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Dear CSAPS/CSPS Members

In our role of educating plastic surgeons in Canada, we would like to provide an update on some of the information, as is presently available, on ALCL.

ALCL Update:

1. There is a rare type of ALCL seen in breast implant patients, both aesthetic and reconstructive, called BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma)¹.
2. BIA-ALCL most often presents as a delayed seroma and, less commonly, as a solid mass (more aggressive)².
3. Ultrasound is helpful in making the diagnosis and obtaining seroma fluid for cytology and specifically CD 30 staining³.
4. In the cases where the implant is known, there is a higher number of textured implants reported. Affected implants from both manufacturers that distribute in Canada have been seen along with other major implant companies worldwide⁴.
5. Many etiologic theories have been proposed, including:
 - i. Textured implants
 - ii. Silicone particulate
 - iii. Genetic predisposition
 - iv. Chronic inflammation/irritation
 - v. Biofilm

In an effort to expand our knowledge of this uncommon entity, CSAPS will work as an independent to collect data using an international version of the PROFILE (**P**atient **R**egistry and **O**utcomes **F**or breast **I**mplants and anaplastic large cell Lymphoma etiology and **E**pidemiology) Questionnaire. The questionnaire is presently being developed in collaboration with MD Anderson and will be shared with a separate and distinct subset of Canadian data.

Informed consent discussions may include:

1. Women with breast implants have a very low but increased risk of developing a rare form of lymphoma called Anaplastic Large Cell Lymphoma (ALCL).
2. Main presentation of ALCL is delayed fluid collection.
3. If you have any changes that you are concerned about, see your plastic surgeon.

I have a suspected case of BIA-ALCL. What should I do?

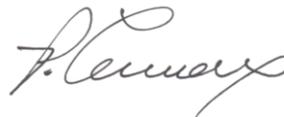
1. Ultrasound is the first screening test for any significant collection of fluid or an avascular mass⁵.
2. If fluid is present it is recommended to obtain **US guided aspiration** prior to any surgical intervention to obtain the diagnosis. It is **very important** to send the fluid for lymphoma protocol including CD 30 markers, ALK, cytology and C+S. **OF NOTE:** in a significant portion of patients, malignant cells have only been found in the aspirate and not the capsule specimen.
3. It is best to have a confirmed diagnosis pre-operatively and have arranged multidisciplinary oncologic consultation. If the disease is isolated within the capsule with no solid mass, treatment by complete capsulectomy and implant removal may be all that is necessary.
4. Not all periprosthetic effusions are BIA – ALCL and proper testing, especially for CD 30 in immunohistochemistry, is paramount to a proper diagnosis.
5. Please email/call CSAPS to report your case at csapsoffice@gmail.com or (905) 655-9889.

If you have any questions or require any further information, please do not hesitate to contact us.

Sincerely,



Eric Bensimon MD, FRCS
President
Canadian Society for
Aesthetic Plastic Surgery



Peter Lennox MD, FRCS
President
Canadian Society of Plastic Surgeons

DISCLAIMER

This document is not intended to define or serve as the standard of medical care. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances. This document should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. This document reflects the state of current knowledge at the time of its publication and CSAPS will endeavour to update and revise this document periodically.

ATTACHMENTS

Courtesy of Dr. Mark Clemens, MD Anderson Cancer Center.

CSAPS 2016 Summary Update on Breast Implant-Associated ALCL

The following is the best available scientific evidence on breast implants and Breast Implant associated anaplastic large cell lymphoma (BI-ALCL).

- In January 2016, the United States FDA provided an update to the 2011 safety communication that identified an association between breast implants and the development of ALCL, a rare type of non-Hodgkin's lymphoma. According to the World Health Organization, BI-ALCL is not a breast cancer or cancer of the breast tissue; it is a lymphoma, a cancer of immune cells. Women with breast implants may have a very low, but increased risk of developing ALCL adjacent to a breast implant.
- The incidence of BI-ALCL is very rare considering the millions of breast implants used throughout the world. The incidence is estimated at 1:500,000 women with textured implants per year, or a lifetime prevalence of 1:30,000 women who have received textured implants. As of September 2015 there were 258 adverse patient reports with possible BI-ALCL reported to the FDA.
- Treatment and outcomes data exist on BI-ALCL, and more information is needed to fully understand risk factors, etiology, and epidemiology. An observation of reported cases indicates a predominance of textured device involvement. The association with breast implants is likely multifactorial and is currently being extensively studied. Possible theories include genetic predominance, biofilm, and texturing particulate chronically stimulating T-cells.
- We recommend educating breast implant patients on the risk of BI-ALCL and the early detection of symptoms. Women with breast implants are encouraged to contact their plastic surgeon if they notice swelling, fluid collections, or unexpected changes in breast shape (Figure 1).
- In symptomatic patients suspicious for BI-ALCL, perform an ultrasound and send suspicious peri-prosthetic fluid for **CD30 immunohistochemistry**, cell-block cytology, and culture. Surgical treatment is essential for the management of BI-ALCL. See Figure 2 for treatment algorithm and is sufficient for cure in the majority of patients.

