February 3, 2011.

The American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons held a webinar tonight on the recent FDA safety communication about ALCL (anaplastic large cell lymphomas) associated with breast implants. The meeting was hosted by Monte Eaves (President of ASAPS) and Phil Haeck (President of ASPS).

There have been sporadic case reports of ALCL associated with breast implants since 1985. There are 34-60 reported cases in 5-10 million implant patients worldwide. Some of the 60 reports are thought to be duplicates. Garry Brody has been instrumental in searching out the information, but he has been stymied by some of the HIPPA rules. The FDA fortunately is not bound by these privacy regulations and the FDA, ASPS and ASAPS are working together to provide us with more accurate information in the future.

The incidence of ALCL at all sites in the body is 1/500,000. The incidence of ALCL in the breast is 3/100,000,000. The classic ALCL is aggressive with a 30% 5 year survival. The ALCL that occurs in association with breast implants follows a benign course much like a skin lymphoma or a basal cell carcinoma. It appears to be a distinct clinical entity which may be eventually reclassified into its own category because it appears to be cured by explantation and complete capsulectomy.

It is important to remember that breast cancer occurs in 1/9 women. 1/500,000 women with breast implants may develop ALCL. This occurs in the breast capsule and is not a disease of the breast itself. Breast cancer is about 60,000 times more common than ALCL. ALCL in the breast may be metastatic from another source and these may be B cell or mixed B and T cell lymphomas (whereas the ALCL found in breast implant capsules is an ALK negative T cell lymphoma).

ALCL has been reported in both aesthetic and reconstructive implant patients. It has been reported with both saline and silicone implants. In most cases the surface texturing is unknown.

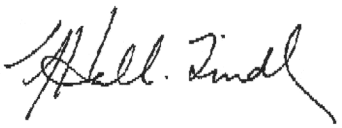
There is no laboratory test for ALCL. The classic presentation is with a late seroma (which is not subtle). There can be a pericapsular mass, pain, a lump, swelling or asymmetry. All of the reported cases had tumours which could be seen on mammography. Not every seroma is associated with ALCL but every ALCL has been associated with a seroma. Patients should therefore follow their normal postoperative routine.

If a patient presents with a late seroma, the surgeon should send fresh seroma fluid for a Wright Giemsa stain. The capsule should be sent for pathology. A cell block immunohistochemistry analysis should be performed for CD and ALK. (Garry Brody is also interested in receiving some fresh (not fixed) tissue samples.)

It is probably not necessary to inform previous patients about the problem. Both implant companies will be providing new package inserts with the implants. Surgeons are required to provide informed

consent for all major risks but we are not required to discuss all minor risks. Each surgeon will need to decide what information is appropriate for his or her patients and this may be best described as a "condition" rather than a cancer because it has such a benign course. Occurrence presents with an obvious late seroma. Surgery is curative.

More information will be provided on the ASPS and ASAPS member pages. I will continue to send out updates to Canadian plastic surgeons as it becomes available.



Elizabeth J. Hall-Findlay, MD, FRCSC

President, Canadian Society for Aesthetic Plastic Surgery