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A RANDOMIZED TRIAL OF HPV SELF-SAMPLING AS AN INTERVENTION TO PROMOTE CERVICAL CANCER SCREENING AMONG WOMEN WITH HIV

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Abstract

Objective—Women living with HIV experience higher risk of cervical cancer, but screening rates in the U.S. are lower than recommended. The purpose of this study was to examine whether an intervention using self-sampling of cervico-vaginal cells for human papillomavirus (HPV) with results counseling would increase cervical cytology ("Pap") testing among women with HIV.

Methods—This was a randomized controlled trial to test the effectiveness of an intervention of self-sampling for HPV and results counseling. Participants were 94 women over age 18, with HIV infection, attending an HIV Clinic for a primary care visit, whose last cervical cancer screening was 18 months or more before baseline. Women were assigned to the intervention or information-only group. The primary outcome was completion of cervical cytology testing within 6 months of baseline. The secondary outcome was the women's perceived threat of developing cervical cancer.

Results—A total of 94 women were enrolled and analyzed in the study. The cytology completion rate overall was 35% by 6 months from baseline. There were no differences comparing HPV positive with HPV negative women, nor comparing them with the information-only group. In the intervention group, a positive HPV test increased perceived threat of cervical cancer.

Conclusions—The intervention did not improve cytology test attendance, though education about HPV and cervical cancer risk as part of study procedures was associated with testing for 35% of this group of women whose previous cytology occurred an average 3.6 years prior to the baseline appointment. Self-sampling for HPV testing was feasible.

Keywords

Cancer Screening Tests; HIV; human papillomavirus; Cancer of Cervix

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INTRODUCTION

Women with human immunodeficiency virus (HIV) bear a disproportionate risk of invasive cervical cancer (ICC) and its precursor, high-grade cervical intraepithelial neoplasia (HG-CIN), which result from greater incidence and longer persistence of high-risk HPV infection. [1 - 4] In particular, women living with HIV have rates of ICC that are 4-5 times higher than for other women. Low (<200) CD4 count and high viral load are associated with development of ICC. [5 – 7]

Despite this, many women living with HIV do not engage in recommended cervical cancer screening. Until recently, HIV clinical practice guidelines recommended two cytology tests in the year following diagnosis, and if both were normal, yearly thereafter. [8] Nationally, only 25% of women with HIV met this recommendation. [9] The median annual cytology test completion rate for federally funded HIV centers was 63% in 2011. [10] Women with HIV miss cytology testing due to disliking the examination, embarrassment, fear of pain or discomfort [11], lack of knowledge about risk [12], and lack of access to services. [13] Women who did not have regular screening reported experiencing cervical screening as negative, did not understand its significance [14] or their increased risk for cervical cancer, [15] and did not like having a male provider perform the examination. [16] They also reported concerns about pain associated with screening. [17]

Self-sampling for HPV may reach women who do not participate in cervical cancer screening programs. The Health Belief Model (HBM) suggests that cues to action, such as interventions that increase perceived threat of disease, can prompt individuals to complete screening. [18, 19] Previous studies of interventions that increase individuals' perception of threat from disease successfully increased screening behaviors like colonoscopy and mammography. [20 – 22] Self-sampled HPV testing could serve as such an intervention. Detection of high-risk strains of HPV indicates increased risk of developing HG-CIN if the virus is not cleared within 2 years, while a negative HPV test predicts a less than 2% risk of developing HG-CIN. [23 – 25]

There are no other studies, to our knowledge, that have studied the link between HPV self-sampling and follow-up cytology testing in women with HIV. We theorized that self-sampled HPV test and results counseling would help women achieve a more accurate perception of their risk for cervical cancer by increasing their perceived threat of cervical cancer if they tested positive for HPV. Therefore, we tested whether self-sampled HPV tests and results counseling would increase the completion rate of cytology testing within six months of the intervention. We also examined whether, among intervention group members, a positive HPV test resulted in higher perceived threat of cervical cancer and, whether those women completed cytology testing at a higher rate.

