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LUVIVA CERVICAL SCAN AS A TRIAGE TEST TO REDUCE UNNECESSARY COLPOSCOPY AND BIOPSY

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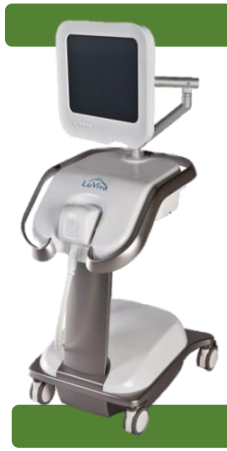
Introduction



LuViva® Advanced Cervical Scan is a medical device that non-invasively measures cervical tissue using hyper-spectroscopic technology(1). Test results are immediately reported as one of three levels to help the physician decide whether a colposcopy exam and biopsy is indicated: low risk (colposcopy not required), moderate risk (additional clinical information should be considered), and high risk (colposcopy required). The study prospectively evaluated LuViva's ability to triage women with abnormal screening tests by indicating likelihood of CIN 2/3 disease.

Methods

LuViva scans were completed on 55 subjects enrolled at clinics in Atlanta, GA (USA) and Halifax, NS (CA)*. Study subjects were referred to these centers based on abnormal Pap and/or positive HPV tests. After the LuViva scan, colposcopy was performed and biopsies taken. Histopathology revealed 16 women as normal (no dysplasia), 27 with CIN 1 and 12 with CIN 2/3 (Table 1). The three LuViva output levels were compared to the corresponding histopathology diagnosis for each subject. Finally, LuViva's continuous outputs were used to calculate a receiver operating characteristic (ROC) curve with the area under the curve (AUC) as an additional metric of prediction performance.

Table 1. Cytology and Histology Matrix	Histology			
Cytology	**Normal**	**CIN 1**	**CIN 2/3**	**Total**
Normal (HPV+)	3	1	0	**4**
ASC-US (repeat or HPV+)	6	16	3	**25**
LSIL	4	4	3	**11**
ASC-H	3	6	6	**15**
Total	**16**	**27**	**12**	**55**

Results

LuViva classified all 12 women with CIN 2/3 as high risk (100% sensitivity). Women with normal histopathology were classified 44% (7/16) of the time in the low risk category and 62% (10/16) of the time in the low or moderate risk categories. Combining women having CIN 1 with normal women, LuViva classified 30% (13/43) as low risk and 47% (20/43) as low/moderate risk (Figure 1). ROC curves (Figure 2) indicate that LuViva was able to discriminate CIN 2/3 from women without dysplasia (AUC = 0.84) as well as when mild dysplasia is included (AUC = 0.77). Forty-two of the 55 women (76%) were positive for high risk HPV, including 11 of 12 with CIN2/3 (HPV sensitivity = 92%).

Figure 1: Pathology Results For Each LuViva Classification

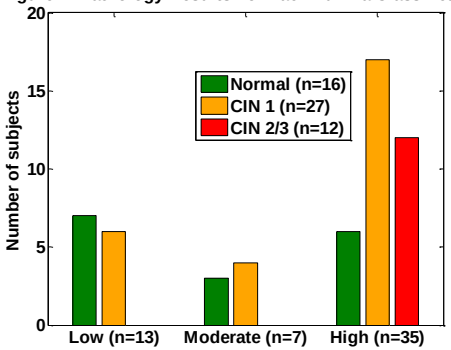
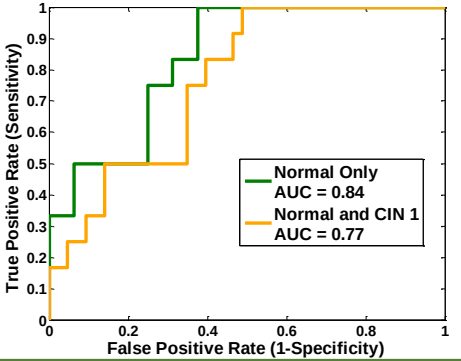


Figure 2: LuViva CIN 2/3 ROC Prediction Performance



Conclusions

This study confirms previously published results(2) that LuViva effectively triages women at risk for cervical cancer referred to busy colposcopy clinics, especially those with ASC-US or LSIL Paps and/or with evidence of high risk HPV. The high sensitivity, specificity and resulting high negative predictive value of LuViva imply that nearly half of the women currently undergoing colposcopy and biopsy could safely avoid those procedures, thereby improving clinic efficiency and resulting in significant savings to health care systems.

References

1. Drezek RA, Richards-Kortum R, Brewer MA et al. Optical imaging of the cervix, Second International Conference on Cervical Cancer. J Am Cancer Soc. 2003; 2015-2027.
2. Twiggs LB, Chaktoura NA, Ferris DG et al. Multimodal hyperspectroscopy as a triage test for cervical neoplasia: Pivotal clinical trial results. Gyn Oncol. 2013; 147-151.

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