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Evaluation of the *"Helicobacter pylori"* Eradication Rate by Bismuth Quadritherapy or Concomitant Quadritherapy in Black Africans

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Abstract

Introduction: Gastric infection by *"Helicobacter pylori"* remains a topical issue due to the evolving scientific data concerning its pathophysiology, the diseases and pathologies concerned, which now extend beyond the gastric or digestive sphere, and the treatment methods faced with the development of antibiotic resistance. Diagnosis of infection involves two inseparable aspects: identification of the bacterium itself and identification of the endoscopic and histological lesions caused by the bacterium. Objective: To evaluate the rate of eradication of *Helicobacter pylori* infection by bismuth quadruple therapy and concomitant treatment. **Patients and methods:** This was a prospective, cross-sectional, analytical study of all outpatients in the hepato-gastroenterology department during the study period from 1 January 2022 to 30 November 2023. All patients had undergone oeso-gastroduodenal fibroscopy and the diagnosis was made by histological examination of the gastric biopsy. **Results:** Our 113 patients comprised 68 men and 46 women. The sex ratio was 1.48 in favour of men. The mean age of our patients was 40.28 years, with extremes of 13 and 80 years. The clinical signs that prompted oeso-gastroduodenal fibroscopy were as follows: epigastralgia (69.91%), dyspepsia (14.16%), vomiting (7.08%), gastro-oesophageal reflux (6.19%) and altered general condition with weight loss (2.65%). The endoscopic lesions were: gastropathy (antral, fundic and diffuse: antro-fundial) (69.02%), bulbar ulcer (6.19%), gastric ulcer (5.31%). *Helicobacter pylori* infection was associated with chronic gastritis

in all our patients; it was mild in 50%, moderate in 41% and severe in 9%. The eradication rate of *Helicobacter pylori* according to the treatment protocol used was 92.30% for bismuth quadruple therapy and 94.12% for concomitant quadruple therapy. **Conclusion:** The eradication rate of *Helicobacter pylori* in our study was 92.30% and 94.12% respectively for bismuth quadritherapy and concomitant therapy. Therapeutic compliance was good in 89.60% for all protocols combined, despite the occurrence of side effects in 36.22% of cases.

Keywords

"Helicobacter pylori" Eradication, Quadritherapy Antibiotics, Conakry

1. Introduction

Helicobacter pylori is a Gram-negative spiral-shaped bacterium that lives exclusively in the human stomach. Contamination, mainly within the family, occurs early in childhood and is responsible for chronic infection with no spontaneous eradication. Half the world's population, with great geographical disparity, is infected with *Helicobacter pylori*, the more disadvantaged their living conditions [1].

In France, the overall prevalence is estimated at 20% - 30% in adults. It is very low in children (<10%) but reaches 50% after the age of 60. Biopsies taken during gastroscopy identify *Helicobacter pylori* infection in one in five adult patients [2] [3].

In developing countries, it is estimated that 80% of the population is affected before the age of 20 [4].

It has been implicated in a number of potentially serious gastroduodenal and extra-digestive diseases, including gastritis, peptic ulcers, stomach cancer and iron deficiency anaemia [5].

Eighty-five per cent of infected patients will be asymptomatic, with 10% - 15% developing a peptic ulcer that is sometimes complicated (haemorrhage, perforation) and recurrent, especially if NSAIDs and aspirin are taken concomitantly. Only 1% will develop gastric adenocarcinoma following a slow cascade of histological lesions (intestinal atrophy-metaplasia-dysplasia-cancer) or MALT lymphoma [6].

The spread of antibiotic resistance is reducing the effectiveness of combination therapies, leading to regular changes in national and international recommendations on the choice of therapeutic strategies and the use of antibiotics, with variations that take account of national medical, economic and regulatory particularities [7].

Various management recommendations have been published and updated, reflecting changes in the management of *Helicobacter pylori-related* diseases, particularly with regard to indications, diagnostic tests and treatment [8].

