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Sentinel lymph node biopsy in a patient with ruptured poly implant prothese (PIP) implants: A case report



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ABSTRACT

INTRODUCTION: Around 400,000 silicone gel breast implants produced by the French company poly implant prothese (PIP) were used worldwide. Following revelations that the company were using non-medical grade silicone for the production of their implants there has been growing concern over the increased rupture rate of these implants and the implications this may have on patients.

PRESENTATION OF CASE: We report the case of a 57-year old lady with ruptured bilateral cosmetic PIP breast implants in whom a right breast lesion was detected on screening mammograms. Biopsies demonstrated a grade 1 tubular carcinoma. Histology from the sentinel lymph node biopsy showed axillary silicone granulomas but no evidence of metastatic disease.

DISCUSSION: To our knowledge, this is the first reported case to describe SLNB in the presence of ruptured PIP implants, although SLNB in ruptured non-PIP implants has been previously described.

CONCLUSION: We conclude that SLNB can be utilised even in the context of concurrent PIP implant rupture and the presence of silicone granulomas in the axillary lymph nodes.

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1. Introduction

Around 400,000 silicone gel breast implants produced by the French company poly implant prothese (PIP) were used worldwide. Initially, the gel used was the standard medical grade Nusil Med3-6300 (Nusil Technology LLC, Carpinteria, CA).¹ The company however gained notoriety in 2011 when it was revealed that they were manufacturing implants with unapproved, in-house manufactured industrial-grade gel (PIP1 and PIP2) instead of medical-grade silicone. The PIP gels contained lower molecular weight silicone which had an increased propensity to diffuse through the implant shell and also had an irritant potential, causing local inflammatory reactions¹ Figs. 1–3

Since this has come to light there has been growing concern over the increased rupture rate of these implants and the implications this may have on patients. However, the UK government has reported that there is no evidence that the implants pose any harm to human health.²

In France, breast cancer has been found in 64 women with PIP breast implants but French health authorities insist there is still no proven link with the disease.³ Despite reports of breast cancer in patients with PIP implants there are no reported cases in the literature to evaluate the role of sentinel lymph node biopsy (SLNB) in the presence of a ruptured PIP implant. Given that 1 in 8 women

will develop breast cancer throughout their lives⁴ it is likely that the assessment of sentinel lymph nodes in the presence of a ruptured PIP implant will become a significant problem in the future. In the presence of ordinary silicone implants there is a theoretical risk that SLNB may be unsuccessful leading to a falsely negative result.⁵ The possibility of disrupted lymphatic channels from previous breast augmentation has been examined previously⁶ with a 100% success rate in localising the sentinel lymph node. The impact of the use of non-medical grade silicone in PIP implants and its effect on lymphatic mapping in SLNB is unknown.

Warbick-Smith et al. (2012)⁷ recently reported a case-report of SLNB performed in the context of ipsilateral non-PIP implant rupture. Our case report is the first to our knowledge of a lady with ruptured PIP implants who underwent surgery for breast cancer and had a SLNB.

2. Case report

Patient X, aged 57 years, underwent bilateral cosmetic augmentation mammoplasty with PIP implants at another institution 7 years ago. The implants used were 330mls each and were placed via infra-mammary incisions in the subglandular position. At her third round of screening on the NHS Breast Screening Programme (NHSBSP), she was recalled after a suspicious opacity was identified on her right mammogram.

Clinical examination confirmed bilateral grade 3 capsular contractures with no palpable breast lumps. Mammography showed

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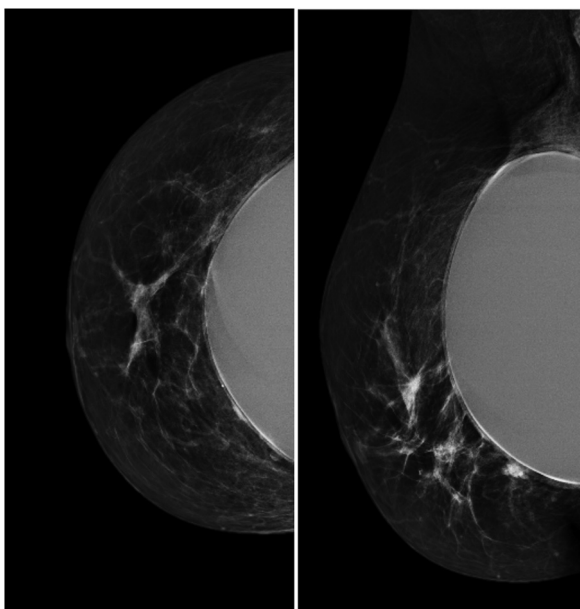


Fig. 1. Right mammogram CC and MLO views (left to right).

a small density adjacent to the right implant in the lower half of the breast which was best seen on the oblique view. An ultrasound scan failed to identify any abnormality and an MRI was performed for further assessment.

This showed that both implants had ruptured and demonstrated the presence of silicone in the right axillary and left retropectoral nodes. The gadolinium enhanced images revealed a lesion in the right breast measuring 9 mm in diameter. A repeat ultrasound scan showed a small echo-poor mass in the right breast at the site of the MRI abnormality and silicone filled nodes in the right axilla. As these nodes did not appear suspicious a biopsy or FNA was not performed preoperatively.

Histology of a core biopsy specimen revealed a grade 1 ER positive Her2 negative tubular carcinoma in the right breast and the patient was counselled for ultrasound skin-marked breast conservation surgery and sentinel lymph node biopsy using the dual technique for localisation.

