BIA-ALCL – an update

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Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) has emerged from an inconspicuous case report in 1997(1) to be recognised as a unique disease by the World Health Organisation in 2016(2). As of July 2019, there have been 59 confirmed reports in the UK(3), and about 600 cases worldwide with 33 deaths(4). Early BIA-ALCL is highly curable with implant removal and total capsulectomy.

BIA-ALCL risk estimates

The risk estimates have changed appreciably over the last 5-years as better data emerges. In 2014 it was thought to affect 1 in 500,000 to 1 in 3,000,000 patients with breast implants(5) but recent figures from the MHRA estimate a risk of 1 in 24,000 per breast implant, based on overall UK implant sales data(3). Whilst world wide variation in incidence may exist due to genetic predisposition, risk estimates are very dependent on accuracy of diagnosis (false negatives are a problem(6)), case reporting and crucially knowing the true denominator (number of implanted people as well as type and texture).

Two recent publications where the denominator for Allergan textured implants was precisely known give much higher risk estimates of 1 in 2,195 at median follow-up of 4-years(7), and 1 in 354 at a median follow up of 7-years (8,9). We await further data to clarify the true risk, but these recent publications are concerning.

Informing patients of the risks of BIA-ALCL

All breast surgeons must carefully counsel any individual considering breast implants (smooth or textured) whether for reconstruction or cosmesis, regarding known implant risks. This must include BIA-ALCL, how it presents, what to look for, and what to do if they have any future concerns. This is particularly relevant when early BIA-ALCL is highly curable.

If and how we update women whose implants were inserted before the risks of BIA-ALCL were widely appreciated, has not as yet been clarified and would be a major logistical challenge. Whether we should raise awareness of BIA- ALCL through a concerted public health campaign, advertising in the national press and through cancer charities is uncertain and remains a topic of discussion. The MHRA(3), ABS(8) and Breast Cancer Now(9) all have information about BIA-ALCL on their web sites.

Meanwhile we are seeing increasing numbers of anxious people in clinics who have first come across BIA-ALCL from sensationalist media reports, or information on social media that is often unbalanced and incites disproportionate fear. The recent article by Patricia McGuire, provides practical guidance for the MDT and worried patients(10).

Presentation and Investigation

The National Comprehensive Cancer Network (NCCN) consensus guidelines(11) and the more recent UK pathology guidelines(11) are excellent resources for the breast MDT providing comprehensive recommendations for investigation and diagnosis of BIA-ALCL. A short summary of the guidance is provided below.

Presentation

The most common symptomatic presentation in the UK and other series, is with a highly visible breast swelling and/or a lump(5, 12). However, less common presentations do occur including a more subtle seroma, a breast rash, intense itching, or in association with capsular contraction. More advanced presentations may have a mass in the breast or regional nodes. Night sweats or weight loss may be indicative of systemic disease.

Investigation

All patient with breast symptoms and implants should undergo a standard breast (triple) assessment but the key to diagnosis of BIA-ALCL is aspiration of ALL the peri implant fluid for cytology (with a small quantity being sent for MC&S) and/or biopsy of any associated mass. The pathology form must request "assessment for possible BIA-ALCL." Detailed guidance can be obtained from the above references on the ABS platform(8).

If cytology is positive for BIA-ALCL

Refer to a centre with MDT experience in the diagnosis and management of BIA-ALCL.

If the cytology is negative

It is likely that the patient has a benign seroma. Even if the seroma resolves after initial aspiration it is recommended the patient is followed up clinically and future investigations determined by symptoms.

But if the seroma fails to resolve, or a significant index of suspicion remains, consider the possibility of a false negative result, consider repeat testing or preferably refer to a centre with MDT experience in the diagnosis and management of BIA-ALCL.

In a small number of a patients a diagnostic (en bloc) total capsulotomy may be required. This is a major undertaking with significant implications for the patient and should only he performed in centres with the necessary MDT expertise.

