



Occult hepatitis B virus infection (OBI)

- * **DEFINITION**
- * **PREVALENCE**

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HBV: Classification

* Hepatitis B infection is categorized into 5 clinical forms:

1. Acute
2. Chronic
3. Fulminate
4. Asymptomatic
5. **Occult HBV infection (OBI)**



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OBI: Definition

- * HBsAg screening of blood donors since 1970s ---→transfusion safety.
- * However, HBV remains the most frequent viral TTI.
- * Occult HBV infection (**OBI**):
 - * defined simply as serologically undetectable hepatitis B surface antigen (**HBsAg neg.**), despite the presence of circulating HBV DNA.
- * OBI was reported for the first time almost 37 years ago in a case report.
- * Tabor E. et al. Studies of donors who transmit posttransfusion hepatitis. *Transfusion* 1979; 19: 725-731

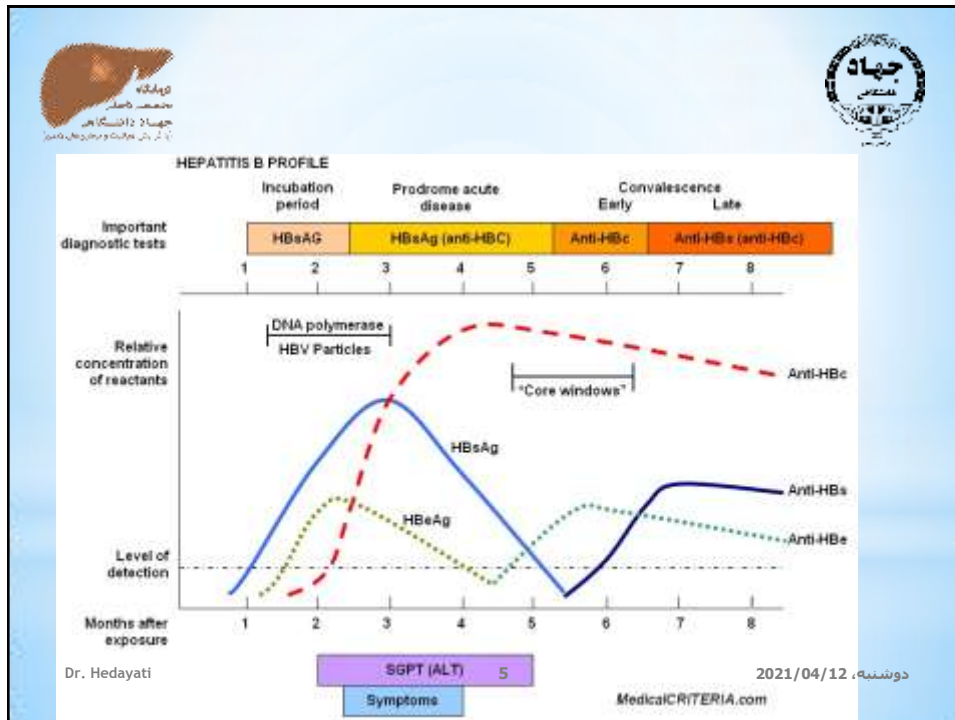
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OBI: Definition

- * Several definitions for OBI have been proposed :
 1. presence of replication-competent HBV DNA in the liver without detectable HBsAg in the serum (**low-level carriers**).
 2. A more specific definition was provided in 2004:
 - presence of HBV DNA without HBsAg, ± HBV antibodies outside the acute phase window period (not transient OBI).



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OBI: Definition

3. 2008 international workshop on OBI endorsed by EASL:
 - * presence of HBV DNA in the liver of individuals testing HBsAg-negative with currently available assays
 - * \pm HBV DNA in the serum; if detectable, usually very low (< 200 IU/mL)
- * Therefore, cases whose serum HBV DNA levels are comparable to those with overt HBV infection are generally due to infection with HBV escape mutants and should be labeled as "false" OBI.

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OBI: Definition

*** OBI:**

- * Detectable HBV DNA among patients negative for HBsAg.
- * presence of the HBV genome in liver \pm serum HBV DNA
- * conversion of HBV DNA to covalently closed circular DNA (cccDNA); a stable and durable mini-chromosome persists within hepatocyte nuclei
- * OBI is a form of HBV with long-term infection, in which immune system is unable to completely clear HBV DNA from hepatocytes.



