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Poly Implant Prothèse (PIP) breast implants: Our experience☆

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ARTICLE INFO

Article history:
Received 16 December 2012
Received in revised form
22 January 2013
Accepted 18 February 2013
Available online 15 March 2013

Keywords:
PIP implants
Breast implants
Rupture

ABSTRACT

Introduction: This study describes our experience on the management of patients with PIP (Poly Implant Prothèse) breast implants between 2000 and 2008.
Materials and methods: The medical records of patients were reviewed. Data was collected on clinical presentation, investigations, management and outcome.
Results: 44 patients, with bilateral breast implants, and a median age of 33 years (18–54 years), were reviewed, and of these, 31 patients were asymptomatic. Symptoms at presentation included lymphadenopathy, capsule formation, breast lump, seroma and breast pain. Patients underwent mammography, ultrasound and MRI scanning of the breasts as part of the imaging investigations.

5 patients declined explantation. Reasons for explantation included patient anxiety, silent rupture, aesthetic breast change, palpable nodes and breast lump.

17 out of a total of 78 implants (21.8%) were noted to have ruptured; 2 had a simple tear and 15 were totally disintegrated. 1 patient underwent removal of the implants, 18 underwent exchange of implants, and 20 patients had a capsulotomy and exchange of implants. Postoperative complications included wound infection, seroma, axillary lymphadenopathy, hypersensitive scar and overgranulation of the wound.
Conclusion: Our series confirms the high rate of PIP implant rupture (21.8%), the majority of which were asymptomatic. The main reasons for explantation were patient anxiety and silent rupture of implants. It is imperative that patients should be appropriately counselled, prior to surgery with regards to removal of the implants, given the increased rupture rates noted.

Introduction

The controversy regarding the PIP breast implants has been well documented over the last two years. The French manufacturer Poly Implant Prothèse (PIP) had been using industrial grade silicone, rather than the purer medical grade, for the gel filler in the manufacture of silicone breast implants over the last 10 years.

In March 2010, the French medical device regulatory agency (AFSSAPS) suspended the marketing, distribution and use of all silicone implants produced by PIP.[1] The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK

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1479-666X/$ – see front matter
http://dx.doi.org/10.1016/j.surge.2013.02.006

followed suit and issued a warning in March 2010, leading to the withdrawal of all PIP implants.[2] Fears about the increased rupture rates of these implants and risks of genotoxicity have subsequently led to increased patient anxiety and media frenzy. Fortunately, studies carried out by the MHRA[3] and AFSSAPS[4] have allayed any fears of toxicity of the silicone gel filler used by PIP.

Most recently, the Department of Health (DoH) published its final expert report on the PIP breast implants, where it acknowledged that, although PIP implants were substandard and had an increased rate of rupture, due to a weakened shell, when compared to other commercially available breast implants, there was no evidence of any increased significant risk of clinical problems in the absence of rupture.[5] The report also provided patients with PIP implants a management algorithm as how to best proceed.

The aim of this study was therefore to review patients with PIP breast implants who were referred for further investigation and management.

Materials and methods

Patients who had undergone breast augmentation with PIP implants between 1999 and 2008 were identified from the hospital database and were invited for a non-obligatory free consultation, according to the MHRA guidance. At the time of consultation and depending on patients' desire and clinical findings, patients were advised to have imaging of their implants, whether in the form of ultrasound scan or magnetic resonance imaging.

The imaging of the implants depended on the referral source and also on how the controversy of the PIP implants evolved in the public domain. Patients initially seen and subsequently referred by the local breast unit underwent triple assessment, which included clinical examination, mammogram and ultrasound scanning of the implants. In May 2010, following the alert by BAPRAS (British Association of Plastic, Reconstructive and Aesthetic Surgeons) and BAAPS (British Association of Aesthetic Plastic Surgeons), the senior surgeon followed his patients with PIP implants with ultrasound scanning, which was provided free of charge by the local private hospital. By 2011, as the media frenzy on the PIP debacle became more apparent, the senior author's patients who had a normal ultrasound scan and new referred patients underwent MRI scanning of the implants, which was provided free of charge by the local private hospital. As such, we noted that the choice of imaging of the implants evolved with the situation.

Results

A total of 49 patients were identified having had PIP breast implants inserted. 5 patients declined any clinical or radiological investigations. All of the remaining 44 patients had their initial breast enhancement procedure done privately. 39 of the 44 patients had the initial procedure carried out at one private hospital. In 24 patients, the initial surgery was performed by various surgeons, other than the senior author.

The median age of the 44 patients was 33 years, with an age range of 18–54 years. The implants were inserted between 1999 and 2008, with the most patients (24) undergoing surgery in 2005. The implants used in 42 patients were round implants, with a median size of 350 cc (range 250–490 cc). No information on the implant size or type was available in 2 patients. Implants were placed sub-pectorally in 20 patients and in a sub-mammary position in 20 patients. The implant position was not documented in 4 patients.

At the time of clinical examination, 35 patients were noted to be asymptomatic. 2 patients had a Baker 3/4 capsule. 4 patients had axillary lymphadenopathy, which were shown to be silicone lymphadenitis. 1 patient presented with a breast lump and 1 patient complained of breast pain. One further patient had a seroma, of which 800 mls was aspirated in theatre (Fig. 1).

In terms of radiological investigations, 3 patients had mammograms, 22 underwent ultrasound scanning of the implants and 31 patients had an MRI. Of the 3 patients who had a mammogram, one was diagnosed with a ruptured implant, which was confirmed at the time of surgery, and one patient had a breast granuloma. 12 of the 22 patients who had an ultrasound were diagnosed with a ruptured implant (Fig. 2), 2 of which were noted to be intact at the time of surgery and 1 implant had gel bleed only. Of the 31 patients who had an MRI scan of the implants, 10 implants were ruptured.

One of these patients refused surgery and one implant was noted to be intact at the time of surgery, but had significant gel bleed. 5 patients declined explantation, including one patient with a ruptured implant noted on MRI. Of the 39 patients who desired explanation of the implants, anxiety was the reason in 18 patients and silent rupture (positive scan) in 15 patients. 3 patients felt that there was an aesthetic change in their breast appearance, 2 complained of a palpable axillary node and 1 patient presented with a breast lump. The mean follow-up time was 7 years. The year of explantation ranged between 2008 and 2012, with most implants (27) explanted in 2012. The median age at explantation was 42 years, with an age range of 24–60 years. Thirty-seven patients had the implant explantation carried out in the private sector, while 2 patients had their surgery performed in the NHS.

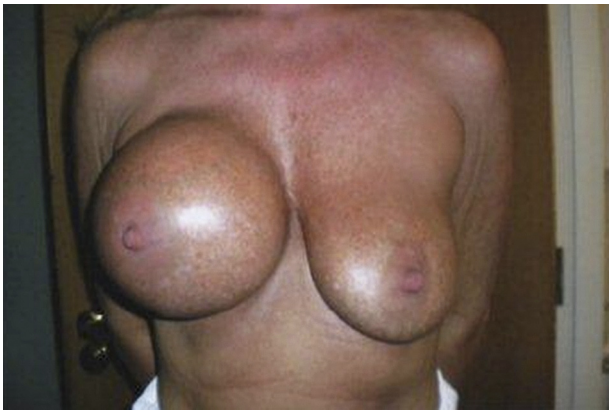

Fig. 1 – Patient presenting with 800 mls of seroma, which was aspirated in theatre.