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Case Report

Complications and Imaging Features of Polyacrylamide Hydrogel (PAAG) Injection for Breast Augmentation

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Polyacrylamide hydrogel (PAAG) was used for breast augmentation from 1997 to 2006 in the regions of Eastern Europe, Russia, Iran, and China. It was assumed that approximately 300,000 women had undergone PAAG injection. Recently, we experienced several cases with PAAG injection-related complications, and two of them had received PAAG injection two years before, after the State Food and Drug Administration of China banned this material in 2006. In this study, we aimed to evaluate the complications and imaging findings of patients with PAAG-injected breast augmentation. Four out of six cases presented suspicious for malignancy findings in imaging work-up. One case was confirmed as invasive ductal cancer in a 25-year-old female. Thorough work-up with multimodal breast imaging and pathologic confirmation with tissue biopsy should be considered in patients with suspicious findings with a history of PAAG injection.

Index words: Polyacrylamide hydrogel; PAAG; Multimodality Imaging; Breast Cancer

Introduction

Soft tissue augmentation using injectable fillers has been applied all over the world, and various types of biomaterials have been developed. Among the injectable fillers, polyacrylamide hydrogel (PAAG) is a stable, nontoxic and nonabsorbable sterile watery gel consisting of 2.5% cross-linked polyacrylamide and 97.5% water. Its high water content allows PAAG to be integrated within surrounding connective tissue and fat. PAAG injection was first introduced in 1994 as a minimally invasive technique for breast augmentation in Ukraine and was introduced into China in 1997. After the development of PAAG, breast augmentation with PAAG injection became popular in Eastern Europe, Russia, Iran, and China (1, 2). PAAG injection was widely used because of its noninvasiveness and simple operation, fast recovery time, easy molding, soft feeling and inexpensive price (3).

Despite its popularity in augmentation

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mammoplasty, an increasing number of complications after PAAG injection have been reported. PAAG injection can cause adverse effects, including induration, lumps, hematoma, inflammation, infection, persistent mastodynia, poor cosmetic results, glandular atrophy, gel migration, and even delayed diagnosis of breast cancer (4, 5) A previous report showed that the incidence of infection during breast feeding was higher than 50% (3). Breast cancer associated with augmentation mammoplasty has been identified as a serious complication, and a number of cases have been reported (5, 6). To date, there are four articles reporting four cases of breast cancer after PAAG injection: pathologically diagnosed as invasive ductal carcinoma (three cases) and lobular (one case) (5, 7, 8). Accordingly, the Russian ministry prohibited PAAG injection for fear that it can lead to glandular atrophy (9). In April 2006, the Chinese State Food and Drug Administration announced that PAAG should be prohibited from production and clinical use for augmentation mammoplasty in plastic surgery.

Although PAAG injections had been banned for augmentation mammoplasty in 2006 in China and are rarely used currently, the exact number of patients who underwent PAAG injections for breast augmentation remains unclear. Approximately 300,000 women are estimated to have undergone this procedure worldwide (10). A large number of patients with augmented breasts using PAAG injection have continued to seek medical advice because of its complications. The diagnosis and treatment of PAAG complications have become a global problem. Recently, Jin et al. (11) described the diagnostic classifications of PAAG injection and strategy based on the classifications by reviewing 287 cases in China. In Korea, however, there was only one case report of long-term complications in a Korean woman who had undergone PAAG filler injection for breast augmentation ten years prior in China (12). In this study, we report six recent cases of complications following augmentation mammoplasty with PAAG in Korea.

Material and Methods

This study retrospectively reviewed and analyzed the medical records of six patients who visited two hospitals due to complications after PAAG breast augmentation. The clinical characteristics of the patients, including the period between the injection and the visit, injection material, medical history regarding breast augmentation and the clinical presentations, were collected. All six patients underwent MG, US and Magnetic Resonance Imaging (MRI) to evaluate possible implant-associated complications. Radiologic findings, surgical treatment and final pathologic findings were also reviewed. All research procedures were approved by the Institutional Review Board of the Seoul National University Boramae Medical Center and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all patients.

Results

Between October 2015 and June 2019, six female patients suffering from complications after PAAG-injection breast augmentation presented at two hospitals. Their ages ranged from 25 to 53 years. The time elapsed from breast augmentation with PAAG injection to presentation with complications in our hospitals ranged from 2 years to 18 years (mean 9.5 years). The patients presented breast pain and palpable breast mass due to gel migration. Table 1 summarizes the patient characteristics and histories.

