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Case Report

A rare reaction to a common procedure - anaphylactoid reaction to PEG push pad found in breast tissue markers

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ABSTRACT

Polyethylene glycol (PEG) is a synthetic polymer used in a multitude of medical and non-medical settings. Allergy to PEG is a rare but potentially life-threatening condition. We report a case of an anaphylactoid reaction to the PEG component of a breast tissue marker and its subsequent removal using a vacuum assisted biopsy device. We believe this is an important case to draw attention to the fact that PEG is an additive in multiple medications and devices and the product information must be carefully reviewed when planning to administer a medication or device in a patient with a known PEG allergy. This case also highlights the use of vacuum assisted excision as an appropriate non-surgical means of intervention in managing this unusual event.

Keywords: Polyethylene glycol, Anaphylaxis, breast, Vacuum assisted biopsy

INTRODUCTION

Allergy to polyethylene glycol (PEG) is an uncommon yet potentially life-threatening occurrence. Recently it has been publicized as an allergen due to its presence as an additive in COVID-19 vaccinations.[1] However, most clinicians do not appreciate that this material can also be found in certain breast tissue markers. We report the case of a middle-aged woman with a known PEG allergy who developed an anaphylactoid reaction after undergoing a routine breast tissue marker placement as part of a breast screening program in the outpatient setting. The responsible element was the small PEG containing push pad which was used to deliver the marker into the tissue. The role of vacuum assisted biopsy (VAB) devices in the management of breast patients has become significantly enhanced in recent years, not only in the utility of these devices to perform large sample biopsies but also in the ability of large bore VAB needles to achieve complete excision of breast lesions (vacuum assisted excision, VAE).[2] In this case a VAB device was used to perform the breast biopsy, but it was also successful in enabling VAE of the inserted allergy inducing marker clip, thus avoiding the need for open surgical extraction. This case highlights the importance of medical practitioners carrying out appropriate checks of the constituent make-up of medical products before they are inserted into the bodies of patients to avoid potential allergic reactions. Even small quantities of allergens can cause significant reactions. It is also the responsibility of manufacturers to provide clear labelling of medical products to inform the health provider.

CASE REPORT

A 50-year-old otherwise healthy woman presented to BreastScreen Australia for routine screening mammography as part of the Queensland statewide breast

screening service. She was recalled for a small focus of calcification within her right breast which was further assessed with additional mammographic films and ultrasound. It was recommended that she undergo a mammographic guided breast biopsy given the lack of benign features on mammography and absence of an ultrasound correlate. This biopsy was performed under mammographic guidance using a 10 G vacuum assisted breast biopsy device. Calcification was obtained within the biopsy specimen and as is the standard of practice, a mammographically visible clip (SenoMark® Ultra 10 Gauge Ribbon marker-SMEC10R) was deployed to identify the biopsy site. (Figure 1).[3]