In Guinea, a country with a high prevalence *of Helicobacter pylori*, to our knowledge no data are available to date on the efficacy of bismuth and concomitant quadritherapy. This lack of data prompted this study.

The aim of this study was to evaluate the rate of eradication of *Helicobacter pylori* infection by bismuth and concomitant quadruple therapy.

2. Patients and Methods

This was a prospective, cross-sectional and analytic study of all outpatients in the hepato-gastroenterology department during the study period from 1er January 2022 to 30 November 2023 treated with bismuth or concomitant quadritherapy.

The inclusion criteria were:

- The presence *of Helicobacter pylori* in gastric biopsy fragments
- Treatment with bismuth quadritherapy
- Treatment with concurrent quadritherapy
- Monitoring the eradication of *Helicobacter pylori* by oeso-gastroduodenal fibroscopy with biopsies
- The male and female sex The criteria for non-inclusion were:
- Lack of endoscopic control with biopsy for histology
- The administration of a treatment to eradicate *"Helicobacter pylori"* other than bismuth quadritherapy or concomitantly
- Patient refusal to take part in the study
- Endoscopic suspicion of malignancy confirmed by histology The FOGD procedure: it was carried out following a symptom:
- Epigastralgia
- Dyspepsia
- Vomiting
- Gastro-oesophageal reflux disease
- Impaired general condition with weight loss

Five gastric biopsies were taken using biopsy forceps: 02 antral, 02 fundic and 01 angular.

The samples were fixed with 10% formalin and sent to the pathology laboratory. No antibiogram was performed. The CERBA pathology laboratory in France carried out the histological study of the gastric biopsies.

FOGD and follow-up biopsies were performed four weeks after the end of *Helicobacter pylori* eradication treatment.

The parameters studied were:

- Socio-demographic: age and gender, which are
- Clinical: indication for FOGD, use of gastro-toxic drugs: aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, antecedents, etc. It should be noted that socio-demographic and clinical data are recorded on an individual form prepared for this purpose.
- Endoscopic: normal, gastropathy (erosive, erythematous, petechial, purulent, nodular), gastric ulcer, duodenal ulcer, duodenogastric bile reflux

- Histological parameters: inflammation, activity, glandular atrophy, metaplasia, dysplasia and the presence *of Helicobacter pylori* using haematoxylin-eosin staining supplemented by Giemsa staining. The intensity *of Helicobacter pylori was* classified as mild (1), moderate (2) and severe (3).

Gastric biopsies were taken using the Sydney-Houston system. Two antral and fundic biopsies must be obtained, as well as a biopsy from the angulus.

The protocols used were concomitant quadritherapy (proton pump inhibitor (PPI), amoxicillin 1 g × 2 per day, metronidazole 500 mg × 2 per day, clarithromycin 500 mg × 2 per day for 14 days) or bismuth quadritherapy (PYLERA 3 capsules × 4 per day: combination of bismuth salt 140 mg, metronidazole 125 mg, tetracycline 125 mg) for 10 days. If one line of treatment fails, the other line is repeated. The *Helicobacter pylori* eradication rate *was calculated by dividing the number of patients cured by the total number of patients included.*

The study was approved by the hospital's ethics committee. All patients gave informed consent before taking part in the study.

The data was entered in Epi-info version 7.1.0.6

The tests used to analyse the data were Pearson's Chi^2 test, the corrected Chi^2 test and Fisher's exact test.

The alpha threshold has been set at 5%.

3. Results

Our 113 patients comprised 68 men and 46 women. The sex ratio was 1.48 in favour of men. The mean age of our patients was 40.28 years, with extremes of 13 and 80 years.

The clinical signs that prompted an oeso-gastroduodenal fibroscopy were as follows: epigastralgia in 69.91%, dyspepsia (14.16%), vomiting (7.08%), gastro-oesophageal reflux disease (6.19%) and altered general condition with weight loss (2.65%). A patient could have several reasons for undergoing FOGD (Table 1).

