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Silicone implants – a possible confounder for urinary platinum background concentrations?

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ABSTRACT

Introduction: Urinary platinum excretion from occupationally unexposed population is very low. Up to now, in Germany, dental noble metal alloys and a platinum based chemotherapy have been identified as reason for elevated urine concentrations. As fabrication of silicone involves platinum as catalyst, this study examines the potential release of platinum from silicone breast implants by quantifying urinary platinum concentration.
Methods and results: Platinum release from three different types of silicone implants into saline solution was measured in a laboratory experiment. It showed a strong increase of platinum concentration during the first 30 min and high platinum concentrations even after 60 h. In the following field study urinary platinum concentrations were determined from 30 women with dental gold alloy restorations and 28 women without such dental inlays. Median platinum concentrations were 5.2 ng/l urine (21.2 ng/g creatinine) for the women with dental gold inlays and 6.0 ng/l urine (5.4 ng/g creatinine) for those without. Compared with the urinary platinum concentrations provided by the German Environmental Survey (GerES) for the general female population the urinary platinum levels of women with silicone implants of the presented study were significantly higher, both for the study groups with and without dental gold alloy inlays.
Conclusions: Silicone breast implants must be considered as a new confounder and as a further contributor to elevated urinary platinum concentrations in human platinum background reference values of women.

1. Introduction

Platinum is a noble metal which is widely used in various industrial sectors. In the 1980s autocatalysts were introduced in order to reduce hazardous components of vehicle emissions. These catalysts contain platinum in very small amounts, but nevertheless platinum is emitted into the environment (Zereini et al., 2012) and contributes to human exposure. Therefore, human biomonitoring was established to collect and provide a large, population-based database on the platinum body burden, which enabled to derive reference values for the German population (Becker et al., 2003) as concerns platinum concentrations in urine. Regarding blood/serum analyses, no relevant valid data were interpretable due to the fact that blood/serum platinum levels mostly were below the detection limit. Altogether, low urinary concentrations (range 1–10 ng/l) for platinum were identified in the general population (Messerschmidt et al., 1992), (Becker et al., 2003; Begerow et al., 1999). However, it could be verified that one reason for elevated urinary platinum concentrations of some individuals is the presence of dental gold alloy restorations (Schierl, 2001), which partly contain platinum. From these restorations small amounts of platinum can dissolve in saliva and subsequently be taken up into the body. For this reason, the German reference value for urinary platinum (10 ng/l) is defined by the German Federal Environmental Agency for adults without any noble metal dental restorations (Umweltbundesamt, 2003). Another cause for higher urinary platinum excretion is a previous chemotherapy with platinum-containing drugs (Cis-, Carbo-, Oxaliplatin), even if the treatment dates back more than 10 years (Gerl and Schierl, 2000).

Breast augmentation with silicone implants is one of the most frequent operations in cosmetic surgery. But there is an ongoing discussion about possible health risks of silicone implants due to "implant bleeding" or the rupture of an implant. In both cases the material of the implant could migrate into the surrounding tissue.

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Platinum is embedded in silicone as a catalyst during fabrication (Brook, 2006b). Although most of the platinum is chemically bound it is possible that platinum gets released as shown in some tissue samples (fibrin layer, fat tissue) adjacent to explanted silicone gel-filled breast implants (range 25–90 ng/g) (Flassbeck et al., 2003). In contrast, various human tissue samples (lung, liver, kidney) of non-exposed, non-augmented persons had platinum levels ranging between 0.03 and 1.42 ng/g (Rudolph et al., 2005). Elevated platinum concentrations (median 2.8 ng/l) in urine (as a correlate to the last member of the emission chain), which obviously resulted from silicone exposure, were shown in a German study on neonates and infants using silicone pacifiers and nipples (Erler et al., 2007). However, data on urinary platinum with regard to silicone breast implants are scarce. Lykissa and Maharaj, who investigated platinum in explants and in different body tissues (hair, nails) and fluids (blood, urine, sweat, breast milk), described elevated platinum levels (Lykissa and Maharaj, 2006b) in the urine of 16 women deriving from silicone breast implants, but this study is under critical discussion because of some shortcomings which has been replied by the authors (Brook, 2006a; Lykissa and Maharaj, 2006a). The aim of our study was to examine the potential release of platinum from silicone breast implants and to assess urinary platinum concentrations in women exposed to silicone implants.

