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### CASE SERIES

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## Anaplastic lymphoma associated with breast implants— Early diagnosis and treatment

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### Abstract

Anaplastic large cell lymphoma associated with breast implants is a relatively new disease that deserves attention from the academic community. Brazil figures as one of the protagonists in plastic surgery, however publications are insufficient and very few cases are reported in comparison to other countries. It is a disease with excellent prognosis when diagnosed early and treated effectively, but for this to happen, it is essential that health care professionals and the patient understand its pathology. We reported two cases in a small town during a short period of time. In both cases reported by this study, the patients presented late seroma, associated with pain as a clinical presentation, at 13 and 9 years after the placement of silicone implants with textured polyurethane surfaces. After the procedure, the patients were screened for cancer. Further research with more robust samples is still needed to fully determine the risks and benefits of using textured versus smooth implants.

### K E Y W O R D S

breast implants, lymphoma, large-cell, anaplastic, lymphoma, non-Hodgkin, neoplasm, seroma

## 1 | INTRODUCTION

Breast augmentation is the most commonly performed cosmetic surgery in the world with around 1.9 million procedures each year.<sup>1</sup> It is estimated that 35 million women worldwide have already had this procedure.<sup>2</sup> Studies have shown an increased risk of anaplastic lymphoma in patients with breast implants.<sup>3,4</sup> Anaplastic large cell

lymphoma associated with breast implantation (BIA-ALCL) is a rare type of non-Hodgkin's lymphoma (NHLs). Primary NHLs account for less than 1% of all breast malignancies and most of them are of B-cell origin, with diffuse large B-cell lymphoma being the most common type. Less than 10% of breast NHLs are of T-cell lineage. Although anaplastic large cell lymphoma (ALCL), a rare T-cell lymphoma, accounts for only 3% of adult NHLs and 6% of

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breast NHLs, it appears to have a tropism for the breast tissue compared to other T-cell lymphomas.<sup>5,6</sup> At present, there have been approximately 600 cases of BIA-ALCL reported worldwide, but there is no consensus on the true incidence rate of BIA-ALCL, since it varies widely from country to country.<sup>7</sup>

According to individual studies and national statistics, the incidence currently stands with Germany presenting 7 cases, France 19, Italy 22, the United Kingdom 41, Holland 43, Australia 72 and the USA 149 cases.<sup>3</sup> Furthermore, a review study carried out with 40 government databases showed that there were 363 reported cases of BIA-ALCL worldwide.<sup>8</sup>

Brazil is one of the world's leaders in numbers of plastic surgeries performed annually, second only to the United States. Augmentation mammoplasty is the most performed cosmetic surgery in Brazil, with around 275 thousand procedures per year.<sup>1</sup> In the BIA-ALCL Global Report of adverse events associated with breast implants, there were no cases of BIA-ALCL in Brazil, as reported by the National Health Surveillance Agency of Brazil (ANVISA).<sup>8</sup> The lack of reported cases and thus, the incidence, as well as relevant information that could be utilized from such cases, makes it difficult to understand the pathology, treatment and the real risk of women developing BIA-ALCL after implant surgery.

Considering the scarcity of cases reported in Brazil, contrary to its outstanding position in augmentation mammoplasty, the objective of this study was to report two cases, of BIA-ALCL, in women with breast implants. They were identified in a city from Southern Brazil. Furthermore, we decided to emphasize the fact that new implants were replaced in both cases because there are no studies, or consensus, on the breast implants revision surgery. The cases were reported based on the 2013 CARE checklist (case report guidelines). The Ethical Committee of the State University of Maringa, number 3.999.625, approved this research in April 30, 2020. All terms of consent from patients, professionals and institutions involved were provided.

## 2 | CASE 1

## 2.1 | Case history

A 42-year-old Caucasian female presented with pain and increased volume of the right breast. She had undergone bilateral augmentation mammoplasty with silicone implants 13 years before. After replacement of implants and total capsulectomy, she was diagnosed with BIA-ALCL and has been undergoing oncological follow-up since then.

