Silicone Related Disorders

Silicone gel breast implant rupture, extra-capsular silicone, and health status in a population of women.

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OBJECTIVE: To assess whether breast implant rupture or extracapsular silicone are associated with selected symptoms of self-reported physician-diagnosed connective tissue disease (CTD). METHODS: Women with silicone gel breast implants responded to a questionnaire that included questions on health status, satisfaction with implants, symptoms of CTD, and physician-diagnosed disease. These women then had magnetic resonance imaging (MRI) of their breasts to determine the status of the implants with respect to rupture and extracapsular silicone. RESULTS: Women with breast implant rupture diagnosed by MRI were no more likely to report a diagnosis of selected CTD than those with intact implants or those with implants of indeterminate status. Women with extracapsular silicone (silicone gel outside of the fibrous scar that forms around breast implants) were more likely to report having fibromyalgia (FM, p = 0.004) or other CTD, which included dermatomyositis, polymyositis, Hashimoto’s thyroiditis, mixed CTD, pulmonary fibrosis, eosinophilic fasciitis, and polyarthritis (p = 0.008) than other women in the study. The association with FM remained statistically significant when adjusted for multiple comparisons (7 diagnoses) and implant age, implant location, or implant manufacturer (p < 0.05 in all cases), but became of borderline statistical significance when adjusted for multiple comparisons and self-perceived health status (p = 0.094) or self-perceived rupture status (p = 0.051). The association with other CTD remained statistically significant when adjusted for multiple comparisons and implant location or implant manufacturer, but became borderline or insignificant when adjusted for multiple comparisons and for implant age (p = 0.051), self-perceived health status (p = 0.434), or self-perceived rupture status (p = 0.145). Logistic regression was used to compute odds ratios of self-reported diagnoses comparing women with and without extracapsular silicone. The odds ratios were 2.8 (95% CI 1.2 to 6.3) for FM, and 2.6 (95% CI 0.8 to 8.5) for other CTD after adjustment for implant age, implant location, implant manufacturer, implant type, self-perceived health, self-perceived rupture status, and site of surgery practice.

CONCLUSION: These data suggest an association between extracapsular silicone from ruptured silicone breast implants and FM. If this association persists in other studies, women with silicone gel breast implants should be informed of the potential risk of developing fibromyalgia if their breast implants rupture and the silicone gel escapes the fibrous scar capsule.

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