

# Public Awareness of Breast Implant-associated Anaplastic Large Cell Lymphoma in Saudi Arabia

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**Background:** Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) was first reported in 1997. Since then, the number of reported cases has been increasing, and patients' knowledge and perceptions about this condition are unclear. This study aimed to evaluate the public knowledge and perceptions toward BIA-ALCL and its association with cosmetic/reconstructive breast implants in Saudi Arabia.

**Methods:** In this cross-sectional, online survey-based study, women aged 18–60 years in Saudi Arabia were the target population on social media platforms. Questions included data on demographics, experience of implants, and knowledge and concerns regarding BIA-ALCL.

**Results:** A total of 543 women participated in this study, with a mean age of 34 years. Only 1.9% had breast implants due to cosmetic or reconstructive reasons, whereas 9.8% expressed their desire of having implants in the future. More than half (57.3%) of the respondents had never heard of BIA-ALCL in comparison with 21.7% who had an established background. After reading the highlights on BIA-ALCL, 60% of the women with breast implants still wanted to keep their implants and 42.5% of the ones who desired breast implants would still aim to have them. Almost all the sample stated that BIA-ALCL should be included in the written consent.

**Conclusions:** Nearly half of Saudi women have not heard of BIA-ALCL, and report that it is an important part of the surgical consultation and informed consent. Our role as plastic surgeons is to raise the awareness of BIA-ALCL through social media and health care settings to maximize the safety of women with breast implants. (*Plast Reconstr Surg Glob Open* 2021;9:e3953; doi: [10.1097/GOX.0000000000003953](https://doi.org/10.1097/GOX.0000000000003953); Published online 22 November 2021.)

## INTRODUCTION

The 1960s witnessed the birth of the breast implants used in breast augmentation, a procedure that skyrocketed in popularity in the coming decades. More than 480,000 implant-based breast augmentation were done in 2019 and 2020 in the United States alone, with the number constantly on the rise, evidenced by an increase of

41% compared with the year 2000.<sup>1</sup> Notably, 84% of the implants used in 2020 were silicone implants.

Despite the popularity and high safety profile, various short- and long-term complications are known to occur in approximately 1% of the cases,<sup>2</sup> of which one is a rare neoplastic condition that was identified in 1997 as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).<sup>3,4</sup> Classified as a non-Hodgkin T-cell lymphoma, this CD30-positive, anaplastic lymphoma kinase negative malignancy is postulated to result from an interplay between genetic predisposition, bacterial contamination, and textured implants, manifesting itself most commonly as periprosthetic fluid.<sup>4,5</sup> As of January 2020, approximately 733 confirmed cases around the world have been reported by the US Food and Drug Administration since it was first reported.<sup>6</sup>

An important pillar of the patient–doctor relationship is constituted when a patient is well aware of possible adverse outcomes of any operation. Although Villarroya-Marquina et al and Lee et al were among those who explored the perception and awareness of patients to BIA-ALCL internationally, the topic is not addressed in the

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Kingdom of Saudi Arabia (KSA), and thereof is the aim of this article.

## METHODOLOGY

In this cross-sectional, survey-based study, we used the questionnaire created by Lee et al. Hosted by Google Forms, the 21-question survey was distributed online through social media platforms (mainly Twitter) to target the women who live in KSA, aged between 18 and 60 years, and with access to these platforms, throughout November 2020. The sample size was calculated based on the estimated number of women in Saudi Arabia aged between 18 and 60 years, which was reported to be 9,897,060. Using this population size, with a 5% margin of error, a 95% confidence interval, and an expected prevalence of 50%, the minimum recommended sample size was 385. It was calculated using the following sample size calculator (<http://www.raosoft.com/samplesize.html>).

After the demographic data, the survey asked if the test takers have had implants before, their type, and their acquaintance with BIA-ALCL. Following that, they were briefed in a simple clear language about BIA-ALCL and were asked about their perception and attitude toward breast augmentation with implants after being informed about BIA-ALCL. The survey was available in Arabic and English, with the ability to choose either language option. No identifier data were asked, nor was access granted to third parties in order to maintain confidentiality. The purpose of the study was stated in the introduction to the questionnaire, and the participants were informed that they consent to joining the study if they proceed to the survey. Furthermore, they were informed that participation was voluntary without any positive or negative impact upon the decision of participation.

