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TRANSMISSION OF HEPATITIS B VIRUS TO MULTIPLE PATIENTS FROM A SURGEON WITHOUT EVIDENCE OF INADEQUATE INFECTION CONTROL

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Abstract Background. Although about 1 percent of surgeons are infected with hepatitis B virus (HBV), transmission from surgeons to patients is thought to be uncommon. In July 1992, a 47-year-old woman became ill with acute hepatitis B after undergoing a thymectomy in which a thoracic-surgery resident who had had acute hepatitis B six months earlier assisted.

Methods. To determine whether the surgeon transmitted HBV to this patient and others, we conducted chart reviews, interviews, and serologic testing of thoracic-surgery patients at the two hospitals where the surgeon worked from July 1991 to July 1992. Hepatitis B surface antigen (HBsAg) subtypes and DNA sequences from the surgeon and from infected patients were determined.

Results. Of 144 susceptible patients in whose surgery the infected surgeon participated, 19 had evidence of recent HBV infection (13 percent). One of the hospitals was selected for additional study, and none of the 124 susceptible patients of the other thoracic surgeons at this

hospital had evidence of recent HBV infection (relative risk, ∞ ; 95 percent confidence interval, 4.7 to ∞). No evidence was found for any common source of HBV other than the infected surgeon. The HBsAg subtype and the partial HBV DNA sequences from the surgeon were identical to those in the infected patients. Transmission of the infection was associated with cardiac transplantation (relative risk, 4.9; 95 percent confidence interval, 1.5 to 15.5) but not with other surgical procedures. The surgeon was positive for hepatitis B e antigen and had a high serum HBV DNA concentration (15 ng per milliliter). Our investigations identified no deficiencies in the surgeon's infection-control practices.

Conclusions. In this outbreak there was surgeon-to-patient HBV transmission despite apparent compliance with recommended infection-control practices. We could not identify any specific events that led to transmission. (N Engl J Med 1996;334:549-54.)

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APPROXIMATELY 24 million operations are performed annually in U.S. hospitals by an estimated 133,000 surgeons.¹ The Centers for Disease Control and Prevention (CDC) estimate that 1900 U.S. surgeons are chronically infected with hepatitis B virus (HBV), but reports of surgeon-to-patient transmission of the virus are uncommon.² Transmission of HBV to patients has been associated with health care workers with highly infectious disease who were positive for hepatitis B e antigen (HBeAg) and has generally involved breaches in standard infection-control practices, although correction of these deficiencies has not always prevented additional instances of transmission.³⁻⁶ We report an outbreak of HBV infection associated with an HBV-

infected thoracic-surgery resident and suggest potential mechanisms of transmission.

METHODS

In July 1992, a 47-year-old woman without identified risk factors became ill with acute hepatitis B four months after undergoing a thymectomy in which a thoracic-surgery resident participated. This surgeon was found to be susceptible to HBV on testing in December 1989 before completing a general-surgery residency elsewhere. He began the thoracic-surgery residency program in July 1991 after a year of research. He was offered the hepatitis B vaccine but never received it. In January 1992, he became fatigued, and in February he had jaundice with detectable hepatitis B surface antigen (HBsAg) and IgM antibody to hepatitis B core antigen (anti-HBc). He withdrew from surgical duty until March 1992, when his symptoms resolved, and he returned to practicing surgery having had no additional tests for HBsAg or HBeAg. He was still positive for HBsAg and HBeAg in July 1992, when the index patient was identified, and was relieved of surgical duties pending an investigation.

To determine whether other patients were infected with HBV, we obtained blood specimens in September 1992 from patients operated on by the surgeon during the study period, July 1991 to July 1992. The surgeon worked at two hospitals during this period, referred to here as Hospital A and Hospital B. For specimens collected within six months after surgery, we asked susceptible patients to provide

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second specimens six months or more after surgery to permit the detection of later seroconversion. Chart reviews and interviews of patients or their parents were conducted with standardized forms; demographic data and information about surgical characteristics, prior HBV infection, and community risk factors for infection were recorded. Sexual and household contacts of infected patients were tested to exclude them as sources of transmission. Patients were defined as having acute HBV infection (case patients) if they were IgM anti-HBc-positive or if they were seronegative within the year before surgery or on initial testing and positive for HBsAg or anti-HBc on final testing.

