Safety Information Message

Reference **SIM2113** Issued **15 Dec 2021** Review Date **15 Dec 2021**

Information about Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) for people with breast implants (update)

Summary

MHRA has updated information on breast implant associated anaplastic large cell lymphoma (BIA-ALCL) for people with breast implants. This notice supersedes SIM2112.

Action

Bring this notice to the attention of all appropriate managers, staff and contractors

Background

The Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) produced advice about BIA-ALCL in November 2021 for people with breast implants. The advice was produced at the request of the Medicines and Healthcare products Regulatory Agency (MHRA) and it is in the form of questions, asked of clinicians in consultation with their patients.

This information has been updated and it can be accessed as a webpage here and a copy can be found in the annexe to this notice. In addition, information is available on a dedicated webpage produced by MHRA in 2017. This resource provides background information for patients, public and healthcare professionals about BIA-ALCL and it is updated regularly.

MHRA published MDA/2018/027 in July 2018 with a request to report all suspected cases of BIA-ALCL to MHRA or respective devolved administrations (report an incident). IRIC is responsible for notifying all Scottish medical device incidents, including BIA-ALCL, to MHRA.

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.

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Information about BIA-ALCL for people with breast implants

Introduction

This advice has been written by the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) at the request of the Medicines and Healthcare products Regulatory Agency (MHRA – UK regulator). It is in the form of questions, asked of clinicians in consultation with their patients. Further information about PRASEAG can be found at the end of the document.

In summary

- *If you have a breast implant(s) and no breast changes but are worried about your breast implants and BIA-ALCL, please read the information below. If you are still worried, please contact your implant surgeon, clinic or hospital where the implant was inserted.*

- *If you have a breast implant and experience unexpected changes in size, shape or feel of your breast, please see your GP for a referral to the local NHS breast unit to be checked. It does not matter if the implants were inserted privately in the UK or anywhere else so long as you are entitled to NHS treatment.*

What is BIA-ALCL?

BIA-ALCL is an uncommon cancer of the white blood cells (lymphoma), that grows in response to the body's reaction to a breast implant. In the UK, the majority of BIA-ALCL is diagnosed early and cured by removal of the implants with surrounding scar tissue (total capsulectomy) with no additional cancer treatment required. However, in a small number of cases further treatment such as chemotherapy, immunotherapy or radiotherapy may be required.

It is not known why some people with breast implants develop BIA-ALCL and others do not. Several theories are being investigated internationally. It is important to be aware of the signs and symptoms of BIA-ALCL.

If you want more information about BIA-ALCL please follow the MHRA link

Who can develop BIA-ALCL?

BIA-ALCL has mainly been reported in people with breast implants which have a rough (textured) silicone surface. However, until the evidence is clearer, we feel it is

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best to assume that ANY breast implant (smooth or textured surface) may have the potential to cause BIA-ALCL.

If you want more information about breast implants, please follow the link

Am I going to get BIA-ALCL?

For more information on current UK reports of BIA-ALCL and estimated incidence, please follow the link to the gov.uk webpage on BIA-ALCL.

To put this estimated incidence of BIA-ALCL in context, breast cancer, which is **not** associated with having breast implants, will occur in 1 in 8 women, who live to 80yrs in the UK.

Should I be checked for BIA-ALCL?

There are no screening tests for BIA-ALCL. People with breast implants, with no breast symptoms or signs, do not require routine clinical checks or monitoring with mammograms, ultrasound or MRI.

If you have no breast symptoms or signs but are worried about BIA-ALCL, please contact the surgeon who put your implant/s in, or the clinic/hospital where you had them inserted for advice.

So how would I know if BIA-ALCL was developing around my implants?

Most cases of BIA-ALCL have occurred years after surgery.

The most common change is a painless collection of fluid (seroma) forming around the breast implant. The amount of fluid grows quickly over a few weeks and causes the breast to swell. The swelling can affect both sides at the same time, but this is very unusual. This is usually the earliest stage of the disease and it is very curable with surgery.

