

Review: Silicone breast implants do not increase the risk for connective-tissue diseases

Janowsky EC, Kupper LL, Hulka BS. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. *N Engl J Med.* 2000 Mar 16;342:781-90.

QUESTION

Are silicone breast implants associated with an increased risk for connective-tissue diseases (rheumatoid arthritis, systemic lupus erythematosus, scleroderma or systemic sclerosis, the Sjögren syndrome, dermatomyositis or polymyositis, all definite connective-tissue diseases, or other autoimmune or rheumatic conditions)?

DATA SOURCES

Studies were identified by searching MEDLINE, TOXLINE, Current Contents Online, and Dissertations Abstracts Online with terms related to breast implants and connective-tissue diseases.

STUDY SELECTION

Studies were selected if internal comparison groups were evaluated and sufficient data were available for analysis of women (not disease events) using 2×2 tables for categories of disease and implants.

DATA EXTRACTION

Data were extracted on year and country of publication; funding; study design; population characteristics and numbers; type, date, and reason for implant; disease characteristics; time from implantation to symptoms; and confounding factors.

MAIN RESULTS

9 cohort studies, 9 case-control studies, and 2 cross-sectional studies met the

inclusion criteria. Medical records provided data on the status of definite connective-tissue disease in 19 studies; 1 study relied on self-reports. Information on other autoimmune and rheumatic conditions came from medical reports in 16 studies and from self-reports in 4 studies. The information in the Table shows that silicone breast implants are not associated with increases in connective-tissue diseases. 1 large cross-sectional study was excluded because of methodologic problems, including unverified self-reports of disease status. Inclusion of this study in the analyses slightly increases all risks, and the risk for all connective diseases becomes significant (relative risk 1.14, 95% CI 1.01 to 1.28). Subgroup analysis

of the 6 studies of silicone-gel implants also shows no increased risk for any disease category.

CONCLUSION

Silicone breast implants, including silicone-gel implants, are not associated with an increased risk for all connective-tissue diseases combined or for individual diseases or conditions after adjustment for confounding factors and study outliers.

Source of funding: Administrative Office of the U.S. Courts.

For correspondence: Dr. E.C. Janowsky, Department of Epidemiology, CB 7400, School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599, USA. E-mail esther_janowsky@unc.edu. ■

Silicone breast implants and the risk for connective-tissue diseases (1 study was excluded for methodologic problems)

Diseases	Number of studies	Adjusted relative risk (95% CI)
All connective-tissue diseases	13	0.80 (0.62 to 1.04)*
Rheumatoid arthritis	7	1.04 (0.72 to 1.51)*
Systemic lupus erythematosus	4	0.65 (0.35 to 1.23)*
Scleroderma or systemic sclerosis	4	1.01 (0.59 to 1.73)*
Sjögren syndrome	3	1.42 (0.65 to 3.11)*
Dermatomyositis or polymyositis	1	1.52 (0.97 to 2.37)*
Other autoimmune or rheumatic conditions	6	0.96 (0.74 to 1.25)*

*Not significant.

COMMENTARY

The controversy about a possible link between breast implants and the development of connective-tissue diseases still smolders. Janowsky and colleagues' meta-analysis includes 8 studies published since the previous meta-analysis in 1996. The method of identifying relevant studies and the inclusion criteria for the analysis were rigorous. The review discusses methodologic issues associated with 1 very large study that is based on self-reported and unverified disease (1). The results of this study disagree with and show a stronger association than most of the results of the smaller studies, and because of its size, the large study swamps the results of the others. To help resolve these issues, Janowsky and colleagues present 2 sets of analyses: one that includes and one that excludes the large study. They conclude, mainly on the basis of the smaller, stronger studies (a choice with which I concur), that there is no evidence of increased risks for classical connective-tissue diseases with silicone breast implants.

All breast implants are enclosed in silicone, and some contain silicone gel. Subanalysis of 6 studies (excluding the study by Hennekens

and colleagues [1]) that present data on silicone-gel-filled implants shows no association with all connective-tissue disorders combined (summary adjusted relative risk 0.82, CI 0.46 to 1.46). Although the question about whether silicone breast implants are associated with connective-tissue diseases may have been settled "beyond reasonable doubt," 1 issue remains unsettled: Do women who have had cosmetic breast surgery with or without implants experience a higher frequency of nonspecific rheumatic and neurologic symptoms (2, 3)? If they do, then these may either be premorbid events in women who elect to have breast surgery or a consequence of the surgery.

*Deborah P.M. Symmons, MD
University of Manchester Medical School
Manchester, England, UK*

References

1. Hennekens CH, Lee IM, Cook NR, et al. *JAMA.* 1998;279:198.
2. Friis S, Mellekjær L, McLaughlin JK, et al. *Ann Plast Surg.* 1997;39:1-8.
3. Winther JF, Bach FW, Friis S, et al. *Neurology.* 1998;50:951-5.