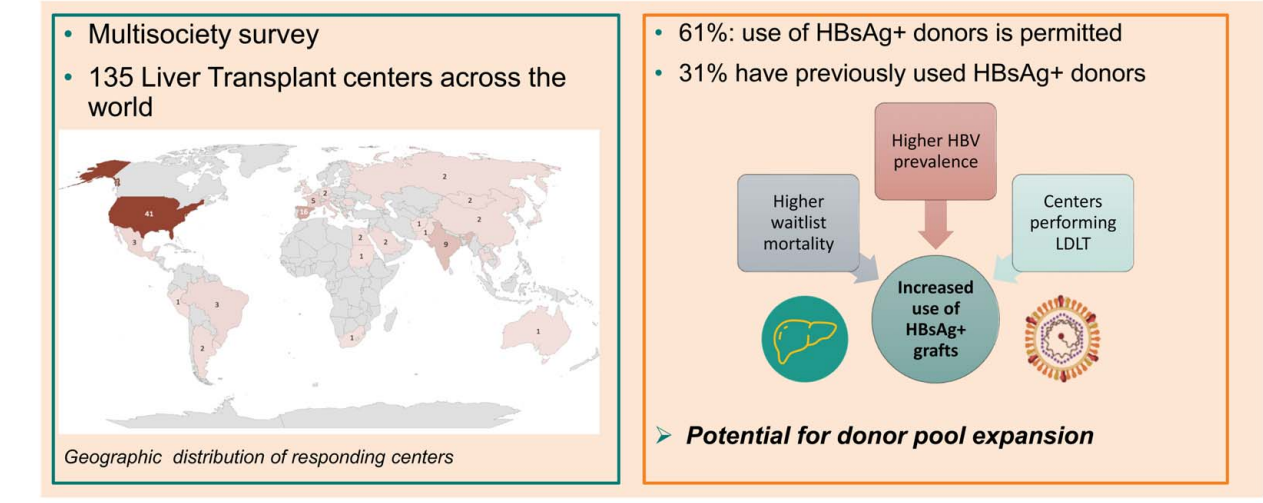
Use of HBsAg-positive donors in liver transplantation: An ILTS-EASL-AASLD multisociety survey

VISUAL ABSTRACT



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ORIGINAL ARTICLE

Use of HBsAg-positive donors in liver transplantation: An ILTS-EASL-AASLD multisociety survey

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Abstract

The gap between organ supply and demand in liver transplantation remains large in most parts of the world. One strategy to increase the donor pool is to use grafts infected with HCV, HBV, and/or HIV viruses. We aimed to explore the current use of HBsAg-positive liver grafts worldwide. A prospective cross-sectional web-based survey was designed, with a total of 28 queries, assessing national and local regulations, center experience, and center-specific experience related to the topic, and sent to all members of International Liver Transplantation Society, European Association for the Study of the Liver, and American Association for the Study of the Liver, and promoted on social media. A total of 135 liver transplant centers answered the survey: 38% from WHO European Regions, 39% from American regions,

Abbreviation: LT, liver transplantation.

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and 9.7% from South-East Asian regions. Most of the participating centers (67.3%) had been performing liver transplantation for over 15 years, with a mean of 66.5 liver transplants per year, and 54% also performed living-donor liver transplants. HBV-related disease was the indication for liver transplantation in an average of 15% of all liver transplantation cases. Regarding national and/or regional regulations, 40% of the centers reported that the use of HBsAg-positive donors was permitted, and an additional 20% could use them under special circumstances. Thirty-two centers (31%) had previously used HBsAg-positive donors. Among these centers, 62.5% conducted living-donor liver transplants and showed an increased inclination toward the use of HBsAg-positive grafts in centers with elevated waitlist mortality. HBsAg-positive donors are underutilized worldwide. The use of HBsAg-positive liver grafts could help to increase the donor pool, particularly in highly endemic areas.

INTRODUCTION

Liver transplantation (LT) is the foremost, if not the sole, viable remedy for severe irreversible liver disease. According to estimates from the Global Observatory on Donation and Transplantation, nearly 35,000 LT procedures were conducted worldwide by 2021.[1] Advances in medical care and organ allocation systems have made significant strides in reducing the mortality rate of patients awaiting transplantation in recent years. Nonetheless, there is room for improvement in increasing organ donation rates and optimizing the allocation of available organs.