Case 1

A 25-year-old woman with a history of breast augmentation with an injection of PAAG 2 years

Table 1. Clinicopathologic Characteristics of Patients

Case	Age (year)	Sex	Period Between Injection and Presentation (year)	Procedure Combined with PAAG Injection	Clinical Presentation	Imaging Modality	BI-RADS Category	Operation Method	Pathologic Diagnosis	
									Core Needle Biopsy	Surgical Specimen
1	25	F	2		Breastpain	MG, US, MRI	C4c	Mastectomy	Invasive ductal carcinoma	Invasive ductal carcinoma
2	50	F	2	Implant mammoplasty (saline)	Breast pain	MG, US, MRI	C2	Foreign body removal		Filler associated change
3	53	F	14		Palpable breast mass due to migration	MG, US, MRI	C4a		Foreign body granuloma with calcifications	
4	50	F	18		BreastPain and Induration	MG, US, MRI	C4a	Foreign body removal	Foreign body granuloma with calcifications	Foreign body granuloma with calcifications
5	49	F	13		Palpable breast mass	MG, US, MRI	C2			
6	49	F	8		Palpable breast mass	MG, US, MRI	C4a		Foreign body granuloma	

F, female; PAAG, polyacrylamide hydrogel; MG, mammography; US, ultrasound; MRI, magnetic resonance imaging; BI-RADS, Breast Imaging Reporting and Data System

prior presented with pain in the right breast. The patient had no family history of cancer and no acute complications following the previous injection. Segmental fine linear pleomorphic microcalcifications were presented in the right upper outer breast on MG (Fig. 1a). On ultrasound, 5 cm from the nipple, a 0.7-cm microlobulated irregular hypoechoic mass with MG correlated microcalcifications was observed (Fig. 1b). Additionally, US depicted anechoic material in the retroglandular location of both breasts with multiple echogenic foci (Fig. 1c). The right breast mass with associated microcalcifications was classified as Breast Imaging Reporting and Data System (BI-RADS) category 4c and underwent US-guided core needle biopsy. Biopsy results demonstrated invasive ductal carcinoma. The patient underwent breast MRI. PAAG showing low signal intensity on T1-weighted imaging (Fig. 1d) and high signal on T2-weighted imaging (Fig. 1e) in the retroglandular area. Multiple nonenhancing masses were present in the breast retromammary fat layer, pectoralis intramuscular space, and chest wall (Fig. 1f). On T1 dynamic subtraction, the sagittal image demonstrates segmental clumped nonmass enhancement and biopsy-proven breast cancer (Fig. 1g). Subsequently, the patient underwent mastectomy, with final pathologic findings showing ER-negative, PR-positive, HER2-amplified invasive ductal carcinoma in the background of DCIS. The patient had no family history of breast cancer or ovarian cancer, and the BRCA mutation test was negative.

