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Evaluating counseling outcome on adherence to prophylaxis and follow-up after sexual HIV-risk exposure: a randomized controlled trial

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Objective. Post-exposure prophylaxis (PEP) is recommended for the management of sexual HIV-risk exposure. However, a high percentage of exposed patients discontinue both their 28-day prophylaxis course before 15 days and HIV testing follow-up before M3. The objective of this study is to assess the efficacy of a counseling intervention in enhancing both adherence to PEP and HIV testing follow-up.

Methods. Between 1 June 2004 and 31 December 2005, 54 patients exposed to sexual HIV-risk exposure were included in a multicenter, prospective, controlled, randomized trial, comparing a group receiving a counseling intervention in addition to traditional medical management (intervention group (IG), $n = 28$) vs. a control group (CG, $n = 26$). Patients in the IG received interactive counseling interventions focused on adherence to PEP and to HIV testing follow-up, led by specially trained nurses. The main outcome measures were proportion of patients achieving 100% adherence to PEP as evaluated on D15 by a self-completed patient questionnaire and on HIV testing on D45 and M3.

Results. Groups were well balanced at baseline for age, sex, and circumstances of exposure. The proportion of 100% adherent patients to PEP was significantly higher in the IG compared to the CG (54% vs. 23%, $p = 0.036$). Patients in the IG were more likely to complete the HIV testing follow-up at D45 (86% vs. 54%, $p = 0.023$) and M3 (68% vs. 38%, $p = 0.056$).

Conclusions. This study suggests the effectiveness of a counseling program to enhance adherence to both PEP and HIV testing follow-up after sexual exposure.

Keywords: HIV; randomized controlled trial; non-occupational post-exposure prophylaxis; adherence; counseling

Introduction

Since 1998, recommendations have been put forward in the USA and Europe for the management of accidental viral-risk exposure, namely through sexual transmission. According to the level of risk, these recommendations advise a standard 28-day post-exposure prophylaxis (PEP). This consists in a triple drug regimen including either three nucleoside analogs or a combination of two nucleoside analogs and a protease inhibitor. Certain guidelines also recommend standardized follow-up of PEP and HIV serostatus at least up to the third month following exposure (Almeda et al., 2004; Center for Disease Control [CDC], 2005; Fisher et al., 2006; Yeni, 2006).

PEP must be initiated within a short delay but recipients are unprepared to cope with a complex treatment regimen and its side effects, which may interfere with treatment adherence (Duran & the

APROCO Cohort Study Group, 2001; Laporte et al., 2002; Lot, Larsen, & Herida, 2007; Yeni, 2006). Difficulty in adhering to follow-up may lead to ineffective prophylaxis and undiagnosed HIV seroconversion. To date, completion of PEP treatment and follow-up remains controversial. Several studies reported low adherence on both treatment and follow-up (Day, Mears, Bond, & Kulasegaram, 2006; Luque et al., 2007; Mayer et al., 2008; Rey et al., 2008), while others showed satisfying rates (Kahn et al., 2001; Lacombe et al., 2006; Sonder et al., 2007). In France, PEP is free of charge and available in every hospital and low adherence jeopardizes its cost-effectiveness (Pinkerton et al., 2004).

Counseling-based programs were setup a long time ago as part of combating the HIV epidemic, but mainly focused on risk-avoidance and screening (Kahn et al., 2001). In HIV-infected patients receiving

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multiple-drug antiretroviral treatment, counseling has proved effective in enhancing treatment adherence (Goujard et al., 2003; Knobel et al., 1999; Pradier et al., 2003; Simoni, Pearson, Pantalone, Marks, & Crepaz, 2006; Tuldra et al., 2000). In view of patients' needs regarding undesired treatment effect and non-adherence to PEP, our aim was to construct a specific intervention model and to evaluate its effectiveness, as, to our knowledge, no such prospective study has yet been described. We therefore hypothesized that a counseling intervention could also improve adherence to prophylactic treatment and care after HIV-risk exposure, particularly in terms of serological follow-up. The present study aimed to evaluate the effectiveness of such an intervention, tailored to this emergency situation.