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OBI: Clinical contexts

1. Recovery from past acute/ chronic infection (indicated by anti-HBs)
2. Chronic carriage only with the presence of anti-HBc (“**anti-HBc alone**” or “**isolated anti-HBc**”)-----> Most commonly in endemic areas
3. Chronic carriage with only HBV DNA pos. (**seronegative**)
4. Chronic hepatitis with surface gene escape mutants

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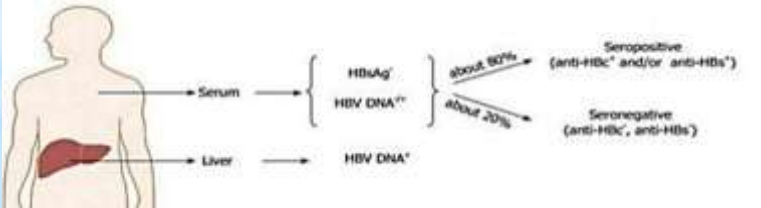
OBI: Serological pattern

*** seropositive OBI:**

- anti-HBc ± anti-HBs
- 50% are positive for anti-HBc and 35% are positive for anti-HBs

*** seronegative OBI:**

- negative for both antibodies (anti-HBc and anti-HBs)



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Table 1 Serological markers and hepatitis B virus DNA in different states of persistence of hepatitis B virus^{2,41}

	HBV DNA	HBsAg	Total anti-HBc	anti-HBs	HBeAg	anti-Hbe
Chronic hepatitis B	+++	+	+	.	+	.
Chronic hepatitis B with variants pre-core	++	+	+	.	.	+/-
Healthy carrier	< 10 ⁶ IU/mL	+	+	.	.	+
OBI seropositive	< 1000 IU/mL	.	+	+/-	+/-	+/-
OBI seronegative	< 1000 IU/mL



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OBI: Prevalence

- * OBI is spread widely throughout the world.
- * The prevalence of occult HBV varies according to factors such as :
 - * endemic disease level (endemic area > non-endemic one).
 - * sub-population examined
 - * tissue specimens tested (liver > serum).
 - * the methods used to assess OBI
 - * Sensitivity of the HBsAg assays used
 - * Sensitivity of the DNA assays used
 - * The sensitivity has markedly increased from around 10^5 - 10^6 to 10 - 10^2 genomes per milliliter, by shifting from Southern blots to PCR.


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OBI: Prevalence

- * The populations in which prevalence of OBI has been investigated are:
 1. patients with liver disease
 - * HCV infected patients, patients with cryptogenetic liver diseases
 2. patients at high risk of parenteral-transmitted infection
 - * intravenous drug addicts (up to 45%), hemophiliacs
 3. patients on hemodialysis
 4. HIV infected patients
 5. apparently healthy individuals
 - * blood donors, general population₁₂

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OBI Prevalence: Patients with liver disease




* There is clear evidence for persistence of HBV DNA in patients with various forms of **acute and chronic hepatitis, and HCC** in both seropositive and seronegative groups with a same figure.

- * The prevalence is higher in anti-HBc pos./ anti-HBs neg. patients: **7%-60%**.
- * The rate is also higher in liver samples, averages 40%-50% (**13%-71%**).

* In patients with acute, particularly fulminant, hepatitis is much less frequent; ~ **10%** in serum and **7%** in liver samples.

* long-term persistence (\approx 10-30 years) of serum HBV DNA has been shown in about **55%** of patients, despite clinical and biological resolution of the acute infection.