2. Methods

2.1. Laboratory experiment

Firstly, we conducted a laboratory study with implants from three different producers in order to examine if and to which extent platinum is released and can penetrate into surrounding tissues. This would be the precondition for platinum excretion via urine. The silicone gel-filled implants were non-sterile, but new, intact products of comparable sizes – one single implant each – from Mentor, Polytech, and TRICONmed and available for sale in Germany. As the study aimed at quantifying a potential platinum release from silicone implants in general and not at comparing different implant products – which is not even scientifically based with only one sample per manufacturer – no further implant informations (e.g. type, model, catalog/lot/serial no.) were shown and implant models were classified as Implants A, B, C without referring to their source. Moreover, silicone chemistry across all manufacturers and the gross characteristics of the breast implants are all very closely related (Brook, 2006b). Each of the three implant models was placed in 500 ml isotonic (0.9%) sodium chloride (NaCl) solution with moderate shaking. After 0, 1, 5, 10, 20, 40, 60, 90, 120, 240, 180, 360, 1500 and 3600 min the platinum concentration in the NaCl solution was determined by voltammetry, a very sensitive standard procedure (Ensslin et al., 1994) having a detection limit of 1.8 ng/l. In order to get reliable results in the range of ng/l a quality scheme was strictly followed. Blanks ($n=8$) were prepared for the total equipment (reagents, glassware, etc.) of which all were below 1 ng/l. We spiked 8 samples with 20 pg platinum and had a sufficient recovery mean of 20.1 pg (SD 1.68 pg). Furthermore, our lab participates two times a year successfully in an external round robin analyzing platinum in serum and urine.

2.2. Field study

As a proof of concept we carried out a small scale human study analyzing the urinary platinum concentrations of women having silicone breast implants. This study was approved by the ethical committee of the medical faculty of the University Munich, Germany. In total 58 women with breast implants were included in the study. Most of them undertook regularly mammography and were asked for participation. After filling in a short questionnaire requesting information on age, type of silicone implants (if known), presence and number of dental alloy restorations, years since silicone implantation, breast symptoms (e.g. sensation of pain or strain, inflammation, fibrosis), the participants provided a urine sample. As personal information could also be offered anonymously, data on women's age was found missing for three samples and on implants' age for one sample. Women who underwent chemotherapy with platinum containing drugs in the past were excluded from the study. Urinary platinum concentrations were analyzed by the same voltammetric technique mentioned above for the laboratory tests.

The statistical analysis was performed with SPSS 21. Distribution of data was evaluated using Kolmogorov–Smirnoff-tests. Since data were not normally distributed, the percentiles were presented. Group differences were tested with Mann–Whitney-U and Wilcoxon tests and correlations with Spearman-Rho-correlations. For statistical calculations values below the limit of detection (LOD) were set as 1/2 LOD. Statistic calculations were performed with the Software program SPSS, Version 21 for Microsoft Windows (SPSS Inc. Chicago, IL, USA).

3. Results

3.1. Laboratory experiment

As the study aimed at quantifying a potential platinum release from silicone implants in general, the implants from the different manufacturers (one implant each) were classified as Types A, B, C without referring to their source. Fig. 1 clearly shows a strong overall increase of the platinum concentration in the NaCl solution during the first 30 min of the laboratory experiment. Obviously, there were differences between the three different implant models, but the trend is the same for each implant. These results underline the possibility of platinum release from silicone implants into the body.

3.2. Field study

In the field study, questionnaire data revealed that 30 (52%) out of the 58 participants had teeth with gold dental alloy restorations with a range of one to ten inlays (mean 3.3). Table 1 shows the descriptive statistics of the study group. Nineteen women (33% of the sample) reported symptoms which were probably causally connected to the implants. These were described as pain and/or induration or fibrosis in the surrounding tissues at least at one breast in 17 women, deformation of the breast in the implantation area in two cases and recurrent inflammation of the breast tissue in one case.

In the statistical calculations no differences in platinum concentrations were found between the women with symptoms and those without. Furthermore, the Mann–Whitney-U-test showed

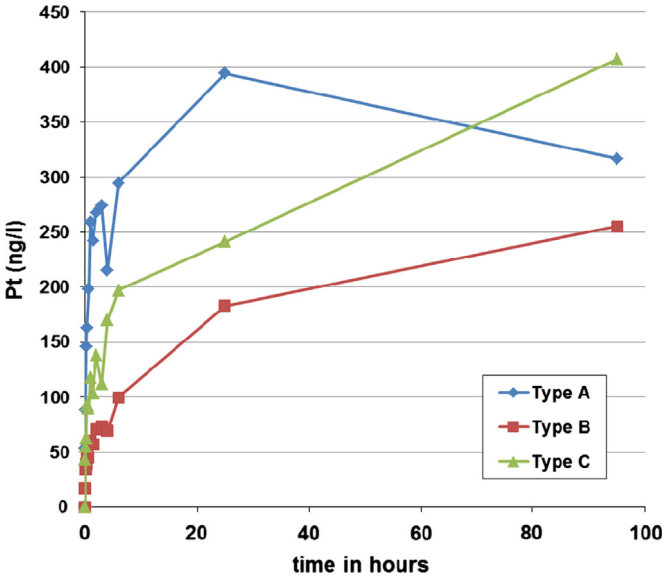

Fig. 1. Platinum release of three different types of breast implants in isotonic saline solution.

Table 1
Descriptive statistics of the study group.

	Min	Median	Max
Age* (years)	20.6	51.1	80.1
Residence time of implants (years)**	0.1	6.7	38.8

* Data on 55 women.
** Data on 57 women.