Case 2

A 50-year-old woman with a history of breast

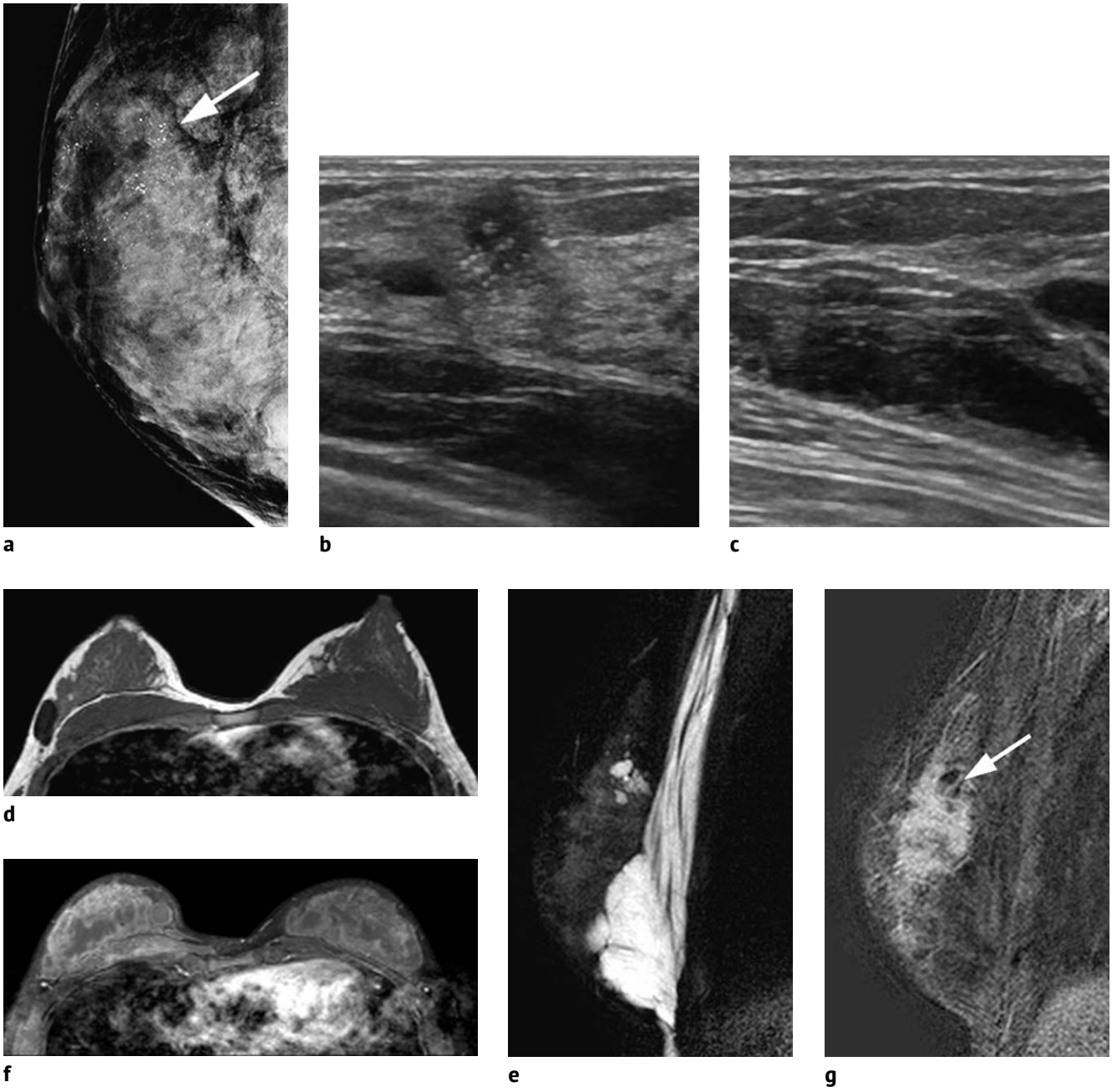


Fig. 1. A 25-year-old woman diagnosed as breast cancer with a history of PAAG injection 2 years ago. (**a**) Right mediolateral oblique view demonstrating segmental linear pleomorphic microcalcifications in the upper outer breast (arrow). Multiple nodular densities at the retromammary fat layer, which may be injected with PAAG materials. (**b**) Ultrasonography shows an indistinct irregular hypoechoic mass with mammography correlating microcalcifications. Core needle biopsy revealed invasive ductal carcinoma. (**c**) Typical sonographic findings of the retroglandular location of a PAAG collection showing a large liquid collection composed of multiple foci. (**d**, **e**) On MRI, PAAG showing low signal intensity on T1-weighted imaging (**d**) and high signal on T2-weighted imaging (**e**) in the retroglandular area. (**f**) A T1 dynamic contrast axial images demonstrated peripheral rim enhancement around both implants, even though there were no signs of inflammation clinically. (**g**) On T1 dynamic subtraction, the sagittal image demonstrates segmental clumped nonmass enhancement and biopsy-proven breast cancer (arrow). The axial silicone-suppression sequence yielded high signal intensity, confirming that the injected material was not composed of silicone, correlating with findings of diffuse PAAG injection.

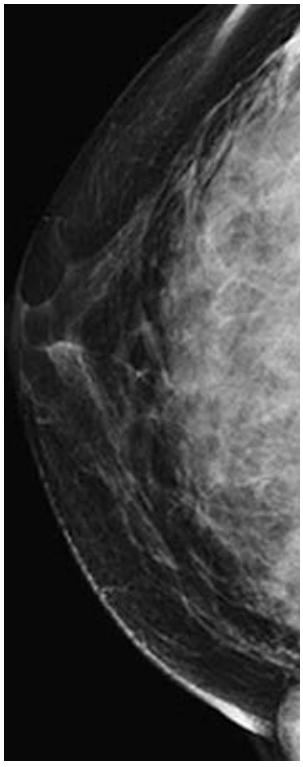
implant mammoplasty of both breasts (with saline implants) 10 years before and augmentation of both breasts with injection of PAAG two years before presented with right breast pain. On MG and US, both implant extracapsular rupture and a large amount of foreign body materials were observed. The patient underwent breast MRI, which demonstrated a large amount of filler injection materials, showing T1 low signal intensity and T2 high signal intensity, correlating with diffuse PAAG injection, distributed diffusely through the superficial to deep layer of the pectoralis muscle and intramuscular area. Additionally, some materials migrated to the right axillary area. The patient underwent bilateral removal of foreign body material. During surgery, filler materials were distributed in the bilateral pericapsular space and pectoralis major muscle. The final pathologic findings were consistent with filler-associated changes.

