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HSV-2 Serologic Testing in an HMO Population: Uptake and Psychosocial Sequelae

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Abstract

Objectives: To prospectively measure the uptake of Herpes simplex virus Type 2 (HSV-2) testing and psychosocial response to a new serologic diagnosis of HSV-2 in a health maintenance organization (HMO) population.

Study Design: Randomly selected urban HMO enrollees were invited to be tested for HSV-2 antibody at a research clinic. Participants had blood drawn and completed demographic and psychosocial questionnaires.

Results: Of 3111 eligible enrollees contacted, 344 (11%) were tested. Eighty-seven (26%) tested HSV-2 seropositive, and 44 (51%) of these did not report a prior genital herpes diagnosis. Distress, measured by the total mood disturbance, was 6.5 points higher on average following a new genital herpes diagnosis relative to baseline (actual range = 109 points, $P = 0.003$) but not statistically different from HSV-2 negative or previously diagnosed participants.

Conclusions: HMO enrollees unexpectedly testing HSV-2 positive showed short-term psychosocial distress that resolved during 6-month follow-up. Findings suggest that concerns about psychosocial burden should not deter voluntary serologic HSV-2 testing in primary care settings.

HERPES SIMPLEX VIRUS TYPE 2 (HSV-2) genital infection is one of the most common sexually transmitted diseases worldwide. Most of HSV-2 infected people do not report symptoms of genital herpes and are unaware of their infection.¹ Even so, they are the source of most new infections among susceptible partners.²

Most STD screening and treatment are conducted in the context of primary care.³ However, seroprevalence studies conducted in urban and suburban primary care settings show clinical diagnosis and examination alone are not sensitive for detecting HSV-2 infection.^{4,5} Accurate FDA-approved, type-specific HSV serologic assays are now commercially available.⁶ Because most people who test HSV-2 seropositive do not report a diagnosis of genital herpes symptoms, serologic tests offer a practical method of diagnosis for this chronic viral infection, since they do not rely on the intermittent presence of virus on the skin or mucosa.

The benefits of a serologic diagnosis are important for persons seeking to avoid HSV-2 transmission, and from the public health perspective of preventing the spread of HSV-2. Most people with unrecognized HSV-2 can be taught to recognize herpes symptoms and counseled to avoid intimate contact while symptomatic.^{7,8} In addition, individuals diagnosed with genital herpes can choose to use condoms and/or suppressive therapy to reduce the risk of transmission to their partners.⁹⁻¹² Serologic testing is especially critical for identifying pregnant women at risk of HSV infection who may transmit to the neonate if they acquire infection toward the end of pregnancy.¹³ Despite these potential benefits, serologic HSV testing is not currently offered during routine clinical care, even among persons being evaluated for STDs. Opponents of voluntary HSV serologic testing argue that the psychosocial burden of an HSV-2 serologic diagnosis should be examined, as the financial and psychological costs may be high and the benefit unclear.^{14,15}

To examine the effects of serologic testing in a primary care population, we measured the uptake and psychosocial sequelae of a new HSV-2 diagnosis among enrollees in a large nonprofit health maintenance organization (HMO). We hypothesized that people agreeing to testing who were unexpectedly found HSV-2 seropositive would experience an adverse emotional response to their new diagnosis, which would decrease with counseling and the passage of time.

Materials and Methods

Study Participants

Group Health Cooperative (GHC) is a nonprofit HMO with facilities in 20 of 39 Washington counties that provide comprehensive health care to over 540,000 enrollees.¹⁶ Research study participants were recruited by the Center for Health Studies, a research institution within GHC. All study procedures were approved by the University of Washington (UW) and GHC institutional review boards, and participants signed a written consent form.

Between November 2002 and March 2003, GHC staff invited 5703 randomly selected enrollees, aged 18 and older, and residing in the greater Seattle area, to participate in a study at the UW Virology Research Clinic. Enrollees were considered ineligible for study participation if they did not speak and read English or had moved out of the greater Seattle area. GHC staff mailed study invitations over 5 months, attempted to reach the nonresponders by mail and phone (Fig. 1), assessed eligibility, and solicited reasons for participation refusal.

Graphic

Fig. 1. Study enrollment and follow-up process.

Following the consent process, participants completed self-administered demographic and psychosocial questionnaires and blood was drawn. Two weeks later, participants received test results by phone. The HSV-2 seronegative participants enrolled within the first 3 months and all HSV-2 seropositive participants were then asked to return for a follow-up psychosocial questionnaire at 2-weeks, 3-months, and 6-months. Compensation was provided for these visits. HSV-2 seropositive participants received information and counseling about genital herpes and risk of transmission to partners.