In 2005, the patient underwent breast augmentation for cosmetic purposes, with the SILIMED texturedpolyurethane surface implants, of 265 mL anatomical model, in the subglandular plane through a periareolar incision. After 13 years, she presented a progressively painful increase in volume of the right breast, without any previous trauma, which persisted for 1 month (Figure 1). Diagnosed as a seroma, she underwent fluid puncture and examinations; however, she proceeded with a recurrence of the seroma and surgery was indicated to replace the implants and capsulectomy. In regard to family history, the mother of the patient had had peritoneum cancer and the patient only has a 15-year-old son.

The patient was examined seated, with arms hanging by the side of the body. There was an increase in volume of the right breast; nonetheless, there were no changes in skin color or nipple-areola complex, nor were there any skin lesions. Breast asymmetry was visible in terms of volume and there was a more pronounced ptosis of the right breast. Palpation of the breasts with the patient seated and lying on supine position did not detect palpable lymph nodes or nodules. An increase in breast volume was observed mainly on the lateral quadrants of the right breast, with generalized pain during breast palpation.



**FIGURE 1** (A) Patient one presenting increase in volume of the right breast without any previous trauma. (B) The capsule of the right breast.

# 2.2 | Differential diagnosis, investigation, and treatment

The initial investigation with an ultrasound of the breasts showed that in the right one, there was evidence of surgical manipulation, breast implant with signs of rupture and the presence of free liquid that extended from the 09:00 to the 06:00 o'clock positions, which might have represented a rupture of the implant. No changes were detected in the left breast or the implant. One year before this examination, the patient did a routine breast ultrasound without any changes. It was then decided to further the investigation with an MRI scan, in which there was no evidence of the implants rupture, but periprosthetic fluid to the right was detected.

Considering the hypothesis of seroma, it was decided to collect a sample of the liquid with a fine cannula guided by ultrasound. About 90 mL of citrus-colored liquid was drained and sent to laboratory tests and pathological anatomy.

Blood tests did not show any significant changes. The liquid was sent for qualitative analysis and presented: pH 7.0, slightly cloudy appearance and light yellow color, protein dosage of 6.0g/dL, glucose dosage of 37 mg/dL, red blood cell count of 85, leukocyte count of 16 (neutrophils 2%, lymphocytes 98%), and gram bacterioscopy did not detect any bacteria. The liquid was also sent for pathological anatomy and was analyzed through three slides of hematoxylin/eosin staining. Microscopy showed cytological smears composed of macrophages, lymphocytes and sparse neutrophils, over a background of fluid plasma and red blood cells. No signs of malignancy were identified in the sample, favoring the conclusion that a chronic inflammatory process was occurring.

Given the recurrence of seroma after 1 month, it was decided to exchange the breast implants, change them to the submuscular plane and perform a bilateral total capsulectomy. After the procedure, the right breast capsule was sent for pathology, as well as the periprosthetic fluid analysis.

In the second sample, after the cytology of the liquid through two slides of hematoxylin/eosin staining, the presence of atypical cells were identified (several isolated and pleomorphic cells, with large horseshoe-shaped or reniform nuclei, amidst clear or eosinophilic cytoplasm), which could be classified as neoplastic cell positive (Figure 2A). The capsule from the right breast was studied with eight blocks containing multiple fragments that showed infiltration in clusters, or a diffuse form, of pleomorphic cells, some with eccentric bean shaped nucleus and clear cytoplasm, while others with also horseshoe shaped nucleus (Figure 2B). In the internal region of the capsule, there was associated fibrinoid necrosis (Figure 2C). The diagnosis was atypical lymphoid infiltrate with pleomorphic/anaplastic cells in the right implant capsule of the breast, with the lymphoid infiltrate compromising the entire thickness of the capsule without invasion of the adjacent breast parenchyma. From the examination of the injury-free circumferential surgical margin, an immunohistochemical study was suggested, which revealed positive CD30 immunoexpression (T-cell markers such as CD3 and CD5), epithelial membrane antigen positivity in addition to negativity for anaplastic lymphoma kinase (ALK), confirming immunohistochemical aspects compatible with anaplastic cell lymphoma.

