Clinical and epidemiological profile of patients who seek post-exposure prophylaxis after sexual exposure to HIV and their adherence to the medication regimen in a specialized center in Cascavel, Paraná, Brazil

Perfil clínico e epidemiológico de pacientes que buscam profilaxia pós-exposição sexual ao HIV e sua adesão à medicação em Cascavel, Paraná, Brasil

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ABSTRACT

Introduction: Post-Exposure Prophylaxis (PEP) is part of a new strategy for the prevention of Human Immunodeficiency Virus transmission adopted by the Brazilian Ministry of Health. The approach involves the use of antiretroviral medication for 28 days after potential exposure to HIV in order to prevent the establishment of infection. **Objective:** To evaluate the epidemiological profile of patients who seek PEP after consensual sexual activity in a specialized center for infectious diseases in Cascavel, Paraná, Brazil. **Methods:** This study involved retrospectively evaluating a cohort based on the medical records of patients who received PEP between November 2011 and July 2016. **Results:** A total of 153 medical records were analyzed and it was observed that more men (77.12%) than women (22.9%) sought PEP. The average age of women and men was 30.05 years and 29.06 years, respectively. Since the implementation of PEP in 2001, the annual demand for the treatment has steadily increased. The majority of patients (96.76%) sought care within the 72-hour deadline for the start of prophylaxis. Although 85.62% of total cases received recommendations for the use of prophylaxis, it was possible to verify adherence to the medication regimen for the recommended time in only 45.90% of cases. Among the patients who adhered to treatment, no cases of seroconversion were observed. A gradual decrease in attendance of follow-up appointments was noted, with approximately 45% of patients abstaining after 30 days of initial care, increasing to nearly 80% after 12 weeks. **Conclusion:** Despite the apparent efficacy of prophylaxis, keeping track of patients undergoing prophylactic treatment remains difficult. Improved knowledge on the epidemiological profile of the population in question may be expected to guide public policies aimed at the prevention of Acquired Immunodeficiency Syndrome.

Keywords: AIDS; post-exposure prophylaxis; HIV.

RESUMO

Introdução: A profilaxia pós-exposição (PPE) faz parte das novas estratégias de prevenção da transmissão do vírus da imunodeficiência humana adotadas pelo Ministério da Saúde do Brasil. A abordagem constitui-se do uso de medicação antirretroviral por 28 dias após potencial exposição ao vírus, impedindo que o mesmo se estabeleça no organismo. **Objetivo:** Avaliar o perfil epidemiológico de pacientes que buscam PPE por atividade sexual consensual em um centro especializado em doenças infecciosas de Cascavel, Paraná, Brasil. **Métodos:** O trabalho consistiu na avaliação de uma coorte retrospectiva baseada na coleta de dados de prontuários de atendimentos para PPE sexual de novembro de 2011 a julho de 2016. **Resultados:** Foram analisados 153 prontuários e observou-se procura superior por PPE por indivíduos do sexo masculino (77,12%) em relação ao feminino (22,9%). A média de idade foi de 30,05 anos entre as mulheres e 29,06 entre os homens. Observou-se tendência de demanda anual ascendente de procura pelo serviço desde a implantação da PPE em 2011. A grande maioria dos pacientes (96,76%) buscou atendimento dentro do prazo limite de 72 horas para o início da profilaxia. Do total de casos, 85,62% recebeu recomendação para o uso da medicação profilática, em apenas 45,90% desses foi possível verificar a aderência à medicação pelo tempo recomendado. Entre os pacientes que aderiram à profilaxia não foram registrados casos de soroconversão. Verificou-se redução gradativa do comparecimento às consultas de acompanhamento, houve abstenção de aproximadamente 45% após 30 dias do atendimento inicial, chegando a quase 80% passadas 12 semanas. **Conclusão:** Apesar da aparente eficácia da profilaxia, ainda existe dificuldade em manter o acompanhamento dos pacientes para os quais o tratamento foi instituído. Espera-se que o melhor conhecimento das informações acerca do perfil da população em questão possa contribuir para o direcionamento de políticas públicas voltadas à prevenção da síndrome da imunodeficiência adquirida.

