Original Article

Characteristics and Outcomes of Non-occupational Post-exposure Prophylaxis in a Thai Tertiary-care Hospital

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Objective: To determine characteristic and outcomes of non-occupational post-exposure prophylaxis (nPEP) in a Thai tertiary-care center.

Materials and Methods: A retrospective cohort study was conducted among persons with non-occupational HIV exposures presented at Thammasat University Hospital between 1 December 2014 and 31 December 2016.

Results: There were 115 individuals included; 108 (94%) were females and the median age was 18 years (IQR 14 to 23 years). Most common reported risks included being raped (64%) and no condom use for vaginal sex (52%). nPEP antiretroviral drugs were prescribed in 69 cases (60%). Only 15 of the 69 cases (22%) can be evaluated for completion of nPEP regimen at 28 days. All of the 15 cases were 100% compliant to nPEP and none had HIV seroconversion. Of the 115 individuals, only 6 (5%) came for follow-up at 1 and 3 months. Independent factors associated with no follow-up were no receipt of nPEP drugs (p<0.001), female sex (p<0.001) and older age (p = 0.004).

Conclusion: Most of the individuals at-risk for non-occupational HIV exposure were young people and the most common risk was being raped. Strategies to improve rates of follow-up are needed to ensure the efficacy and safety of nPEP and further HIV transmission prevention.

Keywords: Non-occupational post exposure prophylaxis, Characteristics, Outcomes, A tertiary-care hospital, Thailand

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Human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) have been one of the world's important public health problems. Globally, there were approximately 37 million people living with HIV and 1.8 million new infections occurred in 2017[(1)]. In Thailand, the prevalence of HIV infection was about 1% among population in reproductive ages and HIV transmission has been ongoing with around 10,000 new infections in 2017[(2)]. To end the HIV/AIDS epidemic, several strategies are required including early identification of infected individuals and linkage to combined antiretroviral therapy (cART) and continuity care, and effective HIV preventive measures for HIV-non-infected individuals.

Post-exposure prophylaxis (PEP) is a strategy using cART to prevent HIV infection among HIV-non-infected individuals after HIV risk exposures. PEP can be categorized into two different types; occupational PEP (oPEP) for individuals who have HIV risk exposures related to work, usually in healthcare settings and non-occupational PEP (nPEP) for individuals exposing to HIV risks from other sources outside healthcare settings, such as unprotected sexual exposures, exposures following sexual assault and injection drug use[(3)]. The efficacy of PEP has been demonstrated in non-human primate studies with the 89% reduction in HIV seroconversion compared to control groups[(4)]. The initial concept about PEP use in humans derived from the mother-to-child transmission prevention studies, which demonstrated 50% and 67% reduction in rates of HIV transmission when administering zidovudine for 1 week and 6 weeks to newborns[(5,6)]. Given the ethical consideration in conducting subsequent PEP research in randomized controlled fashion, the best available evidence of PEP efficacy are from a case-control and a prospective cohort studies in 1990s and early 2000s[(7-9)]. For oPEP, a study among healthcare personnel (HCP) with percutaneous exposures to HIV-infected blood showed that receipt of zidovudine after the exposure was significantly associated with less HIV infection[(7)], while a study among men who have sex with men (MSM) in Brazil demonstrated benefits of taking zidovudine and lamivudine as nPEP in reduction of HIV infection after risk exposures[(8)]. In addition, a study from Canada revealed a success rate of 99.96% among nPEP users after sexual risk exposures[(9)].

Most of the PEP studies in Thailand involve oPEP and were conducted among HCP[(10-13)]. These studies described characteristics of risk exposures, oPEP regimen and

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prescription, factors associated with no completion of oPEP, outcomes of oPEP and compliance to the oPEP guidelines. Given the difficulties in monitoring and following-up PEP outcomes in non-HCP populations, research on nPEP has been scarce. There has been only one nPEP study which focused on intention to take, completion and outcomes of nPEP among Thai MSM[14]. To evaluate nPEP in Thailand, this study was conducted to describe characteristics of HIV risk exposures, nPEP regimen, compliance, and outcomes among individuals presented at a tertiary-care hospital.

Materials and Methods

Study design, setting and population

This is a retrospective cohort study conducted among individuals presented to Thammasat University Hospital (TUH) after non-occupational HIV risk exposures. TUH is a 600-bed tertiary-care hospital in central Thailand serving patient populations in Pathumthani and nearby provinces. The study period was from 1 December 2014 to 31 December 2017. This study was approved by Human Ethics Committee of Thammasat University No. 1 (Faculty of Medicine). Participants' informed consents were waived due to the retrospective study design.

