Important new information about a case of breast anaplastic large cell lymphoma in a woman who has had breast implants prefilled with silicone gel PIP (French company Poly Implants Prothèses)

Breast anaplastic large cell lymphoma with breast implants.

This is a malignant tumour of the lymphatic system developed at the expense of particular T lymphocytes and not of epithelial tissue of the breast. Several cases of this type of lymphoma have been described in the literature, which led the FDA to publish in January 2011 a review of this new risk potentially associated with breast implants.

In the United States,
The FDA has identified in January 2011, 60 cases associated with a breast prosthesis and reported worldwide, including 34 located in the breast and documented (17 in USA.). This particular type of lymphoma is very rare among all lymphomas: as recorded by American cancer registers (SEER), it is estimated that one woman out of 500,000 suffers from this type of lymphoma each year in the United States. The location in breast of this form of lymphoma is even more rare. The projection in the United States is of 3 cases per year over 100 million women.
Considering that nearly 4 million women have been implanted with breast implants in the United States between 1998 and 2009, the FDA believes that in the United States, the incidence of anaplastic large cell lymphoma is higher in women with breast implants compared with the epidemiological data observed for the general population.

About anaplastic large cell lymphoma, the FDA concluded in January 2011:
1. to a "possible" association of this type of lymphoma with prosthesis, reinforced by the fact that the cases described occurred preferentially in areas at the near proximity of the prosthesis;
2. to be today unable to connect reliably this serious event to a type of prosthesis;
3. that the physiopathological cause of this serious event is not established today;
4. that, given the extremely low frequency of this type of lymphoma and given evidence collected today on breast implants, the safety of these products is not in question.

In France,
A fatal case has been reported to Afssaps on November 25th, 2011. The concerned patient, carrier of PIP prostheses, presented a breast anaplastic large cell lymphoma.
This case reported in France is in itself a factor to be considered epidemiologically as occurring in a woman among the 30 000 carriers of PIP prosthesis which have been removed from the market.

PIP prostheses removed from French market on March 29th, 2010.

The first abnormalities clinically observed and reported within the medical device vigilance system, showed at the end of 2009, an increase of rupture for the PIP breast implants, leading to a rupture rate higher than the rate observed with implants from other manufacturers.
Abnormal oozing phenomenon (also called perspiration or transudation) of the gel was also observed.

Inspections and controls performed by Afssaps have documented several nonconformities justifying the suspension of PIP prostheses from the market on March 29th, 2010.

These failures were :

- On the nature of the silicone gel inside the prosthesis: the gel did not have the degree of quality of a silicone gel for breast implants;
- On the mechanical strength of the prosthesis: the tear elongation test was not in compliance. This result showed a weakness of PIP gel-filled envelopes and corroborates the observations of retrospective surveys conducted by Afssaps with many user establishments of these prostheses. They revealed a rupture rate higher than the average;
- On the "irritant behaviour" of the silicone gel used for PIP prostheses which is neither found with silicone gels of other prostheses nor with the gel described in the technical documentation for the placing on the market. This can lead to inflammatory reactions in some patients,
- On the lack of genotoxicity of the gel used, which does not exclude that the oozing of the gel in contact with the capsule may have contributed to the development of anaplastic large cell lymphoma: in fact, abnormal oozing of a particularly irritating gel could be a factor of risk of occurrence of this rare tumour.

Follow-up of recommendations

These recent events in France led Afssaps to update its recommendations sent to the whole medical profession in April 2011 to enable it to respond to each individual situation:

- Patients should routinely receive a clinical examination and an ultrasound scan every 6 months, targeting for each of these examinations, breast and axillaries lymph node areas;
- Any rupture, suspected rupture or oozing of a prosthesis should lead to its explantation, as well as that of the second prosthesis.

Afssaps recommends that patients contact their surgeon to discuss the possibility of explantation even without clinical signs of deterioration of the prosthesis. The concerned women will consider the most appropriate attitude according to their personal situation, their feelings, the age of their prostheses and their expectations at the aesthetic level. This choice will take place after evaluation with the surgeon of the individual risk / benefit ratio.

Conditions for medical expenses within health insurance in France are :

- All women with PIP breast implants will be reimbursed for their medical and surgical expenses related to explantation (ultrasound, analysis, implant removal, examination post-operative).
- Women who are recovering from a reconstruction after breast cancer surgery will also be reimbursed for the implantation of a new prosthesis.

Necessary information is available on the website of the French Health Insurance:
http://www.ameli.fr/assures/soins-et-remboursements/combien-serez-vous-rembourse/implantsmammaires.php