Retrospective Cohort Studies

A retrospective cohort study was conducted at Hospital A to determine whether the surgeon had transmitted HBV to the index patient and possibly others. We compared the risks of infection among patients he operated on and among patients who underwent thoracic surgery without his participation from November 1991 to July 1992. Patients who had thoracic surgery without the surgeon's participation were contacted by letter and follow-up telephone call and asked to provide demographic information and serum for evaluation. This retrospective cohort study included all patients who underwent thoracic surgery during the months when the surgeon was not working at Hospital A and every third patient of other thoracic surgeons during the months when he was working there.

A second retrospective cohort study evaluated risk factors for infection among the patients the surgeon operated on at Hospital A, where data were more complete. The study period was the same as that of the first retrospective cohort study. Data regarding characteristics of operations and surgical procedures were collected with standardized forms.

Additional information was collected by informally interviewing the surgeon, operating-room personnel (thoracic-surgery fellows, attending physicians, anesthesiologists, scrub nurses, and perfusionists), and nurses in the intensive care unit. The work schedules of nurses, phlebotomists, and respiratory therapists were reviewed for possible opportunities for transmission by circulating hospital personnel. The vaccination records and the results of serologic tests for HBV of operating-room personnel were reviewed, as were records of transfusions in patients. Testing was conducted at the CDC for HBsAg and antibody to HBsAg (anti-HBs) by radioimmunoassay and for anti-HBc and IgM anti-HBc by enzyme immunoassay (Abbott Laboratories, North Chicago, Ill.). In several instances, samples were tested at local clinical laboratories. Samples with detectable HBsAg were analyzed for HBsAg subtype by enzyme immunoassay with monoclonal antibodies.⁷

Analysis of Serum Samples

Serum from the surgeon, from the infected patients, and from an unrelated, acutely and chronically infected convenience sample of controls from the state in which the outbreak occurred were subjected to amplification by the polymerase chain reaction (PCR) to detect HBV DNA. Twenty microliters of serum was digested with proteinase K solution for one hour at 65°C, followed by phenol-chloroform extraction and alcohol precipitation. HBV1858 (5'ACTGTTCAAGCCTCCAAGCTG3'), HBV2437 (5'TTGAGATCTTCTGCGACGCGC3'), and 5 units of Taq polymerase were added to the precipitate for amplification (30 cycles consisting of denaturation at 95°C for 30 seconds, annealing at 55°C for 30 seconds, and extension at 72°C for 45 seconds). The samples were purified and the sequence of 160 bases in the core region was determined with use of HBV1858P⁸ or the ABI automated sequencer and dye terminators (Applied Biosystems, Foster City, Calif.). The sequences were analyzed with the Pileup program, which performs progressive, pairwise comparisons and plots the results in a dendrogram to indicate similarity of sequences.⁹

The HBV DNA concentration in the surgeon's serum was determined by dot blot hybridization¹⁰ and by PCR end-point dilution. Tenfold serum dilutions were amplified by PCR and evaluated by agarose-gel electrophoresis. The threshold of HBV DNA detectability was

compared with that of similarly diluted serum containing 100 million chimpanzee-infectious particles per milliliter.

Statistical Analysis

The relative risks and 95 percent confidence intervals were calculated with the use of Epi Info¹¹; the associations between exposures and infection were assessed by univariate and stratified analysis; and the significance of differences in proportions was assessed by the chi-square test with the Mantel-Haenszel correction for independent samples or with Fisher's exact test.

RESULTS

Identification of Cases

The surgeon operated on 239 patients (162 at Hospital A and 77 at Hospital B) from July 1, 1991, through July 16, 1992. Twenty-eight patients died before the investigation; none had recognized evidence of hepatitis. Of the remaining 211 patients, 184 (87 percent) were available for initial serologic testing, with 170 (81 percent) tested six months or more after surgery. Of these 170, 11 reported prior HBV infection or hepatitis B vaccination and had markers consistent with their histories; they were excluded from the analysis. Nineteen patients had evidence of acute HBV infection, as indicated by the presence of IgM anti-HBc or by anti-HBc seroconversion. Fifteen additional patients had HBV serologic markers but were negative for IgM anti-HBc and had no evidence indicating the presence or absence of seroconversion; seven of these patients had other risk factors for HBV infection. For purposes of analysis, these 15 patients were assumed to have been infected before surgery. The overall attack rate was therefore 13 percent (19 of 144) among susceptible patients available for follow-up.