Study protocol

The study participants were identified by chart review for the diagnosis of "HIV risk exposure", "sexual assault" or "counseling for postexposure prophylaxis" in the emergency department (ED) and all outpatient departments during the study period. Exclusion criteria include risk exposures related to work of HCP and incomplete data for the study's outcomes of interest. At TUH, individuals with non-occupational HIV risk exposures were initially evaluated by ED physicians or general practitioners. Infectious diseases consultation and referral were required if antiretroviral drugs for nPEP were prescribed while consulting obstetric and gynecologists (OB-GYN), psychiatrists, and forensic medicine specialists are needed for sexual assault cases. In addition, individuals less than 15 years old were seen by pediatricians for further evaluation. Antiretroviral therapy for nPEP was offered and prescribed to the at-risk individuals based on the TUH PEP protocol and the national guidelines[15]. Follow-up appointment is generally arranged at 1 and 3 months after the risk exposures to assess for HIV infection and other sexually-transmitted infections (STIs) status according to the TUH protocol and guidelines. For at-risk individuals prescribed nPEP antiretroviral drugs, appointment with an infectious diseases specialist was made within 2 weeks to assess for nPEP drug compliance and adverse reactions. The participants' data were extracted from their paper and medical records. Data collected included demographic and clinical characteristics, risk exposures, nPEP regimens, compliance, and adverse reactions, follow-ups, and outcomes after nPEP.

Statistical analysis

All analyses were performed using SPSS, version 15.0 (SPSS, Chicago, Illinois). Descriptive data were presented in number, percentage, median and interquartile range (IQR). Categorical variables were compared using the Pearson's χ^2 or Fisher's exact test as appropriate. Continuous variables were compared using Mann Whitney U test. The *p*-values less than 0.05 were considered statistically significant. Variables associated with no show for follow-up visit with a significance level of $p<0.20$ were entered into multivariable logistic regression model in stepwise backward fashion. Significant variables that were thought to be covariates were grouped, and only one variable from each group was chosen for model entry. The model's overall robustness was confirmed by Hosmer-Lemeshow goodness-of-fit statistic. Adjusted odd ratios (aORs) and 95% confidence interval (CI) were calculated in multivariable logistic regression analysis to determine factors associated with no show for follow-up visit.

Results

There were 115 individuals at-risk for HIV exposure presented to TUH during the study period. Of these 115 individuals, 108 (94%) were females, the median age was 18 years (IQR 14 to 23 years), 55 (48%) were students, 63 (55%) were single, and 5 (4%) had underlying psychiatric disorders. The median duration from the time of exposure to hospital presentation was 24 hours. The most common reported HIV risk exposure was being raped (64%) (Table 1). Among the 108 female individuals, most of them were students (47%) and single (54%). Forty-nine individuals (45%) reported ever had sexual intercourse before the current risk exposures while 15% reported history of past pregnancy, 10% had children and 7% reported history of abortion. On physical examination, 58 females (54%) had abnormal OB-GYN examination, of which the most common findings were hymen injury (93%), followed by vaginal injury (22%) and cervical injury (10%). The most common reported HIV risk exposures were being raped (69%), followed by no condom use with vaginal sex (56%).

Of the 74 individuals reported being raped, all were females, 30 (41%) were students, 45 (61%) were single, 5 (7%) had history of psychiatric disorders, and 4 (5%) had history of drug abuse (Table 2). Most of the raped individuals reported being raped by one rapist (88%), raped by known individuals (76%) and being intimidated or hurt (61%). Only 16% reported condom use with rape and 34% reported ejaculation inside the vagina. Other rape characteristics and behaviors are shown in Table 2.

Of the 115 individuals evaluated at TUH, 69 (60%) were offered nPEP antiretroviral drugs (Table 3) and all accepted nPEP. The median time from presentation to receipt of nPEP drugs was 2 hours (IQR 1 to 3 hours). Among these 69 individuals, the most common prescribed nPEP regimens were zidovudine (AZT), lamivudine (3TC) and boosted lopinavir/ritonavir (LPV/r) (86%), followed by tenofovir (TDF), 3TC and LPV/r (12%) and 7% developed adverse drug reactions, all of which required the regimens changed. Only 15 of 69 individuals