METHODS

Study Design and Sample

A randomized controlled trial was conducted within a U.S. mid-Atlantic inner city HIV clinic over a fourteen-month period in 2012-14. This clinic provides HIV care to

approximately 900 women. Eligible participants were women over age 18, with HIV infection, attending the Adult HIV Clinic for a primary HIV care visit, whose last cervical cancer screening occurred 18 months or more from the baseline visit date, and who agreed to have a cytology test for cervical cancer screening at the hospital where the HIV clinic is based, so that the test result would be in the patient's chart. The study was approved by the Johns Hopkins Medicine Institutional Review Board.

Study procedures

Electronic records were searched to identify eligible women with HIV care appointments. Women were told about the study by clinic staff or responded to posters or fliers in the clinic waiting area. When women approached the researcher (JM) for information about the study, they were informed about HPV's significance and the importance of annual cervical cancer screening ("Pap testing") for women with HIV. Once enrolled in the study, women were interviewed about demographic characteristics, and answered questions from the perceived threat subscale of the Champion HBM scale, which was modified to reflect cervical cancer and screening for it. [26] Participants were randomly assigned into the intervention or information-only group using a computer-generated random list of assignments from Research Randomizer (Research Randomizer (Version 4.0). Urbaniak, G.C. and Plous, S. 2013. Retrieved from: https://www.randomizer.org). The medical record was abstracted for the following variables: previous cytology date and results, CD4 count (nearest in time to baseline visit), CD4 nadir (lowest recorded in chart), HIV RNA viral load measurement (nearest in time to baseline visit), whether the patient was taking antiretroviral therapy (yes/no), history of substance abuse (present or absent in chart), and insurance status.

Champion HBM scale

The Champion HBM Scale was originally designed to measure HBM constructs in relation to breast cancer [28]. We adapted a 10-item subscale to measure perceived threat in relation to cervical cancer by replacing breast cancer and mammography with cervical cancer and Pap testing in test items. [26, 29 – 30] Items were rated on a 5-point Likert scale (from 1 = strongly disagree to 5 = strongly agree), and responses within the scale were summed. The range of possible scores was 10 to 50, with a higher score indicating higher perceived threat of cervical cancer. The control group was used to compute test-retest reliability scores of the Champion HBM measure. There was excellent test-retest reliability of 0.9675. Cronbach's alpha for the pre-baseline was 0.7802, and 0.6962 for post-baseline, demonstrating acceptable internal consistency.

Intervention and Control conditions

The intervention was not blinded. The researcher gave intervention-group women a test kit for Hybrid Capture II high-risk HPV DNA test (Qiagen. 2003. Gaithersburg, MD, USA.), including a soft cytobrush and receptacle tube with preservative. The researcher reviewed an instruction sheet detailing the use of the cytobrush to collect cervico-vaginal cells from the vagina. Following institutional protocols for biohazard safety and specimen labeling, women went to a nearby washroom to perform self-sampling, and returned to the researcher with the sealed, bagged specimen. Afterward, women were encouraged to make their appointments for cervical screening, and received a $15 gift card. HPV test results counseling was

completed by telephone about two weeks after the baseline visit. Three to five weeks after the baseline visit women were interviewed to complete the perceived threat subscale of the modified Champion HBM scale. Women in the information-only group were reminded at the end of the baseline visit to make their appointments for cervical screening. They received a $15 gift card for completing the baseline visit. Two weeks afterward, they received a brief reminder call for attention control purposes. In an additional call 3 – 5 weeks after baseline, the perceived threat sub-scale of the modified Champion Health Belief Model scale was administered. Both groups were offered an additional incentive $20 gift card for the final call.

Outcome measurement

If no cytology test was located in the laboratory results section of the record, then the most recent medical visit was located and read for evidence of completion. All test dates and results were recorded. For the final dichotomous outcome measurement, 183 days or less between cytology and baseline dates was coded as a completed test, while 184 days or more, or no test, was coded as not completed.

