Original research

A cohort analysis of sexually transmitted infections among different groups of men who have sex with men in the early era of HIV pre-exposure prophylaxis in France

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1. Introduction

After decades of progress at reducing sexually transmitted infections (STIs), the industrial countries are seeing a dramatic reversal of fortunes. Indeed, the CDC has documented sharp increases in the number of cases of chlamydia, gonorrhoea, and syphilis since 2013. Indeed, the full story of STI, and links to primary care of MSM. It is therefore crucial to multiply epidemiological data in order to assess STI incidence in the context of ChemSex and substance use. However, the relationship between HIV and other STIs among high-risk groups is complex. The STI burden of disease is high worldwide. Therefore, it is important to consider the impact of PrEP on the incidence of STI.

Indeed, the CDC has documented sharp increases in the number of cases of chlamydia, gonorrhoea, and syphilis since 2013. Indeed, the full story of STI, and links to primary care of MSM. It is therefore crucial to multiply epidemiological data in order to assess STI incidence in the context of ChemSex and substance use. However, the relationship between HIV and other STIs among high-risk groups is complex. The STI burden of disease is high worldwide. Therefore, it is important to consider the impact of PrEP on the incidence of STI.

The use of PrEP may lead to increased incidence of STI, especially in the context of the PrEP era and carefully evaluate PrEP effects on public health.
health since its implementation. The purpose of the present cohort study was to assess incident STIs in different MSM populations. We comparatively evaluated STI incidence among different at-risk groups of MSM participants [PLWHIV, HIV-negative PrEP (HIV-neg) users and HIV-neg no-PrEP users] during the first two years after PrEP implementation in France.

2. Methods

2.1. Population and settings

This study was conducted on data collected retrospectively on 636 MSM regarding STI (chlamydia, gonorrhoea, mycoplasma, syphilis, HIV, hepatitis A and C) incidence rate in the period between September 2016 and October 2018. Participants were followed up in the Infectious Diseases Department of the European Hospital of Marseille (France) in the context of HIV, PrEP treatment or regular follow-up for HIV-neg no-PrEP participants having a history of STI, namely on a 3-month basis for HIV-neg PrEP users, and on a 4- to 6-month basis for PLWHIV and HIV-neg no-PrEP participants. Follow-up visits systematically included STI pre-registration website platform (https://www.health-data-hub.fr). Information was given to all patients for being included in the study.

According to French regulations, the study was registered as a reference methodology (MR-004) on the Health Data Hub French registering website platform (https://www.health-data-hub.fr). Information was given to all patients for being included in the study.

Chlamydia, gonorrhoea, mycoplasma, syphilis, HIV, hepatitis A and C were systematically screened for using standard methods, namely, validated serology tests for syphilis, HIV, hepatitis A and C; and molecular biology methods for the organisms Chlamydia trachomatis, Neisseria gonorrhoea, and Mycoplasma genitalium (polymerase chain reaction, or PCR, performed on anal swabs, throat swabs, and urine samples). Each time STI screening was positive, a specific treatment was proposed according to the French STI treatment guidelines.

The STI incidence rate (IR) and incidence rate ratio (IRR) [95% CI] were assessed among the 3 groups of patients for the whole two-year period (P), and IRR was also evaluated separately for the first period (P1: September 2016–September 2017) and second period (P2: October 2017–October 2018) of the study.

2.2. Statistical analysis

Continuous data were reported using median and interquartile range (IQR); qualitative data were reported using frequencies and percentages. The Kruskal-Wallis test was used to compare age among groups (PLWHIV, HIV-neg PrEP users, and HIV-neg no-PrEP users). The multiple comparison Tukey test was used to compare frequencies of STIs among groups. STI IRs and their 95% CI were assessed assuming a Poisson distribution. The follow-up duration was calculated for each patient to assess the person-years (PY) statistic. Crude comparisons of overall STI risk among groups were expressed using an OR with their 95% CI. Multivariate logistical regressions were assessed to compare overall STI risk ratio, sites of infection, and type of infections among groups after adjusting for age and number of visits. To compensate for family-wise error rate, a Bonferroni correction for multiplicity of secondary endpoints analyses of STI risk factors was applied (sites of infection analyses, type of infections analyses, and longitudinal analysis): alpha level was corrected to 0.006.

All tests were two-sided. Calculations were performed using SAS V9.4 software (SAS Institute Inc., Cary, NC).

