

# Latex Sensitization

## A Special Risk for the Obstetric Population?

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### ABSTRACT

**Background:** Previous studies have reported a greater frequency of sensitization to latex in the female population and a higher incidence of anaphylactic reactions to latex during cesarean section. In this study, the authors investigated the prevalence of latex sensitization in obstetric patients compared with nonpregnant subjects.

**Methods:** Two hundred ninety-four healthy pregnant women who were at term with a singleton fetus and scheduled for caesarean section (group A) were compared with 294 healthy nulliparous women with childbirth potential undergoing gynecologic surgery (group B). Before surgery, patients completed a questionnaire, and venous blood samples were collected to measure specific immunoglobulin E serum concentrations with a fluorescent enzyme immunoassay test. Skin-prick tests were performed if adverse reactions occurred during surgery. Latex allergy was diagnosed on the basis of immunoglobulin E results and/or positive skin-prick tests.

**Results:** The prevalence of latex sensitization was higher in group A than in group B (15/294, 5.1% vs. 5/294, 1.7%;  $P < 0.05$ ). A significant difference in specific immunoglobulin E serum concentration was noted between pregnant and nonpregnant patients who had a positive fluorescent enzyme immunoassay test (median serum concentration: 1.93 kilounits/l; interquartile range = 2.28 vs. 0.78 kilounits/l; interquartile range = 1.07;  $P$  less than 0.05). Two patients in group A experienced an anaphylactic reaction to latex. Sta-

### What We Already Know about This Topic

- Latex sensitization is more common in women, but whether there is a special risk during pregnancy is not known

### What This Article Tells Us That Is New

- In nearly 600 women undergoing cesarean delivery or gynecologic surgery, the prevalence of latex sensitization was three times greater in the pregnant women (5.4% versus 1.7%)

tistical analysis disclosed no association between latex sensitization and accepted risk factor for latex allergy.

**Conclusions:** The authors report a higher prevalence of latex sensitization in the obstetric population than in nonpregnant subjects undergoing gynecologic surgery.

**A**NAPHYLAXIS is a severe and potentially fatal systemic allergic reaction that occurs suddenly and is triggered by the binding of allergen to specific immunoglobulin E. It implies previous exposure and sensitization to the triggering substance or a cross-reactive allergen.<sup>1</sup>

In the general population, the incidence of anaphylaxis during general anesthesia has been estimated to be 1:10,000–1:20,000.<sup>2,3</sup> Muscle relaxants are the anesthetic agents most frequently associated with intraoperative anaphylactic reactions (60–70%),<sup>4</sup> followed by natural rubber latex and antibiotics.<sup>5</sup>

The incidence of latex sensitization is approximately 1:100 in the general population. Patients with spina bifida and urogenital abnormalities, those undergoing multiple surgical procedures, healthcare workers, and subjects with allergy to fruits carry a higher risk of this event.<sup>6–9</sup> Moreover, latex sensitization is more common in women; therefore, latex anaphylaxis could occur frequently during obstetric and gynecologic surgery.<sup>10</sup>

We previously reported a higher incidence (1:310) of anaphylactic reactions to latex in the obstetric population than that observed in other reports.<sup>11</sup> Such events may be life threatening for both the woman and the fetus because an instability in maternal hemodynamic can impair placental perfusion. Therefore, anaphylactic reactions represent a serious concern for obstetricians, anesthesiologists, and neonatologists.

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This study evaluates the prevalence of latex sensitization in the obstetric population in comparison with nulliparous patients undergoing gynecologic surgery.

## Materials and Methods

### Study Setting and Design

Between July 2003 and September 2008, 588 consecutive patients were enrolled in this study, which was conducted at the Department of Anesthesiology and Intensive Care, Catholic University of Sacred Heart, Rome, Italy. Patients were assigned to one of the following groups. Group A had 294 American Society of Anesthesiologists physical status classification system I patients with singleton term pregnancy scheduled for elective cesarean section under spinal anesthesia. Group B had 294 American Society of Anesthesiologists physical status classification system I nulliparous patients, with childbirth potential, scheduled for benign gynecologic surgery under general anesthesia (diagnostic laparoscopy, myomectomy, hysteroscopy). The local Ethical Committee (Rome, Italy) approved the study design, and every patient signed a written and educated informed consent.

