



## Seroma, an alert of pathologies related to breast implants. Evidence based medicine

### Seroma: una alerta de patologías relacionadas a implantes mamarios. Medicina basada en evidencia

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#### Keywords:

Periprosthetic fluid, seroma, implant complications, lymphoma, breast pathologies, breast implants, breast prostheses.

#### Palabras clave:

Líquido periprotésico, seroma, complicaciones implantes, linfoma, patologías mamarias, implantes mamarios, prótesis mamarias.

#### ABSTRACT

There is an under recording of the incidence of seroma related to breast implants. There is no uniform criterion regarding the treatment and the amount of fluid accumulated, to consider it as a pathological manifestation; to answer the questions of a scenario that frequently presents itself to a plastic surgeon, such as a woman with breast implants of several years of evolution has increased volume in one breast accompanied by swelling (we performed a systematic review). All patients with breast implants should have an annual medical check-up by their surgeon. When there is an increase in volume, asymmetries, and inflammation, the presence of a seroma should be ruled out. To check this an ultrasound and / or an MRI is required. In the case a seroma is confirmed, a puncture-aspiration of the liquid should be performed and sent to a laboratory study for cytochemical analysis, cultures, pathology studies, immunomarkers and flow cytometry. There are several breast pathologies that can be detected by the study of the aspirated fluid; the most dreaded is BIA-ALCL lymphoma. Most seromas resolve satisfactorily with conservative treatment. In a group of patients, seroma is an alert sign of different pathologies related to breast implants. The study of the fluid accumulated around the prostheses is very useful to determine the etiology of seromas.

#### RESUMEN

Existe un subregistro de la incidencia del seroma relacionado a implantes mamarios. No hay un criterio uniforme con respecto al tratamiento y a la cantidad de líquido acumulada para considerarla como una manifestación patológica. Para dar respuesta a las preguntas de un escenario que frecuentemente se presenta a un cirujano plástico como el de una mujer con implantes mamarios de varios años que tiene aumento de volumen de una de sus mamas acompañado de inflamación, realizamos una revisión sistemática. Todas las pacientes con implantes mamarios deben tener una revisión anual médica por su cirujano. Cuando presenten aumento de volumen, asimetrías e inflamación, se deberá descartar la presencia de un seroma, cuya confirmación requiere de ultrasonido y/o resonancia magnética. En caso de confirmarse un seroma, se deberá realizar una punción-aspiración del líquido y enviarlo a estudio de laboratorio para análisis citoquímico, cultivos, estudios de patologías, inmunomarcadores y citometría de flujo. Son varias patologías mamarias que pueden detectarse por el estudio del líquido aspirado, la más temida es el linfoma BIA-ALCL. La mayoría de los seromas se resuelven satisfactoriamente con un tratamiento conservador. En un grupo de pacientes el seroma es una manifestación de alerta de diferentes patologías relacionadas a los implantes mamarios. El estudio del líquido acumulado alrededor de las prótesis es de mucha utilidad para determinar la etiología de los seromas.

#### METHODOLOGY

We carried out a systematic review of the following information sites, both in Spanish and in English in: PubMed, Embase, Cochrane, Medline, Fistera, Medigraphic, and Google Scholar. The key words in Spanish that

we used were: periprosthetic fluid, seroma, implants complications, BIA-ALCL lymphoma, breast pathologies, breast implants, and breast prostheses. In English: periprosthetic fluids, seroma, implant complications, lymphoma, breast pathologies, breast implants, and breast prostheses. To issue recommendations we use

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publications with a level of evidence I-IV. We performed the analysis and comparison of the updated publications.

### CLINICAL SCENARIO

The case of a 42-year-old woman with round textured breast implants, which were fitted in 8 years ago in the retro muscular plane by a periareolar access is studied. On examining this patient, we found: increased volume and turgidity of her right breast, pain and erythema. She maintained it was detected by her, while she was doing exercise: weightlifting, and mentioned she had a sore throat.