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OBI Prevalence: Patients with liver disease




TABLE 4. HBV DNA in the Liver and/or Serum of HBsAg-Negative Patients With Acute Benign and Fulminant Hepatitis

No. Tested	Sample	HBV DNA (+)		Anti-HCV (+)	Histology	Geographic Area	Reference
		Anti-HBV ± Anti-HBs	Seronegative				
12	Serum	0	8/12	3/12	FH	Japan	Inokushi et al. J Hepatol 1996;24:298-304
10	Serum	0	0/10	1/10	FH	USA	Mason et al. HEPATOLOGY 1996;24:361-363
10	Liver		3/10				
17	Serum	0	0/17	0	FH	USA	Liang et al. Gastroenterology 1993;104:556-562
9	Liver		0/9				
22	Liver	0	0/22	0	FH	England	Maitimer et al. Gut 1995;36:433-436
10	Serum	0	0/10	0	FH	USA	Wright et al. Lancet 1992;339:932-933
12	Liver		6/12				
23	Serum	0	1/23	0	FH	France	Feray et al. Gastroenterology 1993;104:540-535
5	Liver		0/5				
10	Serum	8/9	0/1	10/10	AH	Japan	Uchida et al. J Med Virol 1997;52:390-405
18	Serum	0	2/18	3/18	AH	France	Thiers et al. J Hepatol 1993;18:34-30

Abbreviations: FH, fulminant hepatic failure; AH, acute hepatitis.

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OBI Prevalence: Patients with liver disease



TABLE 1. HBV DNA in the Liver and/or Serum of HBsAg-Negative Patients With Chronic Hepatitis

No. Tested	Sample	HBV DNA (+)		Anti-HCV (+)	Histology	Geographic Area	Reference
		Anti-HBc ± Anti-HBs	Seronegative				
61	Serum	3/19	12/42	42/61	CH	Hong Kong	Chung et al. HEPATOLOGY 1995;22:25-29
67	Serum	20/31	11/36	44/67	CH	Israel	Liang et al. HEPATOLOGY 1991;13:1044-1051
42	Liver	13/20	16/22	NT	CH	Egypt	Atallah et al. Trans R Soc Trop Med Hyg 1998;92:516-517
31	Serum	20/31*		NT	CH		
36	Serum	1/21	1/15	22/36	CH	France	Porchon et al. J Hepatol 1992;16:184-189
46	Serum	20/46	0	29/46	CH	Germany	Jäg et al. J Hepatol 1995;23:14-20
36	Serum	7/36	0	NT	CH	Canada	Scully et al. J Med Virol 1994;44:293-297
36	Serum	20/36	0	NT	CH	Germany	Joller-Jemelka et al. J Hepatol 1994;21:269-272
18	Serum	0/18	0	13	CH	Spain	Sanchez-Quijano et al. J Hepatol 1993;17:288-293
30	Serum	0	21/30	0/30	CH	Japan	Fukuda et al. Microbiol Immunol 1996;40:481-488
88	Serum		3/88*	35/88	Alcoholics	Italy	Zignego et al. HEPATOLOGY 1994;10:577-582
101	Serum	0/30	0/08	0/101	CH	Spain	Berasain et al. Gut 2000;47:429-435

Abbreviations: CH, chronic hepatitis; NT, not tested.

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OBI Prevalence: Patients with liver disease



TABLE 2. HBV DNA in the Liver and/or Serum of HBsAg-Negative Patients With HCC



No. Tested	Sample	HBV DNA (+)		Anti-HCV (+)	Histology	Geographic Area	Reference
		Anti-HBc ± Anti-HBs	Seronegative				
42	Serum	16/16	14/26	0/42	HCC	Japan	Yotsuyanagi et al. J Infect Dis 2000;181:1920-1928
23	Serum	10/17	7/8	0/23	HCC	Japan	Shiota et al. J Med Virol 2000;62:161-168
31	Serum	4/29	0/2	21/31	HCC	Taiwan	Shen et al. Gastroenterology 1992;103:1322-1327
25	Liver	0/29	0/2				
25	Liver	17/28	6/13	NT	HCC	Europe/S. Africa	Paterlini et al. N Engl J Med 1990;323:80-85
367	Serum	87/10					
367	Serum	37/98	31/203	185/267	HCC	Europe	Brechot et al. J Hepatol 1998;29:173-183
54	Liver	11/19	13/34				
54	Serum	7/23	3/31	40/54	HCC	Spain	Ruiz et al. HEPATOLOGY 1992;16:637-641
40	Serum		2/40†	35/40	HCC	Spain	Enriquez et al. Eur J Epidemiol 1994;10:189-194
22	Serum	31/10	0/12	11/22	HCC	France	Paterlini et al. HEPATOLOGY 1993;17:28-29
132	Liver	2/5	3/5				
132	Serum	33/119	1/13	3/132	CH; HCC	China	Zhang et al. HEPATOLOGY 1993;17:538-544
31	Liver	8/17	0				
31	Serum		18/31†	NT	HCC	Senegal	Coursaget et al. FEMS Microbiol Lett 1991;67:35-38

Abbreviations: NT, not tested; CH, chronic hepatitis.

