Prevalence of Rupture in PIP Silicone Breast Implants, recalled since 2010 from the European market

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Abstract

Background

Known complications of silicone breast implants are rupture and silicone leakage, which is not only related to generation and implant age, but also to the manufacturer. Implants from the French manufacturer Poly Implant Prosthèses (PIP) showed more rupture than expected and were banned from the European market in 2009. Clinics in Europe recalled their patients, but prevalence of rupture in these implants has not been previously reported.

Methods

All women who underwent breast augmentation in 2000 and 2001 in the Jan van Goyen Clinic Amsterdam, the Netherlands, were informed about concerns regarding the quality of their implants. Medical records were used to trace manufacturer and implantation specifics. 112 women with proven PIP implants were enrolled in this study. All women underwent physical examination, magnetic resonance imaging and were interviewed for complaints to determine the prevalence of symptomatic and asymptomatic rupture.

Results

224 PIP implants were evaluated with a mean implant age of 122 months. Of these 224 implants 54 had ruptured. Magnetic resonance imaging showed that 33 percent of women had at least one ruptured implant. There was no significant difference in rupture rate of implants manufactured in 2000 and 2001.

Conclusion

1 in 3 women who had undergone breast augmentation with PIP implants were shown to have at least one ruptured implant after 10 years, 45.9 percent was bilateral and 13.5 percent had extra-capsular leakage. These were mostly asymptomatic ruptures. The rupture prevalence rate for PIP implants after 10 years is 24 percent.

Level of Evidence

Risk study:III

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INTRODUCTION

Silicone breast implants have been used for breast augmentation for over 5 decades. There have been 5 generations of silicone breast implants and they come in different shapes, sizes, shell layers and levels of projection. In the USA these implants were a subject of debate and introduced again on the market since their abolishment ended in 2006. In Europe they have been safely used throughout.

Rupture and silicone leakage are well known complications (1-3) of breast implants. The prevalence rate of rupture is not only related to generation and implant age, but also to the manufacturer (4). Case reports from 2006, have shown an unexpected high prevalence of rupture and silicone leakage in women with implants from the French manufacturer Poly Implant Prostheses (PIP) (5-6). Due to these reports, the manufacturer was inspected by the French health watchdog AFSSAPS (Agence Française de Sécurité sanitaire des Produits de Santé) in 2009. It was found that the silicone gel used in these implants from the manufacture year 2001 onwards was unauthorized for medical use, and approved instead for usage in matrasses and cushions (7). Since March 2010 PIP implants were therefore banned from the European market. Plastic surgeons were advised to recall women with PIP implants from the year 2001 onward to come for physical examination and in case of a suspected rupture to perform magnetic resonance imaging or ultrasound. If one of the implants was found ruptured, the advice was to remove both implants.

At our institution the brand PIP was the most frequently used breast implant for cosmetic augmentation in the years 2000 and 2001. It was decided to contact all women, who underwent augmentation in those years, although the advice was to recall women from 2001 only. The prevalence of rupture was determined using magnetic resonance imaging screening and the results are compared to the literature.

PATIENTS AND METHODS

All women (475) who underwent augmentation at the Jan van Goyen Clinic, Amsterdam, the Netherlands, in the years 2000 and 2001 with breast implants from the manufacturer PIP were informed by letter about the concerns of the quality of their implants. They were requested to come for follow up. All these women's medical records were used to trace manufacturer and implantation specifics. A cross-sectional study was designed without a control population to determine the point prevalence of implant rupture after 10 years.

Not all the women could be reached, because their contact information was found to be out of date. Of the 475 letters sent, 165 resulted in a follow up visit. During first enrollment, some women were found ineligible for the study for reasons such as having a different implant manufacturer (13 had Monobloc hydrogel, 18 had Mc Ghan, 5 were unknown), because no medical record could be found, an implantation date outside of the range or a contraindication for magnetic resonance imaging (13: pregnant, breastfeeding, claustrophobia, breast cancer, clear rupture on USS, cancelled and changed implants before follow up date). An additional four women had previous revisions and change of implants, excluding these and the above noted women, 112 unselected women with 224 proven PIP implants were enrolled in the study (see Figure 1 for study flowchart).

All women were interviewed and underwent a standardized clinical examination by a plastic surgeon, which included inspection and palpation. The following abnormal findings were documented: asymmetry, changed form, consistency and/or size and palpable masses in breasts or axilla. Capsular contractures was documented according to Baker classification (8).

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All women were referred to a single magnetic resonance imaging facility to conduct (silent) rupture screening according to an established protocol. All subjects completed magnetic resonance imaging screening within 6 weeks of the physical examination and 85 (76 percent) within 2 weeks. We obtained magnetic resonance images using a 1.5-T unit (Siemens Magnetom Symphony, Siemens Medical Solutions, Erlanger, Germany.) Open CP Breast array coils were used for imaging both breasts of each patient. STIR T2-weight axial images were obtained in all cases with image parameters as follows: echo times of 70 msec. STIR T2-weight axial and sagittal images with spectral suppression of silicone were obtained with echo time of 84 msec. STIR T2-weight axial and sagittal images were obtained with spectral suppression of water with echo time of 84 msec. All had repetition times of 2120 msec, IR of 140 msec, slice thickness of 4mm, 256 x 128 matrix and field of view of 320 x 320 mm.

