Silicone breast implants linked to increased risk of some rare harms

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Women receiving silicone breast implants may be at increased risk of several rare adverse outcomes compared to the general population, reports a study in *Annals of Surgery*.

"We are reporting an analysis of the largest prospective study to date on silicone breast implant safety," comments Mark W. Clemens, MD, and colleagues of The University of Texas M.D. Anderson Cancer Center, Houston. "We are sharing critical information on complication rates and rare associations with systemic harms. This data gives women important safety information about silicone breast implants to have real expectations and to help them choose what is right for them." Based on an FDA-mandated "postapproval" database, the analysis is the largest study of breast implant outcomes to date.

First Analysis of Data Collected after Re-Approval of Silicone Breast Implants

In the early 1990s, the FDA prohibited the use of silicone breast implants in response to public concerns about health risks including cancer, connective tissue diseases, and autoimmune diseases. Subsequent research found no link between breast implants and these diseases. In 2006, the FDA approved silicone gel-filled implants from two manufacturers (Allergan and Mentor Corp), stipulating that the manufacturers conduct large postapproval studies (LPAS) to monitor long-term health and safety outcomes.

"Despite abundant data collection, and open public access, the LPAS database had not yet been analyzed and reported," according to Dr. Clemens. The researchers analyzed data on nearly 100,000 patients enrolled in the LPAS between 2007 and 2009-10. More than 80,000 patients received silicone implants; the rest received implants filled with sterile saline solution.

Seventy-two percent of the patients underwent primary breast augmentation, 15 percent had revision augmentation, 10 percent had primary breast reconstruction, and three percent had revision reconstruction procedures. The large size of the database enabled researchers to assess the risk of rare adverse outcomes.

Women receiving silicone implants were at increased risk of several rare harms compared to the general population. The elevated risks included three conditions classified as autoimmune or rheumatologic disorders: Sjogren's syndrome, with a risk about eight times higher than in the general population; scleroderma, a seven-fold increase in risk; and rheumatoid arthritis, about a six-fold increase in risk.

"These findings are associations compared to the general population and determining why these associations are observed or any causation requires further study," says Dr. Clemens.

Silicone implants were also associated with a 4.5-fold increase in the risk of stillbirth, but no significant increase in the risk of miscarriage. Risk of melanoma, a serious type of skin cancer, was nearly four times higher in women with silicone implants. There was no significant association with the risk of suicide, which had been suggested by a previous study. The database included just one case of breast implant-associated anaplastic large cell lymphoma—a rare but serious type of cancer previously linked to breast implants.

Compared to saline-filled implants, silicone implants were also linked to a higher risk of some surgical complications. These included capsular contracture (scarring around the implant), which occurred at a rate of 5.0 percent with silicone implants versus 2.8 percent with saline-filled implants. Capsular contracture occurred in 7.2 percent of primary breast augmentation procedures, and was the most common reason for reoperation in this group.

While certain rare harms appeared to be more common in women with silicone implants, absolute rates of these adverse outcomes were low. The researchers emphasize that their results are inconclusive, due to limitations inherent in the use of postapproval databases—including the lack of complete patient information and individual follow-up data.

"To resolve the remaining uncertainty in the evidence base, it is important that this data be analyzed in an unbiased manner," Dr. Clemens and coauthors write. "It remains the plastic surgery community's duty to provide definitive evidence for the risks associated with breast implants."

More information: "US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients" DOI: 10.1097/SLA.0000000000002990 , journals.lww.com/annalsofsurge …x?PRID=AOS_PR_091718

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