REVIEW WORK

Management of chronic seroma in patients with breast implants in relation to the diagnosis of anaplastic lymphoma of giant cells

Manejo del seroma crónico en pacientes con implantes de mama en relación con el diagnóstico de linfoma anaplásico de células gigantes

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Giant cell anaplastic lymphoma, BIA-ALCL, breast implants, chronic seroma, seroma, implant-associated lymphoma.

Palabras clave:
Linfoma anaplásico de células gigantes, BIA-ALCL, implantes mamarios, seroma crónico, seroma, linfoma asociado con implantes.

ABSTRACT

In recent years, we have acquired more knowledge about a rare disease related to breast implants: the giant anaplastic lymphoma. Although there are few cases, and the incidence is variable, we want to mention what we have done in our country in this regard and the measures we suggest to handle a possible case. It is important to mention that not all cases of chronic seroma have been related to lymphoma. Therefore, we explain what should be done in a suspected case, how to handle a seroma when the diagnosis is negative for BIA-ALCL and recommend that implants should not be removed or changed in asymptomatic patients, at that time. Finally, as an annex to this article, the infographic on the subject made by the Safety Committee are added to guide plastic surgeons, health personnel and patients.

RESUMEN

En los últimos años hemos tenido mayor conocimiento de una enfermedad poco frecuente y relacionada con los implantes mamarios, se trata del linfoma anaplásico de células gigantes. Aunque son pocos los casos y la incidencia es variable, queremos mencionar lo que hemos hecho en nuestro país al respecto y las medidas que sugerimos para atender un posible caso. Es importante mencionar que no todos los casos de seroma crónico se han relacionado con linfoma, por lo que exponemos lo que se debe hacer ante un caso sospechoso, cómo manejar un seroma cuando el diagnóstico es negativo para BIA-ALCL (breast implant associated-anaplastic large cell lymphoma, por sus siglas en inglés) y recomendar que en este momento no hay indicación de retirar o cambiar implantes en pacientes asintomáticas. Al final —como anexo a este artículo— se agrega la infografía sobre el tema, hechas por el Comité de Seguridad para orientar a los cirujanos plásticos, personal de salud y pacientes.

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INTRODUCTION

The first records in the literature on anaplastic giant cell lymphoma are in the 1990s. In the journal of our specialty, the first case is reported in 1997:[1,2] since then, we have seen an increase in its incidence. Reports on this have increased in number and knowledge of this pathology has expanded.

In 2016 we reviewed the literature where we find 80 cases;[3] currently; we have more than 600 cases according to Global Task Force. This number will rise possibly when we have more knowledge. This pathology has caused a high impact on health authorities, medical societies, media, and patients. The information that is generated produced, is often controversial and not consistent. Although

the cases we have in our country are few, we should not downplay the disease. Given one case deserves our attention, we must strive to find the most effective and safest procedure in the aesthetics of the breasts.

The first report in our country was made in 2016 by Dr. Cesar Torres Rivero in the state of Querétaro.[4] We have found six confirmed cases, thereafter. The number will undoubtedly continue to grow as time goes by, as we have more knowledge about the disease and more surgeons are convinced of the importance of disease detection.

It is worth mentioning that in the Latin American region, we made a consensus at our Annual Congress in Cancun to know what was happening with this disease.[5] With this information, we performed a protocol for the detection of the disease and its management.

It is important to mention that not all countries report the same number of cases; the greater the number of implants placed, the greater the number of reported cases. In addition, there are other intrinsic factors of each country such as: demographic, genetic, cultural and environmental aspects. For example, in the United States, which is the main country where these types of procedures are practiced, there is a record of 200 cases. In Europe, not all countries report the same numbers. There is a greater number of reports in France with 55 cases; in Germany or Central European countries such as Romania, the number is smaller.[6] There are few reports in black or Asian patients. In Latin America we have verbal knowledge of several cases in different countries; however, this has not been written/published to have more detail of what is happening in our region.

