

TAVI: Use of HBV-Positive Donors in Solid Organ Transplantation Working Group

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National Organ Transplant Data – USA

> 1 million transplants done in USA since 1988

		To Date	2025	2024	2023	2022	2021	2020	2019	2018	2017	2016	2015	2014	2013	2012	2011
All Organs		1,023,665	7,816	48,137	46,629	42,889	41,356	39,036	39,719	36,530	34,770	33,610	30,974	29,540	28,956	28,059	28,553
Kidney		602,288	4,449	27,759	27,332	25,500	24,670	22,817	23,401	21,167	19,849	19,060	17,878	17,108	16,896	16,487	16,816
Liver		224,798	1,941	11,458	10,659	9,528	9,236	8,906	8,896	8,250	8,082	7,841	7,127	6,730	6,455	6,256	6,342
Pancreas		9,514	18	114	102	108	143	135	143	192	213	215	228	245	256	242	287
Kidney / Pancreas		28,748	128	733	812	810	820	827	872	835	789	798	719	709	762	801	795
Heart		97,320	712	4,572	4,545	4,111	3,818	3,658	3,552	3,408	3,244	3,191	2,804	2,655	2,531	2,378	2,322
Lung		55,707	540	3,340	3,026	2,692	2,524	2,539	2,714	2,530	2,449	2,327	2,057	1,925	1,923	1,754	1,822
Heart / Lung		1,588	11	64	54	51	45	58	45	32	29	18	15	24	23	29	27
Intestine		3,577	17	97	95	82	96	91	81	104	109	147	141	139	109	106	129

And yet, > 1,700 people die each year waiting for a liver transplant – we need to expand the organ pool

*UNOS data downloaded 8 April 2025

<https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

In 2023, 41,111 liver transplants were performed worldwide, a 10% increase from 2022

Scope of Donors and Recipients

- ~ 70 sAg+ donors per year in USA (SRTR)
- 2009 – 2021: only 89 HBsAg-positive liver allografts were transplanted to HBV seronegative recipients^{1,2}
- Nearly 60% of HBsAg-positive liver allografts were discarded in the United States in 2020 and 2021^{1,2}
 - During the same period, ~12,000 candidates on the liver wait list
- AASLD-ILTSEASL survey: 32 of 135 global liver tx centers had ever used an HBsAg-positive liver allograft³
 - greater use seen in regions of higher HBV prevalence
 - (HBV in recipients: 2% USA, 50-80% China)

1. Bhatnagar A, Prakash S, Lymberopoulos P, Goff C, Shaikh A, Kim D, et al. Transplanting hepatitis B surface antigen-positive livers in the United States: Outcomes and opportunities. *Am J Transplant.* 2023;23:1221–6.

2. Ali SE, Vutien P, Bonham CA, Landis C, Kwo P, Esquivel C, et al. Use and outcomes of hepatitis B virus-positive grafts in orthotopic liver transplantation in the United States from 1999 to 2021. *Liver Transpl.* 2023;29:80–90.

3. Vinaixa C, DiMaira T, Russo FP, Goldberg D, Mazzola A, Walabh P, et al. Use of HBsAg-positive donors in liver transplantation: An ILTS-EASL-AASLD multisociety survey. *Liver Transpl.* 2024;30:1116–22.

ORIGINAL ARTICLE - GASTROENTEROLOGY (CLINICAL)

Utilization of hepatitis B virus surface antigen positive grafts in liver transplantation: A matched study based on a national registry cohort

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- Retrospective study of China Liver Transplant Registry between January 2015 and September 2018.
- By propensity score matching (1:1), 503 eligible patients who received HBsAg+ liver grafts were c/w 503 matched patients who received HBsAg negative liver grafts.
- Similar outcomes