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OBI Prevalence: Patients with liver disease

- * collectively, around 30% to 35% of HBsAg-negative subjects with **chronic hepatitis** ± HCC have positive serum HBV DNA (**5% to 55%**).
- * The overall figures do not significantly differ among patients ± HCC.
- * Some studies report that **19-31%** of patients with **cryptogenic liver disease** present with OBI.
- * The proportion of a detectable HBV DNA in cirrhosis patients is higher in compared to chronic hepatitis patients. The latter is also more prevalent in compared to NASH or cases with non-specific changes in liver biopsies.
- * Follow-up studies of patients with HBsAg + chronic hepatitis whose became HBsAg neg., spontaneously or on therapy, have shown persistence of the viral genome **28%** in serum and **94%** in liver.


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OBI Prevalence: Patients with liver disease

- * Patients infected with chronic **HCV hepatitis** are at risk of OBI.
- * The first study of OBI prevalence in these patients published in 1999.
 - HBV sequences were found in liver tissue from **33%** of 200 HCV infected patients and in **14%** of the 50 HCV negative patients.
 - OBI was significantly correlated with cirrhosis among HCV infected patients; **33%** of patients with HCV and OBI had cirrhosis as compared with **19%** with HCV and no OBI.
- * Cacciola I, et al. Occult hepatitis B virus infection in patients with chronic hepatitis C liver disease. *N Engl J Med* 1999; 341: 22-26.

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OBI Prevalence: Patients with liver disease




* A review of studies on HCV patients using PCR concluded **20%-30%** and **40%-50%** of serum and livers, respectively, showed HBV DNA.

* Bréchet C, et al. Persistent hepatitis B virus infection in subjects without hepatitis B surface antigen: clinically significant or purely "occult"? *Hepatology* 2001; 34: 194-203.


Table 3. HBV DNA in the Liver and/or Serum of HBsAg-Negative, Anti-HCV-Positive Patients With Chronic Hepatitis With or Without HCC

No. of Cases	Sample	HBV DNA (+)		Histology	Geographic Area	Reference
		Anti-HBc ± Anti-HBe	Seronegative			
21	Serum	805	1112	CH	Japan	Uchida et al. <i>J Med Virol</i> 1997;32:389-393
93	Serum	1425	2090	CH	Japan	Fukuda <i>J Med Virol</i> 1999;30:201-207
52	Liver	2352*		CH	Japan	Mikata et al. <i>Am J Clin Pathol</i> 1989;54:1133-1138
31	Serum	811	0	CH	Korea	Lee et al. <i>J Gastro Hepatol</i> 1997;12:893-894
88	Serum	2490	1520	CH	Spain	Gonzalez <i>J Med Virol</i> 1993;43:368-373
200	Liver	49309	20000	CH	Italy	Cacciola <i>Am J Med</i> 1989;341:22-26
128	Serum	14128*		CH	Italy	Zingone et al. <i>Am J Med</i> 1997;7:333-344
38	Serum	7119	819	CH	Italy	Vita et al. <i>Dig Dis Sci</i> 1993;40:6-13
79	Serum	2971	0	CH	Italy	Taguchi et al. <i>Hepatology</i> 2000;32:1086-1110
24	Serum	1010	58	HCC	Japan	Shimizu et al. <i>Cancer</i> 2000;86:2428-2430
13	Liver	48	07	HCC	Japan	Ohnishi et al. <i>Gastroenterol Jpn</i> 1991;26:728-731
33	Liver	108*		HCC	Japan	Sugawara et al. <i>Scand J Gastroenterol</i> 1989;54:954-958
94	Serum	894*		HCC	Japan	Tokusho et al. <i>Kansenshogaku Zasshi</i> 1995;70:103-107
23	Liver	1314	40	HCC	Japan	Takamachi et al. <i>Dig Dis Sci</i> 1987;49:2204-2209
31	Liver	3819*		HCC	Japan	Tanemura et al. <i>Hepatology</i> 1989;28:3426-3434
36	Serum	8316	0	HCC	Korea	Lee et al. <i>J Gastro Hepatol</i> 1997;12:875-881
21	Serum	8319	182	HCC	Taiwan	Shen et al. <i>Gastroenterology</i> 1992;103:1322-1327
Dr. Hed	Liver	610	182			
40	Serum	820	420	HCC	Spain	Rodríguez et al. <i>Hepatology</i> 1992;38:837-841
31	Serum	27	26	HCC	5 African France	Parlier et al. <i>Hepatology</i> 1993;17:26-29

