Breast implants and Anaplastic Large Cell Lymphoma (ALCL)

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Information for clinicians and patients.

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What is ALCL?

Anaplastic Large cell Lymphoma (ALCL) is a rare type of non-Hodgkin's lymphoma of which there are several sub-types. In 2016, World Health Organisation defined a specific type of ALCL called Breast Implant Associated Anaplastic Large Cell Lymphoma or BIA-ALCL*.

This has specific diagnostic criteria which are ALK- and CD30+.

MHRA's investigation into BIA-ALCL is ongoing and as with all issues we take an evidence-based approach. Research into this area is yet to provide a definitive answer as to how BIA-ALCL develops although there are several competing theories.

Current UK advice

Patients

The most common symptom for ALCL in women with breast implants is a seroma (a collection of fluid) that forms around the breast implant six months or more after the breast implant surgery.

Most cases have happened years after surgery. Very rarely it has been found when a lump develops next to the implant or within the tough fibrous tissue building up around the implant (known as capsular contracture).

ALCL is very rare but it is important healthcare professionals and women who have implants know about it. If you develop a seroma, a breast lump or swelling around

your implant more than six months after having the breast implant (regardless of how many years later), you should seek advice from your surgeon or clinic.

If the surgeon or clinic which did the original implant operation is no longer available then the patient should see their GP for referral to another surgeon.

As with any implant it is important anyone undergoing breast implant surgery discusses the risks and benefits with their surgeon.

If you have had an issue with a breast implant you should report it via the Yellow Card Scheme so we can investigate further.

Clinicians

When reporting a case of ALCL in patients with breast implants, please include:

- diagnostic criteria e.g. CD30+/-, ALK +/- status
- device details e.g. manufacturer, model, surface texture
- clinical outcomes

To enable MHRA to build an accurate picture of the prevalence of this issue, reports should be made to MHRA via the Yellow Card Scheme.
Please also ensure patients are informed about the Breast and Cosmetic Implant Registry (BCIR) and given the option to consent to their information being recorded.

MHRA actions

Patient safety is our highest priority. MHRA continues to collect and analyse information from UK healthcare professionals and other sources about this issue in order to build a fuller picture of the occurrence of this rare disease in association with breast implants.

Medical Device Alerts (MDA)
MHRA has informed surgeons about the potential risks of ALCL in woman with implants in two Medical Device Alerts issued in February 2011 (MDA/2011/017) and July 2014 (MDA/2014/027).

Both alerts advise surgeons to strongly encourage patients to check for symptoms such as lumps, swelling or distortions through continued regular self-examination and to consult their doctor if they have concerns.

MHRA regularly reviews the information it provides to hospitals, clinics and surgeons to determine if any updates are required. Further or updated advice is issued as appropriate.

Formation of an expert advisory group

We have formed an independent expert advisory group, the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG), who are already engaged in the process of reviewing risks associated with breast implants.

The group in the first instance have been tasked to consider BIA-ALCL, with the aim to provide a greater understanding of the disease and potential risk to patients and will help to guide any future necessary MHRA action. PRASEAG members represent specialties which include breast and reconstructive surgery, toxicology, and imaging. There is also a patient advocate on the group.

Collaborations

UK

We work closely with clinical stakeholders including the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), Association of Breast Surgeons (ABS) and the British Association of Aesthetic Plastic Surgeons (BAAPS).

EU

MHRA is part of an EU Task Force monitoring BIA-ALCL with the aim of getting a Europe-wide picture of the issue.

The Breast and Cosmetic Implant Registry (BCIR)

The Breast and Cosmetic Implant Registry (BCIR) was launched by NHS Digital in October 2016 to capture the details of breast implant procedures undertaken in England by both the NHS and independent healthcare providers.
The registry aims to provide the data needed to detect any early safety signals in relation to an implant and provide a mechanism for managing patients in the event of an implant recall. This will further aid MHRA in its role of monitoring the safety of breast implants for patients.

The European Commission's Scientific Committee on Health, Environmental and Emerging Risks

The European Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has a mandate to provide advice on the state of scientific knowledge regarding a possible connection between breast implants and anaplastic large cell lymphoma. SCHEER published their preliminary scientific advice in April 2017.

Additional information on ALCL

UK professional associations

- British Association of Aesthetic Plastic Surgeons (BAAPS)
- British Association of Plastic Reconstructive and Aesthetic Surgeons(BAPRAS)
- Association of Breast Surgery (ABS)

Regulatory agencies from outside the United Kingdom

- The Australian Therapeutic Goods Administration (TGA)
- The United States Food and Drug Administration (FDA)

Footnote

*'A provisional WHO entity distinguished from other ALK- ALCL' – Blood Journal, Swerdlow, S.H, (2016), Vol. 127, No. 20, p.5