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Position on the management of occult infection by hepatitis B virus (OBI) and anti-HBc + in hemodialysis units

Posicionamiento sobre manejo de la infección oculta por virus B de la hepatitis (obi) y anti-HBc + EN unidades de hemodiálisis

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Introduction

The prevalence of hepatitis B virus (HBV) infection is low in hemodialysis units in Spain.[1,2] However, the different serological patterns against HBV or the detection of HBV DNA in HBs-Ag patients^{-} elicit doubts regarding the notion of following up with these patients in hemodialysis units. This scenario represents the main reason a group of experts drafted this position in coordination with the multidisciplinary working group on viral diseases of the Spanish Society of Nephrology (SEN).

This position does not replace national and international clinical practice guidelines on HBV in cases of hemodialysis; rather, it aims to clarify the management of patients with occult HBV infection in hemodialysis units by using the best available evidence.

Definition and significance of hidden infection by hepatitis B virus (HBV):

- In all patients who have had previous contact with HBV, the viral genome is incorporated into the nuclei of infected hepatocytes in the form of covalently closed circular DNA (ccc DNA); therefore, regardless of their serological status, these patients are susceptible to reactivation in certain cases of immunosuppression.[3,4]
- HBV reactivation is defined as an increase in viral replication (usually >1 log of HBV-DNA) in people with a previously detectable viral load or as HBV-DNA positivity in people with a previously undetectable viral load or resolved infection. For practical purposes, we consider reactivation as the positivity of HBsAg or the detection of a high viral load (>200 IU/mL).
- The mechanism through which reactivation occurs is related to an increase in HBV replication and the expression of its antigens in hepatocytes during immunosuppression, followed by the destruction of infected hepatocytes mediated by T lymphocytes during immune recovery.

- In patients with HBsAg^{+}, reactivation is characterized by a rapid increase in the level of HBV-DNA, followed by an increase in transaminases.
- In patients with HBsAg^{-}, this process is usually preceded by a positive confirmation of HBsAg.[5]

Reactivation under conditions of immunosuppression can be serious for patients and can result in the transmission of the infection to their environment.

Regardless of the reactivation process in patients who have previously had contact with HBV, we can identify small viremias of variable duration, which are characterized by the absence of detectable HBsAg in serum and the presence or absence of anti-HBs or anti-HBc. This situation has been referred to as hidden HBV

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Table 1
Differential diagnosis of occult HBV infection.

Situation	Characterized by	Requires
OBI	Stable or intermittent viral load (always measured at < 200 IU/mL HBsAg$^-$) and independent of anti-HBs or anti-HBc	Recommendations of this document
Reactivation	High viral load (> 200 IU/mL) or clearly increasing or positivity of HBsAg	Referral to a hepatology department for treatment and isolation
Acute infection in the initial period	Small viremia without HBsAg and frequently without anti-HBc. In the follow-up sample, the typical parameters of acute infection appear	Requires referral for follow-up, isolation and epidemiological study to identify the source of infection and to rule out that it is an infection of hospital origin
Chronic HBV infection with escape mutations in HBsAg	Mutations in the HBsAg sequence	Requires referral to a hepatology department for monitoring and isolation, due to the fact that antigenic escape mutants can also escape vaccine protection

HBsAg: hepatitis B virus surface antigen; anti-HBc: hepatitis B core virus antibody; anti-HBs: hepatitis B virus surface antibody; OBI: hidden B virus; HBV: hepatitis B virus.

infection (OBI).[6] Therefore, OBI is characterized as the presence of HBV- DNA in the blood of people who exhibit negative HBsAg serological test results.[7–10]

This situation, which exhibits a variable prevalence worldwide,[11] could have possible clinical implications, such as the risk of HBV transmission and the risk of reactivation in immunosuppressive conditions (which represents the most frequent possibility). It is unknown whether patients with these small viremias demonstrate a higher risk of reactivation of the infection.

