Special Feature

Field Effectiveness of Needle Disinfection Among Injecting Drug Users

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Summary: To examine the putative protective effect of disinfectant use on HIV seroconversion among injecting drug users, we conducted a nested casecontrol study of black heterosexuals comparing 34 HIV seroconverters with 154 persistent seronegatives matched on gender, cocaine injection (yes/no), date of study entry, and duration of follow-up. Injecting drug users who reported using disinfectant all the time had an odds ratio of seroconversion of 0.87, as compared with those who reported no use of disinfectants; the corresponding odds ratio was 1.00 for those who used disinfectants less than all the time. We examined the effect of drug use and sex practice variables, and responses to a socially desirable responding scale as possible confounders for the effect of needle disinfection on HIV seroconversion; the adjusted odds ratios for disinfectant use and HIV seroconversion were unchanged in this analysis. Despite limited statistical power and the potential for residual confounding, these data suggest that disinfection of injection equipment is not a substitute for abstinence from drugs or use of sterile injection equipment. Key Words: Human immunodeficiency virus—Acquired immunodeficiency syndrome—Substance abuse—Prevention.

Public health strategies to prevent parenteral transmission of human immunodeficiency virus (HIV) infection among injecting drug users include promotion of abstinence through treatment for drug abuse, use of sterile needles and syringes, disinfection of injection equipment between uses, and reduction in the frequency of injecting behaviors (1). Although these strategies seem sensible when considered in an hierarchical order, data on the effectiveness for each of these strategies are limited.

Disinfection of injection equipment is one strategy that has been widely promoted and readily accepted by both injecting drug users and the communities where they live (2). However, in an earlier

report, we observed that the risk of HIV seroconversion was reduced by only 23% among injecting drug users who used disinfectants all the time compared to those who denied use of disinfectants (3). This preliminary analysis was limited by small sample size, concern about validity of self-reports, and a concern that the association might be confounded by behaviors associated with sexual transmission of HIV infection. The purpose of this report is to update and expand our earlier analyses with a larger sample size and to examine the association of HIV seroconversion and use of disinfectants among injecting drug users in the presence of additional potential confounders.

METHODS

Sample

Between February 1988 and March 1989, injecting drug users were enrolled into a cohort study of natural history of HIV-1

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infection (ALIVE, AIDS Linked to Intravenous Experience, Study). Injecting drug users were recruited by word-of-mouth from a variety of community agencies, including drug abuse treatment centers, city health department clinics, emergency rooms, state probation and parole offices, university hospital HIV clinics, homeless shelters, and the street outreach AIDS prevention (SOAP) program of a local community health education group. Clinic staff also distributed brochures at selected housing projects and locations where intravenous drug use was suspected. Also, study participants were encouraged to refer eligible friends to the study clinic. Eligibility for enrollment in the study included an age of 18 years or older, a history of injecting illicit drugs at any time within the previous 11 years, and being free of AIDS at baseline. Of 2,921 participants enrolled, 90% were Black, 83% were male, and 92% had needle marks on their upper extremities. The Baltimore City Health Department and the SOAP program have promoted bleach use through the distribution of small bottles of bleach with instructions for its use since 1987.

Data Collection Procedures

At the initial visit (baseline), eligible and consenting injecting drug users were enrolled and assigned a unique and confidential study number used as the coded identifier on data collection instruments. After venipuncture to collect serum for HIV-1 antibody assays, each participant was questioned face-to-face by a trained interviewer in a private room. This standardized baseline interview schedule elicited demographic data, a medical history, and a history of drug injection and sex practices. The rationale, organization, and methods of the study have been described in detail elsewhere (4,5). Participants were instructed to return in 2-3 weeks to receive test results; 630 HIV seropositives and a sample of 160 seronegative individuals were enrolled into a follow-up component of the study, which included appropriate medical referrals. All seronegatives were encouraged to return at 6-month intervals for serologic rescreening and interviews about risk behavior during the interval. The individuals who were seronegative at their baseline visit were studied for the relationship between disinfection practices of their injection equipment and HIV seroconversion.