One day prior to surgery, the patient had injection of the radioisotope Tc^{99} into the right breast and ultrasound guided skin marking of the breast lesion itself. Sentinel lymph node biopsy was performed by subareolar injection of 2 ml of Patent Blue dye and sentinel nodes were identified using the dual technique. Lymph nodes which were both blue and had high signals were excised with the largest measuring 15 mm. Intra-operative assessment of the axilla revealed no palpable residual lymphadenopathy. Specimen X-ray revealed adequate circumferential margins but spicules towards the deep margin, closest to the implant surface.

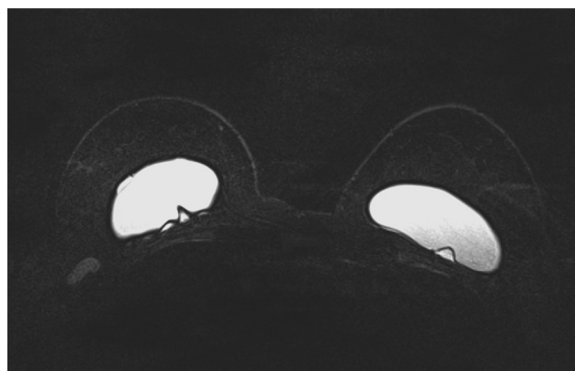


Fig. 2. MRI showing silicone filled right axillary lymph node.

Formal histology of the specimen revealed a 6 mm grade 1, ER positive, Her2 negative tubular carcinoma which was completely excised, the deep margin being nearest at 1 mm. Five lymph nodes were analysed from the sentinel lymph node biopsy all of which were negative for metastatic disease. There was evidence of florid granulomatous inflammation within all the nodes consistent with silicone granulomas.

The patient declined postoperative radiotherapy but at her own request underwent bilateral removal and exchange of implants with capsulectomy by a plastic surgeon.

3. Discussion

SLNB for breast cancer was rapidly incorporated into mainstream practice after its introduction by Giuliano et al.⁸ SLNB is now regarded as the surgical nodal staging technique of choice for patients with clinically node negative disease. As experience and comfort with the procedure has grown, studies have shown that SLNB is both feasible and accurate in staging the axilla in many clinical situations which may have initially felt to represent contraindications.^{9–12} The 2014 American Society Clinical Oncology guidelines¹³ support the practice of SLNB in women with previous non-oncological breast and axillary surgery.

Advances in implant technology have minimised the rate of silicone lymphadenopathy by reducing release of gel from rupture or bleeding of silicone. Zambacos et al.¹⁴ reported on silicone lymphadenopathy following implant augmentation before and after the year 2000. Pre-2000, the mean age of implant at explantation was 11.16 years compared to 4.06 years post-2000—the difference accounted for by the vast number of PIP implants used post-2000.

Implant rupture and implications for subsequent SLNB is an important topic. Authors of a recent case report have cautiously suggested that SLNB was viable even in breasts exposed to leaking or ruptured silicone implants.⁷ There have been several other studies describing the success of SLNB in augmented breasts but none describe SLNB in patients in the presence of ruptured PIP

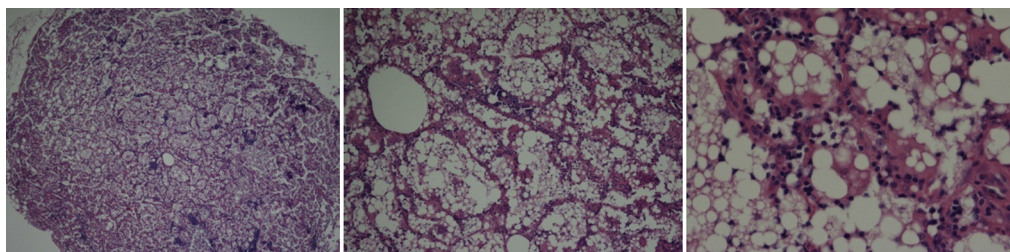


Fig. 3. Histology of SLN showing silicone granulomas – 4×, 10× and 40× magnification (left to right).

implants.^{15,16} The use of non-medical grade silicone in PIP implants adds another level of uncertainty. There is no evidence to suggest that despite the increase rate of rupture in such implants there is a link to cancer.

In the UK, it is estimated that over 40,000 women had PIP implants for mainly cosmetic surgery (95%). Advice on removal of these devices has varied globally with certain countries (for example France) recommending the routine removal of these implants. An expert advisory group in the UK convened by Professor Sir Bruce Keogh recommended that the routine removal of PIP implants in the absence of symptoms was not necessary.¹⁷ In addition, the NHS would remove PIP implants but not replace them in circumstances where private clinics had failed to support this group of women. Much controversy still exists today and it is likely that future reviews will assess the regulation of cosmetic surgery practices.

Our case is the first to our knowledge to describe SLNB in the presence of a ruptured PIP implant and provides evidence that the procedure can be performed successfully. The sentinel lymph nodes retrieved had evidence of blue dye and radioactivity confirming that this is reliable even in the context of concurrent implant rupture and the presence of silicone granulomas in axillary nodes.

These cases are complex and best managed in a multi-disciplinary setting. Formal axillary dissection is likely to represent over-treatment in a subsequently node-negative axilla. In addition, discussions about adjuvant radiotherapy need to involve the radiation oncologist and cosmetic surgeon as issues of post-radiotherapy capsular contracture need to be considered and counselled appropriately.

In conclusion we suggest that SLNB is feasible in patients with ruptured PIP implants.

Conflict of interest

No conflict of interest.

Funding

None declared.

Ethical approval

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Author contributions

All authors contributed to either the writing, reviewing and submission of this case report.

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