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OBI Prevalence: Patients with liver disease



Place	Population	Sample size	OBI (%) Total	Study
Tehran	Chronic hepatitis C virus	103	19.4	Alavian, 2009
Tehran	Chronic liver disease patients (77.1% HCV+)	35	22	Honarkar, 2004

Place	Population	Sample size	OBI (%) Total	Study
Shiraz	HBsAg- patients with chronic hepatitis	104	1.9	Kaviani, 2006 (1997-2001)
Zahedan	Families of patients with acute and chronic HBV	110 anti-HBc +	2.7	Sharifi-Mood, 2009 (2005-6)
Amol	Children born to HBsAg-positive mothers	75 Children immunized by HBIG and HBV vaccine	28	Shahmoradi, 2012






OBI Prevalence: Multi-transfused patients

- * OBI prevalence is high in patients receiving frequent blood transfusions.
- * OBI has been observed in up to 50% of hemophilia patients.

	Disease	Country	Region, City	Prevalence of OBI^a, %
Toyoda <i>et al.</i> (11) (2004)	Hemophilia	Japan	ND	51.2
Borhany <i>et al.</i> (12) (2011)	Hemophilia	Pakistan	Karachi	1.73
Windyga <i>et al.</i> (13) (2006)	Hemophilia	Polish	ND	0
Singh <i>et al.</i> (17) (2003)	Thalassemia	India	ND	31.4
Arababadi <i>et al.</i> (14) (2008)	Thalassemia	Iran	Kerman	0



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OBI Prevalence: Hemodialysis patients

- * Hemodialysis patients are at high risk of acquiring parenterally transmitted infections, because of:
 - the large number of received blood transfusions
 - the invasive procedures that they undergo
 - their immunosuppressed state
- * Several studies have shown that 0-36% of patients on hemodialysis, and nearly 10% of patients on peritoneal dialysis, suffer from OBI.
- * Most of studies have investigated the presence of OBI among HD patients in the context of chronic HCV infection.

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OBI Prevalence: Hemodialysis patients

Table 1. The Prevalence of OBI and HBV Serological Markers Among Blood Recipient Patients

	Disease	Country	Region, City	Prevalence of OBI ^a , %
Aghakhani <i>et al.</i> (18)(2010)	Hemodialysis	Iran	Tehran	3.11
Arababadi <i>et al.</i> (2)(2009)	Hemodialysis	Iran	Kerman	0
Di Stefano <i>et al.</i> (20)(2009)	Hemodialysis	Italia	ND	26.6
Abu-El-Makarem <i>et al.</i> (22)(2012)	Hemodialysis	Egypt	ND	4.13
Sav <i>et al.</i> (25)(2010)	Hemodialysis	Turkey	ND	16.9
Kanbay <i>et al.</i> (24)(2006)	Hemodialysis	Turkey	ND	15.2
Goral <i>et al.</i> (28)(2006)	Hemodialysis	Turkey	ND	0
Siagris <i>et al.</i> & Mina <i>et al.</i> (10, 29)(2010)	Hemodialysis	Greece	ND	0.9-20.4
Motta <i>et al.</i> (31)(2010)	Hemodialysis	Brasilia	ND	15
Gabrenizo <i>et al.</i> (30)(1997)	Hemodialysis	Italy	ND	5.8
Gwak <i>et al.</i> (32)(2008)	Hemodialysis	South-	ND	0

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OBI Prevalence: Hemodialysis patients

Country	OBI % in HD patients
USA	3.8
Turkey	17-27.5
Iran (Tehran)	50
Iran (Kerman)	0

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OBI Prevalence: HIV infected patients

- * OBI in HIV infected patients may be viewed as the result of opportunistic reactivation of HBV due to cellular immune deficiency, as reflected by the decreased CD4 counts in HIV infection.
- * Reported OBI prevalence in HIV patients have been **0-89%**.
- * HIV patients with OBI have significantly lower CD4 counts and high plasma HIV RNA loads.
- * In a cross-sectional investigation on a group of HIV-positive patients referred to Research Center for AIDS, Tehran:
 - * 178 sera were all HBsAg neg., of whom, **18%** were positive for HBV DNA.
 - * 109 patients were IDUs, of whom, **70%** were OBI-positive.