The 19 case patients with acute HBV infection ranged in age from 14 months to 83 years (median, 51 years). Six (32 percent) had symptoms of acute hepatitis, one of whom required hospitalization. Three of the remaining patients died of other causes. Chronic HBV infection developed in 9 of the 16 surviving case patients (56 percent); 3 of these 9 had been receiving immunosuppressive therapy, and another was two years of age.

All 19 case patients or their parents reported no other risk factors for HBV infection. Sexual and household contacts of all but three patients underwent HBV testing; none were HBsAg-positive. Of the 19 case patients, 15 had had surgery at Hospital A and 4 at Hospital B. The procedures included coronary-artery bypass surgery (eight), orthotopic heart transplantation (four), repair of congenital heart defects (four), valve replacement (one), thymectomy (one), and open-lung biopsy (one). The procedures occurred throughout the study period without apparent clustering in time (Fig. 1), even after we controlled for the number of susceptible patients undergoing surgery each month (data not shown).

Determining the Source of the Outbreak

We conducted a retrospective cohort study to determine whether patients of other surgeons at Hospital A

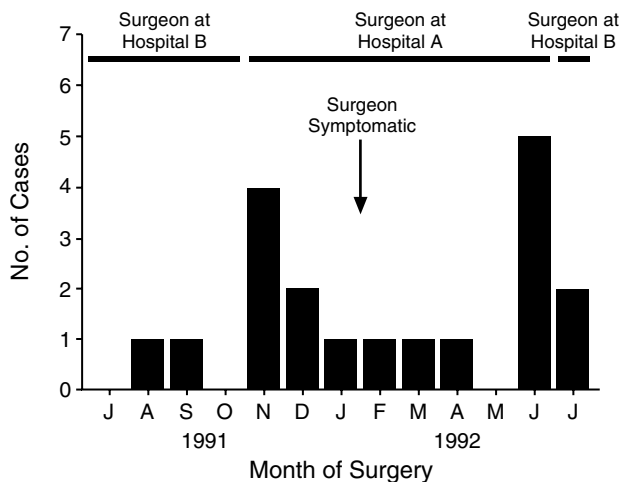


Figure 1. Hepatitis B Virus Infections among Patients Operated on by the Infected Surgeon, According to the Date of Surgery.

had acute HBV infection: a sample of 280 of 510 such patients who underwent surgery from November 1991 through June 1992 was selected for evaluation, including all patients who underwent thoracic surgery at Hospital A while the HBV-infected surgeon was not working there and every third patient of other thoracic surgeons at Hospital A while he was working there. Of these patients, 259 were alive; 124 consented to be tested, were determined to be susceptible at the time of surgery, and had six-month follow-up data available (Table 1). None of the 124 had evidence of recent HBV infection. This result contrasts with the 15 who had such evidence (14 percent) among the 106 patients who were operated on by the surgeon at Hospital A (Table 1) (relative risk, ∞ ; 95 percent confidence interval, 4.7 to ∞).

The two cohorts did not differ significantly according to age, sex, race, or the distribution of procedures (data not shown), although the average duration of surgery was longer for patients operated on by the infected surgeon than for patients operated on by other surgeons (5.4 vs. 4.5 hours; $P < 0.001$). When patients undergoing thoracic surgery who had evidence of prior, but not recent, infection were included in the analysis as case patients, the difference in infection rates for the two cohorts remained significant: 24 of the 115 patients operated on by the infected surgeon were HBV-infected (21 percent), in contrast with 7 of the 131 patients operated on by other surgeons (5.3 percent) (relative risk, 3.9; 95 percent confidence interval, 1.8 to 8.7).

Opportunities for transmission from other nosocomial exposures were investigated. Twelve of 15 case patients at Hospital A (80 percent) had received blood transfusions, all from different donors. No other surgeon, anesthesiologist, nurse, phlebotomist, or respiratory therapist had documentation of HBV infection, and none treated more than seven case patients. Transmission to patients occurred at both Hospital A and

Hospital B; the surgeon was the only common factor at the two hospitals.

The HBsAg subtype from the surgeon and from 13 of the 19 case patients at both hospitals for whom subtyping could be performed was adw2. We amplified HBV DNA from the surgeon, 9 case patients, and 19 unrelated community controls (7 with acute infection and 12 with chronic infection). The sequences from the surgeon and the case patients were identical. The sequences from all but 4 of the 19 community controls were different from each other and from the sequence from the surgeon (Fig. 2).