Non-Hodgkin lymphoma is not exclusive to breast implants. There are reports of lymphoma in other prostheses, such as: hip, knee, dental, gluteal, endovascular and even in a bariatric surgery band.[7-12] Although the demographic characteristics are different; in most cases, lymphoma manifests itself as a local problem with a mass or redness around the prosthesis. In the case of the breast or gluteus, the disease occurs in most cases, as a chronic seroma. Chronic seroma is defined for anyone who presents a period of time greater than one year after the placement of the prosthesis.

Next we will mention the most relevant points of lymphoma related to BIA-ALCL breast implants oriented towards early detection and treatment.

Clinical presentation of the BIA-ALCL

Lymphoma associated with breast implants is called anaplastic giant cell lymphoma BIA-ALCL. Unlike the one presented in a breast without a prosthesis, the behavior is different. Although in the BIA-ALCL generally, when removing the capsule and the implant; the prognosis is favorable. Most cases with BIA-ALCL present with unilateral breast growth caused by a chronic seroma. This pathology occurs ten years, on average, after the placement of the prosthesis in the body, with a range of 1 to 40 years as reported in the different series.[3,4] Less frequently the growth is bilateral. In a smaller number of cases, there are adenopathy and/or a palpable mass and some cases are asymptomatic. It is recommended that patients with breast implants are checked once a year, regardless of the routine follow-up that is done in all women for the detection of breast cancer.

There is a classification of TNM for BIA-ALCL, which is presented in the following *Tables 1 and 2*. The important thing is to make an early diagnosis, especially when the disease is located in the capsule or seroma; the treatment is less aggressive and the prognosis is better. When the disease

Table 1: TNM LACG associated with breast implants.

TNM	
T1	Seroma or inside the capsule
T2	Capsule early infiltration
T3	Cellular aggregates or infiltration in all capsule layers
T4	Extension beyond the capsule
N0	No ganglion invasion
N1	A regional ganglion
N2	Multiple nodes
M0	No distant metastasis
M1	Extension to other organs

Table 2: Stage according to the TNM.

Stadium	
IA	T1N0M0
IB	T2N0M0
IC	T3N0M0
IIA	T4N0M0
IIB	T1-3N1M0
III	T4N1M0
IV	M1

already affects the nodes or there is distant disease, more aggressive management by a multidisciplinary team is required and the prognosis is bleak.[5] In all cases of patients with breast implants and who have an increase and/or inflammation of one of their breasts, it is important to study the seroma and the capsule; when changing implants under routine conditions, the capsule and fluid study should also be performed. Sending specimens to specialized laboratories has allowed us to detect 6 cases of lymphoma and other pathologies such as mycobacterial infections, lymphoproliferative reaction to silicone and synovial metaplasia. To confirm the diagnosis in the case of seroma, in addition to ultrasound and magnetic resonance imaging studies, it is important to perform a guided ultrasound puncture, to facilitate puncture / aspiration and avoid implant damage. The pathologist should be advised to study the sample without spending much time. If the sample is not checked on the same day, a 50 to 50 percent ratio should be set with 96% alcohol for later study.[5]

If in spite of this the sample is negative and the problem persists, the capsule must be removed and sent to study. The capsule can be sent in formalin. The pathologist should be notified about the possibility of lymphoma as more cuts and immunomarkers are required to identify the pathology. It is recommended to discuss with the patient the possibility of removing the implants. If something is placed again, use a smooth texture and if the diagnosis is confirmed, the implants must be removed.[5]

In suspicious cases diagnostic studies should be guided by a multidisciplinary team; the hematologist is a key piece.[4,5]

Surgical treatment is aimed at bilateral capsulectomy with removal of breast implants; the complete resection of the capsule is very important, it is advisable to extract it in one piece and without ruptures; not all capsules are easy to remove, especially when the capsule is thick, resection becomes difficult; If there is a rupture and leakage of seroma fluid in the surgical bed, the surgical procedure should be continued.[4,5] It is important to inform the patient about the possibility of making a larger wound than the original wound when the implant was made.