After data collection conclusion, it was transformed from Excel format to SPSS (23rd edition, Microsoft, Redmond, Wash.) for the analysis. Descriptive statistics were used to present categorical variables in frequencies and percentages, and continuous data were presented in the form of measures of dispersion. Chi-square test was used to detect significant difference among categorical data, whereas the nonparametric Mann-Whitney *U* test was used to look for significant mean difference among continuous data.

## RESULTS

A total of 543 women participated in this study, surpassing the minimal calculated sample size of 385 people. The vast majority responded to the Arabic version of the survey ( $N = 515$ , 94.8%). With a mean age of 34 years, only 1.9% ( $N = 10$ ) had breast implants due to cosmetic or reconstructive reasons, and 14.9% ( $N = 81$ ) knew a relative with breast implants, while 9.8% ( $N = 53$ ) expressed their desire of having implants in the future. Further demographic details can be found in [Table 1](#).

When asked about the depth of background about risks and benefits of having breast implants, 40.9% ( $N = 222$ ) participants admitted superficial knowledge in contrast to only 6.4% ( $N = 35$ ), who reported robust knowledge.

## Takeaways

**Question:** What is the level of knowledge and perception of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) among women in Saudi Arabia?

**Findings:** Through this observational cross-sectional study, it was found that more than half of the participants have not heard about BIA-ALCL; moreover, almost all participants agreed on the importance of BIA-ALCL being mentioned in the breast augmentation consent form.

**Meaning:** Our role as plastic surgeons is to raise the awareness of BIA-ALCL through social media and healthcare settings to maximize the safety of women with breast implants.

Furthermore, more than half ( $N = 311$ , 57.3%) of the respondents had never heard of BIA-ALCL in comparison to 21.7% ( $N = 118$ ) who had prior information about it; among the latter, television and social media constituted the most prevalent source where they came across BIA-ALCL ( $N = 40$ , 33.6% and  $N = 43$ , 36.1%). Please refer to [Figures 1](#) and [2](#) for more details.

More than half of the women who recognized BIA-ALCL ( $N = 77$ , 65.3%) believed that a strong association between this condition and implants exists. After reading the highlights on BIA-ALCL, 60% of the women with breast implants still wanted to keep their implants, and 42.5% of the ones who desired breast implants would still aim to have them. Furthermore, 80.4% would still recommend peers and relatives to have breast implants. Finally, almost all the sample stated that BIA-ALCL should be included in the written consent, even though it has a rare incidence. Please refer to [Table 2](#) for more details.

In the Mann-Whitney *U* test, there was no significant difference ( $P = 0.21$ ) in the level of awareness about advantages and disadvantages of breast implants between those who desired augmentation and those who did not (mean = 2.04 versus mean = 2.31). Using Chi-square testing, all who wanted to have breast implants, who were disinterested, and those who were undecided showed no significant difference in knowledge about BIA-ALCL ( $P = 0.06$ ).

## DISCUSSION

In the absence of data concerning the patients' awareness and perception of BIA-ALCL in KSA, we undertook this cross-sectional study that involved 543 women residing in KSA to explore this gap, and contrast our data with other international studies. A minority of our population was acquainted with BIA-ALCL, 21.7% ( $N = 118$ ), considering that more than 75% of the study sample expressed their willingness to have breast implants. This is added to the overall picture of having a limited conception of the risks and benefits of having breast implants among at least 40.9% ( $N = 222$ ) of the women in the sample. Of those who heard about BIA-ALCL, 25.4% ( $N = 30$ ) and 65.3% ( $N = 77$ ) think that there is a weak and strong relationship between the implants and this condition, respectively.