Methods

Study design

We conducted a randomized, controlled, prospective multi-center trial (RCT) on a sample of patients attending two French university hospitals following sexual HIV-risk exposure to evaluate the impact of a counseling intervention delivered by specially trained nurses on adherence to both PEP treatment and serological follow-up.

Patients were randomized to an intervention group (IG) or a control group (CG) following medical prescription of standard PEP. Randomization was centralized and conducted by telephone by the Nice University Hospital, Public Health Department. Both groups received a standard oral information concerning recommendations for treatment dosing and post-exposure-related preventive measures, as well as a customized appointment schedule for clinical and laboratory follow-up delivered by each physician as recommended by the French expert panel (Yeni, 2006), i.e., a medical visit immediately following risk exposure (D0) and on D15, D45, and M3.

In addition, patients in the IG were offered a program consisting of four individual counseling and educational sessions conducted by trained nurses, one immediately after enrolment (D0) and the following on D15, D45, and M3, coinciding with the scheduled appointments. There was neither telephone reminder nor financial incentive.

Population

Following sexual exposure, persons who attended the medical departments specializing in HIV infection at Nice and Marseilles University Hospitals in south-eastern France were offered to participate in the study by the attending physician if they fulfilled the following eligibility criteria: (a) age 18 years or

above; (b) risk exposure following sexual intercourse excluding sexual assault; (c) prescription of standard four weeks' PEP within 48 hours following exposure; (d) no current inclusion in another protocol; and (e) presenting during the nurse's available time for counseling. Patients were asked to provide informed consent. The study was approved by the National Ethics Committee. Standard triple antiretroviral PEP was delivered to all patients according to current recommendations for high-risk exposure (CDC, 2005; Yeni, 2006).

Implementation

Counseling was patient-centered, based on motivational interviewing. The research framework required a standardized intervention and nurse interviews were structured with written guidelines. Counseling sessions included a part dedicated to supporting treatment adherence and care follow-up, and a specific part focusing on reducing the risk of recurrence. Each patient's individual needs were assessed and feedback provided to PEP prescribers. Four 45-minute counseling interviews were planned following medical visits.

The following specific targets were to be met at each counseling interview: on D0, it focused on treatment initiation, anticipation of potential problems related to drug intake and stress management; on D15, it concerned management of adverse events and adjustment to PEP-related constraints; on D45 (treatment discontinuation), it assessed how the patient perceived this experience, provided information, explored motivations toward subsequent follow-up and also prevention of recurrence; lastly, an M3 counseling session focused on customized risk reduction.

Prior to implementing the intervention, six nurses with several years' HIV-treatment counseling experience attended a six-day specialized training course, focusing both on biomedical aspects of contamination, adherence theories and counseling skills, including motivational interviewing. A clinical supervisor regularly reviewed the written material completed by the nurses for each of the four sessions: after each session, each nurse received a confidential feedback with remarks and suggestions to improve his/her skills. In addition, the nurses attended two supervised group sessions, during which the difficulties they had encountered were identified, discussed, and possible strategies were explored.

Outcome measures and procedures

Treatment adherence was recorded via a self-administered questionnaire completed on D15 at the HIV clinic. The following outcome measures were studied: proportion of patients achieving an adherence level of

100% to PEP on D15 and undergoing HIV serology follow-up at D45 and M3. Treatment adherence was measured using a formerly validated score based on five questions concerning PEP uptake (Carrieri & the APROCO cohort, 2001). Patients were classified as 100% adherent only if they consistently declared the following in the self-administered questionnaire: 100% intake of their prescribed pills when filling out a detailed table of the daily number of pills they had actually taken during the four days prior to the visit for each drug included in the PEP regimen; having taken all their prescribed doses of PEP, never having taken all their tablets at once, and never having altered the prescribed schedule during the same four-day period; and finally not having skipped a dose during the week-end preceding the visit. Patients not attending the scheduled HIV clinic sessions were considered non-adherent both to PEP and to HIV serologic follow-up.

