Breast Implant Associated Anaplastic Large Cell Lymphoma – Supporting Information

Introduction

BIA-ALCL is a rare type of non-Hodgkin's Lymphoma, occurring in individuals who have breast implants. It was given World Health Organisation (WHO) provisional recognition as a type of ALCL in 2016.

The US Food and Drug Administration (FDA) collects medical device vigilance data via its Medical Device Reporting (MDR) System. From analysis of their medical device reports, the FDA have reported that, of the 573 cases of BIA-ALCL, 481 cases are associated with Allergan BIOCELL implants and that, of the 13 deaths attributed to BIA-ALCL where the manufacturer was known, 12 of the cases were associated with Allergan BIOCELL implants. The FDA have estimated that the risk of BIA-ALCL associated with Allergan BIOCELL implants is approximately 6 times the risk of other textured implants.

The most common presentation of BIA-ALCL is a large spontaneous periprosthetic fluid collection occurring at least one year, and on average 7-10 years, following breast implant surgery. Up to 24% of patients may present with an associated palpable mass and up to 12% may have lymphadenopathy. Less commonly described (<5% of cases) are local and systemic symptoms including skin rash and fevers [1].

Implant Surface Texturing and BIA-ALCL

Breast implants may have a range of surface textures of an increasing degree of texturing; these are commonly known as smooth, microtextured, macrotextured or Polyurethane Foam Coated. There are a number of different systems that can be used to categorise the surface texture of breast implants, including standard ISO14607. In general, average surface roughness can vary significantly between implants from different manufacturers. The degree of texturing is thought to affect the ability to successfully position the implant and to reduce the risk of contracture of the capsule over time. Higher average surface roughness may be associated with lower rates of capsular contracture and implant malposition.

The risk of developing BIA-ALCL appears to be related to the degree of surface texturing, with higher rates of the disease seen in individuals with macrotextured or polyurethane foam coated surfaces. A range of breast implants with different degrees of surface texturing have been used in Ireland.

BIOCELL is a proprietary surface texturing technique based on salt elution, to produce a macrotextured surface. Allergan implants with a BIOCELL surface had been commonly used in Ireland prior to a European recall of these implants in December 2018. The BIOCELL surface was used in a range of Allergan breast implants including:

- Natrelle Inspira Textured (But not Natrelle Inspira Smooth implants),
- Natrelle 410 and 510
- Tissue Expanders

Please note that these implants may have been previously marketed under the brand names 'McGhan' or 'Inamed'. For a full list of implants affected by the December 2018 recall, please see the Field Safety Notice on the HPRA website.

Other breast implants may have a different risk of developing BIA-ALCL and the risk appears to be related to the degree of surface texturing on the breast implant. Implants with a lesser degree of surface texturing appear to have a less common association with BIA-ALCL. A range of breast implants with different degrees of surface texturing have been used in Ireland.

In reports made to medical device regulators worldwide, the majority of cases of BIA-ALCL have been seen in Allergan BIOCELL implants. A recent journal article estimated there is one case of BIA-ALCL for every 3,345 of these specific implants used [2].

Reporting cases of BIA-ALCL to the HPRA

As part of its role of monitoring the safety of medical devices on the market in Ireland, the HPRA maintains a vigilance reporting system which receives reports from users, members of the public and manufacturers, in relation to medical device issues. It is important to report all cases of BIA-ALCL to the HPRA, to help us make informed decisions on the safety of these devices. We would encourage you to report any case of BIA-ALCL that you have encountered and the following data would greatly aid the follow-up of these cases (Please note patient identifying information is not required on this reporting portal):

- Device details (Manufacturer and Model, Surface Texture of the implant)
- Implantation date details (Initial, Revision and Explantation if applicable)
- Diagnostic specifics of the ALCL (including CD30 and ALK status)
- Details of any previous implants
- Clinical Symptoms and Management to date

The portal for reporting these cases, and any medical device incident, can be found on our website. Please contact us if you have any further queries about this information notice.

Breast Implant Illness

Some individuals who have breast implants may describe systemic symptoms such as joint pain, rashes, memory loss, 'brain fog' or other symptoms. These symptoms and what causes them are not well understood at this time. Some individuals and some health researchers have used the term 'Breast Implant Illness' to refer to the experiencing of these symptoms in association with having breast implants. There is ongoing research to try to understand these symptoms and their origin.

It is very important that individuals with breast implants, and the healthcare professionals who look after them, are aware that 'Breast implant illness' and BIA-ALCL are different conditions with different symptoms, treatment options and outcomes.

1. Clemens, MW. Et al, 2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant Associated Anaplastic large Cell Lymphoma Aesthetic Surgery Journal 2019, Vol 39(S1) S3–S13.
2. The Epidemiology of Breast Implant–Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand Confirms the Highest Risk for Grade 4 Surface Breast Implants. Magnusson M. et al. *Plast. Reconstr. Surg. 143: 1285, 2019*.