Less commonly BIA-ALCL may present as a lump in the breast very close to the implant or even as a build-up of thick scar tissue (capsular contracture) around the implant which can cause a painful breast shape change/distortion.

Is there anything I can do to prevent BIA-ALCL?

We do not understand why or how BIA-ALCL happens so there is, at present, nothing we or you can do to prevent BIA-ALCL developing.

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However, if you have a breast implant please remember as part of your usual breast health awareness and regular self-examination, to seek help/medical advice if you notice any of the typical BIA-ALCL signs of

- rapid, painless and visible swelling of the whole breast
- a breast lump
- severe capsule contracture (e.g., hardening, misshape and pain)

I am very worried about cancer: should I have my breast implants removed to prevent BIA-ALCL?

It is agreed, internationally, that there is no need for people with breast implants, who do not have any signs or symptoms of BIA-ALCL, to have them removed routinely. This is because the risk of complications due to invasive surgery and anaesthesia are likely to harm more people than the risk of developing BIA-ALCL at present.

However, people who remain worried but well and are considering implant removal must be aware:

1) Surgery to reduce the risk of BIA-ALCL will require removal of the implants under general anaesthetic, and that still carries a risk even having had a previous general anaesthetic. That risk is greater than the risk of developing BIA ALCL and may result in life threatening conditions, such as infection, including sepsis, and deep vein thrombosis (DVT) which can lead to a pulmonary embolus (a blood clot in the lung).

2) It is unknown if complete removal of the implant capsule (scar tissue, which always develops around any implant) at the time of implant removal reduces the future risk of developing BIA-ALCL. Patients must, therefore, be aware that total capsule removal (capsulectomy) is a very complex operation requiring removal of the scar tissue, attached to the pectoral muscles and to some of the ribs, which protect your lungs. Complications of capsulectomy can be very serious and potentially life threatening , such as pneumothorax (collapse of a lung during removal of the scar attached to the ribs) and also include chronic pain, chronic seroma (persistent collections of fluid in the cavity where the implants had been).

3) Your surgeon will discuss what performing a total capsulectomy entails in your case and its risks but please be aware, en bloc capsulectomy is not available on the NHS unless clinically indicated.

Finally, if you do decide to have surgery to reduce the risk of BIA-ALCL, it is not recommended to have another implant inserted so there may be obvious breast size and shape changes, which may require additional procedures to correct e.g., a breast lift (mastopexy). You should discuss this with your surgeon as part of shared decision making, before giving your informed consent to your chosen treatment option.

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What should I do if I have an implant and notice breast changes?

If the implant was inserted within the last year and you think your breast changes are caused by complications from the surgery, please contact your surgeon, clinic or hospital (either private or NHS) who put them in.

If your implants have been trouble-free for many years and then you develop new breast changes, please remember these are most likely to be caused by benign breast or implant related conditions and not BIA-ALCL. As with any new breast changes, please see your GP or nurse. Not all GP's or nurses are aware of BIA-ALCL because it is a relatively new condition, so please ask for a referral to the local NHS breast clinic.

My implants were inserted by a private surgeon in a private clinic: can I be seen in an NHS clinic?

Yes. Anyone entitled to NHS treatment can be seen in an NHS breast clinic if they have worrying breast signs and symptoms. It does not matter if the implants were inserted privately or if they were inserted in another country. The NHS will offer removal of the implants and capsulectomy if necessary. If your implants were put in for cosmetic rather than reconstructive reasons, you will not be offered any other treatment such as a new implant or a breast lift.

Further information about breast implants:

I cannot remember what type of breast implant I have

Check your personal health files. After your implant surgery you should have been given a 'credit card' sized implant card showing details such as implant type, size and manufacturer.