Data collection

A medical questionnaire was completed by the attending physician on D0, namely recording information concerning the HIV sero-status of the source person, the estimated risk of viral contamination, and PEP prescription. Patients also completed a questionnaire on their own, following the medical visit, with no assistance from any of the care-givers. Self-administered questionnaires focusing on PEP adherence over the previous four days were completed on D15, since the following visit was scheduled on D45, i.e., two weeks after normally scheduled treatment discontinuation. They included data concerning patients' socio-demographics, circumstances of exposure, and associated adverse events (using the French version of the NCI-CTG5-point toxicity scale).

Statistical analysis

Few published data concerning PEP adherence after sexual exposure being available when the study was designed (Kahn et al., 2001), we assumed a 50% adherence in the CG. To have an 80% chance of detecting as significant (at the two-sided 5% level), a 25% difference between the two groups for the percentage of adherent patients, 55 patients were required in each group. The statistical analysis was conducted following the recommendations put forward by Moher, Schulz, and Altman (2001). The primary analysis was conducted on an intention-to-treat basis and involved all patients in each group. The IG and the CG were compared on D0, D15, D45, and M3 using the Chi-square test for categorical variables while student's *t*-test was used for continuous variables. Two-sided significance tests were used. Statistical analyses were performed using SPSS® software (Carry, Inc. 11.0).

Results

Figure 1 depicts that between June 2004 and December 2005, 263 adults presented at one of the two centers following sexual exposure. Among them, 176 (67%) did not meet randomization criteria and 33 (12%) refused to participate. Fifty-four subjects were thus included, 28 in the IG and 26 in the CG. No statistically significant difference in gender and age distribution was found between patients who refused to participate and study participants.

Table 1 shows no significant difference between groups for socio-demographic characteristics, such as gender, age, educational level and professional activity, family, and housing circumstances.

Type of viral exposure did not differ between groups (Table 2), with a majority of heterosexual exposure. A history of sexual exposure was reported with equal frequency (39%). Both groups were also similar regarding PEP regimens at D0; the most frequent treatment combinations were zidovudine + lamivudine + nelfinavir and zidovudine + lamivudine + didanosine. Neither switch from tri-therapy to bi-therapy after treatment initiation was observed, nor any treatment discontinuation for adverse events. Concerning answers about adverse events (38/54), 32 (84%) declared having experienced undesirable effects. The major reported discomfort was diarrhea (38% of patients), nausea or vomiting (31%), abdominal pain (19%), and fatigue (9%).

Counseling intervention

In the IG, 68 counseling sessions took place between D0 and M3, i.e., 61% of scheduled sessions (68/112). All the initial interviews on D0 were conducted; 22 persons (79%) presented for the D15 interview, 12 (43%) for the D45 interview, and eight (29%) for the M3 interview. Mean number of interviews was 2.4 per patient.

Table 3 shows that the percentage of patients reporting 100% PEP adherence on D15 was higher in the IG compared with the CG (54% vs. 23%, $p = 0.036$). A higher proportion of patients underwent HIV serology follow-up tests among the IG compared to CG at D45 (86% vs. 54%, $p = 0.023$), while the difference did not reach statistical significance at M3 (68% vs. 38%, $p = 0.056$). No HIV contamination was observed in either group.

Discussion

This study suggests that counseling interviews conducted by nurses may improve both treatment adherence to PEP and to follow-up.

