Epidemiological Profile in Portugal of Breast Implant-Associated Anaplastic Large Cell Lymphoma: A Cross--Sectional Study

Perfil Epidemiológico em Portugal do Linfoma Anaplásico de Grandes Células Associado a Implantes Mamários: Um Estudo Transversal

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ABSTRACT

Introduction: Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare T-cell neoplasm that is predominantly associated with the use of textured implants. Recently, several countries have tried to clarify their epidemiological profile of BIA-ALCL. This study aims to estimate the number of cases of BIA-ALCL in Portugal and to describe the pattern of use of breast implants at a national level.

Material and Methods: This is a cross-sectional study including 57 healthcare institutions - 29 public hospitals and 28 private institutions. Each department of Plastic, Reconstructive and Aesthetic Surgery was asked to provide information concerning the main manufacturer(s) and respective device texture of the breast implants used, and to report the number of registered cases of BIA-ALCL.

Results: In our study sample, the response rate was 58%. In our sample, most hospitals reported using textured breast implants from Mentor (45.45%), Allergan (42.42%) and Polytech (39.39%). Only one private institution referred using smooth-coated implants from Mentor and Motiva. Despite several hospitals reporting late-onset seromas, there was only one confirmed case of BIA-ALCL after proper investigation with immunohistochemistry and histological procedures.

Discussion: BIA-ALCL may represent a shift for surgeons regarding selection of implant type. Smooth-coated implants or autologous tissue represent adequate alternatives that could surpass the risks associated with textured devices.

Conclusion: In the future, the creation of a national patient registry and proper recognition of BIA-ALCL by plastic surgeons could be useful tools to clarify the impact of the disease nationally and to mitigate potential risk factors.

Keywords: Breast Implants/adverse effects; Lymphoma, Large-Cell, Anaplastic/epidemiology; Lymphoma, Large-Cell, Anaplastic/etiology; Portugal

RESUMO

Introdução: O linfoma anaplásico de grandes células associado a implantes mamários (BIA-ALCL) é uma neoplasia rara de células T predominantemente associada ao uso de próteses texturizadas. Recentemente, vários países procuraram clarificar o seu perfil epidemiológico. Este estudo pretende estimar o número de casos de BIA-ALCL em Portugal e descrever o padrão de utilização de próteses mamárias a nível nacional.

Material e Métodos: Este é um estudo transversal realizado em 57 serviços de saúde - 29 hospitais públicos e 28 instituições privadas. A cada departamento de Cirurgia Plástica, Reconstrutiva e Estética foi solicitada informação sobre os principais fabricantes e respetiva textura dos implantes mamários utilizados, bem como número de casos registados de BIA-ALCL.

Resultados: Na nossa amostra, a taxa de resposta foi 58%. Considerando o universo de respostas obtidas, a maioria dos hospitais referiu usar implantes mamários texturizados da Mentor (45,45%), Allergan (42,42%) e Polytech (39,39%). Apenas uma instituição privada mencionou utilizar implantes lisos da Mentor e Motiva. Vários hospitais reportaram a ocorrência de seromas tardios. Contudo, apenas um caso de BIA-ALCL se veio a confirmar após investigação imunohistoquímica e histológica adequada.

Discussão: O BIA-ALCL poderá determinar uma alteração do paradigma de seleção do tipo de implante mamário, onde alternativas como os implantes lisos e tecido autólogo poderão superar os riscos inerentes aos dispositivos texturizados.

Conclusão: De futuro, a criação de um registo nacional de doentes e reconhecimento do BIA-ALCL pelos cirurgiões plásticos poderão ser importantes ferramentas para clarificar o seu impacto no território nacional e mitigar potenciais fatores de risco.

Palavras-chave: Implantes Mamários/efeitos adversos; Linfoma Anaplásico Cutâneo Primário de Células Grandes/epidemiologia; Linfoma Anaplásico Cutâneo Primário de Células Grandes/etiologia; Portugal

INTRODUCTION

Recent estimates report that approximately 10 million women worldwide have breast implants[1] and that the use of these medical devices tends to rise each year, both in the cosmetic and reconstructive fields.[2] Nevertheless, several concerns have been raised regarding their safety. In 1997, the first case that suggested a possible association between breast implants and a rare T-cell neoplasm - anaplastic large cell lymphoma emerged.[3] Since then, the number of cases increased substantially and, in 2016, the World Health Organization recognized breast implant-associated

