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Supporting Women's BIA-ALCL Decision-making: Role of the Individual Consult in Empowering the Patient–Physician Team

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Background: Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is a T-cell non-Hodgkin's lymphoma and an uncommon risk of textured breast implants. Over the past decade, concern about BIA-ALCL has been increasing among both patients and surgeons. Patients are seeking a better understanding of their BIA-ALCL risk toward identifying a personalized care plan. This quality improvement project examines the value added by pairing group-based patient education seminars with one-on-one consults.

Methods: Individual consults were held following educational group seminars. Consult field notes underwent qualitative thematic analysis. Themes were cross referenced against a quantitative chart review of patient BIA-ALCL prophylaxis decisions over time.

Results: Four key themes were identified: weighing, perceiving, guiding, and supporting. *Weighing* considers the risk-benefit assessments patients make when weighing their BIA-ALCL risk. *Perceiving* describes the underlying psychosocial factors that frame patient perceptions of BIA-ALCL risk. *Guiding* presents the levels of guidance that patients require when making BIA-ALCL prophylaxis decisions. *Supporting* explores the therapeutic value of the individual consult. Ultimately, 41% of post-seminar consult attendees sought explantation, compared with 4% among patients who did not participate in this program ($P < 0.001$).

Conclusions: Key lessons include the following: (1) patients weigh BIA-ALCL risk against perceived surgical risks and the value of their reconstruction; (2) patients can benefit from a personalized balance of autonomy and surgeon guidance when selecting a BIA-ALCL prevention plan; (3) surgeons should seek to understand the psychosocial factors that may underlie patient perceptions of BIA-ALCL risk; and (4) individual consults can be therapeutic and help strengthen the patient–surgeon relationship. *(Plast Reconstr Surg Glob Open 2021;9:e3843; doi: 10.1097/GOX.0000000000003843; Published online 14 October 2021.)*

INTRODUCTION

Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is a T-cell non-Hodgkin's lymphoma recognized as an uncommon risk of breast implants.[1] BIA-ALCL was initially thought to be a one to three in a million risk,[2] but more recent research showing that the risk is specific to textured implants has refined this estimate. Among the implants available in Canada, Allergan Biocell implants carry the highest risk at 1:3817, whereas Mentor Siltex implants carry a 1:60,631 risk.[3] These findings led Allergan to globally recall its Biocell implants in 2019.[4] Although clinical guidelines do not recommend explantation,[5] many women are unsure how to address their BIA-ALCL risk and prophylaxis of the same.[6]

Herein the authors present findings from a BIA-ALCL risk education and support program targeted at breast reconstruction patients. The aim was to help plastic surgeons by elucidating the variability in patient responses, highlighting the importance of engaging patients in sympathetic discussion and shared decision-making, and demonstrating the value of individual consults.

METHODS

Patient Recruitment and Group Seminars

As this analysis is part of a two-pronged quality improvement project, the patient population assessed is shared

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with a prior publication.[6] Patients were recruited from a single surgical practice in an academic centre in Calgary, Alberta, Canada. A total of 358 patients were identified from a practice-specific database of implant-based reconstructions dating back to 2012 and were sent personalized notification letters between late 2018 and early 2019. Letters described BIA-ALCL, outlined current clinical guidelines, listed each recipient's implant brand and texture, and invited patients to reach out to the surgeon's office if they wished to schedule a consult. The large number of consult requests prompted inviting patients seeking consults to one of five educational group seminars held between July and December of 2019. Ultimately, 53 patients attended a seminar.

Findings from the seminars were presented in a previous publication and revealed that patient BIA-ALCL informational needs center around clinical presentation, understanding risk, and options for management. Significant efforts were made to effectively communicate BIA-ALCL risk to patients. The surgeon contextualized the risk of BIA-ALCL and different implants by citing risks related to other health behaviors, such as sun exposure and melanoma, and everyday activities, such as driving. Current evidence was cited showing that the prognosis for BIA-ALCL is generally quite positive and rarely fatal, though some deaths have occurred.[7] Further, it was related that BIA-ALCL can typically be resolved through surgical excision, often without any chemotherapy or radiotherapy.[8] Nevertheless, the surgeon acknowledged that breast implants are clearly linked to BIA-ALCL and that patients deserve to have all information available to be the best judges of their own risk tolerance in relation to this disease. A second key finding from the seminars was that discussing BIA-ALCL with patients can be emotionally charged, but can help to re-establish patient trust in their surgeon.