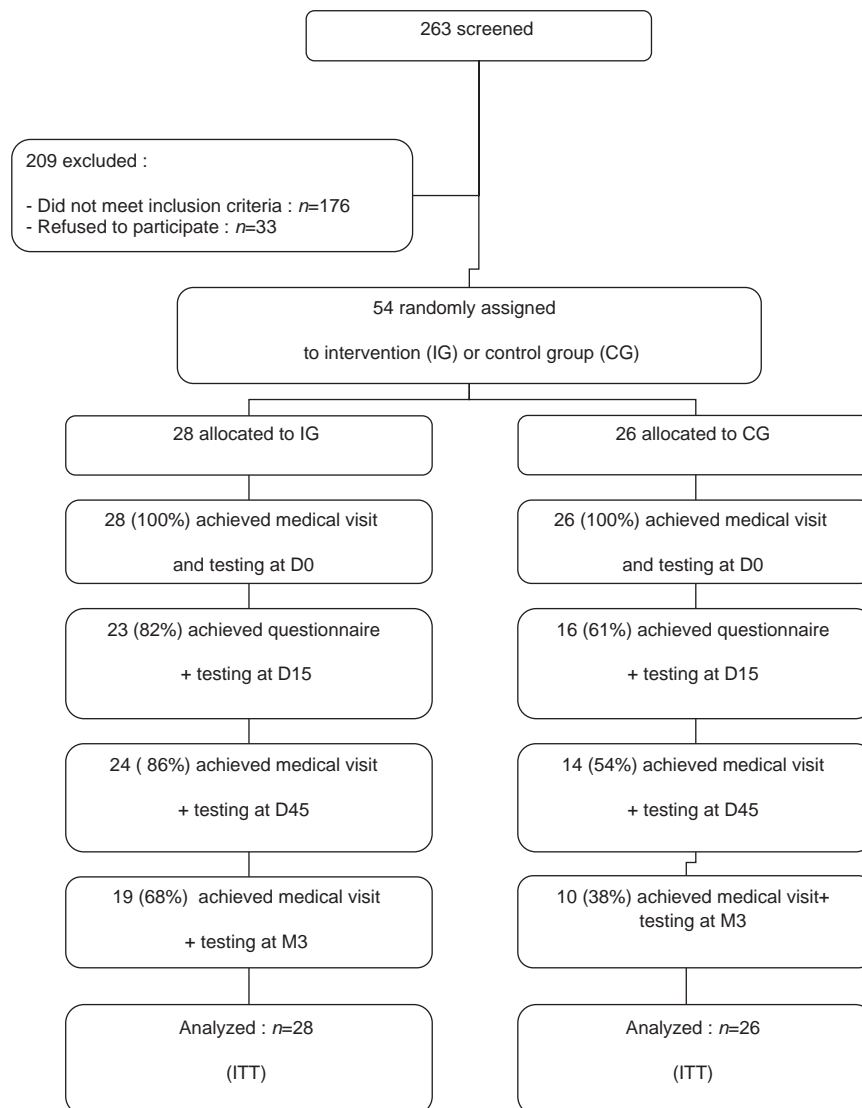


Figure 1. Study enrollment and outcomes.

We used the previously developed model to improve adherence to antiretroviral treatment among HIV-infected patients (Pradier et al., 2003), considering that RCT are the gold standard to demonstrate the effectiveness of an intervention (Stephenson & Imrie, 1998). Published studies illustrate the difficulties encountered in adherence after sexual exposure (Day et al., 2006; Luque et al., 2007; Mayer et al., 2008; Rey et al., 2008) and many recommendations advise additional counseling and support in the initial management of care (Almeda et al., 2004; CDC, 2005; Yeni, 2006). To our knowledge, few results have been published concerning counseling for PEP follow-up, and none assessed counseling by means of a RCT in spite of acute needs (Golub, Rosenthal, Cohen, & Mayer, 2008).