#### Team questions in suspicion of a seroma

- What other clinical data should I look for?
- What are the imaging studies that will be useful for diagnosis?
- When is liquid aspiration indicated? How do I do it?
- What laboratory and pathology studies should be performed on the aspirated fluid?
- What pathologies can be detected with the study of seroma?
- In case of there being a positive result of the culture, what is the recommendation to treat the patient?
- In case of recurrence of seroma, suggestive images of tumor masses or result of doubtful pathology, what should we do?
- If the pathology result is positive for BIA ALCL, how should one proceed where to send the patient?

### INTRODUCTION

The periprosthetic fluid collection between the implant and the capsule, called seroma can occur months or years after fitting a breast implant. Late seroma occurs after 1 year. It has an incidence of 0.8 to 1.8%.<sup>1</sup>

The most frequent cause of seroma is idiopathic, followed by hematoma caused by trauma, infection, implant rupture, synovial metaplasia, and inflammation with lymphoproliferative disorders, double capsule and lymphoma.<sup>1-13</sup> The occurrence of malignant neoplasms related to late seroma is extremely

rare and is usually represented by anaplastic large cell lymphoma associated with breast implants (BI-ALCL).<sup>2-14</sup>

The mechanisms related to the formation of seroma are:

- Dead spaces, which allow movement of the implants and the accumulation of liquids.
- Wide detachments with lymphatic disruption.
- Chronic inflammation produced by the foreign body effect of the implant and by the effect of biofilm.
- The hypoxia of the tissues around the implants, which activates the macrophages, responsible for the inflammatory process.
- Traumatic destruction of the lymphatic vessels produced by the use of the electrocautery used during surgery produces accumulation of fluid and inflammatory process. Some authors have considered this. They can detach the textured implant, causing micro trauma, with small hemorrhages and plasma fluid leakage. The affected area forms proliferative tissue of neo-formation. This mechanism plays an important role in the pathophysiology of breast seroma.<sup>1,3,5,11-30</sup>

#### When should I suspect that my patient has a seroma? How important is timely and adequate diagnosis?

In patients with seroma, a timely diagnosis and adequate treatment are necessary; a delay can cause extrusion of the implant, infection or the development of malignant pathologies.<sup>15-23</sup>

Patients with seroma have breast asymmetry, due to an increase in the volume of one of their breasts. It can also be accompanied by edema, turgidity, and palpation or not of the liquid around the implant and is often confused with capsular contractures and implant leakage. Implant rupture may be accompanied by seroma; some clinical data are the loss of consistency of one of the breasts and the presence of axillary adenomegaly. It is important to look for palpable evidence of tumor mass. Factors that increase the suspicion of lymphoproliferative processes of malignancy include the presence of weight loss, night sweats, fever of unknown origin

and axillary adenomegaly.<sup>1,3-14</sup> The infection of the implanted material, can have their origin in remote infections: such as, in the urinary tract and throat. Identifying the infection and providing adequate treatment, can avoid this complication.<sup>24-27</sup> Careful study will increase the identification of patients with this problem.<sup>15-23</sup>

