



Drug Monitor

Potato-Based Drug Relieves Human Papillomavirus Infections

Immunomax[®], a novel immunostimulant manufactured from potato sprouts, may bring relief to patients who have human papillomavirus (HPV) infections, prostatitis, prostate carcinoma, or bacterial infections of the urogenital tract.

In a study conducted at the Russian University of Peoples' Friendship in Moscow, 30 patients being treated for recurrent anogenital warts caused by HPV were selected as participants. All patients were age 18 years or older and had a history of recurring anogenital warts after their removal. Patients were given 6 intramuscular injections over 10 days of Immunomax 200 U (20 patients) or 100 U (10 patients). Large warts were surgically removed during treatment administration. A dermatologist/venereologist examined each patient before the trial, 3 times during the treatment, immediately after the treatment course, and 3 months following the end of treatment.

The treatment's effectiveness was estimated by the amount of HPV in the material sampled from affected foci before and after therapy. At baseline, the material from 12 patients contained large amounts of oncogenic HPV types; 2 patients had a moderate amount. Nononcogenic HPV types were "abundant" in the affected tissues of 12 patients (47%) and moderate in 14 patients (47%).

Immediately after the Immunomax treatment, large amounts of oncogenic HPV types were found in the material from pathologic foci from 8 patients (27%), with moderate amounts in the material from 2 patients (7%). Large

amounts of nononcogenic HPV types were detected in 4 patients (13%) and no patient had a moderate amount of these types of HPV.

At 3 months, 26 patients (87%) were completely cured, as judged by clinical etiologic characteristics. The material from pathologic foci from only 3 patients contained large amounts of oncogenic HPV types and material from just 1 patient contained moderate amounts of the virus. Two patients had an abundance of nononcogenic HPV types and none had a moderate amount. In 2 patients, the 3-month follow-up examination revealed both oncogenic and nononcogenic types of HPV.

As a rule, the researchers say, small warts (0.1 cm to 0.3 cm) disappeared within 2 to 4 days after the first injection of Immunomax. Three months after treatment, anogenital warts reappeared in only 4 patients. Moreover, the researchers say, it is noteworthy that the number of warts in those patients declined "drastically" and the remission increased by a factor of 2 to 3.

Both doses produced practically the same results. Eight of the 10 patients who received the single doses of 100 U were clinically and etiologically cured of recurrent anogenital warts—similar to the number of cures using single doses of 200 U. Therefore, the researchers pooled the results on both doses.

All patients reported that the itching, burning, and other symptoms of inflammation had disappeared within 3 months of treatment initiation. The patients tolerated treatment well: A slight feeling of discomfort remained in 6 of the patients. The effects of Immunomax on blood and urine biochemical parameters also were moni-

tored during the trial and remained within normal ranges. Patients with asthma or atopic dermatitis did not exhibit any allergic or other undesirable reactions.

Interestingly, monotherapy with Immunomax also led to the disappearance of some associated infections: Herpes simplex type 2 virus disappeared in 6 of 7 patients, *Ureaplasma urealyticum* in 5 of 7 patients, *Mycoplasma hominis* in all 6 infected patients, *Trichomonas vaginalis* in the only infected patient, and *Candida albicans* in 2 of 8 patients.

The researchers cited a pilot study in which 8 patients with chronic prostatitis IIIa were treated with Immunomax. Eight weeks after the start of therapy, the drop in leukocyte count was marked and significant: from 230 ± 129 leukocytes/ μ L to 76 ± 37 leukocytes/ μ L. Immunomax treatment also tended to reduce the volume of residual urine, though the reduction was not significant. The study also found an "impressive" reduction in The National Institutes of Health Chronic Prostatitis Symptom Index scores. The beneficial effects of treatment were still being seen 4 weeks after treatment ended.

In studies of patients with prostate carcinoma, Immunomax treatment also produced hopeful results. The researchers cited 2 reports of cases in which Immunomax was combined with androgen blockade. Androgen blockade alone increased prostate-specific antigen, which was normalized by Immunomax. The patients responded well to treatment with a long-lasting slight reduction in prostate-specific antigen and no adverse reactions detected.

Finally, the researchers note, Immunomax can be used to treat

purulent surgical processes. Daily injections have been shown to speed healing, reducing the need for antibacterial drugs and preventing the formation of rough scars.

Source: *JMH*. 2010;7(4):396–405.

Do Antidiabetic Drugs Raise Risk of Acute Pancreatitis?

According to reports, the incidence of acute pancreatitis has been increasing over the past 40 years. The reason is unclear; however, a concurrent trend is the worldwide increase in obesity and type 2 diabetes. Three observational studies revealed a two- to threefold increased risk of acute pancreatitis among patients with diabetes. To further assess this link, researchers from Centro Español de Investigación Farmacoepidemiológica, Madrid, Spain; Departamento de Genómica Estructural, Seville, Spain; and Novartis Pharma AG, Basel, Switzerland, conducted a population-based cohort study of nearly 300,000 patients between 1996 and 2006.

Researchers based their analysis on information from The Health Improvement Network (THIN)—a UK longitudinal primary care medical record database that includes diagnostic and prescribing data. The population in this database is representative of the general UK population. They found 85,525 patients with type 2 diabetes, who they matched with 200,000 nondiabetic patients who were randomly sampled from the THIN population.

The researchers followed both cohorts from the date when an indi-

vidual met eligibility criteria until the earliest occurrence of either a recorded diagnosis of acute pancreatitis, cancer, his/her 80th birthday, death, or the end of the study period. Average follow-up was 3.8 years in the diabetic cohort and 4.0 years in the general population cohort.

Their study revealed 176 cases of acute pancreatitis among the type 2 diabetes cohort and 243 cases in the nondiabetic cohort, for an incidence rate of 54 and 30 cases per 100,000 person-years, respectively. Their cohort analysis yielded a statistically significant 77% increased risk of acute pancreatitis associated with diabetes, or about 23 additional cases for every 100,000 patients with diabetes each year. In addition, patients with type 2 diabetes had a 79% increased risk of a first-ever episode of acute pancreatitis.

After adjusting for demographic and lifestyle variables, comorbidities, and drug exposure, the risk was reduced to borderline significance. During the first year after diagnosis of diabetes, the risk was somewhat higher than thereafter; that difference, however, was not statistically significant.

Researchers also evaluated the effect of antidiabetic drugs on acute pancreatitis risk. Insulin users were found to be at a decreased risk compared with nonusers. In fact, the reduced risk was seen across all different treatment durations, with a reduction in risk of 60% to 70%. Metformin and sulfonylureas—the most commonly prescribed drugs—were associated with decreased and increased risk, respectively, but only among long-term users. Other drugs, such as thiazolidinediones, were not

associated with acute pancreatitis, although the number of patients using them was small. Of the diabetic patients, 73% were receiving some form of antidiabetes drug treatment.

Overall, when the researchers separately analyzed the risk of pancreatitis among treated and nontreated patients with diabetes, they observed that the patients not currently on drug treatment (one-quarter of the study population) had the highest risk. The researchers speculate that this may be due to the slightly increased risk of acute pancreatitis immediately after the diagnosis of diabetes.

To the best of their knowledge, the researchers say, this is the first study suggesting a reduced risk of acute pancreatitis associated with insulin and metformin use. But they caution that it is “premature to propose potential mechanisms before these findings are replicated.” Other risk factors observed in this study, including smoking, alcohol use, use of ACE inhibitors, and exposure to paracetamol, have been replicated in previous reports. ●

Source: *Diabetes Care*. 2010;33(12):2580–2585.
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