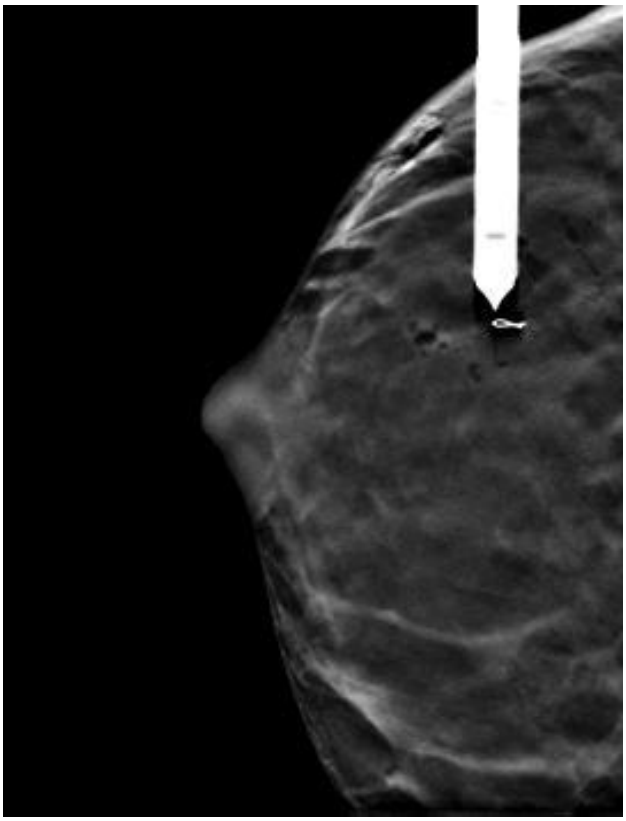

Figure 1: Breast tissue marker seen with mammography after being deployed.

The subsequent histopathology showed benign changes only consistent with fibrocystic change. The patient had a known allergy to polyethylene glycol (PEG) diagnosed after having previously required ICU admissions. She had historically suffered reactions to Macrogol (Movicol) oral laxative, hepatitis B vaccine and the COVID-19 vaccine made by Pfizer, all of which contain PEG in their formulations. Her PEG allergy had been confirmed by immunological skin testing.

Following clip deployment, the patient was observed for a short time due to biopsy related hematoma before being discharged. Shortly thereafter she began to experience symptoms that she associated with her previous allergic reactions (generalised pruritus, hives, rash, shortness of breath, wheeze and presyncope). She self-administered adrenaline in the form of an EpiPen that she carried with her and presented to a medical facility whereupon she was given another EpiPen, and an ambulance was called for transport to hospital.

Following antihistamine medication and observation in the emergency department she was allowed to go home. Despite returning to work the next day she continued to feel unwell with no overt anaphylactic signs. She contacted the breast screen facility, and the ingredients of the deployed clip were interrogated, at which time it was realized that PEG was listed as an ingredient of one of the components of the clip.

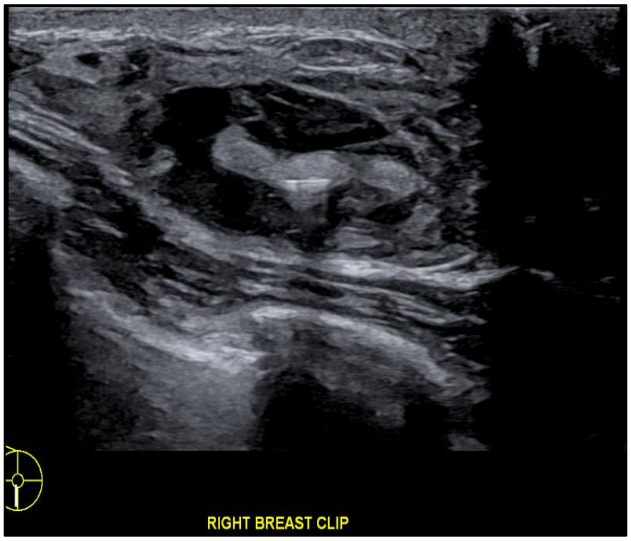

Figure 2: Marker pads with clip within haematoma.

It was recommended that she present to hospital where she was admitted under the breast and endocrine surgical team with immunology consultation, and following discussion between radiology and surgery it was elected to attempt removal of the clip under imaging guidance. Ultrasound of the biopsy site revealed a hypoechoic haematoma which corresponded to a clinically apparent lump in the inferior breast. Within the haematoma, there were a number of echogenic tubular structures representing the expandable pellets of the clip deployment. One of these pellets contained a linear very echogenic structure corresponding to the metallic clip (Figure 2). A subcutaneous dose of adrenaline was drawn up and a crash trolley positioned within the procedure room in case the procedure triggered a further anaphylactic reaction. Local anaesthetic (combination of 1% lignocaine, and 1% lignocaine with 1:1000 adrenaline) was injected underneath the haematoma to develop a plane for the subsequent placement of a 7-gauge vacuum biopsy needle using BD EnCor Enspire brand device. Under real time ultrasound visualisation, the multiple echogenic pads were removed and the haematoma evacuated. Subsequent examination of the biopsy sample demonstrated the pellets, and radiograph confirmed the clip had been removed and was contained within the specimen. (Figures 3-5).