Following the group seminars, attendees were offered an immediate individual consult with their surgeon, and 47 of the 53 seminar attendees went on to a consult. Two additional patients attended a consult without first coming to their scheduled seminar.[6]

Data Collection

Qualitative Data

Content from the individual consults following four of the five group seminars was recorded in detailed field notes. The July consults, wherein field notes were not taken, prompted recognition of the value their content offered, and field notes were recorded thereafter with patient consent. Field notes were recorded by an experienced qualitative researcher and described consult details, including conversations and nonverbal cues. The team opted against verbatim audiovisual recording, which may have influenced patient behaviour.[9]

Quantitative Data

A retrospective chart review of all consult attendees was conducted 1 year after the consults. The following data were collected: date of birth, implant brand and texture, initial BIA-ALCL prophylaxis plan at the consult, and any deviations from this plan going forward. Intervention plans were categorized as self-monitoring without follow-up, scheduled follow-up visits, monitoring via diagnostic imaging, implant exchange to smooth surface implant, or explantation without exchange (ie, "going flat").

Additionally, surgery completion records were reviewed to identify patients who underwent implant removal but had not attended a seminar. These included patients who predated the BIA-ALCL education program or who had opted out of participation. A chart review was conducted for these patients to determine whether BIA-ALCL risk was a motivator for their decision to have their textured devices removed.

Data Analysis

Qualitative Analysis

Three independent researchers coded the field notes using inductive and deductive approaches. NVivo 12 software (QRS International Pty Ltd., Chadstone, Australia) was used. Codes underwent qualitative thematic analysis through an iterative process of code comparison, revision, and consolidation. This collaborative thematic analysis defined mutually agreed upon themes to characterize patterns in patient and surgeon behaviors and dialogue.

Quantitative Analysis

Data from patient charts underwent descriptive quantitative analysis aimed at following BIA-ALCL decision-making over time and to characterize the distribution of demographics (eg, age, Allergan versus Mentor implant texture exposure) between decision groups and to analyze differences in BIA-ALCL prophylaxis intervention-seeking between consult attendees and nonattendees. Differences between BIA-ALCL prevention decision groups and between consult attendees and nonattendees were assessed using two-tailed unpaired Student's *t*-tests and chi-square tests, with a P value less than 0.05.

Quantitative findings were cross referenced against qualitative themes to characterize the relationship between these two analyses.

Ethics

A locally approved and hosted program, A pRoject Ethics Community Consensus Initiative (ARECCI), classified this project as a quality improvement initiative. The project was thus scrutinized and approved through a second opinion review process.

RESULTS

Qualitative analysis of consult field notes identified four recurring themes: weighing, perceiving, guiding, and supporting. *Weighing* presents factors and comparators that patients consider when assessing BIA-ALCL risk. *Perceiving* characterizes interactions between patients' BIA-ALCL risk assessments, emotional expression, and psychosocial contexts. *Guiding* outlines the different levels of support that patients may seek or benefit from when deciding on a BIA-ALCL prophylaxis intervention. *Supporting* explores the therapeutic value that personal and caring interactions between surgeons and their patients may offer.

Quantitative results from the chart review of patient BIA-ALCL decisions over time are summarized in Figure 1.

Theme 1: Weighing

Patients Weigh BIA-ALCL Risk against Surgical Risks

Faced with the risk of BIA-ALCL, various courses of action were available to patients: self-monitoring for signs of BIA-ALCL, noninvasive imaging monitoring for seroma, and explantation with or without implant replacement and with or without *en bloc* capsulectomy. Patients weighed their perceived risk of BIA-ALCL against various considerations when deciding on which course to pursue. Often, patients balanced BIA-ALCL concerns against risks of surgery and anesthesia. Many patients saw surgical risks as a key barrier to pursuing explantation, with some stating that they would only incur these risks if they had an additional motivator, such as a desire for revisions. Others perceived risks of surgery as trivial, with one patient chuckling at the thought of getting a perioperative infection.

