Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Breast implant associated cancer: health professionals information

Information about breast implant associated-anaplastic large cell lymphoma (BIA-ALCL) for health professionals.

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This page is based on our post-market review of breast implants and tissue expanders, and advice from an expert working group (https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/breast-implant-expert-and-consumer-working-groups).

For a full list of breast implants included in the post-market review and actions taken, view the Current status of breast implant products in Australia (https://www.tga.gov.au/news/safety-alerts/current-status-breast-implant-products-australia) web page.

As breast implant associated cancer, also known as Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) is rare, various aspects of this disease are not fully characterised. A more complete picture is expected over coming years. Health professionals should keep informed of the latest evidence.

Breast implant associated ALCL

BIA-ALCL is a rare form of non-Hodgkin lymphoma. 2016 saw the World Health Organization (WHO) release a new classification for BIA-ALCL.

Unique characteristics include:

- being purely T-cell
- having no anaplastic lymphoma kinase gene translocation (ALK-)
- being CD30 receptor protein positive on immunohistochemistry (CD30+)
- being in close anatomical association with a breast implant.

The aetiology of BIA-ALCL appears complex and multi-factorial. As with other cancers, the exact cause is unknown, according to the expert working group. Implants are likely to cause BIA-ALCL, but they're not the only cause. Inter-related factors have been proposed that include:

- textured implants (with a higher risk for high surface area textures)
- bacterial contamination at the time of surgery to cause inflammation
- patient genetic predisposition
- time for the process to develop.

Most cases happen between three and 14 years after insertion (median: 8 years; range: 1-37 years). More texturing of the implant increases the estimated risk of BIA-ALCL. A review of BIA-ALCL cases reported to the TGA, up until the end of 2021, indicates the following risk rate:

- polyurethane-coated implants have an estimated risk of 1 in 1,800. This kind of breast implant is no longer included in the ARTG; they may remain implanted in some people.
- macro-textured implants have an estimated risk of 1 in 2,400. This kind of breast implant is no longer included in the ARTG; they may remain implanted in some people.
- micro-textured implants have an estimated risk of 1 in 18,000.
- there are no confirmed cases of BIA-ALCL in Australians that have only had smooth implants.

BIA-ALCL cases in Australia are much higher than expected based on the population. About 1 in 7 of all cases reported globally are Australian cases.

In Australia, there haven't been any cases of BIA-ALCL in patients with only smooth implants. To date, all Australian cases involve polyurethane or textured implants. Until 2016, about 85% of implants used in Australia were textured. In the United States, 70-90% of implants are smooth.

The FDA says the connection with smooth implants cannot be ruled out since the full history of implants isn't known.

Discuss the risk of BIA-ALCL with your patients

As part of getting informed consent, you need to talk to the patient about BIA-ALCL. It's important for patients to know about the risks and benefits of different types of breast implants (). They should also be provided with educational material to read and consider at leisure.

After implantation, you should provide patients with the:

- name and type of implant
- procedure performed
- breast implant manufacturer's labelling
- patient information leaflet, and
- the patient-specific implant card (https://www.tga.gov.au/products/medical-devices/breast-implant-hub/patient-implant-cards-and-information-leaflets).

It's best to teach all breast implant patients how to self-examine regularly.

Patients with implants should know the common presenting symptoms including:

- asymmetry
- pain
- delayed effusion or seroma, or
- a mass or lymphadenopathy (less common).

Any changes in the breast or implant need immediate clinical assessment. Surgical treatment can be curative when diagnosed early. A disease that spreads through the capsule, forms a mass, or spreads to the lymph nodes has a worse prognosis.

Generally, breast implants are not lifetime devices, regardless of breast implant associated cancer. After 10-15 years, they're usually removed. The longer you have the implant, the more likely it will need to be removed. Common reasons for removal are contracture, rippling, movement or rupture of the implant.

Steps to reduce the risk for your patients

Current data suggest that the lower the surface area texture of the implant, the lower the risk of ALCL.

ALCL may be caused by T-cell stimulation from chronic bacterial biofilm infections. Implant placement requires standard precautions, like antibiotics, pocket irrigation, sterility, and skin preparation. Further, such precautions might reduce contracture risk.

A group of Australian breast implant researchers have made the following recommendations:

1. Use intravenous antibiotic prophylaxis at the time of anaesthetic induction.
2. Avoid periareolar incisions. In both laboratory and clinical studies, pocket dissections have been shown to cause a higher rate of contracture.
3. Use nipple shields to prevent spillage of bacteria into the pocket.
4. Perform careful atraumatic dissection to minimise devascularised tissue.
5. Perform careful haemostasis.
6. Avoid dissection into the breast parenchyma. The use of a dual plane, subfascial pocket has anatomic advantages.
7. Perform pocket irrigation (refer to hospital or health department guidelines).
8. Use an introduction sleeve. We have recommended the use of a cut-off surgical glove to minimise skin contact.
9. Handle the implant with new instruments, drapes, and surgical gloves.
10. Minimise the time of implant opening.
11. Minimise repositioning and replacement of the implant.
12. Use a layered closure.
13. Avoid using a drainage tube, which can be a potential site of entry for bacteria.
14. Use antibiotic prophylaxis to cover subsequent procedures that breach skin or mucosa.