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anaplastic large cell lymphoma (BIA-ALCL) as a novel and particular type of lymphoma.[1] Currently, 626 cases of BIA-ALCL[4] and 24 deaths have been reported around the world.[5]

BIA-ALCL is a rare T-cell neoplasm that arises in the fluid or capsule surrounding the implant. All reported cases of BIA-ALCL are CD30-positive and ALK-negative, which reinforces its unique antigenic profile.[6] Most patients present with a delayed seroma while less common manifestations include a mass, regional lymphadenopathy, skin lesions or B symptoms (such as weight loss, fever and night sweats).[7] In the presence of these symptoms, patients should undergo an ultrasound, which is recommended as the first-line imaging test.[3] Ultrasound is considered to have similar or better sensitivity and specificity in the detection of an effusion or a mass compared to magnetic resonance imaging and computerized tomography.[8] The establishment of the diagnosis requires CD30 positive staining in immunohistochemistry, cytological examination showing large anaplastic cells and flow cytometry showing clonal expansion.[7] Complete capsulectomy and implant removal is the standard of treatment for localized disease,[9] whereas chemotherapy and/or antibody-drug conjugates (such as brentuximab vedotin) are recommended in more advanced stages.[10] In most cases, BIA-ALCL has an indolent course with excellent prognosis, although fatalities have also been reported.

The device texture seems to have a role in the pathogenesis of the disease. Scientific evidence suggests that BIA-ALCL is predominantly associated with the use of textured rather than smooth-coated implants[1] and the risk seems to be higher for more robustly textured or polyurethane-covered implants.[4] As of July 2019, and considering both US and global BIA-ALCL cases reported to the US Food and Drug Administration (FDA), 67% were associated with textured implants, 5% were related to smooth-coated implants and in 28% of the cases the texture was not specified.[11] Nevertheless, the FDA states that in the cases associated with smooth implants, there was prior exposure to a textured implant or a history of prior implants was unknown.[11] Manufacturers estimate that 70% to 80% of implants sold in Europe are textured, while 70% to 80% of those sold in North America are smooth.[12] This preference towards textured implants in Europe might be explained by their supposed lower rates of capsular contracture and implant rotation in comparison with smooth breast implants.[1] Furthermore, patients who require reconstructive surgery often look for a natural shape and projection of the breast, which led to the expansion of anatomic implants.[13] These devices are always textured in order to improve adherence to the surrounding capsule and prevent device rotation.[6] Moreover, tissue expanders used in two-stage breast reconstruction have textured surfaces.[6] Prolonged time of exposure to the implant seems to be a common denominator in cases of BIA-ALCL, which occurs on average nine years after implantation.[14]

Several theories have been proposed to explain the etiology of BIA-ALCL. Some authors believe that the release of silicone degradation products is capable of activating a local immune response via T helper 1/ T helper 17 cells.[15] However, the most accepted hypothesis is that textured implants, with their greater surface areas and enhanced bacterial adhesion, lead to higher rates of biofilm formation and subsequent lymphocytic activation.[9] Hu *et al* documented a significantly greater proportion of *Ralstonia* spp., a gram-negative bacteria, in BIA-ALCL specimens compared with non-tumor capsule specimens.[16] Besides, Collett *et al* reported that high-textured high-surface area implants (grade four surface) have greater potential to harbour microorganisms and, thus, carry the highest risk of BIA-ALCL.[3]

Since breast-implants are foreign bodies, concerns have been raised regarding the possibility of their implication in 'foreign-body carcinogenesis' or as an immune trigger in the ontogenesis of other cancers, such as sarcomas, hematopoietic malignancies, cervical, vulvar and lung cancers.[17] Nevertheless, a systematic review found no evidence that breast implants alter the risk of non-breast malignancies.[17] On the other hand, several implantable devices share similarities with breast prosthesis, raising questions regarding the possibility of triggering the same neoplastic response.[18] However, there was only one confirmed case of anaplastic large cell lymphoma (ALCL) in association with an orthopedic device and most implantable devices seem to be predominantly associated with B-cell lymphomas rather than with ALCL.[18]

Due to this recent scientific information, health authorities from several countries took measures to minimize the risk of BIA-ALCL. In April 2019, the French medicines agency (ANSM) suspended the distribution and demanded the withdrawal of numerous macrotextured shell and polyurethane breast implants.[19] Several manufacturers were affected by this decision, including Allergan, Polytech, and Eurosilicone. Furthermore, ANSM is presently advising surgeons to preferentially use smooth surface implants in the cosmetic and reconstructive fields. In May 2019, Canada also suspended the licenses of macrotextured breast implants.[20]