#### *Recommendations<sup>1,27-31</sup>*

*(Level of evidence I-III; recommendation A-C)*

1. Obtain information about the surgery, such as: type and size of implants, placement plane, use of drainage and time of stay, immediate evolution, formation of hematomas or immediate seromas.
2. Look for a history of: trauma, abrupt physical exercises, or recent mastography, remote infectious foci, family or personal history of autoimmune and tumor inflammatory diseases.
3. Patients with breast implants must have an annual medical check up and an ultrasound every 2 years, to detect implant conditions, the presence of seromas or pathologies related to the implants.
4. In patients with breast implants that have an increase in volume of 1 or 2 breasts, a seroma should be suspected and the cause should be sought.
5. The identification of a seroma and its study can diagnose different pathologies related to implants, such as chronic infections, immune diseases, lymphoproliferative processes and malignant pathologies.
6. Although there is a small number of patients with late seroma, they may have a lymphoma. Due to the severity of this pathology and the indolent nature of the disease, in any patient with late seroma, lymphoma should be ruled out.
7. Axillary adenomegalies should be sought, they can be caused by extracapsular silicone leakage, chronic implant infections or malignant lymphoproliferative processes of the breast.
8. It is likely that each implant has a minimal or insufficient amount (5-10 mL) of surrounding fluid, and this incidental finding in an asymptomatic patient does not require a biopsy or further investigation.<sup>31</sup>

#### **What studies should I do to help me with the diagnosis?**

The imaging studies useful in the diagnosis of this pathology are ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI). A mastography needs to be valued against the potential risk of increasing damage; it can produce more injuries in the case of a hematoma, create a surgical emergency, or be painful and not tolerable by the patient. In addition, the sensitivity and specificity is low. Magnetic resonance imaging helps detect implant rupture, identify the quality of periprosthetic fluid, detect tumor masses and can be extended to the armpit for the study of nodes; it is considered elective, in these cases. New high resolution ultrasound methods are currently being evaluated in the hope that they will provide a more cost effective alternative to magnetic resonance imaging.<sup>5,16,27-35</sup> The Food and Drug Administration of the United States currently recommends that patients with breast implants undergo magnetic resonance imaging, from the third year after the operation and every 2 years after. However, there is no solid scientific basis for these recommendations.<sup>5,14,27-35</sup> If there is palpable or radiological evidence of a tumor mass, patients should be referred to an oncologist.<sup>4</sup>

#### *Recommendations<sup>2,4,5,16,27-50</sup>*

*(Level of evidence I-IV; recommendation A-D)*

1. Every patient with breast implants should have a periodic ultrasound (the FDA recommends every 2 years) or in the best case an MRI, to determine the conditions of the implants, breasts and axillary nodes.
2. In patients with inflammatory processes in their breasts, increased volume of 1 or 2 breasts or recent breast asymmetries, they should have a breast ultrasound or an MRI in search of a seroma, thickening of the capsule, tumors and implant conditions.<sup>36,48-50</sup>
3. Imaging studies help differential diagnosis in cases of seroma.
4. Consider performing a breast MRI with contrast if the initial ultrasound is inconclusive.<sup>36-38</sup>

5. Ultrasound is the initial study of image and choice to evaluate periprosthetic seroma, masses and lymphadenopathy.<sup>36-38</sup>

#### **What is the importance of puncture/ aspiration of periprosthetic fluid?**

The aspiration of the periprosthetic fluid; in addition to being with adjuvant in the treatment of seroma, will be very useful to determine its origin. The presence of cloudy fluid is suggestive of an infectious process or malignancy.<sup>23</sup> The cytological study of periprosthetic fluid has achieved the identification of several lymphomas.<sup>3-14</sup>

Several authors have made recommendations for the safe extraction of periprosthetic fluid. They mention that fine needle aspiration is the optimal method to collect the liquid sample; have recommended draining as much fluid as possible (minimum 50 mL); pointing out that fine needle aspiration, after previous drains, blurs the liquid and makes diagnosis difficult. The use of ultrasound is useful for directing the needle and can also help in the displacement and protection of the implant.<sup>36-41</sup>

Becker has proposed an effective technique for both fluid extraction, with minimal risk of damage or perforation of the implant. He uses a catheter protected with plastic material and discovered at the tip, inserts it through the skin and subcutaneous tissue at an oblique angle. The capsular access is achieved using the electrocautery in its cutting mode, which allows the catheter tip to be advanced, without the risk of puncturing the implant because silicone is an insulator that does not conduct electricity. Once in the periprosthetic space, the fluid is aspirated with a syringe.<sup>15</sup>

#### *Recommendations<sup>3-15,23,36-41</sup>*

*(Level of evidence I-IV; recommendation A-D)*

1. The aspiration of the periprosthetic fluid should be performed by puncture or by open surgery and laboratory and pathology studies, to determine the origin of the seroma.

