Silicone Related Disorders

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Risk of Connective Tissue Disorders among Breast Implant Patients

Louise A. Brinton1, Lenore M. Buckley2, Olga Dvorkina3, Jay H. Lubin1, Theodore Colton4, Mary Cay Murray5 and Robert Hoover1 1 Epidemiology and Biostatistics Program, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Rockville, MD.

2 School of Medicine, Virginia Commonwealth University, Richmond, VA.
3 State University of New York Health Science Center at Brooklyn, Brooklyn, NY.
4 School of Public Health, Boston University, Boston, MA.
5 Abt Associates, Inc., Chicago, IL.

In a US retrospective cohort study (1960–1996), 351 (4.8%) of 7,234 patients with breast implants and 62 (2.9%) of 2,138 patients who had undergone other types of plastic surgery reported subsequent rheumatoid arthritis (RA), scleroderma, systemic lupus erythematosus, or Sjögren’s syndrome (relative risk = 2.0, 95% confidence interval (CI): 1.5, 2.8).

Risks of RA, scleroderma, and Sjögren’s syndrome were elevated both before and after 1992, when the Food and Drug Administration changed the status of breast implants to investigational. When records for these diseases were retrieved (35–40% retrieval rate) and blindly reviewed, two expert rheumatologists assessed only a minority of the cases as being “likely” (e.g., regarding RA, 16.5% for implant patients and 23.5% for comparison patients).

Recalculation of incidence rates using “likely” diagnoses found relative risks of 2.5 (95% CI: 0.8, 7.8) for RA, scleroderma, and Sjögren’s syndrome combined and 1.9 (95% CI: 0.6, 6.2) for RA only. When the proportions deemed “likely” were applied to all self-reports, the estimated relative risks were 2.0 (95% CI: 0.7, 5.4) for the three disorders combined and 1.3 (95% CI: 0.5, 3.8) for RA.

These results indicate that self-reports of connective tissue disorders are influenced by reporting and surveillance biases. Given the diagnostic complexities of these diseases, excess risks, if they exist, may be beyond detection even in a study of this size. Key Words: arthritis, rheumatoid; breast implants; connective tissue diseases; risk; scleroderma, systemic; Sjögren’s syndrome Abbreviations: CI, confidence interval; CTD(s), connective tissue disorder(s); RR, relative risk.

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