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OBI Prevalence: HIV infected patients

Population	Sample size	OBI (%) Total	OBI (%) Among anti-HBc +	Study
HIV + patients	106	2.8	13.6	Azadmanesh, 2008
HIV + patients	92	3.2	6.3	Ramezani, 2009
HIV + patients	64	4.6	25	Khorvash, 2014

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OBI Prevalence: Blood donors



- * prevalence of OBI in blood donors has a regional variance, not only internationally but also nationally.
- * OBI has been reported in **0.1%-2.4%** of seropositive blood donors in Western countries, where only 5% of the population has prior exposure to HBV.
- * Up to **6%** of BDs in endemic areas have OBI. In anti-HBc only group, the rates range from **0% to 15%** (median of 1.1%).

TABLE 5. HBV DNA in the Liver and/or Serum of HBsAg-Negative Subjects Without Liver Disease

Sample	HBV DNA (+)		Anti-HCV (+)	Histology	Geographic Area	Reference
	Anti-HBc ± Anti-HBs	Seronegative				
Serum	7/36	0	NT	BD	Japan	Matsumoto et al. J Virol Meth 1997;66:61-69
Serum	12/175	0/119	NT	Blood Units	Japan	Iizuka et al. Vox sang 1992;63:107-111
Serum	0/45	0/5	NT	BD	China	Zhang et al. Hepatology 1993;17:538-541
Serum	7/172	2/34	NT	BD	Taiwan	Wang et al. J Infect Dis 1991;163:397-399
Serum	2/11	0	0	BD	USA	Mosley et al. Transfusion 1993;33:5-12
Serum	0/119	0	22/119	BD	USA	Douglas et al. Transfusion 1993;33:212-216
Serum	0/21	0	NT	BD	Canada	Scully et al. J Med Virol 1994;44:293-297
Serum	10/20	0	NT	BD	Brazil	Gomes et al. Acta Virol 1996;40:133-138



OBI Prevalence: Blood donors



Region	HBsAg negative & anti-HBc-positive (± anti-HBs)	HBsAg negative & anti-HBc-positive only
North America	0.1-1.05	2.03-2.8
Europe	0-1.6	0
Middle East and Asia	1.09-3	8.1

Place	Sample size	OBI (%)	Study
Mexico (Yucatan)	158	8.2	Garcia-Montalvo, 2005
Brazil (Brasilia)	150	3.3	Silva, 2005
Iraq (Diyala)	178	3.9	Hasan, 2012
Oman (Muscat)	200	0	Kaminski, 2006



OBI Prevalence: Blood donors



* Collectively, 1%-2% of Iranian blood donors have indicated OBI.

Place	Sample size	OBI (%) Total	OBI (%) Among anti-HBc +	Study
Rafsanjan	270 14 (5.2%) anti-HBc +	-----	28.6	Jafarzadeh, 2008
Rafsanjan	3700 352(9.5%) anti-HBc +	1.5	16.1	Arababadi, 2010
Isfahan	545 43 (7.9%) anti-HBc +	0.9	11.6	Pourazar, 2005
Shiraz	2000 131 (6.6%) anti-HBc +	0.8	12.2	Behzad-Behbahani, 2006
Tehran	2000 230 (11.5%) anti-HBc +	0.15	1.3	Amini Kafiabad, 2004
Arak Dr. Hedayati	531 11 (2.1%) only anti-HBc +	----- 29	0	Sofian, 2010 دوشنبه، 2021/04/12



OBI Prevalence: General population




* There are few studies about OBI prevalence in the general population.


