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CASE REPORT

Complication after Aquafilling® gel-mediated augmentation mammoplasty—galactocele formation in a lactating woman: a case report and review of literature

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Abstract
Augmentation mammoplasty using hydrogel fillers such as polyacrylamide gel (PAAG) or Aquafilling® has been performed commonly in some countries as an alternative to breast augmentation with saline or silicone implants. However, the safety of this procedure remains controversial, and many complications associated with the use of large-volume hydrogel injection have been reported in recent years. We present the case of a 33-year-old woman with a history of bilateral Aquafilling® injection augmentation mammoplasty who presented with an enlarged left breast while breastfeeding. Based on the clinical presentation and ultrasound findings, the patient underwent surgical incision as abscess formation caused by infection of the filler material could not be ruled out with certainty. Surgery revealed a galactocele with drainage of large amounts of milky fluid. Remaining filler material was removed as thoroughly as possible, and vacuum assisted wound dressing was performed. Galactocele formation in lactating women is a known complication after injection of hydrogel. Hence, it is important to be familiar with this uncommon but possibly severe complication in order to make an accurate diagnosis and initiate adequate treatment. To that end, it is recommended that patients who underwent Aquafilling® injection for breast augmentation should avoid lactation and that women intending to breastfeed should not undergo augmentation mammoplasty with injection of Aquafilling®.
Level of Evidence: Level V, risk / prognostic study

Keywords Augmentation mammoplasty · Aquafilling® gel · Complications · Galactocele · Breastfeeding

Introduction

Aquafilling® is a hydrophilic gel that was originally developed as a dermal facial filler in 2005. Since then, it has been increasingly used as a less invasive breast augmentation method in plastic surgery in some countries, notably Turkey, Serbia, Japan, China, Korea, Russia and Iran [1]. Similar to the well-known polyacrylamide gel (PAAG), Aquafilling® gel is injected with a needle under the fibroglandular breast tissue through the skin. Compared to surgical breast augmentation with implants, injection of soft-tissue fillers is a minimally invasive procedure performed under local anaesthesia [2, 3].

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Several studies confirmed that hydrogel injection for breast augmentation achieved favourable outcomes, and the use of Aquafilling® has become a popular option [4]. However, this procedure is not globally approved as an increasing number of related complications have been reported [5–7]. The use of Aquafilling® gel and PAAG is not FDA-approved [8], and their use for injection augmentation mammoplasty is prohibited in some countries [9, 10]. However, these filler injection augmentation procedures are still commonly practised.

A variety of late adverse effects following PAAG injection for breast augmentation has been described, and more recently breastfeeding complications have been reported among several women. So far, 4 cases of lactation-associated galactocele formation and 1 case of lactational mastitis with skin fistula related to PAAG-injected breast augmentation have been reported [11–15]. Based on these reports, Wang et al. analysed the rising filler-associated complications occurring during breastfeeding, and they

found that 58 of 102 women receiving PAAG injection for augmentation mammoplasty developed infection during lactation [16].

We only found two reported cases of breastfeeding-associated complications in patients who had a history of, namely, Aquafilling® gel injection in both breasts. One patient presented with a unilaterally largely inflated breast and MRI revealed a large cystic mass in the retroglandular area [4]. The second case involved a woman who experienced gel migration from the left breast to the vulva trough the abdominal wall 4 months after Aquafilling® injection and who presented with secondary mastitis of the right breast while breastfeeding one year later [7].

Even though the manufacturer of Aquafilling®, recently renamed Los Deline® (Biomedica, Prague, Czech Republic), initially claimed that the gel had features differentiating it from PAAG, the overall composition of polyacrylamide in both gel types seems to be quite similar, and the complications after injection of PAAG and Aquafilling® for breast augmentation are thought to be equivalent [1, 4, 9, 17]

On these accounts, possible breastfeeding problems subsequent to filler injection for augmentation in young women should not be disregarded. Patients might present with markedly enlarged and painful breasts, and distinction between galactocele formation and inflammatory processes based on physical examination and ultrasound findings can be challenging. Inadequate management of these complications can cause serious consequences. In this article, we report a young breastfeeding woman presenting with a considerable one-sided breast enlargement after undergoing breast augmentation by Aquafilling® injection in Turkey 5 years earlier.