Gastrointestinal toxicity was distributed as follows: smoking (19.47%), NSAIDs (13.27%) and corticosteroids (6.19%).

The endoscopic lesions were: gastropathies (antral, fundic and diffuse: antro-fundiac) (69.02%), bulbar ulcer (6.19%), gastric ulcer (5.31%) and no lesion (19.47%).

Histology showed:

- Mild gastritis (56%), moderate gastritis (41.9%) and severe gastritis (2.10%).

Table 1. Breakdown of patients by reason for FOGD.

Reason for the FOGD	Workforce	Percentage (%)
Dyspepsia	28	24.77
Vomiting	18	15.92
Gastro-oesophageal reflux disease	10	8.84
Impaired general condition with weight loss	3	2.65

- Density of *Helicobacter pylori* infection: mild at 50%, moderate at 41% and severe at 9%.
- Lymphoid follicles: absent in 47.8% of cases, mild in 33%, moderate in 10.2% and severe in 9%.
- Atrophy: absent (52%), mild (28%), moderate (15%) and severe (5%).
- Metaplasia: absent (75%), mild (19.5%), moderate (5%) and severe (0.5%).

The *Helicobacter pylori* eradication rate according to the treatment protocol used was 92.30% for bismuth quadritherapy and 94.12% for concomitant quadritherapy (Table 2).

The other 7.7% received treatment with concomitant quadritherapy.

The 5.88% of patients who failed the concomitant quadritherapy received bismuth quadritherapy as a second-line treatment

The main side-effects were abdominal pain (4.6%), metallic taste (7.9%), nausea and vomiting (10.12%), diarrhoea (5.9%), dysgeusia (3.7%), headache (2.7%) and dizziness (1.6%) (Table 3).

4. Discussion

We carried out a study evaluating the rate of eradication of *Helicobacter pylori* by bismuth quadritherapy or concomitant quadritherapy in black Africans.

The limitations of this study were the small sample size of 113 patients, which could affect the power of the statistical tests. This low sample size could be explained by the lack of acceptance of follow-up fibroscopy by most patients, the high cost of endoscopy and histological analysis, the fact that histology was not performed on site due to the delay in delivery of the results and the quality of the results, and the short duration of the study.

Table 2. *Helicobacter pylori* eradication rates according to treatment protocol.

Type of treatment	Eradication	
	Success n (%)	Failure n (%)
Bismuth quadritherapy	32 (92.30)	3 (7.70)
Concomitant quadruple therapy	73 (94.12)	5 (5.88)

Table 3. Breakdown of patients according to side-effects of treatment.

Side effects	Workforce	Percentage (%)
Abdominal pain	5	4.6
Metallic gutter	9	7.9
Nausea and vomiting	11	10.12
Dysgeusia	4	3.7
Diarrhoea	7	5.9
Headaches	3	2.7
Dizziness	2	1.6

The mean age of our patients was 40.28 years, with extremes of 13 and 80 years. The median age was 38, with a standard deviation of 13.30. The age group]30 - 50 years] was the most affected (60%), followed by those over 50 years (26.50%) and those ≤ 30 years (13.50%).

This young age has also been found in numerous studies in sub-Saharan African countries [9] [10]. This could be explained by the youth of the population and the early onset of *"Helicobacter pylori"* infection in our developing countries; unlike in developed countries, the highest prevalence (66%) is recorded at the age of 60 [11]. In developing countries, *Helicobacter pylori* infections affect around 80% of the population, with transmission occurring very early in childhood. Lack of hygiene, unsanitary drinking water, poor food hygiene and overcrowding all play a role in transmission [12].

In our series, there was a predominance of males (60.17%) with a sex ratio of 1.48 in favour of males. Our results are similar to those of Attia *et al.* [9] in Côte D'Ivoire and Dare *et al.* [13] in Togo, who found a male predominance of 66.6% and 59.10% respectively.

