

Post-Prostatic Massage Fluid/Urine Is Acceptable and Feasible as a Method to Assay HIV Shedding

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Abstract

Background: Sampling the male genitourinary tract is necessary to investigate HIV-1 infectivity. Collecting semen specimens by masturbation has proven difficult in many settings. Practical alternative methods with high acceptability are needed. We evaluated the acceptability and feasibility of urine collected after a prostatic massage versus semen collected by masturbation in a Kenyan clinic.

Methods: HIV-1 seropositive men were recruited to provide genitourinary samples at quarterly study visits. Men were asked to observe 48 hours of sexual abstinence before sampling. At each visit, a clinician performed prostatic massage until expressed prostatic secretions (EPS) were visualized, then post prostatic massage fluid/urine (post-PMF/U) was collected. Participants provided semen specimens one week later. An audio computer assisted self-interview (ACASI) occurred after each sample collection to evaluate adherence to instructions, acceptability, and current genitourinary symptoms.

Results: Of 45 men enrolled, 5 (11%) were lost to follow-up and one withdrew to move from the area. Post-PMF/U was successfully obtained at 95 of 118 post-PMF/U visits (81%), and with EPS obtained at 60 (63%) of successful post-PMF/U collections. Semen was submitted at 96 follow-up visits (81%). Thirty-four men (76%) provided both samples, 5 (11%) only semen, 3 (7%) only post-PMF/U, and 3 (6%) produced neither. Men reported adherence to the prescribed 48-hour abstinence period at 91% of post-PMF/U collections and 98% of semen collections. In ACASI, more men expressed reservations about the acceptability of post-PMF/U versus semen (12 vs. 5) and more experienced some discomfort (12 vs. 2), but all men said they would provide both samples again.

Conclusions: Post-PMF/U and semen collections were acceptable to this population of Kenyan men. Retention was high, and all participants stated they would provide each sample again. Collection of post-PMF/U is both acceptable and feasible as an alternative to semen collection for studies of male HIV-1 infectivity.

Introduction

- Semen is the primary vehicle for HIV-1 transmission from infected men to their partners
- Blood plasma viral load does not accurately predict seminal HIV-1 RNA levels
- Direct assessment of male HIV-1 infectivity is difficult due to
 - Poor acceptability of semen collection by masturbation (Price *et al.*, 2005)
 - Need for rapid sample processing after collection
- Alternative genitourinary sampling methods are needed

Objective

- To evaluate urine collected after a prostate massage (post-prostatic massage fluid/urine or pPMF/U) as a potential marker for HIV-1 infectivity that could be used in place of semen
 - Acceptability
 - Ease of laboratory processing
 - Reliability as a method for regular collections (see poster WEPEA106)

Methods

Clinical

- HIV-1-seropositive Kenyan men sampled at quarterly visits
- Prescribed 48-hour abstinence before post-PMF/U or semen collection
- Massage until prostatic fluid expressed, then post-PMF/U and blood collected
- Semen specimens collected 1 week later
- Audio computer assisted self-interview (ACASI) after each sample collection
 - Adherence to prescribed abstinence period
 - Acceptability
 - Genitourinary symptoms

Laboratory

- Participants submitted 5 cc of post-PMF/U in a 50 cc conical tube
 - After centrifuging at 500 rpm for 5 minutes, aliquots of supernatant transferred into labelled cryovials and stored in liquid nitrogen
- Semen samples processed immediately after submission
 - If submitted in condom, contents carefully transferred into the labelled specimen cup
 - Volume, appearance and degree of liquefaction noted, with warming in incubator until complete liquefaction if needed
 - Wet-mount examined under 40x power for motility
 - Aliquots diluted in distilled water for hemocytometer sperm count and round cell count
 - Giemsa-stained slide prepared for round cell differential (% leukocytes / 50 cells)
 - Remaining sample stored in labelled cryovials

Statistical

- Participants and nonparticipants compared with chi-square and Mann-Whitney U tests
- Acceptability and discomfort compared using Wilcoxon signed rank test

Results

Table 1. Participant Characteristics (N = 45)

Characteristic	Median, range or N (%)
Age, years	30, 19 – 54
Education, years	8, 0 – 16
Marital status:	
Single	22 (79%)
Married	4 (14%)
Divorced	2 (7%)
Sexual orientation:	
Heterosexual	7 (16%)
Bisexual	24 (53%)
Homosexual	14 (31%)

Study Population

- No difference compared to men who declined participation (data not shown)
- Men attended 2 visits median (range 1-5) by time of analysis
- 5/45 participants (11%) lost to follow-up and one withdrew to move from clinic area

Successful Collections

- Specimens per visit:
 - Post-PMF/U at 95 of 118 visits (81%)
 - EPS at 60 of 95 post-PMF/U collections (63%)
 - Semen at 96 of 118 expected visits (81%)
- Specimens per participant:
 - Both types: 34 men (76%)
 - Only semen: 5 men (11%)
 - Only post-PMF/U: 3 men (7%)
 - Neither: 3 men (6%)

Adherence and Refusals

- Reported adherence to prescribed abstinence period
 - 91% of post-PMF/U collections
 - 98% of semen collections

- Reasons given for pPMF/U refusal:
 - Discomfort (3)
 - Embarrassment (3)
 - Pain (2)
 - Other (3)

- Reasons given for missed semen collection:
 - Unable to produce (2)
 - Too busy (1)
 - Forgot (1)
 - Other (4)

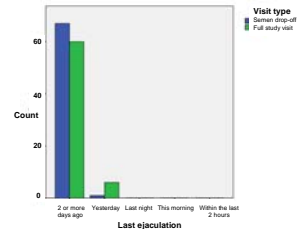
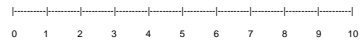


Figure 1. Comparison of Acceptability

Visual Analog Scale for Acceptability of Specimen Collection

Did you find the _____ collection acceptable? Mark the number you would pick on the scale below.

Examples: 0 means it was not at all acceptable to you
 10 means it was completely acceptable to you



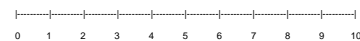
Study ID: _____ pPMF/U: median 10, IQR 10 – 10, range 0 – 10
 Specimen type: _____ Semen: median 10, IQR 10 – 10, range 0 – 10
 Date: ____/____/____ No difference in acceptability (p = 0.2)
 Distance from 0 in cm: _____

Figure 2. Comparison of Discomfort

Visual Analog Scale for Discomfort during Specimen Collection

Did you have any discomfort during the _____ collection? Mark the number you would pick on the scale below.

Examples: 0 means you had no pain or discomfort
 10 means you had severe pain



Study ID: _____ pPMF/U: median 0, IQR 0 – 1, range 0 – 10
 Specimen type: _____ Semen: median 0, IQR 0 – 0, range 0 – 5
 Date: ____/____/____ More discomfort with post-PMF/U (p = 0.02)
 Distance from 0 in cm: _____

Summary

- Both post-PMF/U and semen collections were acceptable to this population of Kenyan men
- Success rate with collections identical
- Despite some discomfort with post-PMF/U, participants stated they would provide sample again
- Good retention in protocol requiring multiple visits

Conclusions

- pPMF/U is a potential marker for HIV-1 infectivity in place of semen
 - Acceptable to men
 - Easier laboratory processing
 - Reliable as a method for regular collections (see poster WEPEA106)

Literature cited

Price MA, Cohen MS, Hoffman IF, et al. Collecting the essence of man: semen collection for HIV transmission studies in sub-Saharan Africa. *Sex Transm Infect* 2005;81(2):185-6.
 pPMF/U validity study: please see Poster WEPEA106

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