Palavras-chave: AIDS; profilaxia pós-exposição; HIV.

INTRODUCTION

The epidemic of acquired immunodeficiency syndrome (AIDS) has caused worldwide concern since the first confirmed case. In Brazil, where universal access to treatment and prevention is available, the disease presents a chronic character, with a reduction in mortality and an increase in life expectancy[1]. Currently, 827,000 people are infected with the Human Immunodeficiency Virus (HIV) in Brazil; however, 112,000 of these people are still unaware of their disease status[2], indicating the need for improved infection prevention strategies . In 2014, during the International AIDS Conference, the 90-90-90 target was presented as a global goal to end the epidemic by 2030[3]. As no single prevention method is able to contain the AIDS epidemic[4], the use of combined prevention strategies has

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become essential[5]. In order to be part of the global trend to end the epidemic, these new strategies were adopted by the Brazilian Ministry of Health to form part of the HIV transmission prevention policy. The use of antiretroviral medications, in the form of Post-Exposure Prophylaxis (PEP) after possible contact with seropositive patients is part of this prevention approach.

PEP is the last available prevention resource to avoid the establishment of HIV infection after failure or non-use of other preventive methods, and thus, it plays a strategic role in fighting the increase in the number of HIV cases[2]. PEP is based on the daily use of antiretroviral medications for 28 days after HIV exposure[6]. Addressing potential HIV transmission after sexual contact involves accepting the demand for PEP, evaluating the exposure circumstance, and characterizing the risk of transmission to consider the indication of chemoprophylaxis[1]. Therefore, sexual PEP has been applied as an emergency precaution in specific situations, to complement, but not replace, other preventive methods[7]. Access to prophylaxis is of major importance in a post-exposure treatment strategy, since antiretroviral prophylaxis should be administered as soon as possible after exposure and the period to start treatment is limited to 72 hours following the occurrence[8]. Prophylaxis is indicated in cases of exposure with a significant risk of HIV transmission, such as unprotective sex with partners with HIV or unknown serology, and considers factors that increase transmissivity, such as rupture of the mucosal barrier and the presence of bleeding or sexually transmitted infections (STIs)[6,8]. At present, the preferred and universally indicated antiretroviral regimen for PEP, independent of the type of exposure and biological material involved, is combined therapy composed of Tenofovir (TDF), Lamivudine (3TC), and Atazanavir/Ritonavir (ATV/r)[6,9].

Patient adherence to the 28-day antiretroviral therapy period is essential to ensure effective prophylaxis. However, published studies have shown that a low proportion of patients complete the entire course of PEP[10]. Limited research has been done to determine ideal rates of PEP adherence and on ways to encourage patient participation. In a study on more than 3,500 participants in the United States, 70% of patients completed the entire course[11]. A recent review of studies on PEP adherence carried out across several continents indicated that adherence rates varied between 49% and 92%[10]. Thus, the World Health Organization considers that improved adherence support could increase PEP completion rates and recommends that enhanced support for adherence with specific interventions be provided as part of PEP treatment[8].

Studies that evaluate the AIDS epidemic at a local level are rare and it is recommended that local policies be reduced to allow cities to take responsibility for planning and organizing health care according to their context[12]. The use of PEP for consensual sexual relations is a recent development in Brazil. The approach was first indicated in 2010[1], but until now assessment of it has mainly been at a local or regional level.

OBJECTIVE

The aims of this study were to characterize the clinical and epidemiological profile of patients who seek PEP after high-risk sexual exposure, to verify the outpatient follow-up, as well as to evaluate adherence to the proposed drug treatment as a form of prevention of HIV infection.

METHODS

Patients

Data for this retrospective cohort study were taken from the medical records of patients undergoing PEP treatment at the Specialized Center for Infectious-Parasitic Diseases (CEDIP) in the city of Cascavel, Paraná, Brazil.

Data collection occurred for nearly 5 years, from November 2011 to July 2016. Medical records of all male and female patients who underwent medical evaluations for consensual sexual PEP and their HIV infection risk were analyzed and included in the study. Patients were excluded if they were undergoing treatment for non-sexual exposure to HIV such as work accidents involving sharp objects, if they formed part of a serodiscordant couple in search of natural conception, and if they received relief from respiratory arrest without contagion risk.

