I am first and foremost a surgeon with my primary responsibilities to my patients, my profession, and to intellectual honesty, which is critical to our role as surgeons.

—Scott L. Spear, M.D., addressing U.S. Food and Drug Administration hearings on silicone breast implant safety, 2006

Fulfilling our commitment to patient safety requires awareness of adverse events, vigilance, and adherence to best-evidence treatment guidelines. Breast implant–associated (BIA) anaplastic large cell lymphoma (ALCL) is a rare T-cell lymphoma that can present as a delayed fluid collection around a textured implant or surrounding scar capsule.1–5 Despite case reports dating back two decades, BIA-ALCL came to limited national attention only after a U.S. Food and Drug Administration safety communication in 2011.1 Awareness has grown exponentially following advisory statements by the World Health Organization,6,7 the National Cancer Institute,8 the U.S. Food and Drug Administration in 2016 and 2017,9 numerous government agencies worldwide,10–12 and media coverage.13 Research efforts have focused on several theories of lymphomagenesis, with most in agreement regarding an inciting multifactorial chronic inflammatory stimulus leading to T-cell dysplasia in a genetically susceptible patient.14–21 Although the exact mechanism of pathogenesis remains elusive, clear data have now been reported on the histopathology,22–30 epidemiology,31–35 imaging,36,37 treatment outcomes,38,39 and practice guidance.40 This article reviews the diagnosis and treatment of BIA-ALCL, with specific focus on established consensus guidelines, published outcomes, and experience following over 500 unique confirmed cases worldwide.

NATIONAL COMPREHENSIVE CANCER NETWORK CONSENSUS GUIDELINES FOR DIAGNOSIS AND DISEASE MANAGEMENT

In 2016, the National Comprehensive Cancer Network established widely accepted consensus guidelines for the diagnosis and management of BIA-ALCL within their clinical practice guidelines for non-Hodgkin lymphomas, now adopted by the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery.41,42 National Comprehensive Cancer Network guidelines represent the authoritative oncology standards used worldwide, and are also important

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in coverage justification by insurance providers. Copyright agreement prevents publishing images of the algorithm, but the guidelines are available for free from www.nccn.org, and the essential elements are summarized in Figure 1. Although the National Comprehensive Cancer Network guidelines represent the most up-to-date evidence-based approach to this disease, many treating physicians may never have encountered the variable disease stages, and therefore individual treatment plans are best formulated in a multidisciplinary fashion.

APPROACH TO SUSPECTED BIA-ALCL PATIENT

Delayed seromas greater than 1 year after implantation occur in approximately 0.1 to 0.2 percent of patients following implantation of textured implants. Of note, and discussed below, smooth implants are likely not associated with BIA-ALCL. In prospective studies, BIA-ALCL has been estimated to occur in 9 to 13 percent of delayed seroma presentations. Any seroma occurring greater than 1 year after implantation not readily explainable by infection or trauma should be considered suspicious for disease. An otherwise postoperative seroma or seroma occurring less than 1 year after the first implant seroma is not part of the disease spectrum of BIA-ALCL. Patients most commonly present with the rapid onset of a spontaneous fluid collection (60-90 percent) or capsular mass (10 to 40 percent) at an average of 8 to 10 years after implantation with a textured breast implant, and are distributed roughly equally between cosmetic and reconstructive indications.38 All reported cases to date where a detailed implant history was available involved a textured surface breast implant. Other more rarely described symptoms have included skin rash, capsular contracture, and lymphadenopathy. However, capsular contracture in isolation as the only disease manifestation has not been described; therefore, its reliability as a symptom of the disease is questionable and may be coincidental. Disease is not confined to female patients, as three transsexual patients with textured implants have been confirmed. Following the National Comprehensive Cancer Network guidelines, initial workup of an enlarged breast should include ultrasound evaluation specifically for a fluid collection, a breast mass, or enlarged regional lymph nodes (axillary, supraclavicular, and internal mammary). For cases where ultrasound is indeterminate or requires further confirmation, physicians may also use magnetic resonance imaging. Adrada and colleagues reviewed 44 BIA-ALCL patients with imaging studies and reported on the sensitivity and specificity for detecting an effusion using ultrasound (84 percent and 75 percent), computed tomography (55 percent and 83 percent), magnetic resonance imaging (82 percent and 33 percent), and positron emission tomography/computed tomography (38 percent and 83 percent). In addition, the sensitivity and specificity to detect a mass were reported for ultrasound (46 percent and 100 percent), computed tomography (50 percent and 100 percent), magnetic resonance imaging (82 percent and 33 percent), and positron emission tomography/computed tomography (64 percent and 88 percent). The sensitivity of mammography was found to be inferior for both effusion and mass and therefore is not considered an acceptable imaging modality for BIA-ALCL. Based on these findings, ultrasound evaluation is used as a screening tool, whereas positron emission tomography/computed tomography is used after an established diagnosis for oncologic workup before surgery (Fig. 2).

