of test (with a noninvasive testing for *H. pylori* in dyspeptic patients) and treat. This study aimed to assess the contribution of monoclonal SAT in an SSA (Burkina Faso) gastroenterologist's practice and the associated behavioral factors among those patients.

2. Materials and Methods

2.1. Study Population

The study was cross-sectional in a cohort of Burkinabe patients from 4th January 2022 to 15th February 2025 in the city of Ouagadougou. Patients' recruitment was conducted at "clinique El-Fateh Suka", a social-private polyclinic. The eligible population was patients referred to the gastroenterologist who were at least 18 years old. The study population included those with gastrointestinal disorder (GID) symptoms and a monoclonal SAT result. Dyspepsia diagnosis was based on A, B, and C Rome IV criteria of functional GID [9] and halitosis. We excluded from this study patients with irritable bowel syndrome and opioid-induced constipation. To be valid, monoclonal SAT must be done remotely from taking proton pump inhibitors (PPIs) for more than 2 weeks and/or an antibiotic and/or bismuth for more than 4 weeks [4].

Patients' data were recorded in a structured questionnaire. Data collected were

sociodemographics (age, sex, residence, occupation) and clinicals (herbal or traditional medicine, alcohol or tobacco consumption and symptoms), if done, results of serological anti-*H. pylori* antibodies, upper digestive endoscopy and histology, and Immunocomb ELISA test. When available, we also noted results of haemoglobin (gram per deciliter) and parasitological test (including examination of their cysts and eggs) of the stool. Young dyspeptic patients are those below 50 years old [1]. The age threshold of 50 varies between 45 and 55 years depending on different countries and regions [1] in relation to the age risk for gastric cancer. So, we divided the patients according to age into 3 age groups: 18 to 44 years; 45 to 55 years; and those over 55 years. Patients were grouped into 6 occupation groups: student, informal sector (shopkeepers, dressmakers, artists, artisans, weavers), housekeeper (including maids, housewives and farmers), civil servant (secretary, nurses, medical officers, accountants, financial), military or paramilitary, and senior manager (business leaders or owners).

The GID symptoms sought were abdominal pain (epigastric pain syndrome (EPS = B1b [9]) and other locations), esophageal disorders (A [9]), belching disorders (B2 [9]), nausea or vomiting disorders (B3 [9]), postprandial distress syndrome (PDS) B1a [9] = feeling of slow digestion or gastric fullness, bloating (C4 [9]), constipation (C2 [9]), diarrhea (C3 [9]), and halitosis (= presence of an unpleasant odor in exhaled air).

2.2. Sampling and Randomization

The sample size for frequency in the population was calculated in OpenEpi® software using the equation sample size n = [DEFFNp(1 − p)]/[(d2/Z2 1 − α/2(N − 1) + p*(1 − p)]. We fixed the population size (for finite population correction factor) (N) at 1,000,000; hypothesized % frequency of outcome factor in the population (p) at 80% ± 5%; confidence limits as % of 100 (absolute ± %) (d) at 5% and design effect (for cluster surveys—DEFF) at 1. The calculated size was 246 at the 95% confidence level. Survey form information was collected from clinical records. Most clinical records were classified alphabetically. Those not classified were grouped together and named NC (unclassified). The next number of files to be included was drawn. The random sampling (in a ballot box) was ordered as follows: B, NC, Z, O, S, D, N, Y, W, P, R, L, M, C, G, H, I, K, T, A, F, J, Q, U, V, X, and E. Patients included were anonymized using a consecutive numeric identifier number increasing to 256.

2.3. Statistical Analysis

The collected data were analyzed with STATA® 16 (College Station, TX) software program. Two by two table statistics and a chi-square test were run to determine associations between monoclonal SAT of *H. pylori* and behavioral factors. A binomial logistic regression test was also run to appreciate the link between monoclonal SAT and some risk factors. A p-value < 0.05 was considered statistically significant.

2.4. Ethics

Helsinki Declaration version 2013 [10] was the reference. Data were collected from each patient in accordance with confidentiality, anonymity, and random sampling. Then, data were compiled and analyzed with the STATA® 16 (College Station, TX) software program.

