Journal of Clinical Virology 58 (2013) 168–175

Contents lists available at SciVerse ScienceDirect

Journal of Clinical Virology

journal homepage: www.elsevier.com/locate/jcv

Evaluation of genital self-sampling methods for HPV detection in males

Brenda Y. Hernandez[a,*], Lynne R. Wilkens[a], Elizabeth R. Unger[b], Martin Steinau[b], Lauri Markowitz[b], Keiko Garvin[a], Pamela J. Thompson[a], Yurii B. Shvetsov[a], Kristen O'Dillon[c], Eileen F. Dunne[b]

[a] University of Hawaii Cancer Center, Honolulu, HI, USA
[b] Centers for Disease Control and Prevention, Atlanta, GA, USA
[c] University of Alabama School of Medicine, Birmingham, AL, USA

ARTICLE INFO

Article history:
Received 16 March 2013
Received in revised form 19 June 2013
Accepted 24 June 2013

Keywords:
Genital
Self-sampling
HPV
Males

ABSTRACT

Background: There are no population-based HPV prevalence estimates in males because optimal sampling methods are unclear.
Objectives: To evaluate the acceptability, feasibility, and validity of different male genital self-sampling methods for HPV detection.
Study design: A total of 450 males, 14–59 years old, were randomly assigned to one of three genital sampling methods: (1) dry polyester-tipped swab; (2) dry foam swab; and (3) emery paper and wetted polyester-tipped swab. Samples were both self-collected and collected by a clinician. Subjects were queried on the acceptability of sampling methods. HPV was genotyped using an L1 consensus PCR assay.
Results: Specimen adequacy (92–96%, $p = 0.28$) and HPV detection (44–49%, $p = 0.68$) were comparable across the three methods. Concordance for HPV detection was observed between self- and clinician-collected specimen pairs for all methods ($\kappa = 0.70$–0.80). The collection procedure was reported to be very easy by 69% of dry polyester-tipped swab users and 64% of dry foam swab users compared to 48% of emery-wet swab users ($p = 0.004$). Similarly, 43–44% of dry swab and foam users reported the collection to be very comfortable compared to 24% of emery-wet swab users ($p = 0.002$). Pain was reported by 10% of emery-wet swab users compared to 3% and 5% of dry swab and foam users, respectively ($p = 0.03$). Self-collection by the emery-wet swab method required an average of 6 min compared to 3.3–3.5 min for the two dry methods ($p < 0.0001$).
Conclusions: The dry collection methods are optimal for use in large epidemiologic studies or surveillance efforts based on their acceptability and feasibility.

1. Background

Human papillomavirus (HPV) is associated with 40–90% of penile, anal, and oropharygeal cancers in men [1]. Clinic based assessments have found that HPV detection is common in healthy men [2,3]. HPV is detected in the external genitals, including the penis and scrotum and, to a lesser extent, the urethra and in semen and urine [4–11]. Although national surveys have generated population-based estimates of genital HPV DNA prevalence in U.S. females [12] and HPV seroprevalence in both U.S. males and females [13], there are no population-based prevalence estimates of genital HPV DNA among US males. A major challenge has been the lack of feasible, acceptable, and standardized sampling methods for males. Investigations of HPV in men have primarily evaluated samples collected from the external penis and have utilized various methods – including dry and wet swabs [5,10,11,14–16], brushes [17–19], and abrasive paper followed by swabs [8,20,21]. The adequacy of specimens collected by these different methods, typically measured by human ß-globin, has ranged widely from 35% to 100% [5,8,10,11,14–21].

Standardized methods of male genital self-sampling which are reliable, efficient, and acceptable would be particularly useful for monitoring male HPV infection in the general population. Self-sampling in males may have several potential advantages over specimens collected by clinicians, including lower costs and greater convenience and acceptability. Self-sampling methods for HPV testing in women have been evaluated and utilized in research and surveillance, including the National Health and Nutrition Examination Surveys (NHANES) [12]. To date, few studies have evaluated genital self-collection methods for HPV detection in males.

* Corresponding author at: University of Hawaii Cancer Center, 701 Ilalo Street, Honolulu, HI 96813, USA. Tel.: +1 808 586 2992; fax: +1 808 586 2982.
E-mail address: brenda@cc.hawaii.edu (B.Y. Hernandez).

1386-6532/$ – see front matter © 2013 Elsevier B.V. All rights reserved.
http://dx.doi.org/10.1016/j.jcv.2013.06.032