Periprosthetic fluid collections should undergo fine needle aspiration. At the time of aspiration, ultrasound guidance may aid in implant protection and displacement, and can be performed either in a clinic setting or by interventional radiology (Fig. 3). A suspicious mass requires tissue biopsy and evaluation by an oncologist to rule out breast cancer. Specimens should be sent for cell block cytology and CD30 immunohistochemistry. Pathologists will require a clinical history and directions to rule out BIA-ALCL. Fluid specimens do not require storage in any specialized media, and should be transported to a pathology laboratory within a reasonable amount of time (<48 hours). Although cells may lyse if left for a prolonged period, diagnostic protein markers in neoplastic cells do not degrade and diagnosis is possible on fixed cell blocks years later. Fluid collections may be centrifuged down to a supernatant to concentrate cells for pathologic evaluation. If after evaluation diagnosis of lymphoma is indeterminate, secondary hematopathology consultation is recommended at a tertiary cancer center with disease experience. Surgeons investigating a suspicious seroma must supply a pathologist with an adequate volume (minimum, 20 to 50 ml; ideally, >100 ml) to thoroughly evaluate and perform further tests such as flow cytometry and molecular studies, which may be necessary for diagnosis.

DIAGNOSTIC CRITERIA

BIA-ALCL is a monoclonal T-cell expansion of large anaplastic (Reed Sternberg-like) cells that
Fig. 1. Diagnosis and treatment follows the National Comprehensive Cancer Network guidelines, which are available for free download from www.nccn.org. The essential elements are summarized in the algorithm. BIA, breast implant–associated; MRI, magnetic resonance imaging; IHC, immunohistochemistry; PROFILE, Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology; PET, positron emission tomography; CT, computed tomography; US, ultrasound; Tx, therapy; CHOP, cyclophosphamide, vincristine, doxorubicin, and prednisone. (Modified with permission from Clemens MW, Butler CE. ASPS/PSF efforts on BIA-ALCL. Plast Surg News 2015;26:8.)
express CD30 within a periprosthetic effusion or mass aggregate. CD30 is a cell membrane protein that serves as a lymphoma tumor marker, although CD30 can occur normally on activated T- or B-cell lymphocytes. A background of CD30+ T cells is estimated to constitute 0.1 to 5 percent of circulating T cells, and a higher concentration may exist in inflammatory states. Increased CD30 expression can be induced on both T cells and B cells as a result of viral infection. CD30+ lymphocytes have been described temporarily increasing from a background of 0.1 percent to as high as 95 percent transiently. Immunoblastic proliferation that occurs in infectious mononucleosis can develop Reed-Sternberg–like cells, temporarily making differentiation from Hodgkin lymphoma difficult. BIA-ALCL, and the entire family of ALCLs, display diffuse CD30 expression on their cell surface. Morphologic evaluation by a pathologist and determination of clonal expansion on flow cytometry are critical to diagnosis. If the pathologic evaluation is negative for ALCL, the patient can be referred to a plastic surgeon for management of a benign seroma. In accordance with the U.S. Food and Drug Administration’s recommendation, histologic confirmation of BIA-ALCL should be reported to the American Society of Plastic Surgeons BIA-ALCL PROFILE (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology) registry (www.thepsf.org/PROFILE). The purpose of this important registry is to increase scientific data on BIA-ALCL in women with breast implants and to support research to characterize the disease. As of February 2018, 518 unique cases of BIA-ALCL across 25 countries have been reported which includes 194 unique US cases to the PROFILE BIA-ALCL patient registry.
PREOPERATIVE ONCOLOGIC WORKUP