Case 3

A 53-year-old woman with a history of both augmentation and injection of PAAG 14 years ago presented a palpable anterior chest wall mass. On MG and US, a large amount of PAAG in a retroglandular location was collected in both breasts (Fig. 2a, 2b). At the anterior chest wall, an approximately 3-cm circumscribed heterogeneous echotexture oval mass was observed on the ultrasound palpable site, which correlated with the PAAG material and most likely migrated to the mid-sternal area (Fig. 2c, 2d). Additionally, a 1.9-cm circumscribed oval hypoechoic mass with increased vascularity was observed in the right lower inner breast (Fig. 2e, 2f). It was classified as BI-RADS category 4a and underwent US-guided core needle biopsy. The samples consisted of thick yellowish gelatinous material extruded from the biopsy site (Fig. 2g). Biopsy results demonstrated foreign body granuloma with calcification.

Case 4

A 50-year-old woman with a history of augmentation of both breasts with injection of PAAG 18 years ago in China before immigrating presented with pain and indurations on both breast. Ultrasound depicted multiple hypo- and isoechoic masses along the lining of the injected foreign body material in both breasts, and some were combined with dystrophic calcifications within the mass (Fig. 3a, 3b). Injected foreign body materials were mainly located in the retropectoral area (behind the pectoralis major muscle) (Fig. 3c). At the left lower outer breast, a hard mass of approximately 1.8 cm was detected with increased internal vascularity. It was classified as BI-RADS category 4a (Fig. 3d). The patient underwent MRI for further evaluation. On MRI, large amount of PAAG collection in the retroglandular area (Fig. 3e). PAAG showed low signal intensity on T1-weighted imaging (Fig. 3f) and high signal on T2-weighted imaging (Fig. 3e). MRI indicated multiple enhancing lesions along the capsule lining of the injected foreign body material in both breasts (Fig. 3g), and it was more prominent in the left lower outer breast, correlating with the US findings. Additionally, multiple injected materials were observed in the retropectoral area. Axial silicone-only MRI for visualizing silicone implants showed low signal intensity, suggesting that the injected material was not silicone (Fig. 3h). The patient wanted PAAG removal, so she underwent bilateral PAAG removal operation. Surgical treatment was performed, along with removal of the PAAG and total capsulectomy of the fibrous capsule containing the gel through an inframammary fold incision. The intraoperative findings showed that the PAAG resembled a purée-like yellowish material (Fig. 4). The Biopsy results demonstrated degenerated foreign body material with dystrophic calcifications and foreign body reaction.



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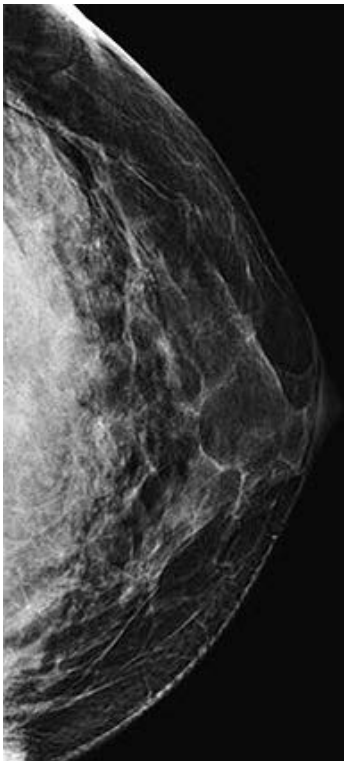

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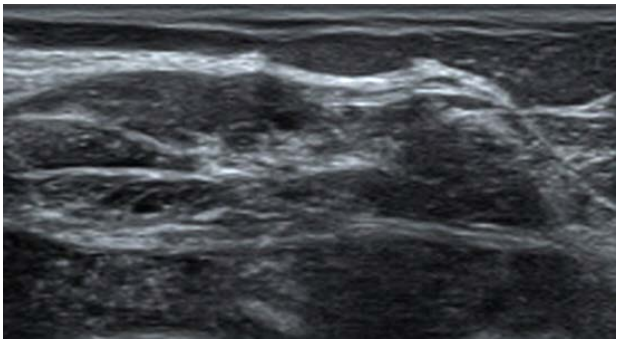

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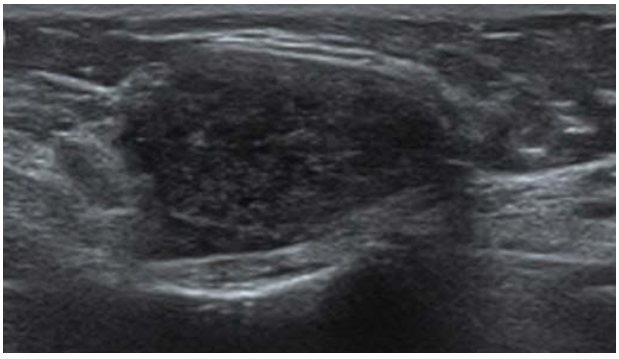

