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Original Article

A Systematic Review of Outcomes Following Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

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ABSTRACT

Background: Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) has increasingly become a significant concern for patients. Focus thus far has been on understanding pathogenesis and establishing treatment pathways. There has been less attention on the assessment of long-term treatment outcomes. The purpose of this study was to perform a systematic review to assess published data on treatment outcomes for BIA-ALCL.

Methods: Using PRISMA guidelines, a systematic search of the literature was carried out from January 1997 to January 2021 using the Web of Science (PubMed) and Ovid Medline. Included in the review were any studies on the management and follow-up of patients, including disease status at a minimum of 18 months following treatment.

Results: A total of 39 articles matched the inclusion criteria. However, 94% of patients were managed with explantation and capsulectomy. Then, 39% of patients had adjuvant chemotherapy, 19% radiotherapy, 6% autologous stem cell transplant, and 4% immunotherapy. The mean follow-up was 19 months (range 3–36 months), and 69% of patients were reported to be alive at 18

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months. The mainstay of treatment was surgical – en bloc capsulectomy with adjuvant treatment for advanced disease.

Conclusions: Robust survival data based on high-level evidence are challenging to establish in BIA-ALCL. Early diagnosis and en bloc capsulectomy with negative margins, whilst considering the need for adjuvant treatment, particularly targeted immune therapy in advanced disease represents the consistent forms of treatment. National databases, prospective studies, and treatment of patients in tertiary centres are all recommended to improve the quality of the research available in the management of BIA-ALCL.

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Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) has been described in the literature since 1997.¹ In 2016, the World Health Organization (WHO) defined it under the entity of non-Hodgkin's lymphoma, of which anaplastic large cell lymphoma (ALCL) associated with breast implants is a subtype² of ALCL T-cell lymphomas. The current incidence in the UK, according to the Medicines and Healthcare Products Regulatory Agency (MHRA), is 1 in 15000 implants sold, and as of December 2020, there have been 83 cases reported.³ As a relatively new pathological finding, the focus has been centred on understanding BIA-ALCL pathogenesis and its potential optimal treatments based on the disease stage at presentation. Diagnosis and Treatment Guidelines have since been published annually since 2017 by the National Comprehensive Cancer Network (NCCN)⁴ in the USA and more recently in the UK⁵ which built upon previous versions⁶ in an attempt to standardise the diagnostic and treatment pathway for these patients. Best Practice Guidelines for Pathologic Diagnosis of BIA-ALCL were developed by a collaboration of MD Anderson Cancer Center, the US National Institutes of Health, and the US FDA in 2020.⁷ The European Society of Medical Oncology (ESMO) has yet to adopt formal guidelines for BIA-ALCL and is a much-needed resource for European Oncologists most likely to encounter this disease.

Accurate disease staging has important implications when considering treatment outcomes. The Ann Arbour staging system for haematological lymphomas⁷ is not considered appropriate for BIA-ALCL, and the MD Anderson Cancer Center TNM staging has been more widely adopted since it has been noted that BIA-ALCL behaves more like a solid tumour rather than traditional haematological "liquid" malignancies. When the Ann Arbour classification was applied to BIA-ALCL, 80–96% of patients had stage 1E disease with 80% of recurrences occurring in stage 1 disease, illustrating that this staging system did not allow accurately describe the tumour stage nor have prognostic value.⁸ The new proposed TNM staging describes local disease infiltration and regional metastasis, allowing more accurate staging classification of patients which is helpful in understanding outcomes from different treatment modalities and in comparing results of various studies at different stages.

