Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): A Review and the Caribbean Perspective

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ABSTRACT

Objectives

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare CD-30 positive, Anaplastic Lymphoma Kinase Negative Non-Hodgkins lymphoma. The current estimated incidence is one to three cases per million implanted women. However, this is likely to rise with the increasing popularity of breast augmentation. This article contains a brief literature review and describes the Caribbean response to BIA-ALCL.

Methods

A literature search was done on the PUBMED Database. Keywords included 'breast implant-associated anaplastic large cell lymphoma', 'brentuximab vedotin', 'breast implant', 'texturized implants'. The Caribbean Association of Plastic and Reconstructive Surgeons (CAPRS) formulated a regional response to BIA-ALCL during their meeting in August 2019.

Results

The Food and Drug Administration (FDA) has received 573 unique medical device reports of BIA-ALCL worldwide. The time from implantation to diagnosis, ranges from 7.5 to 10 years and the median age at diagnosis ranges from 47 to 58 years. The pathophysiology of BIA-ALCL is likely multifactorial and involves chronic inflammation in response to textured implants and chronic biofilm, in a genetically susceptible person. Early presentation has a good prognosis with treatment (5-year survival rate of 70-90%).

Conclusion

Recommendations included development of a regional breast implant registry, which will facilitate study on implant use and its complications. They also concluded that texturized devices should be avoided and utilization of smooth alternatives or autologous reconstruction be performed. Additionally, if requested by asymptomatic women, explant of textured implants and total capsulectomy is not unreasonable. However, these patients must be appropriately counselled.

INTRODUCTION

Primary breast lymphomas account for 0.04-0.5% of all primary breast carcinomas with only 5-10% of these cases being of T-cell origin.[1-3] Breast implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare subset of primary breast T-cell lymphomas.[1,4] It is a CD-30 positive, Anaplastic Lymphoma Kinase (ALK) negative Non-Hodgkins lymphoma, which is similar in pathology and morphology to primary cutaneous ALCL.[1,4] The current estimated incidence is one to three cases per million implanted women, however true incidence is difficult to assess.[5] Recent awareness may have artificially increased numbers.[5]

BIA-ALCL arises in a peri-implant effusion or on the inner layer of the fibrous capsule surrounding an implant. The first reported case was in 1997 by Keech and Creech.[6] It occurred in a 41-year-old Caucasian female with a saline filled breast implant.[6] However, the Food and Drug Administration (FDA) only formally acknowledged the link between implants and this CD30+ lymphoma in 2011.[7,8] While early literature referred to it as a lymphoproliferative disorder, in 2017, BIA-ALCL was designated as a malignancy in the revised 4th edition of the World Health Organisation (WHO) classification of lymphoma.[4] The increased awareness of this condition has prompted responses from countries and breast implant manufacturers worldwide.

Millions of implant-based breast augmentations are being performed worldwide per year, so although rare, BIA-ALCL represents a serious health risk which will lead to significant health and financial ramifications in the future. In response to this emerging health issue, different regions including the Caribbean, have sought to establish a response to the crisis. This article contains a brief review of the literature and describes the Caribbean perspective and response to a potential health crisis.

METHOD

A literature search was done on the PUBMED Database. Only articles in English were included. Keywords included 'breast implant associated anaplastic large cell lymphoma', 'brentuximab vedotin', 'breast implant', 'texturized implants'. Studies were also derived from the references section of studies reviewed. Ethical Committee approval was not applicable to this study.

LITERATURE REVIEW

Epidemiology

To date, the FDA has received 573 unique medical device reports (MDR) of BIA-ALCL worldwide with 33 deaths.[7] 36% of these cases arose in the United States of America (USA) with the remaining 64% reported in the rest of the world.[7] Data from other registries report 656 cases as of November 2018 with 17 deaths.[5] The majority of these cases occurred in the US, Australia, France, UK and Netherlands (Figure 1).[5] Of note, relatively few cases of BIA-ALCL arose in Asian and African countries and no cases to date have been reported in the Caribbean. It is unknown whether BIA-ALCL is linked to ethnicity.

As a result of underreporting, under diagnosis, rarity of the condition and difficulty in acquiring accurate sales data, literature reports a wide variation in the estimated risk for BIA-ALCL. In 2019, Magnusson et al reported an overall estimated risk of 1 in 30,000 implants, in a prospective study conducted by a multidisciplinary alliance throughout Australia and New Zealand.[9] However, limitations of this study include reliance on the accuracy of sales data provided by companies to estimate the prevalence of breast implants. In addition, there may be cases that have not yet been diagnosed. With increased awareness of the malignancy, they noted a 47% increase of cases between December 2016 and 2019.[9] A true estimate of incidence and risk would not be able to be assessed until the incidence plateaus.[5]

BIA-ALCL is indolent, with the median time from implantation to diagnosis, ranging from 7.5 to 10 years.[4,10,11] The median age at diagnosis ranges from 47 to 58 years.[11,12] It has a good prognosis, with a 5-year survival rate of 70-90%.[13] This is in contrast to ALK negative systemic ALCL, which has a 5-year prognosis of only 36-48%.[10]