Case report

A 33-year-old female patient presented to our lactation consultant in October 2020 with atypical enlargement of the left breast which she had started to notice 6 weeks earlier. She had given birth to her first child in June 2020 after a complication-free pregnancy and started breastfeeding her child immediately. The patient was a healthy smoker, and she was not on any medications. She had a remote history of augmentation mammoplasty by Aquafilling® injection performed in Turkey in 2015 and was so far pleased with the cosmetic result of the procedure. One month after the onset of breastfeeding, she was first diagnosed with lactational mastitis of the left breast, and antibiotic treatment with amoxicillin/clavulanic acid was prescribed for 10 days. Two weeks after completing the course of antibiotics, engorgement and tenderness of the affected breast persisted, and she developed fever up to 38.5 °C. Another course of oral antibiotics was prescribed. Her general condition improved with slackening fever, but diffuse swelling and tenderness of the left breast aggravated progressively. The patient tolerated the discomfort until the pain worsened urging her to consult our lactation counsellor who referred her to our breast centre.

Upon first presentation, she denied systemic symptoms and was continuing to breastfeed from both sides. Physical examination showed asymmetry with a considerably enlarged and tender left breast with discrete erythematous skin change, painful palpation and minimal warmth (Fig. 1). Blood leucocyte count and C-reactive protein levels were in the normal range. Ultrasound of the left breast showed inhomogeneous tissue with interspersed floating materials and complex fluid collections suspicious for abscess formation (Fig. 2). Normal breast tissue could barely be identified. The right breast showed normal lactating glandular breast tissue with dispersed collections of gel material. Based on those findings, we suspected a septic collection in the left breast caused by infection of the filler material. We decided to perform a surgical exploration under general anaesthesia.

After inframammary incision was performed, 600 mL of yellowish-milky fluid, which did not appear to be pus, and gelatinous particles were drained from a probable galactocele cavity (Fig. 3). Culture swabs and breast tissue samples were taken. Microscopically, the biopsy showed sclerosed, partially necrotic tissue with signs of florid, purulent infection, although the cultures did not show any bacterial growth after incubation. After removal of all gel residues, extensive irrigation with H_2O_2 and saline was performed. Due to the depth of the remaining cavity, we opted for vacuum-assisted wound dressing. A vacuum-assisted closure (VAC) system was emplaced and exchanged 2 times in the operation room before secondary wound closure could be accomplished 9 days after initial incision. The patient consented to weaning, and delactation treatment with Cabergoline was initiated. She presented for follow-up 4 weeks and 6 weeks after final wound closure. The left breast had significantly decreased in size after surgical treatment and was smaller compared to the right breast (Fig. 4). Palpation revealed discrete tenderness of the left breast but no erythema or

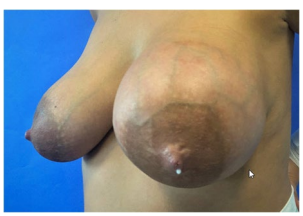

Fig. 1 Initial presentation of a 33-year-old woman in our clinic with painful engorgement of the left breast 3 months after initiation of breastfeeding. The patient underwent Aquafilling® hydrogel injection augmentation mammoplasty 5 years prior. View from 30° angle

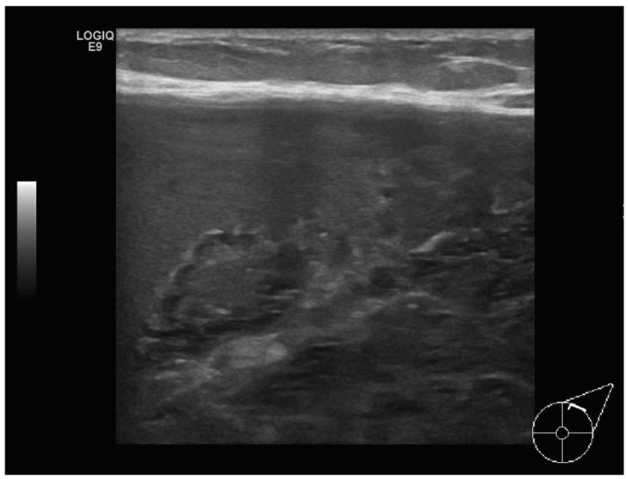

Fig. 2 Ultrasound image of the left breast showing a heterogeneous turbid liquid collection with interspersed hyperechoic gelatinous material and anechoic cystic-fluid collections scattered through inhomogeneous lacunar fibroglandular tissue

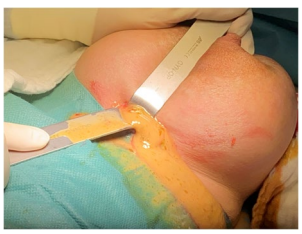

Fig. 3 Surgical exploration of the left breast through a small inframammary incision with galactocele drainage with outflow of large amounts of milky-viscous fluid

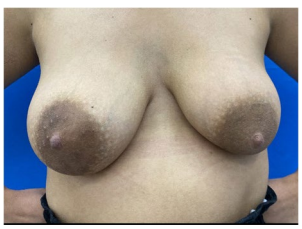

Fig. 4 Six-weeks-follow-up front view of the patient showing a moderate asymmetry with atrophic deformity of the left breast

pain. Ultrasound showed a large anechoic fluid collection most likely due to seroma formation and small hypoechoic collections of remaining gel. Another follow-up appointment was arranged for 3 months later. The patient was unsatisfied with breast asymmetry and already expressed her desire to discuss surgical interventions to achieve best cosmetic results.