#### **What clinical laboratory and pathology studies should I perform on the aspirated fluid?**

Laboratory studies have been recommended as: cytochemical, cultures including Gram

negative and mycobacteria; PCR for mycobacteria. The identification of an infection and the responsible germ will allow specific treatment.<sup>42-48</sup>

Periprosthetic fluid aspirate should be evaluated for the presence of a lymphoproliferative disorder, including anaplastic large T-cell lymphoma or breast adenocarcinoma.<sup>22,31</sup> It has been recommended to send a sample of the liquid to the pathology laboratory for the histochemical study, which includes immunomarkers, mainly CD30. To establish the diagnosis and exclude other malignancies, additional biomarkers are required: CD2, CD3, CD4, CD5, CD7, CD8, CD45, and anaplastic kinase lymphoma expression (ALK). Santanelli di Pompeo et al, consider that the most important studies in the study of seromas are ultrasound and cytological study.<sup>14,34-41</sup>

Flow cytometry (FC) uses the immunofluorescence of cells; it is a fast, sensitive and affordable technique, ideal for the detection of lymphocytes, lymphoproliferative processes and rare cells. This resource ensures a high recovery of the cells and requires a small amount of liquid for analysis; It is highly recommended for the study of BIA-ALCL.<sup>48-50</sup>

#### *Recommendations<sup>14,34-50</sup>*

*(Level of evidence I-IV; recommendation A-D)*

1. The material obtained from the periprosthetic fluid should be studied to rule out inflammatory, immune, infectious or tumor processes.
2. Avoid traumatic and repeated shots, which can cause difficulty in identifying tumor processes.
3. The use of a blunt tip cannula protected with plastic and the use of an electrocautery can be useful for taking the sample.
4. Cytochemical study should be requested; this will help to classify seroma.
5. The cultures should be the usual ones for Gram positive and negative; in addition, they should include culture for mycobacteria.
6. Request PCR for mycobacteria, which is a test that produces results in a shorter time.
7. Send a smear in a foil and liquid to pathology. The liquid obtained should be

- kept refrigerated, at around 5 degrees, and sent immediately to the pathology laboratory.
8. If the shipment to the pathology laboratory cannot be sent immediately, add 1: 1 alcohol to the aspirated liquid.
  9. The CD30 immunohistochemistry is a fundamental part of the diagnostic tests for BIA-ALCL, but it is not in itself pathognomonic of the disease, because of the CD30 expression. It is nonspecific and can be expressed in benign inflammatory processes.<sup>35</sup>
  10. Scarce CD30 lymphocytes with normal morphology are considered a normal finding and do not require further investigation.<sup>35</sup>
  11. The BIA-ALCL is always ALK negative. However, a finding of a negative ALK alone does not confirm a diagnosis of lymphomas.<sup>35</sup>
  12. When the resource is available to develop a flow cytometry, it should be carried out, since it is very valuable for the diagnosis of lymphoma.<sup>36,48</sup>

#### **What should I do in case positive cultures are found?**

Infection is one of the most frequent causes of seroma. Before starting antimicrobial therapy, periprosthetic fluid should be aspirated, for cytochemical study and for cultures. If there is a high suspicion of infection, antimicrobial therapy should be initiated after aspiration, with a smear orientation towards Gram positive or negative. In non-severe cases, wait until culture results are available.<sup>23</sup>

Seroma can affect only one breast or both. Spear, et al recommend the aspiration of the liquid and the application of antibiotics. With this strategy, most of the cases are solved. Other authors prefer implant removal, fluid study, capsule biopsy and immediate placement of smooth round implants. With this strategy, they achieve success for treated patients.<sup>5,12,15</sup>