Following confirmation of diagnosis, surgery consisting of en bloc capsulectomy and explantation with excision of associated masses and excisional biopsies of involved lymph nodes is recommended. In patients that present with an advanced disease stage, systemic adjuvant therapy is considered in an attempt to improve outcomes. The systemic treatment regime for BIA-ALCL traditionally followed those applied to systemic ALK-negative ALCL, specifically cyclophosphamide, hydroxydaunorubicin (doxorubicin), (onco)vincristine, and prednisolone (CHOP).⁹ However, significantly improved efficacy has been reported with the use of Brentuximab Vedotin as a primary agent for CD30-positive peripheral T-cell lymphomas, including BIA-ALCL. This CD30 targeted immunoconjugate demonstrates a significantly improved median progression-free survival from 20.8 months to 48.2 months.¹⁰ This has been an NCCN guidelines recommendation since 2018 for single agent primary treatment of BIA-

ALCL, but it remains a secondary treatment of relapsed/refractory BIA-ALCL after CHOP failure in the UK as a single agent therapy.⁵ European guidelines from ESMO are currently lacking for BIA-ALCL and still follow systemic ALCL treatment.

Despite the progress made on refining the staging, diagnostic pathway, and management of BIA-ALCL, the literature on reporting of outcomes for this condition is inconsistent. Traditional oncological objective outcome measures, such as overall survival and disease-free survival, are challenging in this patient group as BIA-ALCL is relatively new, uncommon, and consensus on treatment has only been recently established. The aim of this literature review was to assess the management of patients presenting with BIA-ALCL and determine outcomes based on the various treatment modalities and stage of disease presentations.

Methods

From 1 January 1997 to 31 January 2021, two electronic databases (Web of Science (PubMed) and OVID SP Medline) were systematically searched. The search terms used were 'breast implant associated anaplastic lymphoma' AND 'survival' OR 'breast implant associated anaplastic lymphoma' AND 'outcome' OR 'breast implant associated anaplastic lymphoma' AND 'treatment'. Reference lists of the relevant papers were hand searched, and abstracts were also reviewed to determine if there was any relevant data on the outcomes of patients following the management of BIA-ALCL.

Inclusion and Exclusion Criteria

A mixture of quantitative, qualitative, and mixed method studies was included in this review. The population studied were women who had implants for either cosmetic, reconstructive, or risk reduction that had a diagnosis of BIA-ALCL (CD30 positive and ALK negative). The papers selected included patients with any stage of BIA-ALCL and the modality of treatment. Articles were also included even if survival data were not stated but follow-up of the patient reported in months could be derived. Papers were excluded if there was no data on management or outcomes; they were not in English as funding for translation services was unavailable; ALK-positive cases and papers relating to the management of primary breast lymphoma which is a different disease entity to BIA-ALCL.

Screening for studies

The authors independently reviewed the citations generated by the search, removing duplicates and those publication types deemed ineligible. This was done by adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement reporting recommendations.¹¹ Following this, all abstracts were screened, and the full-text version of the relevant papers was retrieved for further assessment. A sample of reports was reviewed to ensure that the selection of papers was consistent with the aims of the review and the inclusion and exclusion criteria. Any doubts regarding this were resolved by discussion between the authors, and the consensus was achieved.

Data extraction

A data extraction table was developed and applied to each of the selected papers that met the inclusion criteria. This table was formatted using standard criteria, such as authors, year, country of publication, study design, patient demographics, reason for implant placement, surface texture of implant if reported, signs and symptoms at presentation, time from implant insertion to BIA-ALCL detection, TNM staging at presentation, management (surgical and oncological), follow-up period (months), and survival at 18 months post-treatment.

Results

The database search produced 597 papers (Figure 1). After duplicates were removed from the search (N= 235), a total of 362 papers were screened against title and abstract. A total of 42 ineligible documents, articles in other languages, and irrelevant articles were then removed. However,

