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## Case Report

# A Rare Cause of Breast Swelling in Lactating Women: Aquafilling® Gel Injection

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### Abstract

Aquafilling® gel has been used in recent years as an alternative method to breast augmentation surgery. In this case report, we aimed to discuss radiological imaging findings and complications of Aquafilling® gel injection. Case: A 34-year-old lactating female patient presented with swelling and pain in the left breast. Ultrasonography showed massive septate fluid collections with dense content in both breasts and between the pectoral muscle fibers. On mammography, both breasts appeared dense with large mass opacities. On magnetic resonance imaging, extensive fluid-signal cystic areas were observed. Peripheral enhancement around the fluid in the left breast was present in the contrast-enhanced series. We learned from her anamnesis that Aquafilling® was applied to both breasts 5 years ago. Ultrasonography-guided sampling was performed from the cystic areas in the left breast and cytological examination revealed basophilic Aquafilling® material surrounded by diffuse inflammatory infiltrates. Breast augmentation history should be questioned in suspicious cases because Aquafilling® gel injection and its complications can present with a wide variety of symptoms and may mimic various other conditions on radiological imaging, such as cancer, abscess, granulomatous mastitis, and parasite infections.

**Keywords:** Aquafilling® gel, augmentation, lactation, mastitis

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Cosmetic surgeries to improve the aesthetics of the body have been performed and widely accepted worldwide for a long time. Breast augmentation surgery is the most performed cosmetic surgery in the world.<sup>[1]</sup> Although this is considered a safe and effective method, patients are concerned about the complications of surgery and dissatisfying results. Surgeon experience is a great factor in choosing the right implant type and size, which among other reasons, drives the cost of surgery up

and is a cause for worry.<sup>[2]</sup> Moreover, revision of the results requires repeat surgery.<sup>[3-5]</sup> For these reasons, nonsurgical alternatives are being sought after by the patients. While the total number of surgical breast augmentations worldwide has decreased by 9.5% in 2020 compared to 2019, the total number of nonsurgical cosmetic procedures increased by 5.7%, according to ISAPS (International Society of Aesthetic Plastic Surgery) Global Survey Results.<sup>[1]</sup> Tissue fillers can be implanted without general anesthe-

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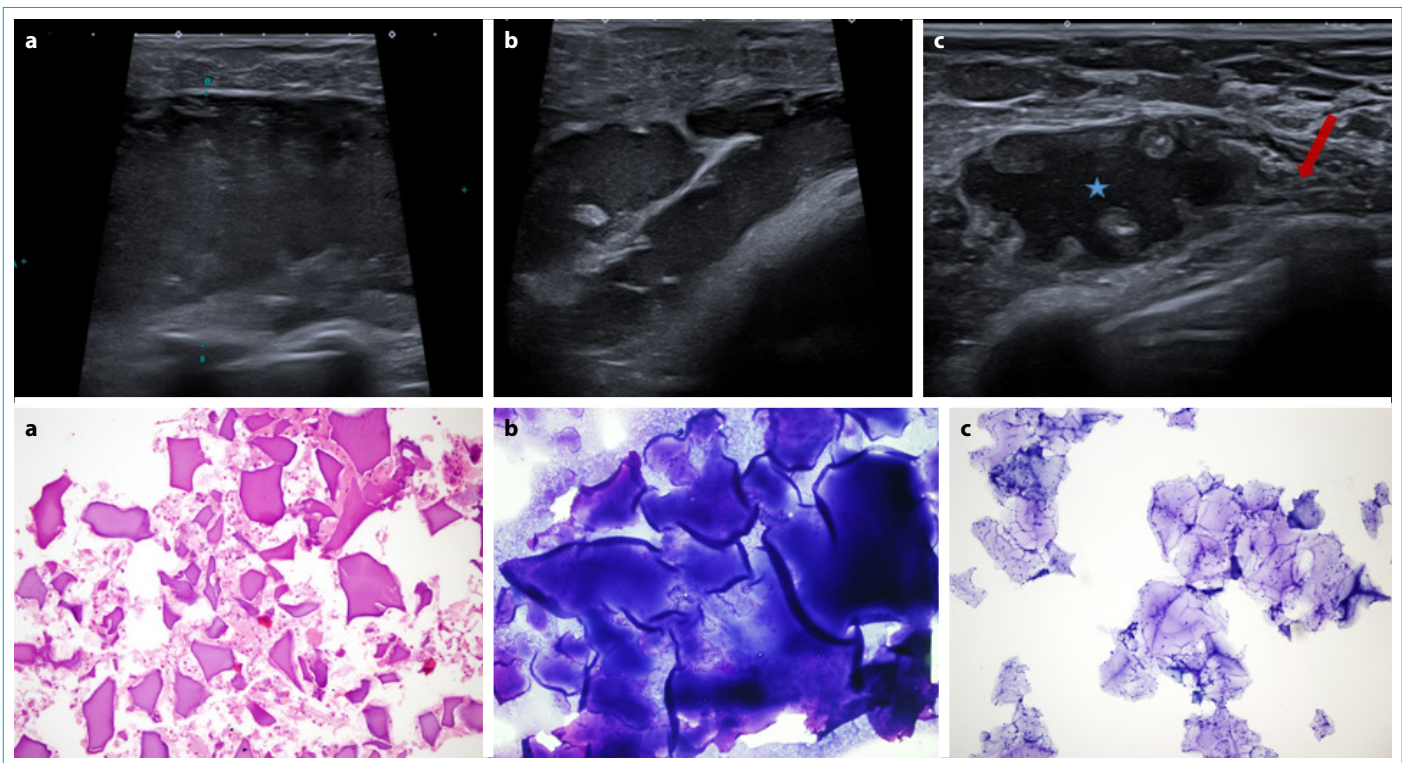