The initial approach was to puncture the fluid, guided by ultrasound, and to investigate the fluid that did not initially reveal neoplastic cells. However, with



**FIGURE 2** (A) Cytology of puncture liquid hematoxylin/eosin stained, with the presence of atypical cells (several isolated cells, pleomorphic, large horseshoe or reniform shaped nuclei with clear or eosinophilic cytoplasm (40×). (B, C) Biopsy of the right breast capsule (hematoxylin/eosin stained) showing.

the recurrence of fluid accumulation and, in the interest of improving the aesthetic aspect of the breasts, it was decided to replace the implants for MENTOR textured 400 mL round shape high profile implants, in the partial submuscular plane after bilateral total capsulectomy (Figure 1B).

The diagnosis of BIA-ALCL was made based on the examination of the capsule as well as the identification of the absence of invasion in the adjacent breast parenchyma and surgical margins free of neoplasm, which directed us towards the treatment of the disease. The patient was referred to a clinical oncology team that expanded the investigation with positron emission tomography (PET/CT) with fluorodeoxyglucose (FDG-18F) that did not show abnormal areas with increased glycolytic metabolism. Tomography of the chest and abdomen revealed areas of retraction in the right renal cortex, probably the consequence of chronic inflammation.

## 2.3 | Outcome and follow-up

After the procedure, the patient underwent oncological follow-up every 6 months, reporting chronic pain in the lateral region of the left breast. She was satisfied with the aesthetic result and showed no signs of recurrence after 1 year of treatment (Figure 3).

## 3 | CASE 2

## 3.1 | Case history

A 30-year-old Caucasian female patient presented with burning pain and a volume increase of the left breast. She had undergone bilateral augmentation mammoplasty with silicone implants 9 years earlier. She was then diagnosed with BIA-ALCL through the analysis of the punctured seroma in the left breast. Implants were removed and bilateral total capsulectomy was performed.

In 2010, the patient underwent breast augmentation for aesthetic purposes with the introduction of textured implants from SILIMED with polyurethane surface and 305 mL anatomical shape, in the subglandular plane through an inframammary incision. After 9 years, she presented with a painful volume increase in the breasts bilaterally, more expressive to the left. Two days after the onset of the symptoms, 140 mL of citrus-colored liquid from the left breast was punctured and sent for analysis and immunohistochemistry. BIA-ALCL was diagnosed. We opted for the removal of the implants and bilateral total capsulectomy. The patient had no family history of

FIGURE 3 Patient one after 1 year of treatment.

cancer and denied any comorbidities or continued use of medications.

The breasts were inspected with the patient seated and the arms hanging alongside her body, with no changes in the skin color and nipple-areola complex, nor any skin lesion were observed. A greater volume was observed in the left breast. Palpation of the breasts was performed with the patient seated and lying on supine position, and there was no palpable presence of lymph nodes or nodules.

## 3.2 | Differential diagnosis, investigations, and treatment

Ultrasonography of the breasts was performed and showed a liquid collection around the circumference of the implants, which was larger in the left breast, without solid and cystic nodular formations, and free axillary extensions. After puncture of the left breast fluid, an MRI of both breasts was requested, which showed intact implants without signs of rupture, the presence of fluid around the implants, which was most significant on the right, and that there were tiny bilateral cysts.

Blood tests showed no changes. The cytology of the left breast aspirate showed findings suggestive of the inflammatory content of the seroma and was negative for neoplastic cells as well as for the culture of the material. The fluid was also sent to immunohistochemistry where the presence of neoplastic cells was identified, demonstrating positive CD30 expression and negativity for ALK, findings indicative of BIA-ALCL. The implant capsules were sent for anatomopathological and immunohistochemistry tests with no signs of malignancy in the samples and negativity



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**FIGURE 4** Total capsulectomy in Patient 2.

for CD30, indicating pseudosynovial metaplasia and an inflammatory response.

After the preoperative diagnosis of BIA-ALCL, it was decided to remove the silicone breast implants and perform a total capsulectomy (Figure 4) without placing new implants. The patient was referred to a clinical oncology team that expanded the investigation using a PET/CT with FDG-18F, which did not show abnormal areas with increased glycolytic metabolism. Tomography of chest and abdomen showed only hepatic hemangioma.