BIA-ALCL has two distinct pathological forms. In-situ BIA-ALCL, is confined to the effusion or inner layer of the capsule, while the infiltrative form involves a mass due to penetration of the capsule.[4,10] The infiltrative form may be accompanied by an effusion.[4,10] Confinement of the cancer to the capsule is an excellent prognostic marker and with treatment, has a 5-year survival of 100%.[4] Presentation with a mass with or without an effusion, has a poorer prognosis.[4] It is associated with a 5-year survival of 72.4% with treatment ($p=0.0002$).[4] In fact,

Figure 1. Bar Graphs showing number of cases and deaths of BIA-ALCL reported worldwide as of November 2018

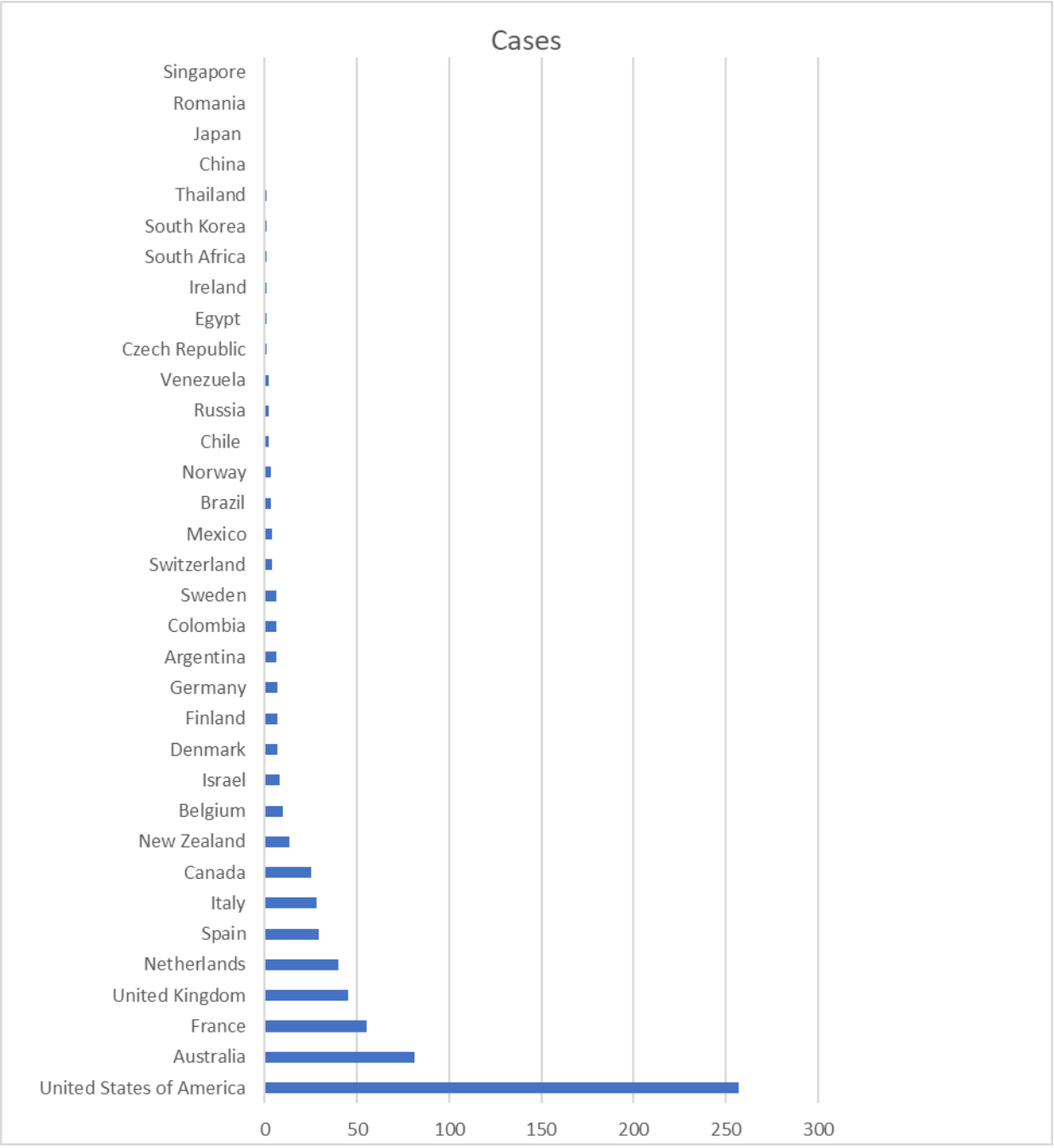


Figure adapted from reference [5].

39% of the 33 deaths to date from BIA-ALCL, presented with a mass.[7]

Unlike systemic ALCL, which has a predilection for the right breast, BIA-ALCL affects both breasts equally.[14] It also demonstrates no association with implant contents, however, has been linked with implant texture which will be discussed later in the review.[14]

Pathophysiology

There are different theories regarding the pathophysiology of BIA-ALCL, however most agree that it is likely multifactorial. One theory, states BIA-ALCL occurs in a genetically susceptible female who is exposed to a textured implant, with or without chronic biofilm.[4] The combination of these factors leads to a chronic inflammatory response.[15] The reactive oxygen species

and cytokines released during this inflammatory process, results in injury to T cell mRNA, leading to reactive dysplasia then malignant transformation.[4,15] There is subsequent expansion of malignant clones leading to lymphoma.[15] The long lag period of the condition is consistent with a chronic inflammatory aetiology.