As part of the interview at each 6-month visit, these seronegative participants were asked to recall their duration of injection drug use, frequency of injection, type of drug injected, number of different needle sharing partners, numbers of injections performed in shooting galleries, whether "backloading" was performed (the practice involving drawing drug up into one syringe and then transferring a portion of the drug to a second syringe) number of sex partners, and details of sexual practices. In addition, participants who reported sharing needles and syringes were asked to describe the procedures they used to prepare their injection equipment immediately prior to use. This open-ended question was coded by the interviewer into an array of techniques (i.e., nothing, rinsing, draw-up and squirt out, soaking, boiling, and flaming), and type of solution (tap water, bleach, alcohol, other). Frequency distributions for these activities among the entire cohort at baseline interview have been reported elsewhere (6). After June 1989, participants were asked about the frequency with which they used procedures to clean/disinfect their equipment (never, 1-2 times, less than half the time, more than half, all the time). To examine a potential effect of socially

desirable responding, we adapted a scale from Paulhus (7), which we have described elsewhere (8). Neither the subjects nor the interviewers were aware of the subjects' HIV seroconversion status (the outcome variable of this analysis) at the time of the interview.

The study protocols were reviewed and approved by the Institutional Review Board of The Johns Hopkins University School of Hygiene and Public Health. All participants received counseling about HIV risk reduction at baseline and at each subsequent study visit, after data collection sessions.

Serologic Tests

Antibody to HIV-1 was detected by a licensed enzyme immunoassay (Genetic Systems, Seattle, Washington). Specimens that were repeatedly reactive in the enzyme-linked immunosorbent assay were assayed by the Biotech HIV-1 Western blot kit (Du Pont Company, Wilmington, Delaware); criteria for seropositivity have been described elsewhere (4). HIV seroconverters were defined as individuals who initially were observed to be negative for HIV by enzyme-linked immunosorbent assay and who subsequently tested positive by both ELISA and Western blot.

Data Analysis

To investigate the hypothesized protective association between disinfection of injection with equipment with bleach or alcohol and HIV seroconversion, we conducted a matched casecontrol analysis nested within a prospective study. To each case (i.e., seroconverter), up to five persistently seronegative controls were matched on potentially confounding variables, and the time interval they were at risk for seroconversion and under observation in our study. In particular, cases and controls were matched on gender, recent (last 6 months) cocaine injection (yes/ no), data of study entry (±3 months), and duration of follow-up (all controls with length of follow-up ≥ case; however, we used the interview of the control that was closest in calendar time and duration of follow-up with the respective case). We matched on date of entry and duration of follow-up to control for possible confounding due to calendar time and maturation, respectively, as participants receive community based interventions outside the study and risk reduction counseling at each study visit. We controlled for gender and cocaine injection as these are potential confounders with HIV seroconversion and use of disinfectants. Because only five of 174 seroconverters were white or male homosexual or bisexual and matches were not found, they were excluded from further analyses. In addition, since use of disinfectants was relevant only for those who reported sharing of needles, users who denied needle sharing were not asked about disinfectant use and were excluded from analysis. Analysis also was restricted to interviews conducted after June 1989 when questions about frequency of bleach or alcohol disinfection were added to the behavioral questionnaire.

Data on needle and syringe cleaning frequency when needles were shared in the prior six months for either bleach or alcohol (non. <all the time. all the time), age, frequency of injection ($\geq 1/\text{day}$, <1/day), number of needle sharing partners (1, >1), and use of shooting galleries (yes/no) were obtained from the interviews of the first seropositive visit for each case and from the visit closest in time to the case for the matched controls. Use

of disinfectant referred to needle sharing; there was no separate question to distinguish cleaning frequency in shooting galleries from needle sharing episodes in general. Data on potential confounders such as number of needle sharing partners were obtained from the same visit; owing to limited number of cases, variables were dichotomized to permit multivariate analysis.

To incorporate the matching and to study the simultaneous effect of several exposures on HIV seroconversion and potential confounders, we used conditional logistic regression as the main analytic procedure (9); odds ratios were estimated to quantify the strength of association between HIV-1 seroconversion and frequency of disinfection.

RESULTS

Between February 1988 and November 1992, the ALIVE study detected 174 HIV-1 seroconverters among 1,532 individuals who returned for at least one repeat serologic rescreening after testing negative at baseline. Of these seroconverters, 169 were black and had no history of homosexual or bisexual behavior; 85 of them reported recent needle sharing. Although analysis was restricted to persons who reported needle sharing because questions about disinfection were asked only to those who reported needle sharing, we did compare those who shared needles and those who did not; nonsharers had fewer numbers of sex partners but higher scores on the "impression management" scale of the social desirability scale (data not shown). Of the 85 who reported needle sharing, 67 had their first seropositive visit after June 1989 when the frequency of needle disinfection questions were added to the study questionnaire. Of these 67, 34 had their first seropositive visit within 12 months from their last seronegative visit. The remaining seroconverters have been excluded from this analysis, and controls also were restricted to black heterosexual injection drug users with two visits including at least one visit after June, 1989.