Breast implant associated-ALCL is very rare, and if it occurs, is highly treatable in the majority of patients. The FDA recommends that all women, including those with breast implants, follow their normal routine in medical care and follow-up, including mammography when appropriate.

The FDA as well as the Institute of Medicine (IOM) maintain that scientific evidence continues to support that FDA-approved breast implants have a reasonable assurance of safety and effectiveness.



Figure 1. Example of BI-ALCL presentation with right breast swelling. Capsule appearance of BI-ALCL mass.

Management of Suspected and Confirmed BI-ALCL

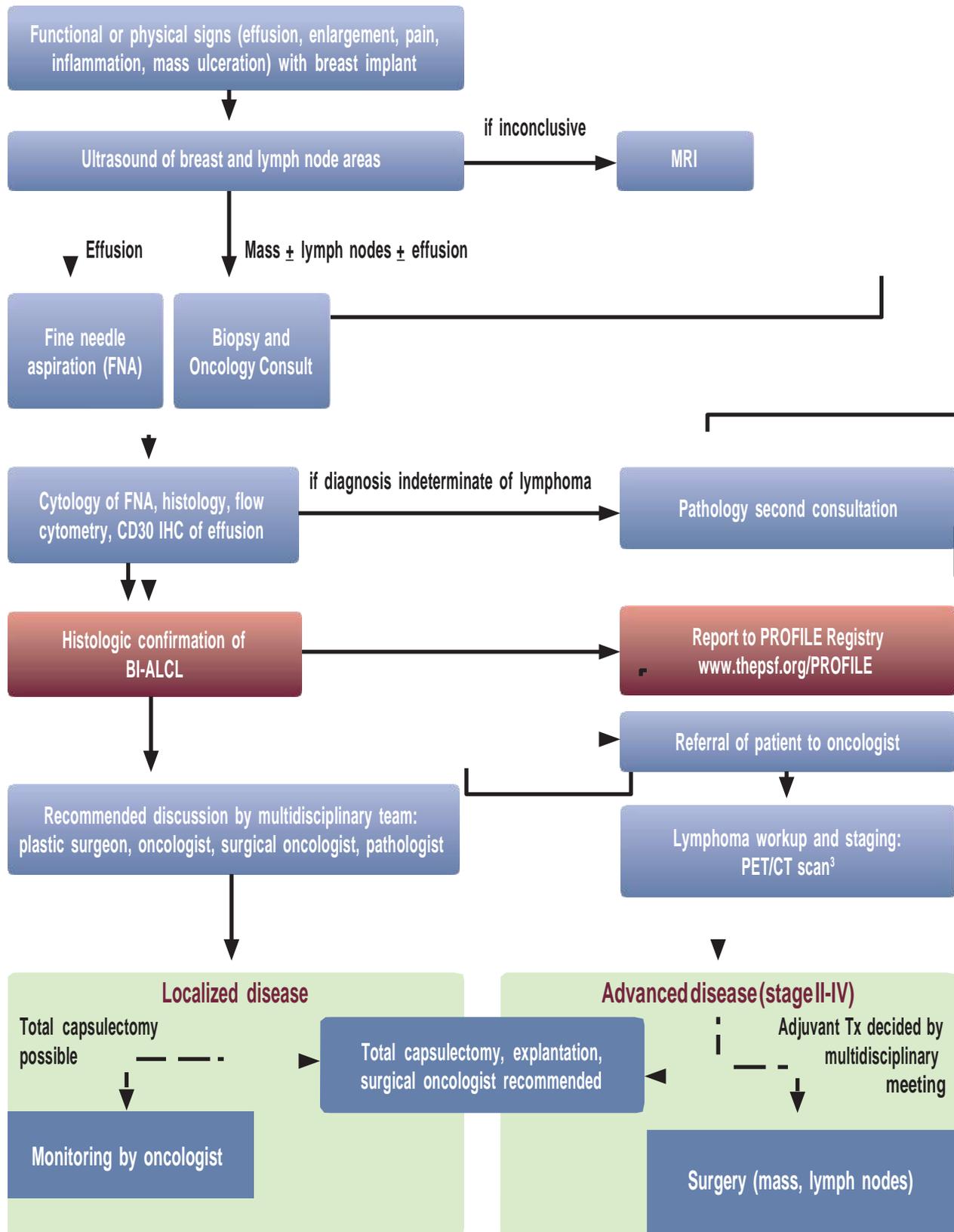


Figure 2. Treatment Algorithm