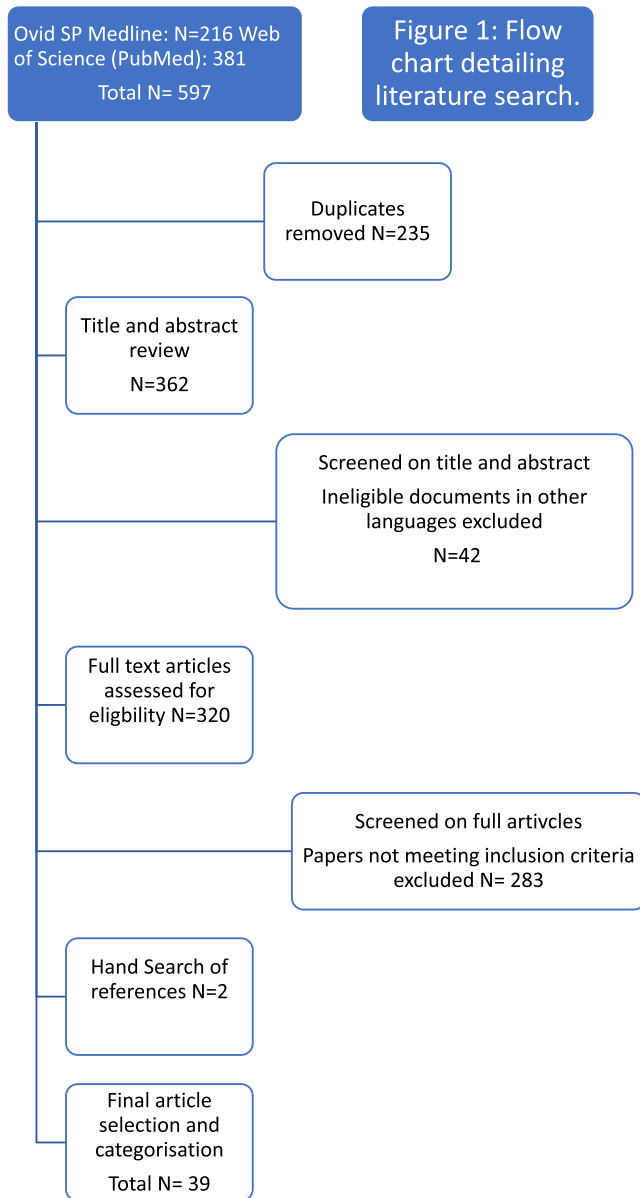


Figure 1. PRISMA flow diagram.

320 articles remained which were screened by abstract and full text. Then, 283 papers were excluded as they did not meet the inclusion criteria. A total of 37 articles remained of which a hand search through all the references produced two additional relevant articles resulting in a total of 39 papers being included in this review.

Characteristics of the selected studies

There were 20 case reports and 7 case series that gave relevant data on stage of presentation,

Table 1
Presentation and management of BIA-ALCL

	N=51 n (%)
Age (years)	
Mean	52.17
Range	32-78
Indication for implant	
Cosmetic	23 (46)
Reconstruction	19 (38)
Risk reduction	1 (2)
Benign disease	2 (4)
Unknown	6 (12)
Textured implant	
Yes	48 (94)
No	0 (0)
Unknown	3 (6)
Presenting symptom	
Swelling	42(82)
Mass	4 (8)
Pain	5 (10)
Time from implant to diagnosis (years)	
Mean	11.69
Range	2-35
Surgical removal of affected implants	
Yes	51(100)
No	0 (0)
Capsulectomy	48 (94)
Mastectomy	3 (5.8)
Axillary intervention	
Yes	13 (25)
No	38 (75)
Clearance	9 (17.6)
Biopsy	4 (8)
Radiation therapy	
Yes	19 (37)
No	27 (52)
Unknown	5 (9.8)
Chemotherapy	
Yes	20 (39)
No	22 (43)
Unknown	9 (17.5)
Autologous stem cell transplant	
Yes	3 (6)
No	48 (94)
Unknown	0
Immunotherapy	
Yes	2 (4)
No	49 (96)
Unknown	0

treatment, and outcomes. There was one prospective observational study reported over a five-year period. There were 5 published guidelines/consensus papers found in this time period on how BIA-ALCL should be managed. There were six review papers that detailed the surgical approach to the condition with outcome reporting. There was no level I evidence of randomised trials found on this topic.