Table 1 shows the frequency distribution of selected demographic drug use and sex practices among the eligible HIV seroconverters and 154 matched seronegative controls. In terms of matching, all used cocaine; eight cases and 39 controls were women, the median duration of follow-up in cases (700 days) was statistically similar to controls (747 days; p = 0.703). Overall, 45% were older than 34 years old. Within the preceding 6 months 70% reported injecting more than once a day; 59% reported more than one needle sharing partner; 25% used shooting galleries; and 80% reported use of bleach or alcohol to disinfect injection equipment. Of those reporting disinfection, 46% reported use

"all the time"; and of these using disinfectant all the time 83 used bleach and three used alcohol.

Table 2 shows the estimated magnitude of association of needle disinfection with HIV seroconversion using conditional logistic regression; there appears to be a modest inverse association related to frequency of disinfection. Using subjects who reported practicing no disinfection as the reference (OR = 1.00), the odds ratios for seroconversion among those reporting disinfection less than all the time and among those reporting disinfection all time were 1.00 and 0.87, respectively. The 95% confidence intervals for each point estimate included 1.00. By comparison, Table 1 shows the univariate odds ratio for HIV seroconversion associated with duration of injection drug use of <5 years was 5.03 (95% CI: 1.42, 17.82), and having more than one needle sharing partner was 2.63 (95% CI: 1.10, 6.24). Age, frequency of injection, backloading, gallery use, number of sex partners, recent history of sexually transmitted diseases, and responses to the scale of socially desirable responding were each not statistically associated with HIV seroconversion. Restricting analysis to women, three reported woman-to-woman sex and all were controls.

To specifically examine the effect of bleach disinfection, we repeated analyses excluding five participants who reported use of isopropyl alcohol (all five were controls). Compared to those who used neither bleach nor alcohol, the univariate odds ratio for HIV seroconversion was 1.02 (95% CI: 0.36, 2.86) for persons who reported bleach use less than all the time, and was 0.92 (95% CI: 0.34, 2.50) for persons who reported bleach use all the time. With no difference between disinfectant use in general versus bleach use in particular, subsequent analyses used the variable disinfectant (either bleach or alcohol). Within the category "less than all the time", the distribution of cases and controls for less than half, half, and more than half the time was statistically similar (data not shown).

Given the limited size of the sample, in subsequent analyses to examine potential confounding and interactions we formed a new reference group by combining the "less than all the time" group with the group not using disinfectant (i.e., disinfectant was dichotomized as "all the time" versus "not all the time"). The crude (i.e., unadjusted) estimate of the odds ratio for disinfectant use all the time was 0.90 (95% CI: 0.38, 2.11) (Table 3); this estimate did not change appreciably by adding variables separately for age, frequency of injection, the

TABLE 1. Univariate comparison of cases and controls by demographic drug use and sex variables, ALIVE Study, Baltimore, Maryland

Variable	Cases, HIV seroconverter (n = 34)	Controls, HIV seronegatives (n = 154)	Odds ratio ^a	95% CI
Age	· ·	· · · · · · · · · · · · · · · · · · ·		7570 CI
<35 years old			1.00	
≥35 years old	20 (58.8%)	65 (42.2%)	1.00	0.07.406
Frequency IV use	20 (38.8%)	63 (42.2%)	1.89	0.87-4.06
<1/day			1.00	
≥1/day	28 (82.4%)	104 (67.5%)	1.00	0.05.5.50
Duration IV use	26 (62.476)	104 (67.3%)	2.18	0.85-5.59
≥5 years			1.00	
<5 years	8 (23.5%)	13 (8 40%)	1.00	
Backloading	8 (23.3%)	13 (8.4%)	5.03	1.42–17.82
No			1.00	
Yes	9 (22 50%)	41 (26 (67)	1.00	0.25.0.01
	8 (23.5%)	41 (26.6%)	0.88	0.35-2.24
>1 needle share partners No			1.00	
Yes	26 (76 50%)	95 (55 301)	1.00	
	26 (76.5%)	85 (55.2%)	2.63	1.10-6.24
Gallery use No			1.00	
Yes	11 (22 407)	27 (22 197)	1.00	
	11 (32.4%)	36 (23.4%)	1.65	0.70-3.92
>2 sex partners				
No	12 (20 20)	15 (20 000)	1.00	
Yes	13 (38.2%)	46 (29.9%)	1.68	0.73-3.87
Any STD				
No	2 (5 000)	12 (0.104)	1.00	
Yes	2 (5.9%)	13 (8.4%)	0.72	0.15-3.44
Recent syphilis				
No	1 (2.00%)		1.00	
Yes	1 (2.9%)	0 (0%)	1.69	0.65-4.40
Social desirability				
Low-medium	14 (41 00)	40.400.000	1.00	
High	14 (41.2%)	60 (39.0%)	1.07	0.51-2.22

^a Univariate analysis from conditional logistic regression matched for gender, race (all were black), use of cocaine by injection, date of study entry (±3 months), and duration of follow-up. Interviews for controls were those closest in calendar time to the first seropositive visit of the cases.

number of needle sharing partners, duration of drug use, backloading, number of sex partners, recent history of sexually transmitted diseases, and score from social desirability response scale.