- The prevalence of occult infection by the hepatitis B virus (HBV) in hemodialysis units varies significantly according to the geographical region and the investigated population; moreover, it is estimated to be between 0.11% and 12.5%.[12–14] In the most recent meta-analysis, the mean prevalence in hemodialysis was 5.14%.[15]

The differential diagnosis of occult HBV infection includes 3 situations that could be confused with what is indicated by OBI, and it is necessary to perform a correct diagnosis because of its clinical implications for the patient and the possibility of transmission to their environment (Table 1):

- *Reactivation in immunosuppressed patients.* In this case, the viral load is high or increasing. This scenario requires referral to hepatology for treatment and isolation.
- *Acute infection in the initial period.* In this case, we can detect a small viremia without HBsAg and often without anti-HBc. The infection should be suspected before the detection of viremia (without HBsAg and without anti-HBc) and through a follow-up sample in which different parameters related to acute infection appear. This scenario requires referrals for follow-up, isolation and epidemiological studies to identify the source of infection and to rule out that it is an infection of hospital origin.
- *Chronic HBV infection with escape mutations in HBsAg* (also known as false OBI). This situation (which is commonly observed in reactivations) implies that HBsAg is not detected because these mutations prevent the proper functioning of immunoassays. The infection should be confirmed by using HBV-DNA sequencing (which is a free service at the National Center for Microbiology and technically possible when the viral load is greater than 100 IU/mL). This process requires referral to a hepatology clinic for follow-up and isolation, due to the fact that antigenic escape mutants can also escape vaccine protection.

- The progressive improvement in the sensitivity of HBV-DNA detection techniques, such as the ability to quantitatively detect up to 10–20 IU/mL of viral DNA, causes these small viremias to be detected, thereby eliciting questions regarding the most suitable perspective regarding follow-up with patients on hemodialysis with OBI,[16] specifically with respect to the periodicity of the monitoring of viremia and the isolation of patients on hemodialysis.
- The limited scientific evidence on HBV transmission from patients with OBI in hemodialysis units,[17] along with the fact that in recent years, routine clinical practice has demonstrated no reported outbreaks of hepatitis B in hemodialysis units in Spain, have guided us in establishing these recommendations.

Objective

Given the concern about the increased prevalence of OBI in hemodialysis patients, the SEN (through its Working Group of Viral Diseases in Hemodialysis) has coordinated a multidisciplinary group of professionals who have agreed on a position regarding the increased prevalence of OBI in hemodialysis.

The main objective is to establish recommendations based on current scientific evidence and expert opinions in the diagnosis, monitoring and treatment of hemodialysis patients with OBI.

Given that the majority of anti-HBc$^+$ patients (even those without a detectable viral load) can develop intermittent viremia during follow-up, the working group considers that all of the recommendations for OBI patients are also applicable to anti-HBc patients. Therefore, OBI and/or anti-HBc$^+$ patients will be discussed throughout this document.

Methodology

This consensus document was derived from the controversies resulting from the symposium of the National Congress of the SEN in 2023. The SEN Working Group on viruses in hemodialysis decided to prepare a consensus document on OBI. Nephrologists from the working group, as well as professionals from hepatology services, preventive medicine and microbiology with experience in hemodialysis OBI, were chosen for this task.

During face-to-face and non-face-to-face sessions, the multidisciplinary group of professionals discussed specific questions among themselves, which constitute the basis of this position paper.

The strength of the recommendations of this document is based on the balance between risks and benefits for patients; on the quality of the evidence; on the values and preferences of patients; and on the estimation of the consumption of resources or costs. Thus, 2 grades of recommendation are established: “It is recommended” was determined if the group of experts considers that all patients should receive the recommended action; and “It is suggested” was determined if the group of experts considers that the action is advisable, although there is insufficient evidence to make it generalizable.

