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RESEARCH

The role of routine screening in blood-borne pathogens in Chinese patients undergoing joint arthroplasty

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Objectives

Surgeons face a substantial risk of infection because of the occupational exposure to blood-borne pathogens (BBPs) from patients undergoing high-risk orthopaedic procedures. This study aimed to determine the seroprevalence of four BBPs among patients undergoing joint arthroplasty in Shanghai, China. In addition, we evaluated the significance of pre-operative screening by calculating a cost-to-benefit ratio.

Methods

A retrospective observational study of pre-operative screening for BBPs, including hepatitis B and C viruses (HBV and HCV), human immunodeficiency virus (HIV) and Treponema pallidum (TP), was conducted for sequential patients in the orthopaedic department of a large urban teaching hospital between 01 January 2009 and 30 May 2016. Medical records were analysed to verify the seroprevalence of these BBPs among the patients stratified by age, gender, local origin, type of surgery, history of previous transfusion and marital status.

Results

Of the subjects who underwent arthroplasty surgery in our institution, pre-operative screening tests were available for 96.1% (11 609 patients). The seroprevalence of HBV, HCV, HIV and TP was 5.47%, 0.45%, 0.08% and 3.6%, respectively. A total of 761 seropositive cases (68.4%) were previously undiagnosed. Pre-operative screening for HIV resulted in a low cost to benefit ratio, followed by HCV and HBV.

Conclusion

Routine HCV and HIV screening prior to joint arthroplasty is not a cost-effective strategy. Considering the high rate of undiagnosed patients and the shortage of protective options, targeted pre-operative screening for HBV and syphilis should be considered for the protection of healthcare workers in China who have not been vaccinated.

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Article focus

- This study investigated the seroprevalence of blood-borne pathogens among pre-operative joint arthroplasty patients in Shanghai, China.

Key messages

- A high seroprevalence was observed for hepatitis B virus and Treponema pallidum infections (5.47% and 3.6%, respectively) among patients undergoing joint arthroplasties in Shanghai, China.
- Many detected seropositive cases were previously undiagnosed, indicating a theoretically increased risk for occupational transmission to unprotected healthcare workers.
- A poor cost-to-benefit ratio was established for pre-operative screening (hepatitis C and human immunodeficiency virus).

Strengths and limitations

- Strength: this is the first cross-sectional study of its kind in China. This study has a large sample size due to high screening rates.
- Limitation: as a retrospective analysis, some demographic risk factors were not routinely collected from medical records at the time of testing.

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Introduction

The most common occupationally acquired infections with blood-borne pathogens (BBPs), such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and Treponema pallidum (TP), can lead to life-threatening conditions with high morbidity and mortality.[1] Arthroplasty procedures are especially high risk for occupational exposure to blood and body fluids.[1-4] Some incidents, such as intra-operative splash, glove perforation and needlestick injuries are common occurrences in arthroplasty surgery, and can potentially transmit blood-borne diseases to surgeons and nurses.[5-7] Conversely, infected healthcare workers (HCWs) can transmit some of these viruses to the patients undergoing exposure-prone procedures.[8] However, unprotected occupational exposure to BBPs makes the risk of transmission greater for surgeons than for patients.[8]

The routine testing of patients before elective orthopaedic operations has been debated.[9-12] The anxiety of occupational transmission might increase the risk of sharp injury when surgeons operate on HIV-positive patients. A finding of negative serological status in surgical patients following universal screening of BBPs alleviates the fear of occupational exposure among HCWs and offers them intra-operative safety.[12] If a patient's positive status is known prior to surgery, HCWs without viral vaccination should receive subsequent post-exposure prophylaxis after needlestick and sharp injuries which could prevent occupational infections. A study from Germany reported that routine pre-operative screening for blood-borne viruses (BBVs) of patients undergoing elective arthroplasty should be not be considered because of the low cost-to-benefit ratio in preventing HCWs from contracting infection.[11] The main reason for this viewpoint is that Germany is a low prevalence country. The seroprevalences of HBV and HCV are considerably higher in mainland China as a virus endemic area. According to a cross-sectional study performed in north-eastern China, positive rates of HBV surface antigen (HBsAg) and anti-HCV antibodies were 6.1% and 3.0%, respectively (227 808 study participants).[13]

Most studies in China were conducted in general and in regional populations, and reported the seroprevalence rates of HIV, HBV, HCV and TP.[13-15] Given that the prevalence of BBVs and TP significantly varies from one geographical area to another, the benefit of routine pre-operative screening of the Asian population should be investigated. To our knowledge, no study has reported the pre-operative findings of BBPs in Chinese patients undergoing major orthopaedic surgery. Therefore, the objectives of this study were: to estimate the seroprevalence of BBPs among pre-operative arthroplasty patients; to determine pre-operative infection status as well as the number of newly diagnosed infections; and to assess the cost-to-benefit ratio for pre-operative screening.