Regulatory reporting

On pathological confirmation of BIA-ALCL it is mandatory to

1. report to the MHRA using the yellow card scheme for a medical device incident: (https://yellowcard.mhra.gov.uk/)
2. as well as record the new diagnosis on the Breast Implant Registry: (https://clinicalaudit.hscic.gov.uk)

Conclusion

BIA-ALCL is a new disease. Clinicians faced with anyone who has breast symptoms and a breast implant must now always consider the possibility of BIA-ALCL and the breast MDT need to be familiar with the diagnosis and treatment guidelines.

BIA-ALCL is an uncommon disease, so clinicians should have a low threshold to seek advice from tertiary centres with MDT expertise in the management of BIA-ALCL.

Figure 1: Inner aspect of capsule opened across its inferior pole, demonstrating a grossly abnormal appearance caused by BIA-ALCL.

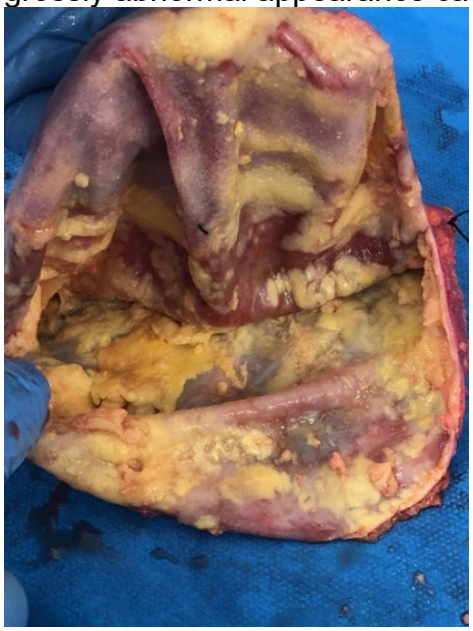
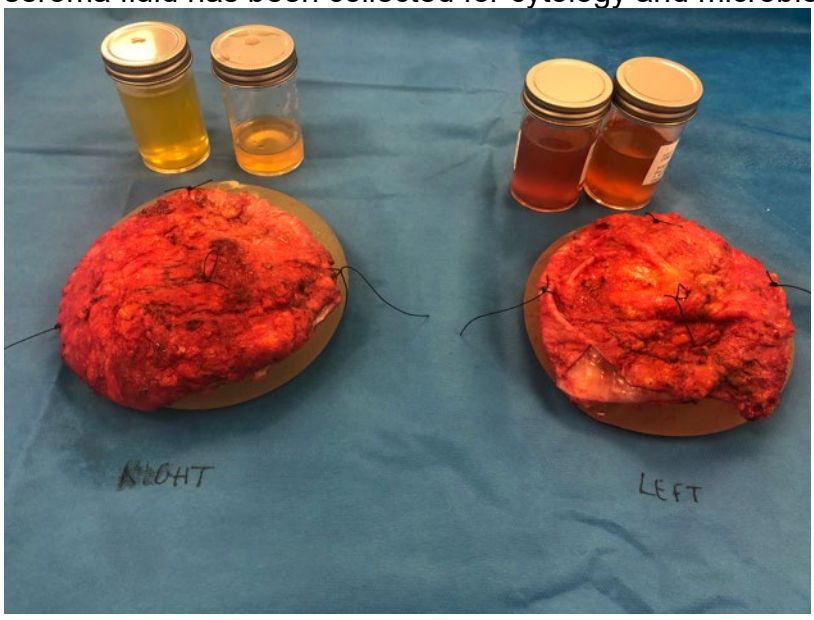


Figure 2. After en bloc capsulectomy the capsules have been orientated with a 2-0 silk suture (short superior, long lateral, medium medial and double loop anterior) after removing the implant via an inferior clam shell capsulotomy. Peri-implant seroma fluid has been collected for cytology and microbiology.



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