Evaluation of Surgery-Related Risk Factors for HBV Infection

To identify risk factors for HBV infection, we conducted a retrospective cohort analysis of the patients the surgeon operated on at Hospital A (Table 2). The infection rates did not differ according to sex or age. The rate was higher among whites than in other racial groups. The infection rate was higher among patients who received blood products during surgery or who had surgery lasting 5.5 hours or longer, but these differences were not statistically significant. The surgeon's patients underwent a variety of surgical procedures, but the infection rate was increased only among patients who underwent cardiac transplantation (relative risk, 4.9; 95 percent confidence interval, 1.5 to 15.5). This association remained significant when the duration of the procedure and the use of blood products were controlled for (data not shown). The infection rates were not asso-

Table 1. Serologic Survey of Patients Who Underwent Thoracic Surgery at Hospital A from July 1, 1991, to July 16, 1992.

STATUS OF PATIENTS	PATIENTS OPERATED ON BY INFECTED SURGEON	PATIENTS OPERATED ON BY OTHER SURGEONS
	no./total no. (%)	
Alive	142/162 (88)	259/280 (92)
Partial evaluation*	135/142 (95)	164/259 (63)
Complete evaluation†	123/142 (87)	143/259 (55)
No. susceptible‡	115/123 (93)	131/143 (92)
No. infected (but not meeting case definition)§	9/115 (8)	7/131 (5)
No. of these with no risk factors	8/9 (89)	2/7 (29)
No. meeting case definition¶	15/106 (14)	0/124
Attack rate (%)	14	0

*Patients evaluated within six months of surgery with no follow-up testing.

†Patients evaluated at least six months after surgery.

‡Patients without reported or laboratory evidence of immunity to HBV infection.

§Patients who were anti-HBc-positive or HBsAg-positive but had no IgM anti-HBc or other evidence of recent seroconversion.

¶Patients who were IgM anti-HBc-positive or were negative for serologic markers within the year before surgery or at the time of the initial serologic survey and were positive for HBsAg or anti-HBc at the time of final testing.

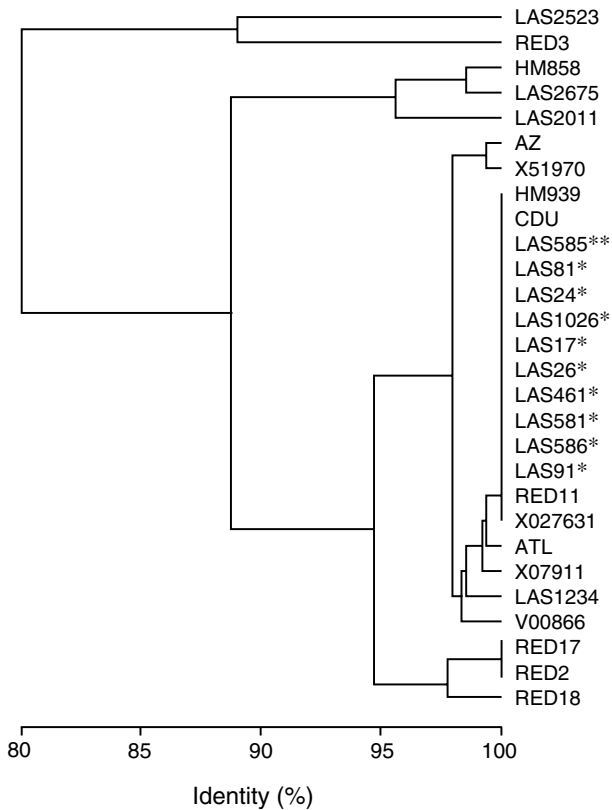


Figure 2. Dendrogram of Multiple-Sequence Alignment Based on Pairwise Comparisons of Sequenced PCR Products.

Case patients in this outbreak are indicated by a single asterisk; the infected surgeon is indicated by a double asterisk. Controls were a convenience sample with community-acquired hepatitis B from the state in which the outbreak occurred. Specimens X51970, X027631, X07911, and V00866 represent the GenBank accession numbers of previously published sequences.

ciated with emergency (as opposed to elective) surgery, the use of a perfusion pump or cell saver, the specific operating room, or prior sternotomy. The analysis of these associations was unchanged by the inclusion of the 15 patients with serologic markers of HBV infection but without evidence of recent seroconversion (data not shown).