Subsequently, the document was reviewed by all members of the group of Viral Diseases in Hemodialysis of the SEN and by professionals in the specialties of nephrology, microbiology, preventive medicine and hepatology. Their contributions have been integrated into the final version of this position, which is now publicly available to all SEN members should they like to make additional contributions.

Recommendations

1 Routine serology against HBV in hemodialysis patients

1.2 What determinations against HBV should be performed in incident patients on hemodialysis?

- It is recommended to determine HBsAg, anti-HBs and anti-HBc in all patients who are beginning a hemodialysis program.
- It is recommended that laboratories perform automatic determination of HBV-DNA in all incident patients on anti-HBc $^{+}$ hemodialysis.

1.3 What determinations against HBV should be routinely performed in prevalent hemodialysis patients? **

- It is recommended that this serology (HBsAg, anti-HBc^{+} and anti-HBs) be repeated every 6 months.
- It is recommended to determine HBV DNA in all patients experiencing any of the following situations:

• Unexplained hypertransaminasemia or
• New-onset anti-HBc^{+} or
• Anti-HBc^{+} that is already known (regardless of positivity or no positivity and the anti-HBs titer) if:

o They exhibit a high degree of fragility and/or malnutrition or are in a state of immunosuppression.
o They will receive immunosuppressants or chemotherapy.

- It is suggested to determine HBV-DNA at least annually in all anti-HBc^{+} patients.

4 On OBI in dialysis

2.5 How to define the patient with OBI?

2.1.6 All HBsAg-negative patients and patients with HBV-DNA detectable by < 200 IU/l. The diagnosis requires 2 determinations that meet the abovementioned criteria in a time frame of less than 2 weeks.

2.1.7 Viral DNA detection below the limit of quantification of the assay used in each center should not be considered as a positive result.

Each center should know the limit of quantification of the assay that is used by its laboratory.

2.1 What laboratory determinations should we perform in OBI and/or anti-HBc^{+} patients?

2.2.2 Before viremia > 200 UI/l and persistent negative HBsAg are detected, surface Ag sequencing is suggested to identify escape variants (which is currently available free of charge at the National Center for Microbiology of Majadahonda). It is also recommended to be referred to a. gastroenterologist.

2.2.3 If te diagnosis of OBI and/or anti-HBc^{+} is confirmed, there is no evidence on the periodicity of the subsequent determination of viremia.

2.2.4 It is suggested to include all OBI and/or anti-HBc^{+} patients in observational clinical studies to obtain evidence on clinical and serological evolution.

2.2.5 It is recommended to monitor the viral load in patients with high fragility and/or malnutrition, the need for immunosuppressant or chemotherapy treatment, or if there is already a state of immunosuppression. The initial viral load, transaminases, growth of the viral load and type of immunosuppression will guide the frequency of determinations and the suitability of antiviral treatment and type (either prophylaxis or treatment).

2.6 What measures should be enacted before OBI and/or anti-HBc^{+} patients are transferred to other units? **

2.3.7 If the abovementioned recommendations have been followed, it is not necessary to determine HBV-DNA levels in OBI and/or anti-HBc^{+} patients prior to transfer.

2.3.8 If patients originate from or have been temporarily treated in units with a high prevalence of HBV (or if there is evidence that the recommendations of this document have not been followed), it is suggested to once more follow the recommendations for incident patients.

2.9 In hemodialysis units, should patients with OBI and/or anti-HBc^{+} be isolated? **

2.4.10 For patients without risk of reactivation, it is recommended to not isolate OBI and/or anti-HBc^{+} patients.

2.4.11 For patients who are at risk of reactivation (patients who are immunosuppressed, malnourished, or treated with immunosuppressants), the following steps should be followed:

2.4.2.12 Close monitoring of viral load is recommended.

2.4.2.13 It is recommended to initiate prophylaxis/treatment according to what is established in point 3.

2.4.2.14 It i suggested to assess isolation according to the evolution of viral load monitoring (including isolation in rooms not devoted to HBV, as long as the reactivation criteria are not met).

