

# HPV Vaccine Does Not Induce Lupus Flares

*Vaccination did not change patients' anti-dsDNA titers, C3 or C4 levels, or SLEDAI or PGA scores.*

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FROM THE ANNUAL EUROPEAN CONGRESS OF RHEUMATOLOGY

LONDON – The quadrivalent human papillomavirus vaccine is safe for patients with systemic lupus erythematosus and should be considered for women with inactive disease who receive stable doses of standard immunomodulatory therapy, according to Dr. Chi Chiu Mok.

Multiple studies have demonstrated higher rates of persistent HPV infections and precancerous lesions in women with SLE, compared with women in the general population, said Dr. Mok.

It has been hypothesized that immune dysfunction related to SLE or to treatment-induced immune suppression may prevent patients with the condition from being able to produce an effective immune response to the vaccine, and could possibly lead to disease flares or the production of new autoantibodies, Dr. Mo explained.

The recombinant quadrivalent HPV vaccine (Gardasil) provides protection against infection of the HPV serotypes 6,

11, 16, and 18, and it has been demonstrated to be safe and efficacious in female patients in the general population aged 9-26 years, according to Dr. Mok. Along with colleagues at Tuen Mun Hospital in Hong Kong, Dr. Mok evaluated the vaccine's safety and immunogenicity in a cohort of SLE patients.

Toward this end, the investigators recruited 50 female patients aged 18-35 years who fulfilled at least four American College of Rheumatology criteria for SLE, and who had received a stable dose of prednisolone or other immunosuppressive agent within the previous 3 months, to participate in the prospective investigation. The mean age of the study participants was 25.8 years, and their mean disease duration was 6.6 years, he reported.

All of the study subjects received intramuscular injections of the vaccine and were evaluated at baseline and at 2 and 6 months post vaccination via the SLEDAI (SLE Dis-

ease Activity Index), PGA (Physicians' Global Assessment), and the SELENA (Safety of Estrogens in Lupus Erythematosus – National Assessment) disease flare index. Additionally, complement levels (C3 and C4) and anti-dsDNA (anti-double-stranded DNA) titers were assessed and patient-reported adverse events were recorded at the same time points, said Dr. Mok. With respect to baseline disease characteristics, the median SLEDAI score was 4; the mean anti-dsDNA titers, C3 levels, and C4 levels were 139 IU/mL, 0.81 g/dL, and 0.15 g/dL, respectively; and none of the patients had SELENA

flares at baseline compared to preceding status, he said.

There were no significant changes in anti-dsDNA titers, C3 or C4 levels, or SLEDAI and PGA scores at any of the time points, Dr. Mok reported. Specifically, the baseline, 3-month, and 6-month measures of disease activity were: C3: 0.79, 0.80, and 0.81 g/dL; C4: 0.15, 0.15, and 0.15 g/dL; anti-dsDNA: 131, 130, and 139 IU/mL; SLEDAI: 3.4, 3.4, and 3.0; and PGA: 0.26, 0.28, and 0.22. "There were three mild to moderate mucocutaneous flares during the study period (one at month 2 and two at month 6), all of which were controlled with usual treatment," he said.

"It's unclear whether a causal relationship exists between the vaccination and the three lupus flares, but the rate of flares [0.08 per patient per year] was lower than the rate observed in our lupus cohort during the previous 5 years [0.10 per patient per year], and no other adverse events associated with the vaccination were reported."

The study findings indicate that the vaccine is safe in SLE patients, and the lack of significant alterations in the various SLE antibody measures suggests it does not induce an increased incidence of lupus flares, Dr. Mok stated. ■

## VITALS

**Major Finding:** The HPV vaccine does not exacerbate disease activity in women with SLE. The baseline, 3-month, and 6-month measures of disease activity were: C3: 0.79, 0.80, and 0.81 g/dL; C4: 0.15, 0.15, and 0.15 g/dL; anti-dsDNA: 131, 130, and 139 IU/mL; SLEDAI: 3.4, 3.4, and 3.0; and PGA: 0.26, 0.28, and 0.22.

**Data Source:** A prospective study of 50 female SLE patients and an unvaccinated cohort of SLE patients who were observed over a 5-year period at the same institution.

**Disclosures:** Dr. Mok disclosed having no financial conflicts of interest.

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