Psychosocial Questionnaire

This questionnaire consisted of 6 psychosocial subscales detailed below, designed to measure the emotional, social, and relationship burdens associated with HSV-2 serologic testing.

Health Belief Model: Perceived Susceptibility and Severity.

The Health Belief Model was developed in the 1950s to assess the acceptability of screening tests for early disease detection, by measuring perceived susceptibility, severity, and benefits of the diagnosis.^{17,18} At baseline, all participants answered 6 genital herpes knowledge questions related to their susceptibility, and rated 13 situations on a 5-point scale, designed to assess degree of emotional arousal by a genital herpes diagnosis.

Profile of Mood States Brief.

Profile of mood states brief (POMS-B) is a shortened version of the original, designed to measure total mood disturbance comprised of 6 individual mood states: tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, confusion-bewilderment.¹⁹ This portion of the questionnaire contained the 30 POMS-B terms and 9 added terms based on HSV-specific themes elicited in qualitative interviews conducted before this study.²⁰ At all visits, participants rated each term, such as "angry," "nervous," and "confused," on a 5-point scale based on how they had been feeling during the past week.

Herpes Related Quality of Life.

The herpes related quality of life (HRQoL) takes into account the episodic nature and stigma associated with HSV-2 infection to measure the nonclinical impact of genital herpes on life quality.²¹ At the visits following testing, HSV-2 positive study participants used a 4-point scale to answer 25 questions. The HRQoL summary score is the sum for each participant visit.

Multidimensional Sexual Self Concept Questionnaire: Sexual Optimism.

This subscale measures expectations for the future aspects of one's sex life.²² At the visits following testing, HSV-2 positive study participants answered 5 questions using a 5-point scale. A mean multidimensional sexual self concept questionnaire (MSSCQ) summary score was calculated for each participant visit.

Current Sexual Satisfaction.

This instrument is designed to measure the degree of satisfaction people presently have in their sexual relationships.²³ Participants with 1 or more current sexual partners were asked at all visits to score 12 items on a 7-point scale. The current sexual satisfaction score is the sum of these items for each participant visit.

Ways of Coping.

This instrument is designed to identify the thoughts and actions people use to cope with stressful situations.²⁴ At all visits, participants used a 4-point scale to rate how often they utilized 6 ways of coping in the past 3 months: distancing, self-controlling, seeking social support, escape-avoidance, using alcohol, and using sex.

Statistical Analysis**Sample Size.**

To calculate sample size, estimated mean differences and variances were used from a study measuring the increase in quality of life associated with suppressive antiviral therapy, which showed a difference of 8.8-10.6 points in the treatment group and 4.6 points in the placebo group at follow-up.²⁵ To achieve 90% power assuming $[\alpha] = 0.05$ for a 2-tailed test, it was estimated 40 participants with a new serologic diagnosis of HSV-2 must be followed to detect a difference of 5 on the HRQoL.

Psychosocial Outcomes.

To assess internal reliability, Cronbach's [*alpha*] was calculated from the baseline and week-2 life quality questionnaire before scoring of the individual psychosocial subscales. To preserve summary score comparability, person-level mean substitution was used to estimate missing responses (<10% of the data were so estimated). Scales with more than 1 missing value were excluded (with exception to the POMS-B and HRQoL, for which 2 missing values were allowed).

Data were analyzed using generalized estimating equations (GEE) with a Gaussian distribution and an exchangeable correlation structure for observations within the same subject. We considered differences between 3 groups of interest: HSV-2 negative participants, previously diagnosed HSV-2 positive participants, and newly diagnosed HSV-2 positive participants. Both persistent and transitory time patterns were examined looking at differences in time patterns by our groups of interest via interaction terms. Race and gender effects were also considered. Persistent time trends were examined by testing whether baseline scores differed from the average follow-up measure. Transitory time patterns were examined by assessing whether measures at 2-weeks post diagnosis were different from all other time points.

Results

Test Uptake and Participant Demographics

Of 3111 enrollees contacted and eligible for participation, 344 (11%) came to the UW Virology Research Clinic to be tested for HSV. Twenty-eight percent of eligible enrollees contacted by GHC staff wanted to hear more about the study from UW staff, and of these, 56% of the eligible contacted came to the research clinic for testing. One-third of those who gave a reason for refusing had time limitations or transportation concerns. Of the 344 enrollees enrolled and tested, 87 (26%) were HSV-2 seropositive, and 44 (51%) of these did not report a prior genital herpes diagnosis. All 87 HSV-2 seropositive enrollees and 114 (44%) of HSV-2 seronegative enrollees were enrolled into the prospective portion of the study. There were no significant demographic differences between the HSV-2 seronegative participants tested and followed and those tested but not followed (data not shown).

