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Case report

Ann. Ital. Chir.
e-publish 28 September 2012
pii: S2239253X12019883
www.annitalchir.com

Adelmo Gubitosi, Giovanni Docimo, Roberto Ruggiero, Alessandro Esposito, Emanuela Esposito, Fabrizio Foroni

Dipartimento di Chirurgia, Seconda Università degli Studi di Napoli

Breast implant (PIP), chronic inflammation and cancer: is there a connection? Case report

The "PIP problem", in the field of the breast augmentation, represents today a surgical epidemiological emergency. The massive media coverage produced a kind of mass fear and many women are asking for explantations. A 47 y.o. female, breasts implanted with PIP devices for breast augmentation in 1998, came to our clinic asking for explantation and excisional biopsy of a 2.5 cm nodule adjacent to the upper side of the breast implant capsule. The outcome of the pathologic examination of the excised nodule was: ductal infiltrating carcinoma of the breast, medium degree of differentiation. After 7 days from the first operation the patient underwent a skin-sparing mastectomy with axillary lymphadenectomy and immediate reconstruction by a submuscular placement of implant. The surgical specimen sent for pathologic examination revealed: "granulomatous inflammation by giant cells around extraneous material, lymph nodes, negative for cancer, showed extensive accumulation of foamy macrophages containing extraneous material". The findings of foreign material in granulomas and macrophages that are the primary inflammation body defense, suggest that the chronic inflammation, coming from mammary implants subject to leakage or/and osmotic shift, increase the risk of breast cancer. We therefore suggest improving the explantation/replacement of old implants.

KEY WORDS: Breast cancer, Extraneous material, Immediate breast reconstruction, Inflammation, Pip Implant.

Introduction

The "PIP problem", in the field of the breast augmentation, represents today a surgical epidemiological emergency. The massive media coverage produced a kind of mass fear and many women are asking for explantations. There are no univocal guide lines and the different European countries health institutions took different

ways to deal with the problem. Our case regards a 47 y.o woman who underwent a PIP implant in 1998 for breast augmentation. The implant was replaced in 2012 and during the operation an excisional biopsy of a nodule was performed (Breast implant replacement and excisional biopsy of a 2.5cm nodule). The patient was therefore scheduled for a skin sparing mastectomy with axillary lymphadenectomy and immediate prosthetic reconstruction, performed after seven days. The surgical specimen examination revealed a chronic inflammation with granulomas around foreign material and macrophages containing foreign material in axillary lymph nodes.

Materials and methods

A 47 y.o. female, breasts implanted with PIP devices for breast augmentation in 1998, came to our clinic (Fig. 1). She referred pain in the upper central area of the

Pervenuto in Redazione Giugno 2012. Accettato per la pubblicazione Agosto 2012.

Correspondence to: Prof. Adelmo Gubitosi (e:mail adelmo.gubitosi@unina2.it)



Fig. 1: Preoperative.



Fig. 2: postoperative (I op.)



Fig. 3: (II op.)

right breast, where a mass was palpable. The mass had approximately a nut like size (2 cm) and it was located along the rib. She previously underwent a breast MRI scan that revealed nothing but the absence of pathologic retraction and a very little periprosthetic fluid collection. She was also worried about the media coverage about PIP implants and asked for explantation. At the operation a 2.5 cm mass was found between the upper quadrants, adjacent to the upper side of the breast implant capsule. The mass was fully excised, the old implant couple was explanted intact and a new breast implant was inserted (Fig. 2). The outcome of the pathologic examination of the excised nodule was: ductal infiltrating carcinoma of the breast, medium degree of differentiation (G2; estrogen positivity <10%; Ki67 negative; C-erb negative). The patient underwent a total body CT scan and a total body bone scintigraphy that were both negative for metastasis. After 7 days from the first operation the patient underwent a skin-sparing mastectomy with axillary lymphadenectomy and immediate reconstruction by a submuscular placement of implant. (Fig. 3). The surgical specimen was sent for pathologic examination and revealed: "granulomatous inflammation by giant cells around extraneous material, large areas of fat necrosis and diffuse fibrosclerosis. Lymph nodes, negative for cancer, showed extensive accumulation of foamy macrophages containing extraneous material". The post-operative time was complication free and the patient was discharged on the third postoperative day. The patient was sent to the oncology unit for subsequent therapy.

