Joint effort on BIA-ALCL – what you need to know

BY NEAL REISMAN, MD, ID & MARK CLEMENS, MD

Editor's note: Breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL) is an entity rapidly gaining attention. The condition is rare and appears to have at least two pathways depending on pathology. ASPS and ASAPS are each working to disseminate information to plastic surgeons, as well as to gather research to better understand how to recognize, diagnose and treat this entity. ASPS under the leadership of Mark Clemens, MD, a RAND panelist on BIA-ALCL and chair of ASPS BIA-ALCL Subcommittee, and Neal Reisman, MD, JD, president of ASERF and chair of an ASAPS International Taskforce, are working together to better understand this entity.

hen faced with a patient who may be presenting with BIA-ALCL, there are several patient safety issues that are important to understand - including the need for early, total and complete removal of the implants and evaluation. The following case, which has been assembled through specific details taken from several examples and compiled into the following scenario, is neither related to nor representative of any particular or individual case. As such, it has no direct relation to any person or patient. Any similarity to any individual patient is wholly coincidental and should not be assumed.

Ginny is 10 years post-breast augmentation, with one replacement and capsulectomy five years ago for capsular contracture in her right breast. She now presents without a history of trauma - but with significant swelling in her same right breast. Ginny was told about BIA-ALCL and she has kept all of her follow-up appointments. She remembers her plastic surgeon explaining about the possibility of future expenses when necessary.

An ultrasound depicts fluid around the implant, yet no masses or lymphadenopathy are observed. Bright, yellow fluid is aspirated and sent for cultures, cytology, CD-30 immunohistochemistry and cell block - all with a call to the pathologist indicating a suspicion of BIA-ALCL.

Pathology is able to use the fluid to diagnose BIA-ALCL and plans are made for a multidisciplinary review, which suggests preoperative workup with PET CT scan, implant removal, total capsulectomy and formal pathology of the effusion, capsule and tissue.

The diagnosis of breast implant-associated ALCL triggers Ginny's insurance coverage. The patient is fortunate in the malignant cells are confined to the fluid, with no pathological signs of invasion into or outside the capsule. This favorable situation usually dictates that no further treatment will be needed

Discussion

It's important to have a preoperative financial agreement with the patient that covers future possible expenses such as lab tests, radiology and pathology specimen, should a BIA-ALCL entity be suspected. It has been established that early recognition and appropriate treatment for the condition can have a very positive result. Having such an agreement in place assists with the understanding of the importance of routine follow-up - especially if a change in breast shape occurs. The usual presentation is a unilateral swelling of a breast, absent a history of trauma.

Informed-consent documents should include information about BIA-ALCL to promote patient follow-up and help ensure that the patient understands that future expenses would be incurred should the course change. This information should reflect the need for recognition of symptoms and early diagnosis of this very rare entity, and for patients to follow-up with their surgeon if they occur. The incidence of BIA-ALCL is reported to be three in 100 million. In other words, of the tens of millions of women who've received implants over the past 50-plus years, there have been approximately 150-160 reported cases worldwide.

BIA-ALCL should be discussed with patients as an extremely rare entity. Patients experiencing unilateral swelling and a change in breast shape should be encouraged to return for follow-up and be aware of the additional financial issues associated with investigations.

It's also a good idea to have a revision policy that includes future revisions as determined by the surgeon along with the patient, for some finite period as long as the patient keeps appointments and follows recommended post-op care and instructions.

This vigilance is important for diagnosing BIA-ALCL, as the plastic surgeon may be the best to suspect this rare entity as well as understand the necessary diagnostic tests and studies. These may include an ultrasound of the breast(s), mammogram when indicated, aspiration for cytology (CD30 immunohistochemistry), cell block and cultures. Formal discussion with the pathologist is recommended.

The exact "cause" of ALCL remains unproven. One observation suggests textured implants may have some increased association, and early research indicates a bacterial biofilm around implants may also have an association. Whatever the source, the association of implants and BIA-ALCL is real but the rarity of this entity limits definitive conclusions. Further ongoing research by Dr. Clemens, ASPS/PSF initiatives, ASERF-sponsored studies and other research may help elucidate this association.

Early diagnosis and treatment appear to result in a successful resolution when the tumor cells are confined within the capsule without invasion. A more severe course may occur when tumor cells have invaded the capsule or are present outside of the capsule.

Please report any cases to The PSF's Patient Registry and Outcomes For Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) registry, as a mechanism to prospectively track patients and outcomes. To add this critical information to the registry, go to thepsf.org/PROFILE. 🖪

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Nominations must be submitted by

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The 2015 honoree was Joseph G. McCarthy, MD, New York, who has made many outstanding contributions to the specialty of plastic surgery, including the development of the concept of craniofacial distraction, which revolutionized the discipline of craniofacial surgery.

Any ASPS member may nominate one or more individuals for the award. Names of candidates and supporting documentation should be submitted in writing to ASPS Trustees Chair Michael McGuire, MD, at awards@plasticsurgery.org; by fax to 847-709-7517; or by mail to Dr. McGuire, c/o ASPS Executive Office, 444 E. Algonquin Road, Arlington Heights, IL

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