Epigastralgia was the most frequent reason for consultation and the main indication for FOGD (69.91%), followed by dyspepsia (24.77%) and vomiting (15.92%). The high frequency of epigastralgia is explained by the fact that it is the main reason for consultation in gastroenterology. This finding is consistent with the literature. Similarly, Attia *et al.* [9] reported a predominance of epigastralgia in 64.7% of cases. The wide variety of indications for FOGD reflects the diversity of symptoms and conditions induced by the bacteria. This could be explained by the anatomical location of the epigastrium, but also by the fact that this symptom is present in the most common oeso-gastroduodenal pathologies, such as hiatal hernia, gastropathy, peptic ulcers, GERD and even gastric cancer. It is therefore important to investigate a patient presenting with epigastralgia by FOGD with biopsies to look for *"Helicobacter pylori"*, as they are indicative of upper gastrointestinal pathology [14].

In our study, gastropathy (antral, fundic and diffuse: antro-fundiacular) was the most frequent endoscopic lesion (69.02%), followed by bulbar ulcer (6.19%) and gastric ulcer (5.31%). These results are superimposed on those found by Attia *et al.* [9] who noted a predominance of erythematous gastropathy in 42.2%. The absence of endoscopic lesions (*i.e.* a normal FOGD) was noted in 19.47% of cases, although histological abnormalities were present. This result is close to those reported in African series, which range from 21.5% to 40% [10]. These results confirm that there is no parallelism between endoscopic and histological data, as a normal FOGD does not exclude chronic *Helicobacter pylori* gastritis, hence the importance of systematic biopsies in cases of normal FOGD in the presence of epigastralgia or chronic dyspeptic syndrome.

All our patients had chronic active gastritis (100%). This gastritis activity was distributed as follows: mild (56%), moderate (41.9%) and severe (2.10%). This finding was reported by Attia *et al.* [9] in Côte d'Ivoire.

Helicobacter pylori infection was associated with chronic gastritis in all our patients, and was mild in 50%, moderate in 41% and severe in 9%. In the series by Attia *et al.* [9], it was predominantly mild in 74.5% of cases.

Intestinal metaplasia from which gastric adenocarcinoma can develop was associated with chronic gastritis in 25% of cases, and was mild (19.5%), moderate (5%) and severe (0.5%). This rate is slightly higher than that reported by Coulibaly B [15] in Côte d'Ivoire, which was 15.6%.

In our series, gastritis was atrophic in 48% of cases: mild (28%), moderate (15%) and severe (5%). This result is corroborated by the study by Attia *et al.* [9] in Côte d'Ivoire, in which mild chronic atrophic gastritis was the most frequent lesion (48%). The frequency of chronic atrophic gastritis indicates an advanced stage of the disease.

Lymphoid follicles accounted for 52.2% of cases in our series; the disease was mild in 33% of cases, moderate in 10.2% and severe in 9%. This result is higher than that of Attia *et al.* [9], which was 36.3%.

The eradication rate in our study was 92.30% and 94.12% respectively for bismuth quadritherapy and concomitant therapy. Our results are comparable to those of Lamarque [16] in France and Nyssen [17] in Spain, who reported eradication rates of 90% and 90.4% for 14-day concomitant quadritherapy and 92% and 93% for 10-day bismuth quadritherapy.

These probabilistic treatments of 10 to 14 days combine either a PPI with 3 antibiotics (usually amoxicillin, clarithromicyne and metronidazole); or a PPI with Bismuth subcitrate and 2 antibiotics: tetracycline and metronidazole [18].

The success of the treatment depends on the quality of the information provided to the patient, so that he or she understands the benefits of eradication, the need to take the treatment until the end for optimum efficacy, and the importance of monitoring eradication. These new recommendations emphasise the need for collaboration between the various specialists involved, with a central role for gastroenterologists in coordinating management, mainly in conjunction with general practitioners [19].

No significant difference was observed between these two protocols, making it impossible to decide which of the two quadritherapy protocols should be used as first-line treatment. One or the other may be preferred depending on the advantages and disadvantages.