Table 1. Characteristics and HIV risk exposures of the 115 study individuals

Characteristics	Frequency (n = 115)
Age (years, median, IQR)	18 (14 to 23)
Female sex	108 (94)
Occupation	
Student	55 (48)
Company worker	21 (18)
Housewife	3 (3)
Farmer	1 (1)
Unemployed	1 (1)
Unspecified	34 (29)
Marital status	
Single	63 (55)
Married	34 (30)
Divorced	12 (10)
Unspecified	6 (5)
Medical comorbidity	
None	111 (96)
Iron deficiency anemia	1 (1)
Hearing loss	1 (1)
Chronic insomnia	1 (1)
Syphilis	1 (1)
History of psychiatric disorders	5 (4)
History of drug abuse	5 (4)
HIV risk exposure	
Duration from exposure to hospital presentation (hours, median, IQR)	24 (8 to 72)
Being raped	74 (64)
No condom use with vaginal intercourse	60 (52)
No condom use with oral sex	7 (6)
Mucosal contact of body fluid	1 (1)

Data are in number (%) unless indicated otherwise

Table 2. Characteristics and HIV risk exposures of the 74 raped individuals

Characteristics	Frequency (n = 74)
Age (years, median, IQR)	18 (14 to 23)
Female sex	74 (100)
Occupation	
Student	30 (41)
Company worker	16 (22)
Housewife	2 (3)
Farmer	1 (1)
Unemployed	1 (1)
Unspecified	24 (32)
Marital status	
Single	45 (61)
Married	23 (31)
Divorced	3 (4)
Unspecified	3 (4)
History of psychiatric disorders	5 (7)
History of drug abuse	4 (5)
Rape characteristics	
Number of rapist	
One	65 (88)
Two	7 (10)
More than two	2 (3)
Raped by known individuals	56 (76)
Concurrent drug use while being raped	
Alcohol use	14 (19)
Sedative drug use	1 (1)
Alteration of consciousness while being raped	13 (18)
Being intimidated/hurt	45 (61)
Rape behaviors	
Type of sexual intercourse	
Vaginal intercourse	56 (76)
Oral intercourse	7 (10)
Unknown	11 (15)
Condom use	12 (16)
Site of ejaculation	
Inside vagina	25 (34)
Outside vagina	6 (8)
No ejaculation	43 (58)
Action done after being raped	
Bathing	34 (46)
None	31 (42)
Vaginal washing	7 (10)
Bathing and vaginal washing	1 (1)
Bathing and oral washing	1 (1)

Data are in number (%) unless indicated otherwise

prescribed nPEP drugs (22%) were evaluable for nPEP 28-day completion, all of which completed nPEP with 100% compliance. There were limited available follow-up test results for HIV infection, hepatitis B, hepatitis C and syphilis (4 to 13%). However, all individuals who underwent these follow-up tests had negative results (Table 3). Of the 115 individuals, 43 (37%) did not show up at all for follow-up visit. In multivariable logistic regression analysis, independent factors associated with no show for follow-up visit were no receipt of nPEP drugs ($p<0.001$), female sex ($p<0.001$) and older age ($p = 0.004$) (Table 4).

Discussion

Our study is among limited number of nPEP studies in Thailand and the first to describe characteristics, risk exposures, nPEP use and outcomes among at-risk non-HCP individuals presented to a tertiary-care hospital. We found that most of the individuals were young female students who were raped. These findings were different from those reported in previous studies conducted in North America[9,16,17], which most at-risk individuals were in early adulthood and were males with HIV risks of unprotected anal intercourse (MSM) or injection drug use. The differences may be due to less chance of being sexual assaulted among males, less proportion of injection drug users and unawareness of nPEP for HIV prevention among MSM in Thailand[14]. In addition, the findings highlight sexual assault problems in young females and students. It should be noted that all of the raped individuals were females and most were raped by their known individuals in association with being intimidated or hurt and no condom use. Altogether, our study suggests the

high-risk exposures among raped individuals and the burden of sexual assault, especially in young females, which require further preventive actions by relevant authorities.

The most common nPEP regimens prescribed in our study was LPV/r-based regimens which were according to the national guidelines. However, such regimens were associated with significant diarrhea and rashes that required regimen discontinuation. Since previous studies demonstrated that adverse reactions of nPEP drugs were significantly associated with non-adherence to nPEP[9,11,18], the newer class of antiretroviral drugs with less adverse reactions, such as integrase inhibitors should be used in the nPEP regimens[19]. Nonetheless, cost and availability of nPEP drugs and medical coverage for nPEP user need to be considered in each setting. Among the 15 individuals who were prescribed nPEP and were evaluable for regimen completion, all reported 100% adherence to nPEP drugs. However, this may not represent the rate of nPEP adherence in our setting given that the other 54 individuals received nPEP could not be evaluated for adherence due to loss to follow-up. Other studies have reported rates of adherence to be 50 to 56% for oPEP[12,13] and 40 to 97% for nPEP[9,14,18]. Factors associated with adherence to nPEP drugs included first-time nPEP user, older age and male sex[9]. These findings suggest that the rates of nPEP adherence may vary depending on settings and factors associated with adherence should be considered for monitoring nPEP users.