The medical records of included cases were collected using a standardized protocol to build the research database, which included patient identification data (initials, gender, age, and marital status), factors related to exposure, indication of prophylaxis, follow-up data, and information on adherence to treatment.

This work was approved by CEP under opinion number: 1.295.811.

Data analysis

After collecting the information using a form, data compilation was carried out in Microsoft Excel (2016), followed by a descriptive analysis. Quantitative variables were represented by their measures of central position, and variability was represented by median and standard deviation (SD). Categorical variables were characterized by their absolute and relative/percentage values. The continuity of outpatient follow-up was determined by analyzing the rate of attendance of previously scheduled medical appointments. Variable analysis corresponding to the characteristics of patients was indicated by the total number, averages, and percentages. The use of prescribed drugs was verified by means of a voluntary verbal response recorded in the patient's medical record.

The research project was previously submitted to and approved by the Research Ethics Committee (REC) of the University Center Assis Gurgacz Foundation (FAG) (Approval Opinion No. 1.295.811).

RESULTS

During the study period, we identified 168 individuals who sought medical appointments for PEP. Of these, 15 were excluded because they did not fulfill the inclusion criteria of exposure by sexual contact; the remaining 153 patients were analyzed. Women accounted for 22.9% (35/153) of cases and men for 77.12% (118/153). The average age of female patients was 30.05 years (SD: 9.988) and 29.06 years (SD: 8.802) for male patients. Among the total number of patients, 58.82% (90/153) were single; 26.80% (41/153) married;

9.15% (14/153) separated, widowed, or divorced; and 5.23% (8/153) did not supply this information.

When we evaluated the recurrent demand for PEP, we found that only 4.57% (7/153) of visits were from patients who sought prophylaxis for more than one occurrence of sexual exposure to HIV.

Regarding the number of medical appointments for PEP during the study period, an increase was observed in the annual average demand since the implementation of the service in 2011 (Figure 1). Concerning the time elapsed after exposure, 96.73% (148/153) of the patients sought PEP within the maximum recommended interval (up to 72 hours after contact), and only 3.27% (5/153) sought PEP after this period. When questioned about the HIV status of their partners, 50.32% (77/153) of patients were unaware of the serology of their partner, 35.95% (55/153) were aware that their partner had positive HIV serology, 4.57% (7/153) requested that their partner undergo testing, and 9.15% (14/153) did not supply this information.

It was not possible to obtain clear data on sexual orientation because patients were questioned on the sexual behavior of their partners and not their own behavior. As for the partners, it was observed that 31.37% (48/153) were men who had sex with men, 56.21% (86/153) were heterosexual, and in 12.42% (19/153) of the cases, no information was available. Furthermore, it was found that only 4.57% (7/153) of the interviewees declared themselves to be sex workers (SW), but 22.22% (34/153) stated that their partners were SW. When habitual sexual behavior was evaluated, 65.36% (100/153) of patients indicated that they use a barrier method (condom), 18.95% (29/153) did not frequently use it, and in the remaining 15.68% (24/153) it was not possible to assess this information.

By using the information recorded in the medical records, it was possible to analyze the type of sexual contact that motivated patients to seek PEP **(Table 1)**. Among women, the great majority (80.55% [29/36]) reported receptive vaginal penetration as the type of sexual contact that motivated them to seek prophylaxis. Among men, the type of contact was mainly reported to be insertive vaginal penetration (47.06% [56/119]), insertive anal penetration (25.21% [30/119]), and receptive anal penetration (16.80% [20/119]).

Since routine testing for other STIs was not established initially, not all patients were tested. However, using the 153 analyzed records we were able to verify that 126 patients were tested for syphilis, with 6.78% (8/126) being positive for the disease. For Hepatitis C, only 0.88% (1/114) of patients presented positive serology, and none presented positive HIV serology, allowing all at-risk patients to receive prophylaxis.