**Table 1. Demographic Data**

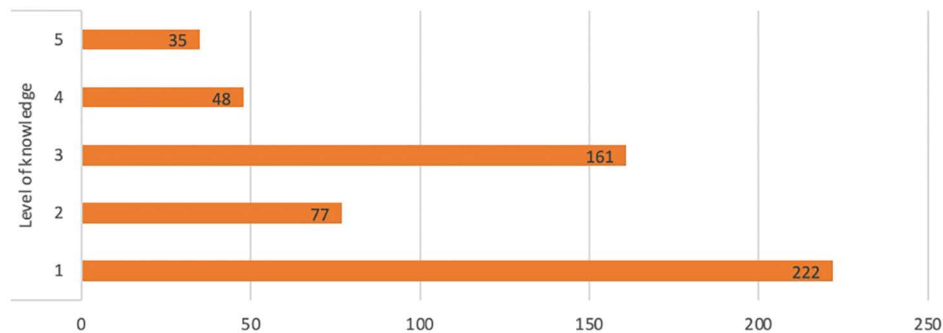
Parameter	Value (%)	Measures of Dispersion
Age	—	Mean = 34 years old SD = 13.4 years old Minimum = 18 years old Maximum = 85 years old
Marital status	Single = 223, 41.1% Married = 293, 54% Divorced = 21, 3.9% Widowed = 6, 1.1%	—
Nationality	Saudi = 529, 97.4% Non-Saudi (Living in Saudi Arabia) = 14, 2.6%	—
Residence	Central = 176, 32.4% Western = 106, 19.5% Eastern = 101, 18.6% Northern = 21, 3.9% Southern = 139, 25.6%	—
Education	Secondary school or less = 105, 19.3% Diploma = 38, 7% Bachelor = 331, 61% Higher degree = 69, 12.7%	—
Career	Student = 156, 28.7% Employee = 179, 33% Unemployed = 208, 38.3%	—
Monthly income in Saudi riyals	Less than 5000 = 277, 51% 5000–9999 = 121, 22.3% 10,000–14999 = 76, 14% 15,000–19,999 = 33, 6.1% 20,000–24,999 = 11, 2% More than 25,000 = 25, 4.6%	—
Has breast implants	No = 533, 98.2% Yes, for cosmetic reasons = 8, 1.5% No, for reconstructive reasons = 2, 0.4%	—
Type of implants*	Smooth = 4, 40% Textured = 2, 20% I do not know = 4, 40%	—
Do you know a friend with breast implants?	No = 462, 85.1% Yes = 81, 14.9%	—
Do you want to have breast implants?	No = 416, 76.6% Yes = 53, 9.8% I do not know = 74, 13.6%	—
What type of implants do you prefer?†	Smooth = 20, 15.7% Textured = 2, 1.6% I do not know = 105, 82.7%	—
Knowledge of BIA-ALCL	No = 311, 57.3% Yes = 118, 21.7% I do not know = 114, 21%	—
Strength of association between BIA-ALCL and breast implants‡	No association = 11, 9.3% Weak relationship = 30, 25.4% Strong relationship = 77, 65.3%	—

\*Among those who confirmed having breast implants.

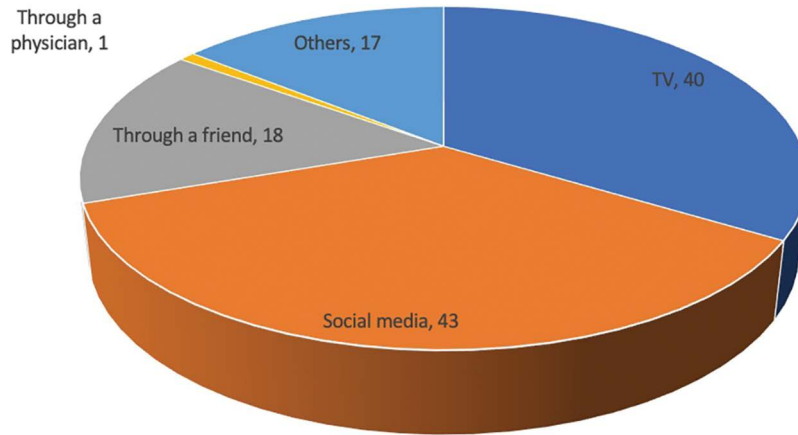
†Among those who wanted to have breast implants.

‡Among those who knew about BIA-ALCL.

**Level of knowledge about the risks and benefits of breast augmentation with implants (N = 543)**



**Fig. 1.** This bar chart shows the level of acquaintance with the positive and negative consequences of having breast implants among our sample. One indicates a poor background, three indicates an average background, and five indicates a very good background.



**Fig. 2.** This pie chart shows how the participants in our sample heard about BIA-ALCL. Note: The sample in this pie chart are the women who knew about BIA-ALCL. Those who did not know about it were excluded from this graph.

Our findings are not far from what is reported in the literature. Lee et al reported that only 14% have previously heard about BIA-ALCL.<sup>7</sup> On the contrary, Bouhadana et al reported that 70% of their sample knew about BIA-ALCL, mainly through newspapers, television, and physicians.<sup>8</sup> Their findings could be explained by the fact that more than 80% of the recruited population had a background of breast cancer and underwent reconstruction with implants.