The estimation of prevalence and incidence of BIA-ALCL faces many difficulties both in the determination of the number of women with implants and the number of cases of BIA-ALCL. Poor registries, underreporting, fear of litigation, lack of awareness and cosmetic tourism are some of the obstacles that prevent a reliable assessment.[3] The highest reported incidence is in Australia and New Zealand (1/2832), whereas the lowest relative incidence is in the Eurozone, China and Brazil.[3] Until recently, Scandinavian countries had no reported cases.[3] Portugal is one of the European countries where the number of cases of BIA-ALCL remains unknown.[1]

The present study aims to estimate the number of cases of BIA-ALCL in Portugal and to describe the main brand manufacturers and texture of breast implants used at a national level.

MATERIAL AND METHODS

This is a national multicenter cross-sectional study.

Fifty-seven healthcare organizations were included in our study, of which 29 were public hospitals and 28 were private institutions. All public institutions with a department of Plastic, Reconstructive and Aesthetic Surgery in Portugal were included. We included private institutions in order to accurately represent cosmetic surgery, an important sub-field of Plastic Surgery and one of the most significant applications of breast implants. The institutions were contacted via institutional e-mail addresses and/or telephone numbers requesting a response from the Plastic Surgery Department. When available, the contact was established directly with the department. Each department was asked to provide information concerning the main manufacturer(s) and the respective device texture of the breast implants currently used at the institution (Fig. 1). Values were reported with 95% confidence intervals. For specific types of brand and texture of breast prosthesis, namely Mentor Smooth, Silimed Polyurethane, Silimed Textured, and Motiva Smooth, the confidence interval was not calculated since the number of cases was too small to ensure reliable intervals.

Additionally, we requested each department to report the number of registered cases of BIA-ALCL (Fig.1). We included all confirmed cases of BIA-ALCL ever registered in each healthcare institution after adequate diagnostic approach (CD30 positive staining in immunohistochemistry, cytological examination showing large anaplastic cells and flow cytometry showing clonal expansion), both in the context of reconstructive and aesthetic procedures. There were no restrictions regarding the sex or age of the patient.

Late-onset seromas that did not match diagnostic criteria were not considered. Incomplete responses from the departments with missing data were not included and were classified as 'non-responses'.

If a case was confirmed, surgeons were requested to provide relevant clinical data, namely the age of the patient, brand and texture of the breast prosthesis involved, number of years after implantation, treatment approach and the current status of the patient. Surveys were implemented between the 3rd March 2019 and the 14thJanuary 2020. All answers received in this period were included in the statistical analysis. The present study was approved by the Ethics Committee of Centro Hospitalar de São João.

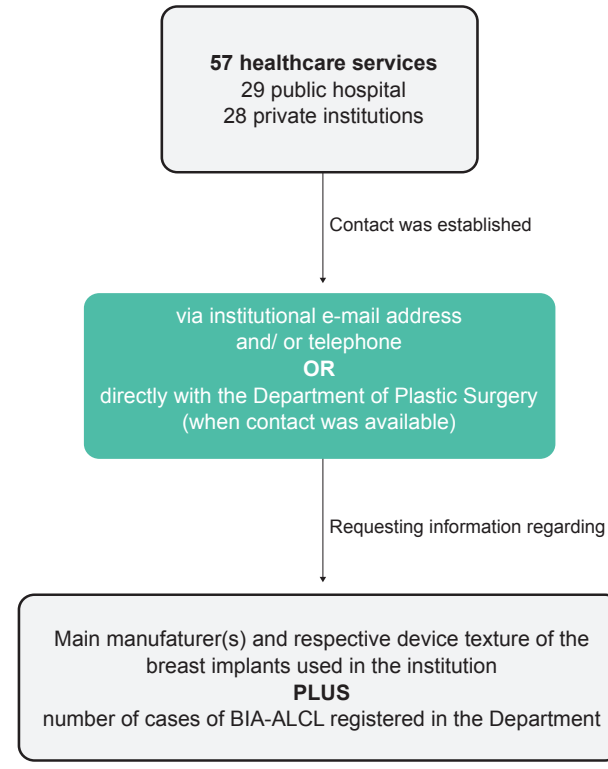

Figure 1 – Methods

RESULTS

In our universe of 57 hospitals, we obtained a total of 33 responses, which corresponds to a response rate of 58%. Considering our universe of responses, we observed that most hospitals reported the use of textured breast implants from Mentor [45.45% (29.84 - 62.02)], Allergan [42.42% (27.22 - 59.21)] and Polytech [39.39% (24.65-56.35)] (Fig.