Patients and Methods

This retrospective observational study was conducted at the Shanghai Sixth People's Hospital in China between January 2009 and May 2016. Our institution is a 1950-bed teaching hospital which includes various departments and clinics that provide medical care to people in Shanghai and throughout mainland China. The study protocol was approved by the local medical ethics committee. All patients undergoing joint arthroplasties (hip, knee, shoulder and elbow) were considered for inclusion. Patients without serological screening for HIV, HBV, HCV and syphilis were excluded. Patients under 18 years of age and those who had previously undergone surgery were excluded from the study. If the patients had several arthroplasty operations during the follow-up period, only the first surgery was analysed.

Sociodemographic data were collected into a computerised spreadsheet, including patient age, gender, ethnicity, local origin, history of previous blood transfusion, marital status, type of surgical procedure, dates of hospital admission, and history of known infection and blood transfusion. Serum specimens (5 mL) were screened for detection of HBsAg, anti-HCV antibodies, HIV antigens/antibodies (HIV-Ag/Ab) and TP antibodies using an automated chemiluminescence microparticle immunoassay (Architect i2000SR; Abbott Diagnostics, Chicago, Illinois). Western blotting (MP Biomedicals Asia Pacific Pte Ltd., Singapore) was used to confirm the positive screening results for HIV-Ag/Ab. The incidence (rate of newly diagnosed infections) and the seroprevalences (seropositivity rate), were defined as the number of new cases per 100 tested and the number of positive tests per 100 tested for BBPs, respectively.

The risk of occupational infection depends on three parameters: the seroprevalence of BBV infection in patients (P); the number of occupational exposures to body fluids (E); and the seroconversion rate after a single occupational exposure (S). The risk of accidental transmission is defined as the product of seroconversion rate after percutaneous contact (S) and seroprevalence of an infectious disease (P).[11] The seroconversion rate after a single percutaneous exposure has been estimated at up to 0.3% for HIV, 10% for HCV and 30% for HBV.[11,16] Assuming that an active surgeon operates over a period of 40 years and has a mean of ten percutaneous blood contacts per year ($E = 40 \times 10$),[16] the cumulative risk (R) of occupational infection is calculated according to this equation: $R = P \times E \times S$.[17] According to the method described by Winkelmann et al,[11] the cost-to-benefit ratio of the pre-operative screening was then calculated according to the screening costs and the screening number per newly diagnosed infection.

Statistical analysis. Data were analysed using the statistical package for Windows, version 17.0 *(*SPSS Inc., Chicago, Illinois). Seroprevalence stratified by demographics was

Table I. The socio-demographic characteristics of patients.

Characteristics	HBV positive (%)	HCV positive (%)	HIV positive (%)	TP positive (%)
Age group (yrs)				
18 to 34	24/521 (*4.61*)	2/521 (*0.38*)	3/521 (*0.58*)	13/521 (*2.50*)
35 to 54	97/1497 (*6.48*)	6/1497 (*0.40*)	5/1497 (*0.33*)	46/1497 (*3.07*)
55 to 74	401/7329 (*5.47*)	32/7329 (*0.44*)	1/7329 (*0.01*)	256/7329 (*3.49*)
> 74	113/2262 (*.00*)	12/2262 (*0.53*)	0/2262 (*0*)	102/2262(*4.51*)
Gender				
Male	258/4178 (*6.18*)	23/4178 (*0.55*)	5/4178 (*0.12*)	125/4178 (*2.99*)
Female	377/7431 (*5.07*)	29/7431 (*0.39*)	4/7431 (*0.05*)	292/7431 (*3.93*)
Procedure				
Hip	383/7290 (*5.25*)	30/7290 (*0.41*)	7/7290 (*0.10*)	278/7290 (*3.81*)
Knee	241/4096 (*5.88*)	22/4096 (*0.54*)	2/4096 (*0.05*)	135/4096 (*3.30*)
Shoulder	9/191 (*4.71*)	0/191 (*0*)	0/191 (*0*)	3/191 (*1.57*)
Elbow	2/32 (*6.25*)	0/32 (*0*)	0/32 (*0*)	1/32 (*3.13*)
Local origin				
Urban	361/6971 (*5.18*)	27/6971 (*0.39*)	4/6971 (*0.06*)	275/6971 (*3.94*)
Rural	274/4638 (*5.91*)	25/4638 (*0.54*)	5/4638 (*0.11*)	142/4638 (*3.06*)
Blood/blood product transfusion				
History	136/2176 (*6.25*)	35/2176 (*1.61*)	4/2176 (*0.18*)	81/2176 (*3.72*)
No history	493/9433 (*5.23*)	17/9433 (*0.18*)	5/9433 (*0.05*)	336/9433 (*3.56*)
Marital status				
Unmarried (never married, divorced, widowed)	73/1491 (*4.90*)	7/1491 (*0.47*)	1/1491 (*0.07*)	63/1491 (*4.23*)
Married	562/10118 (*5.55*)	45/10118 (*0.44*)	8/10118 (*0.08*)	354/10118 (*3.50*)
Totals	635/11609 (*5.47*)	52/11609 (*0.45*)	9/11609 (*0.08*)	417/11609 (*3.59*)