Management and outcomes of reported cases of BIA-ALCL

A review of the 27 relevant articles with a total of 51 patients was analysed (Table 1). The mean patient age was 52.2 years. A total of 46% had implants placed for cosmetic reasons followed by 38% for reconstruction. In 6% of cases, there was no information on the surface texture of the implant

Table 2
Pathological stage at presentation and patient follow-up

Pathological stage	
1A	20 (39)
1B	15 (29)
1C	4 (8)
IIA	2 (4)
IIB	3 (6)
III	5 (10)
IV	3 (6)
Follow-up (months)	
Mean	19.04
Range	3–36
Disease free at 18 months reported	
Yes	35 (69)
No	16 (32)

Table 3
Adjuvant treatment administered according to the stage of BIA-ALCL

Stage	Chemotherapy (N) %	Radiotherapy (N) %	Autologous stem cell transplant (N) %	Immunotherapy
1A	4/20 (20)	3/20 (10)	0/20 (0)	0/20 (0)
1B	3/15 (20)	3/15 (20)	0/15 (0)	0/15 (0)
1C	1/4(25)	1/4(25)	1/4(25)	0/4 (0)
IIA	0/2 (0)	0/2 (0)	1/2(50)	0/2 (0)
IIB	1/3 (33)	2/3 (66)	0/3 (0)	1/3 (33)
III	5/5 (100)	5/5 (100)	0/5 (0)	0/5 (0)
IV	3/3 (100)	3/3 (100)	1/3 (33)	0/3 (0)

reported. Of the reports that gave information on implant surface, it was found that all cases were textured. However, 82% of patients presented with a swelling of the breast, 10% with pain, and 8 % with a palpable breast mass. The mean time from implant placement to the diagnosis of BIA-ALCL was 11.7 years. Then, 39% of patients presented with stage 1A disease, 29% with stage 1b disease followed by 10% with stage III disease (Table 2).

All patients underwent implant removal, and 94% of patients had capsulectomy (not specified whether partial or en bloc) as the mainstay of surgical treatment with three reports of mastectomy. A total of 25% of patients had an axillary intervention, with 9 patients underwent axillary node clearances and 3 had open biopsies of affected nodes. There was one case of sentinel node biopsy.

Overall, 39% of patients had adjuvant chemotherapy, commonly with CHOP regime. Using the MD Anderson staging system discussed above, adjuvant chemotherapy was administered to 23% of patients that presented with stage 1 disease, 17% patients with stage 2 disease, and 100% of patients with stages 3 and 4 disease.

A total of 37% of patients had radiotherapy, which was administered to 27% of patients with stage 1 disease, 33% of patients with stage 2 disease, and all patients with stages 3 and 4 disease (Table 3). Three patients had autologous stem cell transplantation, and brentuximab vedotin was administered to two patients (Table 1). The mean follow-up period was 19.04 months with 69% of patients reported to be disease free at 18 months (Table 4).

Analysis of Reviews on BIA-ALCL

Reviews were analysed if there was data on management and follow-up of patients presenting with BIA-ALCL. Most of the reviews consisted of analysis levels III and IV evidence. Reviews assessed have consistently reported the mainstay of surgical treatment to be implant removal and capsulectomy all cases presenting with BIA-ALCL. There was no specification of the type of capsulectomy performed in these cases (partial, total, or *en bloc*) and as a result that information was difficult to accurately

Table 4

Details on the existing reviews which have synthesised the evidence relating to surgical treatment and outcomes

