The drug was safe and well tolerated in postmenopausal women who were treated for 12 months.

**Major Finding:** After 12 months, mean area under the curve SLEDAI scores were 18.7 for raloxifene-treated patients and 20.3 for placebo-treated patients, and mean area under the curve patient assessment scores were 2.2 in the treated group and 2.3 in the placebo group.

**Data Source:** A subgroup analysis of data from a 12-month randomized controlled trial looking at the effect of raloxifene and placebo on bone turnover, BMD, and disease activity in 62 postmenopausal women with SLE.

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

## Cardiovascular Risk Factors Predict Damage, Death in SLE

**BY DIANA MAHONEY**

Researchers have identified a number of predictors of damage and/or death in patients with systemic lupus erythematosus. Data from the inception cohort of 160 SLE patients show that predictors of new damage or death in this population include older age at diagnosis, organ involvement, cumulative glucocorticoid dose, and renal failure.

Researchers at the University of Birmingham, Birmingham, England, analyzed data from the BILAG-2004 system, the development of damage across the follow-up period, and the cumulative burden of damage, using the BILAG-2004 Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score at entry to the study.

The investigators included only SLE patients from the multicenter study, which began in 2004, who achieved the fourth American College of Rheumatology criteria for an SLE diagnosis within 12 months at the time of recruitment. Patients had a mean age of 35 years, and the median follow-up was 39 months with a total follow-up of 497 patient-years.

Two of the 160 patients died, and 33 instances of damage occurred in 30 patients. Damage was musculoskeletal in 31% of cases; ophthalmic in 23%; neurologic in 17% of cases; renal; vascular, or diabetes mellitus in 6% of cases; and pulmonary, cardiac, cutaneous, or a malignancy in 3% of cases each. The incident rates of development of damage across the follow-up period were 73, 86, 82, 42, 24, and 112 cases per 1,000 patient-years for follow-up years 1-6, respectively, and about 70 cases per 1,000 patient-years overall.

My results highlight the importance of managing cardiovascular risk factors and carefully monitoring patients with associated antiphospholipid syndrome.

As demonstrated by these data, the development of damage starts in the first year and most commonly affects the musculoskeletal, ophthalmic, and neuropsychiatric systems. The rate at which damage occurs, however, is slower compared with that seen in previous studies, Dr. Yee said, noting that antimalarials appear to confer some protection against damage and death.

Findings from previous studies have shown that hydroxychloroquine provides such protection, so this was not a surprising finding. In the current study, though, there was only a 2% reduction in risk with hydroxychloroquine, Dr. Yee said.

“Mepacrine, however, was strongly protective in our study, and this was somewhat surprising,” he added, noting that the finding should be interpreted with caution pending confirmation in future studies.

Dr. Yee said this study is the only one of which he is aware to report on the development of damage from a well-characterized inception cohort of SLE patients who were followed-up prospectively.

“My results highlight the importance of managing cardiovascular risk factors and carefully monitoring patients with associated antiphospholipid syndrome,” he said, noting that there is a need for more interventional studies on SLE patient with associated antiphospholipid syndrome, as this group of patients is often excluded from clinical trials.

Dr. Yee disclosed that he has received grant and/or research support from Aspreva/Vifor Pharma, and has served as a consultant for Genentech, Parexel, and Teva.