HBV, Hepititis B virus; HCV, Hepititis C virus; HIV, Human immunodeficiency virus; TP, Treponema pallidum

compared using Fisher's exact test and reported as the odds ratio (OR) with 95% confidence interval (CI). Continuous variables were compared using a two-tailed unpaired Student's *t*-test and reported as the mean and 95% CI of the difference of the mean. Statistical significance was defined as $p < 0.05$.

Results

Of the 12 078 patients who were admitted to our institution, 112 refused the screening test, 357 had repeat admissions for surgery and the remaining 11 609 (96.1%) underwent the screening assay. Table I shows the socio-demographic characteristics and infection status among patients undergoing joint arthroplasties.

HBV had the highest seroprevalence of all tested pathogens. Of all patients with a detected infection, 761 cases (68.4%) were previously undiagnosed. These newly diagnosed infections were 412 HBV, 31 HCV, six HIV and 312 TP. As shown in Figure 1, the seroprevalence of HBV varies according to the patient's age and gender. The data indicates that 6.18% (258/4178) of the total male population and 5.07% (377/7431) of the total female population were positive for hepatitis B infection (OR = 1.23; 95% CI 1.05 to 1.45; $p = 0.01$). Similarly, hepatitis C was also common in male patients, with 0.55% (23/4178) testing positive, compared with 0.39% (29/7431) of female patients. Conversely, the seroprevalence rates of TP were higher in female than in male patients (OR = 1.33; 95% CI 1.07 to 1.64; $p = 0.009$). The overall seroprevalence of each BBV in the rural regions was slightly higher than that in the urban region ($p > 0.05$).

The total charges associated with screening the four pathogens are approximately 2 855 814 Chinese Yuan, with a mean cost of 246 Chinese Yuan per patient (in 2016, \$1 = 6.6 Chinese Yuan). The direct screening cost for every newly detected infectious patient is 3752.71 Chinese Yuan. Considering needlestick injuries occur in 1% to 15% of all surgical procedures[11] and carry a risk of accidental transmission, one HBV transmission occurs in every 61 needlestick injuries (406 to 6094 surgical procedures), one HCV transmission occurs per 2222 needlestick injuries (14 815 to 222 222 surgical procedures) and one HIV transmission occurs per 416 667 needlestick injuries (2 777 778 to 41 666 667 surgical procedures). A range of 14 815 to 222 222 patients would need to be screened for HCV in order to diagnose an occupational transmission from a source patient to a HCW following needlestick injuries, which would lead to screening costs of 1 481 500 to 22 222 200 Chinese Yuan (Table II). In the case of HIV, the screening costs would add up to 166 666 680 to 2 500 000 020 Chinese Yuan (2 777 778 to 41 666 667 patients).

Discussion

This study reports a high seroprevalence for HBV and TP (5.47% and 3.6%) among patients undergoing joint arthroplasty at a teaching hospital in Shanghai, China. These values are higher than those of Western countries and other Asian countries. The seroprevalences of HCV and HIV were low but not negligible at 0.45% and 0.08%, respectively. Previous studies have demonstrated that there is a geographical variation in the seroprevalences of HBV, HCV and HIV (Table III).[9-12,14,19-27]