Patients Weigh BIA-ALCL Risk against Satisfaction with Their Reconstruction

Many patients described satisfaction with their reconstruction as a key consideration when choosing whether to undergo another operation. Some patients were pleased with their results, making them more hesitant about explantation. On the other hand, less satisfied patients indicated that BIA-ALCL risk was further motivation to pursue revisions they may have already been considering.

Patients Weigh BIA-ALCL Risk against the Importance of Their Breast Reconstruction

Patient perceptions of the value of their implants also vary. Some patients expressed that their implants helped them to feel normal, whereas others described their implants as alien or not integral to their body image or sense of self. Patients who valued their implants highly often wanted to keep or replace them, whereas patients who placed less value on them more often considered going flat.

All of these patients at one time viewed breast reconstruction as important enough to undergo the procedure. This is particularly notable given that the patients from this practice undergo two extensive, hour-long consults to facilitate shared decision-making for reconstruction planning.[10] Initial reasoning for reconstruction was likely multifactorial, including personal motivations, societal pressures, and influence from close others or their healthcare team. However, perhaps the importance of reconstruction changes over time. Several patients attributed this change to aging. Yet, although age may play a role,[11] it should be recognized that women placing less importance on body image with age fits into the dominant discourse surrounding aging and female body image.[12] Therefore, although patients may have felt that age was a socially acceptable explanation for the change in their perception of their reconstruction, this change might have equally resulted from having had extra time to grieve the loss of their breasts and accept their postmastectomy body. Indeed, three patients expressed that their implants lost value over time, with one explicitly stating that, although she was now considering going flat, at the time of her cancer diagnosis she would not have undergone a mastectomy if not for the option of reconstruction.

Over Half of Patients Were Still Weighing Their Options at Their Post-seminar Consult

During the post-seminar consults, half of patients remained undecided, opting to schedule an ultrasound to check for seroma and/or a follow-up appointment to allow more time to consider their options. Only 51% (25) of consult attendees had a concrete BIA-ALCL risk response plan by the end of their consult: 22% (11) were content to self-monitor for signs and symptoms, while 29% (14) requested explantation, of whom three wanted to go flat.

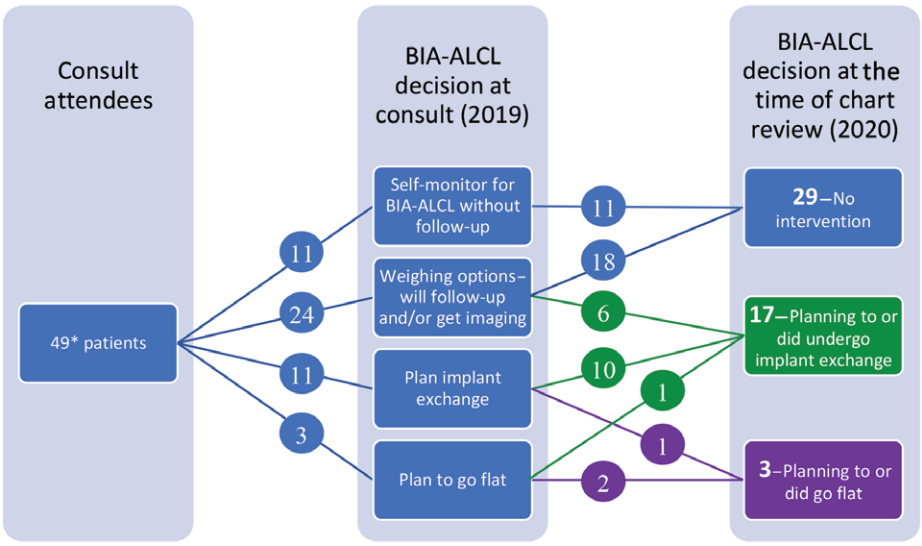

Fig. 1. Chart review: patient BIA-ALCL prophylaxis decisions over time.
*Although 53 patients attended a group seminar, not all stayed for their individual consult.

