

MULTIMODAL SPECTROSCOPY AS A TRIAGE TEST FOR WOMEN AT RISK FOR CERVICAL NEOPLASIA: RESULTS FOR ADOLESCENT SUBJECTS Flowers, LC, Tadros, TS*

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OBJECTIVE: Recent changes to guidelines for managing cervical disease in adolescent women are intended to reduce expensive and potentially unnecessary follow up procedures which also may result in morbidity. The potential trade-off of this strategy is delayed diagnosis of potentially significant cervical dysplasia. The objective of the current study was to 1) determine the prevalence of Cervical Intraepithelial Neoplasia (CIN2+) or worse disease in women under the age of 21 and 2) to evaluate the performance of multimodal hyperspectroscopy (MHS) in this population.

METHODS: In this seven-center pivotal study, 1,607 mostly urban women at risk for cervical neoplasia were tested using MHS (LightTouch, Guided Therapeutics, Inc. Norcross, GA), including 1,456 with abnormal Papanicolaou (Pap) cytology, one with no referral Pap results and 150 with normal or benign cytology, but were at risk for other reasons including positive Human Papilloma Virus (HPV) results, previous dysplasia and/or recurrent benign findings. Minimum age for enrollment was 16 years.

RESULTS: For the 1,607 women in the study, 290 (18%) were between the ages of 16-20. A histopathology quality assurance procedure diagnosed 52 biopsies of these adolescent women with CIN2+ (18%), including five identified at subsequent follow up visits. The prevalence of CIN2+ for women in the study aged 21 and older also was 18% (232/1317). Of the 238 adolescent women without CIN2+, 131 (45%) were diagnosed with CIN1 and 96 (33%) were diagnosed with benign or normal cervixes. For 11 women (5%), biopsy was either not performed or the tissue sample was insufficient for diagnosis. Sensitivity for CIN 2+ of MHS for all evaluable adolescent subjects (n = 245) was 91% (42/46). By comparison the standard of care at the time of enrollment detected 80% of CIN 2+ (37/46). Specificity of MHS for adolescent women with CIN1 was 25% (30/118) and 33% (27/81) for women with normal or benign cervixes.

CONCLUSIONS: Significant dysplasia was found in 18% of the adolescent population from the MHS pivotal clinical trial, calling into question recent guidelines for reducing surveillance of cervical disease in women below the age of 21. MHS is a cost effective point of care test that provides immediate results and demonstrated an ability to identify 91% of adolescent women with CIN2+. MHS also showed potential to reduce by a third the number of adolescent women without dysplasia that were referred to biopsy and colposcopy.

KEY WORDS: cervical intraepithelial neoplasia (CIN), adolescent women, early detection, spectroscopy