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Case Study: A New Treatment for HPV Related Anal Neoplasia

Amelia Kahn[1], Robin H. Miller, MD MHS[2]

[1,2] Triune Integrative Medicine, Medford, Oregon

Abstract: ***Following random biopsies of a scar from a previous anal polyp removal 12 years prior, a 70 - year - old white female was diagnosed with a high grade squamous epithelial lesion in 2015. A year later she developed tenderness at the site and the lesion was found to be superficially invasive. She was HPV positive. Rather than the usual care of topical chemotherapy, laser, cryotherapy or further excision, with the help of her primary care physician she opted for lopinavir - ritonavir, an antiviral drug used in the treatment of HIV, that has been used experimentally to treat lesions related to HPV. She used the drug as an anal suppository twice daily for 2 weeks. It was repeated yearly. Treatment was started in 2017 and by March of 2018 the lesion was gone. By June of 2020 she was HPV negative and has remained so with no recurrence as of May 2024. Lopinavir - ritonavir is a relatively simple, effective treatment for HPV related anal lesions. More research is needed.***

Keywords: anal cancer, HPV, Lopinavir - ritonavir, case study, experimental treatment

1. Introduction

Anal cancer is relatively rare accounting for 2% of gastrointestinal cancers. Although 5% of all cancers in the world are associated with human papillomavirus (HPV) the proportion of anal cancer related to HPV is 90%. The peak incidence is between the ages of 58 and 64 years (3).

Cervical cancer is caused by HPV infection. A British team of physicians ran a clinical trial in Kenya to help women with early - stage cervical cancer. They repurposed a drug used for HIV called lopimune (Lopinavir - ritonavir). They made it into soft - gelatine capsules as a pessary for two weeks. Sixty percent of the women reverted to normal pathology and 19% regressed to a low - grade disease within three months.

The usual treatment of a high grade squamous intraepithelial lesion (HSIL) is ablation such as hyfrecation/fulguration and infrared coagulation. The patient often requires multiple treatments and complications can occur. Surgery may also be recommended. Topical therapies are an alternative approach, however, there are no FDA approved topical therapies for anal HSIL. Patient applied imiquimod, 5 - fluorouracil and cidofovir have been used (2). There are a few, small clinical trials that have been done.

Patient applied imiquimod and 5FU appear efficacious against HSIL. They need to be applied often. In cases where resolution of the lesion is not complete, the amount of disease is reduced. There are frequent side effects and topical analgesics, and dose reductions are often needed. Most patients can complete their treatment. The treatment with Lopinavir - ritonavir is easily administered with no side effects and was 100% efficacious at eradicating HPV and the disappearance of the HSIL. A full - scale clinical trial is warranted. However, in the meantime, this is a low risk, high benefit treatment to utilize.

2. Methods

This case report follows the treatment plan of a patient diagnosed with a HSIL of the anal area who was HPV positive. She was treated with a twice daily dose of Lopinavir - ritonavir anal suppository for 2 weeks that was continued yearly. She was followed every 6 months. The lesion was completely resolved after 3 years in 2020 with eradication of her HPV infection. She was dismissed from care with no reoccurrence in 2024.

3. Case Report

A 71 - year - old white female presented to a prominent university cancer institute in 2016.

In May of 2004 she had an anal polyp removed. At the time it was identified as carcinoma in situ. She developed a scar at the site which was excised in July of that year. She had regular follow - ups.

In April of 2015 random biopsies of the anal region during colonoscopy revealed a high grade squamous intraepithelial lesion. The high resolution anoscopy was negative. She was followed closely and in November of 2015 her digital rectal exam was negative as well as anoscopy. In August of 2016 she developed tenderness at the anal canal and in September she had an excision at that site of a superficially invasive squamous carcinoma showing a high grade squamous intraepithelial lesion. She tested positive for HPV.

There was a question of lympho - vascular invasion. However, the concern for damage to the sphincter negated the use of surgical exploration. MRI of the pelvis and abdomen was done and was negative. It has remained negative to this day.

The patient was advised about the options of chemotherapy and radiation. Her primary care physician and compounding pharm D suggested a trial of Lopinavir / Ritonavir given by

rectal suppository (200 mg+50 mg per 5G gel) inserted twice daily for 14 days. This combination has been found to eradicate HPV infections and cervical cancer in recent clinical trials.

This was discussed with her surgeon who agreed to the trial in August of 2017. At that time, she had a high grade squamous intraepithelial lesion on the right anterior portion of the rectum. In October of that year, she had a very small remnant of the lesion and new areas of small lesions that were hyfrecated.

By March of 2018 she had no lesions, no masses and no indurated areas. As of June 2020, the patient tested negative for HRHPV. She has had continued follow - up every 4 - 5 months. She has had no further evidence of masses or indurations on digital anal exam, no lymph nodes palpable and cytology reveals atypical squamous cells of undetermined significance. She tested negative for HPV on vaginal exam.

She has been treated with the combination of Lopinavir/ritonavir as a rectal suppository twice daily for two weeks each year. She continued close follow - up. As of May 2024, she is cancer free and HPV negative. She has been dismissed from cancer care. Her cancer was deemed to be cured.

4. Discussion

HPV related cancers offer a unique opportunity when it comes to treatment. It appears that if the infection is eradicated, the cancer remits. This has been seen when it comes to treating cervical cancer and now in our case, anal cancer. Direct contact with the infected tissue with the medication may be the key. Certainly, this possibility deserves further exploration.

What we know is that cervical cancer was either cured or the cancer grade decreased in a single - arm, proof - of - concept trial of Lopimune conducted in Kenya (1). Granted, this is a small trial, but it warrants further study.

The treatment for cervical cancer and anal cancer can be uncomfortable and invasive (2). The use of a drug such as Lopinavir - ritonavir would make treatment easier, and a cure is possible.

This treatment approach should be explored and utilized going forward. The lack of side effects and ease of treatment when given rectally should be considered in any patient with an anal high grade squamous intraepithelial lesion who is HPV positive.

References

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