#### **Recommendation<sup>12-15,23</sup> (Level of evidence IV; recommendation D)**

1. Identify infectious foci in throat, skin and the urinary tract. Take samples for cultures to give specific antimicrobial treatment.
2. Draining of the liquid and the application of antimicrobials help to solve the majority of

- cases. In these patients, surveillance should continue for several years.
3. In severe cases of infection, the implant should be removed, performing a total capsulectomy and wait up to 1 year before attempting to place a new implant.
  4. The extrusion of the implant can occur if the seroma is not resolved and also, when an implant change is made.

#### **What should be done if there is a result of doubtful pathology, infection or recurrence of seroma?**

Late-onset seromas (older than 1 year) should be investigated by breast ultrasound, chest wall and regional lymph nodes exploration. When ultrasound is inconclusive, magnetic resonance imaging or computed tomography support the diagnosis. After two weeks, the ultrasound-guided aspiration of the seroma can be repeated, request cultures, cytology, flow cytometry and cell analysis, mainly for CD30 expression and negativity for ALK.<sup>49</sup> In relapses of seroma or infection, general manifestations, identification of capsule irregularities, detection of peri-prosthetic granulomas, doubtful pathology results, a total capsulectomy should be performed, with implant removal, with or without placement of new implants and perform specific studies to detect lymphoma or infection.<sup>3,14,23,42</sup>

#### **Recommendation<sup>3,14,23,31,41</sup> (Level of evidence IV; recommendation D)**

1. In cases where the ultrasound is equivocal or doubtful, magnetic resonance imaging is recommended.
2. In cases of recurrences, large seromas, or seromas associated with other alterations of the implant or breast, a careful, surgical examination should be performed.
3. Resection of the entire capsule is highly recommended, including the portion attached to the chest wall.
4. If there is presence of tumors or granulomas visible, attached to the capsule, a careful excision should be performed.
5. Send the entire resected capsule and periprosthetic fluid for pathology study.

Send the specimens to an experienced pathologist who has the immunomarkers available, contact in advance and agree to send the samples.

6. In case of minimum suspicion of malignancy or without infection data, a new implant may be placed. Do it on a different plane.
7. Place new implants, only in cases where the loss of volume will severely impact patients' self-esteem. They should be informed that there is a high risk of exposure and that if the lymphoma test is positive, the implants should be removed.

#### What to do in case of positive lymphoma result?

If there is palpable or radiological evidence of a tumor mass, positive or suspicious result of BIA-ALCL in the study of pathology of the aspirated fluid, or as a surgical finding when performing the removal of the implants, it is recommended to send the patient to a multidisciplinary team that includes: hematologists, pathologists, oncologist surgeons, and plastic surgeons.<sup>3,14,23,31,35</sup> The removal of the implant and capsule are the main cancer treatments, the application of CHOP chemotherapy has proven to be very useful. Most patients respond adequately to this treatment. Deaths have been associated to a delay in treatment and genetic conditions.<sup>31-42</sup>

Once the diagnosis of BIA-ALCL is confirmed, the authors suggest a bone marrow biopsy for patients with a high suspicion of systemic ALCL, such as patients with aggressive local invasion or lymph node metastasis. For any confirmed case of BIA-ALCL, a preoperative positron emission, computed tomography (PET/CT) is optimal for demonstration of masses in the associated implant capsule and chest wall. Due to significant inflammation induced by surgery, PET/CT scans are not reliable for assessing local disease if performed within 2 to 3 months after surgery.<sup>31</sup>

Cases of BIA-ALCL in its effusive or seroma form (stage 1A) have a better prognosis and can be treated with implant removal and capsule resection. In cases of major invasion, complete resection and adjuvant chemotherapy is required. Radiation therapy is indicated

when there are positive margins in excision, unresectable or residual tumor.<sup>48</sup>

#### *Recommendations<sup>3,14,23,31,35,42,49</sup>*

*(Level of evidence IV; recommendation D)*

1. Palpable masses or those identified in ultrasound or magnetic resonance should be sent to the oncologist.
2. In cases with a positive or suspicious result of BIA-ALCL in the pathology study of the aspirated fluid, they should be sent to the oncologist.
3. In cases that were not suspected and important seromas, granulomas or tumor masses are found during surgery; a complete resection of the capsule should be done and the liquid and the capsule sent for pathology study.