A notable concern is the considerable disparity between the demand for organs and their availability, resulting in prolonged waiting times for patients on the transplant waiting lists and, regrettably, fatalities in some instances while awaiting intervention. According to the Global Observatory on Donation and Transplantation's 2020 report, the global mortality rate for patients on the LT waiting list was ~10%. One strategy for bridging the gap between organ supply and demand involves broadening the criteria for organ donation. For instance, this may encompass grafts from individuals infected with viral HBV and HBC or HIV. This approach is currently feasible because of the availability of highly effective antiviral medications that can either control or eradicate these viruses.[2]

One area that requires additional data for worldwide implementation is the use of HBsAg-positive liver organs. The Guidelines of the American Society of Transplantation and the position statement and recommendations of the European Liver and Intestine Transplantation Association recommend that HBsAg-positive donors should be carefully considered in all adult transplant candidates after an individualized assessment of the risks and benefits and appropriate patient consent.[3,4] The decision to use an HBsAg-positive liver donor depends on various factors, including the recipient's health status, the availability of other suitable donors, and the potential risks and benefits of transplantation. Notably, if the recipient is HBsAg-negative, there is a clear risk of transmission of a new hepatitis B viral infection from the donor's liver.

This risk can be mitigated using antiviral medication after transplantation to prevent the virus from replicating and establishing HBV-related graft damage in the recipient's body. Close monitoring of the recipient's liver function and viral status is necessary to detect potential complications early and manage them appropriately. In a recent analysis of the Organ Procurement and Transplantation Network database, transplant recipients of HBsAg-positive liver allografts did not experience increased rates of graft loss or mortality.[5] This consideration is even more relevant in endemic regions with a high prevalence of HBsAg positivity among the general population and, thus, potential donors.[6]

A task force was formed in 2022 by the International Liver Transplantation Society, the European Association for the Study of the Liver, and the American Association for the Study of the Liver to investigate the global clinical practice and obstacles of transplanting such organs using a multidisciplinary online survey. Herein, we report the results of the survey and their implications, which may help LT centers to harmonize practice care worldwide.

METHODS

A prospective cross-sectional web-based survey aimed at exploring the utilization of HBsAg-positive organs in adult liver transplant recipients was designed based on this task force. Data were collected anonymously using the SurveyMonkey platform (www.surveymonkey.com), including a combination of single-choice and open-answer queries. The questionnaire comprised 3 sections with a total of 28 queries assessing national and local regulations, general center experience, and center-specific experience related to the topic (Supplemental Material, http://links.lww.com/LVT/A615).

The authors conducted a 1-month pretesting phase of the proposed questionnaire among LT centers of the European Association for the Study of the Liver-American Association for the Study of the Liver-International Liver Transplantation Society Infectious Diseases Special Interest Group task force, allowing for correction and clarifications. The final version of the digital survey was published online on December 5, 2022, and remained available until February 20, 2023. This survey was prominently featured on the websites of all 3 societies, and invitations to participate were extended through e-mail to all physicians. To prevent duplicate entries, the system was configured to accept only 1 questionnaire per adult liver transplant unit within each institution. The survey was also promoted through social media platforms (Twitter and Facebook accounts of participating societies).

Statistical analysis

A survey analysis was performed considering the hierarchical structure formed by 3 primary sampling units: (i) World Health Organization Regions, (ii) countries, and (iii) LT centers. In this study, stratification and finite population corrections were deemed unnecessary, assuming population stability and that the sampling fraction was larger than 5% of the sampled population. Data are presented as percentages with corresponding 95% CIs. The normality of continuous variables was assessed using the Shapiro-Wilk test. Multinomial and linear regression analyses were performed according to the variable distributions. In the subgroup analysis, p values were reported following grand mean comparison and Bonferroni correction.

Statistical significance was set at $p < 0.05$. Statistical analysis was performed using the Stata 15 software (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX, StataCorp LLC).

RESULTS

Survey participation and center profile

One-hundred thirty-five centers responded to the survey: 38% from WHO European Regions, 39% from American regions, 9.7% from South-East Asian regions, 7% from Western Pacific regions, 4.4% from Eastern Mediterranean regions, and 3% from African regions (Figure 1). The detailed participation by country is summarized in Supplemental Table 1, http://links.lww.com/LVT/A615.