Additional Fact-Finding

The surgeon reported no risk factors for HBV infection and was unaware of any percutaneous exposure to blood from HBV-infected patients. He indistinctly recalled only one or two needle sticks during the period under investigation, and he reported no injuries from sternal wires or other sharp objects. He reported that he always handled sharp objects with an instrument and did not blindly palpate suture needles. Although the surgeon reportedly often applied hemostatic material to sternal incisions with his gloved hands rather than with the protection of a sponge (the usual practice of other surgeons at the two hospitals), he recalled no

glove punctures from this procedure. He performed no invasive procedures on case patients in the intensive care unit or the recovery room.

Other surgical personnel attested to the surgeon's good technique. He was left-handed, which sometimes interfered with the passing of instruments or simultaneous suturing by more than one surgeon. He did not use double gloves, but after contracting hepatitis B he modified his behavior by frequently changing gloves during operations. All surgical staff members, including the surgeon, reported that blood was routinely present on their hands when they removed their gloves after an operation, whether or not visible tears were present in the gloves and regardless of the type of gloves used.

In previous years, the surgeon had had a skin irritation that resolved after he changed to the routine use of hypoallergenic latex gloves. In addition, he had periodic pain over the radial side of the index fingers that he attributed to shear forces from tying sutures.

The serum HBV DNA concentration in the surgeon just after the index patient was identified was 15 ng per milliliter. The serum was estimated by semiquantitative PCR to contain 1 billion infectious particles per milliliter.

DISCUSSION

The infected thoracic surgeon whom we studied transmitted HBV to at least 19 patients during surgery. No patients undergoing procedures performed by other thoracic surgeons had evidence of recent infection. The timing of the infections and the absence of other identified sources of infection among the case patients were consistent with transmission from the surgeon during surgery. The infections occurred at two different hospitals without common equipment or staff members other than the surgeon. The presence of HBsAg subtype adw2 in the surgeon and in the 13 case patients in whom the subtype of the antigen could be determined is unlikely to have occurred by chance alone.¹² The DNA sequences of the HBV core region from the surgeon and from all 9 case patients who could be evaluated were identical and were different from that of all but 4 of the 19 community isolates.

Although reporting of HBV infection is not complete, both outbreaks and sporadic transmission of HBV from surgeon to patient appear to be uncommon. Evidence that the risk is low is limited and includes retrospective studies involving patients of infected health care workers,¹³⁻¹⁶ two case-control studies of patients with acute hepatitis B that found no association between disease and surgical history¹⁷ (and unpublished data), and the relatively small number of reported outbreaks of HBV given the estimated pool of infected surgeons.

Outbreaks provide information about specific mechanisms of transmission of HBV from surgeon to patient. Since the early 1970s, 29 such clusters have been reported worldwide,^{3,5,18-24} including 9 involving thoracic surgeons.^{5,19,22-24} Data from these outbreaks indicate an increased risk of HBV transmission from HBsAg-

positive surgeons and during particularly invasive procedures.^{5,21,25} Transmission during many of these outbreaks was presumed to be caused by deficiencies in infection-control measures. Although this outbreak involved a high attack rate, our investigation did not identify any breaches in infection-control practices, despite an extensive search for potential modes of transmission. Unreported or unrecalled percutaneous exposures by the surgeon or operating-room staff are unlikely to explain such a high rate of transmission.

Although this is the first reported outbreak involving a thoracic surgeon in the United States, four such outbreaks have been reported in the United Kingdom during the past decade.^{5,24} We found no specific features characteristic of thoracic surgery that were associated with transmission. Surgical fields are generally well visualized during thoracic surgery, and blind needle palpation is not often practiced. Thoracic surgery is, however, inherently highly invasive and of long duration, and these features have been linked to percutaneous exposure,²⁶⁻²⁸ glove failure,²⁹⁻³¹ and HBV transmission.²¹ Indeed, whether caused by the duration of surgery or by specific factors such as the closure of sternotomy incisions, frequent glove punctures during thoracic surgery have been reported.^{26,28,31,32} In this outbreak, there was no association of HBV infection with the duration of surgery or the use of blood products (a possible indication of the invasiveness of a procedure); two case patients, in fact, underwent brief procedures requiring no blood products (a thymectomy and an open-lung biopsy). We found no associations between HBV transmission and specific procedures, with the exception of cardiac transplantation, although in relative terms these were not long or complex procedures. Perhaps the minimal infectious inoculum of HBV is lower for patients receiving immunosuppressive therapy. Some surgeons have suggested that closure of the median sternotomy incision is associated with injury, although data to support this assertion are inconclusive.^{31,32} In our study, the surgeon's technique of applying hemostatic material to the sternal incision without a sponge may have caused injuries that were not apparent. However, one case patient underwent an open-lung biopsy that did not involve a median sternotomy.