If you do not have that information, you can contact your original surgeon, clinic or hospital because they have to keep a record for 7 years after your last contact with them, but they may have been legally destroyed if it is longer than 7 years. If they have been destroyed, your GP may have the information on your records, if they have your original discharge letter on record.

If your implant was inserted after 2016 your details may be registered on the breast and cosmetic implant registry (BCIR) held by NHS Digital. You can request through your surgeon, hospital or clinic where you were treated, that your details are added retrospectively to the BCIR.
Link to BCIR

If you want more information about breast implants please follow the link
[insert links the NHS choice breast enlargement page and reconstruction pages]

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Current UK position on BIA-ALCL and recommendations for future work.

Why does PRASEAG not currently advise MHRA to ban ALL breast implants if they might cause cancer?

- **The risk of BIA-ALCL is low** in comparison to other cancers, including breast cancer, and those related to long term use of HRT, and it usually presents with clear and diagnosable breast changes in the early curable stages of the disease.
- **Personal choice:** A person must be fully informed about the potential, known risks as well as the benefits of using breast implants. It must be a personal choice.
- **Alternatives to breast implants are not always possible:** Over 70% of breast reconstructions use implants after breast removal for cancer or to prevent cancer. Textured implants have advantages over smooth implants and implant based breast reconstruction improves the quality of life for very many women, who may not be suitable for the other reconstruction options.

Why does PRASEAG not currently advise MHRA to ban only textured implants if they cause the most BIA-ALCL cases?

Breast implants have the potential to cause BIA-ALCL and research is continuing to better understand how BIA-ALCL develops.

However, textured silicone implants are felt to have some advantages over smooth silicone implants. Textured implants are less likely to rotate/move and, depending on where the implant is placed (under or over the muscle), less likely to form a hard scar tissue capsule (capsular contracture). Breast implant rotation and capsular contracture often require revision surgery to correct. More information about these are provided below:

- **Capsular contracture** (**scar tissue forming in the breast around the implant)** is the most common reason for people to need revision surgery and replacement of breast implants. For people having breast augmentation with implant insertion under the breast gland, textured implants have a significantly lower rate of scar capsule formation compared to smoother breast implants. Breast enhancement using smooth implants would need to be placed below the chest wall muscle to minimise capsular contraction: this is more complex surgery and more difficult to revise if required.

- **A more natural looking appearance:** Anatomical (tear-drop shaped) implants are thought to give a more natural looking breast appearance but need to be textured as any rotation of a tear-drop breast implant would be

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visible. Smoother implants which also can rotate/move are always a round, dome-like shape so the rotation is not visible, but they are thought to give a less natural appearance.

- Some surgeons use mesh slings (either made of synthetic material or an animal product) to keep the implant in place. The long-term outcomes of using a mesh with an implant are not currently known.

Should people with breast implants be told about BIA-ALCL?

Yes. However, as this is a new condition, some people who already have breast implants may not have been told about BIA-ALCL before their surgery so they may not know what signs and symptoms to look out for. This is because not enough information may have been known about BIA-ALCL at the time of their surgery.

As more information is now known about BIA-ALCL, all people with breast implants should now be told about it and what to look out for.

We are still not clear which is the best way to reliably, safely and responsibly find and tell all people with implants about BIA-ALCL. This is because:

- Finding out who has breast implants is difficult:
    - There is no central register of people with implants with up-to-date contact details. The BCIR only started to register people with breast implants in 2016 so the numbers that can be readily and accurately contacted are limited.
    - Cosmetic clinics/hospitals may have gone out of business and many have legally destroyed their records after 7 years.
- There is no screening test for BIA-ALCL. So healthy people with implants and with no breast changes do not need to be seen routinely for an implant or breast check.
- It is essential the information that is sent gets to the person to whom it applies and there may well be legal (General Data Protection Regulation - GDPR) issues regarding confidentiality if someone other than the person with the implant (e.g., a previous partner) receives the information.