Most of the participating centers (67.3%) had been performing LT for > 15 years. On average, these centers performed 66.5 liver transplants per year. Furthermore, over half of the participating centers (54%) also performed living-donor liver transplants (LDLT), accounting for an average of 35.6% of all liver transplants performed at these centers.

Hepatitis B-related disease was the indication for LT in an average of 15% of all LT. Most of the centers (94.2%) reported managing HBV suppression after

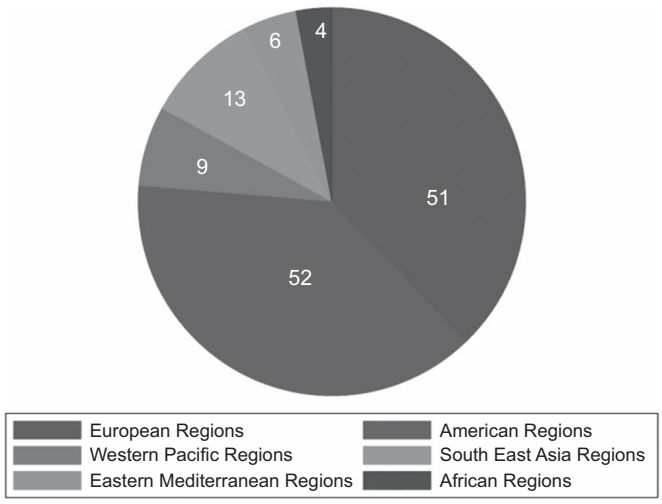

FIGURE 1 World Region's distribution of responding centers.

TABLE 1 Center profile/policies

LT experience (> 15 y)	0.673 (0.557, 0.772)
Number of LT per year per center (mean; 95% CI)	66.53 (57.38, 75.67)
LDLT (%, 95%CI)	0.55 (0.43, 0.66)
Percentage of LDLT out of all LT (%, 95%CI)	35.63 (-2.12, 73.37)
Percentage of HBV LT over all indication	15.18 (0.75, 29.61)
HBV infection suppression after transplant	0.942 (0.74, 0.99)
HBV recipient vaccination	0.827 (0.76, 0.88)

Abbreviations: LDLT, living-donor liver transplants; LT, liver transplantation.

transplant and mandated HBV vaccination for waitlisted patients (82.7%) (Table 1).

Regulations

Regarding national and/or regional regulations, 40% of the centers reported that the use of HBsAg-positive donors was permitted, and an additional 20% could use them under special circumstances, including in HBsAg-positive or anti-HBc-positive recipients or in cases of urgent need for a liver transplant.

Concerning the national and regional regulations for the use of anti-HBc-positive donors and HCV-positive donors, only 14.1% and 19.3% of the centers, respectively, reported not being authorized to use these grafts (Table 2).

Liver transplants from HBsAg-positive donors

Several reasons were cited for abstaining from using HBsAg-positive donors, primarily legal restrictions (50.7%), concerns about the transmission of HBV or the development of HCC (34.2%), and the absence of HBsAg-positive donors within their own centers (24.7%). Other reasons included a low waiting list death rate and risk of HDV recurrence. Regarding HBsAg-positive potential donors per region, the responding centers estimated it to be < 1% (Table 3).

Delving further into the characteristics of the 32 centers that had used HBsAg-positive donors, it was observed that most of these centers were located in the European region (34%) and the American region (37%), with the Western Pacific region accounting for 16%. In addition, 62.5% of these centers conducted LDLT. Notably, centers with elevated waitlist mortality exhibited a greater inclination to use HBsAg-positive grafts, while utilization was notably lower in centers with lower waitlist mortality ($p = 0.02$, as indicated in Table 4). We also explored whether the use of HBsAg-positive grafts was higher in regions with higher hepatitis B prevalence, finding that 55.6% of centers from the Western Pacific region and 100% from the African region had used these grafts, versus 29% and 28% from the European and American regions ($p = 0.21$).

Management of transplant from HBsAg-positive donors and outcomes

Most centers (68%) reported the need for a special consent form for using organs from HBsAg-positive donors. Acceptance rates of HBsAg-positive donors for different situations were as follows (multiple answers were allowed): HBsAg-positive recipients only (35.5%), HBsAg-positive recipients (51.6%), HBsAg-negative and anti-HBc-positive recipients (45%), and patients who are HBsAg-negative and anti-HBc-negative (38.7%).

