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Chronic viral hepatitis B: evaluation of the care of patients monitored at the SMIT in Tivaouane, Sénégal

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ABSTRACT

Objectives: Chronic hepatitis B is a liver-tropic disease caused by hepatitis B virus (HBV) with hepatitis B surface antigen persisting beyond 6 months. According to a 2024 report by the Pasteur Institute, the prevalence of chronic HBV infection in Senegal is alarming, ranking among the highest in the world, between 10 and 17%. Senegal currently does not have a standardized algorithm for the management of chronic hepatitis B. Since 2017, the European Association for the Study of the Liver (EASL) has proposed a new classification of chronic hepatitis B and a surveillance scheme. The objective was to evaluate the management of patients with viral hepatitis B in rural areas according to the EASL criteria.

Methods: Retrospective and prospective, descriptive study with analytical aim from March 15, 2022 to December 7, 2024, at the SMIT Mame Abdou Aziz Sy Dabakh hospital in Tivaouane. Included were patients with chronic hepatitis B who had benefited from an initial management assessment according to the criteria of the EASL. Data were captured using Kobocollect software, encoded, and analyzed using R software, V.4.4.0. Ethical considerations were respected.

Results: We collected 72 patients. The median age was 34 years (28-41), with a female predominance (56.9%). Housewives (34.7%) and teachers (16.7%) were the most represented. The notion of familial liver cancer (16.67%) was reported with 41.67% in the first degree as well as in the second degree. The discovery of HBV carriage was made during an assessment initiated by the practitioner (63.9%), prenatal assessment (19%), and during a blood donation (9.7%). Nine patients (12.51%) were symptomatic. The hepatitis B e-antigen dosage was negative in 69 patients (95.53%). The median alanine aminotransferase levels were 23.10 IU/l (16-32.25) and viral load 379.5 IU/ml (37-1562). Two hepatitis D virus/HBV co-infections were observed. Fibrosis (F0-F1) was found in 82.5% of cases, F2-F3 in 14.3%, and cirrhosis in 3.2%. Tenofovir disoproxil fumarate treatment was initiated in 10 patients (13.9%), according to the 2017 EASL guidelines. Ineligible patients (86.1%) were placed on surveillance, the rate and frequency of which depended on the initial phase. Among the patients lost to follow-up, 42 were under surveillance (67.64%) and four were under treatment (40%). Lack of treatment and high cost of care were the main reasons for exclusion from follow-up. In multivariate analysis, no factor was significantly associated with loss to follow-up.

Conclusions: Our study highlights the challenges of managing chronic viral hepatitis B in rural areas. The high cost of monitoring and the lack of treatment for the majority of patients contribute to loss of follow-up.

Introduction

Viral hepatitis B is a systemic liver-tropic infection caused by the hepatitis B virus (HBV). It can be acute or chronic. Chronic infection is characterized by persistent viral replication in the host for at least 6 months after infection. It is often associated with liver inflammation, which can lead to various long-term complications, including cirrhosis and hepatocellular carcinoma (HCC). Approximately 8-20% of people with chronic hepatitis B develop cirrhosis, of which approximately 20% will experience decompensation, and 1-5% will develop HCC [1].

Chronic hepatitis B remains a major public health problem and represents a significant challenge for the World Health Organization, despite the implementation of response programs within the framework of the Global Health Sector Strategies on HIV, viral hepatitis, and sexually transmitted infections (2016-2030). In 2022, the latest World Health Organization estimates indicate that approximately 1.2 million people

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were newly infected with HBV worldwide, and a total of 254 million people are currently living with this infection. Although approximately 1.1 million HBV-related deaths occur each year, less than 13% of infected people are diagnosed, and only about 3% of them access treatment [1,2].

Sub-Saharan Africa is among the most affected areas, characterized by high endemicity and a prevalence greater than 8%. Like other countries in the region, hepatitis B represents a public health problem in Senegal, where 11% of the population is a chronic carrier of hepatitis B surface antigen (HBsAg) [3]. In Senegal, despite the multiple actions implemented by the national hepatitis control program, including the introduction of vaccination at birth in 2016, the treatment subsidy does not currently have a standardized algorithm for chronic hepatitis B management. In 2017, the European Association for the Study of the Liver (EASL) proposed a new classification dividing the natural history of chronic hepatitis B into five phases: chronic hepatitis B e-antigen (HBeAg)-positive infection (phase 1), chronic HBeAg-positive hepatitis (phase 2), chronic HBeAg-negative infection (phase 3), chronic HBeAg-negative hepatitis B (phase 4), and the HBsAg loss phase (phase 5), as well as a surveillance scheme [4].