After confirmation of BIA-ALCL diagnosis, preoperative consultation with a lymphoma oncologist and consideration of a surgical oncologist are recommended. Oncologic workup should proceed before any operative intervention. A bone marrow biopsy may be indicated but is only performed in rare select cases at the oncologist’s discretion to differentiate from other peripheral T-cell lymphomas. Testing for anaplastic lymphoma kinase translocation status also differentiates from anaplastic lymphoma kinase–positive systemic ALCL, a much more aggressive disease. Note that BIA-ALCL is always anaplastic lymphoma kinase–negative, and therefore anaplastic lymphoma kinase is not a screening tool but a descriptive tool for established disease. For confirmed cases, a positron emission tomographic/computed tomographic scan is beneficial for demonstrating associated capsular masses, chest wall involvement, regional lymphadenopathy, and/or distant organ metastasis. A positron emission tomographic scan can act as a roadmap for

Fig. 3. Disease diagnosis should be made prior to any surgical intervention to allow for an adequate preoperative oncologic work up and staging. (Above) In a clinical setting, a periprosthetic fluid collection is aspirated under ultrasound guidance and facilitated by implant displacement. (Image with permission and courtesy of Olaya Sanchez Crespo, M.D.) (Below) A BIA-ALCL effusion aspirate is shown and may appear serous, viscous, and/or bloody. Fluid specimens should be sent in entirety, at least 50ml, to facilitate an accurate diagnosis.

Fig. 4. A malignant effusion in a BIA-ALCL patient demonstrates large pleomorphic cells with prominent horseshoe-shaped nuclei, and nuclear folding and strong diffuse CD30 reactivity by immunohistochemistry (CD30 immunohistochemistry with hematoxylin counterstain, original magnification, × 1000). Inset demonstrates a single T-cell population on flow cytometry. Positive cytollogy and a diffuse expression of CD30 are required for diagnosis.

Fig. 5. CD30 immunohistochemistry of a benign late seroma demonstrates a normal mixture of small lymphocytes, histiocytes, and rare eosinophils. Histiocytes display abundant clear cytoplasm with nuclei of variable size. Note that most lymphocytes and all histiocytes are negative for CD30 except for rare isolated morphologically normal lymphocytes (CD30 immunohistochemistry with hematoxylin counterstain, original magnification, × 1000).
surgical planning, resection strategy, and timing of surgery. For instance, unresectable chest wall invasion may become resectable following neoadjuvant chemotherapy.

**Table 1. Reported Stages of BIA-ALCL**

<table>
<thead>
<tr>
<th>References</th>
<th>No.</th>
<th>Ann Arbor Stage (%)</th>
<th>M. D. Anderson Solid Tumor TNM Stage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brody et al., 2015&lt;sup&gt;39&lt;/sup&gt;</td>
<td>173</td>
<td>89.6</td>
<td>10.4</td>
</tr>
<tr>
<td>Clemens et al., 2016&lt;sup&gt;38&lt;/sup&gt;</td>
<td>87</td>
<td>86.2</td>
<td>13.8</td>
</tr>
<tr>
<td>Loch-Wilkinson et al., 2017&lt;sup&gt;44&lt;/sup&gt;</td>
<td>55</td>
<td>96.4</td>
<td>3.6</td>
</tr>
<tr>
<td>de Boer et al., 2017&lt;sup&gt;47&lt;/sup&gt;</td>
<td>32</td>
<td>81.3</td>
<td>18.8</td>
</tr>
<tr>
<td>Campanale et al., 2017&lt;sup&gt;35&lt;/sup&gt;</td>
<td>22</td>
<td>81.8</td>
<td>18.2</td>
</tr>
</tbody>
</table>

TNM, tumor, node, metastasis; NR, not reported.
*Lympoproliferative.
†Invasive lymphoma.

**SOLID TUMOR STAGING**

BIA-ALCL was formally staged as a liquid tumor; however, tumor biology has preferentially supported staging as a solid tumor. The Lugano...
revision to the Ann Arbor Staging System is a liquid tumor staging, with stage IE disease limited to breast involvement only and stage IIE disease limited to the breast and ipsilateral axillary lymph nodes. Using this system, nearly all BIA-ALCL patients have low-stage disease, either stage IE (83 to 96 percent) or stage IIE (3.6 to 18.8 percent) (Table 1).