### Study Procedures

After overnight fasting, all patients preoperatively received 100 mg intravenous ranitidine and 10 mg intravenous metoclopramide. In group A, spinal anesthesia was performed at L3–L4 interspace using hyperbaric solution of 8–10 mg bupivacaine, 0.5%, plus 5  $\mu$ g sufentanil to improve the block and minimize the risk for maternal and fetal side effects. After discharge, 20 IU oxytocin was administered in a 500-ml glucose solution (5%). In group B, general anesthesia was induced with 4–5  $\mu$ g/kg fentanyl, 2 mg/kg propofol, and 1 mg/kg vecuronium bromide. After intubation, anesthesia was maintained with sevoflurane and 50% air in oxygen. In both groups, postoperative analgesia was maintained by the administration of intravenous paracetamol and intravenous morphine.

### Assessments

The protocol included a questionnaire regarding age, weight, previous history of allergy (atopy and/or food, drug, latex allergy), and number of previous surgical procedures (see Appendix 1).

Perioperative allergic reactions were recorded and graded according to Rüggeberg's criteria.<sup>12</sup> Immediately before surgery, venous blood samples were collected to measure serum concentrations of specific antinatural rubber latex immunoglobulin E by a fluorescent enzyme immunoassay test (UniCAP System; Pharmacia, Uppsala, Sweden). A specific immunoglobulin E concentration less than 0.35 kilounits/l was considered normal.<sup>13</sup> Patients experiencing allergic reactions during surgery underwent a skin-prick test with a standard latex extract (500  $\mu$ g/ml; ALK Abellø, Madrid, Spain). Because glove powder may include cornstarch, the presence

of allergy to corn extract was also tested. Skin-prick tests and intradermal tests with oxytocin or other drugs administered in the study were performed to exclude drug allergy in patients who experienced adverse reactions. Skin-prick tests were performed with a Morrow–Brown needle (ALK Abellø) on the volar surface of the forearm. Glycerine solution and histamine (10 mg/ml) were used as negative and positive controls, respectively. Skin-prick tests were assessed after 20 min and results considered positive when wheal diameters were more than 4 mm; if results were judged negative, a minimal amount (0.02 ml) of the testing material was injected intradermally. Natural rubber latex allergy was diagnosed on the basis of specific immunoglobulin E results and/or positive skin-prick test.

### Statistical Analysis

Sample size estimation was performed with a significance level of 5% and a power of 80%, by Epi Info Version 3.3 software (Centers for Disease Control and Prevention, Atlanta, GA). We expected a disease frequency of 5% in this obstetric population,<sup>14</sup> whereas the prevalence of disease in the general population was set at 0.05% according to the prevalence recently reported by Monitto *et al.*,<sup>15</sup> Turjanmaa and Makinen-Kiljunen,<sup>16</sup> and Brehler.<sup>17</sup> To limit the potential bias to the statistical analysis caused by the possible presence of patients with no response, the sample size was increased by 15%, so the sample size included 588 patients.

Data were analyzed by descriptive statistics; categorical variables were described by frequency and percentage. The continuous variables with normal distribution were represented by mean  $\pm$  SD, whereas those with nonparametric distribution were described by reporting the median and interquartile range.

The univariate analysis was performed by chi-square test and Fisher exact test for dichotomous and categorical variables, as appropriate; Student *t* test (variables with normal distribution) and Mann–Whitney U test (variables without normal distribution) were used for continuous variables (age and immunoglobulin E serum concentration).

The Kolmogorov–Smirnov test was performed to examine the normality distribution. Only the age appeared to present a Gaussian distribution (age:  $P = 0.083$  group A,  $P = 0.414$  group B; immunoglobulin E concentration level:  $P < 0.001$  for both groups). A two-tailed  $P$  value  $< 0.05$  was considered statistically significant. Data were analyzed by SPSS 12.0 software package (SPSS Inc., Chicago, IL).