The images were evaluated by an experienced radiologist using signs defined by protocol as either evidence for rupture or not and evidence for extra-capsular leakage or not.

In all analyses, the unit of observation was the woman, not the implant. The data was analyzed using SPSS 17.0. Quantitative standard statistical significance was used in Pearson chi-square tests of the data tables. The critical level of statistical significance chosen was $p < 0.05$.

RESULTS

At magnetic resonance imaging screening of 224 PIP implants 54 (24 percent) implants showed rupture. In 112 women magnetic resonance imaging showed rupture of at least one of their implants in 37 women (33 percent), of which 17 (45.9 percent) were ruptured bilateral and 5 (13.5 percent) presented with evidence of extra-capsular leakage. Of the 37 women with at least one ruptured implant only 12 (32.4 percent) had any pre-existing complaints, so called “symptomatic” ruptures, and the majority (68.6 percent) were asymptomatic or “silent” ruptures.

The mean age of the 112 enrolled women at the time of their implantation was 33.5 years (range 17 to 52 years.) Of these women 55 got augmented with PIP implants in 2000 and 57 in 2001. Their 224 proven PIP implants had a mean implant age of 122 months (range 111 to 133 months) at time of their physical examination. All implants were round shaped textured PIP silicone breast implants. The most frequently implanted size was 330ml and varied from 185 to 430ml. Of the 112 women 19 had their implants placed in a subpectoral position and 93 had their implants placed subglandular. Table 1 summarizes all characteristics of our study group and the results of the magnetic resonance imaging screening. We found no significant correlation between prevalence of at least one ruptured implant and the following factors: the volume and location of the implants, the age of the women at implantation and the implantation year. Most of the implants were positioned subglandular in our study group. Of the 93 women with subglandular implants 32 (34.4 percent) had at least one ruptured implant compared to the 5 out of 19 women (26.3 percent) with subpectorally placed implants, the difference however was not significant.

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Of the 112 women assessed by physical examination, 12 showed physical signs of rupture, 6 of which (50 percent) were confirmed by magnetic resonance imaging results. Table 2 lists the physical signs found and the frequency. Of the other 100 women (89.3 percent) not suspected of rupture by physical examination still 31 women had at least one ruptured implant on magnetic resonance imaging. There were 14 women with capsular contraction with Baker score 3 of which 7 had at least one of their implants ruptured and only one woman with Baker score 4, which was ruptured.

Only 34 of the 112 women (22 percent) mentioned any pre-existing complaints when interviewed. Table 3 lists the complaints raised by women. It must be noted however that in these women their symptoms were not a reason for them to come to the clinic independently for follow up. In the 78 women who reported no complaints magnetic resonance imaging still found rupture of at least one of their implants in 25 of these patients (32.5 percent).

Of the 55 women implanted in 2000, 17 (30.9 percent) had at least one ruptured implant compared to 35.1 percent in women who were implanted in 2001. In 2001 we saw more bilateral ruptured implants, 50 percent versus 41.2 percent in 2000 and more extra-capsular leakage.

DISCUSSION

Our study was initiated to study the prevalence of rupture from the manufacturer Poly Implants Prothèses, which have been banned from the European market since 2010, to investigate whether the case reports and suggested higher incidence of rupture in this brand could be objectified. A point prevalence of 24 percent rupture of implants after 10 years was found. To judge whether or not this is unacceptably high compared to other manufacturers, results were compared to the literature.

Silicone breast implants come in many generations. The second generation was found to have a higher prevalence of rupture, than the first and 3rd. The 3rd generation was made in an attempt to create a more cohesive silicone gel, but felt less natural. In Europe, the most recent generations “form stable” single-lumen enhanced cohesive silicone gel implants became available since the mid-1990s (9-11). The high cohesive silicone gel fillers have been replaced by moderately less cohesive gel and less cross-linking, in an attempt to prevent capsular contraction and to maintain a softer and more natural feel (9). The Poly Implant Prostheses (PIP) silicone implant is one of these newer implants and the cohesive silicone gel implant was advertised to have a strong elastomer shell which contains the PIP silicone gel, which is soft, retain memory and will not leech away from the shell, even when cut in half.

Our study was a direct consequence of the recall of these PIP implants with unauthorized content ordered by Europeans authorities in 2010. Until now the exact content of this silicone gel remains unclear. This makes it difficult to compare the prevalence of rupture in these implants with other implants introduced by other manufacturers around the same time. Macroscopically these implants do not differ much from other implants of the same fabrication year from other manufacturers. Image 1

shows modern moderate cohesive silicone gel breast implants that have been sliced open. The two outer implants shown are from the last generations of the manufacturer McGhan. The example in the middle is a PIP implant. The authors do have the opinion that the physical properties of the unauthorized gel used in 2001 has al less cohesive feel, than the gel of other implant brands.