What has MHRA being doing about BIA-ALCL?

- MHRA issued medical device alerts in 2011 and 2014 that there were reports that a rare type of lymphoma had been found adjacent to breast implants and that any cases found in the UK should be reported to MHRA. BIA-ALCL was classified as a disease associated with breast implants by the WHO in 2016.

- MHRA set up PRASEAG (link to see membership) and tasked them with reviewing the risk of BIA-ALCL. Based on PRASEAG's advice, MHRA issued another Medical Device Alert in 2018 stating that patients undergoing breast implants, for any reason, should be warned about BIA-ALCL in informed

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consent for the operation. A webpage dedicated to BIA-ALCL where future updates would be published was also established.

- PRASEAG also works with specialist surgery associations to educate clinicians so they can inform people with breast implants about the breast symptoms and signs that could indicate BIA-ALCL.

- MHRA and PRASEAG continues to monitor new BIA-ALCL evidence and related issues and updates advice as required.

- MHRA continues to maintain close collaboration with international regulators to build a better global picture of BIA-ALCL to protect the health of the public worldwide.

What are PRASEAG's recommendations and ongoing work?

- PRASEAG is considering how to safely, reliably and responsibly identify and communicate with as many people with breast implants as possible. PRASEAG will collaborate with MHRA to ensure safety messages are widely communicated to the public.

- PRASEAG members have produced nationally endorsed BIA-ALCL diagnosis and treatment guidance for clinicians. These UK clinical guidelines have been published simultaneously in the British Journal of Haematology, The European Journal of Surgical Oncology and the Journal of Plastic, Reconstructive and Aesthetic Surgery and available at the following links.

    - British Journal of Haematology
    https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.17194

    - European Journal of Surgical Oncology
    https://www.ejso.com/article/S0748-7983(20)30688-0/fulltext

    - Journal of Plastic, Reconstructive & Aesthetic Surgery
    https://www.jprasurg.com/article/S1748-6815(20)30562-3/fulltext

- PRASEAG members are producing patient information leaflets on the risks of BIA-ALCL for people considering
    - Breast enlargement or re-shaping (augmentation/ mammoplasty).

- PRASEAG and its members have individually championed for funding to research BIA-ALCL and to create and maintain a national tissue bank of BIA-ALCL cases including full genome sequencing.

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- PRASEAG has been actively championing for UK based funding of the BCIR to support more implant data analysis. The association between breast implants and BIA- ALCL is proven and, with an active, fully funded BCIR, PRASEAG believes patient safety will be improved.

About PRASEAG

Who are PRASEAG and what do they do?

To assist us in our work, and to advise us on how we communicate and engage with patients and healthcare professionals on implants we have formed an independent expert advisory group; PRASEAG, is the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group. They meet regularly to review published evidence about reported health risks for breast implants, this includes breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

PRASEAG members are peer nominated, independent from MHRA and provide their time on a voluntary basis.

Members of the group have world recognised expertise in specialities relevant to breast implants risks. The group help the MHRA to better understand the risks and conditions that may be caused by breast implants (including BIA-ALCL). PRASEAG help guide MHRA statements, advice and recommendations which are updated (if required) after every PRASEAG meeting.
For more information about PRASEAG please follow the link

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- If you have a breast implant and experience unexpected changes in size, shape or feel of your breast, please see your GP for a referral to the local NHS breast unit to be checked. It does not matter if the implants were inserted privately in the UK or anywhere else.

Links to other resources

[link to MHRA BIA-ALCL webpage]

[Link to UK Clinical Guidelines on Diagnosis and Treatment of BIA-ALCL]

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[link to UK guidelines for pathological diagnosis and management of BIA-ALCL]

[Link to Breast Cancer Now Facebook live Q&A on BIA-ALCL https://www.facebook.com/breastcancernow/videos/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl/730727127365421/]

Links to the three UK Associations: BAPRAS, ABS, BAAPS