sia, easily with a fast procedure, and are inexpensive compared to surgery. Historically, there have been many fillers used for breast augmentation, such as paraffin, silicone, and PAAG (polyacrylamide gel).<sup>[6]</sup> Due to various complications of these fillers, such as pain, infection, and deformities, none have been approved by the USFDA (United States Food And Drug Administration) for use in breast augmentation procedures.<sup>[7]</sup> Aquafilling® (Biomedica spol, s,r,o, Czech Republic) is a hydrophilic gel composed of 98% sodium chloride solution (0.9%) and 2% cation copolyamide described as a sterile synthetic biocompatible with human tissues.<sup>[8]</sup> Aquafilling® gel was developed in 2005 as a dermal filler for the face and buttocks. Later, it was approved for breast augmentation in Europe in 2008.<sup>[9]</sup> Shin et al.<sup>[8]</sup> suggested in 2015 that it could mitigate the problem of complications associated with other breast augmentation methods. The product has been used for face, breast, and buttocks augmentations in the European Union, Turkey, Serbia, South Korea, Japan, and Malaysia. However, there have been reports of many complications in the long-term follow-up of the patients. Such as septic and aseptic inflammation, breast deformity, pectoral muscle infiltration, filler migration, and fistula formation.<sup>[3,4,10]</sup> As a result, the Korean Academic Society of Aesthetic