Patient Risk Perceptions Are Influenced by Implant Risk Comparisons

One year after the initial consults, 41% (20) of patients pursued explantation, with or without replacement. There was a significant association between implant brand and whether patients chose to remove them, with Allergan brand dominating the implants removed (61% of patients with Allergan implants chose explantation, versus 14% of those with Mentor, $P < 0.001$). One might consider whether patients with Allergan implants perceived their 1:3817 BIA-ALCL risk,[13] which is uncommon, to be high because of the comparison with the 1:60,631 risk of Mentor implants.[13] In contrast, patients with Mentor implants may have perceived their risk as especially low. This comparison was expressed by some patients who described Allergan as the *bad* implants or Mentor as the *good* ones. This correlates with the observed tendency to categorize risks in a binary of safe versus dangerous.[14] Further, during their consults, many patients with Mentor implants described learning they did not have Allergan implants as a relief.

Theme 2: Perceiving

Patient Perceptions of BIA-ALCL Risk Vary Widely

Patients attending individual consults expressed a wide range of emotions, hinting at the variability in patient morale and response to learning about BIA-ALCL risk. Many appeared upbeat and friendly, one patient greeting the surgeon with a hug. Others seemed calm and unphased. A few patients appeared angry, frustrated, sad, anxious, or overwhelmed. Similarly, patient perceptions of BIA-ALCL risk varied widely from unconcerned to so anxious that they wanted to go flat for fear that even smooth implants would increase risk. Of note, most patients who presented as calm or upbeat appraised BIA-ALCL's risk as low, suggesting a link between low-risk perceptions and a lack of distress in response to the news of BIA-ALCL risk.

Patient Perceptions of BIA-ALCL Risk Are Framed by Their Medical Histories

Patient medical histories were reviewed during risk discussions. Several patients who had personal or family histories of serious, rare, or autoimmune conditions described feeling they were unlucky and would likely be the one in several thousand[13] to develop BIA-ALCL. Further adding to their concern, they often expressed a belief that they would have an atypical, nonseromatous presentation of BIA-ALCL, leading to diagnosis of advanced disease. These patients had a heightened perception of BIA-ALCL risk.

This program's patient population is largely made up of breast cancer survivors, which may impact risk perceptions such that any mention of cancer is distressing. One patient explained that she had been actively avoiding thinking about her cancer history, but that the news of BIA-ALCL risk forced her to revisit these unpleasant memories. Another felt BIA-ALCL risk had undercut her efforts to minimize her health risks after her breast cancer.

Medical comorbidities, such as a breast cancer recurrence, also play into risk assessments. Many of these patients felt their current condition framed BIA-ALCL as relatively low risk in comparison. Their current health issues were perceived as more urgent than prophylaxis of this uncommon disease.

Surgeons Should Consider Patient Perceptions of BIA-ALCL Risk within the Psychosocial Context

In addition to health concerns, many patients indicated that general life stressors, such as work and relationships, influenced their response to BIA-ALCL risk. Patients found these concerns reduced their bandwidth for processing additional stressors, leaving them overwhelmed by the added task of addressing BIA-ALCL risk.

The consults thus helped to elucidate the breadth of individual BIA-ALCL risk perceptions and responses. Understanding this range of responses and reasoning can be highly valuable for surgeons supporting patients regarding BIA-ALCL risk. Open-ended questioning at the beginning of the consult can help surgeons uncover factors contributing to each patient's perceptions to better address their specific worries.

Theme 3: Guiding

Many Patients Needed Further Guidance beyond the Post-seminar Consults

Patients who initially decided on either implant removal or self-monitoring had largely followed through with these decisions at the time of chart review one year later, excepting one patient opting to go flat instead of implant exchange, and another opting for exchange instead of going flat. The biggest shift over time was among the 24 patients who were still undecided at their individual consult. Most either never sought follow-up or remained weighing their options, while 25% (6) ultimately chose implant exchange. It is apparent that patients need different amounts of reflection, time, and guidance to decide on a BIA-ALCL risk management plan. Notably, patients who were decisive early on were unlikely to need further decision-making support.

