BIA-ALCL IN BREAST AUGMENTATION PATIENTS

There have been recent reports in the medical literature about the risk of a rare type of lymphoma developing in the capsule surrounding breast implants. This is known as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Overall the risk of BI-ALCL is extremely low and you should not be in any way alarmed.

The risk of BIA-ALCL is one that Mr Stone has warned his patients about since it first became known. For the past ten years or so, Mr Stone has used Nagor implants. Although cases of BIA-ALCL have been reported with these implants, they have not been as numerous as in patients with other types of implant.

If any of Mr Stone's patients are worried about the risk of BIA-ALCL associated with their implants, and would like to discuss this with him in person, please contact him via Exeter Medical on 01392 35 00 52 or email toni.moore@exetermedical.co.uk.

You may also find the following information helpful.

Anaplastic Large Cell Lymphoma (ALCL) is a sub-type of CD4+ T cell lymphoma. There is now a recognised association between implantable devices and the development of peri-prosthetic ALCL. In most cases BIA-ALCL are found adjacent to the inner aspect of the implant capsule around the implant, or in seroma fluid. The diagnosis of BIA-ALCL is made by aspiration of the seroma and analysis for the CD30 marker, and by histological examination of the capsule.

In 2011 the FDA concluded: 'there is a possible association between breast implants and ALCL. Based on available data, the incidence of ALCL, even in breast implant patients, appears to be very low… *The FDA does not recommend prophylactic breast implant removal in patients without symptoms or other abnormality.*'

The MHRA responded with a medical device alert, issued on 16 February 2011, which states: '*There is uncertain evidence that women with breast implants may have a very small but increased risk of anaplastic large cell lymphoma (ALCL) of the breast. The MHRA has not received any adverse incident reports identifying ALCL in association with breast implants in the UK… No change to current best practice is needed.*'

In 2013 a Danish study of 19,885 women who had undergone breast augmentation surgery between 1973 and 2010, no cases of BIA-ALCL were identified. The outcome of treatment for BIA-ALCL in breast augmentation patients was investigated in a North American longitudinal study of 60 patients, and the findings published, in 2013. A peri-implant seroma was the presenting feature in 42 patients, 39 of whom achieved complete remission, while 18 patients presented with a capsule-based mass; of these 13 achieved complete remission (72%). Overall survival following a diagnosis of BIA-ALCL has been reported as 93% and 89% at 3 and 5 years, with those patients who had spread of the lymphoma beyond the implant capsule having a worse prognosis; complete surgical excision of the implant capsule is essential.

By February 2017 359 cases of BIA-ALCL had been reported to the FDA. A recent update by the FDA stated: *'All of the information to date suggests that women with breast implants have a very low but increased risk of developing ALCL compared to women who do not have breast implants. Most cases of breast implant-associated ALCL are treated by removal of the implant and the capsule surrounding the implant and some cases have been treated by chemotherapy and radiation.'*

In 2017 it was estimated that the risk of BIA-ALCL is up to 1: 50,000 or a lifetime prevalence of 33 per 1 million persons with textured breast implants. However, there is some evidence that the incidence may actually be higher than this. The highest estimated risk as expressed as cases of BIA-ALCL per number of implantations was found for the Allergan Biocell texture at 1:3,817 as compared with Silimed Polyurethane at 1:7,788 and Mentor Siltex texture at 1:60,631. Higher surface area textured implants are therefore shown to significantly increase risk of BIA-ALCL in Australia and New Zealand. Between 2012 and 2016, 23 cases of BIA-ALCL were diagnosed in the UK.

There is a possible association between the formation of a bacterial biofilm around breast implants and BIA-ALCL. Biofilm formation is also linked with capsular contracture. Textured implants are thought to support a higher bacterial load than smooth implants and are overrepresented in patients who develop BIA-ALCL.

A majority of breast / plastic surgeons both in the UK and internationally stated in an informal poll in 2015 that they do not routinely warn patients of the risk of BIA-ALCL, and in a study of 3,038 patients no patient declined surgery as a result of having been made aware of the risk of BIA-ALCL. BAPRAS advises that '*until further evidence is presented there is no need to routinely remove breast implants as a matter of course. We continue to advise that any women with breast implants who experience any sudden unexplained changes, lumps or swelling should speak to their surgeon.*'

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