3. Results

During the study period, in patients with dyspepsia A, B, C2, C3, or C4 of Rome IV criteria of functional GID [9] or halitosis, 398 monoclonal SAT of *H. pylori* were prescribed. Among them, 6 patients were not Burkinabe people, 16 patients were under 18 years old, and the result of the test was not found in 75 records. Those 97 records were excluded. Following the ordered random sampling, we reached the sample size of 246 in the T group records.

The monoclonal SAT results of the 246 patients were recorded 15th February 2025. Monoclonal SAT was positive in 137/246 patients, or a prevalence rate of 55.69%. The sex ratio was 0.81. The average age of patients was 41.62 years ± 13.89. The youngest was 18 and the oldest was 86. Most (69.11%) resided in urban areas. Alcohol consumption was mostly beer (62.65%), wine (15.66%), liquor (4.82%), and multiple types (16.87%).

The records were outpatient, but some had transient hospitalization (less than 48 hours). All of the patients were symptomatic. Many had various medical histories, chronic diseases, and other associated symptoms reported in "Table 1".

Table 1. Medical history, chronic diseases, and other associated complaints (with the number of cases).

Medical history and chronic diseases (165)	Other associated symptoms (128)
Arterial hypertension (26)	Widespread malaises (37)
Hepatitis B virus (16)	Fever (17)
Other hepatitis and hepatomegaly (15)	General Pain (14)
Obesity (14)	Weight Loss (12)
Pancreatitis (10)	Palpitations (12)
Anxio-depression (9)	Asthenia (9)
Diabetes (8)	Paresthesias (6)
Hemorrhoidal disease (5)	Anorexia (4)
Heart disease (5)	Arthralgia (4)
Metabolic syndrom (5)	Vertigo (7)
Severe dengue (5)	Cough (6
Cholelithiasis and gallstone (4)	
Myome (4)	
Others (39)[a]	

a. drepanocytosis, hydronephrosis, cholecystitis, cancers, epilepsy, malaria, human acquired immunodeficiency virus, asthma, polycystosis (hepatic, ovarian, renal…).

Despite epigastric symptoms, other locations of abdominal pain were present and summarized in "Table 2".

Table 2. Other locations of abdominal pain according to the results of Monoclonal SAT.

Other location of abdominal pain	Monoclonal SAT	
	Positive	Negative
Aroud umbilicus	6	13
Chest pain	1	3
Right hypochondrium	3	11
Left hypochondrium	2	1
Hypochondrium (both right and left)	2	2
Left lower quadrant	2	1
Lower back (lumbar)	2	1
Pelvic pain	3	3
Right flank	0	1
Sub-costal	1	1
Total (=58)	21	37

The social, demographic, and clinical risk factors of the study population, depending on the results of Monoclonal, are summarized in "Table 3".

Table 3. Social, demographic, and clinical risk factors of the study population.

Risk factors	Monoclonal SAT of *H. pylori*			p
	Positive (%)	Negative (%)	Total (%)	
Age group (Years)				0.03
18 to 44 years	93 (58.13%)	67 (41.88%)	160 (65.04%)	
45 to 55 years	18 (39.13%)	28 (60.87%)	46 (18.70%)	
Over 55 years	26 (65%)	14 (35 %)	40 (16.26%)	
Sex (ratio male/female = 0.81)				0.74
Male	60 (54.55%)	50 (45.45%)	110 (44.72%)	
Female	77 (56.62%)	59 (43.38%)	136 (55.28%)	
Residence				0.36
Urban	98 (57.65%)	72 (42.35%)	170 (69.11%)	
Rural	39 (51.32%)	37 (48.68%)	76 (30.89%)	
Occupation				0.48
Student	18 (66.67%)	9 (33.33%)	27 (11.02%)	
Informal sector	29 (55.77%)	23 (44.23%)	52 (21.22%)	
Housekeeper	35 (61.40%)	22 (38.60%)	57 (23.27%)	
Civil servant	45 (48.39%)	48 (51.61%)	93 (37.96%)	
Military or paramilitary	6 (66.67%)	3 (33.33%)	9 (3.67%)	
Senior manager	4 (57.14%)	3 (42.86%)	7 (2.86)	

