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Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Individuals with breast implants have a risk of developing breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer—it is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. Precise risks are difficult to determine due to lack of information about how many patients have received breast implants in the US and worldwide.

Background

In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL).

At that time, the FDA knew of so few cases of ALCL that it was not possible to determine what factors increased a patient's risk. In a report (http://wayback.archive-it.org/7993/20171115053750/https:/www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) summarizing the Agency's findings, we emphasized the need to gather additional information to better characterize ALCL in individuals (cis- and trans-gender women and men) with breast implants.

Over time, we have strengthened our understanding of this condition. In 2016, the World Health Organization (http://www.bloodjournal.org/content/127/20/2375) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global breast implant sales data (https://www.ncbi.nlm.nih.gov/pubmed/28157770). At this time, most data suggest that BIA-ALCL occurs following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

FDA Actions

We continue to collect and evaluate information about ALCL in individuals with breast implants.

On an ongoing basis, we:

- Receive and review medical device reports (MDRs).
- Review the current medical literature.
- Exchange information with other U.S. and international regulators and scientific experts.
- Review data from the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Etiology and Epidemiology (PROFILE Registry) (http://www.thepsf.org/research/clinical-impact/profile.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (a collaborative effort with the American Society of Plastic Surgeons (ASPS) and the Plastic Surgery Foundation (PSF)).
- Review information that breast implant manufacturers include about BIA-ALCL in their patient and health care professional labeling (/medical-devices/breast-implants/labeling-approved-breast-implants).
- Review information provided from on-going post-market studies.
- Monitor adverse events from other real-world data (e.g. National Breast Implant Registry (https://www.thepsf.org/research/registries/nbir) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

Current Status

Since 2016, there have been several advances in the description of the disease and treatment recommendations. These are summarized below:

- The World Health Organization (http://www.bloodjournal.org/content/127/20/2375) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) recognized breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a unique form of ALCL that can develop following breast implant, implantation.
- Professional organizations including the Plastic Surgery Foundation (https://www.thepsf.org/research/registries/profile) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and the National Comprehensive Cancer Network (NCCN) published information to help physicians understand the disease and provide diagnosis and treatment.
- Regulatory bodies outside the United States issued communications on BIA-ALCL.
    - The Australian Therapeutic Goods Administration (TGA) reported (https://www.tga.gov.au/alert/breast-implants) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) a detailed analysis of the 46 patients with confirmed cases of BIA-ALCL in Australia, including the deaths of 3 women. As of September 2016, TGA has confirmed 10 additional cases in Australian patients.
    - The French National Agency for Medicines and Health Products Safety (ANSM) asked manufacturers of textured breast implants to perform biocompatibility testing (http://ansm.sante.fr/var/ansm_site/storage/original/application/aa533f4eacc8b36bd6504894235f7f29.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (testing to determine how living tissues react to textured implants) and to report their findings.

Medical Device Reports

As of September 30, 2018, the FDA had received a total of 660 medical device reports (MDRs) (/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma) of BIA-ALCL, including the death of nine patients.

Of the 660 total BIA-ALCL related MDRs the FDA received, many MDRs were identified as duplicate reports, including additional follow-up reports that were submitted to the FDA. The FDA has carefully reviewed the 660 MDRs to provide a more accurate analysis and to only provide unique BIA-ALCL reports. The resulting data reflected a total of 457 unique MDRs for BIA-ALCL.

While the MDR reports provide information regarding the implant at the time of BIA-ALCL diagnosis, they do not typically give information about a patient's history of breast implants. It is important to note that at the time of diagnosis, patients may have their original breast implants or they may have had one or more replacements.

The MDR system is a valuable source of information. However, it depends on accurate reporting, and therefore may contain incomplete, inaccurate, untimely, unverified, or biased data. Over time, we may gather more information about a report and thus the numbers listed above may change.

In addition, it is difficult to determine the total number of cases or estimate risk from the MDR reporting system due to potential under-reporting of events, possible duplicate reporting, and lack of data about the exact number of breast implants.

Medical Literature

A significant body of medical literature (https://www.ncbi.nlm.nih.gov/pubmed/?term=breast+AND+%28implant*+OR+prosthesis+OR+prosthes*+OR+endoprosthes*%29+AND+lymphoma*) has been published since our 2011 report (http://wayback.archive-it.org/7993/20171115053750/https:/www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), including additional case histories and comprehensive reviews of the natural history and long-term outcomes of the disease. Most of the cases reported in the literature describe individuals who have had textured implants. Several recent journal articles explore possible risk factors for developing BIA-ALCL, including the methods used to create the textured surface and the role of biofilm. Most of the published information about treatment describes removal of the implant and the capsule surrounding the implant, and in some patients, treatment with chemotherapy and radiation.

