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Patient-Reported Outcomes

Initial Development and Content Validation of a Health-Related Symptom Index for Persons either Treated or Monitored for Anal High-Grade Squamous Intraepithelial Lesions

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ABSTRACT

Background: Anal cancer, caused by oncogenic types of human papillomavirus, is a growing problem in the United States. A key focus of anal cancer prevention has been screening for and treating precancerous high-grade squamous intraepithelial anal lesions (HSILs). **Objectives:** To develop a health-related symptom index for HSIL using qualitative techniques because anal HSIL and its treatment may have a negative impact on health-related quality of life (HRQOL), and no HRQOL measure specific to this condition and treatment currently exists. **Methods:** Expert consultation was used to guide one-on-one concept elicitation interviews with participants to identify HRQOL aspects they attribute to their anal HSIL and its treatment. This resulted in a draft instrument, which was administered to an independent participant sample, where cognitive interview techniques assessed comprehension. **Results:** Eighteen anal HSIL-related concepts were identified by the expert panel. Across the 41 concept elicitation interviews, 23 items representing physical symptoms, physical impacts, and psychological symptoms were identified to comprise the initial measure, which was then evaluated during three rounds of cognitive interviews (n = 45). Several questionnaire aspects were refined on the basis of participant input, with three additional items added per expert/participant recommendation. One item was removed because of poor comprehension, resulting in a 25-item measure. **Conclusions:** Using state-of-the-art qualitative methodology, we have established the content validity of this new instrument, the ANCHOR Anal HSIL Health-Related Symptom Index. Quantitative validation efforts are currently underway. The participant-driven process of developing this tool will facilitate a participant-centered evaluation of the impact on morbidity for treatment of anal HSIL or observation without treatment.

Keywords: ANCHOR trial, health-related quality of life, neoplasms, patient-reported outcomes.

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Introduction

Anal cancer is a growing problem in the United States [1], with the incidence rising in the most common type of anal cancer, squamous cell carcinoma, from the year 1992 to 2011 [2]. In the US general population, the incidence of anal cancer from the year 2009 to 2013 was 1.8 of 100,000 among men and women [3], but there is a markedly higher incidence among subpopulations. The cumulative incidence of anal cancer among HIV-infected adults was reported to be 1.5% by age 75 years, compared with 0.5% among HIV-uninfected adults [4]. Human papillomavirus (HPV) infection is causally associated with the development of anal

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cancer [2]. Anal high-grade squamous intraepithelial lesions (HSILs), the precursor lesion to anal cancer [5], are also associated with persistent HPV infection [6].

HPV vaccination as primary prevention may reduce the risk of anal cancer in the long- term, but this approach is limited by suboptimal uptake of vaccination, nonadherence to vaccination series among targeted populations, and the large number of persons already infected with HPV [7]. Similar to programs to reduce the incidence of cervical cancer, secondary prevention of anal cancer includes screening for and treating anal HSIL before progression to anal cancer [8]. High-resolution anoscopy (HRA) is used to visually identify areas of possible anal HSIL and allow for target biopsy to confirm the lesion histologically. Treatments for anal HSIL include ablative procedures such as infrared coagulation, electrocautery and laser, surgical excision under anesthesia, and the use of topical antineoplastic agents, such as 85% trichloroacetic acid and 5% fluorouracil cream [9–14].

Treatment of anal HSIL is increasingly being undertaken to reduce the risk of anal cancer, even as the effectiveness of doing so is not yet known. It is important to assess physical symptoms and concerns related to health-related quality of life (HRQOL) in those diagnosed with and either in surveillance or treated for anal HSIL, because these may be important considerations in treatment decision making for participants and their care providers. There is a paucity of data on symptoms and concerns related to the HRQOL of persons treated for anal HSIL, and the published studies are descriptive and without control groups. In one longitudinal study, 37 persons diagnosed with anal HSIL were treated with surgical excision and followed up every 3 to 6 months to examine the safety and efficacy of HRA and surgical treatment [15]. The findings highlighted the importance of assessing pain associated with bowel movements and anal sexual functioning.

