BIA-ALCL Resources

By the numbers, and what they mean

By Mark Clemens, MD

On July 24, 2019, the U.S. Food and Drug Administration (FDA) released a safety communication updating the current understanding of BIA-ALCL, the number of known worldwide cases, and calling for a voluntary recall of higher risk devices. Many members have expressed confusion over much of the data surrounding BIA-ALCL. The purpose of this document is to discuss and bring clarity to some of the figures surrounding this rare disease.

573

The recent BIA-ALCL update reported that the FDA has been made aware of 573 unique and pathologically confirmed BIA-ALCL cases worldwide related to breast implants. This is in comparison the FDA previously reporting 660 medical device reports (MDRs) in March 2019, 414 MDRs in March 2018, 359 MDRs in March 2017, 258 MDRs in January 2016 and 64 MDRs in January 2011. For the first time, the FDA has systematically reviewed the MDRs, removed duplicates, in an effort to identify unique cases meeting the pathologic criteria of BIA-ALCL. When a manufacturer was listed, the FDA reports 90.5% of world cases involved an Allergan implant, 7.1% Mentor implants and 1% Sientra implants.

4.5%

The recent FDA update of 573 reports included 26 (4.5 percent) smooth implant reports. This is similar to last year's update of 414 reports in 2018 including 30 (7 percent) smooth implants and 359 reports in 2017 including 28 (8 percent) smooth cases, and 258 patients which included 11 (4 percent) smooth implant reports in 2016. Very important, in the 26 cases of smooth implants, 12 have unknown prior history of implants, 7 have a history of textured implants, and 7 have a history of prior implants with an unknown texture. There are no reports of cases associated with

tissue expanders. **To date, no purely clinical history of purely smooth-surface devices and BIA-ALCL has ever been reported in any series, registry or case report with a detailed history.** The FDA confirms that BIA-ALCL is predominantly associated with textured surface implants.

33

The FDA reports 33 unique deaths worldwide. While seroma is the most common presentation for all BIA-ALCL cases (53%), a capsular mass was the most common presentation among the deaths (39%) likely indicating more advanced and invasive disease.

288

288 suspected/confirmed United States cases have been reported to the PROFILE registry. The PROFILE registry is a joint collaboration between the FDA and ASPS/PSF to prospectively track BIA-ALCL patients. Based upon a global network of international plastic surgery societies sharing tracking of cases, ASPS is now aware of 735 unique cases worldwide.

1:2,207-86,029

The current lifetime risk of BIA-ALCL is estimated to be a range of 1:2,207 - 1:86,029 based upon variable risk with different manufacturer types of textured implants. US Epidemiology was reported in 2017 with an overall textured implant risk of 1:30,000 Importantly, this was an average of Allergan and Mentor textured implants which were demonstrated to have a 6:1 ratio. BIA-ALCL cases from the Allergan prospective CA/CARE trial have been reported to demonstrate a risk of 1:2,207 with Allergan Biocell. This year, researchers in Australia and New Zealand reported a 1:3,345 risk with Allergan Biocell and a 1:86,029 risk with Mentor Siltex.

1,400

There are 1,400 patients per year diagnosed with ALCL. ALCL is a family of diseases from the very aggressive systemic ALCL to the indolent lymphoproliferative disorder primary cutaneous ALCL. For the first time in 2016, the World Health Organization added BIA-ALCL as a provisionally recognized lymphoma to the family of existing ALCL. It is important to differentiate BIA-ALCL from primary lymphoma of the breast which is predominantly a B-cell lymphoma with an incidence of approximately 1:4 million. ALK+ disease and B cell pathology should be concerning for primary lymphoma of the breast rather than BIA-ALCL.

5%

Approximately 550,000 total breast implants are placed per year in the U.S. Of these, approximately 70,000 textured breast implants are placed, representing 12.7 percent of the market as of 2017. In March 2019, the FDA reported that this market share may have recently decreased to approximately 5%.

93%

93 percent of patients are disease free at 3 years follow-up, which is an excellent prognosis when treated appropriately. The National Comprehensive Cancer Network defines optimal treatment which is total capsulectomy and implant removal for the majority of patients with disease confined to the capsule (35 percent of patients) or a resectable mass (40 percent of patients). Advanced disease with lymph node metastasis (14 percent of patients) or organ metastasis (1 percent of patients) may require further treatment with chemotherapy using either CHOP anthracycline based-protocol and/or targeted immune therapy with brentuximab vedotin. Radiation therapy is only reserved for local unresectable disease such as into the chest wall and mediastinum. Advanced disease is the end of the spectrum of cancer stages, and these patients substantiate the World Health Organization classification of BIA-ALCL as a lymphoma and not benign or lymphoproliferative.

30

For a suspected patient with a delayed seroma (>1 year), a minimum of 50ml fluid should be aspirated and sent for CD30 immunohistochemistry, cytology and flow cytometry. CD30 is the main diagnostic test that must be performed on the seroma fluid as routine pathology or H&E staining can frequently miss the diagnosis.

**Page last updated on August 5, 2019*

BIA-ALCL RESOURCES

- **BIA-ALCL Summary and Quick Facts (08/2019)**
- **BIA-ALCL By The Numbers (08/2019)**
- **Allergan Announces Worldwide Recall of Biocell Textured Implants (07/2019)**
- **BIA-ALCL Sample Letter To Patients (07/2019)**
- **BIA-ALCL Safety Advisory (06/2019)**
- **Free Educational Brochure: What Patients Need to Know (03/2018)**
- **ASPS Literature on BIA-ALCL**

- ASPS Recommended Insurance Coverage Criteria for Third-Party Payers
- BIA-ALCL NCCN Guidelines (Free Registration)
- Free CME Class on BIA-ALCL
- Informed Consent Language (02/2019)
- PRS BIA-ALCL Supplement
- BIA-ALCL Patient Resources

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