Author & year	Title	Number of papers	Treatment	Outcome
Co M et al. 2020 ¹⁴	Breast Implant-associated anaplastic large cell lymphoma, a Systematic Review with Pooled Analysis	77	61% capsulectomy and implant removal, 2% mastectomy 33.7% chemotherapy 18.7% radiotherapy 4.3% stem cell transplant	Median follow-up 24 months, 4.3% recurrence
Quesada et al. 2018 ¹⁸	Breast-implant associated anaplastic large cell lymphoma: a review	Descriptive	Limited surgery 85%, completely surgery 5% Chemotherapy- 26%, radiotherapy 29%	Median OS 12 years (Miranda) Confinement to capsule 5-year OS 100% vs 72.4% if there is extension
Ramos- Gallardo et al. 2017	Breast Implant and Anaplastic Large Cell Lymphoma. Meta-Analysis	42	80% capsulectomy, 10% mastectomy 76.5% chemotherapy 49% radiotherapy	Median follow-up 26.62 months
Gidengil et al. 2014 ¹³	Breast Implant-associated Anaplastic Large Cell Lymphoma: A systemic review	27	89% capsulectomy and implant removal 57% chemotherapy, 48% radiation, 11% stem cell transplant	Median follow-up 26.4 months, 26% recurrence
Kim et al. 2011 ¹⁹	Anaplastic Large cell lymphoma and breast implants – A systematic Review	34	95% capsulectomy and implant removal 76% chemotherapy, 75% radiotherapy	Mean duration of follow-up – 25.2 months, 6% recurrence
Thompson et al. 2013 ¹²	Breast Implant-Associated Anaplastic Large Cell Lymphoma: A Systematic Review of the Literature and Mini-Meta Analysis	49 cases from the literature analysed	90% capsulectomy and implant removal, 49% chemotherapy, 28% radiotherapy, 2% autologous stem cell transplantation	Median follow-up 22 months, no report on recurrence

interpret from the case report descriptions. All reviews reported on the rates of chemotherapy and radiotherapy if known, with the CHOP regime being the most commonly cited. Some reviews reported on the use of autologous stem cell transplant as part of the treatment pathway for these patients.^{12–14} There were prospective case series on the use of immunotherapy as a treatment option specific to BIA-ALCL. The median follow-up was reported to be between 22–26.62 months. Recurrence rates were variable as demonstrated in [Table 4](#).

Discussion

The aim of this review was to assess all available outcome data on patients with a diagnosis of BIA-ALCL. All studies on treatment and related outcomes were reported in retrospective case series and reports. As a result, long-term survival data using this level of evidence is challenging to extrapolate. Nevertheless, the reported literature has been used to establish some key points regarding the presentation, management, and outcomes of BIA-ALCL.

Our data revealed that most patients were reported to have presented with stage 1A (effusion limited) disease, and as a result, the mainstay of treatment was found to be total capsulectomy with implant removal in most cases. Reports were not consistent as to whether the completeness of the capsulectomy. There were few cases of simultaneous mastectomy, despite BIA-ALCL not being a disease of breast tissue. One report demonstrated the safety of immediate smooth implant reconstruction at the time of tumour ablation.¹⁵ The TNM stage of presentation of BIA-ALCL was not universally

reported and had to be derived from clinical and histological reports. It is likely that these reports were published before the time of the proposed TNM staging in 2016 prior to wide adoption. As a result, the use of chemotherapy, radiotherapy, and autologous stem cell transplant was not translated to stage at the presentation of BIA-ALCL with as much consistency as current guidelines would advise. Nevertheless, it was found that all patients presenting with disease at stage IIB and above received adjuvant chemotherapy and radiotherapy following surgery. There was more variance in this practice in patients that presented with stage IA to IIA disease.

The average follow-up was found to be 19.04 months which is in keeping with most of the reported literature. One prospective study following patients with BIA-ALCL reported on the management of a case series of 52 patients.¹⁶ Their five-year follow-up revealed stage 1a to be the most common stage at presentation with all patients undergoing capsulectomy and implant removal. However, 40% of patients had adjuvant chemotherapy, and 19% of patients had radiotherapy. There were two patients with disease recurrence. All patients achieved complete remission by the five-year mark. A total of 69% of patients were disease free at 18 months with the rest unreported.