#### DISCUSSION

Several authors consider that there is an underreport of the incidence of seroma related to breast implants and also, that there is no uniform criterion regarding the treatment and the accumulated amount of liquid to consider them as a pathological manifestation.<sup>1-5</sup> One of the current recommendations issued by different health organizations and the FDA is to perform studies of breast ultrasound every 2 years for patients with breast implants.<sup>5,14,27-35</sup> This strategy will be very valuable in the detection of seromas. Seromas detected should be aspirated and studied in the clinical and pathology laboratory. A significant increase in the incidence of this alteration is expected and in a few years, we can determine the role played by periprosthetic fluid as an alert or a manifestation of pathologies related to breast implants.

Seroma can be caused by different causes. The study of the aspirated fluid should be studied to identify its etiology. In the clinical laboratory, usual cultures, cultures for mycobacteria, PCR for mycobacteria and cytochemical study should be performed. Histopathological studies, immunomarkers and flow cytometry will be carried out in the pathology laboratories.<sup>31,34-49</sup> It is important to send the samples to laboratories that have the resources for the requested studies and to pathologists with experience in this disease

and that have the immunomarkers and/or technology to perform a flow cytometry.

The study of seroma allows identifying different pathologies related to implants; such as: infectious, inflammatory, allergic, immune and tumor, the most severe is BIA-ALCL lymphoma.<sup>1-14,31</sup> The most frequent manifestation of BIA-ALCL lymphoma is seroma and is the first alteration that occurs.<sup>48</sup> In the cytological study of seroma, several cases of lymphoma have been detected, it is important and mandatory in all patients with seroma that the liquid be sent to pathology to rule out this disease and other pathologies related to breast implants.

Seroma aspiration can be performed with a fine needle, or with a catheter protected with plastic material. The use of ultrasound can help puncture and aspiration.<sup>15,31,38-42</sup> Total capsulectomy and implant removal has been indicated in cases of persistent seromas, in infections or in the presence of capsule irregularities, detection of periprosthetic granulomas or doubtful pathology results.<sup>2,3,14,23,42</sup> In a standard implant replacement; it is common for the surgeon to find fluid around the prosthesis. It is advisable to take a sample by aspiration and send it for study.

Strict surveillance of patients who have breast implants, with a guided physical examination, ultrasound studies and periodic magnetic resonance imaging, as of the date of surgery, will help identify a bigger number of patients with seromas and lymphomas related to breast implants. In the near future, we will know the true incidence, prevalence and impact that these alterations have.

### FINAL CONSIDERATIONS

All patients with breast implants should have an annual medical checkup by their surgeon. When there is an increase in volume, asymmetries, and inflammation; the presence of a seroma should be ruled out. The initial study will be an ultrasound and / or an MRI. In case a seroma is confirmed, a puncture-aspiration of the liquid should be performed and sent to a laboratory study, following the recommended protocol. There are several breast pathologies that can be detected by the

study of the aspirated fluid; the most feared is BIA-ALCL lymphoma. Most seromas resolve satisfactorily with conservative treatment. We are obliged in every patient with breast implants that develops a seroma, to rule out severe pathologies such as lymphoma.

### CONCLUSIONS

Seroma is a warning manifestation of different pathologies related to breast implants. All patients with breast implants should be closely monitored by surgeons having periodic check ups with a guided scan to look for alterations related to implants and ultrasound and/or magnetic resonance imaging studies. With these recommendations, we will be able to detect a bigger number of seromas and help to understand their impact on the patients' health. The study of the fluid accumulated around the implants will be very useful to determine the etiology of the seromas.