Parallel to reports from other studies,<sup>7</sup> the overwhelming majority in our population (more than 95%) suggest that plastic surgeons should mention BIA-ALCL as a possible complication while consenting for the operation. Combining this with the fact that after briefing our participants about BIA-ALCL, 90% of the women with implants admitted that they were worried ( $N=9$ ), 10% considered explantation ( $N=1$ ), and 42.5% no longer desired having breast implants ( $N=54$ ), may add to the concern of losing patients as a result of including BIA-ALCL in the informed consent. However, we believe that transparency bolsters the physician–patient relationship; therefore, BIA-ALCL should be clearly stated and explained to the candidate. This could be done at a personal level between surgeons

and their patients or through utilizing the tools through which the majority of our participants received information about BIA-ALCL, as roughly two-thirds identified television and social media platforms as their main source of information. High-quality videos from authorized sources in simple, comprehensible language could be the best modality of information transfer.<sup>9</sup> These should emphasize the lower incidence of 0.1–0.3 per 100,000 women and the statistical inconsistency among different studies, but highlight the recently reported higher incidence (one in 559 and one in 355) among those with textured implants,<sup>10–12</sup> the common signs and symptoms, and the relatively better prognosis if detected early. Although healthcare personnel formed the least important source of information on BIA-ALCL in our cohort, it was the most important source for the sample in the study by Lee et al.<sup>7</sup>

The robustness of the findings in this study could be challenged by multiple factors. First, due to the lack of statistics on the prevalence and frequency of breast augmentation in KSA, it is unclear whether our study reflects the characteristics of the Saudi population. In addition to using social media platforms, which limits the characteristics of the sample, the required population was geographically bound. Moreover, the nature of the survey was reachable by certain socioeconomic classes of people more than others. However, our findings coalesce with that available in the literature, giving the impression that the attitude and perception toward BIA-ALCL could be universal. Our findings lead us to an important question that could be investigated in a future study. As BIA-ALCL could take place 8–10 years after implantation,<sup>10</sup> it is likely that if symptoms of BIA-ALCL arise, a patient might visit a physician other than the plastic surgeon who originally performed the augmentation. Hence, the awareness of “frontier physicians,” namely family physicians and general surgeons, about the condition is an important aspect to be determined and raised. A notable contribution was the article by McKernan et al, which was directed at guiding internal medicine physicians to better understand and handle BIA-ALCL cases.<sup>13</sup> The role of The National Comprehensive Cancer Network guidelines

**Table 2. Response of the Participants to Some Questions after Reading a Summary on BIA-ALCL**

Parameter	Value (%)
Level of concern about BIA-ALCL*	Not concerned = 1, 10% Concerned to an extent = 7, 70% Very concerned = 2, 20%
Explantation consideration*	No = 6, 60% Yes = 1, 10% I do not know = 3, 30%
Do you still desire having implants?†	No = 54, 42.5% Yes = 20, 15.7% I do not know = 53, 41.7%
Would you still recommend breast augmentation with implants to peers?	No = 436, 80.4% Yes = 54, 10% I do not know = 52, 9.6%
Should BIA-ALCL be included in the written consent?	No, because it is rare = 21, 3.9% Yes, because there is a risk = 522, 96.1%

\*Among those who confirmed having breast implants.

†Among those who wanted to have breast implants.



on BIA-ALCL have been recognized by the US Food and Drug Administration and widely advocated by other national specialty societies. These guidelines have helped create a standardized treatment for BIA-ALCL at all stages of the disease. Recommendations focus on parameters for achieving a reliable diagnosis and management, and emphasize on the critical role of complete surgical ablation of breast implants.<sup>12</sup>

## CONCLUSIONS

Breast implants went through an eventful timeline from total restriction to absolute popularity. Although their safety profile far outweighs that of risk, BIA-ALCL could be one of the rarest complications that arises due to multiple, incompletely understood factors. Candidates for prosthesis-based breast augmentation, both cosmetic and reconstructive, should be aware of this condition, and a significant part of the responsibility falls on the shoulders of plastic and reconstructive surgeons. Our findings suggest that more awareness campaigns and programs should be launched to spread awareness among the community. These should not serve as a deterrent from pursuing breast augmentation among those interested, and the surgeons should not refrain from mentioning the condition during the informed consent process.

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*This project conforms to the Declaration of Helsinki.*

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