2.4.2.15 It is recommended to not isolate B-positive virus patients. If reactivation is confirmed, the patient should be considered as an HBV-positive patient and should be isolated.

2.16 Are OBI and/or anti-HBc^{+} patients considered to be contagious in a hemodialysis unit? **

2.5.17 A literature review of the working group revealed no evidence of HBV transmission by OBI and/or anti-HBc^{+} patients on hemodialysis; thus, the risk of transmission (if it exists) should be considered to be very low.

2.5.18 No special dialysis monitors are needed. The disinfection of dialysis monitors will be the same as in the rest of the patients, without the requirement of additional measures.

2.5.19 As with all dialysis patients, standard precautionary measures should be implemented to avoid the transmission of viral diseases during dialysis, with special emphasis on the cleaning and disinfecting of the external surfaces of the monitor.

2.5.20 Regarding serological protection against HBV:

2.5.4.21 It is recommended that health professionals working in hemodialysis units implement serological protection against HBV.

2.5.4.22 It is recommended that patients receiving dialysis in proximity to OBI and/or anti-HBc^{+} patients possess serological protection against HBV.

23 Regarding the treatment of patients with OBI and/or anti-HBc^{+}, should the patient be treated for OBI and/or anti-HBc^{+}? **

3.24 In the absence of immunosuppression, it is recommended to not indicate therapeutic reactivation prophylaxis.

3.25 In the presence of immunosuppression, it is recommended to evaluate the suitability of therapeutic reactivation prophylaxis in conjunction with the digestive system service.

3.26 It is suggested that patients with OBI and/or anti-HBc^{+} be vaccinated against HBV. The working group has not found sufficient evidence regarding the usefulness of revaccination in nonresponders.

27 Preventive measures for health professionals

4.28 How should accidental inoculation of a professional by a hemodialysis patient with OBI and/or anti-HBc^{+} be treated? It is suggested to follow the same protocol as with accidental inoculation with HBs-Ag-positive patients.

29 What should the considerations be for OBI and/or anti-HBc^{+}

Table 2
Risk of HBV reactivation according to immunosuppressive therapy and HBV serological status.

Type of immunosuppressive treatment	Risk of HBV reactivation	
	$HBsAg^+$	$HBsAg^-$ and (OBI and/or anti-HBc^+)
B-lymphocyte depleting treatments (rituximab, natalizumab, alemtuzumab, etc.)	**High**	**High**
Immunosuppression by bone marrow transplantation	**High**	**High**
Potent TNF⟨ inhibitors (infliximab, adalimumab, certolizumab, golimumab, etc.)	Moderate-**High**	Low-Moderate
Less potent TNF⟨ inhibitors (etanercept)	Moderate	Low
Anthracycline derivatives (doxorubicin)	**High**	**Low-Moderate**
Local treatment of hepatocellular carcinoma (TACE)	**High**	**Low-Moderate**
Systemic chemotherapy	**Moderate**	**Low-Moderate**
Inhibitors of cytokines or integrins (abatacept, ustekinumab, natalizumab, vedolizumab, etc.)	**Moderate**	**Low-Moderate**
Cyclophilin inhibitors (cyclosporine)	**Moderate**	**Low-Moderate**
Tyrosine kinase inhibitors (imatinib)	**Moderate**	**Low-Moderate**
Proteasome inhibitors (bortezomib)	**Moderate**	**Low-Moderate**
Histone deacetylase inhibitors (romidepsin)	**Moderate**	**Low-Moderate**
Antimetabolites (azathioprine, 6-mercaptopurine, methotrexate, etc.)	**Low**	**Low**
Intra-articular corticosteroid injections	**Low**	**Low**
Prednisone (or equivalent)		
Prednisone ≥10 mg/day ≥4 weeks	**High**	Moderate
Prednisone <10 mg/day ≥4 weeks	Moderate	Low
Prednisone <1 week	Low	Low

Source: Modified from Rodríguez et al.[5]
Anti-HBc^+: hepatitis B core virus antibody-positive; $HBsAg^+$: hepatitis B surface antigen positive; OBI: occult hepatitis B virus infection; TACE: transarterial chemoembolization; TNF: tumor necrosis factor; HBV: hepatitis B virus.

and renal transplantation? **

5.30 Is any action necessary for active patients on the waiting list for a kidney transplant?

5.1.31 It is recommended to measure a baseline viral load just before the initiation of immunosuppressant treatment for renal transplantation.