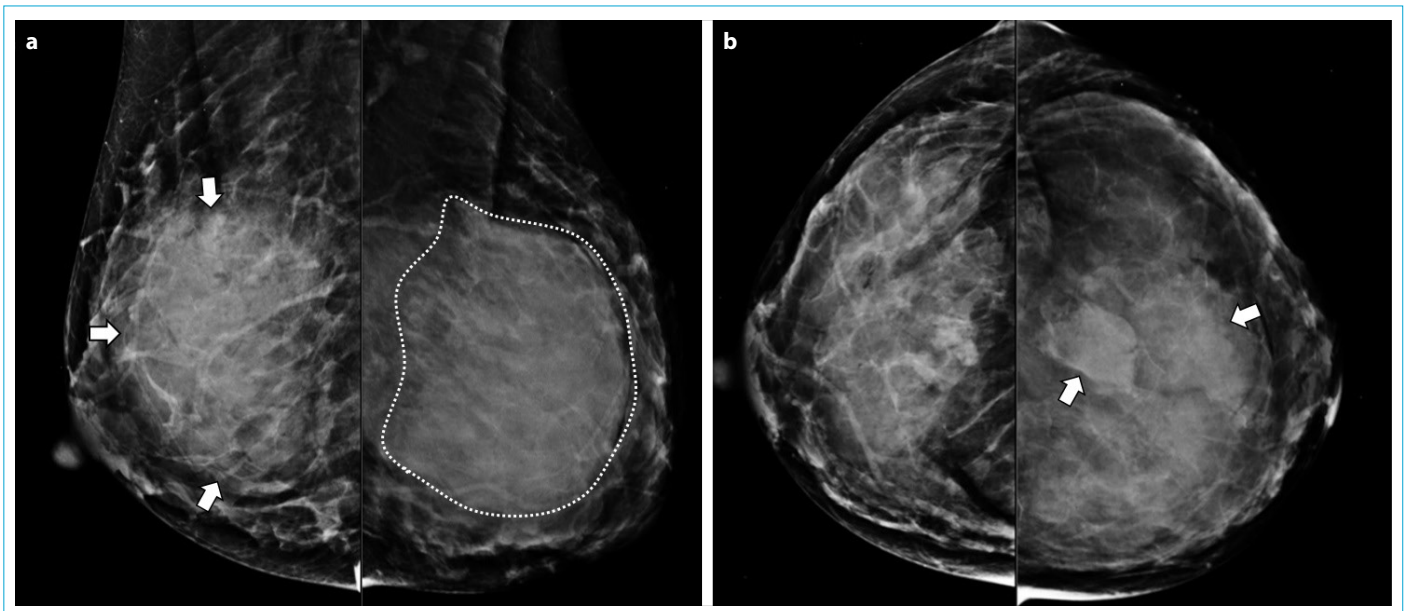
and Reconstructive Breast Surgery prohibited the use of Aquafilling® for breast augmentation surgery in 2016.<sup>[11]</sup> In their letter, they also expressed concerns about components of Aquafilling® being too similar to PAAG fillers. Later a study concluded, via nuclear magnetic resonance analysis, that the copolyamide filler Aquafilling® appears to be similar to PAAG fillers in terms of composition.<sup>[12]</sup>

## Case Report

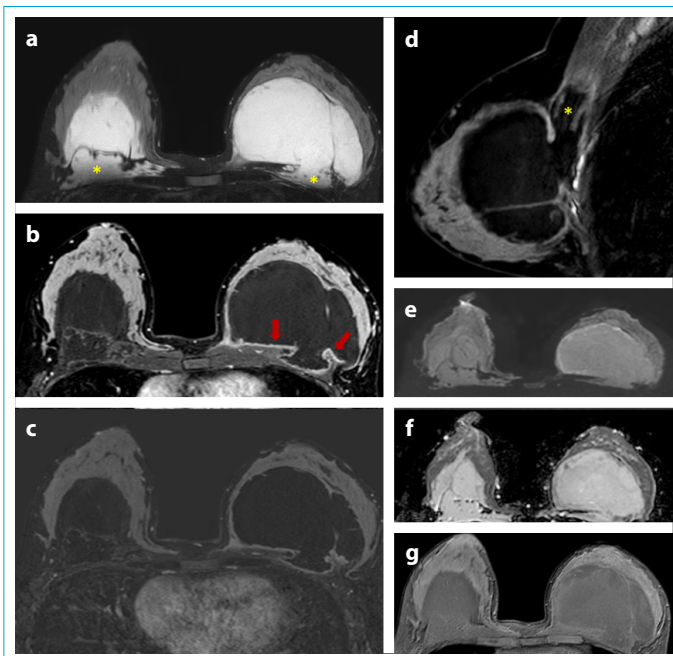
A 34-year-old breastfeeding woman, who had a breast augmentation history 5 years prior, presented with a lump in her left breast. Initially, ultrasound revealed heterogeneously and asymmetrically scattered, septate, fluid-like, anechoic collections in both breasts that also had transpassed in between the pectoralis muscle fibers (Fig. 1). Mammography showed dense breast parenchyma and nodular mass-like densities (Fig. 2). We performed MRI (magnetic resonance imaging) which revealed bilateral cystic lesions that demonstrated fluid signal intensities. Aquafilling® material was also apparent in between pectoralis muscle fibers. The material in the left breast was accompanied by thin rim enhancement (Fig. 3). 3 cc of filler material was aspirated from the left breast, cytological analysis showed basophilic Aquafilling® material surrounded by diffuse inflammatory