To determine whether HBsAg-positive organs were suitable for transplantation, they were routinely biopsied in 57% of the centers. In 44% of patients, the fibrosis stage limit for accepting an HBsAg-positive donor was F1 (scale to F4). Regarding steatosis grade, 35% of the centers accepted < 10% of steatosis, 18% accepted 10%–20%, and 30% of the centers accepted > 30%. Other histological features, such as nuclear and cytoplasmic patterns, were not relevant in 91% of the responding centers. Other nonhistological exclusion criteria for the use of organs from HBsAg-positive donors included naïve HBV recipients (26%), HDV coinfection (61%), LDLT (35%), HIV coinfection (48%), donors over 65 years old (26%), injection drug use, or other factors associated with an increased risk of HDV (17%).

In the post-LT setting, most centers (90%) reported using only the last generation of antivirals (entecavir, tenofovir disiproxil, and tenofovir alafenamide) in

TABLE 2 National and regional regulations

Donor serology	Can be used (95% CI interval)	Cannot be used (95% CI interval)	Under special circumstances (95% CI interval)
HBsAg-positive	0.4 (0.289, 0.52)	0.39 (0.27, 0.52)	0.21 (0.15, 0.28)
Anti-HBc-positive	0.79 (0.60, 0.91)	0.14 (0.05, 0.33)	0.19 (0.07, 0.44)
Anti-HCV-positive	0.689 (0.51, 0.83)	0.19 (0.09, 0.16)	0.12 (0.09, 0.17)

TABLE 3 Potential HBsAg-positive donors

Estimation of HBsAg-positive potential donors per region	0.73% (0.04, 1.42)	
Case of HBsAg-positive donors	0.31 (0.23, 0.40)	
% of LT performed related to the total number	2.19 (−2.70, 7.09)	
Cause of not performing LT	Legally not accepted	0.51 (0.28, 0.73)
	Risk of HVB transmission or HCC	0.34 (0.19, 0.53)
	Lack of HBsAg-positive donors	0.24 (0.14, 0.40)
	Low waiting list death rate	0.04 (0.02, 0.11)
	Lack of suitable HBsAg-positive donors that fulfill our requirements	0.22 (0.08, 0.49)
	Risk of HDV recurrence	0.01 (0.001, 0.12)
	Others	0.14 (0.02, 0.56)

Abbreviation: LT, liver transplantation.

seronegative patients (HBsAg-negative) transplanted with HBsAg-positive donors. Regarding the administration of HBIG following LT in recipients who were HBsAg-negative but received grafts from HBsAg-positive donors, one-third of the centers abstained from HBIG use, while two-thirds employed it, with half of them opting for lifelong treatment. Of the centers that discontinued HBIG, this was done at a mean of 7 months post-LT.

Most centers (96%) did not use a specific tailored immunosuppressive regimen for recipients of organs from HBsAg-positive donors. Post-LT monitoring of recipients of organs from HBsAg-positive donors was more stringent virologically and serologically in 70% and 30% of centers, respectively, compared to HBV-positive recipients. HBV DNA was monitored every 3 months in 65% of cases and every 6 months in 22% of cases. Additional histological monitoring was performed in only 13% of the centers. HCC surveillance, regardless of transplant indication, was performed in 35% of the centers (Table 5). Only 1 center reported having a patient who experienced HBV-related mortality post-LT after receiving an HBsAg-positive graft.

DISCUSSION

There is a significant shortage of available liver organs, with an increasing demand for LT. Organs previously discarded are increasingly being used to expand the donor pool.[5] Using the United Network for Organ Sharing database, Bhatnagar et al recently demonstrated good short-term posttransplant patient survival outcomes in recipients of livers from HBsAg-positive donors, even in those without chronic HBV infection before transplant. In propensity-matched analyses, HBV patients who received HBsAg-positive livers had overall similar 1- and 3-year post-LT survival rates compared with those who received livers from donor after cardiac death donors, HCV nucleic acid testing-positive donors, extended-criteria donors, and average-risk donors.[7]

In this multinational multisociety survey of 135 liver transplant centers, we found that although 60% of centers worldwide are allowed to use livers from HBsAg-positive donors, fewer than 30% have ever used such a donor for a small fraction of all transplants. The under-utilization of HBsAg-positive donors is most commonly due to regulations forbidding their use in half of centers, with concerns regarding HBV transmission along with HCC development risk being cited by one-third of centers and a lack of such donors cited by a quarter of centers. These data highlight important practice variability worldwide and identify the potential opportunity to perform more life-saving transplants, especially in centers with higher waitlist mortality and/or a larger number of HBV-positive recipients and/or donors.