Of these 201 participants followed, the median age was 46 years (range 19-67 years); 60% were women, and 84% were white (Table 1). Sixty-three percent were married or living with a partner, and 61% reported an annual household income above \$50,000. In comparison to the overall GHC population, the mean age was similar, but the proportion of women in the study was 7% higher, and the level of education and annual household income were slightly higher among the study population.²⁶ Seventy-two percent of the participants reported having sexual activity in the 2 months before study enrollment, and 5% reported having more than 1 sex partner during this interval. Participants were predominantly heterosexual; 5 women and 9 men reported having a same sex partner in the last year. Participant retention remained high throughout the study; 97% of participants returned at 2 weeks, 94% at 3 months, and 93% at 6 months.

Graphic

TABLE 1. Demographics and Risk Factors of Study Population Followed Prospectively

Psychosocial Outcomes

Health Belief Model: Perceived Susceptibility and Severity.

At the baseline visit before testing, 37% of participants thought it was likely they were infected with HSV-2, and this response was strongly associated with HSV-2 positive test results ($P < 0.001$). The theoretical trauma associated with receiving a new HSV-2 diagnosis at baseline in this population was similar to committing a minor violation of the law, being in a car accident without hospitalization, failing a course in school, or receiving a poor work evaluation (Fig. 2). Previously diagnosed participants ranked a theoretical genital herpes diagnosis as less traumatic than participants who reported no prior genital herpes diagnosis (0.6 points, $P < 0.001$).

Graphic

Fig. 2. Perceived severity subscale at baseline visit.

Profile of Mood States.

For the newly diagnosed HSV-2 positive participants, the total mood score was 6.5 points higher on average following diagnosis

relative to baseline ($P = 0.003$) (Fig. 3, Table 2). Using the enrollees' actual range of total mood disturbance (109 points), this difference corresponds to a 6% increase. The following specific moods scores increased among this group from baseline: anger-hostility 1.5 points ($P = 0.002$), depression-dejection 1.1 points ($P = 0.03$), confusion-bewilderment 1.1 points ($P = 0.002$), tension-anxiety 1.1 points ($P = 0.017$), and HSV-specific 2.5 points ($P = 0.002$). The vigor-activity subscale demonstrated a slight decrease after diagnosis for all groups (0.5 points lower, $P = 0.013$); however, no other changes were observed over time for HSV-2 negative or previously diagnosed HSV-2 positive participants.

Graphic

Fig. 3. Mean total mood disturbance by HSV-2 status. Higher score corresponds with increased mood disturbance. Measurements occurred at 4 visits over time points indicated by dotted vertical lines.

Graphic

TABLE 2. Profile of Mood States, by HSV-2 Status and Study Visit

While the newly diagnosed showed time trends not present in other groups, at no time point was there a statistical difference detected between groups, except within the HSV-specific mood disturbance composite, which was 2.7 points or 9% higher ($P = 0.002$, actual range = 30 points) at follow-up on average among the newly diagnosed. No differences by gender or race were observed in total mood disturbance or any individual mood scale.

Herpes Related Quality of Life.

HRQoL responses did not differ over time and this was consistent among newly and previously diagnosed HSV-2 positive participants, as no group by time interactions were significant (Table 3). Since this score was only computed among HSV-2 seropositive participants, numbers were insufficient to consider race. No gender related changes were detected.

Graphic

TABLE 3. Life Quality Subscale Scores, by HSV-2 Status and Visit

Sexual Satisfaction and Optimism.

Sexual satisfaction and optimism did not differ over time and this was consistent among groups of interest, as no group by time interactions were significant (Table 3). No gender- or race-related changes were detected.

Ways of Coping.

At the 2-week visit, newly diagnosed HSV-2 positive participants "wished the situation would disappear" more often than HSV-2 negative and previously diagnosed HSV-2 positive participants (0.038 points higher, $P = 0.014$), and more often relative to other time points (0.37 points higher, $P < 0.001$) (range = 4 points) (Table 3). Similarly, the newly diagnosed also "tried to forget" more often at week 2 relative to the other groups (0.29 points higher, $P = 0.049$), and other time points (0.21 points higher, $P = 0.043$). In addition, the newly diagnosed had slightly increased alcohol use after receiving results (0.08 points higher, $P = 0.021$), but no significant differences in alcohol use were found overall between the 3 groups. Coping strategies did not differ persistently over time, which was consistent among all groups of interest.

