

 Updated Epidemiology Of Breast Implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL) In The United States 		
BACKGROUND Breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) is a hematological malignancy identified in 1997, recognized by the FDA in 2011, and classified by the World Health Organization in 2016. A cornerstone in BIA-ALCL epidemiology is to determine an accurate incidence rate, prevalence, and risk, but also to implement a reliable methodology for estimating a denominator in the absence of readily available manufacturer data or mandatory/opt-out breast implant registries. Epidemiological studies on BIA-ALCL suffer from discrepancies and a lack of homogeneity in reporting or estimation of the denominator (ie, the number of individuals with breast implants), which is inferred by population estimates or calculated from implant sales data. The United States provides a unique perspective: despite the market there being dominated by smooth implants, it still reports the highest number of BIA-ALCL cases worldwide, with 505 from the total of 1130 unique reported cases as of April 1, 2022. Current US-based reports provide very wide risk estimates, ranging from 1:355 to 1:51,000 individuals, which may explain the wide author/geographic variations in epidemiological assessment from implant markets with different smooth/textured ratios or industry shares	MATERIAL AND METHODS Systematic Literature Review Manuscripts Published from 1996-2023 Numerator and Denominator Calculation The US numerator was calculated by averaging the US FDA (MAUDE) database, and the PROFILE registry, updated as of February 1, 2023 The US denominator was estimated by the method of Santanelli di Pompeo et al, which includes the transgender population, and is based on US demographic data. Prevalence, Incidence Rate and Risk Calculation Prevalence was calculated as the ratio between the number of BIA-ALCL cases and the number of individuals bearing breast implants × 100,000. The Incidence Rate was defined as the number of new cases diagnosed during a specified time interval. Lifetime risk was calculated as the ratio between the number of BIA-ALCL cases and the number of individuals bearing breast implants but not suffering from BIA-ALCL	CONCLUSION Accurate Disease Tracking And A Denominator Based On A Cohort Of Patients Bearing Textured Breast Implants, BIA-ALCL Incidence Rate, Prevalence, And Risk Are Considerably Higher Than Previously Reported. ↓ The Risk Of 1:913 Applies To Patients Bearing Textured Devices, Where Prevalence Has Been Calculated To Be As High As 109.4 Per 100,000 Patients And Incidence Rate Was Confirmed As 31.1 Per 100,000 Persons Per Year. ↓ These Findings May Influence The Surveillance Of Existing Patients And The Use Of Macrotextured Implants In Other Parts Of The World Where They Remain Widespread
AIM 1. Systematic Review of the Scientific Literature Concerning US-Based BIA-ALCL Epidemiology 2. Calculate a More Accurate Denominator, by Using a Validated Radiography-Based Methodology, Within the US Population 3. Offer Updated Estimates of the Prevalence, Incidence Rate and Risk of BIA-ALCL in the US	RESULTS The US prevalence of BIA-ALCL in the literature ranged from 1:300 to 1:500,000 and the Incidence Rate from 4.5 per 10,000 to 31.1 per 100 million persons per year Numerator was 453.5 BIA-ALCL cases Denominator of 4,264,618 individuals with implants Textured Implant Specific Denominator of 414,521 individuals Prevalence of 109.4 cases per 100,000 individuals Lifetime risk of 1:913	