DISCUSSION

If disinfection with bleach or alcohol protects against HIV infection, then HIV-seronegative in-

jecting drug users who practice disinfection should be observed to have a lower risk of seroconversion, as compared with those not practicing disinfection. The point estimates from this study indicated that disinfection was associated with a somewhat lower risk, but these estimates were not precise and confidence intervals included the null value. One concern about the observed association between HIV seroconversion and use of disinfectants is the po-

TABLE 2. Comparison of cases and controls by frequency of disinfectant use, ALIVE Study, Baltimore, Marylanda

Frequency of disinfectant	Cases, HIV seropositive (n = 34)	Controls, HIV seronegative (n = 154)	Odds ratio	95% CI
None	7 (20.6%)	31 (20.1%)	1.00	
Less than all the time	12 (35.3%)	52 (33.8%)	1.00	0.36-2.82
All the time	15 (44.1%)	71 (46.1%)	0.87	0.32-2.37

^a Univariate analysis from conditional logistic regression matched for gender, race (all were black), use of cocaine by injection, date of study entry (±3 months), and duration of follow-up. Although duration of follow-up in controls was greater than cases, analysis used the interview of controls that was closest in calendar time to that of matched case.

CI, confidence interval; STD, sexually transmitted disease; Cases, incident HIV infection; controls, HIV seronegative.

TABLE 3. Adjusted odds ratios for HIV seroconversion by frequency of disinfectant use when other terms were added separately to conditional logistic regression model^a

Variables added to model	Adjusted odds ratio for disinfectant use	95% CI
Age, ≥35 years old	0.87	0.41-1.86
IV use, ≥1/day	0.93	0.44-1.97
Duration IV use of <5 years	0.99	0.45-2.15
Backloading	0.86	0.41-1.81
>1 needle share partner	0.96	0.45-2.05
Gallery	0.93	0.44-2.00
>2 sex partners	0.91	0.43-1.94
Any STD	0.86	0.41 - 1.82
Syphilis	0.79	0.36-1.72
Social desirability "high"	0.87	0.41-1.83

^a Basic model: odds ratio (95% CI) for HIV seroconversion by use of disinfectant all the time compared to less than all the time was 0.90 (95% CI: 0.38, 2.11); conditional logistic regression matched for gender, race (all were black), cocaine use by injection, date of study entry (± 3 months), and duration of follow-up.

tential confounding effect of sexual transmission of HIV infection. We considered whether sexual transmission of HIV infection, as measured by the number of different sex partners and a recent history of a sexually transmitted disease, might have been more likely among those who used disinfectants all the time. If so, then sexual transmission could confound the observed modest association between HIV infection and use of disinfectants. However, this analysis showed that statistical adjustment of sexual transmission variables between cases and controls did not appreciably alter the primary association. Although it is possible that no difference by the number of different sex partners could mask unavailable information about the HIV serostatus of these sex partners or the partners' injection drug use status, the lack of association for recent history of sexually transmitted diseases in our participants serves at least partially to attenuate this concern. These results suggest that variables other than sexual transmission need to be considered in understanding the observed results.

Other risk factors for HIV seroconversion in this study population of injection drug users included a relatively short duration of injection drug use and having more than one needle sharing partner. These data from a prospective study of HIV seroconversion are consistent with data from cross-sectional analyses of seroprevalent data (4,10), and seroincidence data from Northern Italy (11). Although not statistically significant, the point estimates for other drug injection behaviors are consistent with other published data. Of note, however, although Dutch

investigators hypothesized a possible association for the practice of "front loading"/"backloading (12) and investigators from New York City reported a positive association with receptive backloading in a cross-sectional survey (13), we found no increased risk for HIV seroconversion with this practice among admitted needle sharers which is consistent with our previously published crosssectional data from this population (14). Although the interview for this study did not distinguish "receptive" backloading, we performed an analysis which used HIV seroconversion as the outcome and used duration of injection drug use and backloading as the independent variables. To this model, we added an interaction term for duration of drug use and backloading. We hypothesized that newer drug users were more likely to be receptive such that the risk associated with backloading should be higher for persons with shorter duration of injection drug use. Although the result were not statistically significant due to the small sample size, it is interesting to note that the point estimate of the odds ratio for HIV seroconversion was 0.80 for persons with duration of <5 years and 0.86 for those with ≥5 years of injection drug use, which does not support the stated hypothesis. Additional studies that carefully specify behavior and control for confounding are needed to clarify the apparent discrepancy across studies (13). For this study, it is important to note that the association between use of disinfectants and HIV seroconversion was unchanged after adjustment for these other drug injection behaviors.