Table 3. Non-occupational post-exposure prophylaxis (nPEP) characteristics and outcomes among the 115 study population

Characteristics	Frequency (n = 115)
Prescribed nPEP	69 (60)
nPEP regimen used	
AZT/3TC/LPV/r	59/69 (86)
TDF/3TC/LPV/r	8/69 (12)
AZT/3TC/IDV/r	1/69 (1)
AZT/3TC	1/69 (1)
nPEP adverse reaction	5/69 (7)
Diarrhea and rashes from LPV/r	4/5 (80)
Nausea from IDV/r	1/5 (20)
Discontinuing nPEP due to adverse reaction	5/5 (100)
Follow-up visit	
Show-up at all visits (1 and 3 months)	6 (5)
Show-up within the first month	72 (63)
nPEP completion evaluable	15/69 (22)
nPEP completion (28 days)	15/15 (100)
nPEP compliance 100%	15/15 (100)
Available HIV infection follow-up tests	15 (13)
Non-reactive result	15/15 (100)
Available hepatitis B follow-up tests	7 (6)
Negative result	7/7 (100)
Available hepatitis C follow-up tests	5 (4)
Negative result	5/5 (100)
Available syphilis follow-up tests	15 (13)
Non-reactive result	15/15 (100)
Further consultation	
Forensic Medicine for legal issues	49 (43)
Obstetrics and Gynecology	29 (25)
Psychiatry	23 (20)

Data are in number (%) unless indicated otherwise.
3TC = lamivudine, AZT = zidovudine, HIV = human immunodeficiency virus, IDV/r = ritonavir-boosted indinavir, LPV/r = ritonavir-boosted lopinavir, TDF = tenofovir disoproxil fumarate

Following-up individuals at-risk for HIV exposures and nPEP users are critical for evaluating adherence to and adverse reactions of nPEP drugs as well as determining the infectious status of HIV and other STIs. This is important for the individuals to receive further management and to prevent transmission of these infectious diseases. Our study findings indicated the high rate of no show-up for follow-up visit among the study participants (37%), while another study reported the no show rate to be as high as 78%[18]. We further identified that older age, female sex and no receipt of nPEP drugs were independently associated with the no show. These findings were consistent with those reported for oPEP[20] and nPEP[9,21]. Other factors reported to be associated with no show for follow-up visit included having a developmental or other disability, having a current mental illness, being assaulted in public, homelessness, cocaine use, no social support, and time from exposure to receiving PEP of more than 24 hours[16,20,21]. These factors should be taken into consideration for counseling and close monitoring nPEP users to ensure follow-up visits. Among the 15 individuals with follow-up test results for HIV infection, none had seroconversion. This result was consistent with previous studies of oPEP and nPEP and confirmed the efficacy of PEP[11,12,14].

The strength of our study is that this is the first study describing demographics, clinical characteristics, exposures, nPEP regimen and outcomes of HIV prevention among non-HCP individuals with HIV risk exposures in

Table 4. Multivariable logistic regression analysis for factors associated with no show for follow-up visit among the 115 study population

Factor	Adjusted odds ratio (95% confidence interval)	*p*-value
Age	1.10 (1.03 to 1.18)	0.004
Female sex	363 (42.41 to 81.11)	<0.001
No receipt of non-occupational post-exposure prophylaxis	770 (75.02 to 197.02)	<0.001

Thailand. Limitations of the study include the retrospective design of the study that inherits data missing and misclassification bias and the small sample size of the study population and a single-center study that may limit generalizability of the study results. In addition, no information available for nPEP users who did not show-up for follow-up visit precludes assessment of the true rates of nPEP drug adherence and adverse reactions.

Conclusion

Most of the individuals at-risk for non-occupational HIV exposures in our setting were young females who were raped. Prescription of nPEP antiretroviral drugs was compliant with the national guidelines and could prevent HIV infection among nPEP user. However, adverse reactions of the drugs can contribute to discontinuation and change of the regimens. Individuals who were older, female and did not receive nPEP drugs at first visit should be counseled and closely monitored for no follow-up. Further studies are needed to determine strategies for improving the at-risk individuals' follow-up and ensuring the efficacy and safety of nPEP for HIV transmission prevention.

What is already known on this topic?