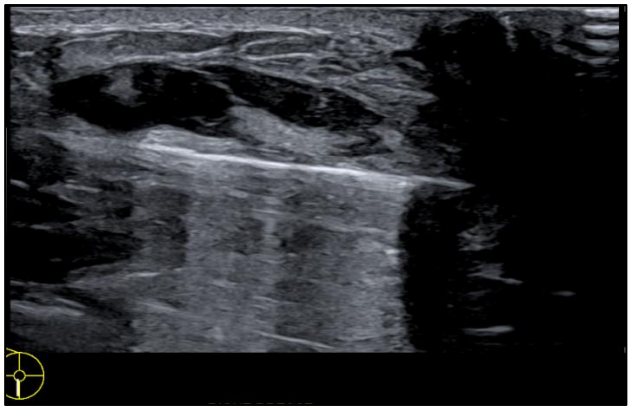

Figure 3: Insertion of large 7G gauge needle.

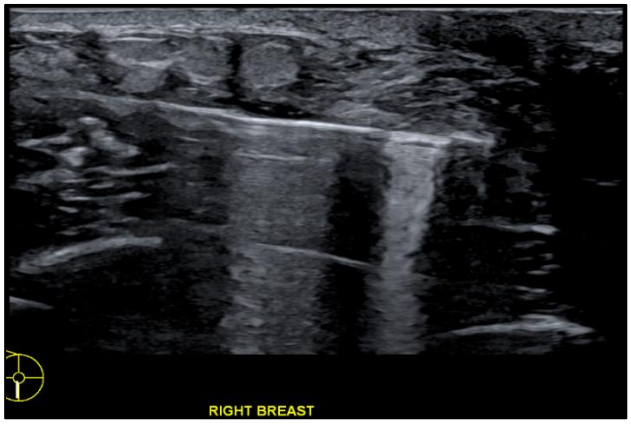

Figure 4: Post removal tissue marker and evacuation haematoma.

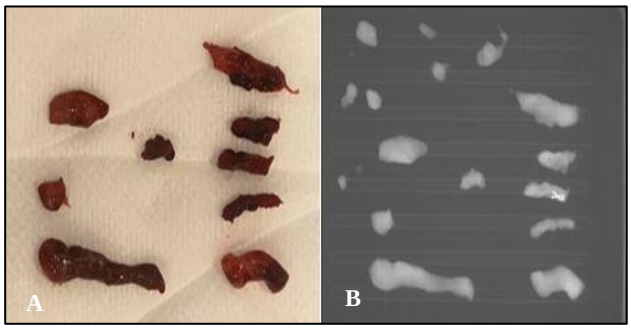

Figure 5 (A & B): Removed tissue with pads and marker along with corresponding X-ray.

There were no immediate complications, and the patient was discharged the next day with immunology review and follow up. She reported that her symptoms completely resolved following removal of the clip and pellets.

DISCUSSION

Polyethylene glycol (PEG) and its derivatives encompass a wide subset of synthetic polymers that are used in a variety of medical and nonmedical settings. They are noted to be water soluble, non-toxic, inert, odorless, colorless, non-volatile, and highly soluble in water and organic solvents making them ideal for delivery of medicines or devices.[4]