3. Results

3.1. Characteristics of participants

Detailed characteristics of participants are described in Table 1. Overall, a total of 636 individuals were enrolled (September 1, 2016–October 30, 2018). This number of individuals corresponded to 2526 medical visits (including treatment visits), of whom 447 were PLWHIV. Among 189 HIV-neg individuals, 105 were on PrEP. The median age of PLWHIV was 48.7 years (IQR 39.5–55.8), 36.6 years (29.6–44.5) among PrEP users, and 40.3 years (30.4–50.1) among HIV-Neg no-PrEP users (Kruskal-Wallis p = <0.0001). PLWHIV were all on effective ART (more than 95% had a plasma HIV viral load of less than 20 copies/mL) and had a satisfactory immune reconstitution status of CD4 T cell count >500/mm3. 152 men (24%) were <35 years of age.

3.2. STIs risk

Over the complete study follow-up period of two years, STI IR was significantly higher in the HIV-neg no-PrEP users’ group (IR: 41.6 [29.3–57.3] per 100 patient-years [PY]) compared to PLWHIV (IR:17.7 [14.9–21.0] per 100 PY) (p < .0001). STI IR was higher in HIV-neg no-PrEP users compared to HIV-neg PrEP users (IR:26.3 [18.9–35.5] per 100 PY), as well as in HIV-neg PrEP users compared to PLWHIV, but these differences were not statistically significant.

Crude comparisons showed that overall STI risk was significantly higher for PrEP users and HIV-neg no-PrEP users than for PLWHIV (OR 1.56 [1.00–2.42] p = 0.0484, and 1.84 [1.14–2.96] p = 0.0121 respectively) (Table 2). PreP users tended to have a lower risk of STIs than HIV-neg no-PrEP users (p = 0.5751).

In multivariate analysis, after adjustment for age (<35 vs. >35 years) and for the number of screening visits, STI risk was not significantly different between PLWHIV and PrEP users (p = 0.3094) (Table 2); in this analysis we confirmed that STI risk was significantly higher among HIV-neg no-PrEP users compared to PLWHIV, and to PreP users (p < 0.0001 for both comparisons).

Table 1

| Characteristics of patients. | PLWHIV | HIV-neg PrEP | HIV-neg no-PrEP |
|-----------------------------|--------|--------------|----------------|
| Number of Participants      | 447    | 105          | 84             |
| Median age (years) (IQR)    | 48.7   | 36.6         | 40.3           |
| (39.5–55.8)                  | (29.6–44.5) | (30.4–50.1)     |
| Number of medical visits    | 1866 (74%) | 471 (19%)   | 191 (7%)       |
| Median number of visits/    | 5 (3–5) | 4 (4–4.6)    | 2 (1–3)        |
| patient (IQR)               |        |              |                |
| Number of STIs (%)          | 134 (30%) | 42 (40%)    | 37 (44%)       |
| • HIV (%)                   | 0                   | 0                 | 10 (11.9%)     |
| • HAV (%)                   | 10 (2.2%)            | 4 (3.8%)          | 4 (4.8%)       |
| • HCV (%)                   | 15 (3.4%)            | 3 (2.9%)          | 0              |
| • Gonorrhoea (%)            | 45 (10.1%)           | 24 (22.9%)       | 6 (7.1%)       |
| • Chlamydia infections (%)  | 32 (7.2%)            | 18 (17.1%)       | 11 (13.1%)     |
| • Mycoplasma infections (%) | 25 (5.6%)            | 9 (8.6%)         | 5 (6.0%)       |
| • Syphilis infections (%)   | 33 (7.4%)            | 8 (7.6%)         | 8 (9.5%)       |
| Participants with ≥ 2 STIs (%) | 28 (21%) | 21 (50%)    | 8 (22%)        |