Few studies have been conducted in Senegal on chronic HBV carriage, particularly in rural areas. The various studies included only patients undergoing treatment or chronic carriers in the complicated stages. Untreated chronic carriers were often excluded from the studies.

It is in this context that we conducted a retrospective and prospective study at the Infectious and Tropical Diseases Department (SMIT) of the Mame Abdou Aziz Sy Dabakh Hospital Center in Tivaouane with the aim of evaluating the management of patients monitored for chronic viral hepatitis B in rural areas according to the EASL criteria.

Methods

We conducted an open, descriptive, retrospective cohort study with analytical aims, with occasional prospective interventions. The cohort consisted of all patients screened and followed up as outpatients or inpatients for chronic hepatitis B during the period from March 15, 2022 to December 7, 2024 (i.e., 33 months). Included were all patients with chronic hepatitis B who had received an initial management assessment according to the recommendations of the EASL. Not all patients were included co-infected with HBV/HIV. Data were collected from patients' medical records using a pre-established standardized data collection form. A targeted semi-structured interview by telephone call was conducted to assess reasons for dropout and irregularity in patient follow-up.

Patients were classified and monitored in accordance with the EASL recommendations. Clinical and paraclinical monitoring was adapted according to patient classification:

- Phase 1: quarterly alanine aminotransferase (ALT) testing, half-yearly viremia testing, and annual monitoring using non-invasive fibrosis markers.
- Phase 3 with a viral load (VL) less than 2000 IU/ml: ALT measurement every 6 to 12 months, viremia and fibrosis every 2 years.
- Phase 3 with HBV DNA greater than 2000 IU/ml: ALT testing every 3 months for the first year, then every 6 months thereafter, with annual viral load and fibrosis measurements.

Socio-demographic, clinical, paraclinical, and therapeutic data were collected. An assessment of patient follow-up was carried out.

Data were entered using Kobocollect software and then transferred to an Excel spreadsheet for coding before being analyzed using R software, version 4.4.0. Ethical considerations were respected.

Results

A total of 115 patients were followed for viral hepatitis B during the study period, with 72 files included for analysis. The population of our study consisted of 31 men (43.1%) and 41 women (56.9%) with a sex ratio of 0.76. The median age of the patients was 34 years (28-41). The age group of 30-39 years was the majority, representing 36.1%. In our sample, 86.1% of patients resided in the department of Tivaouane. Married people were the majority and represented 84.72% of our sample, of which 72.1% were in a monogamous relationship.

Table 1
Socio-demographic and clinical characteristics of patients monitored for chronic hepatitis B virus.

Features	Number	Percentage (%)
Age	34 (28-41)	
Sex		
Men	31	43.1
Women	41	56.9
Geographical origin		
Tivaouane	62	86.1
Outside the Thiès region	7	9.7
Department of Thiès	3	4.2
Marital status		
Married	61	84.7
Bachelor	9	12.5
Widower	2	2.8
Circumstance of diagnosis		
Systematic review	46	63.9
Blood donation	7	9.7
Prenatal check-up	19	26.4
Comorbidities		
Diabetes	3	4.2
High blood pressure	3	4.2
Lupus	1	1.4
Chronic kidney disease (dialysis stage)	1	1.4
History of liver cancer	12	16.67
First degree	5	41.67
Second degree	5	41.67
Functional signs		
Abdominal pain	4	5.56
Chest pain	2	2.78
Muscle cramps	1	1.39
Dyspnea on exertion	1	1.39
Low back sciatica	1	1.39
General signs		
Weight loss	2	2.78
Overweight/obesity	2	2.78
Physical asthenia	1	1.39

The circumstances of discovery were during a systematic assessment (63.9%), a blood donation (9.7%), and during the prenatal assessment (19%). No personal history was reported. Socio-demographic and clinical characteristics were reported in Table 1.

