

## **Oral contribution from the European Taskforce on Breast Implant Associated-ALCL for FDA Hearing on Breast Implants, 25 – 26 March 2019**

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare sub type of non-Hodgkin's lymphoma. In 2016, World Health Organisation (WHO) defined specific diagnostic criteria for this rare disease.

The European taskforce was established to enable Member States to pool data and share information on this rare disease, which has proved to be a complex task, as it is a multifaceted issue.

By 20 March 2019, 243 cases were reported to the taskforce, out of which 211 were confirmed cases of BIA-ALCL. Of the confirmed cases, 166 were reported to be textured implants at the time of diagnosis. These include polyurethane coated, microtextured or macrotextured implants. The surface texture of the implants in the other reports remains unknown. Internationally there have been some reports of BIA-ALCL associated with smooth breast implants at the time of diagnosis, however the previous implant history for these reports are unknown.

Although a predominance of the reports of BIA-ALCL have been in patients with textured implants, to date, no controlled clinical trials that compare homogenous samples of patients implanted with smooth and textured implants have been carried out.

The investigation into BIA-ALCL is ongoing and, as with all issues, an evidence-based approach is being taken by members of the taskforce. There are several competing theories on the pathogenesis of BIA-ALCL, however scientific proof of a causal relationship has not been established and the cause and the mechanism for the development of BIA-ALCL is yet to be determined. International research in this area continues worldwide.

The European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) advised in October 2017, that there was insufficient scientific information available to establish a methodologically robust risk assessment to investigate a possible association of breast implants with ALCL development. It was therefore seen as necessary to intensify research in the field of BIA-ALCL and to continue to devote greater attention to better understand this disease.

In this context, members of the taskforce participated in the workshop on BIA-ALCL organised by the Dutch National Institute of Public Health and the Environment (RIVM) in November 2018. This concluded that given the relatively low number of BIA-ALCL cases seen per country and the variety of factors to take into account, a coordinated international and multidisciplinary approach is necessary. Future research topics include looking into the characteristics of the patient, implant and tumor, as well as biofilm formation around the implant. The participants who attended the meeting agreed to set up an international consortium with the task of preparing research proposals, and plan to meet again in the second half of 2019.

When addressing questions about the continued availability of textured implants, an important consideration is that surface textures of breast implants are not all manufactured in the same way. Some literature reports that they appear to be associated with different levels of risk. Currently there is no international consensus on a single classification system for surface texture. Harmonised classification system would need to be established in order to collate scientific evidence on the risks and benefits of each type. The taskforce understands that there are various systems developed to categorise the surface type of implants, and welcomes the ongoing work of the International Collaboration of Breast Registry Activities (ICOBRA), to develop an internationally agreed system. This will ensure registries are using harmonised taxonomy, which will enable future pooling of global data, to aid the identification of any trends or commonality in the types of complications recorded.

Another factor to be considered is that anatomically shaped implants are commonly textured in some way. Clinically, the choice between round and anatomically shaped implants is determined by anatomic aspects of the chest wall, and the patient's preferred aesthetic outcome. However, due to the BIA-ALCL discussion, a European Competent authority (ANSM) and some European scientific medical societies recommend preferential use of smooth implants if the outcome is acceptable.

It is understood, the use of textured implants is preferred in most European countries to prevent the undesirable movement or rotation of the implants, and more importantly reduce the risk of capsular contracture, which is often cited as the most common cause of revision in smooth implants. Movement or rotation is particularly undesired with anatomical implants, as this could result in an unacceptable aesthetic outcome, when the aim is to provide a natural looking augmentation. Additionally, there are a limited number of alternatives to the use of textured implants, and the alternatives are also associated with their own risks and contraindications.

In summary, the acceptability of the risk of BIA-ALCL associated with textured implants should be evaluated taking into consideration the following points:

- To date, BIA-ALCL is considered a rare disease. There have been approximately 800 confirmed and unconfirmed reports of BIA-ALCL worldwide, and this should be viewed in the context of an estimated 10-35 million breast implants that have been implanted as approximated in the scientific literature;
- The majority of known cases of BIA-ALCL in Europe involve textured breast implants. However it has not been proven that smooth implants are not involved in the pathogenesis of BIA-ALCL;
- Physicians should always discuss the risks with their patients pre-operatively, so that the patients are informed including to be vigilant of potential symptoms indicative of this condition and able to identify them. In the vast majority of cases of BIA-ALCL, the prognosis is favourable when diagnosed and treated at the early stage. Postoperative follow-up plays an important role for early detection of the disease;
- Currently there is no single classification system for surface texture used by all manufacturers;
- Further research is needed to determine the mechanism for the development of BIA-ALCL and guide effective and targeted action to reduce risk;
- Many individuals have reported benefits from receiving textured implants without reporting complications;
- Other alternatives to the use of textured breast implants are also associated with risks and complications.

## **Conclusion<sup>1</sup>**

BIA-ALCL is a topic of significant concern and the data is continuing to emerge. The taskforce's evaluation of BIA-ALCL is ongoing and, as with all issues, we take an evidence-based approach. The Taskforce will continue to evaluate this data.

There are no preventive explanation recommendations in relation to the BIA-ALCL.

It is imperative that the risks of having either textured or smooth-surfaced implants are fully discussed with all individuals before surgery, so that they can make fully informed choices.

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<sup>1</sup> The content of this contribution is without prejudice to the responsibilities of the Member States to define their health policy and the organisation and delivery of health services and medical care.