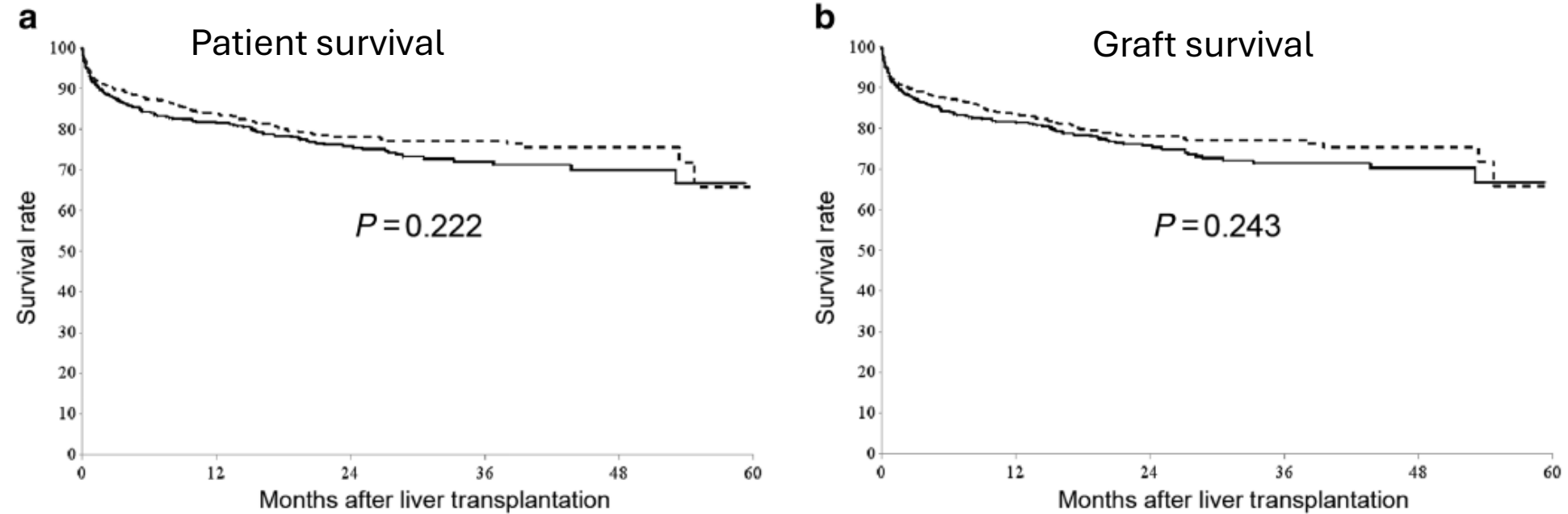


Figure 1 Patient and graft survival of liver transplant patients with HBsAg+ versus HBsAg- grafts. (a) Patient survival; (b) graft survival. HBsAg, hepatitis B virus surface antigen. —, HBsAg+ liver graft (N = 503); - - - - - , HBsAg- liver graft (N = 503).

Expanding the donor pool: **Kidney transplantation** from serum HBV DNA or HBeAg-positive donors to HBsAg-negative recipients, Yu et al, Liver International 2023 (Chengdu, China)

- Kidney transplant from HBsAg(+) donors to HBsAg(-) recipients, retrospective, 1 July 2017 to 31 Dec 2020, n=105
 - Control group: HBsAg(-)/HBcAb-positive (HBcAb[+]) donors to HBcAb(-) recipients (n=516)
- **De novo infection rate after a median follow-up of 23.0 months: 4/105[3.8%] vs. 2/516[0.4%], $p = .009$**
 - All four infected recipients receiving HBsAg(+) kidneys had HBsAg clearance after treatment
- **Graft and patient survival were comparable** between the groups ($p = .630$, $p = .910$).
- HBV infection rate was lower if the **donor had received antiviral treatment** (4/42[9.5%] vs. 0/63[0%], $p = .023$).
- **HBsAb(-) recipients had a higher HBV infection incidence than HBsAb(+) recipients** (3/25[12.0%] vs. 1/80[1.3%], $p = .041$).
- ***“These findings help expand the donor pool and emphasize the role of donor antiviral treatment and recipient HBV immunity in establishing optimal prophylactic regimens.”***

Special Article

Solid Organ Transplantation From Hepatitis B Virus–Positive Donors: Consensus Guidelines for Recipient Management[†]

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Recipients of any organ from HBsAg+ Donors:

- Organs from HBsAg+ donors may be carefully considered in all adult transplant candidates after an individualized assessment of the risk and benefits and appropriate patient consent (weak; low).
- HBsAg+ livers should only be considered when significant donor liver disease has been ruled out by histology (strong; low).
- Indefinite prophylaxis with entecavir or tenofovir is recommended for all recipients (strong; low).
- HBIG should be considered in all recipients when the anti-HBs titer is <100 IU/L (strong; low).
- HBV DNA with or without HBsAg should be monitored every 3 months for 1 year and then every 3–6 months indefinitely (strong; low).

Practice Gap: the safety of using HBsAg+ organs

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- Diagnostics: can we improve risk assessment of donors and recipients? Nucleic acid testing, serology, others
- Prevention: Best vaccination methods? How effective is HBV immunoglobulin +/- antiviral therapy?
- Treatment: how effective are antivirals in this setting?
- Long-term outcomes: does transmission of an **oncogenic virus** in the setting of solid organ, transplantation and the associated immunity suppression result in a higher rate of malignancy? Is this acceptable? Liver vs other transplants? Best screening methods?

There are many interesting aspects of HBV sAg+ donors that could be studied, including rates of disease transmission, best methods of prevention and treatment, and long-term outcomes including HBV-associated cancers.

Based on what you have learned today, do you think further study is an appropriate allocation of resources for TAVI?

Strongly Disagree

Disagree

Neutral

Agree

Strongly Agree

Please Rank Each Of These Topic Areas By Priority (1 = highest, 5 = lowest)

- Diagnostics: further evaluate emerging advanced diagnostics to improve risk assessment of donors and recipients (e.g. nucleic acid testing, serology, cellular mediated immunity, others)
- Prevention: efficacy of antiviral therapy +/- HBV immunoglobulin
- Prevention: efficacy of pre-transplant and post-transplant HBV vaccination in preventing and managing infection
- Treatment: efficacy of antivirals in this setting. Are they at risk for breakthrough/resistant HBV infection.
- Does transmission of an **oncogenic virus** in the setting of solid organ, transplantation and the associated immunity suppression result in a higher rate of malignancy? Liver vs other transplants? Best screening methods?