

28 August 2017

Statement in response to media coverage on the Medical Journal of Australia's paper on Breast implant associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)

Facts associated with BIA-ALCL

1. It is a cancer of lymphatic cells and a form of Non-Hodgkin's Lymphoma
2. It is not a breast cancer
3. It occurs in association with breast implants and to date exclusively with exposure to textured implants (i.e. No case has been reported with exposure to smooth implants alone).
4. It occurs in women who have had implants for both cosmetic and reconstructive indications
5. It takes an average of 7-10 years after implant insertion before it develops.
6. The commonest presentation is a fluid swelling around the breast implant and in the space between the implant and breast implant capsule – late seroma. The diagnosis of the tumour is made by examination of the seroma fluid.
7. Early stage disease is curative with surgery alone.
8. Disease which has spread through the capsule, forming a mass or which has spread to local lymph glands carries a worse prognosis.

Risk

The most accurate risk published to date is from a detailed study of numerator and denominator in Australia and New Zealand. This showed that the risk for implants with high surface area texture (biocell, Allergan and polyurethane, Silimed) were around 10 times higher (1 in 4,000 to 1 in 7,000) compared with implants with lower surface area texture (1 in 60000 for siltex Mentor). The risk was calculated only for companies that complied with a request for provision of sales data.

We did see ALCL arising from other implant manufacturers, but were not able to calculate risk due to their refusal to supply data for analysis.

The study also identified clusters of multiple cases arising from the same practice. These clusters are currently under investigation, with the consent of the centre and/or surgeon, and there is insufficient evidence presently to comment as to likely causative factors.

Causation

Yesterday the News Corp Network released an article suggesting that there is a link with cut-price providers. **There is no such link that has been established to date by analysis of evidence.**

A **unifying theory** was proposed by the ANZ epidemiology paper and has become widely accepted worldwide as the best explanation for factors that cause BIA-ALCL.

The unifying theory cites four inter-related factors

1. **Textured implants** (with a higher risk for high surface area textures)
2. **Bacterial contamination** at the time of surgery to reach a threshold to cause inflammation
3. **Patient genetic predisposition**
4. **Time** – for the process to develop

Bacteria have been identified in association with these tumours, similar to the association between gastric lymphoma and *Helicobacter pylori*.

Breast implant surgery in Australia

The exact numbers of breast implants in women is hard to define however last year about 1.5 million were inserted worldwide (International Society of Aesthetic Plastic Surgery, ISAPS) and about 150,000 had implants removed.

Implants are not life devices and all will need revision in due course.

The commonest reasons for revision are capsular contracture, implant migration, poor aesthetic result, size change and rupture.

Different types of implants perform differently, give different outcomes and have different relative risks of these complications.

Conservatively there are 30 million women (60 million implants) in the world with textured implants. There are 388 independent confirmed case of BIA-ALCL. 55 confirmed cases in Australia. There are only 12 deaths worldwide with many of these occurring before treatment principles were better understood. 3 of these deaths were in Australia.

The risk for Australian women of breast cancer is about 1:8. These are separate diseases.

We support the maturing of the Australian Breast Device Registry as the best way to prospectively collect outcome data following breast implant surgery.

Recommendations

All patients undergoing breast implant surgery must provide informed consent that includes a discussion of risks of BIA-ALCL

Implant selection should take into account what the patient already has, what the goals are, the patient's lifestyle and the risks relative to various implant options.

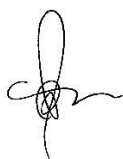
Implant specific risk should be discussed in the context of overall benefits of a particular implant type and/or texture.

Routine implant removal is not indicated for asymptomatic women with breast implants including textured implants.

All women with implants who note changes in their breasts should seek advice. The overwhelming majority will not have BIA-ALCL.

We recommend the use of anti-bacterial strategies (the 14 point plan) to mitigate against the risk of bacterial contamination of implants at the time of implant insertion. These steps have been shown to reduce the risk of capsular contracture and re-operation. They may also (as supported by the unifying hypothesis) reduce the risk of developing BIA-ALCL.

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