Patients underwent paraclinical assessment of the various parameters reported in Table 2. The median VL was 379.5 IU/ml (37-1562). The majority of patients (79.2%) had a VL below 2000 IU/ml, of which 29.2% had an undetectable VL. However, 20.8% of patients had a VL above 2000 IU/ml. The search for viral markers, HBeAg was negative in 69 patients (95.53%) and positive in three patients (4.17%), anti-hepatitis B e-antibody positive in 6/10 patients, and anti-hepatitis B surface antibody negative in 11 patients. The search for hepatitis C virus (HCV) co-infections was negative in 34 patients (47.22%). Hepatitis D virus (HDV) serology was positive in 4/10 patients.

Abdominal ultrasound revealed hepatic dysmorphism (6.2%) and hepatic steatosis (6.2%). Fibroscan was performed in 63 patients (87.5%), with a mean of 5.93 kPa ± 2.39 (3.10-17.30 Kpa).

After the initial evaluation, the majority of patients, 62 (86.1%), presented with chronic HBeAg-negative infection (phase 3). Among them, 58 patients (93.54%) had a VL ≤2000 IU/ml, whereas four patients (6.54%) had a VL between 2000 and 20,000 IU/ml. We present the distribution of patients according to stage, according to the EASL nomenclature (Figure 1).

Treatment was initiated in 10 patients (13.9%). The reasons for initiating antiviral treatment were mainly due, in half of the cases (5/10), to patients classified in phase 4 and two patients in phase 2. Two other

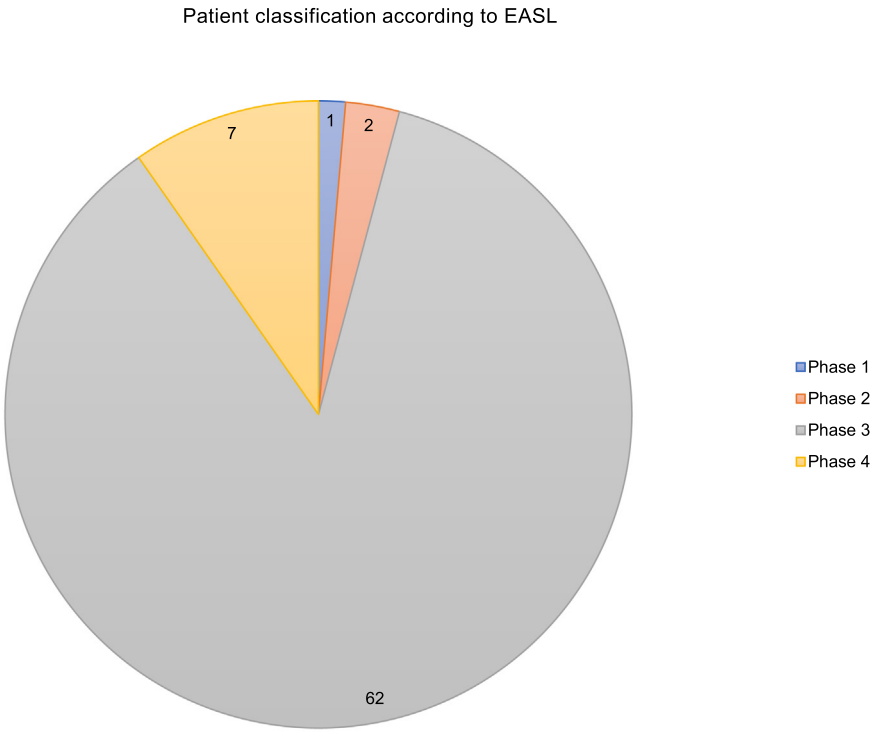

Figure 1. Distribution of patients according to the EASL classification. EASL, European Association for the Study of the Liver.

Table 2
Paraclinical data of patients monitored for chronic hepatitis B virus.