5.1.32 After renal transplantation, the approach established in clinical practice guidelines for renal transplantation should be followed.[18,19]

Justification of the recommendations and suggestions

This consensus document highlights the need to unify criteria against hidden infection by B virus in hemodialysis units, due to the fact that there is currently no uniformity of action in terms of the determination of serologies and their frequency of repetition, policies of isolation or comprehensive approaches to these patients.

The determination of serological studies against HBV is important because it allows for the estimation of whether the patient has had contact with HBV and whether he or she is responsive (or not) to vaccination against the virus.[20] The group considers that as of the time of creation of this consensus, serological markers, vaccination policy and standard precautionary measures (formerly known as universal prevention measures) that are used in dialysis units have been successful and have not been translated into outbreaks of hepatitis B; thus, it is only considered necessary to determine HBV DNA on an annual basis, and the isolation of OBI and/or anti-HBc^+ patients is not needed.

Unlike HCV (and as explained in the Introduction section), the viral genome of HBV is incorporated into the nuclei of infected hepatocytes, which are susceptible to reactivation in certain situations of immunosuppression; therefore, the possibility of infectivity in immunosuppressed patients exists (Table 2).[5,21–23] This scenario explains why viral load monitoring is suggested for all anti-HBc^+ immunosuppressed patients (regardless of whether they have OBI), as long as the immunosuppression state persists.

Generally, an immunosuppressed patient is defined as follows:

1 Patients with a reduced capability of fighting infections, either because they have certain diseases (such as acquired immunodeficiency syndrome or certain genetic disorders that affect the immune system, among others) or because of the treatment that they are receiving.
2 Patients who present with a state of severe malnutrition.
3 Patients receiving immunosuppressive drugs or chemotherapy or with an absolute neutrophil count <500 □l.

Hepatitis B transmission from patients with OBI and/or anti-HBc^+ described thus far have occurred through blood transfusions (depending on the volume of transfused blood), liver transplantation and mother/child vertical transmission,[8,9,24,25] without reports of infections in hemodialysis units.[24] This indicates that the isolation of patients with OBI in different dialysis rooms is not justified. However, as has already been reported, in immunosuppressed patients, the possibility of virus reactivation must always be considered; in this case, if reactivation occurs, it would have to be evaluated in conjunction with a gastroenterologist and the isolation policy could vary. Hence, the monitoring of these cases and chemoprophylaxis in patients who will undergo immunosuppression is important.[26]

Of utmost importance is the knowledge and compliance with the standard precautionary measures that should always be applied, regardless of the serological status of the patients in the unit. Furthermore, the fact that both professionals who work in dialysis units and patients who undergo dialysis are susceptible to *de novo* infection by any blood-borne virus should always be considered; therefore, these individuals could be vehicles of transmission of such infections.[27,28]

Therefore, the adoption of additional preventive measures should be considered, such as active HBV vaccination policies for patients and health professionals in dialysis units and the organization of dialysis centers that avoid proximity between OBI patients and patients without serological protection against HBV.

The suggestions and recommendations adopted by this group of experts have been made based on the existing literature and to prevent possible reactivations of HBV. In the future, they may be adapted when there is more experience and evidence obtained on the subject. In this sense, the group of experts considers it convenient to conserve biological samples that can be analyzed by research groups and that allow for the generation of the necessary evidence to support decision-making on the clinical and epidemiological significance of OBI.

Declaration of competing interest

The authors have no conflicts of interest to declare.

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