TABLE 5. HBV DNA in the Liver and/or Serum of HBsAg-Negative Subjects Without Liver Disease

Sample	HBV DNA (+)		Anti-HBcV (+)	Histology	Geographic Area	Reference
	Anti-HBc ± Anti-HBs	Seronegative				
Serum	6/87	2/20	NT	NLT	Taiwan	Shih et al. J Med Virol 1990;32:257-260
Serum	79/746	0	NT	NLT	Taiwan	Pao et al. Am J Clin Pathol 1991;95:991-996
Serum	16/47	0	12/47	NLT	Germany	Jilg et al. J Hepatol 1993;23:14-20
Serum	33/357	0	NT	NLT	Germany	Weinberger et al. J Gen Virol 2000;81:1165-1174
Serum	11/21	0	NT	NLT	Germany	Jurinicke et al. Genet Anal 1998;14:97-102
Serum	0	1/58	0/38	BD	Spain	Berainin. Gor 2000;47:429-435
Serum	20/63	0	19/63	G ⁰ population	Sweden	Noborg et al. Scan J Infect Dis 2000;249:252
Serum	0/33	0	2/33	NLT	Turkey	Stuhli et al. Scan J Infect Dis 2000;32:315-316
Serum	17/96	0	NT	Children	Senegal	Chabesaud et al. Arch Virol 1993;8:123-131
Serum	7/42	0	NT	G ⁰ population	Senegal	Coursaget et al. FEMS Microbiol Lett 1991; 83:35-38
Liver	14/20	0	0	Liver Donors	Japan	Maruzawa et al. J Virol Meth 1997;66:61-60

Abbreviations: NT, not tested; BD, blood donors; NLT, normal liver tests; G⁰ population, general population.



OBI Prevalence: General population




Place	Population	Sample size	OBI (%) Total	OBI (%) Among anti-HBc +	Study
Italy	Individuals free from liver disease	98 liver specimens	16.3	62.5	Raimondo, 2008
North America	General population	487	9.6	18	Minuk, 2005
South Korea	Subjects with normal serum ALT	195	15.9	16.2	Kim, 2007
South Korea	general adult population (routine check-up)	1047	0.7	-----	Song, 2009
Hong-Kong	Stem cell donors	124	15.3	17	Hui, 2005


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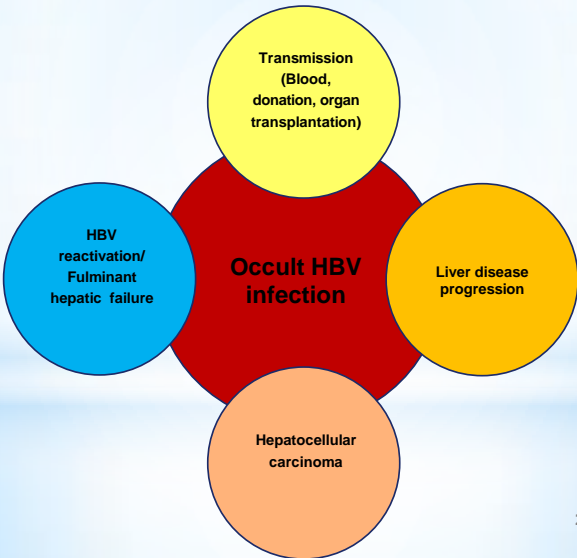
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OBI: Clinical Significance






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OBI: Clinical Significance




Immune suppression

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OBI: Screening

- * No published guidelines are provided categorizing those who should be screened for OBI.
- * However, investigations should be considered in the following situations:
 1. HCV-infected patients especially with flares in viral replication and liver damage
 2. Patients becoming immune deficient mainly by receiving immuno-suppressive regimens for various clinical conditions
 3. People with unexplained liver diseases
 4. Blood units for immuno-compromised recipients where proper recruitment and selection of donors are highly recommended

Dr. Hedayati

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دوشنبه، 2021/04/12



OBI: Screening



- * In some countries, including the USA and Japan, parallel screening for HBsAg and HbC-Ab is performed in all donors for the rejection of at-risk blood units.
- * Screening of anti-HBc is feasible in non-endemic areas, but would cost an unnecessary loss of blood donations in endemic areas ($\approx 90\%$ of adults are positive for both anti-HBc and anti-HBs due to past exposure to HBV).