FAQs breast implant-associated ALCL (1 May 2019)

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare type of lymphoma that develops near breast implants.

Regulatory Agencies around the world are investigating the safety of breast implants on the market following an increasing number of cases of BIA-ALCL being reported. The French and Canadian regulators have taken action to remove selected textured implants from their market. Other regulators, including the United States Food and Drug Administration and Australia's Therapeutic Goods Administration (TGA) have deferred making a decision until more information is available.

A breast implant expert working group has been convened by the TGA and Medsafe will be involved in future meetings of this group. The TGA's latest information on BIA-ALCL can be found here.

Medsafe, New Zealand's Medicines and Medical Devices Safety Authority, has received six reported adverse event reports where BIA-ALCL has been diagnosed.

Medsafe's advice for recipients of implants remains unchanged. Those who do not experience any changes or symptoms need take no action. Those who experience sudden, unexplained changes such as pain, lumps or swelling should see their general practitioner or the surgeon who carried out the breast implant surgery.

Background

The New Zealand Association of Plastic Surgeons has been kept up-to-date with the work of the TGA and the expert advisory panel, convened in 2016. The Association has had regular discussions about the latest information on BIA-ALCL with Medsafe.

Frequently asked questions

What is BIA-ALCL?

BIA-ALCL is a rare type of non-Hodgkin's lymphoma, which is a cancer of the cells of the immune system. Most cases of BIA-ALCL are cured by removal of the implant and the capsule surrounding the implant.

What are the symptoms of breast implant-associated BIA-ALCL?

The most common symptom is a swelling of the breast, typically 3 to 14 years after the operation to insert the breast implant. This swelling is due to an accumulation of fluid. BIA-ALCL has been known to occur as soon as 1 year after the operation and as late as 37 years after the operation. Less commonly, BIA-ALCL can take the form of a lump in the breast or a lump in the armpit.

What should New Zealand women with breast implants, or who are considering breast implants, who are concerned about BIA-ALCL do?

Women who have no symptoms have no cause for concern.

Women who experience sudden, unexplained changes, such as lumps or swelling in the breast, or who have any concerns about their implants should see their general practitioner for referral to a specialist with knowledge of breast implants, or the surgeon who carried out their breast implant surgery.

Women who are considering breast implant surgery should discuss the risks and benefits of the procedure with their surgeon.

What about women who had their breast implant surgery overseas or whose surgeon is no longer practicing?

Women who are unable to contact their implant surgeon should see their general practitioner for a referral to a surgeon experienced in implant surgery.

How is BIA-ALCL diagnosed?

If a woman develops swelling of an implanted breast her doctor will send her for an ultrasound scan to see if this is due to a fluid collection. If fluid is present it will be removed and sent to the laboratory for analysis. Most fluid collections are not ALCL, but the laboratory test will be able to tell for sure.

Other investigations such as MRI and CT-scans would typically be done if the laboratory analysis of the fluid confirms a diagnosis of BIA-ALCL.

Mammograms are not helpful for diagnosing BIA-ALCL.

What causes BIA-ALCL?

One current theory is that chronic, low grade, non-clinical bacterial contamination possibly contracted at the time of implant placement, or in the immediate postoperative period can develop into BIA-ALCL in the long term. The theory is that because the body can't get rid itself of the contaminated implant, there is chronic irritation over a period of time that stimulates the immune system, causing some of the cells to potentially transform into ALCL. However, this theory has not been proven.

There are many potential sources of bacteria that may contaminate an implant and while surgeons do many things to prevent bacterial contamination, such as washing out the breast cavity with antibiotic solution, re-prepping or covering the skin and only using a new pair of sterile gloves to touch the implant, it is not possible to completely eliminate this risk.

How is BIA-ALCL treated?

Most cases of BIA-ALCL are cured by removal of the implant and the capsule surrounding the implant. Usually both implants will be removed, even if BIA-ALCL has only occurred in one breast. This is because there is a small but real risk that BIA-ALCL can develop in the opposite breast.

Sometimes there is a solid lump (not just fluid). In these cases, chemotherapy or radiotherapy may be required.

The management of BIA-ALCL is multidisciplinary, with all patients requiring a referral to a surgeon experienced with breast implants and the involvement of a haematologist who specialises in lymphoma for initial and ongoing investigations and management.

How many cases of BIA-ALCL have there been in New Zealand?

In November 2018, the American Society of Plastic Surgeons' publication reported Global Numbers of BIA-ALCL Cases and Related Deaths, stating that in New Zealand there were 13 cases reported with 1 death.

Some of these cases are women who have had breast implant surgery overseas.

What is the risk of BIA-ALCL?

Based on the currently available data, it is not possible to provide an accurate estimate of the risk of BIA-ALCL. Current expert opinion puts the risk at between 1-in-3,000 and 1-in-60,000. Most (95 percent) of cases of BIA-ALCL occur between 3 and 14 years after the implant. The average time for cases to appear is 8 years after implant surgery.

There are no cases of BIA-ALCL in patients with smooth walled implants only.

Other ways of expressing the risk are:

- One woman will be diagnosed with BIA-ALCL for every 3,000 to 60,000 women with breast implants.
- Taking the middle of the experts' range as the best estimate of risk of BIA-ALCL in women who have breast implants of being 1-in-5000 women, this would mean that one woman in 5000 with breast implants will develop BIA-ALCL over a period of about 3-14 years following an implant.

