

Panel Fails to Recommend Colposcopy Adjunct

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GAITHERSBURG, MD. — A Food and Drug Administration panel in a 9-2 vote recommended against approval of a spectroscopy-based cervical imaging device designed to be used as an adjunct to colposcopy in women with ASCUS/LSIL Pap smears, citing weaknesses in clinical trial data for effectiveness and other concerns.

At a meeting last month, the FDA's Obstetrics and Gynecology Devices Panel reviewed the results of the two pivotal trials of the device, the LUMA Cervical Imaging System, manufactured by Massachusetts-based MediSpectra Inc.

The indication under FDA review is for use as an adjunct to colposcopy for identifying high-grade disease (cervical intraepithelial neoplasia-CIN 2/3+) in women who have an ASCUS or LSIL cervical cytology result and are referred for colposcopy.

This proposed indication is accompanied by the statement that the device is not intended to replace colposcopy and that "a thorough colposcopic evaluation with an identification or selection of biopsy sites must be performed independently and prior to the viewing of the LUMA results."

The LUMA device is a stand-alone, mobile optical analysis system, with components that include a console that contains an ultraviolet laser, an illumination probe, and a computer. The system uses ultraviolet and visible light to illuminate the cervix, producing an image with areas highlighted in blue that may not have been seen on colposcopy and that can then be biopsied. The scan is obtained, and the colposcopic exam and biopsies are performed. Then the LUMA scan is displayed on the device console.

The two studies enrolled 2,526 patients aged 18 years and older who were seen at 13 institutions. The women had abnormal Pap smear results: atypical cells of undetermined significance (ASCUS), low-grade squamous lesions (LSIL), high-grade squamous lesions (HSIL), or cancer. Colposcopies were performed by 52 expert colposcopists. The primary effectiveness endpoints were the true positive (patients with at least one biopsy diagnostic of CIN 2/3+) and false-positive rates.

In the first study, the true positive rate was only 1.9% greater among those who had colposcopy with the LUMA scan than among those who had only a colposcopy—a statistically insignificant difference.

The false-positive rate was 3.1% higher among those having both procedures, which was considered clinically acceptable (defined as a false-positive rate that was not more than 8% greater than that of colposcopy alone).

Among women with ASCUS/LSIL results, the true positive rate was 3% higher with the addition of LUMA, which was statistically insignificant.

In the second study of 227 women, the LUMA scan was done but not revealed to the colposcopist until after the colposcopy was completed; biopsies were then taken

based on the LUMA scan results. With the LUMA scan, the overall true positive rate increased by 4.7%, which was significant, but the false-positive rate increased by 18%, which did not meet the prehypothesis that the false-positive rate would not exceed 15%.

When only ASCUS/LSIL patients were analyzed, neither the true nor the false-positive rate endpoint was met.

In voting against approval, Hugh Miller, M.D., of the Arizona Health Science Cen-

ter, Tucson, said that he was not convinced that the device "would provide a significant benefit over and above a skilled colposcopist doing an adequate number of biopsies."

He described it as "a technology in motion," which had certain risks that included over- and underdiagnosis, as well as "potentially a dumbing down of a skill set," that needs to be improved. He and others raised the concern that over time, colposcopists might lean more on LUMA for

directing their biopsies and rely less on colposcopy, which is more effective.

Other panelists voting against approval cited concerns that included the potential regression of CIN 2 lesions in younger patients without treatment, and that the benefit appeared to be mostly in younger patients.

After the panel vote, MediSpectra officials had no comment regarding their plans. The FDA usually follows the recommendations of its advisory panels. ■

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