Continued

Herbal or traditional medicine				0.65
Yes	58 (56.31%)	45 (43.69%)	103 (43.64%)	
No	71 (53.38%)	62 (46.62%)	133 (56.36%)	
Alcohol consumption				0.45
Yes	48 (57.14%)	36 (42.86%)	84 (34.57%)	
Withdrawal	1 (25%)	3 (75%)	4 (1.65%)	
No	85 (54.84%)	70 (45.16%)	155 (63.79%)	
Tobacco consumption				0.89
Yes	9 (50%)	9 (50%)	18 (7.38%)	
Withdrawal	4 (57.14%)	3(42.86%)	7 (2.87%)	
No	122 (55.71%)	97 (44.29%)	219 (89.75%)	
GID symptoms				
A: esophageal disorders	73 (53.68%)	63 (46.32%)	136 (55.28%)	NA[a]
B1a: PDS	18 (58.07%)	13 (41.93%)	31 (12.6%)	NA[a]
B1b: EPS	81 (57.86%)	59 (42.14%)	140 (56.91%)	NA[a]
B2: belching disorders	41 (53.25%)	36 (46.75%)	77 (31.3%)	NA[a]
B3: nausea or vomiting	28 (63.64%)	16 (36.36%)	44 (17.89%)	NA[a]
C2: constipation	54 (53.47%)	47 (46.53%)	101 (41.06%)	NA[a]
C3: diarrhea	8 (61.54%)	5 (38.46%)	13 (5.28%)	NA[a]
C4: bloating	93 (50.27%)	92 (49.73%)	185 (75.2%)	NA[a]
Halitosis	2 (33.33%)	4 (66.67%)	6 (2.44%)	NA[a]

a. Non applicable.

There were no responses in patients' habits or history: 10 (4.06%) for herbal or traditional medicine, 3 patients (1.22%) for alcohol, or 2 patients (0.81%) for tobacco consumption.

The complementary paraclinical explorations have been compared to the results of Monoclonal SAT in "Table 4".

Table 4. Complementary paraclinical explorations according to the results of Monoclonal SAT.

Complementary paraclinical	Monoclonal SAT of *H. pylori*			p
	Positive (%)	Negative (%)	Total (%)	
Anti-*H. pylori* antibodies			**123 (50%)**	0.17
Positive	23 (57.50%)	17 (42.50%)		
Negative	37 (44.58%)	46 (55.42%)		
Hemoglobin (grams per deciliter)			125 (50.81%)	0.59
≤11.9 (anemia)	8 (53.33%)	7 (46.67%)		
>12 (normal)	67 (60.55%)	43 (39.45%)		

Continued

Upper digestive endoscopy	81 (66.94%)	40 (33.06%)	**121 (49.19%)**	
Peptic (reflux) esophagitis				0.93
Yes	54 (66.67%)	27 (33.33%)		
No	27 (67.50%)	13 (32.50%)		
Mycotic esophagitis				0.98
Yes	10 (66.67%)	5 (33.33%)		
No	71 (66.98%)	35 (33.02%)		
Gastric abnormalities			**120 (99.17%)**	0.6
Congestive	6	5		
Ulcerations	5	2		
Erosions	25	18		
Polyps	1	1		
Erythema	11	7		
Nodular	8	0		
Endoscopic atrophy	1	2		
Duodenal abnormalities			**116 (95.87%)**	0.27
Congestive	4	3		
Ulcerations	8	5		
Erosions	6	5		
Polyps	1	1		
Erythema	4	0		
Nodular	8	2		
Stenosis	0	1		
Ulcers				0.44
Yes	**19**	12	**31 (25.62%)**	
No	62	28		
Histology	26 (76.47%)	8 (23.53%)	**34 (13.82%)**	0.58
H. pylori positive	24	6		
H. pylori negaitive	2	2		
Gastritis				0.11
Acute gastritis	1	1		
Subacute	0	1		
Chronic gastritis	25	6		
Atrophy			**26**	0.42
No	6	1		
Mild	6	1		
Moderate	10	5		
Severe	4	0		
Dysplasia[b]	**1**	0	**1**	NA[a]

a. Non applicable. b. Metaplasia, Adenocarcinoma, or Lymphoma.