The survey methodology, including centers from all across the world, allowed us to understand the

TABLE 4 Centers using HBsAg -positive donors according to waitlist mortality

	Waitlist mortality							
HBsAg+ donor	**< 5%**	**5–10%**	**11–15%**	**16–20%**	**> 20%**	**Other**	**Total**	***p***
No	17 (77.3)	13 (37.1)	4 (19.1)	5 (41.7)	2 (28.6)	3 (50)	44 (42.7)	0.023
Yes	5 (22.7)	22 (62.9)	17 (81)	7 (58.2)	5 (71.4)	3 (50)	59 (57.3)	—
Total (n)	22	35	21	12	7	6	103	—

Note: *p*-value was obtained following grand mean comparison and Bonferroni correction.

TABLE 5 Use of HBsAg-positive donors

Special consent	0.68 (0.52, 080)
Acceptance rates	
HBsAg-positive recipients only	0.36 (0.2, 0.74)
HBsAg-positive recipients	0.52 (0.25, 0.77)
HBsAg-negative, anti-HBcore-positive recipients	0.45 (0.23, 0.64)
HBsAg-negative, anti-HBcore-negative recipients	0.39 (0.14, 0.71)
None of above	0.03 (0.001, 0.54)
Biopsy is required prior LT	0.567 (0.266, 0.823)
Allowed degree of histologic fibrosis	
F1	0.44 (0.13, 0.80)
F2	0.22 (0.07, 0.53)
F3	0.22 (0.07, 0.53)
F4	0.04 (0.05, 0.30)
Allowed degree of histologic steatosis	
< 10%	0.35 (0.31, 0.39)
10–20%	0.17 (0.07, 0.37)
20–30%	0.09 (0.002, 0.85)
> 30%	0.30 (0.16, 0.50)
No	0.09 (0.03, 0.22)
Nuclear/cytoplsmatic pattern requirements	
No	0.91 (0.32, 0.995)
Nonhistologic exception	
Naive recipient	0.26 (0.08, 0.58)
HDV coinfection	0.61 (0.08, 0.97)
Live donor	0.35 (0.18, 0.56)
HIV coinfection	0.48 (0.17, 0.80)
Elderly donors (> 65 y)	0.26 (0.06, 0.68)
IV drug use or other factors associated with increased risk of HDV	0.174 (0.03, 0.59)
Use of last generation antivirals in seronegative patients	0.90 (0.53, 0.99)
Use of HBIG post-LT in seronegative	
Lifelong	0.33 (0.10, 0.68)
Discontinued	0.33 (0.10, 0.68)
Month of discontinuation (mean, 95% CI)	6.9 (3.08, 10.80)
No	0.33 (0.15, 0.55)
Specific immunosuppressive regimen	
No	0.96 (0.57, 0.10)
Post-LT monitoring	
More stringent virologically	0.70 (0.50, 0.84)
More stringent serologically	0.30 (0.06, 0.76)
HBV DNA every 3 mo	0.65 (0.26, 0.91)
HBV DNA every 6 mo	0.22 (0.05, 0.61)
HBV DNA every 12 mo	0.05 (0.001, 0.70)
Histological monitoring	0.13 (0.03, 0.42)
HCC surveillance post-LT (independent of pre-LT HCC status	0.35 (0.15, 0.62)

Abbreviation: LT, liver transplantation.

significant variability in HBsAg-positive graft use, as previous reports of liver transplants from HBsAg-positive individuals originated from either single centers or registry data evaluated on a national basis.