It is not recommended under any circumstances as long as the evidence does not prove otherwise to remove or change breast implants from one texture to another in asymptomatic patients; the change for another implant with a different texture does not make the procedure safer and with less risk. In addition, doing so is adding more aggression. There are few reported cases of BIA-ALCL with smooth implants; in most of these cases they had a previous textured implant. If the simple change of implants is done, it is important that the surgeon and the patient understand the importance of studying the capsule.

Seroma is defined as liquid accumulation without fibrinogen or other clotting factor that can be separated from coagulated blood. The seroma differs from the plasma in that the latter contains uncoagulated blood fluid in which blood cells are suspended, also presenting coagulation factors.[13-15] Upon examination of the liquid, seroma has acellularity and small amounts of proteins less than 2.0 g/dL, compared to an exudate in which the amount is greater than 2 g/dL.[16]

Tebbets defines seroma as that accumulation of liquid corroborated by some imaging method with a volume greater than 20 mL.[17,18] Failure to comply with these characteristics will be defined as «periprosthetic liquid».[19-21] Regarding temporality, seroma can be classified as:

- Seroma early: < 6 months.
- Intermediate seroma: 6 months-1 year.
- Late or chronic seroma: > 1 year.[22]

In the literature an incidence between 0.88 and 1.84% is reported having different theories regarding the pathophysiology among which they stand out:[22,23]

1. Infection
2. Hematoma
3. Trauma
4. Lymphoproliferative diseases
5. Idiopathic
6. Synovial metaplasia
7. Infectious

Infectious: Gram + bacteria have been found colonizing the pocket, secondary to their contamination at the time of placement.[24,25]

Hematoma: The presence of an undrained hematoma causes chronic irritation, which can manifest itself with the appearance of seroma.

Trauma: A trauma can evolve in a bruise or only cause an inflammatory process that will evolve into seroma formation.[26-28]

Synovial metaplasia: Caused by mechanical shearing between the implant and the capsule which causes a chronic inflammatory state with the resulting development of seroma.[29,30]

A higher incidence of seroma has been found in patients with risk factors such as obesity, history of radiation, diabetes mellitus, and use of dermal matrix.[31-33]

In breast reconstruction it must be managed with another section, since associated factors of these patients have been found, such as hypovascular state of the tissues, increased dead space, biofilm contamination, foreign bodies, and lymphatic disruption contributing to the development of seroma, infection and prosthetic loss.[34]

Once there is clinical suspicion an ultrasound should be performed and if possible a guided puncture with culture. The chronic seroma should be sent to an immunohistochemical study to assess the possibility of BIA-ALCL; the aspiration should be performed until obtaining 20 to 100 mL of liquid. In addition to cytochemical and cytological it is important to perform histopathological typing of it intentionally seeking the following:[5]

- Perform culture (intentional search for mycobacteria).
- Cell count and cytology to discard data suggestive of ALCL.
  - CD30 +
  - ALK -
  - Expression of cytokeratin
  - Translocation t[5]

Once the existence of BIA-ALCL is ruled out, its management will continue as a chronic seroma not associated with ALCL.[5] There are several risk factors associated with seroma;[19,20] to prevent it, pre and intraoperative general care has been recommended to avoid contamination and biofilm, such as *(Table 3)*:

Table 3: Measures to reduce seroma in patients who place breast prosthesis.

Use of intravenous antibiotic prophylaxis in anesthetic induction	Perform pocket irrigation with triple antibiotic solution or Betadine® solution
Avoid periareolar incisions when galactorrhea occurs	Use of introducer pocket
Use of nipple protectors to prevent bacterial spread in the pocket	Minimize implant exposure time
Perform atraumatic dissection to minimize devascularization	Change of surgical gloves prior to implant management as well as clean instruments
Careful hemostasis	Avoid use of drains because they are potential bacteria
Avoid dissection of breast parenchyma	Use of closing by planes
Dual flat pocket use	Antibiotic prophylaxis to cover subsequent procedures involving skin or mucosa

