Silicone Gel Mammary Prostheses in Albania and Breast-Feeding

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Abstract

We would define the security of silicone gel prostheses for the mother, the effects of an eventual contamination of maternal milk, if this condition is associate with elevate concentrations of silicone in the blood of their sons and if the silicon presence in correlate with immune pathology in the newborn. The aim of our study is to give an answer to these questions. From the December 2014 to December 2015, we were selected 20 women with ending pregnancy and mammary silicone gel prostheses. A commonly instruments were used to evaluate the concentration of antibodies, the silicone concentration was evaluated by spectroscopic analysis and devices silicone free were used. The tests results was elaborates statistically to verify the relation coefficient between the prostheses presence and the values of tests. The antibodies rate in all groups was compared and the difference wasn't significant. The evaluation of the concentration of inflammatory proteins in the newborn blood was performed at the start of the breast-feeding. The results were compared by t Student test. Our results concord with the other present in literature. The search of haematic and antibody markers, helpful in the diagnosis of immune pathology, not put in evidence a peculiar relation cause-effect and it's absolute not specific. The same result is observe in the analysis of the newborns antibody rates in A group that in all tests haven't a statistic significance.

Keywords: Augmentation mammoplasty, mammary prostheses, silicone, breast-feeding.

1. Introduction

Augmentation mammoplasty was object of numerous controversies: could the mammary prostheses presence consider as risk factor for woman' pregnancy, lactation or fetus development? Could the silicone during the puerperium contaminates the milk and predisposes the newborn for immune pathology?

The clinical trials, present in literature, were born to give an answer to these questions, but often feel the effects of mistakes in the sampling. They resulting often without statistical significance or in contradiction.

The aim of our study is to give an answer to these questions. We would define the security of silicone gel prostheses for the mother, the effects of an eventual contamination of maternal milk, if this condition is associate with elevate concentrations of silicone in the blood of their sons and if the silicon presence in correlate with immune pathology in the newborn.

2. Materials and Methods

The study was conduct by the Department of Plastic, Reconstructive and Aesthetic Surgery Tirana (Albania). From the December 2014 to December 2015, we were selected 20 women with ending pregnancy and mammary silicone gel prostheses.

The exclusions criteria were: fibrocystic mastopathy, mastitis, immune pathology. The pregnancies secondary to assisted fecundation were excluded.

The A group was flanked by a control group B that include 20 women with ending pregnancy without breast implants.

The A group show a mean age of 26 ± 6 years old. The mean time of implant permanence is 55 ± 25 months. 60% (12) of patients have the prostheses in subglandular plane and the 40% (8) submuscular plane. The mean pregnancy time is 39 ± 2 weeks and of breastfeed 28 ± 2 weeks. The B group has a mean age of 24 ± 2 years old, a pregnancy rate of 39 ± 2 weeks and the mean time of breastfeed is 23 ± 6 weeks.

At the pre-partus admission, we performed the evaluation of, Ig A,G and M classes and ANA, ENA antibody test in all patients.

The same laboratorial parameters were dosed in the sons of our patients at the star and at the end of the breastfeeding. We also performed the evaluation of silicone concentration in the whole blood in the mothers, in the sons and in maternal milk.

A commonly instruments were used to evaluate the concentration of antibodies, the silicone concentration was evaluated by spectroscopic analysis and devices silicone free were used.

The tests results was elaborates statistically to verify the relation coefficient between the prostheses presence and the values of tests.

3. Results

The silicone in the maternal blood resulted more concentrated in the patients of A group, the difference hasn't statistic significance. The antibodies rate in all groups was compared and the difference wasn't significant. The silicone concentration in the milk of both groups was super imposable. This condition points the absence of correlation between the mammary implant and the silicone rate in the milk. The evaluation of the concentration of inflammatory proteins in the newborn blood was performed at the start of the breast-feeding. The results were compared by *t* Student test. The antibody rate was studied in the newborns of both groups in the same mode of the other tests.

4. Discussion

The silicon (Si) is one of the most concentrates elements on the earth crust and traces can be finding in the foods, makeup, in the drugs, dresses and in the hair of same person, too.

Numerous are the compounds presenting in nature based on Si but only for its crystalline form had been define the pathogenicity, because responsible of lung fibrosis and mesothelioma of pleura.

The organic form of Si, like silicone, is used to prepare prosthesis implant used in medicine.

The controversies on the security of mammary implants made in silicone gel had start from the 1985. The numerous case reports about patients with immune pathology that were considered as a consequence of augmentation mammoplasty brought the FDA to forbid the sale of silicone gel prosthesis from February 1992. In those period the augmentation mammoplasty by silicone gel implant had been reserve only to the patients received a mastectomy or volunteers enlisted in experimental trials. This phenomenon conducted to the start of numerous studies that affirmed or denied the relations between a local and/or systemic illness and the silicone gel prosthesis.

Actually the exact mode by the silicone could interact with the biologic tissues isn't completely known also the mode to act as a trigger for immune pathology. All prosthesis, independently from the other substances added to the silicone, induces a fibrous reaction from the periprosthetic tissues.

The cases of lymph-node biopsy reported in literature that put on evidence the presence of silicone depends by the phagocytosis process of the silicone molecules by macrophages and the successive transport of the material to the lymphatic stations.

The silicone caught from the macrophages can be derived from a premature prosthetic failure to the capsule formation or the bleeding of the gel through the prosthesis envelope.

The target of our studies is to define the relation between the silicon gel implants and the onset of immune pathology in the carrier and their sons, too. Our results concord with the other present in literature. The search of haematic and antibody markers, helpful in the diagnosis of immune pathology, not put in evidence a peculiar relation cause-effect and it's absolute not specific. The same result is observe in the analysis of the newborns antibody rates in A group that in all tests haven't a statistic significance. On the silicone concentration in maternal whole blood we observed great values in patients with prosthesis. This difference not appear liked to the silicone gel. Instead the silicone concentration dosed in the maternal milk and in the newborns blood is super imposable in all groups. The silicone is not sure the ideal material, but in our experience, today it's the best synthetic product available for the plastic surgeon, safety for female population.

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