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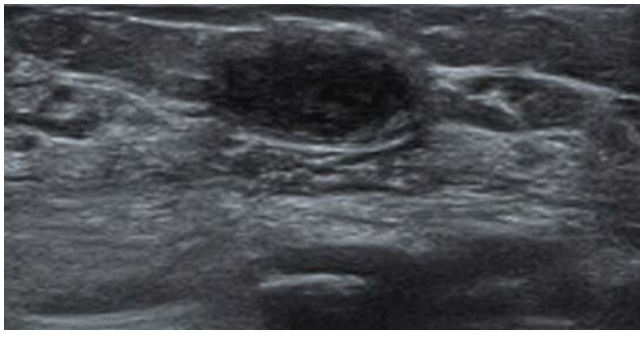

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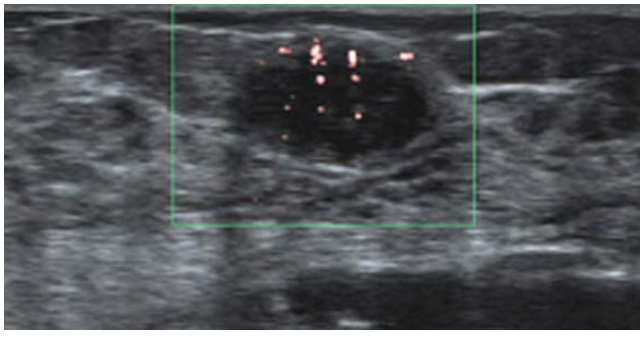

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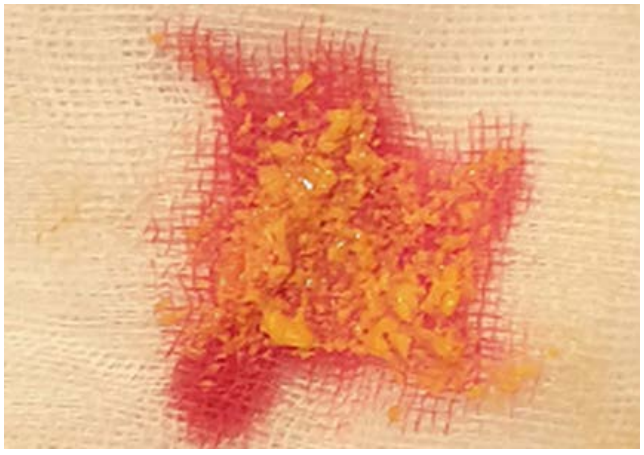

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Fig. 2. A 53-year-old woman with a history of PAAG injection 14 years ago. (**a**, **b**) Both craniocaudal views demonstrating isodense diffuse foreign body material in the retromammary area. (**c**) Ultrasonography shows diffusely scattered heterogeneous echogenic PAAG collections in different layers, from the subcutaneous layer to the pectoralis muscle. (**d**) An approximately 3-cm heterogeneous echoic oval circumscribed mass at the anterior chest wall, probable PAAG gel migration. (**e**, **f**) An approximately 1.9-cm oval complex solid and cystic mass with increased internal vascularity was observed in the right 4 o'clock area. Subsequently, a core needle biopsy was performed. (**g**) During biopsy, a yellowish gelatinous material extruded. Core needle biopsy revealed foreign body granuloma with calcification.