An M. D. Anderson tumor, node, metastasis staging system is modeled after the American Joint Committee on Cancer tumor, node, metastasis system (Figs. 6 and 7 and Table 2). Using this system, BIA-ALCL is a spectrum of disease consisting of stages IA (35.6 percent), IB (11.5 percent), IC (13.8 percent), IIA (25.3 percent), IIB (4.6 percent), III (9.2 percent), and IV (0 to 9 percent) (Table 1). The World Health Organization currently classifies BIA-ALCL as a lymphoma at all stages. Clinical observation of effusion-limited (IA) disease demonstrates a typically indolent course, and therefore this stage may be more akin to a lymphoproliferative disorder. However, BIA-ALCL can become an invasive lymphoma and metastasize at more advanced stages. Other malignant lymphoproliferative disorders include lymphomatoid papulosis and primary cutaneous ALCL. Both can regress spontaneously and have an observed progression rate to invasive lymphoma of 5.6 to 9 percent and 10 to 27 percent, respectively. It is not yet possible to determine
the progression rate of effusion-only (IA) BIA-ALCL to invasive lymphoma, as the staging requires pathologic examination of the resected capsule (in essence, treating the disease). Therefore, how indolent the disease is or quantifying what amount of delay in treatment will lead to progression of disease is not yet possible. It is important to note that all of these designations and nomenclatures are still referring to a cancer. Patients with BIA-ALCL can have progression of their disease, lymph node involvement, and death as a result of disease, particularly with significant delay in diagnosis or suboptimal treatment.54 These patients are described as having local or regional extension of their disease or very rare distant organ metastasis, which is more similar to solid tumors. This emphasizes the solid tumor classification and that this is a distinct entity that progresses locally.

**SURGICAL TREATMENT**

Timely diagnosis and complete surgical excision of disease, implants, and the surrounding fibrous capsule is the optimal approach for the management of BIA-ALCL in the majority of patients. Disease localized to the capsule (Lugano stage IE, M. D. Anderson stage IA to IIA) may be treated with surgery alone in the majority of cases (Fig. 8). Surgical goals are a total capsulectomy with removal of the breast implant, excision of any associated capsular mass, and excisional biopsy of suspicious lymph node(s). In retropectoral or dual-plane implants, adherence to the ribcage may make resection difficult, and tumescence of the anatomical plane can facilitate capsulectomy55 (Fig. 9). Care should be taken when dissecting capsule off of intercostal muscles to avoid a pneumothorax. It remains unclear what effect inadvertent spillage of the seroma during capsulectomy has on local seeding of disease; however, clinically, this has not been observed to influence recurrence rates. Complete mass excision with negative margins is essential, as retained disease likely will subject the patient to otherwise unnecessary adjuvant chemotherapy. At present, there

<table>
<thead>
<tr>
<th>Tumor size</th>
<th>T1</th>
<th>Early capsule invasion</th>
<th>T2</th>
<th>Mass aggregate, confined to capsule</th>
<th>T3</th>
<th>Tumor locally invasive out of capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>T</td>
<td>Confined to effusion or as a layer on luminal side of capsule</td>
<td>N1</td>
<td>One regional lymph node</td>
<td>N2</td>
<td>Multiple regional lymph nodes</td>
<td></td>
</tr>
<tr>
<td>Lymph nodes</td>
<td>N0</td>
<td>No lymph node involvement</td>
<td>M0</td>
<td>No distant spread</td>
<td>M1</td>
<td>Other organs/distant sites</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metastasis</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>


†Stages: stage IA, T1N0M0; stage IB, T2N0M0; stage IC, T3N0M0; stage IIA, T4N0M0; stage IIB, T1-3N1M0; stage III, T4N1M0; stage IV, TanyNanyM1.

