Ustekinumab Aided Sexual Function in Psoriasis

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MIAMI — Treatment with ustekinumab significantly improved sexual function in patients with moderate to severe psoriasis, according to a secondary analysis of phase III study data.

"It has become really clear that psoriasis has an influence on sexual function in our patients," Dr. Lyn Guenther said during a poster discussion session.

There is, however, a paucity of published data—with only a few researchers quantifying sexual function and none examining possible benefits of medical treatment in this patient population.

To find out if ustekinumab could improve sexual function, Dr. Guenther and her colleagues assessed quality-of-life data from the phase III PHOENIX I (Lancet 2008;371:1665-74) and PHOENIX II (Lancet 2008;371:1675-84) trials.

At baseline, 23% of the combined 1,996 study patients reported that psoriasis affected their sexual function. Impaired function was defined by a patient response of "very much" or "a lot" of sexual difficulties related to their skin disease on the Dermatology Life Quality Index (DLQI). All participants had moderate to severe psoriasis, and 69% were men; 28% of women and 21% of men reported impaired sexual function.

DLQI scores range from 0 to 30. Mean DLQI patient score at baseline was 12, "indicating a very large negative effect on patients' lives," said Dr. Guenther, professor of dermatology at the University of Western Ontario, London. The mean Psoriasis Area and Severity Index (PASI) score was a "fairly significant" 20, she said, and mean percentage of body surface area affected by psoriasis was 26%.

Worse sexual dysfunction was significantly associated with increased psoriasis disease severity. As an example, 54% of the women with a PASI score greater than 30 reported a significant impact of their condition on sexuality. "At each of the PASI severity cutoff points, it's almost a linear increase," Dr. Guenther said.

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"Can we make a difference?" she asked. After 12 weeks, the percentage of patients who reported sexual function impairment dropped from 23% to 3% in both ustekinumab dosage groups, with no change observed in the control group. "It was surprising to me to see how quickly we could improve the impairment," she said.

Similarly, at week 12, DLQI scores in the treatment groups decreased by a mean of 9.1 points versus a 0.5-point decrease in controls, a statistically significant difference. Both men and women "improved dramatically," Dr. Guenther said.

The PHOENIX I and II trial investigators randomized 1,334 patients to ustekinumab (45 mg or 90 mg) at weeks 0, 4, and every 12 weeks thereafter. They also randomized another 662 patients to placebo at weeks 0 and 4, with crossover to ustekinumab (45 mg or 90 mg) at week 12. Placebo patients who crossed over to ustekinumab experienced similar benefits. "The lessening of the sexual dysfunction continued to week 24," she said.

The mechanism of action for improved sexual function is unknown, but patients treated with ustekinumab might experience less fatigue and more hope about their condition improving, she suggested. "Why these people have [sexual function] problems is not clear. Future trials will be done to identify the reasons," Dr. Guenther said. She added that further research using validated sexual dysfunction instruments is warranted. ■

Disclosures: *Dr. Guenther was a consultant for Johnson & Johnson, sponsor of the study. Ustekinumab (Stelara) is manufactured by Centocor Ortho Biotech, a wholly owned subsidiary of Johnson & Johnson.*