Paraclinical data	Number	Rate
Biological parameters		
Alanine transaminase	72	23.10 IU/l (16-32.25)
Aspartate transaminase	72	23.95 IU/l (18-36)
Hemoglobin level	36	13.20 g/dl ± 1.5 (8-17)
Creatinemia	36	9.039 mg/l (6-20)
Fasting blood sugar	27	0.96 g/l (0.85-2.27)
Viral markers		
Hepatitis B virus viral load	72	379.5 IU/ml (IQR: 37-1562)
Anti-hepatitis B core antibody		
Positive	6	100%
Hepatitis B e-antigen		
Positive	3	4.17
Negative	69	95.53
Anti-hepatitis B e-antibody	10	13.88
Positive	6	60
Negative	4	40
Imaging remove		
Abdominal ultrasound	32	44.44
Normal	28	87.6
Liver dysmorphism	2	6.2
Fatty liver disease	2	6.2
Transient elastometry		
F0-F1	52	82.5
F2-F3	9	14.3
Cirrhosis	2	3.2

patients with a family history of HCC and one patient with HDV co-infection were treated. The mean duration of follow-up was 25 months ± 6.60 (9-33). The group whose duration was greater than 24 months was the majority (30.6%). Pre-treatment renal assessment was normal in all patients.

Among the 10 patients who received tenofovir disoproxil fumarate (TDF), transaminase monitoring was performed in only 50% of patients after 3 months, 40% after 12 months, and 30% after 18 months. Only 30% underwent fibroscan monitoring after 12 months of treatment. Serum creatinine monitoring was performed in 30% of patients after 3 months of treatment and 40% after 12 months.

In the cohort of patients not eligible for treatment (62/72), transaminase monitoring was only performed in 32.26% of patients after 6 months, 29.03% after 12 months, and 17.04% after 18 months of follow-up. Among the 62 untreated patients, VL monitoring was only performed in 29.97% of patients after 12 months and 16.13% underwent fibroscan monitoring after 12 months of follow-up.

In our study, 46 patients (63.9%) were lost to follow-up, whereas the other 26 (36.1%) had irregular follow-up. Among the 46 patients lost to follow-up, four were on treatment (8.7%). No regular follow-up was noted. We were able to contact 11 of the 46 patients lost to follow-up to elucidate the reasons for their absence, including three who were undergoing treatment. Six patients reported that the absence of treatment, after a long journey to complete the initial evaluation, which was costly and entirely at their expense, was the main reason for their exclusion from follow-up. Three patients under treatment, lost to follow-up, were contacted; the reason for discontinuation of treatment was self-medication with herbal medicine.

In bivariate analysis, no parameter analyzed shows a significant association with loss of sight.

Discussion

The population of our study was relatively young, with a median age of 34 years (28-41). The age group 30-39 years was the most represented (36.1%). Vinikoor et al. [5] had found a median age of 33 years in Zambia. The median age was 30 years in Aberra et al. [6] in Ethiopia, with the most represented age group (26-35). In the study by Stasi et al. [7] in Italy, patients were older, with a median age of 50 years. The majority of patients were between 45 and 54 years old, representing 23% of the sample.

In Senegal, young people under 35 years of age represent 75% of the population, as shown by national figures from 2023 [8]. The young age of our study could be explained by the fact that it is a highly endemic country, where the infection is contracted mainly during the perinatal period, with a high risk of progression to chronic disease, but also by the fact that HBV vaccination was introduced in Senegal in 2005 into the vaccination program.

A female predominance with an F/M sex ratio of 1.32 was found in our study. Gomtse et al. [9] in Mali had obtained similar results, an F/M sex ratio of 1.13. This female predominance contrasts with data from the literature, which generally reports a male predominance. In their study, Diallo et al. [10] in Dakar reported a sex ratio of 2.2, whereas Lovett et al. [11] in Australia found a ratio of 2.28.

The comorbidities observed were diabetes (4.2%), high blood pressure (4.2%), lupus (1.4%), and chronic kidney disease in the dialysis phase (1.4%). It is essential to look for these comorbidities, particularly diabetes and chronic kidney disease, to implement adequate monitoring and management of its chronic carriers [12].

The notion of familial liver cancer was observed in 12 patients (16.67%). This rate is significantly higher than that reported by Diallo et al. [10] at Dantec Hospital (3.7%) and by Lemoine et al. [13] in Gambia (5%). No notion of familial HBsAg carriage was reported. This contrasts with the study by Zounon et al. [14] in Thiès, who found a rate of 27.08%.