**Table 2. BIA-ALCL Tumor, Node, Metastasis Staging**

Fig. 8. A 77-year-old woman underwent postmastectomy prosthetic reconstruction for breast cancer. Eleven years after implantation, she developed rapid swelling of the right breast manifested as marked breast asymmetry. (Left) BIA-ALCL was diagnosed on fine needle aspiration. (Right) The patient then underwent a total capsulectomy and implant removal.
is no role for radical mastectomy, sentinel lymph node biopsy, or full axillary dissection. According to the National Comprehensive Cancer Network guidelines, surgeons may consider removal of the contralateral implant, as approximately 4.6 percent of cases to date have demonstrated incidental ALCL in the contralateral breast implant. Consultation with a surgical oncologist may be beneficial for plastic surgeons unaccustomed to oncologic ablation and lymph node excisional biopsies.

Pathologic evaluation of both the periprosthetic fluid and the capsule are important for staging of the disease (Figs. 10 and 11). Evaluation of the capsule may be performed by either widely sampling the internal lining; alternatively, the capsule may be opened and set out flat and sampled after fixation. Timing and type of reconstruction remain controversial and are currently being prospectively studied with institutional review board oversight. Replacement with smooth implants can be done depending on patient’s preferences, but replacement with textured implants should be avoided because of likely genetic predisposition and demonstrated susceptibility.

**INDICATIONS FOR ADJUVANT TREATMENTS**

Adjuvant chemotherapy will frequently be warranted in patients with advanced disease (2 to 18 percent) such as lymph node metastasis (Lugano stage II to IV; M. D. Anderson stage IIB to IV) (Table 1). Systemic ALCL is treated with an anthracycline-based regimen (cyclophosphamide, vincristine, doxorubicin, and prednisone) for first-line therapy. Anthracycline-based multiagent chemotherapy with or without radiation therapy followed by autologous stem cell rescue...
is the standard approach for most patients with newly diagnosed systemic T-cell lymphomas. However, National Comprehensive Cancer Network guidelines allow physicians to consider following either a systemic ALCL chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin, and prednisone) or alternatively with brentuximab vedotin as a first-line agent. Brentuximab vedotin is a toxin-antibody conjugate to CD30. Pro and colleagues reported 4-year survival data from an ongoing Phase II study of brentuximab vedotin in patients with refractory systemic ALCL that demonstrated an objective response rate of 83 percent and a complete remission rate of 62 percent. A randomized Phase III study is evaluating brentuximab vedotin in combination with cyclophosphamide, doxorubicin, and prednisone for frontline treatment of CD30+ mature T-cell lymphomas, including systemic ALCL. Outcomes of chemotherapy regimens in BIA-ALCL are from case reports; however, complete remissions have been achieved in patients with organ metastasis when treated with brentuximab vedotin. The drug may also have a role as a neoadjuvant targeted agent for downgrading chest wall invasion. Stem cell transplant and external beam radiation therapy are reserved only for unresectable disease in a salvage setting.

**FOLLOW-UP AND DISEASE SURVEILLANCE**

Patients are best followed by an oncologist that may monitor for disease recurrence and evaluate for adjunctive therapy. Treated patients with no evidence of disease are evaluated every 3 to 6 months for 2 years, and then as clinically indicated. Physicians may include computed tomographic or positron emission tomographic/computed tomographic scans every 6 months for 2 years and then only as clinically indicated. Relevant surgical codes for diagnosis and management of BIA-ALCL are listed in Table 3. Most insurance companies do not specify whether treatment for BIA-ALCL is a covered benefit; however, Blue Cross Blue Shield and Aetna have recently guaranteed coverage for implant and capsule removal with a confirmed diagnosis of BIA-ALCL in both cosmetic and reconstructive implant patients.

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
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<tbody>
<tr>
<td>10022</td>
<td>Fine needle aspiration with imaging guidance</td>
</tr>
<tr>
<td>19101</td>
<td>Breast biopsy, open, incisional</td>
</tr>
<tr>
<td>19260</td>
<td>Excision of chest wall tumor</td>
</tr>
<tr>
<td>19328</td>
<td>Removal intact mammary implant</td>
</tr>
<tr>
<td>19371</td>
<td>Breast peri-prosthetic capsulectomy</td>
</tr>
<tr>
<td>38525</td>
<td>Biopsy/ excision, lymph node; open or deep axillary node</td>
</tr>
</tbody>
</table>