Results

The outcomes were satisfactory from both the oncological and aesthetical viewpoints of, (Fig. 3). It was planned to improve the aesthetics of the breast, in the near future, with a new operation, looking for nipple reconstruction and volume adjustment.

Discussion and conclusion

There are no univocal guide lines and the different European countries health institutions took different ways to deal with the "PIP problem". On the 22nd of December 2011 MHRA (Medicines and Healthcare products Regulatory Agency – UK) emailed DH private offices with a further update following an EC teleconference, saying it was likely that the French would announce routine explantation and attach press lines that say the UK would not change its advice. The advice emphasised that there were no claims from any member states, including France and that they had new evidence concerning a causal link between cancer and breast implants. On the 23rd of December 2011 the French Ministry of Health announced its recommendation that all women with PIP implants should have them removed, on a preventative / non-emergency basis. It stated that there was no increased risk of cancer – the risk came from ruptures which may lead to inflammatory reactions. MHRA emailed DH private offices with an update following a further EC teleconference after the French announcement. France has not provided evidence supporting their action and other EC states have indicated they would not be following the French lead ¹. In Italy on the 22nd of December 2011 the "Consiglio Superiore di Sanità – sezioni congiunte II e V", having consulted with the main European health authorities, expressed the following opinions: 1) PIP implants are filled by a material that does not correspond to the European standards; 2) PIP implants were removed from the Italian market from the first of April 2010; 3) There is no increased risk of cancer; the risk comes from ruptures which may lead to inflammatory reactions; 4) Women with PIP implants have to meet their surgeons; 5) Hospitals and any health facility that inserted PIP implantations have to recall all the patients who underwent a PIP breast augmentation; 6) The Italian SSN (National Health Care) will cover the charge of any medical or surgical

needs in case of specific clinical indication ². Concerns about PIP implant elastomer and filler gel have been expressed in the literature since 2007 ³ and leakage and osmotic shifts in these devices has been reported ⁴. A recent report states that the media interest has been focussed on device safety, longevity and recently a possible association with lymphoma, specifically anaplastic large cell lymphoma (ALCL) ⁵. In the same paper the overall patient rupture rate for the PIP implant is 15.9–33.8% ⁵. In our case the pathological findings were represented by a “ductal infiltrating carcinoma of the breast, medium degree of differentiation (G2; estrogen positivity <10%; Ki67 negative; C-erb negative)” and “granulomatous inflammation by giant cells around extraneous material, large areas of fat necrosis, diffuse fibrosclerosis. Lymph nodes, negative for cancer, show extensive accumulation of foamy macrophages containing extraneous material”. In our patient the PIP implant was made in 1998 and the pathological findings show that there have been leakage and osmotic shift for a long time exposing the mammary tissues to a long chronic inflammation. The relationship between chronic inflammation and breast cancer has been described in the literature ⁶⁻¹³. The findings of foreign material in granulomas and macrophages that are the primary inflammation body defense, suggest that the chronic inflammation, coming from mammary implants subject to leakage or/and osmotic shift, increase the risk of breast cancer. We therefore suggest improving the explantation/replacement of old implants especially if they are low quality devices and the structure of the external layers of the implant is not whole, allowing leakage and osmotic shift. The decision to perform immediate breast reconstruction was made prior to psychological patient attitude bound to the aesthetics of her body, while respecting the relationship between psychological aspect and immune apparatus strength ¹⁴⁻¹⁶ together with technical and oncological feasibility ¹⁷⁻²².

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