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# SECURITY RECOMMENDATIONS



## Seroma an alert of pathologies related to breast implants

Designer: Jonathan Morales

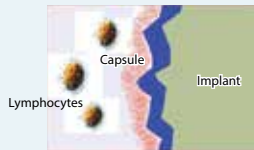
### Etiology

- Idiopathic
- Trauma
- Infections
- Implant rupture
- Immune disorders
- Lymphoma



### Pathogeny

- Foreign body reaction
- Chronic inflammatory response
- Lymphoproliferative process
- Microtrauma
- Implant detachment



Velcro patch effect; when detached produces trauma and fluid formation

It is common to find fluid around breast implants; there is no consensus regarding the quantity and its content, to consider it as pathological. Periprosthetic fluid or seroma is an alarm signal of pathologies related to breast implants. The study of the liquid will determine the etiology. Many cases of lymphoma have been diagnosed in this way.



Seroma is the main manifestation of BIA-ALCL lymphomas.

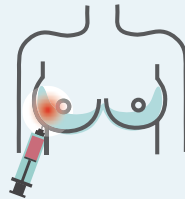
### Image studies



Magnetic resonance is the most useful study in the diagnosis of seroma and related pathologies. An alternative is a high resolution ultrasound. The mastography is of little use and can increase the seroma.

### What to do in case of a seroma that doesn't cure with medical treatment?

- While the patient is sitting
- Identify the seroma site; direct the puncture by ultrasound to protect the implant
- Use cannula or fine pointe needle and use electrocautery to open the capsule
- Extract the largest amount of liquid
- Keep the liquid in refrigerated and send to the laboratory and to pathology. If shipment cannot be done immediately, add alcohol (1:1)



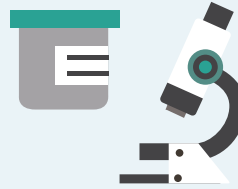
### What are the studies I must request?

#### Clinical laboratory:

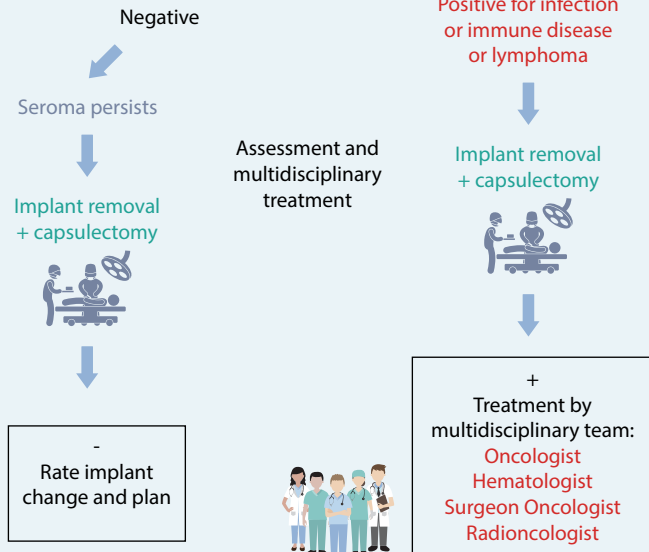
- Cytochemical study
- Standard culture
- Culture for mycobacteria

#### Pathology laboratory:

- Histological study
- Immunomarkers
- Infection detection
- Flow cytometry



### Results



### Highly recommended

- In a routine implant change, if you find periprosthetic fluid, you must send it to a clinical laboratory and pathology. Take capsule biopsy or capsulectomy and send to pathology.
- A guided examination, ultrasound and magnetic resonance studies are recommended every two years in all patients with breast implants.

These recommendations are useful for determining the incidence of seroma and for the timely diagnosis of breast pathologies related to implants.