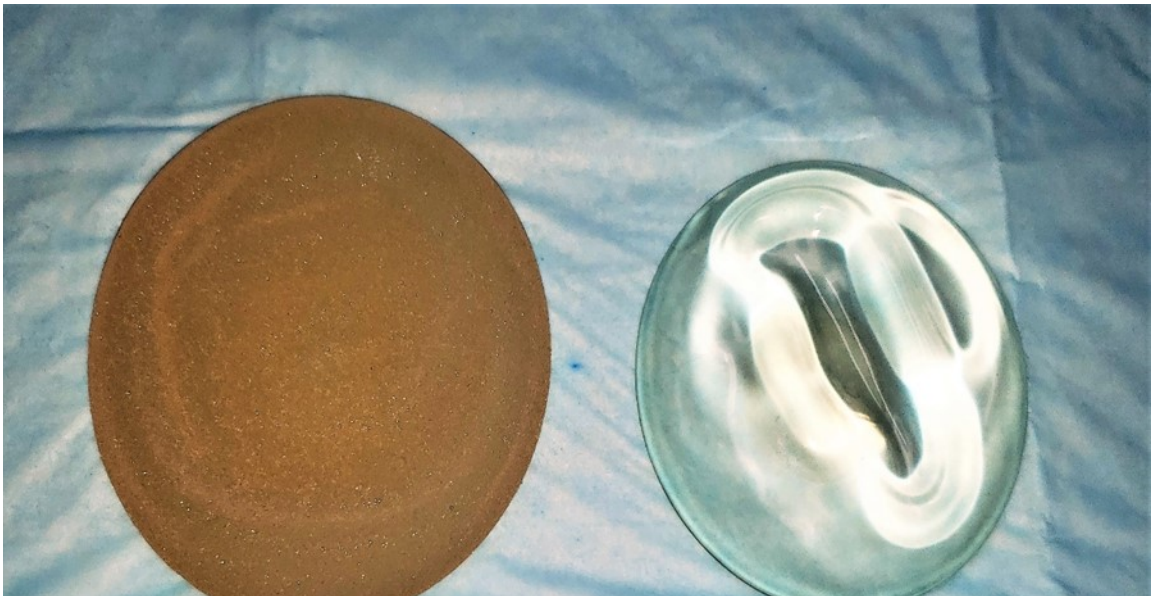
BIA-ALCL however remains rare, despite the popularity of implant-based breast augmentations or reconstructions. This may be due to the genetic susceptibility present in affected women. Mutations resulting in overactivation of the JAK/STAT pathway, has been implicated in the pathogenesis of BIA-ALCL.[4,8,10,11,16,17] Lechner et al. conducted a prospective in-vitro study in which three cell lines were cultured from BIA-ALCL cases ranging from indolent to aggressive.[16] They noted upregulation of anti -apoptotic genes for survivin ($p<0.05$), increased activation of STAT 3 ($p<0.05$) and downregulation of its negative regulator SHP-1 ($p<0.05$).[16] In addition, they reported that STAT-3 specific inhibition produced dose dependent cell death in BIA-ALCL cell lines.[16] Chemotherapeutic agents that increase SHP-1 protein also produced dose related cell death.[16] The limitation of this study is that it was a completely in vitro study and they did disclose that one of the researchers received grants from Mentor. Oishi et al also implicated the JAK/ STAT pathway in the pathogenesis of BIA-ALCL.[17]

Textured Implants

There is a clear association between BIA-ALCL and textured implants (Figure 2). Textured implants were introduced in the 1980s and became popular due to the reduced risk of capsular contracture. Barnsley et al conducted a meta-analysis in 2006, that concluded capsular contracture was five times more likely to occur with smooth implants.[18] This was confirmed by a 10-year risk analysis conducted by Calobrace et al in 2018.[19] However, this claim remains controversial. Systematic reviews concluded that textured implants may decrease the incidence of capsular contracture in sub-glandular augmentation, however research on the topic may suffer from inadequate description of implants or short follow up periods.[5] Textured implant use was also associated with a reduced risk of migration and rotation of the implant. While rotation does not affect the efficacy of round implants, resistance to rotation is an integral quality in anatomical implants.[10,20]

To date, of the cases reported by the FDA where implant texture was known, 94% of the cases had a history of textured implant at time of diagnosis, while only 6% presented with a smooth implant.[7] Of note, of the 6% who presented with smooth implants in-situ, all had a history of textured implant or their implant history was unknown.[7] There are no cases of BIA-ALCL with a pure history of smooth implants.[4,5,7] Similar results were

Figure 2. Textured implant shown on left has increased surface area and rougher texture than smooth implant shown on right.



reported in 2018, with the majority of cases occurring with textured implants.[21] In addition, there are no cases of BIA-ALCL reported in the pre-textured era of implantation.[8]