Sample size

Sample size for the study was calculated using 80% power to detect an increase of 30% in the proportion of women completing cytology testing, comparing women who tested positive for HPV to women in the information-only group, using a one-sided, two-group test for the difference in proportions. [22 – 24] Using a high-risk HPV prevalence estimate of 50% among women with HIV [27], we allocated participants to the intervention group and the information-only group in a 2:1 ratio respectively. Ninety-four women were enrolled in the study; 63 in the intervention group and 31 in the information-only group.

Statistical methods

Study data were collected and managed using REDCap (Research Electronic Data Capture. Harris, PA et al. Hosted at Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA). [32] Summary statistics included calculation of means and standard deviations for continuous variables, and numbers and percentages for categorical variables. Differences between group means were tested using one-way analysis of variance (ANOVA) if the data were normally distributed and the Kruskal Wallis test if the outcome variable was not normally distributed. Differences between groups on categorical variables were tested using one-way ANOVA. Differences between groups on dichotomous variables were tested using Chi square. The main outcome measure of completion of cytology testing by 6 months after the baseline visit was tested using a one-sided, two-group test of proportions set at an alpha level of 0.05. The effects of predictors on the odds of cytology completion were assessed using logistic regression. The effects of predictors on mean perceived threat scores were analyzed using multiple linear regression. All analyses were performed by intention-to-treat. All statistical analyses were conducted using STATA 11 (Stata Statistical Software: Release 11. StataCorp LP. 2009. College Station, TX, USA.) [32]

RESULTS

A total of 347 women's charts were assessed for eligibility prior to their clinic visit. Of those, 104 women came to their appointments and approached the researcher for study screening during November, 2012 – September, 2013. Ten women did not participate; six women refused (6/104, or 5.7%), citing lack of time or general reluctance to participate in studies. Another four women were ineligible, due to either recent cervical screening or to hysterectomy. Ninety-four women were enrolled and randomized. (Figure 1)

Thirty-one women were randomized to the information-only group, and 63 were randomized to the HPV self-sampling intervention group. (Table 1 lists demographic characteristics.) Among the 63 women randomized to the intervention group, 27 tested positive for HPV for an HPV prevalence of 42.9%. The information-only, HPV positive and HPV negative groups of women were similar in age, race, CD4 count, CD4 nadir, viral load, ART use, previous history of substance abuse, household income, and type of insurance.

Primary outcome: Cytology testing within 6 months

There was no statistically significant difference in cytology completion within six months of baseline between the information-only group (12/31) and the intervention group (22/63, 2 group test of proportions, p = 0.59). There also was no significant difference in cytology completion within 6 months between the HPV negative group (11/36, 30.5%), and the HPV positive group (10/27, 37.0%) (2 group test of proportions, p=0.30), nor between the HPV positive group (10/27, 37%) and information-only group (12/31, 38.7%) (2 group test of proportions, p = 0.55). Considering the entire sample, 33/94 or 35.1% (95% CI 55-74%) of the group completed testing by 6 months. All of the demographic and other factors listed in Table 1 were tested in bivariate logistic regression models to see if they predicted the final outcome of cytology completion. None of the factors predicted the main outcome. Women were also asked if they received incentives to complete cervical screening (e.g. a gift card from an insurance company). Nine women reported that their insurance company had offered incentives to complete cervical cancer screening, 5 in the HPV negative, 4 in the HPV positive, and none in the information-only group. This difference did not reach statistical significance (chi-square =4.91, p=0.09), and did not result in increased cytology test completion in six months (OR 0.92 (95% CI 0.2 - 3.9), p=0.91). In a secondary analysis of a subgroup of 71 women with documented previous cytology results, the HPV positive group had a significantly higher proportion of women with a history of previous abnormal cytology (Table 1). This group showed no increase in cytology test completion at 6 months (p=0.482).

A post-hoc power analysis revealed that with 94 participants the study had 86% power to detect a 30% difference in testing between the HPV positive and control groups.

Secondary outcome: perceived threat of cervical cancer

Eighty-five of the 94 women completed the follow-up perceived threat scale for a follow-up rate of 90.4%. The nine women who were lost to follow-up were significantly more likely to have a lower CD4 count, a higher viral load, and a history of substance abuse. Because of

this, multiple imputation using linear regression modeling with these demographic variables was used to estimate follow-up mean perceived threat scores.