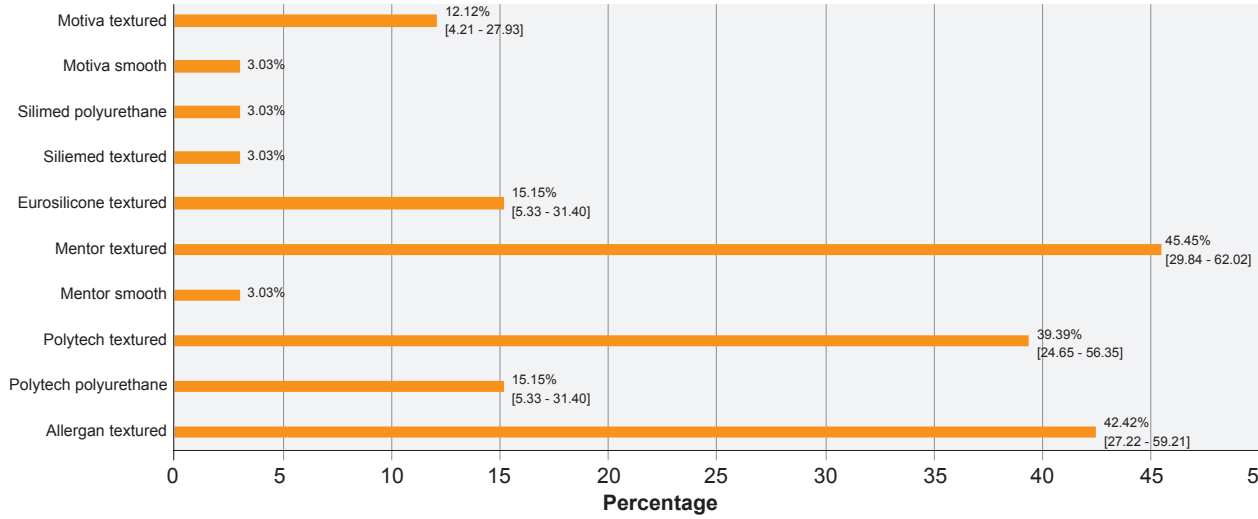

Figure 2 – Pattern of use of breast implants in the sample by texture and manufacturer

2). Polyurethane implants from Polytech and textured implants from Eurosilicone were reported to be used in a significant number of the hospitals that responded, each representing [15.15% (5.33 - 31.40)] (Fig. 2). Only one private institution reported using smooth-coated implants from Mentor and Motiva. Recently, in light of emerging scientific information, Centro Hospitalar de São João replaced the use of textured implants from Allergan with smooth implants from the same brand manufacturer.

Despite several hospitals reported having suspicious cases, there was only one confirmed case of BIA-ALCL after investigation with adequate immunohistochemistry and histological procedures (Table 1). Instituto Português de Oncologia (IPO) Porto, Centro Hospitalar de São João, Centro Hospitalar de Lisboa Central, and several others admitted having late-onset seromas that did not match the criteria to be classified as a BIA-ALCL after a proper diagnostic approach.

Table 1 – Healthcare institutions contacted (n = 57) and number of reported cases of BIA-ALCL

