

Trends in the injection of midazolam and other drugs and needle sharing among injection drug users enrolled in the AIDS VAX B/E HIV-1 vaccine trial in Bangkok, Thailand

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Received 4 June 2004; received in revised form 18 February 2005; accepted 21 February 2005

Abstract

Midazolam injection may increase the hazards of drug use. Its ability to cause amnesia may be associated with increased HIV risk behaviour and its interaction with other licit and illicit drugs may cause overdose and death. We analysed midazolam injection among injecting drug users (IDUs) participating in the AIDS VAX B/E HIV-1 vaccine trial in Bangkok, Thailand. From March 1999 to August 2000, 2545 IDUs were enrolled and randomised to receive AIDS VAX B/E or placebo. An interviewer-administered questionnaire assessed demographics (at baseline) and drug use behaviour (every 6 months). Reports of midazolam injection were statistically evaluated. During 36 months of follow-up, injection of any drug decreased from 94 to 51% and needle sharing decreased from 33 to 16%. Among those who continued to inject, midazolam injection increased from 10 to 31% (all $p < 0.0001$). Earlier study visit, lower education and less frequent injection were independently associated with less frequent midazolam injection; younger age, reports of needle sharing and receiving methadone treatment were independently associated with more frequent midazolam injection. Preventive interventions to educate IDUs and midazolam prescribers are urgently needed.

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Keywords: HIV-1; Midazolam; Vaccines; Risk behaviour; Injection drug use; Thailand

1. Introduction

In March 1999, a phase III HIV vaccine trial (AIDS VAX B/E, VaxGen, Inc., Brisbane, CA, USA) was initiated among injection drug users (IDUs) attending drug treatment clinics of the Bangkok Metropolitan Administration (BMA) (Vanichseni, Tappero, Pitisuttitham, Kitayaporn, Mastro, Vimutisunthorn 2004). Participants were asked at every study visit whether they had injected drugs, and if so, whether they

had injected heroin, methamphetamine or 'other drugs'. We noted that a drug called Dormicum® was frequently mentioned under the category other drugs.

Dormicum® is the Thai brand name for midazolam, a rapid-onset, short-duration benzodiazepine, also known as Versed and Hypnovel. It has anxiolytic, sedative, hypnotic, muscle relaxant, and anticonvulsant effects. It is used primarily for sedation in hospital, emergency, and preoperative settings. Parenteral administration of midazolam induces short-term anterograde amnesia. Physical dependence can develop with prolonged use, and abrupt discontinuation of the drug can lead to withdrawal symptoms (F Hoffmann-La

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Roche Ltd., 1997; Perera and Lim, 1998; Munzar, Yasar, Redhi, Justinova, & Goldberg, 2001).

In Thailand, midazolam is usually prescribed in tablet form (15 mg) and classified as a psychotropic substance, schedule 2, meaning that it is legally accessible with no associated registration system. Some Thai physicians prescribe midazolam over methadone for drug addiction treatment, on account of its sedative effects. IDUs, in turn, inject midazolam in combination with heroin or as a substitute for heroin, if the latter is in short supply or too expensive.

The ability of midazolam to induce amnesia may affect IDUs' recall following injection, which may increase their HIV risk behaviour. Drug injection in Thailand usually is a social behaviour, practiced by circles of friends or 'brothers'. Since midazolam injection may involve multiple injections during consecutive or overlapping periods of time, IDUs may not be able to identify their own injection equipment, which may lead to needle sharing. There are also reports of interaction with other illicit and licit drugs, notably HIV antiretroviral drugs, increasing the risk of overdose and death (Centers for Disease Control and Prevention, 2001). In light of the dangers of midazolam injection, we analysed its frequency of use and association with other drug-use risk behaviours among IDUs enrolled in the AIDS VAX B/E vaccine trial.

2. Method

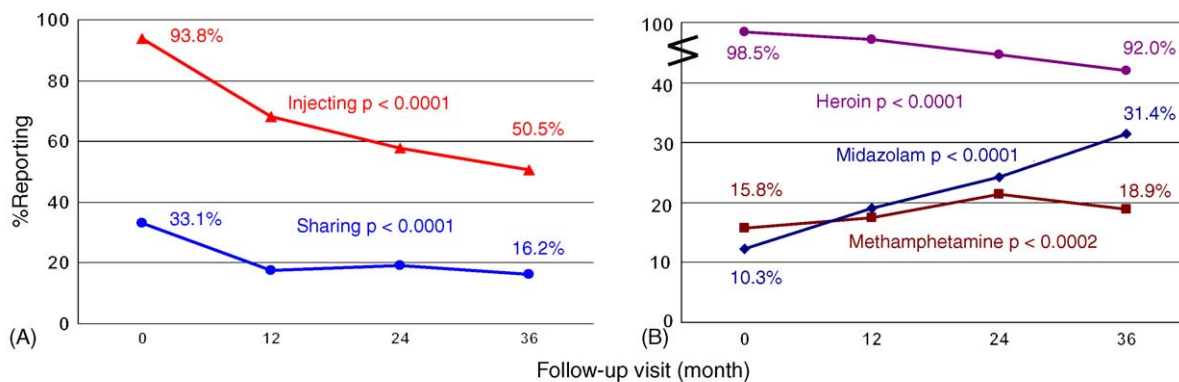
A description of the study design is presented elsewhere (Vanichseni et al., 2004). Briefly, between March 1999 and August 2000, 2545 IDUs were enrolled and randomised to receive AIDS VAX B/E or placebo. The trial was completed in June 2003. Risk-reduction counselling was provided at every study visit and male condoms and bleach to clean in-

jection equipment were demonstrated and provided free of charge. An interviewer-administered questionnaire assessed demographics (at baseline) and HIV risk behaviour (every 6 months). Those who reported to have injected drugs other than heroin and methamphetamine were prompted to specify the type of drugs. All participants whose answers included 'Dormicum' or 'midazolam' were classified as having injected midazolam. An Institutional Review Board of the Centers for Disease Control and Prevention, Atlanta, GA, USA, and the Ethical Review Committee of the Thailand Ministry of Public Health approved the study.

Reports of midazolam injection and needle sharing over time were statistically evaluated using chi-square tests. We adjusted for repeated within-subject measures to evaluate variables independently associated with midazolam injection. To do this, we used generalised estimating equation analysis for logistic model estimation with statistical inferences and 95% confidence intervals (Diggle, Liang, & Zeger, 1994). Variables significant in univariate analysis ($p < 0.05$) were evaluated in multivariate models to analyse midazolam injection as a function of time and these covariates.

3. Results

Participants were 93% (2376) male, their median age was 26 years (range: 20–59 years) and 1711 (67%) had at least completed 9th grade education. During the 6 months prior to baseline, 2388 (94%) reported having injected drugs, of whom 789 (33%) reported having shared needles, and 2092 (82%) reported receiving methadone treatment. Heroin injection was reported by 2351 (99%) participants, methamphetamine by 376 (16%), and midazolam by 243 (10%). Daily injection was reported by 936 (39%). Reports of injection during the past 6 months decreased over time (Fig. 1A)



Number of participants					Number of participants injecting				
Injecting*	2388	1614	1289	980	Heroin†	2351	1569	1220	902
Sharing†	789	283	248	159	Midazolam†	243	274	282	307
					Metham- phetamine†	376	283	276	185

Fig. 1. Drug injection and needle sharing (A) and types of drugs injected (B) among injection drug users participating in the AIDS VAX B/E vaccine trial in Bangkok, Thailand, through 36 months of follow-up, by study visit.

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