Clemens and colleagues have reported on survival following a diagnosis of BIA-ALCL (Figure 2).⁸ They demonstrated that the overall survival for BIA-ALCL was 94% at 3 years and 91% at 5 years, respectively. Overall, the earlier the stage of presentation the higher the survival rates. Furthermore, it was found that complete surgical excision had a significant impact on the overall survival compared with other therapeutic interventions; therefore, adjuvant treatment is considered a poor substitute for completion surgery. Importantly, complete surgical excision referred to an en bloc capsulectomy with explantation, excision of associated masses with negative margins, and excisional biopsies of involved regional lymph nodes. Complete surgical excision is predicated on performing preoperative imaging with PET CT scan or CT scan to evaluate for locally invasive or regionally metastatic disease. Therefore, the preoperative metastatic imaging workup is essential prior to any surgical intervention. Although this data was derived from a combination of retrospective published reports and prospectively treated patients, with significant additional information was gathered by contacting institutions and treating physicians to determine further clinically relevant unpublished details.

Our literature search did not find any studies on patient-reported outcomes for BIA-ALCL. Given its exclusive causation with textured surface breast implants which have been used for many years for cosmetic breast augmentation, these patients in particular potentially face a difficult situation once the disease has been diagnosed and treatment recommended. Attempts found to address immediate or delayed reconstruction were mainly prospective single institution experiences, one of which revealed that 94% of patients undergoing reconstruction following treatment for BIA-ALCL were satisfied.¹⁵ However, like most other published studies in this area, the sample of patients was heterogeneous, consisting of those who had been treated for varying stages of disease with no stratification based on the type of reconstruction offered, implant versus autologous following treatment and outcomes of such. Furthermore, the outcome measurement used was a Likert scale which does not allow for a validated quality of life assessment following BIA-ALCL. Additionally, these questions may fall out with the scientific remit which lies within establishing causality, management, and survival and requires further studies that use validated patient-reported outcomes as their method of assessment.

Challenges and Recommendations

Significant progress has been made in establishing causation, diagnosis, and management of BIA-ALCL since the first case report. The current literature consists of prospective and retrospective reports with incomplete data sets on presentation, histology, and aspects of management. The relatively low occurrence of the disease is challenging as clinicians with little experience in treating this condition results in variation in the treatment pathway or default to algorithms for systemic ALCL, a disease with a significantly different and aggressive natural course.

Additionally, as illustrated, there is variability in the number of cycles of chemotherapy, inconsistent indications for the use of autologous stem cell transplant, and the type and number of fractions of radiotherapy that should be given for each stage of presentation of the disease. As a comparison, success in the oncological management of breast cancer has been progressive due to the high level of