Should women have their breast implants removed, just in case?

Because BIA-ALCL is rare, experts do not recommend removal of breast implants for women who have no problems with their implants.

Generally, breast implants are not lifetime devices regardless of breast implant-associated ALCL. The longer a woman has the implant, the more likely it will need to be removed. Common reasons for removal are capsular contracture (hardening of the scar tissue around the implant that causes physical deformity and pain) or movement of the implant.

Should women with implants be screened for ALCL?

Based on external expert clinical advice received by the TGA, regular screening is not recommended at this time.

Are some women more at risk of BIA-ALCL than others?

BIA-ALCL can develop regardless of whether the implant is inserted for cosmetic reasons or for reconstruction of the breast following breast cancer. It can occur with both saline- and silicone gel-filled implants.

All Australian and New Zealand cases of BIA-ALCL have occurred in women who have had textured or polyurethane implants. No Australian or New Zealand cases have been reported in women who have only had smooth implants.

Based on the currently available data:

- It is uncertain whether textured (either micro or macro) and polyurethane implants carry different risks.
- It is uncertain whether different brands of textured and polyurethane implants carry different risks.
- It is not possible to predict which women with textured or polyurethane implants will develop BIA-ALCL.

However, there are sound clinical reasons to use textured implants – in particular to reduce the incidence of capsular contracture, and to enable the use of anatomical (shaped) implants for breast reconstruction.

Is there a higher incidence of BIA-ALCL in New Zealand (and Australia) or is the worldwide incidence of it being under-reported?

While it is possible that the worldwide incidence of BIA-ALCL is under reported, the reason this was looked at in New Zealand and Australia is because we have good reporting.

There appeared to be a higher incidence rate in Australia and New Zealand, so there was a need to know as much about it as possible. Data collection suggests that Australia and New Zealand's rate of BIA-ALCL could be higher than that published in other countries so far. However, everything about the incidence of BIA-ALCL to date is a 'best guess'.

In New Zealand and Australia, we were able to obtain anonymised breast implant sales data from 1999. It's the best data available internationally and important because the average time for cases of breast implant-associated ALCL to appear is eight years after implant surgery and as much as 14 years.

No one knows how many New Zealand women have breast implants. Breast implant surgery is not regulated here and not all breast implant surgery is carried out by plastic surgeons. Some general surgeons and cosmetic surgeons also do breast implant surgery.

Some New Zealand women have had breast implant surgery overseas.

Are there clusters of BIA-ALCL related to individual surgeons?

While some surgeons and surgical groups have reported higher numbers of BIA-ALCL than others, there is a difference between surgeons identifying cases of BIA-ALCL and surgeons doing the original implant surgery.

For example, one surgeon in New Zealand identified four women with BIA-ALCL, but had only performed the implant surgery on one of them.

The research appears to implicate high surface area textured implants. Are these used in New Zealand?

All cases of BIA-ALCL have involved textured implants rather than smooth surfaced implants, including those where a woman may have originally had smooth surfaced implants that were later replaced by textured implants.

The vast majority of breast implants used in New Zealand are textured. One possible issue with breast implants is capsular contracture. A couple of decades ago it was determined that textured implants greatly reduced the risk of capsular contracture, with the result that most of those doing breast implant surgery switched to using textured implants. Anatomically shaped implants widely used for reconstruction are all textured.

What has the New Zealand Association of Plastic Surgeons done to educate its members about BIA-ALCL?

The New Zealand Association of Plastic Surgeons has continued to provide its members with the latest information about BIA-ALCL, including how to manage patients with suspected or proven BIA-ALCL.

The Association will continue to evaluate all available information to better understand the nature and possible factors contributing to BIA-ALCL and work with researchers and regulatory authorities to reduce its incidence. At the upcoming Plastic Surgery Congress in Melbourne in May there will be further updates for our members.

The Association is in close contact with our Australian and United States Plastic Surgery Societies and we are able to swiftly share information as it comes to hand.

Why doesn't New Zealand have a breast implant registry like Australia? While there is a breast implant registry in Australia, it is a voluntary, opt-in system for hospitals and other facilities doing breast implant surgery, rather than individual surgeons. It also relies on these facilities providing breast implant information to the registry.

The New Zealand Association of Plastic Surgeons would like to see a breast implant surgery registry in New Zealand and has been working towards this with the regulatory authorities for some time. The Royal Australasian College of Surgeons has included the need for a Breast Implant Registry in their recent submission to the Ministry of Health regarding registries for certain implants and cancers.

New Zealand privacy laws are the biggest barrier to establishing a comprehensive register. There would also need to be a commitment to participate by all those providing breast implant surgery for it to be of any real value. It would also be useful for breast implant manufacturers to provide sales data to help with data matching. Not all breast implant surgery in New Zealand is carried out by plastic surgeons. Some general surgeons and cosmetic surgeons also do breast implant surgery.

Where can I find more information?

The following regulatory authorities publish information on BIA-ALCL:

Medsafe (New Zealand)

Therapeutic Goods Administration (TGA) in Australia

United States Food and Drug Administration

The United Kingdom Medicines and Healthcare products Regulatory Agency

International Collaboration of Breast Registry Activities