## 3.3 | Outcome and follow-up

After the procedure, the patient was screened for cancer and reported bilateral hypersensitivity in the breasts. One year after the removal of the implants and capsule, the patient insistently opted for the placement of new implants and the surgery was performed uneventfully, followed by the discharge from the clinical oncology team.

## 4 | DISCUSSION

The lack of well-reported cases of BIA-ALCL in Brazil makes it difficult to establish the precise incidence of this

pathology. The availability of these data, particularly in terms of the number of cases and their specific details, could influence in the form of treatment and also offer greater knowledge of the real risks that women may face after undergoing implant surgery. Despite the scarcity of reported cases in Brazil, we found two cases in a city from Southern Brazil.

After research in the available literature, the oldest reported case of BIA-ALCL was in 1997.<sup>9</sup> The large cell anaplastic lymphoma associated with the breast implant began to be recognized as a unique disease by the World Health Organization in 2016.<sup>10</sup> The US Food and Drug Administration (FDA) reported 573 cases worldwide, with 33 deaths in 2019.<sup>11,12</sup> Although Brazil is the country with the second largest number of breast implants on the world, there has only been one case of BIA-ALCL, published in 2017, clinically presented as a tumor mass, differing from the typical presentation of seroma.<sup>13</sup>

In both cases reported in this study, the patients presented late seroma associated with pain at 13 and 9 years after the placement of silicone implants with textured polyurethane surfaces. The most common presentation of BIA-ALCL is actually a large collection of spontaneous periprosthetic fluids that could occur as early as 1 year of post-surgery, but mostly from 7 to 10 years on average, after the placement of textured surface implants.<sup>14</sup> Other symptoms described include skin rash,<sup>15</sup> capsular contracture<sup>16</sup> and lymphadenopathy.<sup>17</sup> It is necessary to consider the possibility of BIA-ALCL in a patient with persistent late onset of peri-implant seroma or mass (>1 year after implantation), and mass or masses adjacent to the breast implant.<sup>14</sup>

The pathogenesis of the disease is still uncertain. Theories relate textured implants to the mammary microbiome, considering that the texture corresponds to a larger surface area, enabling increased bacterial adhesion and biofilm formation, thereby causing greater local inflammatory activity and the potential for malignant transformation<sup>18</sup> associated with genetic predisposition.<sup>19</sup> Silicone has been shown to be immunogenic and to incite a chronic inflammatory response. Saline implants are also often surrounded by an impermeable silicone elastomeric capsule that might be immunogenic by itself. Because chronic inflammation has been associated with development of lymphomas, such as Helicobacter pylori infection in gastric extranodal marginal zone lymphoma, it is possible that chronic inflammatory stimulation may be related to the development of breast implant-associated BIA-ALCL.<sup>20,21</sup> This is in keeping with the fact that BIA-ALCL originates from activated mature cytotoxic T cells.<sup>22</sup>

The pathological analysis is essential for making the diagnosis, combined with the cytological analysis of the

liquid from seroma, and the histopathology of the implant capsules. Microscopically, the tumor cells are present in the seroma or in the fibrous capsule of the implant. The cells in the effusion fluid are typically identified along the inner surface of the fibrous capsule, either as individual cells, as cell clusters, or occasionally as coherent sheets. Immunophenotyping is still essential in diagnosing, with the anaplastic cells characteristically showing strong and uniform membranous expression of CD30. The tumor cells variably express T cell antigens including CD3 (30%–46%), CD45 (36%) and CD2 (30%), but have low or no expression of CD5, CD7, CD8, and CD15.<sup>23,24</sup>

To date, there have been no confirmed cases of BIA-ALCL in patients with an exclusive history of smooth implants use. In 2018, the FDA recognized 30 cases that occurred in patients with smooth implants, however all patients had a mixed history of smooth and textured implants. In both cases in this report, patients had textured implants with SILIMED polyurethane surface, which has the largest surface area and roughness on the market.<sup>25</sup>