3.2.1. Population and settings

3.2.2. Statistical analysis

3.3. Results

3.3.1. Characteristics of participants

Table 2

| Unadjusted OR [95%CI] (p) | Multivariate OR [95%CI] (p) |
|---------------------------|-----------------------------|
| Group                     | Unadjusted OR [95%CI] (p)   | Multivariate OR [95%CI] (p) |
| HIV-neg no-PrEP vs. PLWHIV| 1.56 [1.00–2.42] (0.0464)  | 1.30 [0.79–2.15] (0.3094)   |
| HIV-neg PrEP vs. PLWHIV   | 1.94 [1.14–2.96] (0.0121)   | 5.02 [2.78–9.03] (<0.0001)  |
| HIV-neg no-PrEP vs. HIV-neg PrEP | 0.85 [0.47–1.52] (0.5751) | 0.26 [0.13–0.52] (<0.0001)  |

| Age >35 vs. ≤35 | Unadjusted OR [95%CI] (p) | Multivariate OR [95%CI] (p) |
|-----------------|---------------------------|-----------------------------|
| 0.81 [0.55–1.18] (0.2698) | 0.67 [0.43–1.05] (0.0802) |

a Adjusted for the number of visits.
Quantitative analysis of STI site of infection suggested that PrEP users and HIV-neg no-PrEP users were more at risk of a urethral STI compared to PLWHIV, while there was no statistical difference among the HIV-neg populations (Table 3). No statistical difference was shown among groups regarding rectal and pharyngeal sites of STIs, apart for pharyngeal STIs in PrEP users compared to PLWHIV (OR 3.34 [1.46–7.66], p = 0.0044).

Analysis of the types of bacterial STIs showed that gonorrhoea was significantly more frequent among PrEP users compared to PLWHIV and to HIV-neg no-PrEP users (OR 3.80 [0.75–19.35], p = 0.0016), while this infection was not significantly different between other groups (Table 4). There were significantly more chlamydia infections in HIV-neg no-PrEP users compared to PLWHIV (OR 4.27 [1.70–10.73], p = 0.0020), while a marginal difference was observed between PrEP users and PLWHIV (OR 2.31 [1.16–4.58], p = 0.0167), and no difference was observed between PrEP-users and no-PrEP users (OR 0.54 [0.19–1.54], p = 0.2482) (Table 4). No statistical difference was shown between groups for mycoplasma infections, while there were slightly more syphilis cases in HIV-neg no-PrEP users compared to PLWHIV (OR 2.70 [1.08–6.76], p = 0.0394), but no difference between other groups.

The number of participants having presented ≥ 2 STIs was significantly higher among PrEP users when compared to PLWHIV and to HIV-neg no-PrEP users (50% vs 21% and 22% respectively, Tukey test for multiple comparisons p < 0.05), but there was no significant difference between HIV-neg no-PrEP users and PLWHIV (22% vs. 21% respectively).

3.3. Age and STI risk

Overall risk of STI did not appear to be significantly different according to age (>35 years vs. ≤35 years) in the unadjusted or the adjusted analysis for the number of screening visits (Table 2).

Overall age of more than 35 years seemed to be a risk factor for STIs in the group of PrEP users (OR 3.51 [1.37–8.99], p = 0.0091), while it acted rather as a “protective” factor in PLWHIV (OR 0.36 [0.20–0.65], p = 0.0007) (results not shown).

A finer analysis of the effect of age on STI risk showed that age >35 years was a lesser risk factor compared to age ≤35 years for chlamydia and rectal and pharyngeal STIs among PLWHIV (Tables 3 and 4). No effect for age group was observed for HIV-neg PrEP or No-PrEP users regarding the type or the site of STIs.

3.4. Longitudinal analysis of STIs risk

Longitudinal analysis allowed an approximative evolution of STI risk early after implementation of PrEP (first and second year), within, as well as between, the three risk groups of participants. The HIV-neg no-PrEP group remained at higher STI risk than PLWHIV and PrEP users during the two periods (Table 5). In the same way, while STI risk significantly increased during the second year for PLWHIV (OR 1.77 [1.23–2.55], p = 0.0020), it marginally increased for HIV-neg no-PrEP participants (OR 2.29 [0.91–5.73], p = 0.0774), and it remained rather stable for HIV-neg PrEP users (OR 1.19 [0.60–2.38], p = 0.6181).

3.5. Relationship between incident HIV/Hepatitis infections and STIs

Overall, we reported 10 cases of HIV seroconversion, all occurring within the HIV-neg no-PrEP group, 18 cases of HCV seroconversion (15 cases among PLWHIV and 3 cases among PrEP users) and 18 cases of HAV seroconversion (10 cases among PLWHIV, 4 cases among PrEP users, and 4 cases among no-PrEP users).

