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Guideline Summary

Navigating Breast Implant-Associated Conditions
(Guidance for Primary Care Providers)

Accompanies: Clinical Practice Guideline BR-021

Cancer Care Alberta

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The assessment and management strategies outlined in this summary and accompanying guideline apply to adult patients with breast implants; they are intended for Primary Care Providers. Refer to the full clinical practice guideline for a detailed description of the clinical questions, recommendations, guideline development methodology, and references.

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Introduction

Breast implantation is an increasingly common surgery done for both cosmetic and therapeutic reasons. There are several uniquely implant-associated pathologic conditions that the primary care provider should recognize and be able to manage in the post-implanted patient.

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Breast implants and tissue expanders are manufactured with either a textured or smooth outer surface. Textured implants are further divided into those that are macrotextured (i.e., Allergan brand, previously known as McGhan brand), or microtextured (i.e., Mentor brand); macrotextured implants have an irregular pattern of pores with a larger diameter and depth than microtextured ones. Textured implants carry a lower probability of implant capsule contracture and malposition within the breast. Unfortunately, they have also been associated with Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), a rare peripheral T-cell lymphoma. There are many unproven theories for this association. The risk of BIA-ALCL appears highest in macrotextured implants; for this reason, the Biocell Allergan implants and tissue expanders were recalled in Canada on April 4th 2019. However, the overall risk of BIA-ALCL is small, so not all patients with textured implants require implant removal in the absence of a proven cancer.

Presentation

The most common presentation of BIA-ALCL is a new large collection of periprosthetic fluid, starting at least one-year post-implantation (mean onset: seven to ten years). Less commonly, patients present with a palpable breast mass, capsular contracture, lymphadenopathy, rash on the breast, and fever. BIA-ALCL can also occur in patients who had textured implants that have been removed.

Workup

1) Physical examination should be done for fluid or masses in the breast and axilla.

2) Attempt to identify the type of implant texture. Patients should have been given a breast implant “Device Identification Card” at the time of their surgery; however, their operative note should also provide that information.
3) Patients should be sent for an ultrasound; if fluid or a mass is identified, refer for ultrasound-guided biopsy/aspiration. Please indicate on the requisition if the patient has a textured implant. The radiologist should send aspirated fluid for cytology and BIA-ALCL-associated tumour markers.
4) Refer to a breast surgeon thereafter, **even if** the biopsy results are inconclusive or benign.

Management

If a malignancy is confirmed, a multidisciplinary team will consult on treatment. Total *en-bloc* capsulectomy is the primary treatment for BIA-ALCL; adjuvant treatment, radiation therapy, and systemic therapy are added for patients with higher-stage disease.

Post-Cancer Surveillance

Post-surgical follow-up of patients with BIA-ALCL is usually done by the specialist(s) until the patient is in remission enough to be discharged back to the primary care provider for long-term monitoring. Thereafter, annual physical exam and imaging as per usual breast cancer follow-up guidelines are required. Any systemic symptoms should be worked up as per standard, with special attention paid to the malignancy history - i.e. symptom-directed testing.

Screening Asymptomatic Patients with Macrotextured Breast Implants

In asymptomatic patients with macrotextured breast implants or tissue expanders, there is no clear indication for increased breast cancer screening outside of current guidelines, or for prophylactic removal of the implants - as the disease is rare. This rarity reduces the efficacy of screening and explantation. Refer to the patient’s breast surgeon if there is further concern.

Summary

1) BIA-ALCL typically presents as a large collection of periprosthetic fluid at least one year post-operatively, but can also present similarly to other breast cancers. As BIA-ALCL is associated with textured breast implants, it is important to identify the type of implant that was inserted.
2) Workup of suspected BIA-ALCL includes physical exam and standard imaging as for other breast concerns; however, any aspirated fluid should be sent for cytology and BIA-ALCL-associated tumour markers.
3) Surveillance after BIA-ALCL treatment is the same as for other breast cancer follow-up.
4) Not all textured implants are associated with BIA-ALCL; concerns about these implants in asymptomatic patients should be redirected to the breast surgeon for further discussion.

Breast Implant Illness (BII)

Some patients with breast implants experience poorly defined systemic signs and symptoms, such as fatigue, "brain fog", arthralgias, myalgias, anxiety, memory loss, alopecia, depression, rashes, autoimmune disease, weakness, inflammation and/or weight problems - which cannot be attributed to an identifiable pathology. While not an official medical diagnosis, this symptom constellation may be attributed to a condition called "Breast Implant Illness" (BII). The prevailing theory on the cause of BII is that it is related to inflammation induced by the implants; however, there are also many other theories - none of which have been proven. This condition is considered a diagnosis of exclusion, as BII lacks identifiable pathology, has unclear diagnostic criteria, and cannot currently be distinguished from other conditions by any evidence-based methodology.

Management:

It is important not to dismiss the concerns of patients concerned about Breast Implant Illness, as much about it is unknown. As BII is a diagnosis of exclusion, the differential diagnosis of BII-like symptoms should be investigated first. If workup fails to reveal alternative pathology, patients should be referred to a breast surgeon to discuss the merits of implant removal. A practical guide for primary care providers encountering patients with concerns about BII is below in Table 1.

