Electrocauterization Has Fewer Side Effects, Better Efficacy, Than Topical Treatments for Anal Lesions

March 23, 2012 By Tim Horn

When it comes to treating precancerous anal lesions, electrocauterization is both more effective and, somewhat surprisingly, better tolerated than repeated topical applications of either Aldara (imiquimod) or Efudex (fluorouracil), according to data presented Thursday, March 8, at the 19th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle. Lead presenter Olivier Richel, MD, of the Academic Medical Center in Amsterdam noted, however, recurrence rates were high with all treatments tested in the study.

As explained by Richel, between 50 and 80 percent of HIV-positive men who have sex with men (MSM) will experience anal lesions—anal intraepithelial neoplasia (AIN)—caused by human papillomavirus (HPV) and that up to 50 percent will develop high-grade AIN, or HGAIN. HGAIN, cause by oncogenic strains of HPV, are precancerous lesions, with approximately 15 percent of HIV-positive MSM developing anal cancer within five years of developing high-grade lesions.

Numerous questions abound regarding the diagnosis and treatment of AIN. For example, it's still not clear if aggressive screening for anal lesions has a profound effect on anal cancer rates, at least not to the extent that regular Pap smears have helped reduce cervical cancer rates among women. It is also unclear whether HIV-positive men and women should be screened for AIN using Pap smears or if more expensive and invasive direct visualization—high-resolution anoscopy, for example—should be the preferred first-line screening method.

As for treatment, Richel noted that numerous options exist. One option is cauterization—an outpatient procedure in which affected anal tissue is burned and destroyed. Cauterization, using either electric or infrared technology, is approximately 50 to 70 percent effective but is associated with high recurrence rates. Aldara, when applied to tissue inside the anus, was found to be partially or completely effective in up to 29 percent of patients in a small study reported in 2010. Efudex was partially or completely effective in up to 39 percent of AIN patients in a small study reported in 2011.

Richel and his colleagues set out to compare these three options in a study involving 148 HIV-positive MSM with biopsy confirmed low-grade or high-grade AIN. The men averaged 47 years of age and had been diagnosed with HIV seven to 10 years prior. More than 80 percent were on an

antiretroviral regimen upon entering the study and more than three-quarters had undetectable viral loads. Average CD4 cell counts were between 535 and 590.

Between 54 and 60 percent of the men had HGAIN and roughly 95 percent had evidence of AIN lesions inside their anuses.

Forty-six men were randomized to receive electrocauterization once a month for four months. Among the 54 men allotted to the Aldara group, the cream was applied three times a week for 16 weeks. The 48 men in the Efudex group received topical treatment twice a week for 16 weeks.

Thirty six, 45 and 43 men, respectively, successfully completed the study as planned. Three men in the electrocauterization group, compared with 5 men in the Aldara group and 2 men in the Efudex group, discontinued treatment in the study because of side effects.

In the strict intent-to-treat analysis—which included all people randomized in the study, regardless of whether or not they completed their treatment course and follow-up appointments—electrocauterization proved most effective, with 41 percent achieving a complete response and 7 percent achieving a partial response. Seventeen percent, however, saw AIN recur within six months after treatment.

In the Aldara group, complete responses were seen in 26 percent and partial responses were documented in 13 percent. Twenty-five percent of the partial or complete responders experienced AIN recurrence within six months.

As for those receiving Efudex, the complete response rate was 17 percent and the partial response rate was 13 percent. Fifty-seven percent experienced disease recurrence within six months.

As for side effects in the electrocauterization group, 60 percent experienced pain and 69 percent had bleeding, though Richel noted that these problems only lasted a few days following the procedure. In the Aldara and Efudex groups, side effects lasted for weeks, and included pain (60 to 67 percent), bleeding (30 to 40 percent), sudden bowel movement urges (Efudex; 26 percent), flatulence (Efudex; 15 percent), flu-like symptoms (Aldara; 13 percent) and fatigue (Aldara; 13 percent).

Richel also noted that severe side effects were more common in the Aldara group (43 percent) and Efudex group (27 percent) compared with the electrocauterization group (18 percent).

“This study showed that regarding both efficacy and side effects electrocautery is superior to [Aldara] and [Efudex] in treatment of AIN, but recurrence rates are substantial,” Richel and his colleagues concluded.

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