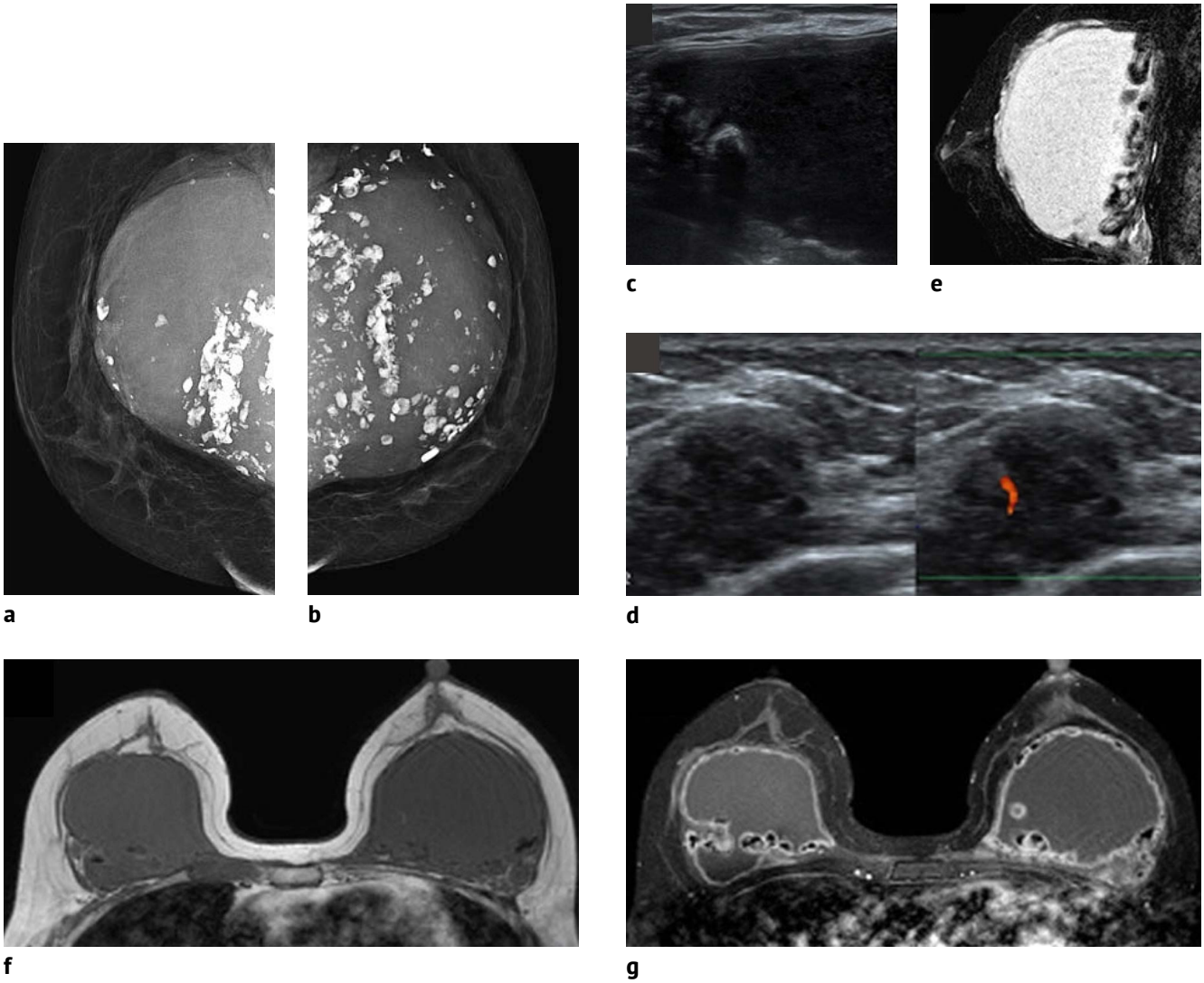
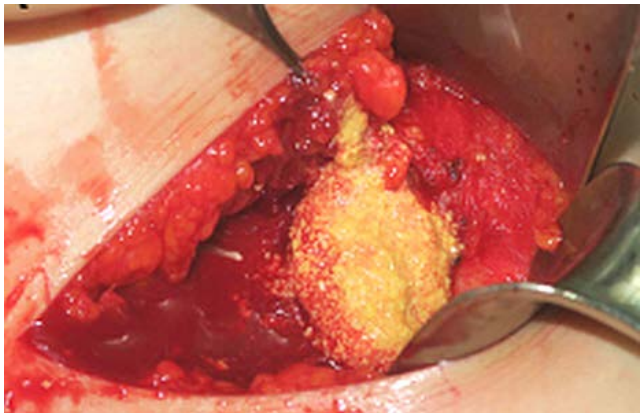


Fig. 3. A 50-year-old woman with a history of PAAG injection 18 years ago. (**a**, **b**) Both mediolateral oblique views demonstrating diffuse foreign body material in the retromammary area with internal dystrophic calcifications. (**c**) Injected foreign body materials were mainly located in the retropectoral area. (**d**) An approximately 1.8-cm irregular hypoechoic mass with increased internal vascularity was observed in the left lower outer breast, palpable area. (**e**) On MRI, large amount of PAAG collection in the retroglandular area with mammography correlated calcifications. (**f**, **e**) PAAG showing low signal intensity on T1-weighted imaging (**f**) and high signal on T2-weighted imaging (**e**) in the retroglandular area. (**g**) On T1, the axial post contrast image demonstrated multiple nodular enhancing lesions along the capsule lining that were more prominent at the left lower outer breast. (**h**) Axial silicone-only MRI for visualizing silicone implants showed low signal intensity, suggesting that the injected material was not silicone.



