What is BIA-ALCL?

Information for Healthcare Professionals

Leigh Day

What is BIA-ALCL?

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare type of lymphoma that can develop primarily around breast implants. BIA-ALCL is rare, but it is important healthcare professionals and patients who have implants know about it.

BIA-ALCL occurs in patients who have textured breast implants (or at least a history of a textured implant when a smooth implant is currently in place) with both silicone and saline implants. To date, there are no confirmed BIA-ALCL cases that involve only smooth implants.

The Medicines and Healthcare products Regulatory Authority (MHRA) is currently investigating the causes of BIA-ALCL and confirms that research is yet to provide a definitive answer as to how BIA-ALCL develops, although there are several competing theories including that the surface texturing on implants may play a role in how some patients react to having an implant in place. Research is ongoing in the UK and worldwide to better understand how BIA-ALCL develops.

Common symptoms

The most common symptom for patients is to present with is a 'late' seroma (a collection of fluid developing at least 1 year following implant) around the breast implant. Very rarely BIA-ALCL has been found when a lump develops next to an implant, or within the tough fibrous tissue, which can build up around an implant (referred to as the capsule).

Patients may also present with a lump in the breast or armpit, an overlying skin rash and/or hardening of the breast. The onset of BIA-ALCL has been reported to range between 2 and 28 years after breast implantation, most commonly occurring between 7 and 10 years post implantation. Unilateral presentation is much more common than bilateral.

Treatment

Cure for early-stage disease (accounting for the majority of patients) can be achieved via complete capsulectomy and implant removal. This is specifically the case when the disease is diagnosed at a presumed early stage when a seroma is contained within the capsule, having not spread to the breast parenchyma, axillary lymph nodes, or underlying bone and other tissue. In these cases en bloc removal of the implant, capsule and contained seroma should be performed where possible.

In later stage cases, chemotherapy and/or radiotherapy may be required, with anecdotal evidence suggestive of superior outcomes with brentuximab vedotin over the standard T cell lymphoma CHOP treatment. If untreated, BIA-ALCL can lead to death. As at July 2019, there were 33 reported deaths worldwide attributable to BIA-ALCL.

Incidence rates

In the UK, the estimated risk of BIA-ALCL, based on the reported confirmed cases, is 1 per 19,000 textured implants. However, significant barriers exist to the accurate estimate of both the number of women with implants and the number of cases of BIA-ALCL, including poor registries, underreporting, lack of awareness, cosmetic tourism and fear of litigation. The incidence and risk of BIA-ALCL have increased dramatically from initial reports of 1 per million to current estimates of 1 per 2,832, and is largely dependent on the "population" (implant type and characteristics) examined and increased awareness of this malignancy.

The estimated lifetime risk of BIA-ALCL with textured implants, in general, ranges widely from 1:1,000 to 1:30,000 breast implants, these figures represent the average risk when sampling a given study population, which contains several implant manufacturers with both high and low risk devices. Risk appears to narrow when reported as implant and manufacturer- specific risk.

Yellow card

If your patient develops any issue with a breast implant please ask them to report it through the MHRA Yellow Card Scheme: https://yellowcard.mhra.gov.uk/. If your patient presents with the above symptoms, ask whether they have breast implants and if they do, make an urgent 2 week referral for to the breast clinic for further investigation which is typically via an ultrasound or MRI to check for fluid or lumps. If fluid is found, aspiration and testing for BIA-ALCL should be performed which has specific diagnostic criteria including uniform positive expression for the marker CD30 and negativity for ALK. Please refer to the 2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

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