BIA-ALCL Risk Counseling Should Balance Patient Autonomy with Appropriate Guidance

In supporting patient decision-making, there were situations in which the surgeon offered advice or guidance. For example, when one patient with Mentor implants expressed her intent to go flat, the surgeon reiterated the low 1:60,631 risk these implants carry.[13] Similarly, if it seemed a patient might be hastily making a decision, the surgeon would encourage her to take extra time to consider available options and seek supports before committing to an operation. This was particularly true for patients wanting to go flat, a course of action that carries everyday implications that patients might not anticipate. The surgeon also offered recommendations based on patients' specific clinical context, such as advising that a woman with a breast cancer recurrence manage her active malignancy before considering explantation for an uncommon risk like BIA-ALCL.

However, although physicians are tasked with providing medical advice to patients, they must also resist

medical paternalism and support patient autonomy.[15,16] In keeping with an approach used in the group seminars,[6] although the surgeon offered advice, she also reiterated that she was open to whichever BIA-ALCL risk management plan suited the patient, ranging from least to most invasive. It is noteworthy, however, that many patients did not have a preferred course of action and explicitly sought the surgeon's guidance on what to do. Thus, while it is important to protect patients' autonomy in BIA-ALCL decision-making, this must be balanced by appropriate guidance, helping women to interpret available evidence and select a care plan suited to their individual situation.

Patient Decisions Are Guided by Close Others and Other Healthcare Providers

Patient decisions may in part be guided by the influence of others. Many patients brought a companion to their consult, most often their partner, but also mothers and daughters. A variety of companion opinions were observed. While some partners were clear that they would support whichever course the patient chose, others preferred that the patient avoid further surgery given the low risk of BIA-ALCL. In contrast, one mother expressed concern that her daughter was not pursuing explantation, and another patient indicated that her family (which was not present) would like her to remove her implants.

External influences also extended beyond the family unit as patients shared BIA-ALCL prophylaxis recommendations they had received from physicians in other specialties. Some recommendations explicitly encouraged implant removal, whereas others reinforced the low risk of BIA-ALCL.

Surgeons counseling their patients on BIA-ALCL risk should anticipate that patients may be influenced by external opinions and acknowledge the importance of these opinions to the patient. By including patients' close others and care providers in discussions about BIA-ALCL risk, the surgeon can gain improved understanding of these contributing viewpoints to better support patients' decision-making. In fact, the surgeon explicitly asked patients' companions' opinions and always followed up with involved physicians to share updated BIA-ALCL information.

Theme 4: Supporting

One-on-One Consults Are Therapeutic for Patients

Although the primary purpose of the group seminars was to meet patients' BIA-ALCL risk informational needs, a key benefit of the individual consults was to better fulfill each woman's need for assurance. This was supported as 89% (47 of 53) of seminar attendees went on to attend their individual consult. Many of these patients did not endorse high concern about BIA-ALCL risk, some of whom said the seminar helped them to recognize this risk as lower than they originally thought, yet they still wanted to connect with their surgeon one-on-one. Further, questions during consults were often more personal compared with those asked in the seminars, suggesting that women were not only seeking information about BIA-ALCL, but also to be assessed as an individual. Women often brought up symptoms that had been concerning them, asking whether these were normal or could be related to BIA-ALCL. Many surfaced concerns unrelated to BIA-ALCL, such as aesthetic or functional issues with their reconstruction, or questions about breast cancer independent of BIA-ALCL. One participant indicated she just wanted a check-up. Thus, unlike group seminars, individual consults allow patients to reconnect with their surgeon, reiterate their medical history, undergo a physical examination, and share personal concerns. This ability to be seen, heard, and counseled as an individual seems to provide therapeutic value and reinforce the patient–surgeon relationship, consistent with evidence that physical examination is a therapeutic tool in and of itself, for both patient and physician.[17,18]

Offering Support Can Preclude the Need for Invasive Interventions

Throughout the consults, there were many instances wherein the surgeon offered patients additional care to address their BIA-ALCL risk concerns. For patients who were not ready to remove their implants but also not content with self-monitoring for symptoms, the surgeon offered two noninvasive options for peace of mind: a follow-up appointment and/or an ultrasound to examine for seroma. All 24 patients who were still weighing their options at the end of their individual consult decided to pursue one or both of these options, and only a minority (25%) ultimately pursued explantation. It thus seems that for the majority of uncertain patients, follow-up or imaging may be sufficient reassurance to mitigate their BIA-ALCL risk concerns, precluding the need for more invasive surgical interventions. Note that there is yet no National Comprehensive Cancer Network recommendation for screening asymptomatic women for BIA-ALCL,[8] nor may there ever be, as screening is not an effective strategy for uncommon diseases.[19] As such, practitioners are left to personalize plans that meet each patient's level of concern.