A second study, conducted in primary care and HIV clinics in Canada, examined psychological symptoms associated with anal cancer screening via HRA in 104 HIV-positive men who have sex with men [16]. Younger participants and those who reported more symptoms and higher psychological distress scores at baseline were more likely to experience higher levels of negative psychological impact from screening. Finally, a third study showed that different anal HSIL treatments (topical imiquimod, topical fluorouracil, or electrocautery) produced different patterns of symptoms lasting different lengths of time [17]. Participants in the electrocautery group were more likely to report anxiety or depression and were less satisfied with their overall sex life at week 16 than participants in the topical treatment groups.

These studies used diverse measures to assess HRQOL, ranging from study-specific ad hoc items [15], symptom instruments designed for HIV-positive persons but not specific to anal HSIL [16], and generic HRQOL measures [17], supplemented with validated sexual functioning items or psychological distress measures [16]. Although many of these measures showed sensitivity to the impact of anal cancer screening or treatment, the various tools used and lack of specificity to anal HSIL diagnosis and treatment indicate the need for a rigorously developed and validated instrument to provide reliable, comparable data across anal HSIL populations and treatments. Because different treatments are used for anal HSIL, it is important to develop an HRQOL measure that can capture the array and severity of symptoms from diverse treatments and active surveillance without treatment.

In 2015, the US National Cancer Institute funded the Anal Cancer/HSIL Outcomes Research (ANCHOR) study, a phase III clinical trial conducted within the AIDS Malignancy Consortium (AMC) to determine whether the treatment of anal HSIL, compared with active monitoring, can prevent the development of anal cancer in persons living with HIV infection. Given the absence of an HRQOL measure specific to anal HSIL, the ANCHOR study presents a unique opportunity to understand the symptoms and experiences of persons being treated or actively monitored for anal HSIL.

The purpose of the present study was to describe the initial steps of developing a health-related symptom index for HSIL for use in the ANCHOR trial (A-HRSI), including three separate phases: 1) solicitation of disease-related concepts from an expert panel of clinicians in the AMC who have worked extensively with HSIL in this participant population; 2) qualitative elicitation of disease-related concepts from participants diagnosed with anal HSIL and either in surveillance or being treated for anal HSIL to inform development of a draft version of the A-HRSI; and 3) the use of one-on-one cognitive interviewing techniques in a separate cohort of participants in surveillance or being treated for anal HSIL to establish the content validity of the draft A-HRSI.

Methods

Participants

Six members of the AMC who are also investigators and clinicians in the ANCHOR trial, each with a minimum of a decade of experience diagnosing and treating anal HSIL, were asked to comprise an expert panel for this study. A cohort of HIV-positive participants who were diagnosed with anal HSIL in the last 9 months and either treated or actively monitored was recruited from the ANCHOR/AMC sites (Laser Surgery Care Center, Montefiore Medical Center, and Weill Cornell Medicine [New York, NY]; Anal Dysplasia Clinic-Midwest [Chicago, IL]; and the University of California [San Francisco, CA]). Providers from these sites provided a study information sheet and encouraged potential participants to contact research staff at the Memorial Sloan Kettering Cancer Center. This referral included a referral identification number and coded information on the type of treatment being used (or surveillance) and the volume of disease. For all participants who contacted study staff and arranged for either an in-person or a telephone-based interview, the research study assistant (RSA) reviewed the study, solicited questions, and confirmed willingness to participate; written or verbal informed consent was not required or collected. For those who agreed to participate, the RSA collected information on age, sex, education, race, and ethnicity for description of the study sample. Study RSAs were trained to ensure interview consistency across participants. In consultation with AMC's expert clinicians who diagnose and treat anal HSIL, we learned that not only treatment status (treated or monitored) and modality of treatment can have an impact on symptom report, but so can volume of disease. A larger volume of disease may mean more extensive treatment and recovery process, leading to prolonged or more severe physical and psychological symptoms. As such, we incorporated low versus high volume of disease as a parameter of recruitment of the participants for this study to ensure that both levels of disease volume were represented. Independent sample sizes of at least 40 participants were planned for both the concept elicitation and cognitive interviewing phases to adequately achieve saturation of concept (i.e., the point at which no novel information was being captured from participants) [18,19]. Because no protected health information was collected at referring sites, the study was reviewed and deemed as exempt research by the National Cancer Institute's Cancer Therapy Evaluation Program and the institutional review boards at each study site.

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