**Figure 1.** On US imaging, diffuse hypoechoic collections are observed in the glandular tissue in both breasts (a), and thick septations (b) are noticeable. These collection areas (blue asterisk) extend into the pectoral muscle fibers (red arrow) up to the axillary tail (c). Cell block with hematoxylin and eosin stain (d) and fine needle aspiration smears with May–Grünwald–Giemsa stain (e–f) showed abundant amorphous gelatinous material.



**Figure 2.** Mediolateral oblique (a) and craniocaudal (b) mammography images of the right and left breasts. Widespread mass opacities covering both breast parenchyma are observed (dashed lines and arrows in A-B).



**Figure 3.** Axial fat-suppressed T2-weighted (a), axial post-contrast fat-suppressed T1-weighted (b), axial post-contrast subtraction (c), sagittal post-contrast fat-suppressed T1-weighted (d), DWI (diffusion-weighted imaging) (e), ADC (apparent diffusion coefficient) map (f) and silicon-suppressed MRI sequences (g). Septate cystic areas are observed, which are hyperintense on T2-weighted imaging of the filling material and do not show diffusion restriction. These areas extend into the pectoral muscles in both breasts (yellow asterisks in A and D). It was thought that the filling material on the left might be infected because of the rim enhancement in the post-contrast series (red arrows in B).

infiltrates. Written informed consent was obtained from the patient for the publication of the case report and the accompanying images.

## Discussion

Aquafilling® gel can appear in a variety of ways under different radiological studies. Hence it can cause a great deal of confusion. Under grayscale US, it will usually appear as hypoechoic cyst-like, occasionally septate collections with increased echogenicity of the surrounding subcutaneous fat.<sup>[3,10]</sup> Coupled with inflammatory symptoms, this will guide the physician toward a diagnosis of abscess formation and secondary mastitis. This can be dangerous because, for Aquafilling-related complications, conservative approaches like aspiration might be ineffective, treatment is mostly surgical, and sometimes repeat surgeries and radiological follow-ups are necessary.<sup>[3-5]</sup> US imaging can also show anechoic or hyperechoic fluid-like material, usually without any appreciable capsule.<sup>[5,13]</sup> Skin fistulae, loculated fluid collection with hypoechogenicity, and increased vascularity with Doppler imaging are some of the changes observed in the tissue around injected Aquafilling® material.<sup>[3,10,13]</sup>

Some reports show hypoechoic nodules, internal multiple echogenic foci, ill-defined margins, and heterogeneous internal echogenicity associated with the Aquafilling® material under grayscale US.<sup>[5,13]</sup> Mammographic features such as nodular asymmetric densities and amorphous isodense lesions also resemble masses.<sup>[3,14]</sup> These characteristic

mass-like findings will complicate cancer screening, MRI may be needed to differentiate from breast masses, which is expensive and hard for the patient to withstand.<sup>[5]</sup>

Even with MRI and computed tomography (CT), sufficient diagnosis is not always possible. MRI findings of migrated material, are sometimes similar to parasitic infections and granulomatous diseases.<sup>[10]</sup> Patient history is another key factor in accurately diagnosing patients with such findings.