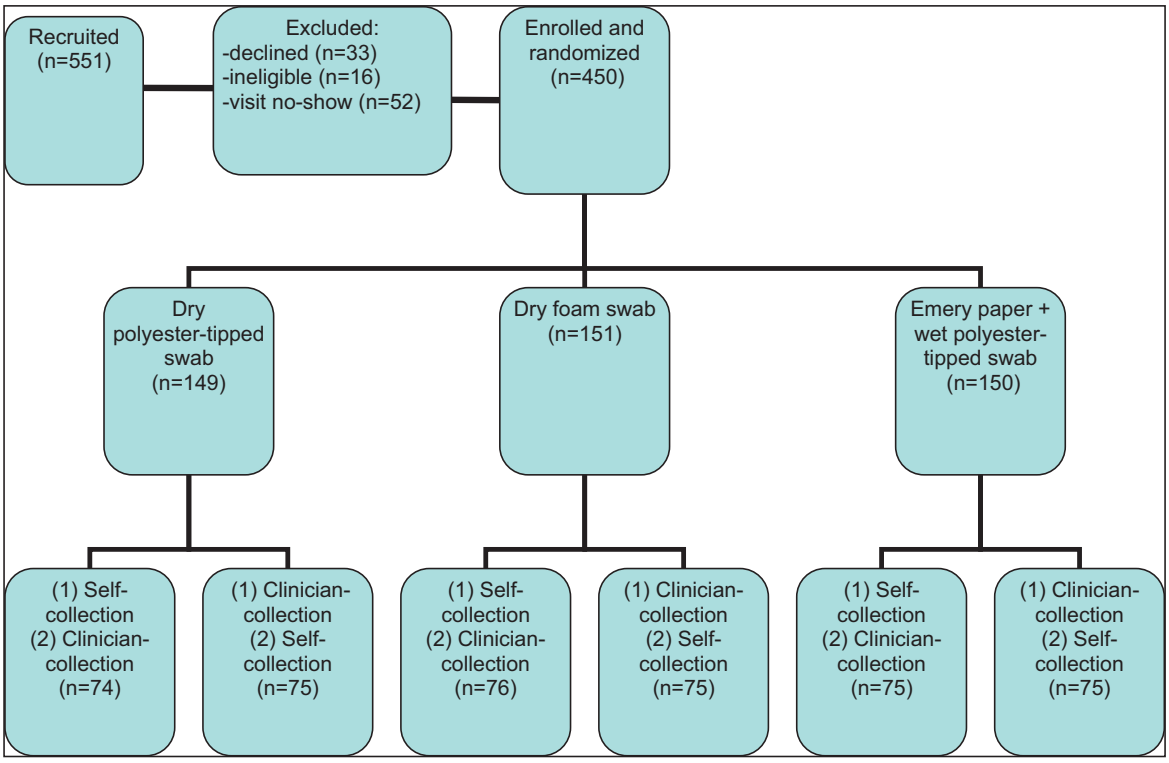

Fig. 1. Randomization of study participants by genital collection method.

2. Objectives

A study was undertaken to evaluate the acceptability, feasibility, and validity of male genital self-sampling methods for HPV detection.

3. Study design

3.1. Study recruitment and subject randomization

Subjects were enrolled in Hawaii, U.S.A. in 2010–2012. The study was approved by the University of Hawaii Committee on Human Studies. Written informed consent was obtained from participants ≥18 years. For subject ages 14–17 years, both written consent from the parent/legal guardian and written assent were obtained. Study recruitment utilized web-based and print media and targeted the general public, a university-based clinic, and pediatric and adolescent medicine practices. Eligibility was limited to males who were aged 14–59 years, able to speak English, not immune compromised, and not enrolled in an earlier study of HPV [8]. A gift card for $50.00 was provided at visit completion. Visits were conducted at the University of Hawaii Cancer Center in Honolulu, Hawaii.

Three methods of external genital self-sampling were compared: (1) rubbing with a dry polyester-tipped swab (Puritan Medical, Guilford, ME, U.S.A.); (2) rubbing with a dry foam swab (EpiCentre/Illumina, Madison, WI, U.S.A.); and (3) abrasion with emery paper (600A-grit) (3M, St. Paul, MN, U.S.A.) followed by rubbing with a saline-wetted polyester-tipped swab. Swabs and emery paper were pre-sterilized.

Study subjects were randomized into three sampling groups of one-hundred fifty (Fig. 1). For each group, half were randomized to complete the self-collection first and the other half to complete the clinician collection first. Blocked randomization, with random block sizes, was used to avoid a large imbalance in size between the three study groups at any time during recruitment. Randomization included stratification by age group (ages 14–24, 25–39, 40–59 years) to ensure balance of comparison methods within age groups.

3.2. Specimen collection

Specimen collection was conducted in private examination rooms. Clinician sampling was conducted by one of two trained clinicians. For the self-collection, study subjects were directed to follow the written and illustrated instructions posted in the examination room to ensure that each participant received identical instructions. Study subjects were left alone in the examination room during the self-collection procedure. Two specimens were collected from each subject, one self-collected and the other collected by a clinician using the same method during the same visit. The clinician- and self-collection procedures were identical with the exception of the clinician wearing disposable gloves and documenting circumcision status and the presence of genital warts or lesions. Self-collection time was recorded based on the duration from entry to exit from the examination room.

A common sampling procedure was utilized with slightly different procedures for circumcised and uncircumcised men. For circumcised men, the instrument (polyester-tipped swab, foam swab, or emery paper/polyester-tipped swab) was rubbed over the entire exterior surface of penis from the glans, including the coronal sulcus, and extending the entire length of the penis shaft. For uncircumcised men, the instrument was rubbed over the entire inner and outer surfaces of the foreskin, followed by the penis glans/coronal sulcus, and lastly, the penis shaft. For the emery-swab group, the emery paper was first rubbed over the entire surface of the external genitals as described above. Next, the polyester-tipped swab was moistened with an individual packet of sterile saline and the wet swab was used to collect the specimen as described.