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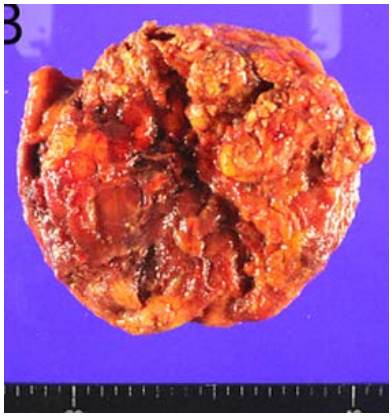

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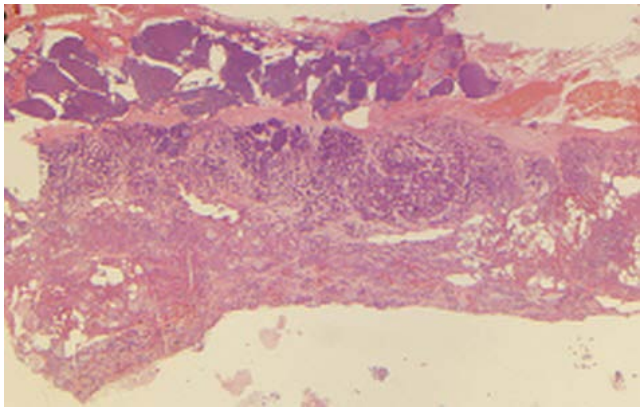

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Fig. 4. Intraoperative findings of a 50-year-old woman with a history of PAAG injection 18 years ago. (**a**) Purée-like yellowish PAAG leaked out of the capsule of the left breast. (**b**) PAAG-containing capsule after total capsulectomy of left breast. (**c**) Histopathological finding stained with hematoxylin and eosin showed multiple giant cells and calcification, suggesting the presence of a foreign body reaction with the PAAG. The stained PAAG was shown as purple materials. Fibrous capsule formation around the PAAG was seen.

Case 5

A 49-year-old woman with a history of both augmentation and injection of PAAG 13 years presented with palpable masses in both breasts. On MG and US, a large amount of retroglandular location of PAAG was collected in both breasts. At both palpable sites, isolated PAAG was observed on ultrasound, correlating with PAAG findings. No other mass was observed. On MRI, a large amount of filler injection material of retroglandular location was identified, showing T1 low signal intensity and T2 high signal intensity. There was no enhancing lesion in either breast.

Case 6

A 49-year-old woman with a history of both augmentation and injection of PAAG 8 years prior presented with palpable masses in both breasts. On MG and US, a large retroglandular location of PAAG was collected in both breasts. Additionally, multiple hypo- and isoechoic masses were observed along the lining of the injected foreign body material in both breasts, and some were combined with dystrophic calcifications. At the left far upper outer breast, an approximately 3.9-cm circumscribed oval heterogeneous echoic mass with increased vascularity was observed, and it was classified as BI-RADS category 4a. The patient underwent MRI for further evaluation. MRI indicated multiple enhancing lesions with wall thickening along the capsule lining of the injected foreign body material in both breasts, correlating with the US findings. Additionally, a lot of injected material was observed in the retropectoral area and in migrated lesions,

showing T1 low signal intensity and T2 high signal intensity, correlating with the findings of PAAG. The patient subsequently underwent US-guided core needle biopsy of BI-RADS category 4a lesions, and pathologic results demonstrated foreign body granuloma.

Discussion

PAAG was banned in 2006 by the China Food and Drug Administration due to massive complications. With the increase in the Chinese immigrant population in Korea and globalization, complications will appear more often in the coming decades. Little has been reported about breast cancer associated with PAAG fillers in the Korean literature. There is only one case reported in Korea who had a prior history of breast augmentation with PAAG injection in China (20). Here, we report six cases of women presenting clinical complications after PAAG injection and associated it with multimodality imaging findings.

Breast lumps was the most common clinical manifestations caused by gel collection, present at different depths and various sizes, as multiple or single masses, and localized or diffuse (1, 4). It is difficult for patients to discriminate a breast mass from filler hardening in the breast and subcutaneous tissue on self-examination, and this might mask the presentation of breast cancer, delaying early diagnosis. For example, there was a report of a patient with breast cancer who had delayed diagnosed after 300 ml of PAAG gel removal (7). Regarding gel migration, thin fibrous capsules around the gel are more likely to cause gel migration (13). PAAG can spread through direct expansion to create subcutaneous palpable nodules in the inframammary fold, axilla, sternum and infraclavicular region if the gel is injected in the subcutaneous layer, as seen in our cases (Case 1, Case 2, Case 3 and Case 6).

Additionally, the breast lump caused by gel collection may mimic malignancy (14). In the work-up of clinically symptomatic patients who have undergone a history of PAAG injection, mammography and ultrasound can be considered in the initial imaging method. On mammography, the density of PAAG is similar to that of normal breast parenchymal tissue, decreased the sensitivity of malignancy detection (13). On ultrasound, the PAAG was usually an anechoic or heterogeneous echotexture oval mass. There are only limited reports with MRI findings of PAAG augmentation complications. In a previous report (15), there was only thin enhancement along the lining of the PAAG material. In our case, enhancement with nodular or mass-like features was observed, which led to higher BI-RADS assessment. As of 2013, the American College of Radiology recommends breast MRI for cancer screening in patients with a history of breast augmentation, including silicone and PAAG augmentation, when it is inappropriate to evaluate whole breast with other imaging modalities.