Districts	Hospitals/ Healthcare Centers contacted	Answers	BIA-ALCL cases
Viana do Castelo	Unidade Local de Saúde do Alto Minho	Yes	0
	Clínica Uniplástica – V. N. Famalicão	Yes	0
	Clínica Art Corpus Braga	No	-
	Clínica Santa Tecla	No	-
Braga	Hospital da Senhora da Oliveira -Guimarães	Yes	0
	Casa de Saúde de São Lázaro	Yes	0
	Misericórdia de Vila Verde	Yes	0
	Hospital de Braga	Yes	0
Vila Real	Centro Hospitalar de Trás-os-Montes e Alto Douro	Yes	0
	Centro Hospitalar de São João	Yes	0
	Hospital da Prelada	No	-
	Centro Hospitalar V.N. Gaia/Espinho	Yes	0
	CUF Porto	Yes	0
	Hospital da Luz Porto	Yes	0
	Hospital Lusíadas Porto	No	-
	Trofa Saúde	Yes	0
	Hospital da Luz Póvoa de Varzim	No	-
	Clínica Artlaser Porto	Yes	0
	CCE Porto	Yes	0
Porto	IPO Porto	Yes	0
	Hospital da Lapa	Yes	0
	Hospital da Ordem da Trindade	No	-
	Hospital Stª Maria	No	-
	Clínica Luso Espanhola	No	-
	Misericórdia de Vila Conde	Yes	0
	Misericórdia de Lousada	Yes	0
	Hospital-Escola da Universidade Fernando Pessoa	Yes	0
	Centro Hospitalar Universitário do Porto	Yes	0
	Centro Hospitalar Tâmega e Sousa	Yes	0
	Unidade Local de Saúde de Matosinhos	Yes	0
Aveiro	Centro Hospitalar Entre Douro e Vouga	Yes	0
Viseu	Centro Hospitalar Tondela-Viseu	Yes	0
	CUF Viseu	Yes	0
Coimbra	Centro Hospitalar e Universitário de Coimbra	No	-
	CUF Coimbra	No	-
	Centro Cirúrgico de Coimbra	No	-
	IPO Coimbra	No	-
	Hospital da Luz Coimbra	No	-

Table continues next page

Districts	Hospitals/ Healthcare Centers contacted	Answers	BIA-ALCL cases
Lisboa	Centro Hospitalar Lisboa Central	Yes	0
	Centro Hospitalar Universitário Lisboa Norte	Yes	0
	CUF Descobertas	Yes	0
	Clínica Faccia	No	-
	Clínica Milénio	No	-
	Clínica Europa Lisboa	No	-
	IPO Lisboa	Yes	0
	Fundação Champalimaud	Yes	1
	Hospital Beatriz Ângelo- Loures	No	-
	Centro Hospitalar Lisboa Ocidental	No	-
	Hospital Prof. Dr. Fernando Fonseca	No	-
	Hospital Garcia de Horta	No	-
Setúbal	Centro Hospitalar Barreiro Montijo	No	-
	Centro Hospitalar de Setúbal	No	-
Santarém	Hospital Distrital de Santarém	Yes	0
Évora	Hospital do Espírito Santo de Évora	No	-
Faro	Hospital de Faro	No	-
Madeira	Hospital Central do Funchal	Yes	0
Açores	Hospital do Divino Espírito Santo	Yes	0
TOTAL		33	1

The only confirmed case of BIA-ALCL in our sample was described by Fundação Champalimaud. The patient had personal history of right breast carcinoma and high genetic risk. Both breasts were intervened as part of the treatment of the oncological disease and as a prophylaxis strategy considering the genetic background. The postmastectomy reconstruction involved the use of textured implants from Allergan. Since the oncological surgery, the patient presented with three late-onset seromas, but the cytological confirmation was only established at the third recurrence. In the most recent recurrence, the patient presented with a bilateral seroma eight years after implantation which had a positive CD30 and negative ALK staining in immunohistochemistry and matched other required criteria to be classified as a BIA-ALCL. Since the tumor was bilateral and confined to the capsule, the therapeutic approach consisted of total capsulectomy and implant removal in both breasts, with subsequent surveillance.

DISCUSSION

This study described the national pattern of use of breast implants and the number of cases of BIA-ALCL in Portugal. Despite its clear association with BIA-ALCL, most healthcare institutions included in our sample reported the use of textured breast implants. Only one private institution reported using smooth-coated implants. In recent years, the popularity of textured implants among plastic surgeons increased substantially due to their allegedly lower rates of capsular contracture and implant rotation. Nevertheless, the theoretical benefit of textured devices has been increasingly questioned. Contrasting with smooth implants, textured implants have been associated with late seromas, double capsules and more recently BIA-ALCL.[21] The rate of capsular contracture between smooth and textured devices remains controversial and the superiority of textured implants regarding this key point remains yet to be proven. Even though Namnoum *et al* observed lower capsular contracture rates with textured implants,[21] two meta-analyses from 2006 found no evidence of a reduction in capsular contracture rates using textured implants when they are placed subpectorally.[5] On the other hand, a study conducted by Sieber *et al* revealed that textured implants rotate in their pockets in 42% of cases,[5] which can compromise their supposed theoretical advantage in adherence. Thus, in light of the current scenario, the benefits of smooth implants might surpass the risks of textured devices.