Discussions

This case report describes the complications for a female patient who received Aquafilling®-mediated breast augmentation 5 years earlier and did not report any related undesirable effects prior to childbirth.

There have been many attempts to establish breast augmentation using injectable materials such as paraffin, liquid silicone and polyacrylamide gel (PAAG) as a routine procedure [18, 19]. PAAG, when first developed, drew attention as an ideal injectable filler because at the time it was considered to be nontoxic and non-absorbent. It was first used for breast augmentation in the former Soviet Union and has become a popular option since then, especially in Asian countries [20]. A few clinical studies have reported satisfactory results for PAAG in breast augmentation [21]. However, the use of PAAG has been shown to be potentially dangerous [22, 23]. So far, none of the named filler materials have been approved by the FDA for breast augmentation due to reports of various complications and irreversible damage related to this procedure [8, 9, 19, 24].

In an attempt to overcome the limitations of PAAG, Shin et al. suggested injection of a temporary soft-tissue filler named Aquafilling® in the space between silicone implants and the skin to correct shape and size after breast augmentation surgery [25]. According to the available literature Aquafilling® is composed of 98% sodium chloride solution (0.9%) and 2% of cation co-polyamide offering stable results for 8–10 years. However, the Korean Food and Drug administration (KFDA) stated that Aquafilling® truly consists of 2% of poly (acrylamide-co–N,N'-methylene-bisacrylamide) and 98% of sodium chloride solution 0.9%. In comparison, the representative product of the PAAG filler, Aquamid®, is composed of 97.5% pyrogenic water bound to 2.5% cross-linked polyacrylamide, which is obtained by the polymerization of acrylamide and N,N'-methylene-bis-acrylamide monomers. There might exist minimal differences in the polymer structure of the Aquafilling® gel and PAAG filler, but the overall composition of polyacrylamide in both gel types appears to be quite similar. Hence, features of PAAG fillers as well as the known complications after injection as body fillers are expected to be similar for the use of Aquafilling® [4, 7, 9, 17, 26].

The usage of both materials for simple breast augmentation has increased despite the growing number of reported serious adverse complications [4, 19, 27]. Fever, redness, breast swelling, delayed wound healing, filler migration, infection of surrounding tissues or the chest wall, pain, tenderness, localized lumps, asymmetry and irreversible deformity are considered most common [6, 18, 19, 22, 28–30]. Unintended injection into blood vessels or intravascular leakage with possible necrosis are rare, nonetheless severe complications [7]. The consensus reached among most of the aforementioned authors seems to be that the use of Aquafilling® in larger volume areas such as breast should not be recommended [4].

Concerns regarding toxicity and oncogenicity of polyacrylamide have been postulated, and 2 cases of patients with malignant breast tumours following breast augmentation

with PAAG have been reported [31, 32]. Accurate cancer detection based on imaging can be complicated by infiltration of the gel into the surrounding fibroglandular tissue. Also, formation of solid hypoechoic nodules after filler injection have been described and may be mistaken as potentially cancerous lesions [5, 7].

The majority of women receiving PAAG and Aquafilling® injection for breast augmentation were young, and some late complications can emerge in the form of breastfeeding difficulties. Loss of the ability to breastfeed has increasingly been reported, in addition to serious manifestations including local and systemic infections or breast inflation due to galactocele formation after initiation of breastfeeding [16].

Galactoceles are benign cysts containing milk. They occur mostly in young women in the setting of pregnancy, active lactation or use of hormonal medications such as oral contraceptives. The aetiology is thought to be related to obstructed ducts associated with increased prolactin levels [33]. Pregnancy-related galactocele formation is a rare complication after augmentation mammoplasty with implants [34–36]. It had never been reported after filler-injected augmentation until Lin et al. reported a case of bilateral galactocele formation in a puerperal woman who underwent breast augmentation by PAAG injection [11].

The mechanism of galactocele formation in puerperal women with of history of PAAG or Aquafilling® breast injection has yet to be fully understood. Since injectable mammary augmentation is often not imaging-guided, the exact injection of hydrogel into retromammary space between gland layer and muscle layer is not guaranteed. Glandular lobes can be damaged by the needle allowing gel particles to spread in glandular tissue and oppress lactiferous ducts resulting in narrowness [18]. Another theory presumes that the retention of PAAG in the breasts might induce a severe foreign body reaction, the inflammation resulting in fibrosis of glandular breast tissue leading to a blockage of lactiferous ducts [11, 34, 37].