When the need for PEP was analyzed, it was observed that 85.62% (131/153) of medical evaluations indicated the use of PEP, whereas PEP was discouraged in 14.38% (22/153) of cases. The main clinical reason for the non-recommendation of PEP was the low risk of infection and exceeding 72 hours after contact.

The rates of outpatient follow-up after the initial appointment, determined by the attendance of previously scheduled appointments, were also evaluated **(Table 2)**. The CEDIP service initially required patients to return after 30 days, 12 weeks, and 24 weeks following the start of PEP treatment in order to follow up and repeat serological tests. However, after changing the clinical protocol in July 2015, the Ministry of Health no longer recommended the 24-week return appointment, and the returns were subsequently analyzed up to the 12-week appointment only.

Upon evaluation of the collected data, it was observed that 54.20% of patients returned for the appointment scheduled for 30 days after receiving initial treatment, and 20.61% returned for the 12-week appointment, indicating a gradual abandonment of follow-up.

When adherence to the PEP regimen was assessed, 83.78% of the 131 patients for whom prophylaxis was recommended and who returned for the follow-up appointment at 30 days or more after treatment initiation adhered to the treatment for the prescribed time; 16.21% (12/74) reported discontinuation of PEP. The remaining 43.51% (57/131) did not return to CEDIP after the initial appointment, and it was not possible to verify whether these patients adhered to the treatment schedule, if subsequent serological tests were performed, or even if follow-up was done at another center.

HIV serological monitoring of patients using a rapid test was mainly performed during the first appointment, after 30 days, and after 12 or 24 weeks. No patients tested positive at their initial appointment, and no instances of seroconversion were observed among any of the patients who attended the subsequent appointment.

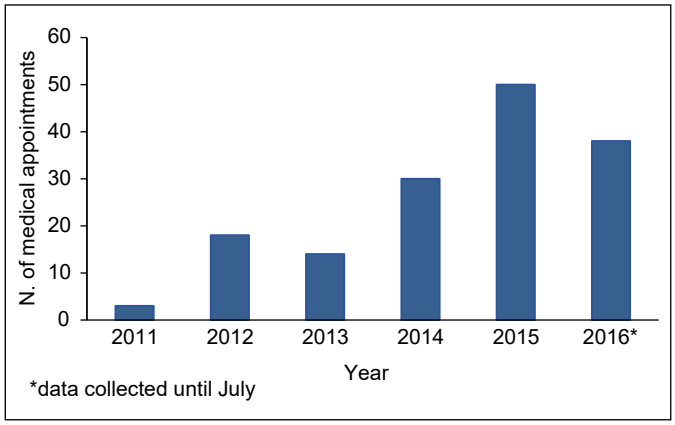

Figure 1 – Annual distribution of the number of medical appointments for PEP in the Center for Infectious-Parasitic Diseases (CEDIP) unit, Cascavel, PR, Brazil, from November 2011 to July 2016.

Table 1 – Type of sexual contact during exposure according to gender.

Type of sexual contact	Female	Male	General
Receptive anal penetration	4	20	24
Receptive vaginal penetration	29	-	29
Insertive vaginal penetration	-	56	56
Insertive anal penetration	-	30	30
Receptive oral sex	3	12	15
Unavailable information	5	13	18

Table 2 – Percentage of attendance of follow-up appointments.

	Number of patients who attended follow-up	Percentage of patients who attended follow-up
30-day return	71	54.20%
12-week return	27	20.61%

DISCUSSION

This study focused on the characterization of the clinical and epidemiological profile of patients treated with PEP due to sexual exposure to HIV, their attendance of outpatient follow-up appointments, as well as the evaluation of adherence to the treatment regimen when established.

It was found that our study population consisted mainly of young adults, represented predominantly by men. This profile was also observed in another Brazilian study, in which only 15.9% of patients seeking PEP after sexual contact were represented by women[13]. In addition, a North American study of more than 3,500 patients found that 92% were men[11]. Approximately 95% of patients sought PEP for the first time; therefore, recurrent use was low.

Since the beginning of prophylactic care in 2011, an increasing number of people have been seeking PEP, indicating that the population may be more knowledgeable on the treatment and that the number of professionals who recommend the specialized centers to patients is increasing.