Using antiretroviral therapy in non-HIV-infected individuals after risk exposures (postexposure prophylaxis; PEP) has been one of the important preventive strategies recommended worldwide. Most of the PEP studies were conducted among healthcare personnel (HCP) with occupational risk exposures. However, data existing for non-occupational PEP (nPEP) among at-risk non-HCP individuals are currently limited in Thailand.

What this study adds?

Most of the individuals at-risk for non-occupational HIV exposures presented to a tertiary-care setting were young females who were raped. Protease-inhibitor-based regimens were the most commonly prescribed nPEP antiretroviral drugs and had some adverse reactions contributing to discontinuation and change of the regimens. Factors associated with no show for follow-up visit included older age, female sex and no receipt of nPEP drugs. These factors should be taken into consideration for counseling and close monitoring nPEP users to ensure the efficacy and safety of nPEP for HIV transmission prevention.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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ลักษณะและผลการให้การป้องกันภายหลังการมีความเสี่ยงต่อการติดเชื้อเอชไอวีภายนอกสถานพยาบาลในโรงพยาบาลระดับตติยภูมิของไทย

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วัตถุประสงค์: เพื่อศึกษาลักษณะและผลการให้การป้องกันภายหลังการมีความเสี่ยงต่อการติดเชื้อเอชไอวีภายนอกสถานพยาบาลในโรงพยาบาลระดับตติยภูมิของไทย

วัสดุและวิธีการ: การศึกษาโดยการทบทวนแฟ้มเวชระเบียนผู้ที่มาพบแพทย์ที่โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติระหว่างวันที่ 1 ธันวาคม พ.ศ. 2557 ถึง 31 ธันวาคม พ.ศ. 2559 ภายหลังการมีความเสี่ยงต่อการติดเชื้อเอชไอวีภายนอกสถานพยาบาล

ผลการศึกษา: การศึกษานี้มีรวบรวมแฟ้มผู้ที่เข้าเกณฑ์การศึกษาทั้งหมด 115 คน ซึ่งเป็นเพศหญิง 108 คน (ร้อยละ 94) และค่ากลางของอายุ 18 ปี (อินเตอร์ควอไทล์ 14 ถึง 23 ปี) ความเสี่ยงของการติดเชื้อเอชไอวีที่พบบ่อยที่สุดคือ ถูกข่มขืนกระทำชำเรา (ร้อยละ 64) และมีเพศสัมพันธ์ทางช่องคลอดโดยไม่ได้ใส่ถุงยางอนามัย (ร้อยละ 52) มีการให้ยาต้านไวรัสเพื่อป้องกันการติดเชื้อเอชไอวีภายหลังการมีความเสี่ยงต่อการติดเชื้อใน 69 คน (ร้อยละ 60) ในผู้ที่รับยาป้องกัน 69 คนนี้ มีเพียง 15 คน (ร้อยละ 22) ที่สามารถติดตามประเมินการกินยาป้องกันจนถึง 28 วันได้ ซึ่งพบว่าร้อยละ 100 กินยาอย่างสม่ำเสมอและตรงเวลา และไม่มีผู้ใดติดเชื้อเอชไอวี ในผู้ที่เข้าเกณฑ์การศึกษาทั้งหมด 115 คน มีเพียง 6 คน (ร้อยละ 5) ซึ่งมาติดตามนัดทุกครั้งจนถึง 3 เดือน ปัจจัยอิสระที่มีความเกี่ยวข้องกับ การไม่มาติดตามนัดในการศึกษานี้ได้แก่ ผู้ที่ไม่ได้รับยาต้านไวรัสเพื่อป้องกันการติดเชื้อเอชไอวีภายหลังการมีความเสี่ยง (p<0.001) เพศหญิง (p<0.001) และผู้ที่มีอายุมาก (p = 0.004)

สรุป: ผู้ที่มีความเสี่ยงต่อการติดเชื้อเอชไอวีจากภายนอกสถานพยาบาลส่วนใหญ่เป็นเพศหญิงที่มีอายุน้อยและความเสี่ยงต่อการติดเชื้อที่พบบ่อยที่สุดคือ การถูกข่มขืนกระทำชำเรา เพื่อให้การให้การป้องกันการติดเชื้อเอชไอวีภายหลังการมีความเสี่ยงมีประสิทธิภาพและมีความปลอดภัยต่อผู้ที่ได้รับการป้องกัน และเพื่อป้องกันการแพร่ระบาดของเชื้อเอชไอวี กลยุทธและวิธีการต่าง ๆ ซึ่งสามารถเพิ่มอัตราการมาติดตามตามนัดในผู้ที่มีความเสี่ยงเหล่านี้จึงมีความสำคัญ