Table 3. Relevant International Classification of Diseases, Tenth Revision, and Current Procedural Terminology Codes for Suspected and Confirmed BIA-ALCL Cases

**Fig. 11.** (Left) Scanning electron microscopic photograph of the textured surface implant and scar capsule interface in a BIA-ALCL patient (original magnification, × 40). Note the shark-tooth impression of the luminal capsule surface that mirrors the implant surface. (Right) Scanning electron microscopic photograph of a textured shell surface with clusters of ALCL cells growing on the surface of the implant (original magnification, × 300).
TREATMENT OUTCOMES

BIA-ALCL generally appears to be a biologically indolent disease with an excellent prognosis when confined to the capsule and treated with complete surgical resection. To date, we have not confirmed a case of BIA-ALCL with spontaneous resolution of disease without any treatment intervention. Regression and healing can rarely occur with other malignancies such as melanoma, but we have not confirmed a case of regression with BIA-ALCL to date.\(^{62}\) Note that gradually lower concentrations of anaplastic cells have been observed after serial aspirations, making diagnosis more difficult after a previous seroma drainage. This may represent dilution of the tumor burden rather than regression, and should still be addressed with surgical resection. Statistically worse prognosis has been identified in patients with mass formation and extracapsular extension.\(^{22}\) Miranda and colleagues reported on the long-term outcomes of 60 patients and found that more patients without a mass achieved complete remission compared with those with a mass (93 percent of 42 patients compared with 72 percent of 18 patients).\(^{22}\) The median overall survival for patients with a discrete breast mass was 12 years, whereas the median overall survival had not been reached for patients who did not have a discrete breast mass. It remains unclear whether the worse prognosis associated with a mass is attributable to a more aggressive variant or more progressed disease, or perhaps is a consequence of inadequate surgical ablation of tumor infiltration.

Clemens et al. reported on the outcomes of 87 patients treated with surgery alone (40 percent); surgery and radiation (9 percent); surgery and chemotherapy (19 percent); surgery, chemotherapy, and radiation therapy (30 percent); or chemotherapy alone (2 percent).\(^{38}\) Both the presence

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**Fig. 12.** Survival curves according to treatment approaches (above) and tumor, node, metastasis solid tumor staging (below). Event-free survival (left), overall survival (right). (Reprinted with permission from Clemens MW, Medeiros LJ, Butler CE, et al. Complete surgical excision is essential for the management of patients with breast implant-associated anaplastic large cell lymphoma. *J Clin Oncol*. 2016;34:160–168.)
of a mass at the time of diagnosis and extracapsular disease extension were associated with an increased risk for recurrence and patient death. At a median follow-up of 45 months, 28 percent had recurrent disease, of whom 73 percent were treated with salvage chemotherapy. Complete surgical excision of the disease had the lowest recurrence rate of 4 percent at 1, 3, and 5 years. Kaplan-Meier survival curves by treatment modality are displayed in Figure 12. At present, a total of 16 patients have been reported dead from BIA-ALCL disease in Australia, Brazil, France, United Kingdom, The Netherlands, New Zealand, Sweden, and the United States. A recurring theme in these tragic outcomes is significant delay in diagnosis, and/or chemotherapeutic treatment of the disease with limited or no surgical resection.

CONCLUSIONS

BIA-ALCL was first described over 20 years ago but has only recently led to a wave of concern among the public, media, and physicians. BIA-ALCL appears to begin as an indolent disease with excellent prognosis in the majority of patients. Early stages are similar to a lymphoproliferative disorder arising in an effusion around a textured breast implant, and can progress to an invasive lymphoma with infiltration of the fibrous capsule, mass formation, and regional metastasis. Diagnosis requires large anaplastic cells on cell block cytology, CD30 immunohistochemistry expression, and surrogate markers for T-cell clonality by flow cytometry. National Comprehensive Cancer Network consensus guidelines have been established and widely adopted for the diagnosis and management of BIA-ALCL. Surgical ablation with explantation and capsulectomy is frequently curative with disease confined to the capsule. Novel targeted chemotherapy agents have demonstrated early success and may be the preferred treatment in advanced disease. Understanding and implementation of a standardized approach is critical to prevent delays in diagnosis, disease progression, and avoidable adverse sequelae. Patient safety is our first and foremost responsibility.

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