De Jong et al estimated an odds ratio (OR) of developing BIA-ALCL with a textured implant of 18.2 in a retrospective case-control study using a population-based database in the Netherlands.[14,22] However due to the rarity of the condition the actual number of cases were small and there was a lack of valid data on the prevalence of women with implants in the Netherlands.[22] A later study by de Boer et al, in 2018, expanded on the work by de Jong. They also conducted a case-controlled study using the population-based registry.[23] At this time, there were now 47 cases versus 11 cases included in de Jong.[22,23] They calculated an OR of 421.8 ($p<0.001$) of BIA-ALCL with textured implants.[23] Of note, 82% of these implants were macro-textured despite only 45% of textured implants sold in the Netherlands are macro-textured.[23] Unfortunately, the numbers of cases in this study are still too small to conclude on modifying factors e.g. implant exposure duration needed to develop BIA-ALCL.[23] In addition, the absolute risks were based on extrapolated data due to incomplete historical sales data.[23]

However, not all textured implants carry equal risk. The incidence of BIA-ALCL varies with the texturization technique utilized. In 2019, BIOCELL (Allergan, Dublin, Ireland) which uses the lost salt technique, accounted for 84% of BIA-ALCL cases according to the FDA.[7] Siltex (Mentor Corp., Santa Barbara, CA), which uses negative stamping, accounted 7% and Sientra (Sientra, Santa Barbara, CA) for 1%.[7] Magnusson et al reported an implant specific risk of 1 in 3,345 with BIOCELL (Allergan) whereas Siltex (Mentor) implants carried the lowest risk of 1 in 86,029.[9] The odds ratio (OR) of developing BIA-ALCL with BIOCELL implants compared to Siltex was 16.52 (95% C.I. $P<0.0001$).[9] The OR for polyurethane (Silimed, Rio de Janiero, Brazil) compared to Siltex was 23.4 (95% C.I; $P<0.0001$).[9] Thus, the highest risk in this study was with polyurethane implant with 1 in 2832.[9]

Polyurethane, which involves covering of the silicone shell with a polyurethane foam, is the most aggressively texturized implant (grade 4) of the three.[9] This is consistent with the theory that the more aggressively texturized the implant, the higher the risk of BIA-ALCL formation. However, this seems discordant with the vast majority of cases being linked with Allergan BIOCELL implants. It is unknown whether this disparity may be due to the relative popularity of Allergan BIOCELL implants when compared to polyurethane implants, rather than due to the texturization technique.

Chronic bacterial colonization has also been implicated in the pathophysiology of BIA-ALCL. This is consistent with the link between texturization and BIA-ALCL, as the increased surface area is conducive to bacterial growth (Figure 2).[3,10,24] Jacombs et al performed an in-vitro investigation of the impact of implant texturization on bacterial colonization.[24,25] They reported that contaminated textured implants held 72 times more bacteria than smooth implants.[24,25] This was supported by Hu et al, who reported a 30-fold increase in bacteria in contaminated textured implants.[3] The authors also reported that the inflammatory response elicited by contaminated textured implants resulted in a 63-fold increase in B- and T- cells when compared to smooth.[3] In addition, the majority of these lymphocytes were of T cell origin.[3] Meza Britez et al, in 2012, also demonstrated a predominance of T cells in the inflammatory response elicited by textured implants.[4,26] This is consistent with the development of a T cell lymphoma such as BIA-ALCL.

The gram negative Ralstonia species has been implicated in the pathogenesis of BIA-ALCL.[3] The lipopolysaccharides in its cell wall bind irreversibly with the silicone elastomer shell and stimulates cytokine production.[3] This in turn causes chronic Th1-cell stimulation which, in genetically susceptible women, eventually leads to dysplasia and malignant transformation.[3] Leberfinger et al further supported this link by demonstrating that in unilateral BIA-ALCL, the unaffected breast had significantly less bacteria than the affected breast.[8]