By evaluating at the level of the individual transplant center, we found that the use of these donors was more common in centers with higher waitlist mortality, an unsurprising finding as HBsAg-positive donors are considered to be at high risk due to the universal transmission of HBV, along with the potential for HCC development and/or transmission of HDV infection. However, the acceptable outcomes among transplants using HBsAg-positive donors suggest that increased utilization of these livers represents a strategy for transplant patients, especially in settings with high waitlist mortality and/or endemic HBV infection areas with a high prevalence of HBsAg positivity among potential donors.

Because HBV is an infection that can be managed but not completely eradicated like HCV, many preferentially allocate livers from HBsAg-positive donors to recipients with preexisting HBV. In the United States in 2021, there were 173 adult LT recipients (2.0% of all adult LT recipients) with HBV, according to the Organ Procurement and Transplantation/United Network for Organ Sharing data[8]; in contrast, 50%–80% of LT in China is performed in HBV-infected recipients.[9] With the increased utilization of these livers and the continued success of their use, they will likely be utilized more broadly based on standard allocation criteria.

The majority of the centers responding to the survey were from Europe and North America, where HBV is an uncommon indication for LT and infrequently encountered among donors (deceased and living). Therefore, opportunities for growth of transplants using livers from HBsAg-positive donors are limited. However, this is not the case in many Asian countries, especially East Asia, where the prevalence of HBV is significantly higher.[9] The utilization of livers from living donors that are HBsAg-positive could be considered on a wider scale, with careful evaluation of the liver, mandated access to optimal antivirals among both donors (if needed) and recipients, and strict monitoring to adequately suppress viral replication. Furthermore, as deceased donations are expanding in several Asian countries, HBsAg-positive donors may represent a unique opportunity for transplantation, especially among younger donors with vertically transmitted HBV and limited liver disease.

This study has limitations inherent to any survey study. The number of centers responding was very high, although response rates varied by region, with more than three-quarters of respondents from European regions and the Americas. Second, we were unable to verify the answers from the respondents, especially with respect to the regulations using these organs. Finally, and most importantly, we were unable

to quantify the potential number of HBsAg-positive donors that were not captured in the national registry data. We hypothesize that they are under-counted; however, we could not quantify their magnitude. Additional limitations with regards to this study include a lack of data regarding (a) the special consent form, (b) the level of HBV viremia used to assess organ suitability for transplantation, and (c) information regarding the concomitant use of HCV-positive and/or HIV+ donors.

In conclusion, we have reported on practice related to the use of HBsAg-positive liver donors in a diverse multinational sample of transplant centers. These data can be used to underline practice variability across the world while highlighting the potential for growth in transplantation using HBsAg-positive donors, especially in regions with a high HBV prevalence. Nonetheless, our current knowledge regarding the use of these grafts is limited, and caution is needed before the use of HBsAg-positive donors can be recommended.

AUTHOR CONTRIBUTIONS

Carmen Vinaixa: conceptualization, data curation, methodology, and writing—original draft. Tommaso DiMaira: data curation, formal analysis, methodology, and writing—original draft. Francesco Paolo Russo: conceptualization, writing—original draft, review, and editing, and supervision. David Goldberg: writing—original draft. Priya Walabh: supervision and writing—review and editing. Jennifer Price, Sanjiv Sagal, and Aleksander Krag: supervision. Alessandra Mazzola, Varvara Kirchner, Tamer Shaker, and Timothy Pruett: conceptualization and supervision. Audrey Coilly and Norah Terrault: conceptualization, supervision, and writing—review and editing. Marina Berenguer: conceptualization, supervision, validation, and writing—review and editing.

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CONFLICTS OF INTEREST

Marina Berenguer received grants from Gilead and consults for Abbvie, Advanz, Chiesi, and Orphalan. Norah Terrault received grants from NIH, GSK, Genentech-Roche, Helio Health, Durect Corp, Gilead Sciences, Eiger Pharmaceuticals, and Madrigal; is employed by AASLD, Hepatitis B Foundation, HBV Forum; and has other interests in Clinical Care Options and Simply Speaking. Audrey Coilly received grants from Astellas, Gilead, Abbvie, Sandoz, and Biotest. Aleksander Krag advises Novo Nordisk and B&I. He received grants from AstraZeneca, Norgine, Echosense, Nordic Bioscience, and Siemens. Jennifer Price received grants from Gilead Sciences, Abbvie, Genentech, VIR, and Zydus. Carmen Vinaixa received grants from Abbvie, Roche, Gilead, and Chiesi.

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