According to the clinical and pathological evolution of the disease classification, first proposed in 2016 by the MD Anderson Cancer Center, and now included in the 2019 update of the National Comprehensive Cancer Network, case report 1 presented lymphoid capsule without invasion of adjacent breast parenchyma, fitting as stage IC (T3N0M0), while case report 2 can be considered stage IA (T1N0M0), presenting neoplastic cells confined to the liquid. Both were treated with complete excision of the capsules with free margins.<sup>14</sup>

In 2016, Clemens and collaborators studied the treatment of 87 patients with BIA-ALCL and concluded that the timely diagnosis and complete surgical excision of lymphoma, implants and surrounding fibrous capsule is the ideal approach for management of patients with this disease. The disease located in the capsule (MD Anderson Cancer Center [MDA] IA-IIA) can only be treated with surgery when complete excision of the capsule and implants is possible.<sup>18</sup> In more advanced cases, where there is infiltration of the breast parenchyma or chest wall, as well as lymph node involvement, the prognosis is worse and adjuvant chemotherapy is necessary, especially in non-resectable neoplasms.<sup>14</sup>

There are no studies, or consensus, on the reimplantation of new breast implants. In the two cases reported in this study, both patients underwent implant reintroduction, case 1 prior to diagnosis with a 2-year follow-up, and case 2 only 3 months after removal and diagnosis. Close monitoring is necessary due to the lack of knowledge about the evolution in these cases. Patients with complete response to treatment can be monitored every 3–6 months for 2 years and then as clinically indicated.<sup>14</sup> One of the most critical aspects affecting treatment and the potential for a better procedure is the lack of diagnostic confirmation prior to surgery.<sup>21</sup> In case 1, the search for neoplastic cells from the previously aspirated fluid did not reveal malignancy, but the guidelines recommend that the samples should be sent for cell morphology by cytology, CD30 immunohistochemistry and flow cytometry for evaluation, quantification and characterization of T cells. CD30 immunohistochemistry is a fundamental part of the diagnostic tests for BIA-ALCL.<sup>14</sup>

We observed that although studies have reported varied incidences worldwide, it is still an uncommon disease, with an excellent prognosis when diagnosed early and treated effectively. We emphasize that knowledge of the pathology by health care professionals and by the patient is essential for early identification of signs and symptoms. Patients must be informed of the risks, especially in regards to textured implants. There is still no recommendation for the removal of implants prophylactically. Nonetheless, as there is considerable underreporting of cases, professionals need to start doing so, to better understand this pathology, so that more informed decisions can be made. Further research with more robust samples is still needed to fully determine the risks and benefits of using textured or smooth implants. Overall, it is a relatively rare pathology, and the lack of studies are an obstacle for gathering significant data and reaching definitive answers.

### AUTHOR CONTRIBUTIONS

Carlos Felipe Pasquini de Paule: Conceptualization; data curation; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing - review and editing. Raissa Bocchi Pedroso: Conceptualization; investigation; project administration; supervision; writing - original draft; writing - review and editing. Maria Dalva de Barros Carvalho: Formal analysis; investigation; methodology; writing original draft; writing - review and editing. Fernando Castilho Pelloso: Investigation; project administration; validation; writing - original draft; writing - review and editing. Aluísio Marino Roma: Funding acquisition; investigation; resources. Renato da Silva Freitas: Formal analysis; funding acquisition; investigation; resources; software. Juliana Magalhães Cavalcante: Formal analysis; funding acquisition; investigation; resources; software. Helena Fiats Ribeiro: Validation; visualization; writing - original draft; writing - review and editing. Sandra Marisa Pelloso: Conceptualization; investigation; methodology; project administration; supervision; validation; visualization; writing - original draft; writing - review and editing.

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### CONFLICT OF INTEREST STATEMENT

The authors declare that there are no conflicts of interest.

### DATA AVAILABILITY STATEMENT

Data supporting how to set up this study are available upon request from the corresponding author. Data is not publicly available due to privacy or ethical restrictions.

### ETHICS STATEMENT

The study was approved by the Standing Committee on Ethics in Research with Human Beings of the State University of Maringá (COPEP/UEM) according to document number 3,999,625 from 4/30/2020.

### CONSENT

Written informed consent was obtained from the patients to publish this report in accordance with the journal's patients consent policy.

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