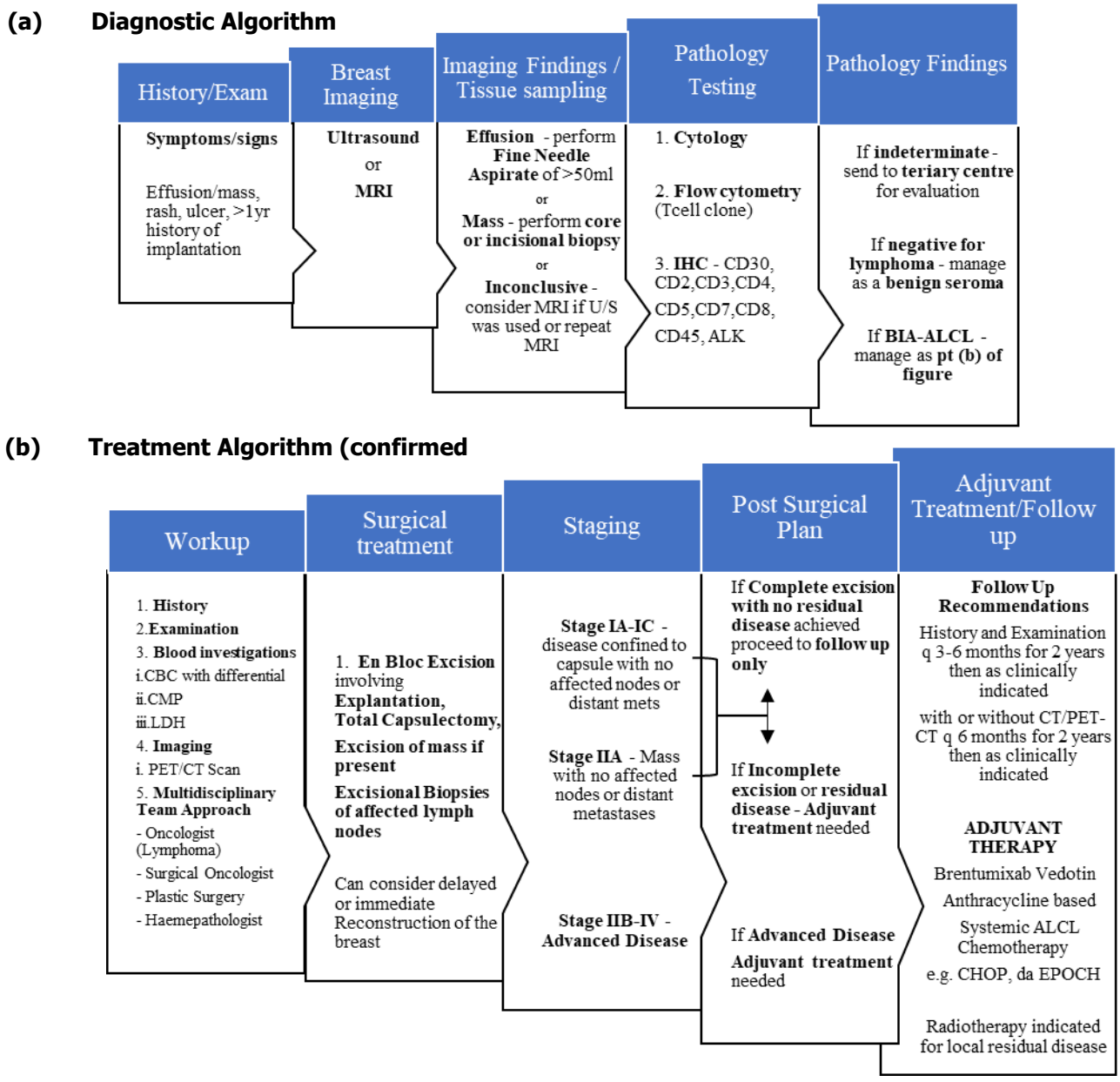
Alternate theories have also been proposed. These include autoimmune aetiology[15], or an indirect or direct immune response and or toxic damage secondary to particle erosion of the implants.[10,11] This theory could also explain why BIOCELL, which is less aggressively texturized, than polyurethane implants resulted in a higher number of BIA-ALCL cases. A study by Webb et al in 2017, used scanning electron microscopy to investigate the shedding of silicone particles by Allergan, Mentor and Sientra.[27] They reported that Allergan-BIOCELL was

responsible for the greatest shedding of silicone particles into the capsule.[27] Silicone is immunogenic so these shed particles can possibly elicit chronic inflammation that leads to BIA-ALCL.[4]

Clinical Features

BIA-ALCL can present in different ways. The most common presentation is a periprosthetic effusion developing more than one year post implantation.[4,8] The differentials include infection and trauma.[4] This effusion

Figure 3: (a) Evidence based diagnostic algorithm of the 2019 NCCN guidelines for investigation of BIA-ALCL. (b) Evidence based treatment algorithm of 2019 NCCN guidelines for management of confirmed BIA-ALCL.



ALK – anaplastic lymphoma kinase; BIA-ALCL – breast implant-associated anaplastic large cell lymphoma; CBC-complete blood count; CHOP – cyclophosphamide, doxorubicin, vincristine, prednisolone; CMP – Complete metabolic profile; CT – computed Tomography; daEPOCH -dose adjusted etoposide, prednisolone, vincristine, cyclophosphamide, doxorubicin; IHC – Immunohistochemistry; LDH – lactate dehydrogenase; MRI – magnetic resonance imaging; PET – positron emission tomography; U/S – ultrasound;
Figure adapted from reference [28]

can range from straw coloured to cloudy white and can be over 500ml in volume.[4] BIA-ALCL can also present with a mass, capsular contracture, painful breast swelling, fever, lymphadenopathy, or a rash which can be erythematous, ulcerative, papular or subcutaneous nodules.[4,7]

Management

The National Comprehensive Cancer Network (NCCN) recommends a multidisciplinary approach to the management of BIA-ALCL.[13,28] In addition to the plastic surgeon, the inclusion of a haempathologist, a lymphoma oncologist and a surgical oncologist is recommended.[13,28] The diagnostic and treatment algorithm recommended by the NCCN is shown in Figure 3. Patients should be assessed with ultrasound which has a sensitivity and specificity of 84% and 75% respectively for detecting an effusion.[4,10,28] Alternatively, an MRI may be used if ultrasound is inconclusive.[28] MRI has a sensitivity of 82% and specificity of 33% for effusions.[4] However, MRI is expensive and may be difficult to procure in low-resource settings, which are common in the Caribbean.

