Imiquimod suppositories help suppress anal warts

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Many microbes are transmitted during sex. One of these microbes is HPV (human papilloma virus). There are at least 90 types of HPV. Some types can cause abnormal growths and cancers in the cervix, vulva, anus and penis. HPV types 6 and 11 are the ones that often cause genital warts.

In people with HIV/AIDS, ano-genital warts can be a troublesome complication. Approaches to treating these warts include surgery, laser therapy or burning the growths with an electric current. However, no matter which therapy is used, warts can recur. This happens for a number of reasons:

- anti-wart therapy does not wipe out HPV
- the immune system is unable to stop HPV from spreading and infecting cells

Imiquimod (Aldara) is approved in North America and the European Union for the treatment of external genital warts and other skin conditions. Imiquimod is applied to the skin, where it stimulates the immune system to activate cells that help destroy abnormal growths and tumours. At very high concentrations, imiquimod causes tumours to self-destruct.

HPV can also trigger the growth of warts inside the anus. Treating this is particularly challenging. Patients must sometimes be put to sleep and then the warts are surgically removed or blasted with an electric current.

Several years ago, researchers in Hanover, Germany, tested suppositories of imiquimod to suppress the recurrence of warts following surgical removal in HIV negative men. They reported that no re-growth of warts was detected after monitoring for nine months.

Now, researchers at St. Josef Hospital in Bochum, Germany, have conducted a pilot study of imiquimod suppositories in men with HIV/AIDS. The suppositories were meant to suppress re-growth of warts after they had been surgically removed from the anus. After eight months of observation, three out of six participants developed recurring warts. This may have been due to HPV re-infection. These and other details are discussed later in this report.

Study details
Researchers enrolled seven men with HIV/AIDS for their pilot study to assess the impact of imiquimod suppositories. The suppositories were used after wart-removal surgery of the anus. All the men were taking highly active antiretroviral therapy (HAART). Their average CD4+ count was 460 cells and most of the men had a viral load below the 40-copy limit. They ranged in age between 26 and 38 years.

Imiquimod is supplied in sachets in a cream formulation. Using this and other compounds, pharmacists made suppositories, each containing 5.2 mg of imiquimod. The suppositories were wrapped in a thin gauze bandage. This helped to reduce irritation caused by exposure to imiquimod in the anal canal.

Four days after surgical treatment of anal warts, participants inserted a suppository three times weekly at night for a total of four months.

Doctors told participants to have condom-protected sex, as this reduces the risk of HPV re-infection.

Extensive laboratory tests and proctoscopic examinations of the anal canal were performed during the study.
Results—Short term
After using imiquimod suppositories for four months, all participants were free from any anal warts. One person failed to return to the clinic for monitoring, so researchers are not sure what happened with him.

Before beginning imiquimod therapy, all participants had high levels of HPV DNA. Use of this drug led to a dramatic decrease in not only HPV types 6 and 11 (associated with anogenital warts), but also in several other types of HPV associated with the risk of ano-genital cancer, including types 16, 18, 31 and 33.

Three participants who had pre-cancerous anal lesions before using imiquimod had these resolve once they started using the drug.

Side effects were described as “moderate” by the research team and included temporary inflammation within the anal canal. However, no serious side effects occurred.

Results—Long term
Participants were monitored up to eight months after they stopped using imiquimod. In three of six men, new anal warts occurred. Researchers suspect that in two of these three cases, recurrence was due to unprotected anal intercourse, as the participants had new HPV types not previously detected. One of them also had an anal lesion because of syphilis.

The results from this pilot study are promising. However, a larger clinical trial is needed to confirm these results. The research team emphasized the use of condoms for anal sex because this reduces the risk of infection with new types of HPV and other sexually transmitted infections (STIs). They note that the inflammation caused by exposure to imiquimod may make the tissue lining the anal canal temporarily more susceptible to STIs.

—Sean R. Hosein

REFERENCES:


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