

# Method Identifies Risk Factors for Second C-Section

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The following factors are associated with an increased risk of emergency cesarean section in women who have had a previous cesarean section and are attempting vaginal birth: older maternal age, low maternal height, male gender of baby, labor induced by prostaglandin, not having had a previous vaginal birth, and later birth.

These are the key conclusions of a study that used a new method to predict the risk of failed vaginal birth after a cesarean section.

"There is, at present, no validated method that allows antepartum assessment of the risks of emergency cesarean section, and counseling of women is, at best, semiquantitative," wrote the investigators, who were led by Gordon C.S. Smith, M.B., of the department of obstetrics and gynecology at Cambridge

University, United Kingdom. "In the present study, we provide a validated model that classifies over half this population as being low or high risk of emergency cesarean section, on the basis of thresholds suggested by a previous systematic review."

He and his associates studied 23,286 women in Scotland, each of whom had one prior cesarean delivery and who attempted vaginal birth at or after 40 weeks' gestation between 1985 and 2001 (PLoS

Med. 2005;2[9]:e252). They randomly divided the women into group 1 (the model development group) and group 2 (the validation group).

In group 1, the investigators tested their method of determining risk of emergency cesarean section by examining various risk factors including the mother's age and height, the sex of the baby, gestational age, and whether the birth was induced. When they applied the model to the women in group 2, they predicted that 36% had a low risk of cesarean section and 16.5% had a high risk. When they compared their predictions

with the actual outcomes, however, they found that the actual rate of cesarean section was 10.9% among low-risk women and 47.7% among high-risk women.

The risk of emergency cesarean section was increased by factors such as the mother being of older age and less height and not having given birth previously. Other factors include a male baby, labor induced by prostaglandin, and later birth.

The investigators also found that as the risk of cesarean section increased, so did the risk for uterine rupture. The observed incidence of uterine rupture among low-risk women was 2.0 per 1,000, compared with an incidence of 9.1 per 1,000 among high-risk women.

The investigators acknowledged certain limitations of the study, including concerns about how the model would apply to other populations. "However, we assessed the robustness of the predictors employed by selecting records for the development and validation groups on the basis of factors that might reflect variation in other populations," they wrote.

"We found the model was similarly predictive in and out of sample when these categorizations were performed by hospital throughput, socioeconomic deprivation category, and year of birth. This finding suggests that the maternal and obstetric characteristics used in the model are likely to be robust even when applied to populations with different obstetric practices."



Brief Summary (See Package Brochure for Full Prescribing Information)

#### Rx only

Plan B® is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Emergency contraceptive pills (like all oral contraceptives) do not protect against infection with HIV (the virus that causes AIDS) and other sexually transmitted diseases.

#### CONTRAINDICATIONS

Progestin-only contraceptive pills (POPs) are used as a routine method of birth control over longer periods of time, and are contraindicated in some conditions. It is not known whether these same conditions apply to the Plan B® regimen consisting of the emergency use of two progestin pills. POPs however, are not recommended for use in the following conditions:

- Known or suspected pregnancy
- Hypersensitivity to any component of the product
- Undiagnosed abnormal genital bleeding

#### WARNINGS

**Plan B® is not recommended for routine use as a contraceptive.**

**Plan B® is not effective in terminating an existing pregnancy.**

#### Effects on Menses

Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and in clinical studies of levonorgestrel for postcoital and emergency contraceptive use. Some women may experience spotting a few days after taking Plan B®. At the time of expected menses, approximately 75% of women using Plan B® had vaginal bleeding similar to their normal menses, 12-13% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within 7 days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses. If there is a delay in the onset of menses beyond 1 week, the possibility of pregnancy should be considered.

#### Ectopic Pregnancy

Ectopic pregnancies account for approximately 2% of reported pregnancies (19.7 per 1,000 reported pregnancies). Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic. A history of ectopic pregnancy need not be considered a contraindication to use of this emergency contraceptive method. Health providers, however, should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B®.

#### PRECAUTIONS

##### Pregnancy

Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins (POPs). The few studies of infant growth and development that have been conducted with POPs have not demonstrated significant adverse effects.

##### STD/HIV

Plan B®, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

##### Physical Examination and Follow-up

A physical examination is not required prior to prescribing Plan B®. A follow-up physical or pelvic examination, however, is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B®.

##### Carbohydrate Metabolism

The effects of Plan B® on carbohydrate metabolism are unknown. Some users of progestin-only oral contraceptives (POPs) may experience slight deterioration in glucose tolerance, with increases in plasma insulin; however, women with diabetes mellitus who use POPs do not generally experience changes in their insulin requirements. Nonetheless, diabetic women should be monitored while taking Plan B®.

#### Drug Interactions

Theoretically, the effectiveness of low-dose progestin-only pills is reduced by hepatic enzyme-inducing drugs such as the anticonvulsants phenytoin, carbamazepine, and barbiturates, and the antituberculosis drug rifampin. No significant interaction has been found with broad-spectrum antibiotics. It is not known whether the efficacy of Plan B® would be affected by these or any other medications.

#### Nursing Mothers

Small amounts of progestin pass into the breast milk in women taking progestin-only pills for long-term contraception resulting in steroid levels in infant plasma of 1-6% of the levels of maternal plasma. However, no adverse effects due to progestin-only pills have been found on breastfeeding performance, either in the quality or quantity of the milk, or on the health, growth or development of the infant.

#### Pediatric Use

Safety and efficacy of progestin-only pills have been established in women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of Plan B® emergency contraception before menarche is not indicated.

#### Fertility Following Discontinuation

The limited available data indicate a rapid return of normal ovulation and fertility following discontinuation of progestin-only pills for emergency contraception and long-term contraception.

#### ADVERSE REACTIONS

The most common adverse events in the clinical trial for women receiving Plan B® included nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), and menstrual changes. The table below shows those adverse events that occurred in ≥5% of Plan B® users.

Table 3 Adverse Events in ≥5% of Women, by % Frequency

Most Common Adverse Events	Plan B® Levonorgestrel N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Other complaints	9.7
Vomiting	5.6
Diarrhea	5.0

Plan B® demonstrated a superior safety profile over the Yuzpe regimen for the following adverse events:

- Nausea: Occurred in 23% of women taking Plan B® (compared to 50% with Yuzpe)
- Vomiting: Occurred in 6% of women taking Plan B® (compared to 19% with Yuzpe)

#### DRUG ABUSE AND DEPENDENCE

There is no information about dependence associated with the use of Plan B®.

#### OVERDOSAGE

There are no data on overdosage of Plan B®, although the common adverse event of nausea and its associated vomiting may be anticipated.

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