Several recent publications have estimated the risk of developing BIA-ALCL in individuals with textured breast implants. Current literature reported various estimates that BIA-ALCL may develop in 1 in between 3,817 to 30,000 women with textured breast implants (Clemens et al, (https://www.plasticsurgery.org/for-medical-professionals/quality-and-registries/bia-alcl-by-the-numbers) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 2017; Loch-Wilkinson et al, 2017 (https://insights.ovid.com/pubmed?pmid=28481803) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm); De Boer et al, 2018).

Recommendations

Health Care Providers:

If you have patients with breast implants, you should continue to provide them routine care and support. BIA-ALCL has been identified in patients undergoing implant revision operations for late onset, persistent seroma (fluid collection around the implant). Because BIA-ALCL has generally only been identified in patients with late onset of symptoms such as pain, lumps, swelling, or breast asymmetry, prophylactic breast implant removal in patients without signs or symptoms is not recommended.

Current recommendations from the Plastic Surgery Foundation and the NCCN include the steps below.

- Prior to implantation, provide all patients with the breast implant manufacturer's labeling, including the patient-specific labeling, as well as other educational material and make sure they are aware of the benefits and risks of the different types of implants. Most confirmed cases of BIA-ALCL have occurred in patients with textured surface implants, although there are known cases in patients with only smooth-surface breast implants.
- Consider the possibility of BIA-ALCL when treating a patient with late onset, peri-implant seroma. In some cases, patients presented with a mass or masses adjacent to the breast implant. If you have a patient with suspected BIA-ALCL, refer the individual's case to a multidisciplinary team for evaluation.
- When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule and send for pathology tests to rule out BIA-ALCL. Diagnostic evaluation should include cytological evaluation of seroma fluid or mass with Wright Giemsa stained smears and cell block immunohistochemistry / flow cytometry testing for cluster of differentiation (CD30) and Anaplastic Lymphoma Kinase (ALK) markers.
- Develop an individualized treatment plan in coordination with the patient's multi-disciplinary care team. Consider current clinical practice guidelines, such as those from the Plastic Surgery Foundation or the National Comprehensive Cancer Network (NCCN) when choosing your treatment approach.
- Report all confirmed cases of ALCL in individuals with breast implants to the FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home). Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.
- Submit case reports of BIA-ALCL to the PROFILE Registry (http://www.thepsf.org/research/clinical-impact/profile-investigating-breast-implant-associated-alcl.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to contribute to a better understanding of the causes and treatments of BIA-ALCL.

Patients:

Educate yourself about breast implants before agreeing to surgery. Breast implants approved in the U.S. can be filled with either saline or with silicone gel. They come in different sizes and shapes and have either smooth or textured surfaces (shells). Additional information is available on FDA's Breast Implants website (/breast-implants).

Before getting breast implants, make sure to talk to your health care provider about the benefits and risks of both textured-surface and smooth-surfaced implants.

If you have breast implants, there is no need to change your routine medical care and follow-up. You should expect swelling and pain immediately after surgery. If you notice changes in the way your breast looks or feels after you recover from surgery—including swelling or pain around the implant—be sure to talk to your health care provider about the possibility of BIA-ALCL.

Although not specific to BIA-ALCL, you should follow standard medical recommendations including:

- Follow your doctor's instructions on how to monitor your breast implants. If you notice any changes, contact your health care provider promptly to schedule an appointment.
- Follow your doctor's instructions for routine mammography screening. Be sure to inform the mammography facility that you have breast implants so enough time is scheduled for your mammogram. Your doctor may also recommend other tests, such as magnetic resonance imaging (MRI).

To improve our understanding of BIA-ALCL, please continue to report all confirmed cases of BIA-ALCL, with as much detail as possible, through FDA's MedWatch Program (/medwatch-fda-safety-information-and-adverse-event-reporting-program).

We will continue to report on significant findings as new information and analyses become available.

Related Information

- Statement from FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., and Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health on FDA's new efforts to protect women's health and help to ensure the safety of breast implants (/news-events/press-announcements/statement-fda-principal-deputy-commissioner-amy-abernethy-md-phd-and-jeff-shuren-md-jd-director-fdas)
- Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) - Letter to Health Care Providers (February 6, 2019) (/medical-devices/letters-health-care-providers/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl-letter-health-care-providers)
- Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma (/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma)
- Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) (/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl)
- Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings and Analyses (http://wayback.archive-it.org/7993/20171115053750/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)