This study provides additional arguments in favor of providing systematic counseling sessions for sexual PEP. The intervention model is based on a patient-centered counseling and motivational interviewing approach (Miller, Zweben, DiClemente, & Rychtarik, 1992), which takes into account cognitive, behavioral, social, emotional, and environmental components known to influence treatment adherence and care follow-up (Chesney, 2000). Whereas all our subjects were considered at high risk for contamination by the attending physician (Yeni, 2006), there was no established French counseling model in the context of PEP that we could follow. Consequently, the counseling program was specially developed for this purpose, thanks to a collaboration between specialists in educational sciences, infectious diseases, and public

Table 1. Baseline socio-demographic characteristics patients included in a prospective, controlled study for evaluation of an intervention to increase adherence to PEP ($n = 54$ – southeastern France).

		Intervention group ($n = 28$)		Control group ($n = 26$)		p -value
Center	A	23	82%	17	65%	0.16
	B	5	18%	9	35%	
Age	Mean \pm SD	31.9 \pm 7.7	–	30.0 \pm 8.9	–	0.57 ^a
	Min–max	19–51	–	19–57	–	
Gender	Male	19	68%	20	77%	0.46
	Female	9	32%	6	23%	
Education	O level, GCSE	5	18%	6	24%	0.11 ^b
	A level	5	18%	7	28%	
	Higher education	14	50%	4	16%	
	Other	4	14%	8	32%	
Occupation	Employee	21	75%	13	50%	0.33 ^b
	Student	4	14%	5	19%	
	Job seeker	3	11%	6	23%	
	Retiree	–	–	2	8%	
Family situation	Single with no regular partner	11	40%	13	50%	0.29 ^b
	Single with regular partner	4	14%	1	4%	
	Couple	9	32%	5	19%	
	Other situation	4	14%	7	27%	
In charge of a child	Yes	5	18%	6	23%	0.63
	No	23	82%	20	77%	
Income	Single wage	14	54%	10	42%	0.16 ^b
	Double wage	8	30%	3	13%	
	Social welfare	2	8%	4	17%	
	Other income	2	8%	7	28%	
Lodging	Owner or tenant	20	74%	16	62%	0.56
	Living with a friend/relative	8	26%	9	38%	

^aStudent's t -test.^bFisher's exact test.

health. Our counseling schedule was based on the standard medical appointment schedule, which includes four hospital visits for laboratory testing.

Overall, between two and three counseling sessions per patient were conducted, which may have been time-consuming for a majority of working patients.

Table 2. Circumstances of exposure and PEP prescription in patients included in a prospective, controlled study for evaluation of an intervention to increase adherence to PEP ($n = 54$ – southeastern France).

		Intervention group ($n = 28$)		Control group ($n = 26$)		p -value
Type of exposure	Heterosexual vaginal insertive	13	46%	16	62%	0.34
	Homosexual vaginal receptive	9	32%	6	23%	
	Anal receptive	3	11%	3	12%	
	Anal insertive	3	11%	1	3%	
Self-declared condom use	Yes	21	75%	22	92%	0.15 ^a
	No	7	25%	2	8%	
Condom accidents (rupture, slippage)	Yes	19	90%	22	100%	0.23 ^a
	No	2	10%	–	–	
History of accidental exposure	Yes	10	36%	11	42%	0.61
	No	18	64%	15	58%	
Type of PEP prescribed	3 NRTI	4	14%	7	27%	0.41 ^a
	2 NRTI + 1 PI	24	86%	19	73%	
Adverse events	Yes	19	86%	13	81%	0.98 ^a
	No	3	14%	3	19%	

^aFisher's exact test.

Table 3. PEP and HIV serology follow-up adherence in patients included in a prospective, controlled study for evaluation of an intervention to increase adherence to PEP ($n = 54$ – southeastern France) intervention group.

		Intervention group ($n = 28$)	Control group ($n = 26$)	<i>p</i> -value
PEP adherence on D15	100%	15 (54%)	6 (23%)	0.036
	<100%	13 (46%)	20 (77%)	
HIV serology follow-up at D45	Follow-up	24 (86%)	14 (54%)	0.023 ^a
	No follow-up	4 (14%)	12 (46%)	
HIV serology follow-up at M3	Follow-up	19 (68%)	10 (38%)	0.056
	No follow-up	9 (32%)	16 (62%)	

^aFisher's exact test.