For further information on the recommendations, see the research article The role of bacterial biofilms in device-associated infection (https://pubmed.ncbi.nlm.nih.gov/23924649/) on the National Library of Medicine (United States) website.

Routine monitoring

Clinical colleges and associations recommend routine monitoring of patients with breast implants. The option of explantation of breast implants in the absence of symptoms requires discussion of risks versus benefits and would be a clinical decision to be made in partnership with a fully informed patient.

Investigation of suspected BIA-ALCL

To diagnose BIA-ALCL, fluid samples and tissue around breast implants are analysed.

The main method of investigation is ultrasound evaluation. This:

- confirms the presence and extent of an effusion;
- determines if there is presence of a mass; and
- evaluates regional lymph node basins for lymphadenopathy.

Fine needle aspiration (+/- or core biopsy) of an effusion (mass) is performed. The aspirate (tissue) is sent for cytology (histology) and flow cytometry +/- molecular studies for diagnosis of BIA-ALCL.

PET/CT scans and MRIs are for confirmed cases only.

There does not appear to be a role for mammography in the detection or investigation of BIA-ALCL.

Management of BIA-ALCL

The management of this condition is multidisciplinary. Patients require a referral to breast implant surgeons and lymphoma haematologists.

The most common treatment is removing the implant and oncological capsulectomy, which includes resecting the capsule. Due to incidental bilateral cases, bilateral breast implants should be removed with complete capsulectomy. Both the capsule and fluid should be sent for pathology.

There are stages to this disease, according to research. In approximately 63% of reported Australian BIA-ALCL cases, the cancerous cells are limited to the fluid (effusion/seroma) surrounding the breast implant. Another 23% of cases had cancerous cells in the seroma and the tissue capsule after the implants were removed.

Most diagnosed cases are treated with complete capsulectomy and implant removal. However, aggressive variants have been reported. As of 26 September 2019, four deaths in Australia have been reported to the TGA.

Medicare benefits for tests and treatment

In addition to the benefits for diagnostic imaging and pathology services, Medicare covers investigations and treatments for breast implant-related cancers.

MBS item 63547: MRI investigation of patients diagnosed with BIA-ALCL.
MBS item 45551: Removal of each breast implant and its capsule.

If lymph node procedures or other types of breast surgery are required, MBS items are available.

For any Medicare-eligible service, the MBS item billed needs to be appropriate for the procedure and clinically necessary for the patient's treatment.

Contribute to the Australian Breast Device Registry

The Australian Breast Device Register (ABDR) (https://www.abdr.org.au/)tracks breast implant long-term safety and performance. The registry is independently managed by Monash University. It's endorsed by plastic and reconstructive surgeons, cosmetic surgeons, and general breast surgeons.

The ABDR:

- is the central repository of data for all breast device issues, including BIA-ALCL.
- collects comprehensive information about breast implants, breast tissue expanders, and dermal mesh.

The registry holds breast device details for more than 36,000 patients. More than 460 surgeons from public and private hospitals and day surgeries use it.

Together with the TGA, the expert working group supports the ABDR as the repository for breast implant surgeries, including reporting of BIA-ALCL cases.

Report problems

The Therapeutic Goods Administration (TGA) monitors the safety of medical devices in Australia. This includes breast implants. If you experience a problem or side effect following a breast implant procedure, report it to us (https://www.tga.gov.au/safety/reporting-problems).

More information

Current status of breast implant products in Australia (https://www.tga.gov.au/news/safety-alerts/current-status-breast-implant-products-australia)

The list of current ARTG entries for breast implants has been updated

Download our fact sheet:

Recall of Allergan textured breast implants: what you should know as a health professional (https://www.tga.gov.au/sites/default/files/recall-allergan-textured-breast-implants-what-you-should-know-as-a-health-professional.pdf) [PDF, 391.95 KB]

Other resources

- Clinical guideline: Recommended management of a patient with a breast implant (), NSW Government, Department of Health website.
- Loch-Wilkinson A, Beath KJ, Knight RJW et al. Breast Implant–Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand: High-Surface-Area Textured Implants Are Associated with Increased Risk. Journal of Plastic and Reconstructive Surgery 2017; 140(4): 645-654. doi: 10.1097/PRS.0000000000003654
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Topics:

Medical devices safety (https://www.tga.gov.au/topics/medical-devices-safety)

原文

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