At all time points, women were slightly more likely to seek social support (0.44 points higher, $P < 0.001$), less likely to keep to themselves (0.35 points lower, $P < 0.001$), or use sex to cope (0.19 points lower, $P < 0.001$). No differences were observed between white and nonwhite participants.

Discussion

This is the first study to measure the psychosocial impact specifically in a primary care population, where the greatest benefits

from HSV-2 serologic tests are likely to occur. We found that a negative emotional response to a new genital herpes diagnosis is normal, but the psychosocial burden associated with a new HSV-2 diagnosis is short lasting and should not deter offering serologic testing in a primary care setting.

After receiving test results, newly diagnosed HSV-2 positive participants in this study had a minor increase in total mood disturbance; depression-dejection, confusion-bewilderment, and tension-anxiety were the specific moods affected. However, scores among the newly diagnosed were not significantly different from HSV negative or previously diagnosed participants, except for the HSV-specific mood score, which was designed to be sensitive to HSV-specific themes.²⁰ The newly diagnosed were more likely to cope by “wishing the situation would disappear” and “trying to forget” at the 2-week visit, but this difference did not persist over time. No statistically significant differences were detected in life quality, sexual satisfaction, or optimism between diagnosis groups over time. The theoretical trauma of a genital herpes diagnosis was moderately severe for all participants, but was significantly lower for HSV-2 positive participants with a previous diagnosis, indicating that people living with a diagnosis of genital herpes perceive it as less of a burden than those who have not been diagnosed.

More than half the eligible enrollees who expressed interest and could be contacted by research staff made time to come to the research clinic for testing. These results are consistent with prior studies, conducted across the spectrum of health care settings, showing that people want the option of HSV-2 serologic testing.²⁷⁻²⁹ Many enrollees could not be reached or declined due to time or transportation concerns, suggesting the uptake of voluntary serologic testing would be higher if offered in conjunction with a routine primary care visit. In previous studies, offering HSV-2 serologic testing in the context of a primary care or an STD clinic visit resulted in approximately 70% of persons accepting the test.^{4,30}

All participants in this study diagnosed with HSV-2 were educated and counseled about symptoms, medication options, and transmission. Participants likely received more information about HSV-2 than typical in a primary care environment. Time constraints in primary care may not permit discussions about genital herpes, but other education alternatives are possible. Recent surveys show patients want this information from their providers, and satisfaction is improved even if the discussion is not lengthy.^{31,32} One study showed an interactive computer-based education program to be an effective teaching tool for patients,³³ and good internet-based education materials exist.

The Seattle HMO population may not generalize to all primary care settings nationwide, because these participants had a higher education and household income level than the median for the general US population. However, our study is consistent with other studies conducted in STD clinics, an HIV clinic, and several combined populations, which also found the impact of a new HSV-2 serologic diagnosis to be minimal, in the context of education and counseling.³⁴⁻³⁸

The psychosocial scales we used are not routinely used to evaluate STD screening programs, and therefore the clinical significance of our results remains a question. However, quality-of-life instruments are routinely used in clinical trials to assess the effect of treatment, and validated disease-specific instruments are more likely to detect small clinically important changes.³⁹ We included such scales to maximize sensitivity, and very few participants were lost to follow-up, minimizing potential bias. Our sample size may not have been large enough to detect a rare severe adverse reaction to a new HSV-2 serologic diagnosis. Our clinical experience is that a severe reaction is unusual, but provider judgment remains essential in offering voluntary HSV-2 serologic testing.

These participants also chose to be part of a research study, and there are substantial differences between research and clinical environments. However, one would expect the motivation for accepting HSV-2 serologic testing would be consistent between research and primary care populations. Over a third of participants suspected they had genital herpes, supporting the notion that testing acceptance is correlated with the suspicion of being infected.⁴⁰ These results suggest uptake of voluntary HSV-2 serologic testing in a primary care setting would be similarly correlated with suspicion of infection, and that persons who volunteer interest in testing are at substantial risk for having been infected.

In recent years, the importance of HSV-2 prevention on the public health agenda has risen dramatically, because the cost of HSV-2 is substantial from both an economic and human resources viewpoint.^{41,42} Studies show that HSV-2 infection is a risk factor for HIV acquisition, and the interactions between HSV-2 and HIV continue to be delineated.^{43,44} Neonatal HSV occurs in an estimated 1500 infants annually in the US and can result in death or permanent impairment.⁴⁵

Control strategies for the HSV-2 epidemic are possible, including condom use and suppressive therapy.⁹⁻¹² A recent study also demonstrated the risk of transmission may be reduced when people know they have herpes and tell their partners.⁴⁶ Knowledge of

infection status is necessary before these control strategies can be implemented, and HSV serologic testing is a reliable and practical method of diagnosis.

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