Table 1: Lab and imaging assessment of and referral for common systemic symptoms reported by patients with breast Implants. (Modified from McGuire at al. 2022)

Symptom	Lab tests of overall health	Additional test to consider	Appropriate specialist(s) for referral
Fatigue	CBC, CRP, iron studies, vitamin B12, extended electrolytes, TSH	Cardiac imaging	Neurologist, psychiatrist, sleep disorders specialist, rheumatologist, internist
Brain Fog	CBC, CRP, iron studies, vitamin B12, extended electrolytes, TSH	Neurological imaging (eg, TIA/stroke, suspected cancer)	Neurologist, psychiatrist
Anxiety	CBC, TSH, ECG, extended electrolytes	None	Psychiatrist
Joint Pain	CBC, CRP, iron, ferritin, electrolytes, TSH, calcium	Radiography and autoantibodies (eg, ANA, RF, anti-CCP)	Orthopedist, rheumatologist
Hair Loss	Iron studies, thyroid tests	As per dermatologist	Dermatologist
Gastrointestinal Symptoms	CBC, CRP, fecal calprotectin, extended electrolytes, iron studies, TSH, H pylori testing	Colonoscopy as per gastroenterologist	Gastroenterologist

ANA, antinuclear antibody; CBC, complete blood count; anti-CCP, anti-cyclic citrullinated peptide; CRP, C-reactive protein; ECG, electrocardiogram; RF, rheumatoid factor; TIA, transient ischemic attack; TSH, thyroid stimulating hormones.

Summary

BII encompasses ill-defined systemic symptoms which may be attributed to inflammation caused by breast implants; it is a diagnosis of exclusion. Following discussion with the breast surgeon, explanation may be warranted if symptom workup fails to reveal an alternate diagnosis.

Screening in Patients with Breast Implants

A. Cancer Screening

Imaging the Augmented Breast in Patients with No Cancer History:

Patients with augmented breasts still retain natural breast tissue, which needs routine cancer screening at the same intervals and starting age (generally age 45) as patients without implants. It is important to specify on a breast imaging requisition whether a patient has implants, as additional mammogram views ("Eklund" or "displacement" views) or breast tomosynthesis imaging can be used to prevent radio-opaque implants from obstructing small lesions.

Note about Patients with Macrotextured Breast Implants:

In asymptomatic patients with macrotextured breast implants and tissue expanders, there is no clear indication for increased breast cancer screening outside of current guidelines, as BIA-ALCL is rare - which thereby reduces screening efficacy.

Imaging the Reconstructed Breast Post-Mastectomy:

There is currently no evidence for regular radiologic screening for cancer in an asymptomatic post-mastectomy reconstructed breast, as there is no significant residual natural breast tissue to image. However, patients who have undergone a unilateral mastectomy with reconstruction still need imaging and physical exam surveillance of the contralateral breast; Cancer Care Alberta recommends a screening mammogram of the intact breast annually. Magnetic resonance imaging (MRI) is a good screening option for patients who have dense breast tissue or are BRCA (BReast CAncer)- gene carriers, as it is more sensitive than mammography in these populations.

Most patients who undergo nipple- or skin- sparing mastectomy also do not need mammogram screening after reconstruction, as there is no evidence to suggest that preserving skin or nipple is less safe than total mastectomy. The nipple and areola still retain some breast tissue after a skin-sparing mastectomy, however, so this area needs routine physical examination - as cancer recurrences in retained nipples still occur.

B. Screening for Implant Rupture

There is insufficient evidence to recommend screening for breast implant integrity in asymptomatic patients, as the risk and cost of screening outweighs benefit. If the patient and physician detect an abnormality, Health Canada recommends a sensible imaging and referral program, as shown below:

Step 1: Patient self-exam
Step 2: Symptom or sign suspected
Step 3: Physician physical exam
Step 4: Ultrasound, mammogram, or both
Step 5: MRI if ultrasound is negative or inconclusive

Step 6: Consultation with surgeon for conversation about the risks and benefits of explantation of suspected implant rupture

Summary:

1) Augmented patients need regular breast cancer screening- generally starting at age 45- every two years, although this screening interval may need adjustment based on family history or BRCA gene positivity.
2) Patients with totally reconstructed breasts do not need routine breast cancer screening of the reconstructed breast, unless they retain a natural contralateral breast. Screening can also be considered in gene-positive patients who opt for nipple-sparing mastectomies.
3) Patient self-exam is the first line for screening for implant integrity. There is no evidence to support routine imaging screening for breast implant rupture.

Radiating Breast Implants

In selected breast cancers, radiotherapy may be a necessary adjuvant treatment to surgery. It is common for a reconstructed/implanted breast to change in appearance after radiation.

Radiating the Augmented Breast

There is little high-quality evidence of adverse effects of breast radiation in a patient with a prior augmentation. Capsular contracture is the main additional sequela of radiation therapy on an implanted breast; this may occur in addition to other typical sequelae, such as skin fibrosis and hyperpigmentation. A radiated implant may also sit higher on the chest and have a tighter, firmer capsule. If post-radiation changes cause pain or are otherwise distressing to the patient, test for implant integrity with a diagnostic mammogram and consider referral back to the breast surgeon. If changes are asymptomatic, no further intervention is required.

Radiating the Reconstructed Breast

Post-mastectomy radiation therapy (PMRT) may be given to cancer patients before or after tissue expander or implant placement. Some advocate delaying breast reconstruction until after radiation therapy is complete, provided patients have autologous option in the future.

Patients who have PMRT after implantation have higher rates of reconstruction failure, pain, infection, deformity, malposition, implant exposure and capsular contracture, compared to post-mastectomy patients who do not receive radiation therapy.

Summary:

Post-radiation, it is common for a reconstructed/implanted breast to change in appearance. If there is bothersome breast distortion or pain, test for implant integrity with a diagnostic mammogram and consider referral back to the breast surgeon for further discussion.