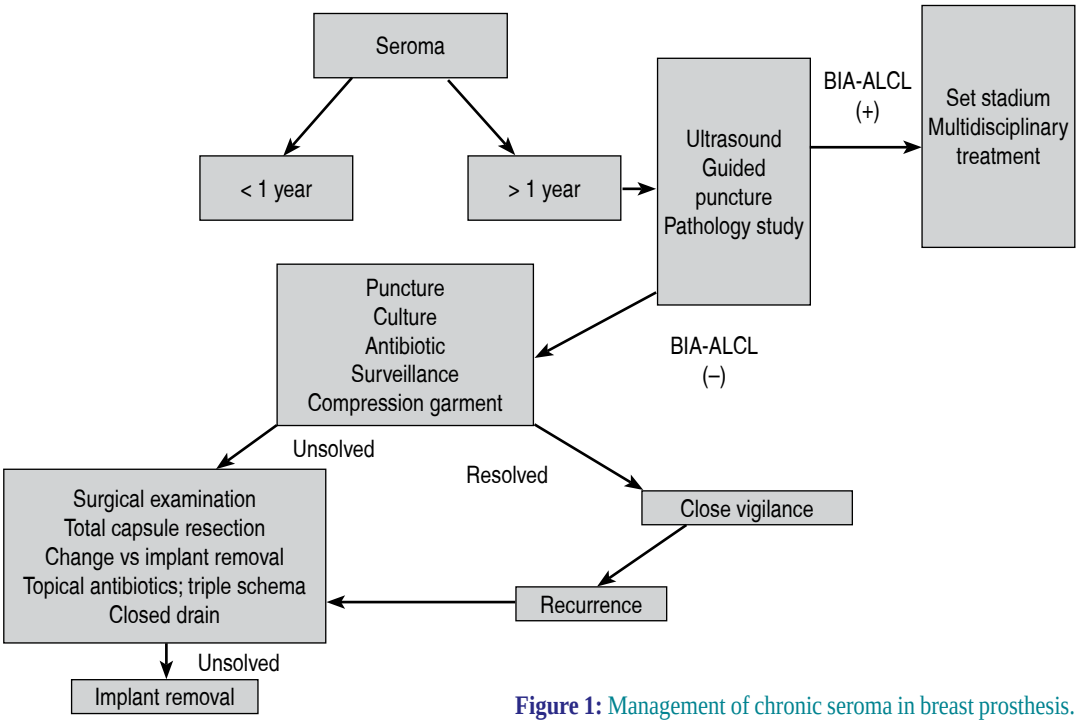

Figure 1: Management of chronic seroma in breast prosthesis.

- Use of prophylactic intravenous antibiotic at the time of induction.
- Avoid periareolar incisions.
- Use of nipple protectors.
- Atraumatic dissection to minimize devascularization.
- Careful hemostasis.
- Use of dual flat pockets.
- Pocket irrigation with triple antibiotic or 50% betadine solution.
- Use of plastic introducer.
- Minimize implant exposure time.
- Change of gloves without talcum powder and use of new toilet.
- Avoid drains.
- Perform closure by plans.
- Use of antibiotic prophylaxis in subsequent procedures that affect skin or mucosa.
- Close large pockets in cases of breast reconstruction.
- Avoid intense physical activity postoperatively for 8 to 12 weeks.

Once the seroma is established, the post-surgical evolution time must be taken into account; in case of being less than 1 year old the therapeutic protocol is to perform evacuative puncture, culture taking with antibiogram, administer antibiotic therapy according to the result, perform close monitoring of the patient and place compressive thoracic devices; if there is no resolution, it is necessary to perform surgical exploration, to perform total capsulectomy, transoperative evaluation of the implant removal versus the exchange of the same for some of smooth surface, to perform irrigation of the breast pocket with triple antibiotic and placement of drains, in case to continue without resolution of the seroma it will be necessary to remove the definitive implant.