The circumstances of discovery in our study were during a systematic assessment (63.9%), a blood donation (9.7%), and during the prenatal assessment (19%). Diallo et al. [10] in Dantec and Zoumon et al. [14] in Thiès were found during systematic screening (26.2%; 64.58%) and blood donation (18.6%, 10.42%), respectively. Our results are in agreement with the data in the literature, which reports that the discovery of hepatitis B is often made incidentally during screening in asymptomatic patients [15]. Clinical examination was normal in all patients (100%), as in the study of Zounon et al. [14], where almost all patients were asymptomatic (95.83%). For their part, Diallo et al. [10] reported a normal examination in 58.6% of their patients, whereas Bobilwindé et al. [16] reported 79.4%.

The disease generally progresses silently, as shown in our study, where 87.5% of patients showed no clinical signs during screening.

Liver cytolysis (elevated ALT) was found in 18.9% of cases. The study by Jaquet et al., carried out in 2014 among prisoners at Rebeuss in Senegal, showed a rate of 25.5% of elevated ALT [17]. Lemoine et al. [13] found cytolysis in 12.2% of cases. An increase in ALT above the normal limit indicates hepatic cytolysis and is a determining factor in the decision to initiate treatment. However, normal ALT levels do not exclude hepatic inflammatory activity, due to the fluctuating nature of ALT levels during the course of the infection, as described in the literature [15].

Thirty-six patients had undergone renal assessment (creatinine measurement). It was elevated in three patients (8.39%), and one patient had chronic kidney disease requiring extra-renal purification and nephrology follow-up. Renal assessment before initiating antiviral treatment is important; it allows renal tolerance to be assessed in relation to TDF and thus the treatment dose to be adjusted [18].

HBeAg testing was negative in 69 patients (95.53%). These results are consistent with the literature, which reports that the majority of chronic HBV carriers in sub-Saharan Africa are HBeAg negative [19–21]. Similar data were reported by Lemoine et al. [13] in Gambia in the prevention of liver fibrosis and liver cancer in Africa (PROLIFICA) study (92.1%), Aberra et al. [6] in Ethiopia (90.7%), and Stasi et al. [7] in Italy (75.3%).

The presence of HBeAg in the blood indicates active HBV replication. HBeAg clearance is followed by the appearance of anti-hepatitis B e-antibodies during the hepatitis B e-seroconversion phase. The absence of hepatitis B e-protein production results from the presence of nucleotide substitutions in the pre-core and/or core promoter regions. The mechanisms that explain, after spontaneous hepatitis B e-seroconversion, why some patients progress to chronic HBeAg-negative infection (chronic inactive carriage) and others to chronic HBeAg-negative hepatitis remain unknown [4].

HBeAg is one of the markers indicative of chronicity in the EASL nomenclature and is a determining parameter in the decision to initiate treatment. The other markers are of less interest once the diagnosis of chronic hepatitis has been made and are almost never tested in our cohort [4].

HBV VL was performed in all patients with a median of 379.5 IU/ml (37-1562). Furthermore, the majority of patients had a VL below 2000 IU/ml (79.2%), of which 29.2% had an undetectable VL (36.97 IU/ml). These results were confirmed in Ethiopia [6] and in Gambia [17], where the majority of patients (57.5% and 91%, respectively) had a low viral replication rate (≤2000 IU/ml). In California, a meta-analysis by Sarkar et al. showed that the VL was less than 2000 IU/ml in the majority of patients (27.6%) at the initial assessment [12].

Although the majority of patients had near-zero viremia, a small proportion of our patients (8.3%) had high viral replication (VL greater than 20,000 IU/ml). Vinikoor et al. [5] in Zambia: 11.8%, Zounon et al. [14] in Thiès: 33.33%, and Ndiaye et al. [22] in Thiès: 23.1% had made the same observation during their work. The level of viral replication is an important parameter for determining the indication for treatment. Although viral replication is correlated with an increased risk of developing complications, including liver cirrhosis and HCC.

The search for co-infections is essential in patients with chronic hepatitis B because the mortality rate in these patients is higher than in those with HBV mono-infection due to more sustained liver inflammation and rapid progression to complications, particularly HCC. In addition, in cases of co-infection, the management differs compared with mono-infected patients [23]. In our study, the search for HCV infection performed in 34 patients (47.22%) was negative. In the literature, the prevalence of HBV/HCV co-infection varies between 5 and 20%, with a highly variable geographical distribution [24,25]. In Senegal, it is estimated at 1.7% according to national figures [26], whereas in France, Larsen et al. [27] found a rate of 24.3%.

