



# Perception of pregnant Japanese women regarding the teratogenic risk of medication exposure during pregnancy and the effect of counseling through the Japan drug information institute in pregnancy

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## ABSTRACT

**Objective:** To confirm the current state of Japanese women's perception of the teratogenic risk of medication exposure during pregnancy, and to assess the effect of counseling by Japan Drug Information Institute in Pregnancy.

**Methods:** We used VAS to monitor the sentiments of pregnant women, before and after face-to-face counseling, about their own teratogenic risk perception, and their intention to continue pregnancy. Pregnancy outcomes were investigated by mailed questionnaires.

**Results:** Among 681 pregnant women, the median estimation of the risk of having a baby with a birth defect was 33.0% (interquartile range 16.0–50.0%) prior to counseling and 5.0% after counseling (2.0–11.0%). The median intention to continue pregnancy increased from 86.0% to 100.0% after counseling. The actual outcome survey revealed that almost all participants (97.1%) continued their pregnancies.

**Conclusions:** Pregnant women tend to overestimate the fetal risks of medication exposure during pregnancy. Counseling would prevent unnecessary termination.

## 1. Introduction

Medication exposure during pregnancy can affect both mother and fetus. In general, pregnant women tend to be very worried about medication use during pregnancy. Overestimation of the risks is problematic because it can lead to discontinuation of necessary treatment or termination of pregnancy.

Teratology Information Services (TIS) have been established in various countries to provide pregnant women with evidence-based information on the safety of medication use during pregnancy. The Motherisk Program in Canada [1] consults with about 30,000 patients every year. Other well-established TIS networks are Mother to Baby (Organization of Teratology Information Specialists, OTIS [2]), and The European Network of Teratology Information Services (ENTIS) [3].

The largest TIS in Japan is Japan Drug Information Institute in Pregnancy [4]. Japan Drug Information Institute in Pregnancy was

established in October 2005 by the Ministry of Health, Labour and Welfare. Japan Drug Information Institute in Pregnancy cooperates and shares information with Motherisk. Like TIS in other countries, Japan Drug Information Institute in Pregnancy provides evidence-based counseling. We used visual analogue scale (VAS) to assess the sentiments of pregnant women, before and after face-to-face counseling, about 1) their own teratogenic risk perception, and 2) their intention to continue pregnancy. Pregnancy outcomes were investigated by mailed questionnaires.

In other countries, several kinds of surveys have been conducted on fetal risk perception related to medication exposure during pregnancy. A large-scale study of 18 countries, including those in Europe, North America, and Australia, reported that pregnant women overestimate the actual risk of antibiotics, antidepressants, and over-the-counter drugs for nausea taken during pregnancy [5]. Other studies showed that pregnant women in Spain [6] and Norway [7] also overestimate the

*Abbreviations:* VAS, visual analog scale; TIS, Teratology Information Services

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fetal risk of medication during pregnancy. Similar results have been obtained by TIS in Canada (Motherisk) [8–13] and Turkey [14]. In addition, TIS have investigated the effects of counseling on the perception of the teratogenic risk of medications and intention to continue pregnancy [15].

In Japan, one study [16] have investigated teratogenic risk perception associated with medication exposure during pregnancy and intention to continue pregnancy, and no study to date has connected intention to continue pregnancy with actual pregnancy outcomes.

Therefore, in this study, we assessed the current status of teratogenic risk perception associated with medication exposure during pregnancy in Japan, and evaluated the effect of counseling on pregnant women.

## 2. Materials and methods

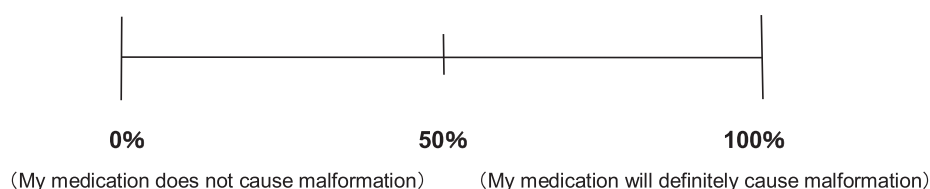
### 2.1. Collection of information on the characteristics of pregnant women

We collected information on the characteristics of pregnant women and their medications using interview sheets by questionnaires completed by the women at the time they applied for counseling. This information included age, gestational age (weeks), height, weight, pregnancy history, alcohol use, smoking, planned or unplanned pregnancy, and medications.

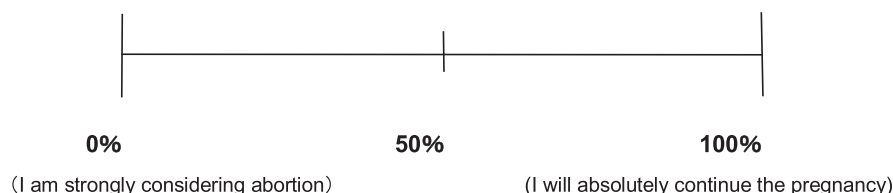
### 2.2. Collection of data on pregnant women’s own teratogenic risk perception and intention to continue pregnancy

At the time of counseling, we used the visual analogue scale (VAS) that a tool developed and published by Koren et al in [8] to ask pregnant women (Fig. 1) about 1) their assessment of the likelihood of congenital anomaly in the fetus (pregnant woman’s own teratogenic risk perception), and 2) the extent to which they wanted to continue the

**1. What do you believe is the probability that malformations will occur in your baby due to exposure to the medication you are currently using, used before consultation? (Pregnant woman’s own teratogenic Risk Perception).**



**2. Please tell us about your current intentions regarding continuing the pregnancy. (Intention to Continue Pregnancy)**



pregnancy (intention to continue pregnancy). We conducted the VAS survey before and after counseling.

### 2.3. Collection of data on pregnancy outcomes

To collect pregnancy outcomes, we sent postcards stamped and personal information protection stickers in the envelope to women who received counseling. The cards were mailed in the month following the expected date of delivery. If we did not receive a response from the pregnant women, we sent another postcard 2 months later (3 months from the expected date of delivery). Women sent personal information protection stickers on the card to us. Based on the responses, we collected data on pregnancy outcomes, including pregnancy continuation (live birth, stillbirth, miscarriage), and pregnancy termination (induced abortion).

### 2.4. Study population

We included pregnant women who underwent face-to-face counseling at the National Center for Child Health and Development, with expected dates of delivery between October 2005 and December 2016. Pregnant women who received counseling after 22 weeks and pregnant women who went to counseling several times were excluded.

### 2.5. Current status of pregnant women’s own teratogenic risk perception and evaluation of the importance of counseling

Based on the VAS results, we compared pregnant women’s own teratogenic risk perception and Intention to continue pregnancy before and after counseling, used this information to evaluate the usefulness of counseling. In addition, we investigated the real pregnancy continuation rate based on information obtained from the postcard.

**Fig. 1.** Visual analogue scale (VAS). At the time of counseling, we used the VAS to ask pregnant women about 1) their assessment of the likelihood of congenital anomaly in the fetus (pregnant woman’s own teratogenic risk perception), and 2) the extent to which they wanted to continue the pregnancy (intention to continue pregnancy).

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