Narrowed lactiferous ducts can lead to poor milk flow and milk accumulation in breastfeeding women with possible subsequent galactocele formation in some patients. Due to its richness of proteins, milk is a good culture medium for bacteria. Hence, galactocele formation renders patients susceptible to infection as confirmed by Wang et al. They retrospectively analysed 102 women receiving PAAG injection for augmentation mammoplasty and found that 58 developed infection during lactation which is a severe complication following breast augmentation. Bacterial contamination of the filler can cause serious consequences and requires appropriate management once diagnosed [16].

Based on the initial clinical picture of our reported patient, lactational mastitis was unlikely due to the indolent clinical course and the lack of systemic infection signs, but galactocele, delayed seroma and abscess were possible diagnoses. Ultrasound imaging showed inhomogeneous turbid liquid collections and scattered hyperechoic and anechoic fluid-like lesions and was not conclusive. Numerous studies have described that ultrasound (US) and magnetic resonance imaging (MRI) findings after filler injection might be nonspecific and difficult to interpret which is why setting of accurate diagnoses based on imaging is considered challenging [5, 7, 38]. US is considered a useful technique to assess palpable masses and determine the location of infected sites, and depending on clinical experience, US has been effectively applied to detect infection-induced abscesses and foreign body cysts [11]. However, the limited field of view makes it difficult to evaluate entirely disfigured enlarged breasts accurately. MRI is considered the most sensitive technique and might be useful as additional modality in order to make an accurate diagnosis if complications occur [14].

Given that we could not rule out a septic collection or abscess formation in the affected breast of our patient based on clinical and ultrasound findings, we decided to perform a surgical exploration.

The operative findings confirmed the presence of a cystic cavity containing large amounts of milky fluid and gelatinous particles. Based on the history of augmentation mammoplasty with Aquafilling® injection and considering the clinical and surgical observations as well as the microbiological and pathological findings, we concluded that the enlarged breast of our patient corresponded to a galactocele with possibly partly sterile pus collection. After drainage, the cavity was cleared from remaining gel material and repeatedly irrigated.

The available literature on the subject demonstrates that once complications after breast injection of PAAG or Aquafilling® gel occur, treatment is difficult, and recurrence is frequently observed [4, 6]. Although simple aspiration of a galactocele can relieve the strain on the breasts, the diagnostic uncertainty bears a risk for severe consequences if the collection is truly an abscess. This might explain why in most reported cases physicians chose surgical treatment. Medical management with a dopamine receptor agonist can be performed if the diagnosis is certain [36].

Our management was consistent with established recommendations, which were based on the results of a retrospective study performed by Wang et al. confirming that hydrogel-induced cysts and abscesses in breastfeeding women were completely cleared by surgical intervention, with no recurrence observed after application of continuous negative pressure drainage for at least 72 h [16]. A satisfactory result without surgery was achieved in one reported case of a patient presenting with breast engorgement and tenderness while breastfeeding. This patient showed bilateral galactocele formation and responded well to antibiotic treatment.

However, this patient underwent breast augmentation with implants and no filler-injected augmentation [34].

It follows that enlargement of filler injection-augmented breasts during breastfeeding, whether due to galactocele or abscess, requires surgical management. Drainage and complete removal of filler material including the affected fibroglandular tissue are necessary to eliminate the risk of recurrence. Resulting breast asymmetry deformities may necessitate reconstruction surgery.

Conclusions

In summary, we have presented the case of a 33-year-old woman with a remote history of injection-associated breast augmentation with Aquafilling® gel who developed a unilateral galactocele while breastfeeding her first child. Pregnancy-related galactocele formation after injection augmentation mammoplasty is not uncommon and important to be included in the differential diagnosis of an enlarged breast post augmentation. The threshold for surgical management should be low as serious complications can arise if the diagnosis is unclear. Given that the overall composition of Aquafilling® (recently renamed Los Deline®) and the better-known PAAG fillers (commercialized under various trade names) is the same, their features as well as their known complications are equivalent. Hence, the mentioned case report related to the use of Aquafilling® gel emphasizes that injection of co-polyamide filler should be avoided in women of reproductive age, especially patients with plans for pregnancy and breastfeeding.

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Data availability Authors can confirm that all relevant data are included in the article.

Code availability Not applicable.

Declarations

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. No ethical approval was necessary for this case report.

Patient consent Written informed consent was obtained from the patient regarding publishing her data and photographs.

Conflict of interest Loesch Julie Marie, Eniste Yasemin-Sibel, Dedes Konstantin, and Frauchiger-Heuer Heike declare that they have no conflict of interest.

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