HDV serology performed in 36 patients (50%) was positive in two patients (5.56%). Tine et al. had found HBV-HDV co-infection in 4.7% of patients [28]. A meta-analysis in Italy reported a rate of 7% [7] and an Ethiopian cohort found 3.7% [29]. HDV plays an aggravating role in the progression of hepatitis B infection; hence, the importance of systematic screening for the Delta virus in all patients with viral hepatitis B. It is associated with acute fulminant and chronic forms of hepatitis, leading to a more rapid progression to cirrhosis and HCC than with HBV monoinfection [30].

Co-infected patients were treated for HBV to slow disease progression in our cohort. Currently, there is no treatment for HDV in Senegal.

Fibroscan is currently considered the gold standard for detecting liver fibrosis. It is a simple, non-invasive test with good reproducibility for assessing fibrosis [31]. It was performed in 63 patients (87.5%). The majority of patients (82.5%) had little or no fibrosis lesions (F0-F1), nine patients (14.3%) had significant fibrosis (F2-F3), and two patients (3.2%) had cirrhosis.

The mean was 5.93 kPa ± 2.39 (3.10-17.30 kPa). Ntagirabiri et al. [32] observed a mean rate of 7 kPa, Touré et al. [33] in Thiès 7.59 kPa, and Zoumon et al. [14], also in Thiès, 9.38 kPa.

Cases of cirrhosis were identified by fibroscan in subjects whose physical examination was normal. The fibroscan result corresponded to the abnormalities observed on liver ultrasound. The latter was performed in 32 patients (44.44%) and was normal in 87.6% of cases. Four patients presented with liver abnormalities, suggesting a possible progression towards the onset of complications. Among them, two patients (6.4%) had hepatic steatosis, whereas the other two had heteromultinodular liver. Abdominal ultrasound is particularly useful in monitoring the infection, especially for the detection of complications [31].

After the initial evaluation, the majority of patients, 62 (83.3%), had chronic HBeAg-negative infection (phase 3). Among them, 58 patients had a VL ≤2000 IU/ml, whereas four patients had a VL between 2000 and 20,78000 IU/ml.

However, these results should be taken with caution because the differential diagnosis with chronic HBeAg-negative hepatitis (phase 4) is sometimes difficult. Indeed, after 1 year of follow-up, a third of patients initially classified as having chronic HBeAg-negative infection (phase 3) had chronic HBeAg-negative hepatitis (phase 4) with fluctuations in VL

and transaminases requiring antiviral treatment [4]. Phase 4 patients represented 9.7%. Phases 1 and 2 were found to be 1.4% and 2.8%, respectively.

Treatment consisted of TDF and was initiated in 10 patients (13.9%). The 2017 EASL eligibility criteria were used to determine the indication for treatment. For these patients, follow-up is performed every 3-4 months during the first year, then every 6-12 months thereafter. For untreated patients, follow-up is generally performed every 6-12 months [4], except for those in phase 3 with viremia ≥2000 IU/ml, for whom monitoring is carried out as for treated patients.

Among the 72 patients in our study, 63.9% (46 patients) were lost to follow-up, including four under treatment, whereas the remaining 36.1% (26 cases) were followed up irregularly (performing monitoring examinations without respecting the chronology and rhythm defined by the department). These results are similar to those obtained by Gomtse et al. [9], who observed that 64.5% of patients were lost to follow-up, whereas the remaining 35.5% were followed up irregularly.

Patients were contacted to determine the reasons for treatment irregularity or even discontinuation. The main reason reported for this irregularity was the high cost of the necessary follow-up assessments. Mattern et al. [34]'s 2019 study in Madagascar reported the cost of care and the availability of treatment in pharmacies as reasons.

In multivariate analysis, no factors were found to be associated with loss to follow-up.

This result may be explained by the lack of statistical power of our study due to the small size of our study population.

Conclusion

Our study highlights the challenges of managing chronic viral hepatitis B in rural areas. The high cost of monitoring and the lack of treatment for the majority of patients contribute to loss of follow-up.

Declarations of competing interest

The authors have no competing interests to declare.

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Ethics approval statement

The study was approved by the ethics committee of the Thiès Health Directorate and Mame Abdou Sy Dabakh Hospital.

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