OM-85 BV: A Bacterial Vaccine Against Respiratory Problems in People with HIV and COPD?

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Can a capsule containing broken down bacteria decrease rates of recurrent respiratory infections in people living with HIV who also are at high risk for chronic pulmonary disease? According to a small observational cohort study conducted in Milan and reported Thursday, July 22, at the XVIII International AIDS Conference in Vienna, this may be possible.

As reiterated in Vienna by Amedeo Capetti, MD, of the Luigi Sacco Hospital in Milan and his colleagues, chronic obstructive pulmonary disease (COPD)—irreversible emphysema or chronic bronchitis—appears to be more common among people living with HIV, at a younger age, compared with rates among HIV-negative individuals in the general population. In addition, the evolution of COPD in people living with HIV appears to be more rapid and insidious.

Smoking among people living with HIV, as it is among HIV-negative individuals, is a leading risk factor for COPD. Another possible, yet unproven, risk factor is HIV infection itself, in light of theories that it is associated with systemic inflammation and, with it, a greater likelihood of inflammatory diseases involving the lungs and other organs.

Recurrent sinus infections (rhinosinusitis) and ear infections (otitis media) are not more frequent among people living with HIV, but Capetti argues that their management adds to the treatment burden among people living with HIV and can contribute to systemic inflammation.

COPD is frequently managed using inhalant corticosteroids, such as Advair (fluticasone/salmeterol) and Spiriva (tiotropium bromide). Both work by suppressing immune system hyperactivity in the lungs. This, in turn, reduces inflammation that further damages tissue and helps minimize respiratory symptoms.

OM-85 BV, sold in some countries by OM Pharma as Broncho-Vaxom and sometimes prescribed as a treatment to manage COPD exacerbations (it is included in Swiss COPD management guidelines), takes a different approach. According to Capetti, it contains freeze-dried remnants (lyophilized lysates) of eight bacteria known to be root causes of recurrent lung disease in people with COPD, rhinosinusitis and otitis media. It purportedly works by sparking the immune system to better control the real bacteria, should they establish infection in the lungs. In effect, it is an oral vaccine against recurrent bacterial infections.

Capetti and his colleagues point out that while there are encouraging data regarding its efficacy as a preventive in people with chronic lung disease, the results from studies have not been consistent enough to confirm clinical benefit. Even less is known about the safety and potential benefits of OM-85 BV in people living with HIV at risk of recurrent respiratory problems.

A group of 386 HIV-positive individuals at high risk for pulmonary disease receiving care through an outpatient clinic at the Luigi Sacco Hospital were selected to participate in an observational study on respiratory infections started in July 2005.

In 2007, 65 subjects with chronic or recurrent respiratory problems were provided with OM-85 BV. The researchers noted a high degree of patient satisfaction following treatment and observed a "dramatic drop" in respiratory tract infections.

OM Pharma's Broncho-Vaxom.

To explore this further, Capetti's group prescribed capsules of OM-85 BV to all their patients at risk for developing seasonal respiratory infections—including all patients with a history of pneumonia—during the summer months of 2008 and 2009. OM-85 BV was taken daily for 10 days at the start of each month, from September to November.

Among the 386 patients included in the analysis, 228 were smokers, 36 were diagnosed with COPD, 21 had recurrent sinusitis, five had otitis media, and six had COPD plus sinusitis. In addition, 62 smokers who did not enter the study with a COPD experienced at least one episode of acute bronchitis requiring antibiotic treatment before enrollment and, in turn, were dubbed "high-risk" smokers.

An untreated control group was not included in the study. Instead, Capetti's group compared rates of respiratory infections during the immunization years (2008 and 2009) with those of previous years (2005 and 2006). Year 2007, in which only part of the population had received OM-85 BV treatment, was excluded from the analysis.

Statistically significant differences were observed in two groups: patients with COPD plus sinusitis and patients who were high-risk smokers. In the COPD/sinusitis group, 92 respiratory infections required antibiotic treatment in 2005/2006, compared with 14 in 2008/2009. Among high-risk smokers, there were 134 acute respiratory infections in 2005/2006, compared with 21 in 2008/2009.

Less pronounced differences in the recurrent sinusitis and recurrent otitis media groups were observed and were not found to be statistically significant.

Of note, approximately one-third of the smokers—and approximately one-half of the high-risk smokers—reporting quitting cigarettes while participating in the cohort.

Though the scientific limitations of this study are notable—a well-designed clinical trial is needed to further evaluate the potential benefits of OM-85 BV in people living with HIV and COPD—Capetti's group conclude that, at least in the observational cohort data reported in Vienna,

bacterial vaccination reduced the frequency of respiratory events requiring antibiotic therapy in at-risk patients, notably high-risk smokers and those also living with COPD.