Analysis of the Champion HBM scale proceeded with the intervention group only. Demographic factors were tested for independent effects on baseline perceived threat scores. CD4 cell count nadir and history of substance abuse were significantly associated with increased level of perceived threat at baseline. A multiple linear regression of CD4 count nadir and substance abuse history on the baseline perceived threat score showed significant effects for CD4 nadir ($\beta = -0.01$, $p < 0.05$), where an increase in CD4 count was associated with a decrease in baseline perceived threat score. History of substance abuse was a significant predictor of baseline perceived threat ($\beta = 3.12$, $p = 0.05$), where a positive history of substance abuse resulted in a 3-point increase in perceived threat. An interaction term of CD4 nadir * substance abuse history entered into the regression equation was not significant, demonstrating independent relationships of the variables with the baseline perceived threat score. Other factors such as age, education, African-American race, viral load, CD4 cell count, and current history of taking antiretroviral medication (HAART) were not associated with the level of baseline perceived threat (Table 2).

In an analysis of covariance with the baseline perceived threat score, HPV positivity, CD4 nadir and history of substance abuse variables were associated with a significant increase in perceived threat for HPV-positive women compared with HPV-negative women, when controlling for the baseline score ($F = 8.8$ $p < 0.05$). In multiple linear regression, backward elimination of factors with a $p < 0.4$ showed a significant increase in follow-up perceived threat scores for the HPV-positive group with no other statistically significant predictors of follow-up perceived threat scores (Table 3).

There was no statistically significant relationship between either baseline or follow-up perceived threat scores and completion of cytology testing by 6 months after the baseline visit (OR 0.97 SE 0.04 $p = 0.41$, and OR 0.97 SE 0.05 $p = 0.6$, respectively).

DISCUSSION

The aim of this study was to determine if self-sampled HPV tests and results counseling overall improved cytology test completion by 6 months among women with HIV, and to test whether positive HPV results would increase cytology test completion or perceived threat of cervical cancer. Our results showed no increase in test completion overall between intervention and control groups, and no difference between women who were HPV positive and those in the information-only group. The results also demonstrated that testing HPV positive resulted in increased perceived threat of cervical cancer, but an increased in perceived threat was not associated with increased cytology testing within 6 months.

Studies of women in the general population not participating in cervical cancer screening demonstrated high follow-up cytology testing rates for women testing HPV positive: 81.0% (24), 90.4% (25) and 100% [25] respectively. It is unlikely that HPV-negative women in these studies have received the same encouragement to attend cytology testing as provided in the present study. Our findings regarding perceived threat of cervical cancer are

consistent with Bish et al.'s 2002 study of prediction of cervical cancer screening, where perceived susceptibility to cervical cancer was predictive of an intention to complete cervical cancer screening, but not with actual cervical screening within 3 months. [29] In our study, all women received the same counseling about the importance of cytology testing, thus information, along with monetary incentives and reminder calls, may have been an effective intervention and obscured the effect of HPV testing.

Among the study's strengths was the randomized controlled trial design conducted in a HIV clinic, and that women readily accepted self-sampling. There was excellent follow-up of over 91% of participants by telephone. Use of medical records review as an outcome measure allowed for accurate measurement of cytology test completion. A limitation to this study is that it was conducted in a single clinic with a relatively homogeneous patient population, thus results may not be generalizable to other patient populations. The study was adequately powered to detect a 30% increase in cytology testing in the intervention group. We chose this effect size because it was appropriate for testing an intervention for use in a clinical setting, though we could not detect smaller differences that might have population-level implications.