Patients Seek Advice, Not Retaliation

The therapeutic nature of the individual consult should reassure surgeons that they need not shy away from discussing BIA-ALCL risk with their patients. In fact, addressing the topic head on may strengthen the patient–surgeon relationship. Only two consult patients showed any overt discontent toward the surgeon herself. In fact, many patients thanked the surgeon for reaching out to them about BIA-ALCL risk, others reiterated their trust in her care, and more than one sympathized with her, recognizing how difficult this issue must be for the surgeon as well. Thus, although the consults were understandably emotional, the treating surgeon was reassured to find that the therapeutic relationship with these women remained intact. Ultimately, it became clear that most patients did not approach the seminars or consults with anger, rather the large majority continue to value their treating surgeon's opinion and are simply looking for some clarity and reassurance. Offering patients time and space to voice their concerns and helping them to process BIA-ALCL

information may thus be considered an important component of comprehensive, sympathetic support for breast implant patients.

Consults Provide Additional Support for Patients Who Are Most Concerned

When interpreting the finding that 41% (20) of consult attendees sought implant removal, it is important to remember that this statistic pertains to only a small portion of the surgeon's 358 patients who received a notification letter. Among patients who did not participate in this support program, only 4% (13 of 303) underwent explantation, many of whom were already planning revisions, independent of any BIA-ALCL concerns. Therefore, when considering the larger population of 358 implant patients from this practice, ultimately only a total of 9% (33) sought prophylactic implant removal.

Our experience is similar to Roberts et al (2019), who sent BIA-ALCL notification letters to 1284 implant patients, 68% of whom were reconstructive.[20] Two hundred sixty-four letter recipients (21%) had textured implants, 16 (6%) of whom attended a consult with their surgeon, and nine of these 16 (56% of textured implant consults, 0.7% of all notified patients) ultimately sought explantation.[20] Of these nine patients, eight (89%) were reconstructive.[20] There is also an account from an exclusively aesthetic practice that notified 1000 breast implant patients about BIA-ALCL risk, resulting in 34 (0.3%) consults and one (0.1%) explantation request.[21]

That 41% of the 49 patients who attended a consult sought explantation, versus only 4% of the 303 who did not participate in the program, suggests that program participants were self-selected to be more concerned and to seek surgical intervention ($P < 0.001$). It is less likely that exposure to the seminars and/or consults prompted them to pursue explantation as multiple patients stated that the educational seminars helped appease their BIA-ALCL concerns and none indicated a heightened concern. This suggests that the program helped the surgeon to target and support patients who were already the most uneasy.

CONCLUSIONS

We previously reported that group seminars can serve as a valuable and efficient tool to help inform patients about BIA-ALCL and its risk.[6] This quality improvement project builds on those findings by identifying how BIA-ALCL care can be further supported by pairing group seminars with individual consults.

One of the most valuable lessons learned from this project was its insight into the variability in patient responses to BIA-ALCL risk and the therapeutic opportunity afforded by personalized medicine. *Weighing* shows how patients view BIA-ALCL risk differently based on risk-benefit comparisons between perceived risk of BIA-ALCL and the risk of surgery, satisfaction with their current reconstruction, and the value of their implants, which can change over time. *Perceiving* explores patients' varying responses to BIA-ALCL risk and how surgeons must seek to understand how each patient's emotional, medical, and psychosocial experiences can frame these responses. *Guiding* describes how patients may benefit from a personalized balance of autonomy and guidance when making BIA-ALCL prophylaxis decisions, and surgeons must recognize and address these varying needs. Finally, *supporting* underlines a key advantage that individual consults have over group-based interventions: the therapeutic value of allowing patients to individually reconnect with and be examined by their surgeon, which strengthens the patient–surgeon relationship.

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