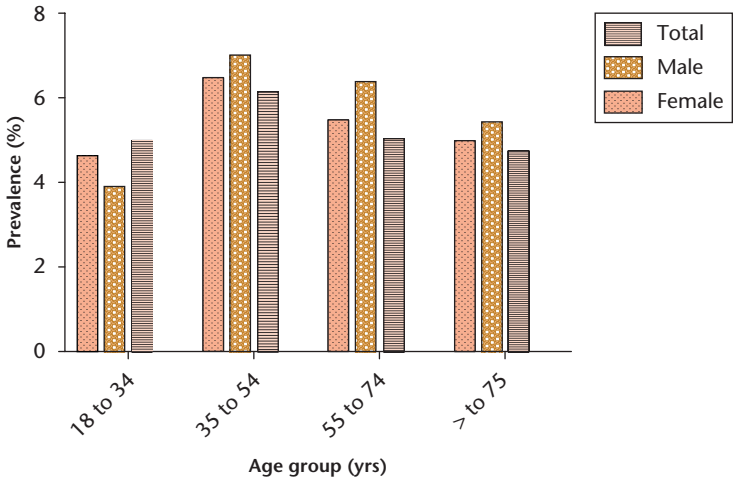

Fig. 1

Graph showing the distribution of Hepatitis B virus seroprevalence among patients by age (years) and gender.

Table II. Theoretical calculation of transmission risk and the cost-to-benefit ratio of pre-operative screening.

Virus	Seroconversion rate (%) (S)	Seroprevalence (%) (P)	Risk of accidental transmission (%) (S×P)	Cumulative risk* (%) (S×P×40×10)	Patients screened (n)	Screening costs (Chinese Yuan Renminbi)
HBV	*30*	*5.47*	*16.41*	*656.4*	406 to 6094	10 556 to 158 444
HCV	*10*	*0.45*	*0.45*	*18*	14 815 to 222 222	1 481 500 to 22 222 200
HIV	*0.3*	*0.08*	*0.0024*	*0.096*	2 777 778 to 41 666 667	166 666 680 to 2 500 000 020

*for a surgeon operating over a period of 40 years on patients and having a mean of ten percutaneous blood contacts per year
HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; S, Seroconversion of single occupational exposure; P, Seroprevalence of blood-borne virus infection in patients

Table III. Seroprevalence of blood-borne viruses in patients undergoing orthopaedic surgery.

Author	Country	Publication year	Patients (n)	HBV (%)	HCV (%)	HIV (%)
Calore et al[17]	USA	2012	381	NA	*8.4*	NA
DelSole et al[12]	USA	2014	14772	NA	*2.11*	NA
Issa et al[23]	USA	2015	1 700 400	NA	*0.47*	NA
Khan et al[21]	Pakistan	2007	1630	*3.12*	*2.02*	NA
Lin et al[26]	USA	2013	5 681 024	NA	NA	*0.14*
Mineiro et al[19]	Portugal	1997	288	*1.4*	*3.1*	*1.7*
Simonian et al[24]	USA	1995	425	NA	*4.5*	NA
Thorburn et al[22]	UK	2003	967	NA	*3.8*	NA
Utkan et al[9]	Greece	2006	1040	*2.3*	*0.6*	NA
Villani et al[18]	Italy	2001	911	*1.09*	*4.06*	NA
Weber et al[10]	Germany	2013	10 011	*0.001**	*0.003**	*0**
Wiegand et al[25]	Germany	2006	2026	NA	NA	*0.6*
Winkelmann et al[11]	Germany	2016	1534	*1*	*2.1*	*0.1*
Yeganeh et al[20]	Iran	2015	320	*2.5*	*3.2*	*0.6*
Our study	China	2017	11 609	*5.47*	*0.45*	*0.08*

*newly recognised infections
HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; NA, not available

In China, mother-to-child vertical transmission of HBV plays an important role in chronic infection, whereas blood or blood product transfusion is considered the major source of transmission of HCV.[14,27] Since 1992, the Chinese government conducted the National Immunisation Programme with a hepatitis B vaccine and offered free vaccines for all infants, however, the vaccination coverage rate in rural areas was lower than that in urban areas.[28,29] An HBV sero-epidemiological survey revealed that the prevalence dramatically decreased from 9.8% (1992) to 7.2% (2006).[14,28] For multiple infections, the most frequent combination was HBV-TP (57/165, 34.6%) in the present study. Only seven male patients and four female patients had co-infection of hepatitis B and hepatitis C. Patients who received a blood transfusion or blood product were at a higher risk of contracting HCV. A higher seroprevalence of HBsAg was observed in the 35 to 54 years age group, whereas most HIV infections were

observed among patients aged 18 to 54 years. In contrast, the seroprevalences of HCV and TP increased with age. These results are significant because the need for surgical care for joint disease also increases with age, thereby creating a higher risk to arthroplasty surgeons of occupational exposure. Our study raises serious concerns about the high seroprevalence of TP antibodies in female patients aged > 75 years. Older patients are more likely to exhibit false positive reactions for syphilis[30] and therefore misinterpretation of the results should be avoided.