U.S. FDA Center for Devices and Radiological Health had issued a report on the safety of PEG, however it noted multiple gaps in the literature including low quality evidence in the randomized control trials that included PEG.[5] Nonetheless, their safety appears to stem from the rare occurrence of adverse events in the number of medications and/or devices that are currently in use.[4] As an active ingredient, PEG is used in laxative and colonoscopy preparations. It is also used as an inactive ingredient (excipient) in multiple medications including but not limited to antibiotics and steroid medications as well as notable certain preparations of the COVID-19 vaccine.[4] Outside the medical environment, low molecular weight PEG is often present in toothpaste, cosmetics, moisturizers, mouthwashes, hand sanitizers, shower gels, and soaps.[6] PEG is also, as in this case, used in the delivery device of certain breast tissue markers. In this specific case, the marker in question "SenoMark® Ultra 10 Gauge Ribbon marker-SMEC10R" is comprised of three polyglycolic acid (PGA) microfiber absorbent pads.[3] The titanium marker is delivered within the central pad. These pads are intended to be ultrasound visible and to expand upon contact with body fluids to help keep the tissue marker in place. A fourth component (a push pad) is also delivered with the clip deployment; this is made of PEG (Figure 6).[7]

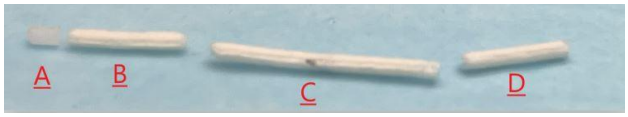

Figure 6: Deployed marker constituents, proximal to distal (A) PEG push pad; (B, D) PGA pads; (C) PGA pad with titanium clip.

PEG allergy appears to be rare and inconsistent. It is categorized as an immediate hypersensitivity reaction mediated by IgE (type 1 reaction). It can manifest with the usual symptoms of anaphylaxis such as a pruritus, tingling, flushing, urticaria, angioedema, hypotension, and bronchospasm.[6,8] German study after the COVID-19 Vaccine reactions found a total of 211 proven cases of PEG allergy worldwide between 1977 and 2022.[1] The manufacturer of the breast tissue marker used in this case (BD, BARD) is presently aware of a total of 3 cases (including this one) of allergic reaction that can be attributed to PEG in the lifetime of the company.[7] The hydrogel marker clip marketed by Mammotome also contains PEG.[9]

In this case the patient experienced a haematoma that was noted to surround the clip and pads at the time of removal. It is speculated that this may have lessened the allergic reaction by limiting the body's exposure to the

antigen, given that the haematoma surrounded the PEG push pad. Notably the patient reported that the general feeling of unwellness that she had experienced from the time of clip placement resolved completely following removal. The removal was performed under ultrasound guidance using a vacuum assisted biopsy device. A 7-gauge needle was selected as the largest available gauge for this particular device in order to maximize the chance of removal.

A generous volume of lignocaine/adrenaline mixture was used for analgesia but also to elevate the haematoma from the chest wall and allow the needle placement deep to the haematoma and foreign material. The vacuum biopsy was directed anteriorly to evacuate the haematoma and remove the clip and additional foreign material. This was confirmed by visual inspection of the removed material as well as radiograph (Figure 6). The procedure was well tolerated and able to be performed under local anaesthetic. Preparations were made for the possibility of a worsening of the patient's allergy; appropriate doses of adrenaline were drawn up and ready and a crash cart was positioned in the procedure room. The patient was also admitted to hospital pre procedure and for observation post. Fortunately, no further allergy was experienced, and the patient was able to be uneventfully discharged the next day.

CONCLUSION

This case illustrates the importance of clarifying the composition of materials being placed into a patient, which goes beyond the device or medication and includes the supportive materials, especially in a patient who is known to have an allergy as in this case. We speculate that the presence of haematoma in this case that surrounded the biopsy clip, pads and push pad may have minimized the allergic reaction by limiting the bodies exposure to the allergen in the push pad. Authors also demonstrated the utility of non-surgical removal of the marker clip using a large bore handheld vacuum assisted biopsy device under ultrasound visualization. This is a reasonable alternative to surgical removal if the appropriate equipment and expertise is available, however should be performed in the hospital environment with appropriate surgical and anaesthetic backup, should it be required.

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