If the patient has an effusion, aspiration of the entire effusion should be performed and the sample sent for cytological examination.[28] Serial drainages should be avoided as they falsely decrease tumour load, decreasing diagnostic accuracy.[28] If a mass is detected, then incisional or core biopsy should be performed.[28] The pathological workup should include cytology, flow cytometry and immunohistochemistry for CD30, ALK and other differentiation markers including CD2, CD3, CD4, CD5, CD7, CD8 and CD45 to rule out other differentials.[28]

Once BIA-ALCL is confirmed, routine metabolic tests should be performed and PET/CT used for staging.[10,28] While traditionally the Ann Arbor classification has been used for lymphomas, its use with BIA-ALCL leads to overtreatment and is a poor predictor of survival. The TNM classification predicts survival better (Figure 4).[1,29] T1-T3 are excellent prognostic markers as is N0.[4] A statistically significant improvement was noted in overall survival (OS) and progression free survival (PFS) in patients who presented without a mass as opposed to those with a mass.[4]

The surgical management of Stage 1 BIA-ALCL, includes en-bloc resection including total capsulectomy and explantation and is curative.[28] It has been shown to significantly prolong overall survival and event free survival (p=0.001).[28] Clemens et al reported an overall 5-year survival rate of 91% of patients post en-bloc resection among 87 patients.[30] More advanced stages require en-bloc resection as above, including associated mass, excisional biopsy of involved nodes, anthracycline based chemotherapy, e.g. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) and treatment with brentuximab vedotin (BV) (Figure 3).[28] Radiotherapy of 24-26 Grays is indicated if there is local residual disease post resection.[28]

At present there is no role for radical mastectomy or sentinel node biopsy in the management of BIA-ALCL.[28] There is also no consensus on whether the implant should be replaced at time of explant or prophylactic management of the contralateral breast in unilateral disease.[28] However, since 2-4% of cases are bilateral, the NCCN recommends consideration of bilateral explant and total capsulectomy.[28]

Brentuximab Vedotin

BV is an anti-CD30 monoclonal antibody which is bound to monomethyl auristatin E (MMAE), an anti-microtubule agent.[4] The anti CD30 chimeric antibody binds to CD30 receptors on lymphoma cells.[4] It is subsequently endocytosed and its contents then undergo lysosomal digestion.[4] MMAE is then released into the cytoplasm where it binds to tubulin, resulting in disruption of the microtubule network and cell death.[4] Brentuximab vedotin is administered at a dose of 1.8mg/kg at three-week intervals.[4] It can be used in combination with CHOP and has been effective in increasing OS and PFS in ALK negative and ALK positive ALCL in Phase 2 Trials.[4] Pro et al conducted a single agent multicentre Phase 2 trial in 2017, assessing the efficacy and safety of BV in relapsed and refractory systemic ALCL over five years.[31] They achieved 57% (66%) complete response rate with an estimated overall 5-year survival rate of 60%.[31] The median OS was not reached during the 5-year study.[31] Amongst the patients who had complete response, the 5-year survival rate increased to 79% and the median PFS was not reached.[31] As of the date of this article ECHELON 2 Phase 3 trials comparing BV and cyclophosphamide, doxorubicin and prednisone to CHOP is still ongoing, however has showed improvement in PFS and OS.[32]

Postoperative follow up recommendations by the NCCN include history and clinical follow up every three to six months for two years, then as clinically indicated thereafter.[28] This can be accompanied by CT or PET/CT every 6 months for two years then as indicated thereafter.[28]

World Response

According to the International Society of Aesthetic Surgeons (ISAPS), breast augmentation is the most popular plastic surgical procedure worldwide.[33] It accounted for 17.6% of all plastic surgical procedures in 2018 and its popularity has been increasing since 2014.[33] As a result, BIA-ALCL, despite its rarity, will continue to represent a significant health concern in the future. The popularity of texturized implants, however, varies with region. Whereas surgeons in the US prefer smooth implants, the use of texturized implants is preferred in Europe, Latin America, Asia, and Oceania.[34] This is interesting as depending on the source, the United States accounted for 36-39% of the cases of BIA-ALCL worldwide.[5,7] This is despite their propensity for smooth implants. In addition, the number of cases in Asian countries are relatively low, compared to the popularity of breast augmentation and texturized implant use in these populations (Figure 1).