CONCLUSION

Interventions targeting practice are important in promoting engagement in care among women living with HIV. For example, in a pre-, post-intervention study, Cross et al. increased the cytology testing rate in an urban HIV clinic by 43% utilizing quality improvement strategies like automated reminder systems, training HIV clinicians how to perform pelvic exams, and instituting changes in routine clinic procedures to facilitate cervical screening. [35] Importantly, our high study participation rate of 95% indicates that self-sampling of vaginal specimens for HPV could play a role in improving cervical cancer screening participation rates for non-adherent women. This remains important as HPV test performance improves and as guidelines move away from annual screening for women with HIV who have normal cervical cytology test results. Recent (2015) guidelines from the Centers for Disease Control and Prevention recommend that if three consecutive cytology tests are normal, screening should be performed every three years. [8] Arbyn et al.'s meta-analysis [36] of accuracy of self-collected HPV versus clinician-collected samples showed similar sensitivity for high-grade cervical lesions when polymerase chain reaction (PCR)-based tests were used. Our study suggests that HPV self-sampling could achieve high rates of screening in this underserved population, and clinicians could focus efforts on following up with HPV-positive women who are at higher risk for cervical disease.

Cervical cancer screening may be a relatively low priority for women aging with HIV. Roman et al.'s study of non-HIV infected, underserved Black, Latina and Arab women in Dearborn, Michigan found that cervical cancer screening in Black women was lower among those reporting higher scores for "competing priorities," a score indicating working two jobs, having low household income, and needing to reschedule multiple appointments [37]. Improving communication in the patient-clinician relationship can increase engagement in HIV care, improving HIV-related health overall [38]. Engagement in gynecologic care will remain a challenge for women with HIV as guidelines evolve and screening intervals

lengthen. Further research should focus on understanding how to improve access to screening, especially for women who avoid gynecologic examinations.

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Abbreviations and Acronyms

CD4	CD4-type T lymphocytes
HBM	Health Belief Model
HG-CIN	High-grade Cervical Intraepithelial Neoplasia
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
Pap	Papanicolaou cytology testing, with or without co-testing for human papillomavirus

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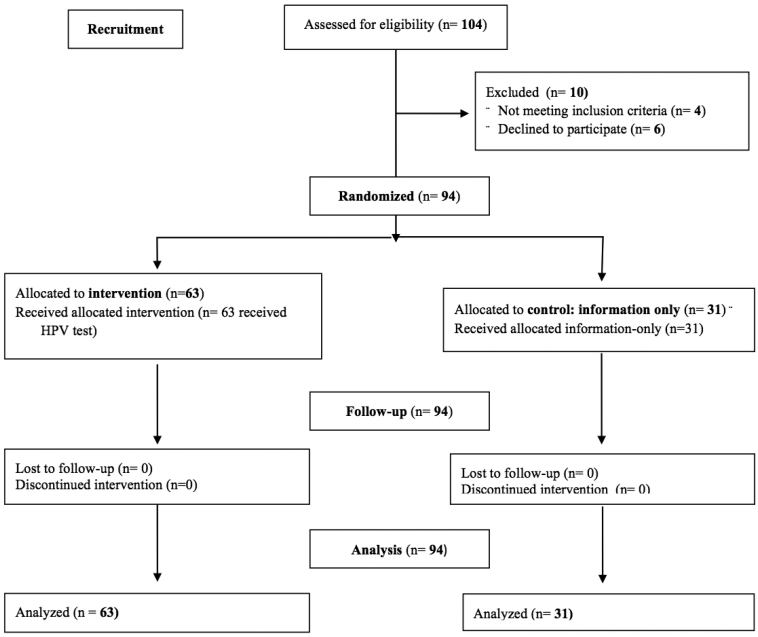

Figure 1. Recruitment Flow Chart

Participant flow chart, following CONSORT guidelines [33].

Table 1

Demographics.