The distribution of endoscopy (121) by age group was: 77 patients (63.64%) among 18 to 44 years; 20 patients (16.53%) among 45 to 55 years, and 24 patients (19.83%) among those over 55 years.

The proportion of patients who underwent endoscopy in each group in the same order: 77/160 patients (48.12%), 20/46 patients (43.48%), and 24/40 patients (60%).

4. Discussion

This study confirms that prevalence remains very high in Burkina Faso. In fact, the prevalence of the infection was over 50%, exactly 55.69%. Indeed, the sample size was reached in just 3 years by one gastroenterologist in one private center. But, the single-center design at a private clinic, may not represent the broader population. Moreover, the rates are likely to be higher in the big public centers and even higher in the whole population in the country. It is recommended to use susceptibility tests like those molecular or after culture before prescribing first-line treatment [3]. Those tests could improve the diagnostic efficacy [5] [7]. For example, *H. pylori* was positive in 30/34 (88.24%) histology while 26/34 (76.47%) had monoclonal SAT positive. Polymerase Chain Reaction (PCR) has better sensitivity and specificity [6]. Despite its high cost, PCR has been used in the country [5] [6] [8].

Middle-aged women residing in urban areas were the most represented among our patients. This configuration is the same as in similar studies in symptomatic Burkinabes. Life expectancy seems to have increased: the oldest year was 71 in 2016 [5], 80 in 2023 [6], and 86 nowadays. There was a statistically significant ($p = 0.03$) association between the age group and results of monoclonal SAT. These findings highlight the need for a population-based *H. pylori* test-and-treat strategy as recommended [1].

Medical history, chronic diseases, and other symptoms frequently associated in referral services attest to patients having severe symptoms. In order of decreasing frequency, the GID symptoms were bloating (75.2%); EPS (56.91%); esophageal disorders (55.28%); constipation (41.06%); belching disorders (31.3%); nausea or vomiting disorders (17.89%); PDS (12.6%); diarrhea (5.28%); and halitosis (2.44%).

Monoclonal SAT can be an appropriate test before and after *H. pylori* treatment [1]. Upper GI endoscopy with biopsies is recommended in dyspeptic patients older than 45 years [1]. In our context, *H. pylori* culture is still a challenge and may be explained by limited resources in our country [3]. In this practice, 49.19% were able to perform endoscopy and under 15% could perform histology. Tests for serum IgG antibodies against *H. pylori* had been done by 50% of all patients and 1/3 (32.52% exactly) were positive. It can serve as a screening test in specific clinical situations [1]. Enzyme immunoassay (EIA) test kits performed better than rapid tests (used in this study). Compared with the presence of *H. pylori* in histology (88.24%) in this research, monoclonal SAT had acceptable sensitivity (76.47%)

but not serum IgG antibodies sensitivity (32.52%); even statistically, it was not significant (p = 0.18 and 0.17).

About the 34 patients (13.82%) who had performed histology, all had gastritis, including 32 chronic; 26 with atrophy and one with dysplasia. Gastric mucosal atrophy is defined as "loss of native glands". Atrophy is the major determinant of non-hereditary gastric cancer risk assessed by endoscopy and histology [1]. We found high prevalence of premalignant lesions in the small histology sample. That directly contradicts the "African enigma" [2] expected riddle of high infection rates with low associated pathology. However, the small subset of patients (13.82%) who underwent histology for comparison. So, it may not represent the broader population. Further community research or population data are still eagerly awaited.

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Avoid the stilted expression, "One of us (R. B. G.) thanks..." Instead, try "R. B. G. thanks". Do NOT put sponsor acknowledgements in the unnumbered footnote on the first page, but at here.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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