As a result, there has been an international response to implant use. In December 2018, BIOCELL implants, which are implicated in the majority of BIA-ALCL cases, were withdrawn from Ireland market, then the rest of Europe.[35] This included a recall of all remaining stock and termination of future supply.[35] However, with the exception of France, other texturized breast implants remained available.[35] In France, as of the April 2019, all macro-textured and polyurethane foam implants were banned.[35]

The US response followed. The FDA conducted a panel in March 2019, which resulted in a recall of said Allergan implants from the US market in July 2019.[7,35] Following this, Allergan initiated a voluntary global recall of BIOCELL textured breast implants and expanders.[35] Health Canada suspended licences for Allergan macro-textured implants in May 2019.[35] Allergan then also instituted a recall of texturized implants in Canada. In September 2019, the Therapeutic Goods Administration of Australia announced a ban on all texturized breast implants and expanders from the Australian Market.[35] Their regulatory actions also included imposition of new

Table 1: List of breast implant registries and their country of origin

BREAST IMPLANT REGISTRY	COUNTRY	BIA-ALCL specific
National Breast Implant Registry (NBIR)	USA	No
Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymhoma Etiology and Epi-demiology (PROFILE)	USA	Yes
Dutch Breast Implant Registry (DBIR)	Netherlands	No
Health Products Regulatory Agency (HPRA)	Ireland	No.
Breast and Cosmetic Implant Registry (BCIR)	UK & Scotland	X card Scheme is specific to BIA-ALCL
Australian Breast Device Registry (ABDR)	Australia	No

conditions on remaining breast implant devices and some voluntary removal of other breast implants from the market.[35]

The development of national and international breast implant registries has also been a pivotal step in the response to BIA-ALCL. There are multiple national and international level registries all over the world (Table 1). These aim to collect data including device details such as manufacturer, type, texturization.[35,36] They also collect surgical details about current and past implants, symptoms, complications and management to date.[35,36] These are advantageous as they facilitate gathering of accurate data on breast implants usage which is not dependent on manufacturer records. In addition, they facilitate tracking of devices regionally and internationally and can highlight trends on usage and complications.[36]

They can also aid research on breast implant complications and related illnesses including insight into aetiology and pathophysiology of these conditions.[35,36] This is especially useful in conditions like BIA-ALCL, where the long lag phase of the disease can lead to loss of important data. Some databases utilize technology to achieve this aim, e.g. the National Breast Implant Registry (NBIR) developed an application which allow simultaneous submission of barcode device tracking information to the registry and manufacturers.[36]

Some of these registries are BIA-ALCL specific, e.g. in US, the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) and in the UK, there is the yellow X card database (see Table 1).[7,36]

Figure 4: TNM staging of BIA-ALCL

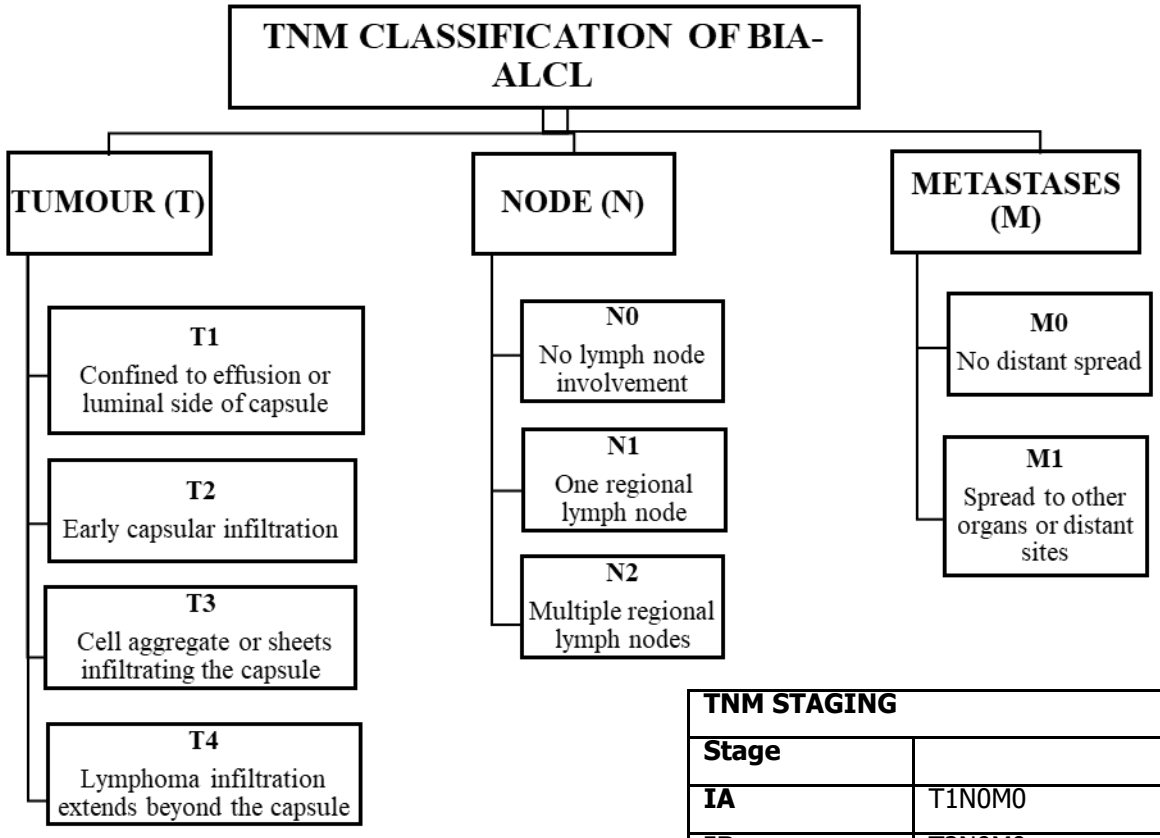


Figure adapted from reference [28].