Characteristic	Entire sample N = 94	Information only n = 31	HPV (−) n = 36	HPV (+) n = 27	p-value
Age, mean (SD)	48.7 years (9.4)	48.6 years (SD 9.1)	49.5 years (SD 9.0)	47.8 years (SD 10.6,)	0.69 *
Education, mean (SD)	11.6 years (2.3)	11.6 years (SD 3.2)	11.8 years (SD 1.8)	11.5 years (SD 1.8)	0.96 **
Race, total (%)	Black 79 (84.0%) White 13 (13.8%) American Indian/Alaska Native 1 (1%) Asian 1 (1%)	29 (94%) Black	31 (86%) Black	19 (70%) Black	0.09 ***
History of substance abuse, total (%)	49 (52.1%)	15 (48%)	17 (47%)	17 (62%)	0.41 #
Currently using ART, total (%)	91 (97.0%)	31 (100%)	33 (92.0%)	27 (100%)	0.90*
Will receive incentive for Pap test from insurance company, total (%)	9 (9.6%)	0 (0%)	5 (13.9%)	4 (14.8%)	0.09#
CD4 count in study period, mean (SD)	581.2 cells/mm^3 (348.1)	653.3 cells/mm^3 (SD 388.9)	600.1 cells/mm^3 (SD 346.4)	473.4 cells/mm^3 (SD 280.5)	0.09 **
Viral load low in study period (<500 copies/mL), total (%) ##	78 (82.9%)	27 (87.1%)	31 (86%)	20 (74%)	0.38 #
CD4 nadir (lowest in chart), median (range)	174.0 cells/mm^3 (1-916)	174 cells/mm^3 (2-761)	163 cells/mm^3 (1-916)	216.0 cells/mm^3 (8-856)	0.60 *
Months since previous Pap test (n = 90), mean (SD)	42.7 months (34.2)	35.9 (3.36)	48.6 (6.68)	40.6 (9.14)	0.76 **
Insurance type, %	Public 71 (75.5%) Private 14 (14.9%) Self-Pay 9 (9.6%)	Public 23 (74%) Private 3 (10%) Self-pay 5 (16%)	Public 26 (72%) Private 8 (22%) Self-pay 2 (5%)	Public 23 (81.5%) Private 3 (11%) Self-pay 2 (7%)	0.41 ***
History of previous abnormal Pap (n=71), total (%)	13 (18.3%)	6 (8.5%)	2 (2.8%)	5 (7.0%)	**<0.05*** **
Household income <$20,000	70 (74.4%)	24 (77.4%)	24 (67.0%)	22 (82.0%)	0.66 ***

* ANOVA

** Kruskal Wallace test for non-normally distributed data

*** Fisher's Exact Test for small cell size

Chi square

Table 2

Linear regression analysis showing relationship between demographic characteristics and baseline Perceived Threat score for intervention group women, HPV (+) vs. HPV (−), n = 61.

	Univariate (Unadjusted)	Adjusted*
History of substance abuse	β = 3.12 p = 0.05	**β = 3.29 p = <0.05**
Age	β = 0.07 p = 0.40	β = − 0.05 p = 0.57
Education	β = −0.18 p = 0.69	-- not included
African-American race	β = −0.08 p = 0.97	-- not included
log Viral load	β = −0.12 p = 0.68	-- not included
CD4 count	β = −0.01 p =0.75	-- not included
Income	No difference among categories p > 0.5	-- not included
CD4 nadir	β = **−0.01 p = <0.05**	**β = −0.01 p =< 0.05**
HAART	β = 2.15 p = 0.51	-- not included

*Factors with p<0.4 were included in adjusted multiple linear regression analysis.

Table 3

Linear regression analysis showing relationship between demographic and study variables and outcome Perceived Threat score for intervention group women, HPV (+) vs. HPV (−), n = 61.

	Unadjusted	Adjusted*
History of substance abuse	**β = 2.99 p = 0.03**	β = 0.66 p = 0.54
HPV positive	β = **3.08 p < 0.05**	**β = 3.08 p < 0.05**
Age	β = −0.01 p = 0.90	-- not included
Education	β = −0.47 p = 0.24	β = −0.47 p = 0.09
African-American race	β = 1.58 p = 0.36	β = 2.10 p =0.10
log Viral load	β = −0.19 p = 0.45	-- not included
CD4 count	β= 0.00 p =0.92	-- not included
Income	No difference p > 0.5	-- not included
CD4 nadir	β = 0.00 p = 0.98	β = -0.01 p =0.07
HAART	β = 4.13 p = 0.21	β = 1.32 p = 0.60

* Factors with p<0.4 were included in adjusted multiple linear regression analysis.