This outbreak may have been related more closely to factors unique to the surgeon than to factors inherent in thoracic surgery: indeed, lung biopsy is a procedure with little resemblance to most other thoracic surgical procedures. Although HBeAg-positive persons almost always have highly infectious disease, the surgeon had an especially high concentration of HBV DNA during the outbreak, which may have contributed to a high risk of transmission. The surgeon's technical skills were apparently not a factor, since operating-room personnel did not recall that he had frequent needle sticks. The hand irritation experienced by the surgeon in previous years had resolved with the use of hypoallergenic latex gloves, and there was no evidence that the surgeon had

Table 2. HBV Infection among Patients Operated on by the Infected Surgeon at Hospital A, According to Demographic and Surgical Factors.

FACTOR	TOTAL NO. OF PATIENTS	NO. INFECTED	ATTACK RATE (%)	RELATIVE RISK (95% CI)*
Demographic				
Sex				
Male	67	7	10	1.0
Female	39	8	21	2.0 (0.8–5.0)
Age				
≤36 yr	53	6	11	1.0
>36 yr	53	9	17	1.5 (0.6–3.9)
Race				
Nonwhite	34	1	3	1.0
White	72	14	19	6.6 (0.9–48.2)
Surgical				
Received blood products				
No	35	3	9	1.0
Yes	71	12	17	2.0 (0.6–6.5)
Volume of packed red cells				
0 ml	41	4	10	1.0
≤550 ml	26	2	8	0.8 (0.2–4.0)
>550 ml	39	9	23	2.4 (0.8–7.1)
Duration of surgery†				
<5.5 hr	47	4	9	1.0
≥5.5 hr	59	11	19	2.2 (0.8–6.4)
Procedure				
Repair of congenital heart defect‡	39	4	10	1.0
Coronary-artery bypass graft§	33	5	15	1.5 (0.4–5.1)
Valve repair¶	10	1	10	1.0 (0.1–7.8)
Transplantation	8	4	50	4.9 (1.5–15.5)
Other**	16	1	6	0.6 (0.1–5.0)

*CI denotes confidence interval.

†Median duration for all procedures, 5.5 hours (range, 0.5 to 10.5).

‡Median duration, 5.0 hours (range, 1.5 to 8.0).

§Median duration, 6.5 hours (range, 4.5 to 10.5).

¶Median duration, 5.3 hours (range, 3.5 to 7.5).

||Median duration, 6.0 hours (range, 4.0 to 8.0).

**Median duration, 3.0 hours (range, 0.5 to 8.0).

dermatitis during the outbreak. Hypoallergenic gloves are subject to the same quality standards as standard surgical gloves.

The surgeon had pain over his index fingers during prolonged suturing. Other surgeons have described similar experiences to us; we are unaware of any studies addressing this phenomenon. While participating in a one-hour simulation of suture tying,³³ the surgeon acquired paper-cut-like lesions on his fingers, and HBsAg and HBV DNA were isolated from washings of his hands. Such lesions, combined with the failure of his gloves, may have allowed contamination of patients with HBV. Although gloves frequently have leaks during surgery,^{27,28,31,34,35} they nonetheless appear to be fairly effective barriers against certain infections, even when leaks are present.³⁶ Although there is increasing evidence that double gloves can prevent exposure of surgeons to blood during surgery,³⁵ there is no evidence regarding the effectiveness of double gloves in protecting patients from blood-borne infections. Furthermore, advisory groups and professional organizations have not generally recommended the use of double gloves by surgeons. Additional studies are needed to assess the validity and generalizability of the suture-tying simulation

and to define the role of gloves in preventing the intra-operative transmission of HBV.

This outbreak has had tragic consequences for the case patients, their families, and the surgeon, who has left surgical practice indefinitely. The entire episode could have been prevented had the surgeon received hepatitis B vaccine.

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