Aquafilling® material is seen as cyst-like nodular or tubular lesions that follow water signal on MRI sequences; hypointense on T1-weighted sequences, hyperintense on T2-weighted sequences, and no enhancement following contrast agent injection.<sup>[10,14]</sup> Thin rim enhancement was apparent in one case report.<sup>[10]</sup> While one case report showed diffusion restriction, another showed no diffusion restriction on DWI and ADC sequences.<sup>[10,14]</sup> Changes in neighboring soft tissues included; diffuse enhancement and fat stranding of the subcutaneous fat layer, skin thickening, and focal fluid collection.<sup>[3,13]</sup>

In previously published case reports, Aquafilling® has been shown to invade breast parenchyma, and pectoral muscle fibers migrate throughout the body to the axilla, subclavian triangles, abdominal wall, and vulva.<sup>[3,5,12,13,14]</sup> Aquafilling® gel appears as diffuse soft-tissue density<sup>[2,5]</sup> or fluid attenuation sometimes accompanied by thin rim enhancement<sup>[3,10]</sup> in contrast-enhanced CT scans. Fluid collection and subcutaneous inflammation were also reported around the material<sup>[10,13]</sup> in some cases.

Invasion into breast parenchyma is concerning because the toxicity of Aquafilling® is unknown. Although acrylamide is inherently neurotoxic, genotoxic, and a carcinogen, PAAG has uncertain toxicity and oncogenicity.<sup>[15]</sup> Aquafilling® injection also causes inflammatory responses independent of visible symptoms.<sup>[4]</sup> Tumor development in the process of chronic inflammation has been seen in multiple carcinomas. For these reasons, Aquafilling® may contribute to the development of cancer. There have been cases where breastfeeding caused inflammation and expansion in the filling and resulted in the cessation of breastfeeding.<sup>[3,5]</sup> There are no studies that show if Aquafilling® permeates into breast milk so the toxicity it could cause to a breastfed newborn is unknown.

Lactational mastitis, abscess, galactocele, and pregnancy-associated breast cancer are the most common pathologies to be considered in the differential diagnosis of a patient who presented with breast swelling and redness during lactation.<sup>[16]</sup> Among them, mastitis is the most common one. However, mastitis generally shows regional or unilateral involvement and can be easily distinguished by regression with antibiotic therapy. In our

case, the bilateral and widespread distribution of the lesions, their extension into the pectoral muscle planes, and the history of prior injection were helpful in the diagnosis. Galactocele is also a common pathology in lactating women with a palpable mass in the breast. They are seen as cysts with smooth contours, which can show fat-fluid levels, and demonstration of milk-like cystic content by needle aspiration leads to the diagnosis.<sup>[16]</sup> Pregnancy-associated breast cancer accounts for 1–3% of all breast malignancies.<sup>[16]</sup> Delayed diagnosis and aggressive behavior of tumor in pregnancy often result in poor prognosis. Similar to our case, such malignant cases may also present with masses of infiltrative and aggressive morphology that may extend to the pectoral muscle planes or axilla. However, the presence of solid components of malignant masses and the detection of accompanying axillary lymphadenopathies may help in the differential diagnosis. Nevertheless, a biopsy may be necessary in suspicious cases for definitive diagnosis.

In summary, non-surgical cosmetic augmentations are in high demand, and new materials are used prematurely without sufficient research. These materials should be extensively researched before being allowed on the market. Aquafilling® gel is among these fillers and its use for breast augmentation is not without complications. Diagnosing these complications is radiologically very complicated and burdensome. Especially breast cancer screening is problematic in the presence of filler material because mammographic and sonographic findings of filler material and breast masses are similar. In this case report and review of literature, we tried to summarize the different radiological findings associated with Aquafilling® material to aid in the diagnosis of such cases. Awareness of radiologists about the characteristics of breast fillers is vital in managing these cases.

## Disclosures

**Informed consent:** Written informed consent was obtained from the patient for the publication of the case report and the accompanying images.

**Peer-review:** Externally peer-reviewed.

**Conflict of Interest:** None declared.

**Authorship Contributions:** Concept – Y.K.; Supervision – İ.O.; Materials – O.A.K.; Data collection &/or processing – S.H.K.; Analysis and/or interpretation – B.P.K.; Literature search – S.A.K.; Writing – S.H.K.; Critical review – Y.K.

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