In our study, we identified one confirmed case of BIA-ALCL in Portugal. Despite its rarity, BIA-ALCL has a tremendous impact not only as a symbol of the medical iatrogenic potential but also in healthcare policies and management. Therefore, the number of cases reported and attempts to estimate the prevalence and incidence of this disease is rising each year. Germany and Denmark have seven reported cases, whereas Poland identified three cases at a national level.[1] Wilkinson *et al* identified 55 cases of BIA-ALCL in Australia and New Zealand between 2007 and 2016.[22] The first report of the PROFILE (Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology) database recorded 186 distinct cases of BIA-ALCL in the USA between 2012 and 2018.[23] The estimated rates of BIA-ALCL (per implant placed) vary widely across different European regions, from 1/25 000 in

Ireland or 1/20 000 in Austria to 1/8928 in France, 1/4500 in Switzerland or even 1/2400 in the United Kingdom.[1] However, the accuracy of these estimates is questionable and is widely limited by poor registries, underreporting, fear of litigation and cosmetic tourism.[3]

While Australia and New Zealand have the highest reported incidence rate, BIA-ALCL appears to be an extremely rare event in Asians, Africans and Native American descendants.[3] These marked variations suggest that ethnicity and genetic factors may also be involved in the pathogenesis of the disease. Mutations in Janus kinase and STAT3 have been described in relation to BIA-ALCL cases, as well as activating mutations in the TP53 pathway.[9] Therefore, BIA-ALCL seems multifactorial in its origin, rather than established through a cause-effect linear relationship.

The present study has several limitations that could lead to an underestimation of the exact number of cases in Portugal. First, we only included healthcare institutions with a department of Plastic, Reconstructive and Aesthetic Surgery. This could be a relevant limitation since breast reconstructive surgery is a wide field that can involve various medical specialties such as General Surgery, Gynecology, Hematology or Pathology. Even though most patients that underwent reconstructive techniques involving breast implants are theoretically followed by plastic surgeons, we cannot ignore the potential existence of BIA-ALCL cases outside this department. The inclusion of Pathology departments, which normally have access to their own patient databases or of Hematology departments may be a crucial point in obtaining reliable estimates and should be considered in future studies that attempt to estimate the prevalence of this rare type of lymphoma. On the other hand, it would be interesting to analyze the total number of breast implants placed *per* institution in order to determine the frequency of this rare event. However, obtaining a reliable and accurate numerator (number of cases of BIA-ALCL in Portugal) is a critical step to properly assess the risk of BIA-ALCL in further studies. Furthermore, our sample included 28 private institutions, but the total number of private healthcare centers where breast cosmetic surgery is performed is markedly higher. Nevertheless, BIA-ALCL is a rare and novel entity and, thus, it is expectable that those cases are referred to specialized, large dimension and experienced centers, such as IPO. All specialized centers were included in this study, thus overcoming this limitation. BIA-ALCL usually develops on average nine years after implantation. In contrast with patients who underwent reconstructive surgery after breast cancer, cosmetic surgery patients seldom follow-up with their plastic surgeon for longer than one year post-surgery.[13] Hence, the absence of cases in some healthcare institutions can simply reflect an incomplete follow-up. Moreover, other medical specialties less aware of BIA-ALCL may delay its diagnosis or even misdiagnose it, when confronted with symptomatic patients in the emergency department.[13] The fear of litigation and the absence of a validated national registry are also potential variables that could contribute to underestimating our results.

Even though our study only identified one confirmed case of BIA-ALCL, several hospitals reported having late-onset seromas that did not match the required criteria to be classified as BIA-ALCL after pathological examination. Seromas that arise more than one year after implantation occur in approximately 0.1% - 0.2% of patients and it is estimated that BIA-ALCL occurs in 9% - 13% of such cases.[9] Some authors propose that BIA-ALCL may originate in a pre-existing lymphoproliferative disorder characterized by an indolent localized (*in situ*) disease that resolves in most cases with capsulectomy and implant removal.[24] The National Comprehensive Cancer Network (NCCN) recommends that symptomatic peri-prosthetic effusions that develop more than one year after implantation should be aspirated and screened for CD30 in immunohistochemistry and flow cytometry.[10] Nonetheless, as mentioned previously, BIA-ALCL can also present as a mass without a coexisting seroma, regional lymphadenopathy or skin lesions,[6] demanding a high index of suspicion.