In case of presenting a resolution of the condition but within a surveillance period of a subsequent year it presents a recurrence, it is necessary to perform the surgical exploration with all the protocol already mentioned above.

In case of being ALCL (-) it is necessary to carry out similar management to a seroma of less than one post-surgical year and continue the flow chart according to its results and evolution. The chronic seroma management algorithm is summarized in *Figure 1*.

Also as an annex to this article the infographic on the subject made by the Safety Committee

to guide plastic surgeons, health personnel and patients are added.

CONCLUSION

Anaplastic giant cell lymphoma associated with BIA-ALCL breast implants is a new pathology. We will have more information when raising awareness among surgeons and patients about the importance of studying the periprosthetic fluid of the capsules that cover the implants. For now, the implant should not be changed in an asymptomatic patient. In cases of routine implant change; the liquid and capsules should be sent for laboratory and pathology studies to rule out lymphoma.

The chronic seroma puncture will be guided by ultrasound to facilitate puncture / aspiration and to prevent rupture of the implant.

Notify the pathologist in case of having a patient to whom a chronic seroma will be punctured. If for some reason the study cannot be done on the same day as the puncture, it is advisable to use 96% alcohol a 1 to 1 ratio, this is 50% of the sample and 50% of alcohol to fix the sample.

Inform the patient about the risk of lymphoma and that it is recorded in the informed consent.

With the current information, we can mention that in Mexico, the incidence of BIA-ALCL is very low (0.000002%; 2 cases: 1 million). Although the numbers are different in other parts of the world, it is necessary to continue monitoring in our patients once a year in order to have more information about this disease.

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SECURITY RECOMMENDATIONS

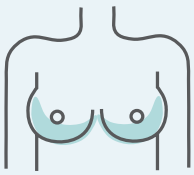
Breast-implant associated anaplastic large cell lymphoma. (BIA-ALCL)

CIRUGÍA PLÁSTICA SEGURA
AMCPER
COMITÉ DE SEGURIDAD

The number of cases has been increasing. Etiology is unknown, but possibly related to:

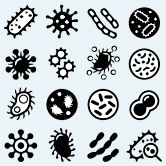
Possible causes:

1. Chronic inflammation



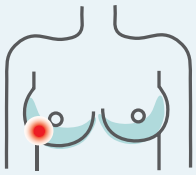
2. Genetics

3. Biofilm ratio



How does it appear?

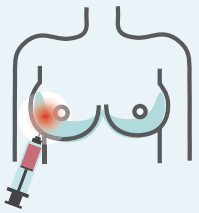
It appears clinically as a late seroma after breast implants. In addition, the following can be found: breast asymmetry, tumor mass around implant, lymphadenopathies, breast inflammation, pain and contracture.



How to proceed in a suspicious case?

- Careful physical examination; look for inflammation, seroma, tumor masses, adenopathies
- Ultrasound and magnetic resonance; look for seroma, tumor masses, lymphadenopathy
- Seroma extraction by puncture and studies of: cytochemicals, cultures, pathology
- Implant removal, total capsule resection with immunomarkers

What to do if we detect a seroma?



- Identify the seroma site; ultrasound or magnetic resonance
- Patient sitting
- 2 mm wound: Insert blunt tip cannula and discharge with the electrocautery to puncture the capsule
- Extraction of the greatest amount of seroma
- Keep the liquid refrigerated and immediately send it to the pathology laboratory

Results

Negative

↓

Seroma persists

↓

Implant removal + Capsulectomy

↓

\- Assess change of implants and position plane

Positive

↓

Implant removal + Capsulectomy

↓

\+ Assessment by multidisciplinary team:
Oncologist
Hematologist
Surgical oncologist
Radiation oncologist

What are the studies that I must request?

Clinical laboratory:
- Cytochemical study
- Usual culture
- Culture for mycobacteria

Pathology Laboratory:
- Pathology study
- Immunomarkers
- Mycobacterial infection detection

If you have a case like this, share it with us!

Together we can have better results detecting and handling this type of pathology.