4. Discussion

To our knowledge, this is the first study to comparatively evaluate acquisition of STIs in different risk groups of MSM participants (PLWHIV, PrEP users, and HIV-neg no-PrEP users) in the current early era of HIV PrEP. Since PrEP approval, there is general concern that expanded use of PrEP may lead to increased incidence of bacterial STIs,11–14 because of the true effect of behavioral disinhibition,14–18 as well as the apparent effect of increased screening of persons involved in preventive healthcare. The overall rates of STIs in our study were lower than in other PrEP trials after adjustment for the number of screening visits, probably because of population differences.19–24 Nevertheless, when compared to the Pre-exposure Prophylaxis Expanded (PrePEx) Study of the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance (ACCESS) clinic network,2 we also observed that STIs were highly concentrated among a subset of persons that probably had more risky behavior.

We observed no statistically significant increase over time for HIV-neg PrEP-users, counter to HIV-neg no-PrEP users and PLWHIV, which might reflect the effect of close monitoring and counseling. It is crucial to notice that the comparative evaluation of STI incidence rates between HIV-neg PrEP and no-PrEP users rather suggests that it was not PrEP initiation per se that caused the observed global increase in STI risk.19 STI incidence did not seem to increase in HIV-neg PrEP users during the second period of our study compared to the first.25

The number of HIV contaminations were all observed in the HIV-neg
suggest that efficient informing and follow-up of ambulatory MSM PrEP users. The apparent difference of STI incidence between PrEP and life setting, because no HIV transmission was observed in the group of.

**Table 4**

| Group                              | Neisseria gonorrhoeae | Multivariate OR [95%CI] (p) |
|------------------------------------|-----------------------|---------------------------|
| HIV-neg PrEP vs. PLWHIV            | 2.67 [1.45-4.91]      | (0.0016)                  |
| HIV-neg no-PrEP vs. PLWHIV         | 1.52 [0.53-4.37]      | (0.4349)                  |
| HIV-neg PrEP vs. HIV-neg no-PrEP   | 1.75 [0.56-5.46]      | (0.3326)                  |
| PLWHIV Age >35 vs. ≤35             | 0.58 [0.25-1.37]      | (0.2143)                  |
| HIV-neg PrEP Age >35 vs. ≤35       | 2.78 [0.92-8.36]      | (0.0689)                  |
| HIV-neg no-PrEP Age >35 vs. ≤35    | 0.51 [0.09-2.89]      | (0.4488)                  |
| Age:≤35                           |                      |                           |
| HIV-neg PrEP vs. PLWHIV            | 0.82 [0.25-2.72]      | (0.7446)                  |
| HIV-neg no-PrEP vs. PLWHIV         | 1.68 [0.39-7.29]      | (0.4886)                  |
| HIV-neg PrEP vs. HIV-neg no-PrEP   | 0.49 [0.10-2.37]      | (0.3730)                  |

**Table 5**

| Period | HIV-neg PrEP vs. PLWHIV | Multivariate OR [95%CI] (p) |
|--------|-------------------------|---------------------------|
|        | 1.80 [1.08-3.01]        | (0.0239)                  |
| HIV-neg no-PrEP vs. PLWHIV         | 3.10 [1.39-6.91]       | (0.0056)                  |
| HIV-neg PrEP vs. HIV-neg no-PrEP   | 0.58 [0.24-1.40]       | (0.2272)                  |

**Conflict of interest**

Authors declare no association that might pose a conflict of interest.

**Funding**

None declared.

**Ethical approval**

Not required.

**Contributions of authors**

CKP, PH and PP designed the study. PP and MD were the trial physicians. PH and KCP coordinated the collection of medical data. HC coordinated serology tests and molecular biology analysis. GP did the analysis with advice from CKP, PH and PP. CKP prepared the original manuscript and contributed to subsequent revisions with advice from

no-PrEP and incidence was slightly higher than in the IPERGAY study, probably because of the real-life clinical setting.

In the limit of the retrospective nature of this study, our results suggest that efficient informing and follow-up of ambulatory MSM participants in the PrEP context would remain an important strategy for mitigating STI among those at risk, probably because of regular STI monitoring and prompt treatment. Even if the Achilles heel of PrEP has been medication adherence, it appears to be quite efficient in our real-life setting, because no HIV transmission was observed in the group of PrEP users. The apparent difference of STI incidence between PrEP and

Adjusted for the number of visits.
PH, PP, FR and GP. All authors commented on the report and approved the final version.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors would like to thank the study team and participants at the Department of Infectious Diseases and Internal Medicine of the European Hospital, Marseille.

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