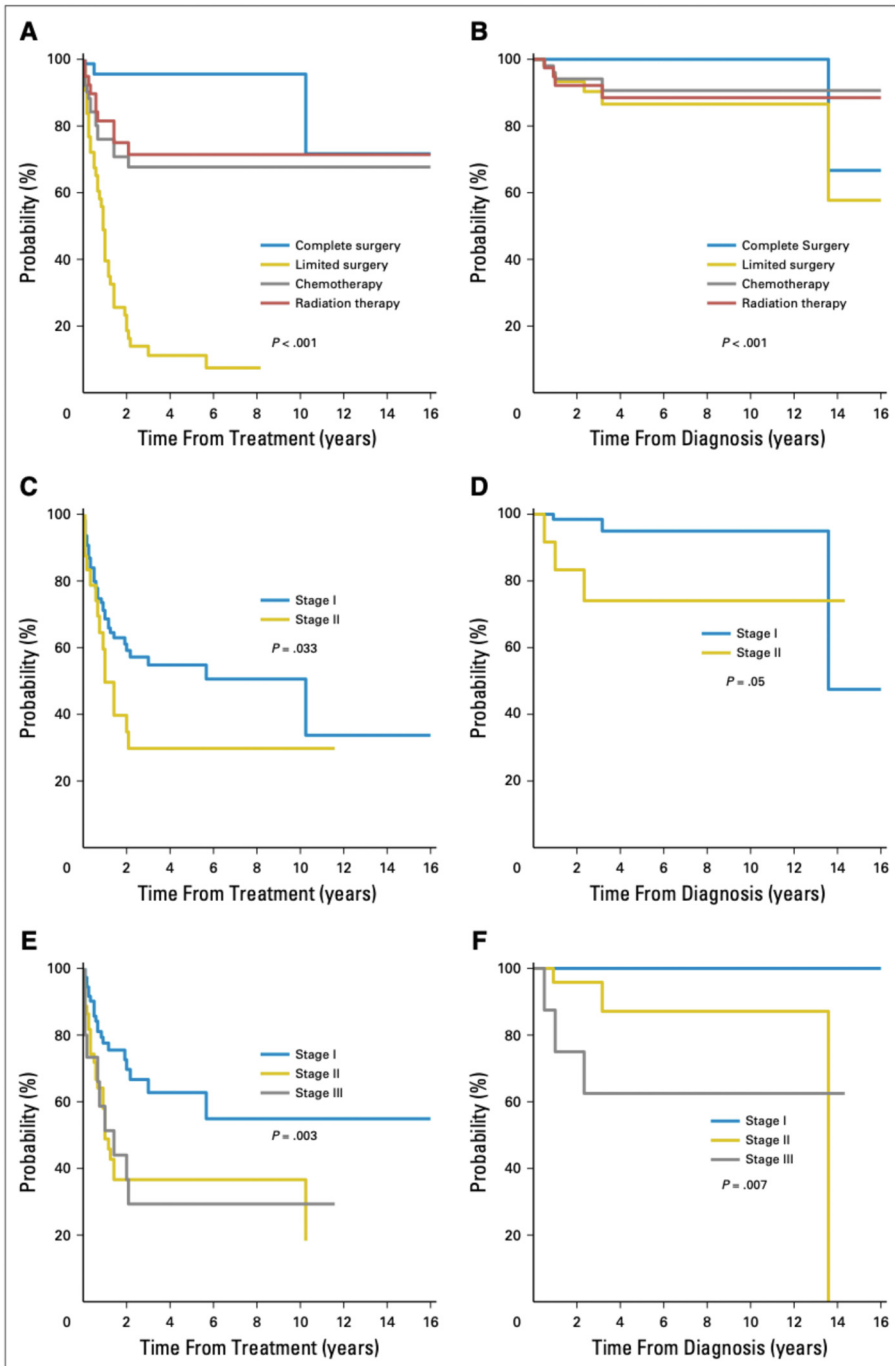


Figure 2. Survival curves according to treatment approaches: event-free survival (A), overall survival (B). Survival curves according to Ann Arbor stage: event-free survival (C), overall survival (D). Survival curves according to proposed TNM staging: event-free survival (E), overall survival (F). Used with permission from Wolters Kluwer Health Inc.

evidence that has been used to establish the optimum treatment for each stage of presentation of the disease.

Methods to improve the quality of evidence for the management of BIA-ALCL and understanding outcomes of this disease have already been implemented by way of national and international databases, such as the Patient Registry and Outcomes for Breast implants and anaplastic large cell lymphoma aetiology and epidemiology (PROFILE) registry.¹⁷

These platforms will allow for systematic and complete data collection to facilitate more robust prospective observational studies to occur. This will allow a better characterisation of patient demographics, causality, and management of the disease. To further facilitate this and as BIA-ALCL is still emerging and an uncommon condition, these patients would benefit from being treated in centralised referral centres of excellence within the setting of a multidisciplinary team with the appropriate breast and lymphoid oncological expertise to allow standardisation of care.⁵ This approach has already been adopted for many rare tumours across the UK. This model is advantageous for patients it will allow less variation in clinical assessment, access and interpretation of diagnostic tests which includes pathological assessments and imaging as they will be treated in centres that are more familiar with the condition. Additionally, it will allow patients to enter clinical trials that are adequately powered to test hypotheses using other oncological and immunological therapies that may benefit this condition but will be challenging to establish without national or international collaboration.

In this regard, the literature reporting of BIA-ALCL will change from a plethora of expert opinion and retrospective case reports to more robust data that allows for evidence-based clinical translation.

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Conflict of Interest

None

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Ethical Approval

Not required

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