Although a control group was not used in this study, 18 women were first enrolled in the study and had magnetic resonance imaging screening, while medical records later revealed they were implanted with Mc Ghan implants instead of PIP implants. Of these, only one woman (5.6 percent) showed a rupture of one of their implants. A point prevalence of 24 percent of implant rupture after 10 years is high when compared to modern generation implants (12-16), but comparable to older generation implants (3, 17-19). Table 4 shows an overview of magnetic resonance imaging studies and the point prevalence's of rupture reported in asymptomatic patients implanted with silicone implants of different manufacturers with a follow up of 10 years or longer. Recent studies on augmentation with modern high cohesive silicone gel implants reported implant rupture prevalence as low as 1.1 percent in Mentor implants(13) and 3.8 percent in Inamed implants (16) but after only a follow up period of 6 years. The 10 years results of these studies are yet to be published. Older studies with a follow up period of 10 years or more on the other hand also found relatively high number of asymptomatic implant rupture of 26 and 55 percent in patients with cosmetic implants (3, 19). These studies, however, include a variety of implants from different generations and manufacturers, which complicates comparison with our results.

The product recalled was from the year 2001 onward, as since March 2001 the unauthorized silicone gel was used, according to the French authorities. We however found a comparable prevalence rate of at

least one of their implants ruptured in women who were implanted in 2000. In 2001, more bilaterally ruptured implants were seen and more signs of extra-capsular leakage. Our study was not intended to investigate whether the cause of the high rupture rate was the unauthorized gel or not, but if the unauthorized gel is used only from March 2001 onward, we can conclude from our study that this unauthorized gel did not significally contribute to rupture rate. The fact that women with implants made by PIP before 2001 have a comparable high prevalence of rupture of their breast implants therefore suggests that not the unauthorized silicone gel, but a poor quality shell is in fact the cause of the higher prevalence of rupture in this specific brand. This theory is supported by previous reports on poor quality of the shell of implants with saline and hydrogel content of the same manufacturer (20-21). Hydrogel breast implants from this manufacturer raised concerns and were voluntarily withdrawn from the European and USA markets in December 2000 (22-23).

French authorities recently advised explantation of all PIP silicone breast implants from 2001 onward, other European authorities stick to the first advice to only explant PIP implants when proven leakage of at least one of both implants, but this has been under debate. Our results show that the international advice to only recall silicone implants from PIP from the year 2001 onward is unjust to women implanted in 2000 with a comparable high rupture rate. We can only conclude on implants from the year 2000, the year before the unauthorized gel was used, but more research is needed to conclude on previous years.

The results of our study provide a reliable estimate of long-term prevalence of silicone breast implant rupture of the French manufacturer PIP, however there are limitations. The exact timing of rupture in

our study is unknown. An incidence of rupture of these implants could only be reported if our cohort would be prospectively followed. Not all patients who underwent breast augmentation in 2000 and 2001 with PIP implants at our institution answered to the recall. Every study on implant rupture has the change of selection bias, but only a minority of our patients reported existing complaints. We therefore believe we managed to include randomly unselected women, who happen to be implanted with these banned PIP implants 10 years ago.

CONCLUSION

More than 1 in 3 patients who underwent breast augmentation with PIP implants were shown to have at least one of their implants ruptured after 10 years. The rupture prevalence rate in our study for PIP breast implants after 10 years is 24 percent, which is higher than in literature reported prevalence data on most modern implants, but comparable to previous generations. The majority of affected women are women with asymptomatic intracapsular rupture of at least one of their implants. PIP breast implants from the year 2000 show no significant difference in prevalence compared to the breast implants with the unauthorized silicone gel from 2001. We suggest that not the unauthorized silicone gel, but a bad quality shell, is the cause of the higher likelihood of rupture in this brand. The advice of European authorities to recall women with PIP implants from 2001 onward seems to be unjustified. The content of the gel doesn't contribute to the high rupture rate in PIP implants, but the fact that the rupture prevalence is unacceptably high, should according to the authors be the reason to explant all PIP implants no matter fabrication year. We suggest that further information is needed regarding the prevalence rate of other brands of modern implant rupturing after 10 years to comparable to our results of PIP silicone implant rupture prevalence.

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LEGENDS

- Figure 1. Study flowchart
- Table 1. Characteristics, frequency and prevalence of ruptured implants in 112 women with implants from the manufacturer Poly Implant Prostèses
- Table 2. Findings at physical examination and frequency
- Table 3. Self-reported complaints and frequency
- Table 4. Review of literature on prevalence of silicone breast implant rupture in asymptomatic women with a follow up of 10 years or more
- Figure 2. Picture of 3 last generation silicone breast implants with a PIP implant between two Mc Ghan implants