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

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. Table 2. Demographics by age for 1,607 subjects 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.

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		

Table 1. Age distribution for 1,607 subjects

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

Flowers, LC, Tadros TS – Emory University School of Medicine, Atlanta, Georgia

CONCLUSIONS: Significant dysplasia was found in 18% of the **RESULTS:** For the 1,607 women in the study, 290 (18%) were adolescent population from the MHS pivotal clinical trial, calling aged 16-20 (Tables 1 and 2; Figure 1). A histopathology quality assurance procedure diagnosed 52 biopsies of these adolescent into question recent guidelines for reducing surveillance of cervical women with CIN2+ (18%), including five identified at subsequent disease in women below the age of 21. MHS is a cost effective follow up visits. The prevalence of CIN2+ for women in the study point of care test that provides immediate results and demonaged 21 and older also was 18% (232/1317) (Tables 3 and 4). Of strated an ability to identify 91% of adolescent women with the 238 adolescent women without CIN2+, 131 (45%) were CIN2+. MHS also showed potential to reduce by a third the diagnosed with CIN1 and 96 (33%) were diagnosed with benign or number of adolescent women without dysplasia that were referred normal cervices. For 11 women (5%), biopsy was either not to biopsy and colposcopy. 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.

	Non	Non	Non	Non	Non			Non		
Age	Hispanic	Hispanic	Hispanic	Hispanic	Hispanic	Hispanic	Hispanic	Hispanic	Hispanic	
	American Indian Alaska Native	Asian	Black or African American	White	Native Hawaiian/ Pacific Islander	Black or African American	White	TOTAL	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 subject	cts with no or equiv	ocal histopatholog	y (n=74)			

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

Figure 1. Histology by age group



"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 1 Dravalance of $CTN2 \perp$ in addlessent women



MEDICINE

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

LightTouchTM is a trademark of Guided Therapeutics, Inc. ©2010 Guided Therapeutics, Inc.