This suggests that the duration of the program might be shortened, but that would require an earlier focus on prevention within the counseling process. Simoni et al. (2006) has indeed pointed out the necessity for multi-faceted interventions addressing the various components influencing success, even if, concerning PEP, treatment complexity and side effects may have played a large part on adherence (Moore et al., 2006).

Although the use of PEP is based on limited direct evidence of its effect, it aims to inhibit the replication of the initial viral inoculum and thereby prevent chronic HIV infection (Cardo et al., 1997). Therefore, optimal adherence during the first days following exposure should ensure maximum treatment effectiveness (Roland, 2007) and we thus chose to assess adherence early after PEP initiation, i.e., between D10 and D14.

Although therapeutic adherence was twice as high in the IG than in the CG, the level achieved was not as high as expected in either group. This may be due to the fact that most treatment regimens included nelfinavir, which is known to be associated with poor adherence in HIV patients (Moore et al., 2006), as it involves a high number of pills and frequent gastrointestinal side-effects (Luque et al., 2007). These results are not consistent with the much higher PEP adherence rate reported in a Paris Hospital with the same standard PEP (Lacombe et al., 2006), but we chose a much stricter measure of adherence. Moreover, patients lost to follow-up at D15 in both groups were also classified as PEP non-adherent, so that non-adherence may have been over-estimated. Moreover, we observed improved adherence to both PEP and post-exposure serology follow-up among patients in the IG, although no telephone reminders or incentives were provided for practical reasons of work load, which might have further improved our results.

A low rate of PEP adherence in the CG was observed as early as D15: the relevance of providing the full 28-day course at once may be questioned. European recommendations advise prescriptions for no more than two weeks at a time (Almeda et al., 2004).

Besides, Sonder reports over 65% adherence to follow-up testing in a highly organized care network in Europe (Sonder et al., 2007), which is in favor of this type of joint management facility between hospitals and municipal health services.

Limitations

Although our results suggest that this type of intervention is applicable in an emergency situation for healthy individuals, its implementation was restricted due to a limited timeframe and unscheduled patient appointments, compared with follow-up in the context of chronic disease, as is the case for HIV-infected patients. In such an emergency situation, time is required for all the follow-up procedures, while most patients are professionally active, not easily available, and under stress, and counseling nurses have limited available time. A larger number of inclusions would have resulted in more statistical power, allowing results to be even more robust. However, the difference in adherence between the IG and the CG, on which we based the sample size estimation, is higher than initially expected.

Second, this study shares with many others the general methodological problems related to adherence assessment based on patients' self-reports (Deschamps et al., 2008), which may be affected by social desirability and recall bias (Miller & Hays, 2000). The sole use of self-reporting may overestimate adherence. As there is no gold standard for adherence measurement, the use of a self-reported questionnaire was considered sufficient, so that we did not require any other methods such as pill counts. However, we cannot exclude that social desirability could lead patients in the IG to overestimate PEP adherence.

It has been suggested that the benefit provided by this type of counseling also includes promotion of screening for other sexually transmitted diseases (CDC, 2006, 2008). This study did not focus on subsequent changes in sexual behavior; but considering that a high proportion of our population describes a history of similar exposure, education,

and counseling on risk-reduction should be systematically offered in order to promote personal prevention, providing this is conducted within the framework of individualized dialog and professional support (Golub et al., 2008; Kahn et al., 2001).

Few studies have been published on this subject, and our results would support the extension of this type of counseling to a wider audience at a time when public health strategies targeting sexual exposure-related risks are a major issue. In view of the multiple aspects to be addressed and the specific organization of care required in such an emergency context, consideration should be given to the need for specific consultations by dedicated nurses.

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