Textured Surface Implants and BIA-ALCL

Subjects: Surgery

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Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a variant of anaplastic large cell lymphoma (ALCL) associated with textured-surface silicone breast implants. Since first being described in 1997, over 1100 cases have been reported worldwide. A causal relationship between BIA-ALCL and textured implants has been established in epidemiological studies.

Keywords: breast lymphoma ; anaplastic large cell lymphoma ; breast reconstruction ; textured implant ; breast implant ; plastic surgery ; aesthetic surgery

1. Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a variant of anaplastic large cell lymphoma (ALCL) associated with textured-surface silicone breast implants [1][2][3][4]. It is now recognized as an anaplastic kinase-negative (ALK-), CD30 + lymphoma, a distinct T-cell–derived lymphoma within the non-Hodgkin's lymphoma spectrum [5]. This neoplasm may present with different clinical phenotypes. A small subgroup of cases presents with solid tumor mass and progressive disease, while most present with delayed-onset (>1 year from surgery) periprosthetic seroma and follow an indolent course, often with a good prognosis [6][7].

BIA-ALCL was first described in 1997 by Keech and Creech, who took part in the treatment of a 41-year-old female presenting with a small mass in the lateral aspect of the right breast five years after breast implant placement [8]. Since first being described, over 1100 cases have been reported worldwide [9]. Mean time from breast implant placement to diagnosis is around 10 years [10].

Although originally believed to be of very rare occurrence, recent studies suggest that BIA-ALCL incidence could be higher compared to previous epidemiological estimates. Current reported incidence ranges between one 1 in 355 and 1 in 30,000 people with a textured surface breast implant and seems to vary further according to manufacturer-specific risks [10][11][12][13].

The disease remains equally distributed among cosmetic and reconstructive patients, suggesting that a history of previous malignancy (e.g., breast cancer) cannot be considered as a risk factor for the development of BIA-ALCL [10][11].

In the past years, the growing scientific evidence on the topic led to the U.S. Food and Drug Administration releasing warning statements and updates associating breast implants with BIA-ALCL [9][14]. As a consequence, media coverage on breast implants and BIA-ALCL is significantly impacting public perception and awareness, causing confusion between facts and suppositions, but also increasing the need for further understanding of this matter [15].

After more than two decades of research, the molecular mechanisms responsible for the aberrant T-cell clonal expansion in BIA-ALCL remain poorly understood [1]. However, to date, consensus on the implant texturization as a known modifiable risk factor and its implication in the development of BIA-ALCL has been reached [16]. Nevertheless, we are still facing a knowledge gap in pathophysiologic mechanisms for developing BIA-ALCL [16].

Several hypotheses have been proposed regarding the etio-pathologic pathways leading to BIA-ALCL, possibly working in concert, including implant immunogenicity due to silicone or its degradation products from textured implants, a genetic susceptibility altering the host autoimmune response, an IL-13 associated allergic response, or chronic inflammation triggered by bacterial biofilm [17][18][19][20].

2. Textured Surface Implants and BIA-ALCL

Textured implants were introduced in 1968 [21]. Modern textured surface implants date back to the 1990s [22]. Their worldwide success and distribution were justified by their potential role in minimizing capsular contracture risk and reducing implant malrotation, two of the most common and troublesome complications of breast implants [22][23].

Ultimately, textured implants were not found to sufficiently reduce capsular contracture, a process in which the mechanisms remain unclear [24][25]. Nevertheless, bacterial biofilm is likely to play a role in the pathogenesis of capsular contracture [26][27][28][29]. An analysis of removed capsules demonstrated that 17 out of 19 cultures obtained from patients with significant contracture yielded positive results for bacterial growth (mainly coagulase-negative staphylococci), compared with only one out of eight samples obtained from patients with minimal or no contracture [28]. In addition, 14 of the 17 positive cultures from significantly contracted breasts yielded coagulase-negative staphylococci. Subclinical infection or bacterial biofilm may trigger the immune reaction to the secretion of profibrotic cytokines and subsequent contracture [28]. In addition, further evidence demonstrated the benefits of intraoperative antiseptic irrigation of the implant leading to a reduction of the incidence of capsular contracture [30][31].

A causal relationship between BIA-ALCL and textured implants has been established due to the consistent findings in epidemiological studies [16][32]. To date, there has not been any definitively confirmed BIA-ALCL in patients who underwent placement of smooth-implant only [6][33]. Although several reports of patients with smooth implants at the time of BIA-ALCL diagnosis have been published, they all had either a history of textured implant/expander or incompletely known history of previous breast implants [16]. Macro-texturization has also been associated with higher risk of BIA-ALCL when compared to lower grade of texturization [34][35][36].

The type of texturization varies between single manufacturers' processing of the outer shell of the implant [34]. Among textured devices, Biocell (Allergan Aesthetics, An Abbvie Corporation, Irvine, CA, USA) and Silimed polyurethane (Silimed Corporation, Rio De Janeiro, Brazil) implants showed higher odds ratio of BIA-ALCL incidence compared to Siltex (Mentor, A Johnson & Johnson Company, New Brunswick, NJ, USA). According to Valencia-Lazcano et al. [37], implant-specific risk of BIA-ALCL was 1:2832 for Silimed polyurethane, 1:3345 for Biocell and 1:86,029 for Siltex implants. One prospective study at a single institution reported even higher risk for Allergan Biocell implants, with 1:355 women developing BIA-ALCL [11]. A time-to-event analysis indicates that the risk of developing BIA-ALCL increases over time [38]. However, existing studies have not assessed the prophylactic value of textured device explantation, with or without capsulectomy, in preventing this disease process. Moreover, current FDA guidelines do not recommend replacing or removing textured implants in asymptomatic patients [39].

Despite the effort of some authors to classify breast implants based on type of implant texturization, all focus only on the device physical properties without addressing biological properties and none of the classification attempts has been clinically validated and universally accepted [16]. The International Organization for Standardization (ISO) updated in 2018 its breast implant classification, which currently is the most used classification system, only accounting for average surface area and roughness through scanning electron microscopy, a relatively nonspecific characterization of texturization [16][34]. Thus, there is room for improvement for a clinically validated classification system that includes parameters beyond "surface roughness" [32][33][34]. Indeed, some authors claim that the incidence per manufacturer does not always correlate with surface roughness and area and therefore the different manufacturing process should also be considered [36]. Increasing attention is being paid to the host's reaction to the implanted device [32]. In animal models, different implant surfaces were associated with variable host inflammatory response (e.g., less rough surfaces induced weaker inflammatory response than rougher) [40], suggesting the need to quantitatively and qualitatively standardize breast implants according to the immune reaction in humans.

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