The failure to detect evidence for a major effect of bleach or alcohol disinfection might be due to a variety of factors, including characteristics of those who choose to use disinfectants. That is, individuals who engage in inherently more risky behavior also may be more likely to adopt use of bleach; steps to control for confounding by the frequency of risky behaviors may have been only partially adequate. For example, we did not have participants distinguish disinfection frequency with needle sharing versus shooting gallery use. However, adjustment for gallery use did not change estimates for use of disinfected and HIV seroconversion. Equally important, a bias in differential exaggeration of selfreporting of use and frequency of protective behaviors between cases and controls might undermine estimates of associations. The potential for socially desirable responses in a self-report interview cannot be excluded in any study setting where there are ethical obligations to provide ongoing riskreduction counseling. However, alternatives to reliance on self-reports of such behaviors are limited. This study examined frequency of disinfectant use only among those who reported needle sharing; information on disinfection among persons who denied needle sharing but who might have used contaminated equipment was not collected nor analyzed as part of this study. We restricted the study to persons who reported ongoing needle sharing, which is not a socially desirable response; this restriction to inclusion of such persons should have reduced an effect of socially desirable responding. In this analysis, we also adjusted for socially desirable responding using a scale that has been previously published (6,7); results from use of this scale did not appreciably change the association observed for HIV seroconversion and disinfection. However, caution is still warranted following the observation that only half of the HIV seroconverters reported needle sharing in the 6 months prior to the first seropositive visit; along with the nonneedle sharers having fewer sex partners but more evidence of social desirably responding, it remains prudent to interpret data from interviews from longitudinal studies with caution. Further development and analyses of measures of validity for selfreported data are needed before firm conclusions can be drawn.

Finally, the estimated strength of any protective effect might be constrained by limited reliability of the disinfectant measurement. Future studies might be strengthened by the addition of more detailed information of when disinfection is performed, visible presence of blood, and duration of disinfectant contact, to name a few variables. Under these circumstances, the trends we observed for a modest level of protection are somewhat encouraging. In passing it is interesting to note that although in vitro laboratory studies indicated HIV was susceptible to a wide variety of disinfectants (15,16) data from Flynn suggested that bleach might be the most effective in the context of needle disinfection (17). When we removed persons who used alcohol and restricted analysis to bleach versus no disinfectant, we found virtually no protective effect for bleach. These data suggest additional caution is needed in development of recommendations about the use of bleach under field conditions as practiced by injection drug users.

With methodological limitations acknowledged, two principles of disinfection warrant consider-

ation, namely bioburden and contact time (18). Bioburden refers to the amount of protein material (i.e., blood) present in contaminated injection equipment to which a disinfectant might bind and therefore be unavailable for virucidal activity. Reduction of bioburden through mechanical cleaning (e.g., with a dilute detergent or even fresh tap water) prior to contact with disinfectants should be performed so as to optimize the effects of disinfectants on residual infectious agents; however, the safety of detergent use under field conditions by injecting drug users has not been established. Contact time refers to the duration of contact between disinfectant and the infectious agent. In vitro studies have reported efficacy of bleach or alcohol against HIV-1 when minimum contact time has been at least 30 s (19). To date, most reports of bleach distribution programs have involved direct contact with disinfectant without prior cleaning, as well as contact times that are shorter than those reported from those recommended by published in vitro studies (20). Whether drug users will accept more effective efforts at disinfection is an open question.

Although preliminary, these data caution against an overreliance upon bleach or alcohol disinfection in prevention of new HIV infection among injecting drug users. A combination of strategies for prevention seems prudent, including promotion of abstinence and reduced injection frequency through drug abuse treatment programs, syringe exchange programs, and promotion of risk reduction through intensive education, counseling, and HIV-1 testing programs. That distribution of bleach or alcohol can be an adjunct to the overall efforts to reduce risk has been suggested by Watters et al. (21). Additional studies will be required to clarify ways to maximize the effectiveness of public health interventions to prevent HIV infections in this population.

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