## Results

We recruited a total of 588 patients; all subjects completed the study. The demographic and clinical variables for the two groups are represented in table 1. Overall, a significantly higher proportion of patients in group A tested positive for latex-specific immunoglobulin E than did those in group B (15/294, 5.1% *vs.* 5/294, 1.7%;  $P = 0.023$ ). Moreover, the median serum concentration of immunoglobulin E in pa-

**Table 1.** Demographic and Clinical Variables in Group A (Obstetric Patients) and Group B (Nonpregnant Patients)

Variables	Group A (n = 294)	Group B (n = 294)	P Value
Age, mean (SD)	33.48 (±4.45)	33.96 (±5.54)	0.247*
Latex-specific immunoglobulin E +, n (%)	15 (5.1)	5 (1.7)	0.023†‡
Latex-specific immunoglobulin E serum concentration (in kilounits/l), median (IQR)	1.93 (2.28)	0.78 (1.07)	0.042‡§
Referred drug allergy, n (%)	34 (11.6)	27 (9.2)	0.344†
Referred food allergy, n (%)	25 (8.5)	19 (6.5)	0.347†
Referred allergy to food with cross-allergenicity with latex, n (%)	18 (6.1)	11 (3.7)	0.182†
Referred other allergy, n (%)	75 (25.5)	68 (23.1)	0.501†
Referred previous reaction to natural rubber latex during medical examination, n (%)	0 (0)	4 (1.4)	0.124
Referred adverse reaction during dental surgery, n (%)	0 (0)	3 (1.0)	0.249
Neurologic disease, n (%)	4 (1.4)	3 (1.0)	0.999
Healthcare workers, n (%)	22 (7.5)	16 (5.4)	0.314†
Non-healthcare professionals with NRL exposure, n (%)	51 (17.3)	46 (15.6)	0.576†
Surgical procedures > 2, n (%)	85 (28.9)	79 (26.9)	0.581†
Referred adverse reaction during surgery, n (%)	2 (0.7)	5 (1.7)	0.450‡
Family history of atopy, n (%)	62 (21)	60 (20.4)	0.839†

\* P value of t test (two-tailed). † P value of chi-square-test (two-tailed). ‡ P value < 0.05. § P value of Mann-Whitney test (two-tailed). || P value of Fisher exact test (two-tailed).

IQR = interquartile range; NRL = natural rubber latex.

tients with specific immunoglobulin E greater than 0.35 kilounits/l was higher in pregnant subjects than in nonpregnant ones (1.93 kilounits/l; interquartile range = 2.28 vs. 0.78 kilounits/l; interquartile range = 1.07; P = 0.044) (table 2).

Two patients in group A experienced anaphylactic reaction approximately 30–50 min after the starting of procedures and oxytocin infusion. The first patient experienced

**Table 2.** Latex Immunoglobulin E Serum Concentration in Patients with Specific Immunoglobulin E Greater than 0.35 kilounits/l

Group A (n = 15)	Group B (n = 5)
100	1.79
41.40	1.66
5.33	0.78
3.61	0.70
3.59	0.61
2.53	—
2.17	—
1.93	—
1.52	—
1.44	—
1.40	—
1.33	—
1.24	—
1.14	—
1.05	—

Data are expressed as kilounits/l. P = 0.044. Group A median serum concentration: 1.93 kilounits/l; IQR = 2.28. Group B median serum concentration: 0.78 kilounits/l; IQR = 1.07. IQR = interquartile range.

facial edema, itching, generalized erythematous rash, and sensation of throat closure. The second patient experienced facial edema, itching, urticaria, profuse sweating, and a decreased level of consciousness. Both reactions were judged as anaphylaxis with level 2 of diagnostic certainty. Neither hypotension nor bronchospasm was observed. Symptoms resolved completely after the administration of intravenous antihistamine, intravenous steroid, and oxygen therapy. In group B, no anaphylactic reactions were observed.

No significant differences between groups were seen in terms of risk factors associated with latex allergy (multiple surgical procedures, high-risk work, atopy, or previous history of allergy).

**Discussion**

In this observational study, we assessed the prevalence of latex sensitization in the obstetric population and found a higher prevalence and higher specific immunoglobulin E serum concentration in obstetric patients than in nulliparous women.

Our data seem to confirm the previous findings of Brown *et al.*<sup>18</sup>: in obstetric patients, the prevalence of latex sensitization is higher than that of allergy with clinical symptoms. Therefore, in patients at an early stage of sensitization, a reduction or avoidance of latex exposure can minimize the progression to symptomatic disease.

However, it must be acknowledged that our observations are related to a very specific population (all of the subjects studied were women) and a very specific setting (obstetric surgery).

