Safer Care Victoria

Support for women at risk of breast implant-associated anaplastic large cell lymphoma

Safer Care Victoria is raising public awareness about a form of non-Hodgkin lymphoma, called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This may result in people who have breast implants seeking your medical advice. This fact sheet outlines important information for you and your patients.

As previously highlighted by the Therapeutic Goods Administration (TGA) in September 2019, breast implants – in particular, textured breast implants – have been linked with BIA-ALCL.

What do I need to know about BIA-ALCL?

BIA-ALCL is very rare.

On average, between 5000 and 6000 breast implant or breast reconstruction procedures are undertaken in Victoria each year. The majority of implants used in Victoria in the past 15 years have been textured. To date, the TGA is aware of about 76 cases of BIA-ALCL nationally.

The cancer cells usually grow in the fluid (seroma) and scar tissue (capsule) that develop around the breast implant.

In almost all cases, the disease develops three to 14 years after a patient's procedure, with an average time to diagnosis of eight years.

What is the reported risk of BIA-ALCL for people who have had implants?

The risk of BIA-ALCL depends on the type of implant and is estimated to be between one in 2,500 and one in 25,000.

The risk appears to be highest for implants with the greatest degree of surface texturing; about 23 times greater than for smooth implants. To date, there have been two known cases worldwide of BIA-ALCL in patients with only smooth implants.

Should patients have implants removed?

The TGA does not recommend removal/ replacement of breast implants or tissue expanders in asymptomatic patients. This is because the risks associated with the surgery are greater than the risk of being diagnosed with this rare form of lymphoma.

Evidence is also emerging that suggests the risk of lymphoma may not be absolved even if the textured implants have been removed.

What are the symptoms of BIA-ALCL?

The most common symptom of BIA-ALCL is swelling of a breast caused by fluid around the implant. Other possible symptoms include pain in the breast, and a rash on the breast or a lump in the breast, armpit and elsewhere.[1]

If patients have any of these symptoms, or are not sure about changes in their breast, they will be directed to see their GP, implant surgeon or the public hospital were the implants were inserted, as soon as possible.[1]

BIA-ALCL prognosis

The TGA states that where BIA-ALCL is detected early, most of these cases are cured by surgery to remove the implant and surrounding capsule.

If there is a solid lump or the cancer has spread (or is more aggressive), chemotherapy, radiotherapy or additional surgery may be required.[2]

UPDATED – May 2021

SUPPORTING A PATIENT WITH CONCERNS ABOUT BIA-ALCL

We have set up a time-limited helpline to provide immediate advice to people who may be concerned or are seeking further advice. The helpline aims to provide reassurance about the risk and recommended treatment for asymptomatic people.

Victorian consumer helpline (03) 9902 0077

Patients will be guided to their GP in the first instance to ensure patients are directed into existing referral systems as required in accordance with clinical need.

What next steps do I take if a patient presents?

Please reassure patients that removal is not recommended if there are no symptoms. For asymptomatic presentations, advise the patient to self-examine their breasts regularly.

Encourage the patient to access the information available for both:

- **Reconstructions**
  www.tga.gov.au/webinar-recording-bia-alcl-and-breast-reconstructions
- **Augmentations**
  www.tga.gov.au/webinar-recording-bia-alcl-and-breast-augmentations

If a patient is experiencing symptoms, encourage them to see their GP, call the helpline or contact their surgeon as soon as possible.

How can I tell if the patient's implant is textured or smooth?

Due to data limitations, not all patients will be able to confirm what type of implant they have received. This is especially true in cases where the surgery was performed prior to 2015.

Where the surgery was performed after 2015, the Australian Breast Device Registry (ABDR) may be able to provide further information. Contact the registery on (03) 9903 0205 or abdr@monash.edu

If the surgery occurred before 2015, an earlier registry, the Breast Implant Registry may have implant details. Contact the registery on (02) 9437 9200.

If the type of implant remains unknown, it is recommended that you assume the patient has received a textured implant.

What action should be taken for a patient who has symptoms?

Symptomatic patients should be referred to a specialist. In addition to this referral, consider the following tests:

- An ultrasound scan to determine whether there is fluid collection.
- If a significant seroma is present this should be aspirated and the fluid sent **fresh** for appropriate examinations including flow cytometry and cell markers. Fluid should also be sent for micro and culture to detect possible infection.
- You may also choose to order an MRI scan or CT scan to assess the extent of local growth or spread of the cancer.
- Other tests such as a PET scan may also be used to assess spread.

Where can I find more information on breast implants and risks?

- TGA consumer hub
  www.tga.gov.au/hubs/breast-implants
- TGA BIA-ALCL webpage
  www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl
- TGA Allergan fact sheet
  www.tga.gov.au/consumer-fact-sheet-recall-allergan-biocell-breast-implants

The information contained in this fact sheet is obtained from the TGA and published research.

[1] https://www.tga.gov.au/sites/default/files/recall-of_allergan-textured-breast-implants-what-you-should-know-if-you-have-implants.pdf
[2] https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl

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