

Lone Umbilical Artery Indicates Need for Fetal ECG

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MIAMI BEACH — A prenatal sonographic finding of single umbilical artery is an indication for fetal echocardiography, Dr. Lami Yeo said at the annual meeting of the Society for Maternal-Fetal Medicine.

In a case series of 430 fetuses with this finding who were identified retrospectively from a database of more than 42,600

patients, 13% had sonographic structural cardiac abnormalities, said Dr. Yeo of Robert Wood Johnson Medical School, Piscataway, N.J.

About 67% of the 430 patients had isolated single umbilical artery, and the remaining 20% had only noncardiac defects, she noted.

Of the structural cardiac abnormalities, 26% were complex cardiac defects, 26% were septal defects only, 19% were left or right hypoplastic heart, 15% were

conotruncal abnormalities, 6% were defects of the atrioventricular canal, and 9% were classified as "other" defects. (Percentages add to more than 100% due to rounding.) Nearly 75% of the defects were significant defects, Dr. Yeo said.

Furthermore, 80% of those with structural cardiac defects also had other anomalies.

The patients were all diagnosed with single umbilical artery from 1994 to 2005 using color Doppler imaging around the

fetal bladder. Previous studies have suggested a connection between single umbilical artery and cardiac defects, but the studies were small, and the rates varied from 2% to 23%, Dr. Yeo noted.

This series—the largest reported from a single institution—confirms the significant incidence of structural cardiac abnormalities and therefore the need for fetal echocardiography in those with a prenatal diagnosis of single umbilical artery. ■



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®.

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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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Thrombophilia Not at Fault in Fetal Losses

TORONTO — Recurrent pregnancy loss was not associated with inherited maternal thrombophilias in a prospective study, adding weight to the evidence against screening for such disorders in patients presenting with a history of first-trimester miscarriage.

"It's probably more important to rule out other possible etiological factors," said lead investigator Dr. Sony Sierra in an interview.

The study, which she presented at the annual meeting of the Society for Gynecologic Investigation, genotyped 915 Hutterite women for inherited thrombophilia polymorphisms including Factor V Leiden (FVL) Arg506Gln, the MTHFR Ala222Val, and the prothrombin G20210A variants. A total of 141 women were identified with inherited thrombophilias and were prospectively followed through 342 pregnancies.

The rate of fetal loss, defined as loss at or before 20 weeks of gestation, was 16% in the cohort, which is comparable to the rate found in the general population, reported Dr. Sierra, of the department of obstetrics and gynecology at the University of British Columbia in Vancouver.

"We also found that the majority of miscarriages occurred at less than 12 weeks—and since there has been evidence to suggest that thrombophilias could be associated with later fetal loss beyond 20 weeks, our findings just lend further support to the data that for early miscarriage there is no significant association," she said.

Genotype analysis was performed on a subset of 72 live offspring and compared with maternal and paternal genotyping. The analysis revealed an expected transmission rate of the MTHFR Val allele to offspring; however, there were significantly fewer children born with the FVL allele (28) than expected (37). (There were no parental carriers of the prothrombin 20210A allele.)

"The significant deficit of children who inherit the FVL Gln allele from either heterozygous parent suggests that there may be preferential early loss of fetuses with this polymorphism," said Dr. Sierra. "This unexpected result suggests selection against inherited thrombophilic variants during embryogenesis."

—Kate Johnson