BIA-ALCL is a rare disease which generally follows an indolent course. Most cases resolve with implant removal and complete capsulectomy. However, 15% of cases correspond to more advanced stages of the disease and require treatment with chemotherapy, antibody-drug conjugates (such as brentuximab vedotin) or both.[20] These modalities of treatment carry high long-term morbidity due to their systemic toxicity. For women who undergo breast reconstructive surgery after malignancy or as a prophylactic measure, the risk regarding BIA-ALCL, even though low, might be unacceptable. Currently, the prophylactic removal of textured prosthesis is not recommended as BIA-ALCL remains an extremely rare and mostly curable disease.[1]

After implant removal and complete capsulectomy in the context of BIA-ALCL, the reconstruction of the breast should be executed with autologous tissue or smooth implants.[21] Furthermore, the NCCN claims that surgeons might consider the removal of the contralateral implant since 4.6% of cases were identified as having an incidental lymphoma in the contralateral breast.[10]

Based on the hypotheses that a subclinical infection might be in the origin of BIA-ALCL, the use of techniques that minimize the bacterial load at the time of surgery, specifically the 14-point plan, might reduce the occurrence of this disease. Adams et al designed a prospective study to test this possibility, following eight plastic surgeons that were asked to perform the 14 point-plan.[25] After the implementation of this technique in women with macrotextured breast implants, no cases of BIA-ALCL were reported, although the expected number according to previous Australian studies would be between eight and nine.[25]

The number of cases of BIA-ALCL has increased considerably in the last 10 years.[26] The increasing use of macrotextured implants, improved awareness and the time-lag required for the development of the disease are some of the factors that might contribute to this upward trend.[26] Nevertheless, it is difficult to establish a reliable determination due to the dispersion of data and single reports.

The adherence to registries and mandatory reporting are the most important vehicles towards adequate surveillance, tracking, and detailed epidemiological profiling.[3] Various countries have already created voluntary national registries concerning BIA-ALCL. In 2012, the American Society of Plastic Surgeons, The Plastic Surgery Foundation and FDA created PROFILE. This patient registry represented a systematic tool to collect and unify data concerning patients diagnosed with BIA-ALCL in the United States.[23] Similarly, the Netherlands has a mandatory registry since 2016.[27] Portugal should also create a national registry regarding BIA-ALCL in order to accurately clarify the epidemiology of the disease in our country.

Patients in the cosmetic field rarely follow-up with their plastic surgeon more than one year post-surgery. However, BIA-ALCL develops on average nine years after implantation. Extending the follow- up of these patients would probably carry a heavy burden on public healthcare systems for a largely curable and exceptionally rare disease. Future clinical practice should focus on informing women with breast implants about the alarming signs of the disease that should motivate the return to their plastic surgeon. In our opinion, all women should be fully informed regarding the type of implant they have and should perform regular self-breast exams. Moreover, other specialties should be educated and made aware about BIA-ALCL, allowing for its recognition both in the emergency department and primary care settings.

BIA-ALCL may represent a shift for surgeons regarding selection of implant type. Smooth implants or autologous tissue represent adequate alternatives for women who wish to undergo a cosmetic or reconstructive procedure. Women should be fully informed about the potential risks and advantages of textured implants and consent to the alternative that is more acceptable for them. Furthermore, manufacturers should offer new alternatives to implant design, materials and surface texture.[4]

CONCLUSION

Despite its rarity, BIA-ALCL remains a potentially fatal disease. The current use of textured implants should be reviewed and the potential harms concerning their application must be weighted in medical decisions.

This study was the first to attempt to bring some light to the epidemiological pattern of BIA-ALCL in Portugal. In the future, prospective, large-dimension national studies and the creation of national patient registries could bring additional and relevant information about the impact of this disease in the national playground.

AUTHORS CONTRIBUTION

AC: Data acquisition, draft of the manuscript.
RH: Data acquisition and critical review.
DB: Data acquisition.

DISCLAIMER

This dissertation was presented as a summary in oral communication in “XLIX Reunião Anual da Sociedade Portuguesa de Cirurgia Plástica, Reconstrutiva e Estética” (Nov 7-Nov 9 2019 in Fundação Cupertino de Miranda, Porto, Portugal) and was never published in a scientific journal.

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PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients’ data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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