The most concerning complication is the increased risk of breast cancer. In our study, four out of six cases showed suspicious findings on image evaluation (Case 1, Case 3, Case 4 and Case 6). One was pathologically confirmed to be malignant (Case 1). Therefore, it is necessary to perform a work-up for malignancy and high-risk lesions in cases with suspicious findings. To date, four cases of sporadic breast cancer following PAAG injection have been reported: pathologically diagnosed as invasive ductal carcinoma (three cases) and lobular cancer (one case) (5-8). Although there is no direct evidence about the carcinogenicity of PAAG in humans, operator should carefully consider the use of this agent, as various studies have indicated that PAAG exhibits cytotoxicity, inhibits the growth of human fibroblasts and causes the apoptosis of human fibroblasts (16-18). Additionally, PAAG induces an increase in the mRNA expression levels of specific genes, for example, c-myc, a regulatory gene that codes for a transcription factor that controls growth.

Diagnosis of breast cancer after PAAG-injected augmentation mammoplasty is more difficult than in previous augmentation mammoplasty patients with silicone implants because the gel lumps interfere with and delay visualization of the lesions. Therefore, invasive tumors and axillary node metastases may be more advanced, and systemic disease may thus have developed with a poor prognosis (5). Despite the lack of clear evidence that PAAG injection is a high risk for breast cancer, close follow-up is recommended for those who have had PAAG augmentation mammoplasty to allow early diagnosis and treatment of breast cancer.

Wang et al. (3) described complications related to pregnancy, showing that PAAG injections cause acute inflammation and galactocele formation during breastfeeding. Large amount of PAAG has the potential to cause mastodynia, due to fibrosis and blockage of ducts due to the osmotic self-expansion of PAAG. This gel-like substance mixes with breast milk and cannot be excreted. These deposits of PAAG gel can become an infection and inflammation source in breast parenchyma tissue. Additionally, the pressure that is a result of injection may suppress lactiferous ducts, resulting in narrowing. The outflow of breast milk is blocked and causes fermentation in a short time, and the rapid growth of bacteria contributes to infection (3).

Recently, Jin et al. (11) described diagnostic classifications for PAAG injection breast augmentation and a management strategy based on the classifications. According to the clinical presentations and imaging findings, complications of PAAG injection can be divided into four types: type I: filler is concentrated in the posterior of the breast tissue and is a single mass without displacement; type II: filler is scattered in different layers of the anterior chest wall (behind and in the breast tissue, subcutaneous tissue and muscle) with no displacement; type III: some of the filler migrates from the original; and type IV: includes both type II and type III (11, 19). According to these classifications, this study included four cases of type III (most common, Case 3, Case 4, Case 5 and Case 6) and two type IV (Case 1 and Case 2). It is difficult to treat widely scattered and displaced materials, especially in type II, III and IV complications. The only treatment for these complications is debridement surgery, which includes PAAG evacuation, capsule removal, lesion excision, and mastectomy (20, 22), and complete surgical removal of PAAG is impossible (23). There are many treatment options reported in the literature, and there is no standard treatment regimen. Therefore, Jin et al. (11) described different treatment regimens based on these classifications.

In summary, although PAAG is banned for use in breast augmentation, the patient population is widespread, and delayed complications were observed. Thus, it is important to know the typical imaging findings of PAAG injection material and related complications to prevent delayed diagnosis.

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유방 성형을 위한 폴리아크릴아마이드 하이드로겔 주입술의 합병증과 영상학적 소견

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폴리아크릴아마이드 하이드로겔은 1997년부터 2006년까지 동유럽, 러시아, 이란, 중국에서 유방 확대 성형을 위해 사용되었다. 약 300,000명의 여성이 폴리아크릴아마이드 하이드로겔 주입술을 시행 받았다. 최근 우리는 폴리아크릴아마이드 하이드로겔 주입술과 관련된 여러 합병증 사례를 경험했으며, 그 중 2 명은 2006년 중국 식품 의약국이 이 물질을 금지 한 후에 폴리아크릴아마이드 하이드로겔 주사를 맞았다. 이 연구에서 우리는 폴리아크릴아마이드 하이드로겔 주입 유방 확대술 환자의 합병증과 영상학적인 소견을 평가하고자 한다. 6 건 중 4 건에서는 악성이 의심되는 영상학적인 소견을 보였다. 그 중 25 세 여성에서 침윤성 유방암으로 확인 된 사례가 1 건 있었다. 따라서 PAAG 주사 병력이 있는 환자에서 특히 의심스러운 소견이 있을 경우 다양한 유방 영상 검사를 통한 철저한 검사와 필요할 경우 병리학적 조직 생검을 고려해야 한다.

Index words: Polyacrylamide hydrogel; PAAG; Multimodality Imaging; Breast Cancer

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