In the present study, it was observed that the majority of patients who sought PEP did so within the maximum allowed time frame to start prophylaxis. Although the knowledge and use of PEP by the public are described as low[14,15], the studied population was shown to be aware of the recommended time limit for beginning treatment.

Nearly 35% of the patients were aware of the seropositivity of their sexual partner; however, more than half of the patients were unaware of their partner's serology. This result is similar to that of an Australian study where 32% of patients were unaware of their partner's serological status[16].

It was observed that among women, receptive vaginal penetration prevailed as the most common form of sexual contact responsible for the search for PEP. Among men, the most commonly reported sexual contact was insertive vaginal penetration; however, when grouping insertive and receptive anal intercourse together, the incidence of anal intercourse approximates that of insertive vaginal intercourse. Considering that PEP has been suggested as a cost-effective prophylactic method for all types of sexual contact between men[17], finding vaginal and anal intercourse to be the main types of contact motivating the search for PEP justifies promoting access to prophylaxis in this population.

The results show that PEP was recommended to a high proportion of patients in the studied population. It was noted that 85.62% of patients were at a high risk of HIV transmission and PEP treatment was therefore recommended. A similar result was found in a study on a North American cohort, where PEP was recommended for 78% of patients[11].

Although interventions to increase treatment adherence are still controversial[7], the Brazilian Ministry of Health recommended the use of strategies to improve follow-up and adherence, such as cell phone messages (SMS) and telephone calls[6]. Based on the progressive withdrawal from follow-up, some strategies may need to be rethought by local policymakers in order to intensify the monitoring of patients receiving prophylaxis.

When considering the patients who maintained follow-up, adherence to the treatment regimen was 83.78%, a slightly improved result compared to other studies where adherence was approximately 80%[10]. It is unlikely that all participants who abandoned follow-up discontinued the use of their medication. However, assuming all patients lost to follow-up discontinued treatment as scheduled, an adherence rate of 43.51% can be expected. This is slightly lower than the rates observed in a review of 17 studies that analyzed adherence to PEP where rates varied between 49% and 92%[10]. Even considering an adherence rate of 43.51%, this is still higher than the nearly 40% adherence rate observed by studies that evaluated PEP use after experiencing sexual aggression[8,18].

Although more than 54% of the followed-up patients underwent testing within 30 days after exposure and no seroconversion was detected among them, it was possible to confirm the absence of HIV infection after 12 weeks in only 20.61% of patients. Whether the prescribed medication was used or not could only be confirmed in patients who returned after 30 days; therefore, this assessment was not possible in more than 40% of cases. The high rate of patient evasion impaired the analysis of data on seroconversion, even though it was part of the CEDIP service's protocol to guide patients on the importance of clinical and laboratory monitoring during and after the prophylaxis period.

Globally, significant progress has been made to eliminate new HIV infections among children; however, the number of new HIV infections among adults remains stable, and our results demonstrate the need to expand prevention measures against HIV infection in this age group[19].

This study presented limitations concerning the difficulties in characterizing the levels of education and socioeconomic status of the participants, the inability to characterize patient adherence to the medication regimen, and the lack of serology of patients who did not return to the CEDIP service for follow-up. Even withthese difficulties, it is expected that the epidemiologic profile of the public who seek PEP may be useful in determining protection measures against HIV infection within a local context. Furthermore, this is the only study on the use of PEP in this region of Paraná State.

CONCLUSIONS

The profile of patients who seek PEP was characterized as being mainly young men who are unaware of the serological status of their sexual partner. The search for prophylaxis was mainly motivated by insertive anal and vaginal intercourse. Additionally, the study demonstrated a low rate of outpatient follow-up. Nevertheless, it was found that among the patients who maintained follow-up, adherence to the treatment regimen was good and no instances of seroconversion were observed in patients, regardless of their adherence to the entire treatment period of PEP. Based on our results, it is clear that strategies aimed at increasing patient adherence to PEP treatment need to be reevaluated and restructured in order to improve prophylaxis monitoring.

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Participation of each author

The authors declare that all authors were active participants.

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Conflict of interests

Nothing to declare.

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