Compliance was good in 89.60% of all protocols, despite the occurrence of side effects in 36.22% of cases. These side effects were dominated by nausea and vomiting (10.12%), metallic taste (7.9%), diarrhoea (5.9%) and abdominal pain (4.6%).

Concomitant treatment combines the 3 antibiotics and the PPI for the duration of the treatment (14 days). Its superiority to other quadritherapies has not been demonstrated. Overall, the randomised trials and meta-analyses published over the last 3 years confirm the better efficacy of quadritherapies without bismuth (80% - 95%) [20]. Quadritherapies with bismuth are difficult to evaluate because of the different dosages of bismuth, tetracycline and metronidazole, and

the duration of treatment, which varies from 7 days (insufficient) to 14 days. In France, we only have one "all-in-one" speciality, PYLERA (bismuth potassium subcitrate 140 mg, metronidazole 125 mg and tetracycline hydrochloride 125 mg), but this requires 3 capsules to be taken 4 times a day for 10 days, in addition to 2 capsules of omeprazole a day [16].

There is no clear-cut debate about the choice of first-line treatment between the two quadritherapies with or without bismuth. One or the other may be preferred depending on the advantages and disadvantages, bearing in mind that there are no controlled trials directly comparing them for PYLERA. The randomised trial by Lui *et al.* [21] showed no difference in efficacy between these 10-day quadritherapies (Esomeprazole as PPI) in first-line treatment, with high eradication rates: 92.4% with bismuth-tetracycline-metronidazole and 89.4% for sequential treatment.

Side effects were more frequent with bismuth quadritherapy (16.7% versus 8.1%, $p = 0.032$). PYLERA has the advantage of combining antibiotics that are rarely or not at all used in France, but requires patients to take a large number of capsules several times a day (140 capsules over 10 days), at a higher cost than quadritherapy without bismuth. In both cases, it is important to obtain the full support of patients by informing them of the risk of frequent but minor side-effects, in order to limit non-compliance, which is the other major factor in failure [16] [18].

Zeriouh in Morocco [22] and Bouchabou in Tunis [23] reported 39.7% and 36.8% side-effects respectively for concomitant quadruple therapy.

In our series, the eradication rate with concomitant quadritherapy (94.12%) was higher than that with bismuth quadritherapy, with a higher rate of side effects with bismuth treatment and a large number of capsules to be taken with restrictive schedules.

The failure rate was 7.7% for bismuth treatment and 5.88% for concomitant quadritherapy. Only poor compliance was significantly associated with failure to eradicate *Helicobacter pylori*. The same observation has been made by several authors [16] [22] [23].

The benefits of eradicating *"Helicobacter pylori"* are numerous, including:

- Sometimes improves dyspepsia in *Helicobacter pylori* positive dyspeptic patients.
- Heals duodenal ulcers and reduces recurrence of gastric and duodenal ulcers and their complications.
- Interrupts the lesion cascade (atrophy-metaplasia-dysplasia-cancer).
- Prevents the development of gastric adenocarcinoma, especially before the appearance of precancerous lesions.
- Reduces the incidence of gastric cancer in 1er degree relatives with gastric cancer.
- Reduces the risk of metachronous cancer after endoscopic resection of gastric cancer.
- Remission or even cure of MALT lymphoma [24] [25].

5. Conclusion

Concurrent and bismuth quadritherapies were effective in eradicating *Helicobacter pylori* infection, with success rates of 94.12% and 92.30% respectively. Therapeutic compliance was good in 89.60% of all protocols, despite the occurrence of side effects in 36.22% of cases. The management of patients infected with *Helicobacter pylori* remains complex and imperfect, with the gastroenterologist playing an essential role. In order to improve management, it is important to apply the universal methods of searching for and eradicating this bacterium in the context of the practice, avoiding unjustified treatments in their indications or protocols, and ensuring the participation of the patient and his or her GP. The success of the treatment depends on the quality of the information provided to the patient, so that he or she understands the benefits of eradication, the need to take the treatment until the end for optimum efficacy, and the importance of monitoring eradication.

Conflicts of Interest

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

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