TNM STAGING	
Stage	
IA	T1N0M0
IB	T2N0M0
IC	T3N0M0
IIA	T4N0M0
IIB	T1-3N1M0
III	T4N1-2M0
IV	TanyNanyM1

However, most of these registries, BIA-ALCL specific or not, are based on voluntary submission by surgeons or patients. There is no legislation making the use of these registries mandatory, which may lead to under or incomplete reporting. There is also variance in the design of these databases. In an attempt to combat this variance, the iCOBRA (International Collaboration of Breast Registry Activities), a multinational database, developed an international consensus on the minimal data set implant registries should collect. This included a unique identifying number, manufacturer and the texture, fill, shape and volume of the implant.[36]

DISCUSSION

The Caribbean response to BIA-ALCL, was as one of the key topics discussed at the meeting of the Caribbean Association of Plastic and Reconstructive Surgeons (CAPRS), in August 2019. To date, there have been no recorded cases of BIA-ALCL in the Caribbean. However, this may be due to underreporting or misdiagnosis. The symptoms of BIA-ALCL are non-specific and can be easily misdiagnosed as infection or a benign seroma. Improved education of all health professionals on breast implant related illness and BIA-ALCL is needed to ensure that these cases are identified in an early and curative stage. In addition, these cases should be managed in a multidisciplinary setting, and so should be referred to a Plastic Surgeon or Breast surgical oncologist.

Alternatively, there may be an ethnic component responsible for the lack of cases in the Caribbean region. While there is a clear genetic component to the pathophysiology, the link between ethnicity and BIA-ALCL is still under investigation. While implant use is prevalent in countries such as India and South Africa, there have been very few recorded cases of BIA-ALCL from these countries. In addition, the countries with the highest recorded numbers of BIA-ALCL have a predominance of Caucasians. The Caribbean region is ethnically diverse, however there is a vast predominance of people of African descent, with countries such as Trinidad and Tobago and Guyana also having a significant population of East Indian descent. This highlights the importance of the development of a breast implant registry to establish the health impact of implant use in the Caribbean population. At present there is no breast implant registry available in Caribbean. As a result, statistics related to breast implant use and their complications for this region is lacking. The consensus was reached that the development of such a registry, was in the best interest of the Caribbean, even beyond the context of BIA-ALCL. This registry will be utilized to further study the complications of implant-based reconstruction and augmentation in the Caribbean community. It will also provide information as to whether BIA-ALCL constitutes a risk to the Afro- and Indo-Caribbean communities who make up the majority of the Caribbean population. However, the risk of BIA-ALCL should be included in the informed consent counselling of patients, especially for use of textured devices.

There is an established association between the use of textured implants and the development of BIA-ALCL. As a result, Allergan has voluntarily removed textured implants from the market and countries like France have banned the use of texturized implant. The recommendation of the panel was that in light of the obvious risks involved with textured implant use and the likely removal of these products worldwide, use of textured implants should be avoided. This will however obviate the use of anatomical implants, as no smooth anatomical implants are currently available. The avoidance of texturized products should also include textured tissue expanders. The pathophysiology of BIA-ALCL is not well understood enough to determine the length of exposure texturization needed to result in BIA-ALCL. As a result, both smooth implants and expanders should be utilized in the future.

The panel also discussed whether or not textured implants which are already in situ should be removed and replaced with smooth alternatives. The FDA has recommended that once asymptomatic, the implant should be left in situ.[7] However, it was concluded that should an asymptomatic patient request removal of a texturized implant, it is not unreasonable to do so after appropriate counselling, as this is in the best interest of the patient psychological health of the patient. It was also recommended that a capsulectomy also be performed, as the length of exposure needed to develop BIA-ALCL is still unknown and there is a long lag phase. If the client would like replacement of the implant, immediate reconstruction with a smooth implant was also deemed reasonable. In the case of reconstructive breast surgery, the surgeon should explore alternative non texturized options including autologous reconstruction.

CONCLUSION

Breast Implant-Associated Anaplastic Lymphoma is a global health issue. Research has revealed a definitive association between the use of texturized implants and BIA-ALCL. This has prompted responses from manufacturers and health authorities worldwide. Recommendations by the CAPRS, include the development of a regional breast implant registry, which will facilitate further study on the use of implants and its associated complications. They also recommended counselling on BIA-ALCL during the informed consent process. As per the recommendations of the CAPRS and the FDA, removal of textured implants in asymptomatic patients is not indicated at this time. However, the explant of texturized implants is reasonable if the patient desires removal, once the patient has been properly counselled. The CAPRS also concluded that the use of texturized implants and expanders should be avoided, with smooth alternatives being utilized.

At present, the evidence available does not support the compulsory cessation of manufacture of all textured devices. Each textured implant varies in its risk of BIA-ALCL. In addition, our region, has no legislation demanding the use of smooth devices only. However, textured devices may be voluntarily withdrawn from the global market, in light of regional bans on textured devices, smooth alternatives and current market trends.

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