MULTIMODAL SPECTROSCOPY AS A TRIAGE TEST FOR WOMEN AT RISK FOR CERVICAL NEOPLASIA: RESULTS FOR ADOLESCENT PATIENTS

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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.

Table 1. Age distribution for 1,607 subjects

Age Category	Number	Percent (%)
Median	27.00	
Range	16-84	
16 – 20	290	18.0
21 - 30	683	42.5
31 - over	634	39.4

Pivotal Study Clinical Sites
1-University of Texas Southwest – Claudia Werner, MD / William Griffith, MD
2-Emory University School of Medicine – Lisa C. Flowers, MD / Talaat S. Tadros, MD
3-University of Miami – Leo Twiggs, MD / Nahida Chakhtoura, MD
4-University of Connecticut – Manocher Lashgari, MD
5-University of Arkansas – Alexander Burnett, MD
6-Medical College of Georgia – Daron Ferris, MD
7-Orange County California – Marc Winter, MD / Daniel Sternfeld, MD

RESULTS: For the 1,607 women in the study, 290 (18%) were aged 16-20 (Tables 1 and 2; Figure 1). 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) (Tables 3 and 4). Of the 238 adolescent women without CIN2+, 131 (45%) were diagnosed with CIN1 and 96 (33%) were diagnosed with benign or normal cervices. For 11 women (5%), biopsy was either not performed or the tissue sample was insufficient for diagnosis. Sensitivity for CIN2+ 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 CIN2+ (37/46). Specificity of MHS for adolescent women with CIN1 was 25% (30/118) and 33% (27/81) for women with normal or benign cervices. This MHS detected 13.8% more CIN2+ than the standard of care and would have saved one third of adolescent women of unnecessary colposcopy and biopsy.

Table 2. Demographics by age for 1,607 subjects

Age	Non Hispanic American Indian Alaska Native	Non Hispanic Asian	Non Hispanic Black or African American	Non Hispanic White	Non Hispanic Native Hawaiian/ Pacific Islander	Hispanic Black or African American	Hispanic White	Non Hispanic TOTAL	Hispanic TOTAL	TOTAL ENROLLED
16-20	1	2	182	36	0	6	63	221	69	290
21-30	2	9	383	101	4	6	178	499	184	683
31-over	0	5	303	113	0	2	211	421	213	634
							TOTAL	1,141	466	1,607

Table 3. Prevalence of CIN2+ for all age groups *

Age	Normal	CIN1	CIN2+	Prevalence (%)
16 - 20	96	131	52	17.9
21 - 30	234	289	129	19.7
31 - OVER	277	221	111	18.2
TOTAL	**601**	**640**	**292**	**19.0**

* Excludes subjects with no or equivocal histopathology (n=74)

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.

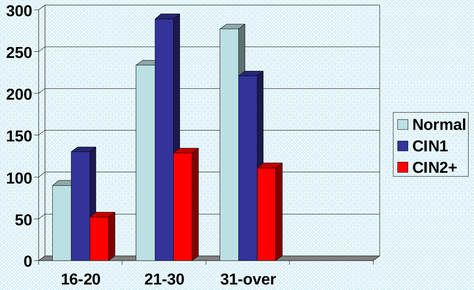
"Significant dysplasia was found in 18% of the adolescent population from the MHS pivotal clinical trial, calling into question recent guidelines for reducing surveillance of cervical disease in women below the age of 21."

Table 4. Prevalence of CIN2+ in adolescent women *

Age	Normal	CIN1	CIN2+	Prevalence (%)
16	2	8	3	21.4
17	10	10	5	19.2
18	18	36	12	17.1
19	28	36	11	13.4
20	32	40	21	21.4
TOTAL	**90**	**130**	**52**	**17.9**

* Excludes subjects with no or equivocal histopathology (n=18)

Figure 1. Histology by age group
Does not include 74 women with no or equivocal histopathology



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Supported in part by grants from the Georgia Research Alliance and the National Cancer Institute.
Also supported by Guided Therapeutics, Inc.

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