

Do breast implants cause cancer? The real facts about Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

March 28 2017 3:25 PM



GLEN CARBON - On March 21, 2017; the US Food and Drug Administration (FDA) released a safety communication to update the public about Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). This release is in response to

information provided by the American Society of Plastic Surgeons (ASPS) and American Society for Aesthetic Plastic Surgery (ASAPS) combined task force. The ASPS / ASAPS / FDA task force has been monitoring BIA-ALCL for approximately 7-8 years.

In the United States, there are 550,000 breast implants placed annually and approximately 70,000 of these implants are textured. From this we can estimate a lifetime risk of BIA-ALCL risk for patients with textured implants at 1 in 30,000 (0.0033%).

FDA's MAUDE database identified 359 cases of BIA-ALCL as of February 1, 2017. The FDA is aware of limitations of this database with limited information and potential duplicates. As such, the task force created the PROFILE database, which has identified 126 confirmed unique cases of BIA-ALCL as of the most recent report available.

One of the key findings of the research is related to implant texturing. Breast implant surfaces may be either smooth or textured depending on the needs of the patient. The texturing has been shown to decrease the rate of capsular contracture (hard fibrous capsule around the implant) when placed in certain anatomic locations.

The FDA databank identified 28 smooth implants with BIA-ALCL; however, some of the information is not provided and each of these smooth devices were placed where a textured device had been removed. This correlates with the PROFILE database. Further geographic differences in BIA-ALCL have been noted, although more research is needed.

It is important to realize BIA-ALCL is a unique form of ALCL. Also, that BIA-ALCL is not the same as breast cancer. BIA-ALCL is still being considered as cancer, but is behaving like a lymphoproliferative disorder, which is when the cells of the lymphatic system grow excessively. There has been no relation to fill material such as silicone.

The FDA MAUDE database identified 9 deaths worldwide from BIA-ALCL and we know there may be as many as 12 deaths identified. Upon further review, it was identified that each of these patients had a significant delay in diagnosis and/or did not follow appropriate treatment guidelines. Most patients with BIA-ALCL have successfully been treated with the removal of the implant and surrounding capsule. As of the most recent literature there is a 100% cure rate for those treated appropriately without a delay in diagnosis.

The key to treatment is identification of the symptoms. The condition usually presents as swelling of the breast 3-14 years after augmentation. This may also present as a lump in the breast or armpit (lymph nodes). If present, an ultrasound evaluation should be completed and fluid sent for laboratory analysis.

If a patient has textured breast implants and no symptoms, the consensus of the ASPS, ASAPS, and FDA is that no treatment is needed. The recommendation is to monitor for symptoms, and if symptoms occur to see a board certified plastic surgeon.

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