A significantly higher incidence of latex-related reactions has been observed in women.<sup>4,19,20</sup> This finding may be

related to the higher predisposition to allergic diseases observed in women, a more frequent exposure to latex objects during everyday life, and a greater mucosal contact with latex through contraceptives.<sup>21,22</sup>

The obstetric population may present additional risk factors. For instance, changes in progesterone levels<sup>23</sup> or in immunomodulation (cytokine signaling, depressed T-cell response, impaired cell-mediated immunity)<sup>24</sup> may contribute to hypersensitivity events, including latex reactions, reported in pregnant women. Many episodes of anaphylactic reactions induced by latex gloves have been reported after normal vaginal delivery or vaginal exploration, likely because of the extensive contact of surgical gloves with highly absorptive membranes.<sup>25–28</sup> Therefore, obstetric and gynecologic procedures appear the most common setting for latex anaphylaxis during surgery and account for approximately 50% of all reactions caused by natural rubber latex.<sup>10</sup> In our study, the higher immunoglobulin E serum concentrations in pregnant women with positive results on fluorescent enzyme immunoassay tests could indicate a greater sensitivity of obstetric patients; it may also be related to the high number of vaginal explorations performed during pregnancy and, possibly, to the physiologic hormonal modifications occurring during pregnancy.

The two adverse reactions reported in our study occurred 30–50 min after the start of the surgical procedure and oxytocin infusion. The delay between the exposure to allergen and the anaphylactic reaction could be related to the injection of oxytocin, which may be a reaction trigger. In fact, oxytocin can induce uterine contraction, which may provoke the release of latex particles from the uterus into the bloodstream.<sup>10</sup> Another possible mechanism could be a cross-reaction between synthetic oxytocin and latex. In fact, oxytocin may be a part of the epitope of latex antigen: in a patient sensitized to latex, the subsequent administration of oxytocin could facilitate the antigen recognition, thus causing an anaphylactic response to latex.<sup>29</sup>

No adverse reactions to latex during surgery were reported in nonpregnant patients. However, all of these patients underwent general anesthesia, so it is not possible to exclude clinical manifestations of anaphylaxis occurring during general anesthesia and not being observed. The sample sizes we observed are too small to estimate whether spinal anesthesia is less safe than general anesthesia.

Our findings have immediate clinical significance. In fact, because our data show that the prevalence of latex sensitization is higher in the obstetric population, identification of high-risk patients during the preanesthetic visit is advisable. Patient history appears to be the most important prognostic tool: in our study, patients who experienced anaphylactic reaction had previously experienced allergic disease and hand itching after the use of rubber gloves. Unfortunately, we found no significant correlations between accepted risk factors (multiple surgical procedure, high-risk work, atopy, cross-reacting fruits/vegetables, or previous history of al-

lergy) and latex allergy, in contrast to the data reported by Chen *et al.*<sup>30</sup>

In conclusion, our data indicate that the obstetric population has a higher prevalence of latex sensitization than do nonpregnant subjects undergoing gynecologic surgery. Additional investigations, carried out in a larger group of patients, are needed to establish the possible causes of this greater sensitization and assess a potential greater risk of adverse reactions to latex in the obstetric population.

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## Appendix 1: Questionnaire Used to Collect Data

Questionnaire n°. . . . . Date. . . . . Patient . . . . .

Age . . . . . years Weight. . . . . kg

Procedure  Gynecologic surgery  Obstetric surgery

Referred Allergy to:

Drugs  No  Yes

Foods  No  Yes

Pollens  No  Yes

Metals  No  Yes

Fruits  No  Yes

Vegetables  No  Yes

Plants  No  Yes

Latex  No  Yes

Others  No  Yes

Previous reaction to natural rubber latex (NRL)?

No  Yes

Dyspnea:  No  Yes; Rhinitis  No  Yes; Conjunctivitis  No  Yes

Urticarial reaction  No  Yes; Angioedema  No  Yes; Erythema  No  Yes; Local symptoms  No  Yes

Suspected reaction during dental surgery?  No  Yes

Neurologic pathology, spina bifida, tracheoesophageal fistula, bladder dysfunction, myelomeningocele, urogenital dysfunction?

No  Yes

Healthcare worker?

No  Yes

Use of latex gloves in work?

No  Yes

More than two surgical procedures?

No  Yes

Suspected reaction during or after surgical procedure?

No  Yes

Family history of atopy?

No  Yes

Notes