Recently, two studies from Germany questioned the rationale of routine pre-operative screening for BBVs.[10,11] The cost model revealed that the prevention of occupational infection through pre-operative screening leads to additional costs of billions of dollars.[11] Nevertheless, the data from Germany, a country with low prevalence of these infections, are not applicable to countries with higher prevalence. A minimum prevalence of 0.1% in the general population is the cost-effective threshold of routine HIV screenings.[31] Given the high cost of universal screening tests and the low seroprevalence of HIV in elderly patients in the present study, a risk-based approach involving pre-operative assessment of patient risk factors for past HIV exposure should be considered by HCWs. For needlestick or cutting injuries, HCWs should ask for an immediate screening of the index patient. Test results for HIV are available within a few hours and thus do not hinder the post-exposure prophylaxis.

More than 400 000 joint arthroplasties are performed annually in mainland China.[32] Thus, the frequency of needlestick injuries is in the range of 4000 to 60 000. In other words, 66 to 984 or two to 27 unvaccinated surgeons are infected annually by HBV and HCV respectively. If we consider an active surgeon (without vaccination), operating over a period of 40 years on patients and having a mean of ten percutaneous blood contacts per year, rough estimates for the lifetime risk of occupational seroconversion are 656.4% (HBV), 18% (HCV), and 0.096% (HIV), respectively. Due to recommended and regularly controlled vaccinations of every HCW against HBV, the risk of HBV transmission from an index patient to a healthcare worker after percutaneous contact with blood is lower than this theoretical calculation. Low-cost vaccines can protect an active surgeon from HBV infection, and cost substantially less than healthcare costs per patient with chronic hepatitis B.[33] Considering that non-immunity to hepatitis B is high,[34,35] a routine screening of patients from highly endemic countries would be useful to diagnose and prevent transmission.

Pre-operative knowledge of serostatus and viral load will significantly influence the operative planning,[12] choice of anaesthesia[36] and intra-operative safety protocol.[1,12] Our study found that unknown seropositivity among patients in China was higher than in other countries.[10,11] If we assume that pre-operative knowledge of the patient's infectiousness reliably prevents occupational transmission to HCWs, pre-operative HIV tests will have the highest costs associated with preventing transmission, followed by HCV and HBV. However, the pre-operative knowledge of serostatus and viral load does not necessarily protect HCWs from needlestick and other sharp injuries. In fact, the anxiety associated with operating on virus-positive patients may increase the risk of sharp injuries. Healthcare workers may suffer from depression after exposure to potentially virus-contaminated blood or body fluids.[37] Apart from sharp needlestick and cutting injuries during arthroplasty surgery, splashes on the skin, eyes, mouth or nasal passage often occur through power instrumentation and lavage.[5,7] The risk of contracting HIV through exposure of mucous membranes is up to 0.1%.[38] Standard precautions applied in Western countries, including wearing a polyethylene gown, body exhaust system and enclosed sterile surgical helmet, efficiently protect the surgeons from exposure to BBPs. Unfortunately, this personal protective equipment is usually not available for surgical teams during major surgical procedures in developing countries such as China. Given the current unavailability of highly effective anti-virus agents and vaccines (HCV and HIV), the high rate of undiagnosed patients further increases the risk of occupational infection for HCWs without protection.

The strength of our study is the large sample size and high screening rates, leading to high statistical power for the detection of the sociodemographic risk factors. Within a large orthopaedic department in a tertiary referral centre where 2000 or more arthroplasty operations are performed annually, achieving epidemiological data over a long time period is possible. To our knowledge, this study is the first of its kind in the orthopaedic Chinese patient population. However, this study has some limitations. As a retrospective analysis, not all demographic characteristics of the patients were routinely collected in the medical records at the time of testing. All four pathogens can be transmitted during sexual intercourse through exposure to contaminated body fluid and intravenous drug abuse. Therefore we can assess the risk for seroprevalence by history of previous transfusion, marital status and household of infectious patients, and not by sexual risk behaviour and drug abuse.

In summary, our results showed high positive rates for HBV and TP infections among patients undergoing major orthopaedic surgery in mainland China. It was established that the cost-to-benefit ratio for pre-operative screening (HCV and HIV) was poor. Considering the high rate of undiagnosed patients and the shortage of protective equipment, targeting hepatitis B and syphilis with the use of pre-operative screening should be considered in order to prevent their transmission to unvaccinated HCWs in China.

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Author Contribution
- T. Cheng: Study design, Data collection, Writing the paper.
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- J-J. Hu: Writing the paper.
- B. Li: Data collection, Writing the paper.
- Q. Wang: Study design, Writing the paper.

Conflicts of Interest Statement
- None declared